



# The Patient Aligned Care Team and the 2010 VA/DOD Diabetes Practice Guidelines

**Len Pogach MD, MBA , FACP**

**National Director Endocrinology and Diabetes**

**Acting National Director, Medical Service**

**on behalf of the VHA-DOD Diabetes Working Group**

**11<sup>th</sup> Annual Advances in Indian Health**

**May 4, 2011**

# Disclaimer

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

# The Chronic Care Model



# Evidence as the Basis for Clinical Policy and Guidelines



# Objectives

- Provide a broader understanding about the process of evidence development in general and for the VHA-DOD Guideline
- Key points of the 2010 VHA Diabetes Guidelines
  - Glycemic Target Setting (Individualized using Absolute Risk Reduction approach)
  - A1c Laboratory Result Interpretation
  - Diagnosis of pre-diabetes and diabetes
- Implementation in the VHA Patient Aligned Care Team (PACT)
  - Shared Decision Making
  - Provider Tools

# Why is Evidence Critical for Diabetes Management? Different Needs

- ~26 million persons with DM; ~11 Million Seniors
- Different populations:
  - 95% type 2, 5% type 1
  - Gestational DM
  - DM in pediatric populations
  - Younger, healthier adults
  - Healthier seniors
  - Major Co-morbid conditions—other medical conditions, mental health conditions, diabetes related complications: advanced, end stage

# Veteran Population with Diabetes

- About one in four veterans (~1.4 million)
- High Illness Burden
- SF36v Low Physical Component Score 36.9
  - CVD 32.4%
  - HBP 66%
  - CKD 30%;
- Low Mental Component Score /45.1
  - Mental Health Disorders 25%-40%
- Even half of veterans less than 65 years of age have decreased life expectancy or major comorbidities
- In 1999,
  - One in seven veterans reported food insufficiency
  - 31% did not complete high school

# Key Concepts in Evidence Based Medicine

- Strength of Evidence
  - Randomized clinical trials (including evaluation of quality)
  - Observational Studies (including pooled data and epidemiological studies)
  - Meta-analyses
  - Expert Opinion
- Strength of Recommendation
  - Balancing benefits (absolute risk reduction) with risk of harms
  - Generalizability



# Clinical Randomized Trials

- Considered gold standard
- Factors to consider: design (randomized, masked; intention treat); population; primary vs secondary endpoints, primary analysis, secondary analysis, post-hoc analysis
- Strengths: Discern effects of experimental intervention versus control
- Weaknesses: homogeneous population; extrapolation from study population to clinical practice

# Epidemiological Research

- Population studies; case cohort studies
- Strengths: Large and diverse populations, long time frames; multiple factors
- Weaknesses: selection biases; failure to identify unspecified covariates; proves significant association, not causality

# How does VA/DOD develop guidelines?

- **Strict approach to conflicts of interest**
- **Multidisciplinary teams**
- Identification of key questions
- Evidence review for key questions
- Groups review evidence, apply grading
- Development of text, treatment algorithms
- Review from trained subject matter experts
- **Transparency of strength of evidence**
- Revisions based on review
- Final CPG reviewed by VA/DoD council

# Attributes of VA-DOD Guidelines

- **Evidence based:** **Transparent** about the strength of evidence and the strength of recommendation
- **Use of numeracy** : Emphasizes **absolute risk reduction**, number needed to treat rather than relative risk reduction
- **Risk stratification:** Classification of patients into **low, medium and high risk categories** for each module for case management and treatment strategies
- **Flexibility:** Provider makes recommendations based evidence & clinical judgment and then **incorporates preferences of patient using shared decision making** to arrive at patient's target goal

# Comparison of Diabetes Guidelines

- Qaseem, Annals Int Med 2007;147:417-22.

**Table 3—Continued**

AGREE Domain	Guidelines								
	AACE	AAFP	ADA	ACS	CDA	ICSI	NICE	SIGN	VHA
Total score	50.5	71	58	70	71.5	64.5	77	74	73

\* 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.

- Process of development of VHA DOD Guidelines (2003) was rated significantly higher than specialty professional societies using GRADE
- VHA-DOD Guidelines promote understanding the evidence, and treating veterans based upon absolute benefit and risk, rather than relative risk reduction

# Use of Evidence for VHA Policy Decisions

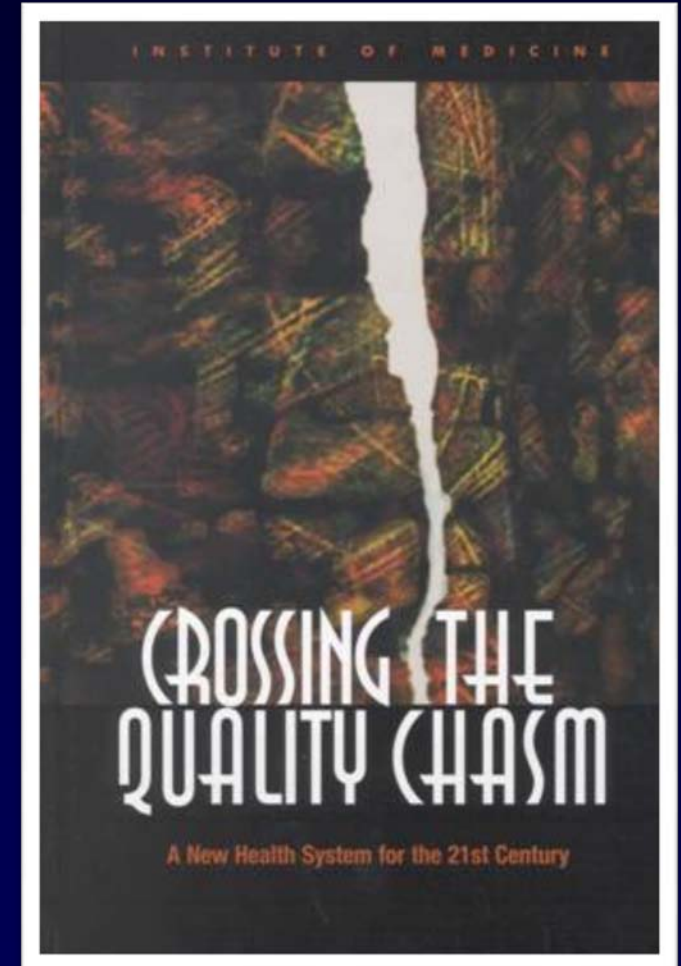
- Life expectancy, co-morbid condition approach risk stratified management using shared decision first proposed 1997, updated 2000, 2003, 2010.
- Every other year eye examinations for low risk patients incorporated into DQIP-HEDIS (1998)
- VHA did not implement NCQA <7% A1c and <130 mmHg measures for accountability (2007)
- “Tight” glucose control in ICUs not mandated (ESP 2007)
- SMBG recommendations reaffirmed (ESP 2006)
- PBM Criteria for Use antedated “ADA Consensus Recommendations”
- Rosiglitazone removed from formulary (2007 PBM Safety Study)

# Population-based Healthcare is a critical part of PACT

- Encompasses the ability to:
  - Identify & assess high risk states within the target population
    - Health/clinical
    - Behavioral
    - Socio-demographic
    - Genomic
    - Preference
  - Implement and evaluate interventions that are designed to improve the health of that population that are
  - Consistent with the community's cultural, policy and health resource values

