

Together2Goal[®]

AMGA Foundation
National Diabetes Campaign



Monthly Campaign Webinar

January 21, 2021

Today's Webinar

- Together 2 Goal[®] Updates
 - Webinar Reminders
 - AMGA 2021 Annual Conference
 - National Day of Action Wrap Report
 - Body Mass Index Provider Tool
- ADA 2021 Standards of Care
 - Robert A. Gabbay, M.D., Ph.D., FACP of American Diabetes Association
- Q&A
 - Use Q&A or chat feature



Webinar Reminders

- Webinar will be recorded today and available the week of January 25th
 - www.Together2Goal.org
- Participants are encouraged to ask questions using the “Chat” and “Q&A” functions on the right side of your screen





AMGA 2021 Annual Conference

VIRTUAL EVENT
April 20-22, 2021
amga.org/AC21

▶ SHARED LEARNING

Real-world case studies and insights from AMGA members, including Intermountain Medical Group, Palo Alto Medical Foundation/Sutter Health, Lehigh Valley Physician Group, and many others

▶ ENGAGING TOPICS

Three days, three topics that address today's most critical issues:

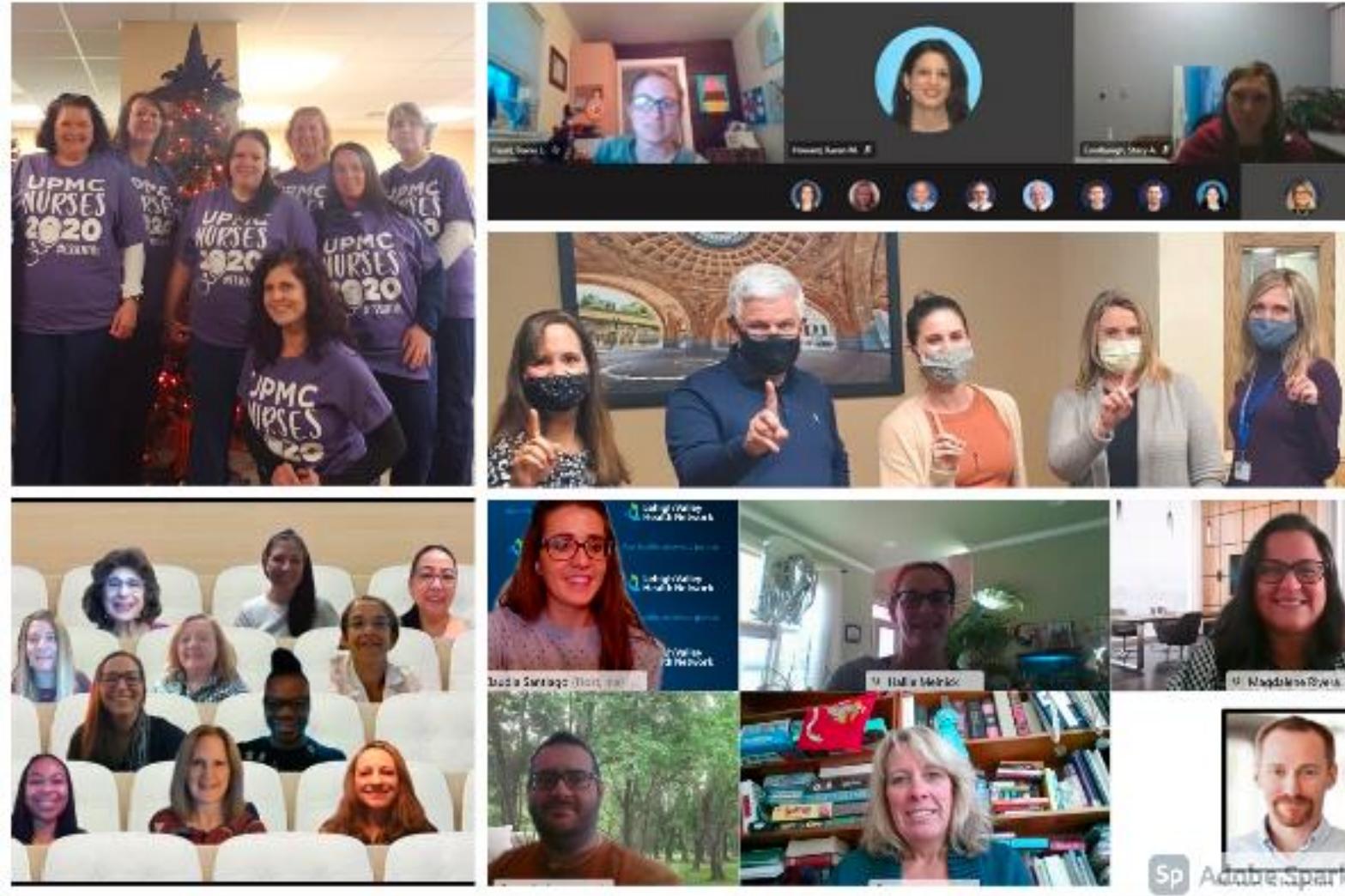
- Innovations in Health Care
- Patient Care and Experience
- Organizational Resiliency

▶ INSPIRING KEYNOTES

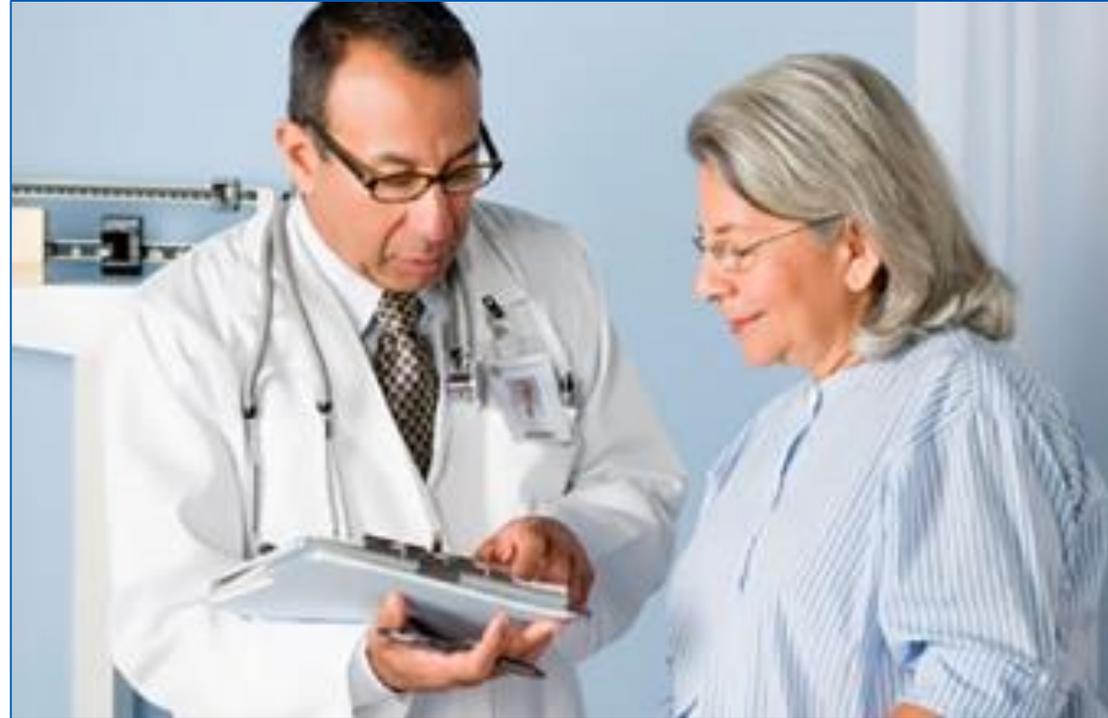
Hear from:

- Futurist Dr. Peter Diamandis
- Google Health's Dr. David Feinberg
- Viral sensation ZDoggMD
- Cityblock's Dr. Toyin Ajayi, and more

