CAnadian PaediAtric diabetes ConsortIum (**CAPACITY**)

Co-designing a nationally coordinated person-centred paediatric diabetes registry

Chapter 2: *Mapping the Data Assets and Developing the Registry*

Prepared by the Family and Child Health Initiative team at the Institute for Better Health at Trillium Health Partners, Mississauga, Ontario, Canada

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Executive Summary

Background: The CAPACITY project aims to develop a nationally coordinated person-centred registry of paediatric diabetes data with healthcare providers, researchers, and people with lived experience, including youth with diabetes and their caregivers. This report continues the CAPACITY registry's co-design phase (Phase 1). In this report, we focus on mapping the registry's data assets to inform the development of and strengthen the registry's governance and policies. The main aim of this component was to engage people with lived experience (i.e. caregivers, youth with diabetes), healthcare professionals, and researchers to collectively shape the CAPACITY registry's functionality, usability, access, and governance. Particularly we focused on: 1) Identifying main challenges within paediatric diabetes in Canada (Problem Identification), 2) Defining existing data gaps impacting working and/or living with paediatric diabetes (Data Gap Identification), 3) Understanding user experience and the data captured related to accessing services, provision of care, and conducting research (User Journey), 4) Delineating which of the identified data are available and where and how these data can be incorporated to inform CAPACITY registry's decision-making around data input, access, and use (Data Ecosystem), 5) Exploring who would benefit from the CAPACITY registry and how they can be involved in the CAPACITY registry data input, access, use and oversight (Data Governance), and 6) Evaluating the co-design process after completion to gain lessons and experience to improve future co-design approaches.

Methods: We used the community-based participatory and co-design approaches to achieve our main objectives by engaging and centring the voices and expertise of caregivers, youth with diabetes, healthcare professionals and researchers. We conducted seven virtual interactive co-design workshops guided by a toolkit from the Data Asset Mapping Tool Series developed by the United Nations (UN) Global Pulse Lab Jakarta to specifically inform the Problem Identification, Data Gap Identification, User Journey, and Data Ecosystem. The current proposed governance structure of the CAPACITY registry was used to get inputs and recommendations for the Data Governance workshop. We used thematic analysis to identify the salient insight and main findings of the collected data and basic descriptive analysis to characterize the survey-based collected data.

Results: The co-design phase of the CAPACITY registry highlighted key challenges for youth with diabetes, centring on mental health, education, and transitioning to adult care. Participants identified stress and anxiety from financial burdens, unmet care needs, healthcare system navigation difficulties, and lack of work/life balance as significant issues, leading to emotional distress and stigma exacerbated by limited diabetes knowledge. Also identified was a need for more support in schools to assist students in adhering to treatment plans and managing diabetes-related effects on physical, emotional, and cognitive functioning. Standardized and continued support across provinces was noted as lacking, impacting academic performance, social integration, and diabetes management. Transitioning to adult care was highlighted as a challenge due to disparities in care, unstandardized processes, and lack of continuity, especially when relocating for education. Participants highlighted the need for comprehensive data, including clinical, self-management, nutritional, social, lifestyle, education, and research-related data. User journey workshops identified data needs to ensure positive outcomes in mental health, education, and transitioning to adult care, including medical history, provider geographic data, quality of life indicators, mental health screening tools, and educational performance data. The data ecosystem workshops defined internal and external data roles and enhanced analysis capabilities through controlled access. Governance recommendations emphasized diverse representation with an emphasis on Indigenous nations, inclusive governance, simplified activities, and multilingual support, with a data access committee facilitating external research proposals to align with registry objectives.

Conclusion: The ongoing co-design phase of the CAPACITY registry, comprising seven workshops, has played a pivotal role in identifying primary challenges and data pertinent to paediatric diabetes management and care, delineating existing data gaps in the field, gaining insights into user experiences and associated data, specifying available data and its integration into the CAPACITY registry, and exploring the beneficiaries of the registry and their involvement in data input, access, utilization, and oversight. Our next steps will be using the functions and features identified in Chapter 1 of this report and the data gaps and desires identified in Chapter 2 of this co-design phase to produce potential use cases for the registry. These use cases will then be further developed during the prototyping and co-implementation of the audit and feedback intervention in Phase 2.

CHAPTER 2: MAPPING THE DATA ASSETS AND DEVELOPING THE REGISTRY

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INTRODUCTION

Diabetes registries and databases exist in healthcare centres and provinces across Canada. However, a lack of standardization and linkages between these registries prevents effective knowledge transfer and application, research, and quality of care.[1,2,3] There is a need for comprehensive and high-quality national data collection and its associated infrastructure in Canada for children living with diabetes.[1,2,3] A person-centred approach is needed to maximize the utility and effectiveness of registries and their data on quality of care, people's health and well-being, research and health system optimization and standards.[4,5] To enhance the potential benefit and

impact of registries and their contained data, it is essential to actively involve users or people with lived experience in a registry's design, including the objectives, planning (co-design), use, and governance.[4]

The CAnadian Paediatric diabetes ConsortIum (CAPACITY) project aims to develop a nationally coordinated person-centred registry of paediatric diabetes data with healthcare providers, researchers, and people with lived experience, including youth and families. Specifically, the project has the following three objectives 1) To co-design a Canadian paediatric diabetes registry; 2) To co-implement the registry; and 3) co-evaluate the impact of the registry. Under objective 1, the Family and Child Health Initiative at the Institute for Better Health, Trillium Health Partners in Mississauga, Ontario, spearheaded active engagement of a diverse range of potential registry users to center their experiences, voices, and expertise to guide the development, data content, usability, and governance of the CAPACITY registry.

Our co-design phase comprised three distinct yet interconnected sequential parts. Part 1 already completed and reported in the previous Chapter titled, "Co-Designing a National Canadian Paediatric Diabetes Registry (CAPACITY): Identifying CAPACITY Needs and Preliminary Functions".[6] Part 2, which is the focus of this current Chapter (Chapter 2), comprises the main findings from the data asset mapping and governance-related co-design activities. These co-design activities were directly informed by the main findings of the CAPACITY registry's needs and preliminary functions reported in Chapter 1. In Part 3 of the co-design process, we will focus on crafting potential use cases that will shape the registry's development, functionality, and impact. These use cases will draw from the key insights outlined in Chapter 2 and will be finalized and reported in Chapter 3.

Data Asset Mapping and Governance: Aims and Objectives

The main aim of this component was to engage people with lived experience (i.e., caregivers, youth with diabetes, healthcare professionals and researchers) to collectively shape and map the CAPACITY registry's functionality, usability, access, and governance.

The specific objectives were to:

1) Identify the main challenges and their associated data when working and/or living with paediatric diabetes in Canada that the CAPACITY registry can address (Problem Identification).
2) Define existing data gaps impacting short- to long-term planning cycles when working and/or living with paediatric diabetes to inform CAPACITY registry development (Data Gaps).
3) Understand user experiences and the data captured related to accessing services, provision of care, and conducting research to incorporate lived experience perspective in CAPACITY registry development (User Journey)
4) Delineate which of the identified data is available and where and how it can be incorporated in the registry ecosystem to inform decision-making for the CAPACITY registry (Data Ecosystem).
5) Explore who would benefit from the CAPACITY registry and how they can be involved in its data input, access, use, and oversight (Data Governance).
6) To conduct an integrated evaluation, gain lessons and experience surrounding the co-design process, inform the interpretation of the findings, and improve future co-design approaches.

METHODS

Continuing our co-design and community-based participatory methodological research approaches, we closely engaged our well-established Project Advisory Board (PAB)[7] (see PAB engagement and profile in Chapter 1) in guiding all activities and decision making[8]. We conducted a series of seven consecutive data asset mapping and registry development workshops to achieve our specific objectives: 1) Problem Identification (Workshop 1); 2) Data Gaps and User Journey (Workshops 2 - 3); 3) Data Ecosystem (Workshops 4-6); and Data Governance (Workshop 7). The methodology used to co design these workshops is detailed below and in Table 2.

The workshops were informed by the main findings of our previous co-design component, the knowledge exchange events (KEE) discussed in the previous chapter.[6] Briefly, the main findings from the KEEs were analyzed, reviewed, and validated by our research team and PAB members and summarized into three main interrelated categories based on their description and common

areas of impact: 1) Quality Improvement (refers to care quality aspects that the registry can contribute to), 2) Research (refers to how the registry can inform and benefit from research), and 3) Lived Experience (LE)-Driven (refers to the direct registry impacts on people living with diabetes and their caregivers). The detailed information informing these categories is presented in Supplemental Table 1.

These findings were then carried forward into this second part of our workshop co-design process, which utilized the Data Asset Mapping Tool Series developed by the United Nations (UN) Global Pulse Lab Jakarta to develop and guide the co-design activities to further explore and build upon the above-identified categories.[9] The UN Development Programme Innovation teams have previously leveraged this Data Asset Tool series to address local challenges related to disaster risk management, welfare, migration, and poverty reduction[9]. Under the guidance of our PAB and guidelines provided by the tools, we adapted the tool series into individual workshop activities to guide the registry's data asset mapping. We utilized all four tools from the series, which were:

1) **Problem Identification Tool**: This tool identifies the critical challenge to be addressed and what data exists on it.
2) **Data Gaps Tool**: This tool identifies internal data gaps across short- and long-term planning cycles.
3) **User Journey Tool**: This tool explores how current data fits into service experiences and what other data can be counted or measured.
4) **Data Ecosystem Tool**: This tool uses the data identified from the previous tools and informs how it can be accessed and incorporated into the registry.

The existing proposed governance structure of the CAPACITY registry and network guided the activities related to exploring data governance.

