specified for most medical devices (n = 32 of 54 [59%]), but when evidence was cited, it consisted of laboratory data (n = 20 [37%]). The EUAs for drugs and vaccines were supported predominantly by randomized clinical trials (n = 7 of 10 [70%]) (Table 2). Most drugs and vaccines (n = 8 [80%]) were not previously approved by the FDA for other indications. Seventeen products (4%) (ie, 2 drugs, 7 medical devices, 8 diagnostics) were revoked by the FDA mainly because of problems with effectiveness or safety (n = 10 [59%]) after a median (IQR) number of 230 (107-429) days. One drug and 1 vaccine were granted FDA approval.

Discussion | Most COVID-19–related EUAs were issued for diagnostic products and supported either by comparisons to various previously authorized assays or by analytical, nonclinical data. Because these diagnostic products were not tested against criterion standard and no evaluation showed that the products correctly identified people with vs without COVID-19 infection, the true sensitivity and specificity as well as real-world frequency of false-positive and false-negative results can only be approximated.3 Authorizations that were supported by such low-quality data are reasonable at the beginning of a pandemic, when diagnostic products are urgently required. In future public health emergencies, the FDA should consider raising the standard of evidence required for EUAs after several diagnostic products are marketed to ensure their accuracy.

Most medical devices were granted EUAs without any documented supporting data, and only a small number were supported by clinical data. Lack of evidence might bring to market devices that are potentially more harmful than beneficial. The rapid uptake of potentially beneficial technologies should be balanced against device-related safety problems.4

The authorization of chloroquine/hydroxychloroquine use for COVID-19 infection was supported by low-quality retrospective data and was swiftly revoked by the FDA.5 Regulators should resist political pressure to authorize products that are not supported by high-quality clinical data.6 Doing so might prevent confusion and mistrust in the soundness of medical science and bolster the FDA’s reputation.5

This study has limitations. The EUA information on the FDA website might be inaccurate or incomplete. Emergency authorizations for COVID-19 might not represent FDA authorizations for other health emergencies.

Most COVID-19–related EUAs are not supported by high-quality evidence. The findings from this study might inform regulators of the current status of EUAs and assist in guiding improvement efforts.

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HEALTH CARE POLICY AND LAW

State Variation in Potentially Burdensome Transitions Among Assisted Living Residents at the End of Life

Although assisted living communities are becoming increasingly common places of care for frail older adults in the US, little is known about the quality of their end-of-life care.1 Unlike nursing homes, assisted living communities are regulated solely by states; prior research suggests that there is considerable state variation in the end-of-life trajectories of assisted living residents.2 In contrast with the abundant literature on the end-of-life experience of nursing home residents, scant data are available on national trends related to the dying experience of assisted living residents, particularly their transitions at the end of life.

Burdensome transitions, such as transitions very close to death and repeated hospitalizations, have been studied as an important factor in the dying experience.3-5 In addition, residents who move from assisted living to a hospital during the last 120 days of life were more likely to die and had repeated hospitalizations.3

Table. Potentially Burdensome Transitions Among 37,668 Decedents Present in Assisted Living on Day 120 Before Death, 2018

<table>
<thead>
<tr>
<th>Potential burdensome transition</th>
<th>No. of decedents (%) [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any type</td>
<td>7015 (18.6) [18.2-19.0]</td>
</tr>
<tr>
<td>Any health care transition(s)</td>
<td>4336 (11.5) [11.2-11.8]</td>
</tr>
<tr>
<td>2 Hospitalizations for pneumonia, sepsis, urinary tract infection, or dehydration during the last 3 d of life</td>
<td>2272 (6.0) [5.8-6.3]</td>
</tr>
<tr>
<td>3 All-cause hospitalizations during the last 90 d of life</td>
<td>1760 (4.7) [4.5-4.9]</td>
</tr>
</tbody>
</table>
The goals of this study were to describe potentially burdensome transitions among assisted living residents at the end of life and to examine variations by US state.

Methods | This retrospective cohort study relies on secondary administrative claims data that were obtained through a data use agreement with the Centers for Medicare & Medicaid Services and was therefore deemed exempt from informed consent by the Brown University Institutional Review Board. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

This study included Medicare beneficiaries who died in 2018 and had resided in a 9-digit zip code corresponding to an assisted living community with 25 or more beds on day 120 before death. Hospitalizations were identified with the Medicare Provider Analysis and Review file. Multiple Medicare administrative claims records were used to infer decedents’ locations for each day in the last 3 days of life (eMethods in the Supplement).