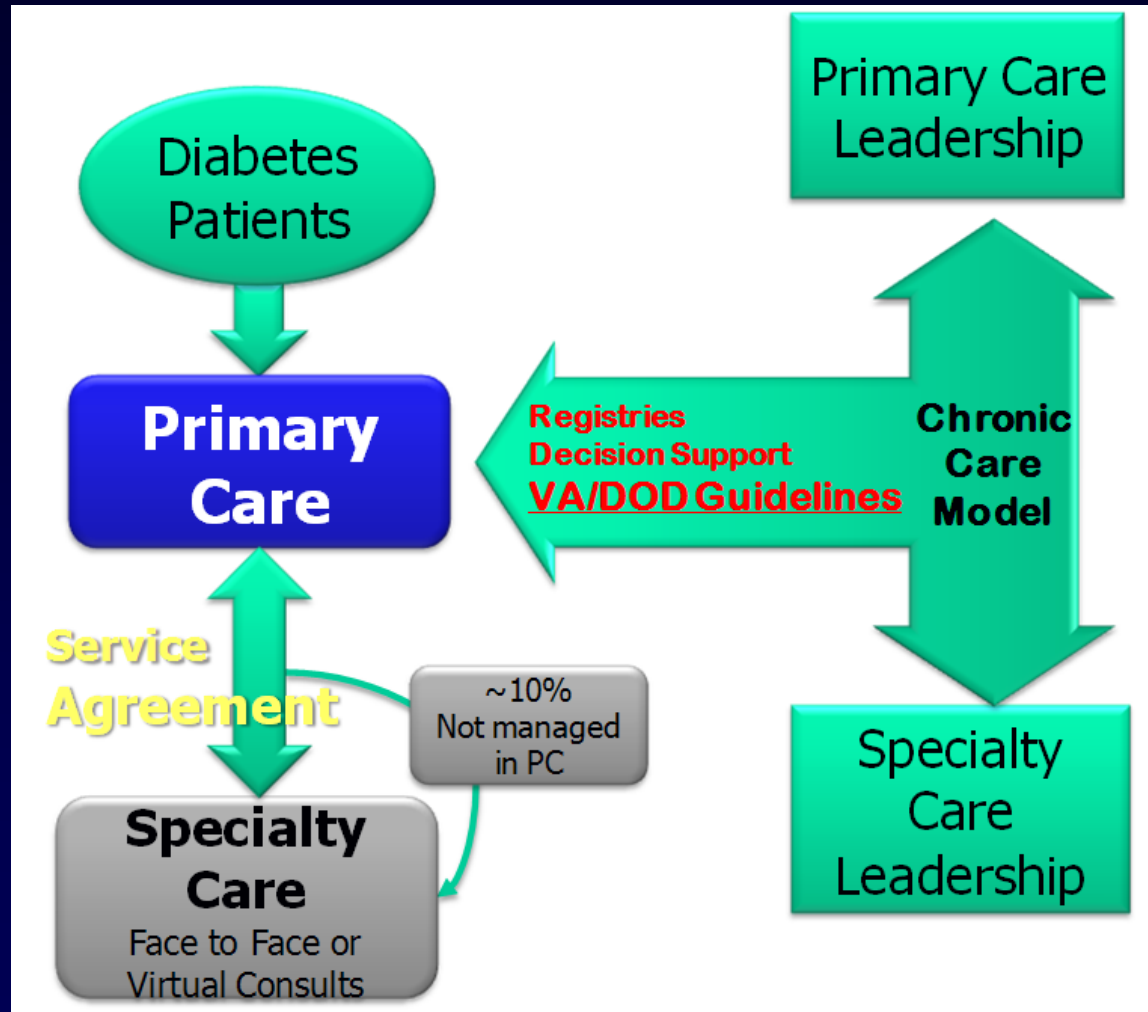
# (Non-)Integration of Research and Clinical Practice

- Long lag time between development of scientific knowledge and introduction into practice
  - Antmann et al. Comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. JAMA 1992;268:240-8.
- There is also a long time between introduction and broad implementation.





# Where does the evidence fit in and how can it get there?



Gordon Schechtman, MD  
Acting Chief Consultant, Primary Care, PCS

# What do the 2010 VA-DOD Diabetes Guidelines say about...

- **Diagnosis of Pre-Diabetes and Diabetes**
- **Self Monitoring of Blood Glucose**
- **A1c targets**
- **Estimated Average Blood Glucose**

# Diagnosis of Pre-Diabetes and Diabetes

# Diagnosis of Pre-Diabetes

A diagnosis of pre-diabetes is made with either of the following:

- Fasting plasma glucose (FPG)  $<126$  mg/dL but  $\geq 100$ mg/dL on two occasions.
- A1c readings with result  $\geq 5.7\%$  but  $<6.5\%$  and confirmed with a FPG  $\geq 100$  mg/dL and  $<126$  mg/dl.
  - *The FPG can be obtained at the same time as the A1c*

# Diagnosis of Diabetes

A diagnosis of DM is made with any of the following:

- $A1c \geq 7\%$  on two occasions using a clinical laboratory methodology standardized to the NSGP (not Point of Care testing
- $A1c \geq 6.5\%$ , confirmed with a FPG  $\geq 126$  mg/dL. These tests can be done on the same or different days; or
- FPG  $\geq 126$  mg/dL on at least two occasions
- Random blood glucose not recommended for screening

# Self Monitoring of Blood Glucose

# Self Monitoring of Blood Glucose

- SMBG is indicated for patients taking insulin
- No evidence for routine SMBG in patients not on insulin
- Patients must be instructed on procedures, importance of recording, and how to interpret results
- SMBG can be used to adjust treatment
- Frequency of testing based on type of treatment, hypoglycemia, goals of treatment
- SMBG is not recommended for pre-diabetes

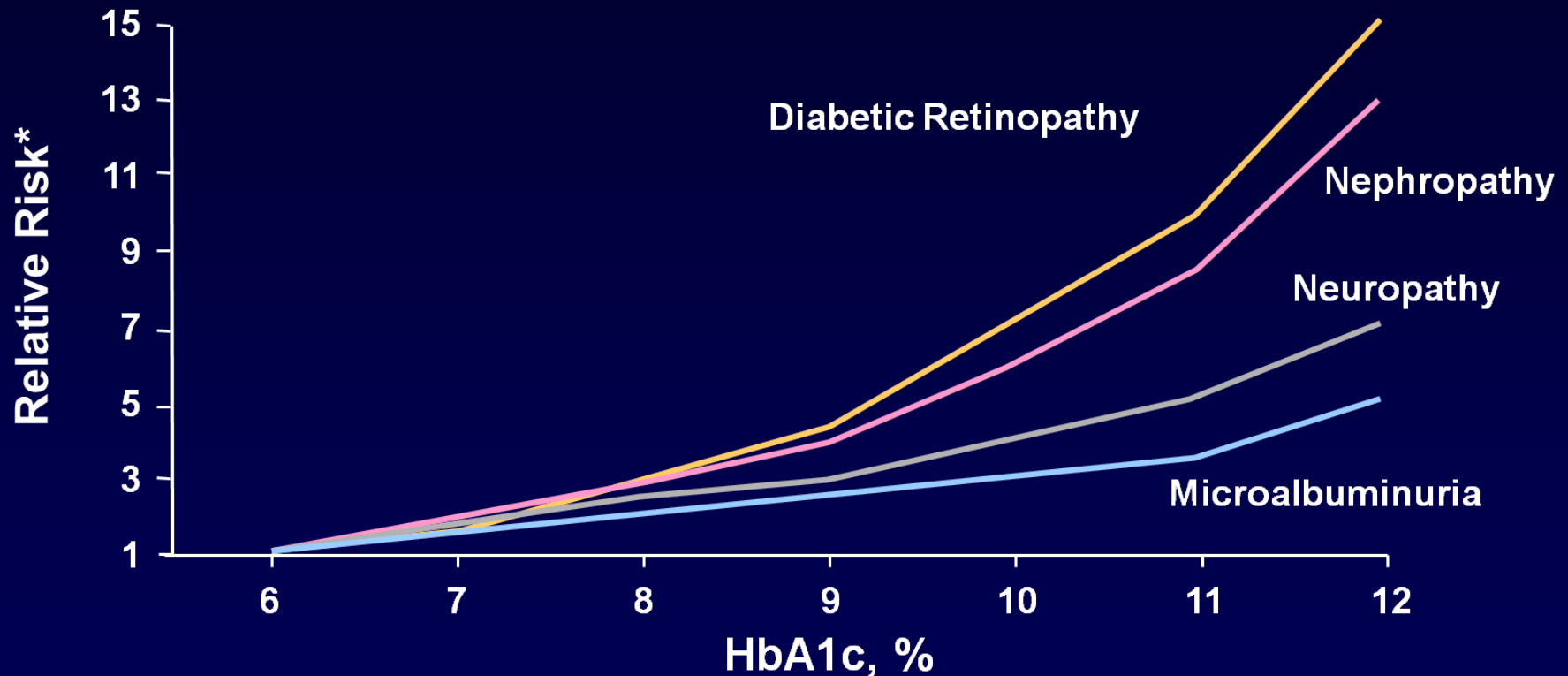
# A1c Targets and Shared Decision-Making



