HOSPITAL MEDICINE SUMMIT

Individualizing Management of T2DM in the Hospital Setting to Reduce Macro and Microvascular Complications

INTEGRITY CONTINUING EDUCATION

PIM Postgraduate Institute for Medicine

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This CEU/CNE activity is co-provided by Postgraduate Institute for Medicine and Integrity Continuing Education.

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Faculty Disclosures

- Consultant: Intarcia Therapeutics, Inc., Janssen Pharmaceuticals, Inc., Merck & Co., Inc., Novo Nordisk, Sanofi
- Speaker: AstraZeneca, Janssen Pharmaceuticals, Inc., Novo Nordisk, Sanofi
- Investigator: AstraZeneca, Janssen Pharmaceuticals, Inc., Lexicon Pharmaceuticals, Inc., Merck & Co., Novo Nordisk, Sanofi

Learning Objectives

- Summarize correlations between macro and microvascular complications of uncontrolled T2DM and hospitalization
- Evaluate the risk/benefit profiles of novel T2DM therapies in achieving glycemic control and reducing vascular complications
- Employ evidence-based strategies to individualize treatment for diverse patients with T2DM to achieve glycemic control and reduce hospitalizations from vascular complications

Diabetes and Its Complications

Introduction

Burden of Diabetes in the US

- Estimated incidence in 2015
  - **30.3 million** with diagnosed diabetes*
  - **7.2 million** undiagnosed
  - **84.1 million** with prediabetes
- Increasing prevalence with rising overweight and obesity rates
- Significant risk for complications, including CHD, stroke, HT, depression, pain, polypharmacy, and functional disability
- Leading cause of new cases of blindness (among adults) and end-stage renal failure

*Approximately 1.25 million children and adults have type 1 diabetes.
CHD, congenital heart disease; HT, hypertension.
Available at: https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf; Available at: http://www.diabetes.org/diabetes-basics/statistics/; Available at https://www.niddk.nih.gov/health-information/communication-programs/ndep/health-professionals/practice-transformation-physicians-health-care-teams/why-transform/current-burden-diabetes-us

Economic Costs of Diabetes in the U.S. in 2017

American Diabetes Association

Diabetes Care 2018;41:917–928 | https://doi.org/10.2337/dci18-0007

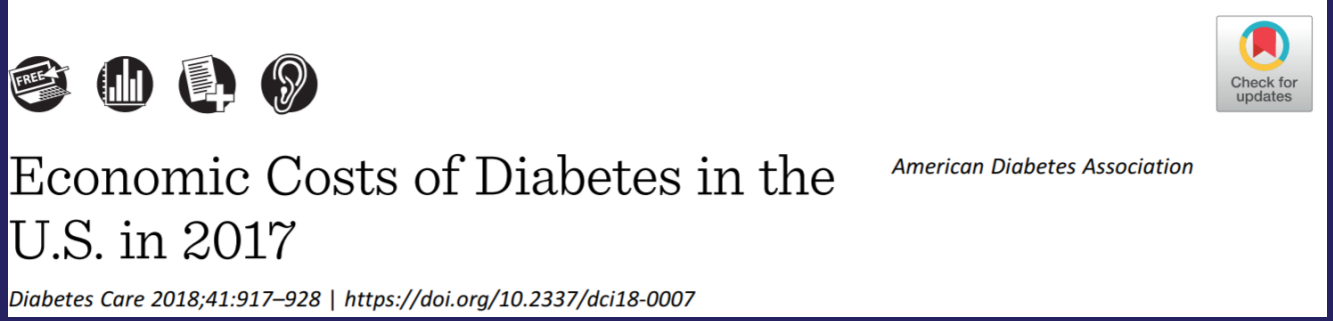
OBJECTIVE

This study updates previous estimates of the economic burden of diagnosed diabetes and quantifies the increased health resource use and lost productivity associated with diabetes in 2017.

RESEARCH DESIGN AND METHODS

We use a prevalence-based approach that combines the demographics of the U.S. population in 2017 with diabetes prevalence, epidemiological data, health care cost, and economic data into a Cost of Diabetes Model. Health resource use and associated medical costs are analyzed by age, sex, race/ethnicity, insurance coverage, medical condition, and health service category. Data sources include national surveys, Medicare standard analytical files, and one of the largest claims databases for the commercially insured population in the U.S.

This report was prepared under the direction of



Economic Costs of Diabetes in the U.S. in 2017

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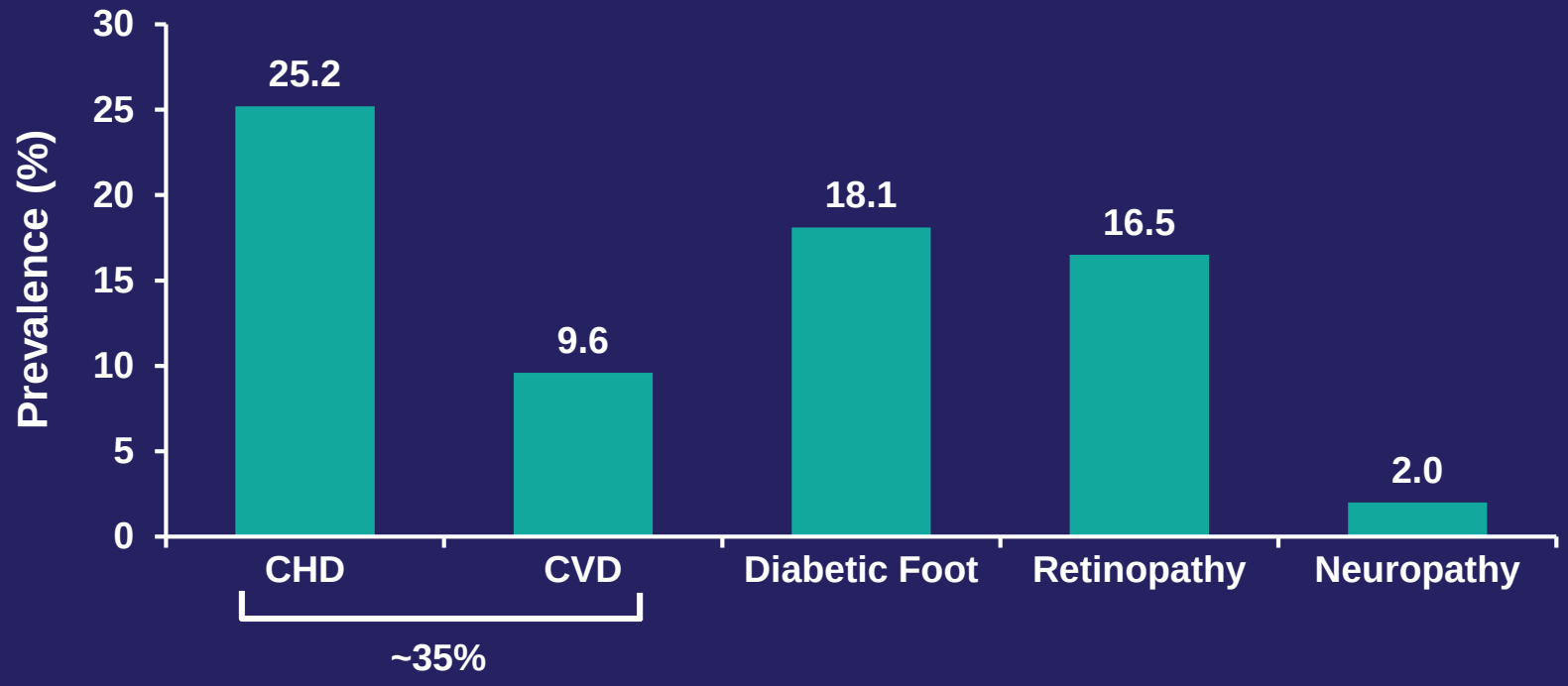
Total estimated cost of diagnosed diabetes in 2017 is $327 billion, including $237 billion direct medical costs and $90 billion in reduced productivity.

Care for people with diagnosed diabetes accounts for 1 in 4 US healthcare dollars; and > half directly attributable to diabetes.

People with diagnosed diabetes incur average medical expenditures of ~$16,750 /year, of which ~$9,600 is attributed to diabetes.

