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American Diabetes Association (ADA) Standards of Care 2023 Guideline Updates



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Center

Goals

Pharmacists

- Discuss revisions of the 2023
 American Diabetes Association
 (ADA) Guidelines
- 2. Evaluate data supporting the 2023 revisions
- 3. Review general approach to glucose management
- 4. Identify new hyperglycemia agents and/or indications on the horizon

Technicians

- 1. Discuss revisions of the 2023 American Diabetes Association (ADA) Guidelines
- 2. Review general approach to glucose management
- 3. Identify brand/generic names and side effects/precautions of hyperglycemic medications

Disclosures

This speaker does not have any actual or potential conflicts of interest to disclose

ADA Standards of Care

- Annual update since 1989
- Publish online in December
 - Diabetes Care Journal
 - https://diabetesjournals.org/care/issue/46/ Supplement_1
- Free access
 - full version
 - abridged version
 - app

ADA Standards of Care

 Updates include language changes to therapeutic recommendations based on most current literature available – presentation focus on changes that effect pharmacy practice

Index

- 1. Improving Care and Promoting Health in Populations
- 2. Classification and Diagnosis of Diabetes
- 3. Prevention and Delay of Type 2 Diabetes and Associated Comorbidities
- 4. Comprehensive Medical Evaluation and Assessment of Comorbidities
- 5. Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes
- 6. Glycemic Targets
- 7. Diabetes Technology
- 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

- 9. Pharmacologic Approaches to Glycemic Treatments
- 10. Cardiovascular Disease and Risk Management
- 11. Chronic Kidney Disease and Risk Management
- 12. Retinopathy, Neuropathy, and Foot Care
- 13. Older Adults
- 14. Children and Adolescents
- 15. Management of Diabetes in Pregnancy
- 16. Diabetes Care in the Hospital
- 17. Diabetes Advocacy

Structure

- Recommendations
 - control "F"
 - #.# recommendation
 - supportive evidence supporting recommendation

Screening and Diagnosis

Recommendations

10.1 Blood pressure should be measured at every routine clinical visit. When possible, individuals found to have elevated blood pressure (systolic blood pressure 120–129 mmHg and diastolic <80 mmHg) should have blood pressure confirmed using multiple readings, including measurements on a separate day, to diagnose hypertension. A Hypertension is defined as a systolic blood pressure ≥130 mmHg or a diastolic blood pressure ≥80 mmHg based on an average of ≥2 measurements obtained on ≥2 occasions. A Individuals with blood pressure ≥180/110 mmHg and cardiovascular disease could be diagnosed with hypertension at a single visit. E

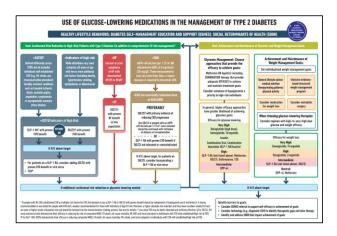
 $\textbf{10.2} \ \textbf{All people with hypertension and diabetes should monitor their blood pressure at home.} \ \textbf{A}$

Blood pressure should be measured at every routine clinical visit by a trained individual and should follow the guidelines established for the general population: measurement in the seated position, with feet on the floor and arm supported at heart level, after 5 min of rest. Cuff size should be appropriate for the upper-arm circumference. Elevated values should preferably be confirmed on a separate day; however, in individuals with cardiovascular disease and blood pressure ≥180/110 mmHg, it is reasonable to diagnose hypertension at a single visit (21). Postural changes in blood pressure and pulse may be evidence of autonomic neuropathy and therefore require adjustment of blood pressure targets. Orthostatic blood pressure measurements should be checked on initial visit and as indicated.

Home blood pressure self-monitoring and 24-h ambulatory blood pressure monitoring may provide evidence of white coat hypertension, masked hypertension, or other discrepancies between office and "true" blood pressure (23.24). In addition to confirming or refuting a diagnosis of hypertension, home blood pressure assessment may be useful to monitor antihypertensive treatment. Studies of individuals without diabetes found that home measurements may better correlate with ASCVD risk than office measurements (23.24). Moreover, home blood pressure monitoring may improve patient medication taking and thus help reduce cardiovascular risk (25).