National Day of Action Wrap Report



Body Mass Index Provider Tool



Body Mass Index (BMI): An Important Tool for Your Patients with Diabetes

Janssen Pharmaceuticals Companies of Johnson & Johnson

Today's Featured Presenter

Robert A. Gabbay M.D., Ph.D., FACP

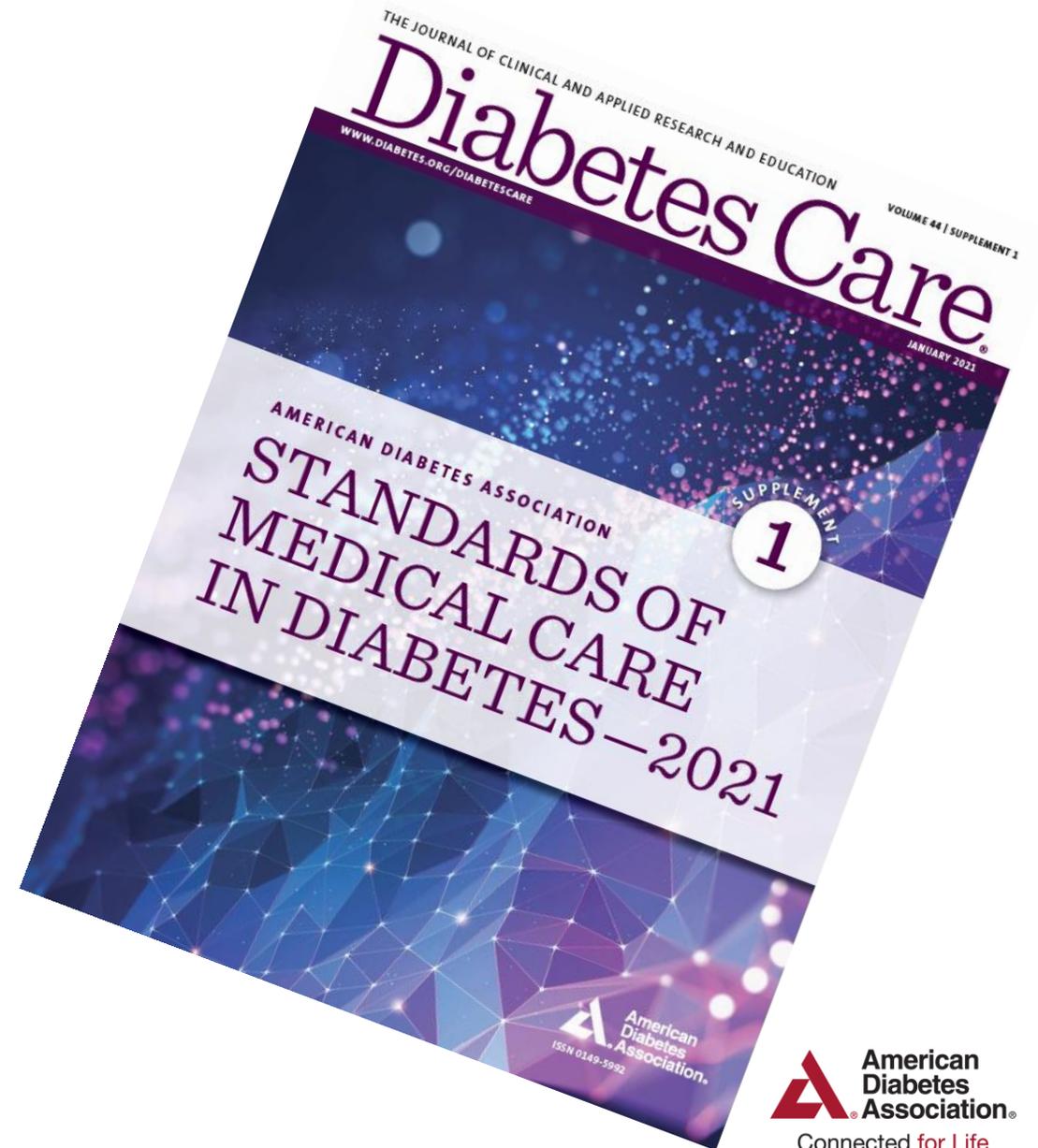


Chief Science & Medical Officer
American Diabetes Association

ADA 2021 Standards of Medical Care in Diabetes

Together 2 Goal

Robert Gabbay, MD, PhD
Chief Scientific & Medical Officer
American Diabetes Association



EVIDENCE



PROCESS



FUNDING



- Search of scientific diabetes literature over past year
- Recommendations revised per new evidence
- Professional Practice Committee
- Reviewed by ADA's Board of Directors
- Living Standards
- Funded out of ADA's general revenues
- Does not use industry support

3 Major Themes

1. Individualize Care
2. Glycemic Assessment and Technology
3. Social Determinants of Health

Individualized Care

For Medications in
Type 2 Diabetes

Start with
COMORBIDITIES

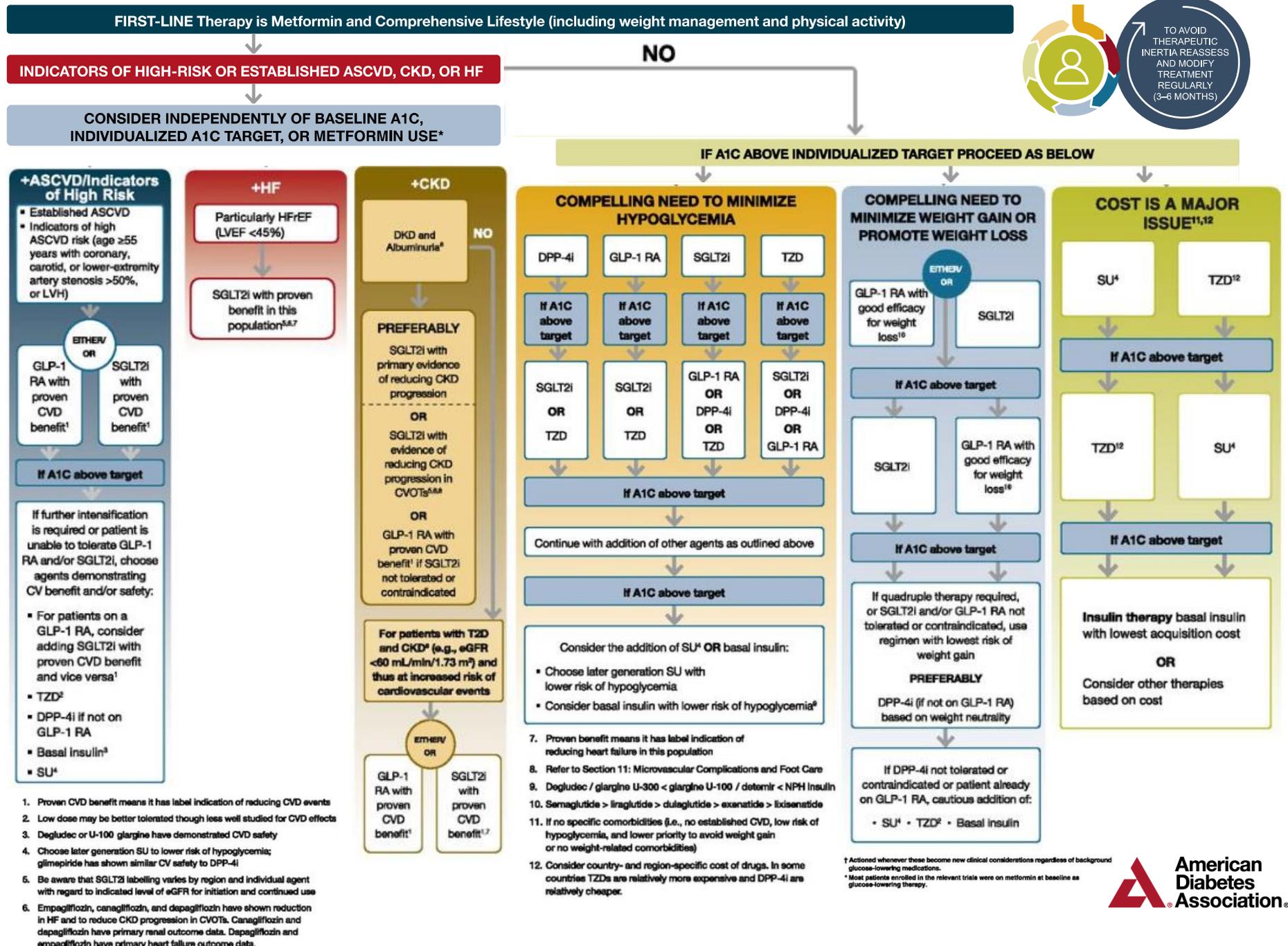


Figure 9.1 - Glucose-lowering medication in type 2 diabetes: 2021 ADA Professional Practice Committee (PPC) adaptation of Davies et al. and Buse et al.

