
Editor’s Note
Making Data Submitted to the Food and Drug Administration More Visible

The visibility of clinical research and its underlying data has grown through efforts such as the National Library of Medicine’s online trial registry, ClinicalTrials.gov, along with data-sharing initiatives, such as the Yale Open Data Access Project (in which I am involved). While the Food and Drug Administration (FDA) has similarly enhanced clinical research visibility by making FDA-prepared documents more widely available, much important material, including clinical trial data, is considered confidential information or trade secrets. A Research Letter in this issue of JAMA Internal Medicine illustrates how this potentially limits our understanding of the research supporting therapies regulated by the FDA. Marciniak and colleagues examined participant standing of the research supporting therapies regulated by the FDA. Their analysis demonstrated substantially estimated loss–to–follow-up rates. While this research has implications for any interpretation of antithrombotics’ therapeutic efficacy and safety, it also demonstrates the need for greater data visibility and the importance of making all clinical trial data submitted to the FDA widely available, including to external researchers for independent scrutiny. As recently explained by the Institute of Medicine, “Patients and their physicians depend on clinical trials for reliable evidence on what therapies are effective and safe. Responsible sharing of the data gleaned from clinical trials will increase the validity and extent of this evidence.”

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Distribution of Opioids by Different Types of Medicare Prescribers

Researchers have suggested that the opioid overdose epidemic is primarily driven by small groups of prolific prescribers and “corrupt pill mills.” For example, the California Workers’ Compensation Institute found that 1% of prescribers accounted for one-third of schedule II opioid prescriptions and 10% accounted for 80% of prescriptions. This propagates a message that opioid overprescribing is a problem of a small group of high-volume prescribers, while general use is likely safe and effective. Medicare data provide the opportunity to address the question of whether such prescribing patterns occur across a national population.

Methods | We examined data from individual prescribers (eg, physicians, nurse practitioners, physician assistants, and dentists) from the 2013 Medicare Part D (prescription drug coverage) claims data set created by the Centers for Medicare and Medicaid Services. Part D covers approximately 68% of the roughly 50 million people on Medicare, the federal insurance program for Americans who have certain disabilities or are 65 years or older.

For each prescriber National Provider Identifier (NPI) number (N = 808,020), the data identify each drug prescribed, total number of claims, and total costs. Each NPI includes location and specialty of practice. The data represent 1,188,393,892 claims for $80,941,763,731. We focused on schedule II opioid prescriptions containing hydrocodone, oxycodone, fentanyl, morphine, methadone, hydromorphone, oxymorphone, meperidine, codeine, opium, or levorphanol.

We calculated the cumulative claims for schedule II opioids from the top individual prescribers (sorted by number of claims) relative to the total claims for all prescribers. For comparisons, we repeated this for prescription costs, for all drugs, and for each state.

Results | Figure 1 reports which Medicare prescriber specialties account for the most opioid drug claims. Figure 2 reports the concentration of drug claims among the most prolific individual prescribers. Respective California Workers’ Compensation Institute data are included. Notably, the top 10% of Medicare prescribers account for a smaller proportion of opioid claims (56.7%) than for all Medicare prescriptions and for the California Workers’ Compensation prescribers. Minimal regional variation is observed across provider states, with per-state values ranging from 56.6% to 57.7%. Excluding hydrocodone (schedule III prior to 2014) yields similar trends with the same top 3 prescribing specialties and 57.9% of claims from the top 10% of prescribers.

Discussion | The data studied represent a comprehensive national population of Medicare Part D prescribers but do not necessarily reflect clinicians’ complete practices, patient factors (eg, comorbidities and prescription indications), or medication dosing to inform morphine equivalents. With those cautions, 2 important findings are evident.

Opioid prescriptions are concentrated in specialty services in pain, anesthesia, and physical medicine and rehabilita-
By sheer volume however, total prescriptions are dominated by general practitioners (family practice, internal medicine, nurse practitioners, and physician assistants).

Contrary to the California Worker’s Compensation data showing a small subset of prescribers accounting for a disproportionately large percentage of opioid prescribing, Medicare opioid prescribing is distributed across many prescribers and is, if anything, less skewed than all drug prescribing. The trends hold up across state lines, with negligible geographic variability. Figure 2 does show greater skewing for total drug costs of Medicare opioid claims, with 78% accounted for by 10% of prescribers. This could be selection of more expensive formulations or higher doses prescribed.

The distribution of any social phenomena has some degree of skewing similar to an “80/20 rule” (eg, 20% of the population controls 80% of the wealth). As of 2013, however, these data argue that opioid prescribing is no more skewed than other prescribing, reflecting a widespread practice relatively indifferent to individual physicians, specialty or region. High-volume prescribers are not alone responsible for the high national volume of opioid prescri-
High-value care is essential for patients and sustainable health care. In 2012, the American Board of Internal Medicine launched its Choosing Wisely campaign to help physicians more thoughtfully consider diagnostic testing. The American College of Physicians published 5 questions physicians should ask before ordering tests. Because educators are encouraged to teach these principles to trainees, we sought to quantify how frequently attending physicians lead their discussion.2-4

Methods | We obtained approval for the study from the University of Colorado multiple institutional review board. Each enrolled attending physician and all observed team members provided written consent to participation. Observers received compensation for their time. No study participant received compensation. We trained fourth-year medical students as nonparticipant observers of medicine teaching rounds. A single observer shadowed a rounding episode led by each enrolled attending physician. Observers used standardized definitions and a stopwatch to annotate specific attending physician teaching behaviors in real time. The observers transcribed these notes to an investigator-developed instrument tracking in binary whether, for each patient, attending physician–led discussion mapped to the following 5 American College of Physicians test-ordering principles:5

1. whether a diagnostic test other than a complete blood cell count or basic metabolic, hepatic, or coagulation panel was previously performed;
2. whether diagnostic test results would affect care;
3. whether a test result represented—or a study under consideration might produce—a false-positive result;
4. whether the patient would experience short-term harm if a test were not ordered; and
5. whether the team considered patient preferences toward a diagnostic study.

We recorded the duration of every encounter, team time at the bedside, duration of teaching by the attending physician, and whether a patient was new or already known to the attending physician. The observer standardization process consisted of having observers annotate events of a 20-minute videotaped encounter and classify events iteratively until findings were consistent across all observers.

Results | We observed 17 different rounding episodes between December 6, 2013, and December 18, 2014, at Denver Health and the University of Colorado Anschutz, consisting of 168 patient encounters and 17 rounding days (11 at a county hospital and 6 at a university hospital) and involving 16 unique attending physicians. Data analysis was conducted from January 6, 2015, to October 9, 2015, at Denver Health. Only 35 (20.8%) of the encounters involved attending physician–led discussion of any test-ordering principle. The Table reports that short-term harm was discussed least frequently (2.4%), and the tests’ effects on care were discussed most frequently (13.7%).

For new patients compared with those who were known, we noted a nonsignificant finding regarding frequent discussion about tests’ effects on care ($P = .09$). We found no correlation with time spent at the bedside. Total attending physi-