

Summary of the American Diabetes Association® Type 1 Diabetes Screening & Awareness Roundtable

Following are the insights and recommendations from the American Diabetes Association's (ADA's) virtual roundtable held on December 15, 2023, supported in part by Sanofi. The meeting **goals** included:

1. Understand opportunities and barriers to type 1 diabetes screening awareness.
2. Use feedback to develop pilot materials targeting both health care professionals (HCPs) and consumers—which will be tested and evaluated.
3. Take these insights to begin targeted messaging to both HCPs and consumers.

As of April 15, 2024, the Roundtable Report was reviewed and endorsed by the American College of Osteopathic Family Physicians, the American Academy of Physician Associates, and the International Society for Pediatric and Adolescent Diabetes.

Opportunities

After decades of research, we finally have ways to detect early-stage type 1 diabetes and to possibly delay its onset.

- Type 1 diabetes screening and monitoring can help people avoid diabetes ketoacidosis (DKA), leading to better health outcomes.
- New teplizumab infusion treatment can delay type 1 diabetes onset by an average of two years, giving people more time to prepare for life with the disease.
- Generating awareness of these developments will help more people benefit from them and may help bring other new therapies to market.
- Screening is also a chance to reclassify people who have been diagnosed with type 2 diabetes, but really have type 1 diabetes.
- The ADA can lead the field with recommendations for who needs to be screened and when, as well as the appropriate health system workflows.

Barriers

- **Education:** The health care community and the public are generally uninformed about recent developments in type 1 diabetes staging, screening, and treatment. Even endocrinologists are challenged by the management of patients with early-stage type 1 diabetes.

1

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- **Culture change:** Type 1 diabetes awareness and screening will require a major shift in primary care. Primary care providers (PCPs) already have so many diseases and conditions to watch for. Can they accept one more, and will they be comfortable with it?
- **Capacity and infrastructure:** Most PCP and endocrinology practices are stretched thin. Not all lab facilities are prepared to conduct blood testing for type 1 diabetes islet autoantibodies. Also, most electronic health record (EHR) systems aren't set up to capture necessary data.
- **Sphere of influence:** Diabetes care professionals are often one or more steps removed from people who are at risk. They need to be able to reach people who are not their patients.
- **Cost and reimbursement:** Type 1 diabetes autoantibody testing is costly to implement. The field is concerned about the complexities of billing and coverage for this care. Each step of the workflow must be reimbursable to be scalable. ICD-10 codes specific for preclinical type 1 diabetes are still pending. (It was later confirmed that stages 1 and 2 do count as a type 1 diabetes diagnosis, which means education and care are eligible for reimbursement.)
- **Patient perceptions:** People at risk may be influenced by common misconceptions about diabetes, starting with the differences between type 1 and type 2 diabetes. Also, it is generally tricky to communicate percentage- and time-based risk in a way that people easily understand (e.g., "Your child has a 44% chance of developing type 1 diabetes in five years.").
- **Social and emotional wellbeing:** A type 1 diabetes diagnosis at any stage comes with emotional and psychological implications. People may be hesitant to screen because they would rather not know the results.
- **Advocacy:** What are the implications for health insurance, life insurance, job applications, military enlistment, pilot's licenses, etc.? Advocacy is required to prevent diabetes discrimination against people with early-stage type 1 diabetes.
- **Do no harm:** The diabetes care community is enthusiastic about type 1 diabetes developments but doesn't want to overpromise the impact of treatment, ignore the risks associated with treatment, or give people a false sense of security. Assessing the risks and benefits is a challenging issue for many PCPs and some specialists. The literature quotes that the general population risk is 0.5% and how many develop type 1 diabetes is not a straightforward topic.

Who to Screen

Given the cost-benefit ratio of type 1 diabetes screening, roundtable experts generally agreed on a stratified public health approach that starts with highest-risk populations (of any age).

- **Phase 1:** Those with a family history of type 1 diabetes and children.
- **Phase 2:** People with a personal or family history of autoimmune diseases (thyroid, celiac, etc.); people of Finnish, Swedish, and German descent; and those from other countries with a high incidence of type 1 diabetes.
- **Phase 3:** General public

Health care professionals should test for type 1 diabetes autoantibodies whenever someone is diagnosed with prediabetes or type 2 diabetes. This could prevent misdiagnoses and inappropriate treatment.

To facilitate and support insurance coverage for testing and treatment, the ADA can and should lead with these recommendations in the *Standards of Care in Diabetes* (including the abridged version often referenced by PCPs). With more time and more evidence, the hope is the U.S. Preventive Services Task Force will follow suit with recommendations and that Medicaid will cover type 1 diabetes screening services.

