IMPROVING REGISTRIES FOR BETTER HEALTHCARE SERVICES AND OUTCOMES FOR PEDIATRIC TYPE 1 DIABETES

PREPARED BY
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Acronyms/ Abbreviations

BMI -	Body Mass Index
[DPV[2]]DIAMAX -	A diabetes management software for diabetes specialists, which was developed by Axaris - software & system GmbH in collaboration with the German Diabetes Association and International Society for Pediatric and Adolescent Diabetes[1]
DKA -	Diabetic Ketoacidosis
DPV -	Diabetes-Patienten-Verlaufsdokumentation
EHR -	Electronic Health Records
EMR -	Electronic Medical Records
HIC -	High-Income Country
LIC -	Low-Income Country
LMIC -	Low-Income and Middle-Income Country
ICDR -	Iceland Childhood Diabetes Register
IDDM -	Insulin Dependent Diabetes Mellitus
NCDR -	Norwegian Childhood Diabetes Registry
NHS -	National Health Service
GP -	General Physician
SWEET registry -	A multi-center, registry started by investigators for patients with diabetes. The acronym SWEET stands for “Better control in pediatric and adolescent diabeteS: Working to crEate cEnTers of Reference”.
T1D -	Type 1 Diabetes Mellitus
T2D -	Type 2 Diabetes Mellitus
WHO -	World Health Organization

Abstract

Background: This paper examines the role and utility of registries in improving healthcare delivery and health outcomes of Type 1 Diabetes Mellitus (T1D). Disease registries play an important role in informing policy and practice decisions aimed at reducing cause-specific morbidity and mortality and the associated cost of care of the diseases for which they are created, thereby contributing to improved health system performance. Registries provide a robust means of gathering disease-specific data which can be analyzed to generate contextually sensitive knowledge—to observe disease trends, compare clinical practices across and within populations, and evaluate patient outcomes.

The paper draws on a comprehensive review of published literature to examine existing pediatric T1D registries to provide evidence-based approaches and practices for the creation and maintenance of such registries. The paper is organized in three parts. In Part One, the paper provides an overview of registries and discusses the current state of registries for T1D globally. Part Two examines the principles of registry creation and maintenance for T1D and analyzes how these principles could be applied for new registries. In Part Three, we describe key findings on the characteristics of existing T1D registries and the data collected within those, including the comprehensiveness and scale of data available in these registries, how the registries have been used to improve efficiency and effectiveness of T1D care, and important resource considerations when creating and maintaining such T1D registries. We further examine data collection processes and structures that govern these registries and discuss these in the context of barriers and enablers that may impact the adoption or otherwise of these processes.

Part One: An overview of T1D registries

Registries

The World Health Organization defines a 'registry' as "a file of documents containing uniform information about individual persons, collected in a systematic and comprehensive way, in order to serve a predetermined purpose."[2] A patient registry specifically refers to registries focused on health information, although no standard definition exists. The term generally refers to both the data collection and the data.

Patient registries, also referred to as clinical registries or disease registries, collect, organize, and display uniform data to evaluate clinical care and outcomes for specific diseases, exposures, or population groups. Registries contain a diverse range of data, including among others, patient identifiers, demographic and socioeconomic data, clinical encounter data, laboratory and diagnostic test results, and patient reported information. Registry data can include clinical patient data from health records as well as those from questionnaires administered to patients. Registries may be hospital-based, containing data on all patients meeting specific criteria within a specific institution, or population-based, with the goal of containing information on all patients within a specific geographic region. Registries may cover an entire country or contain data from international collaborations.[2,3]

Registries are multi-purpose and could be used for research in many ways. For example, they can be used to recruit patients for clinical trials and to evaluate effectiveness of care and health outcomes. Registries can also be used for epidemiological surveillance and to inform health system planning by tracking disease incidence and prevalence in a population. For patients and healthcare providers, registries can include data access portals that allow them to easily access their own data and compare it to population-level data. Some registries may also contain or link to a biobank of blood or other tissue samples.

In contrast to registries, databases generally contain larger quantities of information from a cohort of individuals with a specific disease or exposure and may not follow those patients over time. Electronic Health Records (EHR) similarly contain information from patients categorized or coded according to a classification system, such as the International Classification of Diseases (ICD) codes, for specific diseases or exposures. EHR include all data collected for clinical care, which may vary from registry to registry depending on how often and in what contexts a patient interacts with that health system. A comparison of typical characteristics of registries, databases and EHR is provided in Table 1.

Table 1. A Comparison of Registries, Databases and Electronic Health Records[3]

	Patients Included	Amount of Data	Time Course	Goal
Registries	Every patient with condition	Limited data	Tracks patients over time	Research, quality-tracking, epidemiology and surveillance
Databases	Cohort of patients with condition	Extensive data	May include one time-point or multiple	Research
Electronic Health Records	All patients with ICD code for condition	All clinical data	Follows patient over clinical course in health system	Clinical care

Source: Williams et al., (2010)

Type 1 Diabetes

Type 1 Diabetes (T1D), also called juvenile diabetes or insulin-dependent diabetes, is one of the most common chronic diseases of childhood. It is caused by the autoimmune destruction of insulin-producing beta cells in the pancreas, resulting in a permanent and critical need for exogenous insulin. It is associated with substantial morbidity and mortality due to longer-term effects and damage to target organs, immunosuppression, complications and comorbidities, such as kidney damage and heart disease. In low-income and middle-income countries (LMICs) barriers to timely access to insulin, diagnostics and care compound these problems.

