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Variation in Use of High-Cost Diabetes Mellitus Medications in the VA Healthcare System

The Department of Veterans Affairs (VA), the largest integrated health care system in the United States, may serve as a model of efficient use of prescription drugs. It consistently ranks among the top of all US health care systems in objective ratings of quality of care for chronic diseases,[1] and it does so with low medication costs. The VA negotiates steep price discounts with pharmaceutical manufacturers and engages in robust formulary management using a national formulary. This centralized approach to pharmacy benefit management stands in stark contrast to Medicare Part D, which contracts with over 1000 private plans, each with its own formulary, and which has substantial regional variation in per capita drug spending.[2] Even within a tightly managed system such as the VA, however, there may also be significant variation across facilities in medication use and spending. We examined national VA data for over 1 million outpatients with diabetes mellitus (DM) to understand how prescribing of high-cost medications varies across facilities.

See Invited Commentary at end of letter

Methods. We identified a national cohort of veterans with type 2 DM using a previously validated approach.[3] We focused on the facility-level use, in fiscal year (FY) 2009, of 2 classes of high-cost DM medications: thiazolidinediones (rosiglitazone, pioglitazone) and long-acting insulin analogues (detemir, glargine). We measured the proportion of patients on oral medications receiving thiazolidinediones, and the proportion of patients treated with insulin receiving long-acting analogues. We chose these 2 classes because of their relatively high cost and lack of clear evidence for improved clinical outcomes relative to other DM medications.[4-7] Thiazolidinediones were available for use with prior authorization at the time of the study. There were no restrictions on long-acting analogues.

To calculate an adjusted rate of thiazolidinedione and analogue use at each facility, adjusting for differences in patient-level characteristics, we used random effects logistic regression. We adjusted for age, race/ethnicity, sex, modified Charlson score (removing DM and DM complications),[8] number of diabetic complications (diabetic retinopathy, neuropathy, nephropathy, or peripheral vascular disease), whether individuals had any visits to an endocrine/DM specialty clinic, and whether they had a medication copay. We centered each of these covariates and used the facility random intercept to compute an adjusted rate of thiazolidinedione/analogue use for patients at that facility with all covariates equal to the population mean. All analyses were performed using SAS statistical software (version 9.2; SAS Institute Inc) and STATA 11 software (StataCorp Inc).

Results. In FY 2009, there were 1 158 809 patients with type 2 DM. Their mean age was 66.5 years, and 97.4% were male. Almost 1 in 7 (13.8%) visited an endocrine/DM clinic, and 30.8% had at least 1 DM complication. Overall, 906 720 patients (78.3%) received 6 182 859 prescriptions for DM medications; 66.7% received an oral medication, and 27.7% received insulin (16.1% received both).

Across the 139 facilities, the adjusted percentage of patients receiving oral DM medications who used a thiazolidinedione ranged from 1.4% at the lowest-using facility to 25.4% at the highest, with a median of 8.2% (interquartile range [IQR], 4.9%-10.5%) (**Table**). The adjusted percentage of patients receiving insulin who used long-acting analogues ranged from 4.0% to 71.2%, with a median percentage of 40.6% (IQR, 28.1%-52.1%). The adjusted facility-level rates of use were almost identical with the unadjusted rates across facilities (correlation $r=0.99$).

Comment. In this cohort of over 1 million patients with type 2 DM, we find substantial variation in use of 2 classes of high-cost DM medications—thiazolidinediones and long-acting insulin analogues. This variation exists in an integrated VA system with a uniform national formulary with established criteria for use of drugs, such as the thiazolidinediones, and clinical practice guidelines supporting conservative use of medications. While some variation is expected given reasonable differences in prescribing practices, the observed 18-fold variation across facilities was unexpected.

