

Prescription Opioid Use Among Disabled Medicare Beneficiaries

Intensity, Trends, and Regional Variation

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Background: Prescription opioid use and overdose deaths are increasing in the United States. Among disabled Medicare beneficiaries under the age of 65, the rise in musculoskeletal conditions as qualifying diagnoses suggests that opioid analgesic use may be common and increasing, raising safety concerns.

Methods: From a 40% random-sample Medicare denominator, we identified fee-for-service beneficiaries under the age of 65 and created annual enrollment cohorts from 2007 to 2011 (6.4 million person-years). We obtained adjusted, annual opioid use measures: any use, chronic use (≥ 6 prescriptions), intensity of use [daily morphine equivalent dose (MED)], and opioid prescribers per user. Geographic variation was studied across Hospital Referral Regions.

Results: Most measures peaked in 2010. The adjusted proportion with any opioid use was 43.9% in 2007, 44.7% in 2010, and 43.7% in 2011. The proportion with chronic use rose from 21.4% in 2007

to 23.1% in 2011. Among chronic users: mean MED peaked at 81.3 mg in 2010, declining to 77.4 mg in 2011; in 2011, 19.8% received ≥ 100 mg MED; 10.4% received ≥ 200 mg. In 2011, Hospital Referral Region-level measures varied broadly (5th–95th percentile): any use: 33.0%–58.6%, chronic use: 13.9%–36.6%; among chronic users, mean MED: 45 mg–125 mg; mean annual opioid prescribers: 2.4–3.7.

Conclusions: Among these beneficiaries, opioid use was common. Although intensity stabilized, the population using opioids chronically grew. Variation shows a lack of a standardized approach and reveals regions with mean MED at levels associated with overdose risk. Future work should assess outcomes, chronic use predictors, and policies balancing pain control and safety.

Key Words: opioid analgesics, Medicare, regional variation, disabled

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BACKGROUND

As prescription opioid consumption rises in the United States, use by the disabled population under the age of 65 warrants careful examination.¹ Growing numbers of Americans are applying for and receiving Social Security Disability Insurance (SSDI).^{2,3} This SSDI program expansion includes a rapid rise in eligibility due to musculoskeletal conditions, often treated with prescription analgesics. In 2011, musculoskeletal conditions such as back pain were the most common SSDI-qualifying diagnoses, accounting for 33.8% of program participants (up from 20% in 1996).² This shift in the composition of disabling conditions, combined with national trends of increasing prescription opioid use and prescription opioid overdose deaths, suggests the potential for substantial opioid use in the SSDI population and raises concern for the overall health and safety of these injured and ill workers.

Although the best approach to pain management and opioid analgesic prescribing, in particular, are debated, intense chronic opioid analgesics use for nonmalignant pain is increasingly recognized as ineffective and potentially hazardous to individuals and to the public.^{1,4–7} In state-level and

national-level analyses, higher use of prescription opioids has been linked to higher drug overdose death rates among patients and, because of drug diversion, nonpatients as well.^{5,6,8–10} Despite these warnings, the use of prescription opioids in the United States continues to climb.^{11–13} The SSDI population may be at high risk for chronic, intense, and potentially hazardous prescription opioid use, but the analgesic consumption of this large and growing national population of patients supported by federal disability insurance has not been studied.

We examined the opioid prescription fill patterns of Medicare beneficiaries under 65 years of age. Disabled workers become eligible for Medicare benefits, regardless of age, 2 years after qualifying for SSDI, and SSDI recipients make up nearly all Medicare beneficiaries under the age of 65 years.³ Our aim was to quantify their use of prescription opioids over time and across geographic areas.

