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Inappropriate Fentanyl Prescribing Among Nursing Home Residents in the United States

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Abstract

Objective: We quantified transdermal fentanyl prescribing in elderly nursing home residents without prior opioid use or persistent pain, and the association of individual and facility traits with opioid-naïve prescribing.

Design: Cross-sectional study.

Setting: Linked Minimum Data Set (MDS) assessments; Online Survey, Certification and Reporting (OSCAR) records; and Medicare Part D claims.

Participants: From a cross-section of all long-stay US nursing home residents in 2008 with an MDS assessment and Medicare Part D enrollment, we identified individuals (> 65 years old) who initiated transdermal fentanyl, excluding those with Alzheimer disease, severe cognitive impairment, cancer, or receipt of hospice care.

Measurements: We used Medicare Part D to select beneficiaries initiating transdermal fentanyl in 2008 and determined whether they were “opioid-naïve,” defined as no opioid dispensing during the previous 60 days. We obtained resident and facility characteristics from MDS and OSCAR records and defined persistent pain as moderate-to-severe, daily pain on consecutive MDS

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assessments at least 90 days apart. We estimated associations of patient and facility attributes and opioid-naïve fentanyl initiation using multilevel mixed effects logistic regression modeling.

Results: Among 17,052 residents initiating transdermal fentanyl, 6190 (36.3%) were opioid-naïve and 15,659 (91.8%) did not have persistent pain. In the regression analysis with adjustments, residents who were older (ages ≥ 95 odds ratio [OR] 1.69, 95% confidence interval [CI] 1.46–1.95) or more cognitively impaired (moderate-to-severe cognitive impairment, OR 1.99, 95% CI 1.73–2.29) were more likely to initiate transdermal fentanyl without prior opioid use.

Conclusion: Most nursing home residents initiating transdermal fentanyl did not have persistent pain and many were opioid-naïve. Changes in prescribing practices may be necessary to ensure Food and Drug Administration warnings are followed, particularly for vulnerable subgroups, such as the cognitively impaired.

Keywords

Nursing homes; fentanyl; prescription opioids; Food and Drug Administration

The US Food and Drug Administration (FDA) has focused important regulatory efforts on inappropriate prescribing.¹ Prescription opioids have been of particular concern due to their associated morbidity and mortality.² Although much of the focus regarding opioids has centered on misuse and abuse by young adults,³ the elderly, including nursing home residents, represent a vulnerable population, given the high prevalence of pain⁴⁻⁶ as well as their advanced age, comorbidities and frailty, and frequent polypharmacy.⁷⁻⁹ Nearly 3 million elderly Americans receive nursing home care each year,¹⁰ including many who receive opioids.^{11,12}

Transdermal fentanyl, a long-acting opioid commonly prescribed for nursing home residents, is dangerous if inappropriately used.¹³ The FDA initially approved transdermal fentanyl in 1990 for patients with moderate-to-severe, continuous pain who have been receiving opioid therapy¹⁴; transdermal fentanyl is contraindicated in patients without moderate-to-severe, continuous pain or who are not opioid-tolerant.^{15,16} Because of reports of fatalities and life-threatening adverse events associated with the use of transdermal fentanyl among this contraindicated population, the FDA issued “Boxed Warnings” on the drug label and targeted risk communications in 2005 and 2007 to the general public and health care providers.¹⁷⁻²⁰

One study assessed opioid-naïve prescribing for long-acting opioids, including transdermal fentanyl, in nursing home residents, but the study population was limited to Rhode Island during 2004 to 2005, just before these FDA actions.¹³ Another study assessed opioid-naïve prescribing for long-acting opioids in a more recent national sample of nursing home residents, but the study did not assess individual or facility factors that might be associated with opioid-naïve prescribing.²¹ In addition, the 2 studies did not assess whether prescribing in residents complied with FDA warnings that fentanyl be used only for moderate-to-severe, continuous pain. Our aim was to pursue these questions further using a comprehensive national nursing home population and examine the degree to which transdermal fentanyl use was consistent with FDA safety communications and the FDA-approved indications for use,

particularly to assess disparities in inappropriate prescribing, including by socioeconomic factors and facility-level characteristics. To do so, we assessed data on nursing home residents, facilities, and medication prescribing in 2008 from the national Minimum Data Set (MDS), the Online Survey, Certification, and Reporting (OSCAR) database, and Medicare Part D. We evaluated the extent of transdermal fentanyl prescribing for elderly nursing home residents and determined whether residents receiving fentanyl prescriptions for the first time had moderate-to-severe, continuous pain and were opioid-naïve. We then assessed whether certain individual and facility-level factors were associated with opioid-naïve prescribing.

