



Developing a Type 1 diabetes screening program in Canada: Insights from citizen panels and a national stakeholder dialogue

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Conflicts of interest

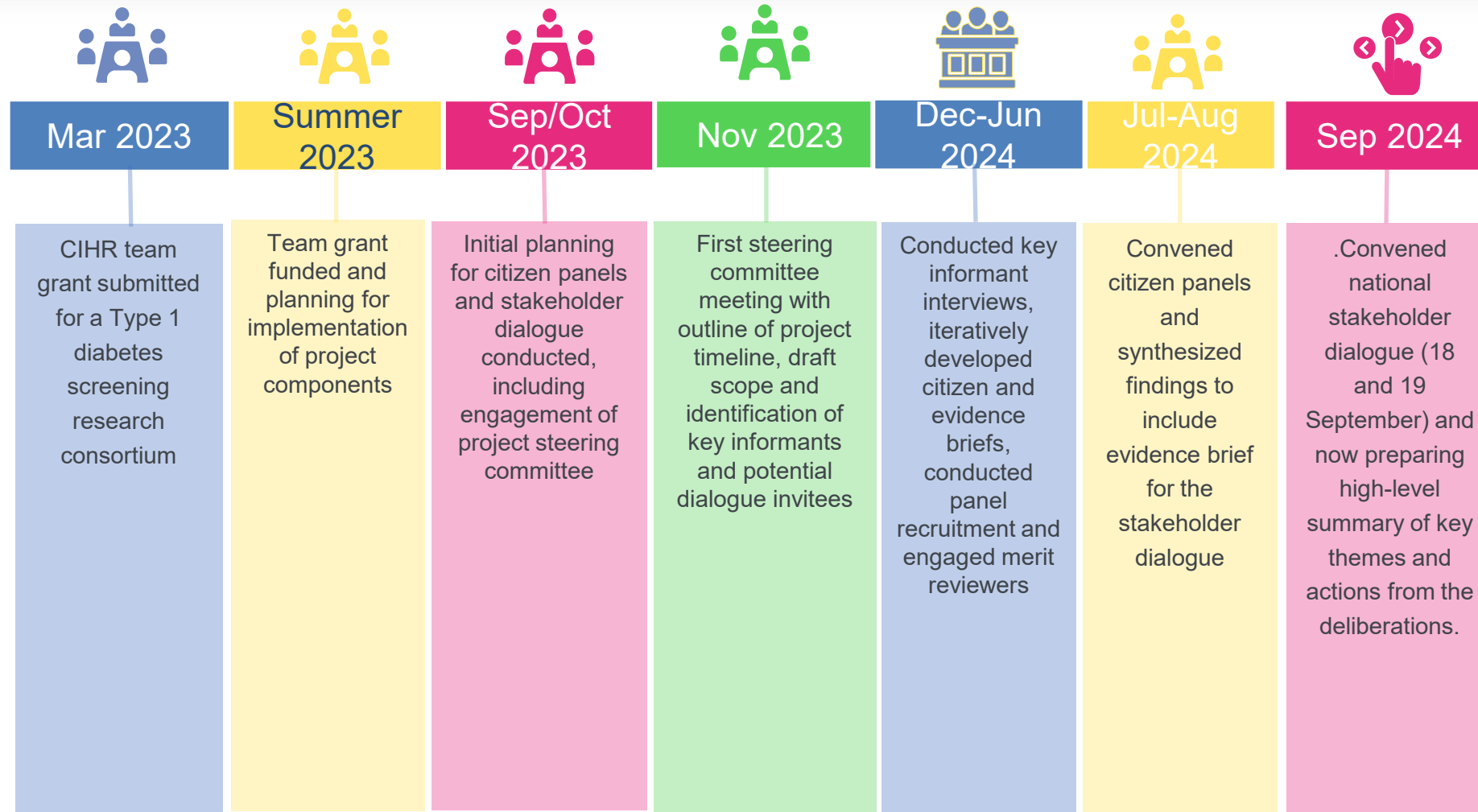
- No conflicts to declare

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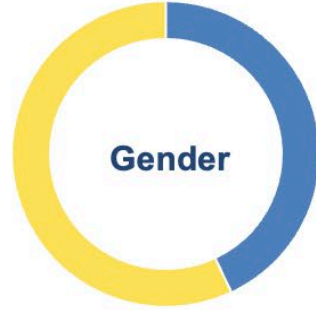
Project timeline



