Diabetes Control Measure Definition

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1 Introduction

1.1 Purpose

This document describes the method for measuring diabetes control among a general population and within populations that received an intervention, which includes social services and programs. This document is intended for health information exchanges (HIEs) or organizations holding data from clinical and community settings who are interested in measuring diabetes control. This measure was collaboratively developed by MITRE and the Chesapeake Regional Information System for our Patients (CRISP), the HIE in Maryland, to measure diabetes control to support the ability of MAC, Inc. and Meals on Wheels of Central Maryland to communicate the potential impact of their nutrition and diabetes self-management interventions on diabetes control. This work is part of an Administration for Community Living (ACL) sponsored project, the Community and Clinical Data Initiative (CODI) Maryland pilot.

1.2 Background Research

MITRE reviewed published diabetes measurement literature to identify candidate measurement approaches or components for consideration. Appendix A summarizes findings from relevant diabetes control literature, which provided measurement thresholds, intervals, and analytic approaches that informed measure development.

The literature review identified a hemoglobin A1C (A1C) target that defines controlled diabetes as less than 7% and poor control at greater than 9%. Additionally, clinical guidelines state that older adults may be less focused on glycemic control and should have less strict glycemic goals (A1C <8%).

1.3 Key Terms

- **Intervention**: A structured set of activities designed to address specific needs or goals. Interventions include programs, such as diabetes self-management classes, and services, such as home-delivered meals.
- **Participant**: An individual who receives an intervention, including participating in a program or receiving a service intended to address specific health-related needs.
    - In the context of the Diabetes Control Measure, all participants should be living with diabetes at the time of the intervention.

1.4 Assumptions

This measure definition makes the following assumptions.

- Diabetes control is assessed among individuals with diabetes. The diabetes control measure will incorporate the existing CODI definition of diabetes prevalence to identify individuals with diabetes.[1] Thus, diabetes control inherits the assumptions of the diabetes prevalence measure, which includes the following:
    - The measure will not identify incident diabetes.

[1] Available at https://mitre.github.io/CODI/

- The measure will not differentiate diabetes by type.
- The measure will not identify individuals with undiagnosed diabetes mellitus.
- For a panel of individuals, not all individuals will have sufficient clinical data to be included in the measure calculation because they either didn't receive any healthcare during the measurement period or because healthcare data from care received during the measurement period has not been shared with the HIE at all or in a usable way (e.g., labs without Logical Observation Identifiers, Names, and Codes (LOINC®) codes).

- Glycemic targets may vary among individuals due to age, co-morbidities, and other factors.
- Panels of individuals include sufficient demographic data to be matched to data in the HIE.

2 Measure Overview

The diabetes control measure is composed of three metrics to accommodate different reporting needs and data availability. An implementer may choose to measure diabetes control by implementing all or a subset of the following three metrics:

- Diabetes Control Surveillance Metric
- Change in Individual A1C Pre/Post Metric
- Change in Diabetes Control Status Pre/Post Metric

During the ACL sponsored CODI Maryland pilot (ending August 2025), all three metrics will be implemented by CRISP to measure diabetes control and will be used by MAC, Inc. and Meals on Wheels of Central Maryland to communicate the potential impact of their respective interventions.

2.1 Source Data

The minimum clinical and intervention data necessary to compute diabetes control are described in Appendix B in the context of the CODI data model.[1]

2.2 Data Quality

The quality of the clinical data used to calculate diabetes control should be assessed regularly to improve the accuracy and reliability of the results. Users are encouraged to assess data quality based on completeness, accuracy and stability, among others. Users should set their own measurement benchmarks and targets for these metrics as appropriate for their data sources.

2.3 Limitations

This measure has the following limitations:

- Diabetes is a complex condition and individuals with diabetes are often receiving more than one intervention (e.g., medical, lifestyle). A1C results are influenced by many factors including the individual's age, previous medical history, medication adherence,

and diabetes control goals. This measure does not control for potential confounding factors that may impact diabetes control.