Methods

Participants

Our source population was the approximately 1.4 million individuals who resided in US nursing homes between January 1, 2008, and December 31, 2008, and had at least 1 prescription drug documented in a Part D record (Figure 1). We limited our sample to residents who received a transdermal fentanyl dispensing/claim in 2008 without having a transdermal fentanyl dispensing within the prior 2 months, and who had at least 1 MDS record and a 90-day continuous stay before fentanyl initiation. Only residents with at least one Part D claim during this 2-month prior window and were 65 years or older were eligible for our study. We excluded individuals with cancer or receiving hospice care, as well as Alzheimer disease or most severe cognitive impairment, defined as an MDS Cognitive Performance Scale (CPS) score of 5 or 6, because of the distinct pain management challenges.²² We also excluded residents in hospital-based facilities. Data were missing for at least 1 covariate for 561 of the remaining 18,800 individuals (3.2% of the sample), whom we excluded, leaving a study population of 17,052 residents (Figure 1).

Measures

We analyzed data from the MDS, a standardized resident assessment instrument measuring each resident on 15 domains, including cognitive and physical functioning, psychosocial well-being, diseases, and pain.²³ All US nursing homes certified for Medicare and/or Medicaid must use the MDS to periodically assess each resident.²⁴ The MDS assessor, a trained nursing home staff person, relies on personal observation, resident and family interviews, medical records, and consultation with clinicians and other staff to complete MDS questions.^{23,25} This MDS information is used by nursing home staff to develop individual care plans for each resident.^{24,25} The nursing home evaluates each resident every 3 months for certain MDS measures (including cognitive and physical functioning and pain), annually for all MDS measures, and on any significant change in resident status.²³ We relied on the MDS 2.0, which has been found to be generally valid and reliable for the domains when used by trained staff.²⁶⁻²⁸ We also relied on OSCAR data for facility factors, which the federal government compiles annually for each nursing home.²⁹ Finally, we analyzed each resident's drug dispensing by using Medicare Part D records.³⁰

Opioid-naïve prescribing

We assessed whether each resident initiating transdermal fentanyl was opioid-naïve, defined as not having filed an opioid prescription with a duration end date within the 2 months prior to fentanyl initiation (ie, the 2-month window). We defined fentanyl initiation as the date of a resident's first transdermal fentanyl prescription during 2008 and each prescription's "duration end date" by adding the number of days' supply to the prescription date. Our prescription opioid definition included the following: codeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, oxymorphone, and propoxyphene.

Persistent pain

We defined persistent pain as moderate-to-severe pain lasting 3 months or longer to follow the drug indication and other study approaches.^{12,15} Each nursing home resident is assessed in the MDS at least every 3 months for the frequency and intensity of any pain over the previous 7 days.²³ This measurement has been found valid for measuring pain frequency and intensity in a scored scale.³¹ We based our assessment of persistent pain on the most recent MDS pain measurements before transdermal fentanyl initiation. Our study considered a nursing home resident in persistent pain if the individual had 2 consecutive MDS reports, at least 90 days apart but no more than 180 days apart, with moderate or severe pain daily during the prior 7-day period.

Statistical Analysis

We first assessed the proportion of residents in our study population receiving a transdermal fentanyl prescription who were (1) not in persistent pain or (2) opioid-naïve at fentanyl initiation. We then tested our hypothesis that individual factors (older age, poorer cognitive functioning, lower socioeconomic status (SES), and nonwhite race/ethnicity) and facility factors (smaller staff hours-to-resident ratio, fewer private pay residents, and for-profit status) would be associated with greater opioid-naïve prescribing based on prior literature about nursing home health disparities^{11,22,32-34} and quality of care.³⁵⁻³⁷ We used a multivariable logistic regression model with opioid-naïve prescribing (versus no opioid-naïve prescribing) as the outcome and included these individual and facility factors. We measured cognitive functioning in the MDS at persistent pain onset based on the CPS score from 0 (intact) to 4 (moderate severe impairment). We measured SES based on highest education level and whether the resident paid for nursing home services out-of-pocket ("self-pay"). We obtained the facility measurements from the most recent OSCAR survey before fentanyl initiation.