People with diagnosed diabetes, on average, have medical expenditures ~2.3 times higher than those without diabetes.
Indirect costs include increased absenteeism ($3.3 billion) and reduced productivity while at work ($26.9 billion)

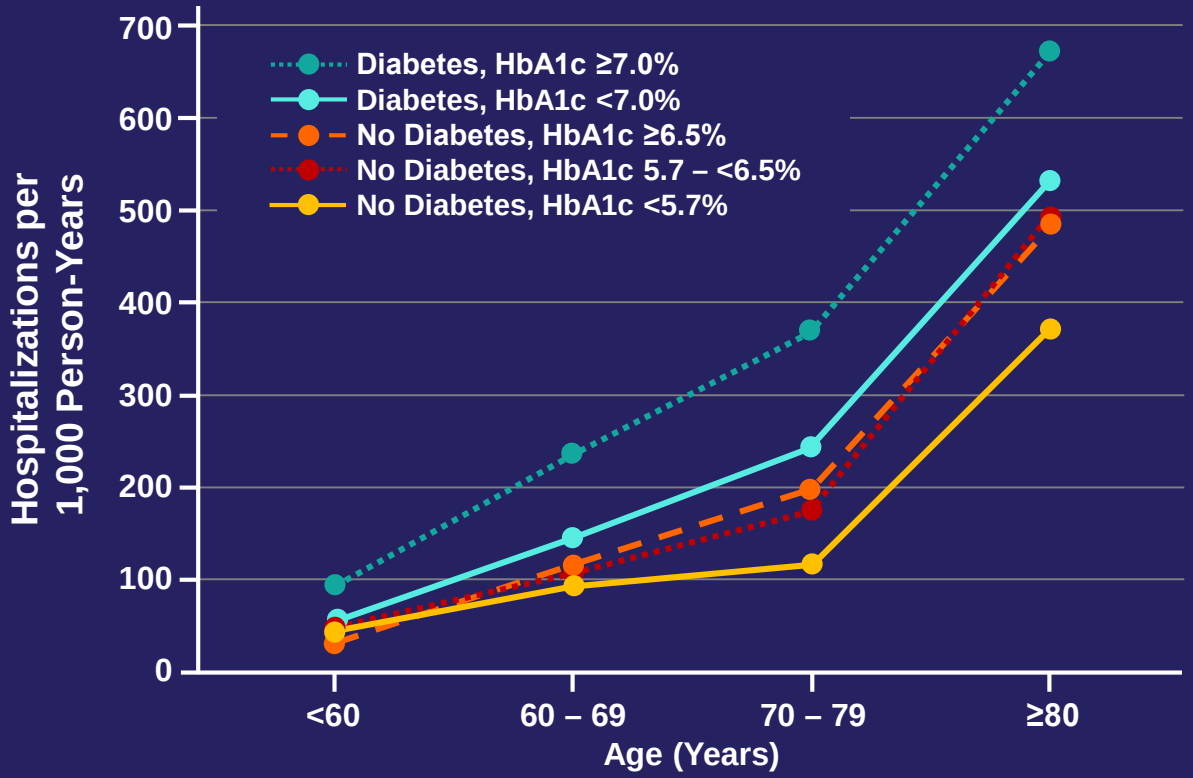
Prevalence of Vascular Complications Among Patients with Diabetes



Morgan CL et al. *Diabetic Med*. 2000;7:7.

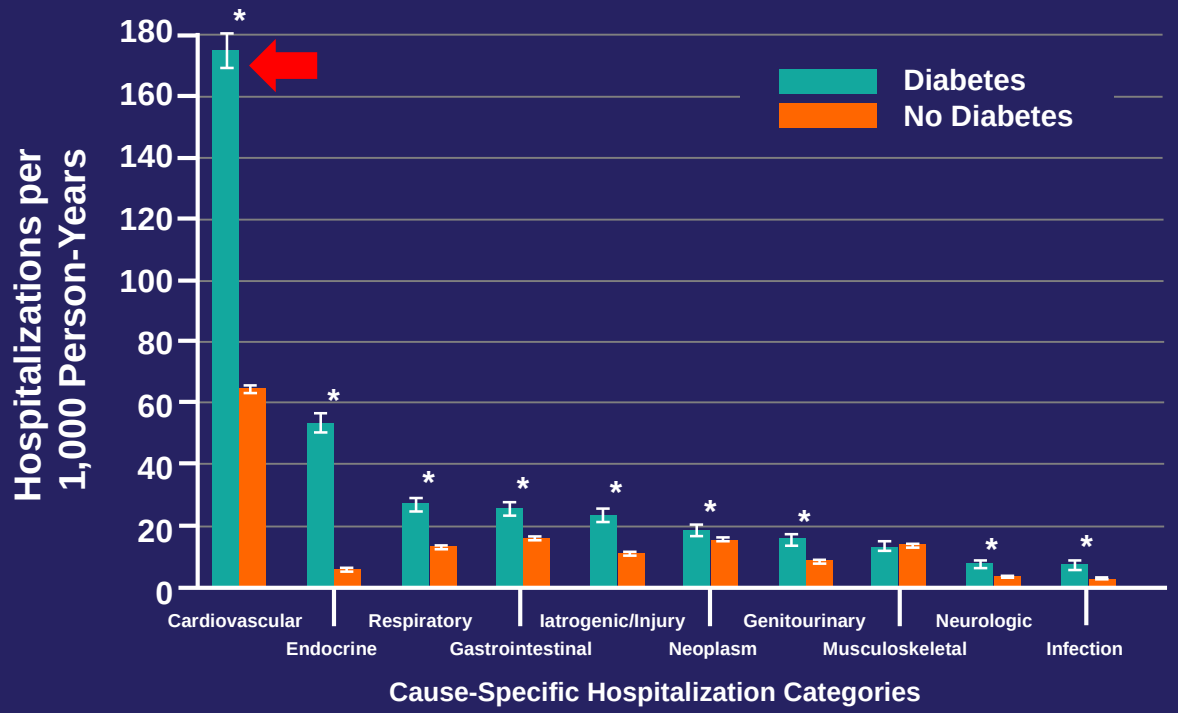
Diabetes in the Hospital Setting

All-cause Hospitalizations Among Patients with Diabetes



Schneider AL et al. *Diabetes Care* 2016;39(5):772-779.

Cause-specific Hospitalizations Among Patients with Diabetes



Schneider AL et al. *Diabetes Care* 2016;39(5):772-779.

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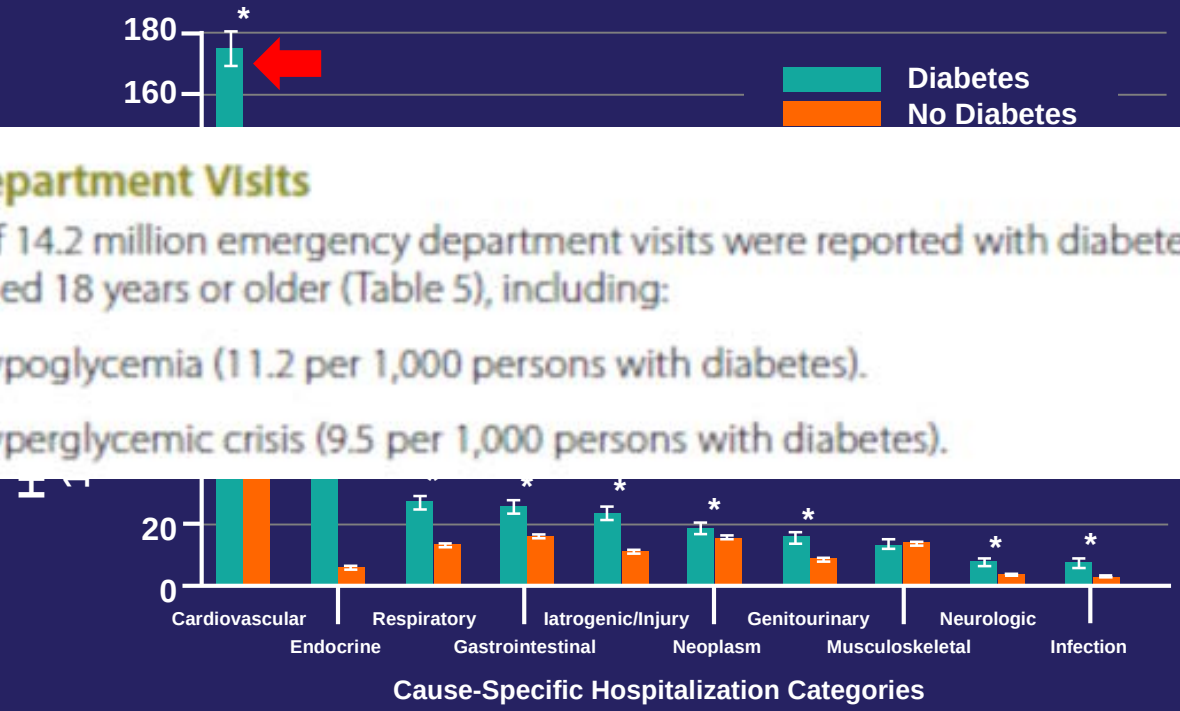


