Association Between Dual Use of Department of Veterans Affairs and Medicare Part D Drug Benefits and Potentially Unsafe Prescribing

Veterans 65 years and older with prescription drug benefits from the Department of Veterans Affairs (VA) are almost universally eligible for Medicare Part D (hereinafter referred to as Part D). Although dual eligibility may increase access to necessary medications, receiving prescriptions from 2 systems (dual use) may also fragment care and undermine prescribing safety. Previous work showed that dual VA-Part D prescription drug use is a risk factor for potentially unsafe medication (PUM) exposure in veterans with dementia and opioid users. However, whether these risks generalize to the entire Medicare-covered population of older VA users remains unknown. We evaluated the association of dual prescription use through the VA and Part D (vs VA-only use) with the prevalence of PUM exposure in a national cohort of dually eligible older veterans.

Methods | We linked national VA and Part D records of use of health care services and prescriptions in a cohort of 279,940 veterans who were continuously enrolled in VA and Part D and received at least 1 medication through the VA in 2015. We further limited the study to veterans 68 years or older on January 1, 2015. We categorized these veterans as dual users (ie, ≥1 medication from the VA and Part D) or VA-only users. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines. This study was approved by the institutional review board of the VA, which waived the need for informed consent.

Results | Among 279,940 Medicare-eligible older veterans receiving a prescription from the VA, 18.9% (95% CI, 18.7%-19.0%) were dual users and 44.3% (95% CI, 37.3%-51.4%) were exposed to at least 1 PUM in 2015. Among dual users, 49.7% (95% CI, 49.2%-50.0%) were exposed to any PUM type, including 38.6% (95% CI, 38.2%-39.0%) to PUM-ACB, 19.3% (95% CI, 18.9%-19.6%) to PUM-HEDIS, and 4.4% (95% CI, 4.2%-4.6%) to PUM-DDI.

In adjusted results, dual use was associated with increased odds of any PUM exposure (adjusted odds ratio [aOR], 1.84; 95% CI, 1.80-1.88) and an additional 19.4 days of exposure (95% CI, 18.1-20.8 days) (Table). Dual use was also associated with increased odds of PUM-HEDIS (aOR, 1.82; 95% CI, 1.77-1.88), PUM-ACB (aOR, 1.53; 95% CI, 1.50-1.57), and PUM-DDI (aOR, 3.25; 95% CI, 3.02-3.48). Dual use measured as the proportion of total 2015 prescriptions from the VA revealed that PUM exposure was lowest among VA-only users, and PUM exposure peaked in veterans receiving prescriptions in near-equal proportions (50:50) from the VA and Part D (Figure).

Discussion | Dual use of VA and Part D prescription drug benefits was associated with an almost 2-fold increase in the odds of exposure to any PUM compared with VA-only use and more than 3 times the odds of exposure to severe drug-drug interactions. Despite the limitations of observational studies, our results show that the prescribing safety risks associated with dual VA-Part D
is possible that the safety risks found in this study of veterans may extend to all patients who receive prescriptions across disconnected health care providers or systems. To mitigate these potential risks, policies intended to expand access to non-VA providers must ensure patient information is shared and integrated into routine practice for all patients seeking care across multiple health care systems.5,6

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Abbreviations: ACB, anticholinergic cognitive burden; aOR, adjusted odds ratio; DDI, drug-drug interactions (drug combinations with high risk for severe interactions); HEDIS, Healthcare Effectiveness Data and Information Set high-risk medication in the elderly; NA, not applicable; PUM, potentially unsafe medications; VA, Department of Veterans Affairs.