An estimated 1.1 million children and adolescents under the age of 20 have T1D globally.[4] Prior studies have estimated the overall prevalence of T1D to range from 2.12 per 10,000 total population in Europe, to 9.6 per 10,000 population in Asia. Africa has the second highest overall estimated burden of 5.3 per 10,000 total population[4]. Africa and Asia, the world regions which include most of the countries classified as LMICs, are disproportionately burdened relative to other regions. However, data specific to T1D incidence, prevalence, care and outcomes are limited particularly for LMICs in these regions, reflecting the inequities in T1D care that exist globally. Furthermore, as seen in Figure 3, there are fewer T1D registries in LMICs in comparison to High-Income Countries (HICs), and for the ones that exist, there are severe gaps in data collected.

This prevalence trend appears to change among children and adolescents under the age of 19 years. The WHO European region has the highest burden of 296.5 per 1000 population and the Africa region the lowest at 25.8 per 1000 population.[5] A summary of these findings is displayed in Figure 1. It is important to emphasize that the severe lack of data in low-income countries is likely to impact the real magnitude of these figures.

Figure 1a and 1b: Comparison of incidence and prevalence of Type 1 Diabetes cases per annum in 0–19-year-olds by country income groups (Figure 1a) and by world region (Figure 1b).[5] Figures shown are per 1000 population.

Figure 1a

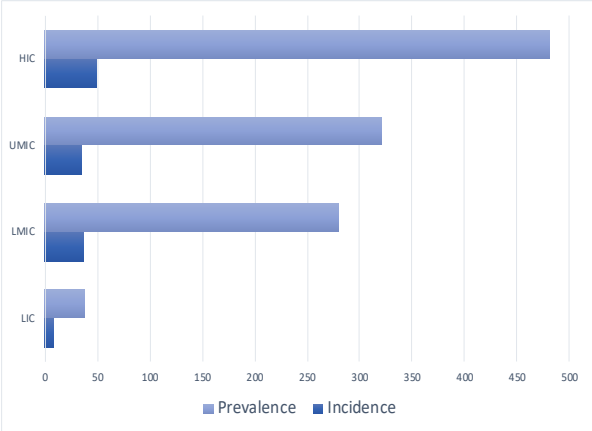
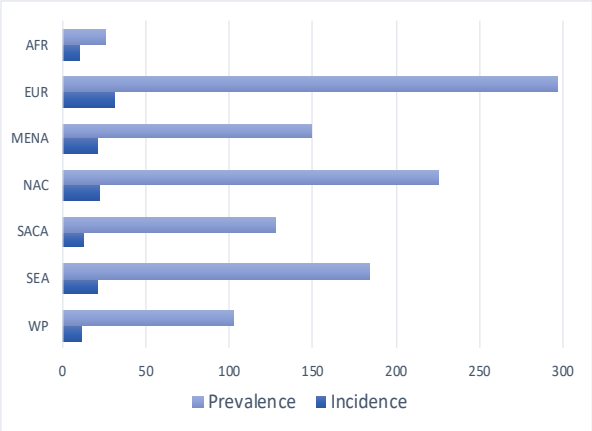


Figure 1b



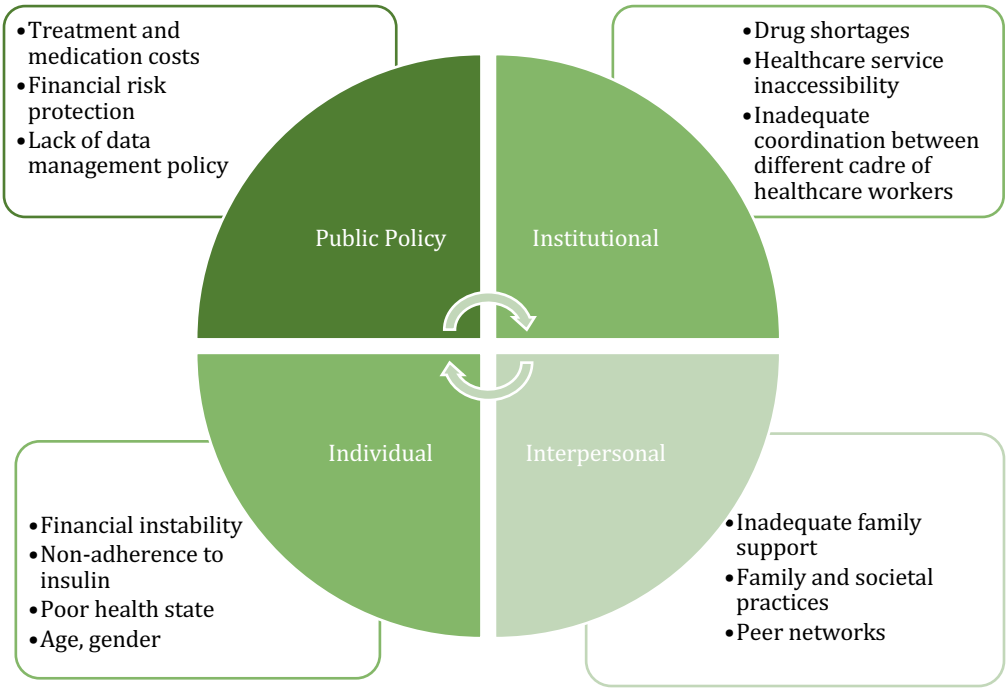
Source: Patterson et al., (2019)

