Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus

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Disclosure

- Angel L Comulada, MD, FACE, CCD
  - Has received honorarium as Speaker &/or Consultant for the following Pharmaceutical Companies: Abbott, AstraZeneca, Daichi-Sankyo, GSK, Lilly, MSD, Novartis, Novo Nordisk, Pfizer Roche, Sanofi-Aventis, Shering Plough
  - Has received Grants &/or has contractual relationship as Principal Investigator for the following Pharmaceutical Companies: Abbott, AstraZeneca, BMS, Lilly, MSD, Novo Nordisk, Pfizer, Roche & Sanofi-Pasteur
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Disclosure:

No Conflicts of Interest to Disclose

This presentation is intended for educational purposes only and does not replace independent professional judgment.

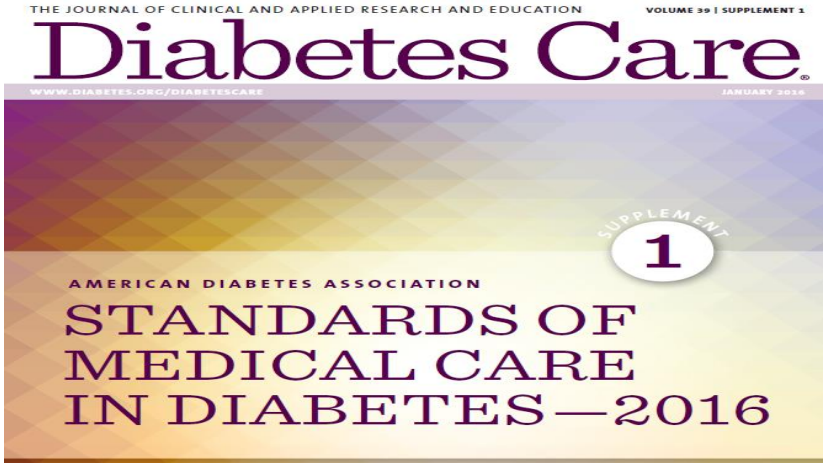
I am expressing my own views based on my reading, analysis and interpretation of the scientific information.

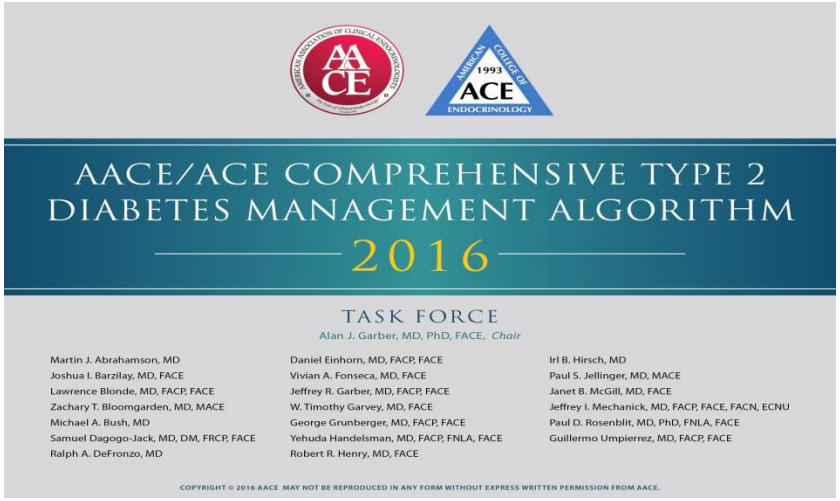
I am a member of SPED but I am **not** speaking in representation of, or presenting the views of the "Sociedad Puertorriqueña de Endocrinología y Diabetología", other Professional Societies, Public or Private Corporation, or Pharmaceutical Company.

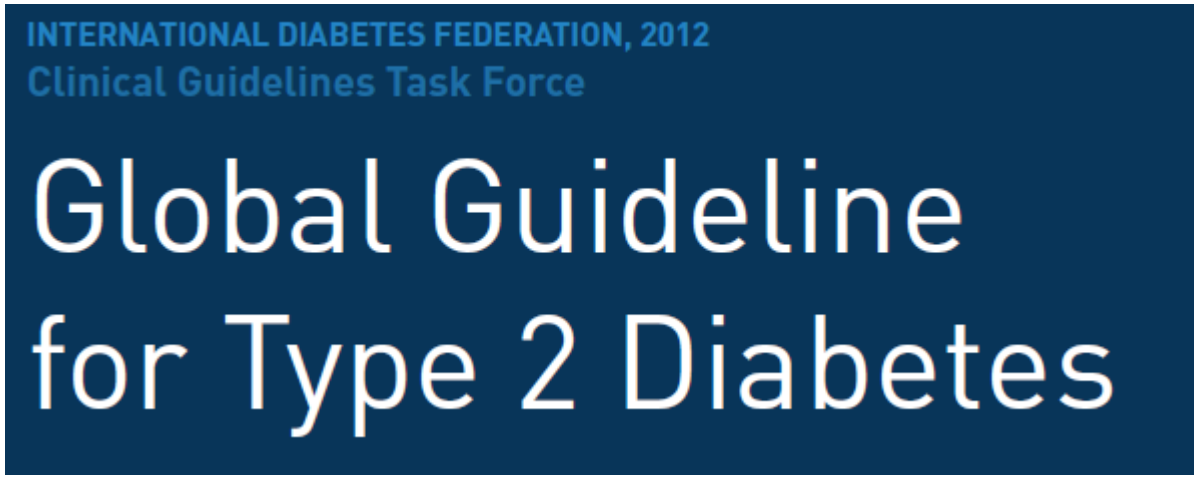
Objectives:

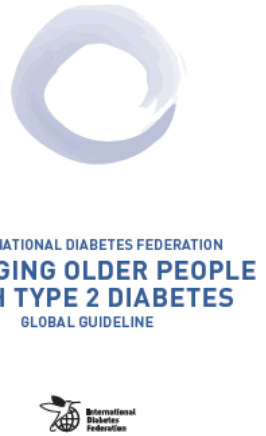
- Review the Guidelines in the Management of Diabetes:
  - ADA
  - AACE
  - IDF
- Contrast difference and similarities between guidelines
- Summarize harmonization between different guidelines

Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus



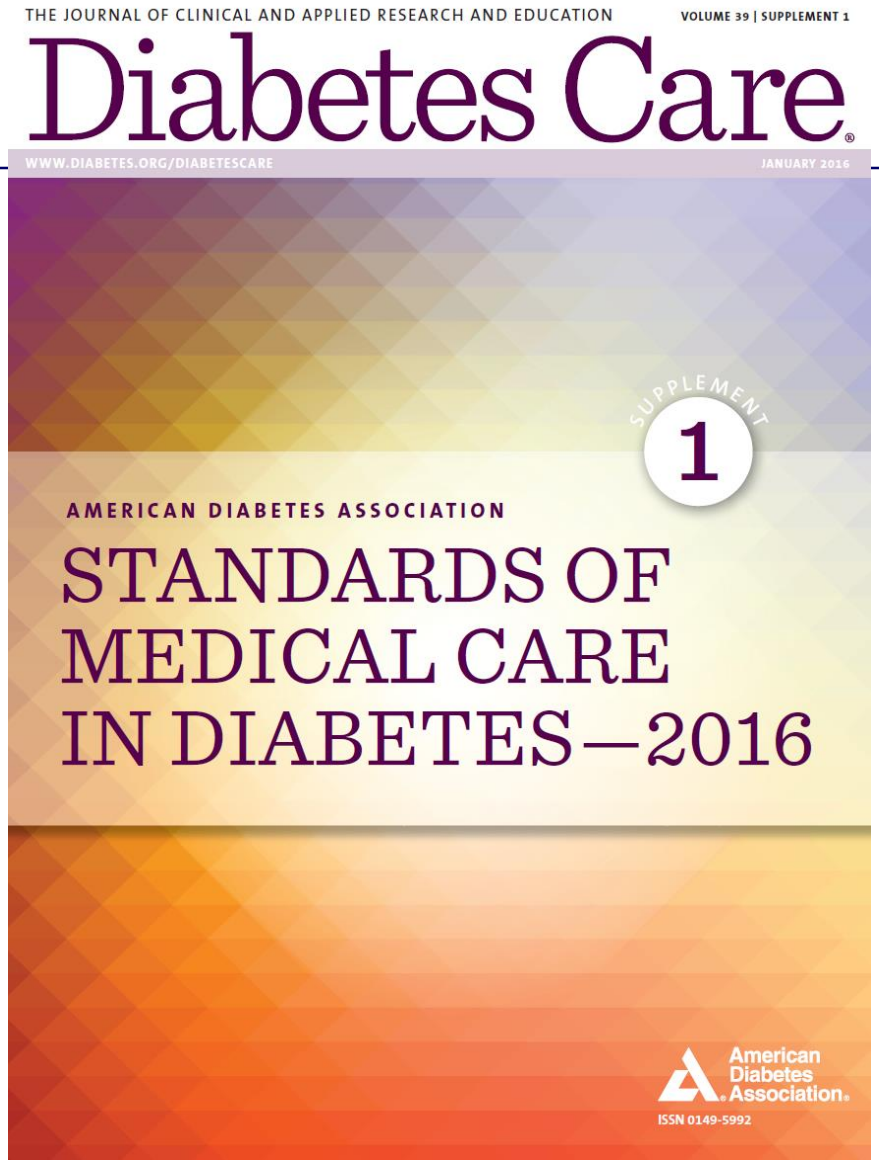






Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus

- Review of Guidelines:
  - Diagnosis
  - Care delivery
  - Glycemic Target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Diabetes Care
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SUPPLEMENT
1
AMERICAN DIABETES ASSOCIATION
STANDARDS OF MEDICAL CARE IN DIABETES—2016
American Diabetes Association.
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Table 1—ADA evidence-grading system for "Standards of Medical Care in Diabetes"

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

ADA 2016 Guidelines

Criteria for Type 2 Diabetes Diagnosis

FPG ≥126 mg/dL (7.0 mmol/L)*
Fasting defined as no caloric intake for ≥8 hrs

OR

2-hr PG ≥200 mg/dL (11.1 mmol/L) during OGTT (75-g)*
Using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water

OR

A1C ≥6.5% (48 mmol/mol)*
Perform in lab using NGSP-certified method and standardized to DCCT assay

OR

Random PG ≥200 mg/dL (11.1 mmol/L)
In persons with symptoms of hyperglycemia or hyperglycemic crisis

- No clear clinical diagnosis? Immediately repeat same test using new blood sample.
- Same test with same or similar results? Diagnosis confirmed.
- Different tests above diagnostic threshold? Diagnosis confirmed.
- Discordant results from 2 tests? Repeat test with result above diagnostic cutpoint.

*In absence of unequivocal hyperglycemia, result to be confirmed by repeat testing
FPG=fasting plasma glucose; OGTT=oral glucose tolerance test; PG=plasma glucose

American Diabetes Association.
Diabetes Care. 2016;39(suppl 1):S1-S106.

Screening for Type 2 Diabetes & Prediabetes in Asymptomatic Individuals

- Type 2 diabetes testing
  - Adults of any age who are overweight or obese* and who have ≥1 diabetes risk factor
  - Begin testing at age 45
  - Normal test? Repeat at ≥3-year intervals
- Prediabetes testing
  - A1C, FPG, or 2-h PG after 75-g OGTT
  - Identify & treat other CVD risk factors
  - Consider testing in children and adolescents who are overweight or obese and have ≥2 diabetes risk factors

Diabetes Risk Factors

- Physical inactivity
- First-degree relative with diabetes†
- High-risk race/ethnicity
- Women who delivered a baby >9 lb or prior GDM diagnosis
- HDL-C <35 mg/dL ± TG >250 mg/dL
- A1C ≥5.7%, IGT, or IFG
- Hypertension (≥140/90 or on treatment)
- CVD history
- Conditions associated with insulin resistance‡

*BMI ±25 kg/m^2 or ≥23 kg/m^2 for Asian Americans
†African-American, Latino, Native American, Asian American, Pacific Islander
‡Severe obesity, acanthosis nigricans, polycystic ovarian syndrome

American Diabetes Association. *Diabetes Care.* 2016;39(suppl 1):S1-S106.

Categories of Increased Risk for Type 2 Diabetes (Prediabetes)

FPG	2-hr PG*	A1C
100-125 mg/dL 5.6-6.9 mmol/L Impaired fasting glucose (IFG)	140-199 mg/dL 7.8-11.0 mmol/L Impaired glucose tolerance (IGT)	5.7-6.4% 39-46 mmol/mol

Risk is continuous, extending below lower limit of range and becoming disproportionately greater at higher ends of range

*In 75-g OGTT
FPG=fasting plasma glucose; OGTT=oral glucose tolerance test; PG=plasma glucose

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Screening for Type 1 Diabetes

Immune-mediated diabetes	➢ Previously "insulin-dependent diabetes" or "juvenile-onset diabetes" ➢ Cellular-mediated autoimmune destruction of beta-cells
Idiopathic type 1 diabetes	➢ Cause largely unknown ➢ No evidence of beta-cell autoimmunity

Blood glucose preferred over A1C to diagnose acute onset of type 1 diabetes with symptoms of hyperglycemia

Inform relatives of individuals with type 1 diabetes of the opportunity to be tested

➢ Testing to occur only in setting of a clinical research study

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Strategies for Diagnosing Gestational Diabetes Mellitus (GDM)

Screening at 24-48 wks in women not previously diagnosed with overt diabetes	
One-step diagnosis strategy	**Two-step diagnosis strategy**
• Perform 75-g OGTT with plasma glucose measurement • Test in the morning after the patient has fasted for ≥8 hrs • Repeat test at 1 and 2 hours after initial measurement	Step 1: • Perform a 50-g nonfasting GLT with plasma measurement at 1 hr • If PG measured 1 hr after the load is ≥140 mg/dL (7.8 mmol/L), proceed to 100-g OGTT
Diagnosis when PG levels meet or exceed: • Fasting 92 mg/dL (5.1 mmol/L) • 1 hr: 180 mg/dL (10.0 mmol/L) • 2 hr: 153 mg/dL (8.5 mmol/L)	Step 2: • Perform 100-g OGTT while patient is fasting Diagnosis when ≥2 PG levels meet or exceed: • Fasting: 95 mg/dL or 105 mg/dL (5.3/5.8) • 1 hr: 180 mg/dL or 190 mg/dL (10.0/10.6) • 2 hr: 155 mg/dL or 165 mg/dL (8.6/9.2) • 3 hr: 140 mg/dL or 145 mg/dL (7.8/8.0)

GDM=gestational diabetes mellitus; GLT=glucose load test; OGTT=oral glucose tolerance test

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Screening Children for Type 2 Diabetes and Prediabetes

Consider for all children who are overweight* and have ≥2 of any of the following risk factors:

- Family history of type 2 diabetes in first- or second-degree relative
- Native American, African American, Latino, Asian American or Pacific Islander
- Signs of insulin resistance or conditions associated with insulin resistance†
- Maternal history of diabetes or GDM during child's gestation

Test every 3 yrs using A1C beginning at age 10 or puberty onset

Children: age ≤18 yrs
*BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% ideal for height
†Acanthosis nigricans, hypertension, dyslipidemia, polycystic ovarian syndrome, or small-for-gestational-age birth weight
BMI=body mass index; GDM=gestational diabetes mellitus

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Common Comorbidities Associated With Diabetes

Assess & address comorbidities that may complicate diabetes management:

- Cancer*: liver, pancreas, bladder, endometrium, breast, colon
- Cognitive impairment
- Depression
- Dyslipidemia
- Fatty liver disease
- Fractures
- Hearing impairment
- Heart failure
- Hypertension
- Low testosterone (men)
- Obesity
- Obstructive sleep apnea
- Periodontal disease

*Possibly only associated with type 2 diabetes

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Diabetes Self-Management Education and Support

At diagnosis and ongoing thereafter, all individuals with diabetes should participate in

DSME:

- Facilitate knowledge, skills, and ability for self care

DSMS:

- Assist with implementing and sustaining skills and behaviors for ongoing self-management

Measure and monitor effectiveness of self-management and quality of life as part of overall care

DSME and DSMS programs should include the necessary elements in their curricula that are needed to prevent diabetes onset

