Welcome

Scott K. Winiecki, MD

Team Lead, FDA Safe Use Initiative, Professional Affairs and Stakeholder Engagement Staff (PASE)

FDA Public Workshop:
Reducing the Risk of Adverse Drug Events Associated with Hypoglycemia in the Older Population

Scott K. Winiecki, MD

Team Lead, Safe Use Initiative

Professional Affairs and Stakeholder Engagement

Center For Drug Evaluation and Research (CDER)

U.S. Food and Drug Administration

September 12, 2017

Disclosures

- I have nothing to disclose.

Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

Welcome

- Wi-Fi Network: FDA-Public
  - Passcode is "publicaccess"
- Opportunities for lunch are limited
  - Consider purchasing lunch from the kiosk to avoid lines at lunchtime

Safe Use Initiative

- **Mission:** Create and facilitate public and private collaborations within the healthcare community.

- **Goal:** Reduce *preventable harm* by developing, implementing, and evaluating cross sector interventions with partners committed to safe and appropriate medication use.

How do you Reduce Preventable Harm?

- Identify patients at highest risk
- Provider and facility feedback and/or self-assessment
- Make meds easier to use
- Patient education
- Improve communication

➢ **There is no "one size fits all" solution**

Safe Use Partners

- Federal agencies
- Healthcare professionals and professional societies
- Pharmacies, hospitals, and other health care entities
- Patients, caregivers, consumers, and their representative organizations

= Almost anyone

Drugs with Active Safe Use Projects

Safe Use has 16 current projects. These involve a wide variety of drugs and potential adverse events.

- Opioids
- Antibiotics
- Anti-hyperglycemic agents
- Stimulants
- Pediatric cough and cold medications
- Appearance and Performance Enhancing Substances
- NSAIDS

https://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm277720.htm

Themes for Today

- Bring everyone to the table
  - Patients, family and professionals who care for patients with diabetes, advocacy groups, professional organizations, industry, healthcare administrators, others
- Moving from ideas to action is challenging
- Individualizing care and evaluating medications
  - takes time and energy
  - Barriers exist at multiple levels
  - Inertia

FDA Safe Use Team Contact Information

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Christine Lee, PharmD, PhD

FDA Safe Use Initiative, PASE

Welcome

FDA Public Workshop

Reducing the Risk of Preventable Adverse Drug Events Associated with Hypoglycemia in the Older Population

September 12, 2017
8:00am - 4:30pm
WO Building 31, Room 1503

Hosted By:
Professional Affairs and Stakeholder Engagement (PASE)
Safe Use Initiative

Keynote Speaker:
Don Wright, MD, MPH
Acting Assistant Secretary for Health HHS
Office of the Secretary

FDA U.S. FOOD & DRUG ADMINISTRATION

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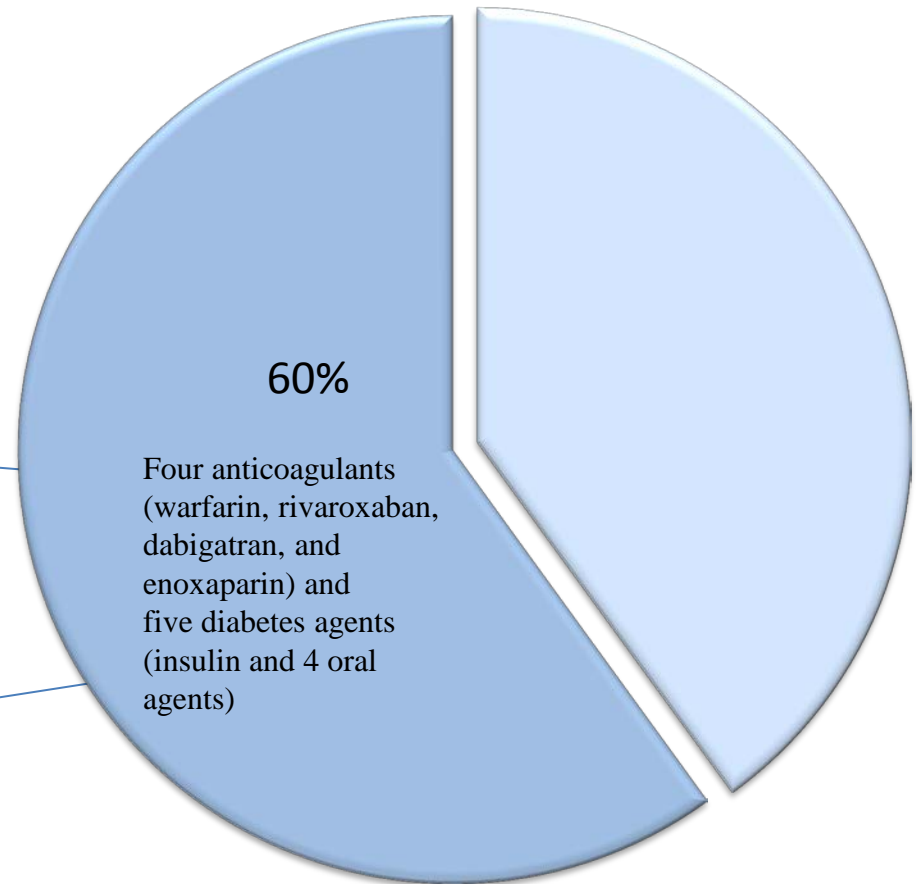
Why are we here today?
Focused Outpatient Medication Safety Efforts

"Of the thousands of drugs available to older adults, it is a really small group of medications that creates most of the hospitalizations."

Among older adults (**65 years and older**), **three drug classes were implicated in an estimated 60 percent of ED visits for adverse drug events**;
1. anticoagulants,
2. diabetes agents, and
3. opioid analgesics

60%

Four anticoagulants (warfarin, rivaroxaban, dabigatran, and enoxaparin) and five diabetes agents (insulin and 4 oral agents)

Ref: Shehab et al. **US Emergency Department Visits for Outpatient Adverse Drug Events, 2013-2014.** *JAMA.* 2016;316(20):2115-2125

FDA **U.S. FOOD & DRUG** ADMINISTRATION

Hypoglycemia

Insulin is the second most common drug associated with ER visits for adverse drug effects (ref: Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med* 2011;365:2002-2012.)

Increasing healthcare burden of hypoglycemia in the United States from 1999-2010. Rates of hospital admissions for hypoglycemia among Medicare beneficiaries increased by 22.3% (94 to 115 per 100,000 person years) compared to a 39.5% decrease in the rate of hyperglycemia admission (114 to 69 per 100,000 person-years)(ref: Lipska KJ, Ross JS, Wang Y et al. National trends in US hospital admissions for hyperglycemia and hypoglycemia among Medicare beneficiaries, 1999 to 2011. *JAMA Intern Med* 2014;174:1116-1124.)

Severe hypoglycemia may result in serious consequences like coma, seizures, and even death. (ref: Bonds DE, Miller ME, Bergenstal RM et al. The association between symptomatic, severe hypoglycaemia and mortality in type 2 diabetes: retrospective epidemiological analysis of the ACCORD study. *BMJ* 2010;340:b4909.)

Even mild hypoglycemic events have consequences, including lower health related quality of life, higher mortality, increased risk for cardiovascular disease, serious fracture related to falls, automobile crashes, and even a higher risk for dementia (ref: Bonds DE, Miller ME, Bergenstal RM et al. The association between symptomatic, severe hypoglycaemia and mortality in type 2 diabetes: retrospective epidemiological analysis of the ACCORD study. *BMJ* 2010;340:b4909.))

FDA U.S. FOOD & DRUG ADMINISTRATION

Why are we here today?

"**Targeting adverse drug events common among specific patient populations**, such as among the youngest (age 19 years or less) and **oldest (age 65 years and older),** may help further **focus outpatient medication safety efforts**" Shehab 2016

"The **question remains how to best leverage the existing system to improve the safety of the process of starting, monitoring, and discontinuing medications,**" Chad Kessler, M.D., M.H.P.E

"**Collaboration** is needed among **physicians** and **other health professionals** in primary care, specialty care, pharmacy, and emergency medicine to answer these questions in the **quest for safer models of patient care**. Furthermore, this **collaboration across health care locations and the continuum of care** will affect how much benefit or harm patients receive from prescribed medications. Integrated health care systems can help lead the way through improved care coordination and transition of care models. **The work by Shehab et al shines a spotlight on the problem of adverse drug events and highlights the need to address this important clinical issue in a more systematic and organized fashion.**" Chad Kessler, M.D., M.H.P.E

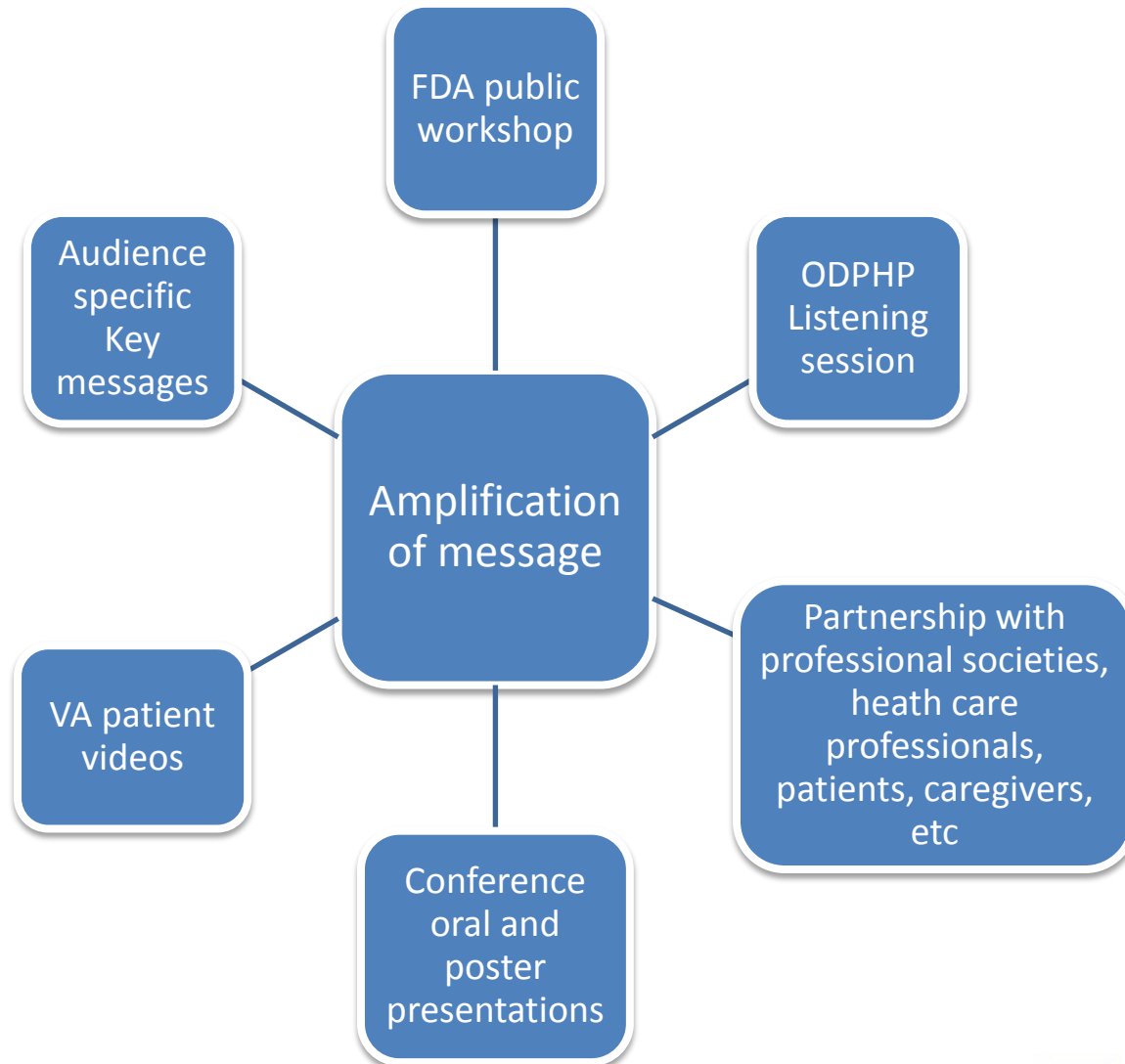Reference: https://media.jamanetwork.com/news-item/study-examines-rates-causes-of-emergency-department-visits-for-adverse-drug-events/

Call to Action!

Dissemination

Implementation

FDA U.S. FOOD & DRUG ADMINISTRATION

Leveraging FDA Safe USE partnerships in ACTION

Dissemination efforts

- FDA public workshop
- Audience specific Key messages
- ODPHP Listening session
- Amplification of message
- VA patient videos
- Partnership with professional societies, heath care professionals, patients, caregivers, etc
- Conference oral and poster presentations

FDA U.S. FOOD & DRUG ADMINISTRATION

Implementation efforts
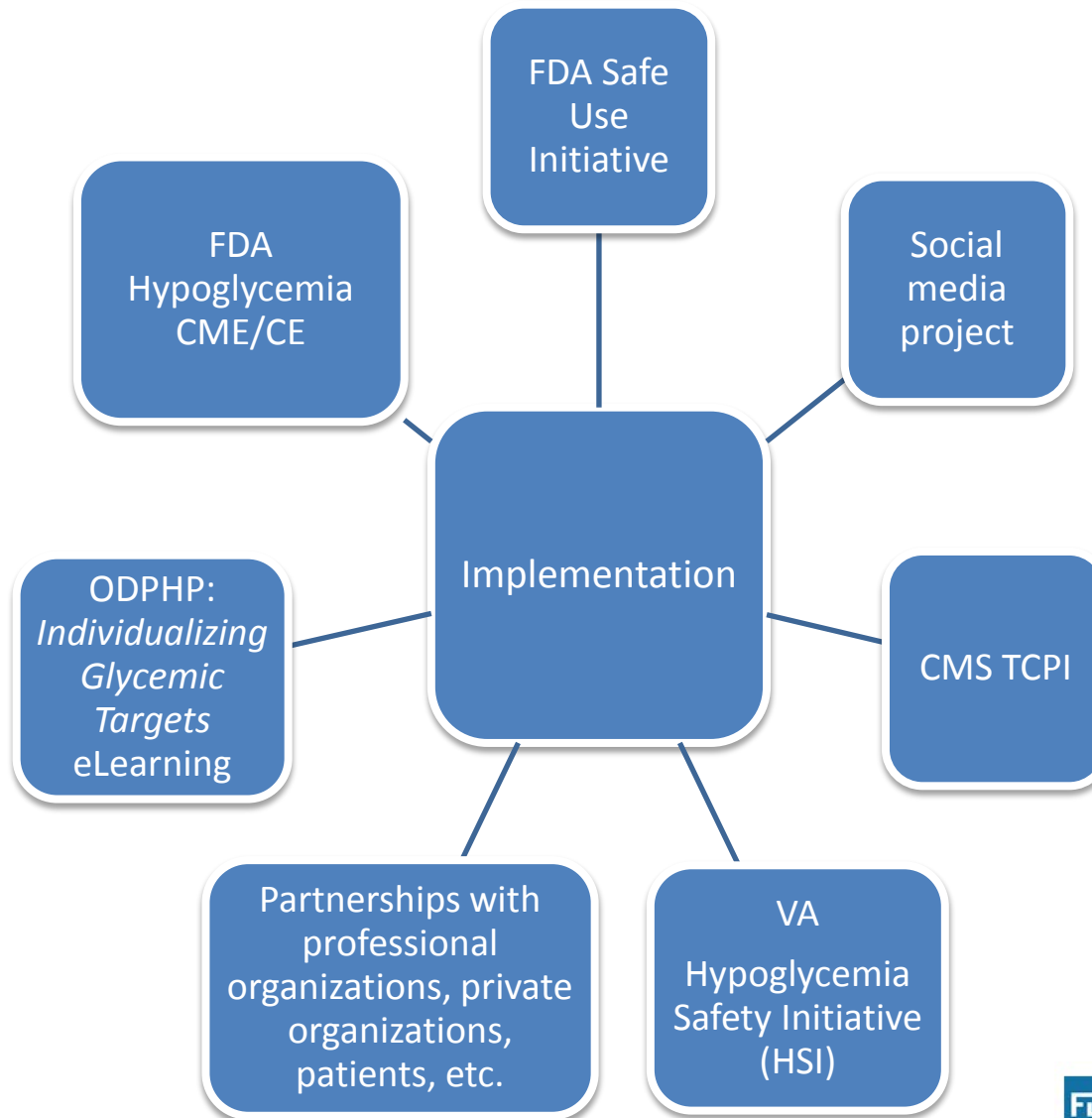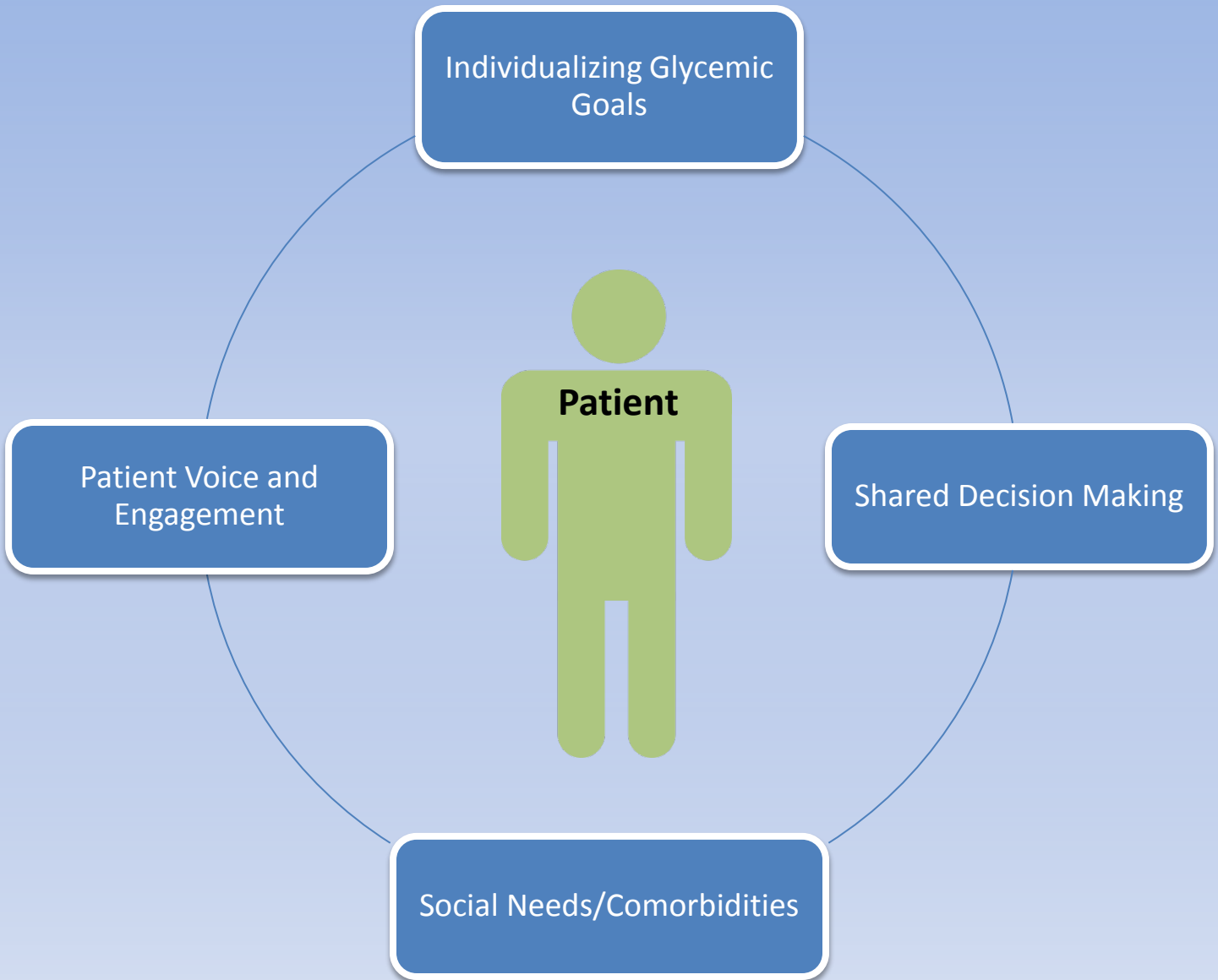
PUBLIC HEALTH BURDEN

Don Wright, MD, MPH

Keynote Speaker

Acting Assistant Secretary for Health

FDA Public Workshop

Reducing the Risk of Preventable Adverse Drug Events
Associated with Hypoglycemia in the Older Population

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**Don Wright,
MD, MPH**

Acting Assistant
Secretary for Health HHS
Office of the Secretary

Mary Julius RDN, CDE

Department of Veterans Affairs

HYPOGLYCEMIA AND FOOD INSUFFICIENCY

MARY M. JULIUS, RDN, CDE, PWD

OBJECTIVES

- Encourage individuals with diabetes to seek support to lower the risk of hypoglycemia.

- Enable all clinicians to recognize the importance of improving safety for food insecure patients at risk for hypoglycemia,

ARE YOU FOOD SECURE?

- During the last year, did you ever worry whether the food in your house would run out before there was money to get more?

- During the last year, was there ever a time when the food in the house just didn't last and there wasn't money to get more?
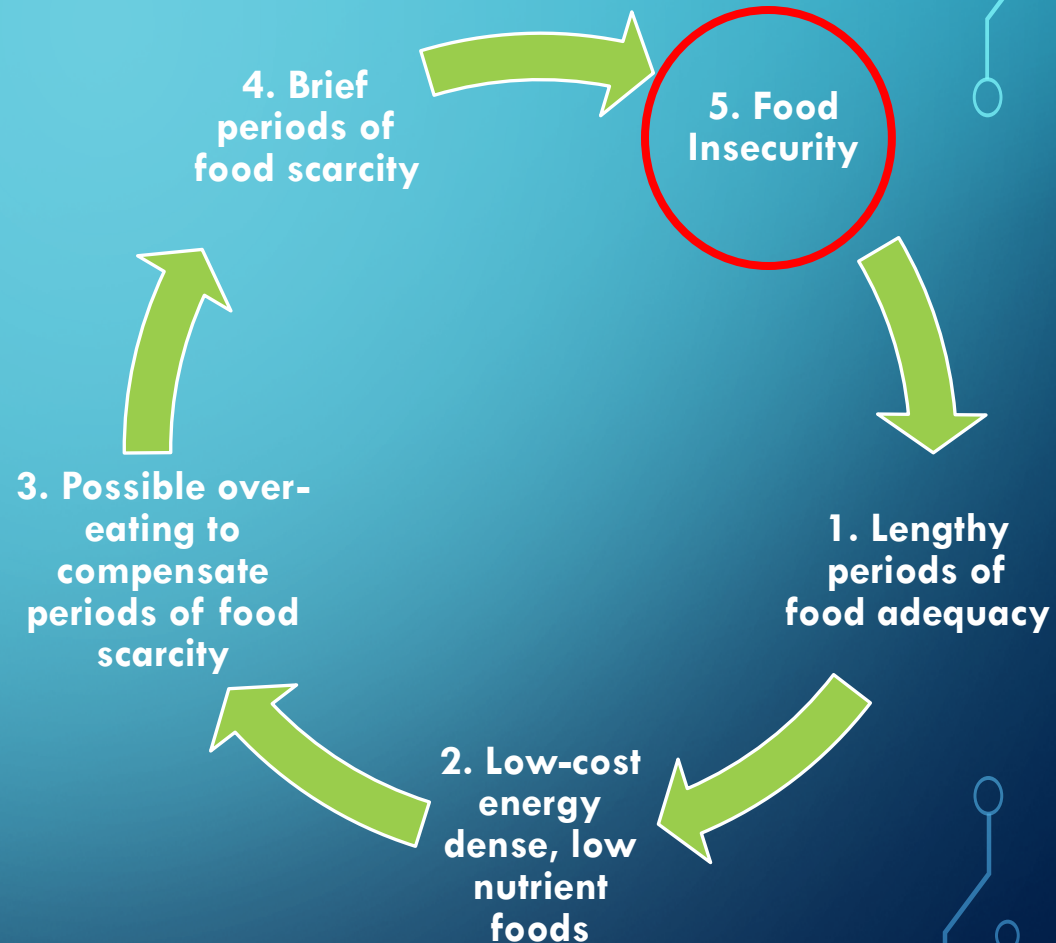
Do you know someone who would answer yes to either of these?

Does that person have diabetes?

- Cyclic and episodic phenomenon

- The average food-insecure household in the United States completes the above cycle _**7 times**_ each year.

May result from:

- High seasonal expenditures
  - heat cost & holiday spending in winter

- Divorce (**$35 per pay for food**)

- Loss of benefits (**COBRA**)

- Unforeseen expenditures (car, home, toilet, broken appliance, etc)

- Time away from work due to illness or injury

- "Pay cycle" phenomenon
  - Depleted funds by the end of month
  - SNAP, SSI, once a month retirement

4. Brief periods of food scarcity

5. Food Insecurity

3. Possible over-eating to compensate periods of food scarcity

1. Lengthy periods of food adequacy

2. Low-cost energy dense, low nutrient foods

SPOTTED ----- WAKE UP

32.8%
- Low-income households with incomes **below 185% of the poverty threshold**
  - The Federal poverty line was only $24,036 for a family of 4 in 2015.

30.3%
- Households with children headed by a **single woman**

22.4%
- Households with children headed by single man

21.5%
- Black, non-Hispanic households

19.1%
- Hispanic households
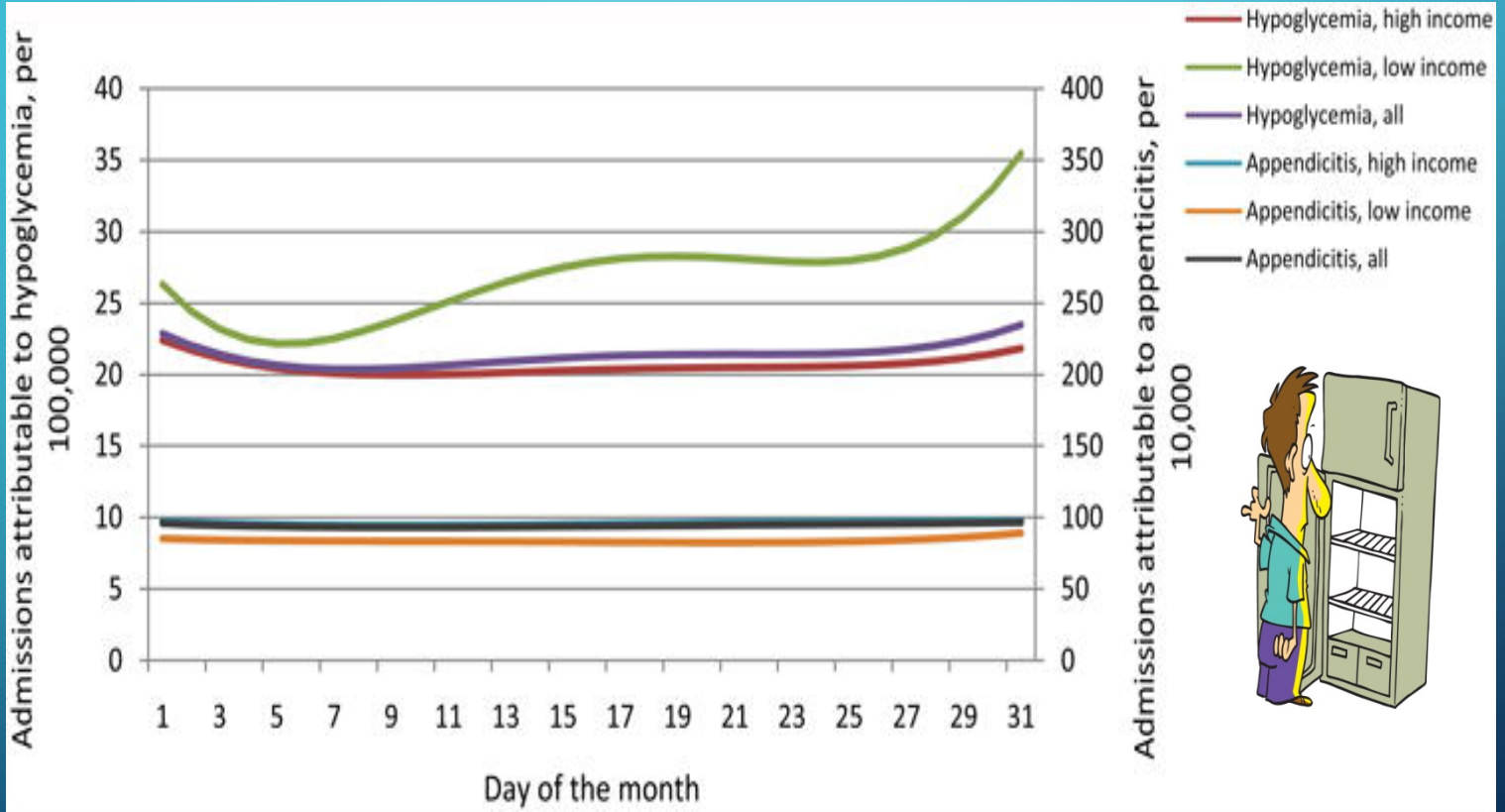
16.9%
- Households with children under age 6

16.6%
- All **households with children**

14.7%
- Women living alone

14%
- Men living alone

- The ADE Action Plan suggests a four-pronged approach to reduce patient harms:
- **Surveillance**
  - **We have an ICD-10 code Food Insufficiency ICD-10 59.3**
  - **We have validated questions.   Social Service and Nutrition.**
  - **Prevention**
  - **#1 cause of Hypoglycemia = missed or insufficient meal**
    - **MARKET; create risk mitigation education**
- **Incentives**
- **Oversight,** and **Research**

HOW I MET THE POPE

REFERENCES

1. "Health Care Quality and Patient Safety." *Home of the Office of Health Promotion and Disease Prevention.* U.S. Department of Health and Human Services, n.d. Web. 16 June 2016.

2. "National Action Plan for Adverse Drug Event Prevention." *Home.* U.S. Department of Health and Human Services, n.d. Web. 16 June 2016.

3. "Quality, Safety & Value." *Hypoglycemia Safety Initiative (HSI) - .* N.p., n.d. Web. 16 June 2016.

Andy Geller, MD

Centers for Disease Control and Prevention

Hypoglycemia Adverse Drug Events: Translating Data into Prevention

September 12, 2017

Andrew Geller, MD, LCDR USPHS
Medical Officer, CDC Medication Safety Program
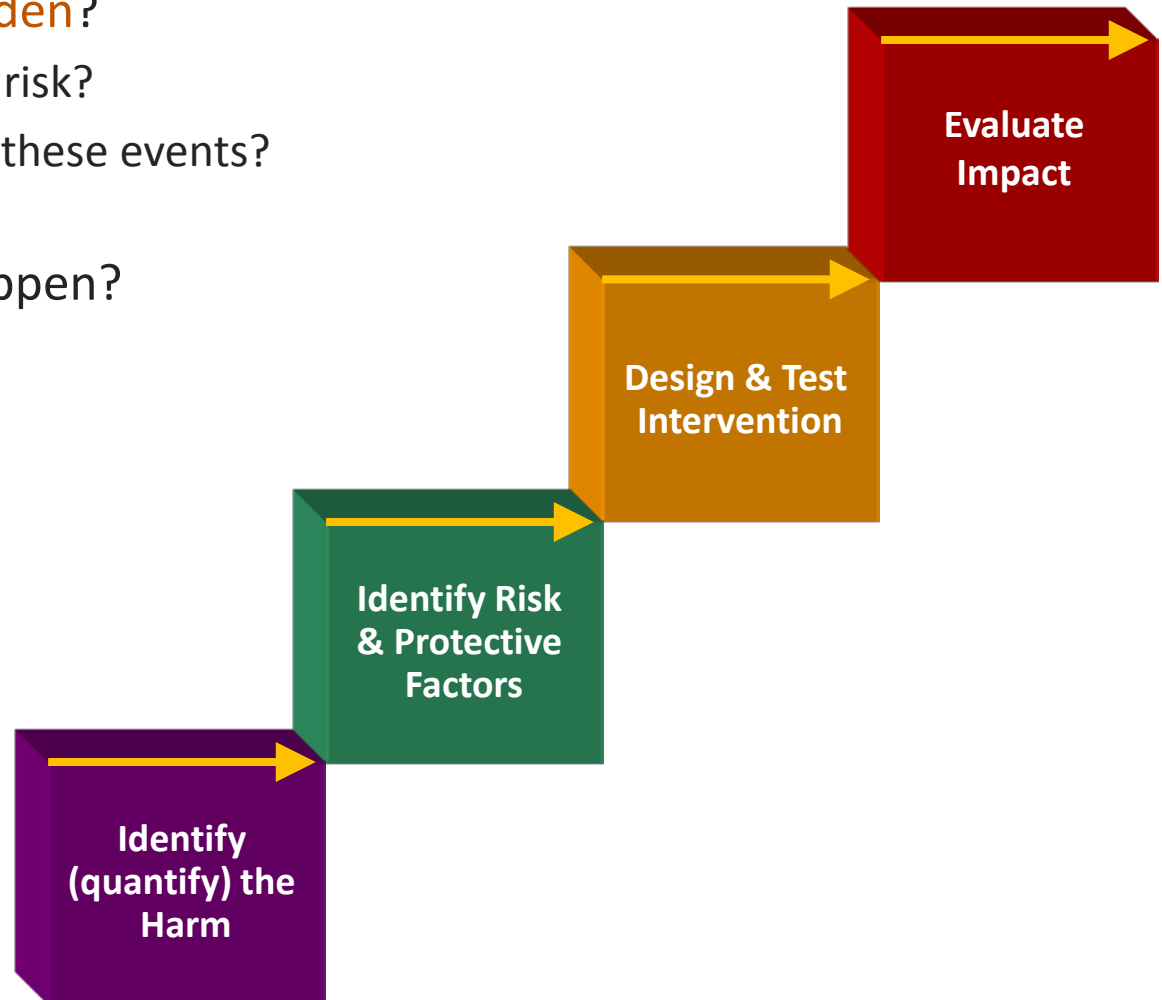
Disclosures

- None

- <u>Disclaimer</u>: The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC). Moreover, any use of trade names is for identification purposes only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.
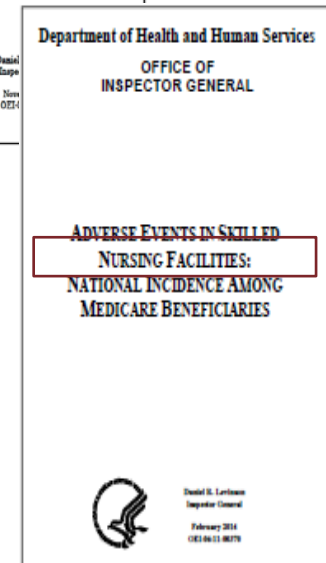
Objectives – Hypoglycemic Adverse Drug Events (ADEs)

- What is the national burden?
  - Who are the patients at risk?
  - How serious/severe are these events?

- Why do these events happen?
  - Precipitating factors
  - Products involved

- Important gaps?
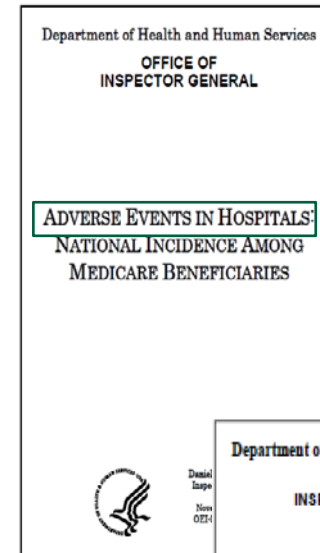 - Surveillance
  - Best Practice

Objectives – Hypoglycemic Adverse Drug Events (ADEs)

- **What is the national burden?**
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- **Why do these events happen?**
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  - Products involved

- **Important gaps?**
  - Surveillance
  - Best Practice

Evaluate Impact

Design & Test Intervention

Identify Risk & Protective Factors

Identify (quantify) the Harm

# How often do inpatients experience diabetes agent ADEs (hypoglycemia)?

- Hospitals:
  - 3rd most common ADE in a nationally-representative sample of hospitalized Medicare beneficiaries (2008)
  - 5 of 12 deaths due to all adverse events (drug and non-drug related) involved hypoglycemia

- Skilled Nursing Facilities (SNFs):
  - 1st most common ADE in a nationally-representative sample of SNF resident Medicare beneficiaries (2011)

HHS Office of Inspector General (OIG). Washington, DC. November 2010. Report No.: OEI-06-09-00090.
HHS Office of Inspector General (OIG). Washington, DC. February 2014. Report No.: OEI-06-11-00370.

# How often do outpatients seek care for all ADEs?

- 4 per 1,000 population (ED Visits)
- Older adults have highest rate
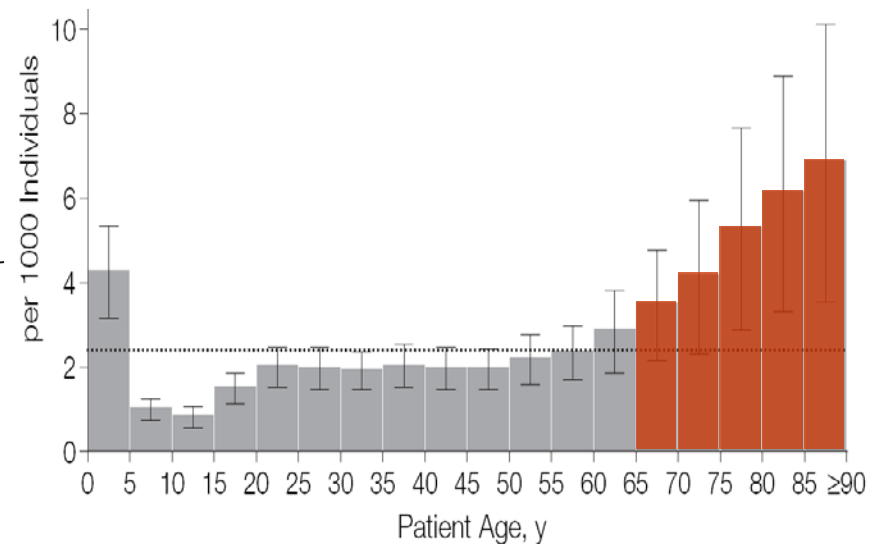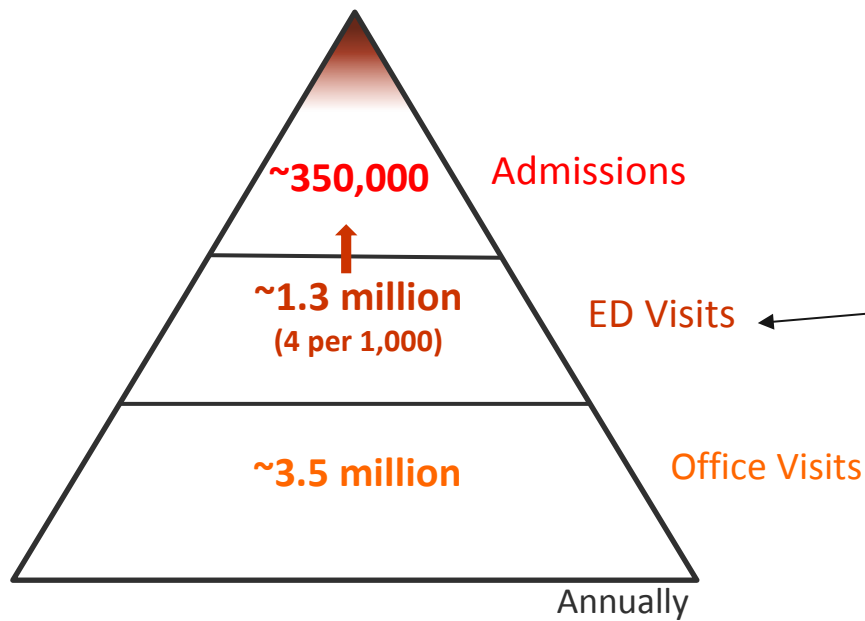
Shehab N et al. *JAMA* 2016;316:2115-25
Budnitz DS et al. *JAMA* 2006;296:1858-66
Bourgeois FT et al. *Pharmacoepidemiol Drug Saf* 2010;19:901–10

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How often do outpatients seek care for diabetes agent ADEs?

- Diabetes agents:
  - ~13% ADE ED Visits (170,000/yr) in 2013-2014
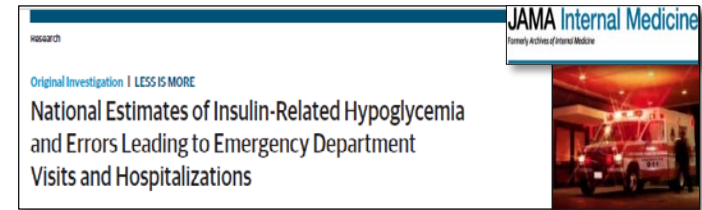   - ~1/3 resulted in hospitalization

~66,000 — Admissions (Diabetes Agents)

~170,000 — ED Visits (Diabetes Agents)

Office Visits

Annually
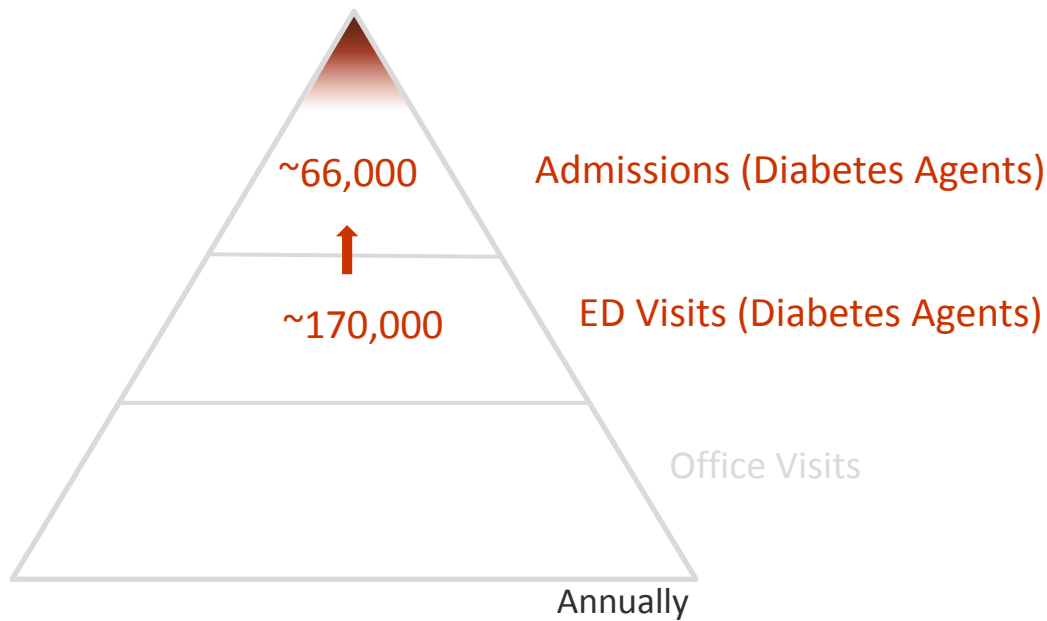
Insulin: second most commonly implicated drug in ADE ED visits

Table 3. US Emergency Department (ED) Visits for Adverse Drug Events (ADEs) From the Most Commonly Implicated Drug Products by Patient Age, 2013-2014[a]

Drug Product	ED Visits for ADEs	
	No. of Cases	National Estimate, % (95% CI)[b]
All Patients (N = 42 585)		
Warfarin	6179	15.1 (12.3-17.9)
Insulin	4859	10.7 (8.6-12.7)
Clopidogrel	1778	4.4 (2.9-5.9)
Amoxicillin	1780	3.8 (3.3-4.3)
Aspirin	1518	3.5 (2.2-4.9)
Sulfamethoxazole-trimethoprim	1152	3.2 (2.7-3.7)
Lisinopril	1096	2.4 (1.8-3.0)
Metformin	766	1.7 (1.4-2.1)
Ibuprofen	722	1.6 (1.3-2.0)

Shehab N et al. *JAMA* 2016;316:2115-25.

How serious are insulin ADEs?

National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations
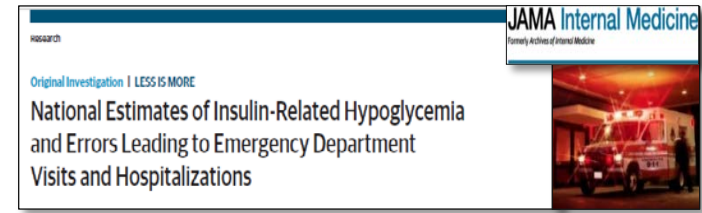
- **Severe hypoglycemic sequelae**
  - ~61% ADE ED visits (~56,000 ADE ED visits) in 2007-11
  - ~1/3 resulted in hospitalization

Case Characteristic	Annual National Estimate of ED Visits for IHEs, % (95% CI)
Clinical presentation of event	
Hypoglycemia	95.4 (93.6-97.2)
With shock, loss of consciousness, or seizure	23.2 (15.5-31.0)
With fall or injury	5.1 (3.7-6.4)
With altered mental status	32.3 (20.6-44.0)
With other neurologic sequelae	4.8 (3.3-6.3)
With presyncope/syncope	4.4 (3.3-5.6)
With other sequelae	5.6 (3.8-7.4)
Without specific sequelae documented	20.0 (13.4-26.6)
No hypoglycemia documented[d]	4.6 (2.8-6.4)
Discharge disposition[e]	
Admitted, transferred, or held for observation	29.3 (21.8-36.8)
Treated and released, or left against medical advice	70.7 (63.2-78.2)

Geller A et al. *JAMA Internal Medicine* 2014;174(5):678-686.

How serious are insulin ADEs?

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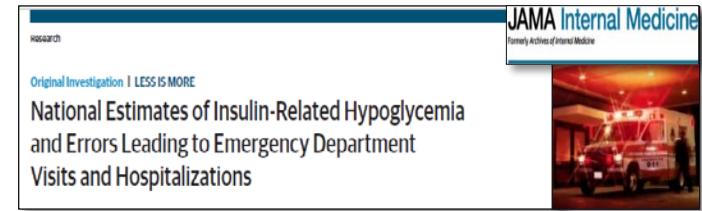
- **Severe hypoglycemic sequelae**
  - ~61% ADE ED visits (~56,000 ADE ED visits) in 2007-11
  - ~1/3 resulted in hospitalization

- **Oldest adults** (aged ≥80 years):
  - ~2.5x as likely to visit ED (as age 45-64)
  - ~Five times more likely to be hospitalized

Patient Characteristic	Annual National Estimate	
	Persons With DM Receiving Insulin Treatment With or Without Oral Antidiabetic Agents, No. (%)	ED Visits per 1000 Persons With DM Receiving Insulin Treatment With or Without Oral Antidiabetic Agents, Rate (95% CI)
Age, y		
<18[b]	152 555 (2.8)	13.7 (4.9-22.5)
18-44	871 150 (15.9)	24.3 (15.0-33.6)
45-64	2 492 704 (45.5)	13.7 (9.1-18.3)
65-79	1 515 077 (27.7)	16.3 (10.7-21.9)
≥80	443 497 (8.1)	34.9 (20.5-49.3)
Total	5 474 983 (100.0)	17.8 (11.8-23.8)

Geller A et al. *JAMA Internal Medicine* 2014;174(5):678-686.

Why do insulin ADEs happen?

National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations
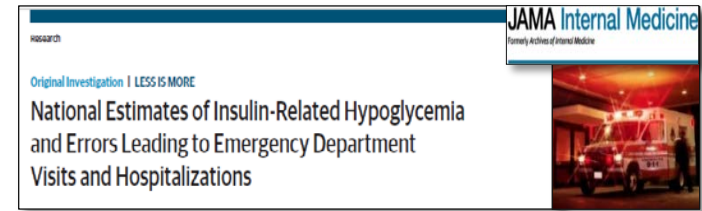
- Precipitating factors documented in 21% of ED visits for hypoglycemia:
  - Meal-related (45.9%)
  - Wrong insulin (22.1%)
  - Wrong dose / confused units (12.2%)
  - Additional ("extra") dose (6.0%)
  - Pump misadventure (1.5%)
  - Other (13.4%)

→

- *75-year-old male with syncope, EMS found patient with blood glucose in the 20s. Per wife, patient has been having low blood glucose and it has been difficult to keep elevated. … has not been eating enough. Diagnosis: hypoglycemia.*

Why do insulin ADEs happen?

National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations
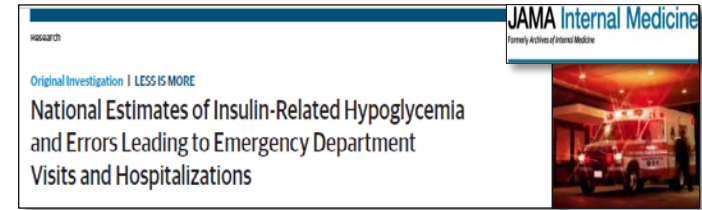
- Precipitating factors for ED visits:
  - Meal-related (45.9%)
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  - Additional ("extra") dose (6.0%)
  - Pump misadventure (1.5%)
  - Other (13.4%)

In one-half* of these ED visits, took rapid-acting instead of long-acting:

- *51-year-old male, per spouse she injected patient with 50 units of NovoLog instead of 50 units of Lantus, blood glucose 33 at time of arrival. Diagnosis: hypoglycemia.*

*National estimate: 52.3% (95% CI: 42.5%-62.0%).

Why do insulin ADEs happen?