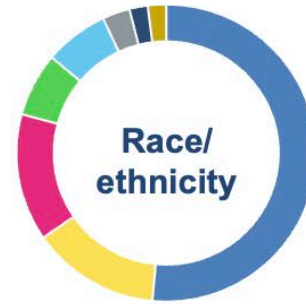
Profile of citizen panel participants (n=58)



- I have Type 1 diabetes
- I am a caregiver to someone under 18 years with Type 1 diabetes
- I have a family member under 18 years with Type 1 diabetes
- I have a family member (not under 18) with Type 1 diabetes
- I do not have Type 1 diabetes and I do not know anyone with Type 1 diabetes



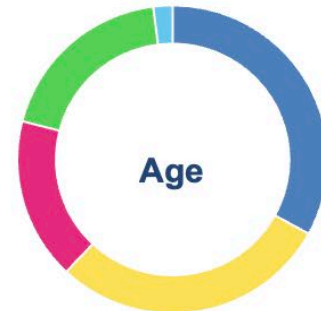
- Male
- Female



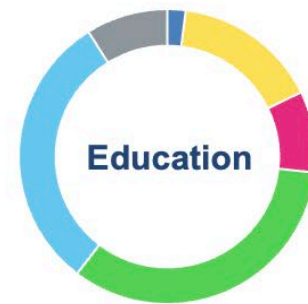
- White
- African/Caribbean/Black
- Arab/Middle East
- Latin American
- Asian, East or Southeast
- Asian, South
- Prefer not to say
- Indigenous



- Full-time
- Self-employed
- Prefer not to say
- Unemployed
- Retired
- Part-time
- Student
- Disabled



- 35–49
- 25–34
- 15–17
- Prefer not to say
- 50–64
- 65 and +
- 18–24



- High school
- Technical school
- Post-graduate training
- Community college
- Bachelor's degree
- Prefer not to say



- \$80K or more
- Prefer not to answer
- \$35–\$49,999
- \$50–\$79,999
- \$20–\$34,999
- Less than \$20K

Profile of national stakeholder dialogue participants (n=19)



One provincial government policymaker



One leader from a citizen group



Nine system and organizational leaders

- Two leaders from one national organization
- Five leaders (one from B.C., three from Ontario and one from eastern Canada from provincial health organizations)



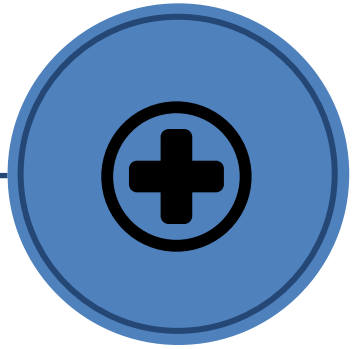
Five academic leaders



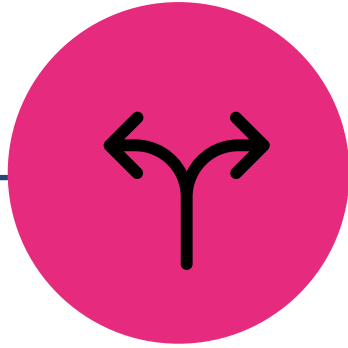
Three professional leaders

Two leaders from Ontario and one from Quebec organizations/groups

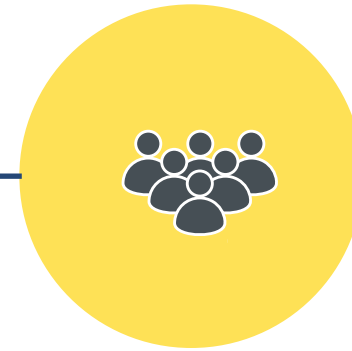
Problem framing for deliberations



Type 1 diabetes is a chronic health condition with life-long implications for patients, their families and caregivers, and health systems in Canada