METHODS

Study Population

Using a 40% Medicare random sample denominator for each of 5 calendar years, 2007–2011, we identified patients under the age of 65, continuously enrolled in fee-for-service Medicare Parts A, B, and D (inpatient, outpatient, and prescription benefits). We analyzed opioid use separately for each calendar year from 2007 to 2011 using all beneficiaries in our 40% sample. Beneficiaries were only included in a calendar year if they were continuously enrolled for the entire 12 months. We obtained individual-level covariates using the Medicare Beneficiary Summary File (denominator file), MedPAR, Carrier, Outpatient, and Hospice files.¹⁴ To eliminate study of opioids used for cancer-related pain or end-of-life pain management, we excluded patients with any hospice use or any ICD-9 diagnosis code for cancer (except nonmelanoma skin cancer) occurring at any time in the enrollment year. To focus our cohort on disabled workers, we also excluded patients qualifying for Medicare due to end-stage renal disease.

Main Measures

We determined individual-level counts of opioid analgesic fill events from the Medicare Part D Prescription Drug Event file. We calculated individual annual pills [or volume of elixir products (<1% of fills)] received. To achieve opioid use measures comparable across products, individual daily morphine equivalent dose (MED) was calculated by dividing total annual morphine equivalents received by 365 (Appendix Table 1, Supplemental Digital Content 1, <http://links.lww.com/MLR/A786>).^{15,16} Annualized, 1 additional daily morphine equivalent approximately equals an additional 5 mg of oxycodone each week. Among chronic opioid users (6 or more fills), we used encrypted unique prescriber identification to calculate the number of unique opioid prescribers. We calculated population measures of opioid analgesic use including: proportion of the population with any use (1 or more fill), proportion of the population with chronic use, total number of opioid pills, and morphine equivalents per user; among chronic users we

calculated number of unique opioid prescribers. Because of high-profile abuse of oxycodone, we measured proportion of all units dispensed as oxycodone products.^{9,17}

Covariates

For each beneficiary in each study year we obtained demographic characteristics from the Medicare Beneficiary Summary File, including age, sex, race/ethnicity (categorized as black, Hispanic, white, or other), and Part D low-income subsidy (LIS) status (a poverty indicator). Year-specific inpatient and outpatient claims were used to obtain Charlson comorbidities, as well as diagnoses important in this population: musculoskeletal disorders (using Social Security Administration range of diagnosis codes), depression and serious mental illness (bipolar disorder, schizophrenia, schizoaffective disorder, and other nonorganic psychoses).^{18–20} Appendix Table 2 (Supplemental Digital Content 2, <http://links.lww.com/MLR/A787>) lists diagnostic codes. We determined individual Prescription Hierarchical Clinical Condition (Rx-HCC) scores.²¹ Rx-HCC is the system used to risk adjust Part D plan payments for health status, and we constructed them using index year data.²² ZIP code was used to assign each patient to a state and one of 306 Dartmouth Atlas of Healthcare Hospital Referral Regions (HRRs).²³

Analysis

We used descriptive statistics to quantify opioid analgesic fills and pills as well as morphine equivalents. To compare national mean population use measures across years, we estimated linear regression models that included age, sex, LIS status, race/ethnicity, comorbidities, an indicator variable for musculoskeletal disease, and year indicators, using 2007 as our reference. Comorbidity counts were used for year-to-year comparisons, rather than Rx-HCC because Rx-HCC is recalibrated periodically and thus not valid for longitudinal comparison. We used quantile regression to obtain adjusted median values for opioid measures. To obtain 2011 adjusted HRR measures, the same analytic approach was used but Rx-HCC was used in place of comorbidity count. We prefer the Rx-HCC to morbidity counts for within-year comparisons because it includes a large number of diagnoses hierarchically and was designed specifically to predict prescription spending, a correlate of prescription use.^{21,22} As musculoskeletal diseases are included broadly in the Rx-HCC, our indicator for these disease was not included in calculation of these 2011 HRR-level measures. In sensitivity analyses, we repeated measures across years, without the indicator variable for musculoskeletal disease.