FIRST-LINE Therapy is Metformin and Comprehensive Lifestyle (including weight management and physical activity)

INDICATORS OF HIGH-RISK OR ESTABLISHED ASCVD, CKD, OR HF†

CONSIDER INDEPENDENTLY OF BASELINE A1C, INDIVIDUALIZED A1C TARGET, OR METFORMIN USE*

+ASCVD/Indicators of High Risk

- Established ASCVD
- Indicators of high ASCVD risk (age ≥55 years with coronary, carotid, or lower-extremity artery stenosis >50%, or LVH)

EITHER/ OR

- GLP-1 RA with proven CVD benefit¹
- SGLT2i with proven CVD benefit¹

If A1C above target

If further intensification is required or patient is unable to tolerate GLP-1 RA and/or SGLT2i, choose agents demonstrating CV benefit and/or safety:

- For patients on a GLP-1 RA, consider adding SGLT2i with proven CVD benefit and vice versa¹
- TZD²
- DPP-4i if not on GLP-1 RA
- Basal insulin³
- SU⁴

+HF

Particularly HFREF (LVEF <45%)

SGLT2i with proven benefit in this population^{5,6,7}

+CKD

DKD and Albuminuria⁸

PREFERABLY

SGLT2i with primary evidence of reducing CKD progression

OR

SGLT2i with evidence of reducing CKD progression in CVOts^{4,6,8}

OR

GLP-1 RA with proven CVD benefit¹ if SGLT2i not tolerated or contraindicated

For patients with T2D and CKD⁹ (e.g., eGFR <60 mL/min/1.73 m²) and thus at increased risk of cardiovascular events

EITHER/ OR

- GLP-1 RA with proven CVD benefit¹
- SGLT2i with proven CVD benefit^{1,7}

NO

IF A1C ABOVE INDIVIDUALIZED TARGET PROCEED AS BELOW

COMPELLING NEED TO MINIMIZE HYPOGLYCEMIA

DPP-4i	GLP-1 RA	SGLT2i	TZD
If A1C above target	If A1C above target	If A1C above target	If A1C above target
SGLT2i	SGLT2i	GLP-1 RA OR DPP-4i OR TZD	SGLT2i OR DPP-4i OR GLP-1 RA
OR	OR	OR	OR
TZD	TZD		

If A1C above target

Continue with addition of other agents as outlined above

If A1C above target

Consider the addition of SU⁴ OR basal insulin:

- Choose later generation SU with lower risk of hypoglycemia
- Consider basal insulin with lower risk of hypoglycemia⁹

COMPELLING NEED TO MINIMIZE WEIGHT GAIN OR PROMOTE WEIGHT LOSS

EITHER/ OR

- GLP-1 RA with good efficacy for weight loss¹⁰
- SGLT2i

If A1C above target

If A1C above target

- SGLT2i
- GLP-1 RA with good efficacy for weight loss¹⁰

If A1C above target

If quadruple therapy required, or SGLT2i and/or GLP-1 RA not tolerated or contraindicated, use regimen with lowest risk of weight gain

PREFERABLY

DPP-4i (if not on GLP-1 RA) based on weight neutrality

COST IS A MAJOR ISSUE^{11,12}

SU⁴ OR TZD¹²

If A1C above target

TZD¹² OR SU⁴

If A1C above target

Insulin therapy basal insulin with lowest acquisition cost

OR

Consider other therapies based on cost



- Proven CVD benefit means it has label indication of reducing CVD events
- Low dose may be better tolerated though less well studied for CVD effects
- Degludec or U-100 glargine have demonstrated CVD safety
- Choose later generation SU to lower risk of hypoglycemia; glimepiride has shown similar CV safety to DPP-4i
- Be aware that SGLT2i labelling varies by region and individual agent with regard to indicated level of eGFR for initiation and continued use
- Empagliflozin, canagliflozin, and dapagliflozin have shown reduction in HF and to reduce CKD progression in CVOts. Canagliflozin and dapagliflozin have primary renal outcome data. Dapagliflozin and empagliflozin have primary heart failure outcome data.

- Proven benefit means it has label indication of reducing heart failure in this population
- Refer to Section 11: Microvascular Complications and Foot Care
- Degludec / glargine U-300 < glargine U-100 / detemir < NPH insulin
- Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide
- If no specific comorbidities (i.e., no established CVD, low risk of hypoglycemia, and lower priority to avoid weight gain or no weight-related comorbidities)
- Consider country- and region-specific cost of drugs. In some countries TZDs are relatively more expensive and DPP-4i are relatively cheaper.

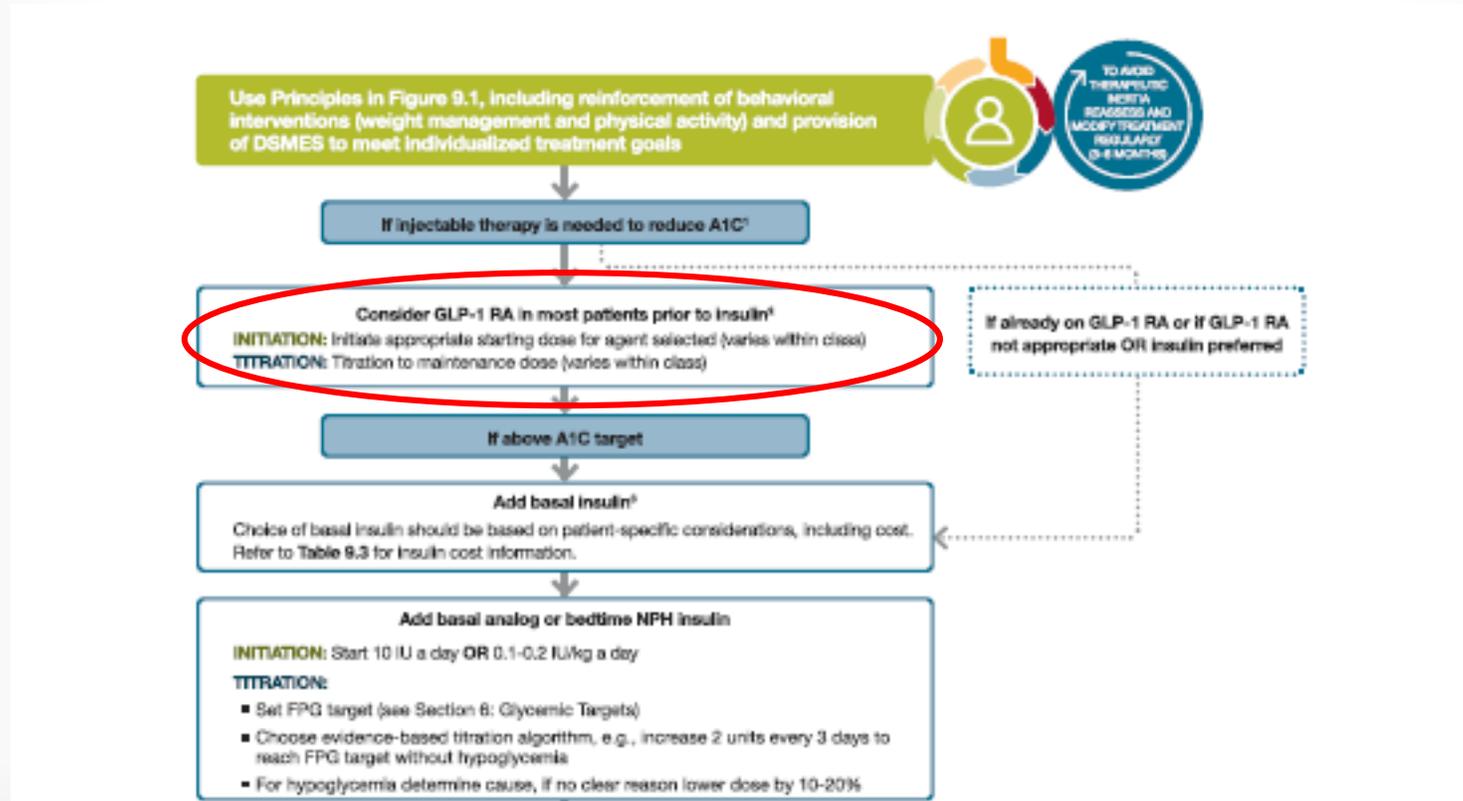
† Actioned whenever these become new clinical considerations regardless of background glucose-lowering medications.

* Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy.

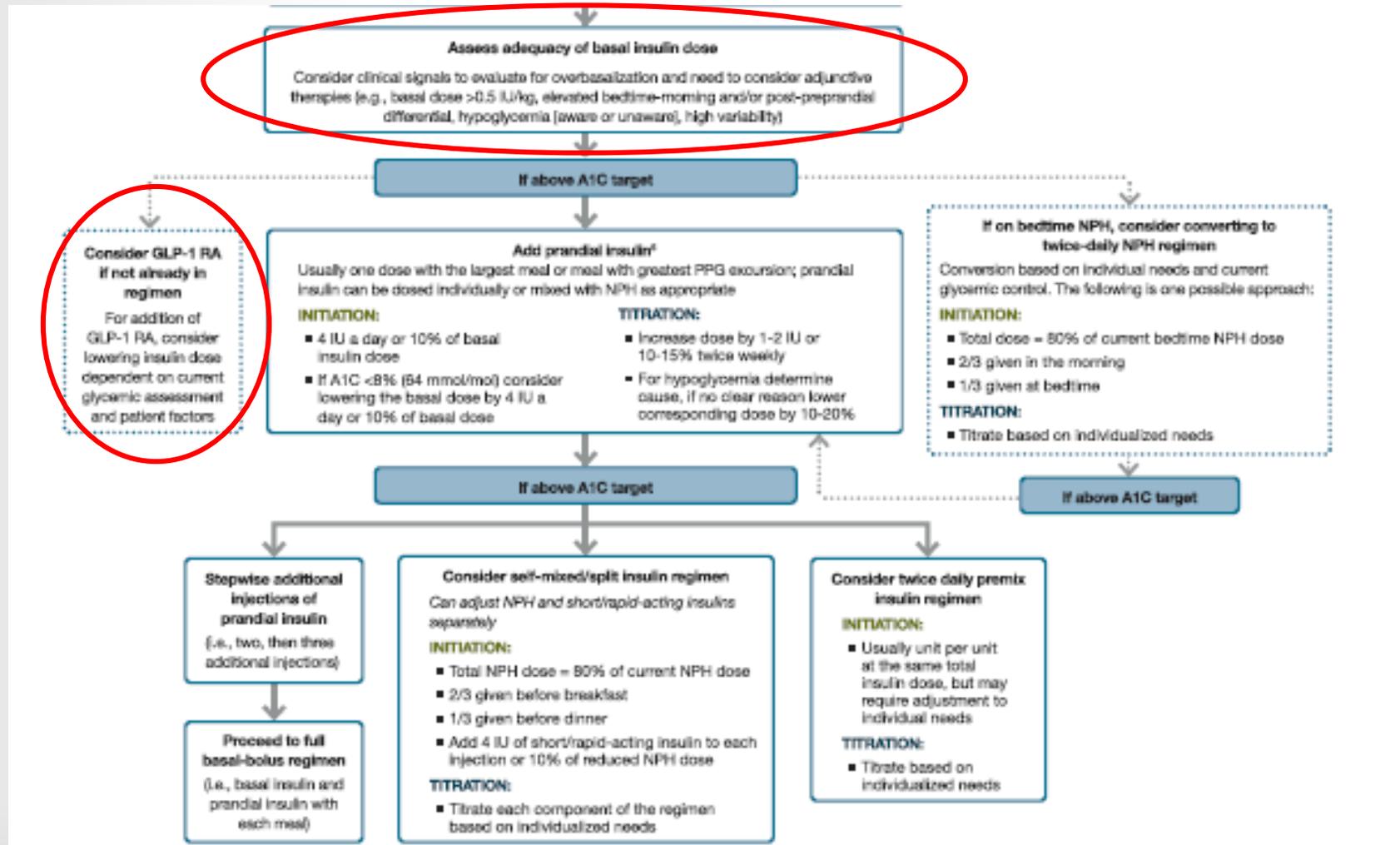
INTENSIFICATION TO INJECTABLE THERAPIES

Revised to include assessment of adequacy of insulin dose and updates regarding the use of glucagon-like peptide 1 receptor agonists.

Intensifying to injectable therapies (1 of 2)



Intensifying to injectable therapies (2 of 2)



**Patient case:
Maggie**



Patient case: Maggie

History of the present illness

- ✓ Maggie is an obese (BMI 32 kg/m²)
- ✓ 60-year-old woman
- ✓ 8 year history of poorly controlled type 2 diabetes for which she takes:
 - Metformin 1000mg twice daily,
 - Glipizide 10mg once daily,
 - Sitagliptin 50mg once daily.