How to Identify People at Risk

The roundtable surfaced several ways to reach people at risk and to improve future identification.

- Start with EHRs and conduct health-system-wide outreach to people at risk.
 - However, search results are typically limited. This strategy must be coupled with a concerted effort to document family history of type 1 diabetes more consistently in EHRs.
- Reach adults with type 1 diabetes through endocrinology practices. Encourage them to have their children screened and deliver that recommendation back to their respective PCPs.
- Reach youth with type 1 diabetes through pediatric endocrinology practices to encourage siblings and younger parents to be screened.
- Collaborate with domestic and international patient advocacy/support groups.
- Collaborate with other specialists who treat autoimmune diseases (e.g., gastroenterologists) and those who do genetic testing.
- The 2023 U.S. News and World Report survey for pediatric endocrinologists now has questions about whether groups are providing education for first-degree relatives of people with type 1 diabetes. This could be another avenue for disseminating messages.

Where to Screen

Roundtable panelists agreed that primary care was the best setting for initial screening. Primary care is covered by insurance more easily than specialty care. Patients should be referred to endocrinology for an official type 1 diabetes diagnosis and next steps.

- In the pediatric population, type 1 diabetes screening could be paired with routine screenings for lead, hemoglobin, and cholesterol levels (ages 1–2, 4–6, 9–11, 11–13).
- PCPs will need to be prepared with conversation guides and other communication/education tools (see more below).
- Screening will be more challenging for remote and other underserved communities that don't have easy access to endocrinologists. Mobile clinics could be a solution, like with type 2 diabetes and other health screenings.

- Public health nurses also could be a good audience to engage, especially for reaching people who don't have established primary care practices.
- Telehealth could also expand access to endocrinologists and facilitate more in-depth consultations.

Motivators to Screen

All:

- Screening, *when combined with consistent monitoring and education about type 1 diabetes signs and symptoms*, can prevent people with early-stage type 1 diabetes from developing dangerous DKA—and thus prevent emergency room visits, hospital stays, and even deaths at stage 3 (traditionally considered type 1 diabetes onset).

For people at risk/caregivers:

- Finding out you have stage 1 or 2 of type 1 diabetes gives you and your family more time to learn all about diabetes management, such as counting carbohydrates, treatment options (insulin administration, diabetes technology), addressing emotional needs, navigating social situations, etc.
- Knowing your risk for type 1 diabetes will help you take advantage of current and future therapies once available.

For people with type 1 diabetes:

- People with type 1 diabetes often worry about the hereditary risk for their family members. With new autoantibody testing, they can now find out for sure—and do something about it.

For health care professionals (HCPs):

- Education is the responsibility of all HCPs involved in the monitoring and care of individuals with type 1 diabetes. You can help your patients make the right choice.
- When we diagnose type 1 diabetes sooner, we can help people achieve better A1C and other outcomes earlier in their diabetes journey.
- Early type 1 diabetes screening gives you a chance to form relationships with people and families when they are healthy and educate them over a longer period of time.
- Type 1 diabetes screening is a chance to help select people with type 2 diabetes who are not responding to initial treatment (because they may really have type 1 diabetes).

Key Messages

The roundtable participants encouraged talking about stage 1 of type 1 diabetes as a disease, just as we do with hypertension and prediabetes. The well-honed TrialNet messaging could provide a useful

4

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initial framework. Colleagues in genetic counseling and newborn screening spheres may also offer insight on effective messaging.

They also agreed clinicians should present all options and let at-risk people/families make the final decision about whether to screen or pursue treatment. Also, messages should be delivered in an empowering, hopeful way.

Takeaways for HCPs:

- There are new type 1 diabetes discoveries you may not know about, but you should.
- Early-stage type 1 diabetes is a disease marked by the presence of islet autoantibodies.
- Screening the right people gives them the best chance at a long, healthy, happy life (especially in pediatrics).
- For the adult population, type 1 diabetes poses a significant health risk.
 - Analogy: With untreated hypertension, someone has a 2–5% chance of heart attack or stroke in the next five years. With the presence of type 1 diabetes autoantibodies, the risk of developing type 1 diabetes is at least 35%.
- Help your patients learn about their risks and make an informed choice.
- In addition to screening, monitoring is important to reduce the risk of DKA.
- You can be reimbursed for time spent on care related to type 1 diabetes awareness, screening, education, and diagnosis.
- The ADA is here to help you with education and tools.