RESULTS

Primary Analyses

The study from 2007 to 2011 included 6.4 million person-years; annual cohorts ranged from 1.21 million (2007) to 1.37 million (2011) people, with substantial year-to-year cohort overlap; on average each unique individual was present in 3.3 of the 5 years studied, creating an 83% to

84% cohort overlap between consecutive years. Demographic, economic status, health status, and eligibility category did not change appreciably from year to year. In 2011, mean age was 49.2; 49.9% were female; 20.2% were Black, and 8.6% were Hispanic; 87.5% received Part D LIS, and 74.0% were eligible for Medicaid; 100% were eligible for Medicare due to Disability Insurance. Mean Charlson comorbidity count was 1.64 (SD 1.85), mean Rx-HCC score was 1.10 (SD 0.61); overall, 65.5% had musculoskeletal disease, 7.1% had serious mental illness diagnoses; 25.2% had depression diagnosis. Demographics, comorbidity counts, and Rx-HCC scores varied substantially across groups defined by opioid use. Compared with nonusers, users with <6 fills had higher proportions of females, more morbidities, more musculoskeletal disease, and more depression. These differences were more pronounced in the comparison of nonusers with chronic users, particularly in the proportion with musculoskeletal disease. Chronic users were more likely to be white compared with nonusers and users with <6 fills. (Table 1) (Appendix Table 3, Supplemental Digital Content 3, <http://links.lww.com/MLR/A788> shows characteristics by year).

Nearly all opioid use measures peaked in 2010, with modest declines in 2011 (Table 2). The proportion of the population with any opioid use was 43.9% in 2007, 44.7% in 2010, and 43.7% in 2011; chronic use rose from 21.4% in 2007 to 23.1% in 2011. Overall, median MED increased from 9.8 mg in 2007 to 11.0 mg in 2010 and the returned to 9.9 mg in 2011. Among patients with chronic use: median MED rose from 32.9 mg in 2007 to 36.2 mg in 2010, mean from 77.1 to 81.3 mg; from 2010 to 2011, both measures decreased to near 2007 levels. Proportion of chronic users with MED \geq 100 mg and MED \geq 200 mg was stable over this period at, essentially,

20% and 10%, respectively. Two measures continued to grow through 2011: median annual pill count increased 30.7%, from 239 in 2007 to 312 in 2011, suggesting, with relatively stable MED, that higher numbers of lower-dose pills were being dispensed. Oxycodone, the second most commonly prescribed opioid (after hydrocodone), rose from 18.8% of all pills dispensed in 2007 to 24.4% in 2011.

Sensitivity analyses repeating all adjusted annual measures without the musculoskeletal disease indicator variable revealed nearly identical values.

Adjusted prescription opioid use varied substantially across the 306 HRRs in 2011 (Figs. 1 and 2 and Appendix Table 4, Supplemental Digital Content 4, <http://links.lww.com/MLR/A789>). The proportion of these beneficiaries per HRR with any opioid fill ranged from 24.9% to 63.0% (5th–95th percentile, 33.0%–58.6%); the proportion with chronic use ranged from 9.6% to 42.4% (5th–95th percentile, 13.9%–36.6%). Among chronic users: MED varied broadly, median from 19.1 to 84.6 mg (5th–95th percentile, 22.8–52.8), mean from 31.0 to 168.0 mg (5th–95th percentile, 44.5–124.5), whereas median number of opioid fills per chronic user varied little, 10.6–15.6 (5th–95th percentile, 12.5–13.9); mean number of opioid prescribers ranged from 2.1 to 4.2. (5th–95th percentile, 2.4–3.7). Overall, the proportion of pills dispensed as oxycodone ranged from 1.7% to 60.5% (5th–95th percentile, 4.0%–48.6%).

