



**T1D**  
*Exchange*

# Data Science Committee Meeting

August 2024

Co-chairs: Ryan McDonough , Nirali Shah

# Agenda

- Introductions-Ryan McDonough and Nirali Shah
- T1D Exchange Updates- Emma
- T1D Data Specification Updates- Emma
  - Version 3.1 and 4.0
- T2D Data Specification Updates- James

# Welcome To Our New DSC Co-Chairs

Dr. Ryan McDonough from Childrens Mercy



“My role as Chief Medical Information Officer has given me a unique opportunity to leverage informatics approaches to ensure highly reliable and quality data. Expanding to chair this committee would allow me to share that expertise with the group more readily.”

Dr. Nirali Shah, Icahn School of Mt. Sinai Adult



“Through comprehensive data analysis, we would seek to identify patterns, uncover novel insights, and contribute to cutting-edge research in the field. Additionally, fostering interdisciplinary collaborations, promoting data-sharing initiatives, and advancing digital health technologies would be integral to the committee's vision.”

# Type 1 Diabetes Mapping Updates

- **37** centers fully mapped (from 35 centers in Q2)
- **4** in validation phase

# Type 2 Diabetes Mapping Update

- **3** centers fully mapped
- **2+** centers still in the mapping process

# Scorecards Update

- Data completeness scorecards are in final processing now

# T1D Data Specification 3.1 Version

## Formatting Changes

- Merged diabetes and core data specification files into one specification document
- Removed type, format, and response columns in all files and added this into the note sections for easier use
- Added all loinc code information into notes columns as well

# T1D Data Specification 3.1 Version

File Name	orgId_observations_YYYYMMDD_v_[spec_version].txt			
Column Position	Variable	Definition	Type	Notes
1	organization_id	Submitting Member Organization ID, assigned from Coordinating Center	string	
2	patient_id	Patient identifier that the observation applies to from the patient's file.	string	Foreign key of Patient.patient_id.
3	encounter_id	Encounter identifier for when the observation was recorded from the encounters file	string	Foreign key of Encounter.encounter_id
4	observation_id	Unique observation ID for each unique patient observation. The observation ID must remain consistent across all files which contain that observation and across all data submissions.	string max(32)	Value should be max 32 characters. Valid characters are among [a-z,0-9,-_#:]
5	category	Classification of type of observation	coded	Allowed Values Among:  social-history: "The Social History Observations define the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, religious affiliation. Race and ethnicity can be reported as observations however they should be properly reported in the patient file." vital-signs: "Clinical observations measure the body's basic functions such as such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pulse oximetry, temperature, and body surface area." laboratory: "The results of observations generated by laboratories. Laboratory results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient and submitted to the laboratory." survey: Assessment tool/survey instrument observations“ Depression screening PHQ, GAD, ASQ SDOH"



# T1D Data Specification 3.1 Version

## Changes to Patient File

- Changed language from gender to sex. Sex is now defined as sex at birth
- Additional languages were added for patient language and caregivers' language
- Additional education levels added

# T1D Data Specification 3.1 Version

## Changes to Observations File

- Point of care (PoC) HbA1c added

# T1D Data Specification 3.1 Version

## Changes to Diabetes File

### Diabetes Insulin:

- added in all smart insulin pen devices, removed non smart insulin pen devices

### Diabetes Monitoring:

- Added G6-pro and G7 CGM for Dexcom and Freestyle Libre 3 (Abbot)

# T1D Data Specification 4.0 Version

## Formatting Changes

- Merged diabetes and core data specification files into one specification document
- Removed type, format, and response columns in all files and added this into the note sections for easier use
- Added all loinc code information into notes columns as well

# T1D Data Specification 4.0 Version

## Changes to Observations File

### Added:

- Diabetes Distress Screeners
  - Different screeners for pediatric and adult centers
- ASQ Suicide Screening

# T1D Data Specification 4.0 Version

## Pending Changes for Stages of Diabetes

- Once ICD-10 codes are released for stages these will be added

# T2D Data Specification 1.0 Version

## Formatting

- Merged diabetes and core data specification files into one specification document
- Removed type, format, and response columns in all files and added this into the note sections for easier use
- Added all loinc code information into notes columns as well