Takeaways for people at risk/caregivers:

- There are new, exciting discoveries in type 1 diabetes research you may be interested in and can benefit from. Take advantage of the latest in detection and management.
- If a close family member has type 1 diabetes, you are 15 times more likely to develop it. However, about 90% of people with type 1 diabetes do not have any family history.
- We used to think type 1 diabetes happened very suddenly. Now, thanks to research, we know this autoimmune disease happens gradually over time as the body attacks the insulin-producing beta cells in the pancreas—long before symptoms show up.
- Knowledge is power. With information about your type 1 diabetes status, you can prepare for a long, healthy, happy life.
 - If you receive a positive result, we may be able to do something about it. There is hope, and you're in control.
 - If you get a negative result, you may need to be screened again.
- If we can delay type 1 diabetes onset by two years (on average), that means 3,000+ fewer injections, 3,000+ fewer finger sticks, 250–300 fewer infusion set changes, 50–75 fewer continuous glucose monitors changes, etc.
- If we can delay type 1 diabetes onset by two years (on average), we may be able to delay the development of diabetes related complications.

- We currently do not have a way to prevent type 1 diabetes entirely. Treatment (teplizumab infusion, ages 8+, in the USA) delays type 1 diabetes onset by an average of two years. But we have no way to predict how it will work for you.
- It is your choice whether to get screened or to pursue preventive treatments.
- We understand this is stressful and scary. Your health care team is here to support you and keep you healthy and do what you love.
- By joining TrialNet or another clinical study, you can help other people with and at risk for type 1 diabetes in the future.

Next Steps After a Positive Screening

Panelists agreed that patient-provider conversations should begin from the moment the type 1 diabetes screening test is ordered and remain ongoing. They recommended an interdisciplinary approach to monitoring and care, with centralized case management.

- HCPs must explain what the type 1 diabetes screening results mean and, if positive, their options for delaying the onset of type 1 diabetes.
- This conversation was estimated to take 30 minutes to two hours. This is too much for most PCPs and even endocrinologists to execute in a typical visit.
 - Certified diabetes care and education specialists (CDCESs) could play an important role in filling this gap. One participant mentioned about one-third of primary care practices have a CDCES already.
 - This diabetes education and support could take place over several weeks.
 - This will require most CDCESs to become trained in the skills and competencies for type 1 diabetes.
- Referral to other specialists may be necessary, such as behavioral health, psychologist, nutritionist, etc.
- The ADA has a 1-800 hotline for general diabetes information. Could this resource support people who have stage 1 and stage 2 type 1 diabetes? This resource could be especially useful for people who must wait weeks or months to see an endocrinologist or CDCES.

Workflow Considerations

- Whenever possible, type 1 diabetes screening should piggyback on routine screenings/blood draws in pediatrics and family practice.
- Positive screening should be followed by prompt confirmation with an endocrinologist.
- Negative screening should prompt periodic follow-up tests for people at risk.
- EHRs will need to be updated to capture the right information.
 - Type 1 diabetes family history needs to be coded and entered.

- Stage 1 or 2 of type 1 diabetes diagnosis needs to be coded and consistently documented to help teams monitor people's A1Cs and provide clues if they begin to present with type 1 diabetes symptoms.
- HCPs must have a repository of handouts, educational videos, etc., to supplement in-person conversations.
- Health systems should be able to easily distribute materials to all the relevant HCPs in their network.

Possible Campaign Materials

All communications and educational materials must be accessible, engaging, and person-centered.

- Public service announcements to help people learn their risk and encourage them to get screened.
- Infographics for HCPs and people with diabetes: Explaining the three stages of type 1 diabetes
- Infographic for HCPs: Does your type 2 diabetes patient really have type 1 diabetes?
- Communication guides for HCPs (talking points/scripts):
 - Explaining type 1 diabetes risk factors and the need for screening
 - Explaining positive results and options for therapy to delay onset, plus the need for ongoing monitoring.
 - Explaining negative results and the need for ongoing screening for people at risk
- Handouts for patients to complement HCP conversations.

Remaining Questions to Consider

- How can we study the motivators for NOT getting or recommending type 1 diabetes screening (finances, fear, don't want to know about something that seems inevitable. etc.)? This will help us craft the most effective messages.
- How firm are the screening recommendations? Are we simply letting people know screening is available and recommending it? Or are we mandating screening with the chance to opt out?
- Could cheek swabs eventually become an alternative to blood tests and further lower barriers to screening?

Next Steps

Interested roundtable participants will reconvene in January 2024. An advisory committee will be formed to guide the development and delivery of the pilot educational materials.

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