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In the Clinic®

Type 1 Diabetes Mellitus

Type 1 diabetes mellitus (T1DM) is an endocrine disorder in which pancreatic β cells stop producing insulin, typically due to autoimmune destruction. This results in hyperglycemia and ketosis; thus, insulin replacement is vital to management. Incidence peaks in puberty and early adulthood, but onset can occur at any age. However, prevalence is highest among adults because persons with T1DM live for many years. Symptoms include polyuria, polydipsia, and weight loss. Acute complications include diabetic ketoacidosis, which requires urgent management. Long-term complications include microvascular and macrovascular disease. Patients with T1DM are at higher risk for other autoimmune diseases and psychosocial issues. Management should focus on optimizing glucose control to reduce acute and long-term complications.

Screening and Prevention

Diagnosis and Evaluation

Treatment

Practice Improvement

CME/MOC activity available at Annals.org.

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Type 1 diabetes mellitus (T1DM) is an endocrine disorder in which insulin-producing β cells of the pancreas are destroyed, leading to insulin deficiency. Without replacement, this lack of insulin leads to hyperglycemia, ketosis, and death. With the discovery of insulin replacement by Franklin Banting in 1921, T1DM went from a death sentence to a chronic, treatable illness.

It is important for all physicians, particularly internists, to familiarize themselves with the care of patients with T1DM. Although less than 1% of the population has T1DM, more than 5% of all patients with diabetes have T1DM (1). For many years, it was believed to be a disorder of childhood, but as many cases are diagnosed in adulthood as in childhood (2).

Screening and Prevention

Are there risk factors for T1DM?

The majority of persons with T1DM are diagnosed before age 18 years (3). For the general population, the risk for developing T1DM is low, at 0.4%. However, family history, particularly in first-degree relatives, is a risk factor. Siblings of persons with T1DM have a 6% to 7% risk, and monozygotic twins have a risk above 70% (4). Children of parents with T1DM are more likely to develop it than the general population, with children of fathers with T1DM at higher risk than children of mothers with T1DM. If symptoms consistent with diabetes develop in patients with a family history of T1DM, it is particularly important to evaluate for it.

The presence of autoantibodies, specifically glutamic acid decarboxylase (GAD) autoantibodies, also indicates elevated risk for T1DM. GAD antibodies, islet cell tyrosine phosphatase 2 (IA2) antibodies, and zinc transporter 8 (ZnT8) antibodies can help in the diagnosis (5) and may also help determine risk in family members of persons with T1DM. Those who are positive for an islet cell antibody have a 68% chance of developing T1DM in the next 5 years, and those with 3 positive autoantibodies, specifically GAD-65 and islet cell antibodies, have a 99% chance of developing T1DM in the next 5 years (6).

Should clinicians screen for diabetes?

Although the U.S. Preventive Services Task Force recommends screening for prediabetes and type 2 diabetes mellitus (T2DM) in adults aged 35 to 70 years who have overweight or obesity, it does not recommend screening for T1DM (7). Patients with a first-degree relative with T1DM may inquire about autoantibody testing to screen for their risk for the disease, and doing so may help prevent complications at diagnosis, such as diabetic ketoacidosis (DKA). The American Diabetes Association (ADA) recommends informing patients with T1DM and their families about TrialNet, an international platform that can help those at risk for diabetes to join research studies (8). However, testing for autoantibodies, such as GAD-65, is now available outside research settings, and primary care physicians can order it.

Is there a way to screen for T1DM versus T2DM?

Screening for abnormal glycemia with hemoglobin A_{1c} or fasting glucose levels is recommended in all adults and younger persons with risk factors. The ADA recommends routine screening of persons with risk factors (including family history) for diabetes (9). When screening reveals hyperglycemia, clinicians should use clinical context to help determine the type of diabetes. Testing for autoantibodies, such as GAD-65, is not recommended for all persons with hyperglycemia found by screening. History and physical examination are the most important tools to help

1. Mobasseri M, Shirmohammadi M, Amiri T, et al. Prevalence and incidence of type 1 diabetes in the world: a systematic review and meta-analysis. Health Promot Perspect. 2020;10:98-115. [PMID: 32296622]
2. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2010;33 Suppl 1:S62-9. [PMID: 20042775]
3. Daneman D. Type 1 diabetes. Lancet. 2006;367:847-58. [PMID: 16530579]
4. Steck AK, Rewers MJ. Genetics of type 1 diabetes. Clin Chem. 2011;57:176-85. [PMID: 21205883]
5. Katsarou A, Gudbjörnsdottir S, Rawshani A, et al. Type 1 diabetes mellitus. Nat Rev Dis Primers. 2017;3:17016. [PMID: 28358037]
6. Pihoker C, Gilliam LK, Hampe CS, et al. Autoantibodies in diabetes. Diabetes. 2005;54 Suppl 2:S52-61. [PMID: 16306341]
7. U.S. Preventive Services Task Force. Prediabetes and Type 2 Diabetes: Screening. 24 August 2021. Accessed at https://uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes on 11 January 2022.
8. Type 1 Diabetes TrialNet website. Accessed at www.trialnet.org/participate on 11 January 2022.
9. Chamberlain JJ, Rhinehart AS, Shaefer CF Jr , et al. Diagnosis and management of diabetes: synopsis of the 2016 American Diabetes Association Standards of Medical Care in Diabetes. Ann Intern Med. 2016;164:542-52. [PMID: 26928912]

distinguish between T1DM and T2DM. For example, a patient with central obesity, a high body mass index (BMI), and a history of prediabetes likely has T2DM, whereas a patient with a low or normal BMI and rapid onset of high blood glucose levels is likely to have T1DM. Autoantibody levels can help confirm T1DM when the clinical scenario is uncertain.

Are there interventions that prevent T1DM?

Research is exploring strategies to prevent T1DM in persons at risk for the disease. There is evidence that teplizumab, an anti-CD3 monoclonal antibody drug, can slow the progression of T1DM when prescribed to those with newly diagnosed disease to protect further β cell destruction and preserve any remaining β cells so that there can be endogenous insulin protection (10). Teplizumab is also being studied as pharmacologic prevention for persons with a family history of T1DM. Although approval from the U.S. Food and Drug Administration (FDA) is anticipated, teplizumab is not currently FDA-approved and is available only in research studies. Other immunosuppressive agents should not be prescribed for prevention of T1DM occurrence or progression.