# T2D Data Specification 1.0 Version

Variable Number	Variable	Code System	Description	Value	Notes
1	ins_regimen	t2d	Insulin regimen	coded	<p>Allowed Values Are Coded Among:</p> <p><b>1: Insulin pump.</b> Notes: Includes hybrid pump/injection regimens (e.g. “untethered” pump use or use of long-acting insulin with insulin pump).</p> <p><b>2: Injection, basal-bolus.</b> Notes: Includes regimen using carbohydrate ratios primarily for prandial insulin even if sliding scale used. Include patients using only basal insulin due to “honeymoon” period of persistent endogenous insulin production.</p> <p><b>3: Injection, mixed/split.</b> Notes: Regimen refers to use of intermediate acting insulin (e.g. NPH) and adjustments (e.g. use of carbohydrate ratios) for variable carbohydrate intake at a majority of meals.</p> <p><b>4: Injection, sliding scale.</b> Notes: Regimen refers to use of fixed prandial doses for meals with adjustments for variable glucose levels even if secondary use of carb ratios for atypical carbohydrate consumption (e.g. snacks or greater than allotted carb amounts).</p> <p><b>5: Injection, fixed dose.</b> Notes: Regimen refers to constant insulin doses independent of most, if not all, ranges of carbohydrate intake and glucose values.</p> <p><b>9: Injection, unknown dose method.</b> Notes: Injections are used but the dose method is unknown.</p> <p><b>11: Inhaled Insulin.</b> Notes: Regimen refers to insulin taken by inhalation</p> <p><b>99: Other regimen.</b> Regimen is known but not among listed regimens</p> <p><b>100: Unknown.</b> Notes: Unknown if pump, injection, or inhalation</p>
2	basal_ins_daily_inj	t2d	Number of daily basal insulin injections.	integer	Average number of long-acting insulin injections daily; Include intermediate, long-acting and premixed insulin types. Value=0 (zero) for patients using basal rates exclusively in insulin pump. For variable injection number, take average of range and round down to nearest integer.
3	bolus_ins_daily_inj	t2d	Number of daily bolus insulin injections.	integer	Average number of short or rapid-acting insulin doses daily used to cover carbohydrates and/or correct elevated glucose values. Include only regular and rapid-acting insulin analog doses. For variable injection number, take average of range and round down to nearest integer. Average number of bolus insulin doses per day on download (for pump) and pt report. (for MDI)
4	mixed_basal_bolus_ins_daily_inj	t2d	Number of daily mixed basal-bolus insulin injections.	1 decimal	
5	t_ins_daily	t2d	Total daily insulin dose (units of insulin) to 1 decimal place.	1 decimal	Sum of all insulin (in units) administered daily. For variable daily doses, provider to use discretion to estimate average total daily insulin dose over any available period which captures typical range. Ranges not permissible. Round to nearest tenth unit. (one decimal point)
6	basal_ins_daily	t2d	Daily basal insulin (units of insulin) to 1 decimal place.	1 decimal	Sum of all basal insulin (in units) administered daily. Include long-acting, intermediate-acting, and premixed insulin doses. For variable daily basal doses, provider to use discretion to estimate average daily basal insulin dose over any available period which captures typical range. Ranges not permissible. Round to nearest tenth unit. (one decimal point)
7	bolus_ins_daily	t2d	Daily prandial/bolus insulin(units of insulin) to 1 decimal place.	1 decimal	Sum of all bolus insulin (in units) administered daily. Include all short-acting (e.g. regular) and rapid-acting insulin doses. For variable daily bolus doses, provider to use discretion to estimate average daily basal insulin dose over any available period which captures typical range. Ranges not permissible. Round to nearest tenth unit. (one decimal point)
8	mixed_basal_bolus_ins_daily	t2d	Daily mixed basal-bolus insulin(units of insulin) to 1 decimal place.	1 decimal	



# T2D Data Specification 1.0 Version

## Changes to Patient File

- Changed language from gender to sex. Sex is now defined as sex at birth
- Additional languages were added for patient language and caregivers language
- Additional education levels added

# T2D Data Specification 1.0 Version

## Changes to Provider File

- Removal of Provider of Service ID, Drug Enforcement Agency number and Other ID.
- Will be moving forward with NPI ID collection.

# T2D Data Specification 1.0 Version

## Changes to Encounters File

- Changed the allowed values for endo\_visit variable to include encounters within primary care.
- For encounter class created a distinction for virtual\_ambulatory and virtual\_education visits.

# T2D Data Specification 1.0 Version

## Changes to Observations File

- Point of care (PoC) HbA1c added
- Collection of ASQ Suicide Screening survey
- Waist Circumference data collection

# T2D Data Specification 1.0 Version

## Changes to Medications File

- Simplified medication status to only include active and inactive prescriptions.

# T2D Data Specification 1.0 Version

## Changes to Diabetes File

### Diabetes Guidelines:

- Added source\_value variable for the collection of unmodified pre mapped versions of specific variables (mostly for device mapping)

### Diabetes Disease:

- Added date of T2D diagnosis (t2d\_dx\_dt)

### Diabetes Insulin:

- Added in all smart insulin pen devices, removed non smart insulin pens
- Updated insulin pump companies to include those from CeQur, Mannkind and Beta Bionics
- Added manual mode option for insulin pump delivery system (ins\_pump\_delivery)
- Updated insulin\_regimen to include inhaled insulin as allowed value

### Diabetes Monitoring:

- Added cgm models G6-pro and G7 CGM for Dexcom and Freestyle Libre 3 (Abbot)