Challenges to T1D care in LMICs

The challenges of T1D care in LMICs are manifold, spanning economic, technological and logistical challenges at individual, interpersonal, institutional and policy levels. Some of the individual level challenges faced include poor health due to a high rate of diabetes-related complications, mostly due to lack of financing to regularly purchase insulin and other diabetes care medications, non-adherence to medication, and inadequate patient education.[6]

Peer support, which has been demonstrated to improve patients' daily behaviors and metabolic control, may be non-existent or non-functional in many LMICs.[7] There is an inequitable distribution of specialist diabetes care physicians that impacts the quality of care received by patients with T1D, coupled with inadequate health worker and patient coordination.[6] High costs of insulin with drug shortages, lack of access to high quality monitoring through laboratory testing, and poor resource allocation due to the double burden of communicable and non-communicable diseases compound inequities, contributing to poor health outcomes in LMICs.[8] There are also challenges related to data management in LMICs, impacted by technical, cultural and ethical issues.[9] The lack of adequate data on T1D across many LMICs is coupled with the lack of robust data management policies (Figure 2).

Figure 2. Challenges to Type 1 Diabetes care in LMICs



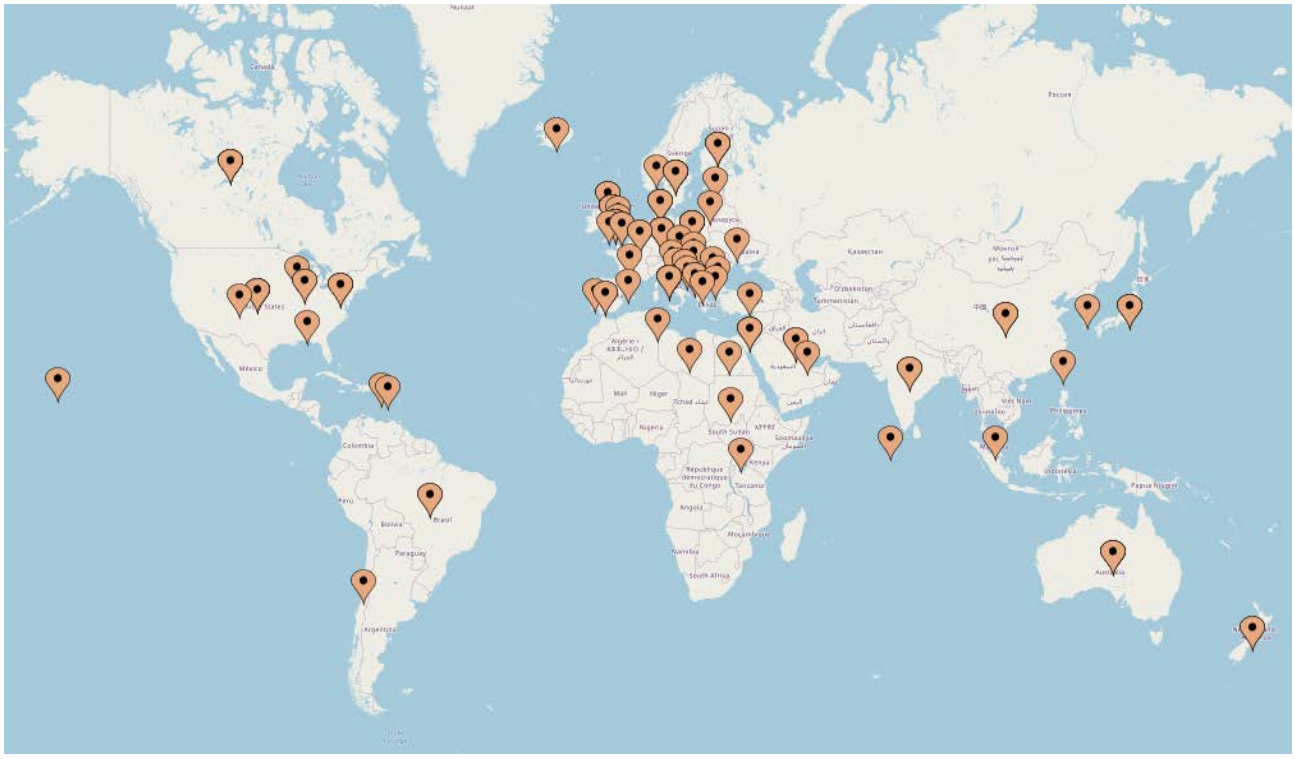
Source: Various Authors[6,7,8,9]

T1D registries in LMICs

There are fewer T1D registries in LMICs compared to HICs. From a review of relevant literature, while there are approximately 22 T1D registries in LMICs, there are 114 in HICs (Figure 3). This imbalance is concerning as LMICs account for 6.5 billion people and 1.755 billion children and adolescents aged up to 15 years, accounting for 27% of the population in this age group.[10]