We also included in our model each of the following covariates that might be associated with any of our hypothesized factors and opioid-naïve transdermal fentanyl prescribing: resident gender, physical impairment, mood symptoms, family care involvement, facility compliance with federal law, and persistent pain. We measured physical impairment in the most recent MDS (at or before fentanyl initiation) by the degree of assistance needed for activities of daily living (ADLs) under the Morris additive scale from 0 (no help required) to 28 (most help needed); mood at the most recent MDS (at or before fentanyl initiation) by the MDS mood scale score from 0 (no mood symptoms) to 8 (most mood symptoms); family care

involvement based on whether a family member or significant other participated in the most recent MDS care plan meeting (at or before fentanyl initiation); compliance with federal law based on whether any significant federal nursing home violations were outstanding, as recorded in the most recent OSCAR survey at or before fentanyl initiation; and whether the resident had persistent pain under our definition.

Because of resident clustering in each nursing home and nursing home clustering in each state, we included random intercepts in the model for these 2 levels to ensure more accurate standard errors. We also conducted sensitivity analyses using a more stringent definition of opioid-naïve status (ie, no opioid prescribing within a 6-month window before transdermal fentanyl initiation) and restricted to residents initiating fentanyl at the highest doses (50 mg/h) or whose initiation was within 10 days of their last pain assessment. Finally, we conducted subgroup analysis in those residents with arthritis and diabetes, as recorded in the MDS, because of their distinct pain experiences with nonopioid drug treatments (eg, corticosteroids for arthritis and gabapentin for diabetic pain). Data were analyzed using SAS, version 9.2 (SAS Institute, Inc, Cary, NC) and Stata version 13.0 (Stata Corp, College Station, TX) software. The study was approved by the Institutional Review Board of Johns Hopkins Bloomberg School of Public Health.

Results

Persistent Pain and Opioid-naïve Status

Only 8.2% of residents initiating transdermal fentanyl had persistent pain under our definition (Table 1). Furthermore, only 21.5% of residents had moderate or severe daily pain and 36.8% of residents had no pain at their last assessment before transdermal fentanyl initiation (Figure 2). More than one-third (36.3%) of residents initiating transdermal fentanyl were opioid-naïve (Table 1). Only 6.6% of residents had received an opioid before fentanyl initiation and had persistent pain (Table 1).

Patient and Facility Characteristics Associated With Fentanyl Use Among the Opioid-naïve

On bivariate analysis, several patient and facility characteristics were associated with the likelihood of transdermal fentanyl use among the opioid-naïve (Table 2). For example, nearly half (45.8%) of the oldest residents (>95 years) were opioid-naïve, much greater than the proportion (29.7%) of youngest residents (65–75 years). Similarly, nearly half (46.9%) of the most cognitively impaired (CPS score = 4) were opioid-naïve, much greater than the proportion (28.2%) of cognitively intact residents who were opioid-naïve.

Multivariable Predictors of Opioid-naïve Transdermal Fentanyl Use

After accounting for potentially confounding covariates, several patient and facility characteristics remained associated with opioid-naïve transdermal fentanyl use (Table 3). For example, such use was greater among patients who were older (compared with ages 65–74, ages 75–84 OR 1.16, 95% CI 1.04–1.29; ages 85–94 OR 1.30, 95% CI 1.16–1.44; ages >95 OR 1.69, 95% CI 1.46–1.95), more cognitively impaired (compared with intact cognitive functioning, borderline intact OR 1.06, 95% CI 0.93–1.20; mild impairment OR 1.31, 95% CI 1.16–1.47; moderate impairment OR 1.60, 95% CI 1.44–1.78; moderate severe

impairment OR 1.99, 95% CI 1.73–2.29), or Asian (compared with white, OR 1.60, 95% CI 1.10–2.35).

