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Original Study

Inappropriate Fentanyl Prescribing Among Nursing Home Residents in the United States

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A B S T R A C T

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 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.

The authors declare no conflicts of interest. CGA is Chair of the Food and Drug Administration's Peripheral and Central Nervous System Advisory Committee; serves as a paid consultant to PainNavigator, a mobile startup to improve patient self-management of pain; serves as a paid consultant to IMS Health; and serves on an IMS Health scientific advisory board. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies.

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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 pain[4–6] 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 therapy[14]; 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).

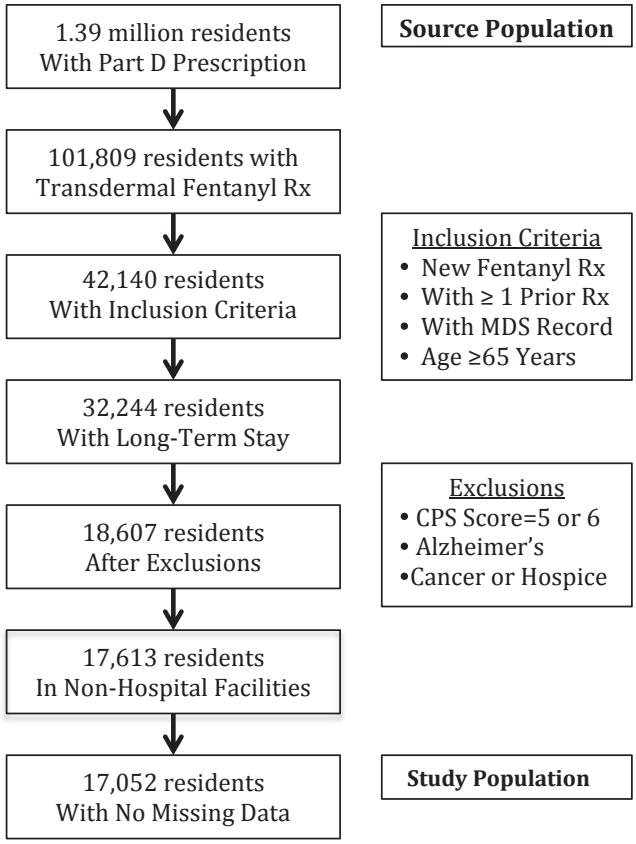

Fig. 1. Source and study populations from Part D and the MDS (2008). Rx, prescription.

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