All workshops were conducted virtually via Zoom and were two hours long, except those exploring the data ecosystem (workshops 4-6), which ranged from 60–90 minutes. During the workshops, simultaneous remote interpretation from English to French was provided via a professional interpretation service to accommodate French-speaking participants. For workshops 4-6, since the internal CAPACITY team completed the tool, there was no French interpretation

(due to a lack of need). All workshop attendees not part of the CAPACITY team received a $75 Amazon gift card for each workshop they participated in.

We used a multi-faceted recruitment strategy to recruit participants for the workshops. We used an online Expression of Interest (EOI) survey via REDCap [10,11] where potential participants could express their interest to participate.[11,12]When completing the survey, participants could choose the role they best identified with (caregiver, youth, clinician, etc.). Since specific workshops were only open to certain groups of participants, they were only permitted to register for the workshops they could attend. The call for EOI was marketed using flyers sent to the CAPACITY study and project team networks. The PAB also circulated the recruitment flyers among their peers and clients/users. Digital flyers were also circulated by the National Indigenous Diabetes Association (NIDA) and JDRF. The final participant composition, number and content of each workshop are shown in Table 1.

Table 1: Workshop Content and Participant Composition

Tool Used & When	Workshop Number	Date	Audience	Total Participants
- *Problem Identification Tool* (Administered During the Workshop Activity)	1	Oct 24, 2023	Caregivers of Youth with T1D Health Professionals (Researchers, Advocates, Clinicians, Data Scientists)	9 Caregivers 11 Health Professionals = 20 Total
- *Data Gaps Tool* (Administered Before the Workshop Activity via REDCap)) - *User Journey Tool* (Administered During the Workshop Activity))	2 - 3	Workshop 2 Nov 3, 2023 Workshop 3 Nov 7, 2023	Workshop 2 Health Professionals (Researchers, Advocates, Clinicians, Data Scientists) Workshop 3 Caregivers of Youth with T1D	Workshop 2: 9 Health Professionals Workshop 3: 14 Caregivers
- *Data Ecosystem Tool* (Administered During and After the Workshop Activity))	4-6	Workshop 4 Nov 27, 2023 Workshop 5 Dec 8, 2023 Workshop 6 Dec 11, 2023	Workshop 4 Internal CAPACITY Team Workshop 5 Maelstrom Team Workshop 6 Data Access Committee	Workshop 4: 8 Workshop 5: 2 Workshop 6: 2
Existing CAPACITY registry's Data Governance structure	7	Dec 6, 2023	Caregivers of Youth with T1D Health Professionals (Researchers,	7 Health Professionals 5 Caregivers

(used During the Workshop Activity)			Advocates, Clinicians, Data Scientists)	= 12 Total

With participants' permission, all workshops were audio-recorded using the audio Zoom recording feature. The recorded data were saved in a password-protected team computer and subsequently transcribed to text verbatim by the study team. This transparent process ensures the security and confidentiality of the data, instilling confidence in our participants. After the transcription, the recorded data was deleted to protect participant's identities and privacy. Workshop facilitators also took notes during the discussions. When conducting the analyses, we used transcribed recordings and discussion notes to add any missing context or information related to the tools completed in the workshops.

Problem Identification (Workshop 1)

To identify the main challenges in working and living with paediatric diabetes, its associated data, and the role of the registry in addressing them, we conducted a two-hour virtual workshop (via Zoom) on October 24, 2023. The workshop was attended by 20 participants, including ten caregivers, nine health professionals and researchers, and one diabetes advocate/community partner. To maximize the available workshop time and gain insights into the primary identified areas of interest (Quality Improvement (QI), Research, and LE-Driven), we assigned workshop participants to one of these areas based on their lived experience (6-7 participants each). Subsequently, the QI group consisted mostly of clinicians, the research group consisted of caregivers and healthcare professionals with a research or academic background, and the LE-driven group mainly consisted of caregivers. Each group had a study team facilitator to guide the workshop activity, take detailed notes of the discussion, and record the group insights. Participants within their assigned groups were requested to reflect on or use their lived experience within paediatric diabetes when providing their insights.

We used the "Problem Definition Tool" (Figure 1) from the UN Pulse Lab Data Asset Mapping Series for this workshop [9] to facilitate the identification of the key existing challenge in peadiatric care and social support, especially to map what data currently exists on the issue, and what data can help solve the problem.[9] The tool's language was adapted to make it specific for paediatric diabetes. The tool was re-created on Miro (an online whiteboarding tool) to facilitate our virtual workshop's interactive and collaborative dynamic. Each group was prompted to complete the workshop activity using the Problem Definition Tool helped by the following series of six sequential questions:

1) What is a problem that you face in your experience or work within paediatric diabetes?
2) Who does the problem impact?
3) What factors contribute to the problem?
4) What data do you have on the problem?
5) Who owns or uses these datasets?
6) What other data could you use?

Each group facilitator shared their screen during the group discussions to allow the group participants to verify and validate the recorded insights they were providing in real-time.

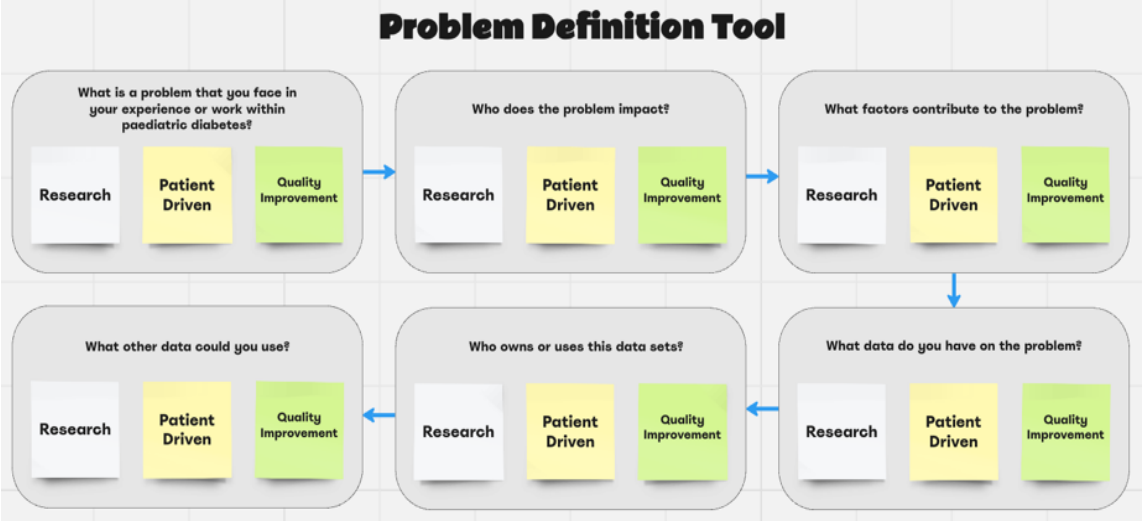

Figure 1: Miro board images of the used Problem Identification Tool during the workshop.

The research team used the Problem Definition tools completed by each workshop's participant group, along with the facilitator discussion notes and workshop transcribed data to identify salient insights and main themes using a thematic analysis approach.[12] The analysis of these data was conducted using two main areas of focus. The first area of focus was identifying the problems experienced within paediatric diabetes, who these problems affect and the factors contributing to this problem. The second area of focus pertained to data related to the issues identified, precisely what data are currently available, who uses these data, and what data would help manage paediatric diabetes in the future. We used these two focus areas to identify common themes among group responses during the activity. The recorded data were refined and simplified into cohesive statements based on discussion notes and the workshop transcript for more comprehensive analysis. We removed duplicate or similar data entries or insights. One research team member examined all data sources individually and identified salient insights,

which were then grouped into overarching themes. The research team members involved in the analysis then compared, identified, and completed the analysis into the most relevant and final themes or categories. Finally, the final themed findings were presented to the study's PAB for further validation.

Identifying Data Gaps and Examining User Journeys (Workshops 2-3)

For identifying the existing data gaps in paediatric diabetes care, and to understand user experiences in relation to working/ living with paediatric diabetes to inform CAPACITY registry development, we used the main findings from the problem identification workshop (Workshop 1) along with the UN Data Gaps tools to develop a data gaps-related survey and conduct two user journey workshops.

Data Gaps Survey: The purpose of the data gaps tool was to define existing data gaps impacting short to long term planning cycles when working and/or living with paediatric diabetes to inform CAPACITY registry development. We used the UN Global Pulse Lab Data Gaps Tool[9] (Supplemental Figure 1) and adapted it into an electronic survey in REDCap, which was sent to workshop registrants before the workshop. Language from the tool was adapted to incorporate paediatric diabetes, and each tool component was translated into an individual survey question. The survey included a total of six questions. Of these, three were around existing data paediatric diabetes care support related data (Existing Data questions), and three on data desires in current paediatric diabetes care and management (Desired Data questions). The main tool's adapted questions were as follows.

Existing Data

1. What data do you rely on day to day in your experience living with diabetes, caring for someone with diabetes, or working with diabetes patients?
2. What data do you rely on for long-term planning of diabetes management and care?
3. What data do you rely on for communicating with/or persuading others?

Desired data

4. What can't you count or measure but still need to evaluate in regard to diabetes management?
5. What new things would you like to count or measure in regard to diabetes?
6. Who uses or benefits from your data?

When completing the survey, participants were asked to identify as either caregiver, researcher, or clinician so data responses could be categorized accordingly. Results (see Result section) from the Data Gaps Tool survey were presented during the first part of the user journey workshops (workshops 2-3). All responses were then discussed briefly (Supplemental Table 2) with the participants to help set the ground and context for the upcoming user journey activity. Since not all participants had completed the survey before the workshop, the data gaps survey continued to accept participant responses until workshop 7 (December 6, 2023) to allow all workshop participants to participate and fill out the survey-based tool.