National Estimates of Insulin-Related Hypoglycemia and Errors Leading to Emergency Department Visits and Hospitalizations

- Precipitating factors for ED visits:
  - Meal-related (45.9%)
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Other cases involved mixups of other insulin types:

- *67-year-old male accidentally took wrong medication. Confused Humalog insulin with Humulin insulin, blood glucose 36. Diagnosis: hypoglycemia.*

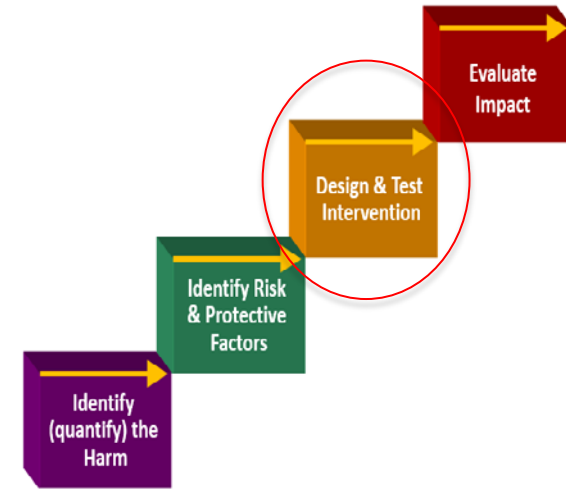Geller A et al. *JAMA Internal Medicine* 2014;174(5):678-686.

Prevention gaps: Surveillance

- Gap: National estimates of hypoglycemia underestimate the problem
  - Surveillance/research need: Identify frequency of self-reported hypoglycemia
  - Validate methods of asking about hypo episodes not presenting to ED or leading to hospitalization

- Gap: Knowledge of hypoglycemia precipitating factors that are most modifiable
  - Identify modifiable factors
  - Focus prevention efforts
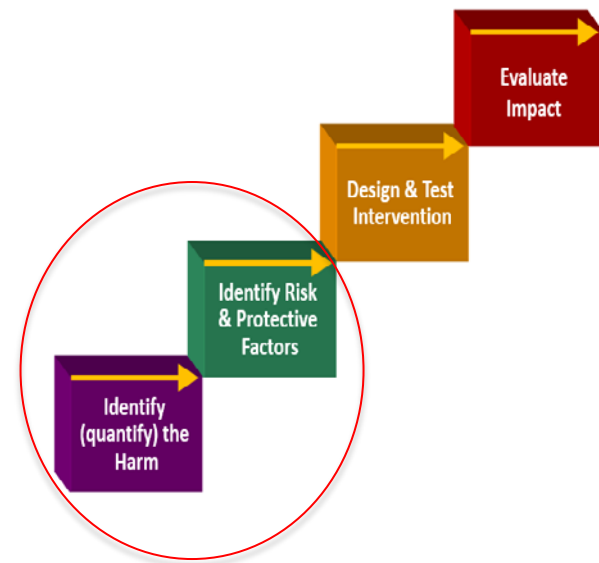
Prevention gaps: Interventions

- Reduce errors that cause harm:
  - Design and test insulin delivery systems that prevent mixups
    - Packaging to distinguish <u>rapid</u>- and <u>long</u>-acting products
      - Differences in shape, color, and texture to improve product distinction?
      - Audible (electronic voice instructions) or visible cues (LED lights)?

Prevention gaps: Interventions

Pens   **Vials**

- Reduce errors that cause harm:
  - Design and test insulin delivery systems that prevent mixups
    - Packaging to distinguish <u>rapid</u>- and <u>long</u>-acting products
      - Differences in shape, color, and texture to improve product distinction?
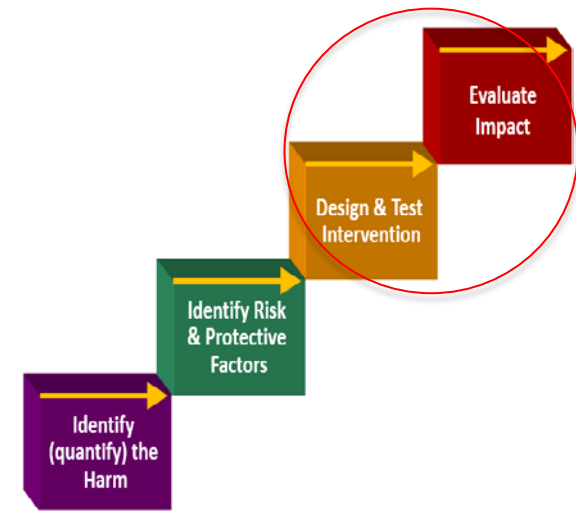   - Audible (electronic voice instructions) or visible cues (LED lights)?

Prevention gaps: Interventions

- Increase uptake of Best Practices
  - Toolkits for older adults
    - Example: VA *Clinicians' Toolkit*

  - Toolkits for patients in nursing homes
    - *Example:* CDC *Core Elements of Outpatient Antibiotic Stewardship for Nursing Homes*

- Are they effective for outcomes that matter to patients?

Prevention gaps: Interventions

- Increase uptake of Best Practices
  - Toolkits for older adults
    - Example: VA *Clinicians' Toolkit*

https://www.qualityandsafety.va.gov

  - Toolkits for patients in nursing homes
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http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html
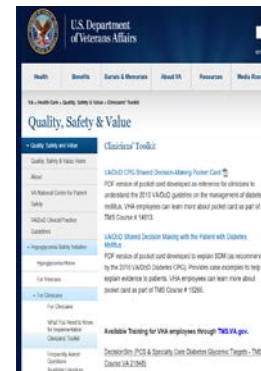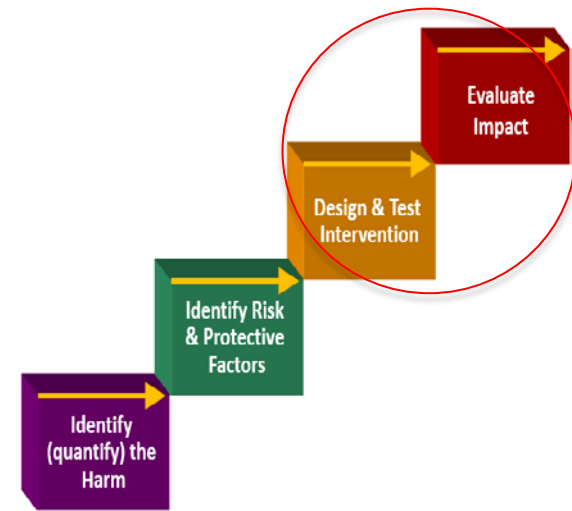
- Are they effective for outcomes that matter to patients?

Thank you

- CDC Medication Safety Program:
  - CAPT Dan Budnitz, MD, MPH
  - Nadine Shehab, PharmD, MPH
  - Maribeth Lovegrove, MPH
  - Katie Rose, BSN
  - Sandra Goring, RN
  - Nina Weidle, PharmD
  - Arati Baral, MS
  - Alex Tocitu, BS, MBA
  - Dee Slaughter

Evidence based guidelines: importance of individualized glycemic control targets for older patients with diabetes

Gerardo Moreno, MD

American Geriatric Society

Len Pogach MD, MPH

Department of Veterans Affairs

The Veterans Administration/Department of Defense 2017 Guidelines for Management of Type 2 Diabetes
Implementing Evidence to Prevent Hypoglycemia

Presented by Leonard Pogach MD, MBA, FACP

National Director Medicine

Office of Specialty Care Services

Office of Policy and Services

Veterans Health Administration

Collaborators

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Mark McConnell   VA/UPMI

Storm Morgan   VACO

Rose Mary Pries   VHA NCP

Jim Warner   VHA EES

Sharon Watts PhD   VA/Cleveland

Samantha Wright PharmD   VA/Chicago

VA/DoD Guideline Working Group

VA/DoD Guidelines 2003

- The target **value for an individual patient** considers the approximate risk-to-benefit ratio of the treatment necessary to achieve it

- Health care providers and their patients to establish individually negotiated targets based on **personal preferences** and **individually appraised risks and benefits.**

- **Intensive glycemic control** is known to **increase** the incidence and severity of **hypoglycemia**.

VA HEALTH CARE | Defining **EXCELLENCE** in the 21st Century

U.S. Department of Veterans Affairs

At-Risk Veterans - FY 2017

1 in 4 Veterans (1.6 million) receiving care in the VA has **diabetes**

70% of Veterans with diabetes are 65 and older

About **30%** of older Veterans receive insulin

60% have serious co-morbid conditions

Provided by: *VHA Support Service Center* (VSSC in the office of Organizational Excellence. April 2017)

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VA/DoD CPG Management of Type 2 Diabetes- April 2017 www.healthquality.va.gov

Process: Evidence Review Conducted by ECRI Institute, Lewin Group Project Management
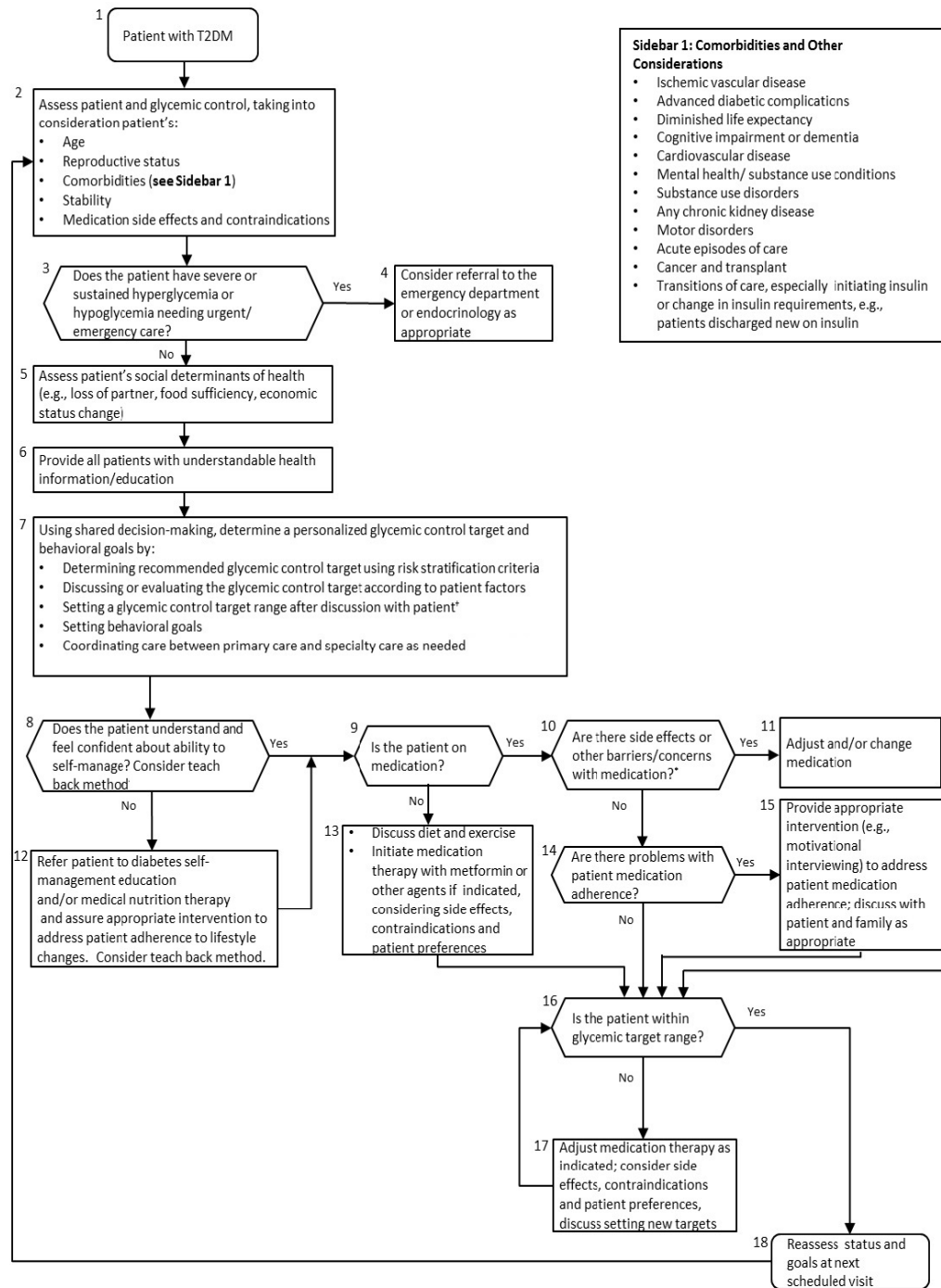
- Interdisciplinary group of Guideline Champions and Workgroup Members
- Peer-Reviewed by FDA, CMS, HHS, NIH, Academy of Nutrition and Dietetics
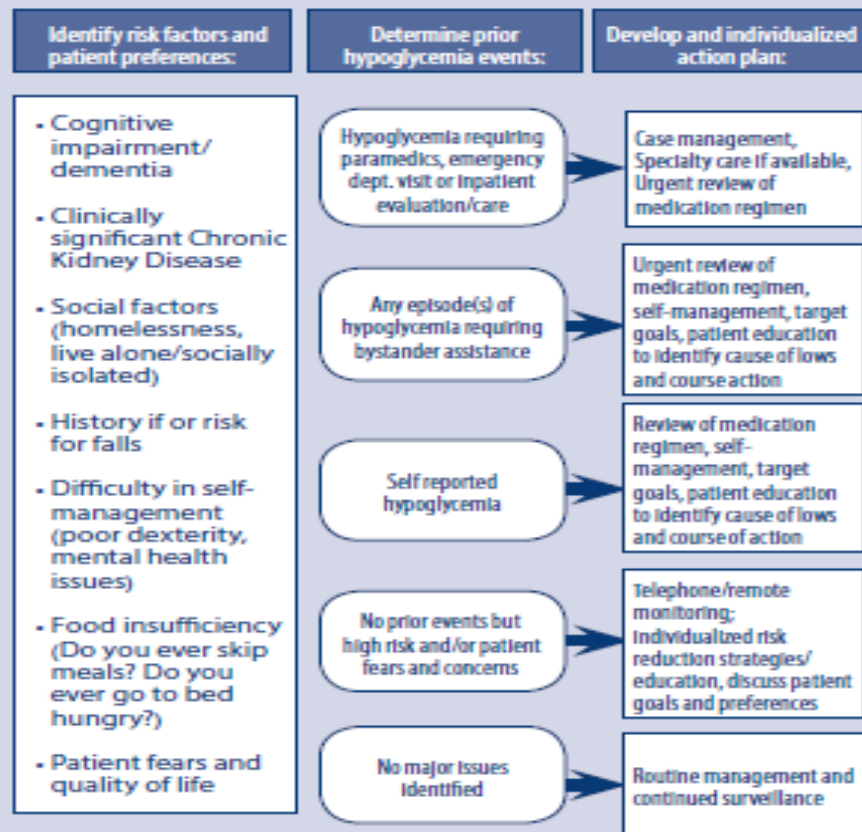
Target Audience

- Physicians, nurse practitioners, nurses, physician assistants, dietitians/nutritionists, diabetes educators, pharmacists, and others
- Primary Care Setting

KEY RECOMMENDATIONS:

- Emphasize shared decision-making
- Assess the patient factors and establish individual glycemic goals
- Glycemic Goals should be a range, not a number.
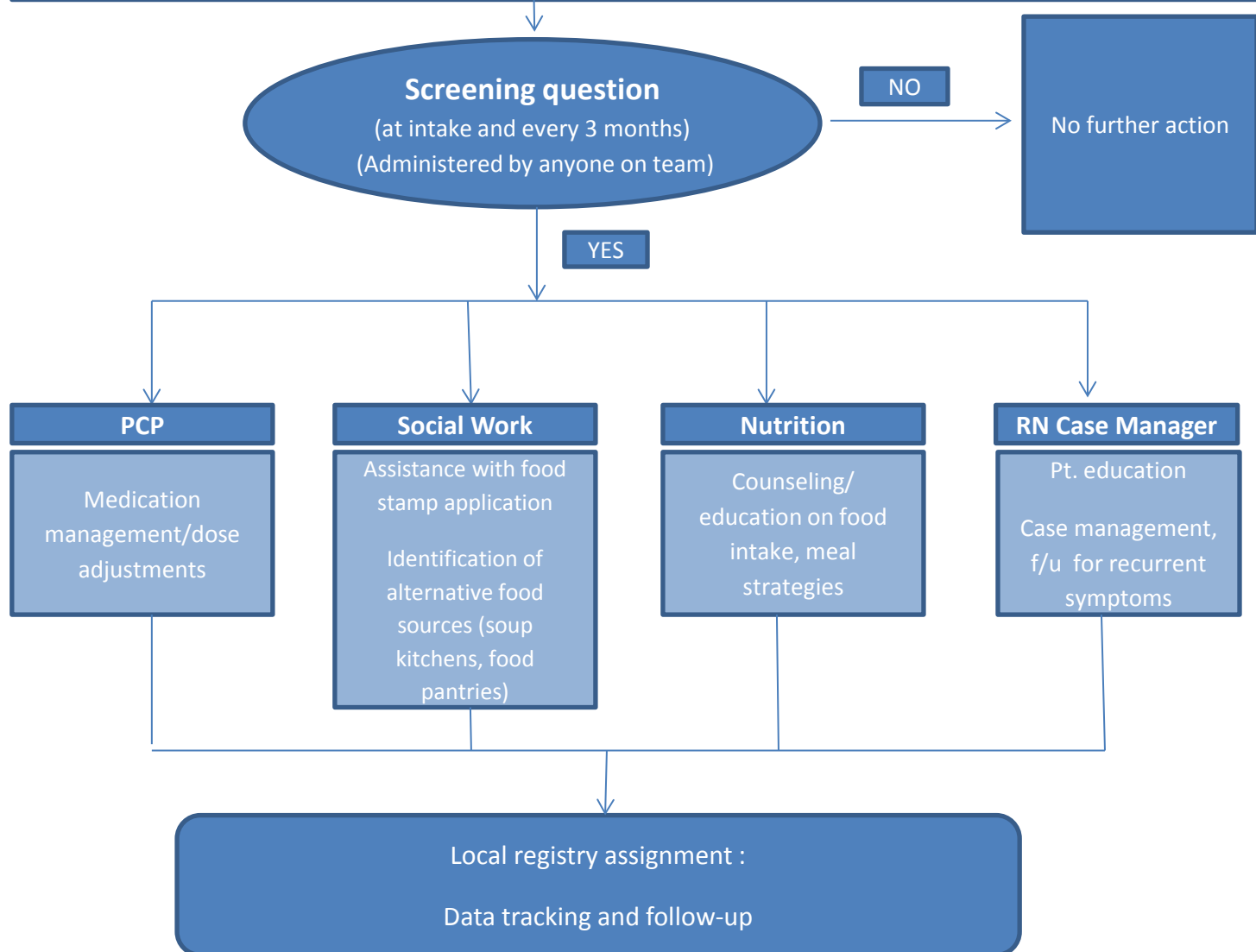- Understand interpretation of the HbA1c test, including racial differences

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1 Patient with T2DM

2 Assess patient and glycemic control, taking into consideration patient's:
- Age
- Reproductive status
- Comorbidities (**see Sidebar 1**)
- Stability
- Medication side effects and contraindications

3 Does the patient have severe or sustained hyperglycemia or hypoglycemia needing urgent/emergency care? — Yes →

4 Consider referral to the emergency department or endocrinology as appropriate

No ↓

5 Assess patient's social determinants of health (e.g., loss of partner, food sufficiency, economic status change)

6 Provide all patients with understandable health information/education

7 Using shared decision-making, determine a personalized glycemic control target and behavioral goals by:
- Determining recommended glycemic control target using risk stratification criteria
- Discussing or evaluating the glycemic control target according to patient factors
- Setting a glycemic control target range after discussion with patient*
- Setting behavioral goals
- Coordinating care between primary care and specialty care as needed

8 Does the patient understand and feel confident about ability to self-manage? Consider teach back method — Yes →

9 Is the patient on medication? — Yes →

10 Are there side effects or other barriers/concerns with medication?* — Yes →

11 Adjust and/or change medication

No (from 8) ↓

12 Refer patient to diabetes self-management education and/or medical nutrition therapy and assure appropriate intervention to address patient adherence to lifestyle changes. Consider teach back method.

No (from 9) ↓

13
- Discuss diet and exercise
- Initiate medication therapy with metformin or other agents if indicated, considering side effects, contraindications and patient preferences

No (from 10) ↓

14 Are there problems with patient medication adherence? — Yes →

15 Provide appropriate intervention (e.g., motivational interviewing) to address patient medication adherence; discuss with patient and family as appropriate

No (from 14) ↓

16 Is the patient within glycemic target range? — Yes →

No ↓

17 Adjust medication therapy as indicated; consider side effects, contraindications and patient preferences, discuss setting new targets

18 Reassess status and goals at next scheduled visit

Sidebar 1: Comorbidities and Other Considerations
- Ischemic vascular disease
- Advanced diabetic complications
- Diminished life expectancy
- Cognitive impairment or dementia
- Cardiovascular disease
- Mental health/ substance use conditions
- Substance use disorders
- Any chronic kidney disease
- Motor disorders
- Acute episodes of care
- Cancer and transplant
- Transitions of care, especially initiating insulin or change in insulin requirements, e.g., patients discharged new on insulin

RISK STRATIFICATION TOOL FOR HYPOGLYCEMIA AND ACTION STEPS

Identify risk factors and patient preferences:	Determine prior hypoglycemia events:	Develop and individualized action plan:
- Cognitive impairment/ dementia - Clinically significant Chronic Kidney Disease - Social factors (homelessness, live alone/socially isolated) - History if or risk for falls - Difficulty in self-management (poor dexterity, mental health issues) - Food insufficiency (Do you ever skip meals? Do you ever go to bed hungry?) - Patient fears and quality of life	Hypoglycemia requiring paramedics, emergency dept. visit or inpatient evaluation/care →	Case management, Specialty care if available, Urgent review of medication regimen
	Any episode(s) of hypoglycemia requiring bystander assistance →	Urgent review of medication regimen, self-management, target goals, patient education to identify cause of lows and course action
	Self reported hypoglycemia →	Review of medication regimen, self-management, target goals, patient education to identify cause of lows and course of action
	No prior events but high risk and/or patient fears and concerns →	Telephone/remote monitoring; Individualized risk reduction strategies/ education, discuss patient goals and preferences
	No major issues identified →	Routine management and continued surveillance

This tool will assist clinicians to assess and address patients' risk for hypoglycemic events of any severity while using oral hypoglycemic prone medications or insulin. Use this tool to increase your awareness of hypoglycemia as a common and important, yet potentially preventable, complication of therapy. It should not be used as a clinical guideline.

Food insecurity Screening Algorithm. **In the 3 months, were there times when the food for you just did not last and there was no money to buy more?**

Screening question
(at intake and every 3 months)
(Administered by anyone on team)

NO → No further action

YES

PCP
Medication management/dose adjustments

Social Work
Assistance with food stamp application

Identification of alternative food sources (soup kitchens, food pantries)

Nutrition
Counseling/ education on food intake, meal strategies

RN Case Manager
Pt. education

Case management, f/u for recurrent symptoms

Local registry assignment :

Data tracking and follow-up

Key Recommendations of 2017 VA/DoD Diabetes Guidelines- Shared Decision Making

#	Recommendation	Strength	Category
B. Shared Decision Making			
4.	SDM should be included, at a minimum, at the time of diagnosis, during difficulties with management, and at times of transition or development of complications	Strong for	Reviewed, New-added

- Greater knowledge of medications and understanding of risks.

- Decrease patient anxiety, increase trust in clinicians, and improve treatment adherence

AHRQ SHARE APPROACH

1. Seek your patient's participation

2. Help your patient explore and compare treatment options

3. Assess your patient's values and preferences

4. Reach a decision with your patient

5. Evaluate your patient's decision
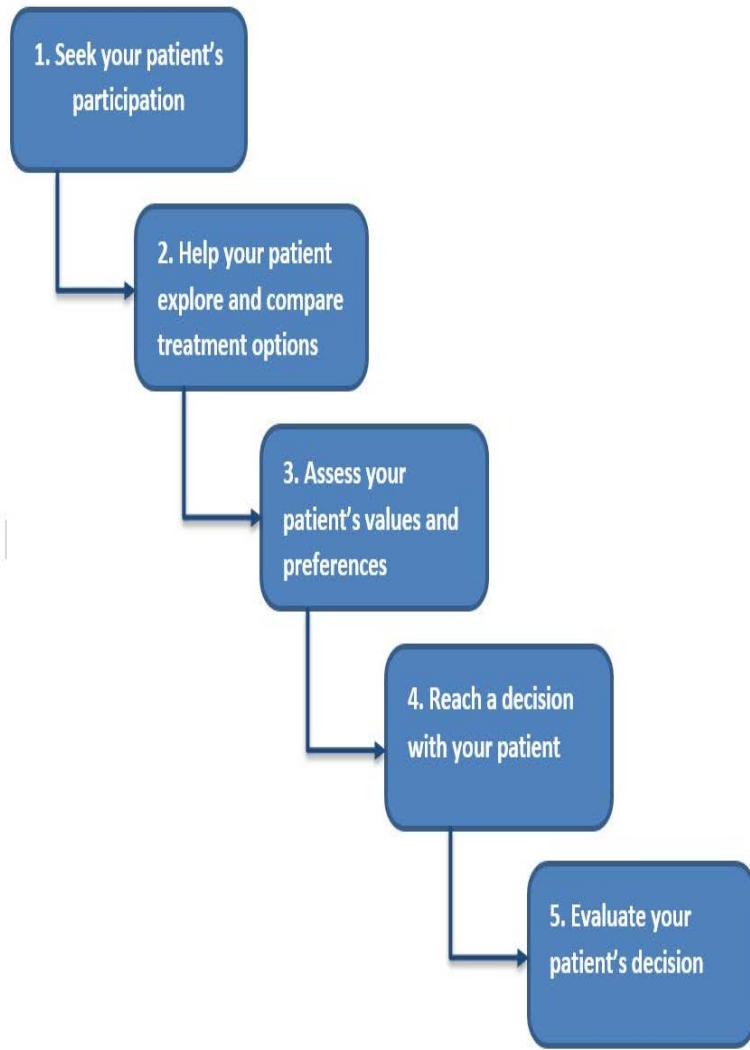
- To share decisions about treatment options, patients need information that they can understand about their condition and treatment choices. To quickly find out how well the patient understood what you discussed, use Teach Back. You can find out in 1-2 minutes using questions like this:

- "We talked about two ways that you might be able to treat your diabetes: either starting medicine right away to lower your blood sugar or increasing your physical activity and following a Mediterranean diet to try to lose a little weight. I want to make sure I explained each option clearly. Would you please tell me how you would explain the two choices to a member of your family?"

- "I want to make sure I was clear about the risks and benefits of taking insulin to control your diabetes. Could you tell me about insulin's possible side effects and how it might impact your life on a day-to-day basis?"

- **If the patient did not understand, say "I must not have done a good job explaining. Let me try again." And use a different approach.**

Glycemic Targets – VA/DoD 2017

- "We recommend setting an HbA1c target **RANGE** based on absolute risk reduction of significant microvascular complications, life expectancy, patient preferences and social determinants of health." – Strong for

Major Comorbidities or Physiologic Age	Microvascular Complications		
	Absent or Mild	Moderate	Advanced
Absent >10-15 years life expectancy	6.0-7.0%	7.0-8.0%	7.5-8.5%
Present 5-10 years of life expectancy	7.0-8.0%	7.5-8.5%	7.5-8.5%
Marked <5 years of life expectancy	8.0-9.0%	8.0-9.0%	8.0-9.0%

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72

Goal 7.5-8.5%

- "…**7.5-8.5%** is appropriate for most individuals with established microvascular or macrovascular disease, comorbid conditions, or 5-10 years life expectancy, if it can be safely achieved" – Strong for

    - No evidence that A1c <8.5% lowers mortality
    - A1c <7% shows no benefit with CVD and may increase mortality
    - Individual benefits of glycemic control must be balanced against risks of medication therapy

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Definitions: Microvascular Comorbidities

Mild

– Early retinopathy, and/or microalbuminuria, and/or mild neuropathy

Moderate

– pre-proliferative retinopathy or persistent, fixed proteinuria (macroalbuminuria), and/or demonstrable peripheral neuropathy (sensory loss)

Advanced

– severe non-proliferative or proliferative retinopathy and/or renal insufficiency (Stage 3b CKD), and/or insensate extremities or autonomic neuropathy (e.g., gastroparesis, impaired sweating, orthostatic hypotension)

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Goal: 8.0-9.0%

- "...**8.0-9.0%** for patients with type 2 diabetes with life expectancy < 5 years, significant comorbid conditions, advanced complications of diabetes or difficulties in self-management" – Weak for

  - 8.0%-9.0% is appropriate for life expectancy <5 years
  - Surrogate markers for life expectancy can include:
    - Functional status
    - Multiple recent hospitalizations
    - Organ failure
    - Cancer diagnosis/treatment plans
    - Advanced medical directives

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Key Recommendations of 2017 VA/DoD Diabetes Guidelines- MAGNITUDE OF BENEFIT

#	Recommendation	Strength	Category
B. Glycemic Control Targets and Monitoring			
4.	We recommend setting an HbA1c target range based on **absolute risk reduction (ARR)** of significant microvascular complications, life expectancy, patient preferences and social determinants of health.	Strong for	Reviewed, New-added

- Using data from systematic reviews to calculate the number needed to treat (NNT) and number needed to harm (NNH) carries high risk for bias. This can lead to over- or under-estimation of risk.

- For example, in UKPDS, there was a 37% RRR for microvascular complications that was continuous and without a threshold. However, the ARR for any microvascular complication was 5.0/100 and the number needed to treat over 10 years was 19.6.

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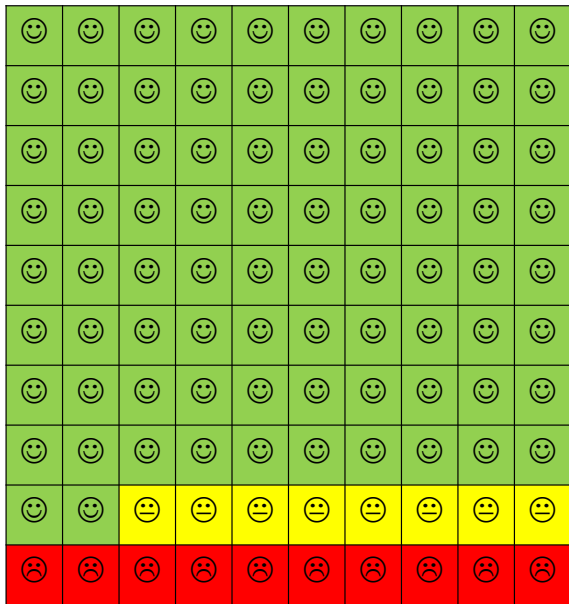
For new onset diabetes, if A1c levels are targeted to be around **7%** for the first 10 years

82 alive with diabetes without microvascular disease

8 alive with diabetes and microvascular disease

10 dead from diabetes

For new onset diabetes, if A1c levels are targeted to be around **8%** for the first 10 years
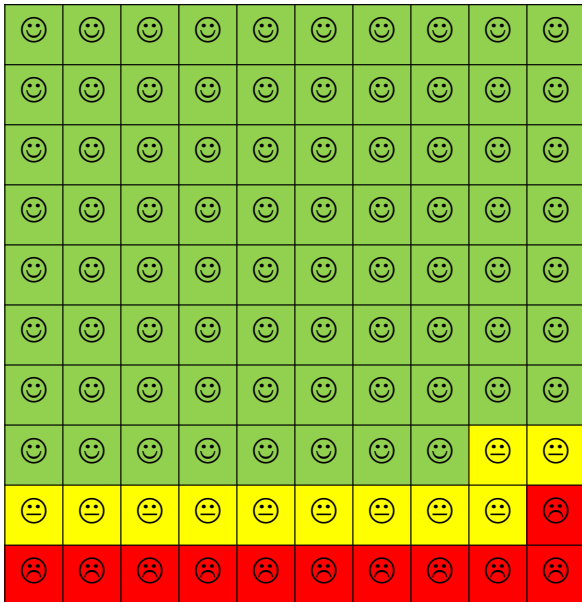
78 alive with diabetes without microvascular disease

11 alive with diabetes and micro-vascular disease

11 dead from diabetes

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).

☺	**Person alive with diabetes and no microvascular complications**
😐	**Person alive with diabetes and with microvascular complications**
☹	**Person dead from diabetes**
	Microvascular complications include retinopathy, nephropathy, and neuropathy

From Health Foundation, UK

Key Recommendation- A1C Range

#	Recommendation	Strength	Category
B. Glycemic Control Targets and Monitoring			
6.	We recommend assessing patient characteristics such as race, ethnicity, chronic kidney disease, and non-glycemic factors (e.g., laboratory methodology and assay variability) when interpreting HbA1c, fructosamine and other glycemic biomarker results.	Strong for	Reviewed, New-added

- A single HbA1c measurement, even from a high quality laboratory, has a margin of error. Its true value is within a range defined by the coefficient of variation.

- Many factors affect HbA1c measurement besides the level of glycemia such as anemia, CKD, hemoglobin variants

- The evidence is strong that African Americans have higher A1c values than Whites for a given level of glycemia

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An A1c Test Result is Within a Range Dependent Upon the Assay
A result of 8.0% is within a 7.84 to 8.16 range from a high quality laboratory (intra-assay coefficient of variation [CV]=2.0%) and between 7.68% and 8.32% if the CV is 3.0%). A CV of 2% will produce a 95% probability that a difference of about 0.5% HbA1c between successive patient samples is a true difference 95 out of 100 times for a A1c value of 8.0%.
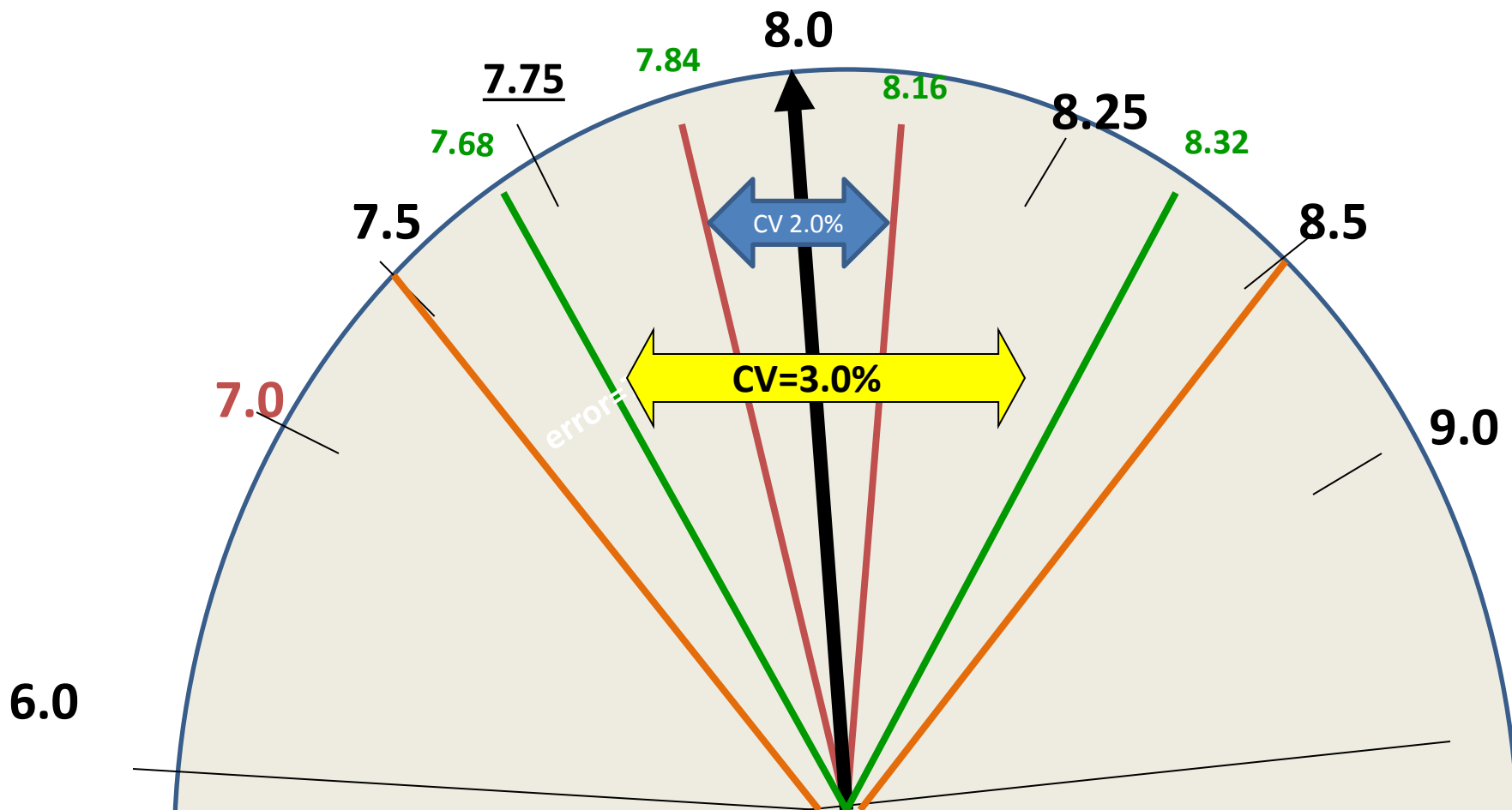
Evidence – Any A1c test result is in a range dependent upon individual factors

- Decrease unnecessary medication adjustments and risk for hypoglycemia from treating numbers, not patients

- Racial differences between HbA1c values and assessment of glycemia

  - African Americans have 0.4% higher A1c than Whites without differences in glycemic measures at time of entry in DPP study and ADOPT Study

  - VA/DoD recommends against use of estimated average glucose which is derived from A1c values using a formula.

Encourage Numeracy, Not Measures
VHA Laboratory Result Comment

- In support of the VHA Choosing Wisely-Hypoglycemic Safety Initiative, the Pathology and Laboratory Medicine Services was asked to append the following comments to A1c reports (including both lab and POC tests):

- **Citing performance measures or target values is not consistent with the individualized target approach advocated by the VA/DOD Guidelines**

```
   Specimen: BLOOD.              SC 1124 484
     Specimen Collection Date: Nov 24, 2015@12:55
      Test name                 Result    units      Ref.    range    Site Code
GLYCATED HEMOGLOBIN              9.8 H      %         4.0 - 6.0          [578]
Comment: Target A1C values should be individualized. Better understanding of
        A1C test result accuracy is essential if clinicians are to
        interpret results for Veterans, and discuss treament options
        through the process of Shared Decision Making.  Contact your
        laboratory for performance characteristics of this assay.
=======================================================================
```

Challenges in Prevention of Hypoglycemia

Measures

- <8% HbA1c measure applies to all older adults 65-75 years
- **DHHS NAP (8/2014):**
- Does not reflect latest evidence
- Does not stratify by medications
- Does not exclude high risk patients
- Does not address overtreatment

SDM Knowledge Gap

- Evidence: Clinicians and Patients

- **Legacy of <7% measures and guidelines**
- Delivery Mechanism
- Tools
- Trainers

EMR: Failure to Identify at Risk Patients

- Risk
- Severity
- Social Determinants
- Patient Preferences
- Patient Individualized Goal
- Prior Hypoglycemic Events

Lack Coordinated Message for Public Health Campaign for Clinicians and Patients

Consumer magazines

- Professional Organizations
- Lay Leadership
- Provider Bias

Challenges in Reducing Glycemic Over-treatment

Response to a vignette of a 77 y/o male with long-standing T2DM, severe kidney disease, HbA1c 6.5%, receiving glipizide 10mg BID (Cavanaugh et al, JAMA Internal Medicine 2015)

	Disagree	Agree
I think this patient would benefit if his HbA1c is maintained below 7%	61.4%	**38.6%**
I worry that this patient would be harmed if his HbA1c is maintained below 7%	**44.9%**	**55.1%**
I would worry that reducing his diabetes medication would lead to an HbA1c that falls outside of current performance measures	57.9%	**42.1%**
It would be helpful to have a clinical decision-support tool that would help me determine whether this patient would benefit from reducing his diabetes medications	30.8%	**69.2%**
It would be helpful to have patient education materials to discuss reducing diabetes medication	14.6%	**85.4%**

A Brief History of VA Hypoglycemia Safety Initiative

2010's

- 2003-2010 VA/DoD guidelines support individualized targets and targets up to 8.5% for complex medical/mental health conditions or limited life expectancy
- **ABIM's Choosing Wisely Campaign: AGS (2012) "Avoid using medications other than metformin to achieve hemoglobin A1c<7.5% in MOST older adults; moderate control is generally better"**
- **VISN 12 Great Lakes Hypoglycemia Safety Initiative 2012**
- VHA-Choosing Wisely Hypoglycemia Safety Initiative 2014

Choosing Wisely®

An initiative of the ABIM Foundation

American Geriatrics Society

AGS Geriatrics Healthcare Professionals

Leading Change. Improving Care for Older Adults.

Five Things Physicians and Patients Should Question

VHA Choosing Wisely:
Hypoglycemia Safety Initiative (HSI) Goals

Foster Shared Decision Making

Inform Best Available Evidence

Reduce Unnecessary Care

Improve Safety

Identification of Patients – EMR tools

High risk cohort

HbA1c < 7%

Insulin or Sulfonylurea

Age ≥ 75 or Dementia / Cognitive Impairment or SCr > 1.7 mg/dL
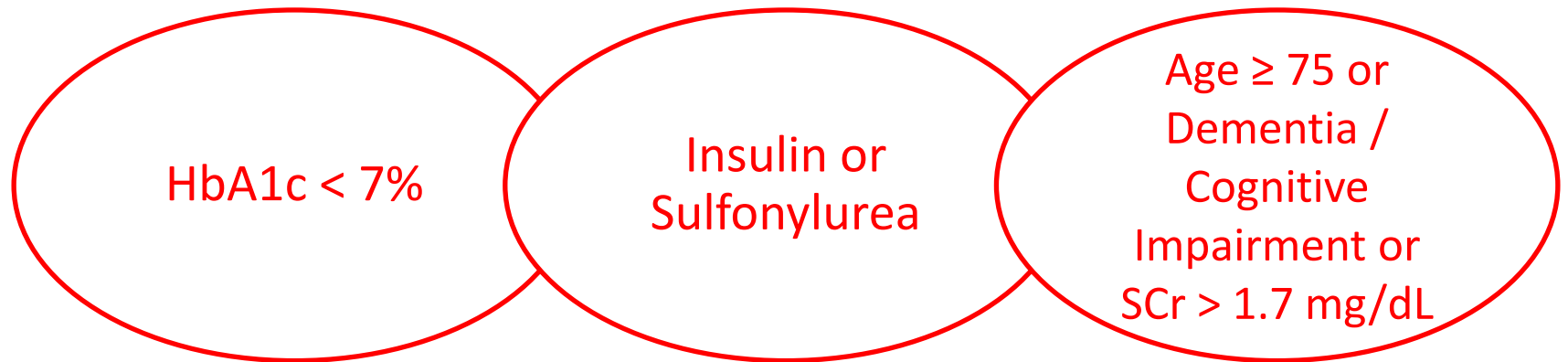
Integrated Approach
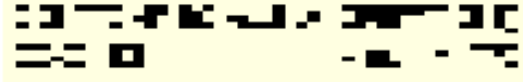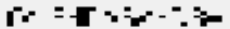
Multi-Professional Education

EMR Tools

Online Panel Reports

EMR Tools, cont.

Clinical Alert - Point-of-care patient identification

EMR tools, cont.

1. Questions

2. Care Plan

3. Data Capture

Each of these also includes a lower section allowing for test ordering and allowing for documentation of any change in a shared decision about intensifying or relaxing management.

○ Patient/Caregiver agrees to an A1C goal of < 7%

○ Patient/Caregiver agrees to an A1C goal of < 8%

○ Patient/Caregiver agrees to an A1C goal of <= 9%

○ A1c goal discussed. Goal under consideration by patient/caregiver.

☑ Order A1C

☑ Enter Outside (A1C)   * [▼] [▼] [   ] [▲▼] [...]