There is a lack of consensus on whether population-level screening is warranted for Type 1 diabetes



If screening for Type 1 diabetes is deemed to be warranted, there is a lack of consensus on how it should be designed



Any approach taken will also face system-level challenges that will need to be addressed to support adoption across Canada

Three elements of an approach to consider for a T1D screening program in Canada



Deciding on whether, when, where and who should offer screening

- **Whether:** Are the benefits (e.g., awareness, follow-up to enhance awareness of symptoms, preventing DKA) worth the potential trade-offs (e.g., false negatives, psychological burden)
- **When:** Newborn, vaccination ~age 4, school age
- **Where:** Physician's office, specialty lab or clinic, pharmacy, schools, at home
- **Who:** Physician, nurse, lab technician, pharmacist, self-administered



Changing system-level arrangements to integrate a new screening program

- Helping parents, guardians and caregivers make decisions on whether they want to have screening done (e.g., decision aids)
- Changing care pathways to follow and engage people identified at risk for Type 1 diabetes
- Using virtual care to provide updates about screening and risk assessments
- Engaging a most responsible clinician or team of clinicians who are responsible for tracking people identified as at risk
- Making sure that the approach is culturally appropriate and addresses other barriers (e.g., language or health literacy)
- Conducting outreach for those who are not connected to the health system
- Engaging citizens in decision-making processes about T1D screening programs



Supporting people identified as at-risk for Type 1 diabetes

- Providing information and educational materials for parents, families and those identified as being at-risk
- Using accessible and easy-to-use ways of communicating information (e.g., online patient portals)
- Updating and communicating adjusted risk assessments over time
- Managing how risk for Type 1 diabetes is shared and implications for confidentiality and insurance
- Providing referrals and coverage for psychological assessment for anxiety and other mental health conditions
- Helping people from all walks of life be engaged in research studies about Type 1 diabetes to evaluate how well screening works and potential therapies for delaying the onset or preventing Type 1 diabetes.

Key themes identified from the citizen panels about **problem framing**



Provincial and territorial health systems lack capacity and resources to support widespread screening and follow-up care for Type 1 diabetes



Families face potential long-term anxiety and stress when identified as high-risk without clear timelines for onset of Type 1 diabetes



Existing data management systems are insufficient to ensure privacy, confidentiality, and appropriate use of screening results



Lack of comprehensive public education and awareness about Type 1 diabetes and the importance of early screening and detection

Key insights from citizens about whether and when to offer screening

- **Whether**

- Broad support for population-level screening for Type 1 diabetes given improved health outcomes that could be achieved
- Emphasis on the importance of making screening free, voluntary and easily accessible to all, regardless of location, language, culture or socio-economic status

- **When**

- Most favoured integrating screening into existing newborn programs given existing infrastructure and processes could be harnessed
 - Some expressed concern about long-term anxiety for families of those identified as at high risk and preferred no screening or other options
- Smaller number of participants supported school-aged screening (e.g., at time of vaccination or later) and highlighted the value of student engagement with those currently living with Type 1 diabetes as having the potential to help with raising awareness and providing education
 - Concerns were raised about: 1) the added burden it may cause schools systems; and 2) coupling screening with vaccination schedules given vaccine hesitancy that could limit the reach of screening and also affect its trustworthiness
- Another small sub-set of participants supported a hybrid model where screening could be offered at multiple times (i.e., newborn, pre-school, and school age) to accommodate different preferences, ensure that it is voluntary and ensure that recent immigrants and refugees are able to benefit from screening, and to identify cases potentially missed by newborn screening alone (i.e., to reduce the number of false negatives)

Key insights from citizens about **where and who should offer screening**

- **Where to screen and who should offer it**
 - All participants strongly preferred screening to be conducted:
 - by trained healthcare professionals to ensure accuracy to support linkage to support and education following a high-risk screening result
 - in controlled, professional environments such as hospitals, doctor's offices, or specialized clinics
 - with a coordinated approach between providers and settings to ensure accurate collection, management, and communication of results
 - Most expressed significant reservations with the idea of using self-administered home test kits
 - A number of participants also indicated that pharmacies and pharmacists or the 'local point of services' model in Quebec could play a role in offering screening and providing follow-up over time to enhance accessibility