Exposure to PUM was measured as any prescription for a Healthcare Effectiveness Data and Information Set high-risk medication in the elderly (PUM-HEDIS), prescriptions with an anticholinergic cognitive burden score of at least 3 indicating any daily exposure (PUM-ACB), and any overlapping days of exposure to drug-drug interactions (PUM-DDI). The proportion of total prescriptions from the Department of Veterans Affairs (VA) was measured as total VA prescriptions divided by total VA plus Medicare Part D prescriptions. A proportion of 0.50 indicates 50% from the VA and 50% from Part D (shaded area).

use are not limited to high-risk subgroups.1,2 Policies that increase veterans' access to non-VA health care professionals therefore may unintentionally jeopardize patient safety. Furthermore, it is possible that the safety risks found in this study of veterans may extend to all patients who receive prescriptions across disconnected health care providers or systems. To mitigate these potential risks, policies intended to expand access to non-VA providers must ensure patient information is shared and integrated into routine practice for all patients seeking care across multiple health care systems.5,6

Figure. Probability of Potentially Unsafe Medication (PUM) Exposure

Table. Adjusted Use of PUM Among Older Veterans in 2015 by VA-Only vs Dual VA–Medicare Part D Usea

<table>
<thead>
<tr>
<th>Medication Safety Measure</th>
<th>Dual VA-Part D Use (n = 52 839)</th>
<th>VA-Only Use (n = 227 101)</th>
<th>Differenceb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any PUM</td>
<td></td>
<td></td>
<td>+14.8 (14.3-15.3)</td>
</tr>
<tr>
<td>Exposure, % (95% CI)</td>
<td>49.7 (49.2-50.0)</td>
<td>34.9 (34.6-35.2)</td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI)</td>
<td>1.84 (1.80-1.88)</td>
<td>1 [Reference]</td>
<td>NA</td>
</tr>
<tr>
<td>Days exposed (95% CI)</td>
<td>72.7 (71.6-73.9)</td>
<td>53.3 (52.5-54.1)</td>
<td>+19.4 (18.1-20.8)</td>
</tr>
<tr>
<td>PUM-HEDIS</td>
<td></td>
<td></td>
<td>+7.7 (7.3-8.1)</td>
</tr>
<tr>
<td>Exposure, % (95% CI)</td>
<td>19.3 (18.9-19.6)</td>
<td>11.6 (11.4-11.8)</td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI)</td>
<td>1.82 (1.77-1.88)</td>
<td>1 [Reference]</td>
<td>NA</td>
</tr>
<tr>
<td>Days exposed (95% CI)</td>
<td>20.2 (19.7-20.8)</td>
<td>16.0 (15.6-16.4)</td>
<td>+4.2 (3.6-4.9)</td>
</tr>
<tr>
<td>PUM-ACB</td>
<td></td>
<td></td>
<td>+9.6 (9.1-10.0)</td>
</tr>
<tr>
<td>Exposure, % (95% CI)</td>
<td>38.6 (38.2-39.0)</td>
<td>29.0 (28.7-29.3)</td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI)</td>
<td>1.53 (1.50-1.57)</td>
<td>1 [Reference]</td>
<td>NA</td>
</tr>
<tr>
<td>Days exposed (95% CI)</td>
<td>49.6 (48.8-50.4)</td>
<td>36.1 (35.5-36.7)</td>
<td>+13.5 (12.5-14.5)</td>
</tr>
<tr>
<td>PUM-DDI</td>
<td></td>
<td></td>
<td>+3.0 (2.8-3.1)</td>
</tr>
<tr>
<td>Exposure, % (95% CI)</td>
<td>4.4 (4.2-4.6)</td>
<td>1.4 (1.3-1.5)</td>
<td></td>
</tr>
<tr>
<td>aOR (95% CI)</td>
<td>3.25 (3.02-3.48)</td>
<td>1 [Reference]</td>
<td>NA</td>
</tr>
<tr>
<td>Days exposed (95% CI)</td>
<td>2.9 (2.7-3.1)</td>
<td>1.2 (1.1-1.3)</td>
<td>+1.7 (1.5-1.9)</td>
</tr>
</tbody>
</table>

