Do No Harm: Putting Safer Pain Management Guidelines into Practice – Module 1

1.1 Introduction

Welcome to the Oklahoma Primary Healthcare Improvement Cooperative's online course - Do No Harm: Putting Safer Pain Management Guidelines into Practice.

This Online Enduring Material educational program is designed for healthcare professionals. The contents of this program are based on the National Academy's Institute of Medicine's white paper Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use and the 2016 CDC, 2017 VA-DOD, 2017 Oklahoma State Department of Health Guidelines for Pain and Opioid management, and Oklahoma law.

The program was developed through a grant from the Oklahoma Department of Mental Health and Substance Abuse Services by the Oklahoma Primary Healthcare Improvement Cooperative of The University of Oklahoma Health Sciences Center and the OU-TU School of Community Medicine. It was released in August, 2019.

1.2 Overview

Hi, I'm Steve Crawford, and will be your guide through the Module 6: Practice Systems. This is the sixth online module in the Do No Harm: Putting Safer Pain Management into Practice. This module is designed for primary care clinicians and their office staff. It accompanies the "Do No Harm" dissemination and implementation support services program provided by the Oklahoma Primary Healthcare Cooperative of the University of Oklahoma's Clinical and Translational Sciences Resources.

Some of the material covered in module 6 has been presented in abbreviated form in earlier modules, particularly module #1. Likewise, some of the questions in the module may be similar to those asked in pervious modules. This redundancy permits you to have a coherent experience with the module's topic and to permit each module to stand on its own.

1.3 Planning and Review Committees

The panel of experts who reviewed this course represent primary care clinicians, pharmacists, educators, and specialists in pain, addiction, and palliative care, and a national expert in the epidemiology of the opioid crisis.

1.4 Relevant Disclosure and Resolution

None of the members of the CME Planning committee have a relevant financial relationship or affiliation with commercial interests to disclose.

1.5 Relevant Disclosure and Resolution for Expert Review Panel

None of the expert reviewers have a relevant financial relationship or affiliation with commercial interests to disclose.

1.6

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1.7 Professional Practice Gap Being Addressed

The knowledge gap being addressed in module 6 is that Oklahoma providers may not have written office policies and procedures for acute and chronic pain management, with particular attention to the safe prescribing and monitoring of chronic opioid therapy that aligns with best practice and Oklahoma law.

1.8 Objectives

At the completion of this online module, you will improve your competence and performance by being able to develop written office policies and procedures for implementing pain and opioid management guidelines.

You will be able to develop workflow strategies for implementation of office policies and procedures.

And you will be able to make changes in your office care delivery design, patient education and self-care support, clinical decision support, and information technology that incorporate community resources.

1.9 Written Office Policies

The 2018 session of the Oklahoma legislature passed Senate Bill 1446 - Best Practices for an Act Regulating Opioid Drugs, requiring prescribers of opioids to adopt and maintain written policies and procedures that includes execution of a written agreement on pain management and patient informed consent on the use opioid medications for more than 3 months, or at doses greater than 100 morphine milligram equivalent dose per day, or the co-prescription of benzodiazepines. The Oklahoma Hospital Association provides a resource related to implementation of opioid practices and the law - the link is provided at the bottom of the slide.

1.10 Summary

Complying with guidelines may be difficult unless you create efficient practice systems to implement them.

Four practice systems described in the chronic care model may be used to implement pain and opioid guidelines. These are: delivery system design, patient education and self-care, clinical decision support, and information technology.

For **delivery system design** you might introduce structured chronic pain visits and clinician and staff teamwork protocols and scripts.

Patient education and self-care support includes self-care for achieving overall better health and a signed informed consent to participate in chronic pain care especially when opioids are prescribed.

Clinical Decision Support includes using algorithms or other materials to guide difficult clinical decisions and following written communication scripts for guiding difficult conversations.

Changes in **information technology** maximize your EHR, use electronic messaging for coordinating co-management with specialist, and for reporting quality measures that drive practice improvement.

1.11 Delivery System Design

Some primary care practices begin implementing guidelines by making changes in the design of their office care delivery system.

Structured visits for chronic pain care assure that requirements for guideline implementation are performed at the suggested intervals. This is similar to structured prenatal visits**.** The content and the tasks of a structured visit can be displayed in a workflow diagram as shown here, as well as being embedded in EHR templates.