Location: [▼]

Enter Lab Value: * [   ]

Shared Patient Centered Plan
○ No change in glycemic management at this time.
○ Relax glycemic treatment
○ Intensify glycemic treatment

| Clear | Clinical Maint | Visit Info | < Back | Next > | Finish |

Online Panel Reports

Proactive Patient Identification

National Results (8/2017)

Evaluation

Nearly **30,000 patients** have been **evaluated** using the EMR template

Occurrence

Hypoglycemia has been reported by **21%** of those evaluated

Action

Of all patients evaluated, **86%** have **documented shared decision making**

Of those reporting hypoglycemia, **53%** have made a **shared decision** with their provider to **relax treatment**

Healthy Living

Ask about Low Blood Sugars

VHA National Center for Prevention
Ask About Low Blood Sugars

Ask About Low Blood Sugars to inform patients and their family members and clinicians about asking about the low blood sugars**.**

Below you will find links to the July Monthly Topic resources from the National Center For Health Promotion and Disease Prevention (NCP). Please use this month's materials and supporting file links to promote awareness about low blood sugars to Veterans and clinicians.

https://www.prevention.va.gov/MPT/2017/docs/July_2017_Resource_Document.pdf

VA Virtual Medical Center Pilot

- Health Professional Education: Shared Decision Making Decision-Simulation based on 3 clinical scenarios addressing Hypoglycemic Safety

- Synchronous Diabetes Self-Management Education employing flipped classroom pedagogy (planned)

- Synchronous and Asynchronous Health Professional training for Shared Medical (Group) Medical Appointment implementation (planned)

Tom's Story: Be Aware
Ask About Low Blood Sugar

http://videos.va-ees.com/default.aspx?bctid=5476595850001

Tom's Story: Be Aware
Ask About Low Blood Sugar

http://videos.va-ees.com/default.aspx?bctid=5476595850001

Current hypoglycemia medication safety efforts

Andy Karter, PhD

Kaiser Permanente

Development and Validation of a Practical Tool to Identify Patients with Type 2 Diabetes at High Risk of Hypoglycemia-Related Utilization

Andrew Karter, PhD
Kaiser Permanente Northern California

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Background

- "**Diabetes agents** were implicated in 1 of 5 ED visits for adverse **drug** events among older adults" -Shehab et al. JAMA 2017

- Hypoglycemia-related utilization is only the **tip of the iceberg**
  - 0.5% annually experience "hypoglycemia-related utilization" (ED visits or hospitalization with primary/principal discharge diagnosis of hypoglycemia)
  - 11% annually self-reported "severe hypoglycemia"
  - 95% of severe hypoglycemia episodes are <u>not</u> clinically recognized

Motivation

- Misconception that hypoglycemia is not a serious concern for T2D
  - Clinicians suffer from their own form of "hypoglycemic unawareness"
  - Clinician messaging has primarily focused on achieving glycemic control ("lower-is-better" myth)
  - Little attention paid toward hypoglycemia prevention

- Lack population management strategies to address this public health problem

Risk Stratification

The presence of an effective but costly intervention to prevent hypoglycemia makes "targeting" high risk patients for population management particularly compelling

Risk Stratification

The presence of an effective but costly intervention to prevent hypoglycemia makes "targeting" high risk patients for population management particularly compelling

→ Identify higher risk patients

|

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Risk Stratification

The presence of an effective but costly intervention to prevent hypoglycemia makes "targeting" high risk patients for population management particularly compelling

→ Identify higher risk patients

→ Intervene

Risk Stratification

The presence of an effective but costly intervention to prevent hypoglycemia makes "targeting" high risk patients for population management particularly compelling

→ Identify higher risk patients

→ Intervene

→ Prevent

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Over-arching goal

Develop a pragmatic, risk-stratification tool to identify type 2 diabetes patients at elevated risk for short-term hypoglycemia-related utilization

|

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Development and Validation of a Tool to Identify Patients With Type 2 Diabetes at High Risk of Hypoglycemia-Related Emergency Department or Hospital Use

Andrew J. Karter, PhD; E. Margaret Warton, MPH; Kasia J. Lipska, MD, MHS; James D. Ralston, MD, MPH; Howard H. Moffet, MPH; Geoffrey G. Jackson, MHA; Elbert S. Huang, MD; Donald R. Miller, ScD
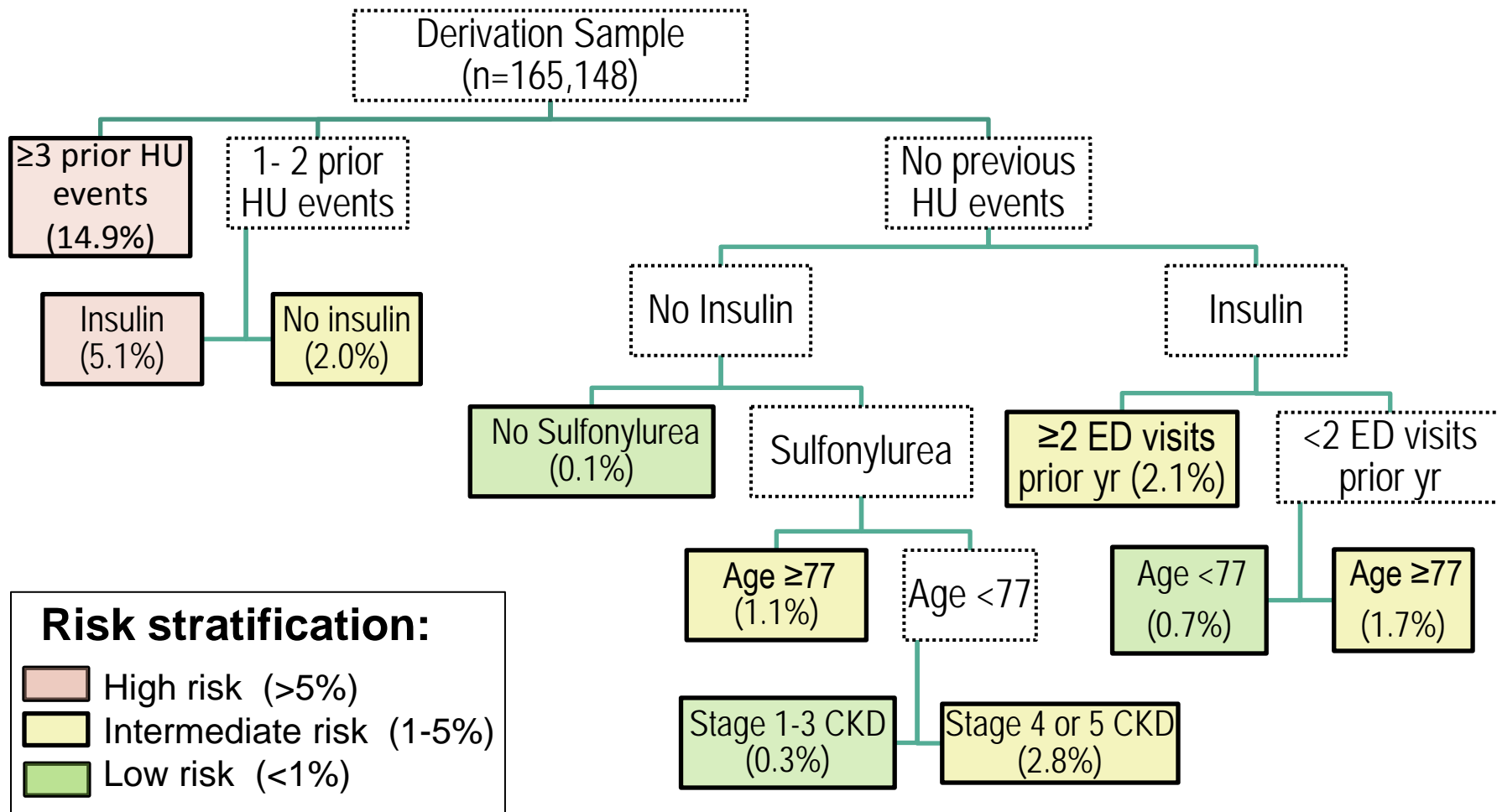
Methods

Internal Sample   206,435 adult with type 2 diabetes (T2D) from Kaiser Permanente Northern California (KPNC)

Outcome: Hypoglycemia-related utilization (HU): ≥1 ED visits with primary or hospitalization with principal discharge diagnosis of hypoglycemia (2014)

Model-Building: Machine-learning (recursive partitioning) using 156 EMR-based variables (from literature)

External Validation   Tested in 2 fully-independent populations: 1,245,352 VA and 15,108 Group Health

Dominant predictors of hypoglycemia-related utilization (annual rate=0.5%)*
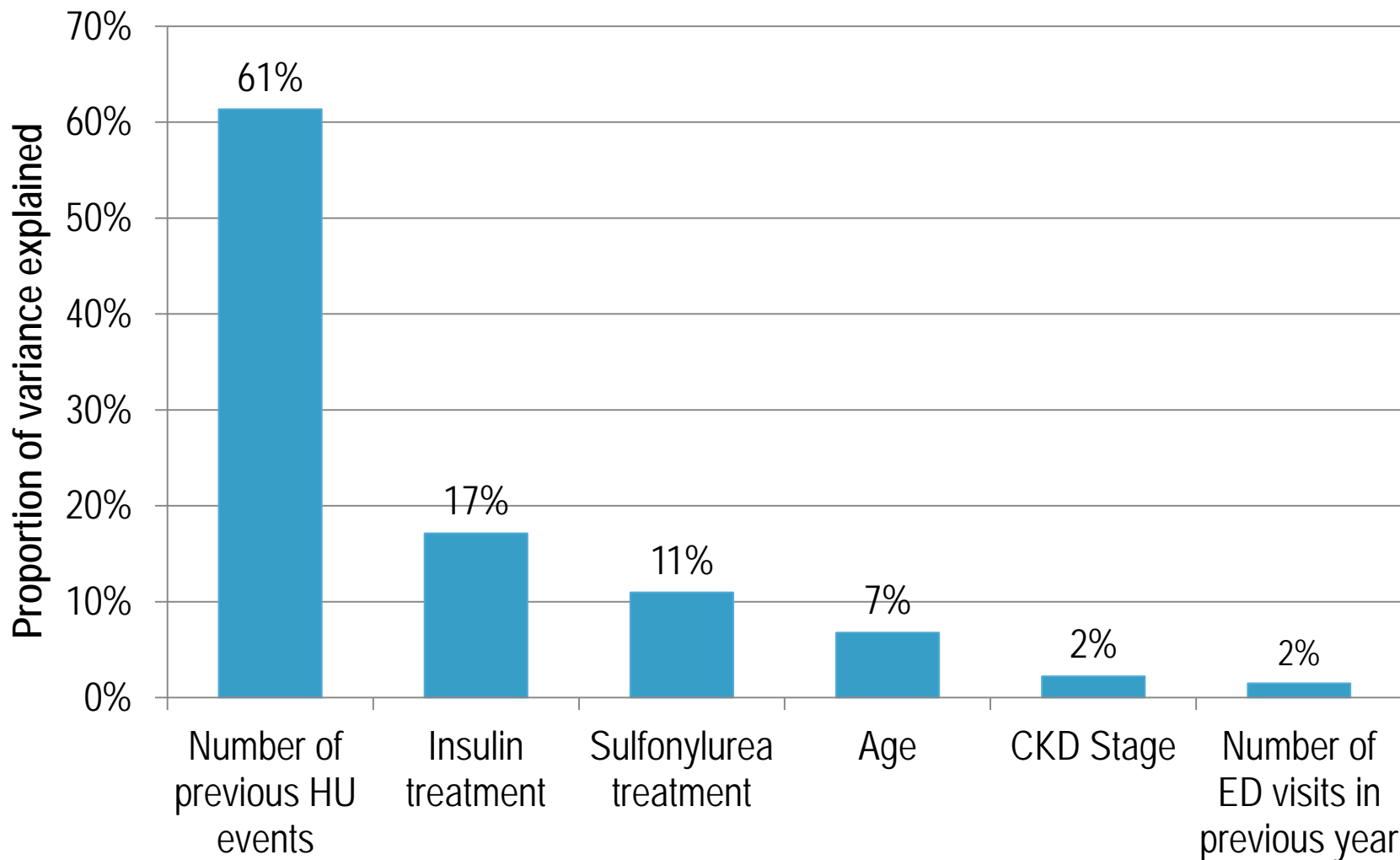
*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014

Classification Tree

Derivation Sample (n=165,148)

- ≥3 prior HU events (14.9%)
- 1-2 prior HU events
  - Insulin (5.1%)
  - No insulin (2.0%)
- No previous HU events
  - No Insulin
    - No Sulfonylurea (0.1%)
    - Sulfonylurea
      - Age ≥77 (1.1%)
      - Age <77
        - Stage 1-3 CKD (0.3%)
        - Stage 4 or 5 CKD (2.8%)
  - Insulin
    - ≥2 ED visits prior yr (2.1%)
    - <2 ED visits prior yr
      - Age <77 (0.7%)
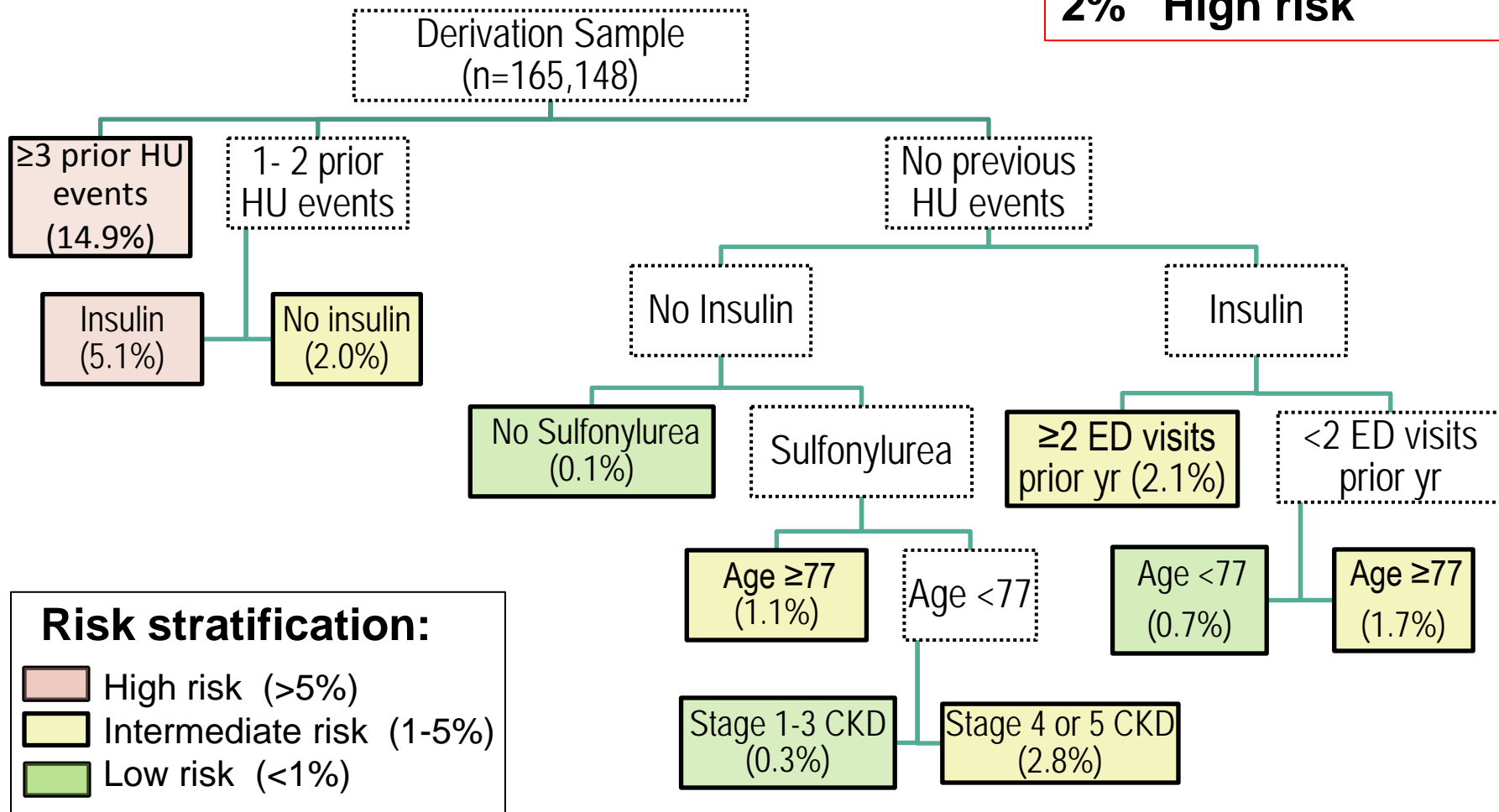   - Age ≥77 (1.7%)

Risk stratification:
- High risk (>5%)
- Intermediate risk (1-5%)
- Low risk (<1%)

*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014; HU risk for each leaf node (solid boxes) in parentheses.

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Classification Tree

87% Low risk
11% Intermediate risk
2% High risk

Risk stratification:

- High risk (>5%)
- Intermediate risk (1-5%)
- Low risk (<1%)

Derivation Sample (n=165,148)

- ≥3 prior HU events (14.9%)
- 1- 2 prior HU events
  - Insulin (5.1%)
  - No insulin (2.0%)
- No previous HU events
  - No Insulin
    - No Sulfonylurea (0.1%)
    - Sulfonylurea
      - Age ≥77 (1.1%)
      - Age <77
        - Stage 1-3 CKD (0.3%)
        - Stage 4 or 5 CKD (2.8%)
  - Insulin
    - ≥2 ED visits prior yr (2.1%)
    - <2 ED visits prior yr
      - Age <77 (0.7%)
      - Age ≥77 (1.7%)

*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014; HU risk for each leaf node (solid boxes) in parentheses.
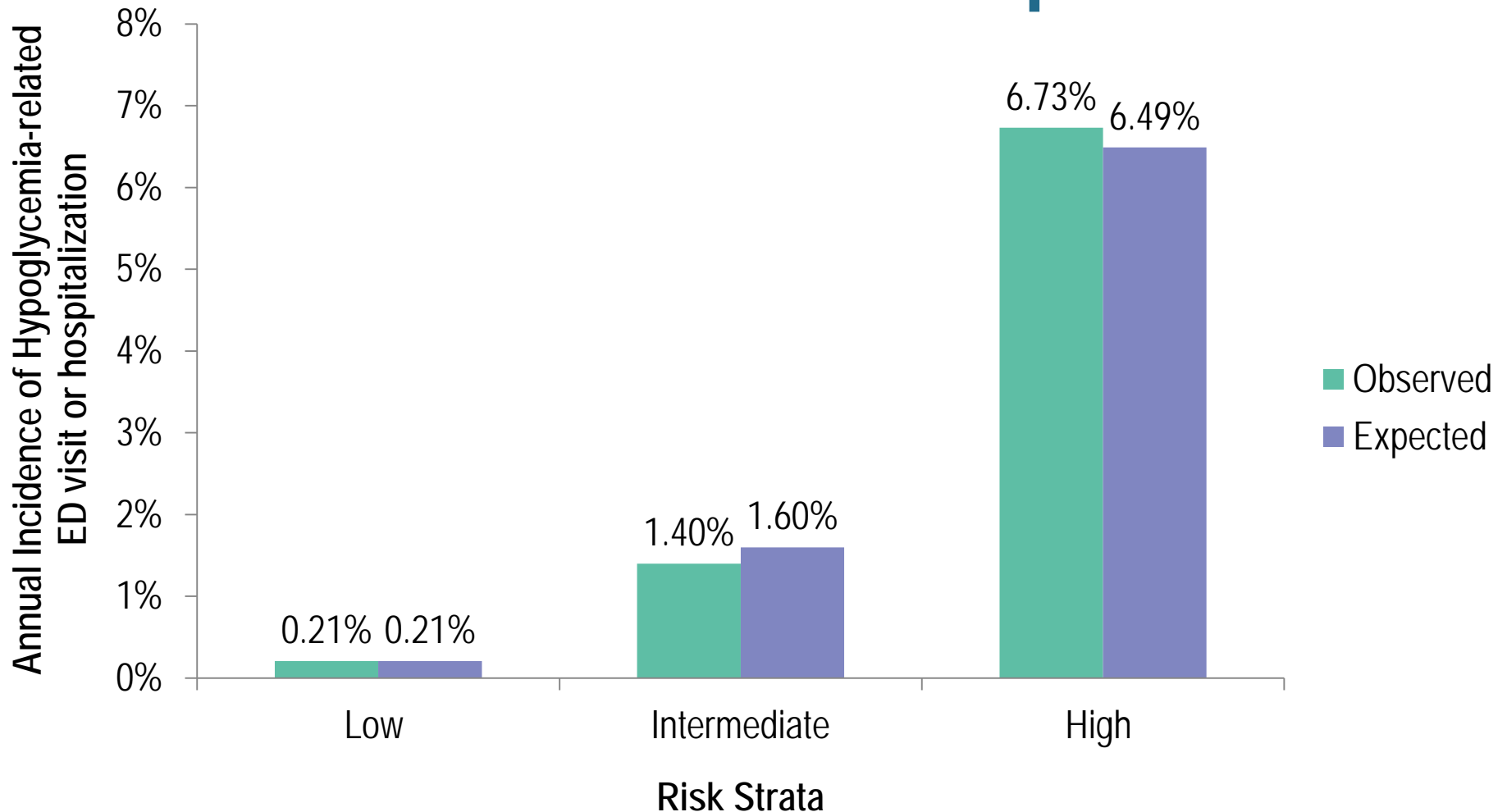
KAISER PERMANENTE®

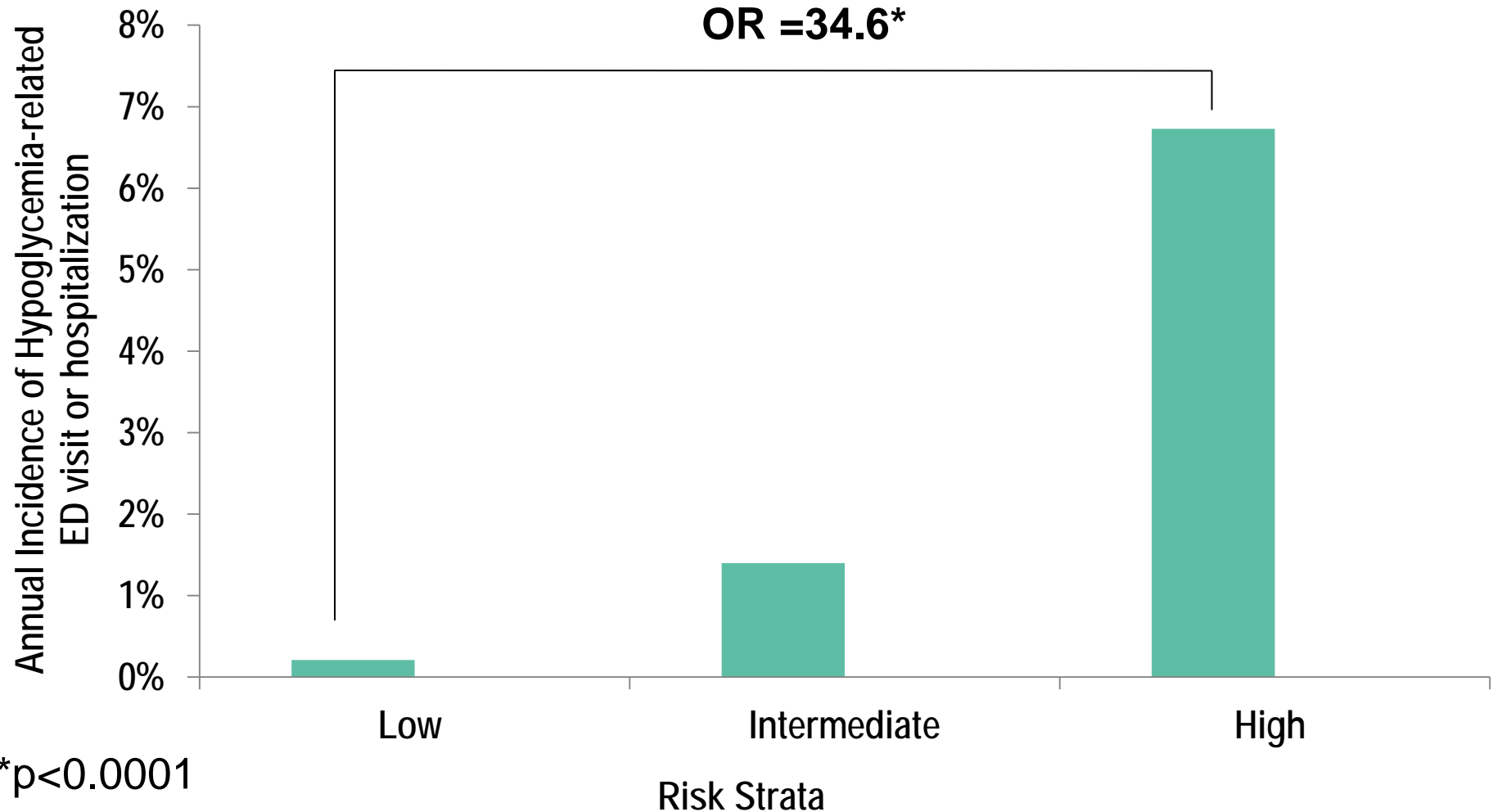# Discrimination: tool distinguishes between those with vs. without HU
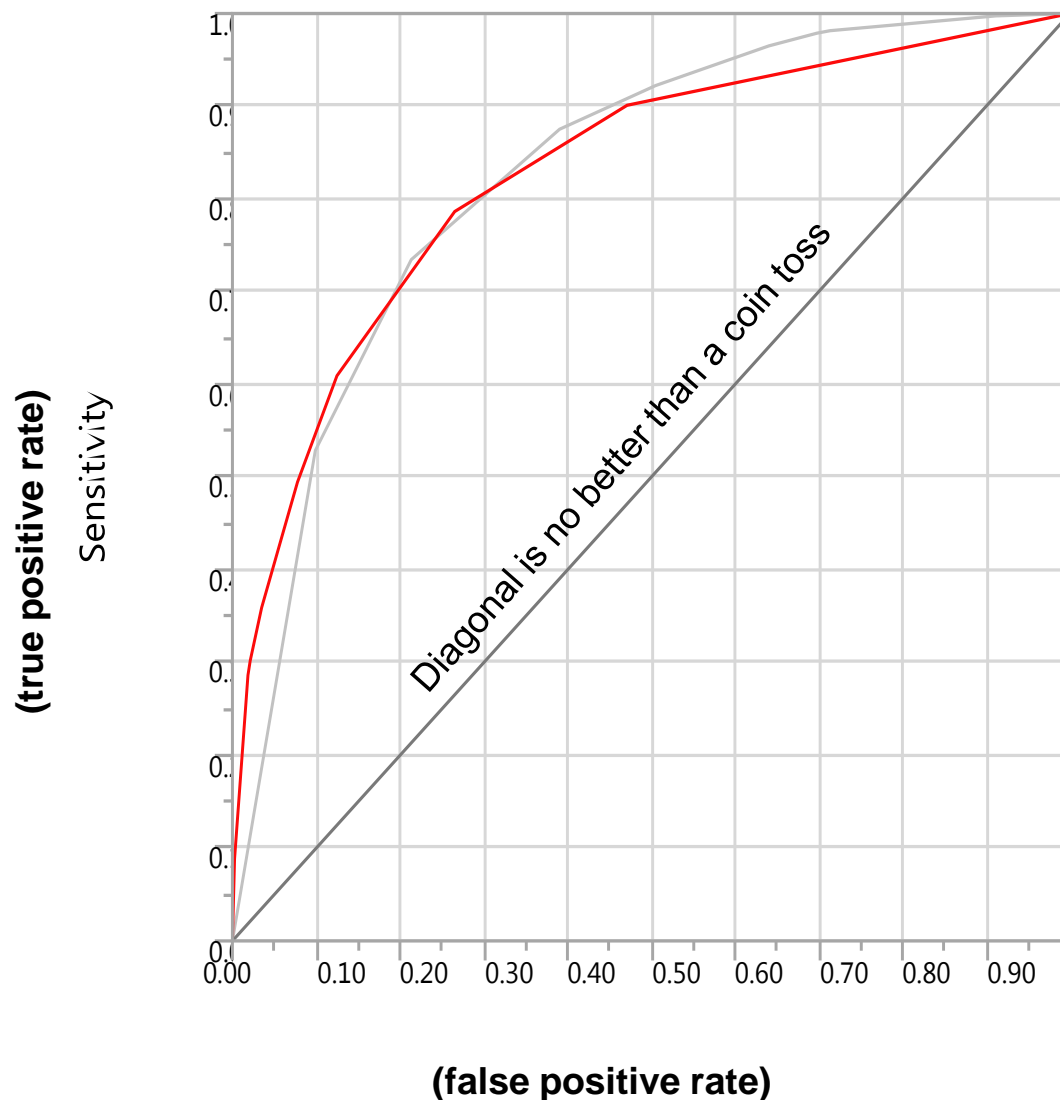
Area under the receiver operator characteristic (ROC) curve (C-statistic) = 83%

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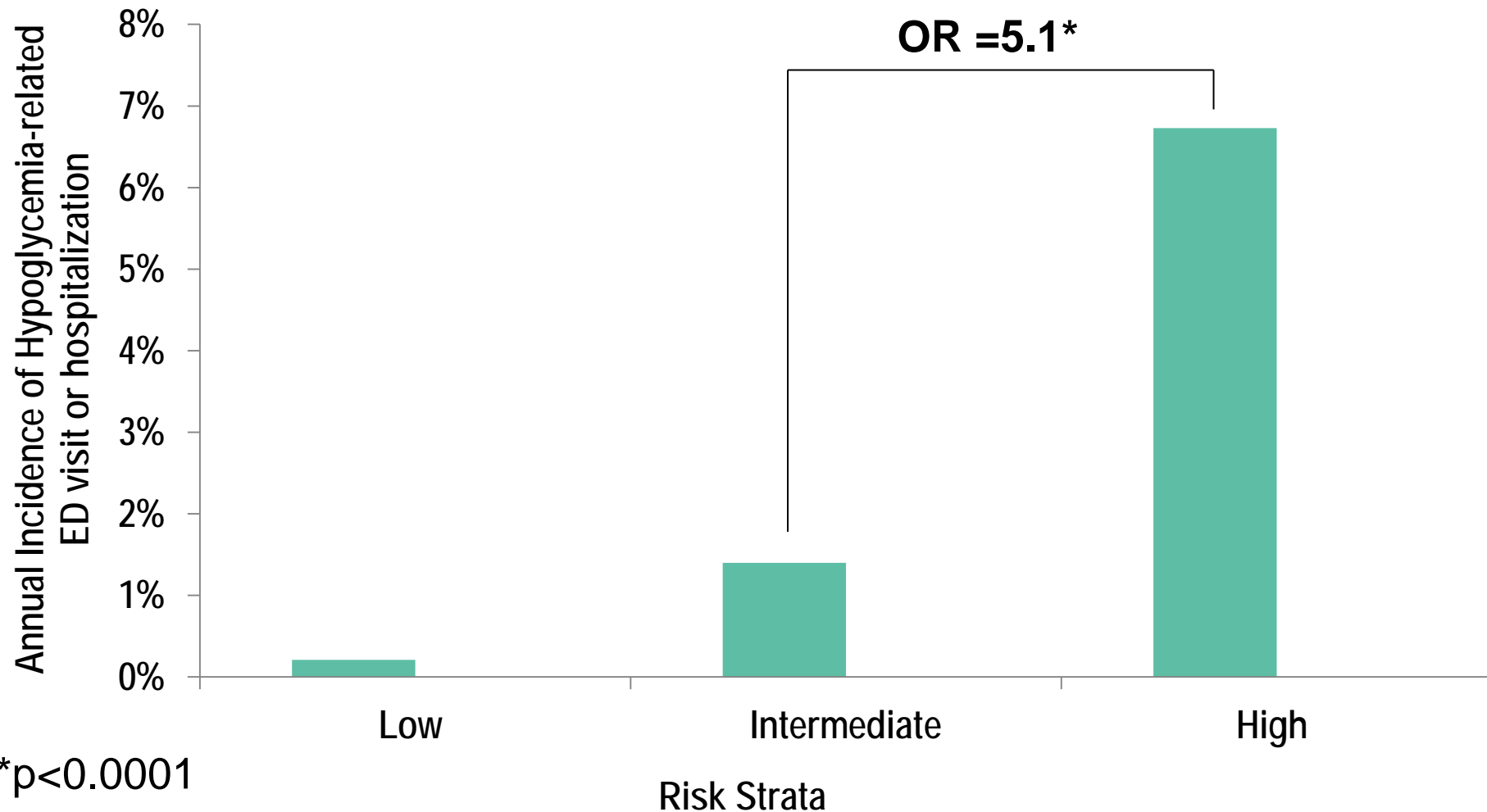# Calibration: Good agreement between observed vs expected

Annual Incidence of Hypoglycemia-related ED visit or hospitalization

- Low: Observed 0.21%, Expected 0.21%
- Intermediate: Observed 1.40%, Expected 1.60%
- High: Observed 6.73%, Expected 6.49%

Risk Strata

Legend: ■ Observed ■ Expected

*Pearson's Chi-Square Goodness of Fit p-value = 0.68

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Clinical utility: 35-fold higher rate of HU in high vs. low risk strata

OR =34.6*

*p<0.0001

Risk Strata

Annual Incidence of Hypoglycemia-related ED visit or hospitalization

Low   Intermediate   High

Clinical utility: 5-fold higher rate of HU in high vs. intermediate strata

OR =5.1*

*p<0.0001

Clinical utility: 7-fold higher rate of HU in intermediate vs. low strata
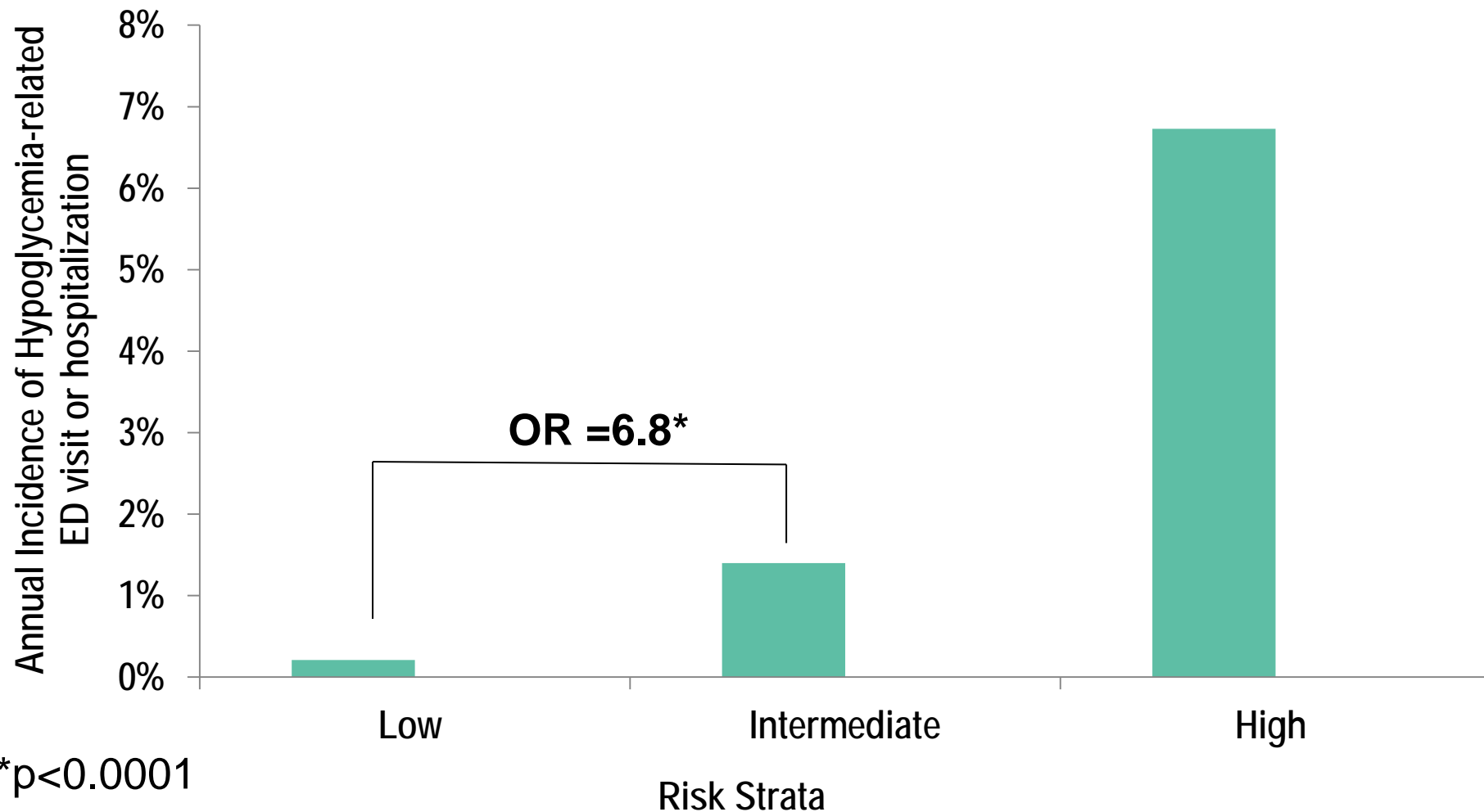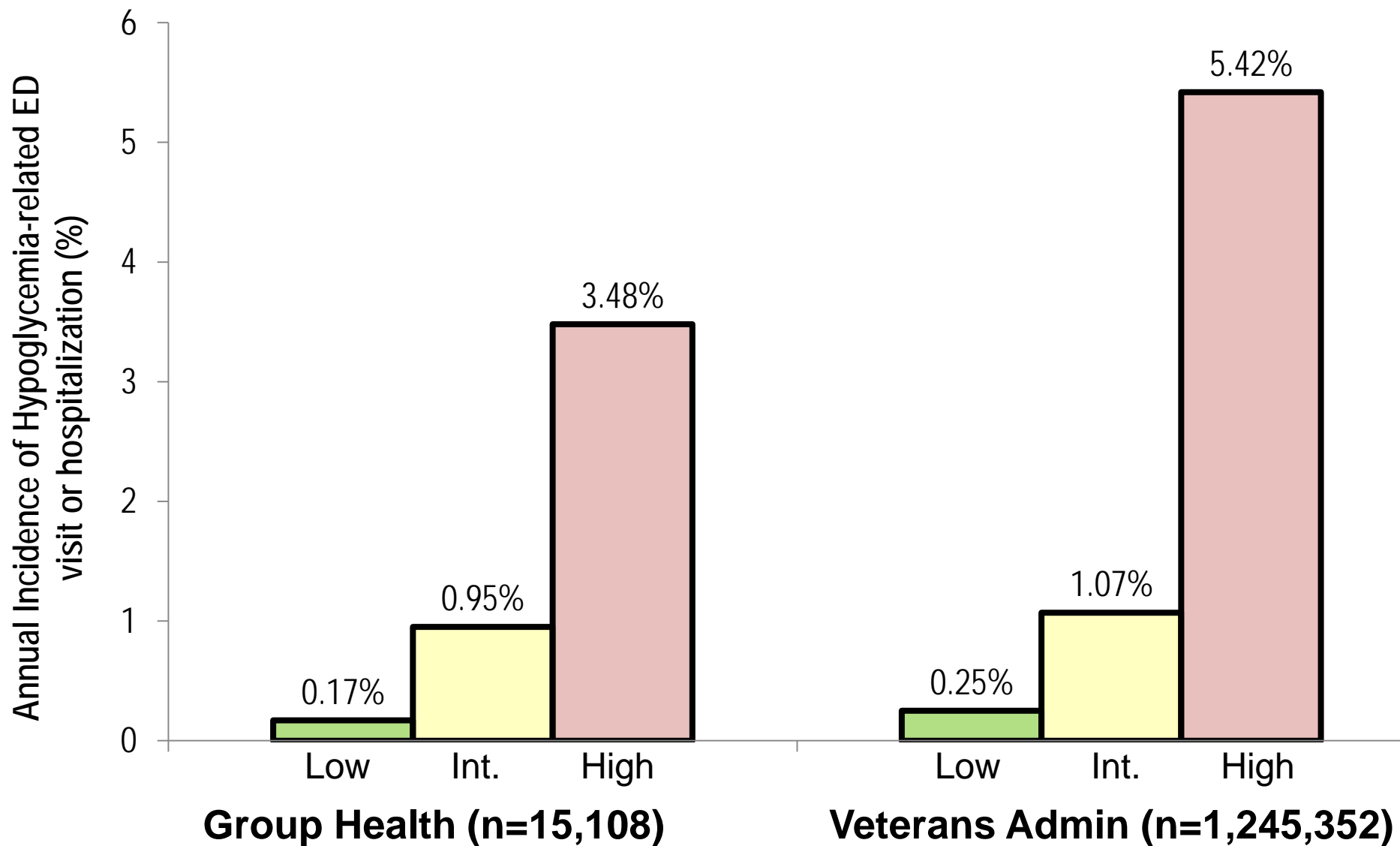

*p<0.0001

Hypoglycemia Risk Stratification Tool

- How many times has the patient <u>ever</u> had hypoglycemia-related utilization in an emergency department (primary diagnosis of hypoglycemia*) or hospital (principal diagnosis of hypoglycemia*) (0, 1-2, ≥3 times)?
- How many times has the patient gone to an emergency department for any reason in the prior 12 months (<2, ≥2 times)?
- Does the patient use insulin (yes/no)?
- Does the patient use sulfonylurea (yes/no)?
- Does the patient have severe or end-stage kidney disease (CKD stage 4 or 5) (yes/no)?
- Is the patient <77 years old (yes/no)?

Instructions: The 6 inputs above are used to identify one of the mutually-exclusive exposure groups and the corresponding risk category (high, low or intermediate) for hypoglycemia-related emergency department or hospital utilization* in the following 12 months. The first five options are defined by unique combinations of predictor variables, while the sixth option is indicated only after ruling out the first five options.

☐	≥3 prior hypoglycemia-related emergency department or hospital utilization	**High risk (>5%)**
☐	1-2 prior hypoglycemia-related emergency department or hospital utilization AND Insulin user	

☐	No prior hypoglycemia-related emergency department or hospital utilization AND No insulin AND No sulfonylurea	**Low risk (<1%)**
☐	No prior hypoglycemia-related emergency department or hospital utilization AND No insulin AND Uses sulfonylurea AND Age <77 years old AND Does not have severe or end-stage kidney disease	
☐	No prior hypoglycemia-related emergency department or hospital utilization AND Uses insulin AND Age <77 years old AND <2 ED visits in prior year	

☐	All other risk factor combinations	**Intermediate risk (1-5%)**

External validation

*p<0.0001 for odds ratios
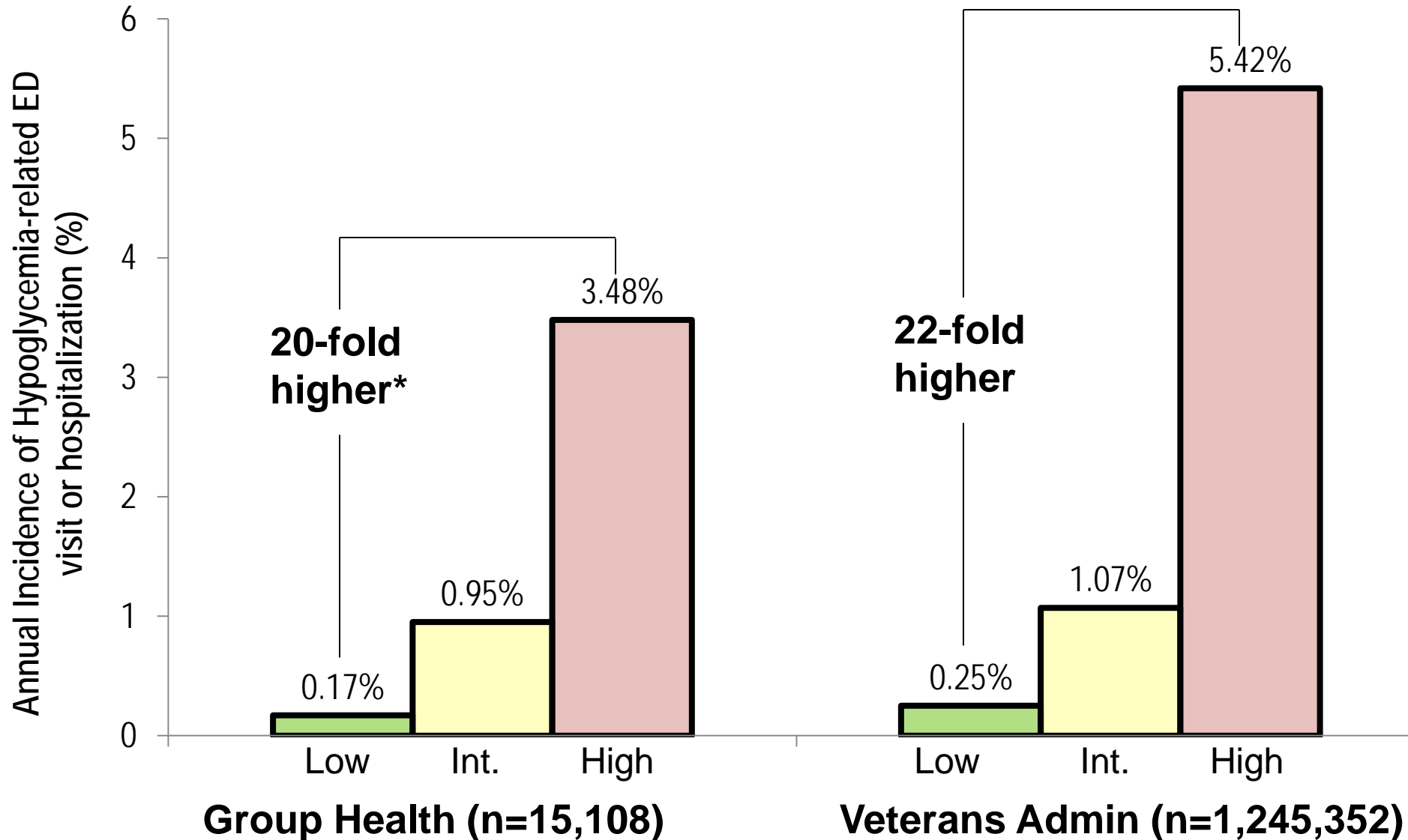
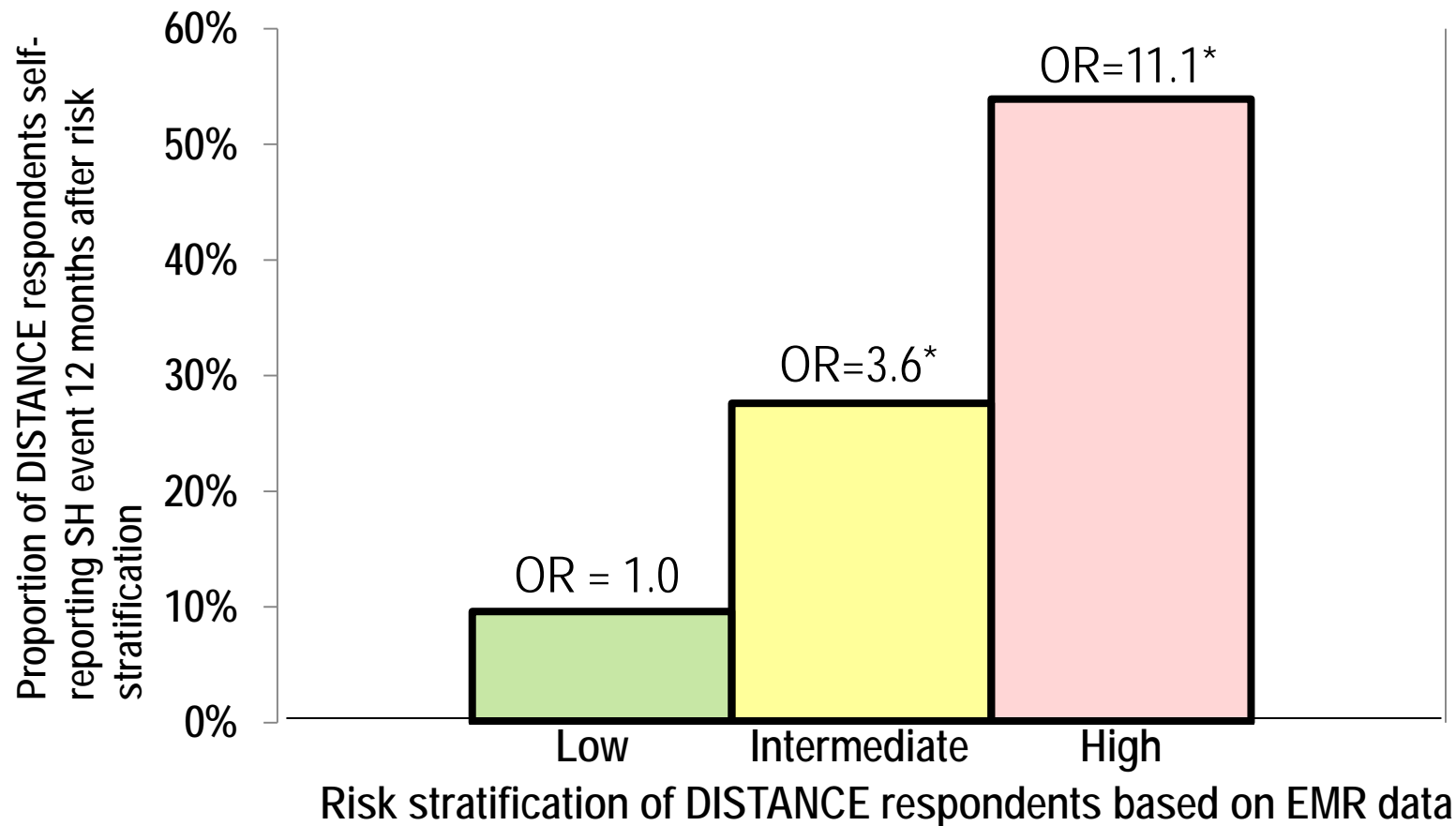# External validation: Good discrimination
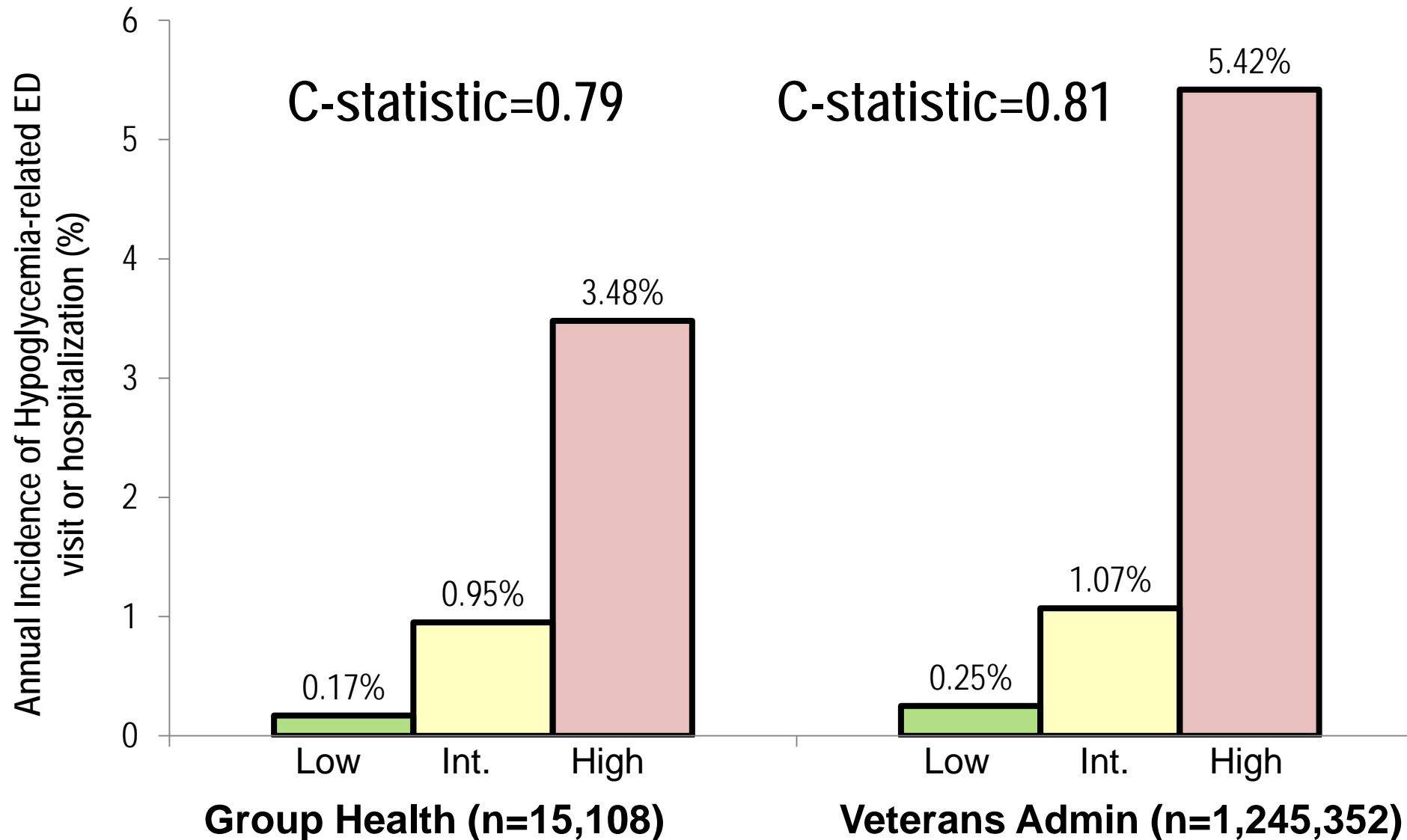
*p<0.0001 for odds ratios

External validation: Good clinical utility

*p<0.0001 for odds ratios

Ecological validity: 54% of patients classified as high risk self-reported experiencing severe hypoglycemia in following 12 months

*P<0.0001; Based on logistic regression of any self-reported severe hypoglycemia (last 12 months) among 14,897 survey responders to the Diabetes Study of Northern California (DISTANCE) (2005-6).

Limitations

- Hypoglycemic utilization is only the tip of the iceberg

- All inputs are EMR-based

  - Patient-reported behaviors (e.g., skipping meals) and social factors (e.g., health literacy, food insecurity) are not factored into the model

- Inappropriate for quantifying individual risk

  - Estimating the probability of rare events is unreliable

- Not optimized for T1D patients

- Does not include utilization due to injuries caused by hypoglycemia (if coded as secondary)

  - <2% of hypoglycemia-related ED encounters fall into this category

Strengths

- Developed in a large sample of ethnically-diverse T2D patients with uniform access to care

- Validated in over 1 million T2D patients from two external populations

- Simplicity: needs only 6 input variables

- Meaningful use: leverages EMR data for decision support

- Robust across validation sites, after including T1D, with varying length of medical history, and calendar year

- Risk strata predicts self-reported severe hypoglycemia and mortality

Summary

- ~20-fold greater rates of HU among patients categorized as high vs low risk

- Over half of patients categorized as high risk self-reported having a severe hypoglycemic episode in the subsequent 12 months

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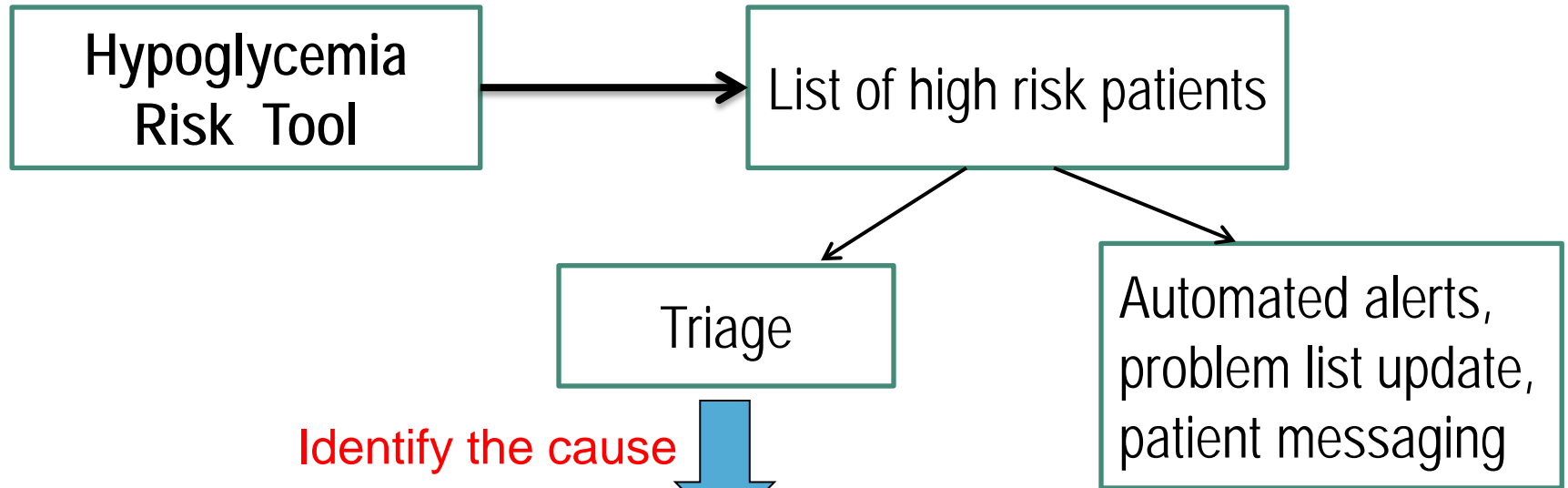# Now that we have a tool to identify higher risk patients, what do we do?

