Standards of Care for Opioid Prescribing: What Every APRN Prescriber and Investigator Need to Know

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Opioid misuse is becoming an epidemic. Knowledge of nationally vetted standardized methods of pain assessment, safe treatment options and modalities, and follow-up evaluation for patients on opioids is essential for health care providers. This article outlines the current standards of care for pain management and safe opioid prescribing that are necessary for APRNs and other providers prescribing opioids. These guidelines should serve as the standards of care for prescribers, as well as boards of nursing and their investigators when evaluating violations that involve poor or inappropriate prescribing, abuse, and other issues related to opioid prescribing.

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Opioid misuse, diversion, and overdose are major public health problems in the United States (Substance Abuse and Mental Health Services Administration, 2013; Sullivan et al., 2010). An increasing number of people misuse opioids for nonmedical reasons (American Society of Addiction Medicine, 2015), and the media’s focus on pain management has increased public awareness of the following: Pain is a common malady, providers can help resolve pain, treatment alternatives are available, and treatments are plentiful and easily obtained. Today, the public focus appears to be shifting away from opioid misuse to an emphasis on untreated pain (Van Pelt, 2012) and the benefits of a controlled treatment plan.

The advanced practice registered nurses (APRNs) who treat patients seeking pain relief are most commonly certified nurse practitioners (CNPs) in family practice settings who, like their family physician counterparts, often lack formal education in pain management (Institute of Medicine, 2011). (See Table 1.) In fact, more than 50% of opioid prescriptions are written by primary care providers, including CNPs (Breuer, Cruciani, & Portenoy, 2010). These providers may face clinical situations in which they make decisions based on past experience or on-the-job training without any knowledge of nationally vetted standards of care (SOCs) for pain management, and such decisions can have unintended consequences, such as opioid diversion or overdose death, that result in formal complaints to state boards of nursing (BONs).

Complaints to BONs regarding opioid-related problems come from law enforcement, patients, family members of opioid abuse victims, employers, and other providers (U.S. Department of Health and Human Services, 2014). The BON investigator must analyze the circumstances of the complaint and determine if a violation of a nurse practice act (NPA) or its rules occurred. A BON investigator may use a contracted pain management clinical consultant for an in-depth record and practice review, but the investigator usually performs the initial assessment to determine if further investigation is warranted by the BON. Some BONs have disciplinary committees or other mechanisms whereby board members must evaluate complaint investigation findings to determine whether an NPA violation has occurred, evaluate risk to the public, and consider the likelihood of repeat violations. The purpose of this article is to provide the BON investigator with an overview of accepted SOCs in pain management and opioid prescribing that can help inform decisions about the severity of a complaint and future actions.

Safe Opioid Prescribing Practices

The complexity of treatments, diversity of approaches, and the number of sources that can be used to determine acceptable practice present challenges to clinicians and investigators. Each case must be evaluated on its merit and its distinct circumstances. However, the evidence supports common safety practices and clinical indicators that can guide assessment, interventions, and safe opioid prescribing. No provider can be responsible for all actions that patients take after they leave the office, but a provider maintains a responsibility to make opioid use as safe as possible. For this reason, both patient-focused and provider-focused national associations have developed and endorsed consistent SOCs to protect the patient and the public from opioid misuse.

Determining whether SOCs are met can be easier for BON investigators if they have a broad understanding of the pain management care process and the ways pain management SOCs are
TABLE 1

Opioid Prescribing: Safe Practice, Saving Lives

The U.S. Food and Drug Administration has approved a risk evaluation and mitigation strategy (REMS) called “Opioid Prescribing: Safe Practice, Saving Lives”. The project is the result of a multidisciplinary collaborative of 10 founding partners and four cooperating organizations that designed a core curriculum based on needs assessment, practice gaps, clinical competencies, and learner self-assessment.

These education programs are available nationally. For certified nurse practitioners, the programs have been offered annually since 2012 at the American Association of Nurse Practitioners conference and at some individual state annual nurse practitioner meetings. The goal of the partnership is to work collaboratively to improve pain management and prevent adverse outcomes (U.S. Food and Drug Administration, 2015).