Adjusting for observable patient characteristics across facilities explained virtually none of the facility-level variation in use of high-cost drugs, suggesting that there are important facility factors at play. Even if some unmeasured patient characteristics are driving some of the variation, the magnitude of the variation is large enough that clinical need alone cannot explain it. Despite the na-

Table. Probability of Thiazolidinedione and Long-Acting Insulin Analogue Use at Department of Veterans Affairs Facilities, Fiscal Year 2009

	Thiazolidinedione, %		Long-Acting Insulin Analogue, %	
Facility-Level Use	Unadjusted	Adjusted[a]	Unadjusted	Adjusted[a]
Range across all facilities	1.5-26.3	1.4-25.4	3.7-71.4	4.0-71.2
5th percentile of facility	2.8	2.7	11.5	11.4
25th percentile	4.9	4.9	28.6	28.1
Median (mean)	8.5 (8.6)	8.2 (8.2)	39.6 (39.6)	40.6 (39.3)
75th percentile	11.0	10.5	51.7	52.1
95th percentile	17.8	17.0	65.3	64.1

[a] Adjusted for all patient-level characteristics, including age, race/ethnicity, sex, modified Charlson score, count of diabetes mellitus (DM) complications, visit to an endocrine/DM specialty clinic, presence of medication copay. The correlations between adjusted and unadjusted outcomes at the facility level are 0.99 for both outcomes.

tional formulary, decisions about approving requests for high-cost medications are not made centrally, but are often made at each VA facility. In addition to such differences in administration, facility-level differences are likely also driven by local physician norms or preferences about the use of newer drugs, which we were not able to measure.

Our findings suggest that while they may exert powerful effects on medication choice,[9] formularies and utilization management tools can only go so far in standardizing health care delivery. While use of more costly agents, such as the thiazolidinediones and long-acting insulin analogues, clearly have a place in the care of patients with DM, more work is needed to understand the mechanisms underlying this variation so that health systems can optimize their use to promote safe, high-value pharmaceutical practice.

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INVITED COMMENTARY

Implementing High-Value, Cost-Conscious Diabetes Mellitus Care Through the Use of Low-Cost Medications and Less-Intensive Glycemic Control Target

Type 2 diabetes mellitus (DM) is a leading cause of morbidity and mortality, affecting nearly 26 million people and costing $174 billion in the United States.[1] Monotherapy with oral agents lower hemoglobin A_{1c} (HbA_{1c}) levels an average of 1% of total hemoglobin. Combination therapy with a second oral medication or insulin leads to an additional 1% to 2% reduction. (To convert HbA_{1c} to a proportion of total hemoglobin, multiply by 0.01.) Most people with type 2 DM will receive more than 1 class of medication: 14% take both insulin and oral medications, and 58% take multiple oral DM medications.[1]

Treatment regimens and glycemic control targets have come under scrutiny, with evidence demonstrating that newer, more expensive medications are not more effective or safer than older, less-expensive medications.[1,2] High-quality evidence also shows that intensive glycemic control (HbA_{1c} levels $<$ 7% of total hemoglobin) does not reduce mortality, cardiovascular or renal events, or clinical microvascular complications compared with less-intensive glycemic control (HbA_{1c} levels of 7.0%-8.4% of total hemoglobin) through at least 15 years, but results in more harms, including severe hypoglycemia, weight gain, and dyspnea.[1-3] Longer follow-up reveals small absolute benefits of marginal statistical significance. While some individuals enrolled in these trials were elderly, had coexisting cardiovascular disease, or had DM of long-duration, they are representative of most individuals with type 2 DM. Yet, few data exist on the consequences of overuse and misuse of health care services for DM or on methods to improve care quality by reducing overuse.

With this background, Gellad et al[4] examined DM medication use in a national cohort of veterans with type 2 DM treated at VA medical centers. They identified wide variation and frequent high use of 2 expensive medications—thiazolidinediones and long-acting insulin analogs—across VA medical centers. Use and variability of expensive DM medications is likely greater in non-VA settings than reported by Gellad et al,[4] and the financial implications to non-VA patients larger, because of high out-of-pocket costs. Variability occurred despite (1) national formulary and use policies that educate health care providers and encourage them to initiate oral monotherapy with metformin or a sulfonylurea and use these drugs as preferred oral combination therapy with or without insulins that are not long-acting analogs; (2) electronic medical records that display medication costs at the point of prescribing; and (3) data from a randomized trial of intensive vs less-intensive glycemic control conducted at VA medical centers convincingly demonstrating that achieving a HbA_{1c} level of 7.0% of total hemoglobin compared with a HbA_{1c} level of 8.4% resulted in no benefit but caused more serious adverse events, including a greater than 3-fold increase in major hypoglycemic episodes.[5]

Variability in medication prescribing is inevitable and likely warranted. Thiazolidinediones and long-acting insulin analogs have a therapeutic role in some patients given that medication risk profiles, patient characteristics, and ability to achieve glycemic targets vary. In addition, Gellad et al[4] did not control for some confounding variables, including HbA_{1c} levels, nor did they determine whether variation is due to differences in regional or local medical center oversight to restrict initiation or continuation of these drugs. Despite these limitations, their findings demonstrate that considerable challenges must be overcome to improve DM care.