Teamwork is a second approach to improve your care delivery system design. In preparation for or during a structured visit, nurses or office staff may execute data collection or order tests by following protocols and standing orders. Some practices use laminated pocket cards for nurses and/or notebooks containing structured visit and common procedure protocols. The practice team agrees on clinical, procedural, and professional principles as well as the specific wording of verbal scripts they will use to execute routine processes like visit frequency, asking potentially embarrassing risk assessment questions, and obtaining urine drug screening.

The delivery system design can be documented in a workflow diagram such as the one on the slide showing the roles and tasks performed in an initial pain assessment.

1.12 Patient Education and Self-Management

Just as pregnant women are often given a packet of information at their first prenatal visit, it is helpful to provide graphical information to pain patients.

A clear description of the chronic pain management plan and an agreement specifying expectations and mutual responsibilities for pain care can be a tool for patient self-management.

You will need to adapt a “Patient Provider Agreement” otherwise known as an “informed consent” document that advises patients about risks, benefits, and potential alternatives to the proposed treatment. When opioids are used for treatment, a “patient-provider agreement” or informed consent is now Oklahoma law. It should not be necessary to create these materials, since plenty of excellent educational resources already exist. However, you will probably want to include a list of local resources with contact information in the plan.

Since many patients may have trouble reading printed materials, practices have developed scripts that nurses may use to verbally teach patients the most important points.

When patients are at risk for overdose, family or caregiver education in the use of naloxone for emergency opioid overdose resuscitation will be important. The practice team should agree upon a protocol and script for teaching how to recognize overdose, how to use the nasal naloxone, and how to obtain it without charge when possible.

1.13 Clinical Decision Support

Clinical decision support includes algorithms and written protocols that may be incorporated into computer templates to guide clinician recommendations. A decision support algorithm for management of a "legacy chronic pain patient" is shown on this slide.

There will be times when you or members of your team will need additional information for making decisions during a visit. Many practices keep copies of relevant guidelines in either printed or electronic form. Other clinicians bookmark useful websites and/or download applications for calculating MME/day and tapering schedules, reminders to ask about adverse effects and drug interactions or other reference materials like interpretation of urine test results.

Scripts for conducting difficult conversations about suspected misuse or questioning about risk for opioid use can be laminated and placed in key locations within the practice for use by clinicians and staff.

1.14 Information Technology

Advances in computer technology have made information available in effective and efficient ways. Important electronic information tools for the management of patients with chronic pain include EHR templates that prompt collecting and documenting information suggested by guidelines.

The online Oklahoma Prescription Management Program (PMP) lists all controlled substance prescriptions filled by a patient.

Automated notification of practices when their patients visit an emergency department or are discharged from a hospital enables better care coordination and case management.

Practice-based registries can be created in many EHRs or by an external program, such as Microsoft Excel, to track data for high risk patients.

Some practices have access to a health information exchange organization that can aggregate clinical and claims information from community sources in one place for care coordination and for quality improvement.

1.15 Delivery System Design

Let's dive a little deeper into the possible content for a structured initial chronic pain assessment.

You might wish to separate the Clinical Staff Teamwork tasks and the Clinician Initial Assessment tasks.

The staff tasks might include a pre-visit protocol for obtaining and inserting into the record prior medical records, lab and imaging reports, and searching the Oklahoma PMP system for opioid and other controlled prescriptions the patient may have filled, the pharmacies, and other prescribers they may have seen.

At check-in, a receptionist might invite patients to self-administer a pain assessment such as the P.E.G. questionnaire. They may request answering behavioral health screening questions. The SBIRT protocol (Screening, Brief Intervention, Referral, and Treatment) incorporates standard and validated screening tools for unhealthy alcohol use (AUDIT), drug use (DAST-10), and depression (PHQ-9). These may be added for chronic pain patients to the medication list and medical history forms completed by the patient before the initial visit.

Using a rooming protocol, a nurse or MA might record observed patient affect, appearance, or behavior, review the medication list and PMP report with the patient, enter the scores of pre-visit screening questions in the EMR, and assemble counseling materials and scripts as indicated.

Clinician Initial Assessment Tasks include reviewing data entered during rooming, performing a history and physical examination including patient goals for better function. The initial assessment includes a diagnosis, prognosis and agreement with the patient of the goals, benefits, risks, and alternatives for treatments.

For an initial pain visit the clinician designs an individualized, multi-modal pain plan. If the plan includes opioids, the clinician obtains a signed informed consent, and arranges for patient education, instructions for monitoring, arranging referrals, and explaining the practice's controlled substances prescription refill policy.

1.16 Delivery System Design

The elements of the ***multimodal pain management plan*** might be recorded using forms embedded in an EHR template.