The lack of T1D registries in these countries is a major barrier to our understanding of T1D in LMICs, including the development of strategies and innovations to improve care in these settings. The reasons for the relative paucity of T1D registries in LMICs are many, including the lack of well-integrated data management systems for collating T1D data. The HIC registries contain more data points than those in LMICs. An example of such a registry is the T1D Exchange Registry discussed on page 9. These differences highlight the challenges that are underpinned by inadequacy of resources for setting up and maintaining registries, which could provide critical data to improve the care of T1D in LMICs. There is thus the need for T1D registries in these settings, which contrary to T2D and combined diabetes registries, are solely pediatric-focused. This will allow for greater emphasis on human, technical and economic resources that will benefit the youth T1D population, who have peculiar needs which differ from adult populations typically seen in combined or T2D registries. The goal is to however develop an interoperable system that can function across all the different types of registries, without compromising pediatric T1D care and control.

Figure 3. Distribution of T1D registries globally



Source: Authors (plotted on https://www.mapcustomizer.com)

Registry case studies:

What data do T1D registries typically include and how do they function?

In this section, we examine specific registries across different countries and discuss below the T1D Uganda registry[11], T1D Exchange registry[12,13,14] and SWEET multinational registry.[15,16,17] (Panels 1, 2 and 3).

The T1D registries in HICs have been used to answer numerous important research questions including the incidence of T1D, complications of T1D, predictors of HbA1C levels, and predictors of mortality. These research studies yield valuable data that can be used to improve several aspects of healthcare, beyond clinical care and into health policy. For example, the T1D Exchange and the Diabetes Prospective Follow-up registries have been used to examine the link between body mass index (BMI) and optimal glycemic control in children with T1D.[18]

Panel 1: LMIC. Uganda T1D Registry[11]

In 2009, the Ugandan government worked with the World Diabetes Foundation to establish T1D-specific clinics for children aged 0-18 years old. As part of this project, electronic medical records (EMR) were established in these clinics and linked to a central database to create a national childhood T1D registry.

Although the registries are based at the clinical centers providing care for children with T1D, they cover the majority of the population since these clinics are the only T1D-specific clinics in the country. Smartphones are used by the healthcare providers in these clinics for data capture and entry and solar powered battery packs are provided to ensure continuity of data entry and data use even during power outages.

In the early phase, the clinics also keep hard copy paper records to ensure data are not lost while transitioning to the digital format.

While initially the registry collected a broad range of data, the number of data items collected was later reduced to ensure that the data collection and entry process did not overburden the healthcare teams.

***Panel 2. HIC*: T1D Exchange Registry**

In 2010, a network of Type 1 Diabetes specialty clinics throughout the United States (US) established the T1D Exchange Clinic Registry, a prospective center-based large-scale patient registry to improve T1D care in the US. Individuals with T1D are recruited for this registry through their participating outpatient clinic.

Data are collected both from medical records and through self-administered questionnaires at enrollment and annually thereafter. The digital technology used to develop the questionnaires allows them to be tailored to individual circumstances. For example, if a participant is pregnant, they are asked a specific set of questions included in the pregnancy module.[12] Questionnaires can be completed either on tablets provided at outpatient clinics or at home on the registry app.[13] The use of self-administered questionnaires for standardized data collection was prompted by the heterogeneity of the data collected in the medical records in each clinic and the variation in the definitions and types of data collected.

While the T1D Exchange Clinic Registry is large (>30,000 individuals)[14], it is not comprehensive as it only covers T1D patients seen at the participating outpatient clinics. This may bias the sample towards higher-income and insured patients and may reduce generalizability of the data to the whole US population.

Panel 3. Large multinational initiative: SWEET registry

106 collaborating centers throughout the world report a concise yet comprehensive standardized prospective dataset twice a year to the SWEET database housed at the University of Ulm, in Ulm, Germany.

Reporting centers can use the openly available [DPV[2]] DIAMAX software or report their data by uploading a standardized Excel file to the secure SWEET website. This allows reporting centers the flexibility to submit data in the most convenient way for their pre-existing and diverse data collection processes. The SWEET team at University of Ulm reviews the data for inconsistent or implausible values and reports potential errors back to the centers for verification and correction following each data upload.

Aggregate data from all collaborating centers is anonymized and combined in ways that are consistent with data protection regulations. Data can then be accessed for research and international benchmarking.[12,13,14]

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Part Two: Creation and maintenance of T1D registries

Creation and maintenance of a T1D registry are two separate but interlinked activities. It is important to carefully consider the processes involved in these activities when launching the registry in order to prevent duplicative work and ensure creation of a user-friendly and sustainable registry.

Registry creation

Engagement of stakeholders

There are a number of important steps involved in the creation of a T1D registry. First, stakeholders should meet to determine registry priorities, longevity, and potential data collection sites. Stakeholders may include pediatric endocrinologists or other primary clinical managers of patients with T1D, diabetes care nurses, funding bodies, community representatives with a special interest in diabetes care, data managers, epidemiologists who will be involved in associated research or population health metrics, patients, and caregivers. If possible, consultations would also include registry managers from neighboring countries or from well-established and functioning registries.