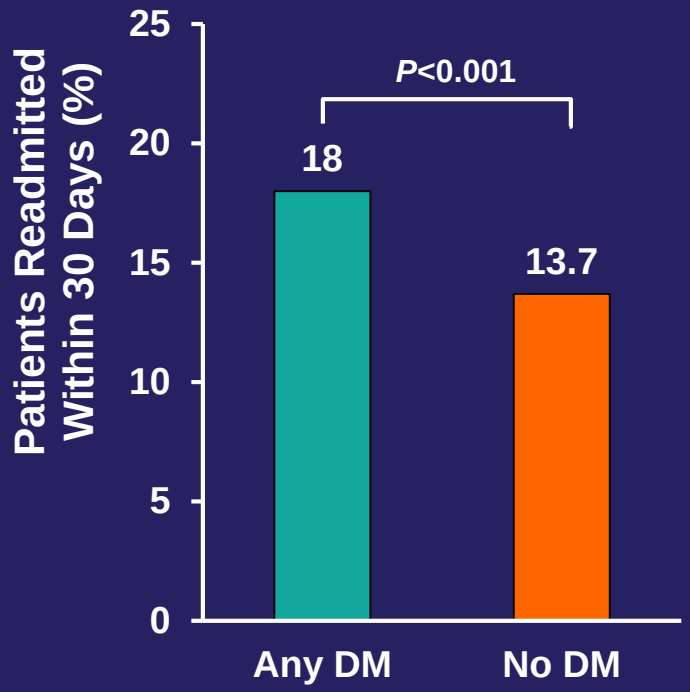
Emergency Department Visits

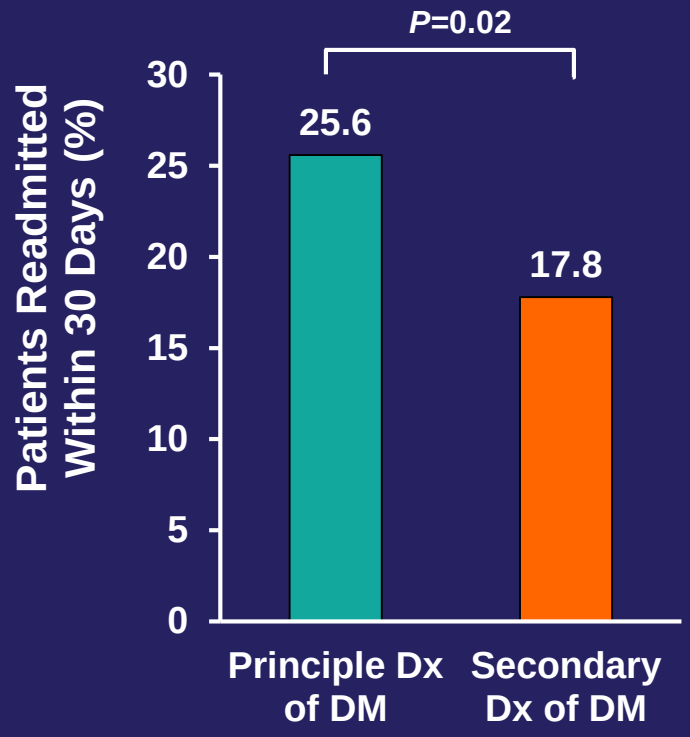
In 2014, a total of 14.2 million emergency department visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older (Table 5), including:

- 245,000 for hypoglycemia (11.2 per 1,000 persons with diabetes).
- 207,000 for hyperglycemic crisis (9.5 per 1,000 persons with diabetes).

Schneider AL et al. *Diabetes Care* 2016;39(5):772-779.

30-day Readmissions Among Patients with Diabetes





Ostling S et al. *Clin Diabetes Endocrinol*. 2017;22;3:3.

Inpatient Management

14. Diabetes Care in the Hospital: *Standards of Medical Care in Diabetes—2018*

American Diabetes Association

Diabetes Care 2018;41(Suppl. 1):S144–S151 | https://doi.org/10.2337/dc18-S014

The American Diabetes Association (ADA) "Standards of Medical Care in Diabetes" includes ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee, are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA's clinical practice recommendations, please refer to the Standards of Care Introduction. Readers who wish to comment on the Standards of Care are invited to do so at professional.diabetes.org/SOC.

In the hospital, both hyperglycemia and hypoglycemia are associated with adverse outcomes, including death (1,2). Therefore, inpatient goals should include the prevention of both hyperglycemia and hypoglycemia. Hospitals should promote the shortest safe hospital stay and provide an effective transition out of the hospital that prevents acute complications and readmission.

For in-depth review of inpatient hospital practice, consult recent reviews that focus on hospital care for diabetes (3,4).

HOSPITAL CARE DELIVERY STANDARDS

Goals of Inpatient Diabetes Management

- Prevent hypoglycemia and hyperglycemia
- Restore glycemic stability
- Initiate long-term antidiabetic treatment/ optimize existing treatment
- Minimize the hospital stay
- Provide effective transitional care to prevent complications and readmission

Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018 American Diabetes Association Diabetes Care 2018;41(Supplement 1)S144-S151.

Factors Complicating Glucose Management in Hospitalized Patients

- Severity of illness
- Medications (eg, glucocorticoids)
- Inconsistent dietary intake
- Patient nutritional status
- Prevailing blood glucose concentration
- History and type of diabetes
- Pre-hospital diabetes treatment regimen

Lilley SH et al. *Am Fam Physician*. 1998;57(5):1079-1088; Hassan E. *Am J Health Syst Pharm*. 2007;64:S9-S14.

Diabetes Care in the Hospital: Standards of Medical Care in Diabetes 2018
American Diabetes Association Diabetes Care Jan 2018, 41 (Supplement 1) S144-S151

- A1C for all patients with diabetes or hyperglycemia*

*If not obtained within last 3 months

Diabetes Care in the Hospital: Standards of Medical Care in Diabetes 2018
American Diabetes Association Diabetes Care Jan 2018, 41 (Supplement 1) S144-S151

- A1C for all patients with diabetes or hyperglycemia*
- Insulin should be administered using validated written or computerized protocols that allow for predefined adjustments in insulin dosage based on glycemic fluctuations.

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Diabetes Care in the Hospital: Standards of Medical Care in Diabetes 2018 American Diabetes Association Diabetes Care Jan 2018, 41 (Supplement 1) S144-S151

- A1C for all patients with diabetes or hyperglycemia*
- Insulin should be administered using validated written or computerized protocols that allow for predefined adjustments in insulin dosage based on glycemic fluctuations.
- Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold >= 180 mg/dL
  - target glucose range of 140–180 mg/dL recommended for majority of critically ill and noncritically ill.
  - More stringent goals, [110– 140 mg/dL] may be appropriate for selected patients, if it can be achieved without significant hypoglycemia. C

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- Basal or basal plus bolus insulin correction for noncritically ill patients with poor oral intake or NPO

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American Diabetes Association Diabetes Care Jan 2018, 41 (Supplement 1) S144-S151

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- Basal or basal plus bolus insulin correction for noncritically ill patients with poor oral intake or NPO
- Insulin with basal, nutritional, and correction components for noncritically ill patients and good nutritional intake

*If not obtained within last 3 months

ADA Recommendations for In-hospital Diabetes Management

- Hypoglycemia
- Level 1 hypoglycemia in hospitalized patients defined as glucose <70 mg/dL but >=54 mg/dL
- Level 2 hypoglycemia (blood glucose concentration <54 mg/dL threshold at which neuroglycopenic symptoms begin to occur and requires immediate action to resolve hypoglycemic event.
- Level 3 hypoglycemia is defined as severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery."

Diabetes Care. 2018;41(Suppl 1):S144–S151.

ADA Recommendations for In-hospital Diabetes Management

- Sole use of sliding scale insulin is strongly discouraged
- Established hypoglycemia management protocol
- An individualized plan for hypoglycemia prevention and treatment
- Medical record of hypoglycemic episodes
- Review of treatment regimen (change as needed to prevent further hypoglycemia)
- A structured, individualized discharge plan

Diabetes Care. 2018;41(Suppl 1):S144–S151.

Management of Diabetes Patients in Non ICU Setting

- Insulin recommended
- Basal Bolus preferred over SSI
- Analog vs. human insulin: Similar A1C control but less hypoglycemia with analogs
- Basal Bolus preferred over premixed insulin
- ? If differences among basal insulin analogs

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Noninsulin Therapies in Hospital

- Safety and efficacy of noninsulin antihyperglycemic therapies in hospital setting area of active research.
- A few RCTs in general medicine and surgery pts reported that dipeptidyl peptidase 4 inhibitor alone or in combination with basal insulin was well tolerated and resulted in similar glucose control and frequency of hypoglycemia compared with a basal-bolus in pts with baseline BG <200 mg/dL
- Pasquel, F. J., et al. (2017). "Efficacy of sitagliptin for the hospital management of general medicine and surgery patients with type 2 diabetes The Lancet Diabetes & Endocrinology 5(2): 125-133.
- 1254-P / 1254 2017 ADA Scientific Sessions - Efficacy and Safety of Linagliptin in General Surgical Patients with Type 2 Diabetes: Linagliptin

Noninsulin Therapies in Hospital

- FDA bulletin - should consider discontinuing saxagliptin and alogliptin in people who develop heart failure
- RCTs using GLP-1 receptor agonists are underway
- SGLT2 inhibitors in hospital - Until safety and effectiveness are established, SGLT2 inhibitors cannot be recommended for routine in-hospital use [ADA]

Pharmacologic Treatment of Hyperglycemia

Approach to AHA Selection for Patients with T2DM

- **Metformin** remains recommended first-line therapy
  - Use may be limited by development of GI intolerability, presence of diabetic nephropathy and/or GFR decline
- **Dual or triple therapy** is typically required to achieve glycemic goals as disease progression occurs
  - One should combine agents with complementary MOAs
  - Newer classes that positively impact body weight, BP, and albuminuria may benefit patients with specific comorbidities or complications

GFR, glomerular filtration rate; MOAs, mechanism of actions; BP, blood pressure.
Schernthaner-Reiter MH et al. *Exp Rev Endocrinol Met.* 2016;11(3):281-296.