- The measure does not include an external control group that would be necessary to demonstrate causality. While the interventions assessed by this diabetes control measure may show correlations between an intervention and changes in participants' A1C results, this measure does not suggest a causal relationship.
- Diabetes control will be measured in aggregate to allow results to be shared with non-health insurance portability and accountability act (HIPAA) covered entities. The patterns of all individuals in a population may not be accurately represented by aggregate estimates. For example, within a population where most individuals' diabetes control improved, there may be individuals whose diabetes control worsened.
- The measure can only use data accessible by the implementing HIE. Data from healthcare providers that do not share data with the HIE are not included. Data from community partners that do not share data with the HIE are not included.
- Laboratory and medication data will not be used to infer a new or existing diagnosis of diabetes mellitus where one was not documented explicitly in the record using diagnostic codes. This may decrease the overall completeness of the denominator in all of the diabetes control metrics.
- The diabetes control measure will use LOINC codes to identify A1C test results. As a result, some available but non-LOINC coded lab results will be excluded. This may introduce selection bias if participants with LOINC coded lab results are different from those with non-LOINC coded lab results.
- Change in diabetes control is assessed using two A1C data points from two different time periods (e.g., look-back period and observation period). Individuals who do not have two A1C test results in the required time periods cannot be assessed for change. This may introduce selection bias based on patterns of A1C testing (e.g., quarterly, every six months, noncompliance).
- Users may define populations of interest based on their participation in or receipt of an intervention during a specific timeframe (e.g., in the past 12 months). The nature and volume of intervention a participant gets during a specific timeframe can vary. This can be in terms of duration (individuals newly-enrolled versus individuals receiving services for a prolonged period of time), amount of intervention (one meal per day vs. three meals per day), and frequency (one day per week vs. four days per week). The CODI dose definition may be used to compute volume of services received during a specified timeframe, if desired, to help contextualize results.[2]

3 Metric 1: Diabetes Control Surveillance

3.1 Metric Description

The surveillance metric is designed to monitor the overall risk of diabetes-related complications within a population of interest by evaluating A1C levels to identify the proportion of individuals with diabetes who are in a defined control state, such as well controlled, moderately controlled, or not controlled. This metric can be used to describe the diabetes control status of a defined

[2] Available at https://mitre.github.io/CODI/

population at a specified time (e.g., calendar year 2024) or can be used to monitor changes in control over time within a population by applying this metric over two time periods. It is a cross-sectional (e.g., point in time) measure driven by a user-selected time period(s).

3.2 Measurement Period

This metric should be evaluated over a user-specified period of time. For example, annually, using a 12-month measurement period. Users of this metric may consider the measurement period that best suits the data available to participating HIEs and the information needs of HIE data-sharing partners like community-based organizations. Users are cautioned that applying an abbreviated measurement period that is less than a year could introduce selection bias. Users should also consider their reporting aims and alignment with other related reporting efforts like clinical quality care measures that are reporting annually.

3.3 Population Selection

The population of interest should be defined based on the demographic, clinical, and/or intervention participation characteristics required for reporting. For instance, a defined population may be all participants that received home-delivered meals from a community-based organization. Determination of which individuals in the population of interest will contribute data to the final metric calculation should be based on the calculation logic described below.

3.4 Age Calculation

Users must calculate individual age as part of this metric. Individuals must have only one age calculated based on a single date in the measurement period to determine if they meet the denominator's exclusion criteria. There are several ways that age can be calculated, but a consistent approach should be used for all individuals.

The recommended approach is to calculate an individuals' age on the first day of the measurement period as follows: Start Date of Measurement Period minus Date of Birth.

3.5 Denominator

Individuals in the denominator are those 18 years or older who have an indication of diabetes unrelated to pregnancy, defined as individuals with one or more ICD-10 diagnostic codes indicating diabetes (E10, E11, and E13)[3] who have at least one documented clinical encounter during the measurement period. An HIE may define a clinical encounter in different ways, for example a hospital or outpatient visit, or evidence of data in particular data type (such as Admission, Discharge, and Transfer (ADT)).