The Data Gaps Tool survey data were thematically analyzed by identifying and categorizing similar findings across all the entries for caregivers and clinicians/researchers. For the final question, the responses were combined to identify the primary users and people who benefit from paediatric diabetes data.

User Journey Workshops: After the survey was sent and preliminary findings analyzed, two workshops (#2 &3) were conducted separately for the following two participant groups: Health professionals, researchers, and scientists (Workshop 2); Caregivers and youth with T1D (Workshop 3). Both workshops were conducted via Zoom and were two hours in duration. Workshop 2 was conducted on November 3, 2023 and attended by nine participants, and Workshop 3 was conducted on November 7, 2023 and fourteen participants (Table 1). The activities of the workshops were informed by the User Journey Tool. The purpose of the User Journey Tool was to help understand the problem from the participant's perspective through service experiences around paediatric diabetes care and support using a journey approach (journey between point A to point B that a person needs to complete). The main components of this diagrammatic User Journey Tool comprised of a challenge to be solved, the starting (point A) and ending point (point B) on the path taken to solve the challenge, the touchpoints (key intermediate steps) required to address the challenge, and lastly, the potential sources of data needed for each of these touchpoints (see Figure 2). [7]

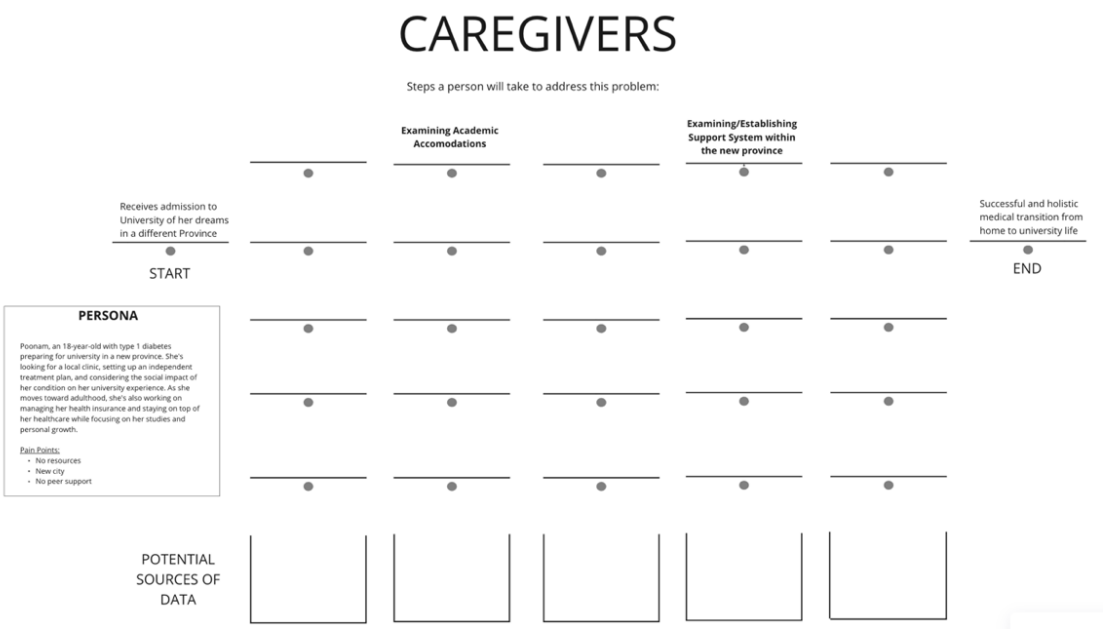

Figure 2: Caregiver Group User Journey Tool for a Transition to Adult Care Problem

We developed six personas and associated diabetes-related challenge scenarios for the User Journey Tool based on the main findings from the previously described Problem Identification Tool. These scenarios pertained to 1) Mental Health, 2) Education, and 3) Transition of Care. Two scenarios were created to focus on each of the three areas, one catered towards health professionals (workshop 2) and one catered towards those with lived experience of paediatric diabetes (workshop 3). We also developed a starting and end point for each scenario to focus the participant's thinking. Each workshop, therefore, had three scenarios: transition to adult care, mental health, and education.

We had nine health professionals (clinicians, researchers, etc.) participate in workshop 2 and fourteen caregivers of youth with lived experience of paediatric diabetes participate in workshop 3. Both workshops began with a brief presentation of preliminary results of the Data Gaps Survey. Participants then completed the User Journey Tool[9] exercise facilitated by a research team member and using the Miro platform during the Zoom-based workshops.

For each persona and each chosen journey scenario, participants were asked to suggest steps the persona would take to achieve the endpoint based on their current knowledge and lived experience with paediatric diabetes. Additionally, we asked them to identify potential data sources needed at each step (See Figure 2).

The facilitators recorded participants' insights using the Miro-adapted User Journey Tool. Two members of our research team reviewed all data inputted in the tools from participants of both workshops (Workshops 2 & 3). We summarized the salient data necessary to navigate each hypothetical persona and user journey scenario successfully. We then examined these data along with the potential data sources identified by the participants and summarized them under the label "required data" for each persona scenario.

Data Ecosystem (Workshops 4 - 6)

To delineate how all the required data could be incorporated within the structure of the CAPACITY registry, we conducted a series of workshops with members of the internal CAPACITY team, the Maelstrom Team (scientific partner), and CAPACITY's Data Access Committee members. All the virtual Zoom-based workshops were facilitated by two research team members who guided the activity and recorded the participants' insights using notes and Zoom audio-recording features. We used the Data Ecosystem Tool[9] (see Supplementary Figure 1) to visualize how data will be accessed and incorporated into the CAPACITY registry and what level of access local active paediatric diabetes registries across Canada will have. This tool used the main findings from the previous tools and workshops (Problem Identification, Data Gaps, and User Journey) to inform how such findings and related data needs can be addressed through the CAPACITY registry data collection, access, use and development processes. The Data Ecosystem Tool shown in Supplemental Figure 2 was comprised of 4 main components: 1) The type of data being accessed in the CAPACITY registry; 2) How these data will be accessed; 3) The format, frequency, and retention period of these data; 4) Who will benefit from these data.

To begin, Workshop 4 was conducted with internal CAPACITY team members (n=8) and occurred on November 27, 2023. Its primary aim was to define and delineate potential sources of external data relevant to paediatric diabetes and explore initial strategies for integrating these external data with the project's internal datasets. For this collaborative session, we used Miro (ww.miro.com) and employed structured brainstorming to itemize and categorize external data sources, laying the groundwork for subsequent data linkage discussions.

Following this workshop, we conducted the subsequent workshop (workshop 5) with the Maelstrom team (n=2) on December 8, 2023 to explore and define internal data in the context of the CAPACITY data ecosystem. Maelstrom (www.maelstrom-research.org) is a scientific

platform based at the Research Institute of the McGill University Health Centre (RI-MUHC), which is providing the data harmonization infrastructure for the co-implementation of the CAPACITY registry in Phase 2.[13] This dialogue centred on understanding the operational intricacies of the data collection and analysis systems, particularly data harmonization and data analysis frameworks. Insights from this workshop with Maelstrom were pivotal in mapping out how data from various contributing sites would be systematically collected, analyzed, and integrated within the CAPACITY project's infrastructure.

We then conducted Workshop 6, during which we consulted with CAPACITY's Data Access Committee representatives (n=2) to refine the ecosystem map further. This discussion clarified data access protocols, focusing on the needs of researchers analyzing the CAPACITY registry's aggregated data. The Data Access Committee outlined the ethical and procedural parameters governing data access, ensuring data utilization aligned with the project's objectives and regulatory standards.

After gathering the responses from workshops 4-6, we summarized and identified the main findings from each set of workshop participants to populate the data ecosystem tool. (See Figure 5). The completed ecosystem tool then served as the final product for the ecosystem mapping workshops.

Data Governance (Workshop 7)

Our final objective of this co-design phase was to explore who could benefit from the CAPACITY registry and how they can be involved, particularly regarding data input, access, use and oversight to strengthen the existing CAPACITY registry governance process. To achieve this, we conducted a final two-hour Zoom-based workshop (Workshop 7) on December 6, 2023, with a focus on data governance, both for the registry and the larger CAPACITY network (all institutions that are directly taking part in the CAPACITY registry's development and implementation). We invited all 20 participants who participated in the Problem Identification workshop (Workshop 1) to this workshop. To guide the workshop participants' insights, the research team presented preliminary main findings from all previously co-designed areas (problem identification, data gap identification, user journey, and data ecosystem) and the existing plans regarding data registry, governance, stewardship, and structure for the CAPACITY registry and network (Figure 3). Additionally, The BC Children's Hospital (BCCH)

CAPACITY registry team (the main study host institution) presented the current committees and sub-committees created within the CAPACITY network and discussed the planned processes that will be implemented to request data access. Finally, to better describe the CAPACITY registry's data storage and access clearly and concisely to the workshop's participants, a diagrammatic explanation of the CAPACITY registry's "condo analogy" (developed by Maelstrom) was displayed, highlighting key players and their respective roles (Figure 4).