Patient goals and objectives might be recorded as the answer to the questions: "What would you like to be able to do that you can't do now because of the pain? Or "What activities are most important to your quality of life?"

The plan template might include prompts for documentation of ***informed consent*** for opioid treatment, recording the ***patient and caregiver education*** provided and a list of referral sources for **mind-body therapy** such as cognitive-behavioral therapy (CBT), mindfulness meditation, hypnosis, physical therapy and exercise, acupuncture, massage, chiropractic and osteopathic manipulation.

The plan template might use a check-list of **pharmacologic therapies,** to prompt clinicians to recommend non-prescription topical anesthetics and analgesics, acetaminophen, NSAIDs, opioid preparations, and pain relieving antidepressants or anticonvulsants. A check-box might document that the patient was informed about the ***opioid and controlled substance refill policy***. In order for all non-prescription topical and oral medication to be captured for performance measurement, they must be entered on the medication list.

The pain plan template might include documentation of pain relieving procedures performed, such as anesthetic or corticosteroid injections, and a list of preferred **co-management referrals** to addiction *specialists*, pain management specialists for procedures such as epidural steroid injections or denervation procedures, and psychologists, psychiatrists, physical medicine specialists, neurosurgeons, orthopedic surgeons.

The last part of the plan is the ***schedule for follow-up face-to-face visits***.

1.17 Delivery System Design

Similar to the initial pain assessment visit, a structured follow-up visit for pain care assures guideline recommendations are followed. The clinical staff assures that a face-to-face clinician visit is scheduled at least every 3 months for chronic pain patients. If opioids greater than 90 MME/Day are prescribed, a face-to-face clinician visit should be scheduled every month, if possible.

The ***staff pre-visit protocol*** might include reviewing care-coordination notes and checking the Oklahoma PMP system. The receptionist might invite patients to complete the ***self-administered P.E.G. score and SBIRT screening questions***.

In addition to the routine rooming tasks, the nurse or MA might record answers to questions about ***adverse opioid effects***, review the ***med list and refills***, confirm and record the ***pre-visit P.E.G. and SBIRT*** scores and, perform a random ***urine drug screen.***

Clinician tasks include reviewing the pre-visit and rooming data, P.E.G. score, SBIRT behavioral health screen, and opioid risk indicators. During the interview and examination, the clinician records the patient's reported effectiveness of each element of the chronic pain plan. In the assessment, the clinician records a statement of the patient and clinician's agreement on the plan's effectiveness and records the rationale for making changes. The clinician ends the visit with revisions to the pain plan, medication changes, and referrals or co-management changes.

1.18 Delivery System Design

The office controlled drug prescription refill policy and procedure specifies how and when controlled substances will be refilled. Requests for exceptions to the plan may be a clue to controlled substance misuse or developing an opioid use disorder. The usual policy states, "replacement prescriptions for opioids that have been lost, stolen, or destroyed will not be provided in order to deter their diversion." Early refills will not be given without a face to face visit. Patients may pick-up prescriptions without being seen if there is no dose change and the patient has been seen within 90 days.

1.19 Patient Self-Care Support

The practice protocol for providing **Patient and Caregiver Self-Care Support and Education** might include embedded EHR materials as well as printed or web-based infographics or videos. The patient education protocol might include written scripts and office staff training in how to deliver the educational message.

Suggested content ***for patient education*** might include a description of chronic pain, emphasis that the goal of treatment is to reduce pain in order to improve function. Emphasis on functional restoration rather than pain relief, self-care through increased physical activity, nutrition and

sleep. The role of non-medication therapies that include social and spiritual restoration, may be effective in healing a brain with chronic pain can also be offered.

Practice education for clinicians and staff might include learning that substance or opioid use disorder is a serious, treatable disease that may be caused by treatment, that chronic pain, symptoms of behavioral health disorders, and the stress of social circumstances are intertwined into a confusing mix of unhelpful patient behaviors. Training in empathic, patient-centered, motivational communication and support improves therapeutic effectiveness. Posters and pamphlets strategically placed around the office may be used to communicate the message that we care and behavioral health problems or substance use disorder are treatable illnesses.

1.20 Patient-Provider Agreement

Oklahoma Law requires clinicians to document a Patient-Provider Agreement that includes "Informed Consent" when pain management includes opioids for more than 14 days for acute pain, or for a continuous prescription for more than 30 days for chronic pain. An agreement should be executed when simultaneous opioids and benzodiazepines are prescribed or when the dose is more than 90 MME per day. The Do No Harm program advises clinicians to execute a Patient-Provider agreement with informed consent when prescribing more than 50 MMED for more than a month. The informed consent specifies the goal of treatment to be reduction in pain in order to improve function in physical activity, relationships, work or avocational activities, and generally improved quality of life.

