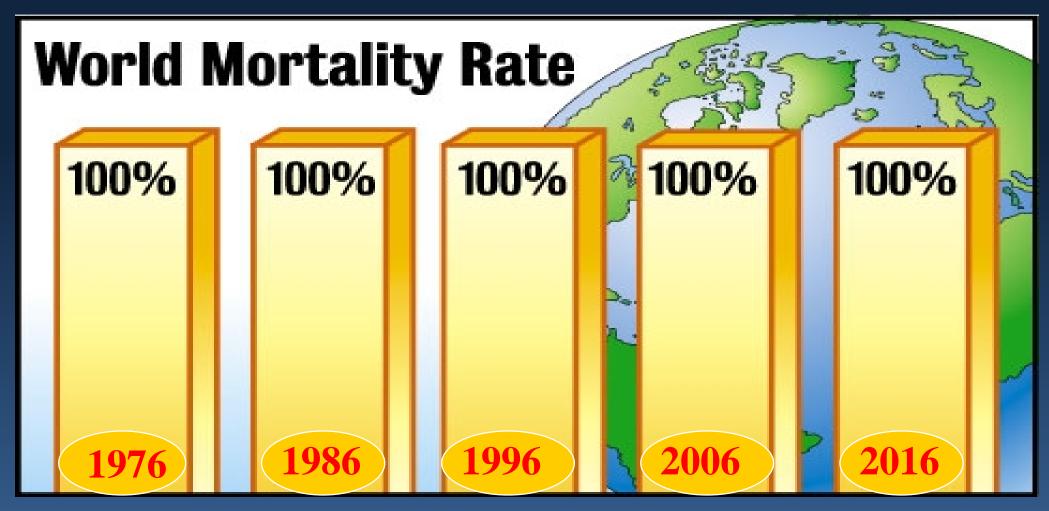
Helping Our Patients to Succeed: A Psychological Perspective on Type 2 Diabetes

William H. Polonsky, PhD, CDE May 25, 2017

Quiz #1: How Has the Growing Diabetes Pandemic Affected World Mortality Rates?

- 1. World mortality rates have worsened A LOT.
- 2. World mortality rates have worsened somewhat.
- 3. World mortality rates have not changed.
- 4. World mortality rates have improved somewhat.
- 5. World mortality rates have improved A LOT.

World Death Rate Holding Steady At 100 Percent



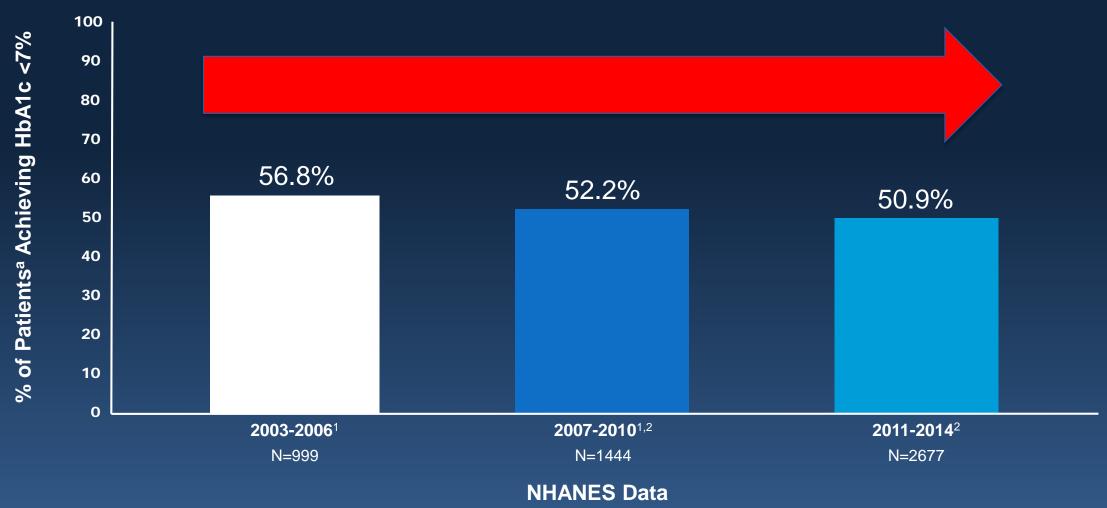
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Quiz #2: How Has Glycemic Control in T2D Changed Over the Past Decade?

- 1. Mean A1C has risen markedly.
- 2. Mean A1C hasn't really changed.
- 3. Mean A1C has dropped markedly.

GLYCEMIC CONTROL OVER THE LAST DECADE



NHANES, National Health and Nutrition Examination Survey. ^aPatients with either Type 1 or Type 2 diabetes.

1. Ali MK et al. N Engl J Med. 2013;368:1613-1624. 2. Carls GS et al. 76th ADA Scientific Sessions. June 10–14, 2016. Poster 1515-P.

COMMERCIAL HMO AND MEDICAID POPULATIONS

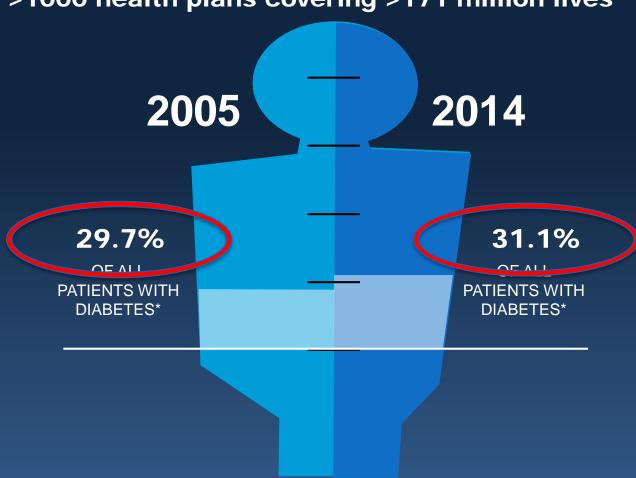
HEDIS data from >1000 health plans covering >171 million lives (2014)



RATES OF VERY POOR GLYCEMIC CONTROL

HEDIS data from >1000 health plans covering >171 million lives

% OF DIABETIC PATIENTS
WITH
VERY POOR GLYCEMIC
CONTROL
(HbA1c >9%)
IN THE US



Quiz #2: How Has Glycemic Control in T2D Changed Over the Past Decade?

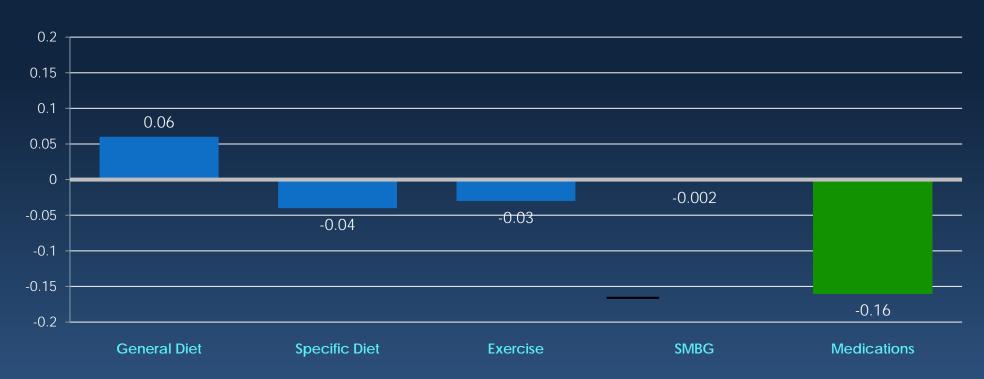
- 1. Mean A1C has risen markedly.
- 2. Mean A1C hasn't really changed.
- 3. Mean A1C has dropped markedly.

Quiz #3: From a Behavioral Perspective, What is Likely to be The Biggest Bang For Your Buck?

- 1. Increasing physical activity
- 2. Make positive dietary changes
- 3. More frequent blood glucose monitoring
- 4. Taking the appropriate medications

The Key Behavioral Contributor to Glycemic Control?

ALL SELF-CARE BEHAVIORS + COVARIATES^a



SMBG, self-monitoring of blood glucose.