Non-insulin Antihyperglycemic Agents (AHA)

Medication	Average A1C Reduction	Potential Adverse Effects and Impact on Weight
Alpha-glucosidase inhibitors	0.5% – 0.8%	Flatulence, diarrhea, abdominal bloating
Biguanides (metformin)	1.0% – 1.3%	Nausea, diarrhea, abdominal bloating; extended-release preparations have fewer GI adverse effects; B12 def
DPP4 inhibitors	0.5% – 0.9%	Headache, pancreatitis (rare); arthralgia
GLP-1 receptor agonists	0.8% – 2.0%	Nausea, vomiting, diarrhea; weight loss of 2.2 - 8.8 lbs likely; pancreatitis (rare);
Meglitinides	0.5% – 1.0%	Hypoglycemia; weight gain with repaglinide
SGLT2 inhibitors	0.5% – 0.9%	Increased GMI & less freq UTI incr LDL; weight loss 1.5 - 7.7 lbs; hypotension possible, hypovolemia can lead to decreased renal function; DKA [rare in absence of intercurrent illness]
Sulfonylureas	0.4% – 1.2%	Hypoglycemia, weight gain
Thiazolidinediones	0.5% – 1.4%	Weight gain, edema, fractures

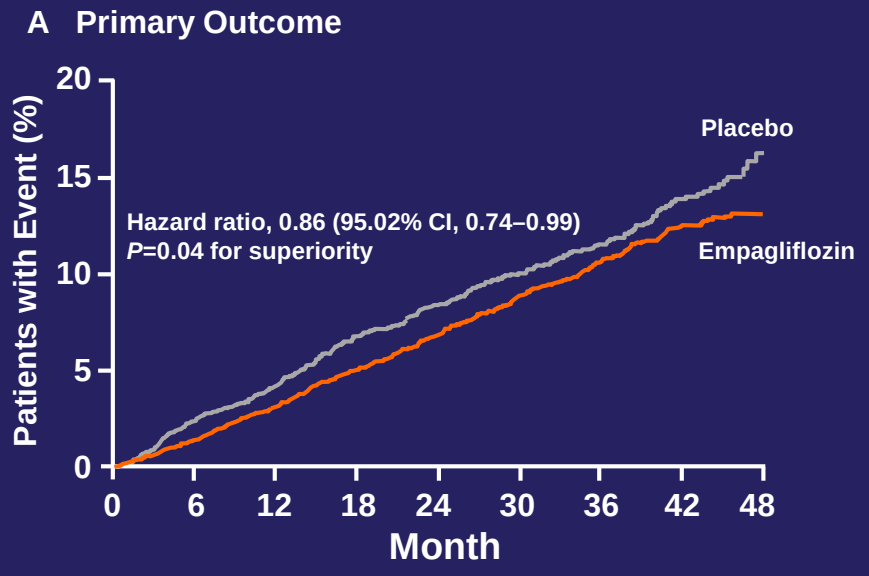
DPP4, dipeptidyl peptidase-4; GLP-1, glucagon-like peptide-1; SGLT2, sodium-glucose co-transporter 2.

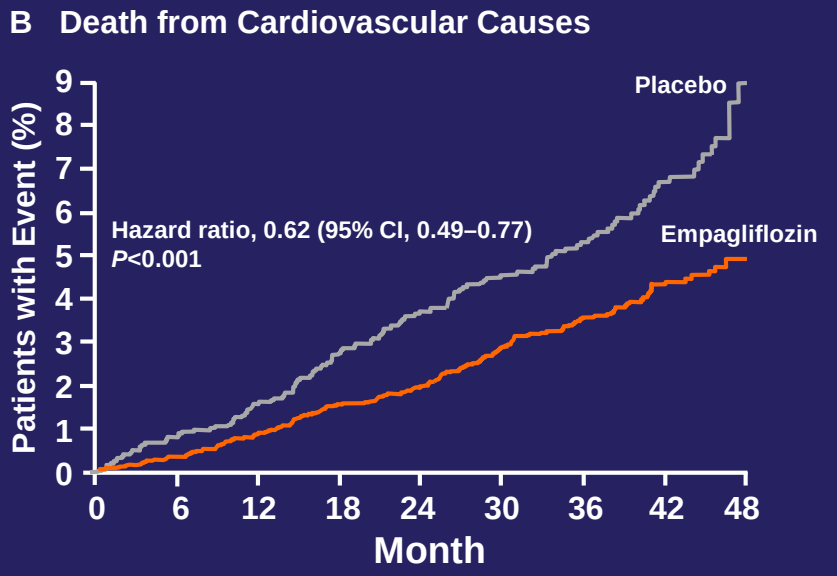
George CM et al. *Am Fam Physician*. 2015;92(1):27-34.

Targeting Vascular Outcomes in T2DM

Addition of EMPA to Standard Care Improves CV Outcomes and Mortality

EMPA-REG Study





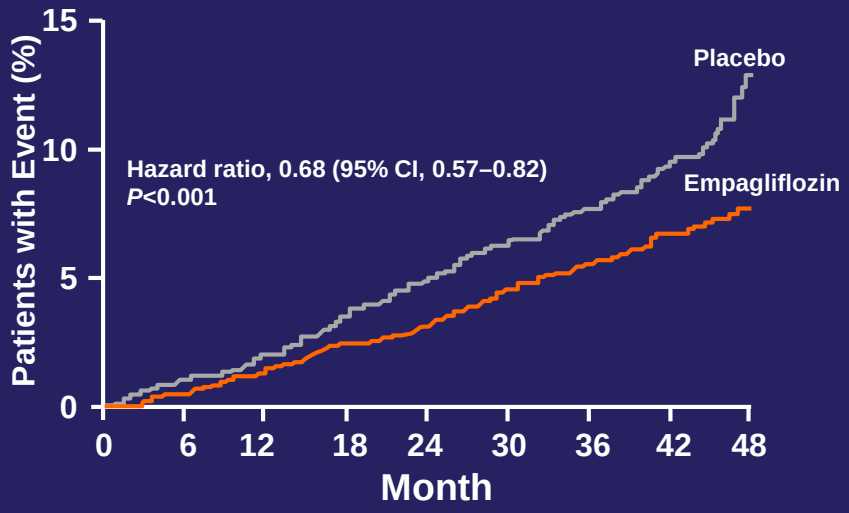
EMPA, empagliflozin.

Zinman et al. *N Engl J Med.* 2015;373:2117-28.

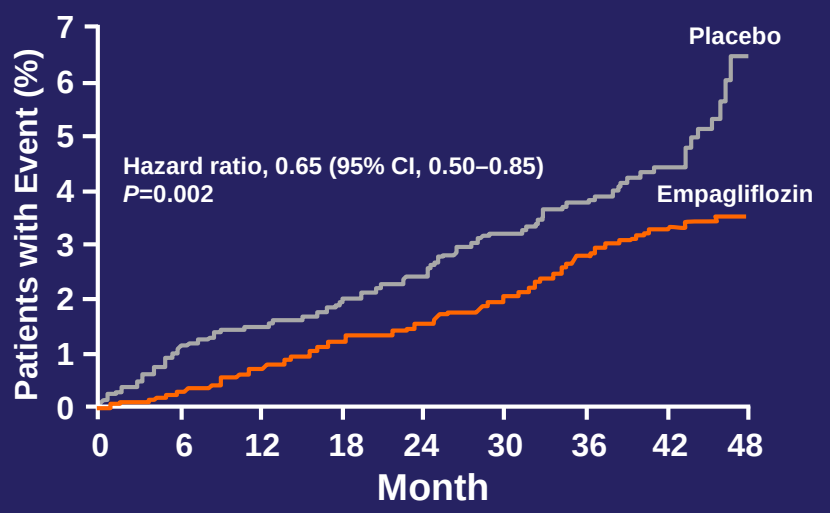
Addition of EMPA to Standard Care Improves CV Outcomes and Mortality

EMPA-REG Study

C Death from Any Cause



D Hospitalization for Heart Failure

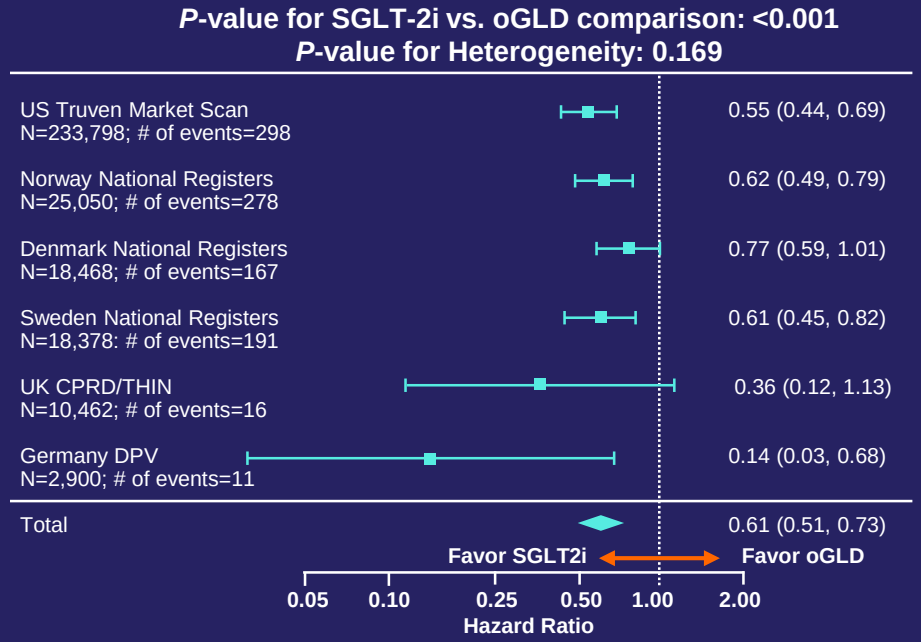


EMPA, empagliflozin.

