Standards of Medical Care in Diabetes – 2022

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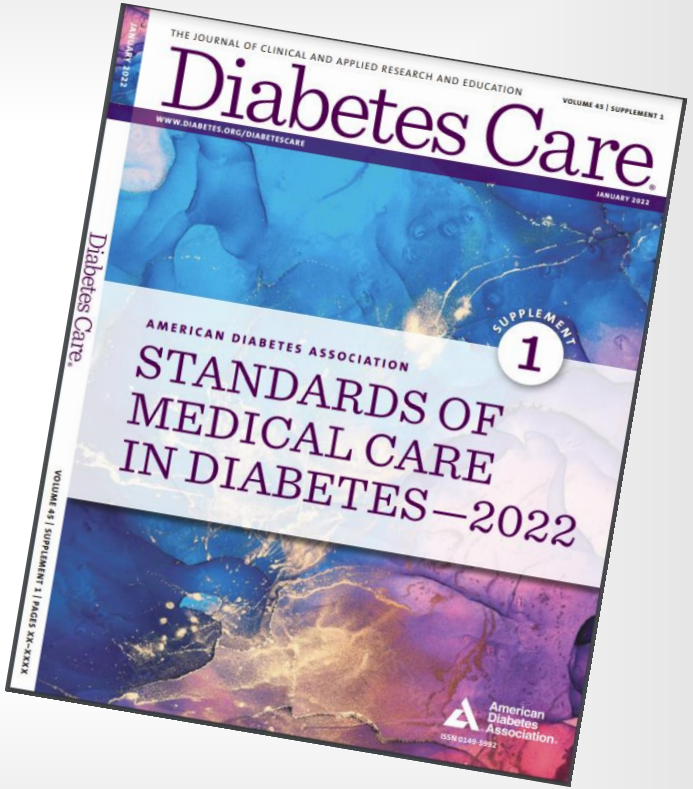
DOC June 2022



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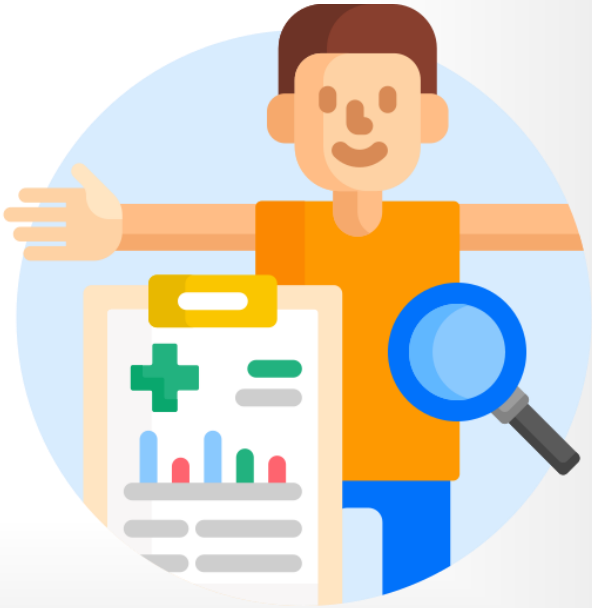
Classification and Diagnosis of Diabetes



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New screening thresholds

Overweight or obesity, age >18 plus with more risk factors should be tested for diabetes and prediabetes

Screening asymptomatic adults starting at age 35

18·35

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More on screening and follow up

NEW: Adequate carbohydrate intake >/150 mg/ d x 3 days prior to OGTT to screen for DM

Normal Test Results = Screen Q 3 years at minimum, sooner if symptoms or changes in risk occur (weight gain)

Exclude POC A1c as a test for diagnosis of diabetes

DM= Diabetes mellitus
D= Day
POC= Point of Care

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Diabetes Diagnosis in DM1 and first-degree relatives of people with DM1 counseling

Useful features in diagnosis of type 1 diabetes

First-degree relatives of type 1 diabetes and the need for counseling on their increased relative risk.