The role of governments and non-government entities in the creation of T1D registries varies by country and is highly context dependent. Inclusion of a government entity as a stakeholder may foster a nationally standardized register that is maintained using government resources. This is an attractive option especially if the primary data collection sites are government-run or government-financed hospitals or health clinics. However, if the registry is intended to serve only a few hospitals or is not dependent on government funding, government involvement is not required for a registry to be created.

Selection of Data Items

The selection of data items can be customized to suit the region's needs but should be comparable to other previously established registries as to allow for comparison between registries if desired. The North East England and North Cumbria Registry is an excellent example.[19] The registry creators in North Cumbria split the data into two levels, which we will refer to here as a *Core* dataset, and a *Core-plus* dataset. The *Core* dataset includes critical data that are easy to collect and enables the calculation of T1D incidence, while the *Core-plus* dataset requires more manual labor for data collection but paints a richer picture of the T1D context.

The decision of which data to be included in the *Core* and *Core-plus* datasets should be made using a multi-stakeholder approach and tailored to the region for which it is being designed based on the particular factors relevant to that region such as access to advanced lab testing.

Table 2: Registry Data Items as depicted in the North East England and North Cumbria Registry.[19]

Core data
Surname • Previous surname • First name • Date of birth • NHS number • Sex • Ethnicity • Date of diagnosis • Type of diabetes • Address at diagnosis • Address at birth • Address at registration • GP at registration • Date of data collection
Core-plus data
• Date of first insulin injection • Change in diagnosis • Clinical results at diagnosis, e.g., pH, glucose, ketones • Other results, e.g., HbA1c • Hospital consultant • Hospital number at registration • Hospital admissions • Family history of diabetes • Birth weight • Height and weight at first clinic appointment • Care planning appointment details • Record of the biomedical indicators shared with the patient prior to appointment

Source: Blakey et al., (2013)

Establishing a data collection template

The group of stakeholders involved in the creation of the T1D registry can establish a standardized data collection template as an analogue data collection sheet, a digital template (such as an Excel spreadsheet) or website with a digital data collection tool which is compatible with all data collection sites.

Standardized data collection will involve the creation of a *data dictionary* and a *codebook*. Both tools are used as centralized guides that describe the data being collected in the registry. Data dictionaries and codebooks may overlap.

A data dictionary is used to explain what the variables in a data set mean. This may include the variable item, a definition, the data units, the allowable data values, source of the data item, and specified missing data codes. The utilization of a data dictionary facilitates standardized data collection by ensuring that each data collection site is utilizing the same data structure. Furthermore, the use of a data dictionary ensures a common language for all parties involved in data entry and analysis.

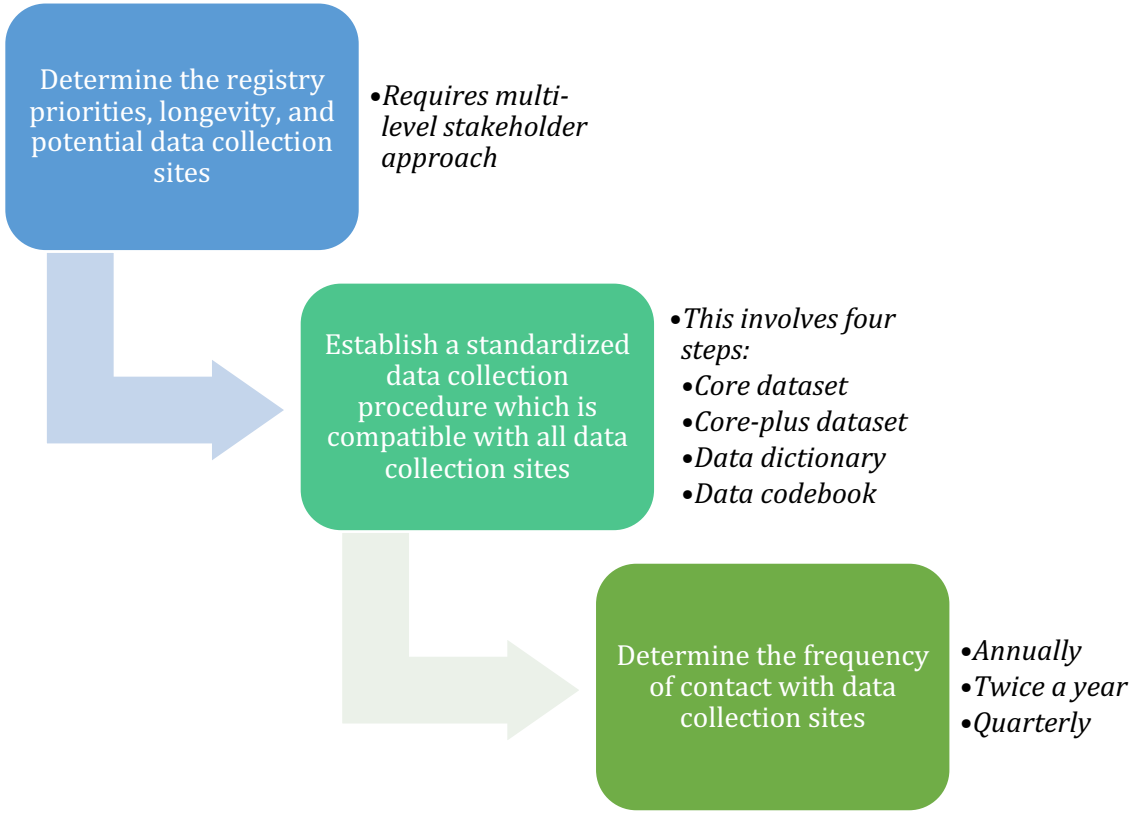
A codebook describes the variables and values in a dataset for the purpose of interpretation. This may include the specific survey question linked to each variable as well as the variable item, allowable values, and definition.