State-level patterns also emerged. When HRRs were ranked on adjusted 2011 mean MED per chronic user, Florida HRRs made up 8 of the top-10; all had values >135 mg. When ranked on proportion of the population with 6 or more fills, 4 of the top-10 HRRs were in Tennessee. When HRRs were ranked by oxycodone use, Newark, NJ was at the top (60.5%); 8 of the

TABLE 1. Medicare Beneficiaries Under the Age of 65, 2007–2011: Demographics and Select Characteristics Overall and by Opioid Use Category

	Overall (N)	Opioid Nonusers (%)	Opioid Users (%)	
			< 6 Fills	\geq 6 Fills
Person-years 2007–2011	6,375,633	54.3	22.2	23.5
2007	1,213,680	56.1	22.6	21.4
2008	1,231,506	54.9	22.5	22.7
2009	1,254,370	53.8	22.4	23.8
2010	1,308,389	53.3	22.1	24.6
2011	1,367,688	53.8	21.3	24.9
2011 population characteristics				
Age [mean (SD)]	49.2 (10.6)	48.4 (11.1)	49 (10.7)	51 (8.9)
Female %	49.9	44.1	56.1	56.2
White %	67.7	64.7	64.7	74.7
Black %	20.2	21.4	22.5	16.9
Hispanic %	8.6	9.8	9.5	5.9
Low-income subsidy (% with any)	87.5	87.8	87.3	87.2
Medicare & Medicaid dually eligible (%)	74	74.1	74.3	74.5
Rx-HCC [mean (SD)]	1.10 (0.61)	1.03 (0.58)	1.14 (0.62)	1.22 (0.62)
Charlson comorbidity count [mean (SD)]	1.64 (1.85)	1.2 (1.53)	1.93 (1.91)	2.36 (2.13)
Musculoskeletal Disease (%)	65.5	47	78.4	94.4
Serious mental illness diagnosis (%)	7.1	7.3	7.3	6.5
Depression diagnosis (%)	25.2	18	29.2	37.5

Rx-HCC indicates Rx Hierarchical Clinical Condition scores based on index year diagnoses on inpatient and outpatient claims. Charlson comorbidities from 1987 Journal of Chronic Disease. Low-income subsidy is Medicare Part D low-income subsidy, an indicator of income \leq 150% of poverty. Serious mental illness is bipolar disorder, schizophrenia, schizoaffective disorder, and other nonorganic psychoses. All diagnoses occur in the year of study for each annual cohort. The annual cohorts include only patients enrolled in fee-for-service Medicare Parts A, B, and D for the full calendar year. Note that the unadjusted percent using opiates and percent with six or more fills shown above differ from the adjusted percent presented in Table 2.

TABLE 2. Prescription Opioid Fill Patterns 2007–2011, Adjusted for Year-to-year Differences in Age, Sex, Race, Comorbidities (Including Musculoskeletal Disease), and Part D Low-income Subsidy Status

	2007	2008	2009	2010	2011
Overall					
Percent of beneficiaries with any opioid fill	43.9	44.5	44.7	44.7	43.7
Percent with 6 or more opioid fills	21.4	22.2	22.8	23.2	23.1
Median annual pills dispensed per user per year	239.1	254.5	279.6	295.6	312.4
Median morphine equivalents per day per user	9.8	10.2	10.8	11.0	9.9
Percent of units dispensed as oxycodone products	18.8	19.6	20.5	22.3	24.4
Chronic opioid users (6 or more opioid fills per year)					
Mean morphine equivalents per day	77.1	77.7	80.7	81.3	77.4
Median morphine equivalents per day	32.9	33.4	35.7	36.2	33.9
Mean unique opioid prescribers per year	3.0	3.1	3.0	3.0	2.9
Mean opioid prescription fill events per year	15.6	15.7	15.6	15.5	15.4
Percent taking >100 mg morphine equivalents per day	20.9	20.9	21.6	21.6	19.8
Percent taking >200 mg morphine equivalents per day	10.0	10.2	10.7	10.9	10.4

Note unadjusted values for percent with any opioid use and percent with six or more fills shown in Table 1 differ from adjusted values in this table.

remaining top-10 clustered on the eastern seaboard (New Jersey, Maryland, Delaware and Massachusetts); 18 of the 20 lowest HRRs were in Texas (Figs. 1 and 2 and Appendix Table 4, Supplemental Digital Content 4, <http://links.lww.com/MLR/A789>).