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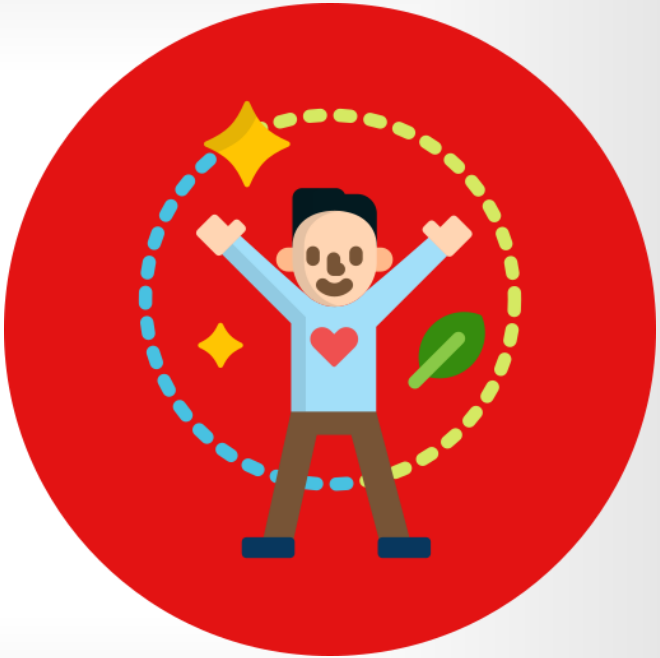
Prevention or Delay of Type 2 Diabetes and Comorbidities



Change in title

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Emphasis on the importance of **individual risk/benefit assessment**

Diabetes prevention measures are intended for individuals with **overweight/obesity at elevated risk of developing type 2 diabetes**

(DPP and outcomes study)

New: Care goals should include weight loss or prevention of weight gain, **minimizing progression of hyperglycemia, and attention to cardiovascular risk and associated comorbidities**

Comprehensive Medical Evaluation and Assessment of Comorbidities

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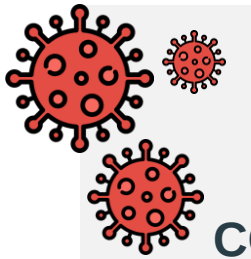
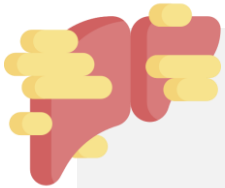


COVID-19 vaccination recommendations updates



NASH updates including management recommendation for patients with NAFLD and NASH

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Facilitating Behavior Change and Well-being to Improve Health Outcomes

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Use of technology including mobile apps, simulation tools, digital coaching and digital self-management interventions diabetes self-management education and support

More emphasis on the **quality of food sources** selected, regardless of carbohydrate amount eaten.

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More information about the **impact of high protein, high fat mixed meals** on glycemia has been added for those who take insulin at mealtime

A new section on **cognitive capacity/impairment** has been added with recommendations for monitoring and referral for formal assessment.

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New additions:

- 5.51: Cognitive capacity should be monitored throughout the life span for all individuals with diabetes, particularly in those who have documented cognitive disabilities, those who experience severe hypoglycemia, very young children, and older adults.
- 5.52: If cognitive capacity changes or appears to be suboptimal for provider-patient decision-making and/or behavioral self-management, referral for a formal assessment should be considered

Glycemic Targets

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Assess glycemic status using a 14-day CGM assessment of TIR and GMI or A1c for use in clinical management and followed remotely

Change of language from “self-monitored blood glucose” (SMBG) to “blood glucose monitoring” (**BGM**)

Time in range, time below range and time above range are all useful tools for **directing changes in medical therapy**

CGM= Continuous Glucose Monitoring
TIR= Time in range

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Time in range (TIR) is associated with the risk of microvascular complications and can be used for assessment of glycemic control.

Table 6.2—Standardized CGM metrics for clinical care

1. Number of days CGM device is worn (recommend 14 days)	
2. Percentage of time CGM device is active (recommend 70% of data from 14 days)	
3. Mean glucose	
4. Glucose management indicator	
5. Glycemic variability (%CV) target ≤36%*	
6. TAR: % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2 hyperglycemia
7. TAR: % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1 hyperglycemia
8. TIR: % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. TBR: % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1 hypoglycemia
10. TBR: % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2 hypoglycemia

CGM, continuous glucose monitoring; CV, coefficient of variation; TAR, time above range; TBR, time below range; TIR, time in range. *Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas. Adapted from Battelino et al. (34).