In addition, residents with higher SES (ie, resident self-pay and college/graduate school education) had greater odds for opioid-naïve prescribing. Few facility factors were statistically significantly associated with opioid-naïve prescribing, except opioid-naïve initiation was less likely for residents within facilities that had low (2.5–3.0) average staff hours per resident or between 10% and 30% and 30% and 50% self-pay residents. In sensitivity analysis with different persistent pain definitions and inclusion criteria, as well as subgroup analyses for residents with arthritis or diabetes, increasing age and greater cognitive impairment were also statistically significantly associated with increased odds for opioid-naïve fentanyl initiation.

Discussion

In our nationally representative analysis of nursing homes, more than 90% of residents prescribed transdermal fentanyl did not have persistent pain and more than one-third were opioid-naïve. More vulnerable nursing home residents, particularly the oldest-old and most cognitively impaired, were more likely to initiate transdermal fentanyl while opioid-naïve. These findings, which followed numerous FDA risk communications regarding transdermal fentanyl, highlight the importance of more effective risk communication and safer use of long-acting opioids in nursing homes.

We also determined that more than 1 in 3 residents initiating transdermal fentanyl were opioid-naïve, estimates similar to a 2004 to 2005 study of Medicaid residents in Rhode Island.¹³ These results are especially troubling in light of FDA-approved labeling that underscores that transdermal fentanyl should be initiated only in opioid-tolerant patients in persistent pain.¹⁶ These results are greater than another study's estimate that 18.5% of residents who initiated a long-acting opioid any time after entering the nursing home were opioid-naïve (ie, not prescribed an opioid in a prior 60-day window).²¹ This finding was in a nursing home population from a national sample taken after our 2008 population, which could suggest improved adherence to the labeling condition in a subsequent time period. We note, though, that the 2 study populations differed in important ways. For example, we excluded individuals with cancer and hospice care, as well as Alzheimer disease and severe cognitive impairment, from the analysis. These individuals were 42.3% of residents who met the initial inclusion criteria (Figure 1). If these excluded residents had a lower rate of opioid-naïve prescribing than the remaining population, then including all of these residents in the analysis would reduce the prevalence finding for inappropriate prescribing. Furthermore, we found that 20% of opioid-naïve initiators in our study were prescribed transdermal fentanyl at higher doses ($> 50 \mu\text{g/h}$), inconsistent with additional precautions in drug labeling and practice guidelines to initiate prescription opioids at the lowest doses and titrate upward if necessary.^{5,16,38}

Our study results that inappropriate prescribing was greater in older residents and those with cognitive impairment is noteworthy. These patient characteristics are well-described barriers to high-quality care in nursing homes.^{11,12,32} In some settings, they may be associated with

lower likelihood of adequate analgesia.^{11,12,32} So these same characteristics may contribute not only to analgesic underuse in nursing homes, but also to misuse, as we describe in this report.

Our finding that only 8.2% of residents in our study initiating transdermal fentanyl had persistent pain is extremely low for transdermal fentanyl initiators. In fact, this figure is not much greater than another study's finding that 4.8% of residents in the general nursing home population had daily pain on 2 consecutive MDS assessments within 120 days (similar to our persistent pain definition).³⁹ Our sensitivity analysis results that at least 30% of residents did not have any pain within 10 days before transdermal fentanyl initiation reinforces this concern. These findings are limited, though, by any inaccuracies or biases in assessing and reporting pain in the MDS.^{40,41}

Our study results that residents with higher SES (self-pay status and more education) had greater odds for opioid-naïve initiation is counter to our hypothesis and should be explored further. In addition, in contrast to our hypotheses, we did not find that most examined facility characteristics were statistically significantly associated with lower odds of opioid-naïve prescribing. A recent systematic review, though, cautioned against overreliance on staff numbers for determining nursing home care quality because of other important staffing factors that may account for such associations, such as turnover rates.³⁶

Our study has important strengths, particularly the findings' generalizability, because the source population included all US nursing home residents who received a transdermal fentanyl prescription in 2008. In addition, we based our measures on comprehensive data for prescribing, resident traits, and facility characteristics. We were able to examine individual and facility-level attributes, as well as control for other unique factors in our model, such as residents' family involvement in care and facilities' compliance with federal law.