DSME=diabetes self-management education;
DSMS=diabetes self-management support

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Medical Nutrition Therapy Recommendations

No one-size-fits-all eating pattern

Medical nutrition therapy recommended for all individuals with diabetes

- Preferably provided by a registered dietitian skilled in diabetes MNT

Goals:

- Healthful eating pattern to improve overall health, specifically:
  - Achievement and maintenance of weight goals
  - Attainment of individualized glycemic, BP, lipid goals
  - Type 2 diabetes prevention or delay
- Attain individualized glycemic, BP, lipid goals
- Achieve and maintain body weight goals
- Delay or prevent diabetes complications

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Physical Activity Recommendations

Adults with diabetes

Physical activity recommendations

- ≥150 min/wk moderate-intensity aerobic activity (50%–70% max heart rate), spread over ≥3 days/wk with no more than 2 consecutive days without exercise
- Resistance training ≥2 times/wk (in absence of contraindications)*
- Reduce sedentary time: break up >90 mins spent sitting

Evaluate patients for contraindications prohibiting certain types of exercise before recommending exercise program†

Consider age and previous level of physical activity

Children with diabetes, prediabetes

Physical activity recommendations

- ≥60 min physical activity/day

*Adults with type 2 diabetes
†Eg, uncontrolled hypertension, severe autonomic or peripheral neuropathy, history of foot lesions, unstable proliferative retinopathy

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Physical Activity in Individuals With Hypoglycemia

Hypoglycemia

If taking insulin and/or insulin secretagogues, physical activity can cause hypoglycemia if medication dose or carb consumption is not altered

Added carbohydrate should be ingested when pre-exercise glucose <100 mg/dL (5.6 mmol/L)

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

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Physical Activity in Individuals With Diabetes Complications

Retinopathy

- Proliferative diabetic retinopathy or severe nonproliferative diabetic retinopathy
- Vigorous aerobic or resistance exercise may be contraindicated

Autonomic Neuropathy

- Can increase risk for exercise-induced injury
- All individuals with autonomic neuropathy should undergo cardiac investigation before beginning more-intense-than usual physical activity

Peripheral Neuropathy

- Decreased pain sensation and a higher pain threshold in the extremities cause increased risk of skin breakdown and infection
- All individuals with neuropathy should wear proper footwear and examine feet daily for leasions
- Foot injury or open sore: restricted to non–weight-bearing activity

Albuminuria and Nephropathy

- Physical activity can acutely increase urinary protein excretion
- No evidence that vigorous-intensity exercises increases diabetic kidney disease progression
- No restrictions needed for individuals with diabetic kidney disease

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Smoking Cessation

Advise patients with diabetes not to use cigarettes, other tobacco products, or e-cigarettes

Counsel on smoking prevention and cessation as part of routine care

Assess level of nicotine dependence

- Associated with level of nicotine dependence

Offer pharmacologic therapy as appropriate

- Adding pharmacologic therapy to counseling more effective than either treatment alone

Some individuals may gain weight post-cessation

- Weight gain does not diminish substantial CVD benefit from smoking cessation

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Psychosocial Assessment and Care

Include psychological & social assessments as part of diabetes management

Psychosocial screening and follow-up may include:

- Attitudes about diabetes
- Expectations for medical management and outcomes
- Mood
- Quality of life
- Financial, social, emotional resources
- Psychiatric history

Screen for and treat depression in older adults (≥65 yrs) with diabetes

Routinely screen for depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment

Stepwise collaborative care approach to manage depression for patients with comorbidities

Refer to mental health professional

Disregard for medical regimen • Depression • Self-harm potential • Stress • Debilitating anxiety • Eating disorder • Cognitive function signaling impaired judgment

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Immunization Recommendations

Provide routine vaccinations for children and adults with diabetes according to age-related recommendations

Influenza vaccine	Annually in all patients with diabetes aged ≥6 mos
Pneumococcal polysaccharide vaccine 23 (PPSV23)	➢ All patients with diabetes aged ≥2 yrs ➢ Routinely in patients with diabetes aged ≥65 yrs
Pneumococcal conjugate vaccine 13 (PCV13)	➢ Routinely in patients with diabetes aged ≥65 yrs
Hepatitis B vaccine	➢ All adults with diabetes

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Recommendations for Preventing or Delaying Type 2 Diabetes

Individuals with prediabetes: IGT, IFG, or A1C 5.7%-6.4%	Refer to intensive diet & physical activity behavior counseling program targeting • Weight loss (7% of body weight) • Increased physical activity (≥150 min/week moderate activity)
Consider metformin therapy for type 2 diabetes prevention in individuals with prediabetes	Especially in presence of • BMI >35 kg/m^2 • Age <60 years • Women with prior GDM

At least annual monitoring of individuals with prediabetes

Screen for and treat modifiable CVD risk factors: obesity, hypertension, dyslipidemia

DSME & DSMS appropriate for prediabetes to receive education and support for diabetes prevention or delay

Metformin is not FDA approved in the United States for type 2 diabetes prevention

CVD=cardiovascular disease; GDM=gestational diabetes mellitus; IFG=impaired fasting glucose; IGT=impaired glucose tolerance

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Self-Monitoring of Blood Glucose (SMBG)

Encourage for patients receiving multiple dose insulin or insulin pump therapy to perform SMBG:

- Prior to meals and snacks
- Occasionally postprandially
- At bedtime
- Prior to exercise
- When low blood glucose is suspected
- After treating low blood glucose until normoglycemic
- Prior to critical tasks (eg, driving)

Results may be useful for guiding treatment and/or self-management for patients using less frequent insulin injections or noninsulin therapies

- Provide ongoing instruction and regular evaluation of SMBG technique, results, and patient's ability to use data to adjust therapy

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Continuous Glucose Monitoring (CGM)

Useful for A1C lowering in select adults (aged ≥25 yrs) with type 1 diabetes requiring intensive insulin regimens	• May be useful among children, teens, and younger adults* • Success related with adherence to ongoing use
May be a useful supplement to SMBG among patients with	• Hypoglycemia unawareness and/or • Frequent hypoglycemic episodes
Variable adherence to CGM	• Assess individual readiness for continuing CGM prior to prescribing • Robust diabetes education, training, support critical for optimal CGM implementation

*Evidence for A1C lowering less strong in these populations
SMBG=self-monitoring of blood glucose

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Frequency of A1C Testing

- A1C reflects average glycemia over several months
- Strong predictive value for diabetes complications

Perform A1C test

At least 2 times each year in individuals who are meeting treatment targets and have stable glycemic control

Quarterly in individuals whose therapy has changed or who are not meeting glycemic targets

Point-of-care A1C testing allows for more timely treatment changes

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Glycemic Targets for Nonpregnant Adults With Diabetes

A1C	<7.0% (53 mmol/mol)
Preprandial capillary PG	80-130 mg/dL (4.4-7.2 mmol/L)
Peak postprandial capillary PG	<180 mg/dL (10.0 mmol/L)*

More or less stringent targets may be appropriate for individual patients if achieved without significant hypoglycemia or adverse events

Individualize targets based on:

- Age/life expectancy
- Comorbid conditions
- Diabetes duration
- Hypoglycemia status
- Individual patient considerations
- Known CVD/advanced microvascular complications

*Postprandial glucose measurements should be made 1-2 h after the beginning of the meal
CVD=cardiovascular disease; PG=plasma glucose

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

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Individualization of Glycemic Targets for Adults With Diabetes

Lowering A1C below or around 7.0% shown to reduce

- Microvascular complications
- Macrovascular disease*
- Mortality (individuals with type 1 diabetes)

More or less stringent targets may be appropriate for individuals if achieved without significant hypoglycemia or adverse events

More stringent (<6.5%)

- Short diabetes duration
- Long life expectancy
- Type 2 diabetes treated with lifestyle or metformin only
- No significant CVD/vascular complications

Less stringent (<8%)

- Severe hypoglycemia history
- Limited life expectancy
- Advanced microvascular or macrovascular complications
- Extensive comorbidities
- Long-term diabetes in whom general A1C target difficult to attain

*If implemented soon after diagnosis
CVD=cardiovascular disease

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

Management of Hypoglycemia

Ask at-risk patients about symptomatic and asymptomatic hypoglycemia at each encounter