DISCUSSION

Prescription opioid use is common among disabled, Medicare beneficiaries under 65 years of age. Each year,

nearly half filled at least 1 opioid prescription; almost 1 in 4 filled 6 or more prescriptions. Although the increase in opioid intensity observed from 2007 to 2010 was not sustained through 2011, average daily dose remained intense in the growing population of chronic users; 20% received 100 mg morphine equivalents per day or more, 10% reached or exceeded 200 mg daily.^{1,5,24–26} Broad HRR-level variation persisted after adjustment for patient-level factors. Wide ranges of opioid use, in this population of patients meeting

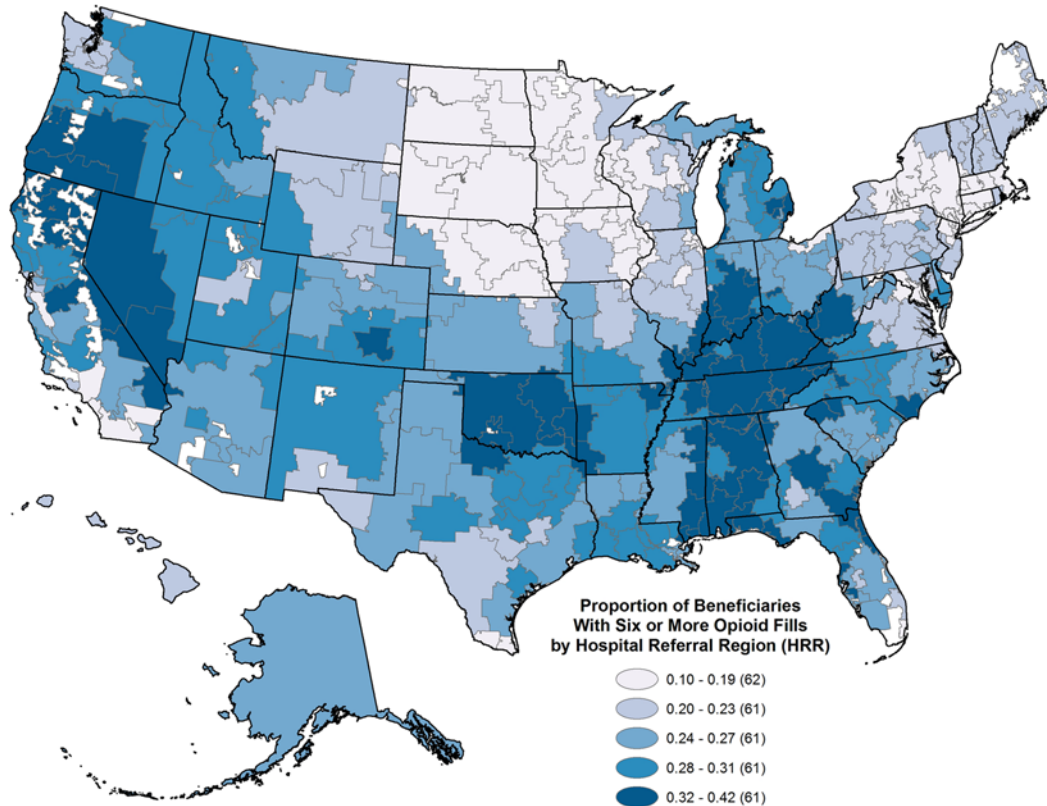


FIGURE 1. 2011 Proportion of the disabled Medicare beneficiaries under the age of 65 filling 6 or more opioid prescriptions by Hospital Referral Region.