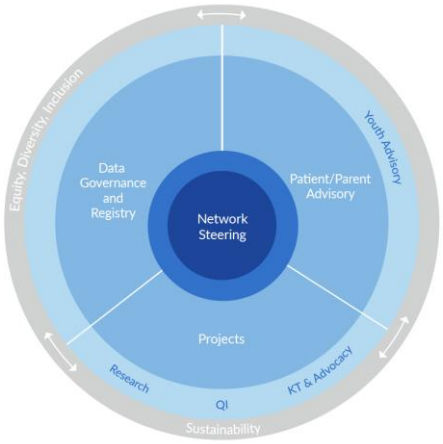

Figure 3: CAPACITY Network committee structure

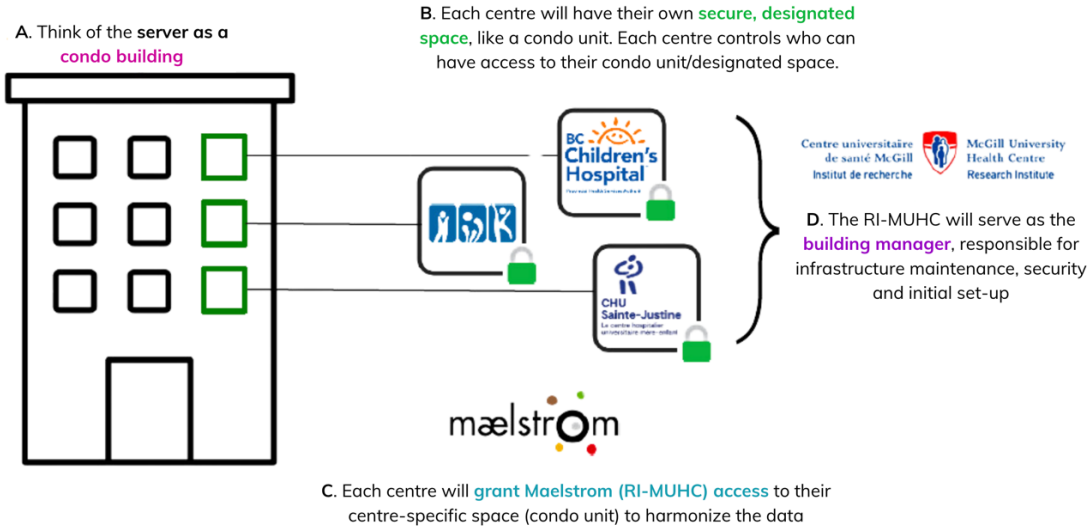

Figure 4: The CAPACITY Network's Data Storage and Access "Condo Analogy" (Source: Maelstrom)

After this detailed overview, participants were divided into two main groups: Group 1 comprised of those with lived experience (caregivers and youth living with diabetes); Group 2 comprised of

healthcare professionals. Both groups were posed the following questions to facilitate their insight and enhance active and constructive discussion:

1) What are their thoughts regarding the current governance structure and what would they change in terms of who should be involved, what should the decision-making processes look like, and what is missing?
2) What are their thoughts regarding current data access procedures and what would they change in terms of who has access and how?

Each group had a research team facilitator who guided the activity took extensive notes and recorded the verbal and written (in the chat) insights from the participants. The research team transcribed audio-recorded data into text and, in conjunction with their notes, utilized a thematic analysis approach to identify key governance themes and recommendations for the CAPACITY registry.

Co-Design Evaluation

We used an integrated evaluation approach to gain experience and learn from the co-design process to inform the interpretation of the findings and improve future co-design processes. To facilitate this, we developed a Likert style survey with some open-ended questions and requested participant feedback on their experience with the co-design activities. After Workshop 4, all participants who attended any of the previous workshops received the anonymous survey created on REDCap to solicit feedback on satisfaction with the workshops, the workshop series' dynamics and methodology, and to provide additional insight that could contribute to refining the ongoing registry co-design processes and beyond. The collected survey data was then organized by identifying and categorizing similar findings across all the entries to elucidate key themes

RESULTS

The main findings are presented below for each workshop and associated tools used in part 2 of this co-design phase (Problem identification, Data Gaps and User Journey, Data Ecosystem, and Data Governance).

Problem Identification Findings

Three overarching main themes emerged as the primary categories encapsulating the challenges, issues, and needs identified by the participants of the problem identification workshop (Workshop 1). The broad and main challenge categories and specific challenges with the associated data are presented in Figure 5. Three main challenge categories were identified and consisted of issues related to: 1) Mental health, 2) Education, and 3) Transition from paediatric to adult diabetes care.

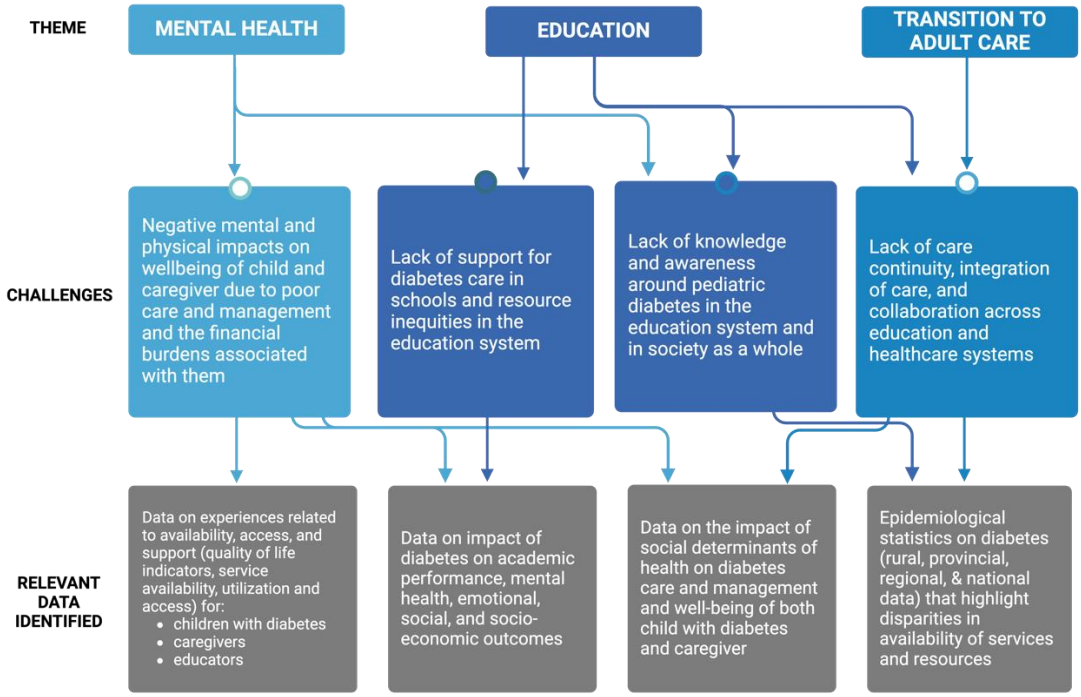

Figure 5: Themes and relevant data identified from the Problem Definition Tool

Mental Health: The main challenges expressed by the workshop participants were stress and anxiety linked to financial difficulties, unmet care and support services needs such as a lack of childcare and nursing services available, difficulty navigating the healthcare system, and balancing a work/life balance, leading to exhaustion, frustration, and emotional distress. Limited knowledge and awareness about diabetes were also discussed as a precursor to the stigma surrounding diabetes and how it exacerbates mental health distress.

Education: Participants expressed the need for more support and resources in education systems for appropriate and timely support for students with diabetes. Support desired comprised of

assistance with adherence to their treatment plans, daily monitoring of their diabetes related biomarkers, and managing negative diabetes effects in their physical, emotional, and cognitive functioning. Also, the lack of standardized and continued support within school settings, within and between provinces, for diabetes-related management were identified as requiring further attention and data-driven evidence. Participants also highlighted the need for support and increased awareness on paediatric diabetes within the education system and settings. Stigma, insufficient knowledge, and lack of preparedness were identified as major obstacles for students with diabetes, impacting their academic performance, social integration, acceptance among peers, and appropriate management of their diabetes. Participants also expressed concerns about limited engagement and collaboration of caregivers and educators in the decision-making and design of diabetes solutions and policies within the school environments. They discussed that this lack of engagement further affected the health, social, and overall well-being of children and youth with diabetes. Finally, diabetes care support and resources was also an important identified issue, as they are systemically scarce in educational settings, especially in rural areas, exacerbating the challenges and frustrations associated with managing the disease for children and youth living with diabetes and their caregivers.

Transition from Paediatric to Adult Care: Participants highlighted the pervasive disparities and inequities in current diabetes care, unstandardized transition processes, and lack of continuity and integration within different systems, making transition challenging for clinicians, people living with diabetes, and their caregivers. These care transition issues were pointed out as problems present between Canadian provinces and within provinces, rural areas, and large urban areas. Ultimately, participants identified challenges in establishing standardized support resources and services in social, nutritional, health, and care aspects for adolescents transitioning to adult diabetes care, particularly when this transition occurs in locations outside of their usual place of residence (e.g., youth who relocate for university education). Evidence-based tracking of some of these indicators was also identified as an important factor to inform the previously discussed challenges.

Identifying Data Gaps and Examining User Journeys

The main findings from the data gap survey and user journey workshops are presented separately.

Data Gaps Survey: We received 16 responses out of 31 total participants of the Data Mapping Workshops, resulting in a survey response rate of 51.6%. The survey respondents consisted of seven caregivers, eight clinicians, and one researcher. Tables 2 and 3 show the findings from the survey on what data exists and what is desired from Caregivers and Clinicians/Researchers, respectively. Survey data were sorted into the following categories: clinical data (e.g. history, diagnoses, and laboratory results), self-management data (e.g. therapeutics, technologies, and pharmaceutics, glycemic data), nutrition data (e.g. eating behaviours, dietetic patterns, grams of carbohydrates), social and emotional data (e.g. social determinants of health, physical activity, quality of life, mental health), educational data (e.g. academic performance and achievement, school attendance), and research data (e.g. data from clinical trials, epidemiological data, data from patient-reported outcome or experience measures) (Table 2).