# A1c Targets: Risk Stratification

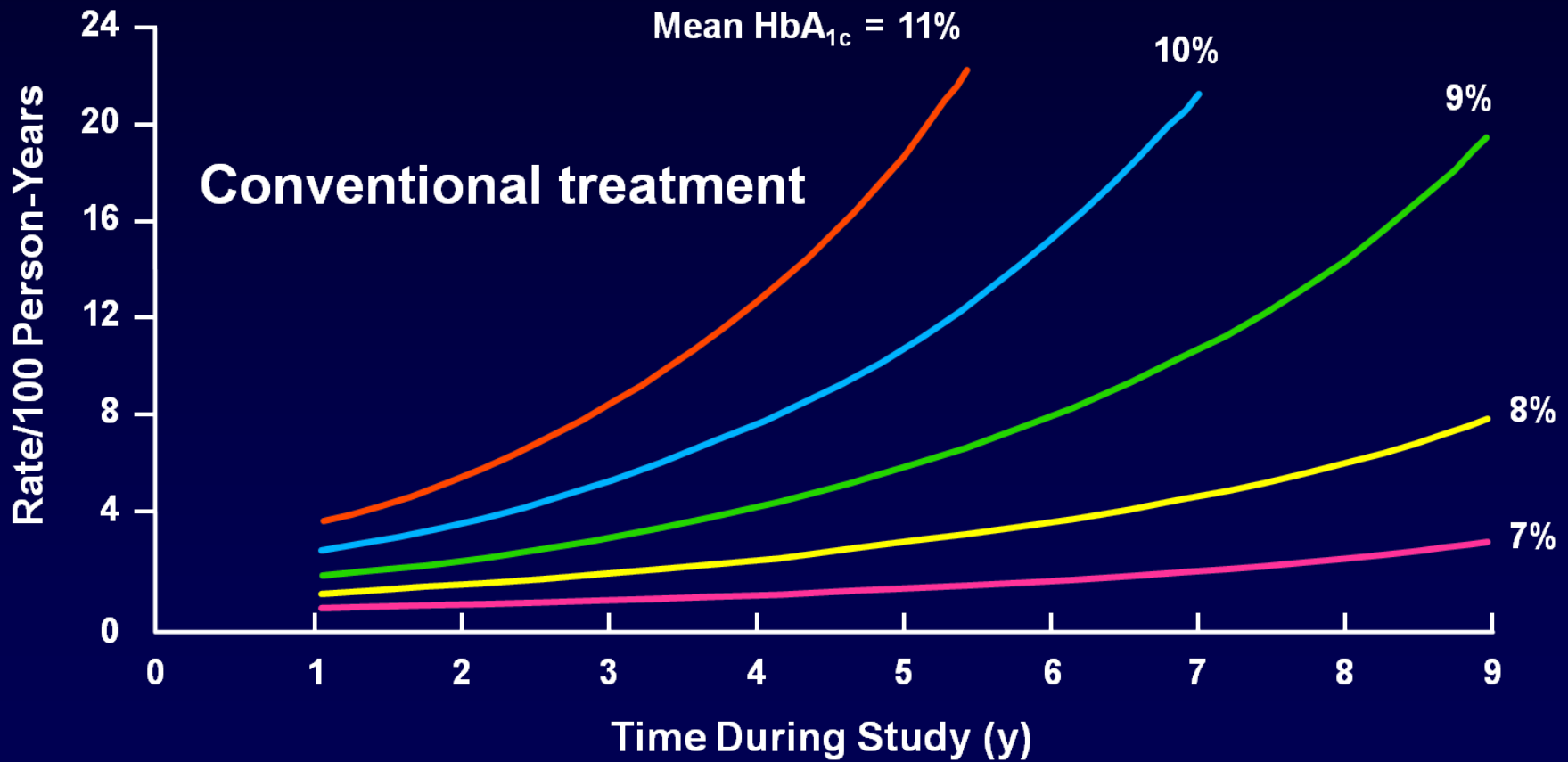
- A1c target <7%, if achievable without risk
  - Mild or no microvascular complications, no major concurrent illnesses and with reasonable life expectancy (>10-15 years)
- A1c target < 8%
  - Longer duration diabetes (>10 years) or with co-morbidities and requiring combination medication regimens including insulin
- A1c target 8-9%
  - Patients with advanced microvascular complications and/or major comorbidities or life expectancy <5 years are unlikely to benefit from aggressive glucose lowering

# Risk of Progression of Complications by A1c



\*Relative risk set to 1 for HbA1c of 6%.

# Risk of Retinopathy Progression by HbA<sub>1c</sub> and Years of Follow-up



# Benefits of Glycemic Risk Reduction (7.9% to 7.0%) over 10 yrs from the UKPDS (Budenholzer et al, BMJ 1245, 2001)

Outcome	OR (95%CI)	P	NNT Per PY	ARR/ 1000 PY	Rate per 1000 PY - Intensive Control	
Any DM Endpoint	0.88 (.79-.99)	<b>0.02</b>	196 (153-272)	<b>5.1</b>	<b>40.9</b>	<b>46</b>
MI	0.84 (.71-1.00)	0.052	370 (279-551)	2.7	14.7	17.4
Stroke	-----	----	---	----	5.6	5.0
Microvasc	0.75 (.6-.93)	0.01	357 (285-478)	<b>2.8</b>	<b>8.6</b>	<b>11.4</b>
Laser Treatment	0.71 (.58-.98)	0.003	323	<b>3.1</b>	<b>7.9</b>	<b>11.0</b>
Diabetes Mortality	0.90	<b>NS</b>	-----	--	10.4	11.5

# Glucose Control and CVD Outcomes

Study Acronym	Participants	Follow-up (years)	Intensive A1c Target	Standard A1c Target	Results
ACCORD	10,251	4	<6.0% Achieved 6.4%	7.0%-7.9% Achieved 7.5%	Higher mortality in intensive group
ADVANCE	11,140	4.5	≤6.5% Achieved 6.4%	Usual care Achieved 7.0%	No difference
VADT	1700	5-7	≤6.0% Achieved 6.9%	8%-9% Achieved 8.4%	Difference not significant