Now that we have a tool to identify higher risk patients, what do we do?

The answer depends on <u>why</u> the patient is at increased risk
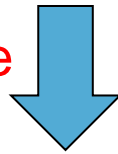
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Hypoglycemia risk factors

- **Medication mismatch** – Overly intensive regimen

- **Clinical vulnerability** – impaired hypoglycemic awareness, glucose counterregulatory failure, renal failure, acute GI illness

- **Behavioral** – Missed meals, alcohol use

- **Psychosocial and cognitive** - depression, dementia

- **Social determinants** - food insecurity

- **Limited health literacy** - not understanding insulin management or recognizing symptoms of hypoglycemia

|

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Potential workflow response

Hypoglycemia Risk Tool → List of high risk patients

List of high risk patients →
- Triage
- Automated alerts, problem list update, patient messaging

Identify the cause

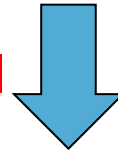- Medication mismatch/ clinical vulnerability
- Psychosocial Cognitive
- Behavioral
- Social determinant
- Health Literacy

Make referral

- Primary Care Provider
- Clinical Pharmacist
- Accountable population manager
- Endocrinologist
- Health Educator

Conclusion

- This risk stratification tool facilitates targeting interventions at high and intermediate risk patients (2% and 11% respectively)

- Given the heterogeneity of causes and risk level, tailoring interventions and resources should be tested as a strategy to lower hypoglycemia rates, improve patient safety and reduce hospital readmissions

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Acknowledgements

COAUTHORS:

FUNDING:

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Extra Slides

Reasons EHR-based surveillance underestimates true incidence

- ~95% of all SH events are cared for outside of the medical system and do not result in an ED visit or hospitalization

  - In 2005-6, 11% of KPNC diabetes patients self-report SH vs. only 0.7% utilized ED or were hospitalized for SH[1]

  - *EMS also care for and release ~1% SH episodes (~15% of Alameda Co. 911 calls are not transported to ED)[2]

- Inadequate patient-provider communication about hypoglycemia

  - 16% of T1D and 26% of insulin treated T2D reported not being asked by their provider about hypoglycemia[3]

  - 82% and 69% of T1D and T2D patients did not inform their general practitioner/specialist about their hypoglycemia[4]

[1]Lipska et al. Diabetes Care, 2013;36:3535-42
[2]Moffet et al, in press
[3]Diabet Med 2014: 31, 92-101
[4]Diabet Med 2016;33:1125-1132

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Focus on primary/principal Dx

- Secondary diagnoses of hypoglycemia are common:
  - Aggressive insulin management in ED or hospital
  - Acute non-metabolic conditions, e.g., sepsis, acute renal failure, nausea/vomiting/diarrhea, and congestive heart failure

- Ignored in model development because:
  - Our objective was to identify T2D patients at elevated risk of hypoglycemia events which <u>were potentially preventable</u> via outpatient interventions (e.g., de-intensified therapy or self-management)
  - Secondary hypoglycemia is poorly aligned with this objective

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Potential workflow response

Hypoglycemia Risk Stratification Tool → List of high risk patients

Population Management

Individual level

System level

Triage team

↓

Identify possible cause(s)

↓

Refer to appropriate provider*

↓

Intervene

Automated updating of alerts, problem lists, patient messaging
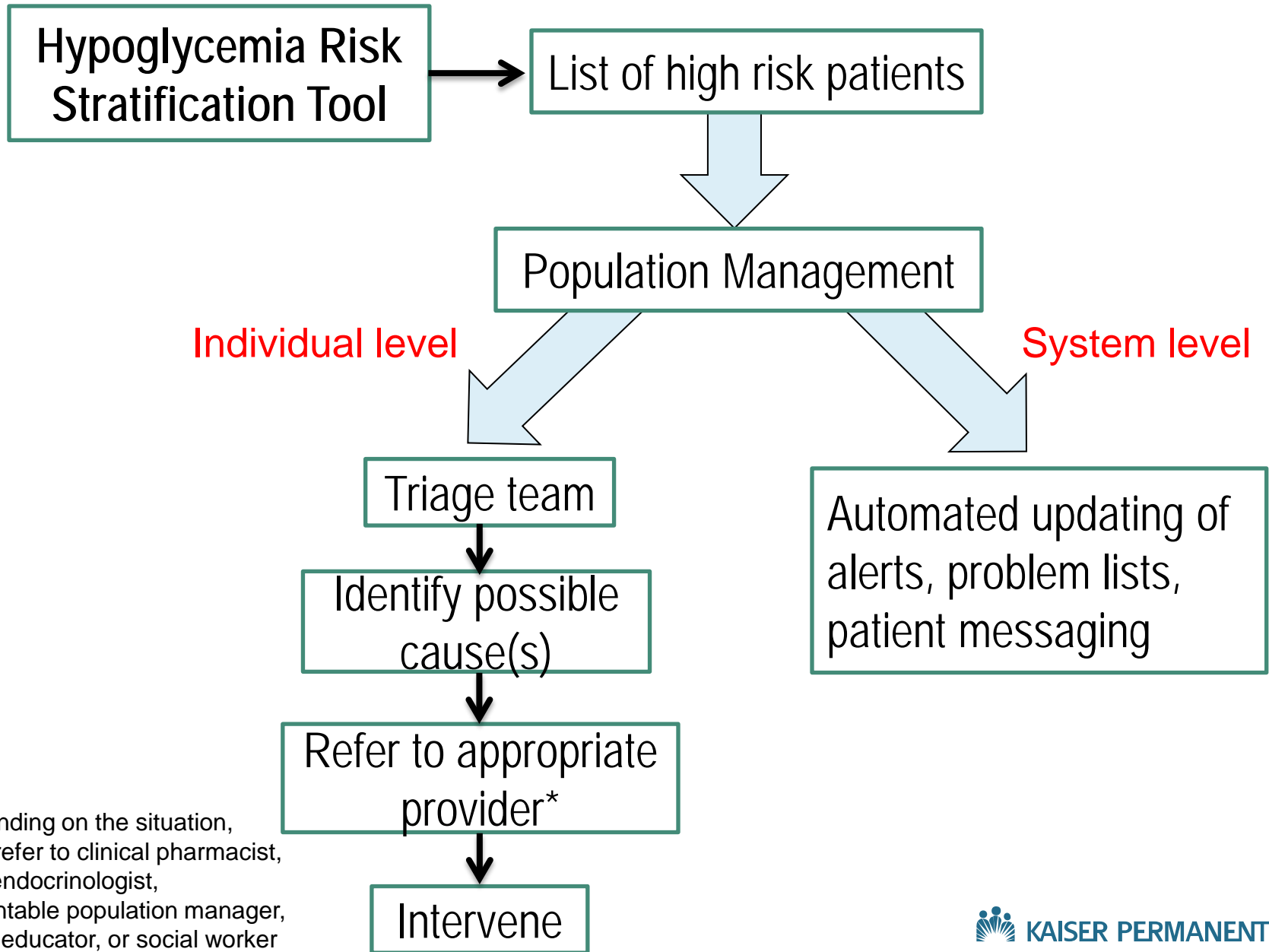
*Depending on the situation, could refer to clinical pharmacist, PCP, endocrinologist, accountable population manager, health educator, or social worker

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Soft touch (low cost) system-level interventions

- Automated updates of EMR
  - Clinical alert flags
  - Include "hypoglycemia" in problem list

- Guidelines modification
  - Automated stratification of glucose targets and step-care algorithm

- Patient messaging
  - Secure message, eLetter, or printed health education flyer

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Patient health educational flyer

Learning About Low Blood Sugar (Hypoglycemia) in Diabetes

Your Kaiser Permanente Care Instructions

Hypoglycemia means that your blood sugar is low and your body (especially your brain) is not getting enough fuel. If you have diabetes, your blood sugar can go too low if you take too much of some diabetes medicines. It can also go too low if you miss a meal. And it can happen if you exercise too hard without eating enough food. Some medicines used to treat other health problems can cause low blood sugar too.

What are the symptoms?

Symptoms of low blood sugar can start quickly. It may take just 10 to 15 minutes. If you have had diabetes for many years, you may not realize that your blood sugar is low until it drops very low.

- If your blood sugar level drops below 70 (mild low blood sugar), you may feel tired, anxious, dizzy, weak, shaky, or sweaty. You may have a fast heartbeat or blurry vision.

- If your blood sugar level continues to drop (usually below 40), your behavior may change. You may feel more irritable. You may find it hard to concentrate or talk. And you may feel unsteady when you stand or walk. You may become too weak or confused to eat something with sugar to raise your blood sugar level.

- If your blood sugar level drops very low (usually below 20), you may pass out (lose consciousness). Or you may have a seizure or stroke. If you have symptoms of severe low blood sugar, you need to get medical care right away.

If you had a low blood sugar level during the night, you may wake up tired or with a headache. Or you may sweat so much during the night that your pajamas or sheets are damp when you wake up.
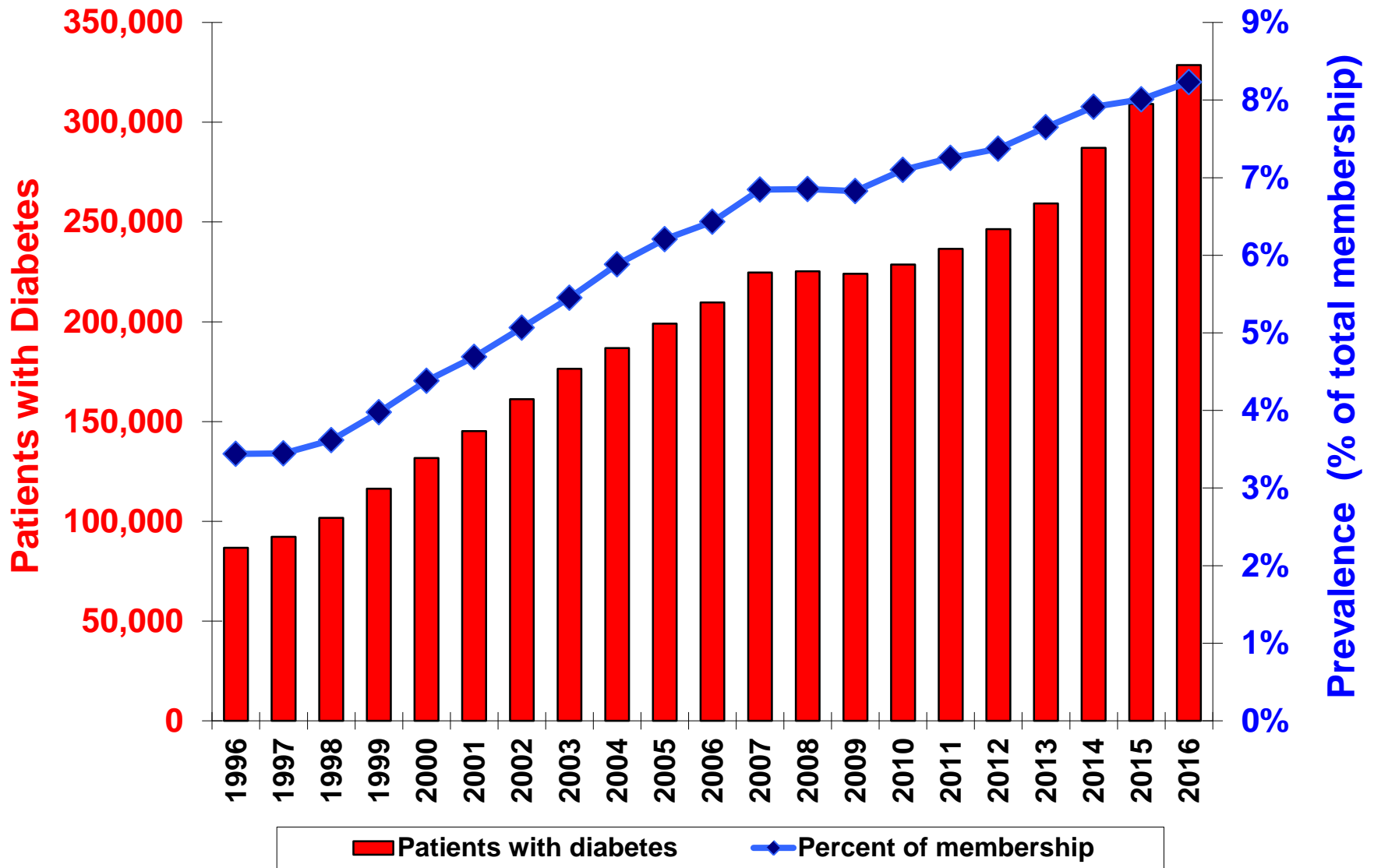
Intensive (higher cost) interventions

- **Monitoring**
  - Continuous Glucose Monitors; Flash Glucose Monitors

- **Medication management**
  - De-intensification Rx: Discontinue, lower dose, or switch
  - Insulin pump with threshold suspend
  - Intervention (raise GLU target) for impaired hypoglycemic awareness

- **Health education programs**
  - Teach recognition of symptoms (e.g., HypoAware, Youtube video)
  - Diet/lifestyle and self-management (e.g., avoid meal-skipping)
  - Teach "Rule of 15": take 15 gm of rapid-acting carbs, wait 15 minutes, then retest blood sugar.

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Intensive interventions- cont.

- Rescue
  - Glucagon kit

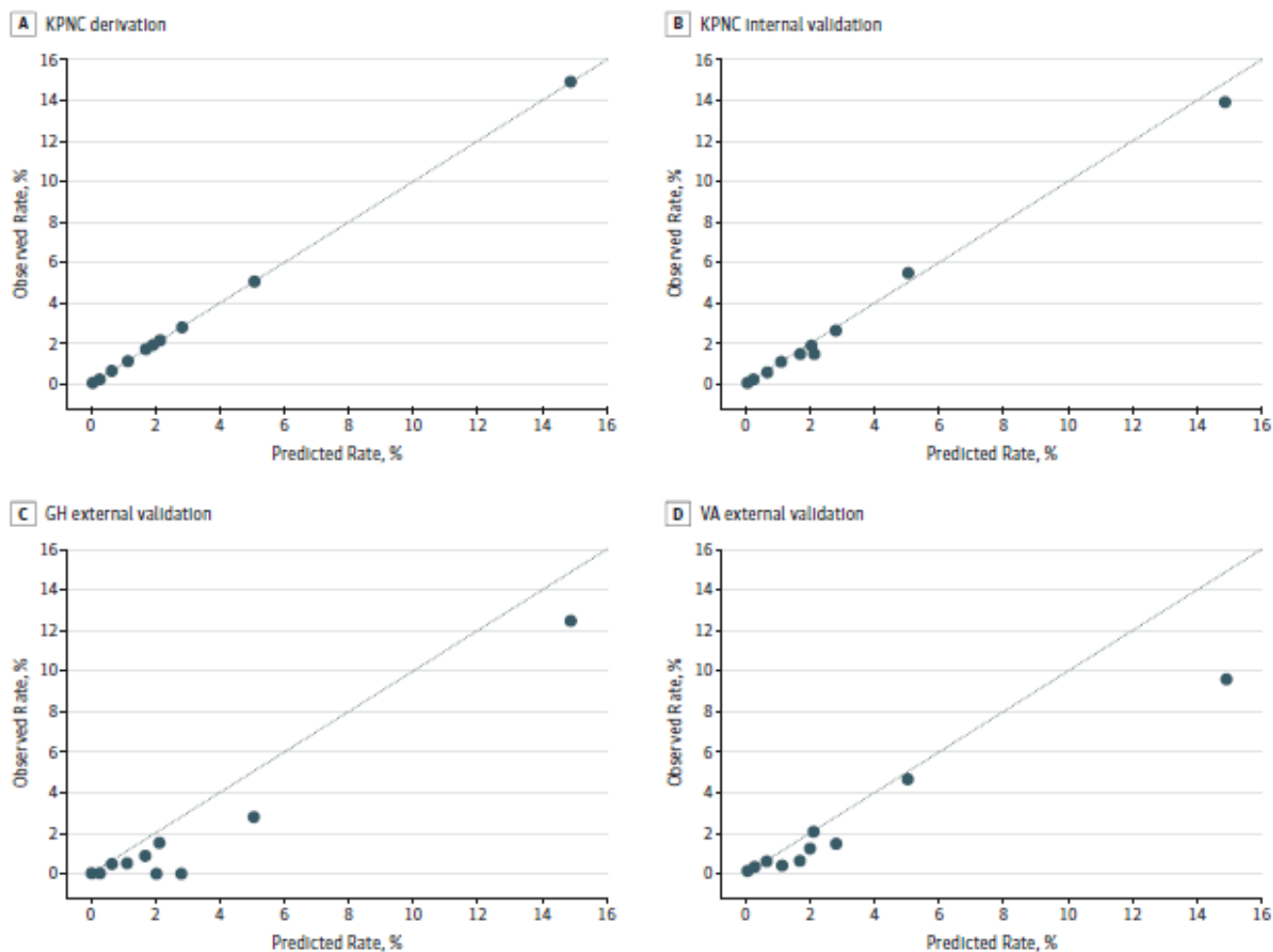- Screening
  - Take hypoglycemia history at each visit
  - Screen for impaired hypoglycemic awareness (Clarke score)

- Hypoglycemia specialty clinic

- Care management to address psychosocial risk factors (e.g., health literacy, food insecurity, depression, impaired cognitive function)

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Prevalence of Diabetes among Kaiser Permanente Northern California members, 1996-2016

Calibration Plots

Figure 3. Calibration Plots Comparing the Expected vs Observed 12-Month Rate of Having Any Hypoglycemia-Related Utilization[a] for the Interval Derivation Sample From Kaiser Permanente Northern California (KPNC) (n = 165 148), the KPNC Internal Validation Sample (n = 41 287), the External Validation Sample From Group Health (GH) (n = 14 972), and the External Validation Sample From the Veterans Administration (VA) (n = 1 335 966)

[a] Hypoglycemic-related utilization was defined by having any emergency department visit with a primary diagnosis of hypoglycemia or a hospitalization with a principal diagnosis of hypoglycemia. Hypoglycemia cases were ascertained with any of the following International Classification of Diseases,

Ninth Revision, codes: 251.0, 251.1, 251.2, 962.3, or 250.8, without concurrent 259.8, 272.7, 681.XX, 682.XX, 686.9X, 707.1-707.9, 709.3, 730.0-730.2, or 731.8 codes.[27]

SCIENCE

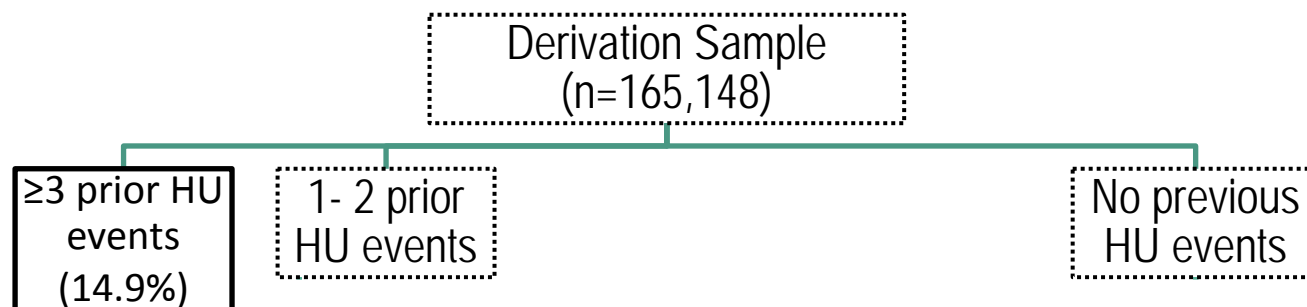Art

Hypoglycemia-related utilization (HU) risk classification tree*

Derivation Sample
(n=165,148)

*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014; HU risk for each leaf node (solid boxes) in parentheses.

Hypoglycemia-related utilization (HU) risk classification tree*

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Hypoglycemia-related utilization (HU) risk classification tree*

Derivation Sample
(n=165,148)

≥3 prior HU events
(14.9%)

1- 2 prior HU events

No previous HU events

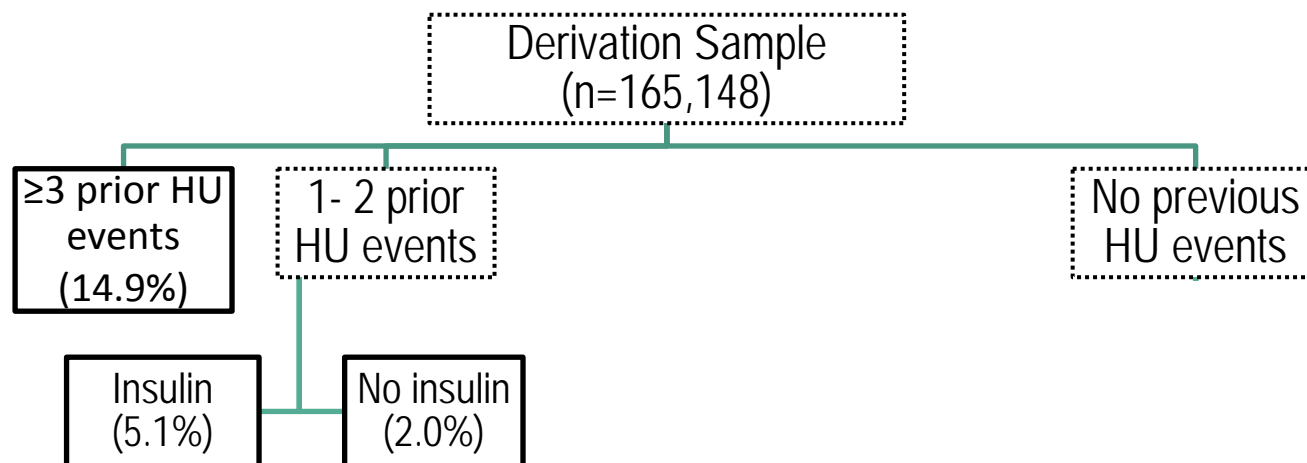Insulin
(5.1%)

No insulin
(2.0%)

*Based on 156 candidate variables linked to 808 HU events (any primary diagnosis in ED or principal diagnosis in hospital for hypoglycemia) occurring in 165,148 T2D adults from Kaiser Permanente (4.9 events per 1000 person years) in 2014; HU risk for each leaf node (solid boxes) in parentheses.

Hypoglycemia-related utilization (HU) risk classification tree*

```
                        Derivation Sample
                          (n=165,148)

  ≥3 prior HU      1- 2 prior                    No previous
  events           HU events                     HU events
  (14.9%)

           Insulin      No insulin       No Insulin              Insulin
           (5.1%)       (2.0%)
```
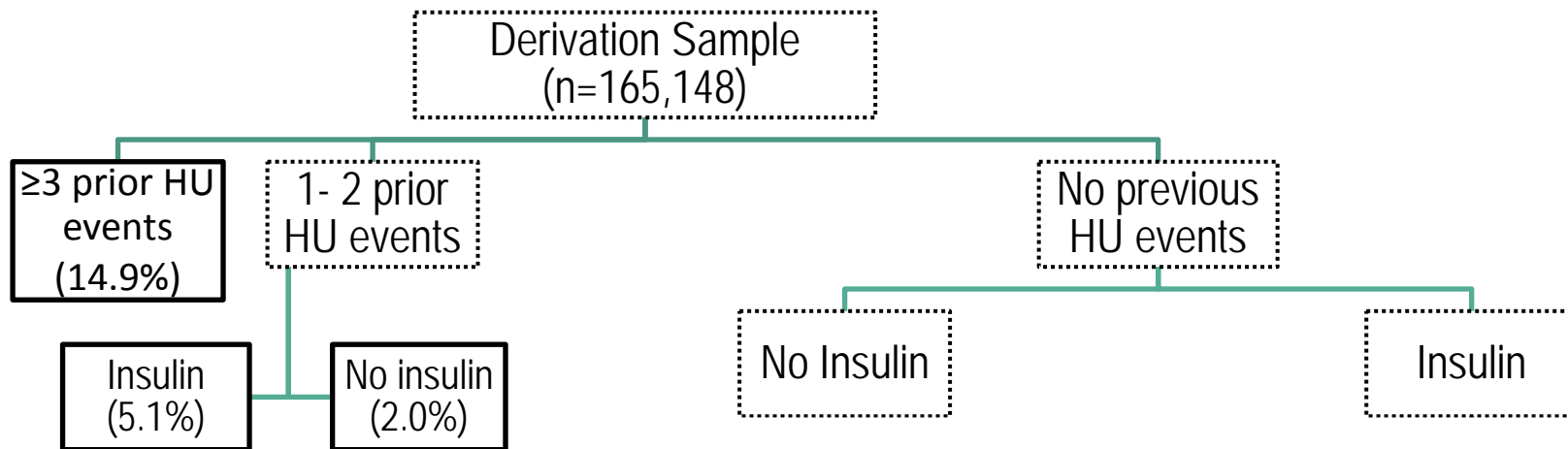
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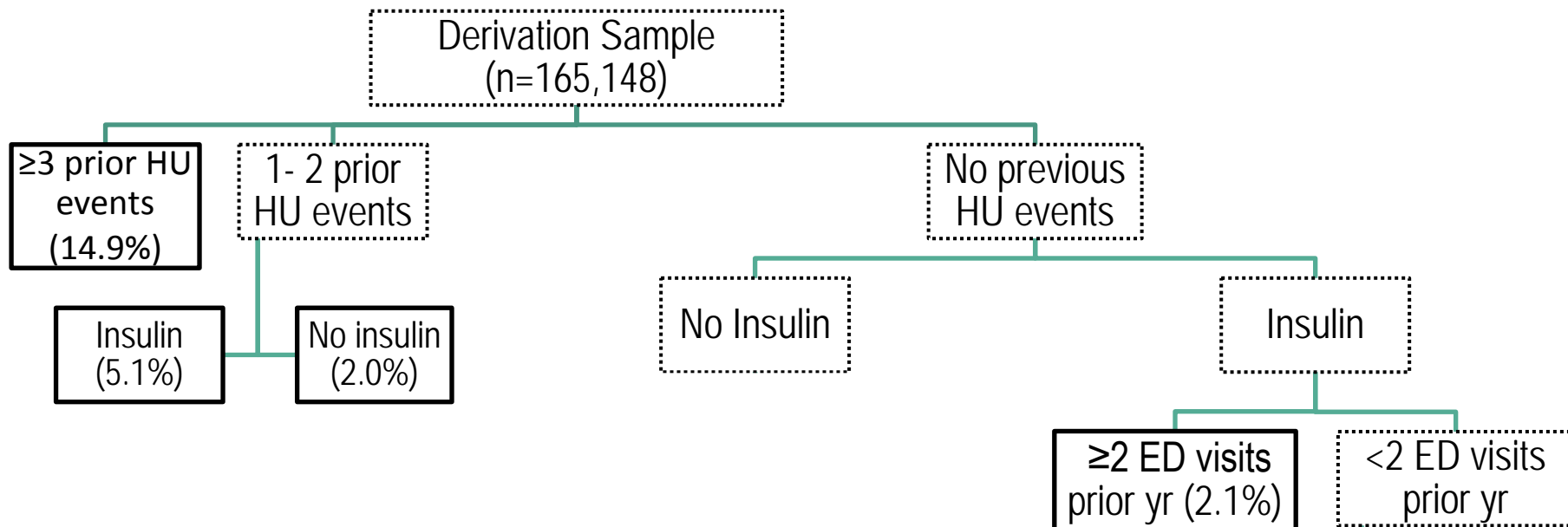# Hypoglycemia-related utilization (HU) risk classification tree*

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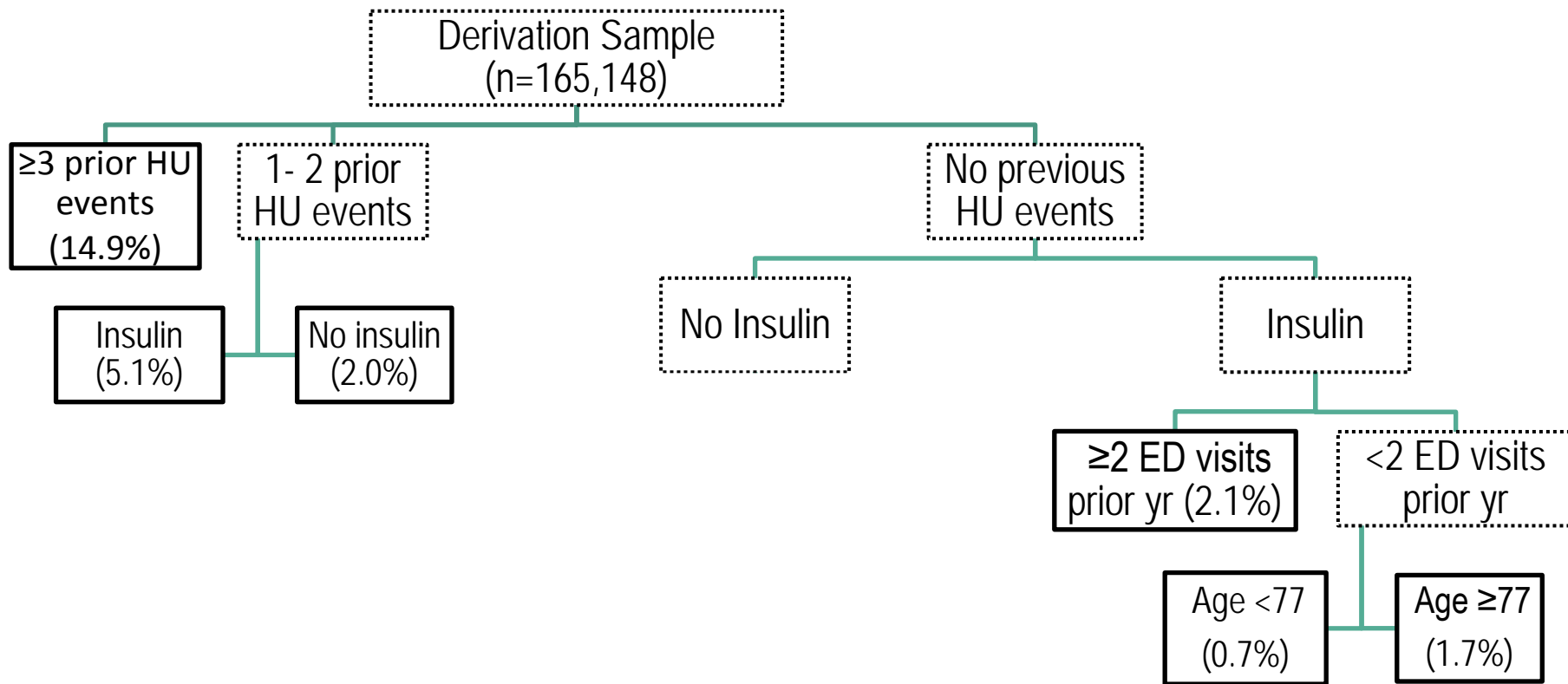# Hypoglycemia-related utilization (HU) risk classification tree*

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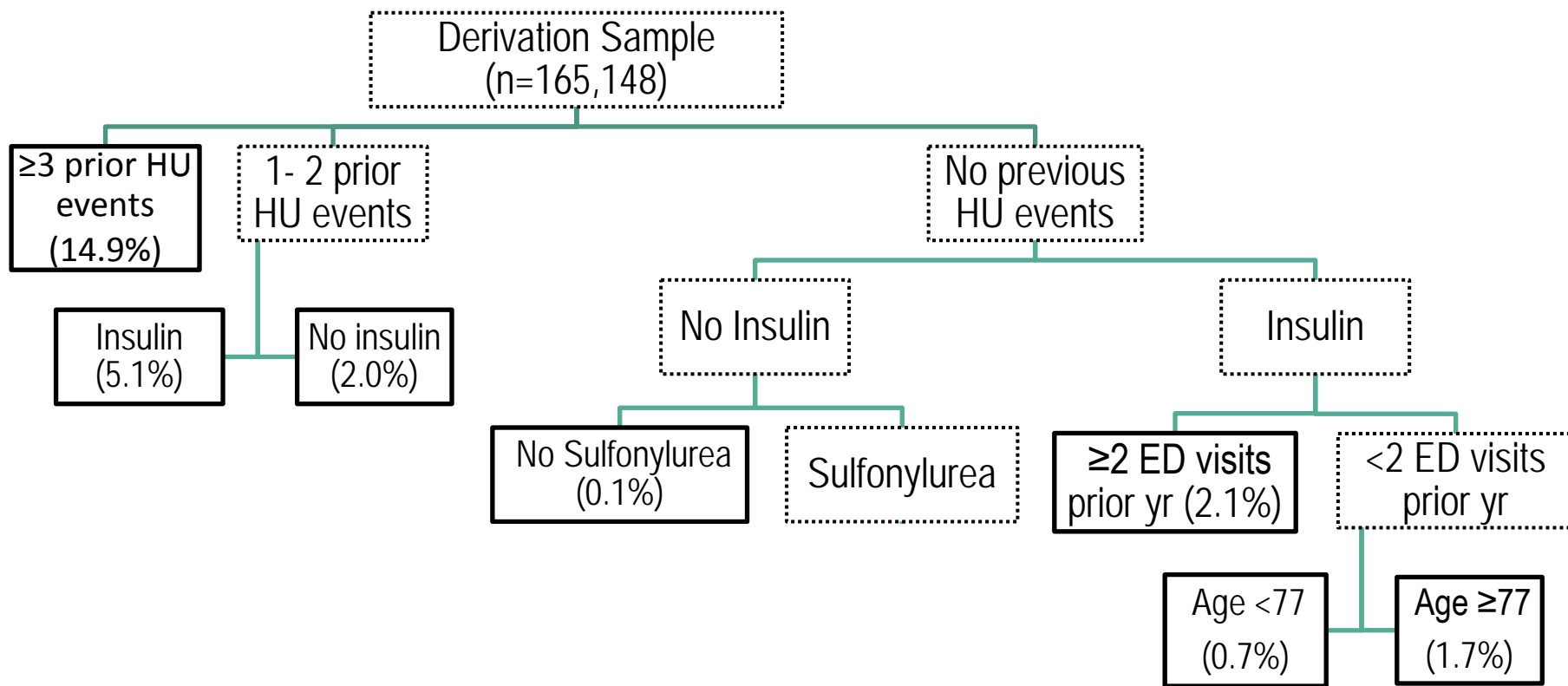# Hypoglycemia-related utilization (HU) risk classification tree*

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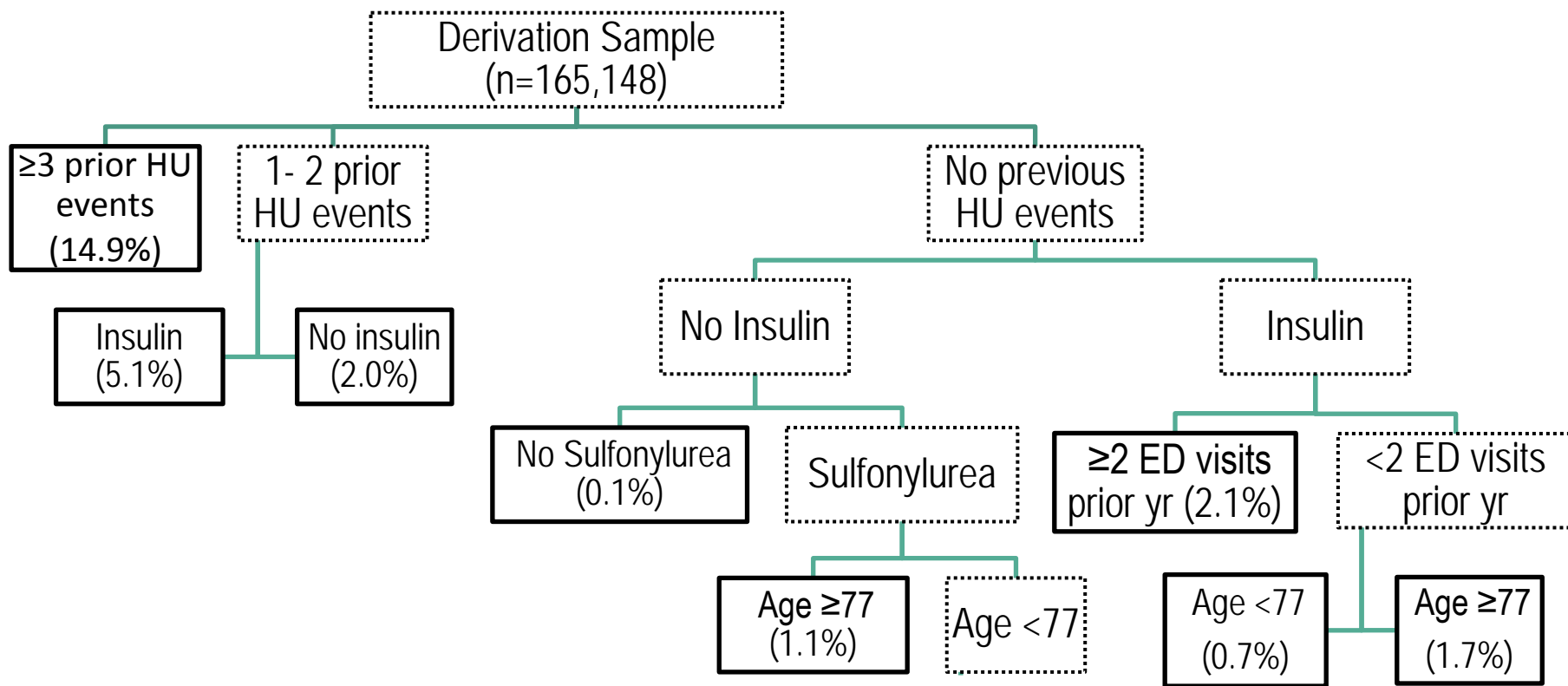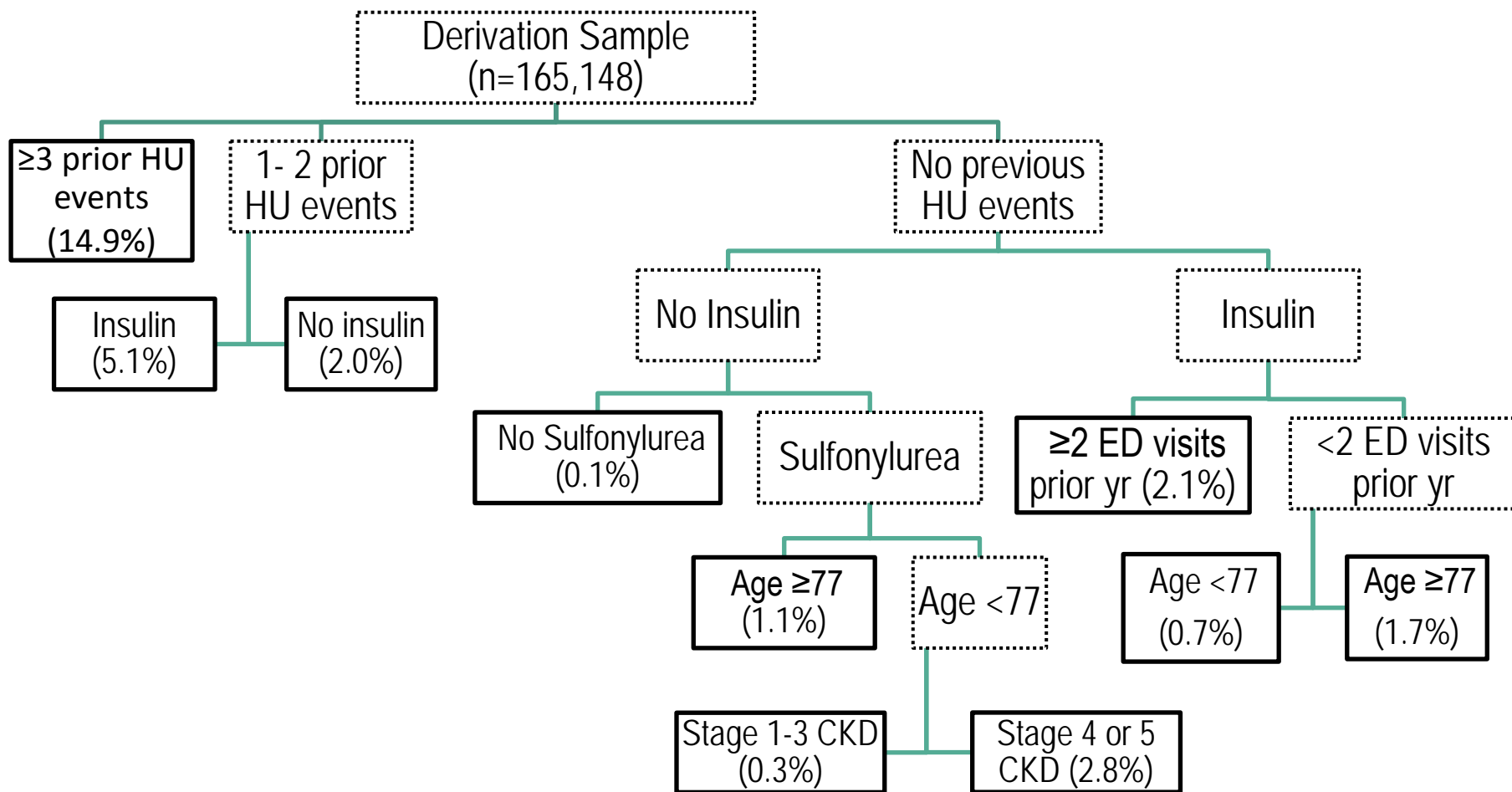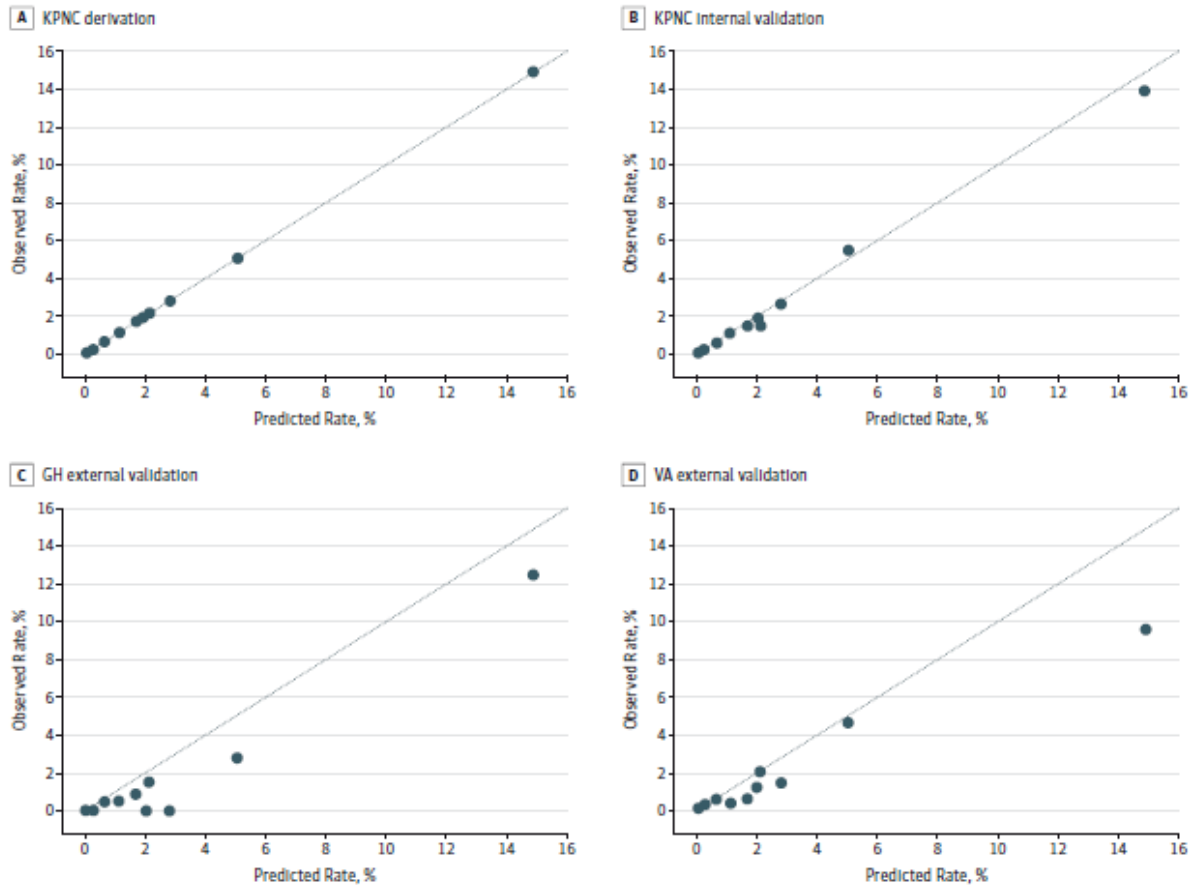# Hypoglycemia-related utilization (HU) risk classification tree*

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Robert Flemming, PhD

Centers for Medicare/Medicaid - Transforming Clinical Practice Initiative

Transforming Clinical Practice Initiative (TCPI)

Robert Flemming, PhD
Director, Transforming Clinical Practice Initiative
Centers for Medicare and Medicaid Services

Sep 2017

TCPI – Background & Overview

- Launched in September 2015
- Practice/clinician based
- **Leading technical assistance track for the Quality Payment Program (QPP).**
- Provides assistance for 100% participation in QPP (MIPs or APMs)
- > 75% of practices to join APMs.

