



Balancing Glycemic Overtreatment and Undertreatment for Seniors: An Out of Range (OOR) Population Health Safety Measure

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Author Disclosure

- Author Disclosure Information: C. Tseng: None. O. Soroka: None. M. Maney: None. D.C. Aron: None.
- L.M. Pogach reports that he is the co-chair of the Department of Health and Human Services National Action Plan for Prevention of Adverse Drug Events (Diabetes Agents) and the Veterans Health Administration (VHA) Choosing Wisely Taskforce
- This project is supported by a VHA Health Services Quality Enhancement Research Initiative (QUERI) Grant RRP 12-492 (Dr. Pogach-PI).
- The opinions expressed are solely those of the authors and do not represent the views of the Department of Veterans Affairs or any other agency.

Background-NQF Measure 0729

- The National Quality Forum (NQF) composite measure (0729) includes a <8% A1c component that is applicable to all individuals 65-75 years without exclusion criteria.
- DHHS National Action Plan for Prevention of Adverse Drug Events stated: “Specifically, the [NQF] measures do not exclude patients for whom HbA1c <8 percent would be inappropriate according to new guidelines, nor stratify by medications (such as insulin). Neither do they address potential overtreatment in high-risk groups.”
- VHA and Centers for Medicare and Medicaid Services submitted public comment (4/2015) that questioned
 - The strength of evidence of a <8% measure (as opposed to 8.0-8.5%) for serious comorbid conditions/limited life expectancy;
 - The failure to have exclusion criteria and/or stratification for those on hypoglycemic agents, especially insulin;
 - The accuracy of A1c tests-both clinical laboratories and POC.

NQF Response to Public Comment

- Confirmed an <8% threshold even for individuals with “poly-pharmacy, inability to recognize and treat hypoglycemia, limited life expectancy, cognitive impairment, end stage renal and liver disease and end-stage complications.”
- Stated the <8% threshold may not be appropriate for all patients, but that “... the 8% cutoff was a reasonable target for a national health care performance measure and that 100% performance on the measure is not expected.”
- Noted exclusions only for “...patients who died, are permanent nursing home residents, or are receiving hospice or palliative care services, which addresses at least some of the concerns voiced by the commenters.”
- Did not comment as to whether A1c test results in every day practice (Clinical Laboratories or Point of Care) is sufficiently accurate to avoid unintended harms from implementing the measure

Objectives

- To propose a new approach for glycemic (A1c) performance measures for patients that balances safety and evidence based care in high risk individuals based upon presence of significant medical, neurologic or mental health related illness
- Evaluate rates of A1c “over-treatment” (OT, $< 7\%$), NQF Endorsed Measure ($< 8\%$), “under-treatment” (UT, $> 9\%$), “out of range” (OOR, $< 7\%$ or $> 9\%$) and “in-range” (IR, $7.5\% - 8.5\%$) by comorbid status
- Evaluate VHA facility level performance on OOR and IR measure.
- To evaluate changes in facility rankings comparing NQF $< 8\%$ measure to the proposed OOR measure

Methods

- **Design:** Cross-sectional analysis in fiscal years (FY) FY 2012-2013
- **Setting:** Veteran Health Administration (VHA) facilities
- **Data sources:** VHA outpatient, medication, laboratory files
- **Denominators:** Study cohort - diabetes patients aged 65-74 years on October 1, 2012 and who received VHA care in 2012, with at least one A1c in 2013, and on any anti-glycemic medication/s (other than Metformin alone) within 60 days prior to the last A1c in 2013.
- Subgroups based upon specified baseline (2012) diagnosis of elevated serum creatinine, neurologic, medical or mental health conditions
- **Patient Level Outcomes:** Percentage of patients with A1c < 7%, < 8%, > 9%, OOR (< 7% or > 9%), and IR (7.5%-8.5%)
- **Facility Level Outcomes:**
 - (1) Facility rates by OOR and IR measures
 - (2) Changes in facility decile rankings based upon OOR measure compared to rankings based upon < 8% measure

Derivation of Study Population

- 1,036,912 patients with diabetes who were alive as of October 1, 2012 and used the VHA for outpatient care during the following 12 months.
- 677,045 were 65 years or older, of whom 574,492 had an A1c test available in FY 2013.
- Excluded 190,920 who had no prescriptions for diabetes medications (33.2%) within 60 days of the last A1c test within the year, and who were on metformin only (14%), resulting in 303,097 (52.8%) patients.
- 176,805 were 65-74 years old on October 1, 2012 (FY2013)