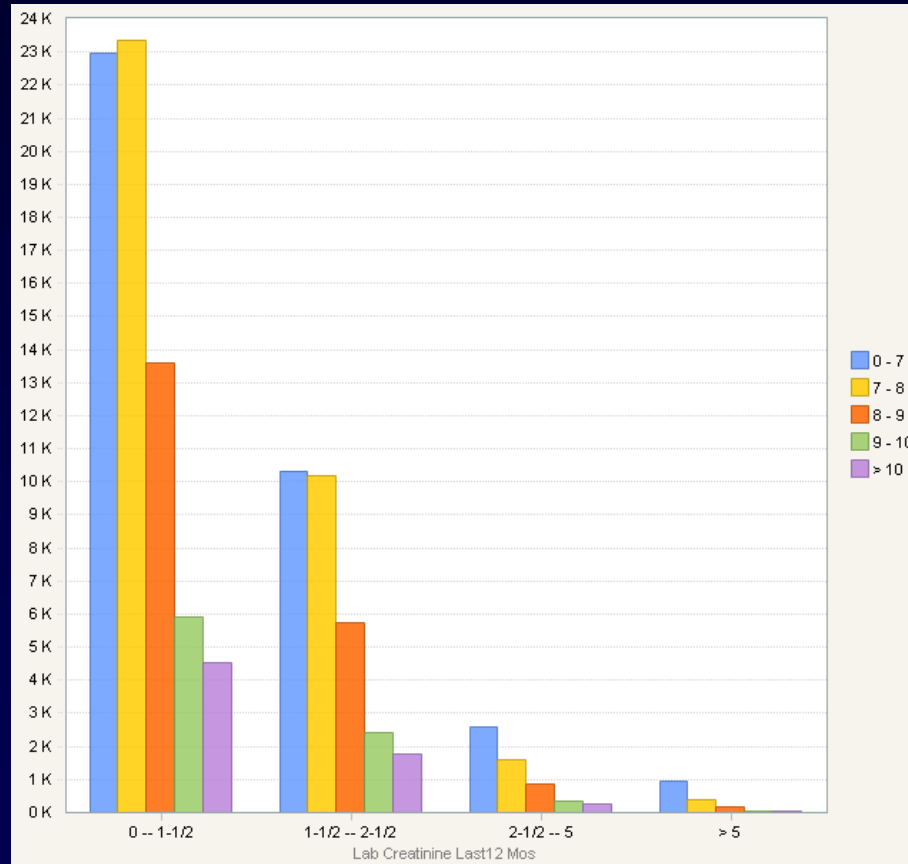
# Outpatient RCT Diabetes Trials

<b>Outcome</b>	<b>United Kingdom Prospective Diabetes Study</b>	<b>Accord</b>	<b>Advance</b>	<b>VADT</b>
<b>Duration of study</b>	<b>11 years</b>	<b>3.5 years</b>	<b>5 years</b>	<b>5.6 years</b>
<b>HbA1c achieved</b>				
<b>Intensive Rx</b>	<b>7.0%</b>	<b>6.4%</b>	<b>6.4%</b>	<b>6.9%</b>
<b>Standard Rx</b>	<b>7.9%</b>	<b>7.5%</b>	<b>7.0%</b>	<b>8.5%</b>
<b>Severe hypoglycemia †</b>				
<b>Intensive Rx</b>	<b>0.71*</b>	<b>4.6*</b>	<b>0.56*</b>	<b>12.0*</b>
<b>Standard Rx</b>	<b>0.20</b>	<b>1.5</b>	<b>0.30</b>	<b>4.0</b>
<b>All-cause Mortality</b>				
<b>Intensive</b>	<b>0.13</b>	<b>1.41*</b>	<b>1.86</b>	<b>2.22</b>
<b>Standard</b>	<b>0.25</b>	<b>1.14</b>	<b>1.99</b>	<b>2.06</b>
<b>Cardiovascular Mortality</b>				
<b>Intensive</b>	<b>0.53</b>	<b>0.79*</b>	<b>0.95</b>	<b>0.83</b>
<b>Standard</b>	<b>0.52</b>	<b>0.56</b>	<b>1.08</b>	<sup>30</sup> <b>0.63</b>

# Hypoglycemia Among Veterans: Observational Data (Miller et al, QUERI 2010)

- From 2000-2004, ICD-9 codes for hypoglycemia is common in diabetes patients. 10% with an event each year (VA and CMS data)
- The strongest predictors are indicators of labile or brittle diabetes: prior hypoglycemia, keto-acidosis, hyperosmolar coma, and high HbA1C; insulin or secretagogue use.
- Strongly associated with recent insulin initiation or recent hospital stay, particularly for infection.
- Related to disability, poverty, being without a spouse or partner

# A1C & Cr, On Insulin, Age >65





# Should Clinicians be Made Aware of Variability in A1c Measurement?

- Not a new concept
- Discussed at NGSP meetings since 2006
- NGSP minutes note comments by some NGSP members that doctors likely think that the test results are “accurate” because they are “standardized”
- Concerns by some NGSP members that the broad range of accuracy and precision among methods is not acceptable

# Sources of Error – A1c testing

## *Assay Methodology*

- Technician
  - Within-observer
  - Between-observers
- Instrument
  - Within-instrument
  - Between-instruments
  - Between laboratories
  - Artifact

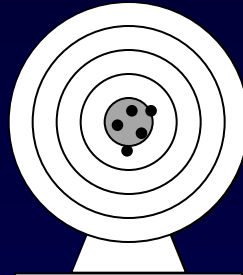
# ACCURACY AND PRECISION

## TARGET MOTIF

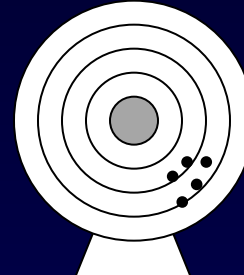
ONE WAY TO LOOK AT ACCURACY AND PRECISION IS TO VISUALIZE WHAT THEY MEAN. FOR EXAMPLE:

### RELIABLE

Most of the measurements lie close to each other and their mean value lies close to the Bull's Eye – reference value. This provides a reliable result without having to make adjustments.



High Precision



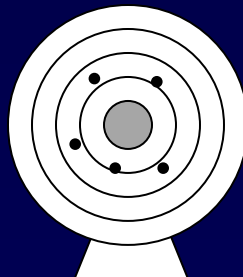
High Precision

### INACCURATE

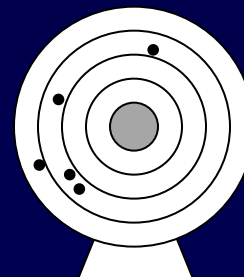
close to each other but their mean value lies far from the Bull's Eye – reference value. Recalibrating to the reference standard provides more accuracy.

### INPRECISE

Most of the measurements lie far from each other but their mean value lies close to the Bull's Eye – reference value. Making more measurements will increase precision but is not feasible in patient



Low Precision



Low Precision

### UNRELIABLE

Most of the measurements lie far from each other and their mean value lies far from the Bull's Eye – reference value. There is no easy way to obtain a reliable result from this system.

