Diabetes Action Canada
Preventing complications. Transforming lives.

Strategy for Patient-Oriented Research SPOR
Putting Patients First
Stratégie de recherche axée sur le patient SRAP
Le patient d'abord

DIGITAL HEALTH RESEARCH:
OPPORTUNITIES FOR IMPROVING THE HEALTH OF CANADIANS

A White Paper submitted by Diabetes Action Canada to the
New Digital Research Infrastructure Organization (NDRIO)

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About Diabetes Action Canada

Diabetes Action Canada is one of the five national Chronic Disease CIHR Strategy for Patient-Oriented Research (SPOR) Networks. Our **mission** is to develop patient- and research-informed innovations in equitable health care delivery designed to prevent diabetes and its related complications and to achieve the Quadruple Aim goals (to improve: patient experience; population outcomes; health professional experience; health system costs). We have established a network of 106 patient-oriented investigators, from 20 research institutions across Canada, who collaborate with 93 Patient-Partners. Our sponsors include Diabetes Canada, JDRF, biopharmaceutical and insurance companies and private donors.

Current State of Diabetes in Canada

Diabetes affects 1 in 10 adults in Canada's general population and is two to three times more common in our Indigenous Peoples. It is the single most common cause of preventable blindness among working aged Canadians, lower limb amputations and kidney failure, and is a major risk factor for heart disease, strokes, cancer, mental health disorders and poor outcomes for all other chronic conditions[1]. Diabetes is easy to define, identify and track at a population level using health data definitions that are common across Canada. Those who are at greatest risk for devastating diabetes complications and whose complex care accounts for a sizeable majority of health system costs, are disproportionately represented by individuals who are most socially disadvantaged, including those living in poverty, isolated older adults, Indigenous Peoples, refugees and new immigrants and especially women within these groups[2].

Canada's current health and social care system is failing to meet the needs of persons with diabetes at highest risk for poor health outcomes[3]. This occurs because elements of the social, financial, and cultural environment affect how psychological and biological determinants of health interact to determine overall outcomes[4]. This urgent challenge can only be addressed by understanding how all these factors interrelate and by working with frontline providers, patients, families and policy makers to co-develop sustainable, transformative solutions. Necessary information about all of these determinants, and the predictive analytics required to illuminate risk of adverse health outcomes for individuals and populations, are the focus of our research Network. Just as the discovery of insulin transformed the lives of persons with diabetes, the application of digital health is ready to become the 'insulin' of the 21st century. However, if mismanaged this application may also increase health care inequalities that have highlighted and widened during the COVID pandemic.

The World Health Organization defines digital health as *"the field of knowledge and practice associated with the development and use of digital technologies to improve health, [including] mobile health- the use of mobile wireless technologies for public health – [as well as] the use of advanced computing sciences in 'big data' genomics and artificial intelligence."*[5] Diabetes Action Canada recognizes the urgent need to establish new standards of care and prevention for persons with diabetes using digital health solutions. The following describes our current projects and future directions related to the use of digital research infrastructure in Canada.

Access to the Right Information at the Right Time

Across the globe those countries (e.g., Denmark[6], Sweden[7], Scotland[8]) that have invested in disease registries that identify those persons with non-communicable conditions, such as diabetes, have demonstrated the value of being able to connect with them, provide evidence-based treatment and prevent adverse outcomes.

Canada has not done this and the COVID pandemic has underscored the **lack of our ability to reach out to individuals who require managed care and to track their outcomes**. To create a framework for population-based digital health, Diabetes Action Canada has established the first National Diabetes Repository (NDR) of primary care electronic medical record (EMR) data with information from 123,000 persons with diabetes from five provinces with age-matched persons without diabetes[9]. These data have been acquired in collaboration with the Canadian Primary Care Sentinel Surveillance Network (CPCSSN). We rely on timely downloads of EMR data from software applications owned by the three major Canadian EMR vendors, TELUS Health, QHR-Accuro (owned by Loblaw) and WELL Health OSCAR. Within our secure management and analytic environment housed at a Compute Ontario facility, these encrypted and de-identified data are used by our researchers to study the impact of diabetes on populations, effectiveness of treatment and gaps in health care.