Key insights from citizens about **system-level arrangements to integrate a new program (element 2) and supporting people identified as at risk (element 3)**

- **Need for coordination between provincial and territorial health systems to ensure consistent standards and data sharing**
 - Viewed as important for helping to ensure equity across the country where everyone would benefit from a similar approach
 - Need for a centralized, secure data management system to store and manage screening results, with clear policies on data access and use to ensure strong privacy standards
- **Ensure availability of sufficient resources and adopt innovative solutions to address resource constraints**
 - Highlighted as part of overall concern about the current strain on the healthcare system (e.g., are there enough specialists? How can primary care accommodate?)
 - Key suggestions for system-level innovations included leveraging pharmacists, community health workers, and nurse practitioners to assist with screening and follow-up care, with specialist support available in ways that make the best use of their expertise and time
 - Some proposed expanding the role of existing diabetes clinics to support the screening program
- **Use a patient-centred approach to integrate a new Type 1 diabetes screening program**
 - e.g., mix of in-person and virtual options; patient decision aids, team-based and culturally-appropriate approaches; ongoing engagement of citizens in decision-making processes

Key insights from citizens about **implementation considerations (important outcomes to measure as part of eventual piloting + ongoing monitoring and evaluation)**

- **Screening rates**
 - Overall + # people identified as high or low risk + # of false positives and negatives (quality of the test result)
 - By province and region within provinces to identify underserved areas to target outreach
 - By equity-deserving groups (e.g., Indigenous peoples, immigrants and refugees, different ethnocultural groups, low socio-economic status)
- **Health-related outcomes** (e.g., by tracking the number of DKA events and emergency room visits averted)
 - Psychological impacts of screening (e.g., stress, anxiety, depression)
 - Rates of blood-sugar control
 - Incidence of DKA
- **System-level outcomes**
 - Emergency room visits related to Type 1 diabetes (e.g., from hypoglycemia and DKA)
 - Children and families connected to treatment and support (i.e., did people get access to what was promised or needed)
 - Costs and cost-effectiveness
- **Patient experiences** (ideally with patient stories)
 - Decision to screen versus not to screen
 - Experience with screening
 - Experience following screening (e.g., during follow-up and identifying whether people were happy with the decision they made)

Key insights from the stakeholder dialogue about problem framing (1)

The balance of potential benefits and harms is unclear

- Potential benefits: Follow-up care, prevention of DKA through early detection, possibility of delaying onset by 3-5 years during formative years of childhood or adolescence
- Potential harms that will require careful study (e.g., short-, medium- and long-term psychological impacts; labelling children at a young age that could lead to challenges such as disordered eating; discrimination)



Limited evidence in many areas which underscores that Type 1 diabetes screening is not ready for population-level screening

- Uncertainty about therapeutics that can delay onset
- No evidence from randomized controlled trials or about cost-effectiveness
- Applicability of polygenic risk scores for the diverse ethnocultural backgrounds of Canadians



Key insights from the stakeholder dialogue about problem framing (1)



Continued lack of consensus about how best to design an equity driven Type 1 diabetes screening program

- System capacity concerns
- Use genetic screening, antibody testing or both?
- No consensus on timing of screening, optimal care pathways
- Data management and privacy and how to achieve a consistent approach nationally



Challenges related to awareness and education about T1D in general and screening specifically (e.g., diagnosis of

- T1D vs. T2D
- Clinical practice guidelines not covering anything about screening yet and awareness among policymakers about the feasibility and affordability of screening and follow-up care needed

Key insights from the stakeholder dialogue about **elements of an approach for a T1D screening program (1)**

Most of the deliberation focused on **whether** and to some extent **how** to move forward with a Type 1 diabetes screening program in Canada, through the lens of feasibility and acceptability