# Sources of Error – A1c testing

## March 11, 2011 DMICC Meeting

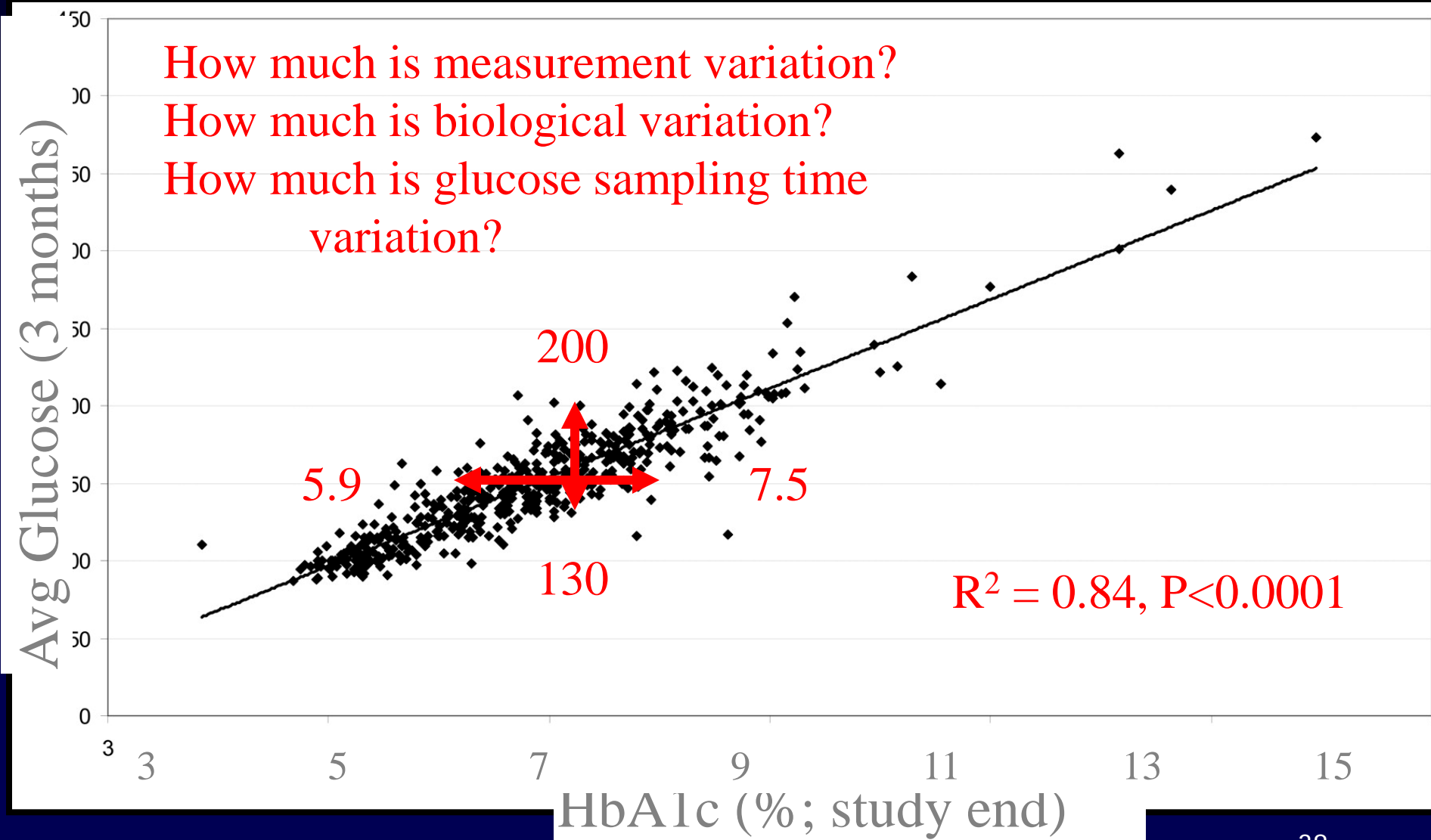
- The critical difference (CD) is the change in a patient's serial test results that can be considered significantly different (e.g. at a probability of 95%).
- 0.5% is a difference that many physicians use as a significant difference in their patients' HbA1c results.
- In order for a 0.5% HbA1c change to be considered significant the assay CV must be  $<3\%$ , ideally  $<2\%$ . Many, but not all, individual assay methods can meet this criterion.
- **Point of Care test performance is unknown and should not be used for treatment decisions**

# Table 1: Estimated Average Glucose

HbA1c (%)	mg/dL	(95% Prediction Interval)
5	97	(76, 120)
6	126	(100, 152)
7	154	(123, 185)
8	183	(147, 217)
9	212	(170, 249)
10	240	(193, 282)
11	269	(217, 314)

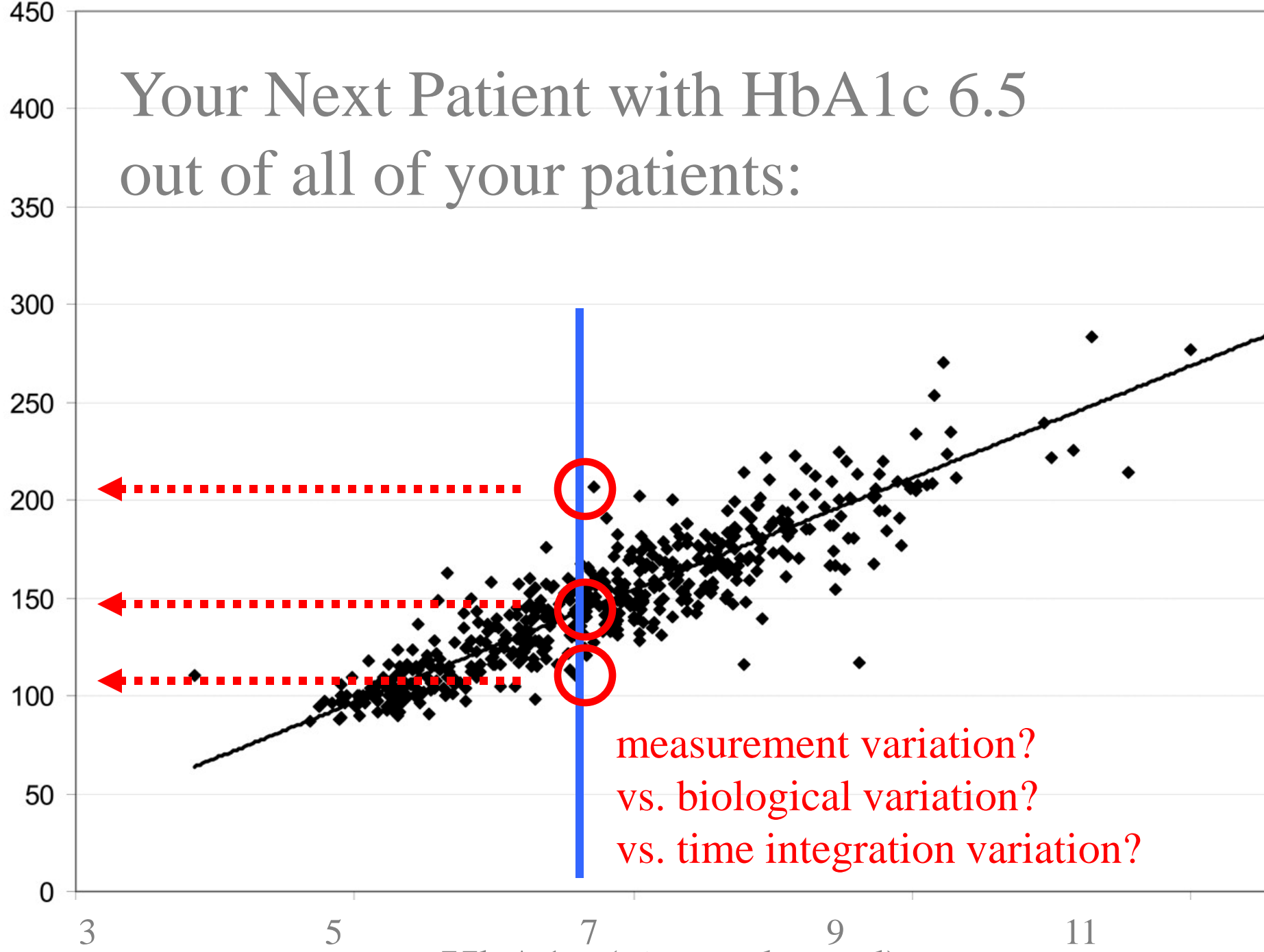
# The A1c-Derived Average Glucose Study

## HbA1c (study end) vs AG (over 3 months)



Your Next Patient with HbA1c 6.5  
out of all of your patients:

Avg Glucose (3 months)



measurement variation?  
vs. biological variation?  
vs. time integration variation?

# Patient Safety Concerns

- Generalization to individuals with multiple complex conditions who would have been excluded from studies
- Multiple medications in persons with co-existing illness
- No monitoring system for hypoglycemia
- A1c of 7 can represent range of 6.5 to 7.5% in practice in commercial laboratories:
  - Is an all or none threshold be used to intensify therapy, especially for insulin?
  - Should we disregard SMBG results?