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Emphasis that **hypoglycemia is an urgent issue** + **guidance on triggers for hypoglycemia avoidance education + reevaluation/ adjustment** of the treatment regimen

TIR= Time in range

Diabetes Technology

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New Recommendations:

- 7.1 The type(s) and selection of devices should be individualized based on a person's specific needs, desires, skill level, and availability of devices. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment), the caregiver's skills and desires are integral to the decision-making process. E
- 7.2 When prescribing a device, ensure that people with diabetes/caregivers receive initial and ongoing education and training, either in-person or remotely, and regular evaluation of technique, results, and their ability to use data, including uploading/sharing data (if applicable), to adjust therapy. C
- 7.3 People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third party payers. E
- 7.4 Students must be supported at school in the use of diabetes technology including continuous subcutaneous insulin infusion, connected insulin pens, and automated insulin delivery systems as prescribed by their diabetes care team. E
- 7.5 Initiation of continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery early in the treatment of diabetes can be beneficial depending on a person's/caregiver's needs and preferences.

BGM needs to be provided to all who use CGM for calibration, verification of BG's as needed and to use if CGM not available.

CGM recommendations are now split into adult and pediatric recommendations

BGM= Blood Glucose Monitoring
CGM= Continuous Glucose Monitoring

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CGM recommendations combine real-time CGM or intermittently scanned CGM systems with differing levels of evidence.

Real-time CGM or intermittently scanned **CGM** should be offered for diabetes management in **adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion** who are capable of using devices safely.

Strengthened specific recommendations for **CGM use in people using basal insulin**

CGM= Continuous Glucose Monitoring

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CGM should be offered for diabetes management in **youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely**

For people with diabetes who require insulin, **insulin pens are preferred** in most cases, but insulin syringes may be used for insulin delivery with consideration of patient/caregiver preference, insulin type and dosing regimen, cost, and self-management capabilities.

CGM= Continuous Glucose Monitoring

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Obesity Management for the Treatment of Type 2 Diabetes

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Dietary supplements and post-bariatric surgery

Lack of evidence to support the use of dietary supplements for weight loss

8:12: There is no clear evidence that dietary supplements are effective for weight loss

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Dietary supplements and post-bariatric surgery

Guidance on post-bariatric surgery management, especially post-bariatric hypoglycemia

8.22: If postbariatric hypoglycemia is suspected, clinical evaluation should exclude other potential disorders contributing to hypoglycemia, and management includes education, medical nutrition therapy with a dietitian experienced in postbariatric hypoglycemia, and medication treatment, as needed. Continuous glucose monitoring should be considered as an important adjunct to improve safety by alerting patients to hypoglycemia, especially for those with severe hypoglycemia or hypoglycemia unawareness.

Pharmacologic Approaches to Glycemic Treatment

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Type 1 Diabetes

Representative relative attributes of insulin delivery approaches in people with type 1 diabetes[1]

Injected insulin regimens	Flexibility	Lower risk of hypoglycemia	Higher costs
MDI with LAA + RAA or URAA	+++	+++	+++
Less-preferred, alternative injected insulin regimens			
MDI with NPH + RAA or URAA	++	++	++
MDI with NPH + short-acting (regular) insulin	++	+	+
Two daily injections with NPH + short-acting (regular) insulin or premixed	+	+	+

Continuous insulin infusion regimens	Flexibility	Lower risk of hypoglycemia	Higher costs
Hybrid closed-loop technology	+++++	+++++	++++++
Insulin pump with threshold/ predictive low-glucose suspend	++++	++++	+++++
Insulin pump therapy without automation	+++	+++	++++

Figure 9.1—Choices of insulin regimens in people with type 1 diabetes. CGM improves outcomes with injected or infused insulin and is superior to BGM. Inhaled insulin may be used in place of injectable prandial insulin in the U.S. The number of plus signs (1) is an estimate of relative association of the regimen with increased flexibility, lower risk of hypoglycemia, and higher costs between the considered regimens. LAA, long-acting insulin analog; MDI, multiple daily injections; RAA, rapid-acting insulin analog; URAA, ultra-rapid-acting insulin analog. Reprinted from Holt et al.