TCPI Supports Quality Payment Program (QPP) in 3 Ways

1. Prepare practices for participation in APMs and Advanced APMs.

2. Provide technical assistance and support to clinicians participating in MIPs.

3. Demonstrate meaningful, impactful, and sustainable transformation of outpatient practices.

Rogers Adoption/Innovation Curve

Innovators 2.5%   Early Adopters 13.5%   Early Majority 34%   Late Majority 34%   Laggards 16%
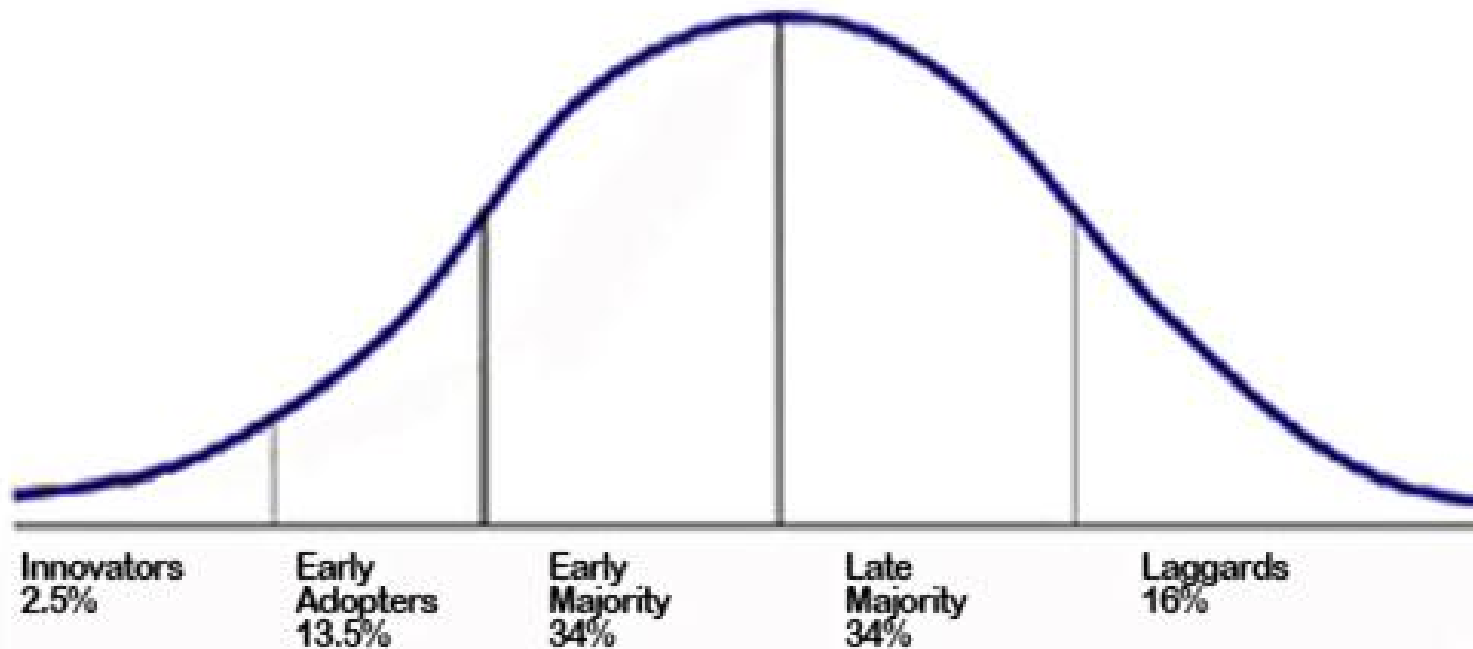
The TCPI Aims

1 Support more than 140,000 clinicians in their practice transformation work

2 Improve health outcomes for millions of Medicare, Medicaid and CHIP beneficiaries and other patients

3 Reduce unnecessary hospitalizations for 5 million patients

4 Generate $1 to $4 billion in savings to the federal government and commercial payers

5 Sustain efficient care delivery by reducing unnecessary testing and procedures

6 Transition 75% of practices completing the program to participate in Alternative Payment Models

7 Build the evidence base on practice transformation so that effective solutions can be scaled

TCPI Change Package: Goals and Drivers

Primary Drivers	Secondary Drivers
Patient and Family-Centered Care Design	1.1 Patient & family engagement 1.2 Team-based relationships 1.3 Population management 1.4 Practice as a community partner 1.5 Coordinated care delivery 1.6 Organized, evidence based care 1.7 Enhanced Access
Continuous, Data-Driven Quality Improvement	2.1 Engaged and committed leadership 2.2 Quality improvement strategy supporting a culture of quality and safety 2.3 Transparent measurement and monitoring 2.4 Optimal use of HIT
Sustainable Business Operations	3.1 Strategic use of practice revenue 3.2 Staff vitality and joy in work 3.3 Capability to analyze and document value 3.4 Efficiency of operation

The 5 Phases of TCPI

Set Aims | Use Data to Drive Care | Achieve Progress on Aims | Achieve Benchmark Status | Thrive as a Business via Pay for Value Approaches

Transforming Clinical Practice Initiative: Practice Transformation Networks (PTNs)

- Arizona Health-e Connection
- Baptist Health System, Inc.
- Children's Hospital of Orange County
- Colorado Department of Health Care Policy & Financing,
- Community Care of North Carolina, Inc.
- Community Health Center Association of Connecticut, Inc.
- Consortium for Southeastern Hypertension Control
- Health Partners Delmarva, LLC
- Iowa Healthcare Collaborative
- Local Initiative Health Authority of Los Angeles County
- Maine Quality Counts
- Mayo Clinic
- National Council for Behavioral Health
- National Rural Accountable Care Consortium
- New Jersey Innovation Institute
- New Jersey Medical & Health Associates dba CarePoint Health
- New York eHealth Collaborative
- New York University School of Medicine
- Pacific Business Group on Health
- PeaceHealth Ketchikan Medical Center
- Rhode Island Quality Institute
- The Trustees of Indiana University
- VHA/UHC Alliance Newco, Inc.
- University of Massachusetts Medical School
- University of Washington
- Vanderbilt University Medical Center
- HQI
- VHS Valley Health Systems, LLC
- Washington State Department of Health

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Transforming Clinical Practice Initiative: Support & Alignment Networks (SANs)

- American College of Emergency Physicians (ACEP)
- American College of Physicians, Inc. (ACP)
- American College of Radiology (ACR)
- American Medical Association (AMA)
- American Psychiatric Association (APA)
- HCD International, Inc. (HCDI)
- National Nursing Centers Consortium (NNCC)
- Network for Regional Healthcare Improvement (NRHI)
- Patient Centered Primary Care Foundation (PCPCF)
- The American Board of Family Medicine, Inc. (ABFM)
- Virginia Cardiac Services Quality Initiative (VCSQI)
- American Psychological Association (APA)

Examples of Ongoing Interventions, Measures, and Aims

Diagnosis	Clinical Intervention	Measure	Aims
Hypoglycemia	Optimizing medication management and safety processes	ED Visits Hospitalizations	Improve Outcomes Reduce Admissions Decrease Cost
Headache	Practice guidelines reviewed with clinicians and patients to reduce testing	CT scans MRIs	Improve Outcomes Unnecessary Tests Decrease Cost
Depression	Primary care clinician calls psychiatrist in real time for clinical guidance	Depression score	Improve Outcomes Decrease Cost
Low Back Pain	Choosing Wisely program implemented	X-ray	Improve Outcomes Unnecessary Tests Decrease cost

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What Participants Are Saying

- *"Working on TCPI has been the most rewarding experience of my entire career."*

- *"We are sitting on all this data; we need to figure out how to unleash it to help our patients."*

- *"I have been working on behavioral health-primary care integration for over a decade; now we have the ability to finally do it!"*

Helpful Links

TCPI: https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/

Healthcare Communities: http://www.healthcarecommunities.org/

Quality Payment Program: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Quality-Payment-Program.html

MACRA/MIPS/APMs: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html

Value Modifier: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html

Healthcare Payment Learning and Action Network (HCP-LAN): https://hcp-lan.org

Learning Diffusion Group: https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CMMI.html

Nilay Shah, PhD

Mayo Clinic

Implementing the Hypoglycemia Risk Tool: Case Study within the Mayo Clinic Practice Transformation Network (PTN)

Nilay Shah
Division of Health Care Policy and Research
Knowledge and Evaluation Research Unit
Center for the Science of Health Care Delivery
Mayo Clinic

Overview – Mayo PTN

MAYO CLINIC in the MIDWEST
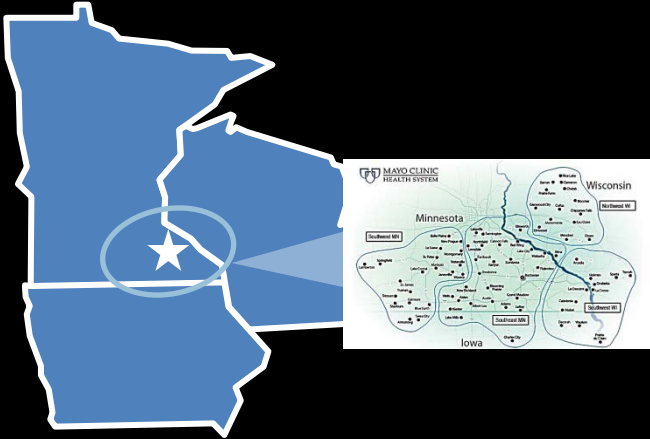
Academic Medical Center
Rochester, Minn.

- 500,000 patients/year
- 2,000 physicians
- 125 primary care providers
- Primary care
- At full risk for PC

Community and Regional Health System
75 communities in Minn., Iowa and Wis.

- 4 regions
- 18 hospitals
- 525,000 patients/year
- 1,000+ physicians
- Primary care
- At risk for PC

Cerner EMR

MAYO CLINIC in the SOUTHWEST

Arizona

- 90,000 patients/year
- Approx. 400 physicians
- Primary care
- At full risk for PC

Separate Cerner EMR

MAYO CLINIC in the SOUTHEAST
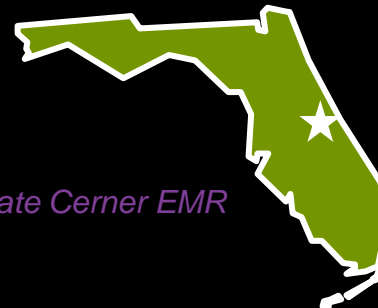
Florida

- 90,000 patients/year
- Approx. 400 physicians
- Primary care
- At full risk for PC

TCPI Aims

- Support more than 140,000 clinicians in their practice transformation work

- Improve health outcomes for millions of Medicare, Medicaid and CHIP beneficiaries and other patients

- Reduce unnecessary hospitalizations for 5 million patients

- Generate $1 to $4 billion in savings to the federal government and commercial payers

- Sustain efficient care delivery by reducing unnecessary testing and procedures

- Transition 75% of practices completing the program to participate in Alternative Payment Models

- Build the evidence base on practice transformation so that effective solutions can be scaled

Preventing Adverse Drug Events

- Opioids
- Anticoagulation
- Beers Criteria Related Medications
- Diabetes medications/insulins
  - hypoglycemia

Increased Mortality of Patients With Diabetes Reporting Severe Hypoglycemia

ROZALINA G. MCCOY, MD[1]
HOLLY K. VAN HOUTEN, BA[2]
JEANETTE Y. ZIEGENFUSS, PHD[2]

NILAY D. SHAH, PHD[2]
ROBERT A. WERMERS, MD[1,3]
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hypoglycemia did have significantly higher rates of death (11,12) as well as micro-, macro-, and nonvascular complications (12). The cause of increased fatal and nonfatal adverse events among pa-

	All	Alive	Deceased	P value
Number of patients (%)	1,013	873 (86.2)	140 (13.8)	
Age at baseline (years), mean (SD)	60.5 (15.2)	59.2 (15.0)	68.1 (13.7)	<0.001
Men, n (%)	555 (54.8)	462 (52.9)	93 (66.4)	0.003
Type 1 diabetes, n (%)	216 (21.3)	195 (22.3)	21 (15.0)	0.049
Diabetes duration (years), mean (SD)	13.6 (11.4)	13.3 (11.3)	15.6 (11.6)	0.025
HbA_{1c} (%), mean (SD)	7.2 (1.4)	7.2 (1.3)	7.2 (1.6)	0.792
CCI, mean (SD)	1.9 (1.9)	1.6 (1.5)	3.6 (3.1)	<0.001
Hypoglycemia, n (%)				
None	388 (38.3)	342 (39.2)	46 (32.9)	0.153
Mild	549 (54.2)	473 (54.2)	76 (54.3)	0.982
Severe	76 (7.5)	58 (6.6)	18 (12.9)	0.010

Mortality data were obtained from the SSDI after 5 years of follow-up. P value compares those alive vs. deceased at time of follow-up. Unless otherwise specified, all values refer to baseline measurements.

Increased Mortality of Patients With Diabetes Reporting Severe Hypoglycemia

Rozalina G. McCoy, MD[1]
Holly K. Van Houten, BA[2]
Jeanette Y. Ziegenfuss, PhD[2]
Nilay D. Shah, PhD[2]
Robert A. Wermers, MD[1,3]
Steven A.

hypoglycemia did have significantly

	OR	95% CI	P value
Age	1.047	1.027–1.066	<0.001
Male sex	1.716	1.135–2.596	0.011
Type 1 diabetes	0.836	0.410–1.706	0.623
Diabetes duration	1.006	0.985–1.027	0.595
HbA$_{1c}$	1.127	0.965–1.316	0.131
CCI	1.437	1.323–1.561	<0.001
Hypoglycemia			
Mild	1.564	0.986–2.481	0.468
Severe	3.381	1.547–7.388	0.005

OR for 5-year mortality was adjusted for age, sex, diabetes type and duration, HbA$_{1c}$, CCI, and hypoglycemia history. Unless otherwise specified, all measures were obtained at baseline.

SELF-REPORT OF HYPOGLYCEMIA AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES

Running title: Hypoglycemia and quality of life

Rozalina G. McCoy, MD[1]; Holly K. Van Houten, BA[2]; Jeanette Y. Ziegenfuss, PhD[3]; Nilay D. Shah, PhD[2]; Robert A. Wermers, MD[1]; Steven A. Smith, MD[1,2]

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	None/Mild (n=337)	Severe (n=81)	P-value
Health Rating, %			<0.001
Excellent	4.5	1.2	
Very Good/Good	77.2	62.9	
Fair/Poor	18.4	35.8	
EQ-5D scores			
Self-care	1.0	1.3	<0.001
Usual activities	1.3	1.5	0.001
Utility index	0.85	0.77	0.002
HFS score: worry/behavior	17.4	31.1	<0.001

Intensive Treatment and Severe Hypoglycemia Among Adults With Type 2 Diabetes

Rozalina G. McCoy, MD, MS; Kasia J. Lipska, MD, MHS; Xiaoxi Yao, PhD, MHS; Joseph S. Ross, MD, MHS; Victor M. Montori, MD, MS; Nilay D. Shah, PhD

Figure 2. Risk-Adjusted Probability of Hypoglycemia as a Function of Patient Clinical Complexity and Treatment Intensity

Source	Adjusted Probability of Severe Hypoglycemia (95% CI)
Low complexity with standard treatment	1.02 (0.87 to 1.17)
Low complexity with intensive treatment	1.30 (0.98 to 1.62)
High complexity with standard treatment	1.74 (1.28 to 2.20)
High complexity with intensive treatment	3.04 (1.91 to 4.18)

Adjusted Probability of Severe Hypoglycemia (95% CI)

Source	Difference of Probabilities (95% CI)
vs low complexity with standard treatment P=.15	0.28 (−0.10 to 0.66)
vs low complexity with standard treatment P<.01	0.72 (0.25 to 1.19)
vs high complexity with standard treatment P=.03	1.30 (0.10 to 2.50)

Difference of Probabilities (95% CI)

High clinical complexity was defined as a composite measure of age of 75 years or older or high comorbidity burden defined by presence of end-stage renal disease, dementia, or 3 or more chronic conditions (myocardial infarction, congestive heart failure, pulmonary disease, non–end-stage chronic renal disease, or cancer). Intensive treatment was defined as a composite measure of intensive baseline regimen (use of greater number of medications than recommended for a given index hemoglobin A_{1c} [HbA_{1c}] level) and treatment intensification despite a low index HbA_{1c} result. Risk-adjusted probabilities are adjusted for patient sex, race, household income, residency region, index HbA_{1c} year, and specialty of treating health care professional. Error bars indicate 95% CIs.

Hypoglycemia Risk Prediction Tool

Tool Inputs

- How many times has the patient ever had hypoglycemia-related utilization in an ED (primary diagnosis of hypoglycemia[a]) or hospital (principal diagnosis of hypoglycemia[a]) (0, 1-2, ≥3 times)?
- How many times has the patient gone to an ED for any reason in the prior 12 months (<2, ≥2 times)?
- Does the patient use insulin (yes/no)?
- Does the patient use sulfonylurea (yes/no)?
- Does the patient have severe or end-stage kidney disease (CKD stage 4 or 5) (yes/no)?
- Is the patient <77 years old (yes/no)?

Instructions: The 6 inputs above are used to identify one of the mutually exclusive exposure groups and the corresponding risk category (high, low, or intermediate) for hypoglycemia-related ED or hospital utilization[b] in the following 12 months. The first 5 options are defined by unique combinations of predictor variables, while the sixth option is indicated only after ruling out the first 5 options.

☐	≥3 Prior hypoglycemia-related ED or hospital utilization	High risk (>5%)
☐	1-2 Prior hypoglycemia-related ED or hospital utilization AND Insulin user	

☐	No prior hypoglycemia-related ED or hospital utilization AND No insulin AND No sulfonylurea use	Low risk (<1%)
☐	No prior hypoglycemia-related ED or hospital utilization AND No insulin AND Uses sulfonylurea AND Age <77 years AND Does not have severe or end-stage kidney disease	
☐	No prior hypoglycemia-related ED or hospital utilization AND Uses insulin AND Age <77 years AND <2 ED visits in prior year	

☐	All other risk factor combinations	Intermediate risk (1%-5%)

Implementing the Hypoglycemia Risk Prediction Tool

90 primary care clinics – Mayo Clinic PTN

Patients attributed to clinicians, care teams and clinics

Patients identified with a diagnosis of type 2 diabetes – n= 52,633

Implement risk prediction tool

Considerations for Implementing the Risk Prediction Tool

Right population

Challenges with observation period

Completeness of medication data

Completeness of utilization data

Hypoglycemia Risk across Mayo Clinic PTN

Bar chart showing values by category:

- 1 or 2 prior SH events, Insulin: 661 (1.35%)
- >=3 prior SH events: 49
- 1 - 2 prior SH events, No Insulin: 100
- No previous SH events, Insulin, <2 ED visits prior year, Age >= 77: 3,375
- No previous SH events, Insulin, >=2 ED visits prior year: 1,290 (12.2%)
- No previous SH events, No Insulin, Sulfonylurea, Age < 77, ESRD: 10
- No previous SH events, No Insulin, Sulfonylurea, Age >= 77: 1,622
- No previous SH events, Insulin, >=2 ED visits prior year, Age < 77: 13,720
- No previous SH events, No Insulin, No Sulfonylurea: 24,706
- No previous SH events, No Insulin, Sulfonylurea, Age < 77, No ESRD: 7,100

Risk of Hypoglycemia by Age

Risk Group	Age (mean)	Range
High (n=698)	59.2 (17.7)	18-99
Intermediate (n=6,281)	79.9 (10.7)	18-104
Low (n=45,637)	63.5 (13.4)	18-87

Age Group Distribution of High Risk Group

- 21.5% >= 18 to <45
- 38.7% >= 45 to <65
- 20.5% >= 65 to <75
- 12.3% >= 75 to <85
- 7.0% 85 and Over
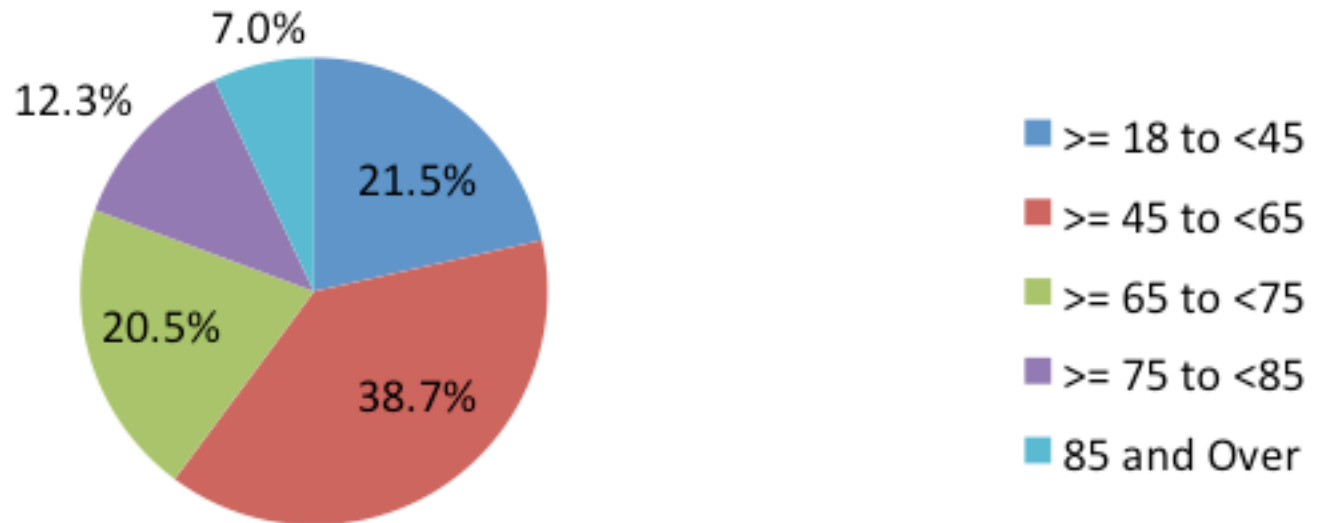
Distribution of Risk by Marital Status
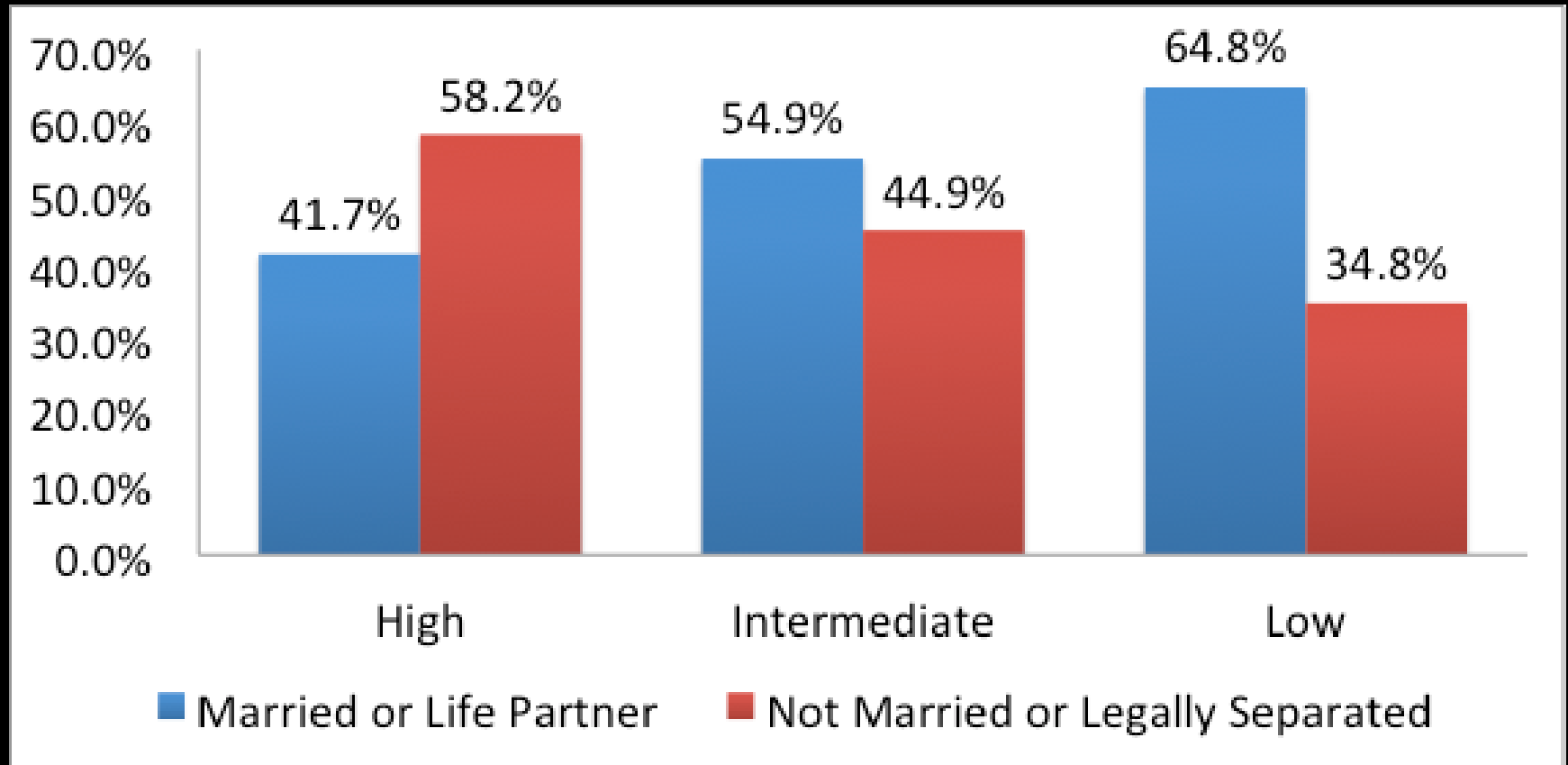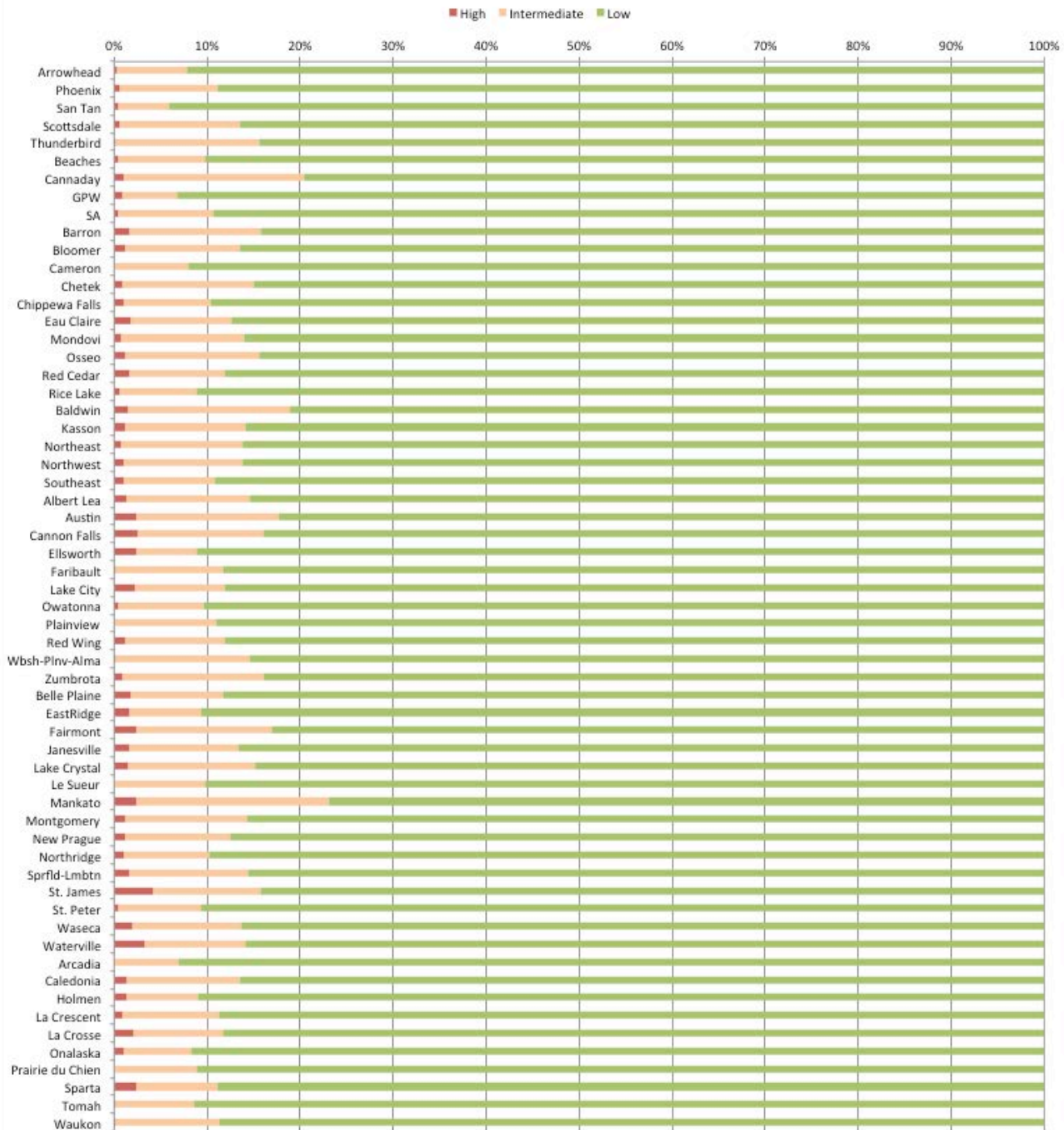
Distribution of Risk Across Clinics

Range of Patients per Clinic (n)   60-4,924

Range of Risk

  High   0.0-4.2%

  Intermediate   5.4-20.8%

Now what?

Two pilot approaches to intervene:

Shared Decision Making

Mullan RJ et al. Archives of Internal Medicine 2009

http://shareddecisions.mayoclinic.org

Shared Decision Making

Mullan RJ et al. Archives of Internal Medicine 2009

http://shareddecisions.mayoclinic.org

Medication Therapy Management Pilot

- Pharmacists part of primary care teams
- Identify patients at high risk
- Proactively contact them and identify self reported experiences and approaches to decrease risk
- Outcomes over time
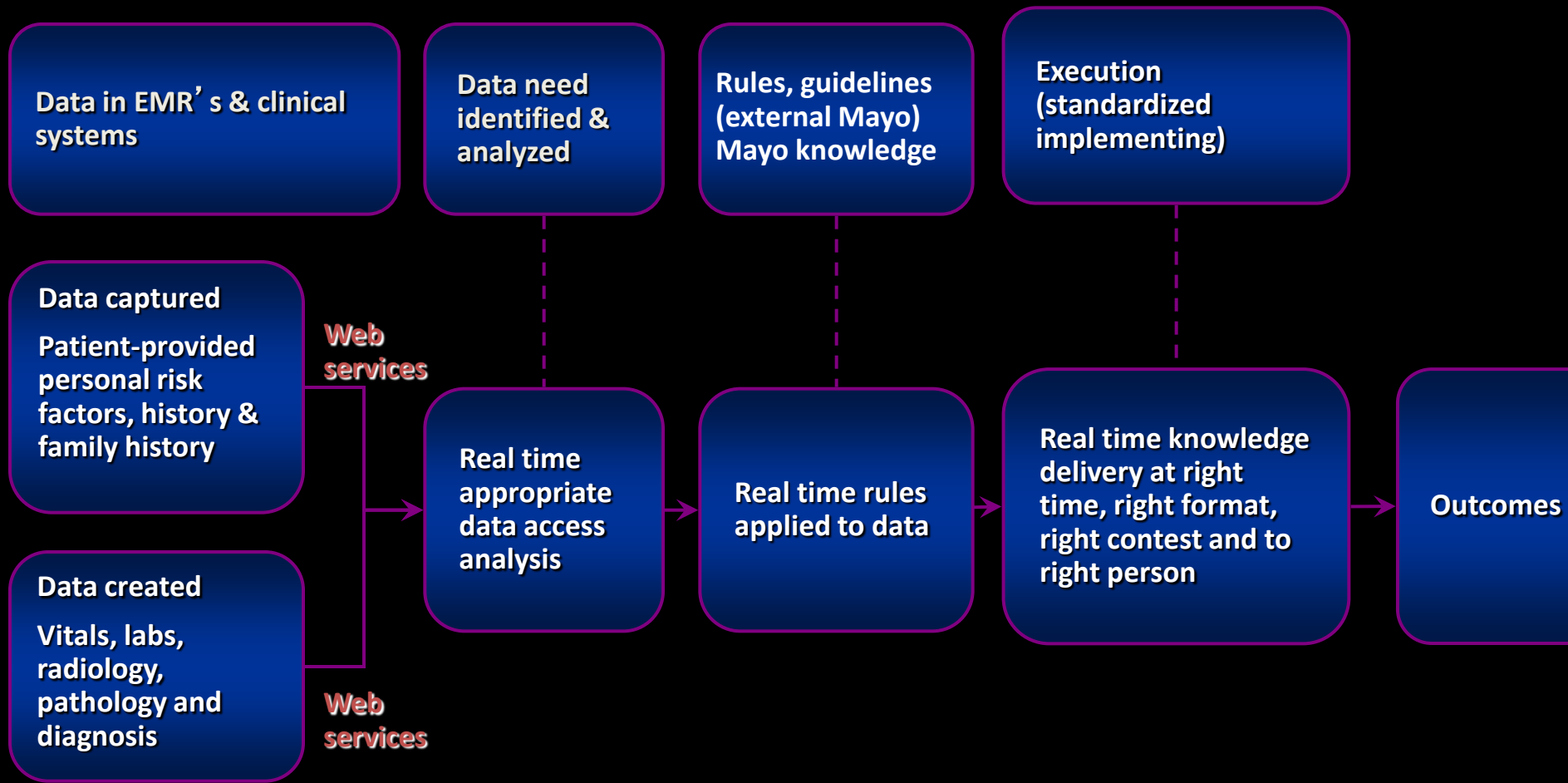
Clinical Decision Support

Generic Disease Management System

Summary for diseases and preventive services

Patient summary

Refresh data   Print report

Clinic # [____] Go
Name [____] [____]
Birth date [____] Age [____] ○ Male ● Female
Prim. Phys. [____]
Has: DM1 ☐ DM2 ☑   CAD ☑ Asth. ☐ Depr ☐
Hypertension ☑   Myeloma ☐ Gammopathy ☐

Last blood pressure	99/56	Date	02/10/2011
Last height		cm Date	
Last weight	48.3	kg Date	02/10/2011
Last BMI		Date	
PHQ-9 score		Date	

Last Asthma Action Plan [____]
Current tobacco use ☐   Last CVI [____]
Last advance directive [____]
Last MAGE screening [____]
Last echo [11/09/2006]
Last ECG [07/15/2009]
Last nuclearstudy [____]
ERA Score [11]
Ejection Fraction [25%]

Labs for past 5 years   History   Graph

	Normal value	Most recent value	mm/dd/yyyy
Hemoglobin	12.0-15.5	15.4 g/dL	07/15/2009
Sodium	135-145	141 mmol/L	07/15/2009
Potassium	3.6-5.2	3.9 mmol/L	02/10/2011
Glucose	70-100	156 * mg/dL	02/10/2011
HbA1c	4.0-6.0	8.3 * %	02/10/2011
AST (SGOT)	8-43	21 U/L	03/23/2010
ALT (SGPT)			
Creatinine	0.6-1.1	1.0 mg/dL	09/23/2009
eGFR			
Total cholesterol		285 * mg/dL	03/23/2010
Triglycerides		275 * mg/dL	03/23/2010
HDL cholesterol		39 * mg/dL	03/23/2010
LDL cholesterol		191 * mg/dL	03/23/2010
hsCRP			
Lipoprotein(a)			
INR	0.9-1.2	2.7 *	12/30/2010
Uric acid			
TSH	0.3-5.0	1.5 mIU/L	11/13/2008
Random Microalb.	<25	26 * mg/g	09/23/2009

Recommended actions

- Colon cancer screening due.
- LDL should be < 100.
- Eye exam due
- HbA1c should be < 8.
- Creatinine due.
- Microalbumin due
- Lipid panel due.
- INR due.

Rec. actions next 90 days

- HbA1c due by May 10, 2011 & recommended every 3 months if HbA1c >= 8.

Preventive services   Hist.   Guidel.

Influenza vaccine	11/04/2010		
Tetanus vaccine	09/02/2010		
Herpes zoster vaccine	09/22/2009		
Pneumococcal vaccine	12/20/2005		
Colon X-ray	11/02/2000		
Mammogram	11/09/2006		
Bone density screening	04/17/2003		

Educational links & forms

My Road to Better Health with Diabetes
Daily Weight Diary
Know Your Risk Factors for Coronary Artery Disease
My Road to Better Health

Alerts

- Recommend advance care planning.
- Consider beta blocker therapy.
- Recommend ACE or ARB.
- Consider cardiac device (AICD) consult.
- Digoxin level due.

	Normal value	Most recent value	mm/dd/yyyy		
Hemoglobin	12.0-15.5	15.6 * g/dL	01/14/2011		
Sodium	135-145	142 mmol/L	02/02/2009		
Potassium	3.6-5.2	4.1 mmol/L	02/02/2009		
Glucose	70-100	261 * mg/dL	01/19/2010		
HbA1c	4.0-6.0	9.8 * %	07/23/2010		
AST (SGOT)	8-43	46 * U/L	01/14/2011		

HbA1c should be < 8.

BP should be < 140/90.

HbA1c due & recommended every 3 months if HbA1c >= 8.

Lipid panel due.

Microalbumin due.

TSH due.

ic #   Go

ne

h date   Age   ○ Male ● Female

n. Phys.

. DM1 ☐ DM2 ☑   CAD ☐ Asth. ☐ Depr ☐

Hypertension ☑   Myeloma ☐ Gammopathy ☐

t blood pressure   169/90   Date 01/18/2011

t height   161   cm   Date 01/18/2011

t weight   94.8   kg   Date 01/18/2011

t BMI   36.6   Date 01/18/2011

Q-9 score   Date

t Asthma Action Plan

rent tobacco use ☐   Last CVI 01/18/2011

t advance directive

t MAGE screening

t echo

t ECG   06/27/2008

t nuclearstudy

A Score   1

ction Fraction

mingham score   20%

AME - Hypertension - Windows Internet Explorer

http://javaprod.mayo.edu/ame/openTopic?page=14&topicID=364

File   Edit   View   Favorites   Tools   Help

AME - Hypertension

AskMayoExpert   [Search]

Feedback

Hypertension

Show introduction

| Mayo Clinic Care Process Model | FAQs | Expert Directory | Guidelines & Resources |

Hypertension

- Why focus on hypertension?
- Why should this approach be implemented?
- What are the objectives from a work up for a patient with hypertension?

eventive services   Hist.   Guidel

n X-ray   09/07/1999

mogram   11/09/2010

e density screening   01/14/2011

test   01/18/2011

enza vaccine   10/28/2010

o vaccine   11/07/2006

es zoster vaccine   09/21/2006

Summary

- Implementation of hypoglycemia risk prediction tool is feasible

- Significant variation in risk across clinics and care teams

- Pilot low-cost approaches may decrease risk, improve health outcomes, and decrease preventable utilization

- Potential benefit from collecting self-reported risk of hypoglycemia

Acknowledgments

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Open discussion
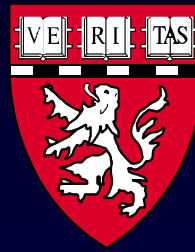
Reducing the risk of preventable adverse drug events associated with hypoglycemia in older adults

Medha Munshi, M.D.

Associate Professor, Harvard Medical School
Director, Joslin Geriatric Diabetes Program
Beth Israel Deaconess Medical Center

Joslin Diabetes Center

3 major points

- Hypoglycemia – frequently unrecognized – are common in older adults

- A1c levels do not correlate with risk of hypoglycemia in older adults

- De-intensification of insulin regimen can reduce the risk of hypoglycemia without compromising glycemic control

Unrecognized hypoglycemic episodes are frequent in older adults on insulin
age>70 yrs; A1C>8%; n=40

Patients with hypoglycemia   n = 26 (65 %)

Patients with A1C 8-9 %   14 (54 %)
Patients with A1C > 9 %   12 (46 %)

Severity of hypoglycemic episodes

60-69 mg/dl	100 %
50-59 mg/dl	73 %
< 50 mg/dl	46 %

Munshi et al; Arch Intern Med. 2011;171(4):362-364

Lack of association between A1c levels and hypoglycemia risk

Baseline A1C (multiple insulin injections)	≤ 7% N=17	7.1-8 % N=27	8.1-9 % N=14	>9% N=7	P-value
Hypo Duration (mins/5 days)					
<70 mg/dL	292 ± 306	292 ± 244	280 ± 260	246 ± 222	0.9
<60 mg/dL	146 ± 225	157 ± 183	160 ± 174	162 ± 168	0.9
< 50 mg/dL	76 ± 184	91 ± 139	74 ± 115	56 ± 70	0.7
Nocturnal Hypo (10 pm-6 am)	119 ± 207	132 ± 205	147 ± 144	175 ± 201	0.6
8-month A1C (once/day bBasal insulin)	≤ 7% N=12	7.1-8 % N=23	8.1-9 % N=18	>9 % N=4	
Hypo duration (mins/5 days)					
<70 mg/dL	34 ± 63	167 ± 216	46 ± 99	104 ± 75	0.09
<60 mg/dL	21 ± 43	87 ± 131	27 ± 72	86 ± 61	0.1
< 50 mg/dL	14 ± 31	43 ± 65	10 ± 35	48 ± 47	0.1
Nocturnal Hypo (10 pm-6 am)	13 ± 34	95 ± 127	26 ± 67	41 ± 83	0.06

Munshi MN et al; Journal of dia and its compli, june 2017

Simplification of Regimen

- **Age >70 yrs**
- **≥ 1 insulin injection/day**
- **High stimulated c-peptide**
- **≥ 1 episode of glucose <70**

Active Intervention (5 months)

Independent Period (3 months)

Evaluation

Simplification of Regimen to Once a day Glargine ± Non-insulin agents

Evaluation

No Active Contact

Evaluation
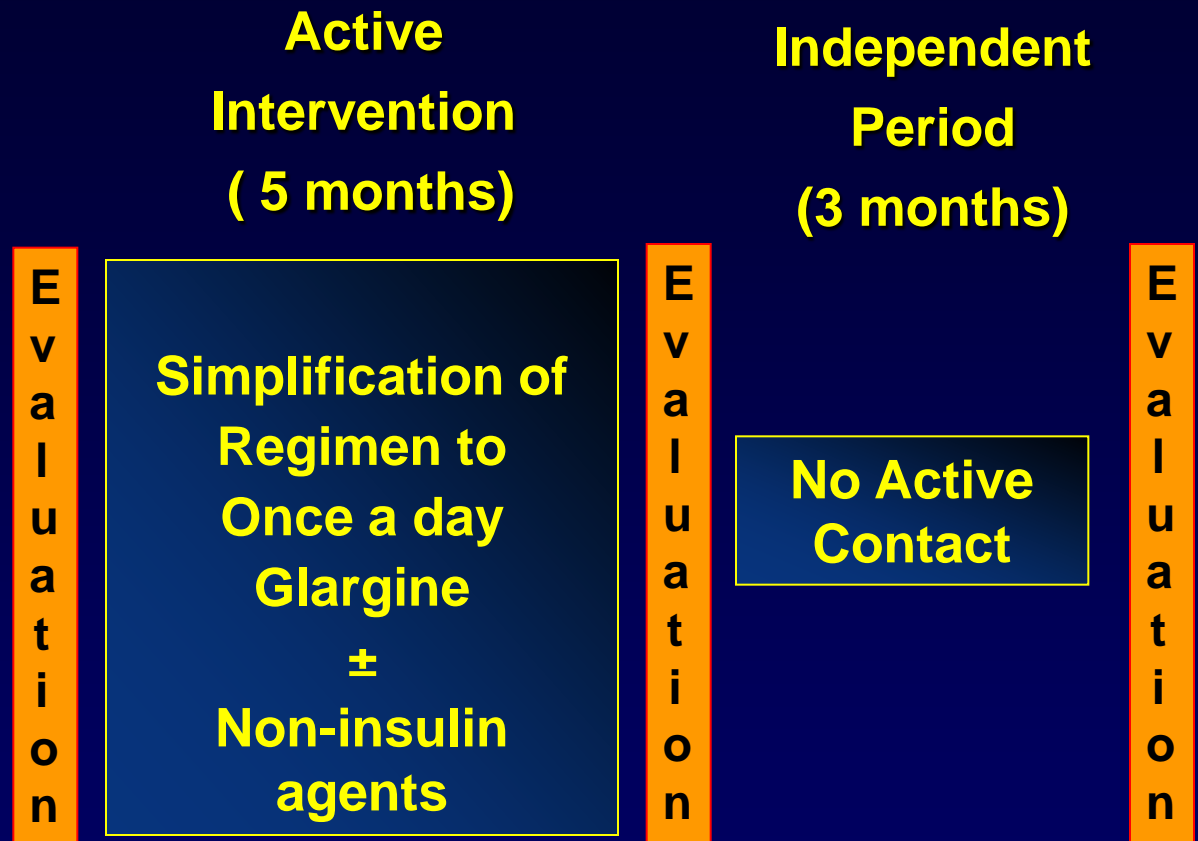
Primary outcome: Duration of hypoglycemia by CGM
Secondary outcome: A1C

Joslin Diabetes Center

Deintensification of insulin regimen improve hypoglycemia without worsening glycemic control
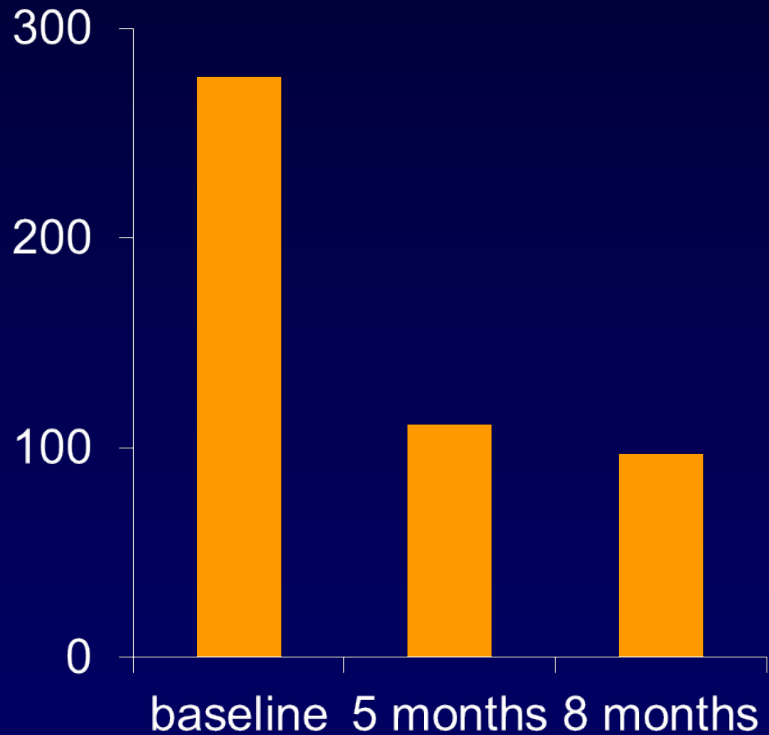
Duration of hypoglycemia
<70 / 5-day CGM

A1C %

Joslin Diabetes Center
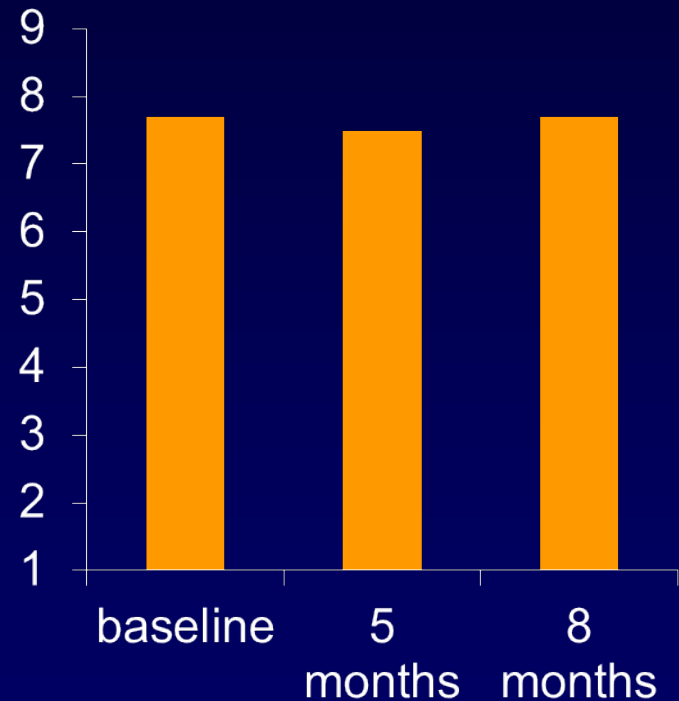
Next steps

- Identify better outcome measure without sole dependence on A1C

- Larger studies and more education regarding "reversed" algorithm to de-intensify complex regimen in vulnerable population

Break for lunch

12 PM-1 PM

Research readiness for implementation and dissemination

William Lee, D.Ph, MPA, FASCP

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Carilion Medical Center
Roanoke, Virginia

Reducing the Risk of Hypoglycemic events in the Older Population through Patient Engagement and Feedback

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Senior Director, Pharmacy System
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540-267-6416

Hypoglycemia in Older Patients

- Challenge for provider

- Challenge for patient

- Too many medications or not enough

- Too tight of Control with Insulin

- A1c Metrics – is that enough

- Are we treating numbers or the Patient

The Diabetic Patient

- Hypoglycemic agents increases risk

- Inaccurate Medication reconciliation

- Comorbidities – hypertension- masking of symptoms with beta blockers.

The Elderly Patient

- Changes in ADME – drug absorption, drug distribution, drug metabolism and drug elimination

- Changes in Cognitive Function and Physical Function can significantly impact medication outcomes

- Changes in Nutritional Status- malnutrition, access to balanced meals, and increased risk of GI problems in this population can impact diabetic care.

- Need for regular and increased monitoring in this population

Life style and More medications

- Appropriate timing and composition of meals.

- Drug – Drug interactions:
  - Diuretics, Steroids, Phenytoin, beta blockers, antipsychotics.

IHARP: Connecting the Dots

- Focus : At Risk Patients in Rural Areas

- Diabetes : One of top three Diseases with Medication Errors Reported

- Major Challenges:
  - Recognition of Signs and Symptoms
  - Optimize medication therapy to prevent therapeutic duplication and/or effect therapeutic de-escalation
  - Development of Individualized Medication Reminders
  - Engage caregivers and Family members
  - Increase patient monitoring/awareness of signs and symptoms of hypo-/hyperglycemia
  - Ensure patient has an emergency plan to treat hypo-/hyperglycemia.
  - Development of tool to track and monitor patient.

Patient Engagement and Feedback

- Opportunities : New Transitional care model
  - Connect with the clinician in the clinic and pharmacist in the community

- Management plan when the patient cannot eat
  - (test, surgery, GI illness)

- Medication titration – challenges
  - Dose changes, medication addition and removal
  - Medication timing

Pharmacists

- Pharmacists are essential to the care team in getting the medications right.

- Pharmacists have the ability to recognize scenarios in which elderly patients are vulnerable to ADE (adverse drug events) and can take action to correct potential problems

- Counseling is key: Utilizing the teach back method with patients and care givers to review: Drug Names, Dosages, Route of Administration, Timing, Duration, Storage and Handling, what to expect, common side effects, adherence, what to do if you miss a dose or meal, contact information in the event additional information is needed

Clinical Efficacy of Pharmacy

Article	Service	Clinical Outcomes
Spence et al.	Outpatient clinical pharmacy service on adherence and clinical outcomes in DM and CAD	1. Higher adherence rates for DM 2. Lower mean and greater reduction in HbA1c 3. Lower mean LDL-C
Polgreen et al.	Collaboration Among Pharmacists and Physicians to Improve BP Now (CAPTION)	1. Average systolic BP was 6.1 mmHg lower and diastolic was 2.9 mmHg lower in intervention group 2. Hypertension control was 43% in intervention vs. 34% in control
Bunting et al.	Community-based MTM program for patients with asthma	1. ER visits decreased 9.9% to 1.3% 2. Hospitalization decreased 4% to 1.9% 3. 55% patients had improvement in severity classification
Cranor et al.	Community-based MTM program for patients with diabetes	1. >50% patients showed A1c improvements at each visit 2. > 50% patients showed improvement in lipid levels
Bunting et al.	Community-based MTM program for patients with hypertension and/or dyslipidemia	1. Significant improvements in systolic and diastolic BP 2. Significant improvements in % patients meet BP goa 3. Change in annual lipid measure significantly lower 4. Statistically decreased risk of CV event

Clinical Efficacy of Pharmacy

Project ImPACT		
Article	**Service**	**Clinical Outcomes**
ImPACT: Depression	Patients with depressive symptoms met with a pharmacist for 2 or more visits over 1 year	1. Significant improvements in PHQ-9 (80% of patients had improvements) 2. 68% of patients had $\geq$ 50% reduction in PHQ-9 3. Clinical improvements and outcomes superior for patients with severe depression at baseline
ImPACT: Osteoporosis	Patients with 1 or more known risk factors for osteoporosis met with a pharmacist for disease prevention and management if necessary	1. Patients given risk for future fracture (78% of patients had no prior knowledge of risk) 2. 70% of patients screened were at moderate or high risk 3. 29% of patients scheduled physician visit after screening (19% initiated on medications)
ImPACT: Hyperlipidemia	Patients with newly diagnosed dyslipidemia and poorly controlled dyslipidemia followed with pharmacist	1. 93.6% of patients achieved medication persistence 2. 90.1% of patients achieved medication compliance 3. 62.5% of patients achieved lipid goal
ImPACT: Diabetes	25 communities in 17 states disproportionally affected by diabetes Patients seen by interdisciplinary care teams including pharmacists	At 1 year: 1. Significant decrease in A1c (-0.8%) 2. 51.7% received eye examinations 3. 72% received foot examinations 4. 41.7% received influenza vaccine 5. 92% of the communities intend to sustain pharmacy services

IHARP and Beyond

- Face to Face interactions preferred
  - Building of patient rapport
  - Support effective patient education
    - Use of glucose meter, disease state, insulin administration

- Long standing relationship as well as Longitudinal relationship

Technology and Apps

- Remote access

- Medical devices– Remote monitoring.
  - Blood pressure and blood glucose machines

- Apps on Tablets, iPhone, Android phones

- Tools for the Healthcare Team

- Screening tools for potentially inappropriate prescribing

- Open Source Platform–sharing of Data

Precision Medicine: Role of Pharmacogenomics

- CRADLE to GRAVE

- Drug-Drug Interaction

- Drug-Gene Interaction

- Drug-drug-gene-interaction

- "Fine tuning" medication regimen

References

- Korczynski M, Rosenfeld B. *Financial viability of an embedded ambulatory care clinical pharmacist as part of team based care.* Accessed July 21, 2017.

