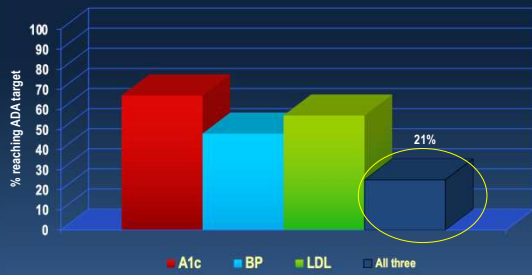


Addressing Problematic Medication Usage in Diabetes

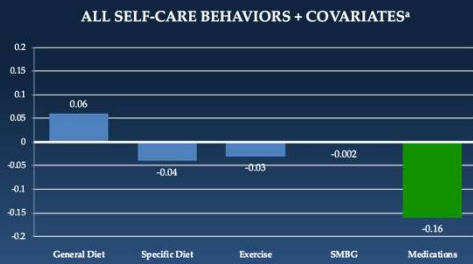
William H. Polonsky, PhD, CDCES
whp@behavioraldiabetes.org

Percentage of Patients Achieving ADA Treatment Targets



Wang et al, 2021

Behavioral Contributors to A1C

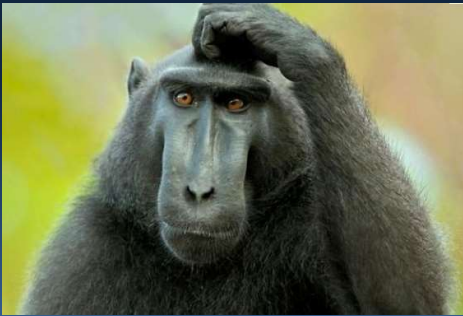


*Covariates: age, gender, race, ethnicity, income, education, insurance status, insulin status and duration of diabetes. HbA1c assessed with a point-of-care device. P<0.05 Osborn et al, 2016

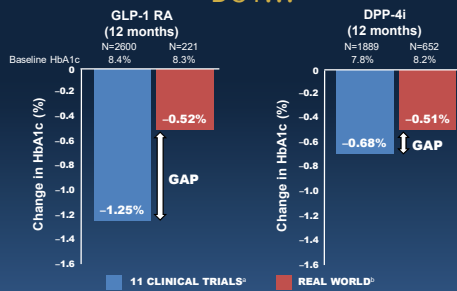
An Explosion in Options



Why Aren't We Seeing Dramatic Improvements?

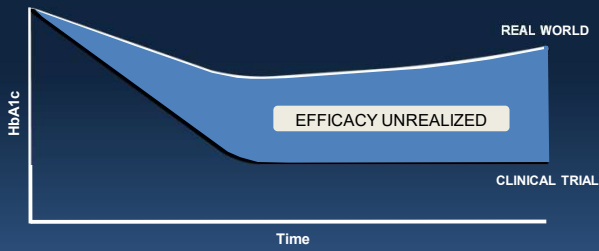


CLINICAL TRIAL RESULTS LOOK GOOD, BUT...

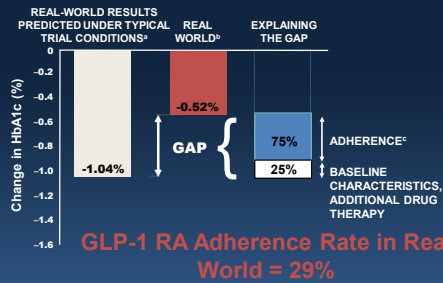


*Identified 11 pivotal randomized controlled trials with published change in HbA1c (7 GLP-1 RA [2000 patients] and 4 DPP-4i [1889 patients]).
*OptimaRx/medica SmartFile database (2007-2014) was used (GLP-1 RA 221 patients; DPP-4i 652 patients). Change in HbA1c measured from drug initiation to 30-90 days later.
Carlis et al. 2017

THE EFFICACY MIRAGE

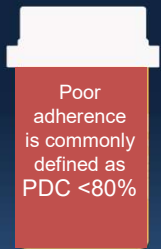


POOR ADHERENCE IS THE KEY



RCT, randomized clinical trial.
 *Linear regression model fitted to estimate the change in HbA1c 1 year after initiating GLP-1 RA or DPP-4 based on baseline and treatment characteristics.
 †Olan-T (Merck) SmartFAX database (2007-2014) was used (GLP-1 RA 221 patients, DPP-4 692 patients). Change in HbA1c measured from drug initiation to 365-90 days later. *Medical 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.

