Outcomes After Opioid Dose Reductions and Stoppage: It’s Time to Start Counting

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“...we didn’t have a heroin crisis in America before OxyContin was approved and started being handed out like candy...We could fix the majority of this problem with a click of our fingers,” declared Vermont’s Governor, Pete Shumlin, in 2016. A crisis unleashed in large part by a torrent of opioid prescribing has taken, by some estimates, the lives of 391,180 Americans since 2000. As clinicians reconsidered the value of a much-oversold drug class, the institutions that govern, regulate, pay, and police health care pushed for reductions. The patients on opioids long-term were, by competing accounts, in pain, dependent, addicted, or “hooked,” as the Washington Post put it in 2016.

A correction, it could be argued fairly, was overdue. Although U.S. opioid prescriptions have fallen across the board by roughly 35% since 2012, the greatest reductions were achieved by curtailing high-dose prescriptions, which fell 43% from 2011 to 2018. The unanswered question would be how such reductions would be carried out, who might measure the outcomes, and whether those outcomes included benefits, harms, or both. Data published in the present issue of the Journal of Substance Abuse Treatment suggest that reductions achieved to date have not been entirely benign.
A study published in this issue, by Mark and Parish, assessed the fate of patients in the Vermont Medicaid system who qualified as long-term recipients of opioids at high dose during the years 2012 through 2017. They identified 694 persons receiving opioids for greater than 90 days and whose dose exceeded a threshold of 120 morphine milligram equivalents (MME). In 2017, that particular dose threshold was designated by the National Committee for Quality Assurance (NCQA) as demarcating poor care. By the metrics put forward by NCQA, any reduction in this number indicates an improvement in care. Across the US, federal, state, and other private agencies have echoed that logic in regulation, in payment policies, and in thresholds for legal investigation, often fixed upon a lower figure of 90 MME from a Guideline issued by the United States Centers for Disease Control and Prevention (CDC). But whether forcing the number of patients at high dose downward serves to protect patients is little-studied. It could depend on how the task is accomplished, including the rate of taper.

In the new paper by Mark and Parrish, among 694 Vermont Medicaid recipients receiving opioids at high dose, 494 were discontinued during the years 2012-2017. The time period from the first dose reduction to stoppage served as a window into the rate of taper. The median time from dose reduction to 0 MME was 1 day. Put another way, half stopped high-dose opioids without taper. While conventional recommendations might favor tapering at rates as fast as 10% a week or slower, 86% discontinued within 21 days. Among these discontinued patients, 49% had an opioid-related adverse event, as defined by the authors. These included emergency department (ED) visits (91%) or
hospitalizations (7%) in which a diagnosis of substance use disorder was applied or a diagnosed opioid poisoning (2%). Multivariable models suggest that the strongest predictors of the opioid-related adverse events were the speed of the discontinuation, and the presence of a substance use disorder diagnosis.

An interpretation of these data must acknowledge what’s not knowable. The data cannot show either the reasons for the original dose escalation or the discontinuations. Given the suddenness of discontinuation, we can reasonably speculate that prescribers responded to unexpected behaviors, aberrant urine drug tests and the professional fears such events induce at a time when physicians are subject to intense regulatory and legal scrutiny from multiple agencies. It is unlikely that any physician has been taught that sudden opioid stoppage represents the standard of care. On the other hand, the notion that sudden discontinuation can cause death is not widely recognized.\textsuperscript{10}

It could be argued that if most adverse events involved an ED visit, perhaps patients were not greatly harmed. But this study could only capture the first harm detectable in a payer database. Under-detection of harm is likely. If an ED visit was followed by worsening disability, for example, that’s not in these data. In short, the findings suggest a problem in the care of high dose opioid recipients. And it is the second new retrospective study to hint at such risks. Earlier this year, a retrospective analysis of long-term opioid recipients in Colorado’s Kaiser Permanente system found that opioid dose fluctuation was associated with increased overdose risk, although attaining full discontinuation was associated with lower risk.\textsuperscript{11} That study, however, did not provide
estimates for rate of taper among discontinued patients, which may prove key to avoiding adverse outcomes.

Both recent studies identify harms that have been discounted in the US national push to reduce opioid prescriptions, until recently. In 2017, when the NCQA issued a quality metric that would incentivize opioid dose reductions in high-dose recipients, it did so despite formal opposition from many, including this writer, who assembled a letter from 80 professionals, signed by four physicians who played distinct roles in the 2016 CDC Guideline on Prescribing Opioids for Pain. Over the next two years, reports of harm from forced opioid taper and discontinuation emerged repeatedly, including suicides. By late 2018, a coalition of scholars and experts issued a letter of protest against forced tapers. Human Rights Watch issued a report (“Not Allowed to Be Compassionate”) on harms to long-term opioid recipients whose pain had previously been treated, rightly or wrongly, with opioids. That month, a CDC-assembled panel of 53 experts registered concern that further prescription benchmarking could result in providers being “incentivized against caring for patients requiring above average amounts of opioid medication.” After a letter from 318 health professionals and three former United States “Drug Czars” went to the CDC in March of 2019, the CDC spoke (note: this writer helped compose that letter). It declared that forced dose reductions to meet a fixed dose target were not in alignment with its Guideline. The FDA issued a near-simultaneous warning against precipitous taper.
These developments underscore the need for data on how opioid reduction is carried out in the real world, as Mark and Parrish have delivered. It remains likely that many long-term, high-dose opioid recipients who pursue opioid dose reduction, in collaboration with an expert professional, will obtain significant benefits. But the institutional standards and professional threats now in play, including the standards articulated by quality metric agencies, do not aim at these benefits. Rather, they reward reduction in a single number, regardless of outcome, echoing the pernicious logic of the pain score, which helped drive opioid prescriptions upward, prior to 2012.

Crucially, today’s opioid prescribing metrics take no count of whether the patient lives or dies. Data from two recent studies strongly suggest it is time to start counting. The sooner quality standards are revised in favor of genuine patient protection, the better.

Disclosure and Disclaimer: Dr. Stefan G. Kertesz reports that prior to 2018, he owned stock in two pharmaceutical companies, Merck and Abbott Pharmaceuticals, not amounting to greater than 5% of his assets, and that these were sold in December of 2017. Views expressed here are his own and do not represent positions or views of any employer, including the United States Department of Veterans Affairs.

References:


