Balancing Measures: Identifying Unintended Consequences of Diabetes Quality Performance Measures

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Disclaimer: *The opinions expressed in the following presentation are solely those of the presenter, and do not represent those of any agency or organization*

Disclosures*:*

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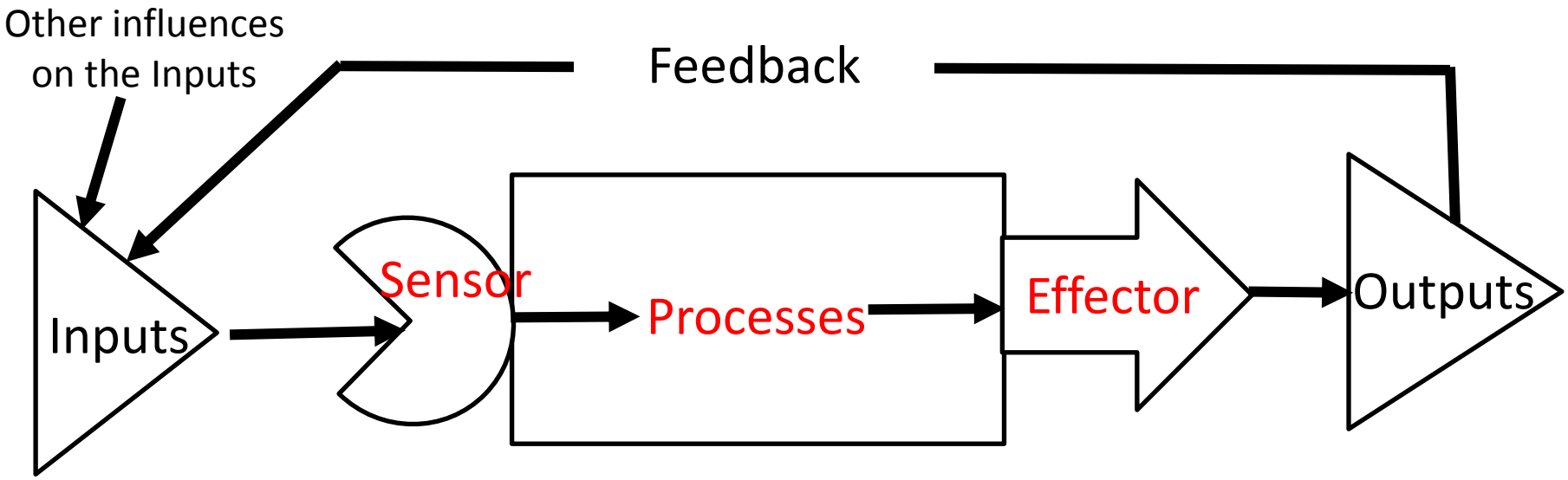
- *DCA is the Endocrine Society Representative to NCQA/AMA on Performance Measures*
- *NO money from Big Pharma, medical device companies, etc.*

The following **presentation is rated R** (for opining and sarcasm which may "inadvertently" seep in). Viewer discretion is advised, but feel free to challenge everything I say.

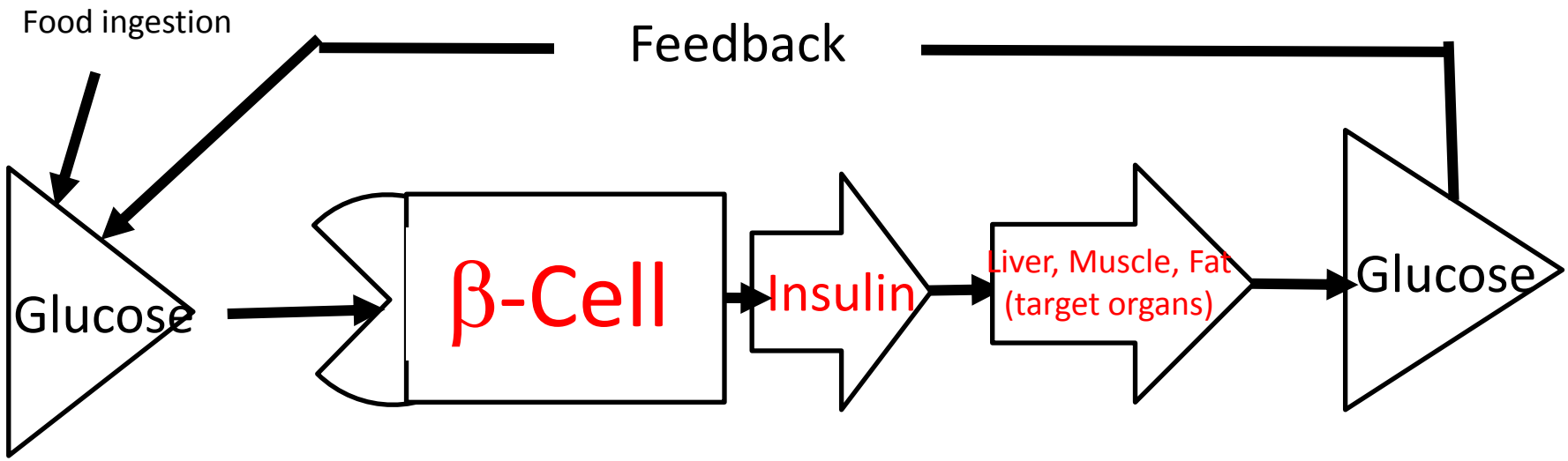
Outline

- A cybernetic model of performance management.
- Performance measures in diabetes
- Unintended consequences
- Balancing measures
- Homeostasis
- Alternatives

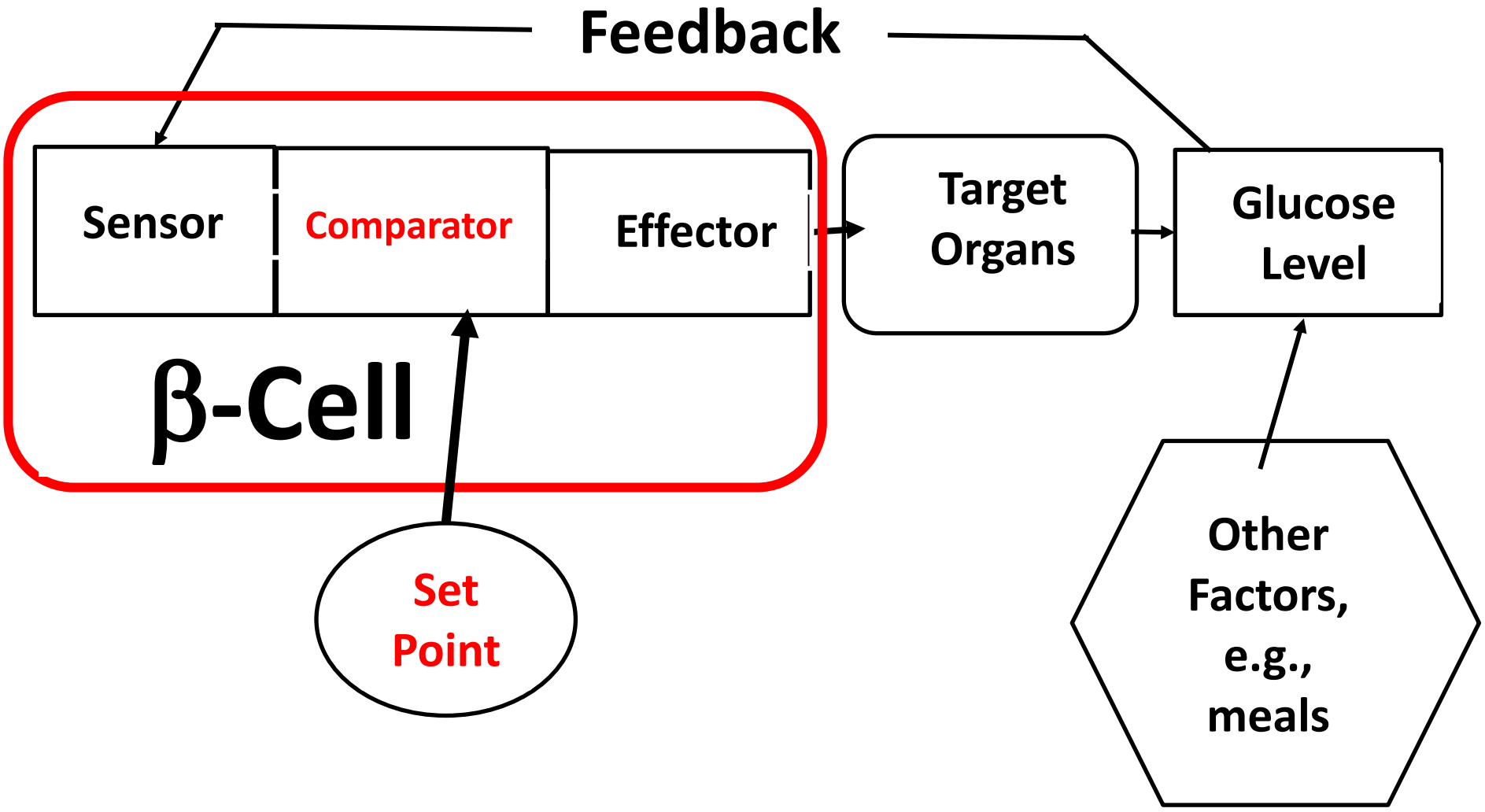
Cybernetic System



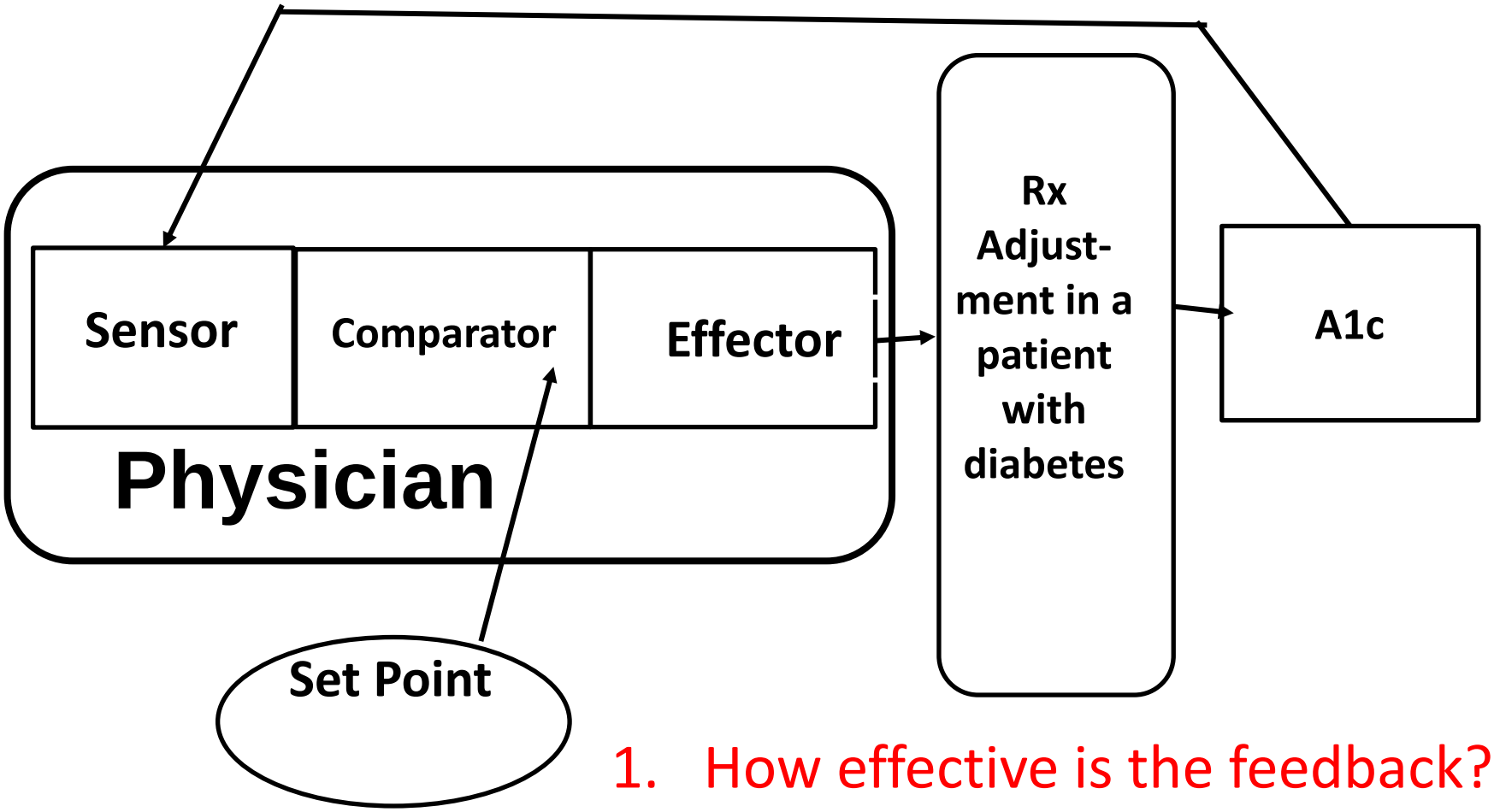
Cybernetic View of Glucose Control by the β-Cell



Cybernetic View of Glucose Control by the β-Cell Expanded



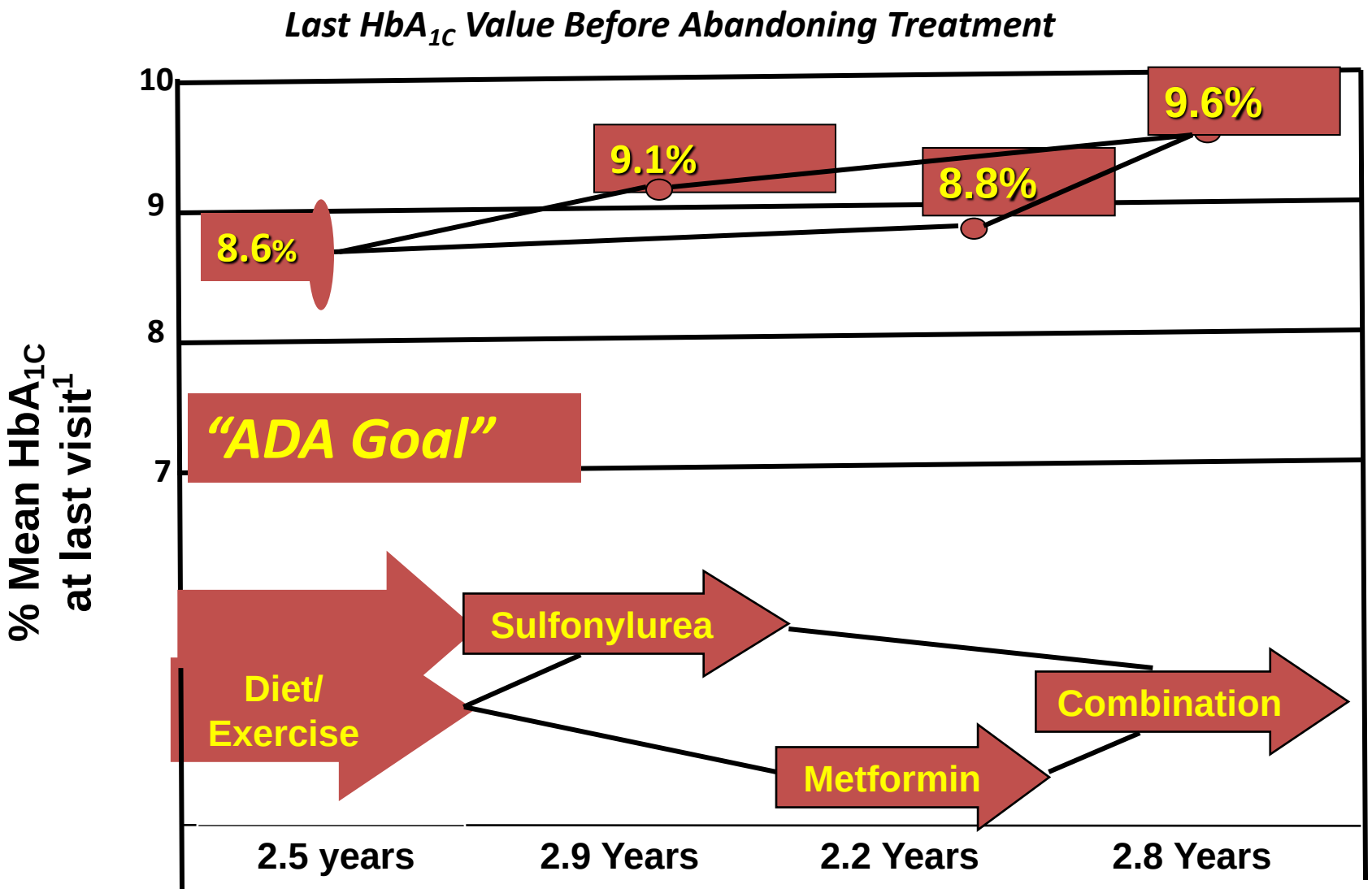
Feedback System (Self-Performance Management)



1. How effective is the feedback?
2. What about the set point?

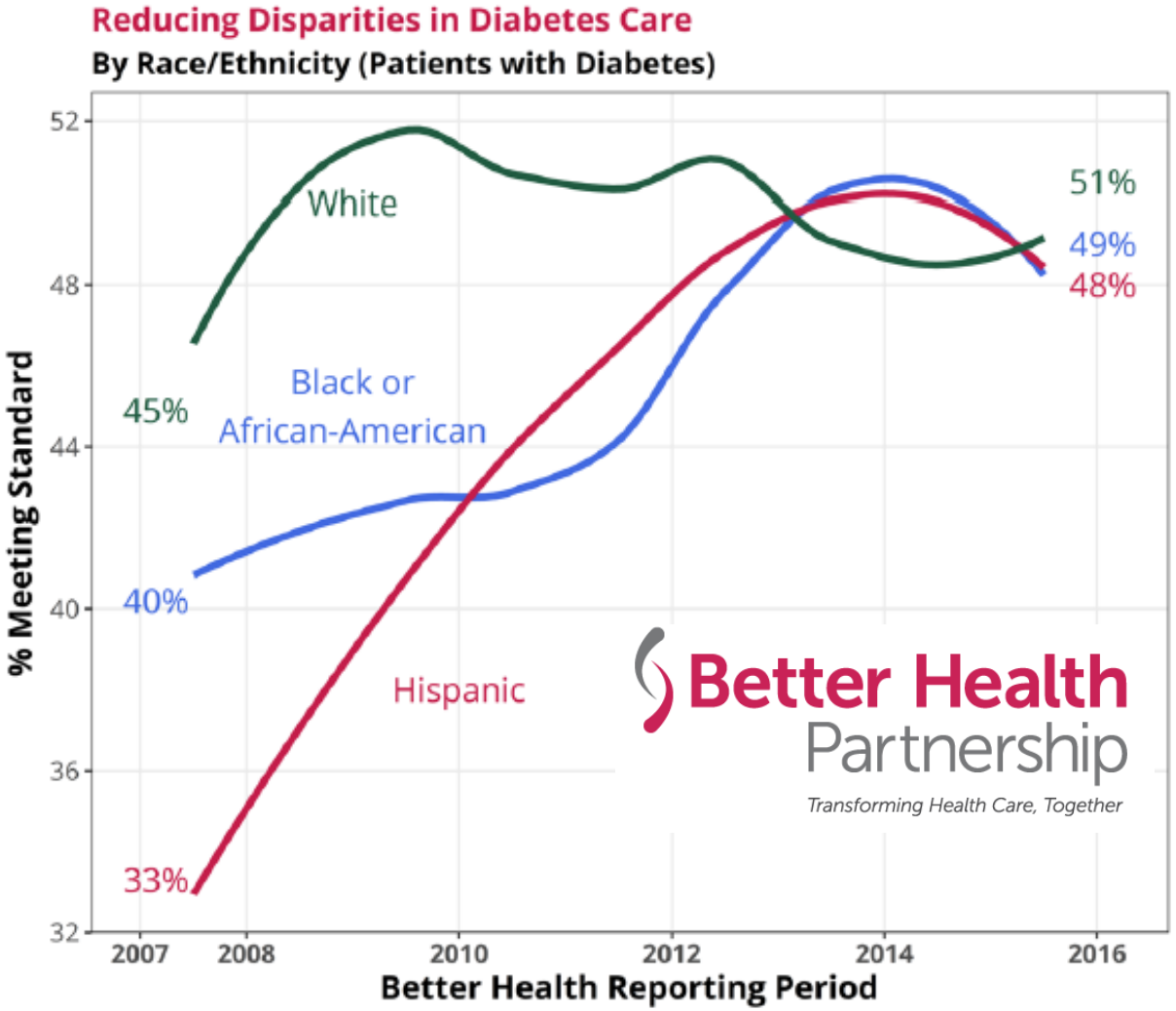
Curr Diab Rep (2014) 14:472

"Clinical Inertia" Failure to alter rx when required



[1]Brown et al. The Burden of Treatment Failure in Type 2 Diabetes. Diabetes Care 27: 1535-1540, **2004**