Approximately $340 billion of health care dollars are spent on unnecessary or inefficiently delivered services.[6] Physicians can play a major role in delivering high-value cost conscious care. Physicians should consider the value of an intervention to be defined as a combined assessment of benefits, harms, and costs.[7] Value should not be interpreted as rationing since it encourages rational care, that is, clinically effective care that avoids overuse and misuse of interventions that do not provide clinical benefit or lead to improvement in clinical outcomes. Reasons for inefficient practices exist, including habits, litigation fear, patient expectations, inadequate time, lack of knowledge, and lack of evidence. These need to be addressed. Initiatives such as "American College of Physicians' (ACP) High-Value Cost-Conscious Care"[7-9] and the "Choosing Wisely" campaign are important starts to helping physicians make smart health care decisions. Patients should also have information and be empowered to ask their physicians whether more testing and treatment and use of more expensive therapies are beneficial and what are the clinical and financial tradeoffs. The collaboration between the ACP and Consumer Reports to develop resources to help patients understand the benefits, harms, and costs of tests and treatments for common clinical issues including DM is a step in the right direction.[10]

An important, but little discussed, contributing factor to low-value DM care and the overuse of expensive DM medications are guidelines and performance measures. Many reward clinicians for intensive glycemic control-achieving HbA_{1c} levels of 7% of total hemoglobin or lower for most patients. Multiple medications are often required to achieve lower glycemic targets, resulting in higher costs and greater harms with little to no benefit: low-value care. A focus for achieving high-value DM care should be development of guidelines and performance measures that specifically encourage use of lower-cost medications that have similar or greater effectiveness, fewer harms, and account for evidence-based appropriately higher glycemic targets (HbA_{1c} level = 7.0%-8.5% of total hemoglobin) than currently recommended for most individuals: higher-value care. Just as performance measures are developed to assess underuse of services, we need to develop valid, evidence-based measures of overuse to encourage provision of high-value services. Measures should encourage medication reduction or discontinuation among patients with HbA_{1c} levels lower than 7% of total hemoglobin, especially among patients at risk for treatment-related harms or with low likelihood of benefit owing to age or comorbidities. By effectively imple-

menting high-value, cost-conscious DM care, we can overcome the challenges and make a positive difference in our patients with type 2 DM.

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COMMENTS AND OPINIONS

Telemonitoring in Older Adults: Does One Size Fit All?

The study by Takahashi et al[1] provides useful information about the effectiveness of telemedicine. We believe that their negative results, although in line with others reported in the literature, should nonetheless be interpreted while taking into account some issues, the most evident being that the much higher mortality in the intervention group casts doubts on the real comparability of the study arms.

Furthermore, the population studied was heterogeneous with respect to the main disease. The experience with comprehensive geriatric assessment, however, clearly demonstrates that elderly and frail patients benefit from a strategy of care tailored to individual needs.[2] There is no reason for thinking that such a conclusion does not apply to telemonitoring. In addition, the efficacy of telemonitoring may change according to the main disease: despite some negative trials, a recent Cochrane review indicates that in patients with congestive heart failure, telemonitoring is effective in reducing the risk of all-cause mortality and congestive heart failure–related hospitalizations.[3] The lack of focus on a specific disease may also reduce the capacity of the telemonitoring team of detecting changes in health status. For example, symptoms of chronic obstructive pulmonary disease exacerbation may be aspecific[4] and may be missed by study personnel not specifically trained for (tele)assisting people with this disease.

The lack of specificity of the study is also reflected in the top-down application of existing technologies to monitor patients regardless of their individual characteristics. A recent qualitative study shows that early detection of acute deterioration is not effectively achieved by current telemonitoring systems because telemonitoring is driven by available technology rather than by users' needs.[5]

In conclusion, this study adds to our knowledge on telemonitoring by indirectly suggesting that homogeneous populations, ie, sharing the main disease, should be the target of these interventions, or, otherwise, the protocol and the technology used should be sufficiently elastic to tailor the telemonitoring to highly different individual needs.

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