Currently, **legislative and technical barriers** prevent us from: 1) linking the EMR data to provincial administrative data; 2) sharing health administrative data across provincial borders; and, 3) proactively reaching out to patients flagged as high risk for diabetes and its complications because administrative barriers limit the permissible use and disclosure of the data. Additionally, each provincial organization holding and managing health data has their own policies and procedures for data quality and standardization.

For the data to be more useful and relevant for digital health solutions, it must be reasonably current and standardized across the nation with mandatory data elements being collected consistently. The Health Data Research Network Canada (HDRN) is bringing together health data centres, networks and initiatives to identify how to improve standardization and timely access to health research datasets. This will enable researchers to study the impact of diabetes and its complications across our diverse populations. The **data needs to be linked** to hospital-based clinical records, provincial billings, diagnostic imaging, referral reports and laboratory information. This could be accomplished by forming a collaboration of provincial networks that feed data into the NDR (and other disease-based registries) that would support research on digital health necessary to **set priorities to address health inequities**. The outcomes would enable the provision of information for preventive services, chronic disease management and the inclusion of community-based care.

Efforts to standardize extracted EMR data across Ontario are under way, through the Ontario Primary Care Learning Network (ORACLE), a collaboration between Practice-Based Networks in Departments/sections of Family Medicine at Ontario's six schools of Medicine and the Alliance for Healthier Communities (Ontario's Community Health Centres). **New digital infrastructure resources are necessary** to develop and sustain this initiative and similar provincial projects across Canada.

Diabetic retinopathy often goes unnoticed until vision loss occurs and is the most common cause of blindness in working aged Canadians. If detected early through screening, blindness is preventable. Data on vision care is not readily available in many EMRs. This noticeable gap in information limits the focus by health professionals on prevention. To bridge the gap and establish a population-based digital health solution, we are collaborating with ICES and the Ontario Alliance for Healthier Communities to utilize ICES' prescribed entity status and data holdings to identify unscreened individuals. Once identified, these individuals will be contacted by their health professionals for screening. However, the data being used currently is not-real time, in fact it is over one year old, which means that we will not capture all those needed for outreach. **Lengthy administrative delays** (agreements, securing personnel) and **high costs to run the project** have been significant barriers. Nevertheless, this type of solution has been established in the UK and eliminated diabetic retinopathy as the leading cause of blindness. We can do the same with the digital solutions we are pioneering.

Diabetes Action Canada, in collaboration with the Vector Institute for Artificial Intelligence and the Fields Institute for Research in Mathematical Sciences, held a workshop in June 2019 to test the feasibility of using **advanced analytics with NDR data**. Following the workshop our researchers are using machine learning and NDR data to develop a **risk calculator** to identify those persons who are predicted to develop diabetic kidney disease – the most common cause of kidney failure in Canada. Early intervention and prevention of renal failure is possible, using accurate predictive models. Application of this risk calculator in primary care would reduce the number of persons requiring dialysis resulting in **major health care cost savings** and improved quality of life for persons with diabetes.

With reliable data and appropriate digital infrastructure, we can empower patients to self-manage their condition and stay out of hospitals. We can flag the high-risk high-needs population, connect them to a virtual care team or care provider and follow the individuals who need care. Being able to provide precision intervention is key to preventing the devastating complications associated with diabetes. To do so – we recommend the following to ensure sustainable financing mechanisms to enable digital health research in Canada.

- **Leverage existing collaborative and coordination mechanisms such as CPCSSN and HDRN, driven by patient-centered principles to engage with stakeholders, including the private sector, to develop, implement and finance an appropriate and sustainable digital health ecosystem, and to share best practices and lessons learned through digital health research.**
- **Establish a learning health research system for sharing and emphasizing the role of digital health investments in catalyzing the achievement of national health priorities to eliminate health and health care inequities across our diverse populations.**
- **Support the cost of acquisition or licensing, implementation and maintenance of necessary hardware infrastructure, software, workforce capacity and other technical and financial resources for the above.**

Pan-Canadian Type 1 Diabetes (T1D) Registry: A Digital Health Research First

A major initiative of Diabetes Action Canada is to engage the broader community **to improve access to personal and clinic data for the purpose of research and care.** To that end, we are launching a first-of-its-kind pan-Canadian research T1D registry. A life-long chronic condition, T1D affects 1 in 100 Canadians, beginning in childhood or adolescence and requires life-saving, self-managed daily insulin treatment and blood glucose monitoring. Launching this Fall, the registry creation involved our community of researchers, clinicians and, most importantly, those living with T1D who framed the importance of the effort **to be focused on the needs of patients as much as the research it is meant to enable**.