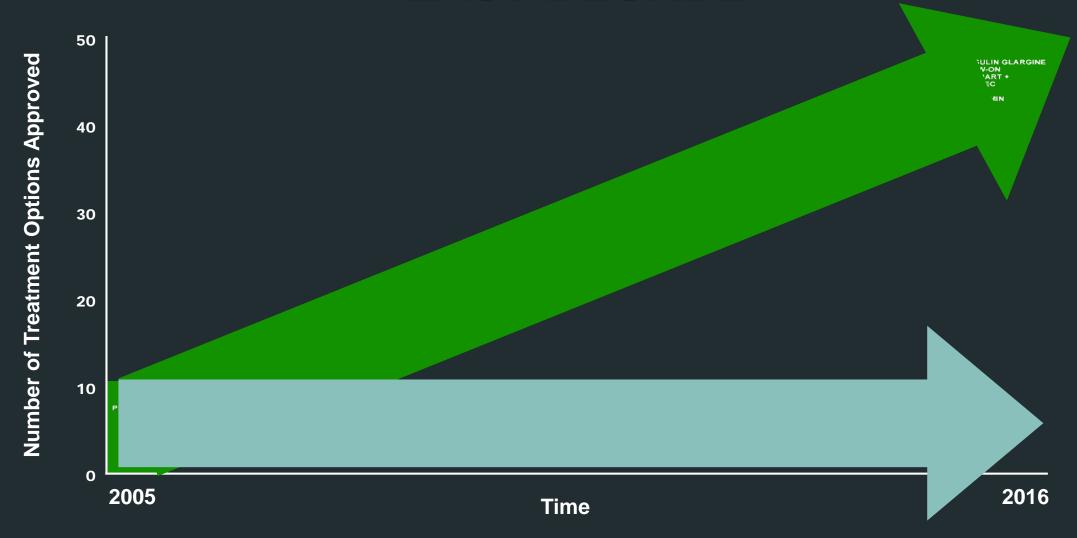
^aCovariates, age, gender, race, ethnicity, income, education, insurance status, insulin status and duration of diabetes. HbA1c assessed with a point-of-care device. ^bP<0.05

Osborn CY, et al. J Clin Pharm and Ther. 2016;41:256-259.

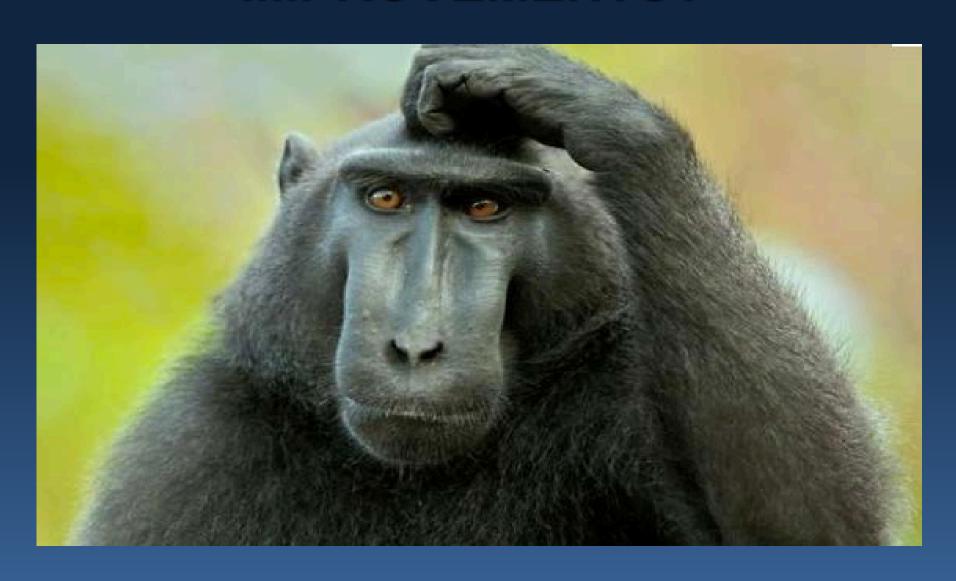
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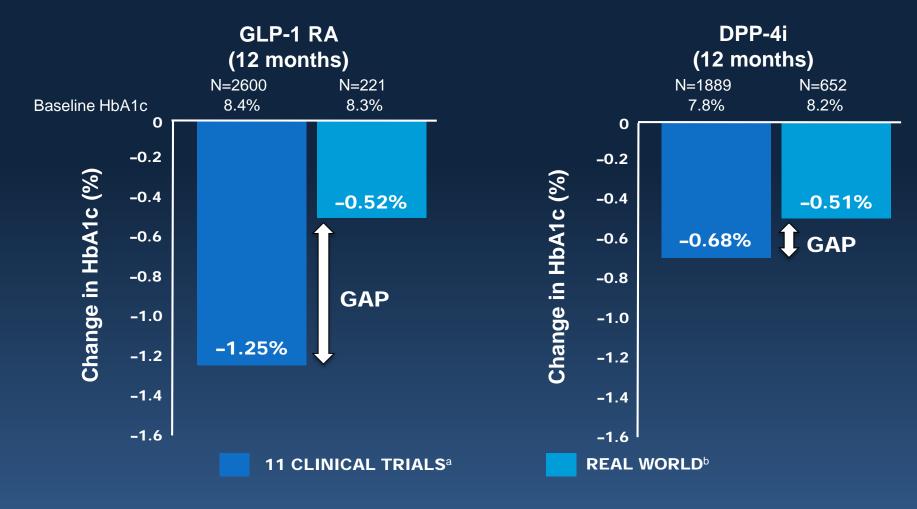
MANY NEW T2D MEDICATION OPTIONS OVER THE LAST DECADE



WHY AREN'T WE SEEING DRAMATIC IMPROVEMENTS?



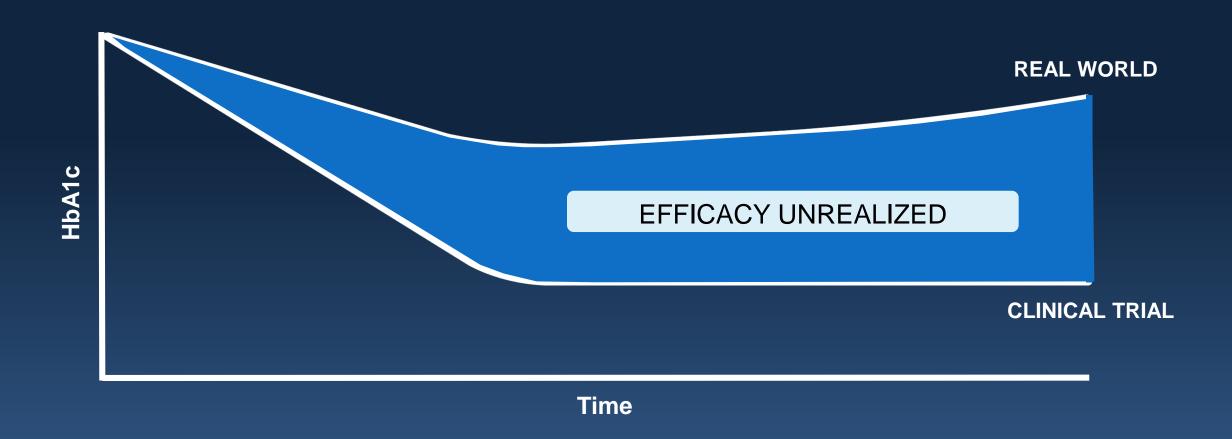
CLINICAL TRIAL RESULTS LOOK GOOD, BUT...



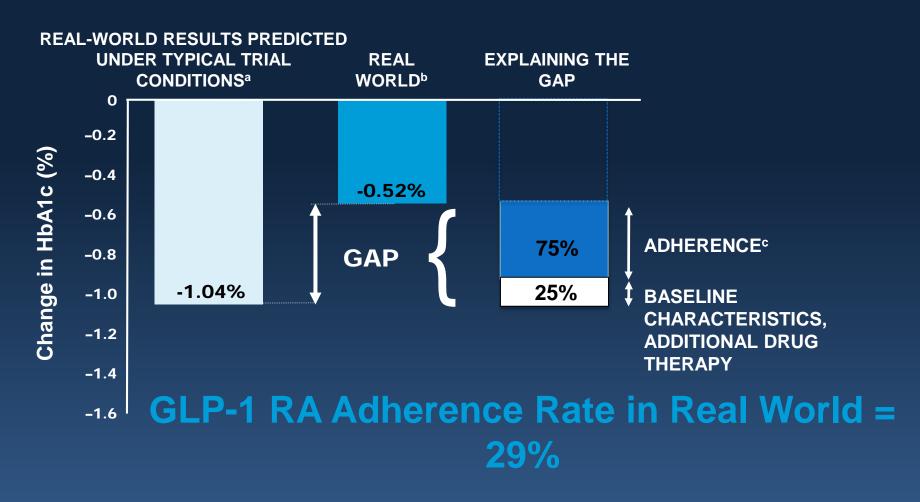
^aIdentified 11 pivotal randomized controlled trials with published change in HbA1c (7 GLP-1 RA [2600 patients] and 4 DPP-4i [1889 patients]).

bOptum/Humedica SmartFile database (2007-2014) was used (GLP-1 RA 221 patients; DPP-4i 652 patients). Change in HbA1c measured from drug initiation to 365±90 days later.