Patients may inquire about prevention or treatment of T1DM with chromium, cinnamon, and other supplements. Although patients with T1DM do seem to have a larger chromium deficit than patients without diabetes, there is no good evidence that supplementation with chromium or other alternative therapies prevents T1DM.

Screening and Prevention... Although screening for hyperglycemia is recommended for persons at risk for diabetes, no T1DM-specific screening is currently recommended. When hyperglycemia is detected at screening, clinical context is essential to differentiate between T1DM and T2DM. T1DM is typically associated with lower BMI, rapid onset of symptoms, and positive autoantibodies, including GAD-65 and ZnT8.

CLINICAL BOTTOM LINE

Diagnosis and Evaluation

What are the clinical presentations of T1DM?

T1DM presents in 3 stages. In stage 1, autoimmune destruction of β cells is beginning, but there are no clinical symptoms or hyperglycemia. In stage 2, hyperglycemia is present but symptoms are not. Most patients are diagnosed during stage 3, when β-cell destruction has occurred and there is profound hyperglycemia along with polydipsia, polyuria, and weight loss.

Patients with T1DM generally present when symptomatic. These symptoms include polyuria, nocturia, enuresis, lethargy, polydipsia, weight loss, and abdominal pain (3). Symptoms typically progress over a shorter period compared with T2DM, averaging 7 to 8 weeks in adults and half that time in children (3).

Symptoms are more obviously indicative of T1DM in children than in adults, in whom symptoms overlap with those of other conditions that are common in adults. T1DM presentation in adults can also be less overt than in children because symptoms can evolve more slowly. For example, in latent autoimmune diabetes in adulthood (LADA), which involves autoimmune destruction of pancreatic β cells, there can be some reserved pancreatic memory enabling management with a small amount of insulin. LADA is not a

10. Herold KC, Bundy BN, Long SA, et al; Type 1 Diabetes TrialNet Study Group. An anti-CD3 antibody, teplizumab, in relatives at risk for type 1 diabetes. N Engl J Med. 2019;381:603-13. [PMID: 31180194]

Table 1. **Diagnostic Criteria for Diabetes Mellitus*†**

Test	*Normal Range*	*Increased Risk for Diabetes (Prediabetes)*	*Diabetes*
Random plasma glucose	–	–	Classic hyperglycemic symptoms or hyperglycemic crisis, and random glucose level ≥200 mg/dL (≥11.1 mmol/L)
Fasting plasma glucose‡	<100 mg/dL (<5.6 mmol/L)	100–125 mg/dL (5.6–6.9 mmol/L)	≥126 mg/dL (≥7.0 mmol/L)
2-hour plasma glucose during an OGTT§	<140 mg/dL (<7.8 mmol/L)	140–199 mg/dL (7.8–11.0 mmol/L)	≥200 mg/dL (≥11.1 mmol/L)
Hemoglobin A_{1c}‖	<5.7% (<39 mmol/mol)	5.7%–6.4% (39–46 mmol/mol)	≥6.5% (≥48 mmol/mol)

OGTT = oral glucose tolerance test.
** Data are from the following sources: 1) American Diabetes Association. Standards of Medical Care in Diabetes–2019. Diabetes Care. 2019;41(suppl 1):S1-S193, and 2) U.S. Department of Veterans Affairs (VA); U.S. Department of Defense (DoD). VA/DoD clinical practice guidelines for the management of diabetes mellitus in primary care. 2017. Accessed at www.healthquality.va.gov/guidelines/cd/diabetes on 16 May 2018.*
† In the absence of unequivocal hyperglycemia, diagnosis requires 2 abnormal test results from the same sample or in 2 separate samples.
‡ Fasting for ≥8 hours.
§ An OGTT involves consumption of a 75-g glucose load dissolved in water.
‖ The American Diabetes Association recommends an NGSP-certified hemoglobin A_{1c} assay that is standardized to the Diabetes Control and Complications Trial assay. The VA/DoD guidelines recommend confirmation of diabetes based on an elevated hemoglobin A_{1c} value of 6.5% to 6.9% with an elevated fasting plasma glucose level ≥126 mg/dL (≥7.0 mmol/L) due to strong evidence supporting racial differences between glycemic control and hemoglobin A_{1c} values for diagnosis and treatment.

diagnosis unto itself, but a term given to slowly evolving T1DM. Of note, one third of patients with T1DM present acutely ill with DKA and require hospitalization (11).

History and physical examination are important in the diagnosis of T1DM. Family history is pertinent to diagnosis, but medication history should also be taken into account. Specifically, T1DM can be an adverse effect of immune checkpoint inhibitors that are often prescribed for solid and hematologic cancer (12). T1DM is also associated with other autoimmune conditions, so clinicians should consider it in a patient with typical symptoms who also has a history of autoimmune illnesses, such as Hashimoto thyroiditis, adrenal insufficiency, celiac disease, myasthenia gravis, pernicious anemia, or autoimmune hepatitis. T1DM is frequently associated with sudden weight loss or lack of weight gain in children but can also present in patients with overweight or obesity (2). Other physical examination findings and symptoms associated with T1DM that can aid in diagnosis include pruritus, necrobiosis lipoidica, and vitiligo (13).

What criteria distinguish T1DM from T2DM?

Diagnostic criteria for all types of diabetes are the same (**Table 1**). Diagnosis is based on blood glucose levels or surveillance markers, specifically hemoglobin A_{1c}. According to the ADA, diagnosis includes a random blood glucose level of 200 mg/dL (11.1 mmol/L) or higher with symptoms, or 2 of the following: fasting blood glucose level of 126 mg/dL (7.0 mmol/L) or higher, blood glucose level of 200 mg/dL or higher after a 75-mg glucose load, or hemoglobin A_{1c} level of 6.5% or higher (14).

