Evaluating Consequences of Opioid Prescribing Policies

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Overprescribing of opioid analgesics is understood to be a root cause of the ongoing US opioid overdose death and addiction crisis. For patients, overprescribing generates unnecessary exposure to risk of opioid-related injuries, opioid use disorder, and other adverse effects. Although the appropriate level of opioid prescribing is not always clear, examples of overprescribing are easy to find. For example, opioids are frequently prescribed for back pain even though they are not superior to other treatment options and not recommended in back pain management guidelines.^{1–3} Even when opioids are clearly indicated, they are often prescribed in larger quantities than needed, resulting in leftover pills that may be misused or diverted.⁴

Policy makers seeking to address the opioid crisis have increasingly translated concerns about opioid overprescribing into a patchwork of rules aimed at modifying prescriber behavior, often by directly restricting prescribing.⁵ The study by Dr. Lowenstein et al. aims to evaluate effects of one such policy—a New Jersey law that restricts all new opioid prescriptions for acute pain to 5 days in duration.⁶ The law was specifically requested by New Jersey Governor Chris Christie to reduce opioid addiction by limiting the supply of prescribed opioids.⁷ No clinical or policy justification was provided for the 5-day limit, the “toughest” state prescribing restriction at the time.

Lowenstein and colleagues aimed to evaluate effects of the 5-day law and a supporting electronic medical record (EMR) alert on opioid prescribing behavior of clinicians in outpatient primary care, obstetrics gynecology, and cardiology clinics within a single health system spanning two states—one affected by the new law (New Jersey) and one unaffected control (Pennsylvania). The study’s primary and main secondary outcomes were total dose in morphine mg equivalent (MME) and number of pills per prescription, respectively. These outcomes directly corresponded to lawmakers’ stated goal to reduce the volume of opioids prescribed. Secondary outcomes to assess potential harm related to underprescribing were refills and encounters (telephone, outpatient, emergency) within 30 days.

The main study result was a greater decline in total dose and number of pills per prescription in New Jersey than in Pennsylvania. New Jersey had an 83 MME and 10.4 pill greater reduction in prescribed opioids overall. These between-state differences were relatively modest, especially considering that total dose and pills per prescription were initially higher in New Jersey (mean 340 MME, 47 pills) than in Pennsylvania (mean 219 MME, 36 pills). New Jersey’s prescribing volume remained higher than Pennsylvania’s in the post-implementation period. Significant differences in refills or visits were not identified. The authors concluded that the law plus EMR alert implementation was associated with reduced opioid prescribing, without evidence of unintended consequences.

The authors appropriately acknowledge limitations of their data source and difficulties in using retrospective observational data to evaluate effects of policy interventions, especially those occurring in the context of other policies and secular trends. Their data included only health system prescription and visit data; they did not have patient-reported data on pain, satisfaction with treatment, or other outcomes. Beyond these acknowledged limitations, study design choices also limit the conclusions that should be drawn from this study.

One important limitation is the choice of overall prescribed opioid volume (assessed as total dose and number of pills per prescription) as the outcome. The decrease in overall prescribing could be caused by a variety of opioid prescribing practice changes, which could have varying clinical appropriateness. For example, the observed reduction could be due to many prescribers reducing their default prescription duration to 5 days or to some clinicians sharply curtailing prescribing while others continued prescribing without changes in their practice. Likewise, prescriptions for some types of patients or pain conditions may have changed more than others. Given that opioid policies are typically blunt instruments, evaluating how they affect appropriateness of opioid prescribing (not just total volume of prescribing) is needed to better understand their potential benefits and harms.

A second important limitation is the restriction of study eligibility to apparently opioid naïve patients with likely acute pain (i.e., the target population for the 5-day law). Narrow inclusion criteria limit the opportunity to identify unintended effects on prescriber behavior or potential consequences for

patients who were not the intended focus of the policy. For example, opioid prescribing restrictions of all types may be particularly likely to harm patients with dependence on opioids due to long-term opioid therapy for chronic pain. Regardless of whether opioids are effective for chronic pain—often they are not—patients receiving long-term opioids cannot simply discontinue opioids.^{8, 9} It is easy to envision scenarios in which misapplication of the 5-day law could cause interruptions in long-term opioid therapy. Such interruptions may harm patients by, for example, inducing acute opioid withdrawal symptoms (including severe pain and psychological distress), disrupting patient-physician relationships, or prompting patients to seek opioids from nonmedical sources. Including a broad population of patients and examining effects on different types of prescriptions or patients would provide a more comprehensive picture of potential consequences of the law.

Ultimately, evaluations of opioid policy must look beyond effects on prescriber behavior and opioid prescribing volume to clinical and public health outcomes. Researchers will not likely be able to determine with confidence the contribution of any individual policy to changing rates of important but complex and relatively infrequent outcomes such as opioid-related deaths. However, researchers should not assume, as New Jersey lawmakers evidently did, that an overall reduction in opioid prescribing is a reasonable proxy for better quality care or reduced population health risk. To move the field forward, researchers should consider how policies may influence practice—in ways intended and unintended, direct and indirect—and design studies that optimize the likelihood of detecting benefit and harm outcomes that are important to patients and communities.

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