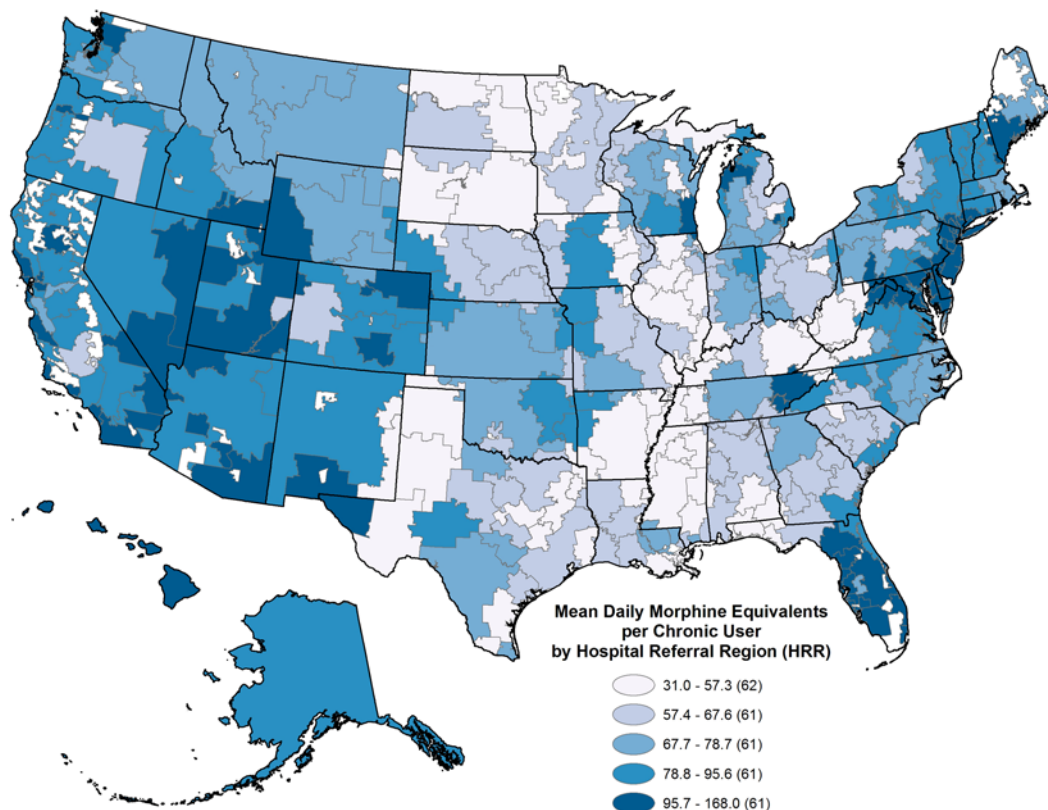


FIGURE 2. 2011 Prescription opioid use intensity among disabled Medicare beneficiaries under the age of 65 filling 6 or more opioid prescriptions, by Hospital Referral Region. Opioid use intensity is measured as mean daily morphine equivalents per user.

national disability eligibility criteria, and universally insured through fee-for-service Medicare, suggest strong regional determinants of the patterns we observed.

We document the intense burden of musculoskeletal disease and the analgesic treatment experience of disabled workers over 5 years. Our findings are consistent with growing evidence of increasing opioid use in the United States but provide granular population and geographic detail. Overall, among disabled Medicare beneficiaries, the presence of some diagnosed musculoskeletal condition is normative (65%); among those using opioids chronically, it was ubiquitous (94%). By comparison, 50% of adults in the general US population reported having some musculoskeletal disease (back, neck, or joint pain) in 2008.²⁷ A study of 2 integrated delivery system health plans in the Western United States reported that 20% of all enrollees in 2005 used some opioid analgesics, whereas 5% were “long-term users.”^{12,27} In a population more comparable to disabled Medicare beneficiaries, a systematic review of studies from 2000 to 2012 estimated 20%–40% of workers’ compensation patients used some opioids.²⁸ For a subset of these patients in 1 state (Ohio) for whom claims data were analyzed, mean daily opioid dose was slightly higher (MED 58 mg) than the average we observed among 2011 beneficiaries with any opioid use (MED 43 mg, overall, MED 22.2–42.5 in Ohio regions); the difference in daily dose likely is due in part to population differences. The Medicare population we studied

suffers diverse disabling conditions that are not necessarily work related.