- Matzke,G, Czar, M. ,Lee,W. Moczygemba, L., Harlow, L. Improving Health of At Risk Rural Patients Project: A collaborative care model. Am. J. Health-System Pharm. 2016;73:e583-91

THANK YOU

David Aron, MD

Department of Veterans Affairso Clinic

REDUCING THE RISK OF PREVENTABLE ADVERSE DRUG EVENTS ASSOCIATED WITH HYPOGLYCEMIA IN THE OLDER POPULATION
RESEARCH ~~READINESS~~ CHALLENGES FOR IMPLEMENTATION AND DISSEMINATION

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Research Challenges for Implementation and Dissemination

- ◘ Complexity of the problem
  - ▪ Multiple targets (each with their own interests/issues)
    - ▫ Clinicians, both prescribers and non-prescribers
    - ▫ Patients and care givers
    - ▫ Organizations – healthcare systems, payors, pharma, interest groups
  - ▪ Interactions among targets
- ◘ Context-dependence and the limitations of research itself

Clinicians, both prescribers and non-prescribers
Knowledge-Attitudes-Behavior
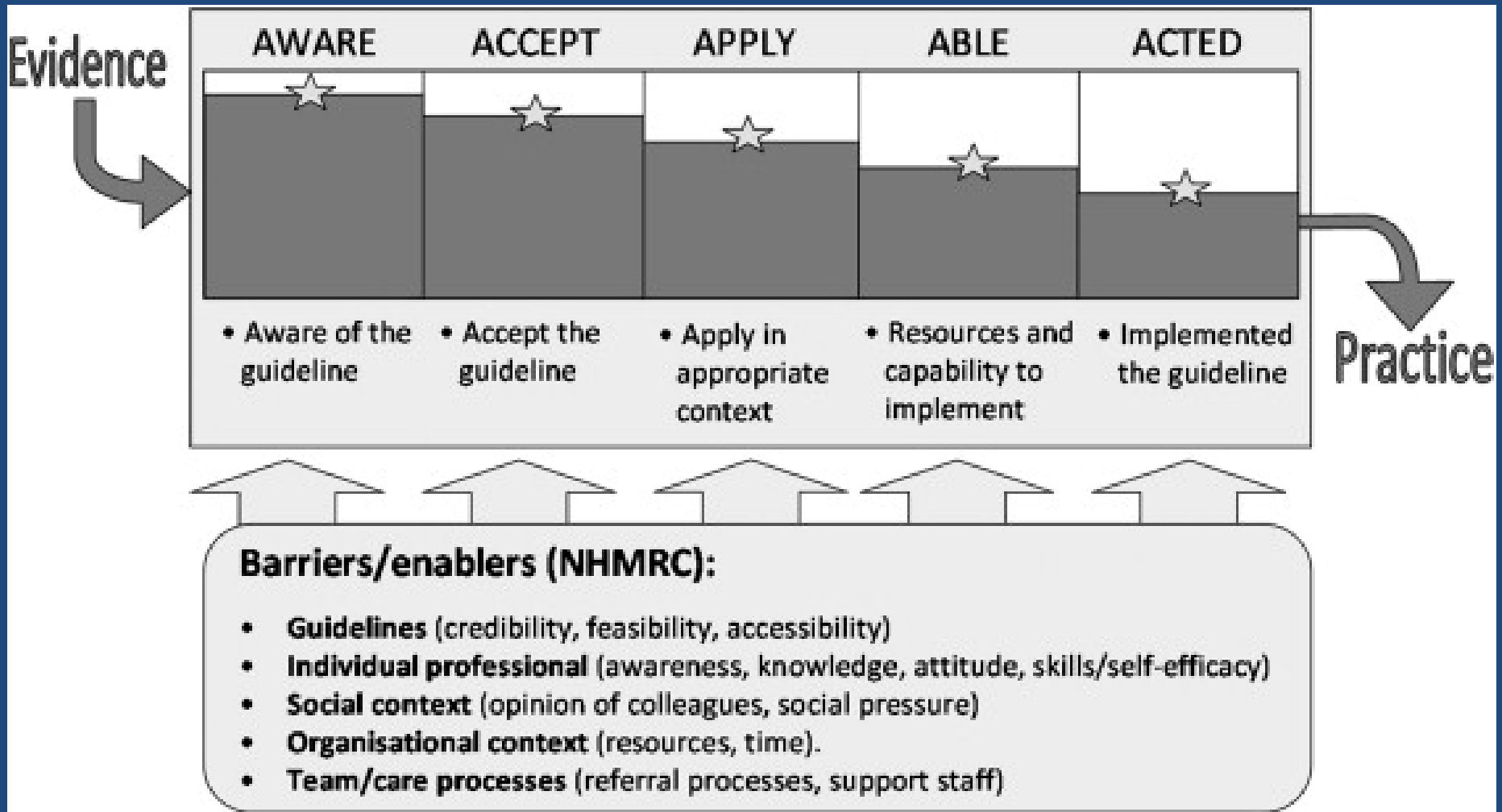
THUMB PINNING EXERCISE

- Goal: pin your partner as many times as possible in 15 seconds. I will tell you when to start.

Model of Unlearning
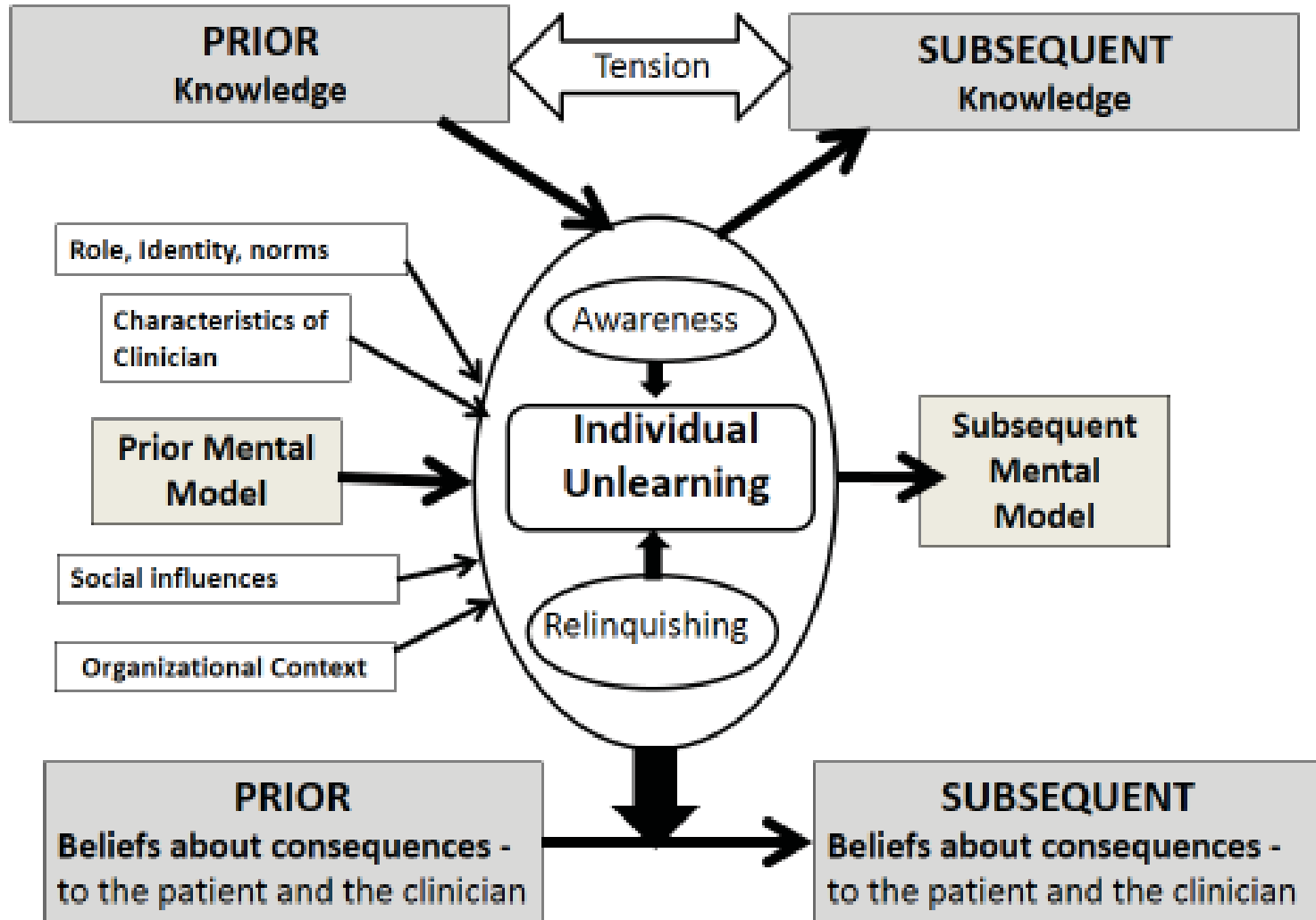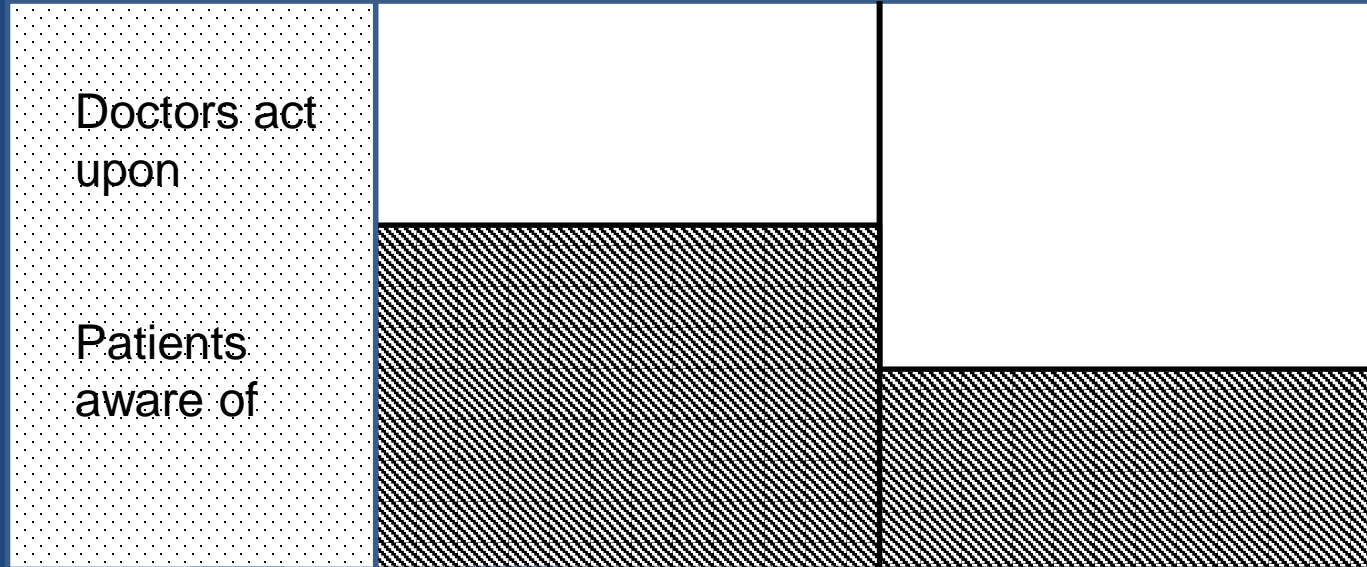
228

Patients and care givers

Organizations – healthcare systems, payors, pharma, interest groups

A1C AND BLOOD GLUCOSE NORMAL, ELEVATED AND SEVERALY ELEVATED LEVEL CHARTS

SEVERALY ELEVATED	A1C LEVELS	GLUCOSE LEVELS
Levels. Risk of serious complications such as Heart Attack, Stroke, Blindness, Kidney failure, Amputations etc.	13	380
	12	345
	11	310
	10	275
ELEVATED and POORLY Controlled levels	9	240
	8	205
	* 7	170
NORMAL Levels	* 6	135
	5	100
	4	65

An A1C Diabetes test above 5.9 is considered Pre-Diabetic.	Under 7 is considered normal or "GOOD" if you already have Diabetes.	Stay under 5.9 to play safe to avoid Prediabetes and under 7 if you already have a Diabetic.

If you are in Elevated or Severely Elevated Levels above, or getting close to 5.9 Prediabetics level, it is extremely important that you **Lose weight, Exercise,** and see a **Doctor** and **Nutritionist!**

© TheDiabetesCouncil.com

THE CAMPAIGN FOR A1C<7%

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

File   Edit   View   Favorites   Tools   Help

Back   Search   Favorites

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

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Home ▸ Practices & Specialties ▸ Healthcare ▸ National Diabetes Call to Action and Blueprint for Change

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

Start   Inbox - Micro...   Disconnected ...   vermont   block 1 2007   print this pag...   Innovation ...   4:55 PM

231

Complexity – Interactions among Targets

"Remember that what the rest of us call health care costs, they call income."
Paul Krugman, NYT*imes 5/10/09*

Reinhardt U. Divide et impera: protecting the growth of health care incomes (costs). Health Econ 2012;21:41-54.
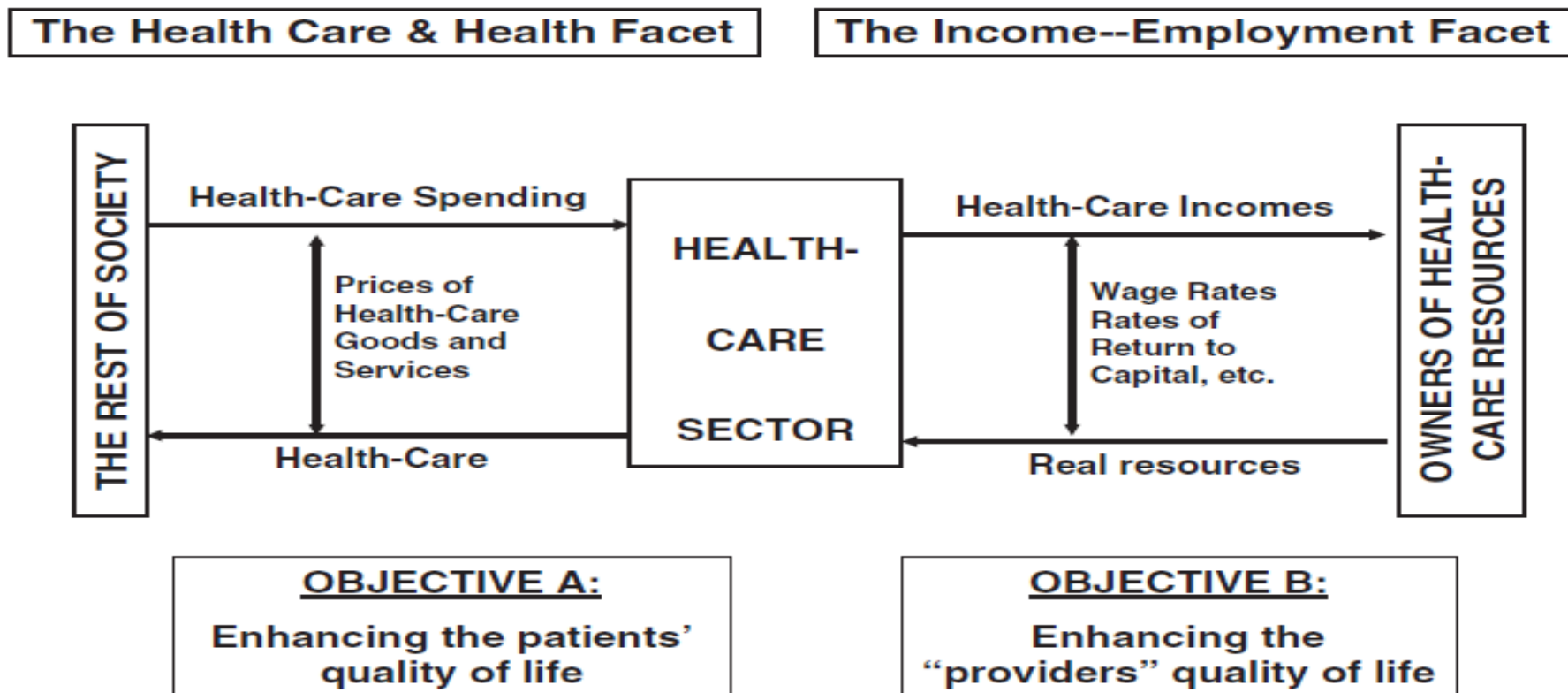
Context-dependence and the limitations of research itself

- The health care "quality problem" is widely recognized, generally accepted and (reasonably) well-understood

- The problem is also the focus of considerable effort

- Yet effective "evidence-based" solutions (and success) remain elusive; a common answer to why we have failed:

  - We lack sufficient evidence and knowledge regarding effective quality improvement (practice change) strategies (intervention/problem matching, effect modifiers, etc.)

Adapted from B. Mittman

- An alternative answer:
  - We have the knowledge, but lack the will and/or ability to act on that knowledge
  - We fail to act on the evidence and advice we receive (and produce)
    - we repeatedly initiate new efforts without attending to barriers, or including elements, previously found to be important
    - **we discount evidence and advice that fail to have universal, total effectiveness**
  - **We continue to seek--and believe in—(non-existent) simple solutions ("the answer")**

Adapted from B. Mittman

Traditional Improvement of Healthcare

Professional (scientific) knowledge

Patient with Need → Knowledge → Operationalize Knowledge → Patient Need Met Well

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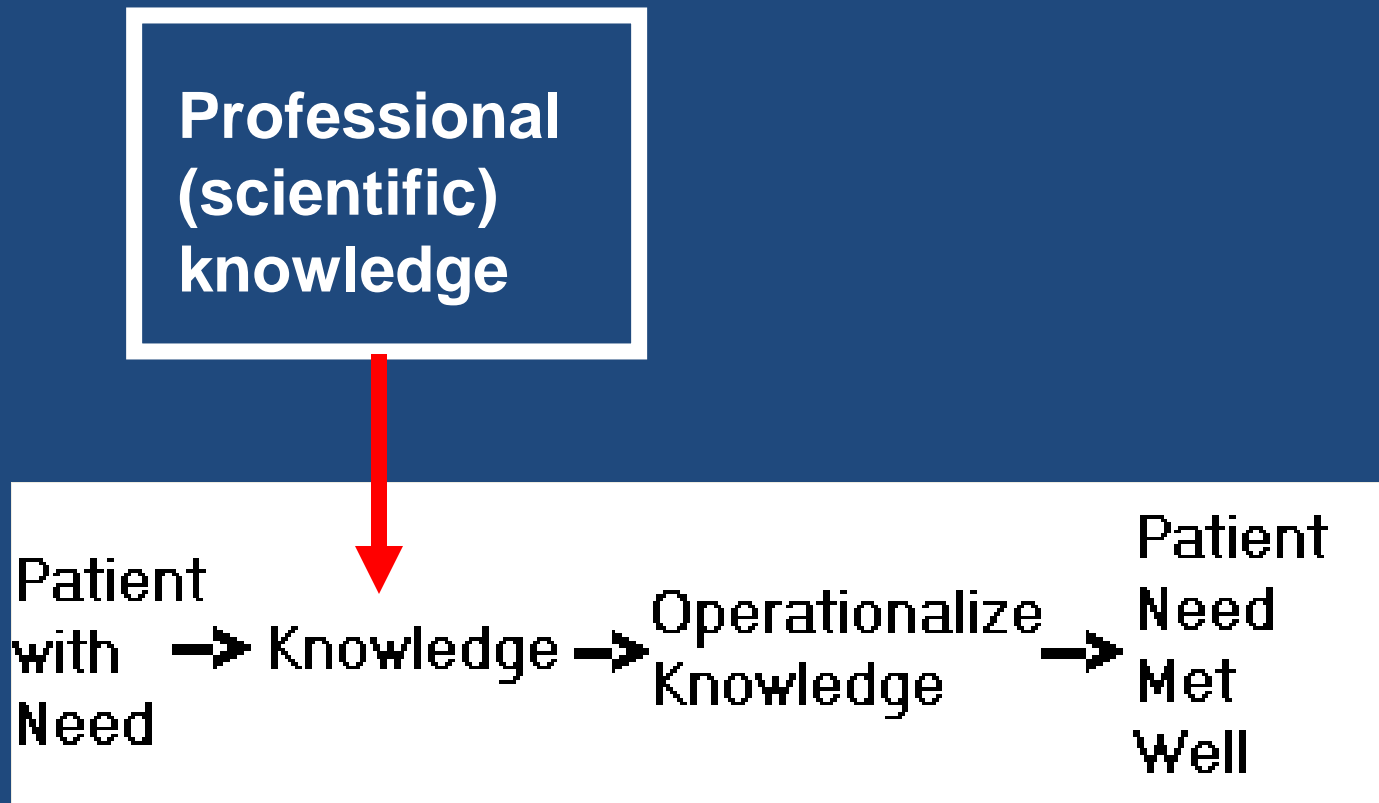
QI – the linear Ramp of Complexity
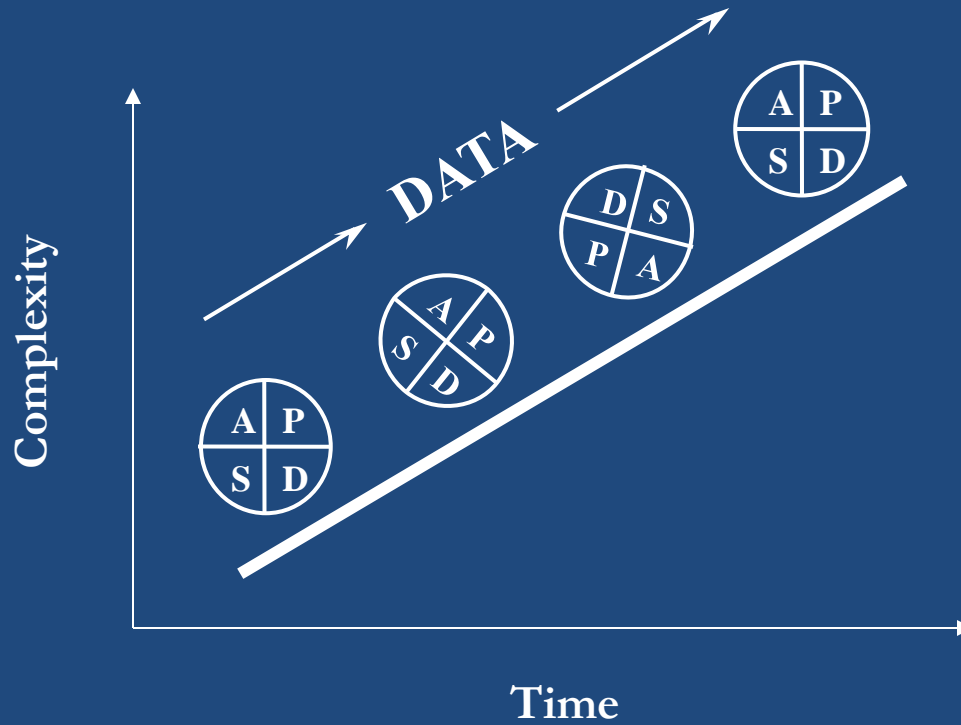
The reality of the (non)linear ramp of complexity.
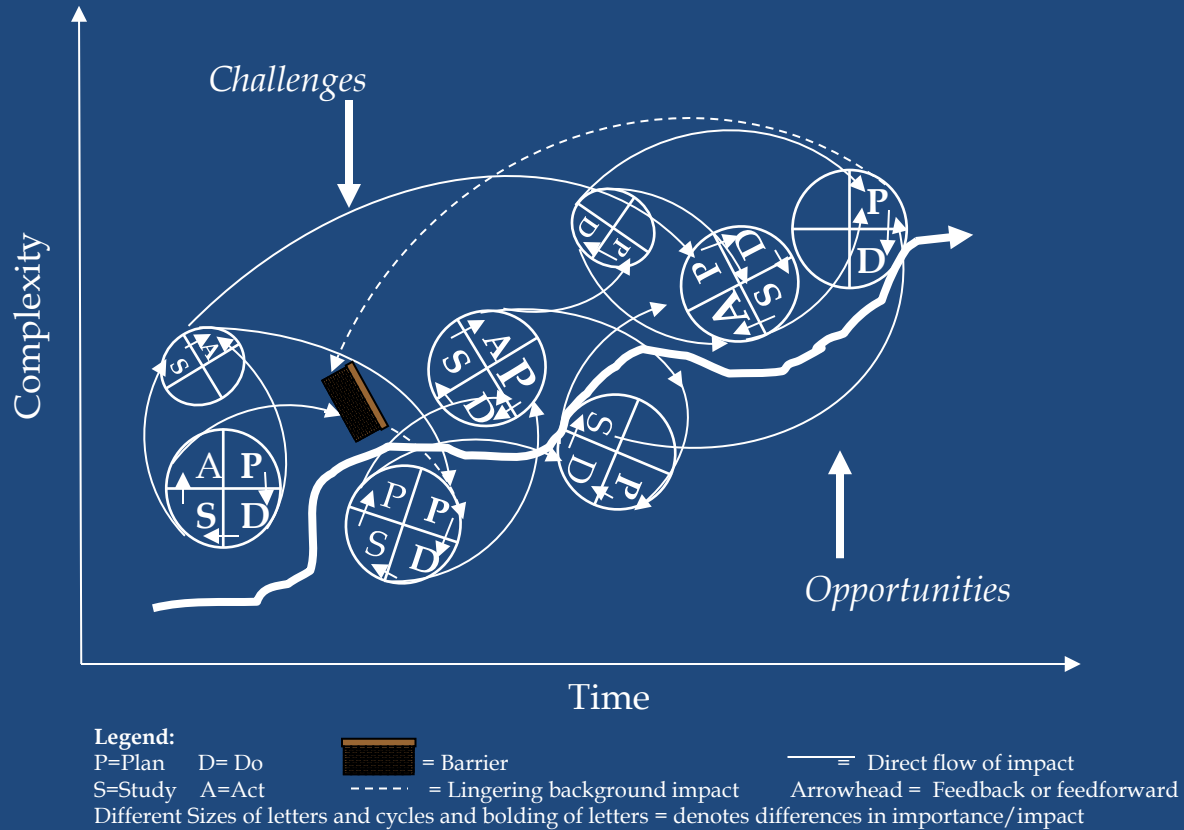
Tomolo, Lawrence, and Aron, QSHC.

Lessons from some research
De-Implementation of Inappropriately Tight Control for Health

Integrated Conceptual Framework based on Greenhalgh et al. Model of Innovation dissemination/diffusion (rounded boxes); Theory of Healthcare Professionals' Behavior and Intention (square boxes) is nested and impacts Adoption/Assimilation
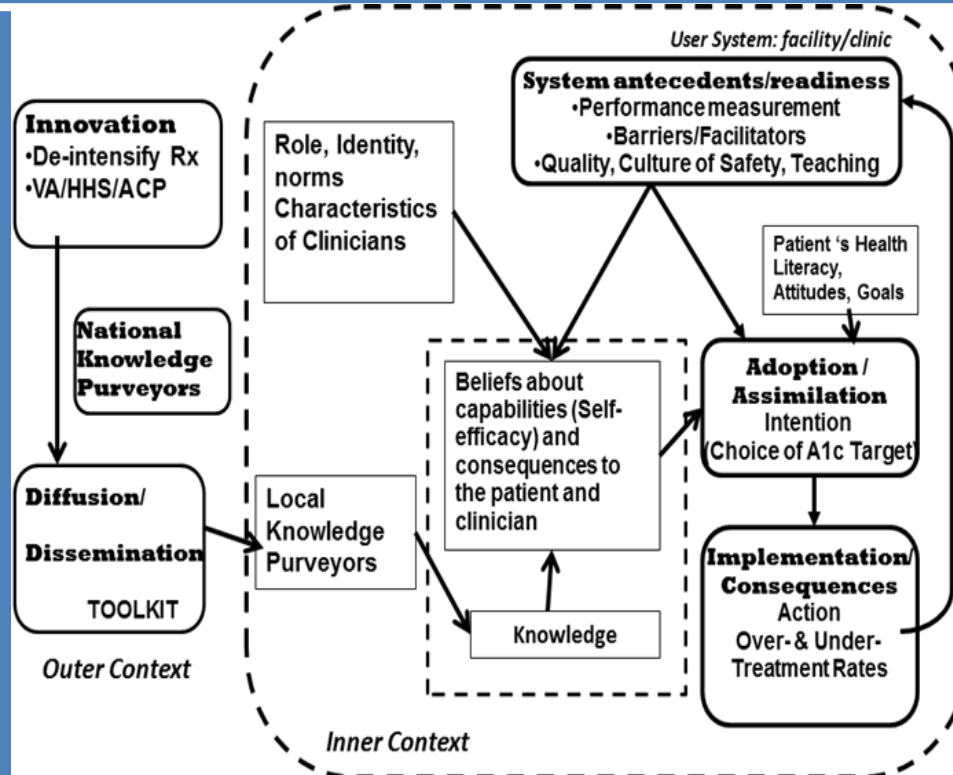
⊡ Gupta DM, Boland RJ Jr, Aron DC. The physician's experience of changing clinical practice: a struggle to unlearn. Implement Sci. 2017 Feb 28;12(1):28.

   ▪ **Finding 1: Practice change disturbs the status quo equilibrium. Establishing a new equilibrium that incorporates the change may be a struggle.**

   ▪ **Finding 2: Part of the struggle to establish a new equilibrium incorporating a practice change involves both the "evidence" itself and tensions between evidence and context.**

Aron DC,Tseng C-L, Soroka O, Pogach LM, Balancing Measures, submitted.
Change in Overtreatment Rate (A1c<7%) vs Change in Undertreatment Rate (A1c>9%)

R= -0.653 p<0.001

Equifinality

*Explanatory factors rarely operate alone
*Multiple configurations of different explanatory conditions can explain the same outcome – therefore QCA (Qualitative Comparative Analysis)

Kurt Richardson.
http://jasss.soc.surrey.ac.uk/5/2/6.html
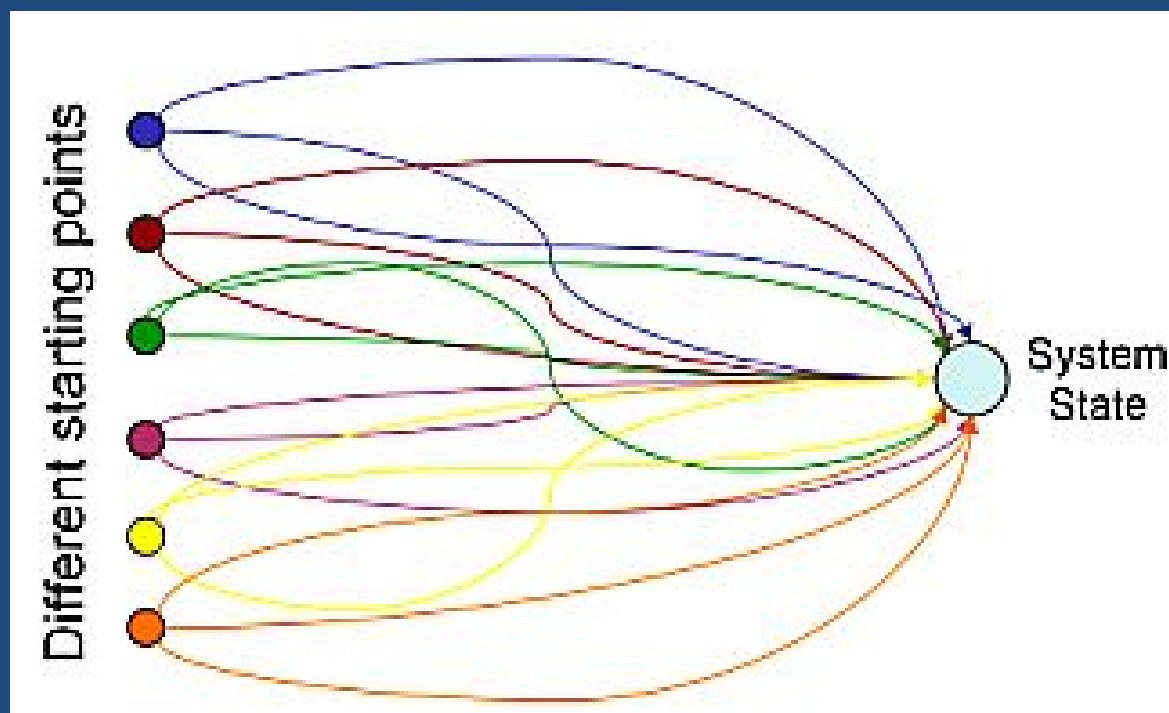
Aron's Heuristics of Implementation and Sustainability

▣ Implementation = f(Intervention x CONTEXT)

- Intervention = Evidence plus Method and Cost of Implementation (although this bears resemblance to the PARIHS model, I place the emphasis on the interaction.)

▣ Sustainability = f($CinOteNrvTenEtiXonT$)

- Sustainability = the degree to which the intervention becomes part of the context - just the way we do business)

- Damschroder,L.J., D.C.Aron, R.E.Keith, S.R.Kirsh, J.A.Alexander, and J.C.Lowery. 2009a. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement.Sci* 4:50.
- Rycroft-Malone,J., K.Seers, J.Chandler, C.A.Hawkes, N.Crichton, C.Allen, I.Bullock, and L.Strunin. 2013. The role of evidence, context, and facilitation in an implementation trial: implications for the development of the PARIHS framework. *Implement.Sci* 8:28

"Let it happen" ⟵ "Help it happen" ⟶ "Make it happen"

Defining Features

Unpredictable, unprogrammed, uncertain, emergent, adaptive, self-organizing	Negotiated, influenced, enabled	Scientific, orderly, planned, regulated, programmed, systems "properly managed"

Assumed Mechanism

Natural, emergent	Social	Technical	Managerial

Metaphor for Spread

Emergence, adaptation	Knowledge construction, making sense	Diffusion	Negotiation	Knowledge transfer	Dissemination, cascading	Re-engineering

Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. The Milbank Quarterly 2004; 82(4):581-629.

The Implementation Gap

It is one thing to say with the prophet Amos, "Let justice roll down like mighty waters," and quite another to work out the irrigation system.

~ Rev. William Sloane Coffin

But *let justice* well up as waters, and righteousness as a mighty stream. Amos 5:24, JPS

Sustaining success –
Moving research into practice; private & public
Partnerships

Clydette Powell, MD, MPH

Office of the Assistant Secretary for Health

Preventing Hypoglycemia: A Public Health Priority

Clydette Powell, MD, MPH, FAAP
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Office of Disease Prevention and Health Promotion
Office of the Assistant Secretary for Health
Clydette.Powell@hhs.gov

ODPHP

Office of Disease Prevention
and Health Promotion

- The increasing burden of serious hypoglycemic events has been recognized as an important public health issue

- Diabetic agents including insulin and secretagogues are common causes of hypoglycemic events across inpatient and outpatient health care settings

- Among adults diagnosed with either type 1 or type 2 diabetes, 18% take insulin only, 13% take both insulin and oral medication, 50% take oral medication only, and 18% do not take either insulin or oral medication

- The *National Action Plan for Adverse Drug Event Prevention* defines severe hypoglycemia as:
  - Requiring third party assistance(e.g., from a family member and/or medical personnel?)
  - Leading to an emergency department visit or hospital admissions
  - Blood glucose lower than 40 mg/dl

- While the *National Action Plan for Adverse Drug Event Prevention* focuses on adverse events from diabetic agents, it recognizes that not all diabetes agents are associated with severe hypoglycemia (e.g., metformin monotherapy)

Persons with diagnosed diabetes whose A1c value is greater than 9% (age adjusted, percent, 18+ years)
By Total

2020 Baseline (year): 18.0 (2005–08)   --- **2020 Target:** 16.2   **Desired Direction:** ↓ Decrease desired

Auto Scale

Total
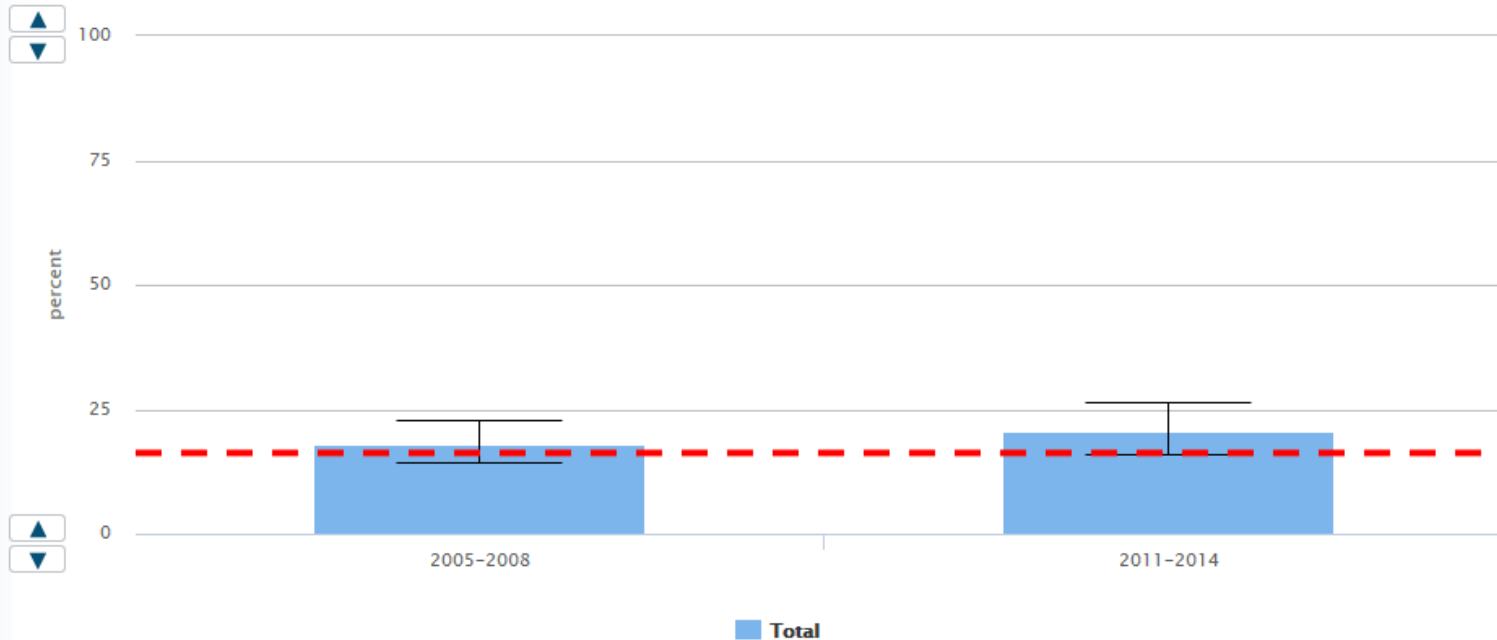
Data Source: National Health and Nutrition Examination Survey (NHANES); Centers for Disease Control and Prevention, National Center for Health Statistics (CDC/NCHS)
Error Bar (I) represents the 95% confidence interval
Additional footnotes may apply to these data. Please refer to footnotes below the data table for further information.

Healthy People Objective Overview

ODPHP

- HP2020 Baseline: In 2005–08, 18.0% of adults aged 18 years and over with diagnosed diabetes had poor glycemic control (age adjusted).

- HP2020 Target: 16.2%, a 10% improvement over the baseline.

- Most Recent: In 2011–14, 20.5% of adults aged 18 years and over with diagnosed diabetes had poor glycemic control (age adjusted).

- Among racial and ethnic groups in 2011–14, the white non-Hispanic population had the lowest (best) rate of poor glycemic control, 14.6% of adults aged 18 years and over with diagnosed diabetes (age adjusted). The rate for the Hispanic population (30.2%, age adjusted) was more than twice the rate of the white non-Hispanic population.

- Rates (age adjusted) for other race/ethnicity groups were:
  - 25.5% among the black non-Hispanic population
  - 17.3% among the Asian non-Hispanic population (not significantly different than the best group rate)

- Persons with diagnosed diabetes aged 65 years and over had the lowest rate of poor glycemic control among age groups, 9.2% in 2011–14. Rates for the other age groups were:
    - 17.8% among persons aged 45–64 years
    - 26.4% among persons aged 18–44 years; more than 2.5 times the best group rate

Office of Disease Prevention and Health Promotion

- Diabetes agents are implicated in **13% of ED visits** for adverse drug events
  - **90%** of cases are associated with **hypoglycemia**
  - **39%** of cases result in **hospitalization**
- Real-world incidence of hypoglycemia is likely much higher
  - Insulin users experience **23** mild/moderate episodes and **1** severe episode per person-year

- Shehab N, Lovegrove MC, Geller AI, Rose KO, Weidle NJ, Budnitz DS. US Emergency Department Visits for Outpatient Adverse Drug Events, 2013-2014. *Jama.* 2016;316(20):2115-2125.
- Edridge CL, Dunkley AJ, Bodicoat DH, et al. Prevalence and Incidence of Hypoglycaemia in 532,542 People with Type 2 Diabetes on Oral Therapies and Insulin: A Systematic Review and Meta-Analysis of Population Based Studies. *PloS one.* 2015;10(6):e0126427.

- Older and more complex patients are at greatest risk of hypoglycemia
  - Diabetes agents are implicated in **>18%** of cases
  - **More than half** of older adults may be **over treated**
- Despite availability of newer agents, hypoglycemia remains a significant problem

- Lipska KJ, Ross JS, Miao Y, Shah ND, Lee SJ, Steinman MA. Potential overtreatment of diabetes mellitus in older adults with tight glycemic control. *JAMA internal medicine.* 2015;175(3):356-362. Feil DG, Rajan M, Soroka O, Tseng CL, Miller DR, Pogach LM. Risk of hypoglycemia in older veterans with dementia and cognitive impairment: implications for practice and policy. *Journal of the American Geriatrics Society.* 2011;59(12):2263-2272.
- Tseng CL, Soroka O, Maney M, Aron DC, Pogach LM. Assessing potential glycemic overtreatment in persons at hypoglycemic risk. *JAMA internal medicine.* 2014;174(2):259-268.
- Lipska KJ, Yao X, Herrin J, et al. Trends in Drug Utilization, Glycemic Control, and Rates of Severe Hypoglycemia, 2006-2013. *Diabetes care.* 2017;40(4):468-475.

Office of Disease Prevention and Health Promotion

Anticoagulants

    primary ADE of concern: *bleeding*

Diabetes agents

    primary ADE of concern: *hypoglycemia*

Opioids

    primary ADE of concern: *accidental overdoses/ oversedation/respiratory depression*

✓ Common

✓ Clinically significant

✓ Preventable

✓ Measurable

Office of Disease Prevention and Health Promotion

Federal Interagency Workgroup: Diabetes Work
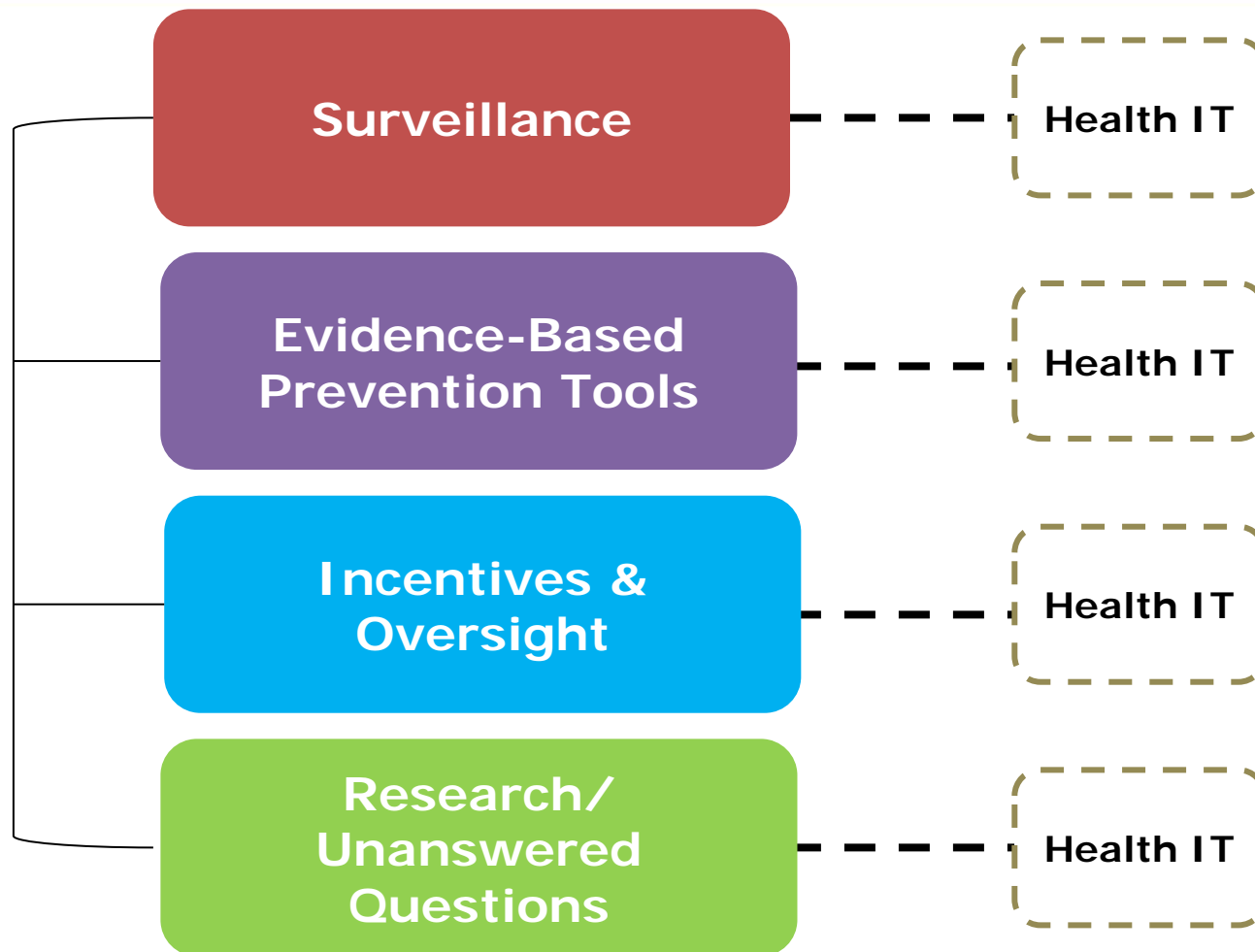
Surveillance

- FDA's FAERS tracks self reported ADEs

Prevention Tools

- ODPHP's Individualizing Glycemic Targets Training

Incentives & Oversights

- CMS' Transforming Clinical Practice Initiative (TCPI) is working with Practice Transformation Networks all over the US to make hypoglycemia a number 1 medication safety issue

Research

- FDA's Safe Use program funds research in preventing adverse drug events : Kaiser Risk Stratification Tool

Development of National Targets and Measures

OCT 2014
ADE Prevention: 2014 Action Plan Conference

AUG 2014
Release of the ADE Action Plan

AUG 2016
Steering Committee Meeting #8
Drug Class Lead(s) Present Proposed Targets and Measures

Drug Class-Specific Workgroups Develop Targets and Measures

MAR 2015
Steering Committee Meeting #7

2016-2017
Finalize Targets and Measures

SEP 2014
Release of the diabetes eLearning

ODPHP

Setting	Measure	Numerator	Denominator	Data Source	Baseline Year	Target Reduction	Departmental Measure Alignment
Inpatient	Rates of adverse events from hypoglycemic agents among U.S. inpatient stays	Number of U.S. hospital discharges with adverse events from hypoglycemic agents	Number of U.S. hospital discharges in which hypoglycemic agents were administered	MPSMS, QSRS	2014	10%	Partnership for Patients
Outpatient	Rate of visits to U.S. hospital EDs for adverse events from insulin	Number of visits to U.S. hospital EDs for adverse events from insulin	Number of patients receiving dispensed insulin in U.S. retail outpatient settings	NEISS-CADES, IMS TPT	2014	10%	*Healthy People 2020* Medical Product Safety Objective 5.2[3]

Inpatient

- **Goals:** Reduce ADEs from diabetes agents among inpatient stays
- **Data sources:** MPSMS and QSRS
  - Both use reviews of medical records from U.S. hospitals
  - As of 2016, QSRS is replacing MPSMS

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Outpatient

- **Goals:** Reduce ED visits due to ADEs from diabetes agents

- **Data sources:** NEISS-CADES (numerator) and IMS Total Patient Tracker (denominator)
  - NEISS-CADES use reviews of medical records
  - IMS TPT uses data from U.S. retail pharmacies
  - IMS data agreement secured through FDA in Dec 2016

ODPHP | Office of Disease Prevention and Health Promotion

- Raising awareness about hypoglycemia is imperative.
  - Education for patients, families, and clinicians about risk factors, symptoms, and treatment
- Clinicians need tools to recognize risk factors and suggest appropriate treatment options.
  - Diabetes care is more than just reducing hyperglycemia
    - Risk stratification tools
  - Risks and benefits of treatment options must be balanced
    - Shared decision making

- Shared Decision Making (SDM)
    - Engaging patients in collaborative goal setting and problem solving
    - Setting individualized glycemic goals can help prevent hypoglycemia
- SDM is endorsed by federal and non-federal organizations.
    - VA/DoD Clinical Practice Guidelines
    - IHS Standards of Care
    - ADA Standards of Care

Preventing Hypoglycemic ADEs

ADEs: Diabetes Agents

Preventing Adverse Drug Events: Individualizing Glycemic Targets Using Health Literacy Strategies is an eLearning course that teaches health care providers how to reduce hypoglycemic adverse drug events (ADEs) in patients with diabetes.

https://health.gov/hcq/training-prevent-ADE.asp

Preventing Hypoglycemic ADEs

Since September 2014, 441 individuals have received CME, CNE, CEU, or CPE for taking Individualizing Glycemic Targets

Credit Type	Registered	Completed	% Completed	Passed	% Passed
CME (physicians)	23	18	78.26%	18	100%
CME (non-physicians)	49	42	85.71%	42	100%
CNE	327	282	86.24%	281	99.65%
CEU	53	44	83.02%	43	97.73%
CPE	65	57	87.69%	57	100%
Audit	16	13	81.25%	13	100%
Totals	533	456	85.55%	454	99.56%

Questions?