DEFINING POOR ADHERENCE



- Proportion of days covered
- Typically measured after first refill
- PDC doesn't account for
 - Prescriptions that are never filled at all¹
 - What the patient actually takes

1. Fischer MA et al. J Gen Intern Med. 2010;25:284-290.

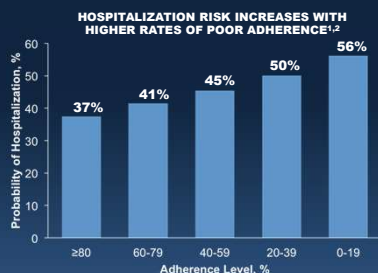
Persistence with Basal-Bolus Insulin Therapy

Conclusions

This study found that only 21%-22% of patients with T2DM were persistent with both basal and bolus insulin therapy over 1 year as defined by 2 different methods. Poor persistence with MDI was associated with greater medical costs, greater HCRU, and poorer glycemic control as compared with persistence among matched patient cohorts. Further research is necessary to standardize the definition of persistence using electronic databases, as well as to identify factors associated with insulin nonpersistence. Interventions are needed to improve basal and

n = 12,882 T2D, Edelman et al., 2019

Impact of Poor Adherence



73%
increased risk
of all-cause
mortality
due to poor
adherence to oral
hypoglycemics²

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. 78th 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

INTERVENTION STRATEGIES TO ADDRESS MEDICATION ADHERENCE

- Written medication instructions
- Goal setting
- Stimuli/prompts to take medications
- Enhancing support from significant others
- Special packaging of medications
- Self-monitoring of medication adherence
- Habit analysis and intervention

Conn and Rupar, 2017

EFFECTIVENESS OF CURRENT INTERVENTION STRATEGIES

Review of 771 RCTs indicate that effects are modest (Cohen's d):

- Overall: 0.29
- Behavioral strategies: 0.33
- Addressing habits: 0.37
- No behavioral strategies: 0.28



"Much room remains for improvement."

Conn and Ruppap, 2017

In Summary

- Only ~50% of patients with T2D have A1C <7%; this has not changed over the last decade
- Clinical trial outcomes are not replicated in the real world due primarily to poor adherence
- Common behavioral interventions not terribly effective



WHAT ARE WE MISSING?



THE PROBLEM: FORGETFULNESS?



THE SOLUTION: FIX FORGETFULNESS?



JAMA Internal Medicine | Original Investigation

Effect of Reminder Devices on Medication Adherence The REMIND Randomized Clinical Trial

Niteesh K. Choudhry, MD, PhD; Alexis A. Krumme, MS; Patrick M. Ercole, PhD, MPH; Charmaine Girdish, MPH; Angela Y. Tong, MS; Nazleen F. Khan, BS; Troyen A. Brennan, MD, JD, MPH; Olga S. Matlin, PhD; William H. Shrank, MD, MSHS; Jessica M. Franklin, PhD

- N = 52,294
- Multiple chronic disease conditions
- Taking ≤ 3 chronic disease medications
- Poorly adherent (MPR < 80%) to ≥ 1 medication

Effect of Reminder Devices on Medication Adherence The REMIND Randomized Clinical Trial

Niteesh K. Choudhry, MD, PhD; Alexis A. Krumme, MS; Patrick M. Ercole, PhD, MPH; Charmaine Girdish, MPH; Angela Y. Tong, MS; Nazleen F. Khan, BS; Troyen A. Brennan, MD, JD, MPH; Olga S. Matlin, PhD; William H. Shrank, MD, MSHS; Jessica M. Franklin, PhD

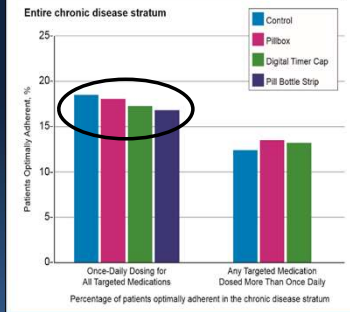
4 conditions:

1. Received nothing
2. Standard pillbox organizer
3. Pillbox strip with toggles
4. Pill bottle cap with digital timer



Choudhry et al., 2017

Optimal Adherence by Study Arm and Outcome Definition



“although forgetfulness is the most frequently reported barrier to adherence, this factor may not have been the primary driver of non-adherence in our study population.”

Choudhry et al., 2017

RESEARCH ARTICLE

Open Access

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

Abhijit S Gadkari¹ and Colleen A McHorney

“Patient’s medication beliefs, especially perceived need for medication and perceived medication affordability, were strong predictors of unintentional non-adherence.”