Table 1: Study Cohort Characteristics

	N	col %
Total N	176,805	100.0
Men	174,342	98.6
VA enrollment priority		
Severe Disabled	80,244	45.5
Moderately Disabled	28,529	16.1
Means Test Eligible	36,880	20.8
Co-pay	28,317	16.0
Diabetes medications		
SU only	22,167	12.5
SU and non-insulin medications	43,768	24.6
Insulin only	50,029	28.3
Insulin in combination with non-insulin medications	58,029	32.8
Other anti-glycemic medications	2812	1.6
Serum creatinine available	155297	87.8
Serum creatinine, mg/dL		
<1.7	138902	89.4
1.7-<2.0	7490	4.9
>=2.0	8905	5.7
HbA1c, mean (SD)	7.67(1.42)	-

Table 1 (continued). Study Cohort Characteristics

# of patients with at least one co-morbid conditions		102,104	57.8%
Number of conditions			
	1	71,409	40.5%
	2	23,587	13.3%
	3+	7,108	4.1%
Diminished life expectancy		20,410	11.51%
	Cancer	19,772	11.17%
Advanced diabetic complications		16,063	9.14%
	Advanced retinopathy	15,548	8.85%
Cognitive impairment or dementia		9,451	5.36%
Other neurological conditions		6,727	3.82%
Cardio-vascular conditions		68,777	38.96%
	Myocardial infarction	4,540	2.56%
	Chronic heart failure	16,034	9.09%
	Ischemic vascular disease	63,176	35.77%
Major depression		11,659	6.56%
Alcohol/substance abuse		8,278	4.71%

Diminished Life Expectancy includes end-stage hepatic disease and cancer (excluding basal and squamous skin cancers).

Advanced Diabetic Complications includes end-stage renal disease, amputation, advanced retinopathy.

Other Neurological Conditions includes gastroparesis, Parkinson disease, aphasia, dysphasia, hemiplegia, apraxia, epilepsy, transient ischemic attack.

Patient may have more than cardio-vascular condition. Subcategories are not mutually exclusive.

Table 2. A1c Outcome Measures by Sub-populations of Comorbid Conditions

		Increased number of patients	Number of patients in denominator	col %	Outcomes measures (%)				
					A1c <7%	<8%	>9%	<7 or >9%	7.5-8.5%
					OT	NQF	UT	OOR	IR
Study cohort			176,805	100%	33.1	66.1	13.7	46.8	28.4
	no specified comorbidities		69,939	39.6%	32.5	66.8	13.3	45.8	28.7
	Co-morbidity Subgroups								
A	creatinine ≥ 1.7 mg/dl		16,395	9.3%	36.5	67.0	13.2	49.7	27.3
B	A +CI/Dem	8,441	24,836	14.0%	36.3	66.7	13.7	50.0	26.9
C	B +advanced diabetes complications	11,983	36,819	20.8%	33.6	64.8	14.6	48.2	28.0
D	C +diminished life expectancy	15,802	52,621	29.8%	34.7	66.1	13.8	48.5	27.5
E	D +major neurological disorders	2,710	55,331	31.3%	34.8	66.2	13.8	48.6	27.5
F	E +cardiovascular diseases	43,984	99,315	56.2%	33.2	65.6	13.9	47.2	28.3
G	F +major depression	4,463	103,778	58.7%	33.3	65.6	14.0	47.2	28.3
H	G +alcohol/drug abuse	3,088	106,866	60.4%	33.4	65.7	14.0	47.4	28.2

OT- over-treatment; NQF - National Quality Forum; UT - under-treatment; OOR - out of range ; IR - in range

