

# Safe Opioid Prescribing: A Long Way to Go

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Chronic pain is one of the most common reasons why patients visit a physician; yet, physicians are poorly trained to manage it. Despite centuries-long therapeutic use of opioids for pain, they fell out of favor for most of the 20th century in the US. However, in the 1980s, medical literature began to support the practice of prescribing opioids for chronic non-cancer pain.<sup>1</sup> Opioid prescribing then escalated over the past two decades,<sup>2</sup> despite lack of strong evidence supporting this practice.<sup>3</sup> Although it started as an antidote to undertreatment of pain, increased opioid prescribing has paralleled increases in opioid misuse including overdoses, diversion and addiction.<sup>4,5</sup> Over the last decade, the medical and public health communities have begun to address this problem by cautioning that all patients prescribed opioids carry some degree of risk for opioid misuse. Recent clinical guidelines based on expert consensus now endorse universal assessment for opioid misuse risk and monitoring for subsequent potential harm.<sup>6–8</sup> The guidelines suggest that patients at “high risk” for misuse should be identified through individual patient risk factors, such as an existing diagnosis of substance use disorder (SUD), mental health problems, history of legal problems and younger age. Treating chronic pain with opioids should include monitoring for harm including urine drug testing to detect any illicit substance use and whether the prescribed opioid is being taken, frequent prescriber visits, pill counts to evaluate adherence with opioid dosing and to minimize diversion, use of state prescription drug monitoring program data, when available, and addressing aberrant opioid taking behaviors<sup>9,10</sup> such as patients requests for early refills. More intensive monitoring is recommended for those with more risk factors. When necessary, physicians should also refer patients to adjunctive mental health or addiction treatment specialists for co-management, when such services are available.

Few data guide the questions on quantity and frequency of monitoring to identify harm or misuse of opioid analgesics for chronic pain. The guidelines suggest conducting urine drug testing every three to six months for low-risk stable patients, and as often as weekly for high-risk patients.<sup>8</sup> In this journal, Starrels<sup>11</sup> and Morasco<sup>12</sup> use administrative data to examine adherence rates to minimal guideline-based care for patients in two different settings: primary care practices within the University of Pennsylvania Health System and Veterans Affairs Health Centers in the Pacific Northwest. Both authors show

that although patients with the identified risk factor of SUD are monitored 2–3 times more closely with urine drug testing than patients without identified SUD, only a minority of these high risk patients are being tested. Morasco and colleagues found that even with the infrequent testing, a substantial portion of patients tested had illicit substances in the urine, including 1 in 20 patients without SUD and 1 in 7 patients with SUD. Furthermore, data from Starrels and colleagues suggest that patients with identified SUD received more frequent early prescriptions on a monthly basis including 1 out of 4 receiving multiple early refills over the duration of time receiving chronic opioids (mean 1.9 years).

Why are monitoring rates in these two systems of care so much lower than that suggested by clinical guidelines? Is it lack of familiarity with recent guidelines, or reluctance to institute time-intensive clinical practices that lack a sufficient evidence base? We believe that several factors may contribute to non-adherence to guidelines. There is a well known lack of formal pain and addiction curricula in medical schools, residencies and in continuing medical education.<sup>13,14</sup> In response to these gaps in medical education, federal agencies have started investing in prescriber education. In 2007 the National Institute on Drug Abuse (NIDA) partnered with eight US medical schools to develop innovative drug abuse and addiction curriculum resources.<sup>15</sup> Recently the FDA met with members of the pharmaceutical industry to outline new requirements for manufacturers of certain opioid analgesics to develop Risk Evaluation and Mitigation Strategies (REMS) that will require physician education.<sup>16</sup> As an additional sign of increased attention, in fiscal year 2010, the National Institutes of Health designated research on prescription drug abuse one of its 220 research topic funding priorities, at which time \$36 million was expended in this area.

Even if the rate of monitoring using urine drug testing can be increased, it is not clear that monitoring alone can improve clinical care and thus decrease the rate of opioid misuse.<sup>17</sup> For example, near-universal implementation of a visual analog pain scale in the VA health system nationally was not associated with improvement in clinical care for pain.<sup>18</sup> Clinical care improvement requires education about interpretation of the assessment or monitoring tests, as well as effective communication skills in talking to patients about concerns about opioid misuse. Urine drug testing in particular is quite complex, and requires knowledge of the opioid chemical derivative (e.g. synthetic, semi-synthetic or naturally occurring) and potential metabolites, the duration of detection of the opioid and time of last ingested dose, and the type of assay performed (liquid chromatography vs. immunoassay) and positive cut-offs used by the lab.<sup>19</sup> Any unexpected result requires appropriate inquiry with the patient to help interpret the findings and place them into context. Furthermore, incorrect interpretation of urine drug testing may result in a

patient being inappropriately discontinued from useful therapy and may lead to a subsequent rift in trust between patient and physician.

Physicians' attitudes toward opioid prescribing vary widely, ranging from no prescribing at all to very liberal prescribing.<sup>20,21</sup> There are geographic variations in both prescribing and abuse of prescription opioid analgesics.<sup>22,23</sup> Thus, the increasing prevalence of misuse of and addiction to prescription opioid analgesics attributable to physician prescription appears to be the result of a perfect storm: inconsistent and inadequate physician education, lack of sufficient evidence of efficacy and safety of opioid analgesia for chronic pain, and lack of adherence to guideline-based risk assessment and monitoring.

A multifaceted approach to improve opioid prescribing efficacy and safety is urgently needed. Such an approach must start with clinical policies to monitor all patients, while basing the intensity of monitoring on the individual patient's opioid misuse risk. It will need to include systems approaches, such as use of the electronic health record (EHR) to track a patient's adherence to guideline-based treatment plans. Using automated systems, point of care clinical decision support tools and statewide prescription drug monitoring program data may not only lessen the burden on physicians but may provide higher quality care.<sup>22</sup> It is critical that primary care physicians collaborate with colleagues in behavioral health, pharmacy, toxicology and specialty addiction and pain medicine to share knowledge and consultation on prescribing, monitoring and treatment plans if a patient is developing problems (e.g., addiction). This necessary collaboration may be facilitated in the setting of patient-centered medical homes. Additionally, patients need education on the limitations of opioid analgesics, appreciation of the risks associated with opioids (e.g., overdose) and ways to mitigate any risks (e.g. no increases in opioid dose in between visits). Research must be conducted in real world clinical settings where a multifaceted systems approach is examined for effectiveness in improving both individual and population-based outcomes.

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