Frequency of data collection

Once the data collection procedure has been established, the frequency of contact with data collection sites should be determined. Most existing registries collect information twice per year, but some collect up to four times per year. At minimum, collection at least once per year is recommended.

A pilot of the registry could be undertaken in order to identify the resources needed for data collection, data entry, and data management and to establish inefficiencies that need to be overcome while creating the registry. However, given the lessons from successful registers in many diverse contexts to date, implementation can likely begin without a pilot but should be introduced in a phased manner, with few functionalities to start with and a Core dataset, which could later be expanded by including Core-plus data modules and additional functionalities.

Figure 4. Major elements of registry creation



Source: Authors

Registry maintenance

Establishment of an integrated data management process

Management of the registry refers to the integrated system of data collection, cleaning, storing, monitoring, reviewing, reporting, and quality assurance. As mentioned above, data collection methods must be determined at the initiation of the registry with careful consideration of clinical workflow and infrastructure to ensure a consistent process, a standardized dataset, and minimal disruption to clinical care and sustainability.

Data collection and management procedures should be documented in a manual (hard copy and/or electronic) with clear descriptions of all data collection protocols, policies and procedures, the data collection instrument (or the template if one is used), and definitions of all the data elements involved. These include patient inclusion and exclusion criteria, the screening process, site-level documentation, training for data collectors, and plans for monitoring, evaluation, and quality assurance.

Data collection forms should be self-explanatory and include supporting information on how they are to be used, which components are Core, which are optional, and how the data will be archived or stored. Consistent procedures are vital to the uniform and systematic collection and maintenance of data, which need to be standardized (Core dataset for example), although data entry and abstraction methods may vary slightly according to local context. Abstracted data, whether from paper records or EHR systems, must be cleaned, coded, stored, and backed up in a harmonized and trackable fashion as to allow for tracing of subsequently discovered data errors.[20]

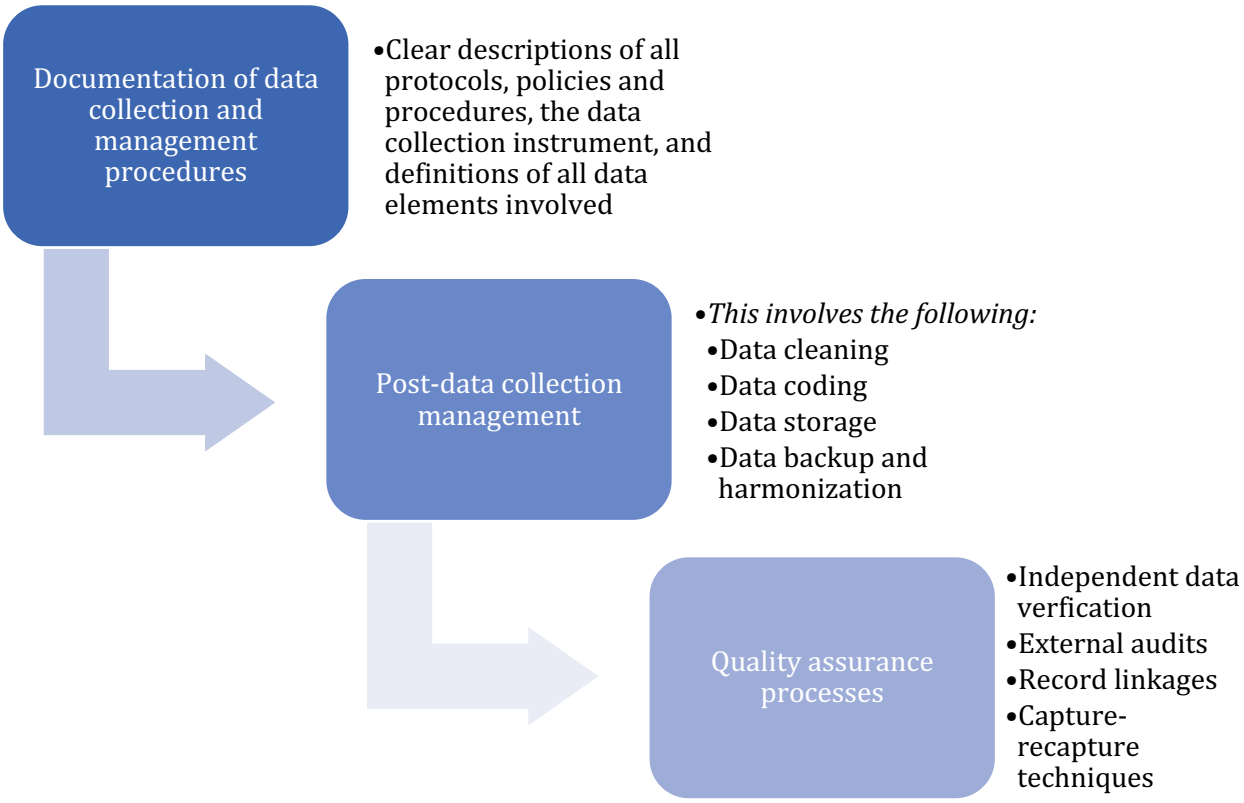
Data Governance

A governing body may be useful to ensure the relevant data governance systems are put in place in alignment with the national regulations pertaining to data collection, storage, data sharing, privacy and data rights.