Distinguishing between T1DM and T2DM in adults can be challenging, but history and physical examination can be helpful. Patients with T2DM are more likely to have obesity or overweight than patients with T1DM. Signs of insulin resistance, specifically acanthosis nigricans, are more often present in patients with T2DM than in those with T1DM (15). **Table 2** compares the characteristics of T1DM, T2DM, and

11. Dabelea D, Rewers A, Stafford JM, et al; SEARCH for Diabetes in Youth Study Group. Trends in the prevalence of ketoacidosis at diabetes diagnosis: the SEARCH for Diabetes in Youth Study. Pediatrics. 2014;133:e938-45. [PMID: 24685959]
12. Gauci ML, Boudou P, Baroudjian B, et al. Occurrence of type 1 and type 2 diabetes in patients treated with immunotherapy (anti-PD-1 and/or anti-CTLA-4) for metastatic melanoma: a retrospective study. Cancer Immunol Immunother. 2018;67:1197-1208. [PMID: 29808365]
13. Lima AL, Illing T, Schliemann S, et al. Cutaneous manifestations of diabetes mellitus: a review. Am J Clin Dermatol. 2017;18:541-53. [PMID: 28374407]
14. American Diabetes Association. Standards of Medical Care in Diabetes–2021. Diabetes Care. 2021;44(Suppl 1):S1-S244.
15. Mayer-Davis EJ, Kahkoska AR, Jefferies C, et al. ISPAD Clinical Practice Consensus Guidelines 2018: definition, epidemiology, and classification of diabetes in children and adolescents. Pediatr Diabetes. 2018;19 Suppl 27:7-19. [PMID: 30226024]

Table 2. **Characteristics of Type 1 Diabetes, Type 2 Diabetes, and Monogenic Diabetes**

Characteristic	*Type 1 Diabetes*	*Type 2 Diabetes*	*Monogenic Diabetes*
Usual age at onset	>6–12 mo	During or after puberty	After puberty (except for MODY2 and neonatal diabetes)
Genetics	Polygenic	Polygenic	Monogenic
Clinical presentation	Acute	Variable; from slow, mild (often insidious) to severe	Variable; sometimes incidental (as with MODY2)
Autoimmunity	Yes	No	No
Ketosis	Common	Rare	Rare; common in neonatal diabetes
Likelihood of obesity	Similar to general population	Greater than general population	Similar to general population
Acanthosis nigricans	No	Yes	No
Parental diabetes	In 2%–4%	In 80%	In ≥90%
Frequency of all diabetes in children and young adults	Usually ≥90%	Most countries <10%	1%–6%

MODY2 = maturity-onset diabetes of the young type 2.

monogenic diabetes. Monogenic diabetes is a less common disorder caused by genetic mutations that includes maturity-onset diabetes of the young (MODY). MODY may require different treatment than T2DM. Patients with MODY typically do not have the symptoms of insulin resistance that those with T2DM have, such as metabolic syndrome, hyperlipidemia, or fatty liver. They are more likely to have incidental glucosuria, less likely to present with DKA, and more likely to present with subtle hyperglycemia than patients with T1DM.

What should the initial evaluation of patients with newly diagnosed T1DM include?

The ADA provides guidelines on evaluation for patients diagnosed with diabetes (14). First, clinicians should determine the type of diabetes; second, they should look for comorbid conditions; and third, they should consider screening for other autoimmune conditions.

The first goal of medical evaluation is to correctly identify the type of diabetes because this is essential to guide appropriate management. History,

Table 3. **Recommended Quarterly and Annual Health Assessment for Patients With Type 1 Diabetes Mellitus**

Quarterly

- Hemoglobin A_{1c}, blood glucose monitoring data, inspection of injection and infusion sites
- Weight, blood pressure
- Visual foot examination (if high risk)
- Assessment of physical activity and diabetes self-management skills
- In children: Height, body mass index percentile, thyroid examination, depression screening

Annually

- Lipid panel, thyroid-stimulating hormone, serum creatinine
- Urine albumin–creatinine ratio (starting 5 y after diagnosis in children)
- Body mass index
- Foot examination (visual examination in children, comprehensive examination in older adolescents and adults)
- Depression screening in adults
- Specialist retinal examination starting within 5 y of diagnosis
- Vaccination history and needs

Table 4. **Recommended Screening for Chronic Complications of Diabetes Mellitus***

Chronic Complication and Clinical Situation	*When to Start Screening*	*Screening Frequency*	*Preferred Screening Test*
Retinopathy			
Type 1 diabetes	5 y after diagnosis	Annually†	Dilated and comprehensive eye examination‡
Type 2 diabetes	At diagnosis	Annually†	Dilated and comprehensive eye examination‡
In pregnant women with either type of diabetes	First trimester	Every trimester and then closely for 1 y postpartum	Dilated and comprehensive eye examination‡
In women with either type of diabetes planning to conceive	During preconception planning	Same as recommendations for pregnant women once conception occurs	Dilated and comprehensive eye examination‡
Nephropathy			
Type 1 diabetes	5 y after diagnosis	Annually§	Albumin–creatinine ratio on random spot urine, eGFR
Type 2 diabetes	At diagnosis	Annually§	Albumin–creatinine ratio on random spot urine, eGFR
Neuropathy (distal symmetric polyneuropathy)‖			
Type 1 diabetes	5 y after diagnosis	Annually	Skin assessment, evaluate for foot deformities, lower-extremity pulse assessment, neurologic assessment (10-g monofilament plus 128-Hz tuning fork, ankle reflexes, pinprick, or temperature)
Type 2 diabetes	At diagnosis	Annually	Skin assessment, evaluate for foot deformities, lower-extremity pulse assessment, neurologic assessment (10-g monofilament plus 128-Hz tuning fork, ankle reflexes, pinprick, or temperature)
Cardiovascular disease			
Hypertension	At diagnosis	Every visit	Blood pressure measurement
Dyslipidemia	At diagnosis and before initiating statin therapy	Annually¶	Lipid profile

eGFR = estimated glomerular filtration rate.