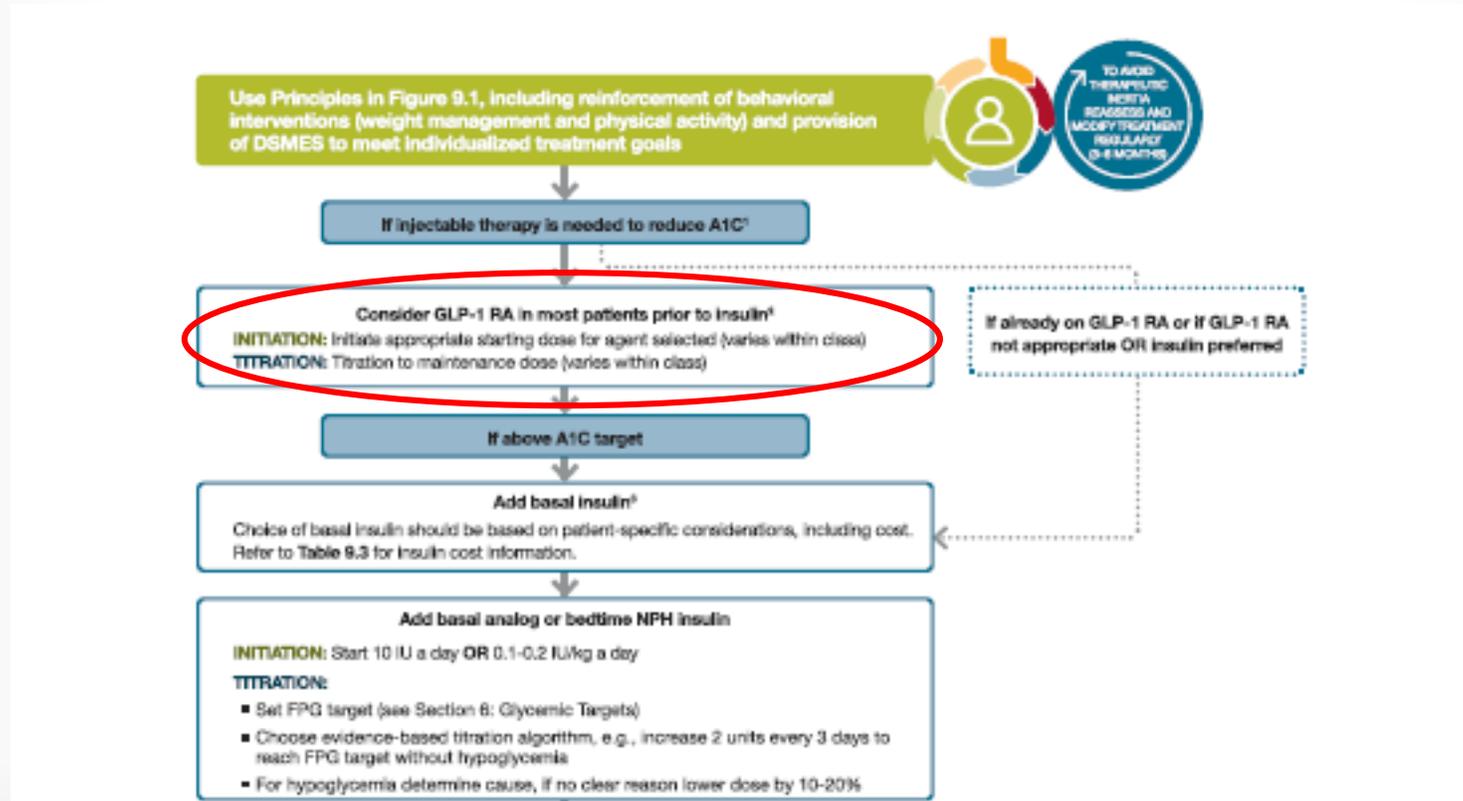
Patient case: Maggie

- ✓ She did not tolerate canagliflozin due to recurrent yeast infections.
- ✓ Her A1C is 8.8% (target < 7.5%).
- ✓ She occasionally has blurry vision, but no other symptoms of hyperglycemia.
- ✓ She has symptomatic hypoglycemia about twice per month.
- ✓ She has CKD with reduced renal function (eGFR 40 mL/min/1.73m²) and albuminuria (UACR 450 mg/g).
- ✓ She does not have ASCVD.



**How would you modify Maggie's
treatment regimen for type 2
diabetes?**

Intensifying to injectable therapies (1 of 2)



Cardiovascular Disease and Risk Management

ACC ENDORSEMENT.

This section is endorsed for the third consecutive year by the American College of Cardiology.

TYPE 1 DIABETES.

Revisions to acknowledge that few trials have been specifically designed to assess the impact of cardiovascular risk reduction strategies in patients with type 1 diabetes.

CLINICAL TRIAL DATA

New clinical trial data included

Table 10.3A—Cardiovascular and cardiovascular outcomes trials of available antihyperglycemic medications completed after the issuance of the FDA 2008 guidelines: DPP-4 inhibitors

	SAVOR-TIMI 53 (194) (n = 16,482)	EXAMINE (200) (n = 5,380)	TECOS (196) (n = 14,671)	CARMELINA (197,201) (n = 6,979)	CAROLINA (173,202) (n = 6,042)
Intervention	Saxagliptin/placebo	Alogliptin/placebo	Sitagliptin/placebo	Linagliptin/placebo	Linagliptin/ glimepiride
Main inclusion criteria	Type 2 diabetes and history of or multiple risk factors for CVD	Type 2 diabetes and ACS within 15–90 days before randomization	Type 2 diabetes and preexisting CVD	Type 2 diabetes and high CV and renal risk	Type 2 diabetes and high CV risk
A1C inclusion criteria (%)	≥6.5	6.5–11.0	6.5–8.0	6.5–10.0	6.5–8.5
Age (years) ††	65.1	61.0	65.4	65.8	64.0
Race (% White)	75.2	72.7	67.9	80.2	73.0
Sex (% male)	66.9	67.9	70.7	62.9	60.0
Diabetes duration (years) †††	10.3	7.1	11.6	14.7	6.2
Median follow-up (years)	2.1	1.5	3.0	2.2	6.3
Statin use (%)	78	91	80	71.8	64.1
Metformin use (%)	70	66	82	54.8	82.5
Prior CVD/CHF (%)	78/13	100/28	74/18	57/26.8	34.5/4.5
Mean baseline A1C (%)	8.0	8.0	7.2	7.9	7.2
Mean difference in A1C between groups at end of treatment (%)	−0.3*	−0.3*	−0.3*	−0.36*	0
Year started/reported	2010/2013	2009/2013	2008/2015	2013/2018	2010/2019
Primary outcome§	3-point MACE 1.00 (0.89–1.12)	3-point MACE 0.96 (95% UL ≤1.16)	4-point MACE 0.98 (0.89–1.08)	3-point MACE 1.02 (0.89–1.17)	3-point MACE 0.98 (0.84–1.14)
Key secondary outcome§	Expanded MACE 1.02 (0.94–1.11)	4-point MACE 0.95 (95% UL ≤1.14)	3-point MACE 0.99 (0.89–1.10)	Kidney composite (ESRD, sustained ≥40% decrease in eGFR, or renal death) 1.04 (0.89–1.22)	4-point MACE 0.99 (0.86–1.14)
Cardiovascular death§	1.03 (0.87–1.22)	0.85 (0.66–1.10)	1.03 (0.89–1.19)	0.96 (0.81–1.14)	1.00 (0.81–1.24)
MI§	0.95 (0.80–1.12)	1.08 (0.88–1.33)	0.95 (0.81–1.11)	1.12 (0.90–1.40)	1.03 (0.82–1.29)
Stroke§	1.11 (0.88–1.39)	0.91 (0.55–1.50)	0.97 (0.79–1.19)	0.91 (0.67–1.23)	0.86 (0.66–1.12)
HF hospitalization§	1.27 (1.07–1.51)	1.19 (0.90–1.58)	1.00 (0.83–1.20)	0.90 (0.74–1.08)	1.21 (0.92–1.59)
Unstable angina hospitalization§	1.19 (0.89–1.60)	0.90 (0.60–1.37)	0.90 (0.70–1.16)	0.87 (0.57–1.31)	1.07 (0.74–1.54)
All-cause mortality§	1.11 (0.96–1.27)	0.88 (0.71–1.09)	1.01 (0.90–1.14)	0.98 (0.84–1.13)	0.91 (0.78–1.06)
Worsening nephropathy¶	1.08 (0.88–1.32)	—	—	Kidney composite (see above)	—

—, not assessed/reported; ACS, acute coronary syndrome; CHF, congestive heart failure; CV, cardiovascular; CVD, cardiovascular disease; DPP-4, dipeptidyl peptidase 4; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; GLP-1, glucagon-like peptide 1; HF, heart failure; MACE, major adverse cardiac event; MI, myocardial infarction; UL, upper limit. Data from this table was adapted from Cefalu et al. (2013) in the January 2018 issue of *Diabetes Care*. ††Age was reported as means in all trials except EXAMINE, which reported medians; diabetes duration was reported as means in all trials except SAVOR-TIMI 53 and EXAMINE, which reported medians. §Outcomes reported as hazard ratio (95% CI). ¶Worsening nephropathy is defined as doubling of creatinine level, initiation of dialysis, renal transplantation, or creatinine > 6.0 mg/dL (530 mmol/L) in SAVOR-TIMI 53. Worsening nephropathy was a prespecified exploratory adjudicated outcome in SAVOR-TIMI 53. *Significant difference in A1C between groups (P < 0.05).