Four Phases of Assessing Pain Management

SOCs help provide the investigator with an approach to evaluating the pain management care process in four phases.

- Phase one concentrates on the pain-related history and physical examination.
- Phase two focuses on the decision to treat the patient with opioids or to refer the patient to a pain specialist.
- Phase three considers the initial prescription and any subsequent dose changes.
- Phase four concentrates on ongoing treatment and evaluations.

The nationally vetted SOCs have specific recommendations for each phase.

BON investigators should seek evidence that the SOC components of treating pain with opioids are implemented and documented by the APRN in each phase of the treatment process. This evidence will help BON investigators determine whether the treatment by the APRN meets the national SOCs. A checklist can be a useful investigative aid in determining if an APRN had an awareness of and complied with the SOCs, documented fully, and provided safeguards to identify and avoid opioid misuse. (See Figure 1.)

Phase One: History and Physical Assessments

In the clinical record, the BON investigator should find interview documentation reflecting a history of the illness or injury that caused pain, mitigating factors related to treatment, and management of comorbidities that are affected by opioids, such as respiratory and renal diseases. The assessment phase includes reports from referrals to therapies, laboratory and imaging study results, electrophysiology studies, opioid abuse screening tool reports (Arnold & Claxon, 2015), urine drug test (UDT) results, reports from state boards of pharmacy’s prescription drug monitoring programs (PDMP), and use of a level-of-pain patient self-reporting scale (Office of National Drug Control Policy, 2011). Screening tools are widely used, and evidence supports their accuracy (National Institute on Drug Abuse [NIDA], 2014a).

Clinical documentation addressing the use of prescription drugs, illegal substances, alcohol, and tobacco provides insight as does a family history of substance abuse or psychiatric disorders or a history of sexual abuse. The social background should identify the person’s current employment, employment history, social networks, marital status, legal history, and behavioral patterns. Three risk factors that have significant association with substance abuse are a personal or family history of alcohol or drug abuse, young age, and a current psychiatric condition (Starrels et al., 2011). All of the data collected during the history and physical examination and evaluation phases is used to formulate a comprehensive plan of care for treating pain that will guide the use of opioids.

If SOC components of treating pain with opioids, such as the use of opioid risk assessment tools, are not documented, the investigator should closely evaluate the documentation throughout treatment. The investigator should also keep in mind that even though recreational marijuana use is legal in some states, the scoring of risk assessment tools based on marijuana use has not changed (NIDA, 2014b). Additionally, BON investigators should question why APRNs who have patients with scores indicating high risk did not refer these patients to pain management or addiction specialists.

Phase Two: Decision to Treat with Opioids

The BON investigator should look for an informed consent document signed by both the APRN and the patient or guardian. This consent serves as documentation that the risks and benefits of treatment have been discussed with the patient and are understood (Cheatle & Savage, 2012). The benefits of opioid treatment include obtaining a level of analgesia so activities of daily living can be maintained. The risks include overdose; life-threatening respiratory depression; drug abuse by the patient, household contacts, or friends; physical dependence or tolerance; drug interactions; neonatal withdrawal syndrome; and inadvertent ingestion by children or others.
FIGURE 1

Investigator Checklist for Evaluating Opioid Prescribing

During the four phases of assessing pain management, the investigator looks for evidence of the following:

Phase One: Initial History and Physical Evaluation With Test Results and Analysis (Based on this information, a decision to proceed with treatment or to refer to a specialist will be made.)
☐ A traditional medical and a pain-specific history that includes prescription and illicit drug, alcohol, and tobacco use
☐ A physical examination that is both comprehensive and pain specific
  ○ A patient self-rating of pain severity score such as Wong-Baker, Faces, or 1-10 that is consistently used with each visit
☐ A baseline urine drug test (UDT) with an explanation of the results (*example might be positive for marijuana metabolite in states with legal marijuana use)
☐ An opioid misuse risk tool evaluation (ORT [Opioid Risk Tool], SOAPP [Screener and Opioid Assessment for Patients with Pain] or other web based available tool)
  ○ Include a discussion of the score and any mitigation strategies implemented as a result of the score
☐ An initial depression screen with result analysis
☐ A review of the prescription drug monitoring program (PDMP)