Structure

Tables and figures



Section 2: Classification and Diagnosis of Diabetes – POC A1c Testing

- Monitoring, but not diagnosis
- Strict criteria for use
 - must follow NGSP and DCCT methods
 - NGSP certified and FDA approved
 - CLIA-regulated or waived setting review package insert
 - training and competency evaluation minimum of proficiency testing three times a year

POC: point of care; NGSP: National Glycohemoglobin Standardization Program; DCCT: Diabetes Control and Complication Trial; FDA: US Food and Drug Administration; CLIA: Clinical Laboratory Improvement Amendments

Section 3: Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

- 3.9 Added: Statins and increased risk of progression to T2DM
 - monitor glucose regularly and implement preventative strategies
 - moderate risk of progression: pooled data HR 1.26 (1.17-1.58)
 - cardiovascular and mortality benefit >>>> risk of diabetes
 - Do NOT stop statin

T2DM: Type 2 diabetes mellitus

Section 3: Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

- 3.10 Added: Address use of pioglitazone in patients with history of stroke with insulin resistance or prediabetes
 - IRIS study (Insulin Resistance Intervention after Stroke)
 - reduction in risk of CVA and MI but increase in weight gain, edema, and fracture
 - patient-specific balance of risk versus benefit decision

CVA: cerebrovascular accident; MI: myocardial infarction

Section 3: Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

- 3.12 Added: Support use of pharmacotherapy for patient-centered goals to reduce progression to diabetes
 - Section 8: Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes
 - Section 9: Pharmacologic Approaches to Glycemic Treatment
 - Section 10: Cardiovascular Disease and Risk Management

Section 3: Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

 3.13 Added: Support use of intensive preventative approaches for individuals at high risk of progression to diabetes

Section 4: Comprehensive Medical Evaluation and Assessment of Comorbidities

Vaccines

- updated COVID vaccine recommendations for current recommendation
 - as of February 9, 2023, COVID-19 included in routinely recommended vaccine schedule
 - o adults: same as new CDC guidelines (bivalent booster)
 - children: updates since publication refer to recent CDC guidelines

Section 4: Comprehensive Medical Evaluation and Assessment of Comorbidities

Vaccines

- Hepatitis B
 - updated since publication ALL adults less than 60 years old (not just DM)
- Pneumococcal pneumonia
 - same as new CDC guidelines (PCV13, PCV15, PCV20, PPSV23)



- Tablet 4.1 Updated: Components of the comprehensive medical evaluation at initial, follow-up, and annual visits
 - Past medical history
 - Family history
 - Behavioral factors
 - Medication and vaccines
 - Technology use
 - Social life
 - Physical exam
 - Laboratory evaluation

Section 4: Comprehensive Medical Evaluation and Assessment of Comorbidities

 Patients with diabetes have higher risk of NASH with significant fibrosis and risk of NASH progression and mortality but there are limited treatments for cirrhosis

Section 4: Comprehensive Medical Evaluation and Assessment of Comorbidities

- Subsection for NASH updated
 - weight loss: lifestyle, GLP1RA, bariatric surgery
 - pharmacotherapy: TZD and GLP1RA
 - o treat steatohepatitis
 - o slow fibrosis progression
 - o decrease cardiovascular disease

TZD: thiazolidinedione; GLP1RA: glucagon-life peptide-1 receptor agonist

Section 4: Comprehensive Medical Evaluation and Assessment of Comorbidities

- TZD
 - increasing glucose and lipid metabolism
- GLP1RA
 - weight loss
 - decrease liver function tests

TZD: thiazolidinedione; GLP1RA: glucagon-life peptide-1 receptor agonist

Section 5: Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes

 Lots of updates, but most more directed at other members of a healthcare team

Section 5: Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes

- Micronutrients and supplements
 - no clear evidence of benefit from herbals and supplements without underlying deficiencies
 - check B12 with metformin or neuropathy
 - no need for routine antioxidants (E and C)
 - added: against beta carotene due to increased lung cancer and cardiovascular mortality risk (ATBC study)

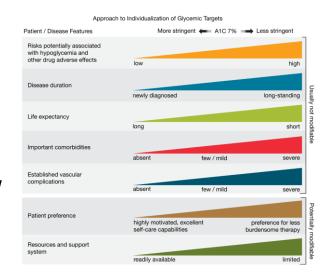
The Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) Study

Section 5: Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes

- Micronutrients and supplements
 - no clear evidence of benefit from herbals and supplements without underlying deficiencies
 - insufficient evidence for cinnamon, curcumin, vitamin D, aloe vera, chromium

