Balancing measures: identifying unintended consequences of diabetes quality performance measures in patients at high risk for hypoglycemia

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Abstract

Objective: To determine if changes in overtreatment rates were associated with changes in undertreatment rates.

Design: Pre-test/post-test study used cross-sectional administrative data from calendar years (CYs) 2013 and 2016.

Setting: The Veterans Health Administration.

Participants: Patients with diabetes at risk for hypoglycemia (n = 171,875 and 166,703 in 2013 and 2016, respectively).

Intervention: Observational study of extant initiatives to reduce overtreatment.

Main Outcome Measures: Overtreatment rate of diabetes defined at the proportion of patients in the group at high risk for hypoglycemia with A1c < 7.0%. Undertreatment defined as A1C > 9%.

Results: There was marked variation in overtreatment rates; for A1c < 7%, overtreatment rates ranged from 26.4% to 58.2% and 26.2% to 49.2% at the facility level in 2013 and 2016, respectively. The mean (±standard deviation (SD)) facility-level overtreatment rates fell from 40.3 (±5.3)% in 2013 to 37.75 (±4.70)% in 2016 (P < 0.001, paired t-test). Facility undertreatment rates ranged from 5.8% to 16.9% and 6.8% to 18.7% at the facility level in 2013 and 2016, respectively. The mean (±SD) undertreatment rate rose from 10.3 (±2.2)% in 2013 to 11.0 (±2.4)% in 2016 (P ≤ 0.001, paired t-test). However, change at individual facilities ranged from a decrease of 4.6% to an increase of 7.2%. Within year correlations were stronger than between year correlations. Overtreatment defined as A1c < 7 in this population inversely correlated strongly with undertreatment (r = −0.653, P < 0.001).

Conclusions: Promotion of overtreatment reduction may be associated with an increase in undertreatment in patients with diabetes. Unintended consequence should be considered when...
implementing and evaluating quality measures and systems should include balancing measures to identify potential unintended harms.

**Key words:** performance measures, unintended consequences, diabetes, overtreatment, undertreatment

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**Objective**

The concept of balancing measures is well-known. The term ‘balanced scorecard’ was introduced in 1992 [1]. This approach involved a collection of measures arranged in four perspectives (financial, customer, internal processes, innovation and learning). Although refinements have been made, the basic structure remains unchanged. In healthcare, the balanced scorecard approach has focused on domains such as quality of patient care, cost/profitability and research/innovation [2]. Similarly, dashboards of measures were developed in the business sector and have been used in healthcare at clinical and managerial levels to provide information on standardized performance metrics in various domains, e.g. waiting times, clinical quality and productivity [3]. While families of measures for a single condition have been developed, such measures typically cover several domains. For example, one family of measures for diabetes includes metrics for glycemic control, blood pressure control, lipid control and several process measures related to eye care, foot care and renal care [4]. The unintended consequences of performance measurement are also well-known [5–8]. One potential consequence results from narrow focus on one measure without considering potential effects, e.g. worsening of a reciprocal measure or condition [9–11]. For example, focus on reducing inpatient length of stay could result in increases in emergency room visits and readmission rates [11]. However, typical families of measures do not directly address this problem. Moreover, there are few empirical studies of balancing measures within narrow domains, e.g. glycemic control.

The problem of inappropriately intensive glycemic control in patients with diabetes at risk for hypoglycemia, i.e. overtreatment, has been increasingly recognized both in the academic literature and by government agencies [12–15]. For example, in 2014, a national action plan to reduce adverse drug events sponsored by the Food and Drug Administration, National Institute of Diabetes and Digestive and Kidney Diseases, Centers for Disease Control and Prevention and the Department of Veteran Affairs (VA) included hypoglycemic agents as a target for intervention [15]. A potential unintended consequence of an emphasis on reducing overtreatment might involve an increase in undertreatment. The objective of this study was to determine in the Veteran Health Administration (VHA) if changes in facility-level overtreatment rates were associated with changes in undertreatment rates and specifically if reduction in overtreatment was associated with an increase in undertreatment.

**Participants**

The study population consisted of patients at risk for hypoglycemia in the medical facilities in the VHA healthcare system; patients were aggregated at the facility level for analysis. Because veterans may obtain care from more than one facility, we determined a patient’s parent facility based on where they received most of their ambulatory care. VHA provides comprehensive healthcare to eligible veterans of the Armed Services in >100 hospitals and their related clinics. During the years of the study, it was organized into 21 regional networks (Veterans Integrated Service Networks or VISNs), each consisting of 3–10 facilities. Facilities vary in the level of complexity depending upon size, scope of clinical activities and other site characteristics.