Phase Two: Decision to Treat
☐ A benefit-vs.-risk assessment and discussion should be documented in the clinic notes
☐ An informed consent form signed by both the patient and provider detailing medication, benefits, risks, and expected outcomes of treatment
☐ A signed patient and provider agreement (PPA)

Phase Three: Initial Prescription and Initial Dosage Changes
☐ A benefit-vs.-risk assessment and discussion when doses are increased or the drug family is changed
☐ A reason for a dosage increase
  ○ A reason for any change in the medication or plan to treatment

Phase Four: Ongoing Treatments and Evaluations
☐ Regular reviews of the PPA during visits with documentation that the discussion happened
☐ Sporadic UDTs (These are not necessary at each visit, but recommended several times annually and when problems are identified.)
  ○ The results should be documented as discussed with the patient and any positive results should have a mitigation plan documented
☐ Regular reviews of the board of pharmacy's PDMP (recommended at visits and when refill prescriptions are given)
☐ Ongoing assessment for adverse effects, aberrant behaviors, or expected clinical outcomes to treatment
☐ Ongoing clinical counseling and education specific to medicines and pain management that includes the patient and family members or others
☐ A prescription for naloxone (also note if this is prescribed by the pharmacist as some states allow this)
☐ A referral to a pain specialist (for complex or problem patients) or documentation of the reason for no referral
☐ A referral or a consultation about the treatments (for patients who fail to respond to treatment)
☐ Appropriate prescriber education (if methadone or other medication [suboxone] was prescribed that requires or offers prescriber continuing education specific to its use)
The BON investigator should also review the patient and provider agreement (PPA), formerly referred to as a pain management contract. The PPA, which should be signed by the patient and the APRN, clearly informs the patient and family about expected behaviors, identifies consequences for noncompliance with the agreement, and gives the provider an exit strategy should the patient be discharged from the practice. Common requirements of PPAs are that a patient will use only one prescriber for pain medicines and only one pharmacy to fill pain medicine prescriptions, will safeguard medications in secure or locked cabinets, will not share medications, will comply with ongoing patient monitoring requirements such as random UDTs and pill counts, and will notify the pain management provider of treatments by other providers or emergency department visits (Starrels et al., 2010).

Phase Three: Prescribing Trial of Opioids

Initial treatment should be considered a therapeutic trial with specific goals, established guidelines, and treatment parameters. During the trial, the opioid dosage may increase, or the prescribed drug may change from one type of opioid to another, such as from oxycodone (OxyContin) to morphine.

Phase Four: Ongoing Treatments and Evaluations

During this phase, most problems tend to surface. The APRN’s familiarity with the patient, the treatment, and prescribing routines can result in lax monitoring, reduced documentation, and a disregard for subtle behaviors that can indicate potential problems. When initial treatment progresses to ongoing treatment, the APRN should continue to document evaluations and care thoroughly (Chou et al., 2009). At each visit, the APRN should obtain the patient’s self-reported pain rating based on a consistently used standard tool (Williamson & Hoggart, 2005). Dosage reduction should be attempted, and justification for dosage escalation should be documented. Common adverse effects, such as constipation, nausea, drowsiness, sedation, and itching, should be evaluated and treated. At each visit, the APRN should document whether the patient is adhering to the treatment plan and the PPA. Monitoring techniques can include recognition and documentation of aberrant drug-related behaviors. Interviews with the spouse and other family members can provide clues and should be documented. The APRN should be documenting in the visit notes reviews of the PDMP at the time of refills, and sporadic UDTs and opioid-misuse risk assessment tool results as indicated in the PPA or when misuse is suspected (PainEDU, 2015). Deviations from the PPA, positive UDTs, and other aberrant behaviors must be documented in the medical record with a mitigation plan for resolution and future monitoring. The treatment plan should have measurable outcomes to evaluate therapeutic success, including assessing improvement in physical and/or psychological functioning to guide continued care and interventions, and a status evaluation should be documented at each visit.