** Recommendations are from the following sources: 1) American Diabetes Association. 9. Cardiovascular disease and risk management: Standards of Medical Care in Diabetes–2018. Diabetes Care. 2018;41:S86-S104. [PMID: 29222380] doi:10.2337/dc18-S009; 2) American Diabetes Association. 10. Microvascular complications and foot care: Standards of Medical Care in Diabetes–2018. Diabetes Care. 2018;41:S105-S118. [PMID: 29222381] doi:10.2337/dc18-S010; and 3) Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm–2018 executive summary. Endocr Pract. 2018;24:91-120. [PMID: 29368965] doi:10.4158/CS-2017-0153*

† It is reasonable to screen every 1 to 2 years if no diabetic retinopathy is present and to screen more often than annually if diabetic retinopathy is advanced or progressing rapidly.

‡ Retinal photography is a possible alternative means of screening for diabetic retinopathy that may improve access to care and reduce costs. Retinal photography, when interpreted by eye care specialists, can detect most clinically significant diabetic retinopathy.

§ The American Diabetes Association guidelines state that it is reasonable to assess progression of disease and response to therapeutic interventions with continued monitoring of urinary albumin–creatinine excretion.

‖ Although diabetes commonly causes peripheral neuropathy, other differential diagnoses to consider during the screening process include vitamin B_{12} deficiency, alcoholism, hypothyroidism, renal disease, cancer and chemotherapies, vasculitis, and inherited neuropathies.

¶ Annual or periodic screening to monitor therapeutic response after initiation of statin therapy. May screen every 5 years if patient is not using statin therapy.

physical examination, and testing for autoantibodies are helpful in classifying diabetes type. As mentioned earlier, history and physical examination provide the most important distinction to help diagnose T1DM from T2DM. In T1DM, patients are more likely to have been losing weight, to have polyuria, to have high blood glucose levels (often >400 mg/dL [>22.2 mmol/L]) at diagnosis, to be thin, or to have DKA at diagnosis. In T2DM, patients are more likely to be overweight and have a history of prediabetes and less likely to have DKA.

Testing for C-peptide can help to confirm the diagnosis of T1DM. C-peptide helps determine whether the pancreas is making insulin, and levels are low in T1DM (16). Additional markers include autoantibodies to GAD, islet cells, insulin, protein tyrosine phosphatase (ICA512 or IA2A), or ZnT8. It is important to remember that false-negative results can occur with autoimmune antibodies depending on disease duration and sensitivity of the laboratory. If it is clear that a patient has T2DM, it is not necessary to check autoantibodies. However, when clinical presentation is unclear, checking autoantibodies will help distinguish diabetes type.

To help assess risk for diabetes complications, evaluation at diagnosis should look at risk factors for and evidence of microvascular and macrovascular disease (14). A lipid profile should generally be performed at diagnosis and at least every 5 years for persons younger than 40 years and then annually at age 40 years and older. However, there is a lack of agreement on when and how often to screen for hyperlipidemia; for example, does a 2-year-old child newly diagnosed with T1DM need annual cholesterol screening? The general consensus is that lipid testing should be considered, even in children, to help determine cardiovascular risk. Nephropathy should be assessed at diagnosis, 5 years after diagnosis, and then annually by checking estimated glomerular filtration rate and urine microalbumin. Retinopathy should be assessed 5 years after diagnosis and then annually with eye examinations. **Tables 3** and **4** summarize recommended routine health assessments.

Because T1DM is an autoimmune condition, patients should be screened for autoimmune thyroid disease via measurement of thyroid-stimulating hormone level. The rationale is that endocrine disorders tend to run together. In addition, other endocrine syndromes can be associated with T1DM, such as polyglandular syndromes and autoimmune thyroid diseases. Screening for hypothyroidism with thyroid peroxidase antibodies can help determine whether autoimmune thyroid disease is present.

Because the presence of one autoimmune disease increases risk for others, patients with neuropathy should also be tested for pernicious anemia by checking complete blood count, vitamin B_{12} level, and intrinsic factor antibody (16). Serum studies to evaluate for celiac disease should be considered for patients with symptoms associated with it, such as abdominal pain, diarrhea, bloating, and weight loss.

When should hospitalization be considered for patients with newly diagnosed T1DM?

Clinicians should consider hospitalizing patients with newly diagnosed T1DM who present with DKA (17). These patients require immediate assessment of electrolytes, blood urea nitrogen, creatinine, arterial or venous blood gas, and urine ketones. Pediatric patients may be hospitalized even when DKA is not present to initiate insulin therapy under close observation. Adults typically do not require hospitalization solely for initiation of insulin therapy.

16. Chiang JL, Kirkman MS, Laffel LM, et al; Type 1 Diabetes Sourcebook Authors. Type 1 diabetes through the life span: a position statement of the American Diabetes Association. Diabetes Care. 2014;37:2034-54. [PMID: 24935775]
17. Wilson JF. Diabetic ketoacidosis. Ann Intern Med. 2010;152:ITC1-ITC16. [PMID: 20048266]

Diagnosis and Evaluation... Criteria for the diagnosis of both T1DM and T2DM are random blood glucose level of 200 mg/dL or higher with symptoms, or 2 of the following: fasting blood glucose level of 126 mg/dL or higher, blood glucose level of 200 mg/dL or higher after a 75-mg glucose load, or hemoglobin A_{1c} level of 6.5% or higher. Clinical presentation helps to distinguish T1DM from T2DM. In addition to typically presenting at younger ages than T2DM, T1DM typically presents with more sudden onset, polyuria, polydipsia, and weight loss. Islet cell autoantibodies are more likely to be positive in T1DM, and it is more likely to be associated with ketosis. Checking C-peptide levels can also help in diagnosis because they are typically low or absent in T1DM. Patients with T1DM should be evaluated for nephropathy, hyperlipidemia, and concomitant autoimmune conditions. Patients with T1DM presenting with DKA should be hospitalized.

CLINICAL BOTTOM LINE

Treatment

How should clinicians determine an initial insulin regimen in a patient with newly diagnosed T1DM?

