Exploration of Endocrine and Metabolic Diseases

Open Exploration

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The 2024 American Diabetes Association guidelines on Standards of Medical Care in Diabetes: key takeaways for laboratory

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Academic Editor: Andreas Barthel, University Hospital Carl Gustav Carus of Technische Universität Dresden, Germany
Received: January 3, 2024 **Accepted:** April 8, 2024 **Published:** July 23, 2024

Cite this article: Tiwari D, Aw TC. The 2024 American Diabetes Association guidelines on Standards of Medical Care in Diabetes: key takeaways for laboratory. Explor Endocr Metab Dis. 2024;1:158–66. https://doi.org/10.37349/eemd.2024.00013

Abstract

The escalating prevalence of diabetes poses a significant health concern. Uncontrolled diabetes leads to a multitude of complications. A comprehensive management plan and continual adaptation of guidelines is needed. The American Diabetes Association (ADA) is a guiding force in this domain, providing diabetes care recommendations for clinicians, laboratorians, researchers, and policymakers since 1989. The latest ADA guidelines present both challenges and opportunities for laboratories. The increased emphasis on glycated hemoglobin (HbA1c) testing for early diagnosis and personalized monitoring is expected to increase testing volumes, potentially leading to a rise in point-of-care testing. Ensuring standardized testing procedures becomes paramount to maintaining consistent and reliable results across laboratories. Moreover, laboratories may need to expand their test menus to accommodate the growing demand for personalized medicine approaches and collaborate closely with healthcare providers to support informed decision-making. This commentary provides a focused analysis of the 2024 ADA guidelines for the laboratory assessment of diabetes.

Keywords

American Diabetes Association 2024 guidelines, cardiovascular-kidney-metabolic health, continuous glucose monitoring, diabetes, diabetic kidney disease

Introduction

The prevalence of diabetes has reached alarming proportions worldwide; the number of adults living with diabetes is predicted to rise to 643 million by 2030 [1]. The dynamic nature of this chronic condition, coupled with its multifaceted impact on health, necessitates regular revisions to guidelines in diabetes care.

The American Diabetes Association (ADA) has played a crucial role in guiding diabetes care by serving as a leading authority in the field of diabetes research, education, advocacy, and development of standards of care. Since 1989 the ADA has provided an annual guidance document on Standards of Medical Care in Diabetes. This commentary aims to distill the updates and recommendations from the latest ADA 2024 standards of care specifically pertaining to laboratory assessments in diabetes management.

Diagnosis and confirmatory testing

Traditionally, the classification and diagnosis of diabetes primarily depended on plasma glucose levels and symptom presentation until the ADA endorsement of glycated hemoglobin (HbA1c) in 2010. HbA1c is a reliable retrospective marker of blood glucose control over the past 6–8 weeks [2]. HbA1c testing offers several advantages over traditional glucose tests, including greater convenience, stability, and less susceptibility to day-to-day variations. Despite its higher cost and limited access in certain regions, HbA1c provides a weighted average of blood glucose levels, offering a more reflective measure of recent glycemic control. Over time, HbA1c has evolved as a pivotal tool in both the diagnosis and management of diabetes. In contrast to the ADA 2023 guidelines, which prioritized fasting plasma glucose, the latest ADA 2024 guidelines affirm the pivotal role of HbA1c for diabetes diagnosis and screening and place HbA1c testing at the forefront of the diagnostic hierarchy for both diabetes and prediabetes. Recommendations for the diagnostic threshold remain unchanged—≥ 6.5% for HbA1c, using a National Glycohemoglobin Standardization Program (NGSP)-certified method that's traceable to the Diabetes Control and Complications Trial (DCCT) [3].

For diabetes screening and diagnosis using point-of-care testing (POCT) HbA1c devices, the ADA emphasizes several factors. The POCT assays should be approved by the U.S. Food and Drug Administration (FDA) or NGSP-certified and can be conducted in laboratories or sites meeting Clinical Laboratory Improvement Amendments (CLIA) certification and quality standards. These standards encompass specific personnel requirements, including documented annual competency assessments, and regular participation in approved proficiency testing programs three times per year. This ensures adherence to high-quality standards in HbA1c testing, promoting accurate and reliable results in diabetes management [3].