Thank you

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Matthew Pickering, PharmD

Pharmacy Quality Alliance

Measuring What Matters: Turning Data into Action

September 12, 2017

Matthew K. Pickering, PharmD, RPh
Associate Director, Research & Quality Strategies
Pharmacy Quality Alliance

PQA

Optimizing Patients' Health by Improving the Quality of Medication Use

If you cannot measure it…

you cannot monitor it.

If you cannot monitor it…

you cannot manage it.

If you cannot manage it…

you cannot improve it.

Dr. H. James Harrington

About the Pharmacy Quality Alliance (PQA)

Mission Statement:

Optimizing patient health by improving the quality of medication use.

Measure Development & Maintenance	Measure Implementation	Research and Demonstration	Communication & Education

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Pharmacy Quality Alliance

PQA Measures within Medicare Part D Star Ratings

2017 Part D Star Ratings Measures		
Measure ID	Measure	Weight
D11	High Risk Medication	3
D12	Medication Adherence for Diabetes Medications	3
D13	Medication Adherence for Hypertension (RAS antagonists)	3
D14	Medication Adherence for Cholesterol (Statins)	3
D15	MTM Program Completion Rate for CMR	1

Due to heavy weighting by CMS on intermediate outcome measures, PQA measures make up almost half of a plan's Star rating

PQA

Pharmacy Quality Alliance

CMS Quality Programs: A 10,000ft View

Hospital Quality	Physician Quality	PAC Quality	Payment Models	Population Health
▪ Meaningful use EHR incentive ▪ Inpatient quality reporting ▪ Outpatient quality reporting ▪ Ambulatory surgical centers ▪ Readmission reduction program ▪ HAC payment reduction program ▪ PPS-exempt cancer hospitals ▪ Inpatient psychiatric facilities	▪ Merit-based Incentive Payment System (MIPS) ▪ Maintenance of certification	▪ Inpatient rehabilitation facility quality reporting ▪ Nursing Home Compare measures ▪ LTCH quality reporting ▪ Hospice quality reporting ▪ Home health quality reporting	▪ Medicare Shared Savings Program (ACOs) ▪ Hospital value-based purchasing ▪ Physician Feedback ▪ ESRD QIP ▪ Innovations Pilots	▪ Medicare Part C ▪ Medicare Part D ▪ Medicaid Adult Core Measures ▪ Medicaid Child Core Measures ▪ Health Insurance Exchange Quality Reporting System (QRS)

Center for Medicare and Medicaid Services (2015). Quality Initiatives. Accessed July 2016 at: http://www.cms.gov/Medicare/Medicare.html.

Quality Improvement:
A Continuous, Evidence-based Process

P4R: Pay-for-reporting
P4P: Pay-for-
  performance
VBP: Value-based
  purchasing

PQA's Measure Development Process

III. *Member Comment*

IV. *Measure Testing*

II. *Development*

I. *Measure Concept*

V. *Endorsement*

VI. *Evaluation*

The Pharmacy Quality Alliance. PQA's Measure Development Process. Accessed February 2017 at: http://pqaalliance.org/images/uploads/files/PQA%20Measure%20Development%20Process%20Steps_2_15_17.pdf

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Deep Thought

1. How do we know what to measure?

2. How do we know what is measured is patient-centered?

3. How do we know that which is patient-centered [*in measurement*], truly matters to patients?

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Deep Thought

1. How do we know what to measure?

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Your New Health Care System

Joint Economic Committee. Understanding the Obamacare Chart. July 2010. Accessed March 2017 at: https://www.jec.senate.gov/public/_cache/files/96b779aa-6d2e-4c41-a719-24e865cacf66/understanding-the-obamacare-chart.pdf.

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Deep Thought

1. *How do we know what to measure?*

2. How do we know what is measured is patient-centered?

3. How do we know that which is patient-centered [*in measurement*], truly matters to patients?

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Choosing What to Measure

Better Care

Healthy People
Healthy
Communities

Affordable Care

PRIORITIES

Health and Well-Being

Prevention and Treatment of
Leading Causes of Mortality

Person- and Family-centered
Care

Effective Communication and
Care Coordination

Patient Safety

Affordable Care
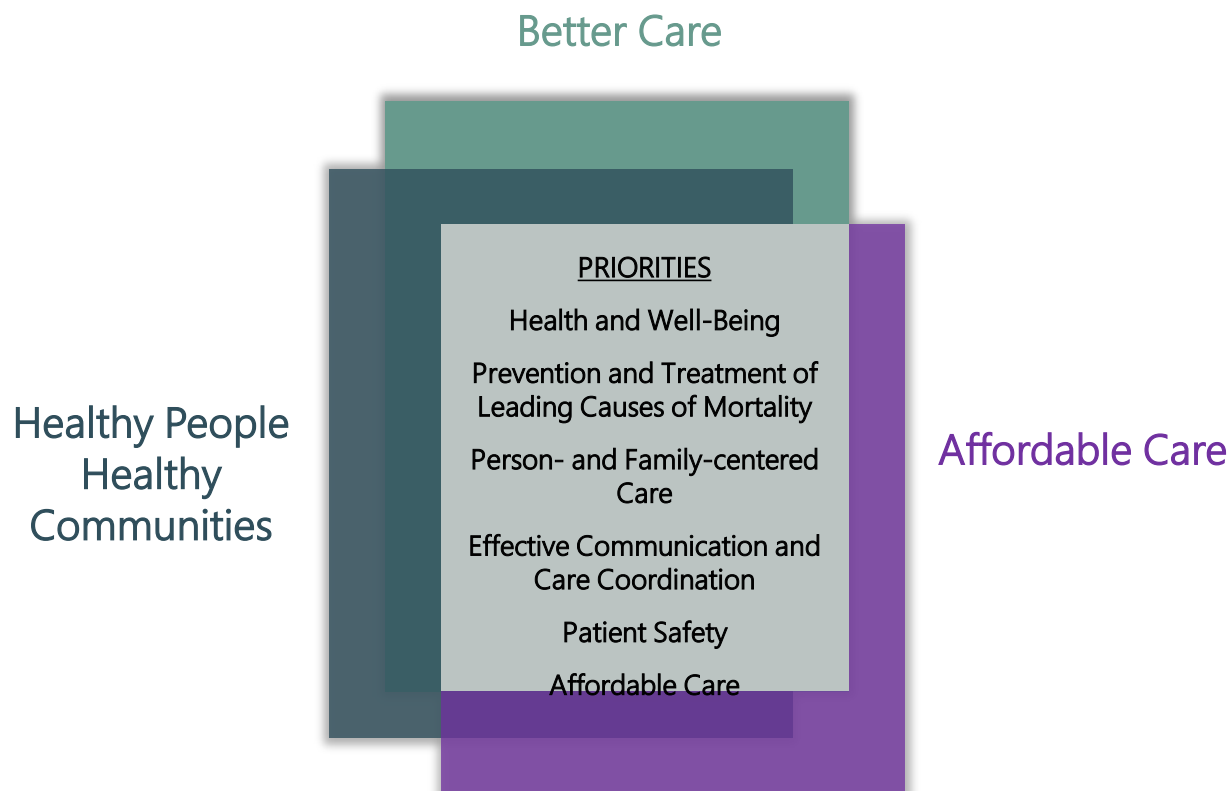
The Triple Aim and priority areas set the agenda for measure
development, endorsement and implementation.
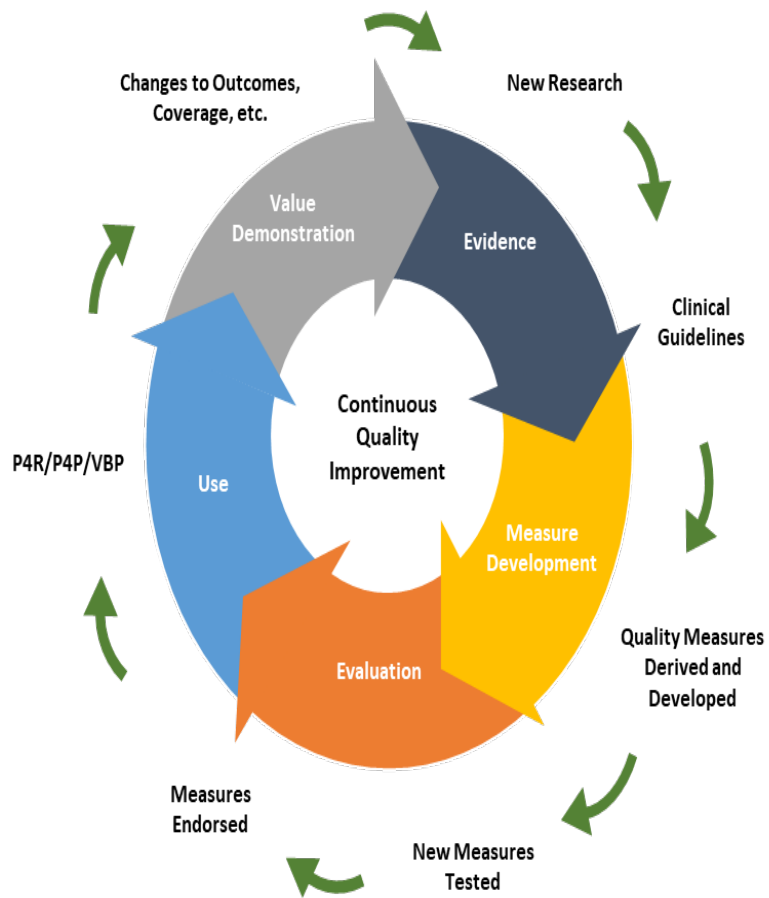
National Priorities Partnership. (2011). Input to the Secretary of Health and Human Services: Priorities for the National Quality Strategy.

PQA
*Pharmacy Quality
Alliance*

Quality Improvement:
A Continuous, Evidence-based Process

P4R: Pay-for-reporting
P4P: Pay-for-
performance
VBP: Value-based
purchasing

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Diabetes Guidelines

- Hemoglobin A1c (HbA1c) goals

- 10-year cardiovascular risk

Measures Targeting HbA1c

+

Measures Targeting Adherence

+

Measures Targeting Statin Use

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Deep Thought

Diabetes Outcome Measures Beyond A1c
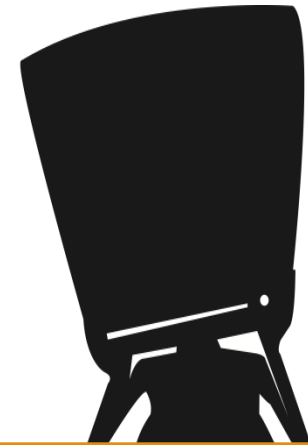
1. How do we know what to measure?

2. *How do we know what is measured is patient-centered?*

3. How do we know that which is patient-centered [*in measurement*], truly matters to patients?

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National Action Plan for Adverse Drug Event Prevention

The three initial targets of the Adverse Drug Event (ADE) Action Plan are:
- Anticoagulants (primary ADE of concern: bleeding)
- Diabetes agents (primary ADE of concern: hypoglycemia)
- Opioids (primary ADE of concern: accidental overdoses/oversedation/respiratory depression)

U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion.   (2014). National Action Plan for Adverse Drug Event Prevention. Washington, DC: Author

Responding to the ADE National Action Plan

Development of a Suite of ADE Measures:

1. *Bleeding Events*
2. *Hypoglycemic Events*
3. *Opioid Overdose Events*

PQA ADE Hypoglycemic Measure

Title: Hypoglycemic Events Requiring Hospital Admission or Emergency Department (ED) Visit Associated with Anti-hyperglycemic Medications

Description: The rate of events among adults receiving anti-hyperglycemic medications that have evidence of a hospitalization or ED visit related to a hypoglycemic event.

Level of Accountability: Health plan

Status: Working with stakeholders for valid ICD-10 codes, at which point, we will test the measure for reliability and validity

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Lamppost Measures

Deep Thought

1. *How do we know what to measure?*

2. How do we know what is measured is patient-centered?

3. *How do we know that which is patient-centered [in measurement], truly matters to patients?*

Patient-Reported Outcome Measures

PRO →	PROM →	PRO-PM
patient-reported outcomes	*instrument, tool, single-item measure*	*PRO-based performance measure*
Information on the patient, told by the patient, without interpretation	Means to collect information told by the patient without interpretation	Means to aggregate information shared by the patient and collected into a reliable, valid measure of performance

EXAMPLE: Patient with clinical depression

Symptom: depression	Patient Health Questionnaire (PHQ-9©), a standardized tool to assess depression	Percentage of patients with diagnosis of major depression or dysthymia and initial PHQ-9 score >9 with a follow-up PHQ-9 score <5 at 6 months (NQF #0711)

Research is needed to determine what matters to patients, and how to prioritize identified gaps in care

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PQA's Measure Development Process

Patient & Caregiver
Advisory Panel

- I. *Measure Concept*
- II. *Development*
- III. *Member Comment*
- IV. *Measure Testing*
- V. *Endorsement*
- VI. *Evaluation*

The Pharmacy Quality Alliance. PQA's Measure Development Process. Accessed February 2017 at:
http://pqaalliance.org/images/uploads/files/PQA%20Measure%20Development%20Process%20Steps_2_15_17.pdf

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FDA Safe Use – Hypoglycemia

- Increasing awareness of hypoglycemia through targeted messaging

- Increasing awareness of the need for measures that matter to patients

- Collaborating with stakeholders to educate and promote proper care coordination

Summary

- Quality measures continue to shape healthcare delivery

- Measures should not only be evidence-based, but they should *matter* to patients

- Improving patient care is a multi-stakeholder effort

Measuring What Matters: Turning Data into Action

September 12, 2017

Matthew K. Pickering, PharmD, RPh
Associate Director, Research & Quality Strategies
Pharmacy Quality Alliance
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PQA

Optimizing Patients' Health by Improving the Quality of Medication Use

Deb Pasko, PharmD

American Society of Health -System Pharmacists

Reducing the Risk of Preventable Adverse Drug Events associated with Hypoglycemia in the Older Population: ASHP Perspective

Deborah A Pasko, Pharm.D., MHA

September 12th, 2017

FDA Symposium

Topic Outline

- **ASHP and Quality**
  - Quality Measures
  - Glycemic Control Measures
- **Current state of medication usage and antidiabetic medications**
- **Polypharmacy**
- **Hospitals and the risk for hypoglycemia**
  - Why is it so complex?
- **Deprescribing**
- **Best practices**
- **Next steps**

ASHP Commitment to Quality

STRATEGIC PRIORITIES AND GOALS

Our Patients and Their Care

- Optimize Patients' Medication Outcomes in All Settings of Care
- Advance Pharmacy Practice in Acute and Ambulatory Care Settings
- Facilitate the Preparation of the Pharmacy Workforce to Meet the Current and Future Needs of Patients
- Support the Continued Competence of Pharmacists and Pharmacy Technicians through the Provision of Contemporary Professional Development
- Advocate for Changes in Laws, Regulations, and Standards that Will Improve Patient Care
- Expand Pharmacy Practice in Ambulatory Clinics and Other Primary Care Settings
- Advance Patient Care and Pharmacy Practice in Small, Rural, and Underserved Settings
- Address the Needs and Interests of Pharmacists Who Practice in Multihospital Systems
- Help Members Address Issues Related to Specialty Pharmacy

Our Members and Partners

- Maintain a High Level of Member Satisfaction
- Grow ASHP Membership
- Help ASHP State Affiliates Facilitate Efforts to Improve Patient Care and Advance Pharmacy Practice
- Improve Member Affinity with ASHP through the Work of Component Groups
- Develop and Maintain Productive Partnerships with External Stakeholders and Customers
- Produce an Innovative and Timely Professional Journal, Website, Drug Information Compendium, and Other Publications that Meet the Needs of Members and Other Customers
- Improve the Discoverability of ASHP Digital Content Assets
- Engage in International Efforts that Support ASHP's Mission and Priorities

Our People and Performance

- Sustain a Working Environment that Encourages Excellence, Supports Teamwork, and Breeds Innovation
- Maintain a Strong Sense of Staff Community, Staff Empowerment, and Workplace Satisfaction
- Maintain Effective Financial Management
- Maintain Effective and Energized Governance
- Effectively Manage Organizational Infrastructure
- Foster High-Performance Leadership and Management by Staff

- **Commitment in Strategic Plan**
  - Our Patients and Their Care
    - Goal 1: Optimize medication outcomes in all settings of care

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ASHP: Quality work

SPECIAL FEATURE

A suite of inpatient and outpatient clinical measures for pharmacy accountability: Recommendations from the Pharmacy Accountability Measures Work Group

MARY A. ANDRAWIS AND JANNET CARMICHAEL

Am J Health-Syst Pharm. 2014; 71:1669-78

ASHP Quality Goals

- Evaluate pharmacist value in quality improvement
- Provide feedback on deployed measures

- Nominate members to measure development
- Respond to proposed measures
- Revise existing measures

Demonstrate

Shape

Support Member Implementation

Raise Awareness

- Member resources
- Highlight process improvements

- Identify pharmacy-sensitive measures
- Support member education
- Pharmacy school curriculum changes

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Pharmacy-Sensitive Accountability Measures

- **Goals**
  - Increase pharmacist awareness of measures that they can be accountable for in a team-based manner;
  - Promote the use of measures in pharmacy department dashboards; and
  - Identify gaps in measurement
- **Process**
  - Identify medication-related measures that address preventable harm in the inpatient and outpatient setting
    - Measure databases: NQF, PQA, AHRQ, HHS

Pharmacy-Sensitive Accountability Measures

- **Results**
  - 4 high-risk clinical topic areas
    - Glycemic control
    - Anticoagulant safety
    - Pain management
    - Antimicrobial stewardship
- **Findings related to glycemic control**
  - Measures focused on screening, adherence, co-morbid condition, disease state management; however, no measure of harm
    - A few measure incidence of hyper/hypoglycemia
  - MIPS quality measures
    - 8 focused on diabetes but no measurement of risk or preventable harm

Glycemic Control Measures

Measure Title	Measure Type	Federal Reporting Program
Chronic Kidney Disease, Diabetes Mellitus, Hypertension and Medication Possession Ratio for ACEI/ARB Therapy	Process	
PDC with RAS antagonists, DM, Statins	Process	Y
DM: Treatment of hypertension	Process	
Adult(s) taking insulin with evidence of self-monitoring blood glucose testing	Process	
Diabetes and Elevated HbA1C – Use of Diabetes Medications	Process	
Glycemic Control - Hyperglycemia	Outcome	
Glycemic Control - Hypoglycemia	Outcome	
Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus	Process	

Usage of Diabetic Agents 25-50% Increases

Trends in Prescription Drug Use Among Adults in the United States From 1999-2012

Elizabeth D. Kantor, PhD, MPH; Colin D. Rehm, PhD, MPH; Jennifer S. Haas, MD, MSc; Andrew T. Chan, MD, MPH; Edward L. Giovannucci, MD, ScD

	1999-2000 (n = 4861)	2001-2002 (n = 5399)	2003-2004 (n = 5029)	2005-2006 (n = 4970)	2007-2008 (n = 5930)	2009-2010 (n = 6212)	2011-2012 (n = 5558)	P for Trend	Difference in Prevalence, % (95% CI)[c]	Ratio of Prevalence, Ratio (95% CI)[d]
Antidiabetic agents	4.6 (3.8-5.5)	5.3 (4.5-6.1)	6.4 (5.5-7.5)	6.4 (5.6-7.3)	7.7 (6.5-9.1)	7.7 (6.8-8.6)	8.2 (7.2-9.3)	<.001	3.6 (2.3 to 5.0)	1.8 (1.4 to 2.2)
Biguanides	2.0 (1.5-2.6)	2.5 (2.0-3.1)	3.6 (3.0-4.3)	3.6 (2.9-4.5)	4.7 (3.9-5.7)	4.9 (4.3-5.7)	5.5 (4.7-6.4)	<.001	3.5 (2.5 to 4.5)	2.7 (2.0 to 3.7)
Insulin	1.1 (0.8-1.6)	1.3 (0.9-1.8)	1.5 (1.2-1.9)	1.6 (1.4-1.9)	2.1 (1.6-2.8)	2.1 (1.6-2.7)	2.6 (2.2-3.1)	<.001	1.5 (0.9 to 2.1)	2.3 (1.6 to 3.3)
Sulfonylureas	2.6 (2.2-3.2)	2.7 (2.3-3.1)	3.3 (2.6-4.1)	2.9 (2.3-3.6)	3.3 (2.8-3.8)	3.0 (2.6-3.5)	3.2 (2.5-4.2)	<.001	0.6 (-0.4 to 1.5)	1.2 (0.88 to 1.7)
Thiazolidinediones	0.5 (0.3-0.8)	0.9 (0.7-1.2)	2.0 (1.7-2.4)	2.0 (1.5-2.6)	1.9 (1.4-2.4)	1.2 (1.0-1.6)	0.8 (0.6-1.1)	.17	0.3 (-0.1 to 0.7)	1.6 (0.86 to 2.9)

JAMA. 2015;314(17):1818-1831

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Polypharmacy

Polypharmacy: America's other drug problem

The opioid epidemic has become a national crisis. The number of overdose deaths involving opioids has quadrupled since 1999.[1] Indeed, the United States, with 5% of the global population, consumes 80% of the global opioid supply.[2] This epidemic has rightly entered the national consciousness as America's major drug problem. The nation also has another persistent drug problem, however—polypharmacy.

See also page 1336.

As the number of medications an individual uses increases, the risks of drug–drug interactions, adverse drug events, and nonadherence also increase. Polypharmacy is especially prevalent among older adults, who are more likely to be living with multiple chronic conditions. Prescribing cascade (i.e., use of a newly prescribed drug to counter adverse effects of another prescribed drug) and poor-quality prescribing among the elderly are common.[3] More than 35.8% of older U.S. adults are prescribed 5 or more medications, and 15% of those patients are taking medications in combinations that pose a risk of major drug–drug interactions.[4] A recent study found that 4 emergency department visits per 1,000 individuals occur secondary to adverse drug reactions annually in the United States, with 27.3% of visits resulting in hospitalization[5]; patients 65 or older accounted for approximately 34.5% of these visits and the highest hospitalization rate (43.6%).[5] One half of patients are not adher-

example, only 35.8% of pharmacists reported participation in discharge planning, a serious gap that is corroborated by other studies. Results of another recent survey indicated that pharmacists complete medication histories in only one third of hospitals[11]; results of a study conducted in the Veterans Affairs system revealed that 44% of patients had at least 1 unnecessary medication at discharge.[12] These gaps are serious and threaten our nation's health.

Recently, ASHP submitted 5 recommendations to the Choosing Wisely campaign, an initiative of the American Board of Internal Medicine Foundation working in partnership with the testing and rating organization Consumer Reports and more than 80 national specialty societies.[13] These recommendations focus attention on the need to reduce unnecessary treatment, prevent adverse events, and enhance patient safety, as follows:

- Do not initiate medications to treat symptoms, adverse events, or adverse effects without determining the cause.
- Do not prescribe medications for patients taking 5 or more medications, or continue medications indefinitely, without a comprehensive review, including nonprescription medications and dietary supplements.
- Do not continue medications based solely on past use unless a reason for use is verified.
- Do not prescribe medications at discharge that the patient was taking prior to admission without verifying the need.
- Use only metric units when prescribing liquid

The prevalence of polypharmacy (use of 5 prescription drugs) increased from an estimated 8.2% in 1999-2000 to 15% in 2011-2012
JAMA. 2015;314(17):1818-1831

Guharoy, R. Am J Health-Syst Pharm. 2017;74:1305-306

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Polypharmacy: Geriatrics

- **Currently defined as 5 medications or more**

- **Geriatric patients**
  - Inappropriate prescribing and polypharmacy in older persons are associated with increased risks of falls, adverse drug events, hospital admissions, and death[1,2]

1.Hajjar ER, et al. Polypharmacy in elderly patients. Am J Geriatr Pharmacother. 2007;5(4):345–51. doi: 10.1016/j.amjopharm.2007.12.002
2.Jyrkkä J, et al. Polypharmacy status as an indicator of mortality in an elderly population. Drugs Aging. 2009;26(12):1039–48. doi: 10.2165/11319530-

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Medication Induced Hypoglycemia

- **Obviously glycemic control agents:**
  - Insulin, oral agents, etc.

- **Non-diabetic hypoglycemia**
  - Reactive hypoglycemia
  - Fasting hypoglycemia
    - Aspirin, sulfa agents, pentamidine, quinine, beta-blockers, quinolones, ACE-I's, dietary supplements
    - Alcohol
    - Tumors
    - Hormone imbalances

- **Systematic review, 2009 found 164 medications**

Murad MH, et al. J Clin Endocrinol Metab 94: 741–745, 2009

Glycemic Agents and Medication Use Cycle: Opportunity for Errors

- **Medication use cycle**
  - Inventory
  - FDA approvals: https://www.fda.gov/forpatients/illness/diabetes/ucm408682.htm
    - All insulins and orals up to 2002
    - 2013-2016 (15 total, 5 insulin)
    - 2000-2012 (22 total, 5 insulin)
    - Before 1999 (10 all insulin)
  - Types of products
    - Injection, oral, inhalation
    - Vials (3 mL & 10 mL)
      - Standard 100 units/mL
      - Concentrated
        » U-500 still in vial
  - So complicated for P & T

Name/Concentration	Insulin/Action
Humulin Regular U-500 • 500 units insulin/mL • KwikPen or Vial	Regular Bolus / Basal
Humalog KwikPen U-200 200 units insulin/mL	Lispro (Humalog) Bolus
Toujeo Solostar U-300 Pen 300 units insulin/mL	Glargine (Lantus) Basal
Tresiba FlexTouch U-200 Pen 200 units insulin/mL	Degludec (Tresiba) Ultra basal

http://diabetesed.net/concentrated-insulins-clearing-confusion/

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Complexities within Hospitals and Health Systems

- **Inventory (both in large stock areas and satellites)**
  - Selection, storage (where in the fridge, labeling), vials, pens
  - Floorstock vs. patient specific
- **Ordering**
  - Order-sets, number of products to choose from
  - DKA, Non-ketotic hyperglycemia, Type I, Type II
    - Weight-based vs. non-weight base
  - Automatic nurse driven protocols for hypoglycemic events
  - Diet protocols – what happens when NPO, feeding tube comes out or clogged
  - Surgical procedures (before, during, after OR)
  - Pumps!!
- **Dispensing**
  - Again, storage
  - Infusions (large risk potential here)
    - More than one concentration? New standard 1 unit/mL
  - Patient specific and insulin syringes vs. 1 mL standard syringe
  - Vials – need to have expiration labeling – TJC!!
- **Administering**
  - Nurse administered vs. patient or parent/caregiver
  - Second checks – yes or no?
  - Anything special for concentrated
  - BCMA

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Medication Errors Associated with Transition from Insulin Pens to Vials

- **450 bed community hospitals transitioning from pens to vials**
- **3 major insulin administration errors**
  - Nurse administered whole vial (10 mL) instead of 1 mL (thought the whole vial was 100 units instead of 1000 units)
  - Patient was ordered 1 unit and nurse gave 100 units instead (thought the vial was the same as the infusion of 1 unit/mL)
  - Nurse confused the furosemide dose 20 mg (2 mL) and gave 2 mL of insulin (200 units) instead of the 1 unit ordered
- **RCA and interventions:**
  - Education to nurses
  - Revising appearance in EHR and MAR
  - Emphasized use of insulin syringes instead of standard IV syringes
  - Performing daily safety rounds
  - Implementation of daily huddles and information/"show and tell" at during the huddle

Trimble A, et al. Am J Health-Syst Pharm 2017;74:70-5

Polypharmacy: When to Deprescribe

- **More than 90% of patients are willing to stop a medication if their doctor says it is possible"**

- **Canada: Caden**
  - www.deprescribing.org
  - Antihyperglycemic agent discontinuation and video

Reeve et al. People's Attitudes, Beliefs, and Experiences Regarding Polypharmacy and Willingness to Deprescribe, Journal of the American Geriatrics Society. 2013;61:1508-1514

ASHP: Deprescribing and Choosing Wisely

- **American Board of Internal Medicine (ABIM)**
- **Started in 2012 with goal of decreasing wasteful diagnostics and reducing harm**
- **Currently over 101 medication related topics on the list**
- **ABIM asked ASHP to get involved**
- **International efforts:**
  - Australia, Brazil, Canada, Italy, Japan, UK, Wales
- **ASHP has contributed 5 topics that are medication focused**

http://www.choosingwisely.org/
https://choosingwiselycanada.org/campaign/international/

The Time Is Now

BEST PRACTICES AND WHERE WE NEED TO GO

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Multifaceted Approach to Reducing Occurrence of Severe Hypoglycemia in a Large Healthcare System

- **Paul E. Milligan et al, St. Louis-based BJC Healthcare**
- **Pharmacist led task force**
  - Automated event detection and dashboards amongst 11 hospitals
  - Implementation of best practices in the network
  - "Hypoglycemic Event Analysis Tool" (HEAT)
  - Assembly of targeted interventions on intranet site: "Hypoglycemia Facility Tracking" (H-FaST)
- **System-wide rate 6.45/1000 patient days in 2009 to 1.32/1000 patient days in 2014**
- **Overall reduction of in hypoglycemia of 80% and severe hypoglycemia of 70-100%**

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Interventions Over Time and Impact

Baseline 6-Month Average 153 events/month

Recent 6-Month Average 31 events/month

2011 Q3
HEAT implemented;
collection of data on
causative factors initiated

2012 Q2
H-FaST
implemented

2013 Q2
High-risk
admission alert
pilot tested

2010 Q1
Identified severe
hypoglycemia as
#1 drug-related
harm event

2010 Q3
Hypoglycemia
Task Force and
dashboards
created

2014
All interventions
continue to be
active

2011 Q2
Best practices
implemented

2012 Q1
High-risk
sulfonylurea
alert
implemented

2013 Q1 & Q2
Hypoglycemia
risk alert
implemented

Rate per 1000 At-risk Patient-Days

2009   2010   2011   2012   2013   2014

We Know Pharmacists Make a Difference, but Now What?

- **Need to connect the hospital, clinic, outpatient pharmacy and home environments**

- **Heightened awareness around hypoglycemia and stratify high-risk patients**
  - ED and other hospital pharmacists critical to close the loop for the community
  - Better communication and transitions of care
  - How can technology be used
  - Continuous monitoring and electronic warnings to MD/pharmacist

- **Pharmacists can do comprehensive care**
  - We aren't just about medications
  - Referrals to others: diabetic educators, dietician, social work, etc.
  - Exercise, diet, foot care, eye care

- **Need pharmacists as providers**

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The Ambulatory Diabetic Care Team

Registered Nurse

Physician/Specialist

Mid-Level Practitioner

Behavioral Health

PATIENT

Diabetes Educator & Dietician

Social Worker

Care Manager

Pharmacist

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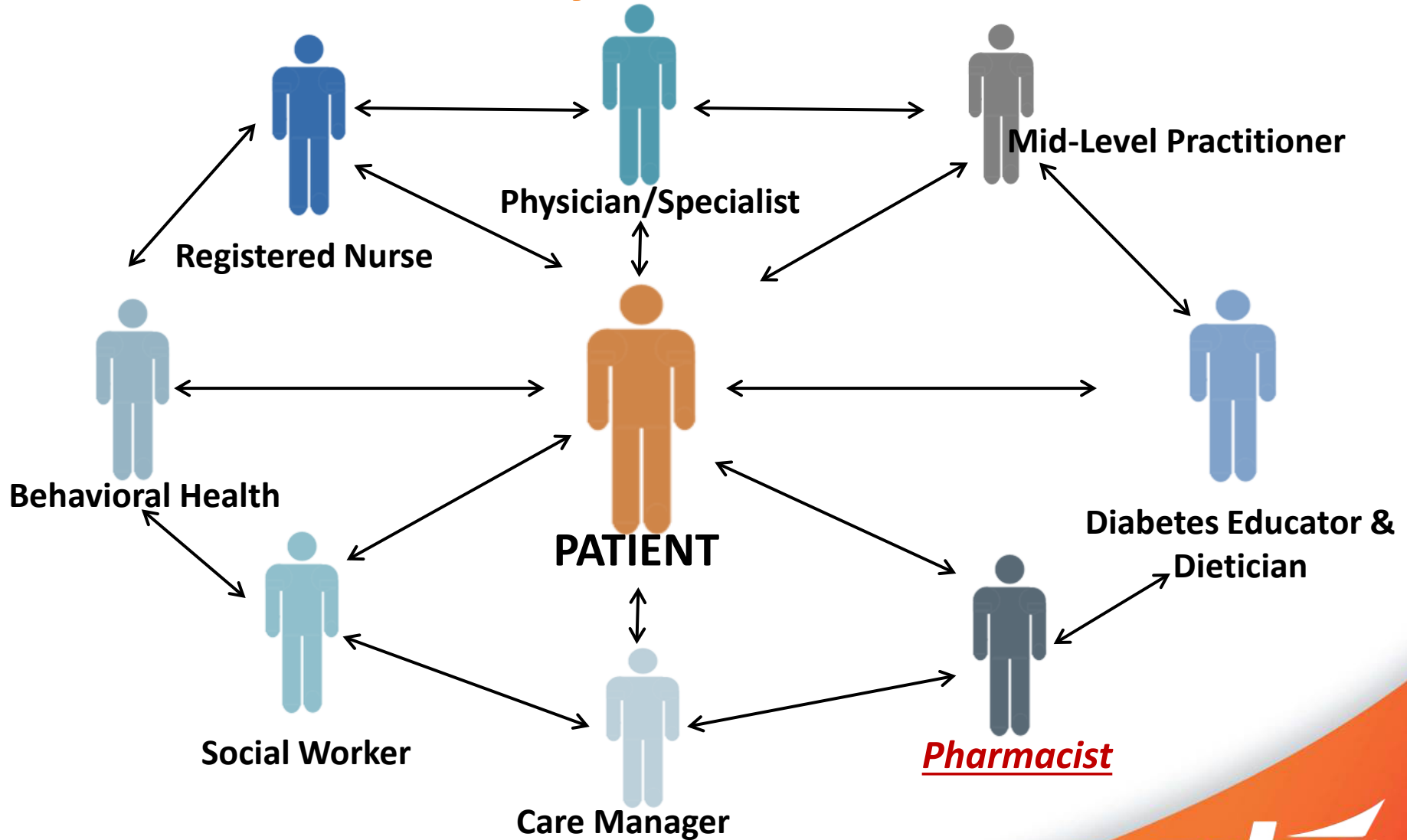
Summary

- **WE WANT TO HELP!**
- **Pharmacists have proven ourselves but why are we still having to fight the good fight?**
- **It takes a team, everyone can play a role**
- **Pharmacists aren't just about medications and can help identify problems such as hypoglycemia**

COMPREHENSIVE CARE

Personalized medicine   Population health
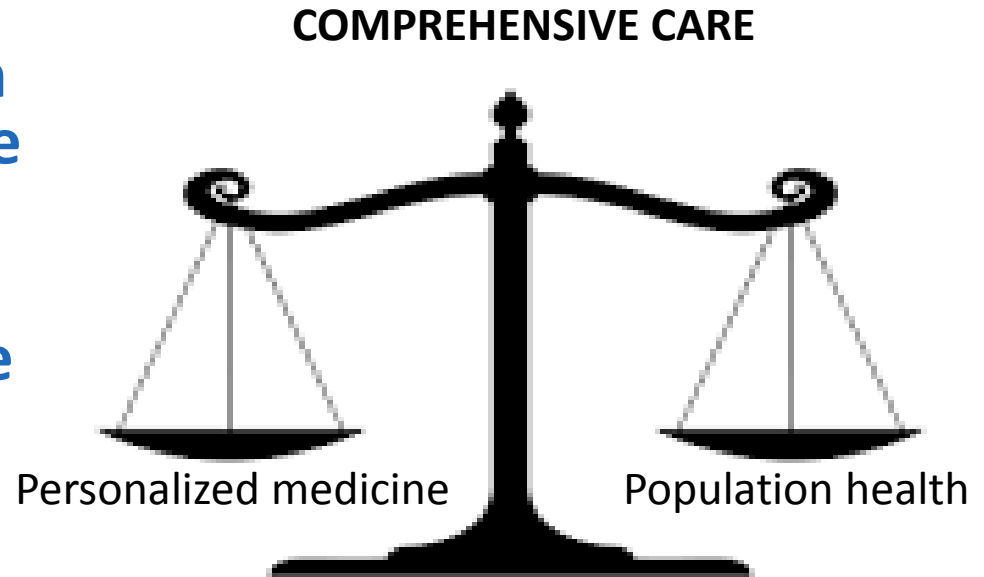
Questions?

- **Deborah Pasko: dpasko@ashp.org**
- **Anna Dopp: adopp@ashp.org**

Robert Lash, MD

Endocrine Society

Impacting the Incidence of Hypoglycemia

Robert W. Lash, MD

Chair, Hypoglycemia Quality Improvement Project Steering Committee

Professor of Internal Medicine, University of Michigan

ENDOCRINE SOCIETY

September 2017

The Substantial Burden of Hypoglycemia

$600M

Estimated spending on ED visits for therapy-associated hypoglycemia between 2007 and 2011

Hypoglycemia is the **largest single** barrier to achieving glycemic control in Type 1 and Type 2 diabetes

The prevalence and impact of hypoglycemia is **substantially underappreciated** in both Type 1 and Type 2, and improved surveillance is urgently needed, especially approaches that leverage electronic health records (EHR)

Multi-Year Effort to Impact Incidence of Hypoglycemia

- *ACA Implementation: Impact on Patients with Diabetes* Summit - 2014

- Hypoglycemia Roundtable - 2015

- Hypoglycemia Quality Collaborative (HQC) – 2016

- Hypoglycemia Quality Improvement Project (HQuIP) - 2017

History of Recent Hypoglycemia Focused Initiatives

JDRF launches multi-stakeholder T1D Outcomes Program to better define clinically meaningful T1D outcomes beyond hemoglobin A1c (HbA1c). Gaining consensus on the definition for hypoglycemia is one of the topics

Endocrine Society begins work on the Hypoglycemia Quality Improvement Project (HQuIP)

Endocrine Society hosts a multi-stakeholder roundtable discussion re: challenges in preventing and managing hypoglycemia among people with diabetes, and potential solutions

After the formation of the HQC, Endocrine Society creates the HQC Blueprint.

HHS releases National Action Plan for Adverse Drug Event Prevention

Endocrine Society launches the Hypoglycemia Quality Collaborative (HQC) project

T1D Outcomes Program publishes Draft Consensus Statement with a public comment period

T1D Outcomes Program will publish Final Consensus Statement

| 2014 | Apr 2015 | Jan 2016 | Jan 2016 | Oct 2016 | Feb 2017 | May 2017 | Fall 2017 |

ENDOCRINE SOCIETY

Endocrine Society Prioritizes Hypoglycemia Prevention

Challenge: Endocrine Society was interested in learning how to increase national awareness of hypoglycemia and facilitate joint action by stakeholders to reduce its incidence.

Establish the Hypoglycemia Quality Collaborative (HQC)	Develop the HQC Strategic Blueprint	Develop Tactical Plans to Support Hypoglycemia Strategic Activities	Partner with Federal Agencies to Raise Awareness
A coalition of diabetes stakeholders including medical specialty societies, payers, industry, patient advocates, diabetes educators, and research organizations	An actionable document and evergreen resource for stakeholders to identify strategic activities and contextualize how the activity contributes to reducing the incidence of hypoglycemia	A high-level overview of specific tasks, rationale, and timing of tasks to advance Endocrine Society's visibility as a leader in diabetes quality with the ultimate goal of improving patient outcomes and reimbursement for its members	A collaborative of Federal agencies, including FDA, CMS, VA, HHS, Endocrine Society, and quality improvement organizations the common goal of raising awareness, improving surveillance, and improving quality of care

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Hypoglycemia Quality Collaborative

The Endocrine Society established the **Hypoglycemia Quality Collaborative (HQC)** in January 2016 to increase national awareness of hypoglycemia and facilitate joint action by stakeholders to reduce its incidence

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Organizations Participating in the Hypoglycemia Quality Collaborative

- Abbott Diabetes Care Inc.
- Aetna
- American Association of Clinical Endocrinologists
- American Association of Diabetes Educators
- American College of Physicians
- American Diabetes Association
- Astrazeneca
- Close Concerns
- Dexcom

- Johnson & Johnson
- Joslin Diabetes Center
- Juvenile Diabetes Research Foundation
- Lilly
- Medtronic Diabetes
- Merck & Co
- Novo Nordisk
- Pharmacy Quality Alliance
- T1D Exchange

HQC Strategic Blueprint

The HQC released a **Strategic Blueprint in November 2016** to articulate its recommendations for action and serve as a key source of information to stakeholders seeking to reduce the incidence of hypoglycemia

Blueprint Domain Recommendations
1. Define and Describe Hypoglycemia to Support Standards of Care
2. Advance Hypoglycemia Evidence to Reduce Gaps in Care
3. Measure and Improve Quality of Care
4. Advocate for Increased Focus on Hypoglycemia
5. Deliver Hypoglycemia Prevention and Management Education
6. Recognize Hypoglycemia as a Public Health Issue

Goals to Advance Hypoglycemia Quality
1. Improve Hypoglycemia Surveillance and Risk Assessment
2. Improve Management of Patients on Insulins and Sulfonylureas
3. Improve Reimbursement for Endocrinologists

HQC Strategic Blueprint: www.endocrine.org/hypoglycemia

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Key Strategies to Define and Describe Hypoglycemia

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Hypoglycemia Quality Improvement Project Goals

Improve outcomes of patients with T2D by:

Decreasing the frequency and severity of episodes of hypoglycemia

Identifying patients at high risk for hypoglycemia in a timely manner

Supporting appropriate clinical interventions for patients in outpatient settings

Hypoglycemia Quality Improvement Project Objectives

1. Improve Hypoglycemia Surveillance and Risk Assessment

The program seeks to understand the rate of hypoglycemia and reduce the economic burden of the condition by implementing strategies that lead to better prevention and surveillance

2. Improve Management of Patients on Insulin and Sulfonylureas

Create and pilot a toolkit, which will support providers in assessing and managing patients at-risk for hypoglycemia. This toolkit can be used to meet quality measure requirements in private and public payer value-based programs

3. Align Provider Reimbursement to Promote Prevention and Management of Hypoglycemia

Develop reliable measures that can be adopted into existing and future incentive programs to increase the use of support tools for the prevention and management of hypoglycemia

4. Enhance the Current Understanding of the Overall Assessment and Treatment of Hypoglycemia

Provide evidence that can be used to understand the epidemiology of hypoglycemia, the pattern in which it occurs, and evidence-based strategies that can be implemented for prevention

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HQuIP Yearly Milestones 2017 Onwards

- Finalize Study Protocol and Toolkit
- Submit Abstracts for Presentations
- Establish Technical Expert Panel and Patient Panel
- Design Study Protocol
- Begin Measure Development

- Potential Inclusion of Measures in CMS MUC List

- Conduct Environmental Scan

- Develop Study Protocol and Toolkit
- Publish Scan Findings

- Launch Pilot
- Test Measures

- Publish Pilot Results
- Submit Toolkit for CPIA Consideration Under MIPS

- Train Pilot Sites

- Analyze Pilot Data

- Develop Measure Concept
- Submit CMS MACRA grant application submission

- Recruit Pilot Sites
- Test Toolkit

- Complete Measure Testing

Q2   Q3   Q4   Q1   Q2   Q3   Q4   Q1   Q2   Q3   Q4

● 2017   ● 2018   ● 2019

Note: Additional ongoing milestones will include: 1) continuous engagement with stakeholders such as CMS and FDA to ensure alignment of activities to support overall goal to decrease incidence and/or severity of hypoglycemia through measure adoption and quality improvement, and 2) presentations at key annual meetings.

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Environmental Scan Will Support Development of the HQuIP

THE OBJECTIVES OF THE ENVIRONMENTAL SCAN ARE TO IDENTIFY:

Risk assessment tools that can be considered while designing the HQuIP protocol

Current and planned outpatient-based quality improvement initiatives focused on hypoglycemia

Quality measure concepts focused on improving hypoglycemia in outpatient settings that are currently being explored by stakeholders

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Three-Pronged Approach to Environmental Scan

RESULTS OF THE SCAN WILL BE USED TO INFORM RECOMMENDATIONS FOR DESIGNING THE HQUIP PROTOCOL

Survey HQC Members	Literature Search	Stakeholder Interviews
• Create a 10 to 15-question online survey to be sent to HQC members. The intent of this survey is to gather preliminary information on currently existing diabetes-related initiatives	• Conduct a white and grey literature search that will identify risk assessment tools, existing payment and delivery programs that incentivize providers to participate in a program such as HQuIP, quality measure concepts focused on improving hypoglycemia, and current and planned outpatient-based quality improvement initiatives focused on hypoglycemia	• Conduct 8 to 10 one-hour interviews with key experts identified through the literature search

HQC: Hypoglycemia Quality Collaborative

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A Wide Variety of Sources Are Being Evaluated as Part of the HQuIP Environmental Scan*

800+
Articles in the white literature were identified

We used structured search strings in PubMed

60+
Sources in the grey literature were analyzed

Sources reviewed include:
- Health Plans Programs
- Professional Societies' Reports and Programs
- Government Agency Reports

30+
Quality measures and measure concepts related to hypoglycemia identified

Sources reviewed include:
- National Action Plan
- Government agency programs
- Professional Societies
- Qualified Clinical Data Registries

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These figures are based on most recent research findings as of September 1, 2017

Review of Clinical Guidance Documents in Diabetes Care

- ADA 2017: ADA Standards of Medical Care in Diabetes

- AACE/ACE 2015: Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan

- ADA/EASD 2016: Glucose Concentrations of Less Than 3.0 mmol/L (54 mg/dL) Should Be Reported in Clinical Trials: A Joint Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes

- ADA/ES 2013: Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society

- Joslin 2013: Joslin Diabetes Center and Joslin Clinic Guideline for Specialty Consultation/Referral

- VA/DoD 2017: VA/DoD Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care

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Challenge: Endocrine Society was interested in learning how to increase national awareness of hypoglycemia and facilitate joint action by stakeholders to reduce its incidence.

Establish the Hypoglycemia Quality Collaborative (HQC)	Develop the HQC Strategic Blueprint	Develop Tactical Plans to Support Hypoglycemia Strategic Activities	Partner with Federal Agencies to Raise Awareness
A coalition of diabetes stakeholders including medical specialty societies, payers, industry, patient advocates, diabetes educators, and research organizations	An actionable document and evergreen resource for stakeholders to identify strategic activities and contextualize how the activity contributes to reducing the incidence of hypoglycemia	A high-level overview of specific tasks, rationale, and timing of tasks to advance Endocrine Society's visibility as a leader in diabetes quality with the ultimate goal of improving patient outcomes and reimbursement for its members	A collaborative of Federal agencies, including FDA, CMS, VA, HHS, provider organizations, and quality improvement organizations with the common goal of raising awareness, increasing surveillance, and improving quality of care

Opportunities Beyond HQuIP

Engagement with Federal Agencies, Provider Organizations, and Quality Improvement Organizations

Endocrine Society is a member of a multi-stakeholder group involved in FDA's Safe Use Initiative focused on decreasing hypoglycemic adverse drug events in patients with diabetes

Conversations have centered around the implementation of hypoglycemia risk assessment tools in the outpatient setting, raising awareness among target audiences, and developing quality measures

Identifying common messages and target audiences is the first priority. Opportunities to employ these messages are being pursued for Diabetes Awareness Month

ENDOCRINE SOCIETY

Opportunities Beyond HQuIP

Application for CMS Measure Development Grant

CMS recently announced it will award up to $30 million in grant funding for measure development to entities engaged in developing quality measures for use in the Quality Payment Program

To support the goals of the HQuIP, the Endocrine Society is currently developing measure concepts related to Type 2 Diabetes and hypoglycemia in preparation to submit a grant application

Thank you!

www.endocrine.org/hypoglycemia

Public comments/ Discussion

Reducing the Risk of Preventable Harm Associated with Hypoglycemia in the Older Population

Paul B. Madden, M.Ed.

Managing Director Diabetes

American Diabetes Association

Living a Bold Life with Type 1 Diabetes for 55+ Years

Significant Contributions to this Presentation:

Pearl Lee, MD; Irl B. Hirsch, MD; Ruth Weinstock, MD;

Len Pogach MD, MPH, Priscilla White, MD and several thousand patients >60 yrs. old, my mother, and diabetes specialists I have worked with over the last 42 years.