Table 10.3A—Cardiovascular outcomes trials of available antihyperglycemic medications completed after the issuance of the FDA 2008 guidelines: DPP-4 inhibitors

Cardiovascular Disease and Risk Management: *Standards of Medical Care in Diabetes - 2021. Diabetes Care 2021;44(Suppl. 1):S111-S150*

Table 10.3B—Cardiovascular and cardiorenal outcomes trials of available antihyperglycemic medications completed after the issuance of the FDA 2008 guidelines: GLP-1 receptor agonists

	ELIXA (183) (n = 6,068)	LEADER (178) (n = 9,340)	SUSTAIN-6 (179)* (n = 3,297)	EXSCEL (184) (n = 14,752)	Harmony Outcomes (181) (n = 9,463)	REWIND (182) (n = 9,901)	PIONEER-6 (180) (n = 3,183)
Intervention	Lixisenatide/placebo	Liraglutide/placebo	Semaglutide s.c. injection/placebo	Exenatide QW/placebo	Albiglutide/placebo	Dulaglutide/placebo	Semaglutide oral/placebo
Main inclusion criteria	Type 2 diabetes and history of ACS (<180 days)	Type 2 diabetes and preexisting CVD, CKD, or HF at ≥50 years of age or CV risk at ≥60 years of age	Type 2 diabetes and preexisting CVD, HF, or CKD at ≥50 years of age or CV risk at ≥60 years of age	Type 2 diabetes with or without preexisting CVD	Type 2 diabetes with preexisting CVD	Type 2 diabetes and prior ASCVD event or risk factors for ASCVD	Type 2 diabetes and high CV risk (age of ≥50 years with established CVD or CKD, or age of ≥60 years with CV risk factors only)
A1C inclusion criteria (%)	5.5–11.0	≥7.0	≥7.0	6.5–10.0	≥7.0	≤9.5	None
Age (years)††	60.3	64.3	64.6	62	64.1	66.2	66
Race (% White)	75.2	77.5	83.0	75.8	84.8	75.7	72.3
Sex (% male)	69.3	64.3	60.7	62	69.4	53.7	68.4
Diabetes duration (years)††	9.3	12.8	13.9	12	13.8	10.5	14.9
Median follow-up (years)	2.1	3.8	2.1	3.2	1.6	5.4	1.3
Statin use (%)	98	72	73	74	84.0	66	85.2 (all lipid-lowering)
Metformin use (%)	66	76	73	77	73.6	81	77.4
Prior CVD/CHF (%)	100/22	81/18	60/24	73.1/16.2	100/20.2	32/9	84.7/12.2
Mean baseline A1C (%)	7.7	8.7	8.7	8.0	8.7	7.4	8.2
Mean difference in A1C between groups at end of treatment (%)	−0.3 [†]	−0.4 [†]	−0.7 or −1.0 [†]	−0.53	−0.52 [†]	−0.61 [†]	−0.7
Year started/reported	2010/2015	2010/2016	2013/2016	2010/2017	2015/2018	2011/2019	2017/2019
Primary outcome§	4-point MACE 1.02 (0.89–1.17)	3-point MACE 0.87 (0.78–0.97)	3-point MACE 0.74 (0.58–0.95)	3-point MACE 0.91 (0.83–1.00)	3-point MACE 0.78 (0.68–0.90)	3-point MACE 0.88 (0.79–0.99)	3-point MACE 0.79 (0.57–1.11)

Continued on p. S140

**Table 10.3B—
Cardiovascular
outcomes trials of
available
antihyperglycemic
medications
completed after the
issuance
of the FDA 2008
guidelines: GLP-1
receptor agonists (1
of 2)**
Cardiovascular
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2021. Diabetes Care
2021;44(Suppl.
1):S111-S150*

CARDIOVASCULAR DISEASE AND RISK MANAGEMENT

Table 10.3B—Continued

	ELIXA (183) (n = 6,068)	LEADER (178) (n = 9,340)	SUSTAIN-6 (179)* (n = 3,297)	EXSCEL (184) (n = 14,752)	Harmony Outcomes (181) (n = 9,463)	REWIND (182) (n = 9,901)	PIONEER-6 (180) (n = 3,183)
Key secondary outcome§	Expanded MACE (0.90–1.11)	Expanded MACE 0.88 (0.81–0.96)	Expanded MACE 0.74 (0.62–0.89)	Individual components of MACE (see below)	Expanded MACE (with urgent revascularization for unstable angina) 0.78 (0.69–0.90) CV death or HF hospitalization 0.85 (0.70–1.04) Individual components of MACE (see below)	Composite microvascular outcome (eye or renal outcome) 0.87 (0.79–0.95)	Expanded MACE or HF hospitalization 0.82 (0.61–1.10)
Cardiovascular death§	0.98 (0.78–1.22)	0.78 (0.66–0.93)	0.98 (0.65–1.48)	0.88 (0.76–1.02)	0.93 (0.73–1.19)	0.91 (0.78–1.06)	0.49 (0.27–0.92)
MI§	1.03 (0.87–1.22)	0.86 (0.73–1.00)	0.74 (0.51–1.08)	0.97 (0.85–1.10)	0.75 (0.61–0.90)	0.96 (0.79–1.15)	1.18 (0.73–1.90)
Stroke§	1.12 (0.79–1.58)	0.86 (0.71–1.06)	0.61 (0.38–0.99)	0.85 (0.70–1.03)	0.86 (0.66–1.14)	0.76 (0.61–0.95)	0.74 (0.35–1.57)
HF hospitalization§	0.96 (0.75–1.23)	0.87 (0.73–1.05)	1.11 (0.77–1.61)	0.94 (0.78–1.13)	—	0.93 (0.77–1.12)	0.86 (0.48–1.55)
Unstable angina hospitalization§	1.11 (0.47–2.62)	0.98 (0.76–1.26)	0.82 (0.47–1.44)	1.05 (0.94–1.18)	—	1.14 (0.84–1.54)	1.56 (0.60–4.01)
All-cause mortality§	0.94 (0.78–1.13)	0.85 (0.74–0.97)	1.05 (0.74–1.50)	0.86 (0.77–0.97)	0.95 (0.79–1.16)	0.90 (0.80–1.01)	0.51 (0.31–0.84)
Worsening nephropathy§	—	0.78 (0.67–0.92)	0.64 (0.46–0.88)	—	—	0.85 (0.77–0.93)	—

—, not assessed/reported; ACS, acute coronary syndrome; ASCVD, atherosclerotic cardiovascular disease; CHF, congestive heart failure; CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; GLP-1, glucagon-like peptide 1; HF, heart failure; MACE, major adverse cardiac event; MI, myocardial infarction. Data from this table was adapted from Cefalu et al. (203) in the January 2018 issue of *Diabetes Care*. *Powered to rule out a hazard ratio of 1.8; superiority hypothesis not prespecified. ††Age was reported as means in all trials; diabetes duration was reported as means in all trials except EXSCEL, which reported medians. †A1C change of 0.66% with 0.5 mg and 1.05% with 1 mg dose of semaglutide. §Outcomes reported as hazard ratio (95% CI). ||Worsening nephropathy is defined as the new onset of urine albumin-to-creatinine ratio > 300 mg/g creatinine or a doubling of the serum creatinine level and an estimated glomerular filtration rate of <45 mL/min/1.73 m², the need for continuous renal replacement therapy, or death from renal disease in LEADER and SUSTAIN-6 and as new macroalbuminuria, a sustained decline in estimated glomerular filtration rate of 30% or more from baseline, or chronic renal replacement therapy in REWIND. Worsening nephropathy was a prespecified exploratory adjudicated outcome in LEADER, SUSTAIN-6, and REWIND. Significant difference in A1C between groups (P < 0.05).