Although overall prevalence of any opioid use in this population changed little between 2007 and 2011, the proportion of the population with chronic use grew steadily. What might explain this increase in chronic use? The prevalence of 1 or more musculoskeletal diseases increased slowly over the span of our study, from 61.1% in 2007 to 65.5% in 2011 (Appendix Table 3, Supplemental Digital Content 3, <http://links.lww.com/MLR/A788>). We adjusted for this growth in our annual opioid use measures and nonetheless observed a steady increase in chronic opioid use (from 21.4% in 2007 to 23.1% in 2011). The growth may simply reflect, to some extent, the effect of time on the experience of patients with substantial disease burden in the United States, where opioid use is increasingly common.^{11–13} It may also reflect population health state changes we have not accounted for in our measures, despite the very inclusive models. The regional variation we observed, and discuss further below, suggests that clinician practice patterns likely explain some of this trend. Whatever the explanation, the large and increasing proportion of this population chronically using opioids at a mean MED of at least 77 mg is worrisome in light of established and growing evidence that intense opioid use to treat nonmalignant pain may not be effective and may confer important risks.^{29–31}

The level of opioid use we observed among the 20% of chronic users with the most intense daily dose (MED 100–200 mg) is especially concerning. Opioid use of this intensity has been associated with risk of overdose death in the general US population.^{1,5,24,25} In a study specifically examining disabled workers in Washington state, investigators found a high risk of opioid overdose death when the daily dose averaged 100–120 morphine equivalents.²⁶ This suggests that the cohorts we studied may be at significant risk of opioid overdose death.

Characteristics we observed among chronic opioid users echo others' findings and raise further concern. Although white men are still the most common victims of opioid overdose death in the United States, the Centers for Disease Control and Prevention have reported growth in opioid overdose deaths among women.¹⁰ In the SSDI population, we find that women were at greater risk than men of being chronic opioid users. Another common condition diagnosed in chronic opioid users was depression (38%). The relationship between opioid use and depression is complex and directionality uncertain. Depression may be experienced as physical pain prompting opioid use, and depression may blunt responsiveness to analgesics reinforcing increased or prolonged use.^{32,33} A recent study of US veterans showed that opioid initiation and continuation was strongly associated with greater risk of developing depression, and the association appeared dose dependent.³⁴ Such evidence is worrisome given the relationship between depression and prescription opioid use in this population, and more generally, the risk of overdose and overdose death due to opioid misuse, suicidality, or hazardous combination of opioids and other sedatives commonly prescribed for mental illness.^{12,25,35}

The variation we observed at HRR and state levels is consistent with a lack of standardized approach to use of opioid analgesics for the management of nonmalignant pain, and reveals regions with mean MED at levels associated with overdose risk. The diversity of approach is highlighted not only by the broad range of any use and chronic use observed but also the lack of substantial overlap between regions at the high end of daily dose among chronic users and those with higher rates of chronic use overall (Figs. 1, 2). That chronic users received prescriptions from a mean of 3 unique prescribers (and as many as 4 in some HRRs) suggests a fragmented approach that may lack the level of coordination and oversight commonly understood as important for safe management of persistent, high-dose opioid use.^{4,26,36} The very high intensity of opioid use by some also suggests that many prescribers are not heeding warnings on the risk associated with chronic high-dose opioid use, warnings published in prominent journals and by the CDC since the early 2000s.^{1,4,5,29,36–39} The decrease in mean daily dose observed between 2010 and 2011 that followed a steady climb of this measure may reflect efforts to curb the riskiest use of prescription opioids by the Drug Enforcement Agency and by states as well as expectations around formal risk mitigation programs sponsored by drug manufacturers that were discussed (but not fully implemented) during this study period.^{13,40} Our findings of regional variability and growing chronic use highlight the importance of further developing policies at all levels that bal-

ance risks with the need for pain control for the population served by SSDI and Medicare.