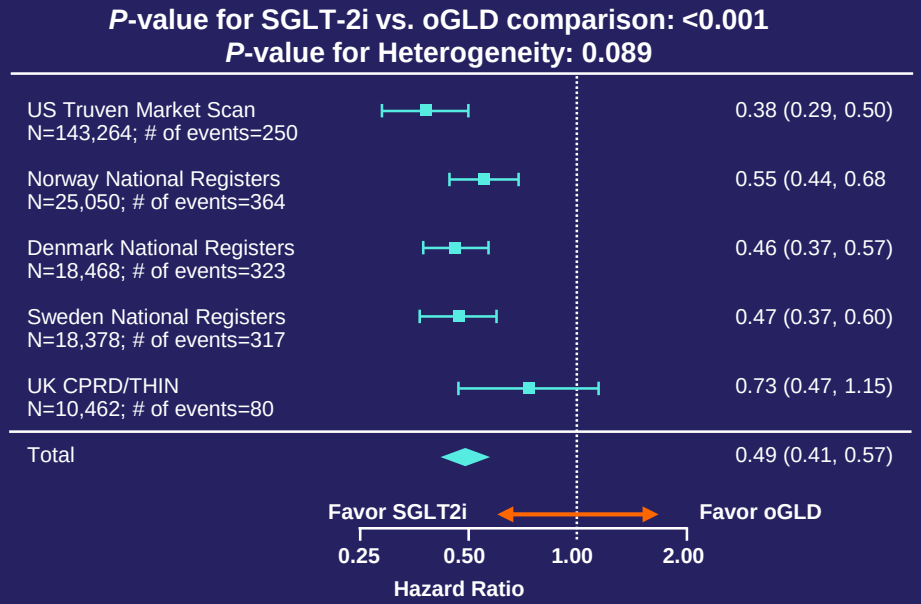
Zinman et al. *N Engl J Med.* 2015;373:2117-28.

SGLT2 Inhibition Lowers the Risk of HF and Death

CVD-REAL Study



Hospitalization for HF



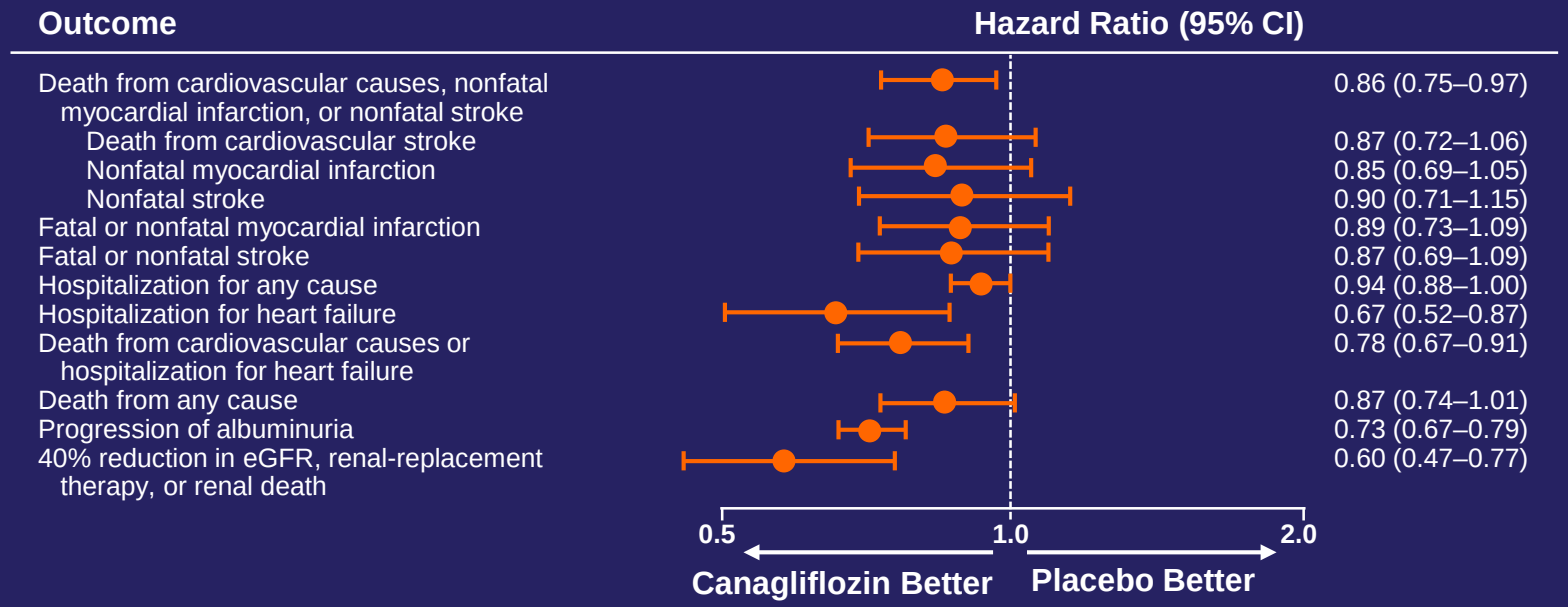
All-cause death

CVD, cardiovascular disease.

Kosiborod M et al. *Circulation*. 2017;136(3):249-259.

Treatment with CANA Improves CV, Renal, and Mortality Outcomes

CANVAS Program



CANA, canagliflozin.

Neal B et al. *N Engl J Med.* 2017;377:644-57.

Impact of Incretin-based Therapies on CV Risk Factors

Risk factor	GLP1RA	DPP-4I
A1c	• Reduced	• Reduced
Body weight	• Reduced	• Potential minor reduction (<1 kg)
BP	• SBP lower (2-3 mmHg) in patients with HT • DBP less consistently affected	• No uniform lowering effect
HR	• 2–3 bpm rise	• No major effects reported
Lipids	• Lower triglycerides • Increased HDL cholesterol • Small reduction in LDL cholesterol	• No major effects on fasting lipoprotein patterns

LDL, low-density lipoprotein; HDL, high-density lipoprotein; SBP, spontaneous bacterial peritonitis; DBP, diastolic blood pressure; bmp, beats per minute.

Nauck M. *Circulation*. 2017;136:849–870.

DPP-4 Inhibitors and CV Risk

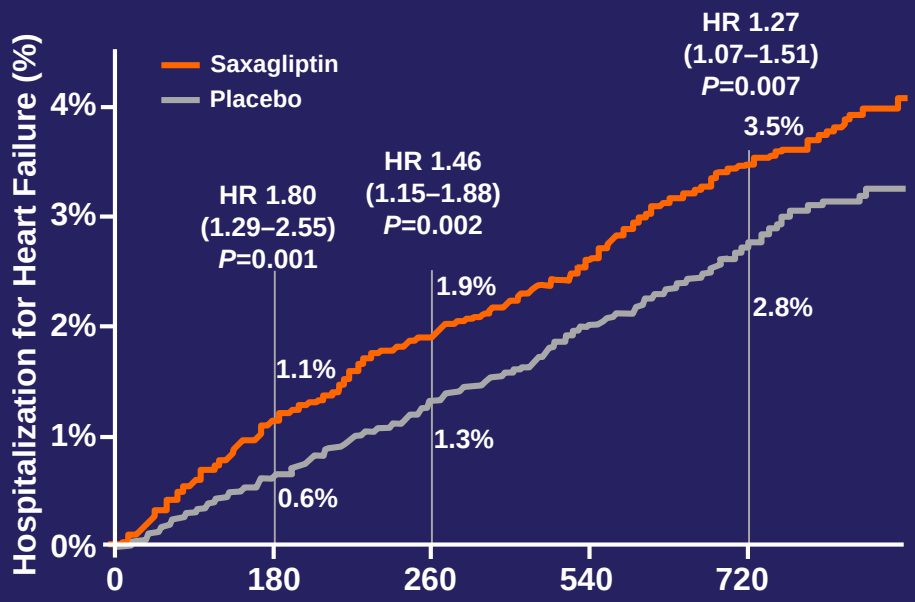
Clinical Trial Findings	AHA Investigated
Neutral for CV risk factors	• Saxagliptin • Alogliptin • Sitagliptin
Increased risk for HF-related hospitalization	• Saxagliptin (significant) • Alogliptin (nonsignificant trend)

In the absence of clear benefits regarding overall CV risk, further mechanistic clarification and caution is recommended for individuals at risk for CHF

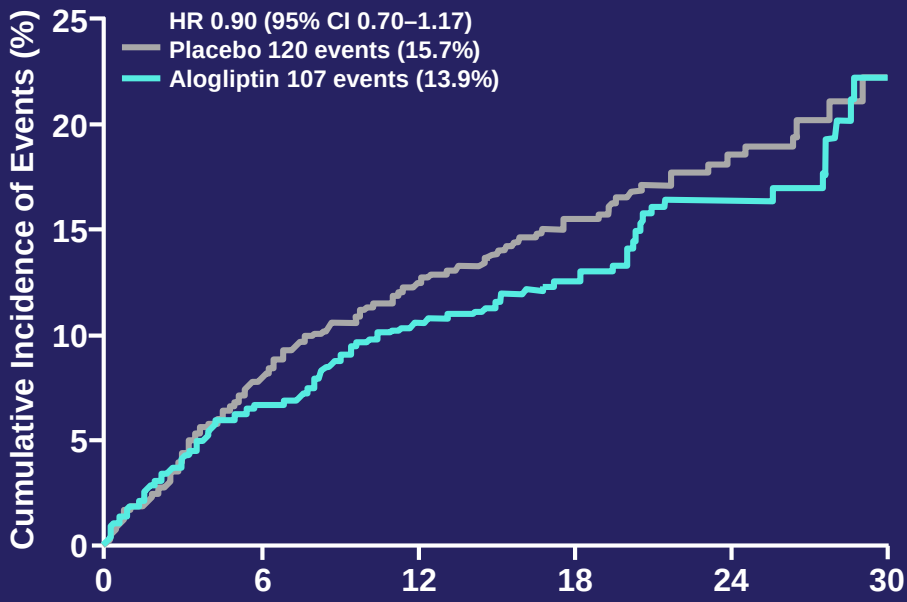
Nauck MA et al. *Circulation*. 2017;136:849-870.