The governing group should be responsible for providing an oversight of the registry with regular advice, guidance and management of adaptive changes to the Core dataset, Core-plus dataset modules, data collection template, data collection manual, and codebook.[21]

The governing body should appoint a 'Data guardian' to ensure data governance systems are in place and are regularly observed by all dealing with the data at the registry.

Figure 5. Registry maintenance procedures



Source: Authors

Quality assurance

Quality assurance processes must be able to effectively protect the registry against errors, including those made unintentionally including errors of interpretation, entry, coding, or transfer and those made intentionally. This may be accomplished through training, studies of data completeness and consistency using independent sources of data such as insurance records or pharmaceutical data on insulin use, or routine and for-cause audits of data collection and maintenance. Additionally, external audits of registry procedures, including assessment of system security and validation, will be helpful in the long-term maintenance of T1D registries for children and adolescents.[21]

Record linkage has often been used to assess the quality and case ascertainment rate of registries, with pediatric T1D registries in many settings linked to national birth and death registries, census data, or administrative databases using basic demographic data or identification numbers.[20]

Additionally, capture-recapture methods have long been part of pediatric T1D registry protocols to capture registry completeness using a secondary data source.

Part Three: Characteristics of major T1D registries and resource considerations related to registry creation and maintenance

This section discusses key findings on the characteristics of existing T1D registries and the data collected, including the existence or lack thereof of data on the comprehensiveness and scale of data available, how the registries have been used to improve efficiency and effectiveness of care for managing T1D, and the important resource considerations when creating and maintaining T1D registries.

Characteristics of major T1D registries

From a review of the literature, major T1D registries have been found to be mostly located within HIC settings. These include the T1D Exchange Clinic Registry discussed on page 9, the DPV registry and the Nordic collaboration of registries (NordicDiabKids), which itself includes the Swedish Childhood Diabetes Registry (Swediabkids), the Iceland Childhood Diabetes Register (ICDR), the Danish Register for Childhood Diabetes (DanDiabKids) and the Norwegian Childhood Diabetes Registry (NCDR). These registries contain data that has been regularly used in research studies and publications, and have advanced data collection techniques and regulatory procedures, some of which are discussed below.

Core Datasets

The following data are the common data items collected by registries that were identified in a scoping review of literature. These are Age, Sex, Date of diagnosis, HbA1c, Address, Weight, Height, Family history, Race/Ethnicity, Pancreatic autoantibodies, BMI and DKA. For consistency, the following data items are recommended to be included in the Core dataset: Sex, Age/Date Of Birth, Ethnicity, Address, BMI, Date Of Diagnosis, Type Of Insulin, Insulin Regimen, SMBG, A1C, Blood Glucose and DKA.

Core Plus Datasets

Beyond the Core dataset, additional data items that may be collected by registries depending on resource availability and feasibility of the data process. These data items include socioeconomic data, advanced complications data such as hospitalizations for hypoglycemia, retinopathy, neuropathy and nephropathy, as well as advanced laboratory data such as lipid measurements, serum creatinine, serum bicarbonate, blood pH, genetic testing data and pancreatic autoantibodies.

Technology used

Technology used in most major T1D registries are digital, using software such as the [DPV[2]] DIAMAX software and DPV software developed by Ulm University[22]. Some paper-based systems exist, particularly in LMICs, an example being the Registry of Diabetes with Young Age at Onset in India[23].

Data collection method

Based on literature review, registries collect data through multiple sources that allowed for data verification and ascertainment. In some settings, health institutions reported cases directly to a central repository such as the Australasian Diabetes Data Network.[24] In other settings, data were obtained from physician notes, hospital discharge data, laboratory results and radiology reports. Examples of registries using multiple methods of case verification included the Australia National Diabetes Register[25] and the SWEET Registry[26]. Using multiple case ascertainment and verification methods reduces missing data and improves the quality and completeness of data collected, as demonstrated in these registries. In addition, data collection techniques can be largely facilitated by institutions with well-resourced laboratories and disease monitoring systems.[27]

Data collection frequency

Data collection frequencies vary across centers. While data collection at local participating centers should be an ongoing process, transmission of collected data to a central repository can occur at pre-determined intervals, which may be quarterly or bi-annually. For example, each participating center of the DPV transmits data twice yearly to the University of Ulm, Germany for the data to be aggregated and analyzed.