Our study also has several limitations. First, nursing home practices, including transdermal fentanyl prescribing, may have changed since the time of our study population in 2008. For example, the American Geriatrics Society revised its clinical practice guidelines for pain management in 2009⁵ and the American Medical Directors Association published its guideline for nursing home pain management in 2011.³⁸ One study assessing long-acting opioid initiation in a national nursing home population in 2011 found lower rates of opioid-naïve prescribing.²¹ However, our study provides important findings about transdermal fentanyl prescribing after the FDA issued its public warnings in 2005 and 2007 about inappropriate use and can be used as a baseline for additional analyses in more recent populations. In addition, even if inappropriate fentanyl prescribing has decreased in more recent years, the disparities we have identified for nursing home residents may still apply, particularly that inappropriate use is associated with older age and greater cognitive impairment.

Second, we did not assess whether those who had evidence of an opioid before fentanyl initiation were opioid-tolerant, and thus, our findings provide a conservative estimate of the magnitude of inappropriate transdermal fentanyl use.¹⁶ Third, there was an average 33-day time lag between the last MDS measurement and fentanyl initiation date for each

resident, and thus some residents may have developed persistent pain after their last MDS assessment. However, significant changes in resident pain status, such as the development of persistent pain requiring a long-acting opioid, should have triggered an MDS assessment if considered a significant change in resident status.²³ Also, in sensitivity analyses, we restricted the sample to residents with an MDS assessment no more than 10 days before fentanyl initiation and found similar results. Fourth, we may have mis-classified some patients as not having persistent pain, because physicians might consider some individual residents to be in persistent pain before 90 days have elapsed. However, even if 50% of patients were erroneously misclassified, it would still suggest that nearly half of residents (46%) were inappropriately prescribed these products.

The high rates of inappropriate prescribing that we describe raise several questions. First, to address potential pain misclassification, future studies could assess residents directly in nursing homes rather than rely on MDS measurements. Second, research should explore the underlying mechanisms for inappropriate fentanyl prescribing in nursing homes, particularly the circumstances for transdermal fentanyl initiation in residents without prior opioid use, especially older and more cognitively impaired residents. The mechanisms for disparities are complex and can be grounded in implicit bias on the part of health care providers.^{42,43} Third, the Institute of Medicine expressed alarm with medicines used to “chemically restrain” nursing home residents, such as psychotropic drugs.²⁴ Future research should explore if transdermal fentanyl is being used for similar purposes.

Based on our study findings, policy makers and practitioners should consider further steps to ensure appropriate transdermal fentanyl use in nursing home residents.⁴⁴ Our findings are more troubling given that the FDA took additional actions to warn the public and practitioners about the serious dangers from initiating transdermal fentanyl in patients who are opioid-naïve or without persistent pain.¹⁷⁻²⁰ The FDA has more recently implemented a Risk Evaluation and Mitigation Strategy (REMS) for long-acting opioids, including transdermal fentanyl, requiring more precautionary steps for prescribing, including health care provider training.⁴⁵ However, little is known regarding any effect that the REMS program may have had on reducing opioid-related injuries and deaths,⁴⁶ and the REMS program for opioids is targeted primarily at opioid abuse in the general population and does not include additional steps for the elderly or nursing home patients. The FDA could tailor transdermal fentanyl safety communications and the REMS plan more specifically for vulnerable populations, such as nursing home residents.

Nursing home practices and policies also could require specific additional steps to ensure transdermal fentanyl is not prescribed to residents who do not have persistent pain and are opioid-naïve. Many recent efforts have focused on improving nursing home pain care and prescribing by multimodal approaches incorporating more accurate pain assessment methods, improved clinician-staff communications, pharmacological and nonpharmacological treatments, and education and training.⁴⁷⁻⁴⁹ These efforts also should ensure that more vulnerable subpopulations within nursing homes (eg, more cognitively impaired and older) are not inappropriately prescribed transdermal fentanyl.

Conclusion

We examined transdermal fentanyl prescribing in a large, vulnerable population and assessed whether the prescribing followed FDA requirements. Our findings, from a study population drawn from all nursing home residents in the United States in 2008, indicate that a large proportion of nursing home residents received transdermal fentanyl inappropriately because they were not in persistent pain and were opioid-naïve. In addition, older residents and those who were cognitively impaired were more likely to be inappropriately prescribed these products. These results support the need for the FDA, health care organizations, and nursing homes to continue their efforts to ensure appropriate transdermal fentanyl prescribing, with particular care for these more neglected subpopulations.