The denominator for this metric includes individuals who meet the CODI diabetes prevalence measure specification, plus additional exclusion requirements specified below.

3.6 Denominator Exclusions

The following exclusions are applied to the denominator population described above:

[3] Individuals who had an ICD-10 code indicating malnutrition-related diabetes mellitus (E12), diabetes due underlying conditions (E08), or drug-induced diabetes (E09) are not included in the denominator.

- Individuals who do not have at least one A1C result that is >4% and <15% during the measurement period are excluded from the denominator. Values outside of this range are considered biologically implausible.
- Individuals who had any ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24) during the measurement period are excluded as they are/were currently pregnant.

3.7 Numerators

Individuals in the denominator are aggregated into the following three control categories based on their last A1C result in the measurement period:

- **Well Controlled**: Individuals with an A1C result of less than 7% (A1C<7%).
- **Moderately Controlled:** Individuals with an A1C result between 7% and less than 9% (7%≤A1C<9%).
- **Not Controlled**: Individuals with an A1C result of 9% or higher (A1C≥9%).

The population in each control category should be calculated as a proportion of the denominator (e.g., percent well controlled).

3.8 Calculation Logic

The diabetes control surveillance metric calculation logic is described below; see Appendix C for the calculation logic diagram.

1. Is the individual 18 years or older? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
2. Did the individual have at least one documented encounter with at least one diagnostic code in the measurement period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
3. Did the individual have one or more ICD-10 diagnostic codes indicating diabetes (E10, E11, and E13) in the measurement period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
4. Did the individual have an ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24) during the measurement period? (Y/N)
    - If yes, exclude.
    - If no, proceed to next step.

5. Did the individual have one or more A1C labs constrained to codes in the HbA1C Laboratory Test value set (OID 2.16.840.1.113883.3.464.1003.198.12.1013[4]) in the measurement period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
6. Did the individual have one or more A1C results >4% and <15% constrained to codes in HbA1C Laboratory Test value set[4] in the measurement period?
    - If no, exclude.
    - If yes, include the individual in the denominator.
7. What was the individual's last A1C result in the measurement period?
    - If the A1C result was <7%, this individual's diabetes control status is classified as "Well Controlled." Calculate as proportion of denominator.
    - If the A1C result was ≥7% and <9%, this individual's diabetes control status is classified as "Moderately Controlled." Calculate as proportion of denominator.
    - If the A1C result was ≥9%, this individual's diabetes control status is classified as "Not Controlled." Calculate as proportion of denominator.

4 Metric 2: Pre/Post Change in Individual A1C

4.1 Metric Description

This pre/post metric compares two A1C results among adult intervention participants diagnosed with diabetes—selecting one A1C result from before a selected intervention starts (pre) and one A1C result following the intervention start date (post) to determine if participants experienced a medically relevant change in A1C.

Because modest variation in A1C results is expected, a medically relevant change for this metric is defined as an absolute difference ≥ 0.5% between the selected pre and post A1C results; the change may either be positive or negative. For example, selected pre and post A1C results of 8.5% and 8.7%, respectively, do not constitute a change for this metric.

4.2 Measurement Period

The measurement period defines the analytic parameters for time that are required to calculate the change in diabetes control among participants receiving an intervention. For pre/post calculations, time has more components and complexity compared to the surveillance measure. There are three relevant dates and time periods to consider when calculating this metric: a participant's intervention start date, the pre-intervention observation period to assess diabetes control before the intervention start date (referred to as look-back period), and a post intervention observation period to assess change after the intervention start date.

For group interventions like cooking classes, participants will have a common intervention start date. For asynchronous interventions such as home-delivered meals, participants may start the intervention on different days. This means that the measurement period may differ for each participant. This metric approaches time based on intervention start date rather than *start* ***and***

[4] Value Set Website: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.464.1003.198.12.1013/expansion/Latest

end dates because interventions, like home-delivered meals, vary in duration and some may be ongoing (i.e., no defined end date).