Table 2: Existing Data used by caregivers in diabetes care, management and support

	Caregivers (n=7)	
	Existing data used in everyday diabetes-related care and support experiences	**Desired or new data needed**
Clinical care and support	- Blood glucose readings (continuous glucose monitoring data (CGM))	*No data were identified*
Self-Management care and support	- Insulin pump data - The total daily dose of insulin - Carbohydrate ratios - Insulin Sensitivity Factor (ISF)	- Long term effectiveness of different therapeutic modalities for different age groups
Nutrition management and support	- Carbohydrate intake - Nutrition labels - Diet - Meal schedule	- Data on blood glucose changes after eating different types of foods - Effects of breastfeeding on infants with diabetes (carbohydrate content of breast milk)
Social & Lifestyle care and support	- Seasonality and its effect on diabetes management practices (Time of year, weather, temperature changes) - Activity duration and intensity - Sedentary behavior - Sleep schedule	- Impact of diabetes on mental health (e.g. stress, fatigue, diabetes distress, depression, anxiety) - Impact of sleep quality and duration on diabetes outcomes - Impact of rural or urban environments on diabetes-related health behaviours - Differences in diabetes care across Canada to identify disparities and most effective care practices
Education Data	*No data were identified*	- Existing school based, public, or private insurance coverage for students and caregivers of youth living with diabetes
Research Data	- Research studies and findings: Understand the individual, family,	*No data were identified*

	contextual, system factors that predict diabetes care, management and support and associated outcomes	

	Clinicians/Researchers (n=9)	
	Existing data used in everyday diabetes-related care and support experiences	**Desired or new data needed**
Clinical care and support	- Blood glucose data & trends (hemoglobin A1c, continuous glucose monitoring) - Laboratory results - Medication history - Patient data (weight, height, age, medical history, etc.)	- Visit frequency and impact on health outcomes of patient and long-term management of diabetes
Self-Management care and support	- Insulin doses & insulin pump data - Insulin to carb ratio (ICR)	*No data were identified*
Nutrition management and support	- Patient reported diet and habits	*No data were identified*
Social & Lifestyle care and support	- Quality of life data - Diabetes distress evaluation - Psychosocial factors - Patient reports and concerns - Healthcare service visit frequency	- Impact of mental health on diabetes management and long-term outcomes and the associated fears, apprehensions, barriers to adequate care and management - Data on the impact of diabetes on mental health outcomes - Impact of different family support/structure and socioeconomic differences on diabetes management and long-term outcomes, and the stressors and barriers present in the household - Effects of growth on diabetes self-management
Education Data	- Records of patient's education notes/history	*No data were identified*
Research Data	- Existing funding models (insurance coverage, payments made by patient, affordability, etc.)	- Satisfaction and adherence with diabetes management & care received - Feasibility of diabetes prevention practices delivered by paediatric healthcare professionals

We found that both caregivers and health professional/researcher groups spoke about using similar existing clinical data for short-and long-term care and managing paediatric diabetes, such as blood glucose readings and bloodwork results (Table 2 and 3). The clinician and researcher respondents mentioned more extensive patient and clinical indicators such as continuous glucose monitoring reports, laboratory test results, and medication history, whereas caregivers mentioned basic glucose reading. Concerning the self-management data category, healthcare professionals and caregivers identified insulin-based treatment (whether pump or non-pump administered) and carbohydrate intake data as valuable information**.** These data assist paediatric patients and caregivers in effectively managing diabetes care on a day-to-day basis and over the long term.

Both groups relied on nutritional data, such as dietary choices, carbohydrate calculation, and nutrition labels, to help them inform their diet patterns, meal composition, and meal scheduling, among others. Regarding social and lifestyle data, caregivers mentioned diet, activity, and sleep. Clinicians focused more on quality-of-life measures and patient and caregiver satisfaction with diabetes care and management practices. Lastly, regarding education and research data, caregivers spoke about using existing studies and diabetes research for the management and long-term planning of diabetes. At the same time, clinicians mentioned using insurance and payment coverage information records of patients' academic history and educator notes regarding their performance and behaviour in school.

Regarding desired data, caregivers desired data (Table 2) about the long-term effectiveness and reliability of insulin pumps stratified by age. They also expressed the desire for data on the impact of different foods on glycemic stability and changes in glucose levels in people with diabetes, as well as the long-term impacts of breastfeeding infants with diabetes compared to formula feeding. Additionally, caregivers mentioned the need for data on sleep quality, epidemiological statistics about diabetes prevalence across Canada to identify disparities and most effective care practices, differences in models of care, and more data to characterize the transition from paediatric diabetes to adult care.

Clinicians and researchers (Table 3) reported the desire for data about patients' fears, apprehensions, and barriers regarding current diabetes care and management practices, the

impact of physical activity on both mental and physical health outcomes, more data on quality of care and its outcomes, and data surrounding family structure and home stressors.

Regarding the social, lifestyle, education, and research data, caregivers, clinicians, and researchers had similar responses (Tables 2 and 3), which included data on the impact of diabetes on mental health indicators, data on diabetes-related stress, mood, and anxiety, and data on financial and socioeconomic factors.

For the survey's final question of the *Data Gaps Tool*, where participants were asked to identify who benefits from and uses their data. Both caregiver and health professionals/research groups identified that youth with diabetes and their families, healthcare providers, educators, and researchers are the main users and beneficiaries of the existing and desired data. Caregivers also spoke about diabetes technology providers using their data and how giving access to these manufacturers could advance diabetes care and management throughout and beyond the health system. Clinicians and researchers' unique responses from caregivers about who will be the main beneficiaries (main users) of existing and new collected/desired data included social workers, health program managers, community members, and health care and research funders, who will all be able to improve their respective practices and roles in diabetes care and management.

User Journey Workshops: Table 4 presents three personas and their associated scenarios: Mental Health, Education, and Transition to Adult Care. It also shows the necessary data to effectively inform, monitor, and ultimately achieve positive outcomes related to diabetes care, social well-being, mental health, and education in children and youth with diabetes.

Table 4: Main findings from the User Journey Workshops

The primary experiential user journey/scenario categories, along with the necessary data to achieve the desired positive outcome						
	Mental Health		**Education**		**Transition to Adult Diabetes Care**	
	Desired outcome	**Data Required**	**Desired outcome**	**Data Required**	**Desired outcome**	**Data Required**
Caregivers of Youth living with T1D	Children with diabetes and their caregivers are thriving mentally and emotionally	- Access to existing clinical data to enable educators and health care providers to conduct regular check-ins with youth with diabetes that have prior mental health history - Academic performance and reported experience data health data including missed learnings and diabetes-related metrics that might show decreased interest in school or friends, increased stress and anxiety, or highlight other mental health challenges	Helping youth with diabetes perform well academically and successfully manage diabetes in a school setting	- Data on symptoms, management strategies, and support resources available within the school - Data on diabetes awareness and stigma in the school system - Data on financial resources and accommodations for diabetes care and management in schools - Costs associated with care of paediatric diabetes and the socioeconomic and diabetes impact on academic achievement and performance - Data on impact on caregivers taking a more active role in child's education and academic performance (I.e. burnout, financial distress, mental health challenges)	Successful transition from paediatric care to adult care	- Medical history and diagnosis information - PREM/PROMs from individuals with paediatric diabetes - Data on existing diabetes accommodations and support services in the education system - Geographic data to help locate healthcare providers, diabetes clinics, support groups, and other relevant resources
Clinicians/ researchers	Improving the mental health and well-being of patients	- Quality of life indicators examining emotional and social health - Mental health screening tools and assessments - Data on referral access and transfer within the mental health system - Personalized resources such as treatment and action plans tailored to the individual's needs	Successfully support patient struggling academically and facing barriers in the educational setting	- Data on learning/developmental disabilities - Data on glycemic stability in educational settings - Satisfaction with educational accommodations - Data on general academic performance and achievements - Data on school absenteeism or missed school days - Availability of assessment scales, such as the diabetes distress scale, to evaluate psychological and social factors existing in the academic setting that might not be present outside school	Allowing a clinician to successfully transition their patient *from* paediatric care to adult care	- Clinical data regarding medical history including diagnosis, co-morbidities, medications, devices, technology -Transition readiness tool or assessment (validated and clinic-specific) - Provider geographic data - Wait times for adult care providers - Database of providers accepting T1D patients - Data on which education institutions have attached diabetes clinicians/providers

For the Mental Health scenario, caregiver participants mentioned healthcare professionals and educators having access to all clinical data, to identify and focus their care on those individuals that have past mental health history or have shown signs of distress and challenges in the education setting or elsewhere. In addition, academic metrics, missed learnings, and diabetes related metrics could be used to improve the mental health/ emotional well-being outcomes and trajectories of those that have prior mental health history or are displaying signs of distress or challenges in and outside of the educational setting. Clinicians stated quality of life indicators, mental health/cognitive functioning screening tools, and data on individual patient needs, and health status as important for improving care and well-are and wellbeing outcomes (Table 4).

In the Education scenario, both groups identified different data as essential for successfully achieving positive schooling and social experiences/outcomes within educational settings/systems. For caregivers, the data about existing strategies, management, and resources in the education system, data on awareness and stigma surrounding paediatric diabetes in the education system, and data on financial resources and academic accommodations, as well as the strain, both financially and mentally, on caregivers were stated as being important. Data identified by the clinician and researcher group as required were data on learning and developmental disabilities and their impact on academic performance in students with diabetes, data on integrated health systems and services, academic performance metrics, biomarkers, and the role, impacts of social determinants of health on their diabetes and intersecting social and health outcomes and trajectories (Table 4).