CLINICAL TRIALS VS. REAL WORLD



POOR ADHERENCE IS THE KEY

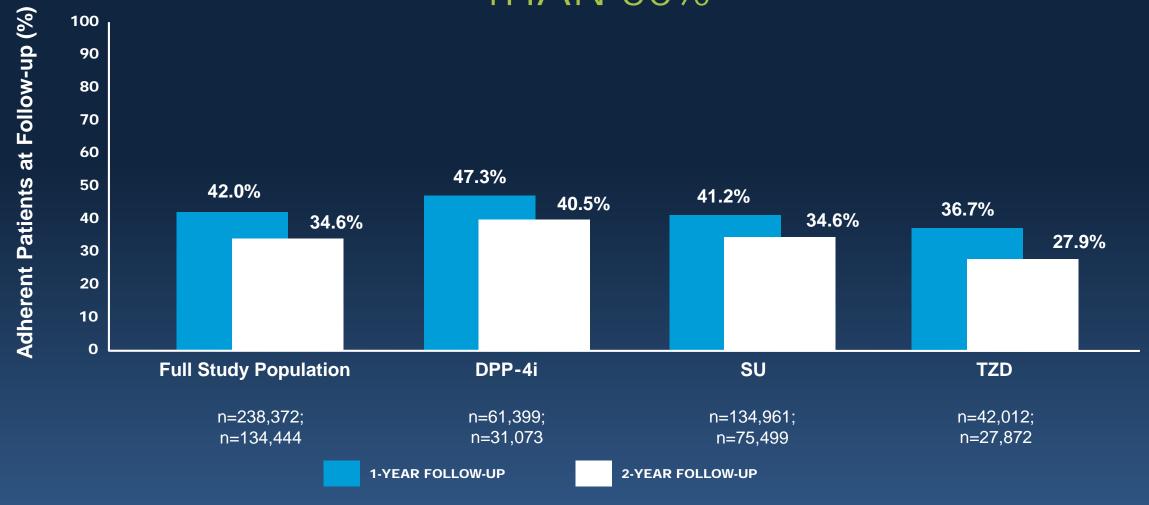


RCT, randomized clinical trial.

^aLinear regression model fitted to estimate the change in HbA1c 1 year after initiating GLP-1 RA or DPP-4i based on baseline and treatment characteristics. ^bOptum/Humedica SmartFile database (2007-2014) was used (GLP-1 RA 221 patients; DPP-4i 652 patients). Change in HbA1c measured from drug initiation to 365±90 days later. ^cMedical adherence classified as poorly adherent if percentage of days covered (PDC) <80%.

Carls GS et al. 76th ADA Scientific Sessions. June 10-14, 2016. New Orleans, LA. Poster 117-LB.

ADHERENCE RATES FOR ORAL AGENTS ARE LESS THAN 50%



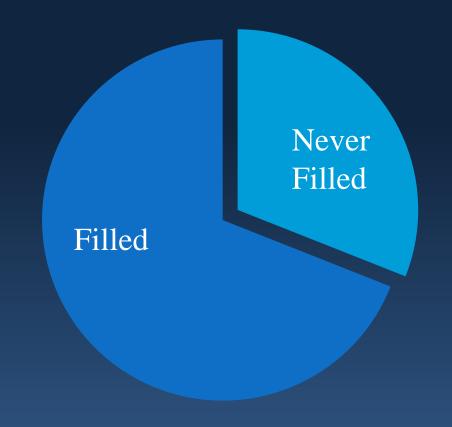
PDC, proportion of days covered; SU, sulfonylurea; TZD, thiazolidinedione.

A retrospective claims analysis of 238,372 patients with T2D with at least 1 prescription claim for a DPP-4i, SU, or TZD from January 1, 2009 to January 31, 2012. Adherence defined as PDC ≥0.8.

Farr AM et al. Adv Ther. 2014;31:1287-1305.

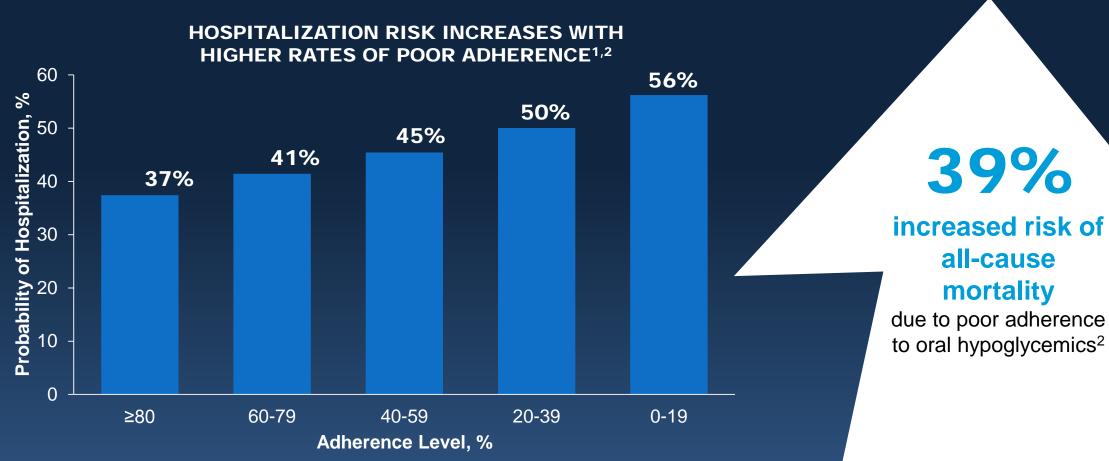
TRACKING NEW E-PRESCRIPTIONS FOR DIABETES MEDICATIONS

AMONG 75,589 INSURED PATIENTS IN THE FIRST YEAR OF A COMMUNITY-BASED E-PRESCRIBING INITIATIVE



31%

CLINICAL IMPACT OF POOR ADHERENCE



Data was provided by a large, Medicare supplemental (MarketScan) database from July 1, 2009 to June 30, 2014. There were 123,235 patients with T2D aged ≥65 who received glucose-lowering agents. Comparisons between adherent (defined as PDC ≥80%) and poorly adherent (PDC <80%) were all statistically significant at *P*<0.001.

1. Boye KS et al. 76th ADA Scientific Sessions. June 10–14, 2016. Poster 1221-P. **2.** Ho PM et al. *Arch Intern Med.* 2006;166:1836-1841.

Poor adherence defined as PDC < 0.8

SO WHAT TO DO?



EFFECTIVENESS OF CURRENT INTERVENTION STRATEGIES

"THERE IS NO SINGLE INTERVENTION STRATEGY, OR PACKAGE OF STRATEGIES, THAT HAS BEEN SHOWN TO BE EFFECTIVE ACROSS ALL PATIENTS, CONDITIONS, AND SETTINGS" 1-4



WHAT ARE WE MISSING?





RESEARCH ARTICLE

Open Access

Unintentional non-adherence to chronic prescription medications: How unintentional is it really?

Abhijit S Gadkari* and Colleen A McHorney

MAJOR CONTRIBUTORS

PATIENT-PERCEIVED MEDICATION BURDEN

(eg, obtaining/taking medication, treatment complexity, out-of-pocket costs, and hypoglycemia)

PATIENT DEMOGRAPHIC FACTORS

(eg, younger age, lower education level and lower income level)

ADHERENCE

ADHERENCE

CRITICAL PATIENT BELIEFS ABOUT MEDICATION

(eg, perceived treatment inefficacy, medication beliefs, and physician trust)

NON-PATIENT FACTORS

(eg, lack of integrated care in many healthcare systems, clinical inertia among healthcare professionals)

PERCEIVED TREATMENT INEFFICACY

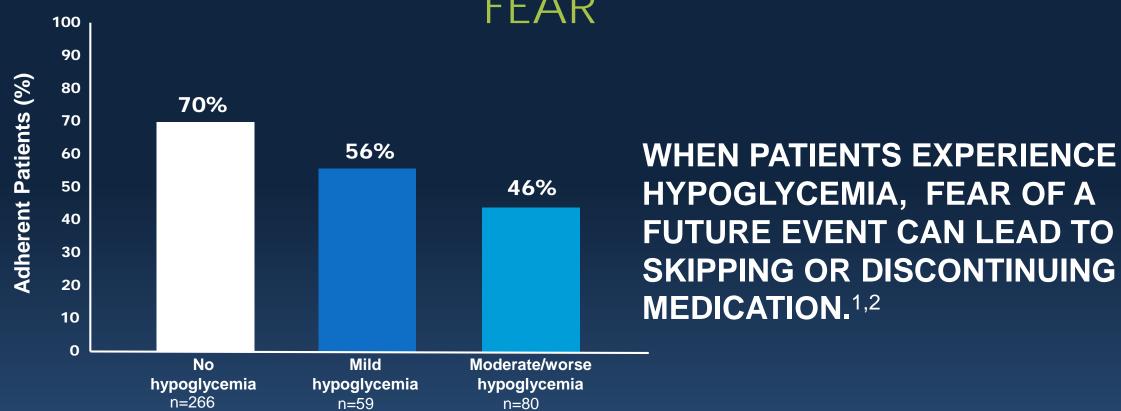
Lack of tangible benefits contributes to discouragement and poor adherence 1,2



COMPETING DEMANDS



HYPOGLYCEMIC EVENTS AND HYPOGLYCEMIC FEAR

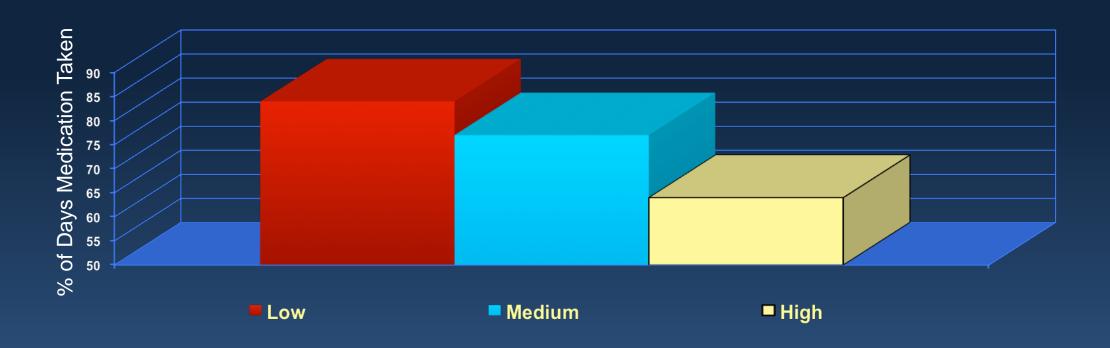


Reprinted from *Patient Preference and Adherence*, volume 8, L. Walz et al, "Impact of symptomatic hypoglycemia on medication adherence, patient satisfaction with treatment, and glycemic control in patients with type 2 diabetes" pages 593-601, Copyright (2014), with permission from Dove Medical Press Ltd.