However, in the presence of hemoglobin variants, pregnancy, glucose-6-phosphate dehydrogenase deficiency, and other conditions that might potentially interfere with accurate HbA1c measurements, plasma glucose levels are preferred. Furthermore, in situations where elevated blood glucose levels might not be consistently apparent, the diagnosis of diabetes necessitates two abnormal test results (HbA1c and plasma glucose) either simultaneously or at different time points. In such scenarios, alternative biomarkers such as fructosamine and glycated albumin emerge as viable options for monitoring glycemic status. Fructosamine reflects the total pool of glycated serum proteins, mainly albumin, reflecting glycemic trends over a span of 2–4 weeks—a relatively shorter duration compared to A1C. Although these biomarkers show a strong correlation and are associated with long-term complications based on epidemiological evidence, the empirical support for their application is not as robust as that for HbA1c [4].

Personalized management

Specific diabetes subsets

The importance of precision medicine in diabetes management cannot be underestimated [5]. To facilitate personalized management, the appropriate categorization of patients into diabetes subtypes is emphasized. This will also facilitate the identification of those who can benefit from early intervention. Additionally, with the recent approval of teplizumab to delay the onset of stage 3 type 1 diabetes in certain individuals, current guidelines underscore monitoring those at increased risk of developing type 1 diabetes [6]. Detection of autoantibodies to specific antigens such as insulin, glutamic acid decarboxylase (GAD), islet antigen 2 (IA-2), or zinc transporter 8 (ZnT8) can be utilized for screening presymptomatic type 1 diabetes [7]. For prediabetes and type 2 diabetes, risk-based screening should be considered at any age in those who are overweight or obese; for all others, screening should begin at the age of 35 years [3]. Subjects taking

second-generation anti-psychotics (clozapine and olanzepine) should also be screened. The major risk factors associated with increased incidence of type 2 diabetes are listed below.

(1) First-degree relative with diabetes.

(2) Body mass index (BMI) >25 kg/m^2.

(3) History of cardiovascular disease (CVD).

(4) Hypertension (> 130/80 mmHg).

(5) Dyslipidemia.

(6) Previously diagnosed with gestational diabetes.

(7) Prediabetes.

(8) Polycystic ovary syndrome.

The possible association between COVID-19 and new onset type 1 diabetes is also mentioned in the current guidelines.

Although seemingly straightforward, some difficulty distinguishing between types 1 and 2 diabetes mellitus (DM) may be encountered as the conventional notion that type 2 diabetes exclusively manifests in adults and type 1 diabetes solely in children does not entirely reflect the reality. Several studies have emphasized the increasing prevalence of adult-onset type 1 diabetes [8]. In adults presenting with phenotypical features suggestive of type 1 DM (such as a lower BMI, unintentional weight loss, and ketoacidosis), islet autoantibody tests should be considered, as mentioned above.

Besides conventional type 1 DM and type 2 DM (T2DM), the updated classification of diabetes includes hybrid forms such as slowly evolving immune-mediated diabetes and ketosis-prone type 2 diabetes [9]. The recognition of these forms would allow healthcare professionals to tailor treatment plans with medications effective for both insulin deficiency and insulin resistance, potentially leading to better outcomes. Certain specific types of diabetes also need to be recognized in order to screen those with associated risk factors. For instance, diabetes associated with exocrine pancreatic dysfunction (referred to as type 3c) should be considered in individuals with a history of acute or chronic pancreatitis, pancreatic cancer, or cystic fibrosis [10]. Post-transplantation DM (PTDM) is another clinical entity requiring a careful assessment as the management is complicated by fluctuating renal function, concomitant immunosuppression, and drug-drug interactions [11]. Here, it should be noted that the oral glucose tolerance test (OGTT) is the preferred screening test for both cystic fibrosis-related diabetes and PTDM [3].

Genetic testing

Diabetes genetics is a rapidly evolving field. Neonatal diabetes (that occurs under 6 months of age) and maturity-onset diabetes of the young (MODY) constitute a group of monogenic diabetes. Individuals diagnosed with neonatal diabetes and those with a strong family history and atypical presentation (no obesity, no autoantibodies, and lacking metabolic features of diabetes) must undergo genetic screening for the common defects, such as *ABCC8* and insulin gene (INS) mutations [12]. Recent studies have demonstrated the cost-effectiveness of genetic screening in the management of monogenic diabetes [13].