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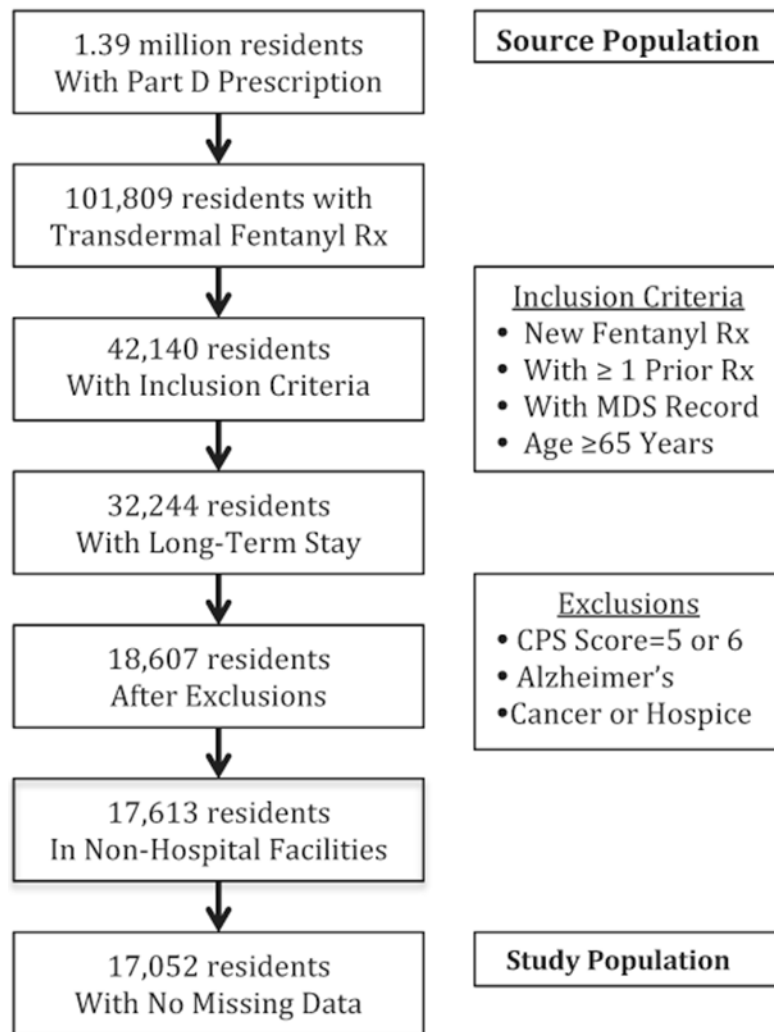
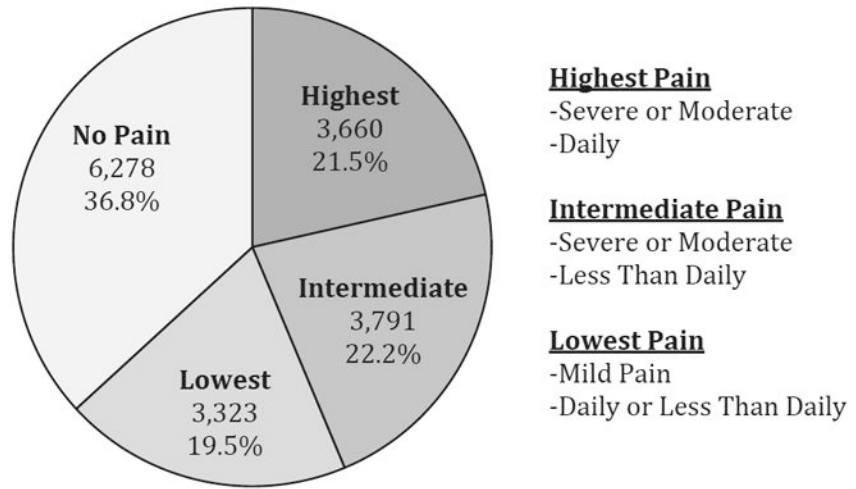


Fig. 1. Source and study populations from Part D and the MDS (2008). Rx, prescription.

