KEY LEARNINGS DEVELOPING GLOBAL T1D DIGITAL REGISTRY AND ECOSYSTEM

BRIEF OVERVIEW

Type 1 diabetes (T1D, often referred to as childhood diabetes) is a lifelong, autoimmune condition which impairs the body's ability to produce insulin. If left undiagnosed or untreated, excess glucose causes damage to organs which can result in severe health complications and, ultimately, in premature death. There is currently no prevention or cure, and the only effective long-term treatment is multiple, daily injections of insulin.

T1D is one of the most common chronic childhood illnesses. In 2022, there were approximately 8.75 million people living with diabetes globally, out of which 1.52 million were under the age of 20 years[1].

However, in low-resource settings, children with type 1 diabetes are often misdiagnosed or lack access to adequate healthcare services to manage their condition. In order to bridge this gap, a public-private partnership established in 2009 which provides comprehensive care for children and young people living with type 1 diabetes in low- and middle-income countries. This includes free life-saving medicine and supplies for persons up to 25 years of age.

The key challenge to support this initiative has been standardized approach to collect high quality patient data over a period. This data can be significant to improve health outcomes, monitoring of T1D diagnosed individuals, manage treatment protocol and research driven innovation in the field of medicine.

To address this, Dure Technologies (Dure) has partnered with Novo Nordisk (Novo) as their digital innovation partner to establish an E-Registry across the globe. Dure with its over a decade of experience in establishing digital systems in low-middle income countries plan to conducts a detailed assessment of this sites and develop a global e-registry which to improve the efficacy and quality of data collection, reporting to improve the quality of life and healthcare experience of children and young people affected by T1D.

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KEY LEARNINGS FROM IMPLEMENTATION

A crucial step was to assess the CDIC/COE clinics in terms of their readiness for a digital Type 1 registry. We realized the key areas to assess were; digital capacity, existing systems if any, existing health records infrastructure, legal and regulatory requirements, facility patient flow, health care staff their capacity and role. This process helped us design a standardized form which the next wave countries can fill, and assessment can be conducted in a more standard and efficient way.

Country adaptation standardization: Our adaptation process was multi-level starting from data variable analysis, core indicator mapping, adaptation of workflow, updating taxonomy, rules and validation of data variable based on the assessment of the wave 1 countries. This led to the creation of a comprehensive adaptation form which can be filled in by the next set of countries along with assessment form. Understanding regional variations in healthcare practices and regulations helps in creating a registry that is both functional and compliant with local standards.

Country data entry framework: This refers to the system and processes used for entering patient data into the registry. It should outline how data is collected, formatted, and entered into the system.

The framework should ensure data accuracy and consistency, specify who is responsible for data entry, and describe how data entry errors are corrected. This framework analysis helped to define and strengthen our smart set-up sandbox and areas of innovations.

Role based access based on patient flow: This point addresses how T1D patients move through the healthcare facility and how their data is captured at each stage of their interaction with the clinic. During the country assessment, this was significant learning how each country is different in terms of their patient touch points and allowed us to develop role-based registry with limited/defined access to the data entry. E.g. Lab values can only be entered by the Lab personnel however doctor user access can allow to modify it and give inference.

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Master Data Variable Taxonomy: Taxonomy refers to the classification and organization of data variables in a structured manner. In the context of a patient registry, this means defining and categorizing the types of data that will be collected, such as demographic information, clinical outcomes, and treatment details. A clear taxonomy ensures that data is consistently recorded and easily retrievable. It helps in standardizing data collection and facilitates the analysis and reporting of patient information across different clinics or regions. This led to development of the Global T1D registry with a standard variable defined and verified by various stakeholders.

Data Variable Standard Units: This involves establishing standard units of measurement for the data variables collected in the registry. For example, if recording blood pressure, the standard unit might be millimeters of mercury (mmHg). Standardizing units ensures consistency in data reporting and comparison across different facilities and time periods. It is crucial for maintaining data integrity and for enabling accurate analysis and interpretation of patient information.

This learning gave us a way forward that it should be defined by the smart-setup sandbox as each country uses different methods and units for data collection and it should provide flexibility to incorporate those.

Historical Data Upload: Incorporating existing T1D patient records into the new registry seems easy through the data upload module. However, many of the wave 1 countries had low quality, incomplete and irregular data. The upload process needs to address data consistency, accuracy, and compatibility issues to ensure that historical data is accurately represented in the new system. Proper integration allows for a comprehensive view of patient histories and facilitates continuity of care. We develop data verification logic for each of the variables with their defined data type and range. This also led to designing and developing the data error table for the user to pinpoint the error in the upload sheet and fix it. Currently over 10,000 patient T1 records are uploaded in the developed registry in the countries.

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Integration with Patient App and chatbot: Integrating the patient registry with a patient app and chatbot involves creating a seamless connection between the registry system and a mobile or web-based application used by patients. This integration allows patients to access their health information, schedule appointments, receive reminders, and communicate with healthcare providers directly through the app. The benefits of this integration include:

Enhanced Patient Engagement: Patients can actively participate in their healthcare by accessing their medical records, tracking their health metrics, and engaging with their care team.

Real-Time Data Syncing: Information entered by patients in the app, such as symptoms or medication adherence, can be automatically updated in the registry, ensuring that healthcare providers have the most current data.

Improved Communication: The app can facilitate secure messaging between patients and providers, appointment reminders, and notifications about lab results or treatment plans.

Convenience and Accessibility: Patients can interact with their healthcare provider and access their health information anytime, anywhere, which can lead to better adherence to treatment plans and overall health management.

Currently, the global T1D registry is integrated with the patient app however many of the wave 1 countries' T1D patients have limited access to mobile phone and internet; however India, Pakistan and Malaysia due to their high digital and internet penetration and can be considered as countries which can inform these use cases in the future.

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