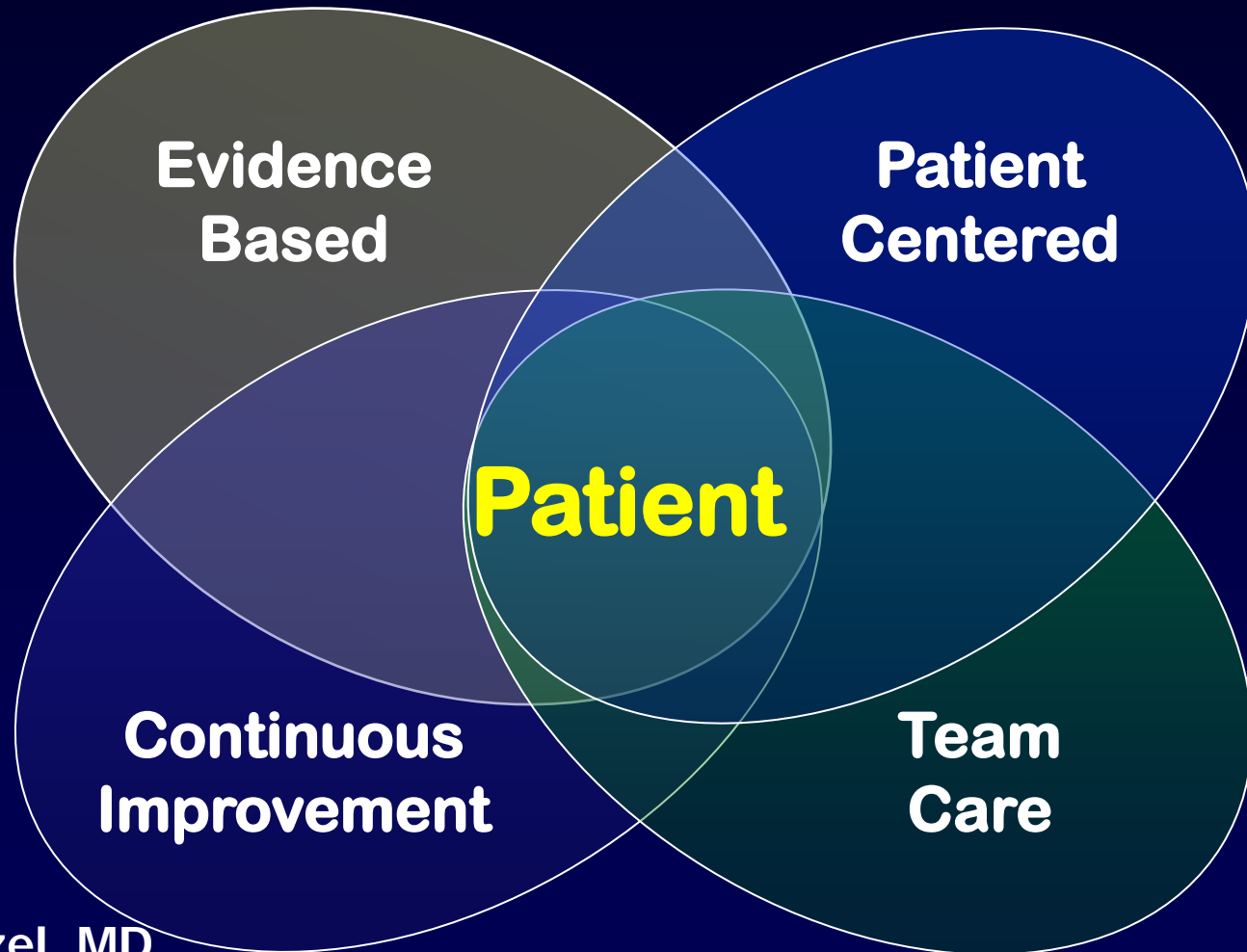
**The cracks can be fixed--it's your cholesterol level that worries me.**

# Returning to the Veteran

## Patient – Centered Care:

- Explores patients' reason for visit, concerns, and need for information
- Seeks an integrated understanding of the patients' world – life issues, emotional needs
- Finds common ground on the problem(s) and mutually agrees on management
- Enhances prevention and health promotion
- Enhances the continuing relationship with the doctor

# Patient Aligned Care Team

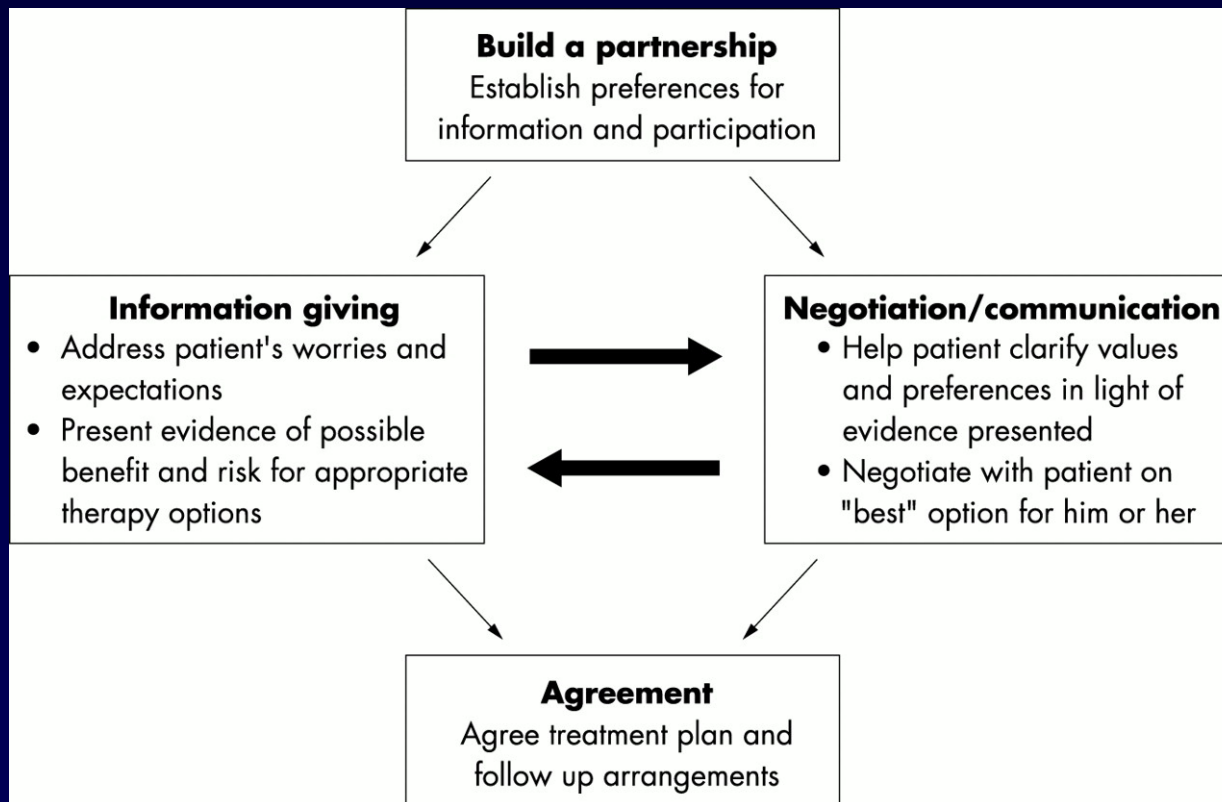


- Robert Petzel, MD  
VHA USH
- March 25, 2010

# Glycemic Management is a perfect example to illustrate these issues.

- Patient centered –

- Shared decision making is an important aspect of care because nothing is simple anymore – tradeoffs between risks and benefits, other conditions, ...