Glucose (15-20 g)* is the preferred treatment for the conscious patient with hypoglycemia

- 15 mins after treatment, repeat if SMBG shows continued hypoglycemia
- When SMBG normal: patient should consume meal or snack to prevent recurrence

Prescribe glucagon for all individuals at risk of severe hypoglycemia

Hypoglycemia unawareness or episode of severe hypoglycemia

- Reevaluate treatment regimen
- Insulin-treated patients: raise glycemic targets for several weeks to partially reverse hypoglycemia unawareness and reduce recurrence

Individuals with low or declining cognition

- Continually assess cognitive function with increased vigilance for hypoglycemia

*Any form of carbohydrate containing glucose may be used
SMBG=self-monitoring of blood glucose

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Pharmacologic Therapy for Type 1 Diabetes Management

Insulin treatment is the mainstay for individuals with type 1 diabetes

- Treat with multiple-dose insulin injections* or continuous subcutaneous insulin infusion (CSII)
- Match prandial insulin to carbohydrate intake, premeal glucose, and anticipated physical activity
- Use insulin analogs to reduce risk of hypoglycemia
- Consider using sensor-augmented low glucose suspend threshold pump in patients with frequent nocturnal hypoglycemia and/or hypoglycemia unawareness

Non-insulin agents	Investigational agents†
Pramlinitide (amylin analog) • Delays gastric emptying • Blunts pancreatic secretion of glucagon • Enhances satiety • Induces weight loss • Lowers insulin dose • Use only in adults	Metformin + insulin • May reduce insulin requirements & improve metabolic control in obese/ overweight with poor glycemic control Incretins • GLP-1 receptor agonists • DPP-4 inhibitors • SGLT2 inhibitors

*3-4 injections/day of basal and prandial insulin)
†Not FDA approved for the treatment of type 1 diabetes in the United States

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Pharmacologic Therapy for Type 2 Diabetes Management

Most patients should begin with **lifestyle changes**

Metformin*: preferred initial therapy when lifestyle changes alone have not achieved or maintained glycemic goals

Consider insulin therapy with or without other agents

At outset in newly diagnosed patients with markedly symptomatic and/or elevated blood glucose levels or A1C

Add 2nd oral agent, GLP-1 receptor agonist, or basal insulin

If noninsulin monotherapy at maximal tolerated dose does not achieve or maintain A1C target over 3 mos

Choice of pharmacologic therapy based on patient-centered approach	
Consider	Efficacy • Cost • Potential side effects • Effects on weight • Comorbidities • Hypoglycemia risk • Patient preferences
Insulin eventually needed for many patients due to progressive nature of type 2 diabetes; insulin therapy should not be delayed	

*If tolerated and not contraindicated

American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Recommendations for Antihyperglycemic Therapy in Type 2 Diabetes

Lifestyle changes: healthy eating, weight control, increased physical activity, diabetes education

Monotherapy

- Metformin

If A1C target not achieved after 3 months of monotherapy, proceed to:

Dual therapy*

- Metformin + Sulfonylurea
- Metformin + TZD
- Metformin + GLP-1 RA
- Metformin + DPP-4 inhibitor
- Metformin + SGLT2 inhibitor
- Metformin + Insulin (basal)

If A1C target not achieved after 3 months of dual therapy, proceed to:

Triple therapy

- Metformin + **SU +** TZD *or* DPP-4 *or* GLP-1 *or* insulin‡
- Metformin + **TZD +** SU *or* DPP-4 *or* GLP-1 *or* insulin‡
- Metformin + **GLP-1 RA +** SU *or* TZD *or* insulin‡
- Metformin + **DPP-4 inhibitor +** SU *or* TZD *or* insulin‡
- Metformin + **SGLT2 +** SU *or* DPP-4 *or* TZD *or* Insulin‡
- Metformin + **Insulin (basal) +** TZD *or* DPP-4 *or* GLP-1

If A1C target not achieved after 3 months of triple therapy and patient (1) on oral combination, move to injectables; (2) on GLP-1, add basal insulin; or (3) on optimally titrated basal insulin, add GLP-1 or mealtime insulin. Refractory patients: consider adding TZD or SGLT2.

Combination injectable therapy†

- MET + Basal insulin + Mealtime insulin *or* GLP-1

*Consider initial therapy at this stage with A1C ≥9.0%; †Consider initial therapy at this stage with PG ≥300-350 mg/dL and/or A1C ≥10-12%; ‡Usually a basal insulin

Inzucchi SE et al. *Diabetes Care*. 2015;38(1):140-149.
American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

ADA 2016 Guidelines

Strategies for Insulin Use in Type 2 Diabetes

Number of injections & regimen complexity

1 (Low)

2 (Moderate)

3+ (High)

Basal insulin
(usually with metformin ± other oral agents)

- Start at 10 U/day or 0.1-0.2 U/kg/day
- Adjust 10-15% or 2-4 U once-twice weekly to reach FBG target
- For hypoglycemia, decrease dose by 4 U or 10-20%

Not controlled after FBG target reached or if dose >0.5 U/kg/day?

Add 1 rapid insulin injection before largest meal

- Start at 4 U, 0.1 U/kg, or 10% basal dose. If A1C <8%, decrease basal dose by same amount
- Increase dose by 1-2 U or 10-15% once-twice weekly until SMBG target reached
- For hypoglycemia, decrease corresponding dose by 2-4 U or 10-20%

Change to premixed insulin twice daily

- Divide current basal dose in 2/3 AM, 1/3 PM, or 1/2 AM, 1/2 PM
- Increase dose by 1-2 U or 10-15% once-twice weekly until SMBG target reached
- For hypoglycemia, decrease dose by 2-4 U or 10-20%

Not controlled? Consider basal-bolus →

Add ≥2 rapid insulin injections before meals (basal-bolus)

← Not controlled? Consider basal-bolus

- Start at 4 U, 0.1 U/kg, or 10% basal dose per meal. If A1C <8%, decrease basal dose by same amount
- Increase dose by 1-2 U or 10-15% once-twice weekly until SMBG target reached
- For hypoglycemia, decrease corresponding dose by 2-4U or 10-20%

More flexible regimen → Less flexible regimen

Inzucchi SE et al. *Diabetes Care*. 2015;38(1):140-149.
American Diabetes Association. *Diabetes Care*. 2016;39(suppl 1):S1-S106.

AMERICAN DIABETES ASSOCIATION
SUPPLEMENT 1
STANDARDS OF MEDICAL CARE IN DIABETES—2016

Recommendations

- A patient-centered communication style that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care should be used. **B**
- Treatment decisions should be timely and based on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities. **B**
- Care should be aligned with components of the Chronic Care Model to ensure productive interactions between a prepared proactive practice team and an informed activated patient. **A**
- When feasible, care systems should support team-based care, community involvement, patient registries, and decision support tools to meet patient needs. **B**