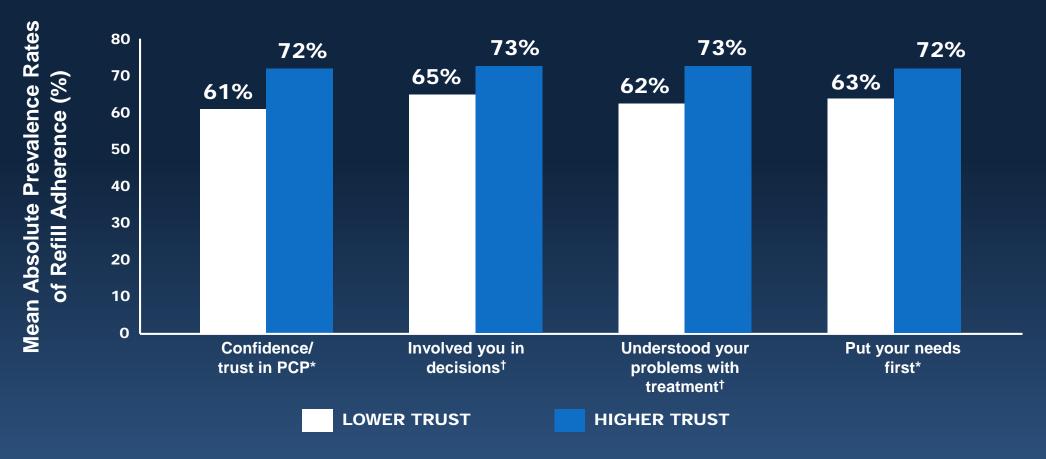
Cross-sectional study of T2D patients in Sweden treated with metformin and a sulfonylurea. Adherence was determined using a self-report adherence and barriers questionnaire.³

1. Hajós TRS et al. *Diabetes Care*. 2014;37:102-108. **2.** Gonder-Frederick LA et al. *Diabet Med*. 2013;30:603-609. **3.** Walz L et al. *Patient Prefer Adhere*. 2014;8:593-601.

CO-PAYS AND ORAL MEDICATIONS



LACK OF PHYSICIAN TRUST



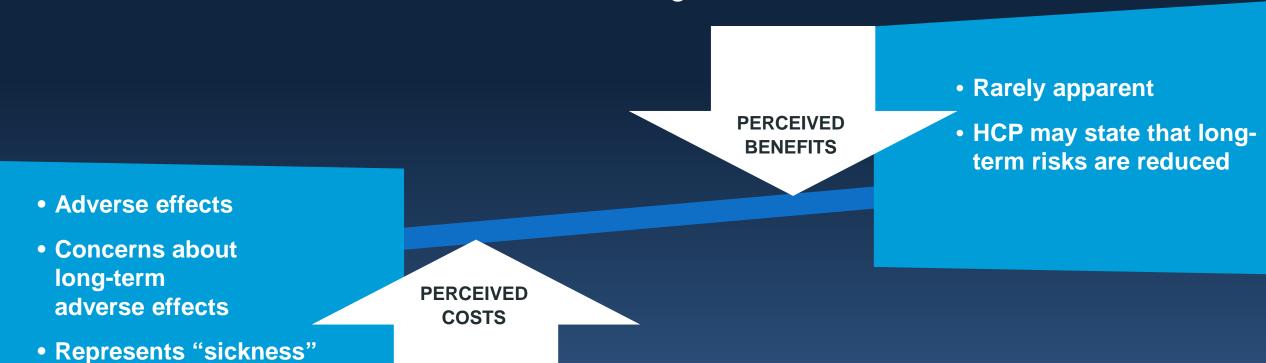
Differences in prevalence of poor refill adherence for any cardiometabolic medication in a cohort of 9377 patients with diabetes. Respondents were classified as poorly adherent when they had no medication supply for >20% of the observation time.

*Trust is defined using 2 items from the Trust in Physicians Scale (TIPS) modified to match the 4-point Consumer Assessment of Healthcare Providers and Systems (CAHPS) scale options during the preceding 12 months. †Shared decision-making was determined using 2 items from the Interpersonal Processes of Care (IPC) instrument during the preceding 12 months.

Ratanawongsa N et al. JAMA Intern Med. 2013;173:210-218.

MEDICATION BELIEFS

Perceived worthwhileness: Does the patient believe the benefits of the medication outweigh the costs?



MEDICATION BELIEFS

ROY

Takes 2 oral medications for T2D and basal insulin; his last HbA1c was 6.8%

WHO IS
DOING
BETTER
WITH HIS
DIABETES?

Doesn't take any medications for T2D; his last HbA1c was 9.1%

ROY. How healthy you are, and your risk of complications, is <u>not</u> determined by how much medication you take.

It is your metabolic results that matter.

Even if you are not taking pills or insulin, high blood sugars will likely lead to future problems.

Saiontz & Kirk, P.A. www.YouHaveALawyer.com

Failure to Warn Claims

Invokana\invokamet If You Suffered

Farxiga Ketoacidosis

Jardiance Kidney Failure

Glyxambi Heart Attack

Xigduo XR Wrongful Death

1-888-LAW-2390



WHY DO PATIENTS FEEL THIS WAY?

- Threatening patients with medication
 - "If you can't make some positive changes, then we'll have no choice but to put you on more medication, and perhaps even start insulin."
- Underlying messages
 - More medication, and especially insulin, should be avoided at all costs
 - You have failed
 - You are to be punished



SO WHAT TO DO?

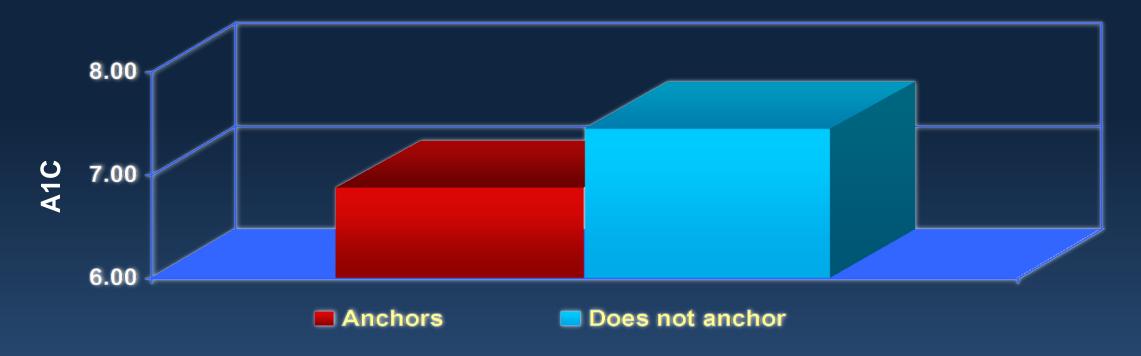
1. Ask correctly

- "Any problems taking those medications?"
 vs.
- "What's one thing about taking your medications that's been challenging?"

SO WHAT TO DO?

- 1. Ask correctly
- 2. Forgetfulness
 - "Aside from forgetting, what else is tough about taking your meds?"
 - Anchoring strategies

Anchoring Medication to Daily Events



[&]quot;A daily event (a meal, TV show, bedtime, brushing my teeth) reminds me."

SO WHAT TO DO?

- 1. Ask correctly
- 2. Forgetfulness
- 3. Treatment complexity
 - Simplify if possible
 - Provide additional details as needed



SO WHAT TO DO?