Associated comorbidities

CVD

Hypertension and dyslipidemia often accompany type 2 diabetes, substantially increasing the risk of atherosclerotic CVD. It is, thus, reasonable to monitor those with diabetes for elevated blood pressure and impaired lipid panel. Individuals with prediabetes or diabetes should have their lipid profile obtained at the time of diagnosis, at initiation of lipid-lowering therapy (if any), and annually thereafter [14]. A novel lipid-lowering agent, bempedoic acid (classified as an ATP citrate lyase inhibitor), has been found to reduce cardiovascular risk among statin-intolerant patients [15].

T2DM increases the susceptibility to heart failure by directly impairing cardiac function as well as through associated comorbidities [16]. It is recommended to screen adults with diabetes by measuring either B-type natriuretic peptide (BNP) or N-terminal pro-BNP (NT-proBNP) to facilitate the prevention of stage C (symptomatic) heart failure at least annually. In those found to have abnormal natriuretic peptide levels (BNP ≥ 50 pg/mL and NT ≥ 125 pg/mL), echocardiography should be performed to identify stage B (asymptomatic) heart failure [14]. However, in the presence of abnormal natriuretic peptide levels, it is critical to take into account conditions that may affect the sensitivity of testing. For instance, renal insufficiency, pulmonary hypertension, chronic obstructive lung disease, obstructive sleep apnea, ischemic and hemorrhagic stroke, and anemia may lead to elevated natriuretic peptide levels, whereas people with obesity may have falsely reduced natriuretic peptide levels. In such scenarios, the results need to be evaluated in the individual context.

Diabetic kidney disease and cardiovascular-kidney-metabolic (CKM) syndrome

Diabetic kidney disease is one of the most common causes of end-stage renal failure and has a prevalence of 20–40% in patients with diabetes [17]. It may be present at diagnosis of type 2 diabetes while it typically develops 5–10 years after the diagnosis of type 1 diabetes [18]. In agreement with the recent Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, ADA emphasizes that albuminuria and estimated glomerular filtration rate (eGFR) should be assessed annually in those with type 1 diabetes of ≥ 5 years duration and in all individuals with type 2 diabetes. Spot urinary albumin-to-creatinine ratio (UACR) can be used as a reliable indicator to monitor renal function in those with established kidney disease [17, 19]. In addition, serum creatinine and potassium levels need periodic assessment in individuals prescribed angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin II receptor blockers (ARBs) [20].

There is growing awareness about the pathophysiological role of metabolic abnormalities in bidirectional heart-kidney interactions. In fact, cardiovascular-kidney-metabolic (CKM) health is an emerging concept that recognizes the intricate interplay between chronic metabolic conditions [like diabetes and obesity, chronic kidney disease (CKD), and CVD] [21]. This interconnectedness poses a significant public health challenge, ultimately leading to premature death and reduced quality of life. Individuals with diabetes, for example, are two to four times more likely to develop CKD, and the presence of both conditions further amplifies the risk of heart disease and stroke. Traditional care models, focusing on isolated conditions, are often inadequate for managing CKM health effectively. Clinicians are encouraged to follow a comprehensive approach that addresses all interconnected risk factors and leverage collaborative efforts from other healthcare professionals. The current guidelines emphasize the importance of addressing obesity as part of a comprehensive approach to managing diabetes. Individuals with diabetes and obesity should be regularly monitored for BMI along with anthropometric measurements, such as waist circumference, waist-to-hip ratio, and waist-to-height ratio [22].

Pregnancy

Concurrent with a notable rise in the prevalence of both type 1 and type 2 diabetes among individuals of childbearing age, there has been a significant surge in reported cases of gestational DM (GDM). GDM is defined as a glucose tolerance diagnosed for the first time during pregnancy and not aligning with either the type 1 or type 2 diabetes criteria [23]. Studies have reported significant associations between maternal plasma glucose elevations during pregnancy and adverse fetal outcomes [24]. Although the effectiveness of first-trimester screening for GDM is debated, preconception counselling has gained significance in achieving normal plasma glucose levels to prevent congenital anomalies in the fetus and mitigate maternal complications in those with diabetes [25]. It is noteworthy that pregnancy is associated with reduced HbA1c levels owing to increased red blood cell turnover; thus, the recommended HbA1c target in pregnancy is < 6%, although this goal can be adjusted to < 7% in cases where there is a risk of hypoglycemia [26]. Considering these alterations, it might be essential to monitor HbA1c levels more frequently, perhaps on a monthly basis during pregnancy. Furthermore, in addition to conventional pre- and postprandial glucose monitoring, continuous glucose monitoring (CGM) can help achieve glycemic

targets in GDM, although its cost-effectiveness is controversial in patients with HbA1c levels < 6% [27]. Nonetheless, lifestyle modifications, including medical nutrition therapy form a crucial part of diabetes management in pregnancy.