DPP-4 Inhibitors and HF Outcomes

EXAMINE



SAVOR-TIMI 53

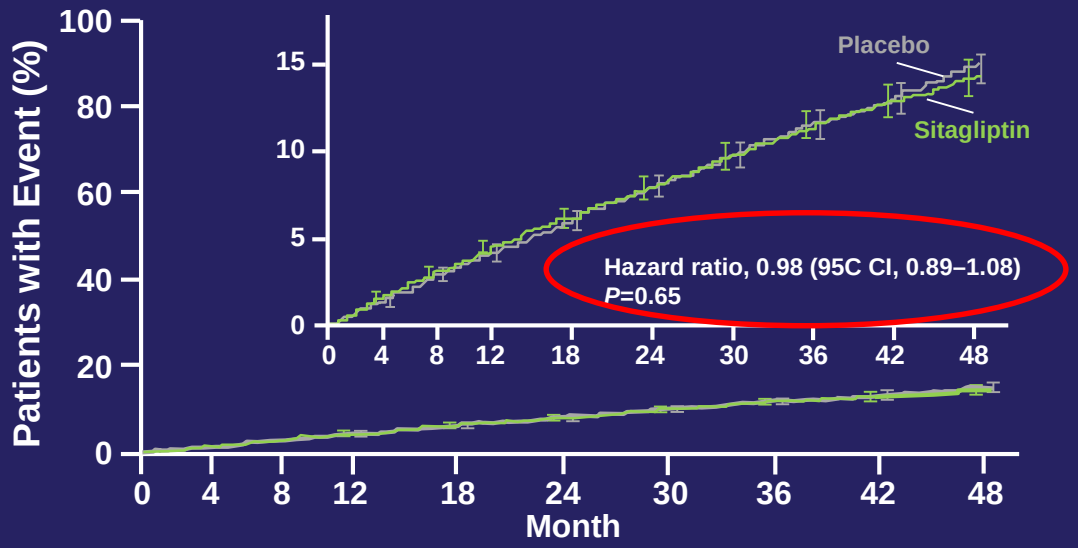


Scirica BM et al. *Circulation*. 2014;130(18):1579-88; Zannad et al. *Lancet*. 2015;385(9982):2067-76.

Impact of Sitagliptin Therapy on CV Outcomes

TECOS Study

Primary Cardiovascular Outcome



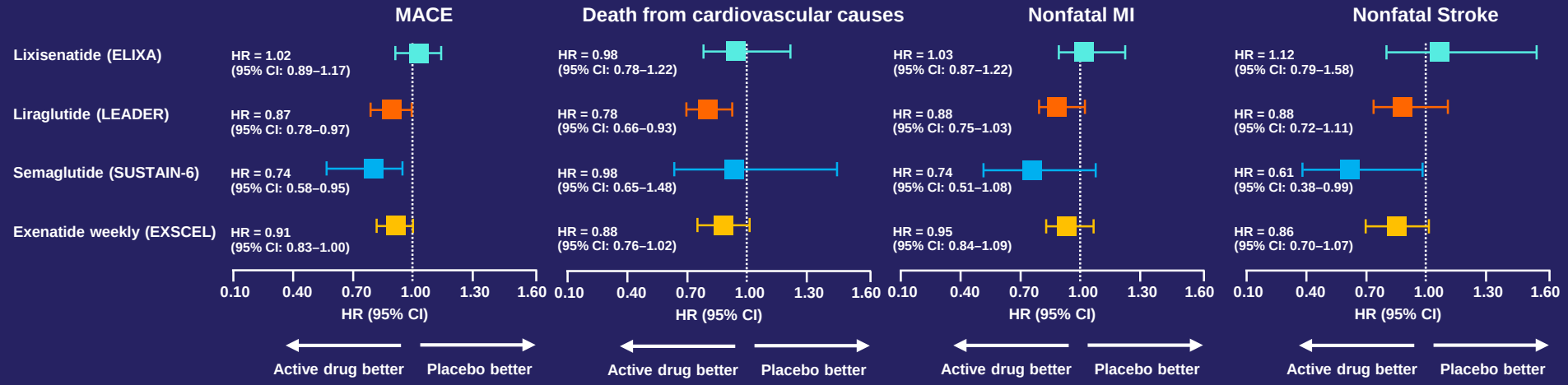
Sitagliptin added on to usual care was **NOT** associated with increased risk for:

- MACE
- HF-related hospitalization
- Other AEs

MACE, major adverse cardiac events; AEs, adverse events.

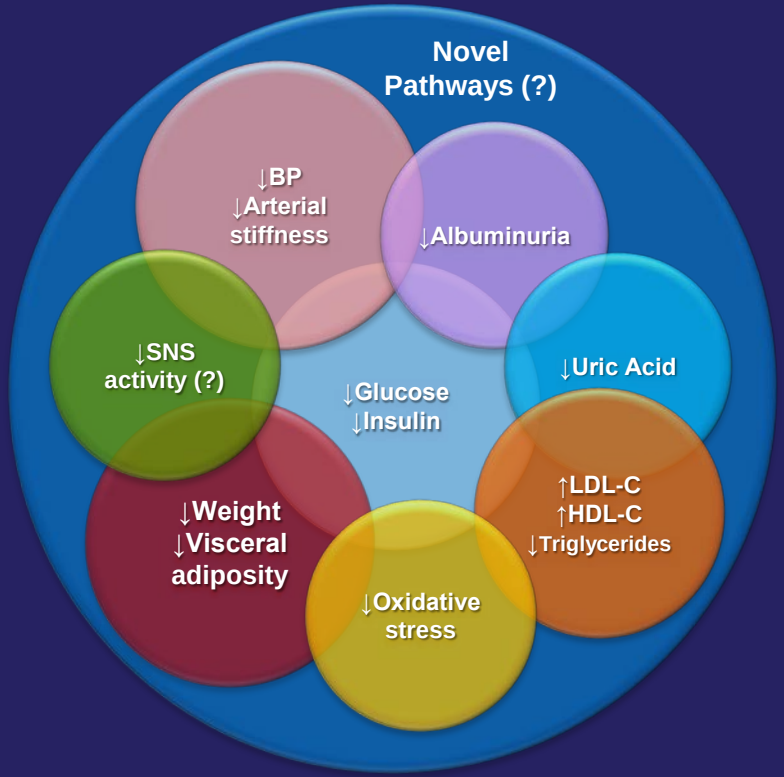
Green JB et al. *N Engl J Med.* 2015;373:232-42.

Overview of the Impact of GLP-1R Agonists on CV Outcomes



Lim S et al. *Trends Endocrinol Metab.* 2018 [Epub ahead of print]

Potential Pathways Associated with CV Effects of SGLT-2 Inhibitors



Inzucchi et al. *Diabetes Vasc Dis Res.* 2015;12(2):90-100.