The ADA's 2021 Standards of Medical Care in Diabetes are helpful in determining T1DM management (14). Unlike in T2DM, patients with T1DM have autoimmune destruction of the pancreas and must always be treated with replacement of both basal and mealtime insulin. Total insulin dosing is based on several factors, including weight and carbohydrate intake. The goal is to use insulin to achieve normoglycemia to prevent complications of diabetes, including microvascular and macrovascular disease. Avoidance of hypoglycemia and its immediate dangers is also critical. For these reasons, continuous glucose monitoring should be recommended at diagnosis. The optimal hemoglobin A_{1c} goal is less than 7.0%, and target blood glucose levels include a preprandial blood glucose level less than 80 to 130 mg/dL (<4.4 to 7.2 mmol/L) and a postprandial (1 to 2 hours after eating) level less than 180 mg/dL (<10.0 mmol/L).

Choosing an insulin regimen can be challenging because short- and long-acting insulins come in many forms. Short-acting insulins include regular insulin, insulin aspart, insulin glulisine, and insulin lispro. Long-acting basal insulins include neutral protamine Hagedorn, insulin glargine, insulin detemir, and insulin degludec. A basal–bolus approach more closely mimics normal physiology and provides tighter glucose control. To begin, 0.3 units per kilogram of body weight can be used as a starting point to determine total daily insulin dosing. Half that amount can be given as basal insulin and the other half as preprandial short-acting insulin. Ideally, patients should be taught how to count carbohydrates and dose mealtime insulin according to carbohydrate intake. In terms of deciding what type of insulin to use, finances are the most practical issue to consider. Insurance coverage of insulin types can change from year to year, so it is important to be aware of the different types of insulin (**Table 5**). Patients should be counseled to let providers know if a prescribed insulin is not affordable or not covered by their insurance so alternative insulins can be prescribed.

Insulin glargine is one of the more commonly used long-acting insulins and is covered by insurance. Insulin glargine does not peak and provides a

Table 5. **Pharmacokinetic Properties of Insulin Products***

Insulin Type	*Onset*	*Peak*	*Duration*
Ultra-rapid-acting analogues			
Aspart, lispro	14–17 min	57–63 min	4–7 h
Rapid-acting analogues			
Lispro, aspart, glulisine	5–15 min	45–90 min	2–4 h
Inhaled insulin	5–15 min	50 min	2–3 h
Concentrated rapid-acting analogue			
Lispro (200 U/mL)	5–15 min	45–90 min	2–4 h
Short-acting			
Human regular	0.5 h	2–5 h	4–8 h
Intermediate-acting			
NPH insulin	1–3 h	4–10 h	10–18 h
Concentrated human regular			
Human regular U-500 (500 U/mL)	0.5 h	2–5 h	13–24 h
Long-acting basal analogues			
Detemir	1–2 h	None†	12–24 h‡
Glargine	2–3 h	None†	20–≥24 h
Degludec	1–3 h	None	24–42 h
Concentrated basal analogue (ultra-long-acting)			
Glargine (300 U/mL)	6 h	None	24–36 h
Premixed insulins§			
70% NPH/30% regular	0.5–1 h	2–10 h	10–18 h
75% NPL/25% lispro	10–20 min	1–6 h	10–18 h
50% NPL/50% lispro	10–20 min	1–6 h	10–18 h
70% NPA/30% aspart	10–20 min	1–6 h	10–18 h
70% degludec/30% aspart	10–30 min	0.5–2 h	≥24 h

NPA = neutral protamine aspart; NPH = neutral protamine Hagedorn; NPL = neutral protamine lispro.
** The time course of each insulin varies significantly between persons and within the same person on different days. Therefore, the periods listed should be considered general guidelines only.*
† Both detemir insulin and glargine insulin can produce a peak effect in some persons, especially at higher doses.
‡ The duration of action for detemir insulin varies depending on the dose given.
§ Premixed insulins containing a larger proportion of rapid- or short-acting insulin tend to have larger peaks occurring earlier than mixtures containing smaller proportions of rapid- and short-acting insulin.

steady (basal) amount of insulin for 24 hours. Insulin detemir peaks at about 16 hours, so dosing can be more challenging in T1DM. Insulin degludec can last almost 48 hours and has efficacy similar to that of insulin glargine for T1DM.

For bolus insulin, carbohydrate counting is the best way to determine dosing. Based on 24-hour insulin needs, one can calculate the total bolus requirement and use a carbohydrate ratio to determine bolus insulin needs. The carbohydrate ratio should be tailored to patient needs, and determining it is very much an art. Patients can be started on 1 unit of insulin for every 10 carbohydrates and can be titrated from there. Blood glucose levels are dynamic, so bolus dosing may change from meal to meal or from day to day.

Premixed insulins containing intermediate and short-acting insulin are difficult to titrate, and the ADA does not recommend their use for patients with T1DM.

How often should patients with T1DM monitor blood glucose levels?

Patients with T1DM should check their blood glucose levels when fasting, before eating, and 2 hours after eating to guide insulin dosing. They should also check their blood glucose level if any symptoms of hypoglycemia are present (14), including confusion, sweating, dizziness, lightheadedness, or change in mental status.

When should continuous glucose monitoring be considered for patients with T1DM?

According to the 2016 Endocrine Society guidelines, continuous glucose monitors (CGMs) are recommended for any patient with T1DM whose hemoglobin A_{1c} level is not at goal or who desires a CGM (18), and the 2021 ADA recommendations advocate continuous glucose monitoring for all patients with T1DM (14). If a patient does not desire a CGM, they should be advised to continue frequent fingerstick monitoring. CGMs allow patients to have more knowledge of their blood glucose levels and make decisions about diet or insulin dosing to achieve better glucose control (19).

CGMs check glucose levels in the interstitium instead of in plasma. Two categories of CGMs are available: adjunctive and nonadjunctive. Adjunctive CGMs also require plasma blood testing with fingersticks, and nonadjunctive CGMs do not require fingersticks. Adjunctive CGMs have sensors that are worn for 6 to 7 days and currently tend to be less commonly used than nonadjunctive CGMs, with sensors that require replacement every 10 to 14 days. The devices offer continuous glucose readings, show upward or downward trends, and can be set to alarm for hypoglycemia or hyperglycemia. There are also devices that provide flash glucose checks without the ability to examine trends or issue alarms. Some CGMs can communicate with insulin pumps to influence changes in insulin dosing.