Throughout the process, investigators should always be aware of the following red flags of inappropriate prescribing of controlled substances, including:

- Lack of documented physical examination/diagnostic testing
- Lack of treatment plan and/or lack of PPA
- High-volume, cash-paying patients
- Prescribes high doses, large quantity
- Care not consistent with national guidelines
- Provider notes unchanged from visit to visit
- Drug Enforcement Administration and law enforcement interest
- Pharmacies refusing to fill prescriptions
- Lack of formal training (education) and precepted experience in pain management

Using the SOC to Evaluate Compliance

The following case studies describe the practices of two APRNs who evaluated patients before prescribing opioids. Case 1 portrays a seemingly compliant patient treated over a prolonged period, and although the APRN meets the SOCs for safe opioid prescribing, misuse is discovered. Case 2 depicts an APRN who failed to follow the SOCs, but the resulting problem is not opioid misuse.

Case Study: SOP Compliance and Opioid Misuse

William, a 45-year-old white male, goes to the CNP’s office as a new patient to establish care because the provider he has seen for the past 10 years is retiring. The CNP knows of the provider’s retirement, accepts the patient, and obtains the patient’s medical records. William’s history includes a motorcycle accident at age 30 that resulted in a fractured femur and a back injury. The femur healed without problems, but the back pain persists. For 6 years, the pain has been managed with oxycodone 60 mg twice daily. William reports that he is a construction worker with seasonal employment and that he has more pain when he is working, which is about 60% of the time. He has been divorced for 5 years and has two children. His only legal issues were at the time of his divorce when his ex-wife obtained a restraining order. He is a clean, well-dressed, muscular male who appears his stated age. William is friendly and answers all questions and agrees to all requests, including requests for a UDT and an opioid-abuse risk assessment. The UTD is positive for oxycodone metabolite and THC from marijuana use. However, recreational marijuana use is legal in the state, and he admits to smoking because he thinks it helps him reduce his use of oxycodone. William answers the five questions of the Screener and Opioid Assessment for Patients with Pain (SOAPP) tool, which has weighted score responses of 0 to 4. William’s score is 5 because he says he has used marijuana frequently, and even though marijuana is legal, it is still scored a 4, indicating illicit drug use. He also scores a 1 (seldom) in responding to this question, “In your lifetime have you ever had a legal problem or been arrested?” The score of 5 places William at high risk for opioid misuse.
In the clinical interview, the CNP discusses and documents the score and obtains clarification on William’s answer to the marijuana question and his explanation about his legal issue. An informed consent and a PPA are completed. The CNP gives William a prescription refill based on his existing treatment plan. William states that he wants to see if he can decrease his dosage and asks not to have a large-dose (40-mg or 60-mg) tablet. Instead, he requests oxycodone 20 mg so he can take one, two, or three at a time as needed, which is his routine. He says that he normally tries to cut down the dose on days off work and at night.

The next visit is straightforward. William receives a 30-day refill prescription for oxycodone 20 mg tablets; the dosage is 60 mg twice daily for a total of 180 tablets per month. This routine continues for 18 months during which William has two UDTs and PDMP reviews every other month without any problems. There is never any evidence that William has successfully decreased his dose, but he has never asked for a dosage increase. Twice he brings in eight unused 20 mg oxycodone tablets, stating that he tried to reduce his usage but that his back pain returned when he went back to work. He resists changing the plan, explaining that oxycodone worked and he is happy with his functional level.

Subsequently, the police investigate the death of a 20-year-old female who was drinking heavily and had taken several oxycodone tablets at a party. Her boyfriend, who gave her the oxycodone, is arrested and reports that he bought the tablets from William. William is arrested for selling drugs, and the prescription is traced to the CNP. William’s records are requested, and the CNP’s prescribing practices are investigated by the BON investigator.