There are numerous challenges that encumbered the development of the registry that may limit its viability and utility in the future. Specifically, the following issues need to be addressed through policy and tactics in order to enable a future DRI ecosystem for Canada.

Medical device interoperability and data portability

Diabetes devices such as insulin infusion pumps, blood glucose monitors, flash glucose monitors, continuous glucose monitors, and insulin pens are exclusively used by patients to self-manage T1D. Together, they represent the most sophisticated digital wearables in practice and are of critical importance in maintaining glycemic control and, for some, lowering the burden of managing the condition. However, accessing the data from these devices requires a patchwork of proprietary software from a range of manufacturers, and necessitates a level of technology literacy that is beyond many users, or simply requires too much personal effort to extract. This has become a major barrier in order to capture these data for research purposes. Much of it however is by design of the device manufacturer. Proprietary practices on the part of these manufacturers is deliberate in order to maintain control and to broker access to the data. The business value of having the data of their users is seen as significant in the long term, and could serve as a source of revenue from patients, clinicians, and researchers.

Canadian public policy on coverage of the devices is uneven across the country, but is improving as the demand and evidence showing improved outcomes is established. It is recommended that insurers use their leverage with manufacturers to have them **discontinue their proprietary data practices** and establish a **patient charter of rights** for Canadians to have **access to their personal health data from medical devices**. In the end, patients should have the ability and right to access data generated from their personal use, **uninhibited to share and donate their data for clinical care and research use.**

EMR vendor data access

Similar to the medical device industry, EMR vendors have practices that limit the access to patient data for research, through additional costs, tolls and delays. It is a pervasive practice in the industry to impose fees for access to a clinic's or patient's own data for secondary use, including research, epidemiology or health system monitoring. This is further rationale to ensure there are legislative and regulatory criteria for vendors to ensure data portability and interoperability for the purposes of patient self-management, quality improvement and research. Enforcing these criteria could be through **the establishment of a Charter enabling access to EMR data to support and improve health care in Canada.**

Patients as custodians of their own health information

Such a **Charter** should set out to recast the pervasive framework of data custodianship. Currently, care providers have been historically tasked as data custodians of patient data. As a result, this has required explicit, informed consent from the patient to access these data for anything other than the routine care, including research. Secondary access to data, fully de-identified, has been challenging to ensure and is a direct result of **the lack of a practical mechanism to obtain consent for use from patients.**

However, **the premise of care providers as custodians is historical and no longer necessary or practical**. In the past, there was no means for the patient to be the custodian of their own data. Today, however, the ubiquitous use of personal computer and smartphone technologies is such that it is now more practical for **the patient to be custodian and aggregator of the personal health information** and have the ability to grant access to care providers and donate their data for research purposes.
The notion of the patient becoming their own data custodians can effectively eliminate the current concept of secondary data, as there will be direct means for patients to grant access, or more appropriately, **donate their data for research purposes.**

Summary and Conclusions

Diabetes Action Canada has focused on what matters most to persons living with diabetes. We achieve this by direct patient engagement in program development and data governance. Overwhelmingly, the needs of those living with chronic disease such as diabetes are related to timely access to care and prevention and bridging the gaps of health inequities. A single device, such as a smartphone, can connect a patient and their health professional team to enable this timely access. As well, information exchanged in this way can be incorporated into electronic records and linked to larger data sets that are invaluable to analytics using artificial intelligence and mathematical modelling. This risk assessment, based on disease patterns, can build understanding about the complexity of health determinants and necessary precision interventions. Through strategic investment, NDRIO can play a key role in supporting digital health research to improve the health of all Canadians.

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