Diabetes technology

One of the most important advances in diabetes technology is the introduction of CGM devices. These devices are equipped with sensors containing a glucose-oxidase platinum electrode to measure glucose concentrations in interstitial fluid [28]. Currently, three types of CGM devices are available: rtCGM (measure and display real-time glucose levels), isCGM (continuously measure glucose levels but require intermittent scanning for visualization), and professional CGM (used to monitor glycemic data in professional healthcare settings). Interestingly, the ADA has now provided clinicians and care-givers guidance on desirable goals for CGM metrics—time in range, time above range, and time below range. These parameters can be used for the assessment of glycemic status and evaluation of treatment plans. Moreover, guidance has been provided on the standardization of reports generated by CGM devices, incorporating visual cues like the ambulatory glucose profile. This would be particularly helpful to guide physical activity, nutritional therapy, and medication management. CGM devices can be beneficial in patients with type 1 or type 2 diabetes on insulin therapy but should be only offered after proper education regarding their use, safety and interfering factors [29]. Another area of rapidly evolving technologies is the integration of CGM data with insulin delivery systems and electronic health records. However, there remains substantial work to improve outcomes in diabetes management arising from these new technologies [30].

Discussion and conclusion

The evolving landscape of diabetes care necessitates continuous updates in guidelines to address the multifaceted nature of this chronic condition. The key revisions made to the ADA guidelines in 2024 are summarized in Table 1.

Table 1. Revisions to the American Diabetes Association (ADA) 2024 guidelines

Section	Key revisions (2024)
Diagnosis	Glycated hemoglobin (HbA1c) resides at the top of the testing hierarchy as opposed to the earlier recommendations where fasting plasma glucose (FPG) was pre-eminent.
	HbA1c should not be used for screening of cystic-fibrosis-related diabetes and post-transplantation diabetes [oral glucose tolerance test (OGTT) is preferred].
Classification	Consideration of standardized islet autoantibody tests in adults who phenotypically overlap with type 1 diabetes.
	Possible association between coronavirus disease 2019 (COVID-19) infection and new-onset type 1 diabetes highlighted.
Associated comorbidities	Recommend screening for heart failure using natriuretic peptides.
Obesity and weight management	Additional anthropometric measurements are to be considered in obese patients.
	The importance of pharmacotherapy for obesity management highlighted.
Diabetes technology	Emphasized the benefits of using continuous glucose monitoring (CGM) in the management of non-pregnant and pregnant individuals with diabetes.
	Guidance provided on CGM metrics and their interpretation.

These guidelines utilize a rigorous level of evidence methodology, categorizing recommendations based on the strength of supporting evidence, ranging from high-quality randomized controlled trials to expert consensus or clinical experience. Accordingly, the recommendations are meticulously assigned ratings of A, B, or C, which directly correlate with the quality of evidence supporting each recommendation. Additionally, expert opinion is denoted by the category E. This systematic approach ensures that recommendations are grounded in the most current and reliable scientific evidence available, enhancing

their credibility and applicability in clinical practice and laboratory settings. Table 2 provides a structured summary of the major recommendations and levels of evidence from the ADA 2024 guidelines.

Table 2. Recommendations from the 2024 American Diabetes Association (ADA) guidelines and their level of evidence