**Table 10.3B—
Cardiovascular
outcomes trials of
available
antihyperglycemic
medications
completed after the
issuance
of the FDA 2008
guidelines: GLP-1
receptor agonists (2
of 2)**
Cardiovascular
Disease and Risk
Management:
*Standards of Medical
Care in Diabetes -
2021. Diabetes Care
2021;44(Suppl.
1):S111-S150*

Table 10.3C—Cardiovascular and cardiovascular outcomes trials of available antihyperglycemic medications completed after the issuance of the FDA 2008 guidelines: SGLT2 inhibitors

	EMPA-REG OUTCOME (8) (n = 7,020)	CANVAS Program (9) (n = 10,142)	DECLARE-TIMI 58 (176) (n = 17,160)	CREDESCENCE (174) (n = 4,401)	DAPA-HF (177) (n = 4,744; 1,983 with diabetes)
Intervention	Empagliflozin/placebo	Canagliflozin/placebo	Dapagliflozin/placebo	Canagliflozin/ placebo	Dapagliflozin/ placebo
Main inclusion criteria	Type 2 diabetes and preexisting CVD	Type 2 diabetes and preexisting CVD at ≥30 years of age or >2 CV risk factors at ≥50 years of age	Type 2 diabetes and established ASCVD or multiple risk factors for ASCVD	Type 2 diabetes and albuminuric kidney disease	NYHA class II, III, or IV heart failure and an ejection fraction <40%, with or without diabetes
A1C inclusion criteria (%)	7.0–10.0	7.0–10.5	≥6.5	6.5–12	—
Age (years)††	63.1	63.3	64.0	63	66
Race (% White)	72.4	78.3	79.6	66.6	70.3
Sex (% male)	71.5	64.2	62.6	66.1	76.6
Diabetes duration (years)††	57% >10	13.5	11.0	15.8	N/A
Median follow-up (years)	3.1	3.6	4.2	2.6	1.5
Statin use (%)	77	75	75 (statin or ezetimibe use)	69	—
Metformin use (%)	74	77	82	57.8	51.2% (of patients with diabetes)
Prior CVD/CHF (%)	99/10	65.6/14.4	40/10	50.4/14.8	100% with CHF
Mean baseline A1C (%)	8.1	8.2	8.3	8.3	—
Mean difference in A1C between groups at end of treatment (%)	−0.3 [‡]	−0.58 [^]	−0.43 [^]	−0.31	N/A
Year started/ reported	2010/2015	2009/2017	2013/2018	2017/2019	2017/2019
Primary outcome§	3-point MACE 0.86 (0.74–0.99)	3-point MACE 0.86 (0.75–0.97)§	3-point MACE 0.93 (0.84–1.03) CV death or HF hospitalization 0.83 (0.73–0.95)	ESRD, doubling of creatinine, or death from renal or CV cause 0.70 (0.59–0.82)	Worsening heart failure or death from CV causes 0.74 (0.65–0.85) Results did not differ by diabetes status
Key secondary outcome§	4-point MACE 0.89 (0.78–1.01)	All-cause and CV mortality (see below)	Death from any cause 0.93 (0.82–1.04) Renal composite (≥40% decrease in eGFR rate to <60 mL/min/1.73 m ² , new ESRD, or death from renal or CV causes 0.76 (0.67–0.87)	CV death or HF hospitalization 0.69 (0.57–0.83) 3-point MACE 0.80 (0.67–0.95)	CV death or HF hospitalization 0.75 (0.65–0.85)
Cardiovascular death§	0.62 (0.49–0.77)	0.87 (0.72–1.06)	0.98 (0.82–1.17)	0.78 (0.61–1.00)	0.82 (0.69–0.98)
MI§	0.87 (0.70–1.09)	0.89 (0.73–1.09)	0.89 (0.77–1.01)	—	—
Stroke§	1.18 (0.89–1.56)	0.87 (0.69–1.09)	1.01 (0.84–1.21)	—	—
HF hospitalization§	0.65 (0.50–0.85)	0.67 (0.52–0.87)	0.73 (0.61–0.88)	0.61 (0.47–0.80)	0.70 (0.59–0.83)
Unstable angina hospitalization§	0.99 (0.74–1.34)	—	—	—	—
All-cause mortality§	0.68 (0.57–0.82)	0.87 (0.74–1.01)	0.93 (0.82–1.04)	0.83 (0.68–1.02)	0.83 (0.71–0.97)
Worsening nephropathy§	0.61 (0.53–0.70)	0.60 (0.47–0.77)	0.53 (0.43–0.66)	(See primary outcome)	0.71 (0.44–1.16)

—, not assessed/reported; CHF, congestive heart failure; CV, cardiovascular; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; HF, heart failure; MACE, major adverse cardiac event; MI, myocardial infarction; SGLT2, sodium–glucose cotransporter 2; NYHA, New York Heart Association. Data from this table was adapted from Cefalu et al. (2023) in the January 2018 issue of *Diabetes Care*. ††Age was reported as means in all trials; diabetes duration was reported as means in all trials except EMPA-REG OUTCOME, which reported as percentage of population with diabetes duration > 10 years, and DECLARE-TIMI 58, which reported median. ‡A1C change of 0.30 in EMPA-REG OUTCOME is based on pooled results for both doses (i.e., 0.24% for 10 mg and 0.36% for 25 mg of empagliflozin). §Outcomes reported as hazard ratio (95% CI). ||Definitions of worsening nephropathy differed between trials. ^Significant difference in A1C between groups (P < 0.05).

Table 10.3C— Cardiovascular outcomes trials of available antihyperglycemic medications completed after the issuance of the FDA 2008 guidelines: SGLT2 inhibitors

Disease and Risk
Management:
*Standards of Medical
Care in Diabetes -
2021. Diabetes Care
2021;44(Suppl.
1):S111-S150* | 27

Cardiovascular Disease and Risk Management (continued)

HYPERTENSION AND CORONARY ARTERY DISEASE.

ACE inhibitors or angiotensin receptor blockers as first line therapy for hypertension in people with diabetes and coronary artery disease has been added with additional discussion.



Older Adults

TREATMENT GOALS.

The reasonable A1C goal for older adults who are otherwise healthy with few coexisting chronic illnesses and intact cognitive function and functional status has been modified to A1C <7.0–7.5%

PHARMACOTHERAPY.

For very complex older patient in poor health- avoiding reliance on A1C and avoiding hypoglycemia and symptomatic hyperglycemia

Older Adults

HYPOGLYCEMIA.

New recommendation on the use of CGM for the reduction of hypoglycemia added based on findings from the Wireless Innovation in Seniors with Diabetes Mellitus (WISDM) trial.



Technology and Glycemic Assessment

- **Beyond A1C: Time in Range**
- **Importance of CGM**

Glycemic Targets

GLYCEMIC ASSESSMENT.

The “A1C” subsection was retitled “Glycemic Assessment” to include other forms of glycemic measurement

GLYCEMIC GOALS

Includes other glycemic measures and recommendation to include time-in-range goals.

TIME IN RANGE

AGP Report

Name _____

MRN _____

GLUCOSE STATISTICS AND TARGETS

**14 days
% Sensor Time**

Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

Average Glucose Glucose Management Indicator (GMI) Glucose Variability

Defined as percent coefficient of variation (%CV); target $\leq 36\%$

TIME IN RANGES

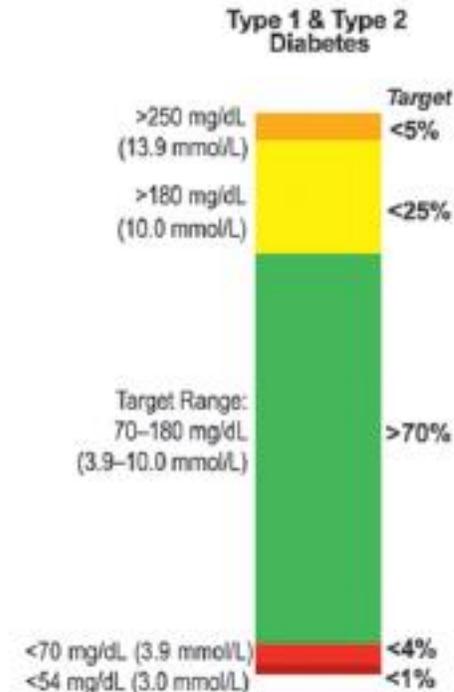


Figure 6.1—Key points included in standard ambulatory glucose profile (AGP) report. Adapted from Battelino et al. (26).

Time in Range

“**Time in range (TIR)** is associated with the risk of microvascular complications, should be an acceptable end point for clinical trials moving forward, and can be used for assessment of glycemic control

If using ambulatory glucose profile/glucose management indicator to assess glycemia,:

A parallel goal is a **time in range of >70%** with **time below range <4%**

Continuous Glucose Monitoring (CGM)

“Blinded” continuous glucose monitoring (CGM) is now referred to as “professional CGM,” which is clinic-based and can include blinded or real-time devices.

Recommend CGM as useful for people with diabetes on multiple daily injections and continuous subcutaneous insulin infusions and other forms of insulin therapy regardless of type of diabetes or age.

Can be helpful in identifying and correcting patterns of hyper- and hypoglycemia and improving A1C levels in people with diabetes on noninsulin regimens.