AACE/ACE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM

2016

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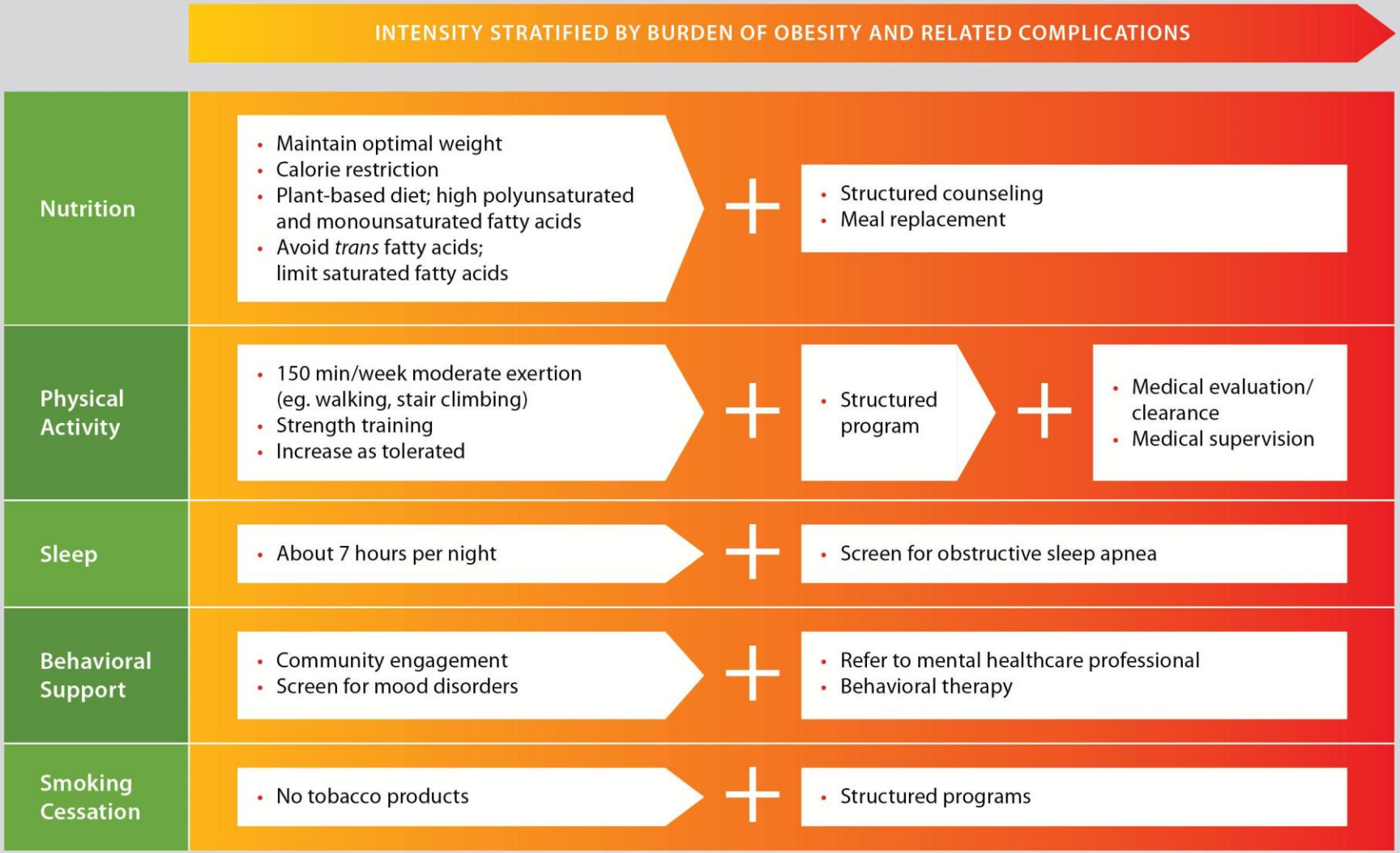
Comprehensive Type 2 Diabetes Algorithm

LIFESTYLE THERAPY

RISK STRATIFICATION FOR DIABETES COMPLICATIONS



COMPLICATIONS-CENTRIC MODEL FOR CARE OF THE OVERWEIGHT/OBESE PATIENT

STEP 1 — EVALUATION FOR COMPLICATIONS AND STAGING

CARDIOMETABOLIC DISEASE | BIOMECHANICAL COMPLICATIONS

NO COMPLICATIONS	COMPLICATIONS	
BMI ≥25	BMI 25–26.9	BMI ≥ 27: Stage Severity of Complications
		MILD TO MODERATE / SEVERE

STEP 2 — SELECT: Therapeutic targets for improvement in complications + Treatment modality + Treatment intensity based on staging

Lifestyle Therapy:	Physician/RD counseling, web/remote program, structured multidisciplinary program
Medical Therapy (BMI ≥ 27):	Phentermine, orlistat, lorcaserin, phentermine/topiramate ER, naltrexone/bupropion, liraglutide 3 mg
Surgical Therapy (BMI ≥ 35):	Gastric banding, sleeve, or bypass

STEP 3 — If therapeutic targets for complications not met, intensify lifestyle, medical, and/or surgical treatment modalities for greater weight loss.

PREDIABETES ALGORITHM

IFG (100–125) | IGT (140–199) | METABOLIC SYNDROME (NCEP 2001)

LIFESTYLE THERAPY
(Including Medically Assisted Weight Loss)

TREAT ASCVD RISK FACTORS

WEIGHT LOSS THERAPIES

TREAT HYPERGLYCEMIA
FPG > 100 | 2-hour PG > 140

ASCVD RISK FACTOR MODIFICATIONS ALGORITHM

- DYSLIPIDEMIA ROUTE
- HYPERTENSION ROUTE

NORMAL GLYCEMIA

Progression

OVERT DIABETES

PROCEED TO HYPERGLYCEMIA ALGORITHM

1 PRE-DM CRITERION

- Intensify Weight Loss Therapies

MULTIPLE PRE-DM CRITERIA

- Low-risk Medications
  - Metformin
  - Acarbose
- Consider with Caution
  - TZD
  - GLP-1 RA

If glycemia not normalized

LEGEND

Orlistat, lorcaserin, phentermine/topiramate ER, naltrexone/bupropion, liraglutide 3 mg, or bariatric surgery as indicated for obesity treatment

GOALS FOR GLYCEMIC CONTROL

INDIVIDUALIZE GOALS

A1C ≤ 6.5%

For patients without concurrent serious illness and at low hypoglycemic risk

A1C > 6.5%

For patients with concurrent serious illness and at risk for hypoglycemia

GLYCEMIC CONTROL ALGORITHM

LIFESTYLE THERAPY
(Including Medically Assisted Weight Loss)

Entry A1C < 7.5%

MONOTHERAPY*

- ✓ Metformin
- ✓ GLP-1 RA
- ✓ SGLT-2i
- ✓ DPP-4i
- ! TZD
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to Dual Therapy

Entry A1C ≥ 7.5%

DUAL THERAPY*

MET or other 1st-line agent +

- ✓ GLP-1 RA
- ✓ SGLT-2i
- ✓ DPP-4i
- ! TZD
- ! Basal Insulin
- ✓ Colesevelam
- ✓ Bromocriptine QR
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to Triple Therapy

TRIPLE THERAPY*

MET or other 1st-line agent + 2nd-line agent +

- ✓ GLP-1 RA
- ✓ SGLT-2i
- ! TZD
- ! Basal insulin
- ✓ DPP-4i
- ✓ Colesevelam
- ✓ Bromocriptine QR
- ✓ AGi
- ! SU/GLN

If not at goal in 3 months proceed to or intensify insulin therapy

Entry A1C > 9.0%

SYMPTOMS

NO	YES
DUAL Therapy OR TRIPLE Therapy	INSULIN ± Other Agents

ADD OR INTENSIFY INSULIN

Refer to Insulin Algorithm

LEGEND

- ✓ Few adverse events and/or possible benefits
- ! Use with caution

* Order of medications represents a suggested hierarchy of usage; length of line reflects strength of recommendation

PROGRESSION OF DISEASE

ALGORITHM FOR ADDING/INTENSIFYING INSULIN

START BASAL (Long-Acting Insulin)

A1C < 8%

TDD 0.1–0.2 U/kg

A1C > 8%

TDD 0.2–0.3 U/kg

Insulin titration every 2–3 days to reach glycemic goal:

- Fixed regimen: Increase TDD by 2 U
- Adjustable regimen:
  - **FBG** > 180 mg/dL: add 20% of TDD
  - **FBG** 140–180 mg/dL: add 10% of TDD
  - **FBG** 110–139 mg/dL: add 1 unit
- If hypoglycemia, reduce TDD by:
  - **BG** < 70 mg/dL: 10% – 20%
  - **BG** < 40 mg/dL: 20% – 40%

Consider discontinuing or reducing sulfonylurea after starting basal insulin (basal analogs preferred to NPH)

***Glycemic Goal:**

- <7% for most patients with T2D; fasting and premeal BG < 110 mg/dL; absence of hypoglycemia
- A1C and FBG targets may be adjusted based on patient's age, duration of diabetes, presence of comorbidities, diabetic complications, and hypoglycemia risk

Glycemic Control Not at Goal*

INTENSIFY (Prandial Control)

Add GLP-1 RA

Or SGLT-2i
Or DPP-4i

Add Prandial Insulin

Basal Plus 1, Plus 2, Plus 3

- Begin prandial insulin before largest meal
- If not at goal, progress to injections before 2 or 3 meals
- Start: 10% of basal dose or 5 units