Patients who met our previously-proposed criteria for a population with risk factors for hypoglycemia were included in the study [14]. Specifically, this population included diabetic patients taking a diabetes drug known to have a relatively high frequency of hypoglycemia (insulin and/or sulfonylurea agents) plus having at least one of the following additional criteria: age 75 years or older, chronic kidney disease defined as last serum creatinine measurement in a year >2.0 mg/dl (to convert to micromoles per liter, multiply by 88.4), or an ICD-9-CM diagnosis of cognitive impairment or dementia in ambulatory care. Diabetes mellitus was defined based on presence of two or more International Classification Of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes for diabetes mellitus (250.xx) associated with clinical face-to-face outpatient care on separate calendar days in a 2-year period or presence of oral diabetes mellitus-specific medication prescription (insulin, sulfonylurea, biguanide, α-glucosidase inhibitor, meglitinide or thiazolidinedione) in the later year of the 2-year period. Among these patients, we retained only those that had at least one hemoglobin A1c (A1c) value documented in CY2013 or CY2016 to be the final study population (at risk group) and denominator for calculation of rates. The last A1c in each year was used, consistent with industry standards. Data sources included the VHA National Patient Clinical Data Set (Austin, Texas; to obtain ICD-9-CM and diagnostic codes) and the Decision Support System (to obtain laboratory data and medication information).

**Intervention**

This was an observational study of extant national initiatives to reduce overtreatment—the National Action Plan to Reduce Adverse Drug Events and the Choosing Wisely campaign [13, 15].

**Main outcome measures**

Our primary outcome measure was facility-level rate of overtreatment of diabetes defined as the proportion of patients in each facility at high risk for hypoglycemia with A1c<7.0%. We chose this level of A1c for two major reasons: First, the recommendation of the American Geriatrics Association for the Choosing Wisely Initiative, i.e. reasonable glycemic targets would be 7.0–7.5% in healthy older adults with long life expectancy, 7.5–8.0% in those with moderate comorbidity and a life expectancy <10 years, and 8.0–9.0% in those...
with multiple morbidities and shorter life expectancy [16]. This recommendation noted that ‘There is no evidence that using medications to achieve tight glycemic control in most older adults with type 2 diabetes is beneficial. Among non-older adults, except for long-term reductions in myocardial infarction and mortality with metformin, using medications to achieve glycated hemoglobin levels less than 7% is associated with harms, including higher mortality rates. Tight control has been consistently shown to produce higher rates of hypoglycemia in older adults. Given the long timeframe to achieve theorized microvascular benefits of tight control, glycemic targets should reflect patient goals, health status, and life expectancy.’ [16] Second, in 2008 NCQA discontinued its measure of A1c < 7% for all patients with diabetes aged 18–74 and limited it to patients <65 years of age or those who had one of a number of exclusions (coronary disease, vascular disease, dementia, stages 4 and 5 ckd, blindness and others). Nevertheless, we recognize that the concept of overtreatment of diabetes is controversial [17]. For example, lower A1c thresholds (e.g. <6.5%) have been proposed [17, 18]. However, there is relatively little controversy that a level of intensive glycemic control indicated by an A1c < 6% has little if any benefit, particularly in patients at high risk for hypoglycemia [19, 20]. Therefore, we also assessed rates of A1c < 6%. To assess undertreatment as an unintended consequence of focus on overtreatment, we determined in each facility the proportion of the same group of high risk patients with an A1C > 9%, a standard measure of (inadequate) quality.

Analyses
Statistical analyses using IBM SPSS 20.0 were primarily description; differences were assessed with paired t-tests and bivariate correlations were assessed using Pearson Chi square tests. The primary unit of analysis was the facility level. However, because quality initiatives affecting diabetes management could be conducted by VISN, we assess performance at the VISN level in addition to the facility level and national level.

Results

Over- and undertreatment rates—changes from 2013 to 2016
Overtreatment—in our selected population (n = 171,875 and 166,703 in 2013 and 2016, respectively), the national VHA rates of A1c < 7% were 40.5% and 38.1 in 2013 and 2016, respectively. The rates of A1c < 6% were 9.2% and 8.7%, respectively. There was marked variation in overtreatment rates at both the facility and VISN levels.