Figure 1. Facility Level OOR and IR Rates by Deciles of OOR Performance

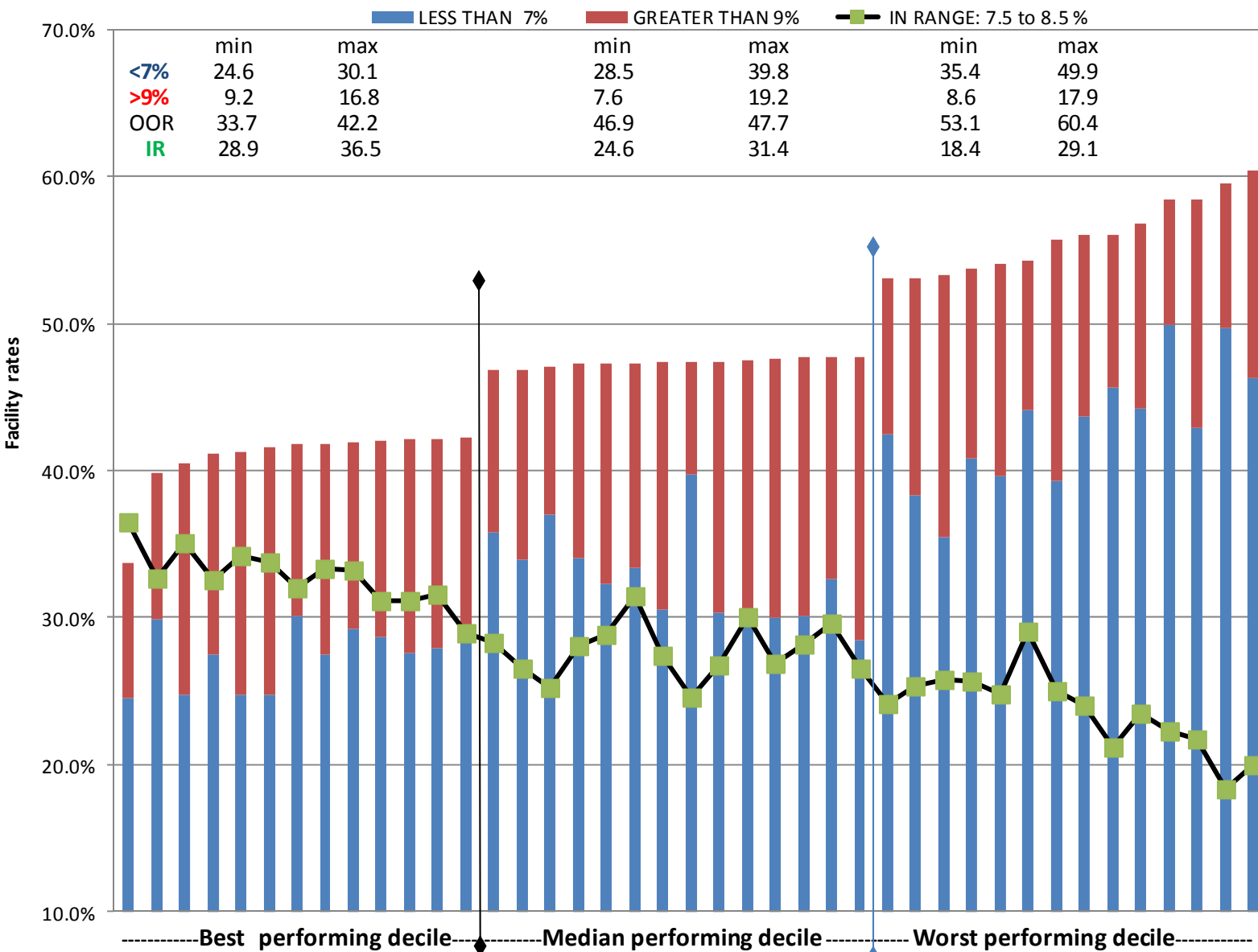


Figure 2. Distribution of 139 facilities based on performance rankings (by decile)

		performance by A1c<8% Measure										
			Worst									Best
		mean rate (%)	58.3	61.3	62.4	63.5	65.2	66.6	67.8	68.8	70.3	73.1
performance by OOR Measure	Best	40.9	4	3	1	2			2		1	
		43.3	1	4	2	1	2	1	1			2
		44.6	1	1	2	2	3	2	1	1	1	
		45.5	1	2		1	3	1	3	1		2
		46.8	1	1	1	1	2	1	2	1	2	2
		47.7	3	1	3	4		1	1			1
		48.5	1		1	2	3	2	3	2		
		49.3	1		2		1	3		4	1	2
		51.2		2	1	1		2		3	5	
	Worst	55.9			1				1	1	2	4

Spearman rank correlation coefficient= -.81 between the two measures

Limitations

- VHA data only; Medicare data unavailable
- Potential under diagnosis of cognitive impairment/dementia and renal disease (eGFR not calculated) in clinical practice
- Illness severity cannot be ascertained
- Activities of Daily Living impairment not available
- Socio-demographic risk factors (food insufficiency, social support, literacy) not available
- Hypoglycemic events and other adverse medication events (including common side effects) cannot be ascertained
- Cross-sectional study design, not intended for evaluation of consequences (hypoglycemia) of potential over-treatment

Conclusion and Implications

- About 6 in 10 VHA patients 65-75 years on medication other than metformin only, have conditions for whom a stringent $< 8\%$ measure may not be appropriate.
- Overtreatment ($< 7\%$) 2.4 fold more common than under-treatment ($> 9\%$).
 - 51.1% of all patients with an A1c $< 8\%$ had an A1c $< 7\%$
- There was a strong inverse correlation ($- 0.81$, Spearman Rank Coefficient) between $< 8\%$ and OOR rankings.
 - 14 of 28 of the best performing facilities on $< 8\%$ were ranked in the two lowest OOR deciles; 12/27 of the worst performing were ranked in the best OOR deciles.
- **These findings suggest that the $< 8\%$ target does not address safety, therefore rankings do not assess quality of care.**
- We propose an OOR measure for accountability and an In-Range measure to guide quality improvement efforts for seniors.

Discussion point:

Can performance measures incentivize over-diagnosis that leads to over treatment and potential harms?

- **NQF Measure: A1c<8% for Patients with Diabetes 65-75 Years Old**
- 2015 ICD-9-CM Diagnosis Code 250.02 Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled.
- ICD-9-CM 250.02 is a billable medical code that can be used to specify a diagnosis on a reimbursement claim.

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