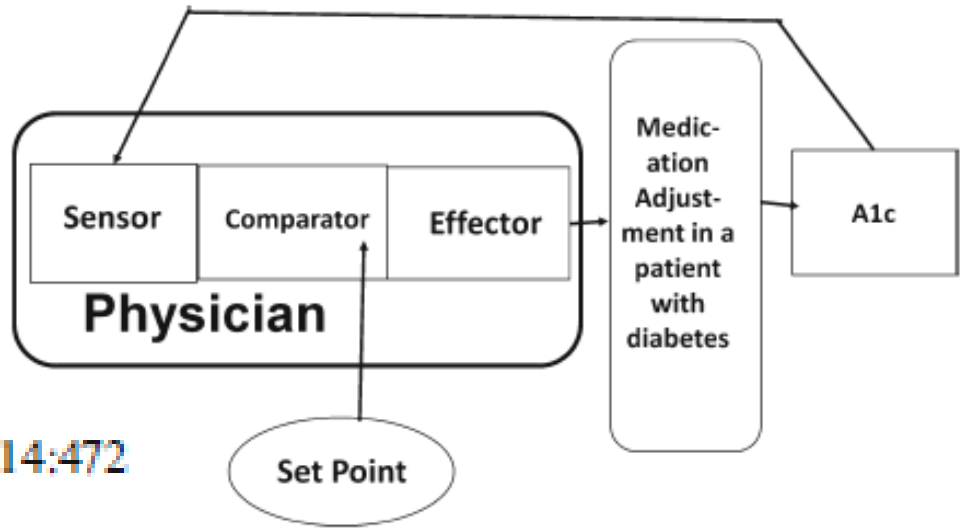
Moving to the performance measure era



Composite measure that includes A1c<8%

Cuyahoga County based initiative

The Set Point in the Cybernetic Model of Physician Treatment of Glycemic Control

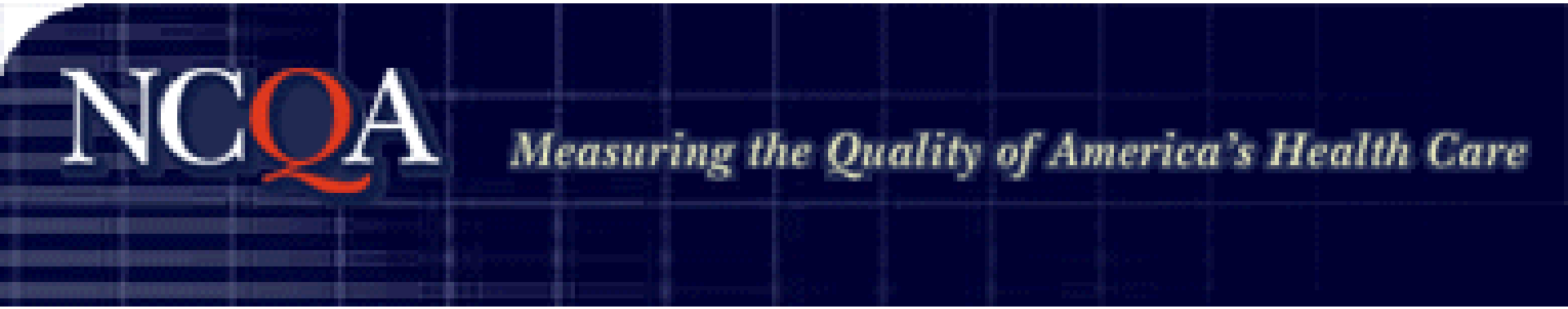


Curr Diab Rep (2014) 14:472

DIAGNOSIS: Inadequate Glycemic Control

- If Set Point is set too LOW → OVER-Dx → OVER-Rx
- If Set Point is set too HIGH → UNDER-Dx → UNDER-Rx

What about the Set Point?
A brief history of the A1c<7% measure for diabetes



- Two new **Comprehensive Diabetes Care** measures assess whether members with diabetes have their blood pressure controlled to 135/85, and whether their HbA1c levels are controlled to less than 7 percent, the *nationally accepted* standard of adequate HbA1c control.

  2004

New NCQA Quality Diabetes Measures Endorsed (4/2004)

- A group of experts representing public health and medical organizations announced April 7 that they strongly supported new diabetes quality of care measures that include a measure of A1C<7% for people with diabetes in line with the clinical guidelines established by the American Diabetes Association.

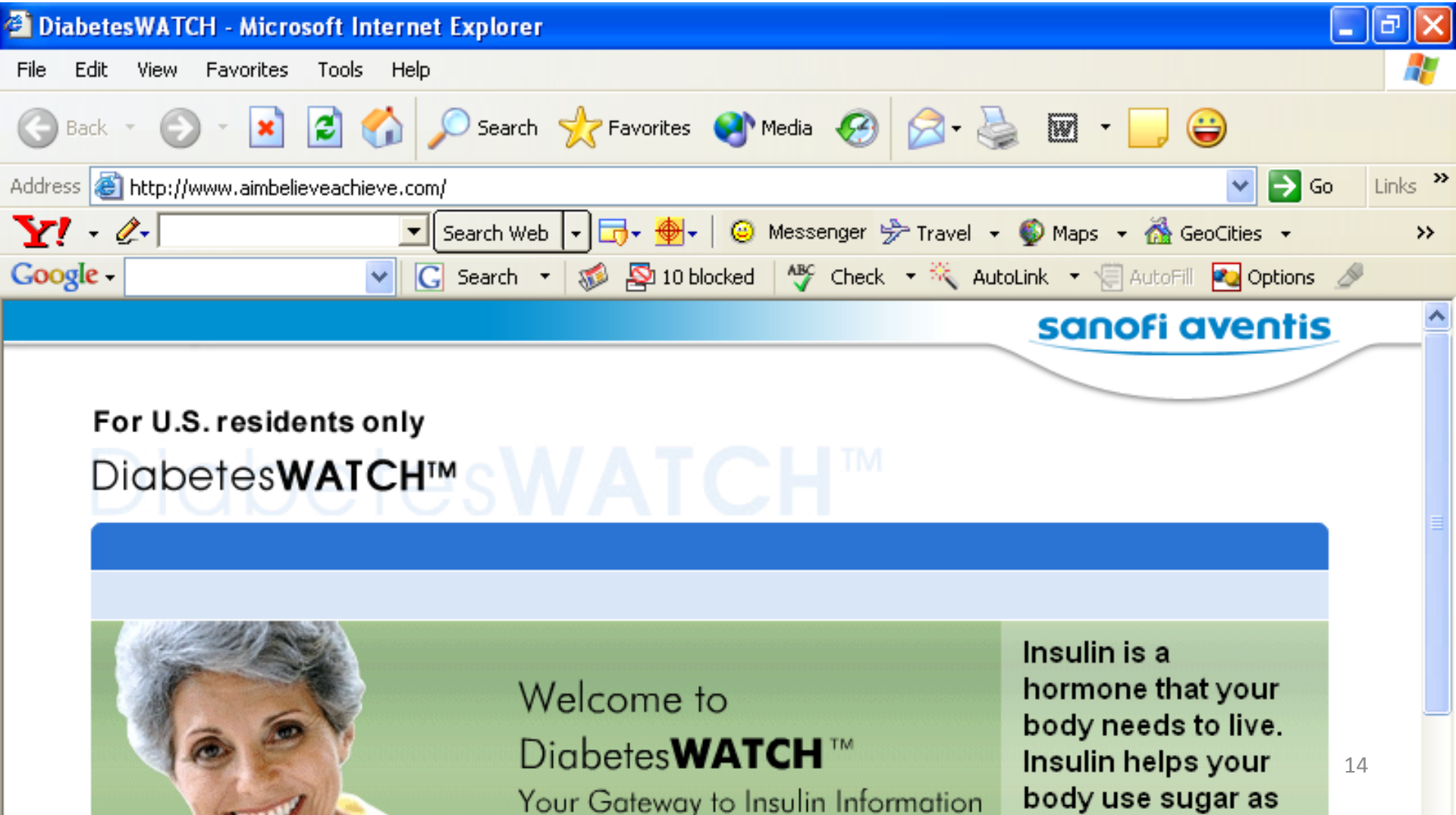
Table 2—Continued

AGREE Domains	Guidelines								
	AACE	AAFP	ADA	ACS	CDA	ICSI	NICE	SIGN	VHA
Total score	50.5	71	58	70	71.5	64.5	77	74	72

* AACE = American Association of Clinical Endocrinologists; AAFP = American Academy of Family Physicians; ADA = American Diabetes Association; AGREE = Appraisal of Guidelines, Research and Evaluation in Europe; ACS = American Geriatrics Society; CDA = Canadian Diabetes Association; ICSI = Institute for Clinical Systems Improvement; NICE = National Institute for Health and Clinical Excellence; SIGN = Scottish Intercollegiate Guidelines Network; VHA = Veterans Health Administration.

- Qaseem, Annals Int Med. 2007

- A national PSA campaign sponsored by the Conference of Mayors in partnership with Aim. Believe. Achieve. The Diabetes A1C Initiative(tm).



WHO RAN THE CAMPAIGN?

Innovation & Insights - CaseStudies - National Diabetes Call to Action and Blueprint... - Microsoft Internet Explorer

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Address http://www.burson-marsteller.com/Innovation_and_insights/Case_Studies/Lists/CaseStudies/DispForm.aspx?ID=59&nodeName=Healthcare&subTitle=National%

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National Diabetes Call to Action and Blueprint for Change

Situation Analysis

Of the 11 million Americans with diabetes, more than half are not achieving their target blood sugar levels, defined as hemoglobin (Hb) A1C of <7 percent. As a result, these individuals remain at a higher risk for serious complications, such as blindness, kidney disease, heart disease, stroke, and amputation. Although insulin therapy is one of the most effective methods for achieving target A1C levels, treatment is often delayed or dosed inadequately for fear of hypoglycemia (low blood sugar) and weight gain. Yet, research shows that a new generation of insulin treatments can significantly reduce these problems.

Aventis wanted to create an initiative to address the growing epidemic of uncontrolled diabetes. Through a host of educational efforts, the company sought to encourage people to know their A1C level, to be aware of the target for good control, and to work with their healthcare provider to learn about the available treatment options (including insulin) that could help them achieve and maintain an A1C<7%.