A1c < 7%: Facility (n = 138) overtreatment rates ranged from 26.4% to 58.2% and 26.3% to 49.2% at the facility level in 2013 and 2016, respectively. VISN overtreatment rates ranged from 35.5% to 45.5% and 33.2% to 43.2% in 2013 and 2016, respectively. The mean (±standard deviation (SD)) facility level overtreatment rates fell from 40.30 (±5.3)% in 2013 to 37.8 (±4.7)% in 2016 (P < 0.001, paired t-test). Although the mean rate of overtreatment dropped, change at individual facilities varied and overtreatment rates were reduced in 63%.

A1c < 6%: Facility overtreatment rates ranged from 3.5% to 20.6% and 3.7% to 15.8% at the facility level in 2013 and 2016, respectively. VISN overtreatment rates ranged from 6.2% to 13.9% and 5.4% to 11.1% in 2013 and 2016, respectively. The mean (±standard deviation (SD)) overtreatment rate based on facility-level rates fell from 9.2 (±2.9)% in 2013 to 8.4 (±2.3)% in 2016 (P < 0.001, paired t-test). Although the mean rate of overtreatment dropped, change at individual facilities varied and overtreatment rates were reduced in 57.2%.

Undertreatment—in our selected population, the national VHA rates of A1c > 9% were 10.3% and 11.0% in 2013 and 2016, respectively. There was marked variation in undertreatment rates at both the facility and VISN levels. Facility undertreatment rates ranged from 5.8% to 16.9% and 6.8% to 18.7% at the facility level in 2013 and 2016, respectively. VISN undertreatment rates (mean of the rates of the facilities within a VISN) ranged from 5.8% to 16.9% and 6.8% to 18.7% in 2013 and 2016, respectively. The mean (±SD) undertreatment rate rose from 10.3 (±2.2)% in 2013 to 11.0 (±2.4)% in 2016 (P < 0.001, paired t-test). However, change at individual facilities ranged from a decrease of 4.6% to an increase of 7.2%. Undertreatment rates were reduced in 42.0%.

Correlation between performance in 2013 and 2016—Correlations between over- and undertreatment rates are shown in Table 1. Within year correlations were stronger than between year correlations. Overtreatment defined as A1c < 7% in this population inversely correlated strongly with undertreatment. Overtreatment defined as A1c < 6% did not correlated significantly with undertreatment.

Correlations between year to year changes are shown in Table 2. Absolute changes in overtreatment were inversely correlated with undertreatment (Table 2 Panel A and Figs 1 and 2). Because of the wide variation in baseline rates, we also assessed relative changes. Relative changes in overtreatment were also inversely correlated with undertreatment, though less strongly than absolute changes (Table 2 Panel B and Fig. 3).

Conclusions
Our study of facility and VISN level rates of glycemic control indicates that the promotion of reduction of overtreatment may be associated with an increase in undertreatment in the same population of patients with diabetes. This association has implications for the

| Table 1 Correlations between rates of overtreatment and undertreatment |
|-------------------------|----------------|----------------|----------------|----------------|----------------|----------------|
| A1c < 7 rate 2013       | 1              | 0.461*          | 0.816*          | 0.479*          | −0.653*         | −0.072          |
| A1c < 7 rate 2016       | 1              | 0.349*          | 0.785*          | −0.185**        | −0.435*         | 0.119           |
| A1c < 6 rate 2013       | 1              | 0.474*          | −0.152          | −0.015          | −0.102          | 0.538*          |
| A1c < 6 rate 2016       | 1              | 0.015           | 1               | 0.538*          | 1               |                |
| A1c > 9 rate 2013       | 1              | 1               | 1               | 1               |                 |                |
| A1c > 9 rate 2016       | 1              | 1               | 1               | 1               |                 |                |
development of quality measures and highlights the necessity to consider unintended consequences well in advance. Moreover, rates of overtreatment based on A1c < 7% far exceeded the rates of undertreatment as defined by A1c > 9% and rates of overtreatment based on A1c < 6% approached those of undertreatment. Our study also illustrated that there is marked facility to facility variation. Some facilities reduced both overtreatment and undertreatment while others reduced one or the other and other facilities showed increases in both. Our data indicate that although there was within year correlation between facility-level over- and undertreatment rates, changes over time were more strongly correlated. Even accounting for baseline rates the relative percentage changes in over- and undertreatment rates were still significantly correlated.