Section 6: Glycemic Targets

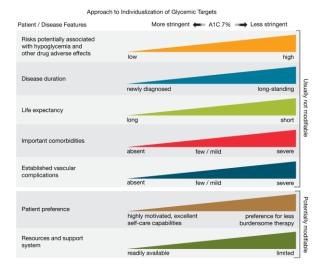
 6.5b Added: Fragility or high risk of hypoglycemia target
 CGM: over 50% time in range, less than 1% below range



CGM: continuous glucose monitor

Section 6: Glycemic Targets

 6.5b Added: Fragility or high risk of hypoglycemia target others (no change): over 70% time in range, less than 4% below range, less than 1% below 54 mg/dL



Section 8: Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

- Language amended to reinforce obesity as a chronic disease
- Focus on
 - nutrition
 - physical activity
 - behavioral counseling
- pharmacotherapy
- medical devices
- metabolic surgery

Section 8: Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

- 8.5 Added: Even small weight loss (3-7%) should be treatment goal, but larger weight loss (10% or more) has better diabetes and cardiovascular benefits
 - November 2022 Meta-Analysis
 - o no change in CV or all cause mortality
 - o limitations to studies

CV: cardiovascular

Section 8: Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

- 8.5 Added: Even small weight loss (3-7%) should be treatment goal, but larger weight loss (10% or more) has better diabetes and cardiovascular benefits
 - Look AHEAD trial
 - o intensive lifestyle sustainable
 - >10% weight reduction or worse baseline A1c subgroups saw reduction in CVE

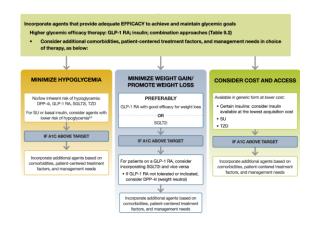
AHEAD: Action for Health in Diabetes; CVE: cardiovascular event

Section 8: Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

 GLP1RA and tirzepatide added as glucose lowering options with potential for weight loss

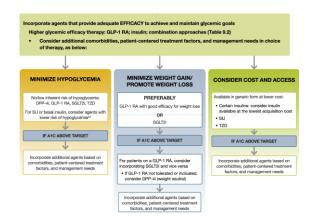
Section 9: Pharmacologic Approaches to Glycemic Treatment

 Aligns with recent consensus statement with European Association for the Study of Diabetes (EASD) September 2022



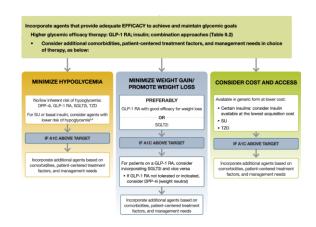
Section 9: Pharmacologic Approaches to Glycemic Treatment

 Change to right side of chart emphasizing efficacy: glucose/weight loss



Section 9: Pharmacologic Approaches to Glycemic Treatment

- Tirzepatide (GIP/GLP1RA)
 - SURPASS trials 1-5 (6 pending (basal/bolus insulin))



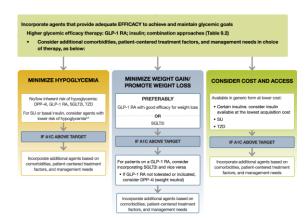
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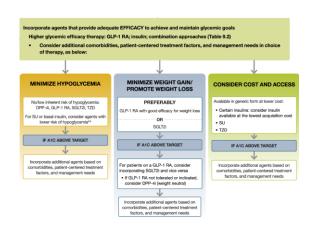
- Tirzepatide (GIP/GLP1RA)
 - 5, 10, 15 mg SQ weekly
 - A1c reduction of 2%+

SQ: subcutaneously

Section 9: Pharmacologic Approaches to Glycemic Treatment

- Emphasized combination therapy earlier based on baseline A1c from goal
 - ≥1.5% from goal, glucose≥300 mg/dL, or A1c ≥10%





Section 9: Pharmacologic Approaches to Glycemic Treatment

- Emphasized combination therapy earlier based on baseline A1c from goal
 - VERIFY study (biguanide vs. biguanide + DDP4i)

Higher glycemic efficacy therapy; CLP-1 RA; insulin; combination approaches (Table 9.2)