Basal Bolus

- Begin prandial insulin before each meal
- 50% Basal / 50% Prandial TDD 0.3–0.5 U/kg
- Start: 50% of TDD in three doses before meals

Insulin titration every 2–3 days to reach glycemic goal:

- Increase prandial dose by 10% or 1-2 units if 2-h postprandial or next premeal glucose consistently > 140 mg/dL
- If hypoglycemia, reduce TDD basal and/or prandial insulin by:
  - BG consistently < 70 mg/dL: 10% - 20%
  - Severe hypoglycemia (requiring assistance from another person) or BG < 40 mg/dL: 20% - 40%

ASCVD RISK FACTOR MODIFICATIONS ALGORITHM

DYSLIPIDEMIA

LIFESTYLE THERAPY (Including Medically Assisted Weight Loss)

LIPID PANEL: Assess ASCVD Risk

STATIN THERAPY
If TG > 500 mg/dL, fibrates, Rx-grade omega-3 fatty acids, niacin

If statin-intolerant

Try alternate statin, lower statin dose or frequency, or add nonstatin LDL-C- lowering therapies

Repeat lipid panel; assess adequacy, tolerance of therapy

Intensify therapies to attain goals according to risk levels

RISK LEVELS	HIGH — DM but no other major risk and/or age <40	VERY HIGH — DM + major ASCVD risk(s) (HTN, Fam Hx, low HDL-C, smoking) or ASCVD*
	DESIRABLE LEVELS	DESIRABLE LEVELS
LDL-C (mg/dL)	<100	<70
Non-HDL-C (mg/dL)	<130	<100
TG (mg/dL)	<150	<150
TC/HDL-C	<3.5	<3.0
Apo B (mg/dL)	<90	<80
LDL-P (nmol/L)	<1200	<1000

IF NOT AT DESIRABLE LEVELS: Intensify lifestyle therapy (weight loss, physical activity, dietary changes) and glycemic control; consider additional therapy

TO LOWER LDL-C:	Intensify statin, add ezetimibe, PCSK9i, colesevelam, or niacin
TO LOWER Non-HDL-C, TG:	Intensify statin and/or add Rx-grade OM3 fatty acid, fibrate, and/or niacin
TO LOWER Apo B, LDL-P:	Intensify statin and/or add ezetimibe, PCSK9i, colesevelam, and/or niacin
TO LOWER LDL-C in FH:**	Statin + PCSK9i

Assess adequacy & tolerance of therapy with focused laboratory evaluations and patient follow-up

* EVEN MORE INTENSIVE THERAPY MIGHT BE WARRANTED ** FAMILIAL HYPERCHOLESTEROLEMIA

HYPERTENSION

GOAL: SYSTOLIC <130, DIASTOLIC <80 mm Hg

ACEi or ARB

For initial blood pressure >150/100 mm Hg:
DUAL THERAPY

ACEi or ARB + Calcium Channel Blocker ✓ / ß-blocker ✓ / Thiazide ✓

If not at goal (2–3 months)

Add calcium channel blocker, ß-blocker or thiazide diuretic

If not at goal (2–3 months)

Add next agent from the above group, repeat

If not at goal (2–3 months)

Additional choices (α-blockers, central agents, vasodilators, aldosterone antagonist)

Achievement of target blood pressure is critical

PROFILES OF ANTIDIABETIC MEDICATIONS

	MET	GLP-1 RA	SGLT-2i	DPP-4i	AGi	TZD (moderate dose)	SU / GLN	COLSVL	BCR-QR	INSULIN	PRAML
HYPO	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate/Severe / Mild	Neutral	Neutral	Moderate to Severe	Neutral
WEIGHT	Slight Loss	Loss	Loss	Neutral	Neutral	Gain	Gain	Neutral	Neutral	Gain	Loss
RENAL/ GU	Contra-indicated CKD Stage 3B,4,5	Exenatide Not Indicated CrCl < 30	Not Effective with eGFR < 45 / Genital Mycotic Infections	Dose Adjustment Necessary (Except Linagliptin)	Neutral	Neutral	More Hypo Risk	Neutral	Neutral	More Hypo Risk	Neutral
GI Sx	Moderate	Moderate	Neutral	Neutral	Moderate	Neutral	Neutral	Mild	Moderate	Neutral	Moderate
CHF	Neutral	Neutral	Possible Benefit	Neutral	Neutral	Moderate	Neutral	Neutral	Neutral	Neutral	Neutral
CARDIAC ASCVD	Benefit					Neutral	?		Safe		
BONE	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate Fracture Risk	Neutral	Neutral	Neutral	Neutral	Neutral

Few adverse events or possible benefits | Use with caution | Likelihood of adverse effects | ? Uncertain effect

PRINCIPLES OF THE AACE/ACE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM

1.	Lifestyle therapy, including medically supervised weight loss, is key to managing type 2 diabetes.
2.	The A1C target must be individualized.
3.	Glycemic control targets include fasting and postprandial glucoses.
4.	The choice of therapies must be individualized on basis of patient characteristics, impact of net cost to patient, formulary restrictions, personal preferences, etc.
5.	Minimizing risk of hypoglycemia is a priority.
6.	Minimizing risk of weight gain is a priority.
7.	Initial acquisition cost of medications is only a part of the total cost of care which includes monitoring requirements, risk of hypoglycemia, weight gain, safety, etc.
8.	This algorithm stratifies choice of therapies based on initial A1C.
9.	Combination therapy is usually required and should involve agents with complementary actions.
10.	Comprehensive management includes lipid and blood pressure therapies and related comorbidities.
11.	Therapy must be evaluated frequently until stable (e.g., every 3 months) and then less often.
12.	The therapeutic regimen should be as simple as possible to optimize adherence.
13.	This algorithm includes every FDA-approved class of medications for diabetes.

INTERNATIONAL DIABETES FEDERATION, 2012

Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

Global Guideline for Type 2 Diabetes

Levels of care

All people with diabetes should have access to the broad range of diabetes services and therapies and no person should be denied any element of effective diabetes care. It is recognised that in many parts of the developing world the implementation of particular standards of care is limited by lack of resources. This guideline provides a practical approach to promote the implementation of cost-effective evidence-based care in settings between which resources vary widely.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **The approach adopted has been to advise on three levels of care:**
  - **Recommended Care**
  - **Limited Care**
  - **Comprehensive Care**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **The approach adopted has been to advise on three levels of care:**
  - ***Recommended care*** is evidence-based care which is cost-effective in most nations with a well developed service base, and with health-care funding systems consuming a significant part of national wealth.
    Recommended care should be available to all people with diabetes and the aim of any health-care system should be to achieve this level of care. However, in recognition of the considerable variations in resources throughout the world, other levels of care are described which acknowledge low and high resource situations.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **The approach adopted has been to advise on three levels of care:**
  - *Limited care* is the lowest level of care that anyone with diabetes should receive. It acknowledges that standard medical resources and fully-trained health professionals are often unavailable in poorly funded health-care systems. Nevertheless this level of care aims to achieve with limited and cost-effective resources a high proportion of what can be achieved by *Recommended* care. Only low cost or high cost-effectiveness interventions are included at this level.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **The approach adopted has been to advise on three levels of care:**
  - *Comprehensive care* includes the most up-to-date and complete range of health technologies that can be offered to people with diabetes, with the aim of achieving best possible outcomes. However the evidence-base supporting the use of some of these expensive or new technologies is relatively weak.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Levels of Care:**

SUMMARY OF THE LEVELS OF CARE STRUCTURE

Recommended care: Evidence-based care, cost-effective in most nations with a well developed service base and with health-care funding systems consuming a significant part of their national wealth.

Limited care: Care that seeks to achieve the major objectives of diabetes management, but is provided in health-care settings with very limited resources – drugs, personnel, technologies and procedures.