Number of Residents in Each Pain Category



17,052 Total Residents

Fig. 2.

Number of residents in different pain categories at last assessment before fentanyl extended release initiation.

Table 1

Numbers of Residents With Persistent Pain and Opioid-naïve Initiation of Transdermal Fentanyl (n = 17,052)

	Opioid-naïve Initiation		Total Population
	No n (%)	Yes n (%)	
Persistent pain			
No n (%)	9736 (57.1)	5923 (34.7)	15,659 (91.8)
Yes n(%)	1126 (6.6) *	267 (1.6)	1393 (8.2)
Total population	10,862 (63.7)	6190 (36.3)	17,052 (100)

All percentages are based on total population of 17,052 residents in denominator.

* Fentanyl prescribing complied with labeling conditions for persistent pain and no opioid-naïve initiation.

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Table 2
 Fentanyl Extended Release (ER) Prescribing: Characteristics of Nursing Home Residents Receiving New Fentanyl ER Prescription in 2008 by Opioid-naïve Status (n = 17,052)

Characteristics	Not Opioid-Naïve Initiation of Fentanyl ER, n (%) *	Opioid-Naïve Initiation of Fentanyl ER, n (%) *	χ^2 Statistic, P [†]
Total population	10,862 (63.7)	6190 (36.3)	
Gender			.332
Female	8574 (63.9)	4847 (36.1)	
Male	2288 (63.0)	1343 (37.0)	
Age, y			<.001
65–74	1981 (70.3)	836 (29.7)	
75–84	3771 (65.6)	1979 (34.4)	
85–94	4246 (61.6)	2644 (38.4)	
95	864 (54.2)	731 (45.8)	
Race			<.001
White	9616 (64.0)	5406 (36.0)	
Black	850 (60.9)	546 (39.1)	
Hispanic	274 (64.0)	154 (36.0)	
Asian	70 (50.0)	70 (50.0)	
Other	52 (78.8)	14 (21.2)	
Cognitive impairment by CPS score			<.001
Intact = 0	2207 (71.8)	867 (28.2)	
Borderline intact = 1	1714 (70.3)	723 (29.7)	
Mild impairment = 2	2186 (65.2)	1167 (34.8)	
Moderate impairment = 3	3768 (59.5)	2561 (40.5)	
Moderate severe impairment = 4	987 (53.1)	872 (46.9)	
Resident self-pay			<.001
No	9525 (64.3)	5301 (35.8)	
Yes	1337 (60.1)	889 (39.9)	
Education level			.152
Less than high school graduate	4340 (64.3)	2406 (35.7)	
High school graduate	5923 (63.5)	3406 (36.5)	

Characteristics	Not Opioid-Naïve Initiation of Fentanyl ER, n (%) *	Opioid-Naïve Initiation of Fentanyl ER, n (%) *	χ^2 Statistic, P †
College graduate, graduate school	599 (61.3)	378 (38.7)	.098
Facility average staff hours per resident			
<2.5	508 (62.5)	305 (37.5)	
2.5–3.0	1617 (65.7)	843 (34.3)	
3.0–3.5	3174 (62.5)	1903 (37.5)	
3.5–4.0	2964 (63.7)	1688 (36.3)	
4.0–4.5	1594 (63.6)	912 (36.4)	
>4.5	1005 (65.1)	539 (34.9)	.001
Facility's proportion of residents' self-pay, %			
<10	1649 (61.6)	1030 (38.5)	
10–30	6408 (64.7)	3502 (35.3)	
30–50	2299 (63.6)	1314 (36.4)	
>50	506 (59.5)	344 (40.5)	.040
Facility for profit			
No	3449 (62.6)	2060 (37.4)	
Yes	7413 (64.2)	4130 (35.8)	<.001
ADL help: Morris additive scale			
0 ADLs	467 (73.7)	167 (26.3)	
1–7 ADLs	1365 (71.0)	558 (29.0)	
8–14 ADLs	1976 (66.6)	990 (33.4)	
15–21 ADLs	4333 (63.1)	2537 (36.9)	
22–28 ADLs	2721 (58.4)	1938 (41.6)	.362
MDS mood scale			
0	5734 (63.2)	3343 (36.8)	
1–2	2712 (63.7)	1543 (36.3)	
3–4	1611 (65.3)	858 (34.8)	
5–6	690 (64.7)	376 (35.3)	
7–8	115 (62.2)	70 (37.8)	.012
Family support			
No	5549 (64.6)	3039 (35.4)	
Yes	5313 (62.8)	3151 (37.2)	