Simplified overview of indications for β-cell replacement therapy in people with type 1 diabetes

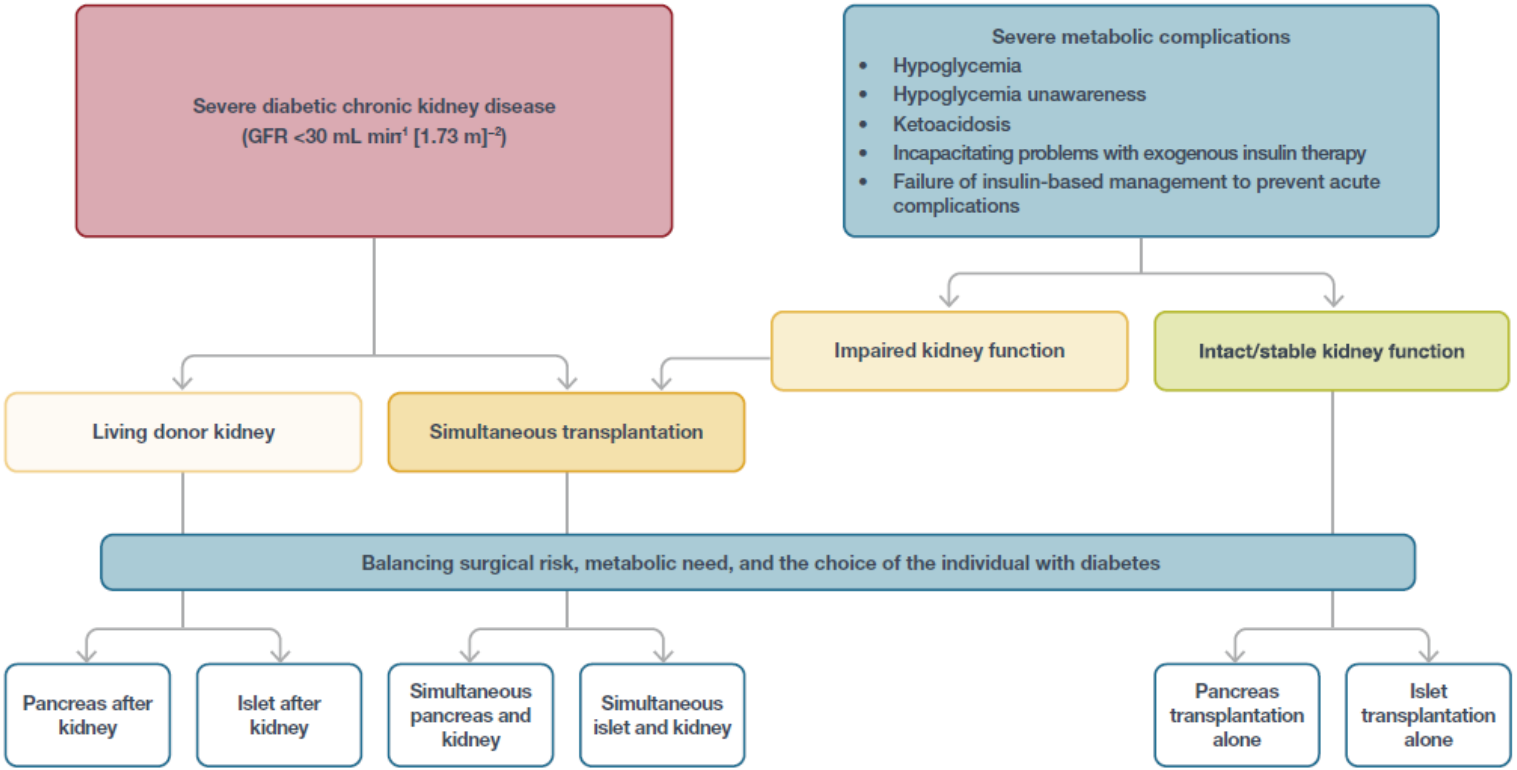

Figure 9.2—Simplified overview of indications for β-cell replacement therapy in people with type 1 diabetes. The two main forms of β-cell replacement therapy are whole-pancreas transplantation or islet cell transplantation. β-Cell replacement therapy can be combined with kidney transplantation if the individual has end-stage renal disease, which may be performed simultaneously or after kidney transplantation. All decisions about transplantation must balance the surgical risk, metabolic need, and the choice of the individual with diabetes. GFR, glomerular filtration rate. Reprinted from Holt et al. (5).