Comprehensive care: Care with some evidence-base that is provided in health-care settings with considerable resources.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Screening and diagnosis:**
  - ***Recommended care:***
    - **Each health service should decide whether to have a programme to detect people with undiagnosed diabetes.**
    - **Detection programmes are usually based on a two-step approach:**
      - **Step 1 - Identify high-risk individuals using a risk assessment questionnaire.**
      - **Step 2 - Glycaemic measure in high-risk individuals.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Screening and diagnosis:**
  - ***Limited care:***
    - **Detection programmes should be opportunistic and limited to high-risk individuals in very limited settings.**
    - **The principles for screening are as for *Recommended care.***
    - **Diagnosis should be based on fasting laboratory plasma glucose (preferred) or capillary plasma glucose if only point-of-care testing is available.**
    - **If blood glucose testing is not available, the presence of glycosuria, especially with classical symptoms, may be used to diagnose diabetes.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Screening and diagnosis:**
  - ***Comprehensive care:***
    - **Resources should be available for diabetes detection programmes.**
    - **HbA_{1c} should be routinely available as an option to diagnose diabetes.**
    - **Investigations to classify type of diabetes (e.g. islet cell related antibodies, C-peptide, genotyping) should be available.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Screening and diagnosis**
  - ***Considerations:***
    - The place of screening for undiagnosed diabetes as part of an overall strategy to reduce the health burden of diabetes is not established. However, many organisations recommend it. The choice of whether to screen or not, and the screening strategy, must be made locally taking into account local considerations.

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ♦ ***Recommended care:***
    - ✦ **Offer care to all people with diabetes, with sensitivity to cultural wishes and desires.**
    - ✦ **Encourage a collaborative relationship, by actively involving the person with diabetes in the consultation, and creating opportunities for them to ask questions and express concerns. Ensure that issues important to the person with diabetes are addressed.**
    - ✦ **Offer annual surveillance of all aspects of diabetes control and complications to all people with type 2 diabetes.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ♦ ***Recommended care:***
    - ✦ **Agree a care plan with each person with diabetes.**
      - ★ **Review this annually or more often if appropriate.**
      - ★ **Modify it according to changes in wishes, circumstances and medical findings.**
    - ✦ **Use protocol-driven diabetes care to deliver the care plan at scheduled routine visits between annual reviews.**
    - ✦ **Provide urgent access to diabetes health-care advice for unforeseen problems.**
    - ✦ **Organise care around the person with diabetes.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ***Recommended care:***
    - **Use a multidisciplinary care team with specific diabetes expertise maintained by continuing professional education.**
    - **Ensure that each person with diabetes is recorded on a list of people with diabetes, to facilitate recall for annual complications surveillance.**
    - **Provide telephone contact between clinic visits.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ***Recommended care:***
    - **Consider how people with diabetes, acting as expert patients, and knowing their limitations, together with local/regional/national associations, might be involved in supporting the care delivery of their local health-care team.**
    - **Use data gathered in routine care to support quality assurance and development activities.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ***Limited care:***
    - **Offer annual surveillance, agree care plans, deliver protocol-driven care, and ensure that each person with diabetes is recorded on a local list of people with diabetes, as for *Recommended care*. Organise care around the person with diabetes. Use an appropriately trained health-care professional to deliver diabetes care.**

INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ***Comprehensive care:***
    - **The principles as for *Recommended care*. The person with diabetes will have access to their own electronic medical record via secure technology from remote sites. They will be able to give permission for any health-care professional to access that record. Decision support systems might be available to the health-care professional, and perhaps to the person with diabetes.**

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Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

	Normal	Target
HbA_{1c}	< 6.0% / 42 mmol/mol	< 7.0% / 53 mmol/mol
Fasting/pre-meal capillary plasma glucose	5.5 mmol/l (100 mg/dl)	6.5 mmol/l (115 mg/dl)
Post meal capillary plasma glucose	7.8 mmol/l (140 mg/dl)	9.0 mmol/l (160 mg/dl)

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Clinical Guidelines Task Force

Global Guideline for Type 2 Diabetes

Treatment algorithm for people with type 2 diabetes

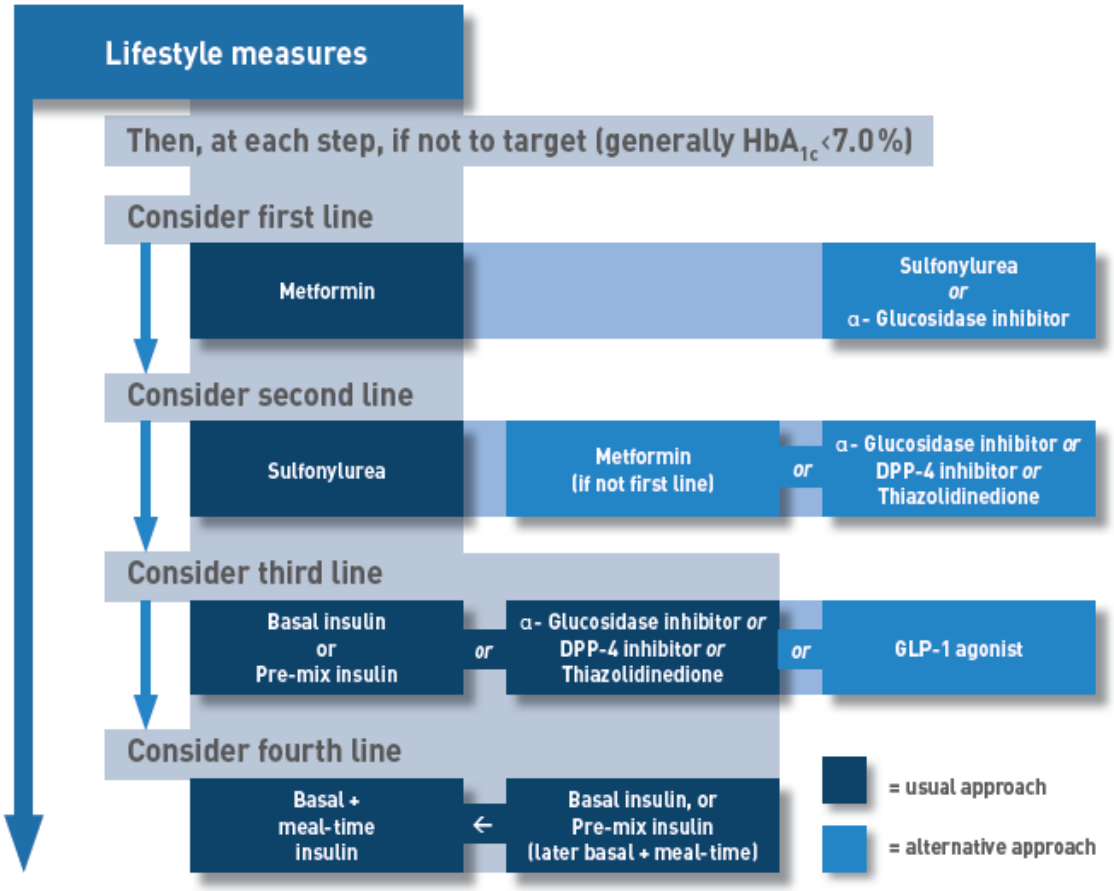


Table CD1

A summary of the assessments to be performed at Annual Review (or annually) for each person with type 2 diabetes

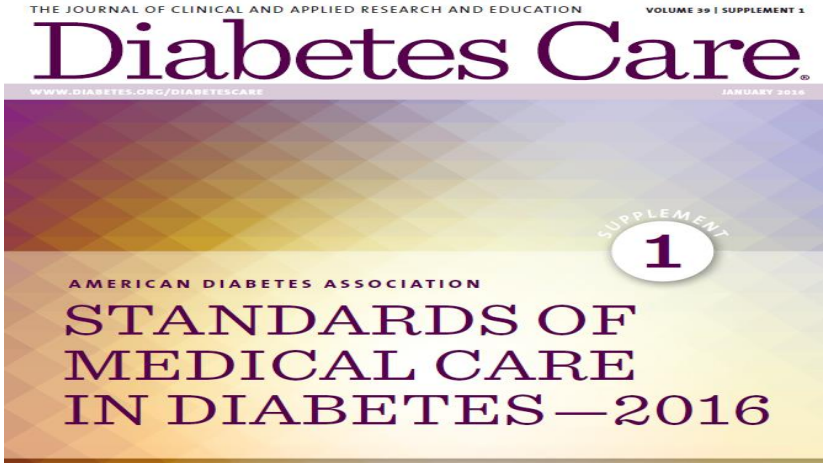
Assessment topic	*Guideline section*
Self-care knowledge and beliefs	*Education*
Lifestyle adaptation and wishes (including nutrition, physical activity, smoking)	*Lifestyle management*
Psychological status	*Psychological care*
Self-monitoring skills and equipment	*Self-monitoring*
Body weight trends	*Lifestyle management*
Blood glucose control	*Glucose control levels; Clinical monitoring; Glucose control therapy*
Blood pressure control	*Blood pressure control*
Blood lipid control	*Cardiovascular risk protection*
Cardiovascular risk	*Cardiovascular risk protection*
Erectile dysfunction, neuropathy	*Nerve damage*
Foot condition	*Foot care*
Eyes	*Eye screening*
Kidneys	*Kidney damage*
Medication review	–