Characteristics	Not Opioid-Naïve Initiation of Fentanyl ER, n (%) [*]	Opioid-Naïve Initiation of Fentanyl ER, n (%) [*]	χ^2 Statistic, P [†]
Facility compliant with federal law			.073
Yes	9788 (63.5)	5630 (36.5)	
No	1074 (65.7)	560 (34.3)	
Persistent pain			<.001
No	9736 (62.2)	5923 (37.8)	
Yes	1126 (80.8)	267 (19.2)	

ER, extended release.

Excludes 561 (3.2%) observations with missing values. Due to rounding, percentages do not all sum to 100.

^{*} All percentages correspond to row totals.

[†] P value corresponds to the χ^2 statistic.

Table 3

ORs for Noncompliant Prescribing of Fentanyl Extended Release (ER) (No Opioid in 2 Months Before New Fentanyl ER Prescription)

Characteristics	Multivariable Model* (n = 17,052)		
	OR	95% CI	P
Gender			
Female	(Ref)		
Male	1.08	0.99–1.18	.069
Age, y			
65–74	(Ref)		
75–84	1.16	1.04–1.29	.007
85–94	1.30	1.16–1.44	<.001
95	1.69	1.46–1.95	<.001
Race			
White	(Ref)		
Black	1.09	0.96–1.24	.173
Hispanic	0.94	0.75–1.17	.566
Asian	1.60	1.10–2.35	.015
Other	0.50	0.27–0.94	.033
Cognitive impairment by CPS score			
Intact = 0	(Ref)		
Borderline intact = 1	1.06	0.93–1.20	.378
Mild impairment = 2	1.31	1.16–1.47	<.001
Moderate impairment = 3	1.60	1.44–1.78	<.001
Moderate severe impairment = 4	1.99	1.73–2.29	<.001
Resident self-pay			
No	(Ref)		
Yes	1.12	1.01–1.25	.031
Education level			
Less than high school graduate	(Ref)		
High school graduate	1.09	1.01–1.17	.026
College graduate, graduate school	1.17	1.01–1.37	.041
Facility average staff hours per resident			
<2.5	(Ref)		
2.5–3.0	0.83	0.69–1.00	.048
3.0–3.5	0.95	0.79–1.14	.577
3.5–4.0	0.87	0.73–1.05	.146
4.0–4.5	0.90	0.74–1.10	.305
>4.5	0.86	0.69–1.06	.157
Facility's proportion of residents self-pay, %			
<10	(Ref)		
10–30	0.85	0.77–0.95	.003

Characteristics	Multivariable Model* (n = 17,052)		
	OR	95% CI	P
30–50	0.86	0.75–0.98	.022
>50	0.95	0.78–1.16	.644
Facility for profit			
No			
Yes	1.03	0.95–1.12	.483
ADL help: Morris additive scale			
0 ADLs	(Ref)		
1–7 ADLs	1.06	0.85–1.31	.606
8–14 ADLs	1.24	1.01–1.53	.039
15–21 ADLs	1.35	1.11–1.65	.003
22–28 ADLs	1.47	1.20–1.81	<.001
MDS mood scale			
0	(Ref)		
1–2	0.91	0.84–0.99	.032
3–4	0.87	0.78–0.96	.007
5–6	0.82	0.71–0.96	.010
7–8	0.85	0.62–1.19	.348
Family support			
No	(Ref)		
Yes	1.01	0.94–1.08	.835
Facility compliant with federal law			
Yes	(Ref)		
No	1.00	0.88–1.14	.981
Persistent pain			
No	(Ref)		
Yes	0.44	0.38–0.51	<.001

Ref, reference.

* Multivariable logistic regression model. Adjusted for gender; age; race; cognitive functioning; resident self-pay status; education; facility average staff hours per resident, facility percentage of residents who self-pay; facility for-profit status; resident number of ADLs on Morris additive scale requiring help; resident score on MDS mood scale, resident family support; facility compliance with federal law; and resident persistent pain. With multilevel modeling at the state and facility levels.