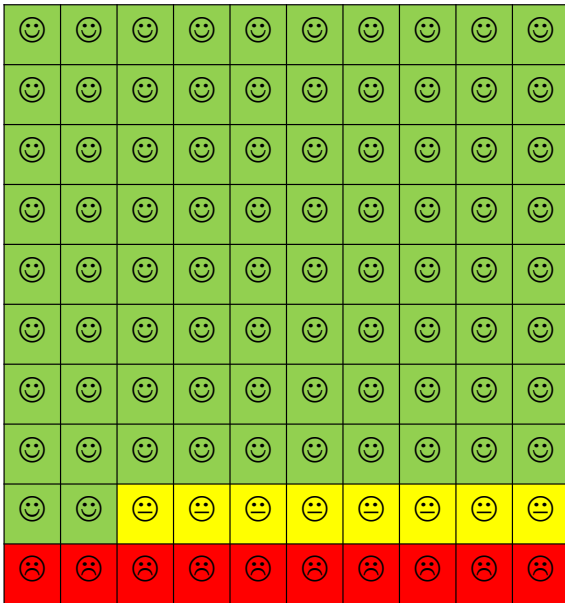
J L Jordan,  
S J Ellis,  
R Chambers  
**Defining shared  
decision making  
and concordance:  
are they one and the  
same? *Postgrad  
Med J* 2002;78:383-  
384**

# Productive Interactions & Shared Decision Making

- Involves presentation—in an understandable manner—the benefits and risks of the intervention individualized for the veteran and family.
- Requires that the veteran has skills of literacy and numeracy to understand the issues and ask appropriate questions
- Requires that the clinician has communication skills and takes into account cultural issues
- Final decision incorporates patient preferences
- **Target ranges may better incorporate laboratory variability and the continuous nature of risk factor reduction**

# Stratified A1c Targets

MAJOR COMORBIDITY	MICROVASCULAR COMPLICATION		
Cardiovascular disease, severe chronic kidney disease, severe chronic obstructive lung disease, severe chronic liver disease, recent stroke, and life-threatening malignancy	<b>ABSENT OR MILD</b> early background retinopathy, $\pm$ microalbuminuria, $\pm$ mild neuropathy	<b>MODERATE</b> pre-proliferative retinopathy, or persistent macroalbuminuria $\pm$ sensory loss.	<b>MARKED</b> severe non-proliferative or proliferative retinopathy $\pm$ serum creat $> 2.0$ mg/dL $\pm$ insensate extremities or autonomic neuropathy
<b>ABSENT</b>	<b><math>&lt;7\%</math></b>	<b>7-8%</b>	<b>8-9%</b>
<b>PRESENT</b> (not end-stage and management achievable )	<b>7-8%</b>	<b>7-8%</b>	<b>8-9%</b>
<b>MARKED</b> either end-stage or management is significantly challenging	<b>8-9%</b>	<b>8-9%</b>	<b>8-9%</b>



For new onset diabetes, if A1c levels are targeted to be around **7%** for the first 10 years

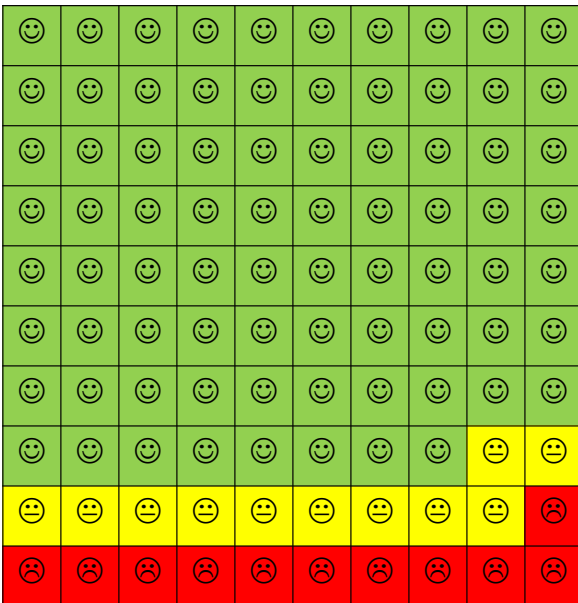
**82** alive with diabetes without microvascular disease

**8** alive with diabetes and microvascular disease

**10** dead from diabetes

**The United Kingdom Prospective Study (UKPDS)**, conducted from the mid-1980s to late 1990s with patients whose average A1c was 9% at time of diagnosis, provides the **primary evidence base for tight control of type 2 diabetes from onset of disease for individuals with a life expectancy of around 10 years** - UKPDS 33 (sulfonylurea/insulin therapy compared to conventional therapy – Lancet 1998); Use of metformin may confer additional benefit; UKPDS 34 (metformin vs. conventional therapy Lancet 1988).

For new onset diabetes, if A1c levels are targeted to be around **8%** for the first 10 years



**78** alive with diabetes without microvascular disease

**11** alive with diabetes and micro-vascular disease

**11** dead from diabetes

	<b>Person alive with diabetes and no microvascular complications</b>
	<b>Person alive with diabetes and with microvascular complications</b>
	<b>Person dead from diabetes</b>
	<b>Microvascular complications include retinopathy, nephropathy, and neuropathy</b>

# ACCEPTABLE RISK

## WE CAN NEVER COMPLETELY ELIMINATE RISK

When making a decision on how we use HgbA1c we need to determine if the overall benefits out balance the potential risk for an adverse outcome.



## WHAT KIND OF RISK ARE WE FACING WITH DIABETES?

Navigating a narrow path between two difficult clinical courses:

✦ **Increased morbidity and mortality due to under treatment**

**Versus**

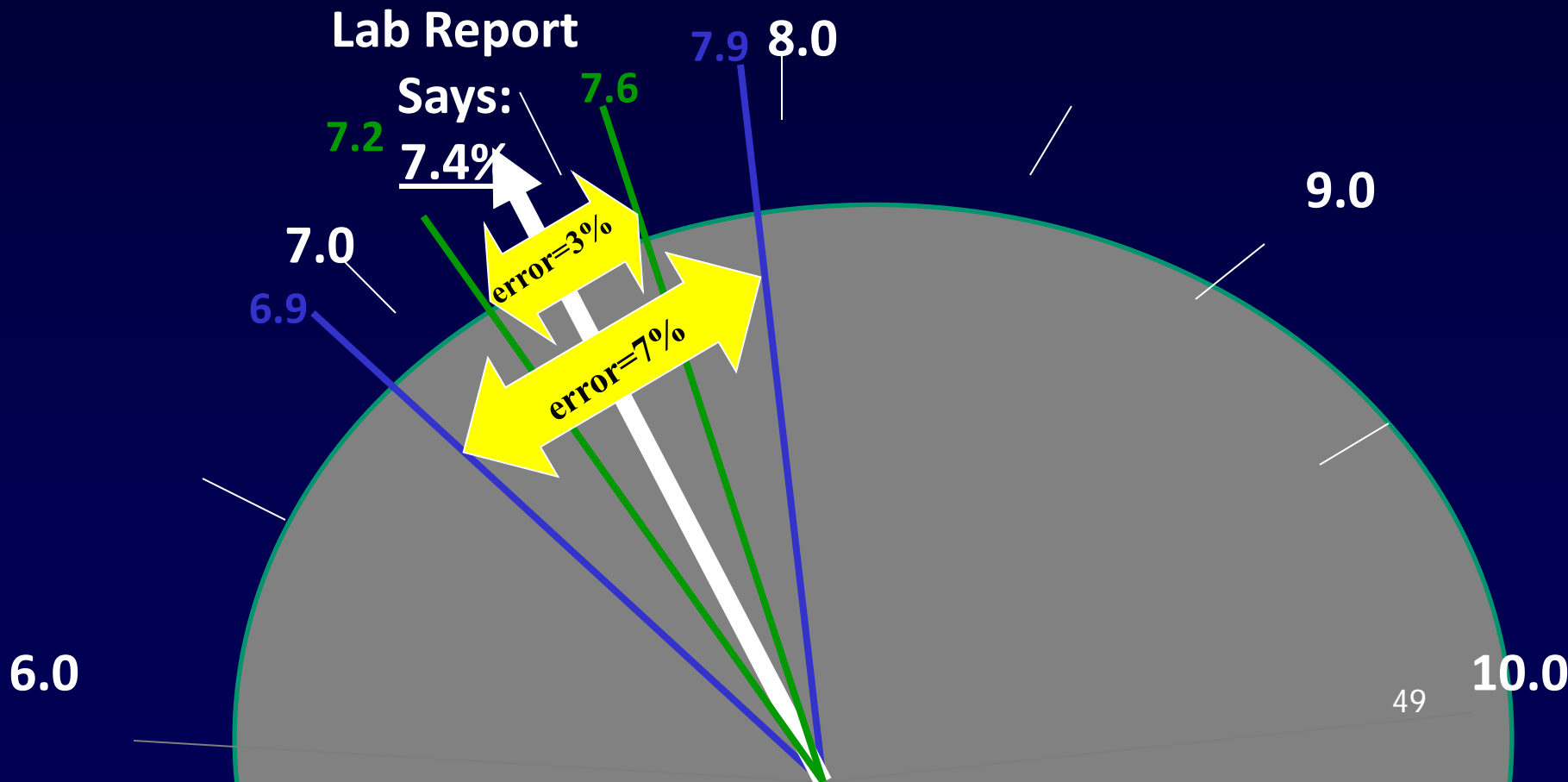
✦ **Risks associated with hypoglycemia due to over treatment.**