Section	Recommendation	Level of evidence
Screening and diagnosis	Diabetes may be diagnosed based on glycated hemoglobin (HbA1c) or plasma glucose levels, FPG, 2-h glucose (2-h PG) value during a 75-g oral glucose tolerance test (OGTT), or random glucose value accompanied by classic hyperglycemic symptoms.	A
	The HbA1c test should be performed using a method certified by the National Glycohemoglobin Standardization Program (NGSP) as traceable to the Diabetes Control and Complications Trial (DCCT) reference assay.	B
	Point-of-care HbA1c testing for diabetes screening and diagnosis should be restricted to U.S. Food and Drug Administration (FDA)-approved devices at Clinical Laboratory Improvement Amendments (CLIA)—certified laboratories and sites.	B
	Plasma glucose criteria should be used to diagnose diabetes in conditions associated with an altered relationship between HbA1c and glycemia, such as some hemoglobin variants.	B
	Screening for presymptomatic type 1 diabetes may be done by detection of autoantibodies to insulin, glutamic acid decarboxylase (GAD), islet antigen 2 (IA-2), or zinc transporter 8 (ZnT8).	B
	Consider screening for diabetes in people taking certain medications, e.g., glucocorticoids, antiretroviral drugs, and thiazides.	E
	Annual screening for cystic fibrosis-related diabetes using OGTT.	B
Genetic testing	All those diagnosed with diabetes in the first 6 months of life should have immediate genetic testing for neonatal diabetes, regardless of their current age.	A
	Genetic testing for maturity-onset diabetes of the young (MODY) in those with an atypical presentation and a family history of diabetes in successive generations.	A
Cardiovascular disease	Perform B-type natriuretic peptide (BNP) or N-terminal pro-BNP (NT-proBNP) testing in adults with diabetes to facilitate the prevention of stage C heart failure.	B
	Bempedoic acid therapy should be considered in statin-intolerant individuals with diabetes.	A
Diabetic kidney disease	Spot urinary albumin-to-creatinine ratio (UACR) and estimated glomerular filtration rate (eGFR) should be assessed annually in people with type 1 diabetes for ≥ 5 years and in all those with type 2 diabetes regardless of treatment.	B
	In those with established chronic kidney disease (CKD), urinary albumin (e.g., spot UACR) and eGFR should be monitored 1–4 times per year depending on the stage of the kidney disease.	B
	Periodically assess serum creatinine and potassium levels when ACE inhibitors, angiotensin II receptor blockers (ARBs), and mineralocorticoid receptor antagonists are used.	B
Diabetes in pregnancy	Screen for gestational diabetes mellitus (GDM) at 24–28 weeks of gestation in pregnant individuals not previously found to have abnormal glucose metabolism in the current pregnancy.	A
	Individuals with a history of GDM should have lifelong screening for the development of prediabetes or diabetes at least every 3 years.	B
Diabetes technology	Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at the time of diagnosis.	A
	When used as an adjunct to preprandial and postprandial glucose levels, CGM can help achieve A1C targets in diabetes and pregnancy.	B
Obesity and weight management	In people with diabetes and overweight or obesity, the preferred pharmacotherapy should be a glucagon-like peptide 1 (GLP1) receptor agonist or dual glucose-dependent insulinotropic polypeptide and GLP1 receptor agonist for greater weight loss efficacy.	A
	Consider additional parameters of body fat distribution, like waist circumference, waist-to-hip ratio, and/or waist-to-height ratio to assess diabetes risk.	E

In conclusion, the latest guidelines on Standards of Medical Care in Diabetes underscore the paramount importance of laboratory assessments in diabetes management, particularly focusing on the diagnostic role of HbA1c and its reliability in diagnosing and screening for diabetes, albeit with considerations for potential interferences. Precision medicine is highlighted, urging the categorization of patients into the correct specific diabetes subsets for personalized management. The guidelines also stress the complexities in distinguishing between diabetes types and acknowledge the emergence of hybrid forms, necessitating tailored treatment approaches. Emphasis is also placed on managing associated comorbidities such as CVD,

diabetic kidney disease, and the intricate CKM syndrome, advocating comprehensive care models. Additionally, the role of CGM devices in achieving glycemic control is highlighted. However, despite technological advances, further research is warranted to improve outcomes in diabetes management. Through this article, laboratory personnel can glean the updates in the latest ADA guidelines on Standards of Medical Care in Diabetes.

Abbreviations

ADA: American Diabetes Association

BMI: body mass index

BNP: B-type natriuretic peptide

CGM: continuous glucose monitoring

CKM: cardiovascular-kidney-metabolic

CVD: cardiovascular disease

DM: diabetes mellitus

GDM: gestational diabetes mellitus

HbA1c: glycated hemoglobin

Declarations

Author contributions

DT: Investigation, Writing—original draft. TCA: Conceptualization, Investigation, Writing—review & editing. All authors read and approved the submitted version.

Conflicts of interest

Prof. Tar Choon Aw is the Editorial Board Member of Exploration of Endocrine and Metabolic Diseases, but he had no involvement in the journal review process of this manuscript. Dipti Tiwari has no conflicts of interest.

Ethical approval

Not applicable.

Consent to participate

Not applicable.

Consent to publication

Not applicable.

Availability of data and materials

Not applicable.

Funding

Not applicable.

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