Type 2 Diabetes

PHARMACOLOGIC TREATMENT OF HYPERGLYCEMIA IN ADULTS WITH TYPE 2 DIABETES

FIRST-LINE THERAPY depends on comorbidities, patient-centered treatment factors, including cost and access considerations, and management needs and generally includes metformin and comprehensive lifestyle modification^

ASCVD/INDICATORS OF HIGH RISK, HF, CKD†

NONE

TO AVOID THERAPEUTIC INERTIA REASSESS AND MODIFY TREATMENT REGULARLY (3–6 MONTHS)

RECOMMEND INDEPENDENTLY OF BASELINE A1C, INDIVIDUALIZED A1C TARGET, OR METFORMIN USE‡

+ASCVD/INDICATORS OF HIGH RISK*

EITHER/OR

- GLP-1 RA with proven CVD benefit[1]
- SGLT2i with proven CVD benefit[1]

IF A1C ABOVE TARGET

- For patients on a GLP-1 RA, consider incorporating SGLT2i with proven CVD benefit and vice versa[1]
- TZD[2]

+HF*

SGLT2i with proven benefit in this population[1]

+CKD**

CKD and albuminuria (e.g., ≥200 mg/g creatinine)	CKD without albuminuria (e.g., eGFR <60 mL/min/1.73 m²)

PREFERABLY

SGLT2i with primary evidence of reducing CKD progression

OR

SGLT2i with evidence of reducing CKD progression in CVOTs

OR

GLP-1 RA with proven CVD benefit[1] if SGLT2i not tolerated or contraindicated

For patients with CKD (e.g., eGFR <60 mL/min/1.73 m²) without albuminuria, recommend the following to decrease cardiovascular risk

EITHER/OR

- GLP-1 RA with proven CVD benefit[1]
- SGLT2i with proven CVD benefit[1]

If A1C above target, for patients on SGLT2i, consider incorporating a GLP-1 RA and vice versa

If A1C remains above target, consider treatment intensification based on comorbidities, patient-centered treatment factors, and management needs

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

Higher glycemic efficacy therapy: GLP-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

No/low inherent risk of hypoglycemia: DPP-4i, GLP-1 RA, SGLT2i, TZD

For SU or basal insulin, consider agents with lower risk of hypoglycemia[3,4]

IF A1C ABOVE TARGET

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

MINIMIZE WEIGHT GAIN/ PROMOTE WEIGHT LOSS

PREFERABLY

GLP-1 RA with good efficacy for weight loss

OR

SGLT2i

IF A1C ABOVE TARGET

For patients on a GLP-1 RA, consider incorporating SGLT2i and vice versa

- If GLP-1 RA not tolerated or indicated, consider DPP-4i (weight neutral)

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

CONSIDER COST AND ACCESS

Available in generic form at lower cost:

- Certain insulins: consider insulin available at the lowest acquisition cost
- SU
- TZD

IF A1C ABOVE TARGET

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

1. Proven benefit refers to label indication (see Table 9.2)
2. Low dose may be better tolerated though less well studied for CVD effects
3. Choose later generation SU to lower risk of hypoglycemia
4. Risk of hypoglycemia: degludec / glargine U-300 < glargine U-100 / detemir < NPH insulin
5. Consider country- and region-specific cost of drugs

^For adults with overweight or obesity, lifestyle modification to achieve and maintain ≥5% weight loss and ≥150 min/week of moderate- to vigorous-intensity physical activity is recommended (See Section 5: Facilitating Behavior Change and Well-being to Improve Health Outcomes).
†Actioned whenever these become new clinical considerations regardless of background glucose-lowering medications.
‡Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy.
*Refer to Section 10: Cardiovascular Disease and Risk Management.
**Refer to Section 11: Chronic Kidney Disease and Risk Management and specific medication label for eGFR criteria.