Therefore, it is critical that you know as much as possible about the risks associated with your clinical decisions and this means:

**KNOWING THE EXTENT OF LABORATORY ERROR AT YOUR FACILITY**



**A Value of A1c of 7.4% could be anything between 6.9 and 7.9 in a assay with an overall error acceptable for clinical use (overall error=7%). If the assay has an overall error of 3%, the range is narrower (7.2-7.6).**



# Recommendations Reporting Hgba1c

Below is a consensus recommendation for the reporting of HgbA1c test results including a 95% confidence interval to show intralaboratory precision as well as the confidence interval adjusted for the laboratory's accuracy against the NGSP reference standard through CAP proficiency testing.

TEST	RESULT	PRECISION - 95% CI	ACCURACY ADJUSTED 95% CI *
HgbA1c	6.5%	6.3 - 6.7%	6.57 - 6.97

=====

\* Confidence interval adjusted for bias of this facility's methodology when compared to the National Glycated Hemoglobin Standardization Program reference standard through CAP Proficiency Testing.

=====

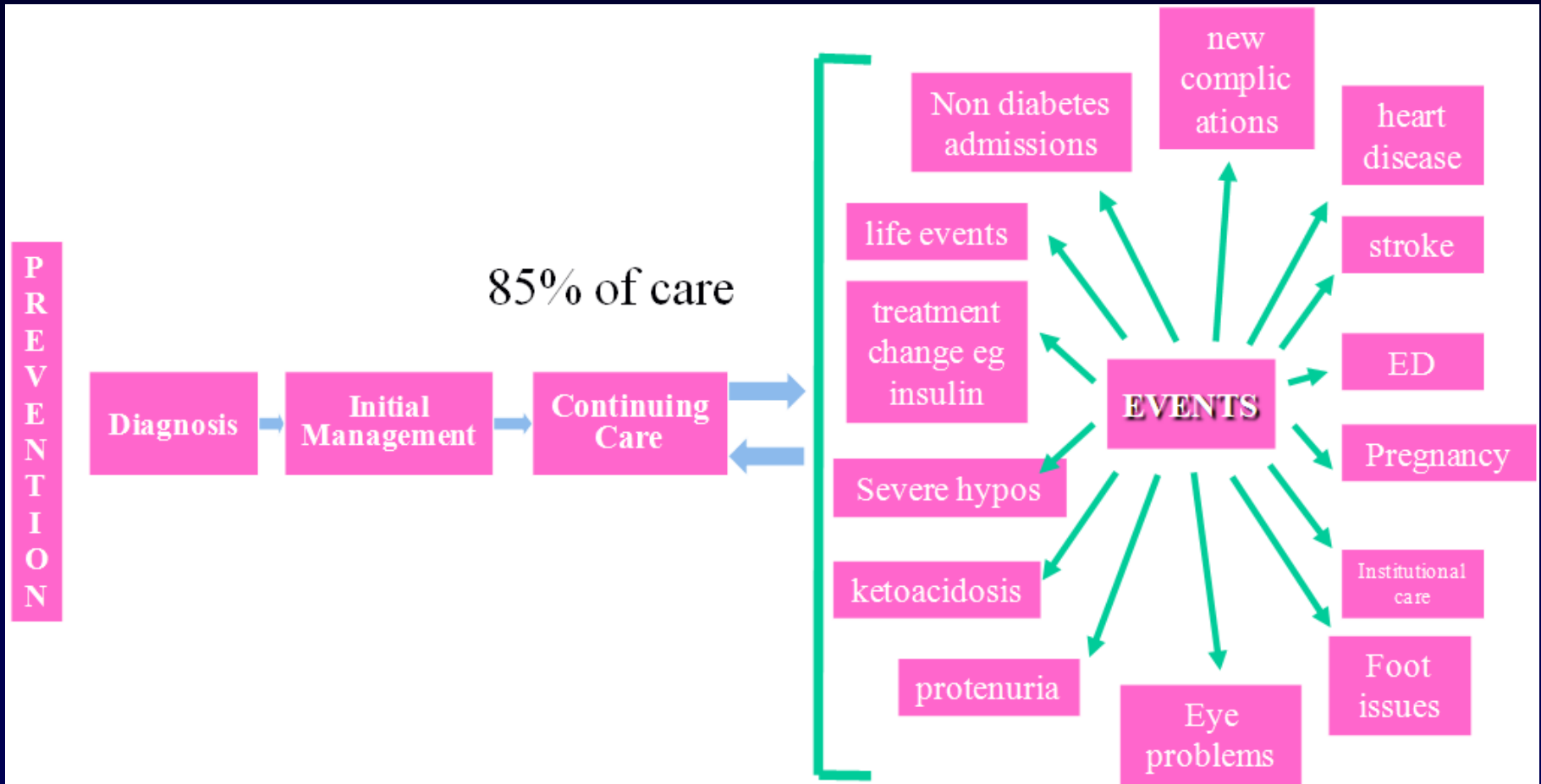
Our ability to deliver this type of report format and content in the VA will depend on the capacity of the VistA and CPRS system to do this so we may have to institute the following alternate report:

TEST	RESULT	95% CONFIDENCE INTERVAL	CI ADJUSTED FOR OUR METHOD*
HgbA1c	6.5%	+/- 0.2%	+ an additional 0.27%

# What is evidence-based medicine?

- Where there is evidence of benefit and value, do it
- Where there is evidence of no benefit, harm, or poor value, don't do it.
- When there is insufficient evidence to know for sure, be conservative

# In the end, it is about the Patient's journey



# Federal Practitioner April 2011

Updates in Specialty Care



Leonard Pogach, MD, MBA; Paul R. Conlin, MD; Curtis Hobbs, MD; Robert A. Vigersky, MD; and David Aron, MD, MS; for the VA-DoD Diabetes Guideline Working Group

**VA-DoD Update of Diabetes Guidelines:  
What Clinicians Need to Know About  
Absolute Risk of Benefits and Harms and A1c  
Laboratory Accuracy**

# Resources

VA DoD Diabetes Practice Guidelines

[http://www.healthquality.va.gov/Diabetes\\_Mellitus.asp](http://www.healthquality.va.gov/Diabetes_Mellitus.asp)

Diabetes: A1c/Questions/Diagnosis

<http://www2.niddk.nih.gov/AboutNIDDK/CommitteesAndWorkingGroups/DMICC/MeetingReports.htm>