The BON investigator uses the checklist SOC evaluation tool to determine if the CNP’s prescribing practices meet the SOC and if sufficient safety strategies were in place to identify or avoid misuse. The investigator determines that the CNP did meet the SOC because there was a documented and thorough pain assessment and a completed risk assessment tool with the score evaluated and justified. Furthermore, a UDT and PDMP review were documented before the initial prescription, and regular reevaluations were performed. The patient did not demonstrate any aberrant behaviors to alert the CNP to a problem. However, there were three red flags: The SOAPP abuse risk assessment tool score indicated a high risk of misuse; the patient resisted a change in medication; and the patient continued to request 20-mg tablets so he could try to reduce his usage, though there was no evidence that he did. William routinely used oxycodone 20 mg twice daily and sold his excess tablets to supplement his income. The UDTs showed presence of oxycodone, but UDTs cannot determine the dose. William’s case is an example of unintended consequences despite compliance with the nationally vetted SOC established to aid patient and public protection.

Case Study: Failure to Refer

Martha, a 57-year-old white female, visits a CNP complaining of back, joint, hip, and rib pain. She has an unremarkable medical history except for a mastectomy at age 45. She is employed as a florist and often lifts medium to heavy flower boxes and works in a refrigerated area. She believes she has arthritis that she has treated with acetaminophen as needed, but the medication has become less effective. She has lived in a rural town of 1,500 people all her life, and her husband is a police officer. Her daughter is an elementary school teacher, and her son is in college. Martha and the CNP go to the same church and know each other socially.

The CNP gives Martha a prescription of hydrocodone 10/325 mg every 4 hours as needed. Over the next year, Martha is seen by the CNP every 4 to 6 weeks for medication refills. After 9 months, the pain has increased, and the prescription is changed from hydrocodone to morphine. The morphine controls the pain much better, and the prescription is refilled monthly. Martha reports some nausea and weight and appetite loss, and the CNP prescribes promethazine as adjunctive therapy. As recommended by the CNP, Martha begins using over-the-counter esomeprazole (Nexium). After a year, Martha’s daughter encourages her to see an internal medicine physician for her continued weight loss and loss of energy. During visits to the physician, it is discovered that Martha has cancer that has metastasized to her bones. The primary site is her breast, which had been treated surgically. The physician reports the CNP to the BON for missing the correct diagnosis and failing to refer the patient.

Opioid misuse was not the problem, but Martha was treated with opioids, and the BON investigator needed to review the record to determine if the SOCs for safe opioid prescribing were met. There was no evidence that risk screening, UDT, informed consent, PPA, or any safeguards were implemented. There was also no evidence that the CNP conducted a proper physical and diagnostic examination nor did the CNP appropriately evaluate the source of pain via diagnostic testing and imaging scans. Thus, the CNP did not meet the SOCs. Despite the facts that an opioid misuse problem was not suspected and the CNP knew the patient and her family, the SOCs still should have been met. Unfortunately, the CNP did not associate the history of mastectomy for cancer treatment with the current symptoms, and failed to conduct a proper diagnostic assessment and examination. The CNP must corroborate the source of pain beyond what is reported by the patient. The SOC that could have assisted in Martha’s treatment was a referral or consultation with a specialist, which was indicated because of dosage increases and a deteriorating physical condition.

Conclusion
Complaints to BONs often involve patients with obvious chronic abuse and manipulative behaviors that are commonly seen in pain management clinics and are becoming more commonly seen in family practice settings. Some patients are more difficult to assess than others. But the drug abuse risk can be just as high for someone who presents as an engaged, employed professional as for someone with a history of depression and unemployment who is in an abusive relationship.
For BON investigators, gathering evidence pertinent to the specific complaint is the primary focus. But APRN practices that fail to meet generally accepted SOCs—whether noted in the patient’s complaint or not—should be identified as substandard and reported because such practices pose a safety risk. Evidence must be documented to demonstrate that appropriate assessments were completed, interpreted, and discussed with the patient and that clinical safeguards, such as informed consent, PPAs, UDTs, and regular ongoing monitoring, were used. Appropriate interventions must be implemented and documented whenever opioid abuse is suspected or confirmed.

References

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