Older Adults are Achieving Lower A1c Levels
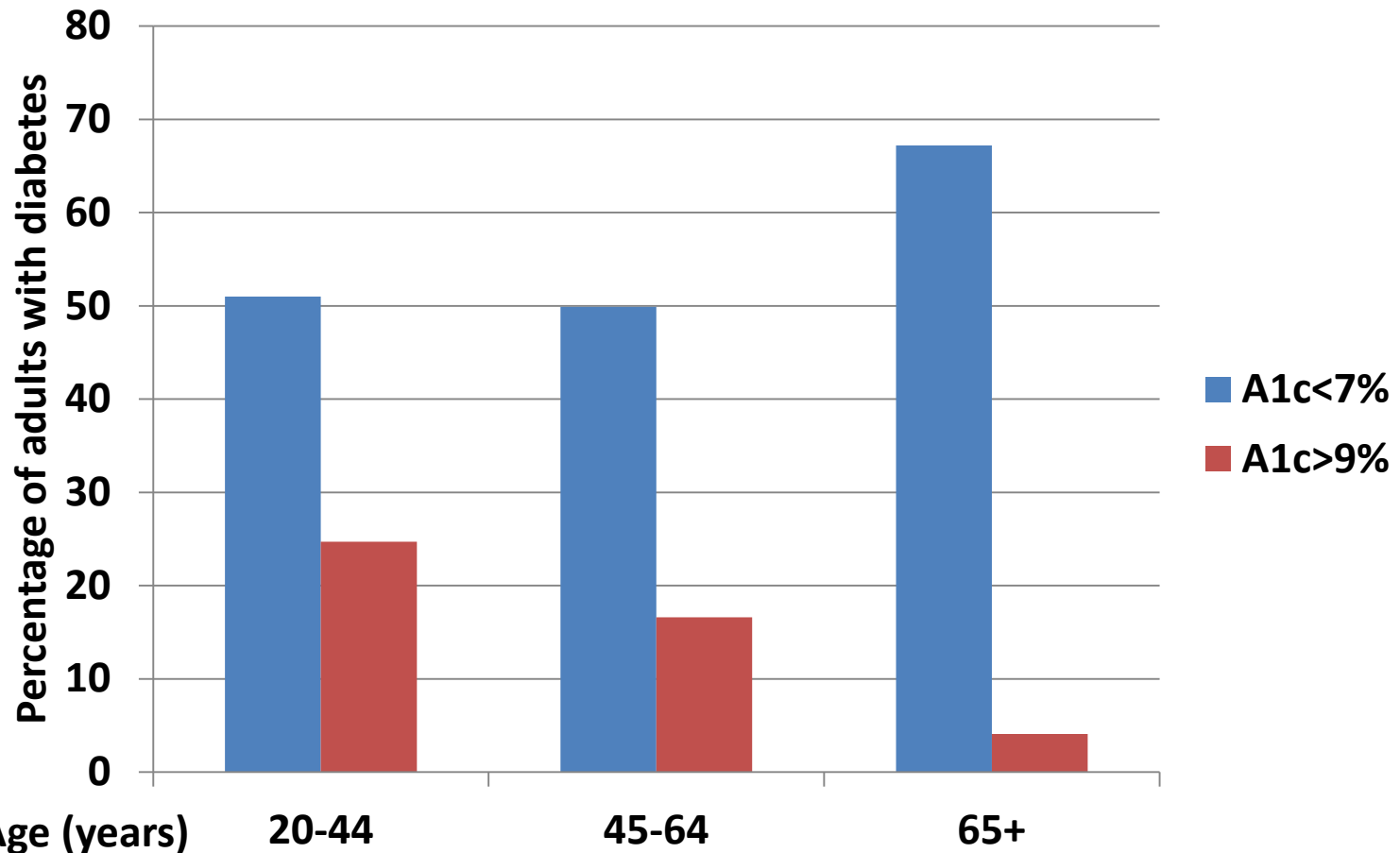
Data Source: CDC's Behavioral Risk Factor Surveillance System, 2010

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National Trends in US Hospital Admissions for Hyperglycemia and Hypoglycemia Among Medicare Beneficiaries, 1999 to 2011
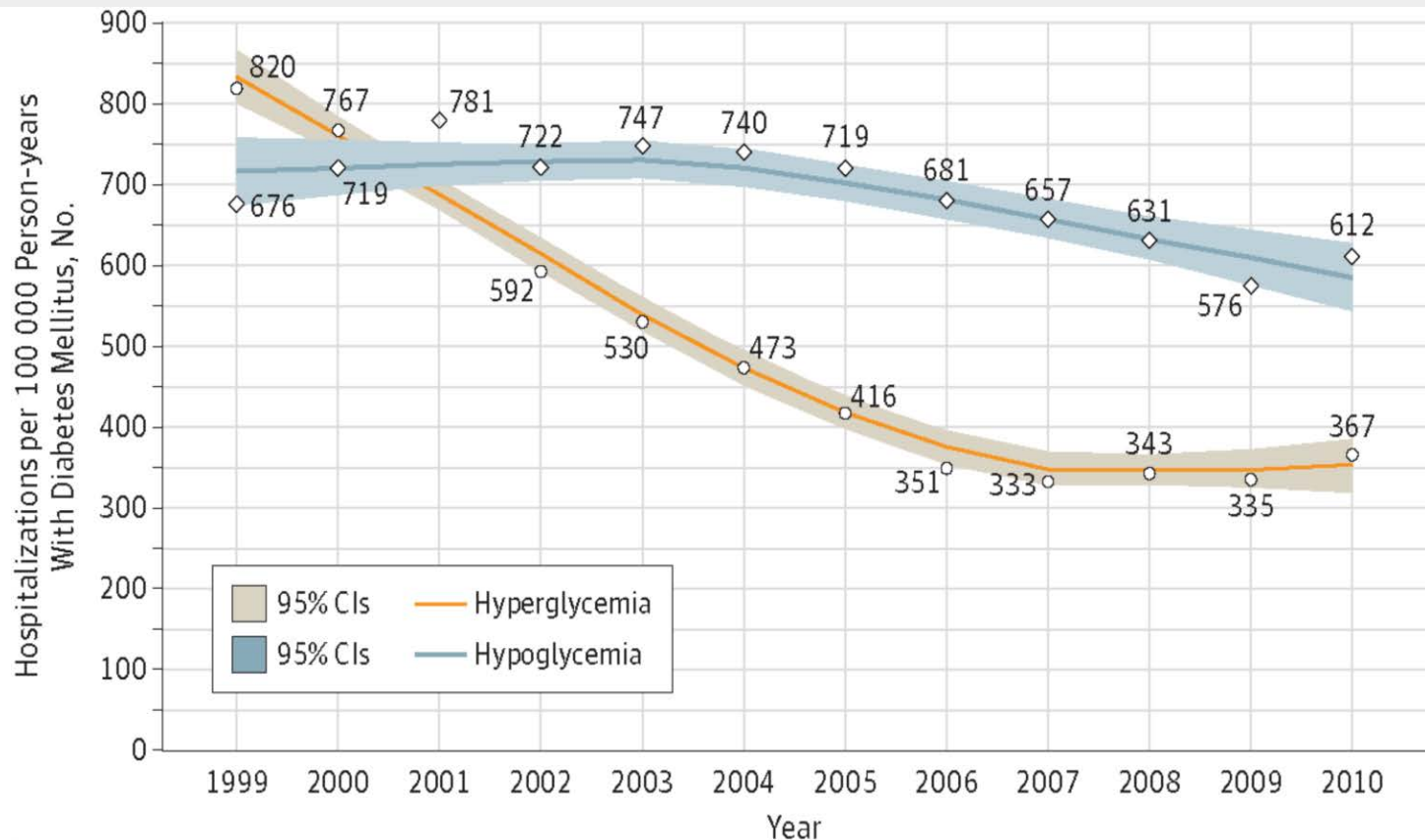

Figure Legend:

Rates of Estimated Hospital Admissions for Hyperglycemia and Hypoglycemia Among Medicare Beneficiaries With Diabetes Mellitus, 1999 to 2010The circles and diamonds indicate observed values; the lines represent the smoothed trend over time.

How Do We Compromise on Glycemic Targets Given All of these Risks?

A reasonable generic glycemic goal is the *lowest A1C* that *1*) does not cause severe hypoglycemia, *2*) preserves awareness of hypoglycemia, and 3) causes an acceptable number of episodes of symptomatic hypoglycemia at a given stage of the evolution of the individual's diabetes.

Reasonable, but misleading when reviewing the newer evidence…

For Multiple Reasons Seniors Require Additional Considerations as Therapy is Tailored to Their Lives.

Cryer PE. *Hypoglycemia in Diabetes.* 2nd ed. Alexandria, VA, American Diabetes Association, 2012.

Risk Factors for Hypoglycemia in Older Adults with Diabetes Mellitus

Physiological

   Cognitive impairment

   Impaired autonomic nervous system function

   Diminished glucagon secretion

   Kidney or liver failure

   Sensory impairment (vision, hearing)

   Functional impairment (mobility, hand dexterity)

Behavioral

   Unhealthy choices, (poorly understood) or irregular, unbalanced nutrition and/or calories

   Irregular, poorly planned (misunderstood) exercise

   Over Use of alcohol or other sedating agents

   Limited support village (family, diabetes experts, friends) available for senior

   Others: Polypharmacy (use of multiple drugs to treat one or more conditions).

HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

The Population of Older Adults with Diabetes is Heterogeneous

RELATIVELY HEALTHY	COMPLEX/ INTERMEDIATE HEALTH	VERY COMPLEX / POOR HEALTH
• < 3 chronic diseases • No cognitive or significant visual impairment • 0 or 1 instrumental activities of daily living (IADL) dependencies	• ≥ 3 chronic diseases • Mild cognitive impairment • Severe vision impairment • ≥ 2 IADL dependencies	• Moderate to severe cognitive impairment • ≥ 2 ADL dependencies • Residence in a long-term nursing facility

*ADL: routine activities people do everyday without needing assistance; eating, bathing, dressing, toileting, walking, continence.

Current diabetes care goals for these patients are:

Likely to benefit -----------------Difficult to implement ----------------Limited benefit

Blaum CS, et al. Medical Care.2010; 48(4):327-334

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Recommendations (guidance)
Figure 1. Modulation of the intensiveness of glucose lowering therapy in T2DM

- **<u>Patient / Disease Features</u>**
- Risks potentially associated with hypoglycemia and other drug adverse effects
- Disease Duration
- Life Expectancy
- Important Comorbidities
- Established Vascular Complications
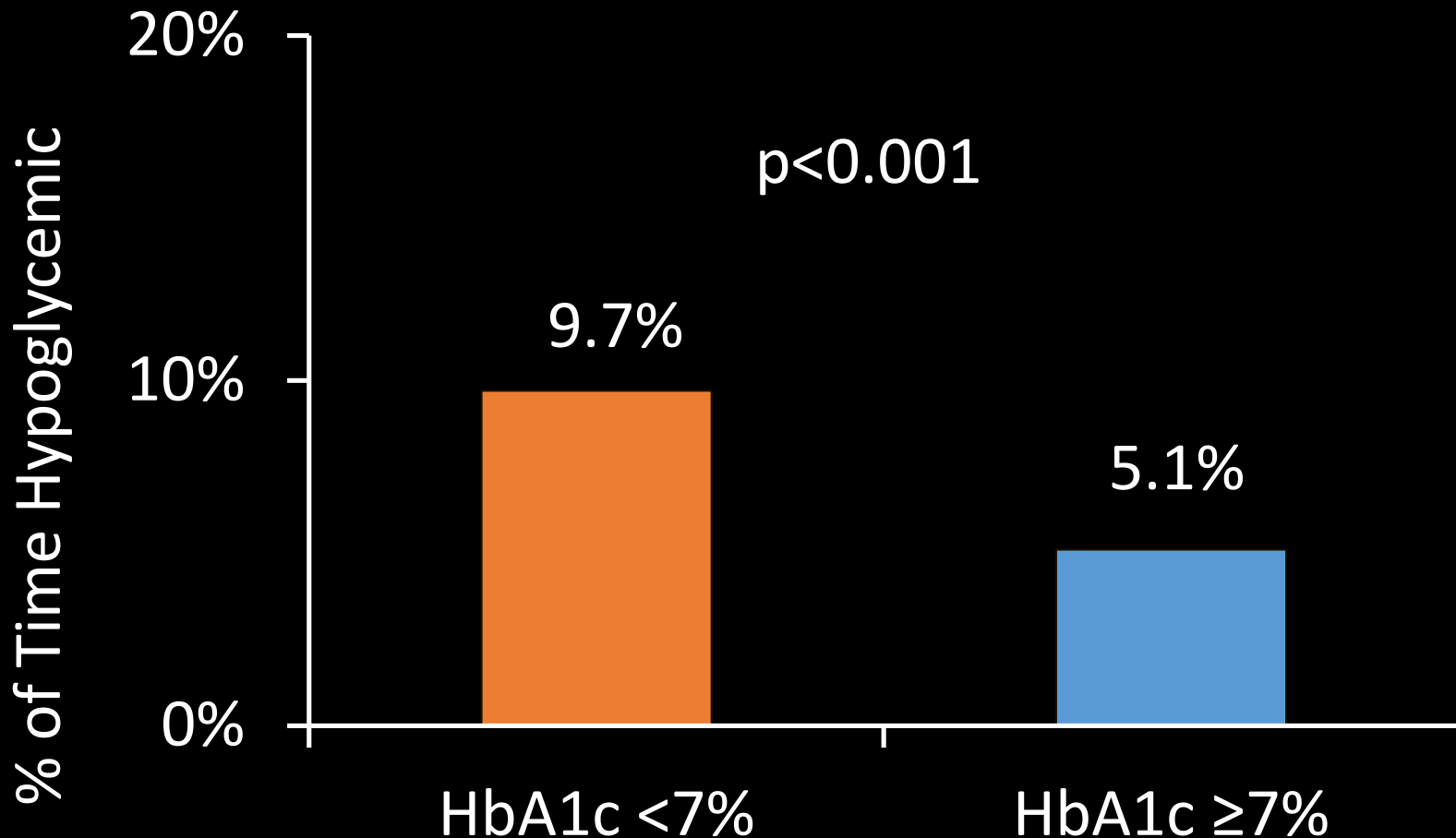- Patient attitude and expected treatment efforts
- Resources and support system

Therapy Considerations; MUST Be Based on best science and the individual's needs and abilities

Hypoglycemia in Older Adults with T1D

- Cases and controls had similar mean glucose and HbA1c
- Cases had
  - increased hypoglycemia unawareness
  - increased CGM glucose variability
  - trend towards more CGM hypoglycemia
  - greater fear of hypoglycemia (quality of life)
  - slightly higher daily frequency of blood glucose monitoring
  - greater use of beta blockers

Weinstock R, et a: Diabetes Care 2016:39:603-610

Secondary Analysis

Percentage of Time Spent in Hypoglycemia (<70 mg/dl) by HbA1c

p<0.001

9.7%

5.1%

20%

10%

0%

% of Time Hypoglycemic

HbA1c <7%

HbA1c ≥7%

Hirsch IB, et al: ADA, Boston, 2015

Hypoglycemia In Adult vs Elderly Type 2 Diabetes Mellitus Patients: Risks, Costs, and Impact on Treatment Persistence

Difference in both all-cause and diabetes-related annual healthcare costs between patients with and without hypoglycemia were greater in elderly ($20,264 vs. $11,897 vs. $11,829 vs. $4,190, respectively than adults ($14,031 vs $9,007 and $7,012 vs. $3,265, respectively,
Compared to adults, elderly T2DM patients exhibit higher risks of treatment- associated hypoglycemia In most treatment groups.

American Diabetes Association.

So What Are Our Current And Future Strategies to Better Address Hypoglycemia in Diabetes?

- **Insulin analogues: becoming unaffordable for many in U.S. This must be addressed by all.**

- **CGM: growing evidence of improvements in hypoglycemic exposure**

- **Movement to "smarter" insulin pumps: hybrid closed-loop to complete closed loop**

- **Encapsulated islets**

- **Glucose responsive insulins**

- **Preventions and Cures**

Resources; Working Together to Improve Lives of Seniors with Diabetes.

Seniors Living with Diabetes and their loved ones.

Colleagues and Associations focused on DM Care

NIH, NIDDK, FDA

American Diabetes Standards of Medical Care

Best Research on Seniors Living with Diabetes

We invite your suggestions on other best research, clinical experiences and information that will benefit this important focus to

improve the lives of seniors with diabetes.

American Diabetes Association.

Diabetes Care®

Lixisenatide Therapy in Older Patients With Type 2 Diabetes Inadequately Controlled on Their Current Antidiabetic Treatment: The GetGoal-O Randomized Trial

G.S. Meneilly, C. Roy-Duval, H. Alawi, G. Dailey, D. Bellido, C. Trescoli, H. Manrique Hurtado, H. Guo, V. Pilorget, R. Perfetti, and H. Simpson, on behalf of the GetGoal-O Trial Investigators

Management of Inpatient Hyperglycemia and Diabetes in Older Adults

G.E. Umpierrez and F.J. Pasquel

Extracellular RNAs Are Associated With Insulin Resistance and Metabolic Phenotypes

R. Shah, V. Murthy, M. Pacold, K. Danielson, K. Tanriverdi, M.G. Larson, K. Hanspers, A. Pico, E. Mick, J. Reis, S. de Ferranti, E. Freinkman, D. Levy, U. Hoffmann, S. Osganian, S. Das, and J.E. Freedman

Proinflammatory Cytokines Predict the Incidence and Progression of Distal Sensorimotor Polyneuropathy: KORA F4/FF4 Study

C. Herder, J.M. Kannenberg, C. Huth, M. Carstensen-Kirberg, W. Rathmann, W. Koenig, M. Heier, S. Püttgen, B. Thorand, A. Peters, M. Roden, C. Meisinger, and D. Ziegler

SPECIAL ARTICLE COLLECTION:
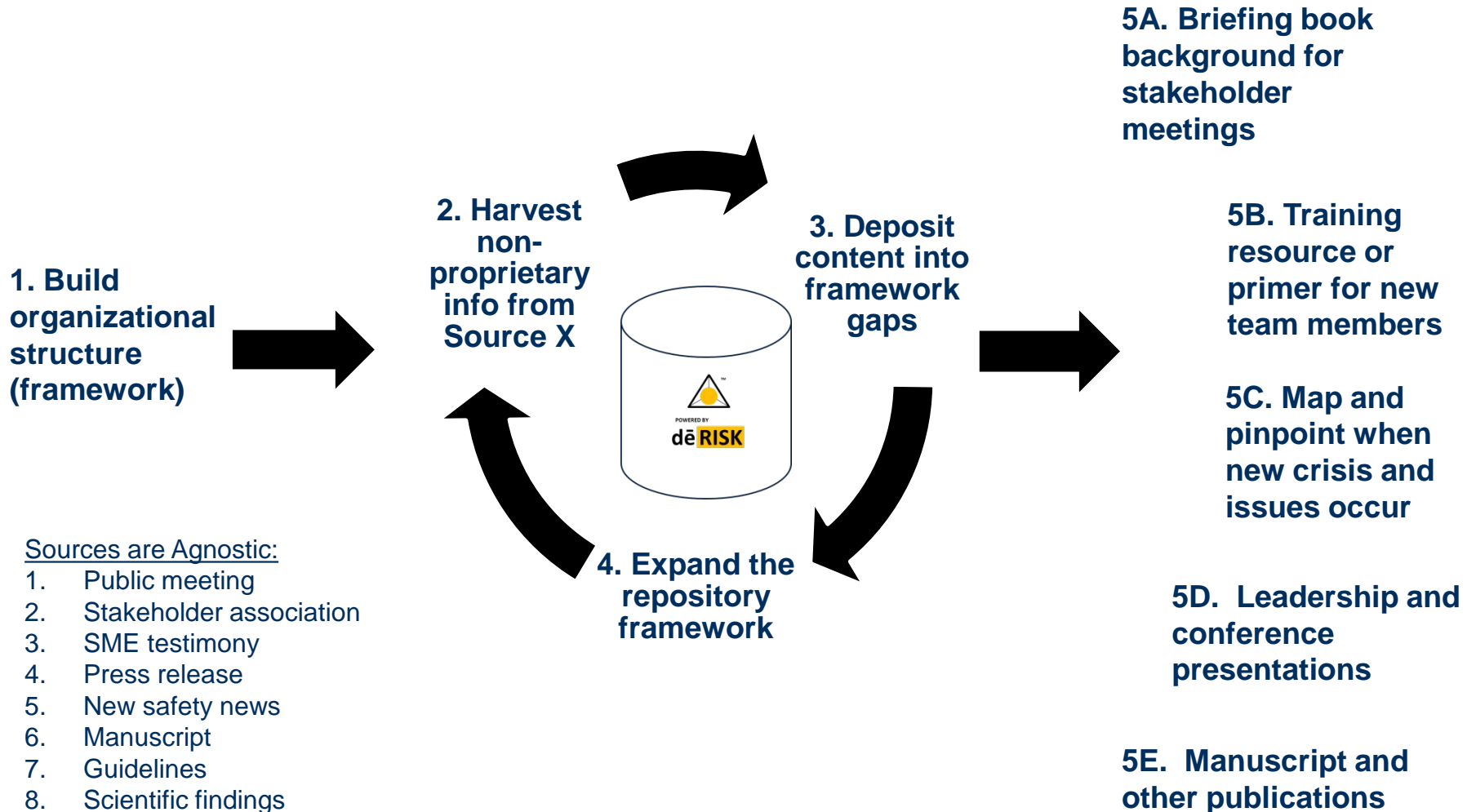Emerging Science and Concepts for Management of Diabetes and Aging

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Systematic Risk Assessment of Hypoglycemia in the Older Population Associated with Anti-Hyperglycemics using the DERISK System

Stephen Sun, MD, MPH
Head of Quality Risk Management Group
qrm@inventivhealth.com

September 12, 2017

Development of a Safe Use Initiative Risk Repository
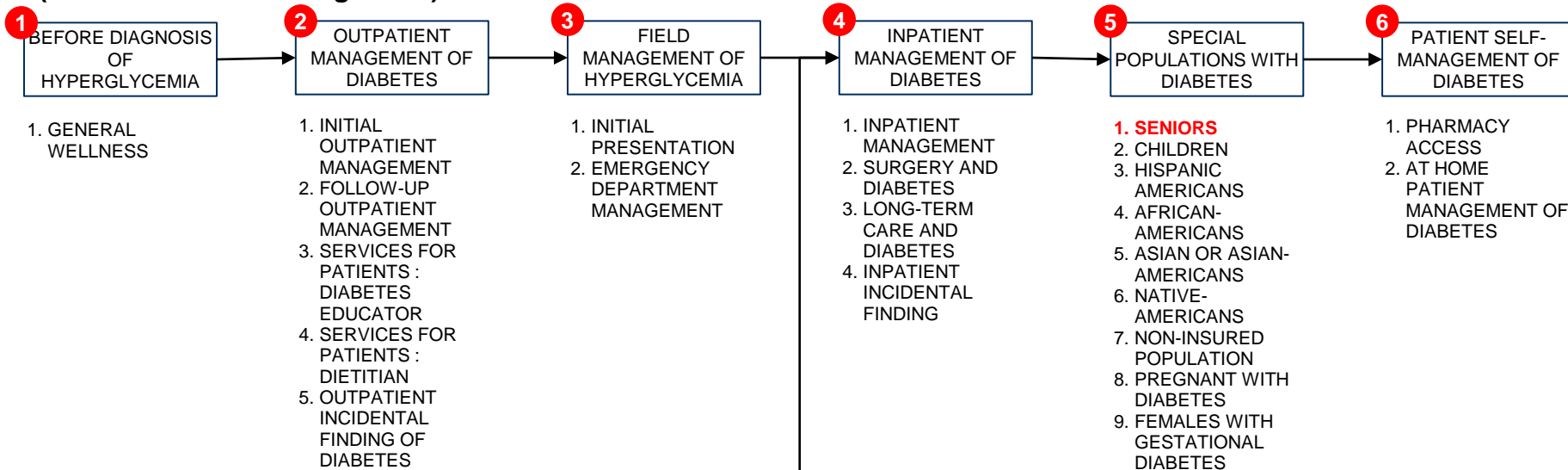## As part of a 3-year Research Collaboration Agreement with the FDA

1. Build organizational structure (framework)

2. Harvest non-proprietary info from Source X

3. Deposit content into framework gaps

POWERED BY
dē RISK

4. Expand the repository framework

5A. Briefing book background for stakeholder meetings

5B. Training resource or primer for new team members

5C. Map and pinpoint when new crisis and issues occur

5D. Leadership and conference presentations

5E. Manuscript and other publications

Sources are Agnostic:
1. Public meeting
2. Stakeholder association
3. SME testimony
4. Press release
5. New safety news
6. Manuscript
7. Guidelines
8. Scientific findings

Codified Risk Library that Grows Smarter With Every Project Using Systematic and Heuristic Methods
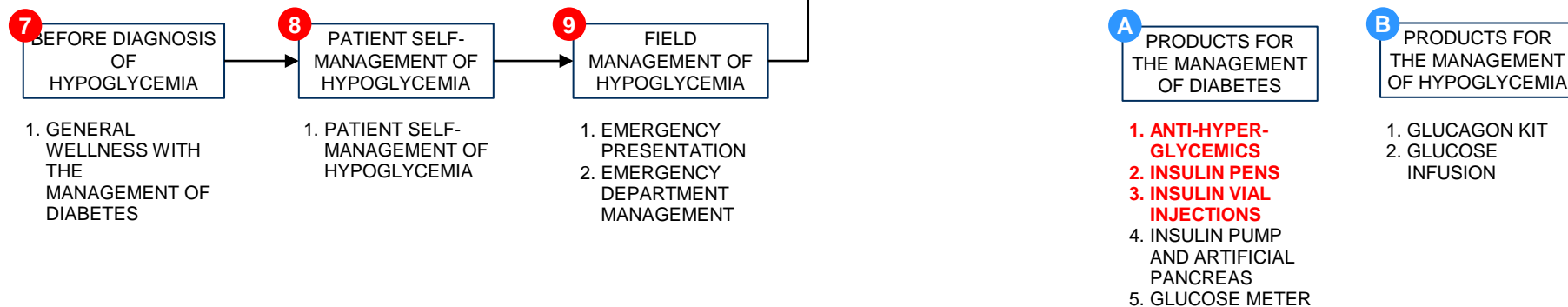

1. Multi-stakeholder journey

2. Learning repository

3. Source-agnostic

4. Web-based

5. Uses engineering FMEA

6. Risk-based score ready

7. Mapped for targeting

8. Designed for "new" info

9. Minimal maintenance

10. Database report outputs

Systematic Risk Assessment for a Patient's Journey in Diabetes and Hypoglycemia Management

(Part 1: Diabetes Management)

1 BEFORE DIAGNOSIS OF HYPERGLYCEMIA

1. GENERAL WELLNESS

2 OUTPATIENT MANAGEMENT OF DIABETES

1. INITIAL OUTPATIENT MANAGEMENT
2. FOLLOW-UP OUTPATIENT MANAGEMENT
3. SERVICES FOR PATIENTS : DIABETES EDUCATOR
4. SERVICES FOR PATIENTS : DIETITIAN
5. OUTPATIENT INCIDENTAL FINDING OF DIABETES

3 FIELD MANAGEMENT OF HYPERGLYCEMIA

1. INITIAL PRESENTATION
2. EMERGENCY DEPARTMENT MANAGEMENT

4 INPATIENT MANAGEMENT OF DIABETES

1. INPATIENT MANAGEMENT
2. SURGERY AND DIABETES
3. LONG-TERM CARE AND DIABETES
4. INPATIENT INCIDENTAL FINDING

5 SPECIAL POPULATIONS WITH DIABETES

1. **SENIORS**
2. CHILDREN
3. HISPANIC AMERICANS
4. AFRICAN-AMERICANS
5. ASIAN OR ASIAN-AMERICANS
6. NATIVE-AMERICANS
7. NON-INSURED POPULATION
8. PREGNANT WITH DIABETES
9. FEMALES WITH GESTATIONAL DIABETES

6 PATIENT SELF-MANAGEMENT OF DIABETES

1. PHARMACY ACCESS
2. AT HOME PATIENT MANAGEMENT OF DIABETES

(Part 2: Hypoglycemia Management)

7 BEFORE DIAGNOSIS OF HYPOGLYCEMIA

1. GENERAL WELLNESS WITH THE MANAGEMENT OF DIABETES

8 PATIENT SELF-MANAGEMENT OF HYPOGLYCEMIA

1. PATIENT SELF-MANAGEMENT OF HYPOGLYCEMIA

9 FIELD MANAGEMENT OF HYPOGLYCEMIA

1. EMERGENCY PRESENTATION
2. EMERGENCY DEPARTMENT MANAGEMENT

A PRODUCTS FOR THE MANAGEMENT OF DIABETES

1. **ANTI-HYPER-GLYCEMICS**
2. **INSULIN PENS**
3. **INSULIN VIAL INJECTIONS**
4. INSULIN PUMP AND ARTIFICIAL PANCREAS
5. GLUCOSE METER

B PRODUCTS FOR THE MANAGEMENT OF HYPOGLYCEMIA

1. GLUCAGON KIT
2. GLUCOSE INFUSION

Systematic Risk Assessment of Hypoglycemia in the Older Population Associated with Anti-Hyperglycemics Using the DERISK System

OLDER POPULATION RISKS:

1. Additional comorbid conditions besides diabetes
2. More prescribed and non-prescribed medications
3. Difficult time understanding and retaining treatment-related instructions
4. Dependence on caregivers
5. Resources such as an elderly support organization
6. More travel limitations
7. Limited income and conserves medications
8. Discontinue use of insulin from hypoglycemia
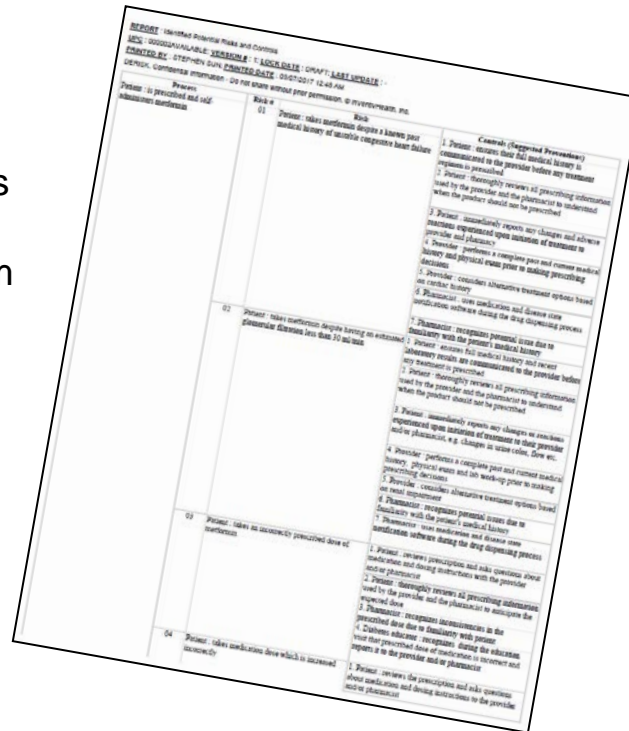
ANTI-HYPERGLYCEMIC RISKS:

1. Metformin
2. Sulfonylureas
3. Thiazolidinediones
4. Dipeptidyl peptidase iv
5. SGLT2 inhibitors
6. Alpha-glucosidase inhibitors
7. Bromocriptine mesylate
8. Colesevelam
9. Meglitinide analogs
10. GLP1 receptor agonists
11. Amylin analogs
12. Insulin pen
13. Insulin with vial and syringes

*A Systematic Risk Assessment (SRA) Report will be updated in the DERISK repository and a report will generated in real-time and be made available to the FDA after any additional learnings are incorporated

Reducing the Risk of Hypoglycemia in the Older Population

FDA Patient Panel, September 12, 2017
Alan C Moses, MD
Global Chief Medical Officer, Novo Nordisk A/S

Disclosures

ACM is a full-time employee of Novo Nordisk and, as such, is compensated by salary and share options.

Hypoglycemia is a Major Healthcare Burden for American Citizens

Hypoglycemia is a risk factor for mortality and adverse cardiovascular (CV) events[1]

- Mild hypoglycemia: **68%** increased risk of death and adverse cardiovascular events (p<0.001)
- Severe hypoglycemia: **133%** increased risk of death and adverse cardiovascular events (p<0.001)

Severe hypoglycemia often requires hospitalisation and inpatient care[2]
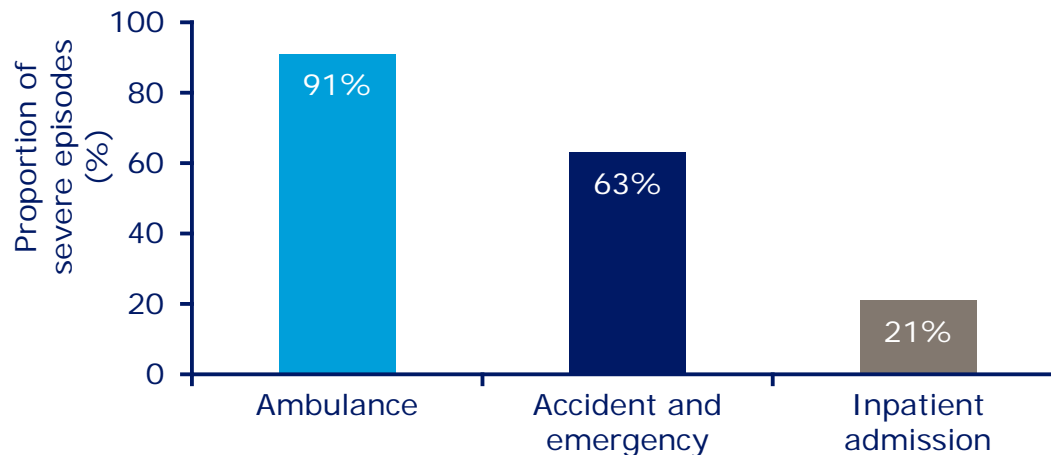
~**USD 7,317** is the total cost of one severe hypoglycemic episode if a patient is admitted to hospital directly[3]

1. Systematic review, Yeh *et al. Acta Diabetol* 2016; 53: 377–92 (hazard ratio 1.68 [95 % CI 1.25–2.26] for mild and 2.33 [95 % CI 2.07–2.61] for severe)
2. Based on 8655 patients with diabetes experiencing 244 episodes requiring help from healthcare professionals (Leese *et al. Diabetes Care* 2003; 26: 1176–80)
3. Curkendall *et al. JCOM* 2011; 18: 455–62

DEVOTE: A CVOT that also Assessed Risk of Severe Hypoglycemia

7637 people with type 2 diabetes

IDeg OD (blinded vial) + standard of care

IGlar OD (blinded vial) + standard of care

- High CV risk profile
- Appropriate for basal insulin initiation or switch
- Current therapy with oral or injectable diabetes therapy

Randomised 1:1

Interim analysis at 150 primary events

Final analysis at 633 primary events

Primary endpoint
The time from randomisation to first occurrence of a 3-component MACE: cardiovascular death, non-fatal heart attack or non-fatal stroke

Key secondary endpoint
Number of severe hypoglycemic episodes*, including nocturnal severe hypoglycemia

*An episode requiring assistance of another person to actively administer carbohydrate, glucagon or take other corrective actions (ADA definition, 2013)
MACE: Major adverse cardiac event; OD: Once daily
Source: Marso SP et al. Am Heart J. 2016 Sep;179:175-83

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DEVOTE Included a High Percentage of Older Patients

DEVOTE baseline characteristics

Parameter	IDeg	IGlar
Age, years*	64.9	65.0
Subjects aged ≥75 years, %	10.0	11.5
Sex, Male, %	62.8	62.4
HbA$_{1c}$, %*	8.4	8.4
FPG, mg/dL* [mmol/L]*	169.8 [9.4]	173.5 [9.6]
Duration of diabetes, years*	16.6	16.2
Insulin treated, %	84.8	84.3
Body weight, kg*	96.1	96.1
BMI, kg/m^2*	33.6	33.6

*Mean value
HbA$_{1c}$ and FPG measured at randomisation. All other parameters measured at the screening visit.
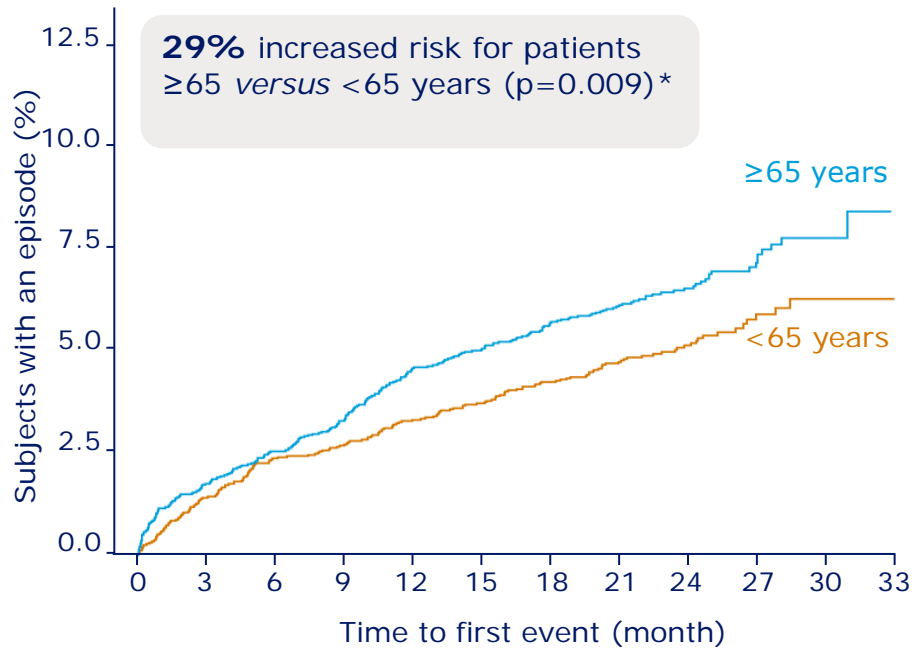BMI: body mass index; FPG: fasting plasma glucose; IDeg: insulin degludec; IGlar: insulin glargine
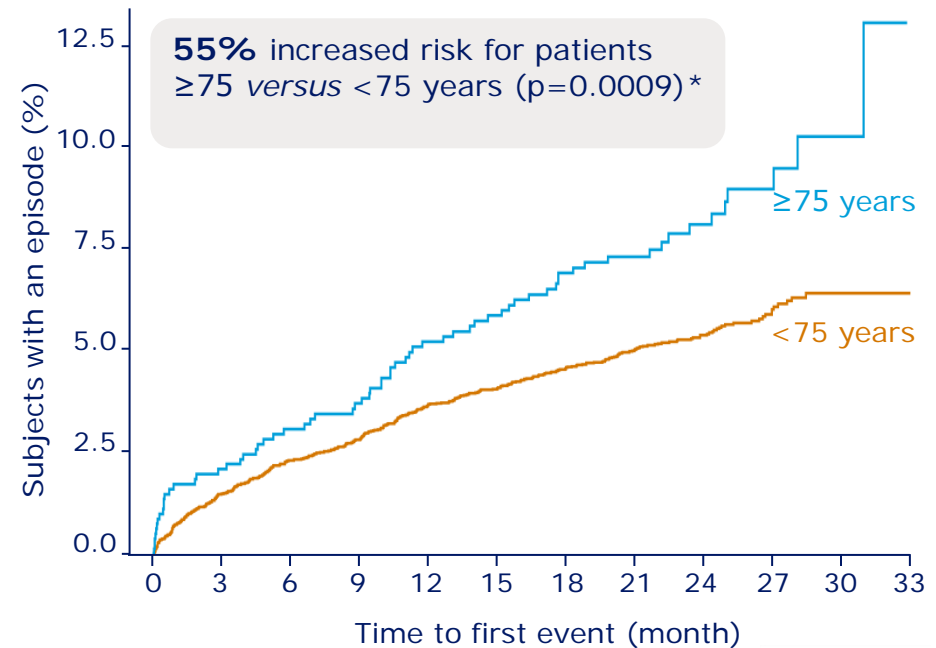Source: Marso SP et al. Am Heart J. 2016 Sep;179:175-83

Risk for Severe Hypoglycemia Increased with Age for people with Insulin Treated T2D

Post-hoc analysis of data from DEVOTE

Time to first severe hypoglycemia episode by age (≥65 and <65 years)

Time to first severe hypoglycemia episode by age (≥75 and <75 years)

29% increased risk for patients ≥65 *versus* <65 years (p=0.009)*

≥65 years

<65 years

Subjects with an episode (%)

Time to first event (month)

55% increased risk for patients ≥75 *versus* <75 years (p=0.0009)*

≥75 years

<75 years

Subjects with an episode (%)

Time to first event (month)

*Hazard ratios for patients ≥65 years, 1.288 [95% CI 1.065; 1.556], and for patients ≥75 years, 1.549 [95% CI 1.196; 2.006], estimated in a Cox proportional hazard model adjusted for treatment and age-group.
Severe hypoglycemia: an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions (ADA definition (2013); CI: confidence interval

Severe Hypoglycemia in LEADER: 31% reduction in the Liraglutide Group
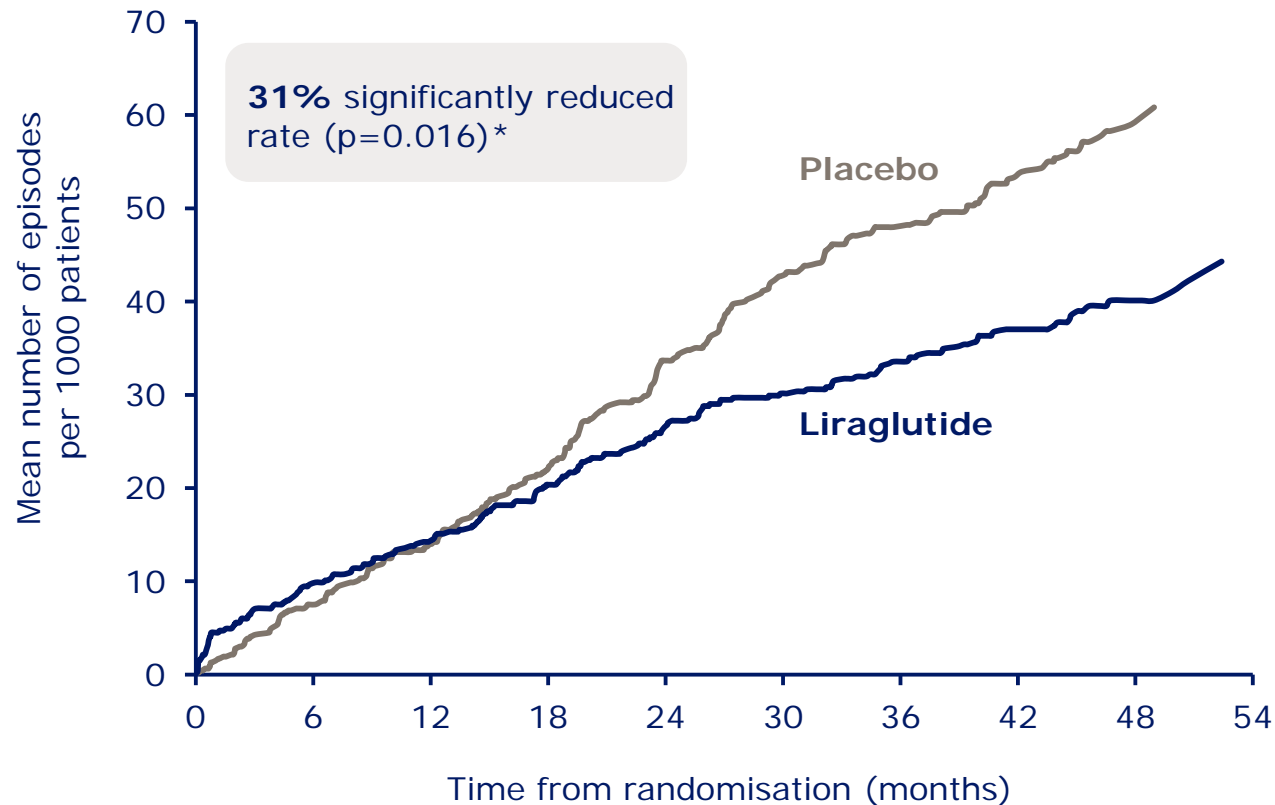
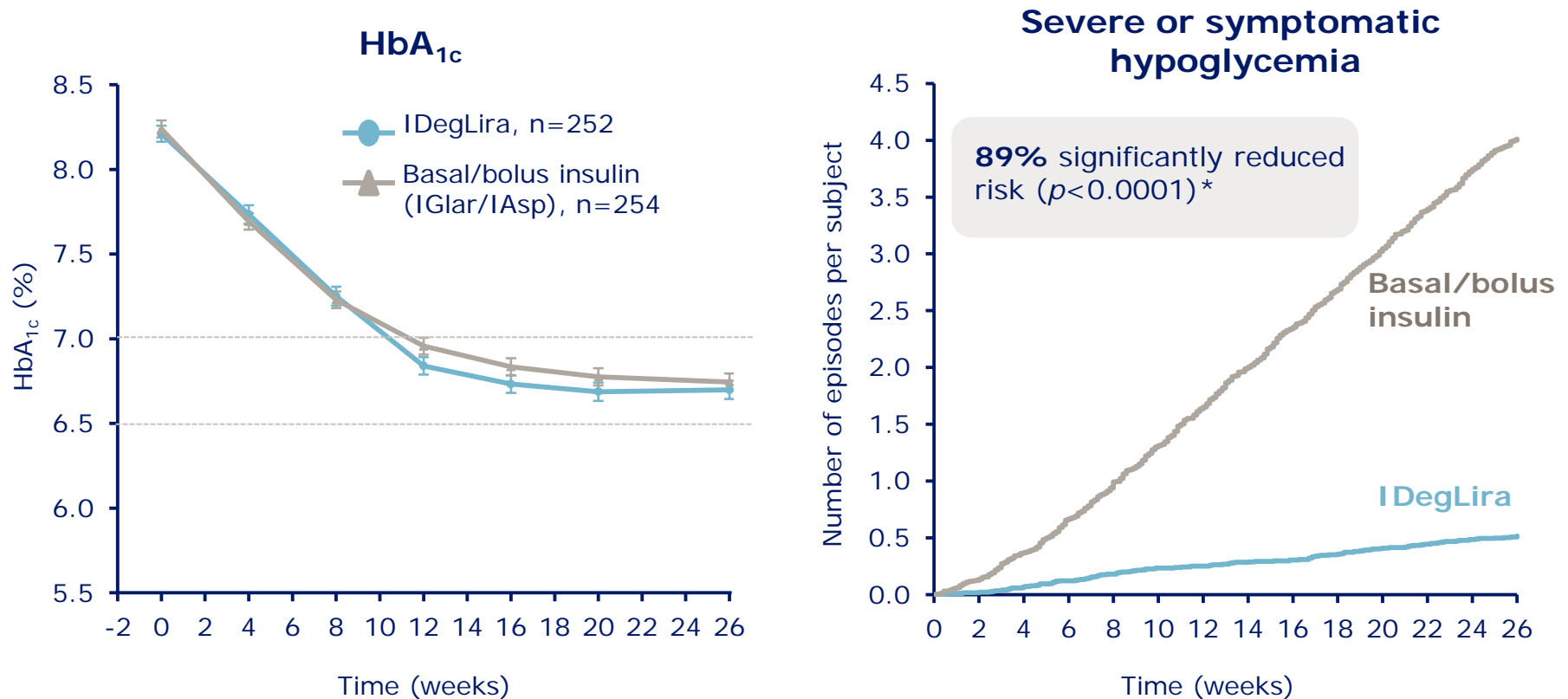**31%** significantly reduced rate (p=0.016)*

Placebo

Liraglutide

Mean number of episodes per 1000 patients

Time from randomisation (months)

*Estimated rate ratio 0.69 [95% confidence interval 0.51–0.93] from analysis using a negative binomial regression model.
Severe hypoglycemia was defined as hypoglycemia for which the patient required assistance from a third party (ADA definition, 2013).
Sources: Marso SP, et al. *N Engl J Med* 2016; 375:311-322 and Novo Nordisk data on file (EX2211-3748).

IDegLira Reduced Risk of Hypoglycemia by 89% Compared to Basal/Bolus Insulin Treatment

Data from DUAL VII

HbA$_{1c}$

IDegLira, n=252

Basal/bolus insulin (IGlar/IAsp), n=254

HbA$_{1c}$ (%)

Time (weeks)

Severe or symptomatic hypoglycemia

89% significantly reduced risk ($p<0.0001$)*

Basal/bolus insulin

IDegLira

Number of episodes per subject

Time (weeks)

Mean observed HbA$_{1c}$ +/- standard error of mean based on full analysis set (left slide). Mean cumulative function of hypoglycemia based on safety analysis set (right side).

*Estimated rate ratio 0.11 [95% confidence interval 0.08–0.17] from analysis using a negative binomial regression model.
Severe or symptomatic hypoglycemia: an episode that is severe according to the ADA classification or blood glucose -confirmed by plasma glucose value <3.1 mmol/L (<56 mg/dL) with symptoms; IAsp: insulin aspart; IDegLira: insulin degludec/liraglutide combination; IGlar: insulin glargine 100 units/mL; n: number of patients
Source: Billings et al. *ADA 2017;136-OR.*

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Conclusions

All individuals with diabetes deserve to be treated to the lowest average glucose level possible without increasing their risk of hypoglycemia

- Individualization of diabetes therapy is essential to achieve medically appropriate goals for each patient

- Goals should be set within the context of the overall health status of an individual and the available medications

- Protection against the risk of hypoglycemia should be a major part of the decision making process by clinician and patient together

New molecules have been and will continue to be developed with the goal to achieve glucose targets with a very low risk of hypoglycemia

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Summary,
Next Steps,
FDA's Role