- **Nature and extent of evidence needed to support whether to implement a new screening program, and the approach needed to use it to advance a new screening program**
 - Some emphasized that screening could not be recommended without evidence from robust RCTs
 - Many noted that such RCTs are unlikely to be feasible for a population-health intervention such as T1D screening
 - Pursuing screening will need to be done through a “start small approach” embedded within a research-driven program with pilots for different approaches
 - (eventually) Use learning and improvement cycles to identify whether and when to scale up (e.g., when likely benefits are clear, likely harms have been documented and GRS scores are refined and tested for the diverse ethnocultural backgrounds in Canada)
 - An open science approach could be beneficial to enable ongoing synthesis of evidence emerging from other jurisdictions (e.g., Australia and the U.K.), which would help Canada as some noted it is behind in generating evidence about T1D screening

Key insights from the stakeholder dialogue about **elements of an approach for a T1D screening program (2)**

- **Adopting an equity-driven approach is essential**
 - Ensure that benefits are realized by all groups (i.e., by ensuring an eventual equity-driven universal approach to screening for Type 1 diabetes, with a GRS that works for all groups)
 - No consensus on whether newborn screening was the optimal approach to deliver equity, or whether offering GRS at a different time will deliver inequities
 - Ability to deliver equitable testing for different ethnocultural backgrounds was questioned
- **Genetic testing is coming and so are the immunotherapies and there is a need to “get ahead of the curve”**
 - E.g., through whole genome projects/sequencing
 - There will be more testing and treatments, and this will mean starting to add new things on
 - Important to start planning now (with time) through in an evidence-based, rather than later in a haphazard and rushed way
- **Adopt co-design with:**
 - Community-care (e.g., pharmacies) and primary-care sectors
 - Existing screening programs (e.g., newborn)
 - Other key pieces of system infrastructure (e.g., laboratories for scaling genetic testing)
 - (not discussed, but emphasized in the citizen panels) Meaningful citizen engagement

Key insights from the stakeholder dialogue about **implementation considerations**

- **Deliberation about design/elements intertwined with implementation considerations, particularly the scope of what to do first**
 - Focus on starting small with research-based pilots and considering it as a way to advance a learning health-system approach by prioritizing small-scale piloting within the context of a research program
 - Risk for misinformation and limited trust if not implemented in ways that are based on robust evidence and/or associated with areas that are already the target of misinformation (e.g., vaccination programs).
- **Limited system capacity or ability to provide needed follow-up care**
 - While there are some structures in place as building blocks for endocrinologists to manage positive newborn screening, implementation will be complex since it requires following based on risk and not diagnosis
 - The meaning and interpretation of a risk score won't become apparent until much later so the responsibility may fall to primary care which is already overstretched
 - While community-based sites (e.g., pharmacies) could be positioned to provide ongoing support, expanded scopes of practice have not been consistently implemented well, and it's unclear whether there is capacity (although the U.K. is using pharmacies, but best match might be for screening and not follow-up)
 - Systems are overstretched and we aren't even able to do continuous glucose monitoring for everyone so how can screening be implemented when we don't meet this level of care?
- **Key stakeholders, funders and community groups will be essential for fostering a clinical community**
- **Need for continued deliberation about feasibility of an RCT**

Key insights from the stakeholder dialogue about **next steps**

- Solidification of what we know (e.g., in the form of a scoping review or a living evidence synthesis)
- Not ready for primetime as there are too many questions to answer
 - Lots of potential to fund future research using an exercise to create a prioritized research agenda (domestically and globally, e.g., for global trials)
 - The real push has to be for a robust research agenda in collaboration with our communities and funders (including several relevant institutes at CIHR)
 - What needs to be reconsidered in current research priorities and what additional priorities and initiatives are needed beyond this
- Enhancing awareness (both about T1D in general, but also more specifically about what GRS scores are and what they mean)
 - Continue to ensure robust public engagement in all stages of the work
 - Also need to engage broader clinical community that will eventually need to be involved
 - Need for engagement of federal, provincial and territorial policymakers
- Address the lack of important infrastructure for this work, including the right assays to test the GRS with different ethnicities

Questions?

- **Contact information**

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