Consider additional comorbidities, patient-centered treatment factors, and management needs in choice of therapy, as below:

MINIMIZE HYPOGLYCEMIA

MINIMIZE HYPOGLYCEMIA

Nolcow interent risk of hypoglycemia;
DP4-2 (Q.P-1 RA) SQLT2; T2D

For SU or basal insulin, consider agents with lower risk of hypoglycemia*
OR

SQLT2

IF A1C ABOVE TARGET

IF A1C ABOVE TARGET

IF A1C ABOVE TARGET

Por patients on a CLP-1 RA, consider incompanies additional agents based on comorbidities, patient-centered treatment factors, and management needs

For patients on a CLP-1 RA, consider incompanies additional agents based on comorbidities, patient-centered treatment factors, and management needs

Incorporate additional agents based on comorbidities, patient-centered treatment factors, and management needs

rate agents that provide adequate EFFICACY to achieve and maintain glycemic goals

DDP4i: dipeptidyl peptidase 4 inhibitor

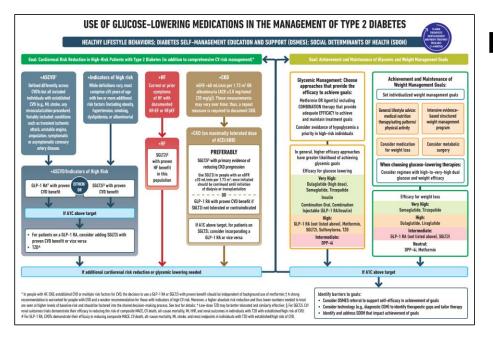


Figure 9.3

Table 9.2

canagliflozin (Invokana®), empagliflozin (Jardiance®), dapagliflozin (Forxiga®), ertugliflozin (Steglatro®) dulaglutide (Trulicity®), liraglutide (Victoza®), semaglutide (Ozempic®, Rybelsus®), exenatide (Byetta®, Bydureon®), lixisenatide (Adlyxine™) tirzepatide (Mounjaro™) alogliptin (Nesina®), saxagliptin (Onglyza®), sitagliptin

alogliptin (Nesina®), saxagliptin (Onglyza®), sitagliptir (Januvia®), linagliptin (Tradjenta®)

pioglitazone (Actos®)

glyburide (Glynase®), glipizide (Glucotrol®), glimepiride (Amaryl®)

NPH insulin (Humulin® N, Novolin® N); regular insulin (Humulin® N, Novolin® N)

aspart insulin (Fiasp®, NovoLog®), lispro insulin (Admelog®, Humalog®, Lyumjev™), glulisine insulin (Apidra®) detemir insulin (Levemir®), glargine insulin (Lantus®, Semglee®, Basaglar®, Toujeo®), degludec insulin (Tresiba®)