Abbreviations: ACB, anticholinergic cognitive burden; aOR, adjusted odds ratio; DDI, drug-drug interactions (drug combinations with high risk for severe interactions); HEDIS, Healthcare Effectiveness Data and Information Set high-risk medication in the elderly; NA, not applicable; PUM, potentially unsafe medications; VA, Department of Veterans Affairs.

a Includes 279 940 veterans. Covariates included age, sex, race/ethnicity, US region, county rurality, VA enrollment priority status, Elixhauser comorbidities, number of comorbidities, Veteran Integrated Service Network number, and low-income subsidy status. All covariates were entropy balanced to a standardized difference of P < .001.

b All comparisons across Drug Benefit User Groups were statistically significant at the P < .001 level. Bias-corrected bootstrapping was used for assessing the number of days.

c Indicates the sum of PUM-HEDIS, PUM-ACB, and PUM-DDI exposure days in 2015. A day when a patient was exposed to all 3 PUMs would count as 3 exposure days.
Author Contributions: Dr Thorpe and Mr Cashy had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: JM Thorpe, CT Thorpe, Carico, Van Houtven.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: JM Thorpe, Cashy.

Critical revision of the manuscript for important intellectual content: JM Thorpe, CT Thorpe, Schleiden, Carico, Gellad, Van Houtven.

Statistical analysis: JM Thorpe, Cashy, Carico.

Obtained funding: JM Thorpe, CT Thorpe.

Administrative, technical, or material support: JM Thorpe, CT Thorpe, Schleiden, Van Houtven.

Supervision: JM Thorpe.

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Invited Commentary | HEALTH CARE POLICY AND LAW
Implications for Veterans’ Health Care:
The Danger Becomes Clearer

The recent decision by Congress and the President to give veterans greater choice in their health care decisions should be applauded. Veterans deserve the best health care the United States can offer, and reform of the current system must continue until that is achieved.

How new policies and laws are executed is often as important as the original intent of the legislation. The specific implementation of the Mission Act, which was signed into law by President Trump on June 6, 2018, will be critical to ensuring that veterans are well served. The Act establishes a single community care program that allows more veterans to seek care outside the Veterans Affairs (VA) system, using new access standards that have recently been released. These access standards allow veterans to seek private-sector care based on relaxed wait times and drive times, availability of service offerings, and failure to meet quality standards and provide new eligibility for urgent care.

In this issue of JAMA Internal Medicine, Thorpe and colleagues offer a cautionary tale of how a poorly designed health policy may have harmful consequences for veterans, even when unintended. These researchers show that veterans who received care within the VA and the private sector had statistically higher rates of potential harm and adverse drug events than those who received care at the VA alone. Veterans receiving care outside the VA were almost 2 times as likely to be exposed to unsafe prescribing practices and 3 times as likely to experience a possible adverse drug-drug interaction.

It should be no surprise that medical care delivered in a fragmented way can lead to poorer outcomes. We know from the study of numerous other clinical scenarios that when care is not coordinated, it can lead to worsening health outcomes. It also makes sense that care delivered within the VA, a system that shares a common medical record and a single formulary and in which health care professionals are trained to work in teams, would have safer medication practices and potentially better overall results. The VA has repeatedly been shown to have better outcomes when compared with community standards of care. As veterans get more of their care outside of the VA system, we must be vigilant that inferior outcomes, as demonstrated in this study, do not occur.

All of this is not to say that veterans cannot safely receive care in the VA and the private sector. The VA offers care and expertise not found in the community, and the private sector offers care and expertise not found in the VA. In fact, I have proposed that veterans would benefit most from an integrated system of care that offers services both within the VA and from the private sector. However, an effective integrated system of care for veterans will require comprehensive care coordination and improved interoperability of data across clinical settings.

The Mission Act will likely dramatically increase the number of veterans getting at least some of their care from the private sector. Within a well-designed system, this can lead to good results. However, the VA’s proposed new access standards, based largely on drive times and wait times, lack the clinical assessment, care coordination, and integrated care approach that is needed.