Strategy & Implementation

In response, Burson-Marsteller (B-M) designed and implemented a national

- Public Affairs
- Corporate and Financial Communications
- Marsteller
- Healthcare
- Technology
- Issues & Advocacy
- Brand Marketing
- Media Relations
- Digital Media
- Specialized Capabilities
- Industry Specialties

Internet

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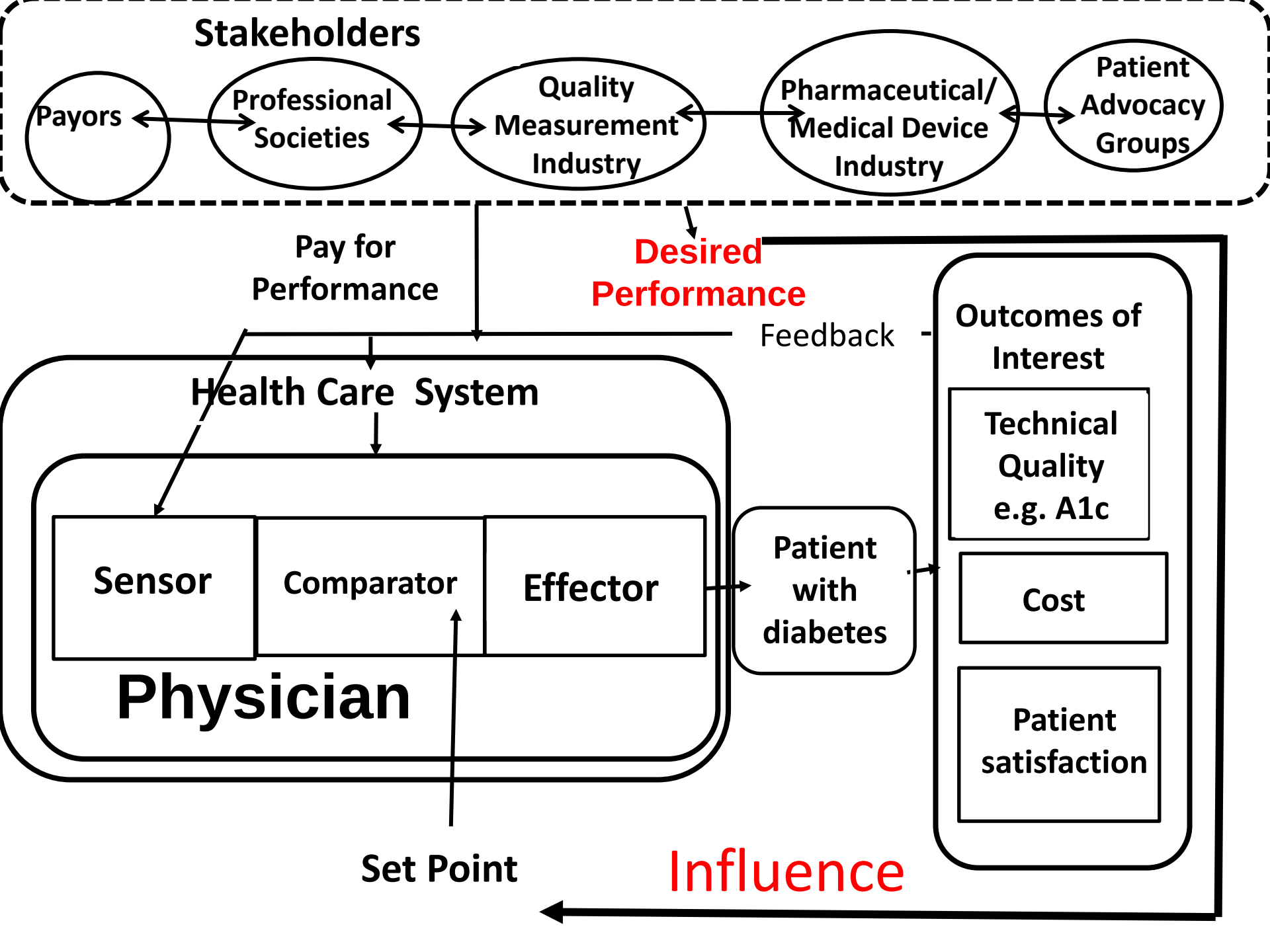

Stakeholders
Payors
Professional Societies
Quality Measurement Industry
Pharmaceutical/ Medical Device Industry
Patient Advocacy Groups
Pay for Performance
Desired Performance
Feedback
Outcomes of Interest
Health Care System
Technical Quality e.g. A1c
Sensor
Comparator
Effector
Patient with diabetes
Cost
Physician
Patient satisfaction
Set Point
Influence

Adam A. Powell, PhD, Katie M. White, Melissa R. Partin, Ph , Krysten Halek, MA , Jon B. Christianson, PhD , Brian Neil, MD , Sylvia J. Hysong, PhD , Edwin J. Zarling, MD7 , and Hanna E. Bloomfield, MD Unintended Consequences of Implementing a National Performance Measurement System into Local Practice J Gen Intern Med 27(4):405–12

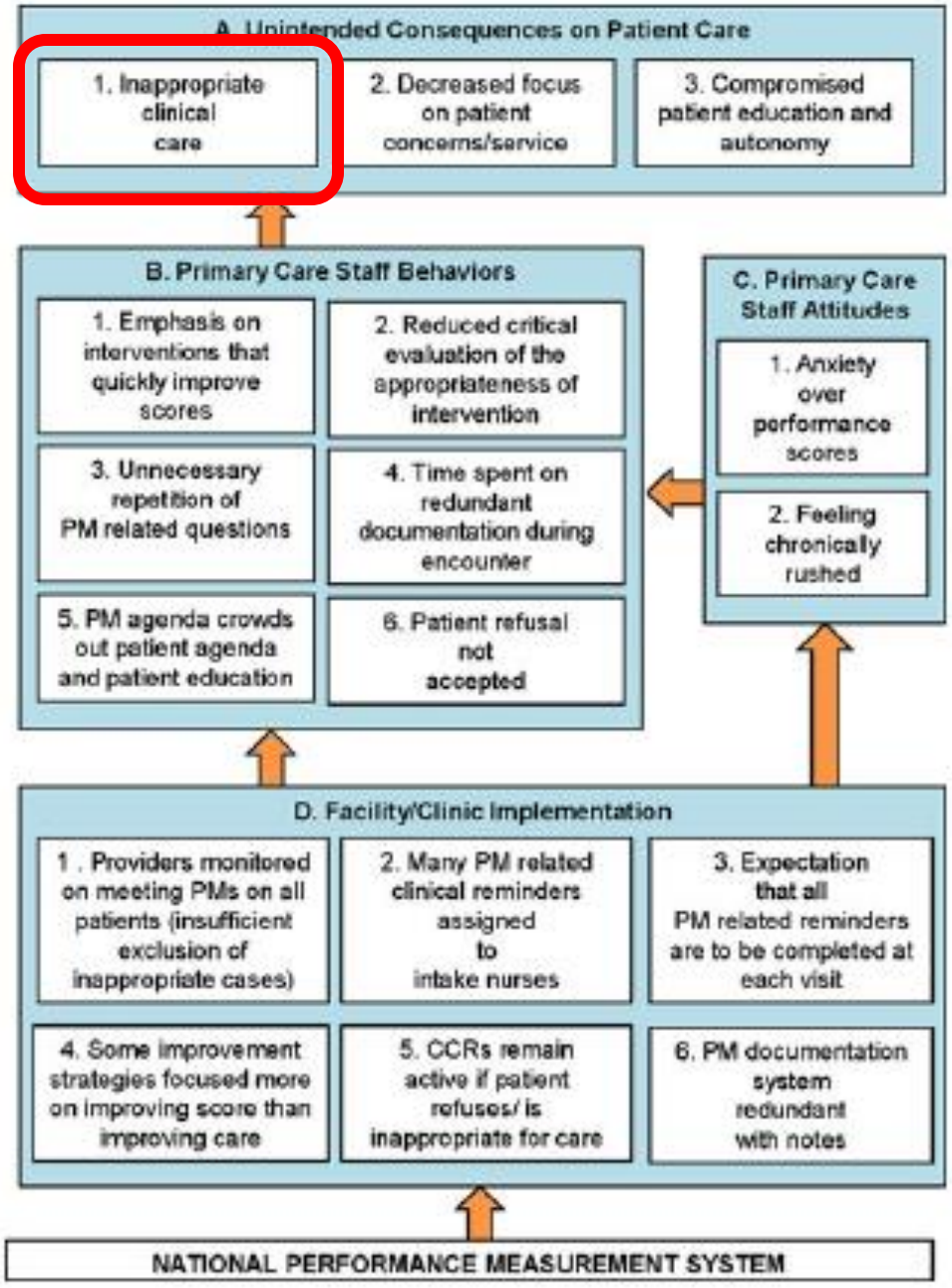
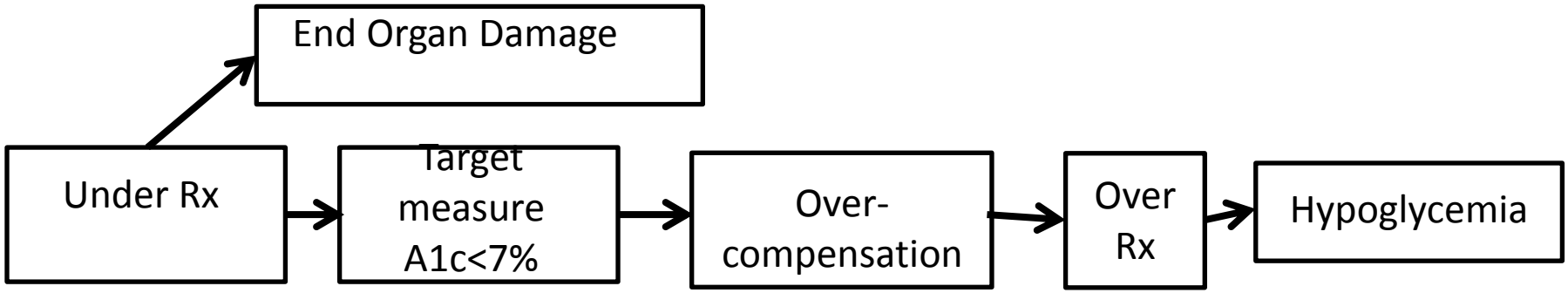


Figure 1. Pathways from national performance measurement systems to unintended effects on patient care.

Overtreatment in groups with high risk of hypoglycemia (an unintended consequence of focus on undertreatment)



- Hypoglycemia is a common side treatment effect, esp. with insulin and sulfonlyureas and in high risk groups and leads to increases in hospitalizations.