Governance

To ensure compliance with international and national guidelines on data processes, prior registries have been regulated by the national governing and ethical review bodies of their participating centers. One such example is the DPV registry, which has its data collection and analysis procedures regulated and approved by the ethics committee of the University of Ulm, Germany as well as local review boards of centers that collect and transmit data to the registry.[28] Another example is the NordicDiabKids collaborative, where each of the four participating countries have steering committees that spearhead registry activities. The collaborating countries hold yearly meetings to debate registry guidelines and to discuss opportunities for growth in their respective centers. The steering committee includes clinicians that have experience in research as well as a registry keeper or 'data guardian'. In particular, the Iceland Childhood Diabetes Register has its processes approved by a National Bioethics committee and a Data Protection Authority[29]. These regulatory processes are essential and will contribute to the quality of each registry, while respecting patient autonomy and privacy. It is however noteworthy that these examples are drawn from countries where there is good healthcare access, relatively high-income economies and, in the Nordic countries, no restrictions on insulin.

Human Resource Considerations

Stakeholders involved in registry creation and maintenance should carefully consider the human, technological and financial resources required to create a registry, collect, aggregate and store data, analyze data, and maintain the registry.

A dedicated healthcare professional member at each collection site, usually a nurse who is involved in the care of individuals with T1D, is needed to identify new patients and enroll them in the registry using the standardized collection form. Additionally, a data manager is needed to collect data from data collection sites at the agreed upon frequency, clean and verify the data, and ensure the registry remains functional.

The data manager should undertake a quality review of the registry functionality, integrity, consistency and use twice a year in order to identify gaps and inaccuracies, thereby ensuring issues are identified early on before they become entrenched problems. Any issues specific to a particular clinic related to the data supplied to the registry can be communicated directly to the relevant clinic, while general issues can be brought before all the stakeholders to review the issues identified, prioritize them and generate potential solutions and actions to resolve them.

If the registry is digital, the data manager's responsibility may also include technological troubleshooting, or additional informational technology staff may be included.

Training of healthcare professionals

Staff training for the data sheet/website is mandated so that all persons involved in data collection and usage fully grasp the intricacies of the data being collected and are able to address any challenges that arise during collection. Additionally, data analyst or researchers are needed to assess registry completeness and validation.

Technological considerations

Digital registries are usually easier to maintain and analyze but are not possible to implement in all situations. If a paper registry is created, secure storage of patient information behind lock and key at a centralized site is required.

Either paper or digital registries that use hardcopy data collection sheets or templates should devise a method to transfer information gathered on those sheets into an electronic format like an Excel spreadsheet. Instead of a paper collection method, digital registries may utilize a website for data collection. This enables data to be aggregated digitally, linked, centralized and stored in the cloud with

very little difficulty. Website based data collection can also facilitate high-quality data management. For example, dropdown menus or units can be provided to guarantee that data is collected in a similar fashion across collection sites.

Technology is advancing rapidly and can be harnessed to create and maintain registries more efficiently.[30] Two particular technological advances are especially attractive for use in T1D registries: data storage in cloud and geocoding.

The cloud is an online storage method that provides enhanced data storage, security, and functional ease. It does not require a stable internet connection, as data entries can be done manually and intermittently, and uploaded to the cloud at a regular frequency, for example once a day. However, if a stable internet connection is available, the entire registry can exist in the cloud and could be accessed real time from any clinic or analysis site that are involved with the registry. Cloud based T1D registries have been successfully established by many European registries.[31] Encryption, patient protection, and other safety measures are necessary to ensure that the registry data included in the cloud remains confidential and private, according to the guidelines provided by the regulations and policies in a particular country.

Geocoding transforms text-based location descriptions into geographic coordinates. This innovation permits subsequent geospatial analysis and identification of regional trends for incidence and prevalence of T1D, the care provided, and the resourcing of the health services for T1D (as facilities can also be geocoded).[32]

Certain factors may inhibit the adoption of these technological advances, particularly in LMICs. Countries have unreliable internet and electricity supply, and digital data systems are less well developed. For such countries, a hybrid approach can be considered, where countries utilize paper-based systems supported with digital innovations as resources allow.

Automated data entry

Automated entry for some data, for example lab data, is another consideration for digital registries. Automation reduces human error in transcribing lab values, but it perpetuates any errors by the lab itself. Either automated or manually entered laboratory data are acceptable for a registry and should be determined based on the coordinating center's capabilities. As noted prior, automated data entry may not be practical in some settings due to the paucity of digital innovation and technology.

Use of unique identifiers

If data are gathered in multiple settings, by different health professionals at multiple time points, individuals whose data are shared with the registry could be issued with a unique identifier to ensure linkage and consistent alignment of the data with the appropriate individual.

Many registries use multiple time points to assess disease progression.[30,33] If the creation of a unique identifier is not possible due to privacy laws or regulations for example, the registry could be fully anonymized, as long as there is a method to prevent duplication of existing participants. Data collected at follow-up should not duplicate demographic data collected at the initial visit, but instead provide updates on the current diabetes status (i.e., HbA1c) and the sequelae (i.e., diabetic retinopathy or nephropathy).

Custom designed standardized follow-up data collection templates would help in ensuring consistency and relevance, while reducing duplication.

Consent

Regardless of data collection methods, approval with consent forms should be required to enroll individuals in a registry. Registries which collect data from a variety of sites or collect human samples, like biopsies, will require a more detailed consent process.

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