Perhaps just as concerning is how these new standards will be paid for. For veterans who have no copayments or deductible, the VA will face the same issues of runaway costs seen during past decades in the private sector. Veterans will make rational economic decisions and use their VA benefits instead of their other insurance, if they can access the same care with lower cost outlays. These additional costs, projected to be tens of billions of dol-
lars, will need to be covered somewhere. Without additional large financial authorizations, these costs will likely result in resource reductions from within the VA, leading to a diminution of capabilities for the system. This would be a bad outcome and ironically may lead to less choice for veterans.

The purpose of a health care system should be to match its capabilities with the clinical needs of the patients it serves. To achieve this, the VA must transition from simply being a provider of care to a network coordinator of care. Although opening the aperture to private care, the VA’s proposed access standards based on nonclinical criteria will not serve veterans’ interests. We should not be using arbitrary administrative rules, such as drive times and wait times (that are not based on clinical evaluations), when it comes to people’s health care. The system should be based on the individual clinical needs of the veteran. Veterans and their physicians (or other licensed health care professionals), not government policy makers, must decide when and where the most appropriate care can and should be delivered.

What is needed is a clinically integrated system that uses the best of the VA and the private sector. This integration can be achieved through building a system of care that offers clinically based decisions with coordinated care between the VA and private sector, transparency of outcomes, and competition based on quality and service. In addition, better predictive analytics for medical management, as well as enhanced efforts to empower veterans with better information about their own care plans, will be essential to improving the safety of the system.

The VA’s efforts to reform are necessary and good. Greater choice for veterans is also good. However, without the appropriate clinical safeguards, as this study by Thorpe and colleagues demonstrates, unintended consequences are possible. It is essential that access standards be based on sound health policy. Our veterans deserve no less.

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Association of Sodium-Glucose Cotransporter 2 Inhibitor Treatment With Risk of Hospitalization for Fournier Gangrene Among Men

Fournier gangrene—a fulminant necrosis of the fascia surrounding the genitals and perineum—is a rare and often fatal urologic emergency that disproportionally affects men at a 10:1 ratio.1 Case reports linking Fournier gangrene with the use of sodium-glucose cotransporter 2 (SGLT-2) inhibitors prompted a US Food and Drug Administration warning in August 2018.2 We examined the association of the risk of hospitalization for Fournier gangrene with initiation of SGLT-2 inhibitor treatment among men.

Methods | This cohort study was approved by the Brigham and Women’s institutional review board, and requirement for informed consent was waived because the research was noninterventional and was performed using data that were already collected. Data were collected from 2 commercial claims databases generalizable to 50% of the US population with employer-based insurance (Optum Clinformatics DataMart [Optum] from July 5, 2013, through September 30, 2017, and IBM MarketScan [IBM Corporation], from April 1, 2013, through December 31, 2016), and Medicare fee-for-service data (from April 1, 2013, through December 31, 2016). These databases include all patients 65 years and older who have type 2 diabetes. For each study participant, data source information included demographics, health care and pharmacy eligibility status, inpatient and outpatient medical claims, and outpatient pharmacy dispensing data. Data analysis was performed from September 17, 2018, to March 3, 2019.

Using a look-back period of 180 days, we created a cohort of men at least 18 years of age who initiated treatment with either an SGLT-2 inhibitor or a dipeptidyl peptidase 4 (DPP-4) inhibitor. Patients with a history of nursing home care, type 1 or secondary diabetes, end-stage renal disease, cancer, or HIV infection or without evidence of type 2 diabetes were excluded from analysis. A hospitalization for Fournier gangrene was defined as a hospitalization with either an International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10) diagnosis code of N49.3 or an International Classification of Diseases, Ninth Revision (ICD-9) diagnosis code of 608.83 and evidence of surgery in


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