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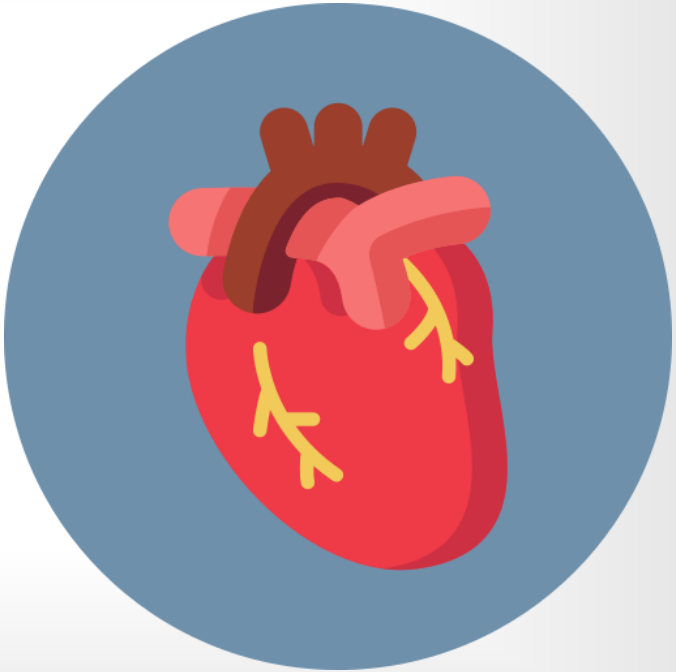
Algorithm updates:

1. Other medications may also be appropriate as initial therapy, depending on comorbidities, treatment factors, and management needs.
2. ASCVD/Indicators of High Risk: Pathway has been streamlined to include classes of glucose-lowering medications with positive evidence for cardiovascular risk reduction and glycemia management.
3. +HF pathway: Pathway acknowledges the positive outcome evidence of SGLT2i in people with HF
4. +CKD pathway: Pathway has been updated based on the populations studied in the renal and cardiovascular outcomes studies.
5. When treatment is intensified or adjusted, current background therapy should be reviewed and adjusted as appropriate.

6. Agents should be considered that provide adequate efficacy to achieve and maintain glycemic goals, while considering additional patient-centered factors.
7. Agents with no/low inherent risk of hypoglycemia are preferred.
8. Agents with good efficacy for weight loss are preferred.