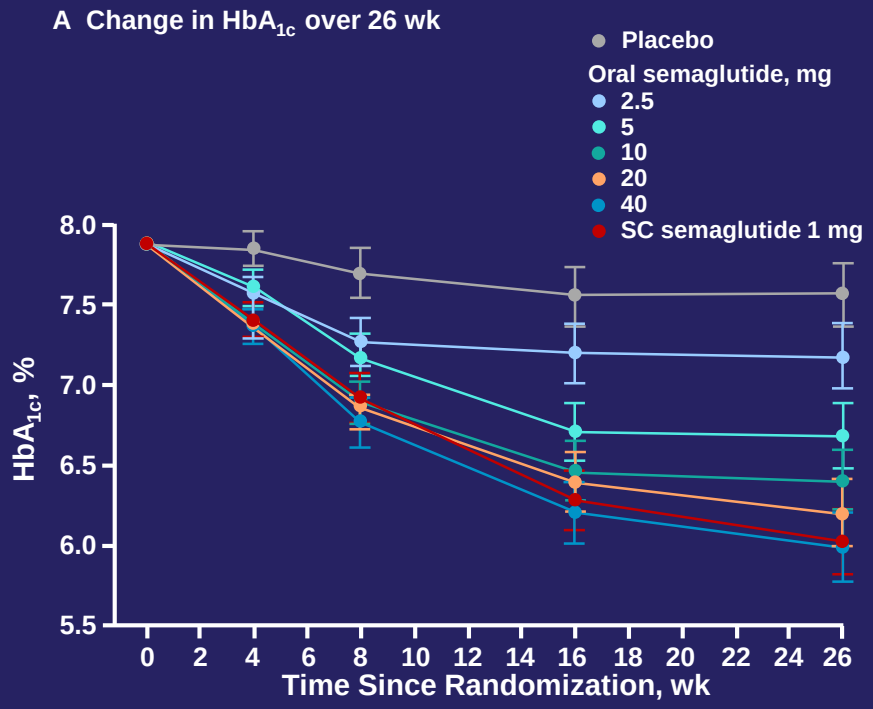
Possible Mechanisms for CVD Benefit

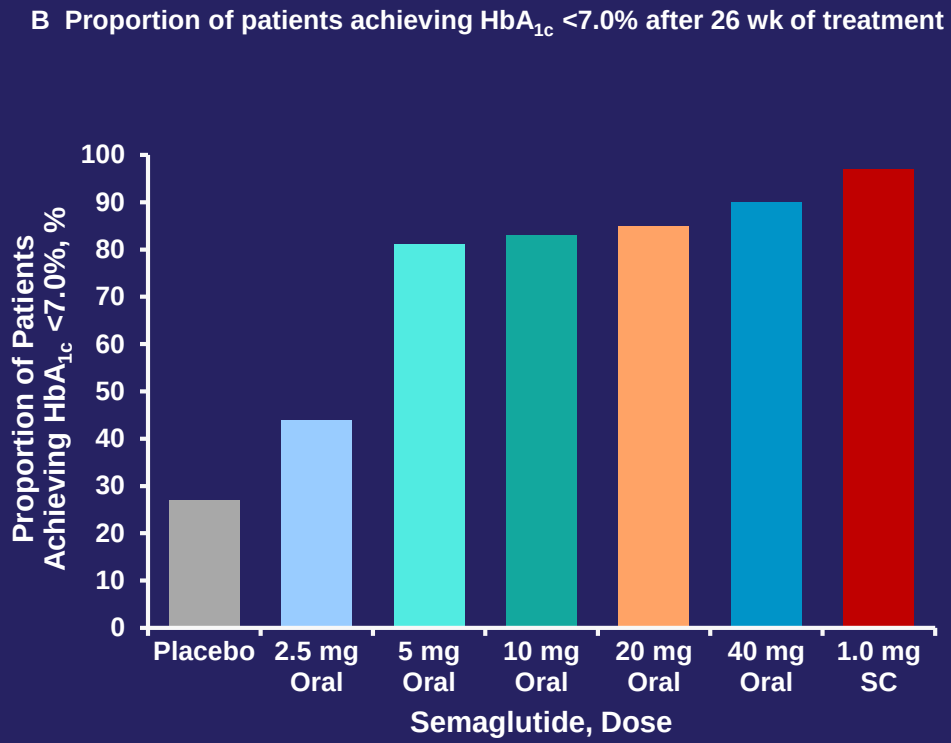
- Not due to glucose lowering alone
- Placebo arm subjects received more sulfonylurea and insulin therapy and had more hypoglycemia
- GLP-1 receptor agonists CV benefit possibly Atherothrombotic Effect
  - Decreased glucose, weight, BP, and lipids may all play role
- Mechanism for SGLT2 inhibitor
  - Unlikely due to SBP effect alone
  - Unlikely due to weight reduction alone
  - Diuresis (but more potent diuretics do not improve CV mortality to this extent)
  - Hemodynamic or neurohormonal mechanisms
  - Decr BP, Volume, arterial resistance
  - ? Metabolic – Fuel Energetics
  - Vascular stiffness and oxidative stress
- Other

Recently Approved Incretin-based Therapies and SGLT2 Inhibitors

Therapy		Approval Date
Single agent	Ertugliflozin	December 2017
	Semaglutide	December 2017
Fixed-dose combination	Ertugliflozin and sitagliptin	December 2017
	Dapagliflozin and saxagliptin	February 2017
	Empagliflozin and linagliptin	January 2015

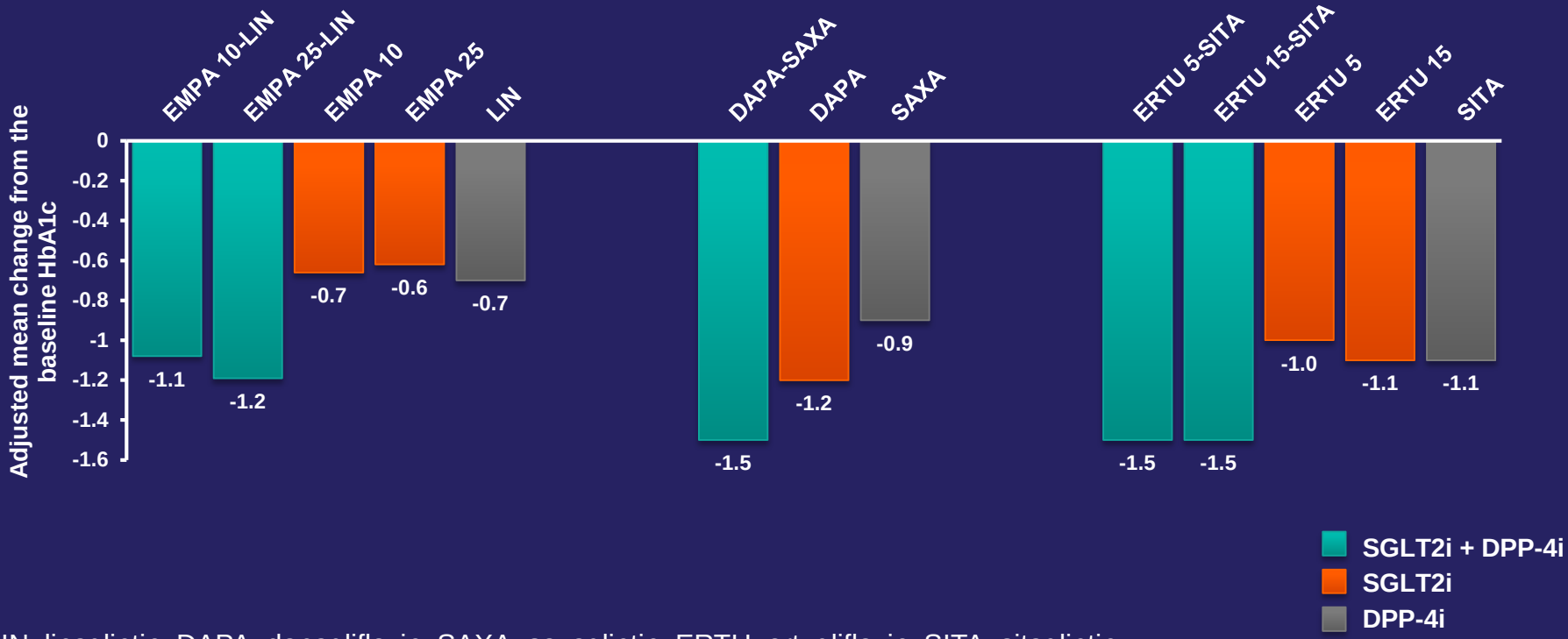
Efficacy of Oral Semaglutide in Patients with T2DM





Davies M et al. *JAMA*. 2017;318(15):1460-1470.

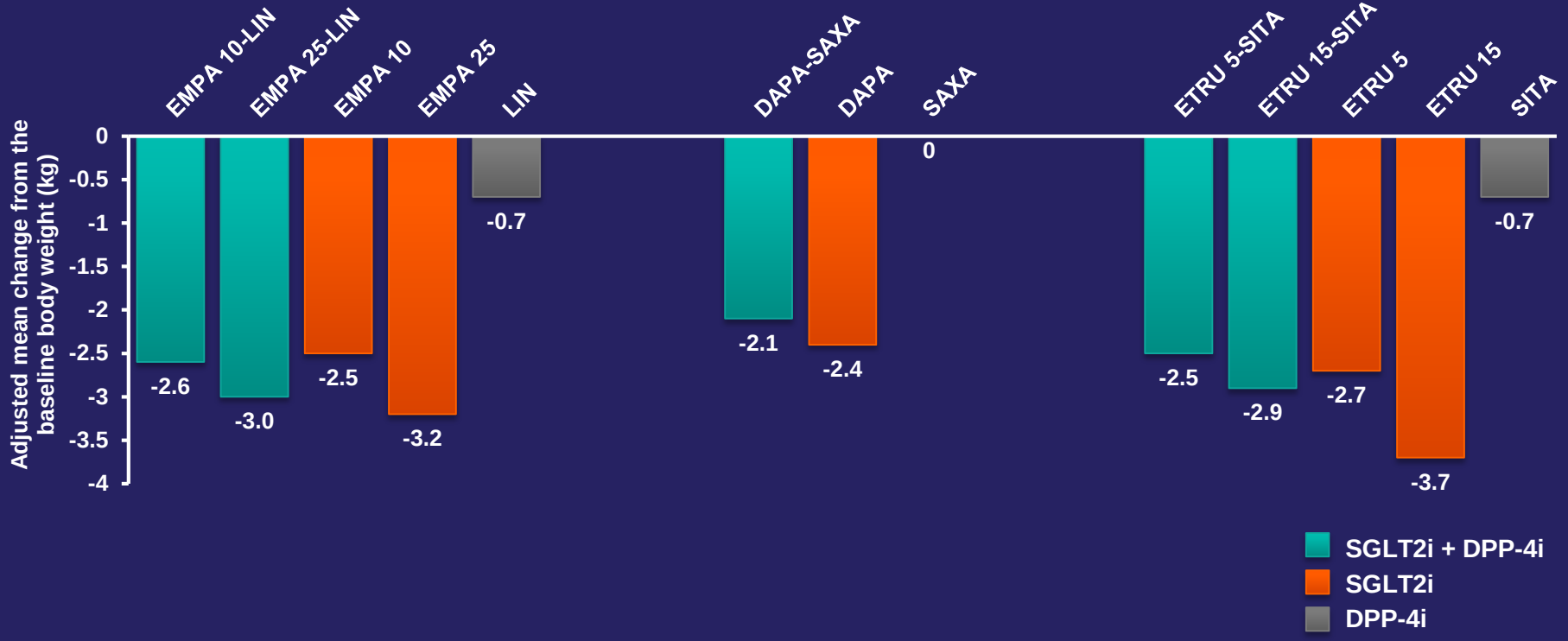
Changes from Baseline A1C with Combined SGLT2 and DPP-4 Inhibition



LIN, linagliptin; DAPA, dapagliflozin; SAXA, saxagliptin; ERTU, ertugliflozin; SITA, sitagliptin.