Unintended consequences of actions are a fact of life [5, 8, 21-29]. Some of these consequences can be expected and mitigating strategies can be implemented in advance. Others may come as a surprise; in any complex systems with its myriad of interactions, responses to any intervention cannot be predicted with certainty [30]. Since the occurrence of hypoglycemia has increased in association with implementation of measures focusing on undertreatment of diabetes, it is should not be surprising that a focus on overtreatment might be accompanied by an increase in undertreatment [31-33]. This process may occur in a fashion illustrated in Fig. 2. In fact, similar findings have been observed by Kerr et al. who studied the effects of a performance measure for hypertension in patients with diabetes at VA medical centers [34]. They assessed a clinical action measure for hypertension (BP < 140/90 mm Hg or BP ≥140/90 mm Hg plus an appropriate clinical action) in a retrospective cohort study in 879 Department of VAMCs and smaller community-based outpatient clinics. However, among all patients with DM, 197,291 (20%) had a BP lower than 130/65 mm Hg; of these, 80,903 (8% of all patients with DM) had potential overtreatment. Facility rates of potential overtreatment varied from 3% to 20% (P < 0.001). In addition, facilities with higher rates of meeting the threshold measure (<140/90 mm Hg) had higher rates of potential overtreatment (P < 0.001). In contrast, when De Vries et al. assessed the introduction of diabetes performance measures in the Netherlands, they found that the improvement of BP undertreatment after introduction of the performance measures did not correspond with an increase in overtreatment. The performance measures appeared to have little impact on improving glucose-regulating treatment. The trends did not differ among patient age groups [35].

In addition, changes in patterns of glycemic control are also subject to secular trends. For example, Li et al. analyzed data from the National Health and Nutrition Examination Survey and the Behavioral Risk Factor Surveillance System in adults with self-reported diabetes [36]. The percentage of patients with A1c < 7% rose from 43.3% to 56.8% in the 1999–2002 and 2003–06 waves, respectively. The percentage then fell to 52.2% in the 2007–10 wave. The frequency of A1c > 9% fell from 18.4 to 13.0 and then 12.6% in the three waves from 1999–2010, respectively. Changes in A1c have also been observed in health plans accredited by NCQA, but the results were very dependent upon the type of health plan [37]. From 2013 to 2015 (years more comparable to our study), the percentage of patients with A1c < 7% (among those eligible for the measure) fell from 39.8% to 36.7% and 34.4% to 32.4% in commercial and Medicaid HMOs, respectively, while rising slightly from 32.2% to 32.6% in commercial PPOs. Percentages of patients with A1c > 9% rose or remained the same depending on the type of plan. In VA overall, the percentage of patients with A1c > 9% (or not done) rose from 16% to 19% over the period 2007–16 [38]. However, none of these patient populations correspond directly with our identified population at high risk for hypoglycemia.
Balancing measures

Limitations

Our study has several limitations. It is a study of a single healthcare system, albeit a large one. As a pre-test post-test design is susceptible to changes in secular trends and the forces affecting over and undertreatment rates in VA could differ from those in the private sector. There is the potential for measurement bias. A1c measurement can be confounded by a number of factors including changes in red blood cell life span, certain hemoglobinopathies, age, race and other factors. We lack individual level data demonstrating the distribution of these factors across facility, but we believe it is unlikely that facility-level distributions changed markedly across time. In addition, there is a coefficient of variation (CV) associated with any laboratory measurement and each laboratory is different. However, this CV is similar at the measured levels of A1c so that the two measures would be similarly affected. Moreover, facility laboratories tend to use the same assay over time. Finally, the magnitude of the changes is modest and the statistical significance may exceed clinical significance. Nevertheless, the restricted population to which we applied the A1c thresholds were at especially high risk for hypoglycemia and represented a substantial number of patients overall. Thus, the study’s limitations notwithstanding, our study supports the importance of a systematic approach to quality improvement that considers potential unintended consequences.

In summary, actions have consequences, both intended and unintended. The implementation of an improvement initiative or a performance measure are actions. When adverse unintended consequences can be anticipated, it is incumbent upon systems to include mitigating actions to ensure that unintended harms are avoided [21, 39]. This unintended consequence should be considered when implementing and evaluating quality measures and systems should include balancing measures to identify potential unintended harms.

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Conflict of interest statement

Dr Aron is the Endocrine Society representative to the NCQA diabetes measures group.

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