9. Access and cost are universal considerations. Classes with medications currently available in generic form are listed

Cardiovascular Disease and Risk Management



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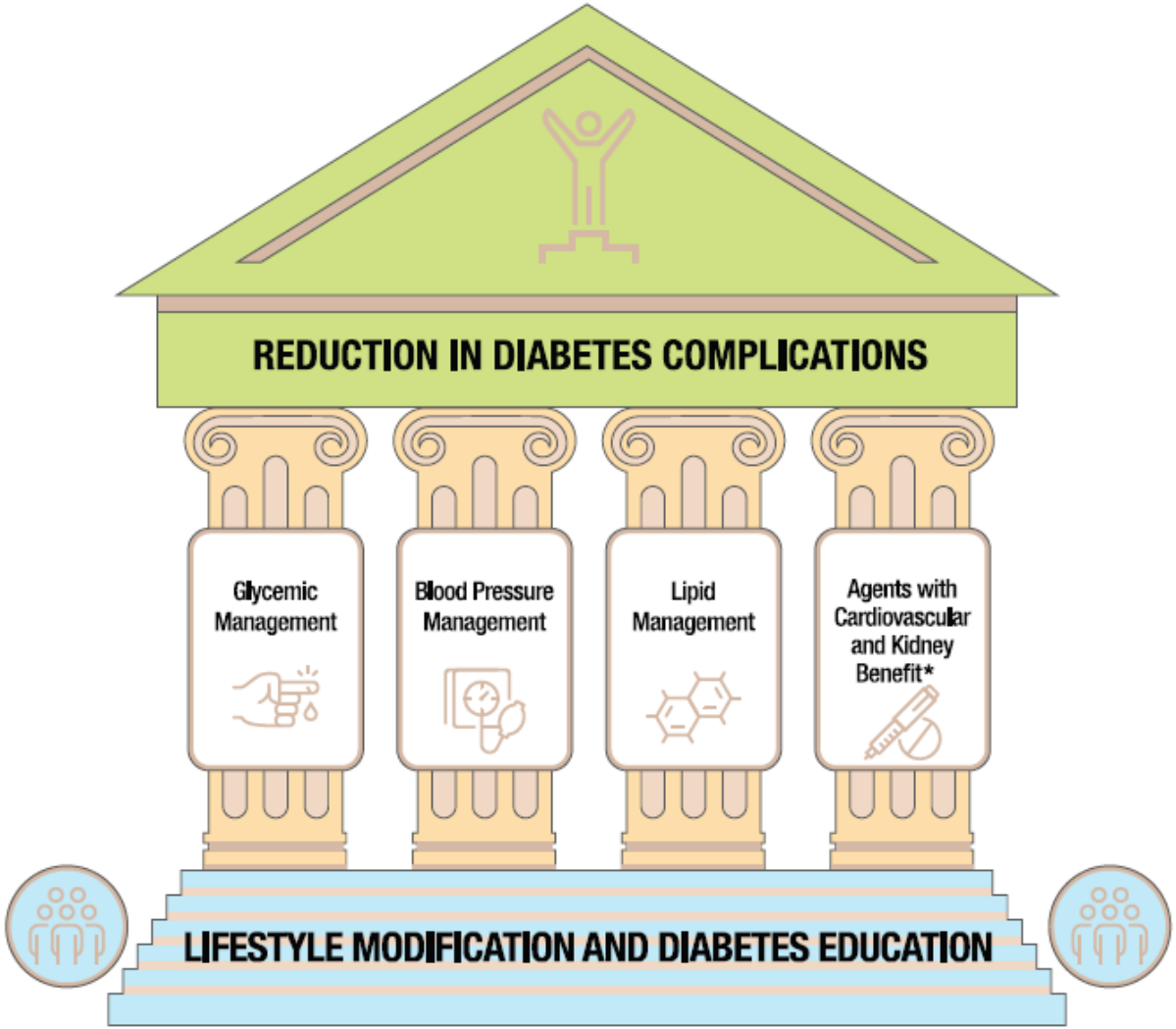

Figure 10.1—Multifactorial approach to reduction in risk of diabetes complications. *Risk reduction interventions to be applied as individually appropriate.

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Consideration of and rationale for **combination therapy** with SGLT2i plus GLP-1RA to address risk of cardiovascular and kidney complications in patients with T2DM and established ASCVD or high ASCVD risk.

Emphasis on how the approach to management will differ in patients with new-onset T2DM vs. those on an existing diabetes medication regimen

SGLT2i= Sodium/glucose cotransporter 2 inhibitor
GLP1-RA= Glucagon-like peptide-1 receptor agonist
T2DM= Type 2 Diabetes Mellitus
ASCVD= Atherosclerotic cardiovascular disease

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Children and Adolescents

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AID

Automated insulin delivery systems (AID) should be offered to all youth with type 1 diabetes.

CGM

Real-time or intermittently scanned **CGM should be offered to youth with type 2 diabetes on insulin**.

CGM= Continuous Glucose Monitoring

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Management of Diabetes in Pregnancy

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Updates made to recommendations regarding preconception and early pregnancy screening

In women who are planning pregnancy, screen those with risk factors and consider screening all women for undiagnosed diabetes.

Before 15 weeks, screen women with risk factors and consider screening all women for undiagnosed diabetes at the first prenatal visit using standard diagnostic criteria, if not screened preconception. Women identified as having diabetes should be treated as such.