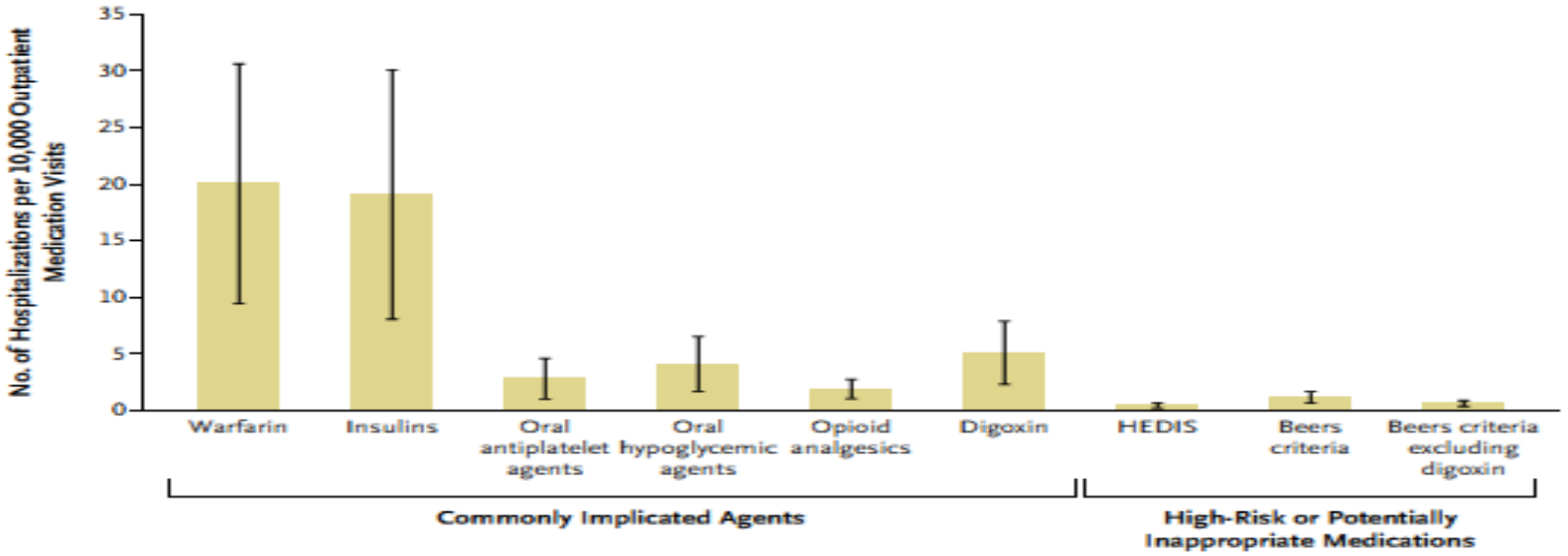


Figure 1. Estimated Rates of Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.

Budnitz DA et al. N Engl J Med 2011; 365:2002-2012

Lipska KJ, Ross JS, Wang Y, Inzucchi SE, Minges K, Karter AJ, et al. National trends in US hospital admissions for hyperglycemia and hypoglycemia among Medicare beneficiaries, 1999 to 2011. JAMA Intern. Med. 2014;174(7):1116-24.

Was increased frequency of hypoglycemia following promotion of intensive glycemic control (A1c<7%) for everyone aged 18-74 a black swan?

What did we know and when did we know it?

"It is important to note that the National Committee for Quality Assurance (NCQA) includes a strong advisory that 100% performance is *not the goal and that clinical judgment* should be used in applying a measure…Although physicians should be aware of guidelines and measures, they need also to apply more nuanced approaches when seeing individual patients. To imply that clinicians would knowingly put patients in harm so they could perform marginally better than other physicians on a clinical performance measure provides a rather dim view of medical practice."

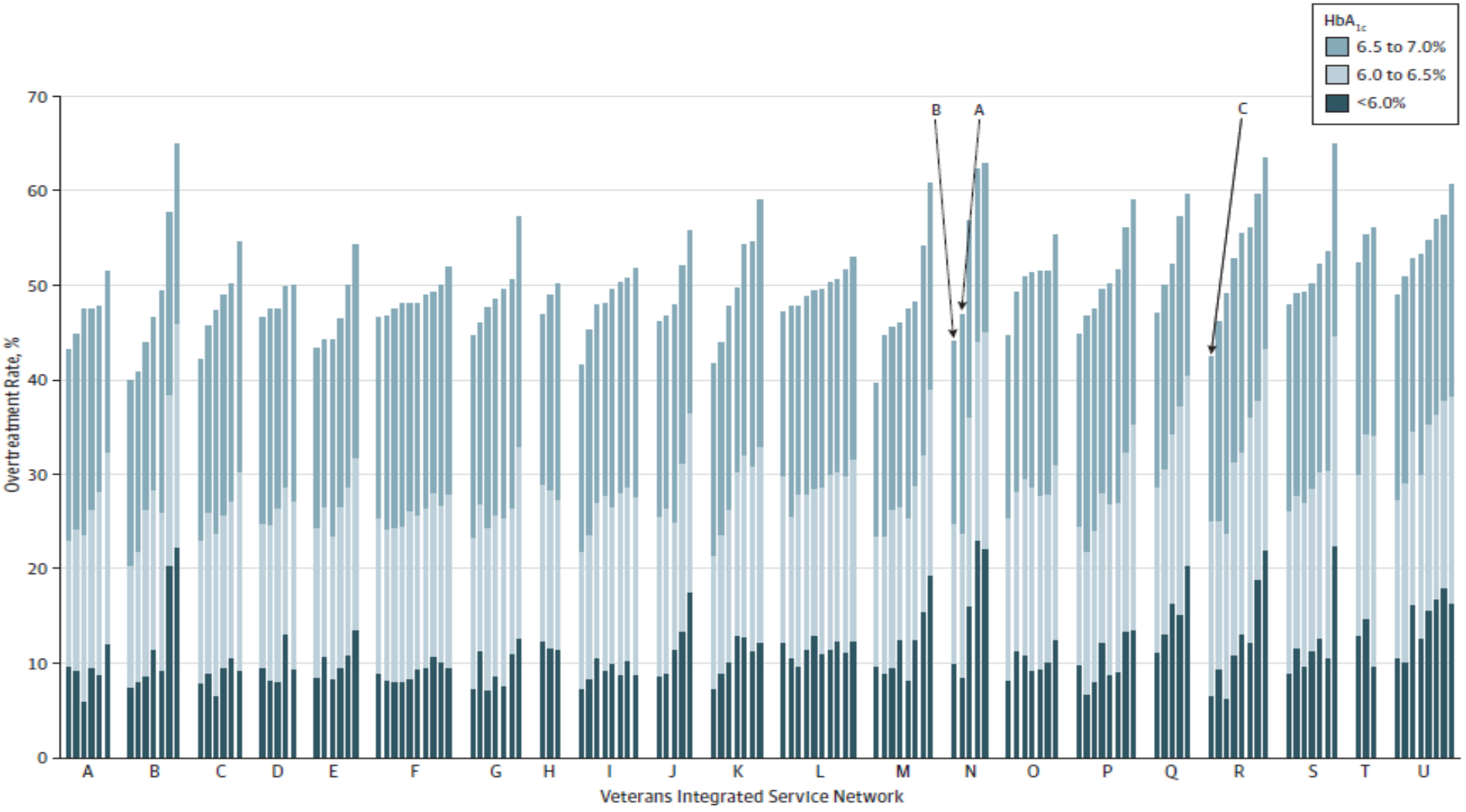
L. Gregory Pawlson, MD, MPH; and Thomas H. Lee Jr, MD AJMC **2010; 16: 16-17**

Assessing potential glycemic overtreatment in persons at hypoglycemic risk. Tseng et al. JAMA Int Med 2014: 174; 259-268

Group	High risk patients	Increased number of patients	Number of patients in denominator	% of study population [a] (n=652,738)	Overtreatment measures (in %). % with A1c			
					<6.0%	<6.5%	<7.0%	7.0-7.4%
A	Age >75y; creatinine >=2mg/dl; CI[b]/D[c]		205,857	31.5	11.3	28.6	50.0	18.1
B	A+advanced diabetes complications[d]	28,035	233,892	35.8	10.7	27.2	47.9	17.9
C	B+diminished life expectancy[e]	37,972	271,864	41.7	10.9	27.3	47.7	17.7
D	C+major neurological disorders[f]	8,075	279,939	42.9	10.9	27.2	47.5	17.6
E	D+cardiovascular diseases[g]	115,767	395,706	60.6	10.0	25.3	44.8	17.4
F	E+major depression	17,268	412,974	63.3	10.0	25.1	44.4	17.3
G	F+alcohol/drug abuse	17,204	430,178	65.9	10.1	25.2	44.3	17.1

[a] Study population: patients with diabetes, on insulin or sulfonylureas, having HbA1c in FY 2009.
[b]CI: Cognitive Impairments. [c]D: Dementia. [d]Advanced diabetes complications: end stage renal disease, amputations, advanced retinopathy. [e]Diminished life expectancy: cancer, end stage hepatic disease.
[f]Major neurologic disorders: gastro paresis, Parkinsons, aphasia, dysphagia, hemiplegia, apraxia, epilepsy, transient ischemic attack. [g]Cardiovascular diseases: myocardial infarction, chronic heart failure, ischemic vascular disease.

Figure 2. Facility Variation in Overtreatment Rates by Veterans Integrated Service Network (VISN)

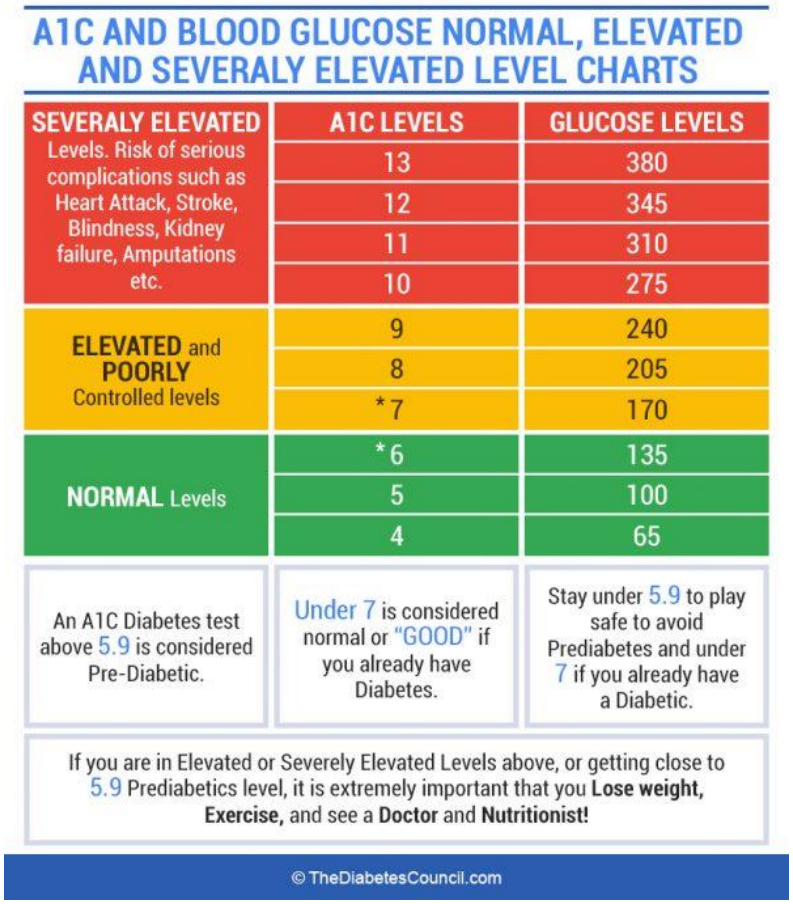


The denominator population: patients 75 years or older; serum creatinine level, ≥2.0 mg/dL; or diagnosis of cognitive impairment or dementia. The VISNs are in ranking based on overtreatment rate for hemoglobin A_{1c} (HbA_{1c}) <7.0%.