Finally, In the Transition to Adult Care scenario, data identified as necessary from both groups were a complete medical history and geographic data of providers available in the area. Unique responses for the caregiver group consisted of existing data on diabetes accommodations and support services such as student clubs, academic accommodations, and grants and bursaries available. In contrast, clinicians and researchers valued patient-reported experience, outcome measures, and various providers' wait times (Table 4).

Data Ecosystem

Figure 5 presents the final resulting Data Ecosystem Tool with consolidated findings from all three workshops (workshop 4 - 6). The results of the Data Ecosystem Tool are categorized into

two main categories: **Internal and External data**. This classification aims to clearly delineate the role and level of access for each type of data within the CAPACITY registry.

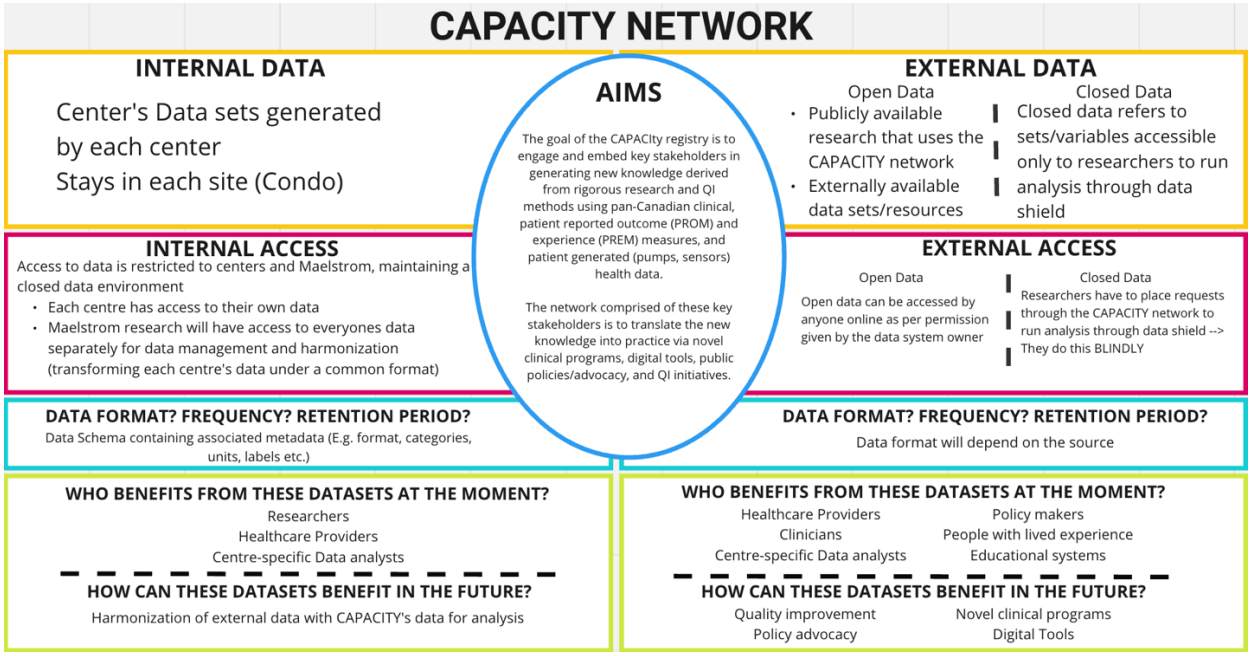

Figure 5: Findings from The CAPACITY Network's Data Ecosystem Tool

Internal data: It was defined as the data sets generated by each paediatric registry site across Canada that will be a partner site of the CAPACITY registry as data providers. This internal data stays in each registry's database center, housed in a closed and protected data environment where only the data-providing partner site will have complete access to their own data with limited access provided to Maelstrom for data management and harmonization purposes only. Harmonization is the achieving or improving comparability of similar measures collected by separate studies or databases for different individuals.[13] Since the datasets have already been collected, retrospective harmonization also leverages the use of existing research data. This allows the establishment of a standard data schema containing variables (e.g. format, categories, units, labels) that will then be used across all the sites linked to the CAPACITY registry network. This is a large part of the standardization and data linkages aim of the CAPACITY registry.

External data was divided into two sub-categories: Open and Closed. Open data refers to the externally available data sets and resources which are publicly available. Permissions for access to this open data would be defined by the platform where the data is being hosted and something outside of the control of the registry. Open data are primarily data sets that can, in the future, be linked to the CAPACITY registry data to enhance further the analysis capabilities of the registry,

such as ICES and CANUE data. Closed data refers to aggregated data sets accessible *only* to researchers and those approved by the Data Access committee and wish to run analysis through DataShield, an open-source software that secures data behind its firewall and ensures data privacy. Data privacy is protecting sensitive information about personally identifiable health care information. It focuses on using and governance a person's data, such as making policies and establishing authorization requirements to ensure that personal information is protected, collected, shared, and utilized correctly.[14] The CAPACITY registry network will not contain any personally identified data but rather disaggregated data that has been de-identified. Closed data would only be accessed through approved requests submitted to the CAPACITY registry network, who wish to run analysis of data through DataShield.

Currently, the people benefitting from internal and external data listed by the participants consist of researchers, healthcare providers, center-specific data analysts, and non-healthcare professionals, such as policymakers, people with lived experience, and educators. However, through harmonization, management, access and integration of these datasets, the participants believed that the CAPACITY registry would have broader benefits for improvement, policy advocacy, innovation of new clinical programs and practices, and improvement of digital tools.

Data Governance and Network Structure Recommendations

During the final workshop, the group of caregivers and youth with diabetes made several recommendations regarding the committee structure and composition. The recommendations encompass the involvement of advocacy groups and representatives from local diabetes clinics in the network steering and projects committee. Additionally, they proposed having caregivers from diverse socio-economic backgrounds with diverse healthcare experiences as representatives within a CAPACITY registry's patient/parent advisory committee. When asked about data access, participants in this group stated that each research, quality improvement, or LE-driven project aiming to use CAPACITY registry data would benefit from being critically reviewed and vetted by the patient/parent advisory committee and other appropriate committees (e.g., an ethics committee, or committees with lived experience participation) to see if they are financially viable or sustainable.

In the clinician/researcher group, some of the recommendations regarding the CAPACITY registry's structure was that the network steering committee should act as a representative for the

entire network, act as an information hub, and ensure that a bioethicist and a representative from each partner site is present in the data governance committee or subcommittees. This group recommended that access depend on the research type being conducted or sought targeted purpose/objective; thus, each proposal should be evaluated independently of the others.

Both groups made several recommendations for changes to the existing governance structure and the members that make up each committee. Participants spoke about the need for youth with diabetes and caregiver representation across all committees to ensure the CAPACITY registry is being governed with a lived experience perspective and to help direct the focus of the decision-makers. The group also suggested that a finance sub-committee be created to discuss budgeting.

Participants also mentioned the need for a more diverse representation of the members of each committee. This includes a more diverse group of healthcare professionals, as the committees currently only consist of paediatric endocrinologists. There is only one dietician, psychologist, and biostatistician in the governance structure and no nurses in the entire governance structure. In addition, members from racialized populations, diverse socio-economic backgrounds, and rural areas across Canada should also have a voice in the CAPACITY registry's committee structure to establish an equitable and inclusive governing body. A significant part of this inclusivity highlighted was to ensure Indigenous representation and voice in the registry's decision-making.

Regarding data access, participants suggested that the CAPACITY governance structure has a data access committee that connects with and facilitates external researchers and their research proposals. By doing so, they mentioned that it would allow for the proposal's aim, objectives, and feasibility to be appropriately evaluated and reviewed before data is made available to the researcher for analysis.

Workshop Evaluation

Of the 31 participants who attended the Data Asset Mapping Tool Workshop Series, 23% (7/31) completed the feedback survey. All the respondents reported feeling somewhat comfortable communicating during the event and felt respected throughout the various activities and discussions. Of the open-ended feedback solicited, respondents commended the facilitators'

enthusiasm and clarity and the benefit of having people with lived experience and caregivers as part of the co-design process.

Constructive suggestions predominantly focused on simplifying the activities to reduce confusion, improve efficiency and use less technical language for better comprehension, especially in the final workshop regarding the registry's governance and stewardship structure. Other recommendations were to conduct the workshop in French or other languages instead of having only interpretation services available.

DISCUSSION

Our co-design workshops highlighted key user challenges, the associated data requirements and user journeys. Our findings will inform how the CAPACITY registry can address critical data gaps and needs within the data ecosystem and governance structure.

Our work detailed in this chapter is grounded by our previous findings from Chapter 1, specifically focusing on key areas of QI, Research, and LE-Driven, aligning with evidence-based strategies for improving paediatric diabetes care practices.[15] Throughout this co-design process, we observed that having caregivers, healthcare providers, and researchers interacting and collectively applying and creating knowledge facilitated a more comprehensive identification of the prevalent challenges in paediatric diabetes care and support. This understanding extends to how the CAPACITY registry can address these challenges and leverage its potential for quality improvement, research, advocacy and policy. By exploring priority challenges, data requirements and innovative ideas, we aim to ensure that the decision-making and implementation of this registry align closely with the needs of diverse users and/or potential beneficiaries of the CAPACITY registry.[15]

Despite the numerous sources of data and resources currently available to researchers, caregivers and clinicians regarding paediatric diabetes in Canada, there are many gaps and challenges impacting diabetes management, care provision, and the overall well-being of children and youth with diabetes. The main challenges were centred on mental health, education, and transitioning from paediatric care to adult care.