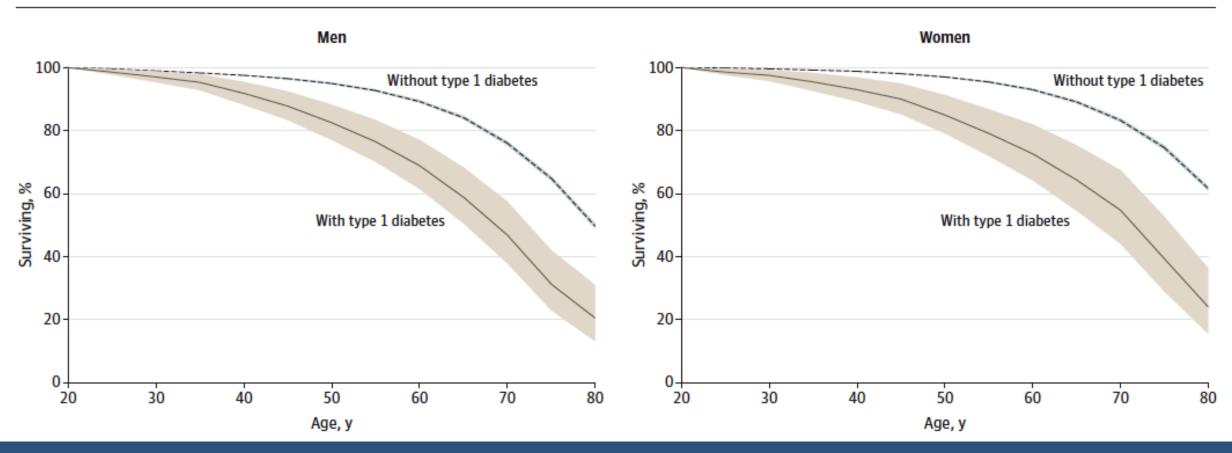
- 1. Ask correctly
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- 3. Treatment complexity
- 4. Provide hope





Bad News about T1D Survival

Figure. Percentage Surviving by Age Among Those With Type 1 Diabetes Compared With the General Population Without Type 1 Diabetes

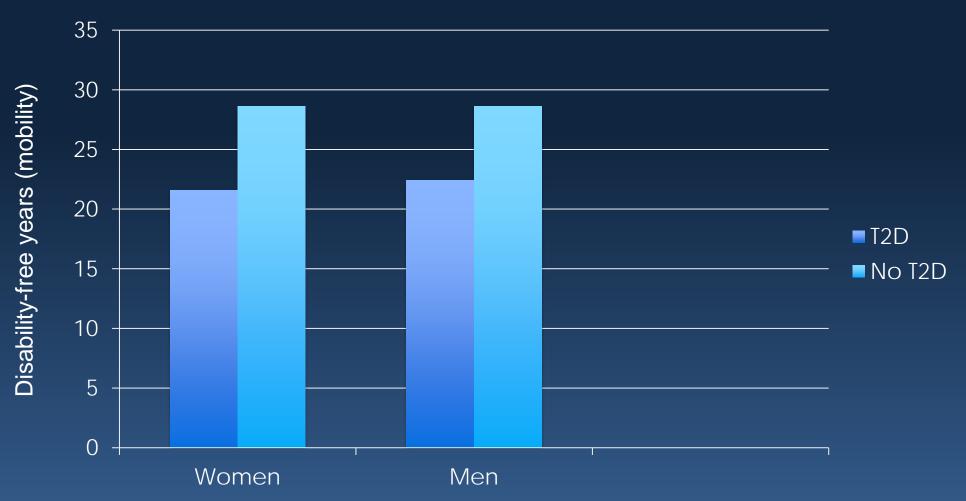


Bad News about T1D Survival

DISCUSSION

This nationwide Swedish study of 33,915 patients with type 1 diabetes and 169,249 controls matched for age and sex shows that for patients with type 1 diabetes who had on-target glycemic control, the risk of death from any cause and the risk of death from cardiovascular causes were still more than twice the risks in the general population. For patients with diabetes who had very poor glycemic control, the risks of death from any cause and of death from cardiovascular causes were 8 and 10 times as high, respectively, as those in the general population. The excess

Disability-Free Years, Age > 50 Years



Diabetes factoid #1:

JABETES IS THE LEADING CAUSE OF KIDNEY FAILURE

source: www.diabetes.org

BLINDNESS

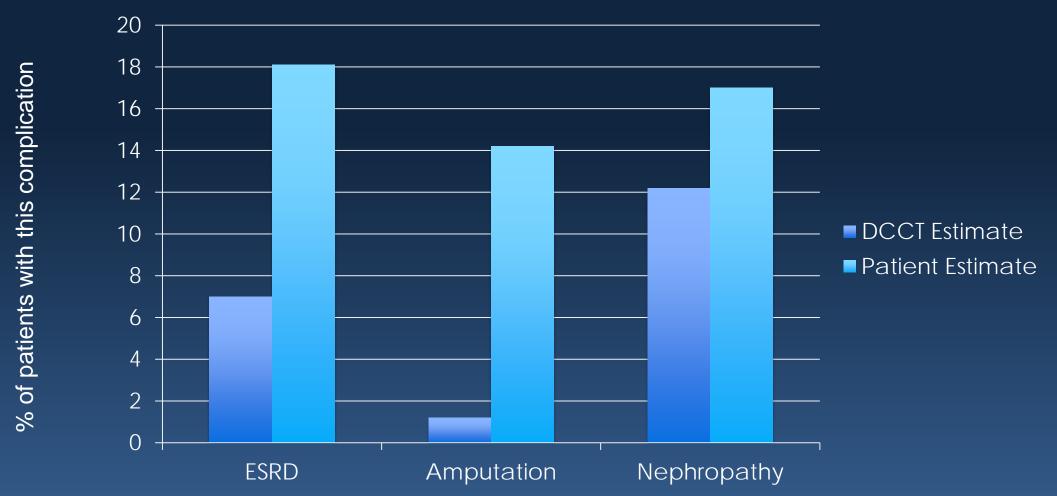
Diabetes is the

LEADING CAUSE



of new cases of blindness among adults aged 20-74.

T1D Patients' Perceptions of Complications Risk Over 20 Years (with Intensive Therapy)



Feeling Hopeless about Diabetes

STATEMENT	POPULATION	A MODERATE PROBLEM, OR WORSE
"I will end up with serious long-term complications, no matter what I do."	254 T1Ds	70.5%
	414 T1Ds	66.4%
	268 T2Ds	74.3%
	424 T2Ds	71.0%