Facilities (A), (B), and (C) refer to positive deviants identified in Figure 3. To convert serum creatinine to micromoles per liter, multiply by 88.4; HbA_{1c} to a proportion of total Hb, multiply by 0.01.

What happened to the NCQA A1c<7% measure

- Piloted in 2005, initiated in 2006
- Modified when ACCORD was stopped.
- 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 with other exclusions in younger patients.
- But A1c<7% is still marketed widely by others



https://www.thediabetescouncil.com/ultimate-guide-to-the-a1c-test-everything-you-need-to-know/ accessed 9/5/17

Meanwhile back at the ranch

Choosing Wisely. An initiative of the ABIM. American Geriatrics Society

- Avoid using medications to achieve hemoglobin A1c <7.5% in most adults age 65 and older; moderate control is generally better.
- 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
    - http://www.choosingwisely.org/doctor-patient-lists/american-geriatrics-society/

National Action Plan to Reduce Adverse Drug Events sponsored by HHS, FDA, CMS, NIH, CDC, and VA

U.S. Department of Health and Human Services OoDPaHP 2014;Pages. Accessed at U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. at http://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf on 5/10/2015 2015.

Source	Evidence
ADVANCE, ACCORD, VADT	Serious hypoglycemia strongly associated with mortality. Association strongest in control arms
Choosing Wisely	3 **Avoid using medications to achieve hemoglobin A1c <7.5% in most adults age 65 and older; moderate control is generally better.** There is no evidence that using medications to achieve tight glycemic control in 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. 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.
VA-DoD	**Table: A_{1c} target recommendations, %[6]** Major comorbidity[a] or physiologic age / Microvascular complications: Absent or mild[b] — Moderate[c] — Advanced[d] Absent, > 10 years of life expectancy: < 7 — < 8 — 8-9* Present[f], 5-10 years of life expectancy: < 8 — < 8 — 8-9* Marked[g], < 5 years of life expectancy: 8-9* — 8-9* — 8-9*
American Diabetes Association and the American Geriatrics Society	**Table 1. A Framework for Considering Treatment Goals for Glycemia, Blood Pressure, and Dyslipidemia in Older Adults with Diabetes**

Patient Characteristics/ Health Status	Rationale	Reasonable A1C Goal (A Lower Goal May Be Set for an Individual if Achievable without Recurrent or Severe Hypoglycemia or Undue Treatment Burden)	Fasting or Preprandial Glucose (mg/dL)	Bedtime Glucose (mg/dL)	Blood Pressure (mmHg)	Lipids
Healthy (Few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.5%	90–130	90–150	<140/80	Statin unless contraindicated or not tolerated
Complex/intermediate (Multiple coexisting chronic illnesses[a] or 2+ instrumental ADL impairments or mild to moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0%	90–150	100–180	<140/80	Statin unless contraindicated or not tolerated
Very complex/poor health (Long-term care or end-stage chronic illnesses[b] or moderate to severe cognitive impairment or 2+ ADL dependencies)	Limited remaining life expectancy makes benefit uncertain	<8.5%[c]	100–180	110–200	<150/90	Consider likelihood of benefit with statin (secondary prevention more so than primary)

Rates of serious hypoglycemia in seniors and high risk not known

In response to all of this, VA launched the Choosing Wisely/Hypoglycemia Safety Initiative (CW/HSI) in 2014

- National voluntary program
- Lists
  - High risk: A1c < 7 and on Insulin or Sulfonylurea who:
    - Are age 75 or greater
    - OR renal impairment (creatinine >2.0)
  - Ultra high risk: A1c <7 and on Insulin or Sulfonylurea who are on Cholinesterase Inhibitor
- Any VISN/site interesting in participating can receive a variety of support materials

Data presented come from a study funded by HSR&D QUERI

Objectives of a Sub-study

- To determine the impact of the CW/HSI on overtreatment rates
- To determine if there was an unintended consequence of increase in undertreatment rates.

If you want to read the grant itself and the critiques see:
Aron et al. Implementation Science 2014, 9:58

Methods 1

- Design/Setting
  - pre-test/post-test, using cross-sectional Veterans Health Administration (VHA) administrative data from calendar years (CYs) 2013 and 2016
- Participants
  - study population consisted of diabetic patients at risk for hypoglycemia in the medical facilities in the VHA healthcare System:
  - taking 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 greater than 2.0mg/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.
    - n=171,875 and 166,703 in 2013 and 2016, respectively

Outcome Measures

- primary outcome measure was rate of overtreatment of diabetes defined at the proportion of patients in the group at high risk for hypoglycemia with A1c<7.0%.
  - Consistent with recommendation of the American Geriatrics Association for the Choosing Wisely Initiative
- Secondary outcome measures: rates of A1c<6% and to assess undertreatment we determined the proportion of patients with an A1C>9%, a standard measure of (inadequate) quality.

This study was approved by VA–Louis Stokes Cleveland VA Medical Center and New Jersey Health Care System Institutional Review Boards.

Results: Facility Rates of Over and Under Rx

measure	2013		2016	
	mean±1SD	range	mean±1SD	range
A1c<7%	40.30 (±5.25)%	26.42 - 58.2%	37.75 (±4.70)%	26.26 - 49.15%
A1c<6%	9.15 (±2.94)%	3.70 - 15.75%	8.37 (±2.34)%	3.70 - 15.75%
A1c>9%	10.32 ±2.21)%	5.76 - 16.86%	11.04 (±2.38)%	6.80 - 18.68%

All differences p<0.001 (paired t tests)

Correlations between Rates of Overtreatment and Undertreatment

	A1c<7 rate 2013	A1c<7 rate 2016	A1c>9 rate 2013	A1c>9 rate 2016
A1c<7 rate 2013	1	0.461†	-0.653†	-0.072
A1c<7 rate 2016		1	-0.185††	-0.435†
A1c>9 rate 2013			1	0.538†
A1c>9 rate 2016				1

† p<0.001 †† p<0.05

Absolute Year to Year Changes in Overtreatment and Undertreatment Rates were Inversely Correlated

	A1c<7% change from 2013-2016	A1c<6% change from 2013-2016	A1c>9% change from 2013-2016
A1c<7% change from 2013-2016	1	0.753†	-0.653†
A1c<6% change from 2013-2016		1	-0.405†
A1c>9% change from 2013-2016			1

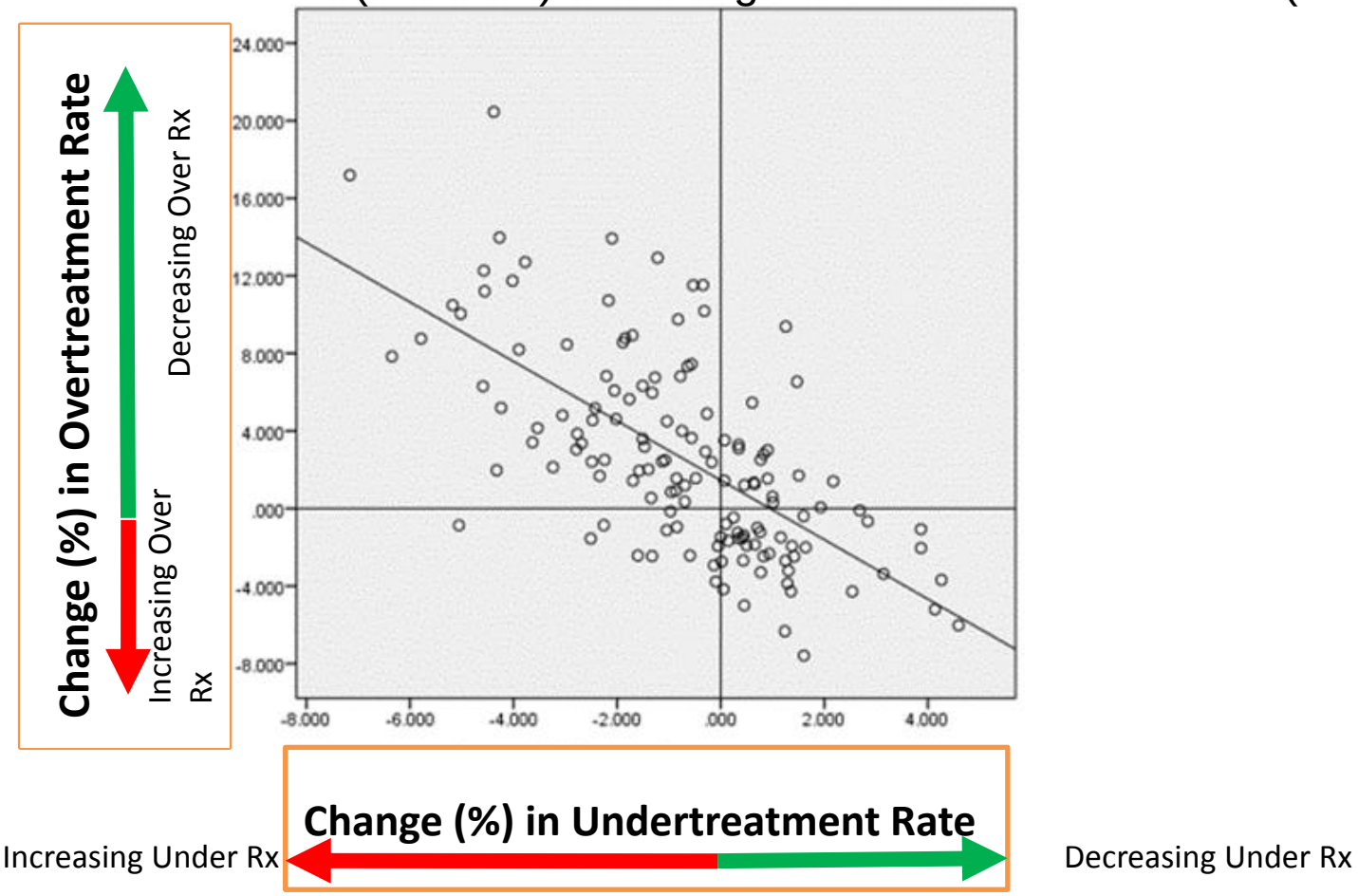
† p<0.001

Relative Year to Year Changes in Overtreatment and Undertreatment Rates were Inversely Correlated