Mental Health

Diabetes can bring about several negative emotions and stressors that are tied to the difficulty with management, the stigma surrounding diabetes, and the lack of support available, which were all identified as challenges in our Data Asset mapping co-design process.[16]Navigating these difficulties can be extremely taxing for children and youth with diabetes and their caregivers, which can lead to various mental health-related issues. Depression is much more prevalent in children with diabetes compared to children without diabetes, leading to poor glycemic control and treatment adherence, increased emergency visits and hospitalizations, and higher diabetes and non-diabetes complications (e.g. diabetic ketoacidosis, severe hypoglycemia).[17,18] Youth with T1D, specifically, are also at an increased risk for developing eating disorders, with prevalence rates being twice as high among adolescent females with diabetes compared to their non-diabetic counterparts.[19]

Some of these disorders are associated with weight gain in paediatric diabetes patients, potentially leading youth to attempt weight loss through deliberate insulin omission or underdosing.[19] These issues highlight the necessity for routine screening for mental health-related issues and resources for appropriate and timely mental health support within and outside of traditional healthcare settings or providers, such as in the community and school settings.[20,21] The call for increased mental health screening was one of the main desired factors pointed out by both caregivers and clinicians in the user journey activity.

Participants identified a need for data on fears, apprehensions, and barriers experienced by patients and caregivers in current paediatric care and management practices. The timely identification of the intersecting challenges and barriers experienced by children with diabetes and their caregivers can enable the development of targeted interventions or advocate for appropriate support. In our Data Asset Mapping workshop findings, caregivers, researchers and health professionals expressed their desire and a need for more data on mental health impacts like stress, mood disorders and anxiety and cognitive functioning to inform effective integrated traditional healthcare and community-based (including school settings) support for children and youth with diabetes. Current studies show that there is a lack of adherence to paediatric diabetes clinical practice guidelines in Canada, and performance is below both national and international standards.[22,23] Several factors influence this poor adherence to proper diabetes care and management, such as fears, barriers linked to family structure, relationships and roles/powers,

challenges in accessing health and social support in school settings, the transition to adult care, and the appropriate understanding of the impacts of mental health status.[22] Participants underscored that each of these mental and cognitive related factors as areas that require more data. Specifically, mental health factors were identified as having a cross-dimensional impact, spanning across management, transitioning to adult care, and education, all currently being discussed.

Caregivers also mentioned the need for data on sleep quality. Extensive research and systematic reviews exist on the impact of sleep on T1D, including the effects of sleeping behaviours and partners in transitioning to adult care. [24] Evidence has shown that individuals with T1D experience a decline in overall sleep quality, poor sleep quality, problems with higher A1C levels, and overnight glycemic changes.[24,25] These findings highlight that the issue is not necessarily a lack of data, but rather a lack of awareness, limited, accessibility, and availability of resources for youth living with diabetes and their caregivers. \

Education

Effective and adequate diabetes care in educational or school settings is essential as children spend most of their time in schools, and their care level reflects their short- and long-term well-being.[26] In British Columbia, support for children with T1D from trained school personnel is standardized across the province. Additionally, in Nova Scotia, there is a diabetes support policy in effect to ensure that students with diabetes are supported in managing diabetes healthcare tasks while at school; however, similar measures across other provinces are limited.[27] The Canadian Paediatric Society recommends that diabetes care in schools be standardized nationwide and emphasizes the necessity for each child to have an individualized care plan, have access to caregivers, teachers, and healthcare providers alike, and allow for collaborative input on how care and management tasks should be supported, executed, and delegated.[28]

Children with diabetes face several challenges in school settings, such as poor academic performance, poor mental health, and absenteeism from classes due to regular medical appointments.[29] Adding to these challenges, students often experience intersecting and interacting barriers such as inadequately trained teachers to help with their diabetes-related care and management, misconceptions and stigma surrounding diabetes, understaffing, and inability

to take time away from class to address hypoglycemia.[29] In the United States, paediatric diabetes organizations have provided expert recommendations for T1D management in schools, such as requiring a written and descriptive plan for diabetes care for each student provided by their caregiver or physician, individually training school staff, and ensuring collaboration with all parties involved in a student's life. These recommendations align with the data needs that caregivers and clinicians/researchers reported in the User Journey activity. This includes collecting data on teaching/learning and diabetes management accommodations available for students with diabetes, implementing responsive mandatory health programs in the education system/setting that are diabetes care sensitive, and gathering statistics on integrating data across health and educational systems.[30]

Transition to Adult Care

Transitioning from paediatric to adult care can bring about several challenges for youth living with diabetes and their primary caregivers; therefore, it is essential to understand the factors leading to this complicated transition process. In Ontario, there is no consistent or standard approach to transitioning to adult care, and smaller rural paediatric diabetes centers transfer few paediatric individuals to adult care, leaving patients with no direction on where to go afterward to continue their appropriate and timely diabetes and overall health care and treatment.[31] In other provinces, however, such as in Nova Scotia, there is a robust approach to youth transition present with plentiful resources available to both youth with diabetes transitioning to adulthood and their caregivers.[32] To alleviate these issues, specific data and resources can aid the process, as highlighted in our User Journey findings. These encompass the timely and successful transfer of patient medical history, quality of life assessments, and clinical data from paediatric to adult care teams. Effective care transition is essential, as inadequate transitioning is associated with increased rates of both acute and chronic complications of paediatric diabetes, elevated hemoglobin A1c levels, and an increase in mental health disorders and decreased mental and emotional well-being.[33]

Co-morbid mental health disorders and psychosocial issues, including depression, anxiety, low self-esteem and self-care challenges, are barriers to successfully transitioning to adult care.[33] Transitioning from adolescence into adulthood brings several challenges that compound the complexities of managing diabetes. [34] Such challenges include decreased family support, new

school environments, workforce entry, financial constraints, barriers to healthcare services, diabetes specialized treatment, and health and social support.[34] Research has revealed reduced follow-up visits post-transition from paediatric care, prolonged intervals and gaps between appointments, and delays in finding a new healthcare provider after leaving paediatric care. [35] These challenges highlight the need for a more cohesive and integrated care system to ensure the successful transition of care for children managing diabetes.[35] Having geographic database of existing specialized diabetes support services (e.g., places for people with diabetes to appropriately self-manage or apply their treatment, access to appropriate food sources, student social and health support) in academic institutions, as well as information on existing support services and care providers accepting diabetes patients, can help young adults with diabetes along with their families to successfully and transition without being solely dependent on the existing healthcare system's information or services.[31]

Understanding the financial challenges impacting and associated with paediatric diabetes for caregivers, specifically the impact of socioeconomic position and resources on diabetes care and health outcomes of children with diabetes, is critical. Financial barriers and socioeconomic differences in children with diabetes were a salient and common finding not only in transitioning care but also in the mental health and education-related challenges. Geographical barriers were another important identified factor negatively impacting a successful adult-care transition. People in more rural areas, such as specific Indigenous populations living in remote communities, must travel great distances to visit adult endocrinologists, and this is associated with high costs and delays in seeking help.[31] Generally, the distribution of care and social support services in more rural or underserved areas, combined with government support and funding for caregivers and families of children living with diabetes, is essential for successfully managing and caring for paediatric diabetes.[36]

Data Ecosystem, Access & Governance

Co-design activities also focused on refining the CAPACITY registry's data governance and stewardship structure and identifying data sharing and privacy agreements required for co-implementing the registry (Phase 2). By collaboratively filling out the Data Ecosystem Tool with members of our internal CAPACITY team and partner organizations, we could distinctly differentiate between internal and external data sources and delineate the user pathways for each

type accordingly. Insights for use and access included the involvement of the data access committee as a "patient data guardian" by assessing the relevance of the proposed data use to shareholders' needs and proposed knowledge dissemination plans for the newly generated knowledge.[37] This lived experience-driven final registry theme is consistent throughout the co-design phase, which is why we have consistently engaged and embedded people with lived experience in all activities. Moreover, in alignment with LE-driven learning health systems, which inform a more responsive and higher quality of care, patients and healthcare users must be involved throughout the co-design stage.[37] Subsequently, having more lived experience representation in the CAPACITY registry (both during co-design and implementation) will ensure the registry is aligned with user needs, especially around the identified challenges related to transitioning to adult care, mental health and education.

Caregivers, health professionals and researchers advocated for diverse representation in the governance structure. Engaging diversity successfully within CAPACITY's registry organizational structure can positively impact quality improvement, increase participation, and promote inclusivity and belonging.[38] The COVID-19 pandemic has already displayed the necessity of addressing and increasing inclusivity, diversity, equity and accessibility in healthcare and health research to address anti-Black and anti-Indigenous racism and dismantle existing colonial structures.[39] To promote diversity in the registry's governance structure, efforts must focus on recruiting people from minoritized or racialized groups, including Indigenous communities, into the governance structure regardless of their knowledge, socio-economic position, area of residency, and identities. Participants highlighted the critical task of setting up clear roles, accountability structures, and unified goals and processes[38]within the CAPACITY registry's governance, all of which have been indicated to be successful in other settings.[38] A clear understanding and recognition of First Nations principles of ownership, control, access, and possession (OCAP), as well as the Engagement, Governance, Access and Protection (EGAP) framework developed by the Black Health Equity working group will also greatly benefit governance.[40] Therefore, targeted efforts to include Indigenous perspectives in the next phases of the CAPACITY registry are necessary and invaluable.[41,42]

STRENGTHS AND LIMITATIONS

Our co-design was predicated on creating a safe and inclusive environment for individuals from all areas of paediatric diabetes lived experience by inviting caregivers of youth with diabetes, researchers, and a diverse group of healthcare professionals. Since CAPACITY is a national initiative, we had participants from across the country attend our co-design activities. Our co-design process still had limitations, which should be highlighted and considered when reviewing and interpreting the findings from the data asset workshops. First, participation could have been more consistent throughout the workshop series, as twenty attended workshop 1; however, only fourteen attended by the end of the series (workshop 7). Second, despite our efforts to reach to diverse communities for participation in these workshops (e.g. through NIDA and JDRF), there was limited participation from racialized communities, which include individuals from Black, African, and Caribbean backgrounds, Indigenous people, and individuals from low socioeconomic backgrounds. Additionally, despite having a national scope, we only had representatives from some of the territories, further emphasizing the need for Indigenous representation and rural user involvement. Lastly, as mentioned in the "Workshop Evaluation Findings", not having the co-design workshops delivered in French or other regional languages served as a potential barrier to having a more diverse participant group and a barrier to greater involvement from participants whose first language is not English.