Gadkari and McHorney, 2012

MEDICINE AND SOCIETY

Debra Malina, Ph.D., Editor

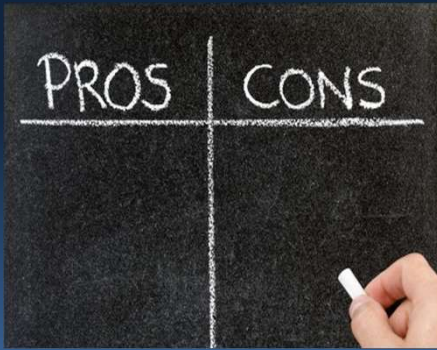
Beyond Belief — How People Feel about Taking Medications for Heart Disease

Lisa Rosenbaum, M.D.

“It’s our job to help patients live as long as possible free of CVD complications. Although most patients share that goal, we don’t always see the same pathways to get there. I want to believe that if patients knew what I know, they would take their medicine. What I’ve learned is that if I felt what they feel, I’d understand why they don’t.”

Rosenbaum, 2015

Necessity-Concerns Framework



Perceived Treatment Inefficacy



Lack of tangible benefits contributes to discouragement and poor adherence

1. Polonsky WH. J Diabetes. 2015;7:777-778. 2. Polonsky WH, Skinner TC. Clin Diabetes. 2010;28(2):89-92.

Out-of-Pocket Costs



Suspicious about Medications



T2D Patient Perspectives on OHAs

Six focus groups, n=50 T2D adults

- OHA intensification was perceived as:
 - Evidence of personal failure
 - Increasing risk of long-term complications (NOT a means towards reducing risk)
- De-intensification was viewed a primary goal
- No concerns about delaying intensification

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

Failure to Warn Claims


Invokana\Invokamet	Call Now If You Suffered
Farxiga	Ketoacidosis
Jardiance	Kidney Failure
Glyxambi	Heart Attack
Xigduo XR	Wrongful Death

1-888-LAW-2390

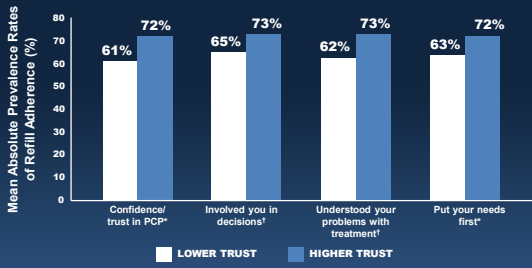


Why Such Negative Attitudes?

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



Lack of Physician Trust



Differences in prevalence of poor refill adherence for any cardiovascular medication in a cohort of 6377 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 (TPS) 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.
 Rabarawongsa N et al. JAMA Intern Med. 2013;173:210-219.

Not Seen as Urgent



Yes, I understand. Diabetes is a serious disease that could be harmful to my health.

And when something falls off or I start feeling bad, I'll be ready to work hard on this. But so far, so good!

SO WHAT TO DO?



THE Critical Skill: Ask Correctly

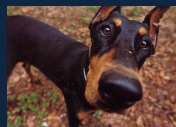
- NOT so good:
 - "Any problems taking those medications?"

THE Critical Skill: Ask Correctly

MUCH better:

- "What's one thing about taking your meds that's been challenging?"
- "What do you like and what do you dislike about those meds you've been prescribed?"
- "What's one thing about your diabetes medicines that bothers you, or concerns you?"

SO WHAT TO DO?



1. Ask correctly

2. Forgetfulness

- "Aside from forgetting, what else is tough about taking your meds?"
- Anchoring strategies
- Simplify the regimen

SO WHAT TO DO?



1. Ask correctly
2. Forgetfulness
3. Patient-provider trust and collaboration
 - Listen, listen, listen

Association Between Primary Care Practitioner Empathy and Risk of Cardiovascular Events and All-Cause Mortality Among Patients With Type 2 Diabetes: A Population-Based Prospective Cohort Study

Hajira Dambha-Miller, MRCGP,
PhD^{1,3}
Adina L. Feldman, PhD²
Ann Louise Kinnonth, FRCGP

ABSTRACT

PURPOSE To examine the association between primary care practitioner (physician and nurse) empathy and incidence of cardiovascular disease (CVD) events and all-cause mortality among patients with type 2 diabetes.