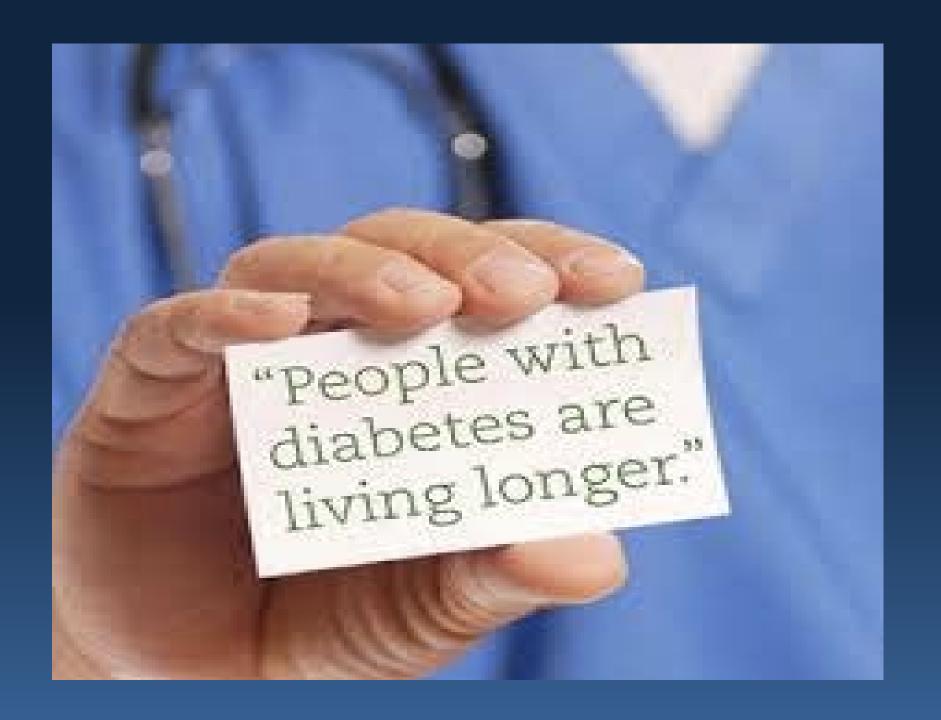




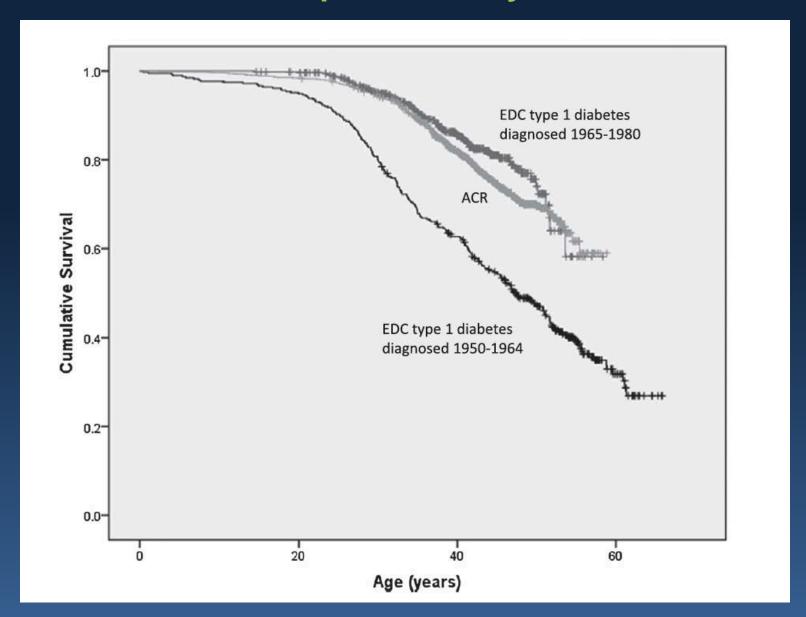
The Good News

1. Overall, things are getting better.

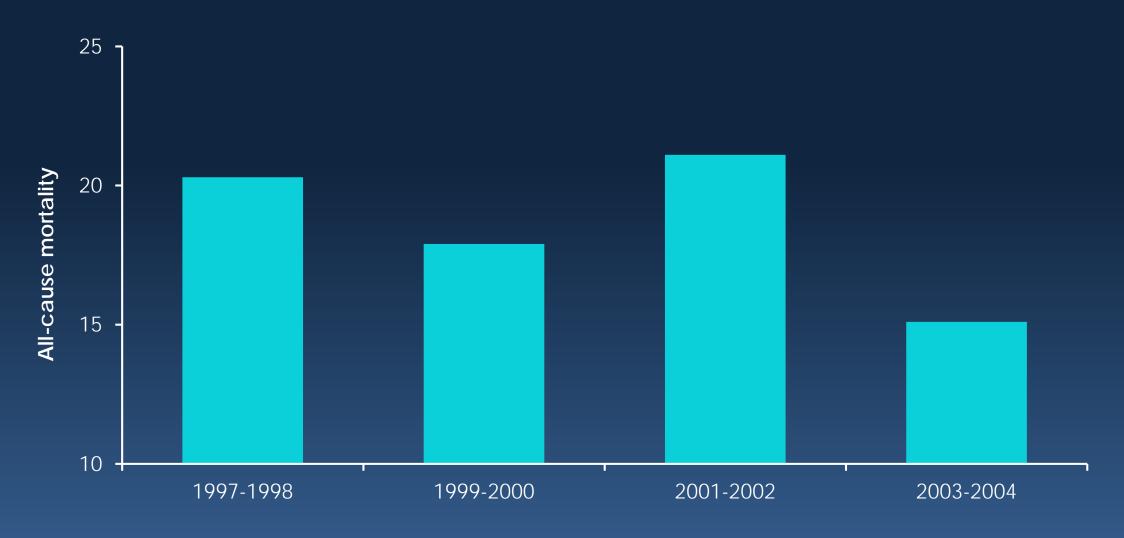




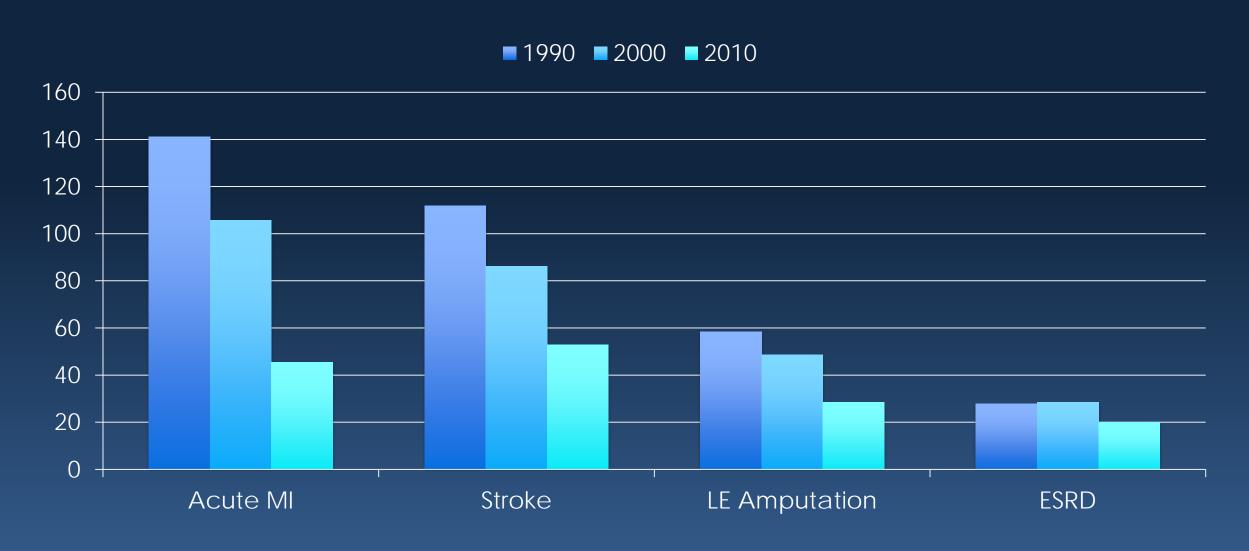
Life Expectancy in T1D



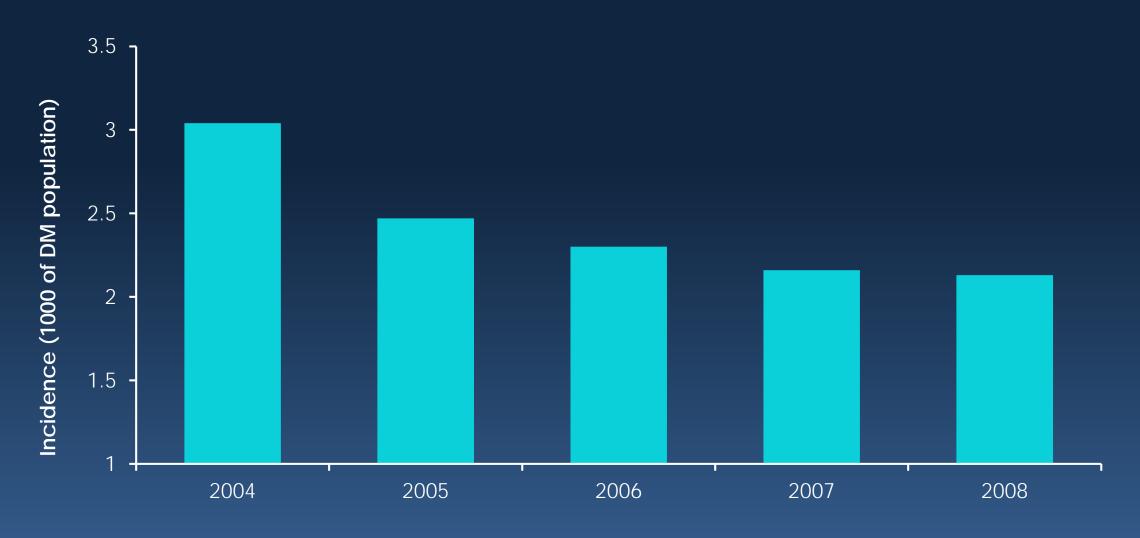
All-Cause Mortality Rates in T2D



Long-Term Diabetes Complications, 1990 - 2010



LEA Rates in Scotland, 2004-2008



RECORD (n=4,447 T2Ds)	Expected
Cardiovascular Event Rate (%)	11.0

RECORD (n=4,447 T2Ds)	Expected	Actual: Rosiglitazone	Actual: Control
Cardiovascular Event Rate (%)	11.0	2.8	2.8

RECORD (n=4,447)	Expected	Actual: Rosiglitazone	Actual: Control
Cardiovascular Event Rate (%)	11.0	2.8	2.8

ACCORD (n=10,251)	Expected
Event Rate Deaths/1,000 pts/year	50

RECORD (n=4,447)	Expected	Actual: Rosiglitazone	Actual: Control
Cardiovascular Event Rate (%)	11.0	2.8	2.8

ACCORD (n=10,251)	Expected	Actual: Intensive	Actual: Control
Event Rate Deaths/1,000 pts/year	50	14	11

SANDS Study

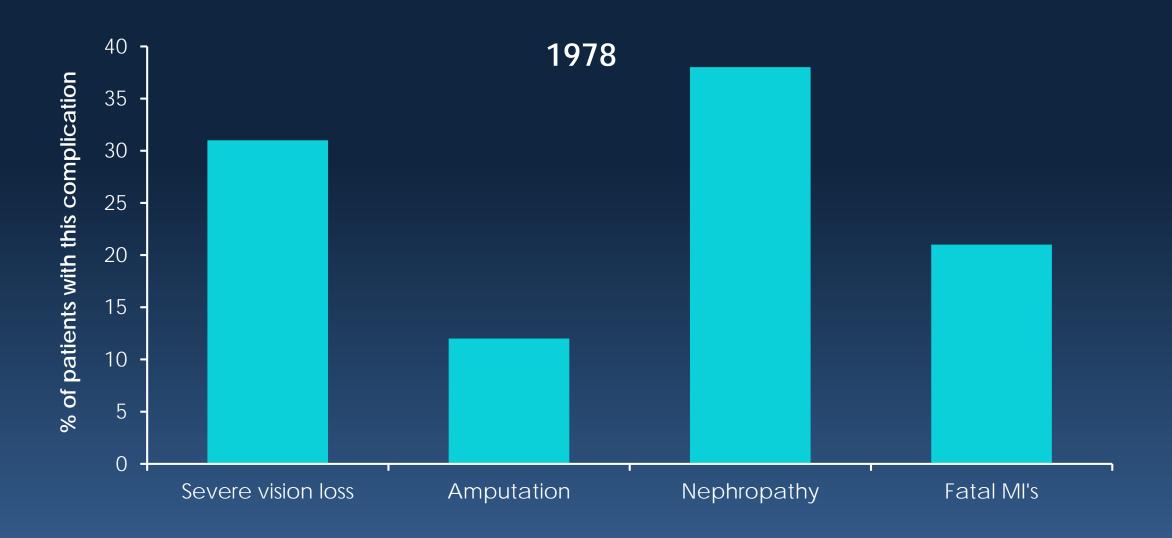
"As the effectiveness of therapy improves and new treatment strategies are widely applied, it is becoming more difficult to conduct a trial in which adequate numbers of clinical end points are achievable in a reasonable length of time for individuals without CVD at baseline."