The informed consent states the limited benefits of opioid therapy and substantial risks for opioid side-effects, dependence and withdrawal, addiction, and overdose death. The consent establishes that improved function is an indication for continuing therapy, and failure to improve function or development of adverse events will be indications for discontinuation.

The consent commits to continuing care, support, and a safe, tolerable pathway for tapering and discontinuing chronic opioid therapy when risk exceeds benefit, when misuse or addiction occurs, or when risk to the public occurs as a result of diversion.

The consent clarifies the policy that prescriptions usually will not be given for early refills, lost, destroyed, or stolen controlled medications. The patient agrees to actively engage in the pain treatment plan, participate in regular monitoring through face to face visits and evaluation of benefit and risk of treatment. The clinician agrees to do what is possible to help patients move

toward their goals, appropriately treat adverse effects, and not suddenly or arbitrarily discontinue opioid therapy.

1.21 Clinical Decision Support

Clinical decision support tools guide clinicians through tough clinical decisions, but do not replace clinical judgment. The algorithm shown here helps answer the question: "Are opioids appropriate for this patient's non-life-terminating illness pain?"

If the patient is not currently taking opioids, follow the left side of the flowchart. Except in severe acute pain, there is no scientific evidence that opioids are superior to other forms of treatment for pain. If the patient has a past or current history of substance use disorder, behavioral health problems, sleep disordered breathing, chronic kidney or liver disease, the risks of using opioids exceed anticipated benefit, and it is better to maximize non-opioid treatment.

On the other arm of the decision, if there is a possibility that a trial of opioids may relieve pain sufficiently to improve function and there is no history of co-morbid conditions that increase risks of opioid adverse events then opioid therapy may be helpful.

For **acute pain,** a short-acting preparation, at the lowest dose and shortest duration may be indicated only if expected benefits for both pain and function are anticipated to outweigh risks. Three days or less will often be sufficient; more than seven days will rarely be needed. This approach helps reduce the opioids in the "medicine cabinet supply."

When pain lasts more than 90 days, by definition it is **chronic pain,** and the clinical decision to initiate opioid therapy is risky. A repeat clinical examination will be needed to make an accurate diagnosis and prognosis, clarify patient goals, and complete an informed consent to use opioids. For chronic pain, a short-acting opioid in the lowest dose for the shortest duration, not continuously but as needed might be prescribed.

When the patient is already taking opioid medications, the question is whether the therapy is achieving patient goals with minimal risks for addiction or mental health side effects. If opioids are improving and not reducing function, are a safer dose of less than 50 MME per day, and there is no evidence of opioid use disorder, then continuation may be appropriate. On the other hand if function is not improving, the opioid dose is greater than 50 MME per day, or there is evidence of OUD, then it is prudent to "do no harm" by NOT abruptly discontinuing the opioid, help patient

understand the risks of continuing opioids, carefully manage withdrawal symptoms, maximize non-opioid treatment, and taper opioids to discontinue and appropriately treat addiction or mental health problems that may be present.

1.22 Clinical Decision Support

One of the most difficult clinical decisions is what to do for patients whose pain has increased or function has deteriorated while taking opioids. Is the failure of opioid benefit the result of a change in the painful condition, the result of an adverse effect of the opioid medication itself, or coexisting psychosocial problems?

If the clinical condition has improved, but pain occurs at times of increased physical activity, or if a new injury, or a limited exacerbation of the disease occurs, prescribing non-opioid interventions is the first step. If necessary, prescribing low-dose, short acting P.R.N. opioids for 3 to 7 days may help after other therapies have been maximized.

If there is no change in physical condition, the cause of lost effectiveness may be development of an adverse opioid event such as tolerance, opioid induced hyperalgesia (OIH), or dependence and fear of withdrawal. **Tolerance** is the phenomenon of needing higher doses of opioids to achieve analgesia. Increasing the dose may return the desired analgesia; however, it also risks developing other adverse effects. Tolerance to the euphoria effect may develop rapidly causing patient to complain about loss of opioid effectiveness and request more medication. Consider slow taper and/or addiction medication such as buprenorphine.