Dambha-Miller et al, 2019

Assessing Your HCPs' Empathy

How good was your HCP at:

1. making you feel at ease
2. letting you tell your story
3. really listening
4. being interested in you as a whole person
5. fully understanding your concerns
6. showing care and compassion
7. being positive
8. explaining things clearly
9. helping you to take control
10. making a plan of action with you

Dambha-Miller et al, 2019

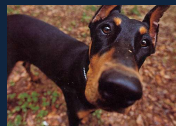
HCP Empathy and Mortality Outcomes

- 10-year follow up of patients with newly diagnosed T2D:
- "those reporting better experiences of empathy in the first 12 months after diagnosis had a significantly lower risk **(40% to 50%)** of all-cause mortality over the subsequent 10 years vs. those who experienced low practitioner empathy."

Dambha-Miller et al, 2019

SO WHAT TO DO?

1. Ask correctly
2. Forgetfulness
3. Patient-provider trust
4. Ask about beliefs about diabetes/meds
 - Perceived necessity (PROs)
 - Perceived concerns (CONS)





SO WHAT TO DO?



1. Ask correctly
2. Forgetfulness
3. Patient-provider trust
4. Ask about beliefs about diabetes/meds
5. Offer new information
 - Addressing perceived necessity (PROs)
 - Addressing perceived concerns (CONs)

Discussing "Necessity"

- "Of all the positive steps you could take, taking your diabetes med is one of the most powerful things you can do to improve your health."
- "This may surprise you, but your med are working even if you can't feel it. Looking at how your A1C changes over time can help us to see that."

Discussing "Concerns"

- "There are *always* pluses and minuses, but the minuses may not be as big as you think."
- "Needing all of these meds isn't because you have done anything wrong."
- "If you need more meds than the next person, this doesn't mean you're sicker; taking fewer meds doesn't mean you're healthier."

But What about Insulin?



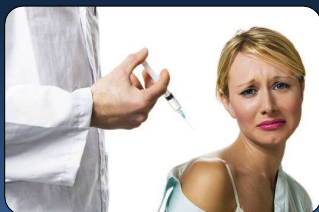
How Common is Initiation Delay?

- 3295 insulin-naïve T2Ds were identified who had been recommended insulin:
- 984 (29.9%) declined
- Of the 984 who declined, 374 (38%) eventually started insulin
- Of the 374 who finally initiated, mean time to insulin initiation was 790 days.

Hosomura et al, 2017

Key Initiation Obstacles

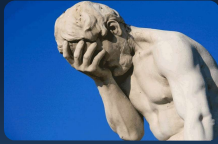
1. Injection pain and anxiety
 - Discomfort/apprehension with injections
 - Needle phobia



Key Initiation Obstacles

2. Personal failure

- “If I take insulin, it means I have failed, that I haven’t done a good enough job taking care of my T2D.”



Peyrot et al, 2005

Seven Initiation Obstacles

3. Concerns about adverse effects

- Negative influence on work/social life
 - “My friendships may suffer (46%).”
- Will lead to poorer health
 - IT “may cause hypo’s, weight gain, or perhaps serious problems with my eyes or kidneys.”
- Represents sickness
 - “Starting insulin means I’m sicker, and my diabetes will become a more serious disease.”

Yoshioka et al, 2013

1. Encourage an Immediate Injection

“Patients [n = 96]... found that giving an injection when insulin was introduced to be very helpful, yet in-office demonstration was reported by only one-half of the PCPs.”



Krall et al, 2015

2. Put Forward a Sense of Control

- The Insulin Challenge:

I'd like you to try insulin for just a month. At the end of the month, if you don't think its been worthwhile, or if it still seems as awful as you're imagining it might be, I promise to help you stop."



3. Ask/Address Personal Obstacles and Misbeliefs

What are some of the reasons why the idea of taking insulin seems so unpleasant to you?"



Addressing Insulin Misbeliefs

Obstacles	Discuss
It means I have failed	<ul style="list-style-type: none">• No matter what you do, you may need IT, because diabetes is "progressive"
I will get complications	<ul style="list-style-type: none">• Review those old family stories• Insulin is much more likely to reduce than raise complications risk
It means my diabetes is getting worse	<ul style="list-style-type: none">• Insulin helps control BG levels and thus keeps the disease from getting worse
Insulin won't help	<ul style="list-style-type: none">• List long-term benefits of good control• Nobel Prize not given for drugs that suck

CONCLUSIONS

Poor medication adherence:

- ... explains a great deal of poor cardiometabolic progress we've seen over the past decade
- ... is commonly an *attitudinal* issue, not just a behavioral issue.
- ... is best addressed by considering the patient's perspective, and encouraging a two-way conversation about the perceived pro's and con's of the medication.

Thanks for Listening!



Behavioral Diabetes Institute
www.behavioraldiabetes.org