The Good News

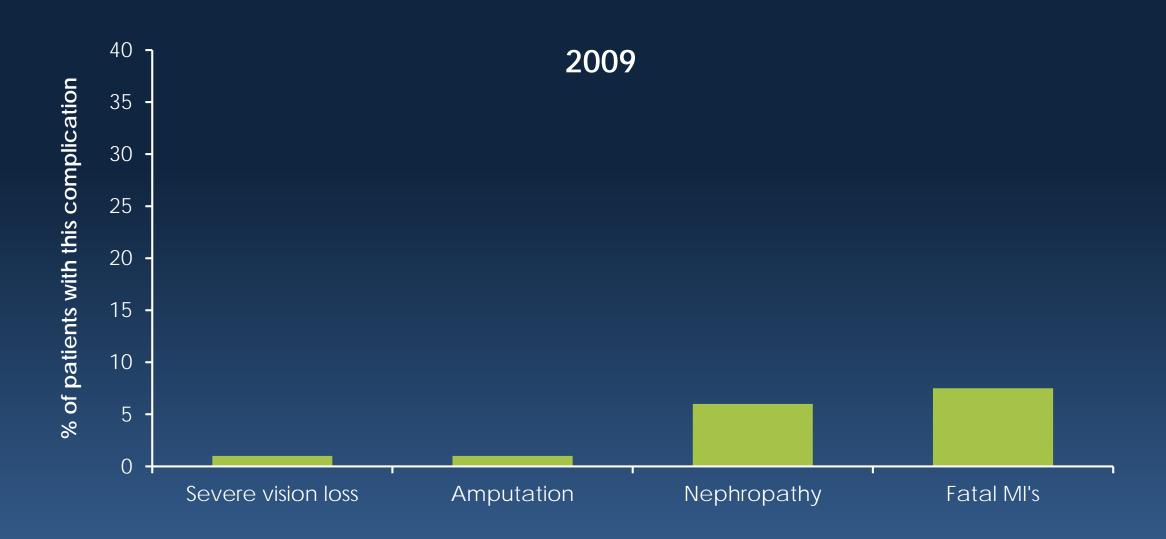
- 1. Overall, things are getting better.
- 2. And with good care...



T1D Complications After 30+ Years



T1D Complications After 30+ Years



In Summary

"Historical reports of frequencies of serious complications in T1D patients are clearly outdated because no one would realistically follow what was then the standard of care with respect to glycemic control.

... rates of complications with 'intensive' treatment, or what would now be considered the standard of care, are substantially lower than in the past. This is indeed good news that should be openly shared with the newly diagnosed patient to help alleviate fears that may accompany the diagnosis.."

Facts & Fictions

Q. Diabetes is the leading cause of adult blindness, amputation, and kidney failure. True or false?

A. False. To a large extent, it is poorly controlled diabetes that is the leading cause of adult blindness, amputation and kidney failure.

Well-controlled diabetes is the leading cause of...
NOTHING!

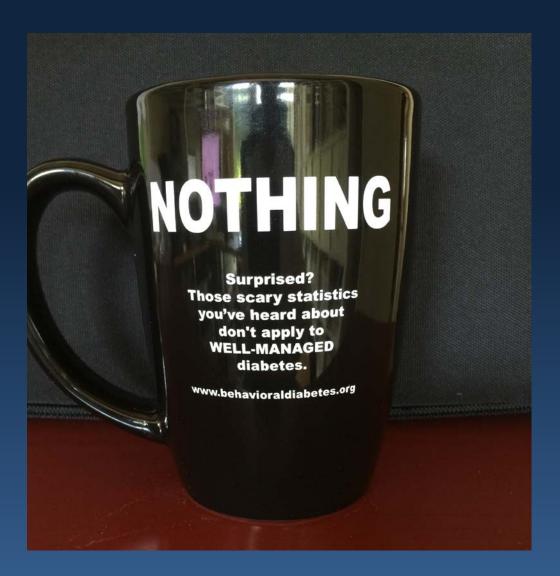
Fact Check

This doesn't mean:
good care will
guarantee that you
will not develop
complications

This does mean: with good care, odds are good you can live a long, healthy life with diabetes

We Even Put it on Mugs!





T1D Mortality Rates

Table 1—DCCT/EDIC deaths and death rates by DCCT intensive versus conventional therapy group, primary versus secondary cohort, and sex, with SMRs relative to the U.S. population, along with RMRs comparing two SMRs

	Observed/expected*	Rate (95% CI)†	SMR (95% CI)‡	RMR (95% CI)§	Р
Total (n = 1,441)	125/114	320 (269, 380)	1.09 (0.92, 1.30)		
Intensive (<i>n</i> = 711)	51/58	263 (200, 345)	0.88 (0.67, 1.16)	1.49 (1.04, 2.14)	0.028
Conventional (n = 730)	74/56	376 (301, 470)	1.31 (1.05, 1.65)		
Primary (n - 726)	61/54	315 (247, 404)	1.13 (0.88, 1.45)	0.95 (0.67, 1.35)	0.76
Secondary ($n = 715$)	64/60	324 (255, 412)	1.07 (0.83, 1.36)		
Females (n = 680)	47/39	252 (190, 333)	1.19 (0.90, 1.59)	0.87 (0.61, 1.26)	0.464
Males (n = 761)	78/75	382 (307, 475)	1.04 (0.83, 1.30)		
Treatment group by sex				Conventional vs. Intensive	
Females					
Intensive	21/21	220 (145, 335)	0.99 (0.64, 1.51)	1.46 (0.82, 2.59)	0.201
Conventional	26/18	284 (195, 415)	1.44 (0.98, 2.11)		
Males					
Intensive	30/37	304 (213, 434)	0.82 (0.57, 1.18)	1.54 (0.97, 2.43)	0.066
Conventional	48/38	456 (346, 600)	1.26 (0.95, 1.66)		
Treatment group by study co	hort			Conventional vs. Intensive	
Primary					
Intensive	27/26	291 (200,422)	1.03 (0.70, 1.51)	1.17 (0.71, 1.95)	0.538
Conventional	34/28	338 (244,470)	1.21 (0.87, 1.69)		
Secondary					
Intensive	24/32	237 (160,353)	0.75 (0.50, 1.13)	1.88 (1.13, 3.12)	0.015
Conventional	40/28	415 (307,562)	1.42 (1.04, 1.93)		

^{*}Number of deaths. †Rate per 100,000 PY with 95% CI from a Poisson regression model with robust information sandwich standard errors. ‡Expected number of deaths from the 2013 U.S. population life table for every year of age in the cohort and the SMR. §RMR obtained from an unadjusted Poisson model, each with 95% CI and *P* value (two sided).

T1D Mortality Rates

Table 1—DCCT/EDIC deaths and death rates by cohort, and sex, with SMRs relative to the U.S.

Observed/expected*

Total (n = 1,441) 125/114

Intensive (n = 711) 51/58

Conventional (n = 730) 74/56

Life Expectancy in a Large Cohort of Type 2 Diabetes Patients Treated in Primary Care (ZODIAC-10)

Helen L. Lutgers^{1,8}, Esther G. Gerrits^{2,8}*, Wim J. Sluiter³, Lielith J. Ubink-Veltmaat⁴, Gijs W. D. Landman², Thera P. Links^{3,5}, Reinold O. B. Gans^{1,5}, Andries J. Smit^{1,5}, Henk J. G. Bilo^{1,2,5}

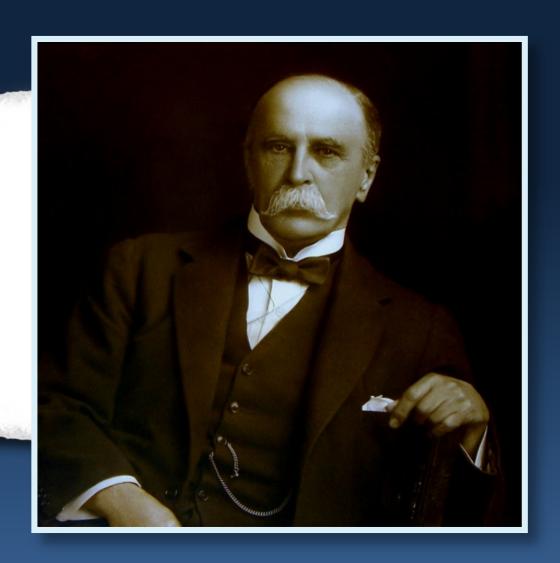
1 Department of Internal Medicine, University Medical Center Groningen, Groningen, the Netherlands, 2 Diabetes Center, Isala Clinics, Zwolle, the Netherlands, 3 Department of Endocrinology, University Medical Center Groningen, Groningen, the Netherlands, 4 Family practice't Veen, Hattem, the Netherlands, 5 Department of Medicine, University of Groningen, Groningen, the Netherlands

Conclusions: "This study shows a normal life expectancy in a cohort of subjects with type 2 diabetes patients in primary care when compared to the general population."