OIH or Opioid induced hyperalgesia is a change in the brain associated with increasing dose and duration of opioids. It creates a generalized increased sensitivity to painful stimuli. Increasing opioid dosage worsens the painful condition and causes pain in parts of the body not initially affected. The appropriate treatment is tapering and stopping opioids.

Dependence with withdrawal symptoms develop in nearly everyone when long-term opioids are stopped abruptly. The earliest symptom of withdrawal is increased anxiety or fear of discontinuing opioids. This fear may drive opioid seeking and increase the risk of overdose. The tough clinical decision weighs increasing opioid dose or frequency to avoid withdrawal symptoms and managing the pain and anxiety of tapering with safer, non-opioid modalities. Generally, the degree of dependence and severity of withdrawal increases exponentially with opioid doses greater than 90 MME per day.

OUD, Opioid Use disorder, or Addiction is a potentially lethal chronic disease that may progress from physical dependence and brain changes affecting the euphoria, well-being, emotion, and decision making functions of the brain. When addiction is suspected, it must be confirmed and appropriately treated. Medication assisted treatment with an opioid agonist such as buprenorphine is an important component of an overall treatment plan for recovery in patients with co-existing addiction and chronic pain.

If opioid adverse effects are not suspected, then the consideration may be that the patient is using opioids to treat psychosocial problems. The clinical approach is tapering the opioid dose and treating or referring the patient for appropriate behavioral health treatment. If a behavioral health problem is not being self-treated, consider social services referrals for help with diversion for financial or recreational reasons.

1.23 Clinical Decision Support

One of the most important clinical decisions is "What do I do with legacy patients?" These are either long-term primary care patients taking chronic opioid medications, or new patients who have left doctors no longer prescribing opioids for chronic pain.

Many of these patients may take less than 50 MMEs per day. Others may be receiving higher doses of opioids, long-acting preparations, or combinations of sedating medications and opioids.

Although there is risk for harm in guideline discordant pain plans, there is also risk of harm in interrupting stable pain plans. Most patients on long-term high dose opioids will experience a withdrawal syndrome when dosing is interrupted or rapidly decreased. Withdrawal may be severe and may include cramps, vomiting, sweating, fever, anxiety, self-treatment, and drug-seeking. Sickness from severe withdrawal symptoms may influence patients to seek other sources of opioids. It is critical to work with the patient to keep them safe.

The suggested approach to legacy patients is to first do no harm! DO NOT abruptly stop opioid medications or dismiss guideline discordant patients from your practice. Provide patient education about the new expectations, and work closely with the patient to implement safer plans that include reduced dosing. Recommend the patient or family obtain naloxone to prevent overdose deaths. Slowly taper opioids and discontinue risky combinations when possible. If progress is slow or plateaus, do not abandon your patient! Be compassionate and persistent. Carefully manage withdrawal symptoms if they occur, and remain vigilant for substance or opioid

use disorders that may become apparent during the weaning process. Refer patients for addiction treatment services or prescribe dependence medications such as buprenorphine when indicated.

1.24 Clinical Decision Support

Unintentional opioid involved overdose is associated with repeated overdose, particularly in patients affected by Opioid Use Disorder and IV opioid use. These patients are best treated with frequent follow-up and intervention to get them into OUD treatment. Enrolling older patients with polypharmacy and multiple chronic illnesses in an intensive high risk care management program may be helpful. Recommending naloxone and training in its use for family and care givers is also important. Resources for obtaining free naloxone and finding OUD resources can be found at www.okimready.org

1.25 Clinical Decision Support

Tapering plans should go slow to minimize symptoms of opioid withdrawal while maximizing pain treatment with non-pharmacologic therapies and non-opioid medications. A fast taper would be a 10% reduction in original dose each week. If the patient has been taking opioids daily for a long time, a slow taper of 5% to 10% per month, or less, may be required. If the patient has developed a moderate to severe opioid use disorder, supervised tapering and detoxification in a hospital setting may be in order. Referral to an addiction specialist and or the use of opioid agonist therapy may provide greater patient safety. If the patient is suspected of diverting opioid medications and the urine drug testing indicates they are not taking opioids, then taper may not be necessary and the patient should be monitored for opioid withdrawal symptoms.

Even with informed consent, patients may be shocked when told their opioid regimen is not achieving the agreed upon goal and that it is best to lower, taper, or stop medications. Patients fear suffering will recur at greater levels and they may fear withdrawal sickness. These fears may lead to demands that opioid or benzodiazepine regimens be left in place, potentially forever, or else the patient will find medications elsewhere.