Our observations regarding the high-profile and potent opioid, oxycodone, exemplify the discordant approaches to opioid analgesic management experienced by these beneficiaries.¹⁷ Use of this analgesic varied from 1.7% to 60.5% of pills dispensed across HRRs. Oxycodone was prominent on the eastern seaboard, whereas Texas prescribers all but eschewed these products. Texas laws create hurdles to prescribing controlled substances (tamper-resistant prescriptions and record keeping) but the state is not unique in such regulation, and many eastern coastal states have enacted such requirements.⁴¹ In addition, many states contain HRRs with both high and low opioid use (with varied oxycodone use specifically) (Figs. 1, 2 and Appendix Table 4, Supplemental Digital Content 4, <http://links.lww.com/MLR/A789>). Differences in state laws are thus unlikely to fully explain the broad range in opioid use we observed. Other factors that deserve research include patient and prescriber-level factors influencing opioid use intensity and product choice.

Limitations

Our claims-based analysis has important limitations. For our annual enrollment cohorts, we do not know the medical condition or combination of conditions that resulted in qualification for disability insurance. Because disability assessments precede Medicare enrollment by 2 years, Medicare claims are not reliable for determining cause of disability. However, current diagnoses do reflect the conditions experienced by beneficiaries at the time of opioid use once enrolled in Medicare. The lack of qualifying disability diagnosis limits our ability to control for disease state differences beyond common morbidities and the presence of musculoskeletal disease measured broadly such that residual confounding could explain some observed variation in opioid use. Moreover, although all providers and states are subject to the same federal criteria for disability qualification, interpretation of and adherence to these criteria may not be uniform over space or time.³ Thus, the disabled population we study may be less homogenous in terms of function and illness than the unifying benefits program suggests.

In addition, our measure of unique prescribers relies on the number of unique encrypted prescriber identifiers appearing on each patient's claims in the Part D data; the validity of this approach has not been proven and cannot yet be tested, as actual identity remains suppressed in this dataset. Invalid prescriber identifiers were recognized as a problem in the first few years of the Part D program.⁴² It is not clear whether this problem persists or how this would affect our measure of unique prescribers.

CONCLUSIONS

Opioid use is common in this national population of disabled, Medicare beneficiaries under the age of 65. Little controversy surrounds intermittent, short-term use of opioid analgesics for acute, severe pain. The overall rise in prescription opioid consumption, however, appears driven not by an increase in the proportion of disabled beneficiaries

using any opioids, but rather by the proportion using opioids chronically, at least 6 and generally 13 prescriptions per year. The effectiveness of such sustained, high dose use is supported by scant evidence and the subject of growing evidence of hazards.^{4,25,29,34} We are not suggesting all chronic opioid use is more harmful than beneficial, but instead, that the common and increasing chronic use we observed seems inconsistent with the uncertainties surrounding such prescribing practice. That regional factors strongly influence this clinically unsettled practice further highlights the need to examine both the determinants and outcomes of the opioid use we observed.

Our findings call attention to the complex and potentially unique health care needs of disabled workers under the age of 65 years. They suffer a high burden of illness and injury, low incomes, and now, a high burden of opioid use. Medicare administrators and clinicians must respond to the importance of high-quality pain management in this population. Approaches might include development and implementation of quality measures for chronic opioid management, measures of prescribing continuity (number of unique opioid prescribers per user), active monitoring through office visits, consultation with pain specialists for patients above a specified daily dose, surveillance for signs of addiction, and ample coverage of addiction services.⁴³ Although such policies and programs might be complex and costly, evidence suggests that inaction will also come at a substantial cost.

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