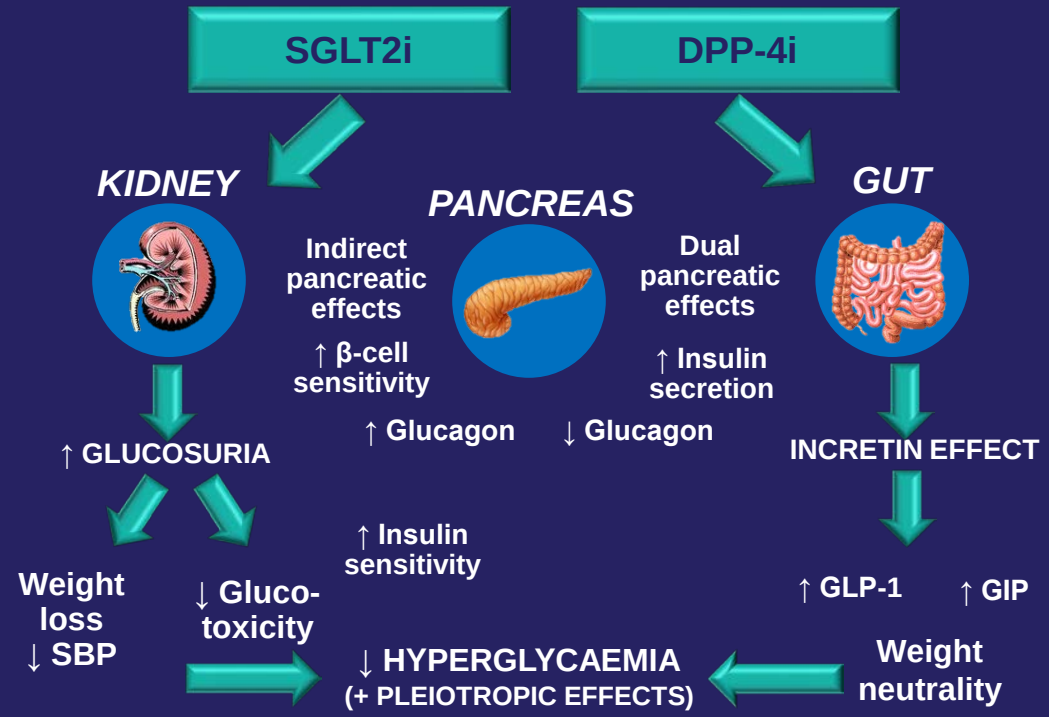
DeFronzo RA et al. *Diabetes Care.* 2015;38:384-393; Rosenstock et al. *Diabetes Care.* 2015;38:376-383; *Diabetes Obes Metab*. 2018;1-10.

Changes from Baseline Weight with Combined SGLT2 and DPP-4 Inhibition



DeFronzo RA et al. *Diabetes Care.* 2015;38:384-393; Rosenstock et al. *Diabetes Care.* 2015;38:376-383; *Diabetes Obes Metab*. 2018;1-10.

Complementary Glucose-lowering Actions of DPP-4 Inhibitors and SGLT2 Inhibitors



Scheen AJ et al. *Exp Op Drug Met Toxicol.* 2016;12;1407-1417.

Potential Advantages of Fixed-dose SGLT2 and DPP-4 Inhibitor Combination Therapies

- Simplify treatment
- Reduce tablet burden
- Increase medication adherence
- May be particularly beneficial for patients for whom reduction of body weight, BP, and CV risk are important

Transitional Care

Discharge Planning

- There should be structured, individualized discharge plan
- Ensure stable blood glucose levels
- Measure A1C before discharge (if not measured during the previous months)
- Simplify treatment regimen for hyperglycemia (if possible)
- Schedule follow-up care within several weeks; If glycemic medications changed or glucose control not optimal, earlier appointment (in 1–2 weeks),
- Communicate with outpatient providers regarding follow-up care

Diabetes Care. 2018;41(Suppl 1):S144–S151.

Agency for Healthcare Research and Quality (AHRQ) recommends that, at a minimum, discharge plans include the following

- Medication Reconciliation
  - The patient's medications must be cross-checked to ensure that no chronic medications were stopped and to ensure safety of new prescriptions.
  - Prescriptions for new or changed medication should be filled and reviewed with patient and family at or before discharge.
- Structured Discharge Communication
  - Information on medication changes, pending tests and studies, and followup needs must be accurately and promptly communicated to outpatient physicians.
  - Discharge summaries should be trans mitted to primary clinician as soon as possible after discharge.
  - Appointment-keeping behavior is enhanced when the inpatient team schedules outpatient medical follow-up prior to discharge.

Diabetes Care. 2018;41(Suppl 1):S144–S151.

Agency for Healthcare Research and Quality (AHRQ) recommends that, at a minimum, discharge plans include the following

- Recommended that following areas of knowledge be reviewed prior to discharge:
  - Identification of HCP who will provide diabetes care after discharge.
  - Level of understanding related to diabetes diagnosis, self-monitoring of blood glucose, explanation of home BG goals, and when to call HCP.
  - Definition, recognition, treatment, and prevention of hyperglycemia and hypoglycemia.
  - Information on consistent nutrition habits.
  - If relevant, when and how to take blood glucose–lowering medications, including insulin administration; Sick-day management; Proper use and disposal of needles and syringes.

Diabetes Care. 2018;41(Suppl 1):S144–S151.

Patient Education, Instruction, and Referral

- **Educate patients/caregivers**
  - Self-monitoring of blood glucose and follow-up to address post-discharge changes (diet, exercise, and physiological stress)
  - Diabetes and self-care
  - Blood glucose targets
  - Signs and symptoms that require HCP consultation
- **Provide specific instruction**
  - Proper medication use
  - Self-monitoring of blood glucose
  - Hypoglycemia and hyperglycemia prevention
- **Refer to a diabetes educator**

Diabetes Care. 2018;41(Suppl 1):S144–S151.

Case Evaluations

Case Evaluation: Patient Description

A 50-year-old woman is admitted to the intensive care unit with significant chest pain, dizziness, nausea, and vomiting. Based upon an electrocardiogram and cardiac enzyme test results, she is diagnosed as having a myocardial infarction.

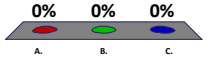
Case Evaluation: Discussion Question

At what point do you recommend testing the patient's blood glucose levels?

A. On admission

B. Once the patient has been stabilized

C. Throughout hospitalization every 24 to 48 hours



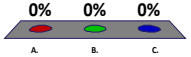
Case Evaluation: Discussion Question

The patient's glucose level is 205 mg/dl. Which of the following would you recommend?

A. Treat her hyperglycemia only if she has a history of diabetes

B. Manage the MI first, then treat her hyperglycemia

C. Treat her hyperglycemia aggressively along with the MI



Case Evaluation: Patient Description

A 68-year-old man is admitted to the hospital following an acute ischemic stroke. He is obese and has a 10-year history of CVD and T2DM. His current diabetic regimen consists of dual combination therapy with a DPP-4 inhibitor and metformin. At the time of admission, his blood glucose level is 270 mg/dl.

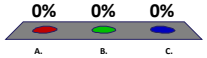
Case Evaluation: Discussion Question

Which of the following would you recommend to address the patient's hyperglycemia during his hospital stay?

A. Sliding-scale insulin therapy after discontinuation of the outpatient diabetes regimen

B. Subcutaneous insulin treatment with a basal-bolus regimen

C. Continuous intravenous insulin infusion



Summary

- T2DM is a chronic, progressive disease closely associated with a range of macro and microvascular complications, which frequently lead to hospitalization.
- Hospital-based clinicians play a crucial role in ensuring optimal glycemic management during the hospital stay as well as providing guidance on antihyperglycemic therapy following discharge.
- Optimal glycemic management requires treatment that takes into account a wide range of patient characteristics, including a high risk for vascular complications and the presence of comorbidities.
- Many antihyperglycemic therapies with good efficacy and safety profiles have been developed, including incretin-based therapies and SGLT2 inhibitors, which have shown beneficial effects on both cv risk factors and vascular outcomes.

Clinical Pearls

- Patients with diabetes are at increased risk of vascular complications and hospitalizations for CV related events compared to patients without diabetes
- Diabetes and hypertension are among the 9 modifiable risk factors that account for >90% of the risk of initial acute MI
- For most hospitalized patients with diabetes, target a glucose level of 140-180 mg/dl
- Newer treatments for diabetes, including SGLT2 and GLP-1 indicators, have been shown to reduce micro and macrovascular events
- More intensive glucose control has been associated with a 20% reduction in kidney disease
- Prior to discharge of a patient with diabetes, ADA guidelines recommend measurement of hbA1c level

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Questions and Answers

Thank You!