Slow taper, consulting experts in opioid use, continuing a supportive relationship, and using alternate therapies to address the fear that may turn to illnesses of anxiety or depression are important parts of the plan. Encouraging the patient through the taper and withdrawal anxiety

with statements such as, “most people have improved function without worse pain” and “you can do this, I’ll stick by you through it.”

In tapering opioids consider adjusting the rate and duration according to the patient’s response.

Should withdrawal symptoms or anxiety develop, don’t reverse the taper. Instead slow the rate or pause the schedule while managing withdrawal symptoms. Once the smallest available dose is reached, increase the interval between doses, and stop when the interval is less than once a day.

Providers should discuss with patients the increased risk of overdose after stopping opioids for as little as a week and abruptly returning to previously prescribed higher dosages.

1.26 Clinical Decision Support

A clinical decision support checklist can help identify patients with Opioid Use Disorder or those at risk for developing OUD. Patients with substance abuse or OUD may hide symptoms because of shame and fear of withdrawal if they are cut off from their supply of drugs. Non-judgmental scripts for asking these questions, addressing possible misrepresentation, and treating OUD as a non-shameful and treatable but potentially fatal condition are helpful tools.

The clues of developing OUD shown on this slide include a checklist of static ***risk factors*** of young age, family or personal history of substance use disorder, an ACE score of more than 4, and current mental illness.

An ***Opioid Risk Monitoring*** protocol provides more objective evidence of developing substance use disorder and prompts a non-judgmental conversation about the meaning of illicit substances or the absence of prescribed drugs in the urine drug screen. Seeking medication from other prescribers as identified from the OK PMP database, requests for early refills, higher doses, or specific medications are clues to developing use disorder or misuse of opioids to self-treat behavioral health conditions. The ***adverse-effect symptom checklist*** provides a third set of data for making decisions about the patient developing side-effects, opioid use disorder or misusing opioids for self-treatment.

1.27 Diagnosing Opioid Use Disorder (DSM-5 Criteria)

Opioid Use Disorder is a problematic pattern of opioid use leading to clinically significant impairment. In order to confirm a diagnosis of OUD, at least two of the DSM-5 criteria should be observed within a 12-month period: Loss of control exhibited by (1) taking opioids in larger amounts or over a longer period than was intended; (2) having a persistent desire or unsuccessful efforts to cut down or control opioid use; or (3) spending a great deal of time in activities necessary to obtain, use, or recover from opioid effects. (4) *Craving* is having a strong desire or urge to use opioids. *Adverse consequences* include: (5) recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home; (6) continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids; (7) giving up or reducing important social, occupational, or recreational activities because of opioid use; (8) recurrent opioid use in physically hazardous situations; or (9) continued opioid use despite knowledge that persistent or recurrent physical or psychological problem are likely to have been caused or exacerbated by the substance.

The last two diagnostic criteria, *tolerance and withdrawal,* without other symptoms*,* are not considered to be met for individuals taking opioids under appropriate medical supervision. *Tolerance*, is a need for markedly increased amounts of opioids to achieve intoxication or desired effect, or having a markedly diminished effect with continued use of the same amount of an opioid. There are two criteria for *Withdrawal Syndrome*: A) after stopping or reducing opioid dose following heavy or prolonged use, *or* after administering an opioid antagonist; and B) within minutes or days, three or more of the following develop: dysphoric mood, nausea or vomiting, muscle aches, lacrimation or rhinorrhea, pupillary dilation, piloerection, sweating, diarrhea, yawning, fever, or insomnia.

1.28 Diagnosing and Managing OUD

When OUD is suspected, the diagnosis should be confirmed with a thorough history and physical examination, urine drug screen and review of the prescription drug monitoring program. Patients may show no physical signs of opioid addiction, the diagnosis relies on respectful and supportive history of the patient's experience with opioids. Clinicians may use the DSM-5 criteria to make a diagnosis or arrange for an assessment by a specialist in addiction. Referrals for Oklahoma are found on the OKI'mReady.org website.

It is also important to remember that OUD exists on a continuum of severity. As a result, a scale for assigning severity was developed in DMS-5 and is based upon the number of criteria that have been met (2-3 for mild, 4-5 for moderate, and more than 6 for severe). This severity distinction has treatment implications.