Diabetes & Your Health

"To live a long and healthy life, develop a chronic disease and take care of it."

- Sir William Osler

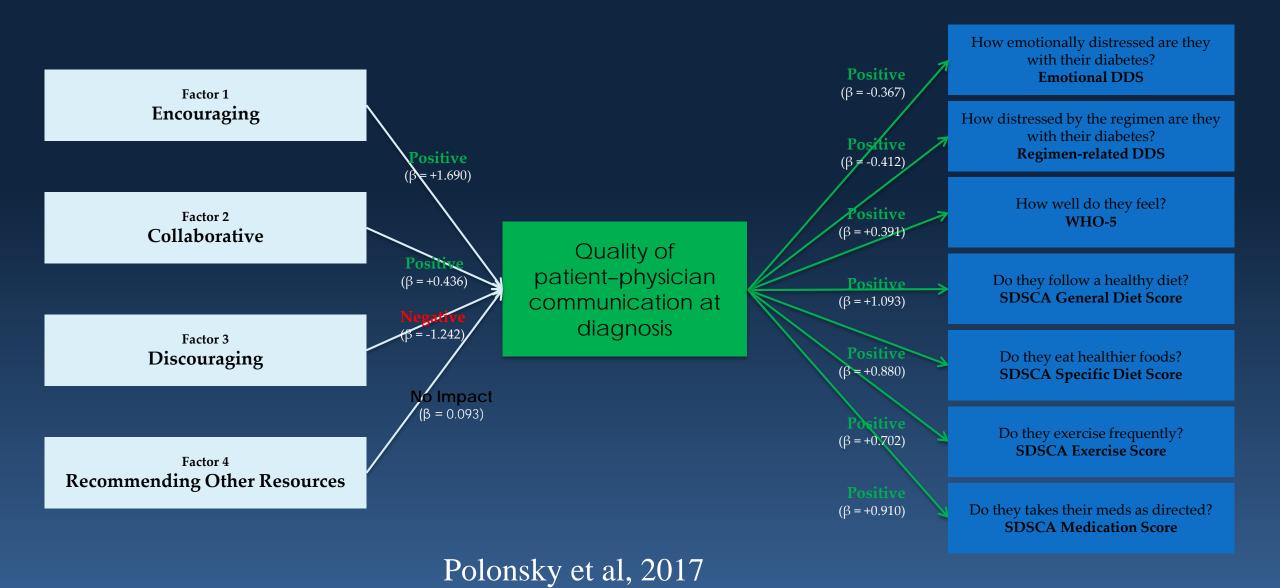


SO WHAT TO DO?

- 1. Ask correctly
- 2. Forgetfulness
- 3. Treatment complexity
- 4. Provide hope
- 5. Patient-provider trust
 - Listen, listen, listen



Conversation Elements



Conversation Elements

Encouraging

- "Told me that with good care and effort, odds are good that I can live a long, healthy life with DM"
- "Told me a lot can be done to control my DM"

Collaborative

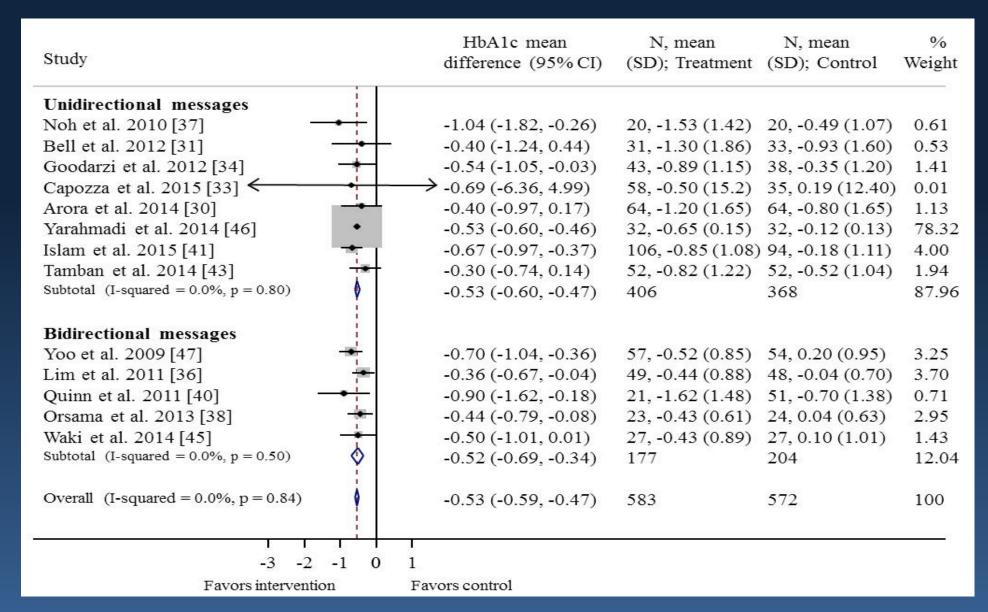
- "Helped to make a treatment plan that I could do in my daily life"
- "Helped to plan ahead so I could take care of my DM even in hard times"

SO WHAT TO DO?

- 1. Ask correctly
- 2. Forgetfulness
- 3. Treatment complexity
- 4. Provide hope
- 5. Patient-provider trust
- 6. Stay in touch



The Value of Ongoing Contact



SO WHAT TO DO?

- 1. Ask correctly
- 2. Forgetfulness
- 3. Treatment complexity
- 4. Provide hope
- 5. Patient-provider trust
- 6. Stay in touch
- 7. Talk about medication beliefs



Challenging Harmful Beliefs

- Out-of-control diabetes can harm you, even if you feel okay
- Treatment should not be delayed

Back on Track Feedback			Name: Molly B.	
<u>Tests</u>	<u>Usual Goals</u>	<u>Your</u> <u>Results</u>	FID #:	
	Your score should be		SAFE : At or better than goal	NOT SAFE: Not yet at goal
A1C	7.0% or less	8.7%		X
Blood Pressure	130/80	125/75	X	
Lipids	100 or less	116		X



Challenging Harmful Beliefs

- Out-of-control diabetes can harm you, even if you feel okay
- Treatment should not be delayed
- Discuss the critical "medication secrets"

Four Medication "Secrets"

- 1. Taking your meds is one of the most powerful things you can do to positively affect your health
- 2. Your meds are working even if you can't feel it
- 3. Needing more medication isn't your fault
- 4. More medication doesn't mean you are sicker, less medication doesn't mean you are healthier

PROS Control of the Contro



Take-Home Messages

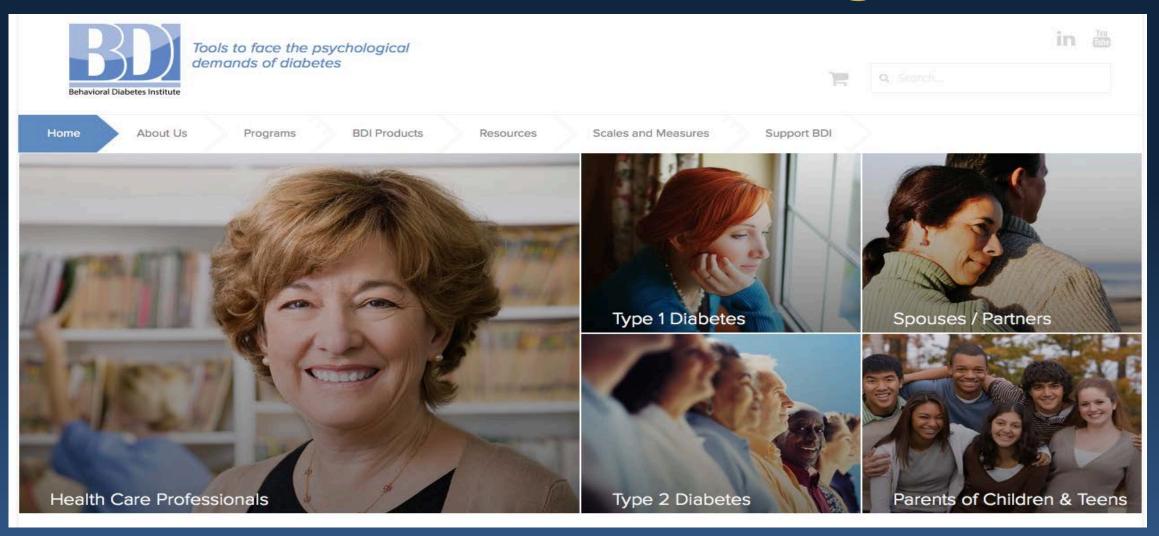
- 1. Ask correctly
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- 7. Talk about medication beliefs



One Step at a Time



Thanks for Listening



www.behavioraldiabetes.org