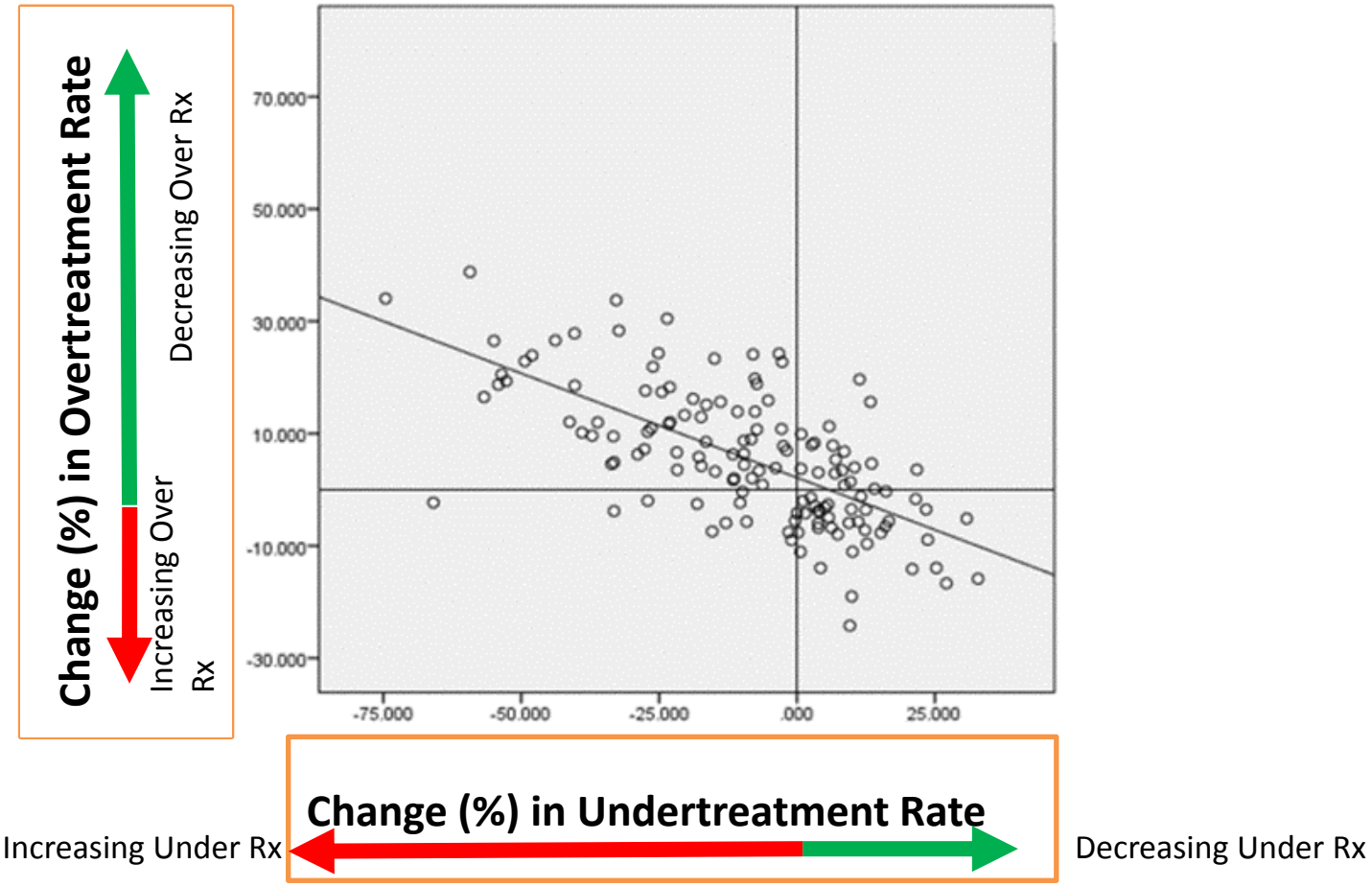
	A1c<7% %change from 2013-2016	A1c<6% %change from 2013-2016	A1c>9% %change from 2013-2016
A1c<7% %change from 2013-2016	1	0.707†	-0.666†
A1c<6% %change from 2013-2016		1	-0.342†
A1c>9% %change from 2013-2016			1

† $p<0.001$

Change in Overtreatment Rate (A1c<7%) vs Change in Undertreatment Rate (A1c>9%)

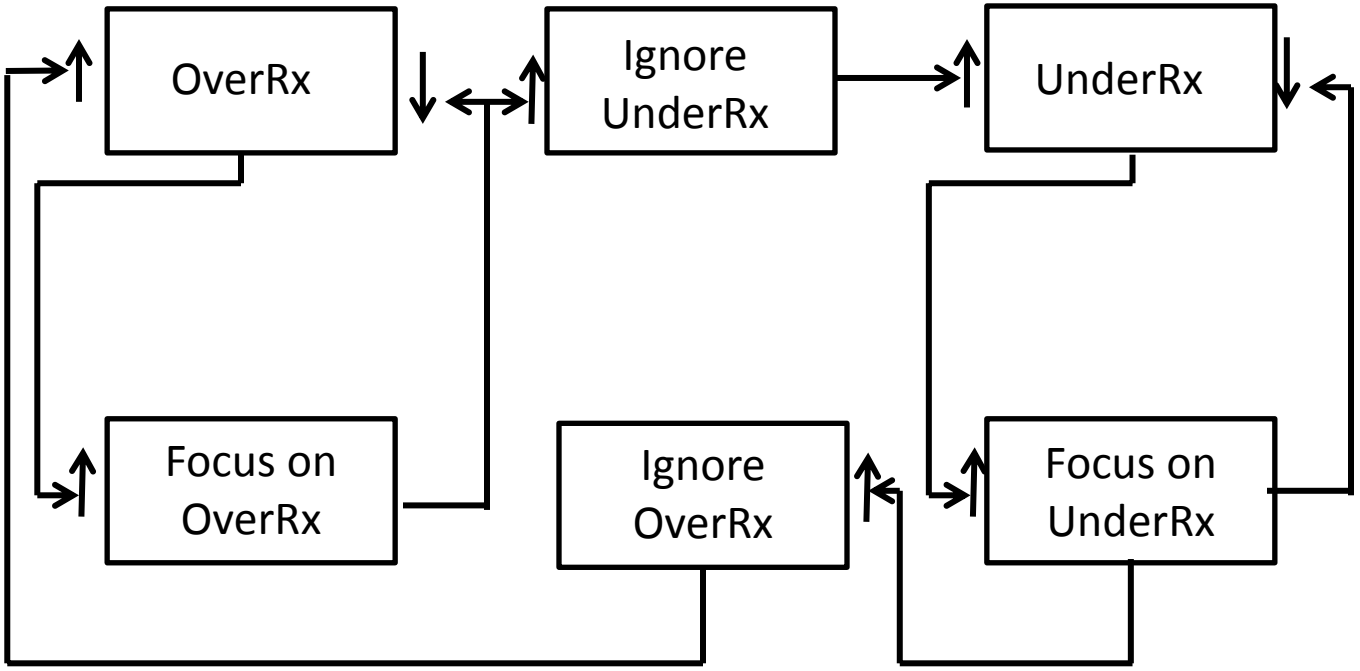


Relative Change in Overtreatment Rate (A1c<7%) vs Undertreatment Rate (A1c>9%)



Conclusions

- Promotion of overtreatment reduction may be associated with an increase in undertreatment in patients with diabetes.
- Systems should include balancing measures to identify potential unintended harms.

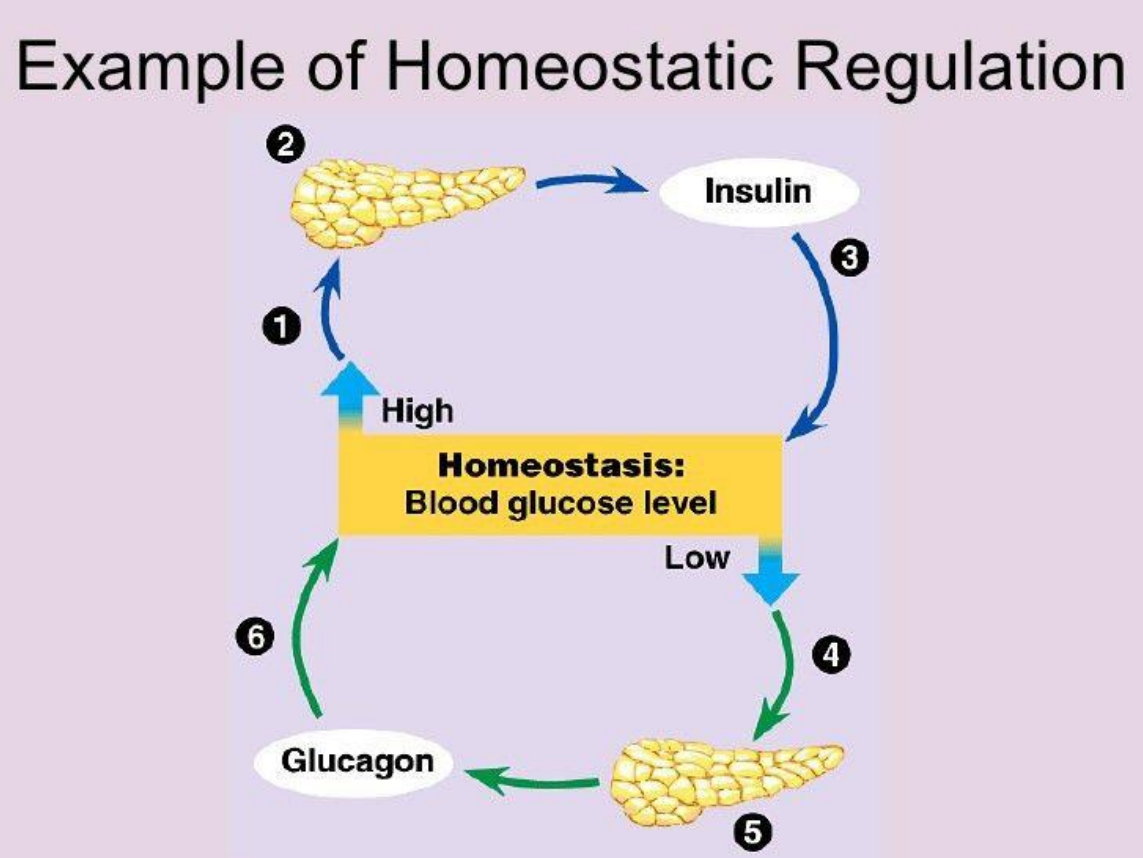


Limitations

- single health care system, albeit a large one.
- 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.
- magnitude of the changes is modest and the statistical significance may exceed clinical significance.