When OUD is diagnosed, it is important to treat the patient like anyone with a serious, potentially fatal chronic illness. Do not dismiss the patient from primary care as they may have underlying or co-occurring diseases or conditions. Approach your patient with compassion to determine the effect opioid use has had on physical and psychological functioning. Empathize with the experience and outcomes of past treatment episodes, and the patient's potential for overdose. Risk factors for overdose include a past history of overdose, a past history of substance use disorder, opioid dosages >50 MME/day, and concurrent benzodiazepine use. Recommend naloxone when one or more of these risk factors are present, and educate the patient and his or her family about the symptoms of opioid overdose and how to administer naloxone. For more information about naloxone, visit OKImReady.org. Educate the patient that OUD is a treatable, serious medical condition and you will provide or arrange evidence-based treatment.

1.29 Clinical Decision Support

The follow-up monitoring process is designed to identify opioid adverse effects. Skillfully communicating the development of opioid side effects to patients may be enhanced by communication skills training and using scripts. The clinician's role is to differentiate and appropriately treat patients suffering from the life threatening illnesses of opioid use disorder or other behavioral health problems from those diverting drugs for illegal trafficking.

Medication side-effects such as constipation, confusion, or sleep disturbances are uncovered with monitoring questions and the clinical decision is to appropriately adjust medications or treat side-effects like constipation. When behavioral health screening questions as contained in the SBIRT protocol, urine drug testing, observed aberrant behavior, or irregular pill counts suggest **opioid use disorder**, clinicians should respectfully inform the patient of the data leading to this conclusion, arrange for a comprehensive biopsychosocial assessment, initiate treatment for OUD with buprenorphine and/or refer for evidence-based addiction treatment.

Screening for depression or anxiety may suggest patient self-treatment of an undiagnosed or undertreated **psychosocial problems**. Patients may use the opioid effect to self-treat depression,

anxiety disorder, post-traumatic stress disorder, or toxic brain injury from adverse childhood events. Opioids usually make these conditions worse. Recognizing the association between opioid use and psychosocial problems permits clinicians to appropriately diagnose, treat, or refer for psychiatric care. The clinician should respectfully discuss the findings and recommend treatment and/or referral to a licensed mental health professional, and begin tapering the opioid medications, carefully managing withdrawal symptoms.

Urine drug screens should be obtained randomly at least 2 to 3 times a year and more frequently if there is concern about misuse. Patients should not know in advance when a urine sample will be requested, therefore it may useful to obtain a urine drug screen from a patient when they visit for an unrelated condition. Absence of the prescribed drug in the urine may suggest, but does not confirm, diversion. The presence of other medications or illegal substances in the urine may suggest substance use disorder. Office-based testing, however, may only test a limited number of drugs, so it is important to take these limitations into consideration when interpreting the test and use confirmatory laboratory testing.

When absence of a prescribed drug in the urine drug screen or aberrant behavior suggests diversion, clinicians should respectfully report the data, indicate how this behavior violates the informed consent agreement, and that the clinician will no longer be able to prescribe opioids or other controlled substances. If the patient is taking some of the opioids, then rapid taper and/or referral for treatment of OUD is warranted. Dismissal may be appropriate ONLY if the patient has committed verbal or physical threats to the provider or staff or if they have engaged in criminal activities involving the clinician's prescribing.

1.30 Information Technology Support

Treating chronic pain with opioids requires good documentation. Templates in the EHR remind clinicians of guidelines and prompts efficient documentation of the necessary elements. The progress note might include a statement of the patient's assessment of progress toward achieving their goals for treatment. It should include an objective measure of pain, interference with enjoyment in life, and interference with general activity. The P.E.G. score provides a numeric value that can be tracked for changes over time. Next should be the results of a PMP check and urine drug testing, if done. The next item might be the patient's response to direct questions

about adverse drug symptoms. Lastly, the note should include a statement about any change in the patient's appearance, mood, or behavior, particularly aberrant behaviors.

In the **Assessment and Plan**, the clinician explains his or her thinking about the patient's current medical status, level of compliance, and rationale for continuing the same regimen, making changes, a new referral, modifying the goals, and discussing any issues of compliance. The plan documents the medications prescribed at the visit, as well as any referrals made or diagnostic tests ordered. The EHR **medication list** provides an accurate record of doses, refill dates and quantity. **Phone calls, faxes, and e-mail communications** between you or practice staff and patient are also documented.

HIPAA and Communication with Family Members - Should a relative call or communicate wishing to provide information about a patient, but the clinician does not have permission to disclose information to this person, clinicians often refuse to speak to the person stating that talking with them would violate HIPAA. A better approach is to say to the caller, "I can't say anything, but I'm ready to listen." This remains HIPAA compliant. The clinician then documents what the caller said in the record, and prepares to take appropriate action on the information.

