

Prescribing an overdose: A chapter in the opioid epidemic

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Research indicates that widespread opioid overprescribing contributed to the opioid epidemic. New research shows that this dangerous trend has apparently been coupled with another: inappropriate use of high-potency

opioids.

A multi-institution research collaboration led by Mayo Clinic will publish its findings Wednesday, April 15, in *JAMA Network Open*. The study showed that more than half of Americans starting the most highly regulated opioids might be receiving inappropriate treatment.

"In pain management, there is a need to use a variety of treatment options, including—when appropriate—extended-release opioids and very strong immediate-acting opioids like fentanyl," W. Michael Hooten, M.D., a Mayo Clinic anesthesiologist and pain medicine specialist.

"However, these particular medications can cause a number of serious adverse effects, so extra safeguards are needed when these medications are prescribed." Dr. Hooten is a study co-author.

"One of the key factors in determining whether these drugs can be used safely is the presence of [opioid](#) tolerance in the patient who was prescribed one of these medications," says Dr. Hooten. "In other words, tolerance to some of the most dangerous adverse effects of opioids, including suppressing breathing and excessive sedation, develops only after a patient takes daily doses of opioids over time. Patients who are not opioid-tolerant should not be receiving high-potency fentanyl or extended-release opioid products because they are susceptible to these life-threatening adverse effects."

The medications examined in the study included high-dose, extended-release oxycodone; all doses of extended-release hydromorphone; fentanyl patches; and all varieties of transmucosal—oral or nasal delivery—fentanyl.

Data behind findings

To determine whether these medications were inappropriately used

across the U.S., the study team used pharmacy and medical claims data, and linked electronic health records from the OptumLabs Data Warehouse. OptumLabs is a collaborative center for research and innovation co-founded by Optum Inc. and Mayo Clinic, and focused on improving patient care and patient value. Examining pharmacy and medical claims data from 2007 to 2016, the investigators identified nearly 300,000 instances of prescriptions during that time period that were for medications reserved for people with opioid tolerance. They removed records of people who had recently been hospitalized or who had an opioid poisoning diagnosis within the preceding six months. They also removed people who did not have at least six months of continuous insurance claims information at the time of the prescription and people with certain missing demographic information.

The remaining 153,385 instances of new outpatient prescriptions of these reserved medications occurred among 131,756 people from across the U.S.

Less than 48% of these showed evidence of prior opioid tolerance.

"Our findings are concerning because it appears that many people starting to use these drugs may be at risk for some quite serious outcomes," says Molly Jeffery, Ph.D., the study's lead author. "In general, physicians are allowed to prescribe drugs off-label—that is, without adhering to the indications or warnings included in the [drug](#) label. But these particular drugs are considered risky enough that the FDA (Food and Drug Administration) requires manufacturers to provide additional oversight and education to physicians to make sure they understand the risks associated with the drugs." Dr. Jeffery is also the scientific director of Emergency Medicine Research at Mayo Clinic.

Furthermore, regulations for one of the drug classes that the team studied—transmucosal immediate-release fentanyl, or TIRFS—require

physicians who prescribe, and pharmacists who dispense, the drugs to complete a [certification process](#) and enroll each patient.

"This process is meant to ensure patient safety while preserving access to the drugs for people who really need them," she says. "All of the drugs we studied have appropriate uses, but that does require that the physicians prescribing the drugs know the risks."

A key contribution of this study is that researchers were able to look for additional evidence of opioid tolerance in linked [electronic health records](#) for about 15% of the group, or 20,044 patients. They determined that between 0.5% and 4% of episodes of use of the reserved medications had additional information in the patient's record that showed evidence of tolerance not indicated in claims data. This additional evidence includes prescriptions showing up in the electronic health record but not in claims.

"Critiques of prior studies using only claims data raised the possibility that patients might have opioid prescriptions that don't show up in insurance claims," notes Dr. Jeffery. "For example, if a person paid for a prescription with cash instead of submitting it to insurance."

Prescriptions noted in the electronic health record may, or may not, have been filled.

"We used natural language processing—a type of artificial intelligence—to look through physician notes in the patients' health records, and also looked at information about prescriptions written," says Dr. Jeffery. "We did not find substantial additional evidence that patients were opioid-tolerant when they started these drugs."

"There was no evidence of opioid tolerance in more than half of the patients in our study," Dr. Jeffery says. "Given how common that was,

we wanted to use the clinical notes to look for reasons why physicians would have prescribed these drugs in people who were not opioid-tolerant.

The team's analysis of clinical notes didn't give any insight into physicians' reasons for prescribing to people who were not opioid-tolerant. However, the physicians on the research team had some guesses about what might be behind these prescriptions.

"My colleagues and I discussed the possibility that, in particular, fentanyl patches might have been prescribed for patients who have serious medical or surgical problems that limit the ability to swallow oral medications," says Dr. Hooten. "Also, fentanyl patches contain a three-day supply of the drug, so patches could be a possible solution for patients who may not be able to take oral medications on a scheduled basis."

Dr. Hooten hopes his fellow clinicians pay attention to these findings.

"I often treat people mired in addiction," he says. "As physicians, our first charge is to do no harm, and with opioids—especially this group of medications—the risk of harm is very real."

"It concerns me that I might have patients coming to me whose substance abuse disorder was exacerbated by inappropriate prescribing practices."

Provided by Mayo Clinic

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