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Before 15 weeks, screen for abnormal glucose metabolism to identify women who are at higher risk of adverse pregnancy and neonatal outcomes, more likely to need insulin, and who are at high risk of a later GDM diagnosis. Treatment may provide some benefit

Screen for early abnormal glucose metabolism using fasting glucose of 110-125 mg/dl (6.1 mmol/l or A1C 5.9-6.4% (41-47 mmol/mol). .

Test for gestational diabetes mellitus at 24–28 weeks of gestation in pregnant women not previously found to have diabetes or high-risk abnormal glucose metabolism detected earlier in the current pregnancy

GDM= Gestational Diabetes Mellitus

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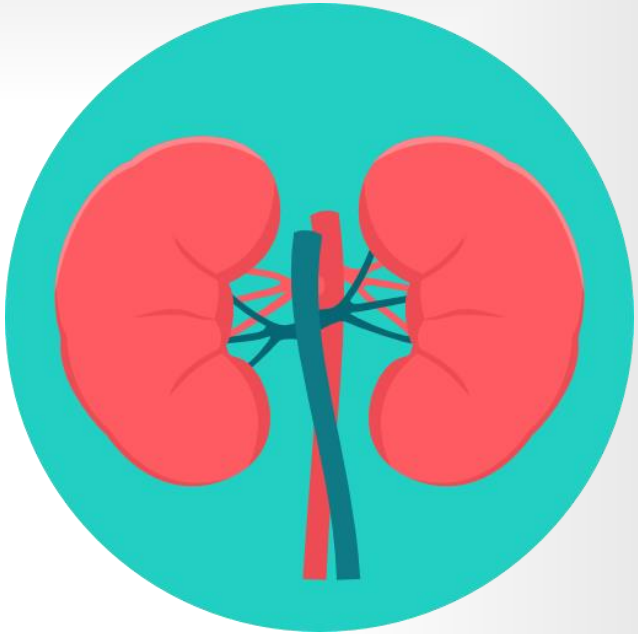
Chronic Kidney Disease (CKD)



Its own section!

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Updates:

If those with CKD + ≥300 mg/day urine albumin, albuminuria must be reduced by 30% or more to slow the progression of CKD

Finerenone should be used in people with albuminuric diabetic kidney disease to reduce CKD progression and heart failure risk

A major emphasis to properly categorize patients with CKD by **measuring albuminuria not just GFR**

CKD= Chronic kidney disease
GFR= Glomerular filtration rate

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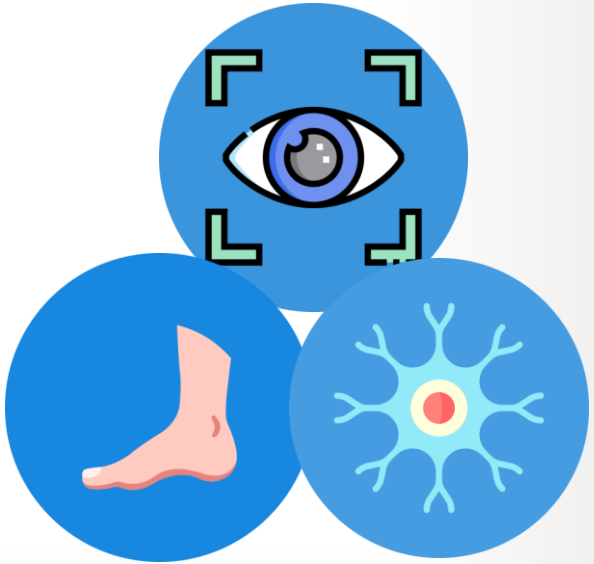
Retinopathy, Neuropathy and Foot Care



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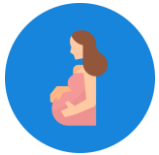
No association between GLP-1RA treatment and retinopathy per se, except through the association between retinopathy and average HbA1c reduction



More detail regarding retinopathy in pregnancy

More emphasis on screening intervals and how they are based on the presence of specific risk factors for retinopathy onset and worsening

GLP1-RA= Glucagon-like peptide-1 receptor agonist

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Standards of Care Resources

- Full version available
- Abridged version for PCPs
- Free app, with interactive tools
- Pocket cards with key figures
- Free webcast for continuing education credit
- Stay tuned for new visuals!

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THANK YOU!

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