When should insulin delivery via a pump be considered?

Generally, initial treatment of T1DM is with a basal–bolus regimen of multiple daily injections, but an insulin infusion device (insulin pump) should then be considered for all patients with T1DM (14). Insulin pumps are appropriate for any patient requiring multiple daily injections. Pumps vary but typically provide both basal coverage of insulin as well as bolus insulin for meals mimicking physiologic releases of insulin. Insulin pumps reduce risk for DKA and can be helpful to avoid nocturnal or exercise-induced hypoglycemia. Use of insulin pumps is also associated with better quality of life for patients (20).

Patient and caregiver preferences and needs should guide the use of a pump versus multiple daily injections. In many settings, a patient must complete diabetes education and show good glycemic control on a basal–bolus regimen of multiple daily injections before moving to a pump. Insulin pumps are expensive and require extensive approval even if covered by insurance, and supplies can require substantial out-of-pocket expenses despite insurance coverage. Unfortunately, finances are a common obstacle to obtaining an insulin pump for many patients.

Insulin pumps are continuous subcutaneous insulin infusion devices. Sensor-augmented pump systems, sometimes called "open-loop systems," display CGM data, allowing the patient to take action based on their glucose level. Some models of sensor-augmented pump can suspend insulin if hypoglycemia is detected. Although no true "closed-loop systems" are currently available that monitor and deliver insulin with bidirectional communication and no input from the patient, there are automated insulin delivery (AID)

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20. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: Dose Adjustment For Normal Eating (DAFNE) randomised controlled trial. BMJ. 2002;325:746. [PMID: 12364302]

and hybrid closed-loop (HCL) systems. Pumps that are not part of an AID or HCL system do not change insulin dosing without the patient programming the pump to do so.

AID and HCL systems involve insulin pump delivery systems, glucose monitoring, and an algorithm to dispense insulin based on blood glucose levels. The algorithm is based on shared decision making between the patient and their clinician. Clinicians who care for patients with T1DM should become familiar with different types of insulin delivery and glucose monitoring systems.

What pharmacologic therapies can assist in glycemic control as adjuncts to insulin, and when should such therapies be considered?

Insulin replacement is fundamental to management of T1DM. However, adjunct therapy to improve glycemic control and patient outcomes is being investigated.

Metformin's mechanism of action is to reduce insulin resistance and increase insulin sensitivity. Theoretically, metformin could reduce the dosage of insulin required by increasing sensitivity. However, this is purely investigational, and the ADA does not recommend metformin in patients with T1DM outside a research setting (14).

β cells make both insulin and amylin, so when T1DM destroys β cells, amylin and insulin are no longer produced. Is there a benefit to replacing amylin as well as insulin? Amylin is involved in glycemic regulation by slowing gastric emptying and regulating release of glucagon. Pramlintide is a medication that is an analogue of amylin and is injectable. In adults who are not meeting glycemic goals, pramlintide can help to achieve goals and can also help with weight loss. Adverse effects include local injection site reactions or gastrointestinal side effects. According to the ADA, pramlintide can be considered adjunctive therapy to insulin (14).

The ADA recommends that persons with T1DM be prescribed glucagon and that they and their caregivers, school personnel, and household members be instructed in its use (14). Clinicians should ask about hypoglycemic episodes at each visit. Intake of 15 to 20 g of glucose is the preferred treatment for a blood glucose level less than 70 mg/dL (<3.9 mmol/L) in patients who are conscious, with repeated administration of glucose if hypoglycemia persists after 15 minutes. However, glucagon injection should be available for treatment if the patient is unable to cooperate with oral intake of glucose.

How should clinicians determine glycemic control targets for individual patients?

According to the ADA, hemoglobin A_{1c} goals in T1DM should be less than 7% in nonpregnant adults and less than 6% in pregnant women who can achieve this goal without hypoglycemia (14). In nonpregnant adults, preprandial glucose targets should be between 80 and 130 mg/dL, and the peak postprandial blood glucose level should be less than 180 mg/dL. Goals vary in pregnancy, and the ADA recommends that glycemic goals be individualized; generally recommended targets include a fasting glucose level of 95 mg/dL (5.3 mmol/L) or less, a 1-hour postprandial glucose level less than 140 mg/dL (<7.8 mmol/L), and a 2-hour postprandial glucose level less than 120 mg/dL (<6.7 mmol/L). In general, glycemic goals should be individualized on the basis of patient age and comorbid conditions.

What is the role of nutrition in the management of T1DM?

Nutrition plays an important role in managing T1DM. All adults with T1DM should be referred to a dietician, and in general, the ADA recommends individualized diet plans for patients with T1DM (14). A good meal plan allows for flexibility and "cheat days" as long as insulin dosing is appropriate for carbohydrate intake and overweight or obesity is not present. For patients with

flexible insulin delivery for short-acting insulin, meaning their insulin bolus is based on carbohydrates ingested, education on carbohydrate counting is critical. For those on fixed-dose bolus insulin, meal consistency is important; they should have predictable macronutrient distribution for each meal. Moderating refined sugar intake is recommended for everyone regardless of whether diabetes is present. The most important thing in persons with T1DM is to appropriately dose insulin according to carbohydrate and fat intake. Meals that are high in fat may lead to slower gastric emptying and generally require smaller amounts of insulin to avoid hypoglycemia than meals that have a similar carbohydrate content but are low in fat.

Patients should receive education about the effect of alcohol consumption on glycemic control. Excessive alcohol intake (>1 drink daily in women and >2 drinks daily in men) can lead to delayed hypoglycemia. Therefore, the carbohydrates in alcoholic beverages should not be accounted for when dispensing insulin to avoid hypoglycemia.

Nutritional supplements do not seem to play a role in T1DM management, though there is some evidence that replacing low vitamin D can lead to tighter glucose control in patients with T1DM (21).

What is the role of physical activity in the management of T1DM?