The idea of balanced feedback is a common feature of homeostatic mechanisms

- Homeostasis: the tendency toward a relatively stable equilibrium between interdependent elements, especially as maintained by physiological processes.
- Glucose levels are maintained in a “range”



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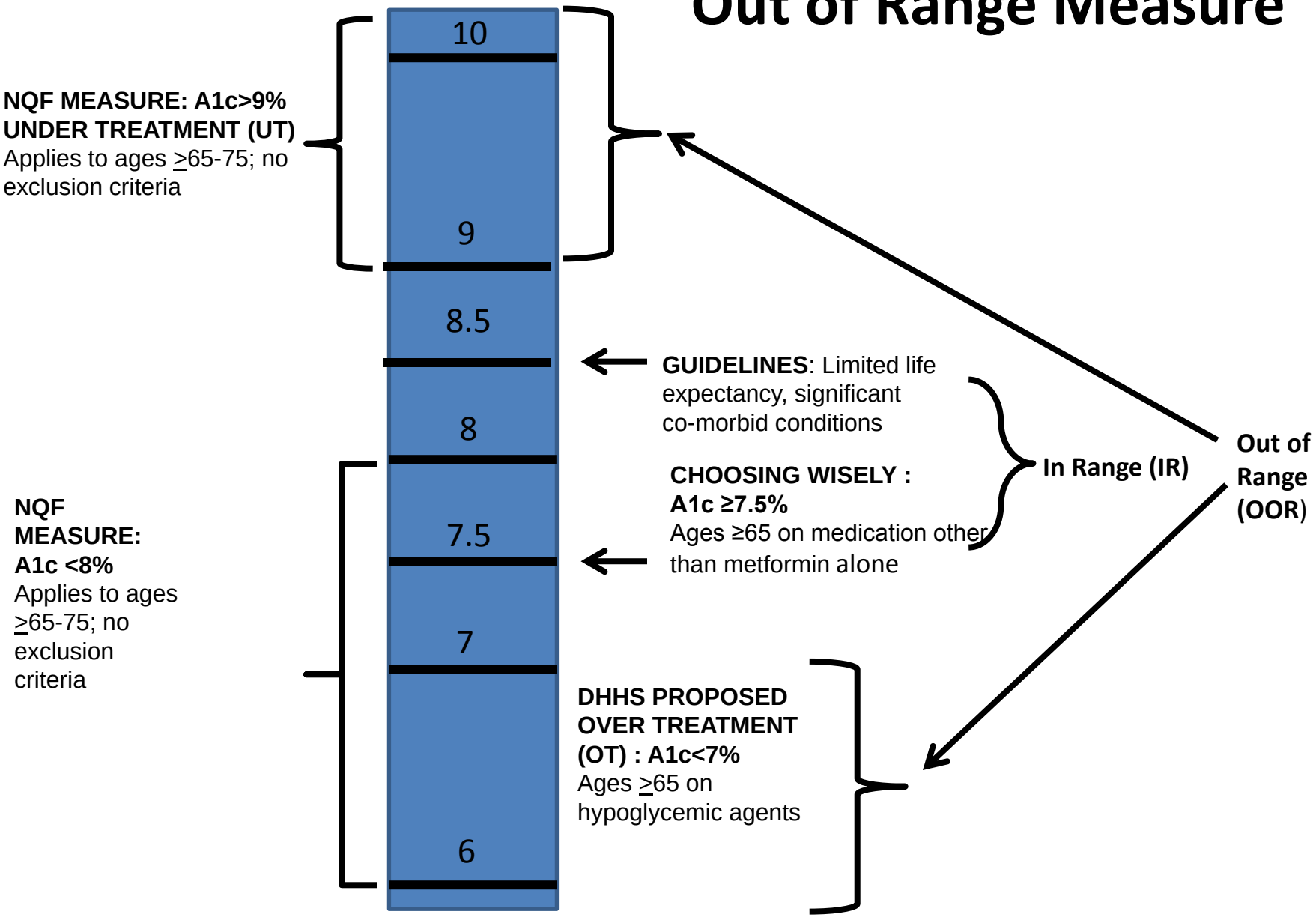
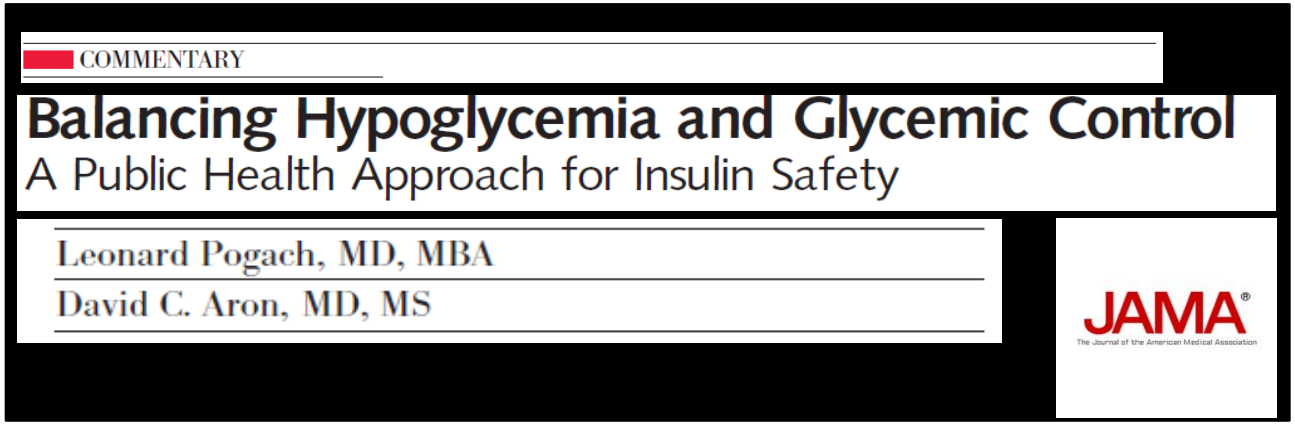
Out of Range Measure



Pogach L, Tseng CL, Soroka O, Maney M, Aron D. A Proposal for an Out-of-Range Glycemic Population Health Safety Measure for Older Adults With Diabetes. Diabetes Care. 2017 Apr;40(4):518-525.

It has been a long quest for Len and me.


COMMENTARY

Balancing Hypoglycemia and Glycemic Control

A Public Health Approach for Insulin Safety

Leonard Pogach, MD, MBA

David C. Aron, MD, MS

JAMA

The Journal of the American Medical Association

- Pogach L, Aron D. Balancing hypoglycemia and glycemic control: a public health approach for insulin safety. JAMA. 2010 May 26;303(20):2076-7
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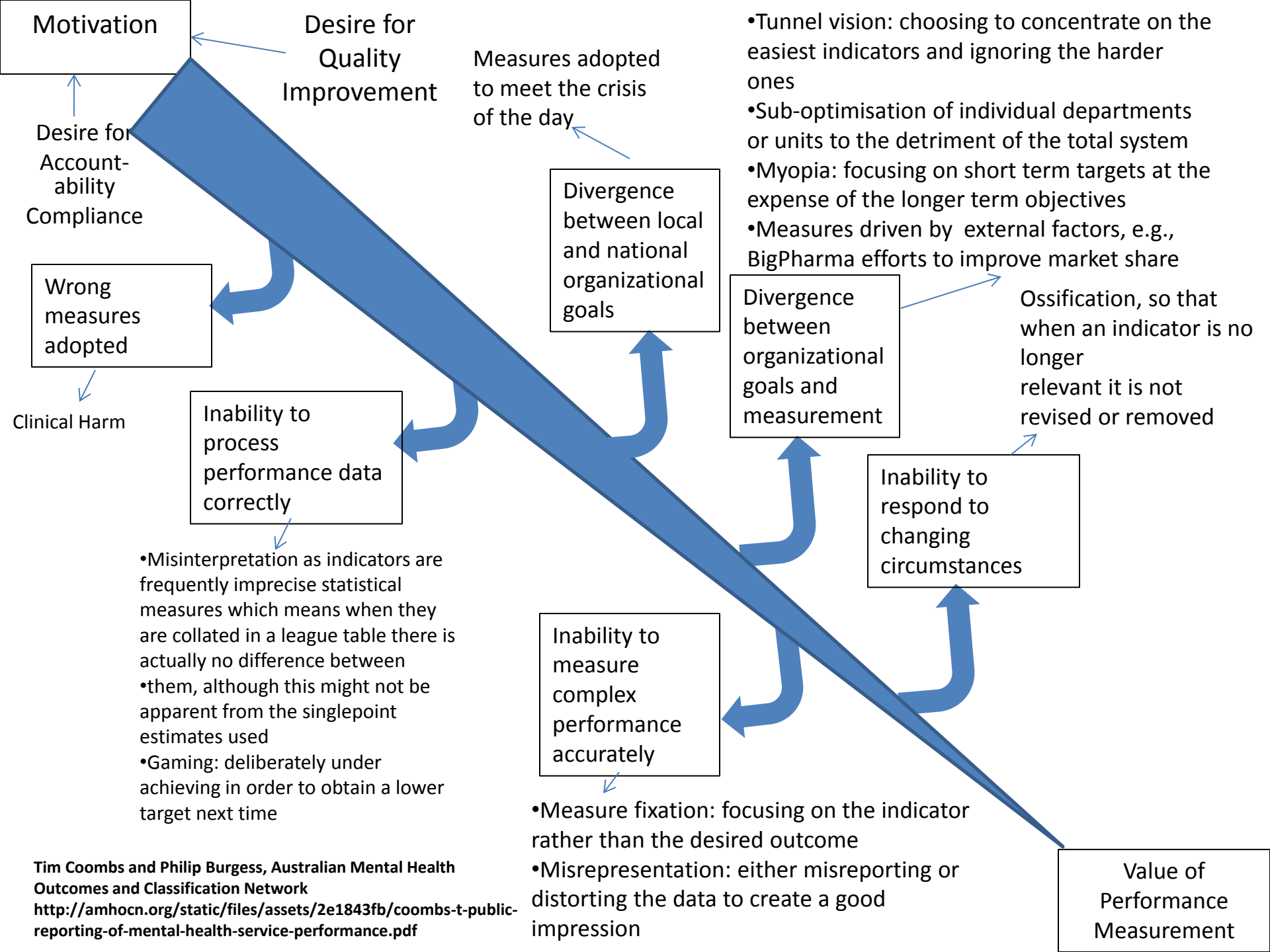
- Pogach L, Tseng CL, Soroka O, Maney M, Aron D. A Proposal for an Out-of-Range Glycemic Population Health Safety Measure for Older Adults With Diabetes. Diabetes Care. 2017 Apr;40(4):518-525.

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 such as counterbalancing measures to ensure that unintended harms are avoided.

Aron DC. No "Black swan": unintended but not unanticipated consequences of diabetes performance measurement. Jt. Comm J Qual. Patient. Saf. 2013;39(3):106-8.



Tim Coombs and Philip Burgess, Australian Mental Health Outcomes and Classification Network
http://amhocn.org/static/files/assets/2e1843fb/coombs-t-public-reporting-of-mental-health-service-performance.pdf

“It is easy to dodge our responsibilities, but we cannot dodge the consequences of dodging our responsibilities.”

Josiah Stamp

Thank you.

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