Diabetes Technology

SKIN REACTIONS.

Information on skin reactions with use of CGM has been added and a new discussion on education and training.

INSULIN PUMPS.

insulin pump use in older adults

TECHNOLOGY + ONLINE COACHING.

Noted the possible benefit of systems that combine technology and online coaching

Patient case: John

Patient case: John

- ✓ 74-year-old man with type 2 diabetes
- ✓ On basal-bolus insulin
- ✓ Hypertension
- ✓ Hyperlipidemia,
- ✓ Chronic kidney disease Stage 3 (i.e. eGFR 30-44, albuminuria 30-300 mg/g)
- ✓ Comes into clinic for a routine 3-month follow-up visit.



Patient case: John

- He presents with his daughter who is concerned that her father lives alone and has had two severe hypoglycemia episodes requiring **glucagon use** in the last year.
- He is testing blood glucose 4x/day with an average fingerstick glucose of 125 mg/dL with 18% of values < 70 mg/dL and an A1C of 6.1%.



Patient case: John

Which aspects of the patient's history would make you consider CGM therapy?

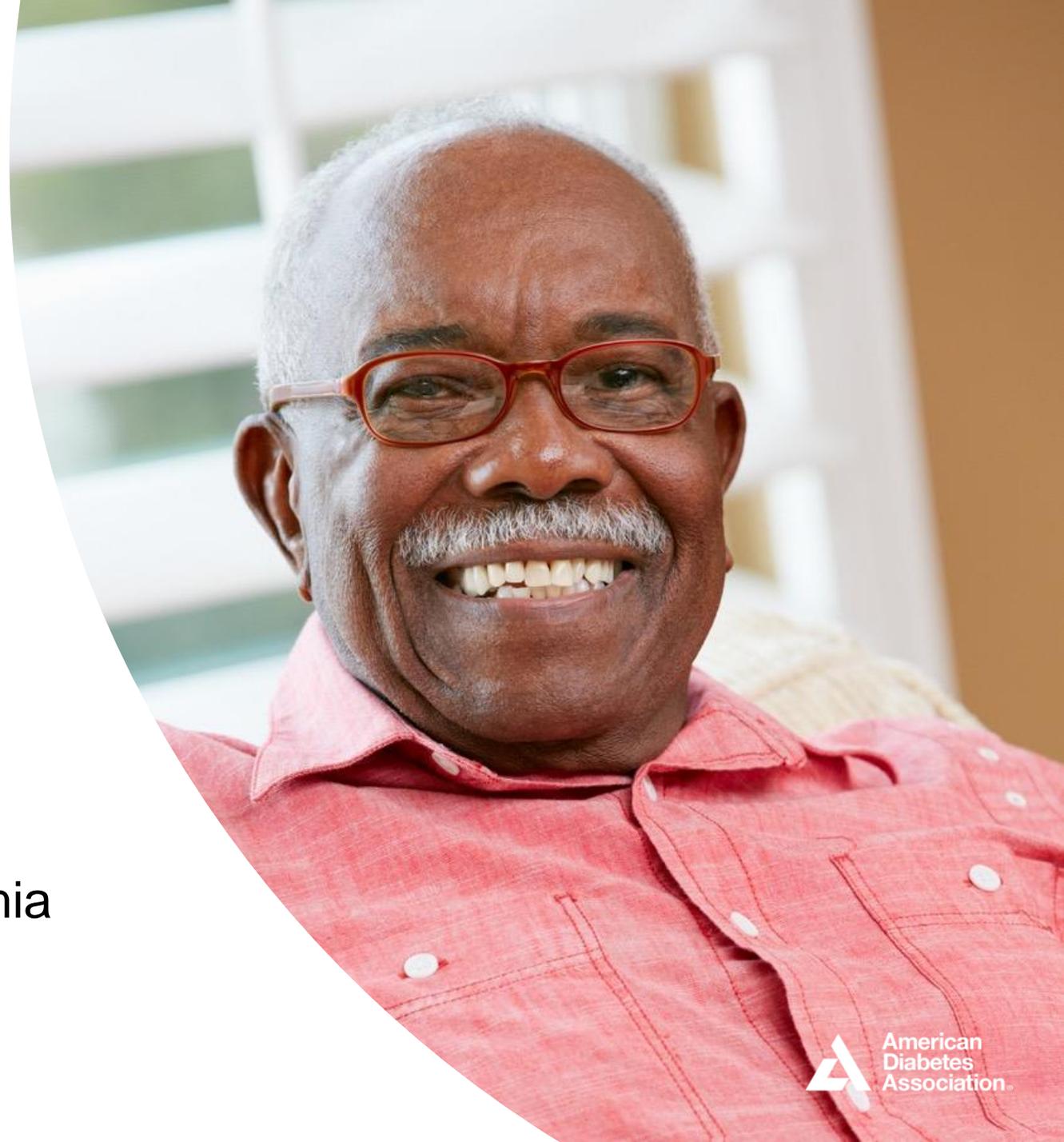
- A. Episodes of severe hypoglycemia requiring assistance from others
- B. 8% of readings in hypoglycemia range
- C. A1C 6.1%
- D. All of the above



Patient case: John

Answer: D, All of the above

- A1C Goal -- factors to consider:
- Support system
- Vascular complications
- Comorbidities
- Life expectancy
- Diabetes duration
- Risks associated with hypoglycemia



SOCIAL DETERMINANTS OF HEALTH.

SOCIAL DETERMINANTS OF HEALTH.

Additional information has been included on social determinants of health in diabetes to reflect the evidence presented in “Social Determinants of Health in Diabetes: a Scientific Review,”

COST-RELATED MEDICATION NONADHERENCE.

Added this concept

Tailoring Treatment for Social Context

- Assess food insecurity, housing insecurity/homelessness, financial barriers, and social capital/social community support and apply that information to treatment decisions.
- Refer patients to local community resources when available.
- Provide patients with self management support from lay health coaches, navigators, or community health workers when available.

Diabetes Self- management Education and Support

DSMES

Based on :

“Diabetes Self-management Education and Support in Adults With Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association,” published in June 2020.

Diabetes Self-management Education and Support

Four critical time points have been defined when the need for DSMES

1. At diagnosis
2. Annually and/or when not meeting treatment targets
3. When complicating factors (health conditions, physical limitations, emotional factors, or basic living needs) develop that influence self-management
4. When transitions in life and care occur

BRING IT ALL TOGETHER

Section 1.

Improving Care and Promoting Health in Populations

Chronic Care Model

The Chronic Care Model includes six core elements to optimize the care of patients with chronic disease

1. Delivery system design (moving from a *reactive* to a *proactive* care delivery system where planned visits are coordinated through a team-based approach)
2. Self-management support
3. Decision support (basing care on evidence-based, effective care guidelines)
4. Clinical information systems (using registries that can provide patient-specific and population-based support to the care team)
5. Community resources and policies (identifying or developing resources to support healthy lifestyles)
6. Health systems (to create a quality-oriented culture)

Diabetes and Population Health.

1.1 Ensure treatment decisions are timely, rely on evidence-based guidelines, and are made collaboratively with patients based on individual preferences, prognoses, and comorbidities. **B**

1.2 Align approaches to diabetes management with the Chronic Care Model. This model emphasizes person-centered team care, integrated long-term treatment approaches to diabetes and comorbidities, and ongoing collaborative communication and goal setting between all team members. **A**

1.3 Care systems should facilitate team-based care and utilization of patient registries, decision support tools, and community involvement to meet patient needs. **B**



3 Major Themes

1. Individualize Care

- High-risk or established ASCVD, CKD, or HF

2. Glycemic Assessment and Technology

- Time in Range, CGM

3. Social Determinants of Health

- Assess and Refer

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

Professional.Diabetes.org/SOC

February Webinar

- **Date/Time:** February 18, 2021 from 2-3 pm Eastern
- **Topic:** Together 2 Goal[®] Group Success Stories
- **Presenter:** Kristine Mendez (Scripps Health – Scripps Medical Foundation)



Questions