The ADA recommends at least 150 minutes of exercise per week for patients with T1DM (14). However, exercise can be associated with increased insulin sensitivity and therefore can lead to hypoglycemia. In addition, hyperglycemia can occur during intensive physical activity. In order to prevent dysregulation of glucose levels, glucose monitoring before and after exercise is important. If glucose levels are less than 90 mg/dL (<5.0 mmol/L), the basal insulin dose should be reduced if the patient is wearing a pump or a carbohydrate should be consumed before exercise to prevent hypoglycemia. If the patient's blood glucose level is over 350 mg/dL (>19.4 mmol/L), exercise should be avoided until levels decrease to the normal range to reduce the risk for ketosis (22).

What are the long-term complications of T1DM?

Emergencies associated with T1DM include DKA and hypoglycemia. Forty percent of adults have had at least 1 significant episode of hypoglycemia in their lifetime (23). Significant hypoglycemia involves the presence of symptoms, such as feeling shaky or having a seizure. With regard to long-term effects, the DCCT (Diabetes Control and Complications Trial) showed that T1DM causes both microvascular and macrovascular complications. Microvascular complications include nephropathy, neuropathy, and retinopathy. In terms of macrovascular complications, patients with T1DM are at elevated risk for coronary artery disease and cerebrovascular disease and are more likely to die of the latter (24). For these reasons, good glycemic control is vital in preventing long-term sequelae of diabetes.

Besides cardiovascular disease, T1DM is associated with infections and bone disease (25, 26). Persons with T1DM seem to have increased risk for stomach, liver, and kidney cancer compared with the general population, and it is not clear that better glycemic control prevents them. Poor control of diabetes leads to poor wound healing and higher risk for infection.

What clinical interventions reduce risk for complications?

The DCCT (24) and the subsequent EDIC (Epidemiology of Diabetic Interventions and Complications) trial (27) were landmark studies that provided insights into the management of T1DM to prevent long-term complications. The DCCT found that intensive therapy to achieve glycemic goals led to better microvascular and macrovascular outcomes. The EDIC trial established a concept called the legacy effect, in which intensive blood glucose control within a year of diagnosis of

21. Aljabri KS, Bokhari SA, Khan MJ. Glycemic changes after vitamin D supplementation in patients with type 1 diabetes mellitus and vitamin D deficiency. Ann Saudi Med. 2010;30:454-8. [PMID: 21060157]
22. Riddell MC, Gallen IW, Smart CE, et al. Exercise management in type 1 diabetes: a consensus statement. Lancet Diabetes Endocrinol. 2017;5:377-90. [PMID: 28126459]
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24. Jacobson AM, Musen G, Ryan CM, et al; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group. Long-term effect of diabetes and its treatment on cognitive function. N Engl J Med. 2007;356:1842-52. [PMID: 17476010]
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26. Schacter GI, Leslie WD. Diabetes and bone disease. Endocrinol Metab Clin North Am. 2017;46:63-85. [PMID: 28131137]
27. Epidemiology of Diabetes Interventions and Complications (EDIC). Design, implementation, and preliminary results of a long-term follow-up of the Diabetes Control and Complications Trial cohort. Diabetes Care. 1999;22:99-111. [PMID: 10333910]

T1DM leads to prevention of microvascular and macrovascular disease (3).

How frequently should physicians see patients with T1DM, and what should be included in follow-up visits?

Patients with T1DM should generally see their physicians every 3 months to check their hemoglobin A_{1c} level, weight, and blood pressure. It is important to assess occurrence of hypoglycemic episodes and other difficulties in blood glucose level control associated with meals, physical activity, or illness. It is also prudent to screen annually for dyslipidemia, thyroid dysfunction, nephropathy, and depression.

When should specialists be consulted in the care of patients with T1DM?

In the United States, the majority of patients using insulin pumps have an endocrinologist involved in their care, but primary care physicians who are knowledgeable about insulin delivery and glucose monitoring systems can also appropriately and safely manage T1DM care. Endocrinologist consultation should be considered if patients are not achieving glycemic control targets, are having difficulty with hypoglycemia or other complications, or require advanced therapy.

Nonphysician professionals are critical to the care of patients with T1DM, regardless of whether this care occurs in a subspecialty or primary care setting. Diabetes educators are integral to care, especially in patients with insulin pumps and CGMs. Nutritionists play a vital role in educating patients about carbohydrate counting, assessing meal content, and managing insulin doses around meals.

Regardless of setting, those caring for patients with T1DM should be familiar with continuous glucose monitoring and insulin delivery systems. It is fairly easy to start a patient on a CGM, particularly if working with a diabetes educator. A critical component of management is being able to download and review the data in the office. Primary care providers should also prescribe glucagon, which can increase blood glucose levels in hypoglycemia, to all patients with T1DM.

When should patients with T1DM be hospitalized?

Blood glucose levels persistently higher than 300 mg/dL (>16.7 mmol/L) are concerning enough that the patient should be recommended for emergent evaluation. Patients with DKA or hyperosmolar hyperglycemic nonketoacidosis (HHNK) generally require hospitalization, but mild DKA can be managed in the outpatient setting (17). Both DKA and HHNK present with increased urination, thirst, and hyperglycemia, and DKA can also present with confusion.

Treatment... Glucose monitoring and insulin replacement are the mainstays of treatment for T1DM. Multiple daily injections are the initial treatment recommendation, but an insulin pump and continuous glucose monitoring should be offered to all patients. Insulin dosing is based on basal and bolus insulin replacement. If multiple daily injections are given, bolus insulin can be administered as fixed mealtime dosing or flexible dosing based on carbohydrate counting. Along with continuous glucose monitoring, insulin pumps can help improve glycemic control, prevent DKA, avoid hypoglycemic episodes, and improve quality of life for many patients; unfortunately, finances are a common obstacle to their use. Adjunct therapies are under investigation, but the ADA currently recommends only pramlintide, an injectable amylin analogue, in adults who are not meeting glycemic goals. All patients should be prescribed glucagon and instructed in its use. Generally, patients should be seen every 3 months to assess glycemic control and should be evaluated at least annually for retinopathy, neuropathy, nephropathy, depression, thyroid dysfunction, and cardiovascular disease.