1.31 Information Technology Support

Co-management and tracking referrals and reports of consultations is important for coordination of care. Ideally an electronic tracking system either built into the ERH or in an external application can be used.

Preparation for referral, consultation and co-management with specialists can be facilitated by identifying the contact information for preferred specialists and treatment centers. A primary care-specialist agreement (also called a "compact") spells out the expectations of both parties for making clinical decisions, ordering tests and procedures, and communicating patient results and progress. Compacts address transitions of care, access, collaborative care management, and patient communication.

Electronic record transfer is most effective, but often not readily available. Care coordination nurses may develop work-arounds to track referrals and information.

Hospitalizations and emergency department or urgent care visits are much more frequent in patients with chronic pain using opioid medications. A tracking protocol might include receiving

an automated, electronic “Admission, Discharge, Transfer” (ADT) notification from hospitals, emergency departments, and if available from urgent care centers. This permits scheduling a primary care visit within 72 hours following these encounters. The ADT notification is a standard messaging format incorporated into institutional billing processes. It is important for clinicians to respond through evaluation and dose adjustment to any information gained about possible misuse, abuse, or addiction, as well as to ED visits or accidents caused by over-sedation or abuse. A prescriber could be held liable for injuries or deaths caused by the use of a controlled substance.

1.32 Information Technology Support

Billing codes exist from various insurers that will pay for pain assessment and screening and intervention for drug and alcohol use.

1.33 Information Technology Support

Successful implementation of guidelines can be motivated by measuring the impact of workflow and staffing changes on the quality of care. You may wish to generate pain and opioid performance measures from the EHR and analyze them at practice meetings to help you and your staff make changes needed to implement the guidelines. You can display the measures over time in charts to demonstrate how changes impact the measures. You and your staff can brainstorm ideas for further improvement, test the best ideas in a small number of patient visits, and when the small test shows improvement in measures, the change can be implemented across the entire practice.

The Center for Medicare/Medicaid Services (CMS) and the National Quality Forum (NQF) have endorsed performance measures that document guideline-based pain assessment, planning, monitoring, and mitigating complications. Most practices must modify their EHR and workflow to generate performance measures. With the MIPPS payment program, reporting performance measures may generate bonus payments. The measures currently in use are: Written pain care plan, screening for substance use disorder, screening for depression, assessment of pain, and monitoring for opioid misuse.

Advanced primary care practices maintain dashboards showing trend lines across various performance measures. Practices participating in a learning collaborative receive benchmarking

performance data to determine how they perform relative to peers. High performers can be identified, and their policies and procedures can be investigated to get ideas that might improve performance in other practices.

1.34 Summary

In summary, to implement pain and opioid management guidelines, you can modify your delivery system design, your patient education and self-care process, your clinical decision support tools, and your information technology.

You might modify your delivery system to introduce structured chronic pain visits and clinician and staff teamwork protocols and scripts to assure consistency of care. You might modify your patient education to enhance self-care for achieving overall better health and use a signed informed consent when opioids are a part of the pain plan.

You might support clinical decision by using algorithms or other materials to guide making difficult clinical decision and following written scripts to deliver difficult messages. You might maximize your information technology with EHR templates, use electronic messaging for coordinating co-management with specialist, use the Oklahoma online PMP system, and report quality measures to drive practice improvement.

The Oklahoma Primary Healthcare Improvement Cooperative provides intensive practice facilitation, peer coaching, and technical assistance to help you implement the pain and opioid management guidelines.

1.35 Instructions

Please answer the following self-assessment question by selecting the single best answer. You will receive immediate feedback and if you selected an incorrect response you may answer the question again.

1.36

Question 1

1.37

Question 2

1.38

Question 3

1.39

Question 4

1.40

Question 5

1.41

Question 6

1.42

Question 7

1.43

Question 8

1.44

Question 9

1.45 Resources

The references on this slide provide additional resources for making changes in practice systems needed to implement practice guidelines

1.46 Closing Instructions

You may print a certificate of completion in order to meet the requirements for annual training by clicking on the reports tab.

In addition, the University of Oklahoma Office of Professional Development is providing CE credits. MDs are eligible for AMA PRA Category 1 Credit, Physician Assistants for AAPA Category 1 Credit, and Nurse Practitioners for AANC contact hours and Oklahoma pharmacology hours.

Until March 1, 2020, the University of Oklahoma will waive the $25 fee.

Click on the web link which will take you to the Office of Professional Development web site where you may register, take a test of knowledge, evaluate your learning experience, and print your CE certificate.