| | | Efficacy' | Homely- | Weight change | CV effects | | Fenal effects | | | 011150 | | Clinical comiderations |
|-----------------------------------|------------------|-------------------------|---------|---|---|--|---|---|--|---------------------------|------------------|---|
| | | Ultrack | comia | Bioght charge. | Effect on NACE | M7 | Progression of BKD | Г | Besing/use considerations* | Unit | Cost | Cirecal conscendors |
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| SGCT2 inhibitors | | Intermediate to high | le . | tess listernedatel | Benefit canaplificale, empagifficale | Benefit caragiffocis, dipoplificole, empaglificole, estaglificole estaglificole | Bosefit canopilifacio, depopilifacio, empopilifacio | | See Later's for renal disse considerations of individual agents. Glacose-Lawering effect is lower for SGLT2 inhibitors allower eGPR | Oral. | Hip | Okt viz. care in 120% disconfision, constant, and host prompt in Supportion the several producing sign in Assess and clinical proceditions for including engingenis (Self disconfision before recluded in cargos (e.g., 3-4 days), during critical Risens, are during protouged frediting for indigate protected. Incremental Act of protection in contractions Incremental Act of this protection in contraction programs, one regards is within prompt insolvanced imagested. Administration section. |
| GUF-1 Rits | | Migh to very high | le . | East Sintermediate to way high! | Serett: delaplatide: lasplatide: semaplatide (SQ) Sentral: | Seatral | Bosefit for mend endpoints in CMTh, drivers by willburninante ox loomes: dubaglarities, foreglaties, samaglaride (SE) | | See Liter's for resal disse considerations of individual apents in desirated the dataset for dataset individual for modificación and position for modificación dataset superior apparetra paretra adversación dataset superior graver a dessación dataset superior dataset dat | St. cral berooglutide) | Hyb | Risk of hayeld C-cell favors in Institut, harvan relevance set determined Dissplation, elsephalitic rescribed invalided relevant. Coursel patients on patiental for CI delin effects and filled hybridly interpress protocy preside patience on Relevant patient for CI delin effects and filled hybridly interpress youthor, preside patience on Relevant patient from the CIII delin effects of the Relevant in the CIII deline elsevant in self-granted on the CIII delin effects of the CIII delin elsevant patients of |
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| GIF and GLF-1 RA | | Wey Bigh | | Less (very high) | Under Investigation | Biolor investigation | Bader investigation | | See Label for renal desir considerations No drew algorithment. Monitor renal function when initiating or excluding dozes in patients with renal languisment reporting sover a adverse. Cl reactions. | 90 | Np. | Raid of hyperf. Coal bases in materia harman eliminace est destromined. Coursel patients on placed for 10 cité de 1914 on the projud in prosproup value previde publicar on métales no missages il cité enfects in hacitat on messions, mestid and para possibles il, place april que mail, calcinos place de l'implication en méssions, mestid unitspar possibles il, place april para filled, place de l'appropriet place de l'implication place de l'implication possible provincia que consideration de l'appropriet place de l'implication de l'appropriet place de l'appropriet place de l'implication de conferencial place de l'appropriet d'appropriet d' |
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| lesalie | Forum Analogs | High to yany high | No. | Sain | Neutral. | Sector | Seatral | | Lower insulin doses required with a documen in off it, titrate per clinical response | SC inhaled SC | tow (SE) High | Injection site reactions Higher risk of hypoglycemia with human inaction SMH or promised formulational vs. analogs |

Section 10: Cardiovascular Disease and

Risk Management

- 10.1 Revised to update definitions of hypertension to align with ACC/AHA: ≥130/80
- 10.4 Blood pressure goals changed: <130/80
- Figure 10.2 Updated

Recommendations for the Treatment of
Confirmed Hypertension in People With Diabetes

Initial BP ≥130/80 and
<100/100 mmHg

Initial BP ≥150/100 mmHg

ACC: American College of Cardiology; AHA: American Heart Association

Section 10: Cardiovascular Disease and Risk Management

- Revisions align now with 2019 ESC/EAS guidelines
 - reduction of 39 mg/dL in LDL = 9% reduction in all death and 13% CV death
- No change: 40-70 years old for primary prevention
 - moderate intensity statin

ESC: European Society of Cardiology; EAS: European Atherosclerosis Society

Section 10: Cardiovascular Disease and Risk Management

- 10.20 Revised: Primary prevention HIGHER risk
 - high risk = at least ONE ASCVD risk factor
 - high intensity statin with LDL reduction of ≥50% and target LDL ≤70 mg/dL
- 10.21 Added: Add ezetimibe OR PCSK9 inhibitor to maximum tolerated statin if unable to reach LDL goal

Section 10: Cardiovascular Disease and Risk Management

- 10.22 Added: Keep statin on even after age 75
- 10.23 Added: May be reasonable to initiate moderate statin after age 75

Section 10: Cardiovascular Disease and Risk Management

- 10.26 Revised: Secondary prevention
 - high intensity statin with LDL reduction of ≥50% and target LDL ≤55 mg/dL
 - add ezetimibe OR PCSK9 inhibitor to maximum tolerated statin if unable to reach LDL goal
 - pending cardiovascular outcome data for new siRNA (inclisiran (Leqvio®))

Section 10: Cardiovascular Disease and Risk Management

- 10.42b Revised: SGLT2i for preserved or reduced ejection heart failure
- 10.43 Added: Add nonsteroidal mineralocorticoid receptor antagonist (finerenone) for CKD with albuminuria treated with target doses of ACEi or ARB

Section 11: Chronic Kidney Disease and Risk Management

- 11.5a Revised: eGFR and urinary albumin levels to initiate SGLT2i changed
 - $-eGFR \ge 20 \text{ mL/min/1.73m2}$
 - urinary albumin: ≥200 mg/g creatinine
- 11.5b Added: Limited but emerging evidence for SGLT2i
 - CKD with normal urinary albumin

eGFR: Estimated Glomerular Filtration Rate

Section 11: Chronic Kidney Disease and Risk Management

- No albuminuria
 - added finerenone first-line option with SGLT2i or GLP1RA (not alternative)