CLINICAL BOTTOM LINE

Practice Improvement

What measures do U.S. stakeholders use to evaluate quality of care for patients with T1DM?

Determination of quality of care for patients with T1DM ultimately focuses on achievement of glycemic control to prevent microvascular and macrovascular complications. Quality of care can be determined by the percentage of patients with a hemoglobin A_{1c} level at or below the goal. In addition, performance metrics include whether blood pressure is at goal and whether annual screenings for retinopathy, neuropathy, and nephropathy are being done. The overarching goal is to prevent microvascular and macrovascular disease.

What professional organizations regularly issue evidence-based recommendations for the care of patients with T1DM?

International and national guidelines for T1DM are available. Nationally, the ADA (14) and the Endocrine Society (18) provide clear and comprehensive guidelines. The ADA's annual Standards of Medical Care in Diabetes is a crucial educational tool for clinicians.

In the Clinic
Tool Kit

Type 1 Diabetes Mellitus

Patient Information

https://medlineplus.gov/diabetestype1.html
https://medlineplus.gov/languages/diabetestype1.html
Information and handouts in English and other languages from the National Institutes of Health's MedlinePlus.

www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes
www.niddk.nih.gov/health-information/informacion-de-la-salud/diabetes/informacion-general/que-es/diabetes-tipo-1
Health information in English and Spanish from the National Institute of Diabetes and Digestive and Kidney Diseases.

www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/4-steps
www.niddk.nih.gov/health-information/informacion-de-la-salud/diabetes/informacion-general/control/4-pasos-controlar-vida
Steps on how patients can manage type 1 diabetes, in English and Spanish, from the National Institute of Diabetes and Digestive and Kidney Diseases.

Information for Health Professionals

https://diabetesjournals.org/view-large/figure/4017489/dci210043f1.jpeg
Flowchart to assist in distinguishing type 1 and type 2 diabetes from the 2021 consensus report by the American Diabetes Association and the European Association for the Study of Diabetes.

https://care.diabetesjournals.org/content/44/11/2589
2021 consensus report on management of type 1 diabetes in adults from the American Diabetes Association and the European Association for the Study of Diabetes.

www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/diabetes
Information on diabetes from the National Institute of Diabetes and Digestive and Kidney Diseases.

www.jdrf.org/t1d-resources/hcp
Type 1 diabetes resources from JDRF.

WHAT YOU SHOULD KNOW ABOUT TYPE 1 DIABETES MELLITUS

What Is Type 1 Diabetes Mellitus?

Type 1 diabetes mellitus occurs when the pancreas stops making insulin, a hormone that controls blood sugar (glucose) levels. Without insulin, sugar from foods cannot get into cells and builds up in the blood. High blood sugar causes symptoms such as increased thirst, frequent urination, and fatigue. Very high blood sugars can lead to diabetic ketoacidosis, a life-threatening condition. Over time, high blood sugar can damage the kidneys, nerves, eyes, and heart. Type 1 diabetes can develop at any age. Treatment prevents short- and long-term complications.

Although type 1 and type 2 diabetes both result in high blood sugar and can cause similar complications, they are different diseases. In type 2 diabetes, the pancreas makes plenty of insulin, but the body does not respond to it normally.

What Are the Signs and Symptoms?

- Frequent urination, including at night
- Increased thirst
- Fatigue
- Abdominal pain
- Weight loss
- Failure to grow normally in children

What Are the Risk Factors?

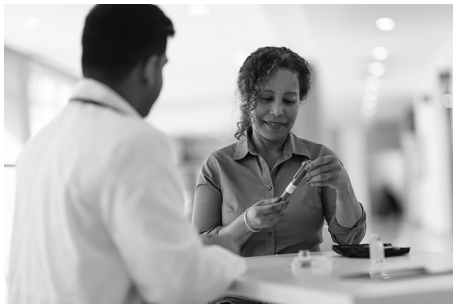
The main risk factor is having a first-degree relative (sibling or parent) with type 1 diabetes. Antibody testing in people with a family history can help determine risk for type 1 diabetes.

How Is It Diagnosed?

When symptoms that could be due to type 1 diabetes develop, diagnosis is made by measuring blood glucose levels and/or hemoglobin A_{1c}, which indicates blood sugar levels over the previous 3 months.

How Do I Know if I Have Type 1 or Type 2 Diabetes?

Type 2 diabetes is likely if the patient has overweight or obesity, has a history of prediabetes, had high blood sugars during pregnancy (gestational diabetes), or has no symptoms or symptoms that developed gradually. Type 1 diabetes is likely if the patient is younger, does not have overweight or obesity, has a family history of type 1 diabetes, and has symptoms that developed rapidly. Testing for autoantibody levels can also help confirm type 1 diabetes.



Can It Be Prevented?

There are currently no known ways to prevent type 1 diabetes. Once diagnosed, it can be managed by working with a health care team to control blood sugar levels and prevent complications.

How Is It Treated?

The focus of type 1 diabetes management is controlling blood sugar to reduce short- and long-term complications of high blood sugar (hyperglycemia) while avoiding dangerously low blood sugar (hypoglycemia). Patients with type 1 diabetes require insulin treatment to replace the insulin their body can no longer make. Many technical advances have occurred in ways of measuring blood glucose and administering insulin, so people with type 1 diabetes should work with a health care team with experience in treating the condition. Management of diet and physical activity are also important, as are tests to screen for and treatments to reduce risk for complications.

Questions for My Doctor

- What are optimal blood sugar and hemoglobin A_{1c} targets for me?
- How often do I need to check my blood sugar?
- Would I benefit from using a continuous glucose monitor?
- How do I know how much insulin to take?
- Would I benefit from using an insulin pump instead of injections?
- How do different foods affect blood sugar?
- How does physical activity affect blood sugar?
- What are symptoms of low blood sugar, and what should I do if it happens?
- How often do I need to see my health care team?

For More Information

Centers for Disease Control and Prevention
www.cdc.gov/diabetes/basics/what-is-type-1-diabetes.html

American Diabetes Association
www.diabetes.org/diabetes/type-1

ACP℠
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Leading Internal Medicine, Improving Lives

Patient Information