In accordance with our previous work, we considered 3 types of potentially burdensome transitions: (1) health care transitions during the last 3 days of life, (2) 3 or more all-cause hospitalizations during the last 90 days of life, and (3) 2 or more hospitalizations for urinary tract infections, sepsis, pneumonia, and dehydration during the last 120 days of life. For this study, the outcome was the percentage of decedents present in assisted living on day 120 before death who experienced any type of burdensome transition. Descriptive statistics are reported for the decedent cohort and by state. This analysis was limited to assisted living communities with 25 or more beds in 48 contiguous states and the District of Columbia. Statistical analyses were conducted with SAS version 9.4 (SAS Institute).

Results | Of 37,668 Medicare beneficiaries who died in 2018 and were present in assisted living on day 120 before death, 7015 (18.6% [95% CI, 18.2%-19.0%]) experienced at least 1 potentially burdensome transition (Table). The most common type was a health care transition during the last 3 days of life, which affected 4336 decedents (11.5% [95% CI, 11.2%-11.8%]). The Figure presents state-level variations in burdensome transitions among assisted living decedents, ranging from 8.9% in Wyoming to 30.9% in North Dakota; half of the states studied had rates between 15.8% and 20.3% (IQR, 4.5%).

Discussion | Our results suggest that nearly 1 in 5 assisted living decedents in this study experienced a potentially burdensome transition in their last 120 days of life. This rate was similar to that found for nursing home decedents. In addition, the rate of potentially burdensome transitions in this study varied widely across states. The most common transition observed in this cohort was a health care transition in the last 3 days of life, which is associated with lower quality of care as reported by bereaved family members and close friends. Our results provide support for quality concerns for end-of-life care among assisted living residents.

Figure. State Variation in the Percentage of Assisted Living Decedents Who Had at Least 1 Burdensome Transition 120 Days Before Death, 2018
This study has some limitations. First, multiple hospitalizations for Medicare Advantage beneficiaries might be underreported because the Medicare Provider Analysis and Review file captures approximately 92% of the hospitalizations.6 Second, our results are not generalizable to persons in assisted living communities with fewer than 25 beds.

Despite its limitations, our study provides a first national look, to our knowledge, at potentially burdensome transitions among assisted living residents at the end of life. Future studies are needed to explain the state variation observed in this study and how it relates to factors such as residents’ comorbidities, cultural differences in end-of-life preferences, end-of-life care practices in assisted living, local hospice practice and utilization patterns, and state regulations of residential care settings.

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Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Wang, Gozalo.

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Supervision: Gozalo, Thomas, Bélanger.

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Association of Cigarette Sales With Comprehensive Menthol Flavor Ban in Massachusetts

In April 2021, the US Food and Drug Administration announced its intention to ban menthol flavors from cigarettes and cigars.1 Before this announcement, Massachusetts was the only state to implement a statewide comprehensive flavor ban on tobacco products in June 2020.2 Evidence of the effectiveness of comprehensive flavor bans on cigarette sales and smoking remains inconclusive in the US; studies have found decreases in menthol and overall tobacco product sales3 and no changes in the intensity of smoking4 after San Francisco’s flavor ban. In addition, no study, to our knowledge, has quantified a potential switch to nonflavored tobacco after banning flavored tobacco products. We examined changes in menthol and nonflavored cigarette sales in Massachusetts compared with sales in states without a flavor ban.

Methods | In this cohort study, we used Nielsen Retail Scanner Data of sales volume (reported in 4-week cycles) of menthol and nonflavored cigarette brands sold by US-based retailers. Our outcomes were state-level sales per 1000 people of packs of menthol, nonflavored, and all (menthol and nonflavored) cigarettes from January 2017 to July 2021 based on state-level annual population data obtained from the US Census Bureau. For the population data not available in 2021, we used the average population growth rate to calculate the population for each state in 2021. We used a controlled before and after design with difference-in-differences (eMethods in the Supplement) to examine temporal changes in cigarette sales in Massachusetts before (January 2017 to May 2020) and after (June 2020 to July 2021) the comprehensive flavor ban. The temporal changes were then compared with changes in...