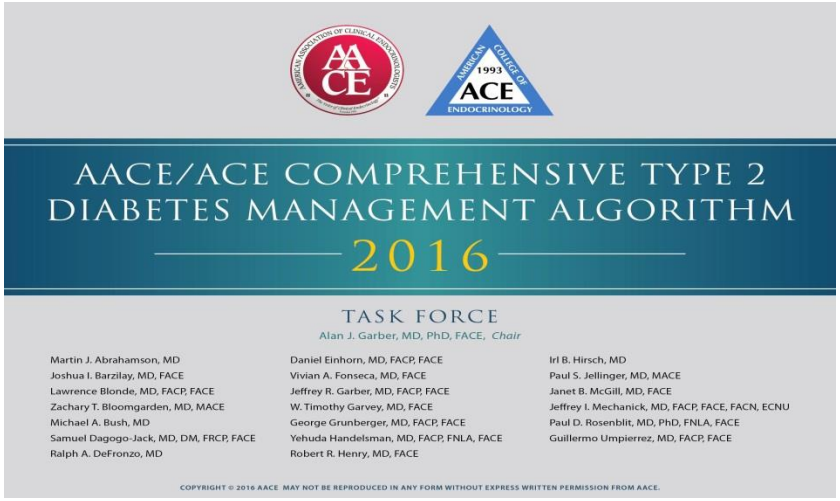
INTERNATIONAL DIABETES FEDERATION, 2012
Clinical Guidelines Task Force

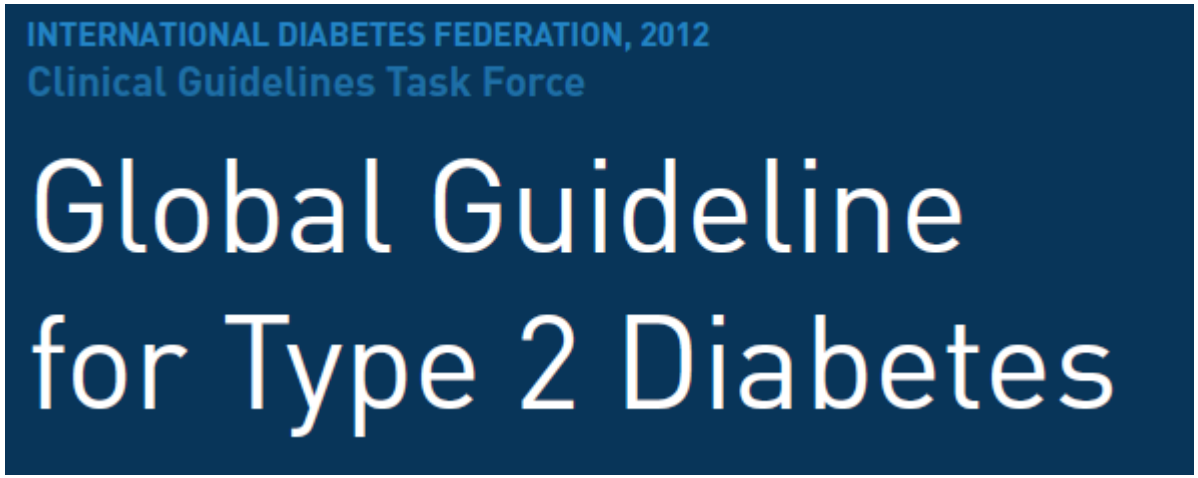
Global Guideline for Type 2 Diabetes

- **Care delivery:**
  - ***Considerations:***
    - Given the diversity of health-care systems around the world, recommendations in this part of the guideline are presented in very general terms. Flexibility, adaptability, and accessibility would seem to be important principles.
    - Empowering patients to find their way in the system through access to their own data and perhaps through use of decision support tools would seem to be a logical development.

Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus







Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus

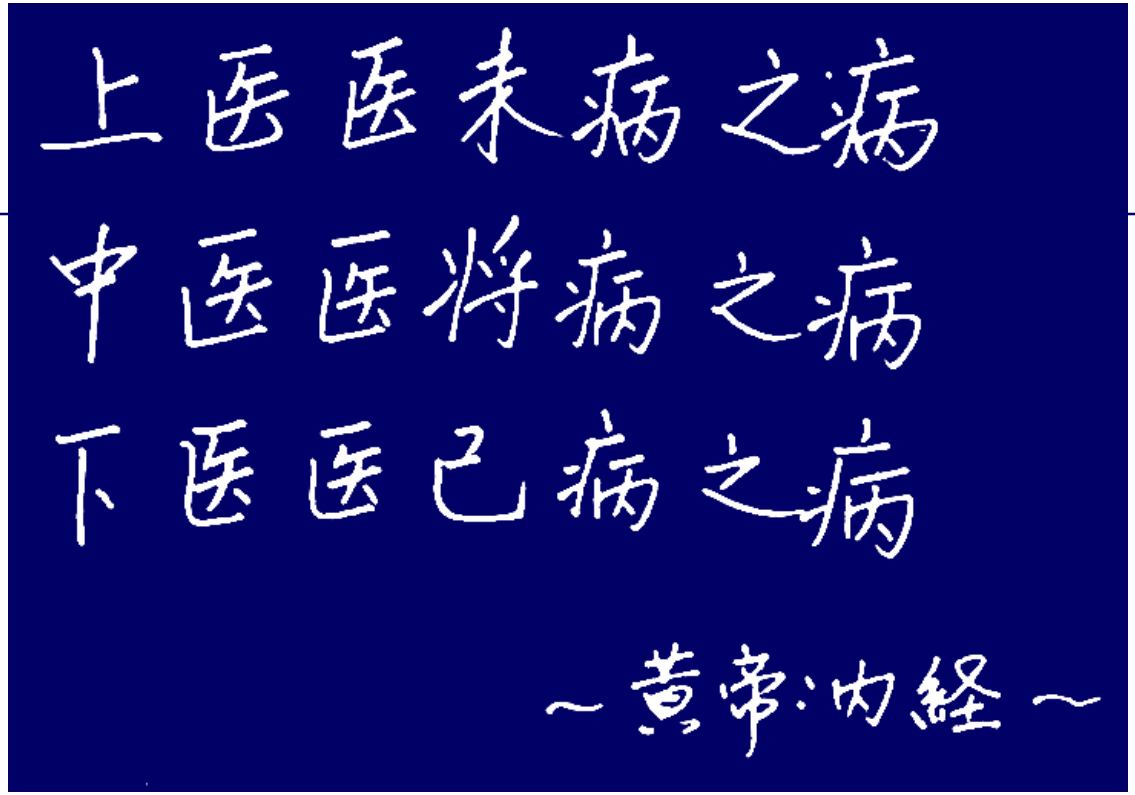
- Differences:
  - ADA
    - Extensive in comorbid related conditions
  - AACE
    - Aggressive intervention
  - IDF
    - Stratified in terms of levels of care

Harmonizing the ADA, AACE and other Guidelines in the Treatment of the Patient with Diabetes Mellitus

- Similarities:
  - Patient centralized care
  - Encourage DSME
  - Promote clinical integration thru multidisciplinary care

Summary

- Management of patient with diabetes mellitus is a very complex process.
- Different organizations establish guidelines and recommendations to prevent, control and delay progression of disease and complications.
- Each guideline should be individualized to patient needs and resources.
- Our goal as providers should be: “First, not to harm”



Superior doctors prevent the disease.

Mediocre doctors treat the disease before evident.

Inferior doctors treat the full blown disease.

— Huang Dee: Nai-Ching (2600 BC; first Chinese medical text).