Section 12: Retinopathy, Neuropathy, and Food Care

- Information, terminology, and clarification added
- 12.20 Revised: First-line agents for neuropathy
 - gabapentinoids
 - o gabapentin, pregabalin
 - SNRI
 - o duloxetine, venlafaxine, desvenlafaxine

SNRI: Serotonin and norepinephrine reuptake inhibitors

Section 12: Retinopathy, Neuropathy, and Food Care

- Information, terminology, and clarification added
- 12.20 Revised: First-line agents for neuropathy
 - TCA
 - o amitriptyline
 - sodium channel blockers
 - o lamotrigine, lacosamide, oxcarbazepine, valproic acid

TCA: tricyclic antidepressant

Special Populations

- Section 13: Older Adults
 - emphasis on deintensification of treatment goals to reduce risk of hypoglycemia and medication burden
 - recommended use of technology
 - o insulin pumps for type 1
 - CGM for hypoglycemia risk regardless of medication therapy
- Section 15: Management of Diabetes in Pregnancy
 - diet, CGM, and breastfeeding updates

Section 16: Diabetes Care in the Hospital

- 16.5 Revised: Glucose target range of 100-180 mg/dL for noncritically ill patients with new or known hyperglycemia (in addition to previous alternative target of 110-140 mg/dL)
- 16.7 Revised: Basal, prandial, and correction components preferred treatment for most noncritically ill patients with adequate nutritional intake

Discussion

Did any of the updates (or lack of updates) surprise you?

What is New and on the Horizon

- Bexagliflozin (Brenzavvy®)
 - new SGLT2i approved JAN 2023
 - T2DM for glucose lowering with eGFR >30
 - o similar A1c reduction, side effects, positive effects
 - o pending CV trials

What is New and on the Horizon

- Teplizumab (Tzield®)
 - MOA
 - o anti-CD3 monoclonal antibody
 - FDA approved July 2022
 - delay onset to symptomatic T1DM in stage 2 patients for at least two years
 - o risk (side effects/\$) vs benefit

What is New and on the Horizon

Tirzepatide

- pending weight loss indication
 - SURMOUNT trials Fast Track designation OCT 2022
 - 15-20% weight reduction (dose specific)
 - about 50% of patients lost at least 10% of weight

- GLP1RA vs. GIP/GLP1RA??
- Pending CV in T2DM (Mounjaro™)
 - **O SURPASS-CVOT**
 - o finishes OCT 2024
- SGLT2i or GLP1RA vs. GIP/GLP1RA??

Knowledge Assessment

Pharmacists

- Discuss revisions of the 2023
 American Diabetes Association
 (ADA) Guidelines
- 2. Evaluate data supporting the 2023 revisions
- Review general approach to glucose management
- 4. Identify new hyperglycemia agents and/or indications on the horizon

Technicians

- Discuss revisions of the 2023
 American Diabetes Association
 (ADA) Guidelines
- 2. Review general approach to glucose management
- Identify brand/generic names and side effects/precautions of hyperglycemic medications

Everyone

- Which statement is correct regarding the treatment of cholesterol for a patient with a history of a myocardial infarction (secondary prevention)?
 - A. LDL target of less than 55 mg/dL
 - B. LDL reduction of 30-50%
 - C. Use of PCSK9 inhibitor
 - D. Use of moderate intensity statin

Everyone

 For a patient without ASCVD, heart failure, or CKD, metformin is first-line therapy for glucose lowering. True or false?

Pharmacists

- Which medication is currently conducting studies to seek cardiovascular outcome lowering indication?
 - A. Semaglutide
 - B. Liraglutide
 - C. Tirzepatide
 - D. Dulaglutide

Pharmacists

 Though data for CGM is mainly in basal/bolus insulin users, the guidelines support use in special populations such as older adults and pregnant patients. True or false?

Technicians

- What is the generic name for Mounjaro™?
 - Empagliflozin
 - Pioglitazone
 - Tirzepatide
 - Metformin

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American Diabetes Association (ADA) Standards of Care 2023 Guideline Updates

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