CONCLUSION AND NEXT STEPS

In summary, the ongoing co-design phase of the CAPACITY registry has played a pivotal role in identifying primary challenges and data pertinent to paediatric diabetes management and care; delineating existing data gaps in the field; gaining insights into user experiences and associated data capture; specifying available data and its integration into the CAPACITY registry; and exploring the beneficiaries of the registry and their involvement in data input, access, utilization and oversight. Through this collaborative approach, we developed a list of data indicators for inclusion in the registry, defined the data ecosystem that will inform data governance and management, and applied stakeholder input and recommendations to refine the CAPACITY registry's governance and stewardship structure and identify any data-sharing agreements required to co-implement the registry in Phase 2.

Using these completed workshops, we characterized the technical and data requirements of the CAPACITY registry, which will now enable us to transition to the final step of this co-design phase, which will be using the functions and features identified in Chapter 1 of this report and

the data gaps and desires identified the workshops in this co-design phase, to produce potential use cases for the registry. These potential use cases will then be developed during the prototyping and co-implementation of the audit and feedback intervention in Phase 2. This will be achieved by 1) informing the selection and collection of additional indicators/variables for co-implementation of the registry, 2) validating and informing the audit and feedback framework, specifically the qualitative interviews that will be conducted with stakeholders, and 3) further informing data ownership and data governance framework.

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CONFLICTS OF INTEREST

Dr. Ian Zenlea (Co-PI) received advisory board fees from Novo Nordisk Canada, Dexcom, and Abbot Diabetes Care.

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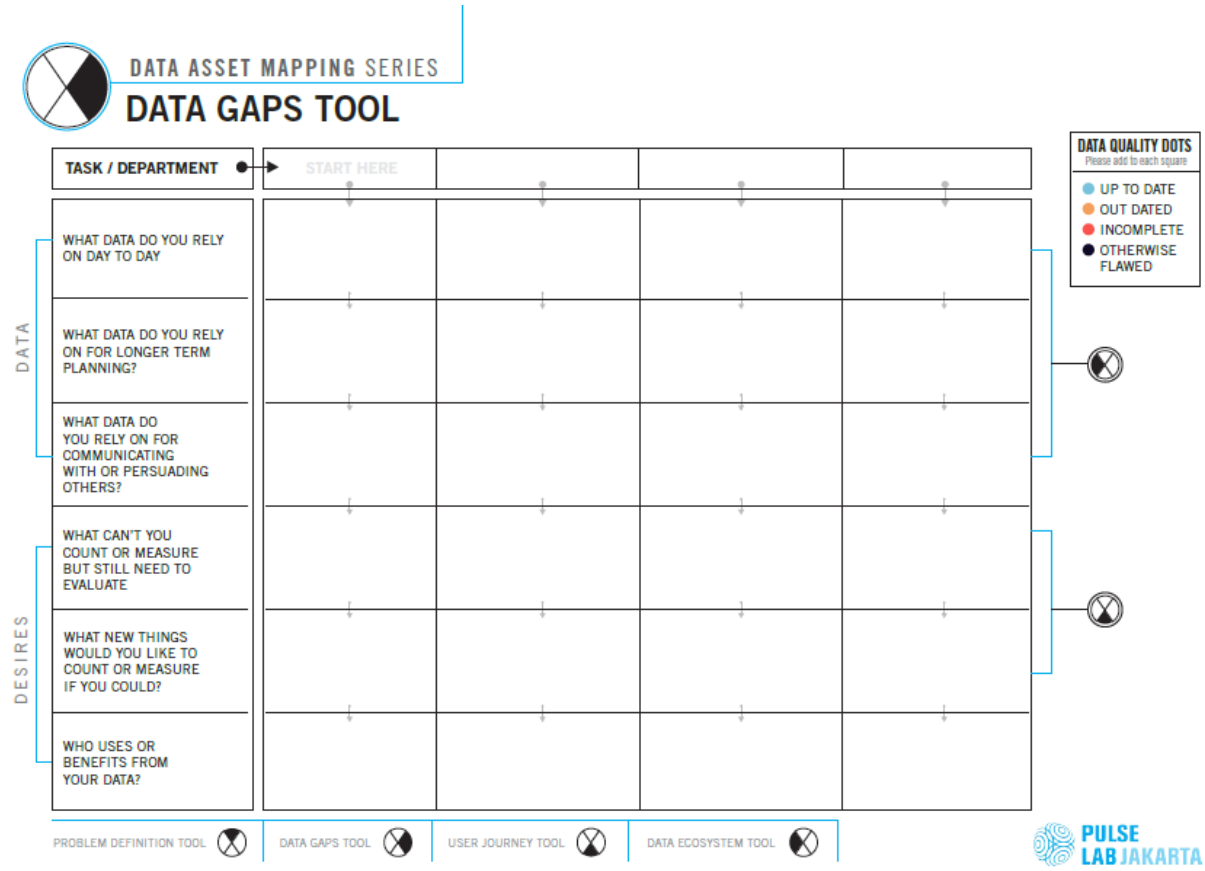
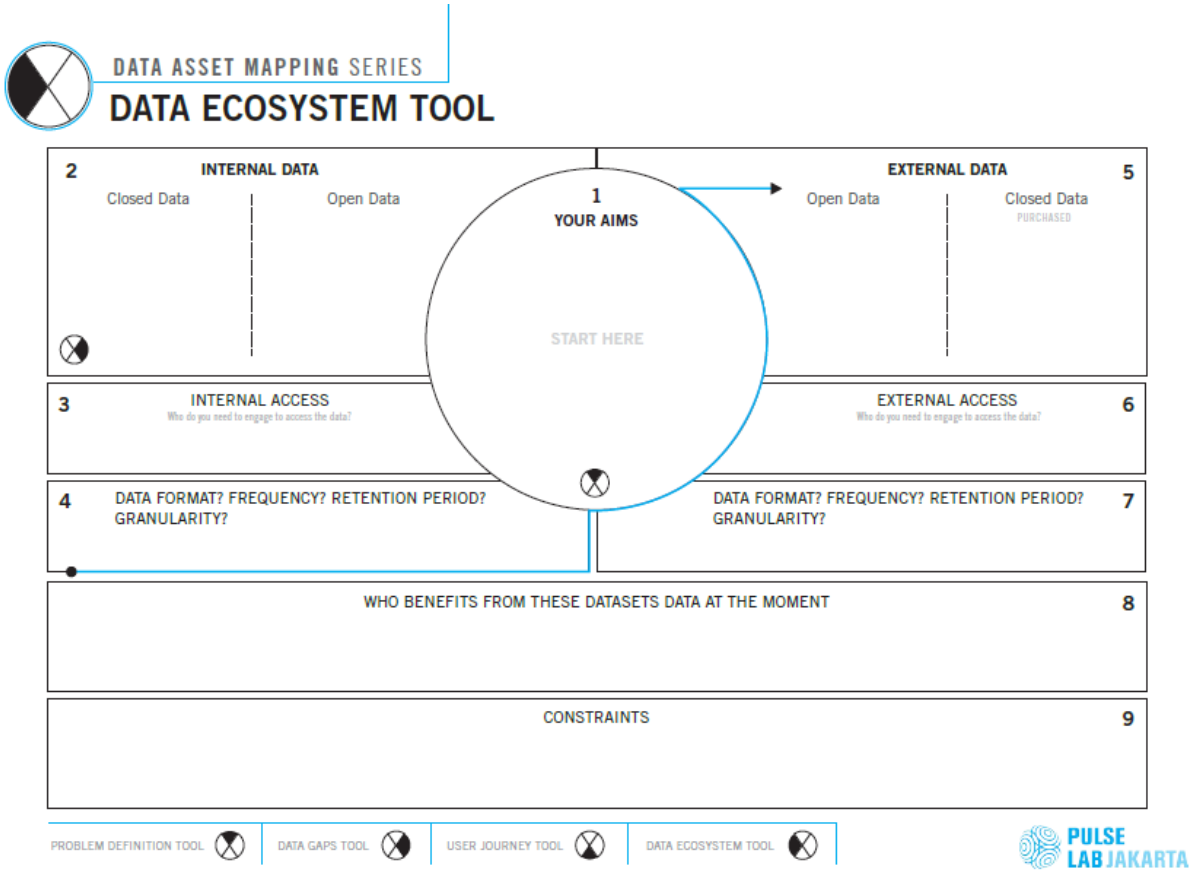
SUPPLEMENTAL INFORMATION

Supplemental Table 1: Broad Categories Generated from Previous Findings

Category	Definition
Quality Improvement (QI)	A focus on improving processes of providing care resulting in improved patient outcomes and experiences (such as utilizing benchmarking, patient-reported outcome and experience measures)
Research	A focus on collecting and/or utilizing data (health services, administrative, etc.) to generate knowledge
Lived Experience (LE) - Driven	A focus on factors that are valuable to the person with lived experience, can include outcomes and experience of care, as well as utilization of benchmarking health indicators and self-management against other people with diabetes



Supplemental Figure 1: Data Asset Mapping Series Data Gaps Tool



Supplemental Figure 2: Data Asset Mapping Series Data Ecosystem Tool