Users will define the measurement period by selecting the duration of the look-back period and post-intervention observation period. All three of the following time components must be populated to define the measurement period for selected participants.

- **Intervention Start Date**: Users will select a date attribute that provides an intervention start date. The selected date attribute should most closely correspond to the date a participant first received an intervention (e.g., participated in a program or first received a service). There may be instances when enrollment information is missing but delivery information is available. When appropriate, users may draw the intervention start date from multiple date attributes so that if one date from a selected attribute (e.g., intervention start date) is missing, a backup date (e.g., enrollment date) can be used to approximate the start. Some interventions may have been operating for more years than clinical data are available; users should verify that the selected intervention start date time period aligns with clinical data availability. Users may improve precision by further constraining the metric to intervention start dates from specific periods of time (like calendar year 2024).
- **Look-Back Period**: Users will select a duration of time (days, weeks, or months) to look backwards from a participant's intervention start date to determine baseline diabetes control (such as 12 months).
- **Observation Period**: Users will select a duration of time to observe from a participant's intervention start date to determine diabetes control after an intervention has begun (such as 12 months). Because some interventions are time limited while others are ongoing, some participants may be receiving the intervention for some, most, or all of the observation period; some participants may still be receiving the intervention after the observation period ends.

Figure 1 illustrates how a participant's intervention start date, look-back period, and observation period are applied to define a participant's measurement period.

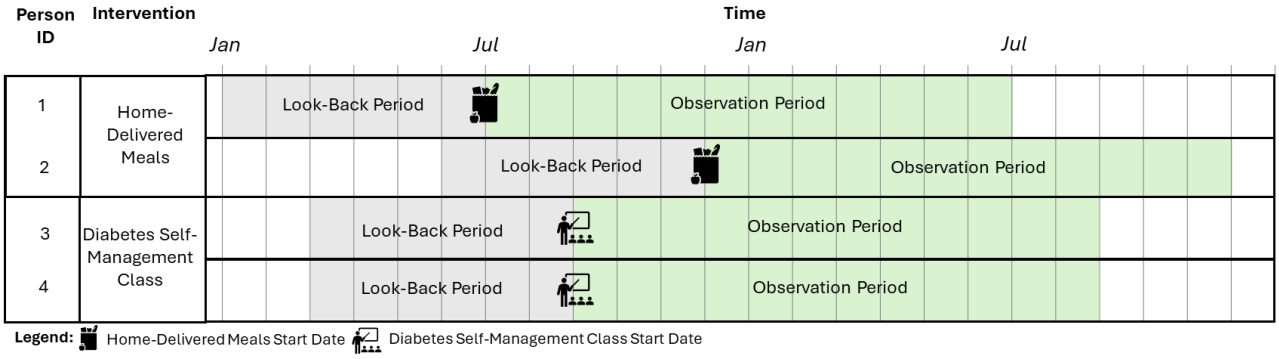


Figure 1. Example 6-Month Look Back and 12-Month Observation Periods Based on Intervention Start Dates

Key Considerations about Time

In selecting look-back and observation periods for pre/post metrics, users should consider their analytic goals, the context of the intervention being assessed, and the following:

- Picking longer date ranges will likely select a more representative sample but is likely to introduce more factors that can influence A1C change.
- For some analyses, having a look-back period and observation period of equal duration may be valuable.
- The amount of time between individual pre and post A1Cs may vary significantly. Date and time period selection should be driven by the intervention of interest and goals of reporting.
- Longer look-back and observation periods will reduce the number of participants excluded based on A1C availability—longer time periods provide more time for individuals to receive healthcare and receive an A1C lab test.
    - Shorter lookback and observation periods may create selection bias due to the expected cadence of A1C testing.
- The observation period must be greater than 90 days following the intervention start date since changes in A1C are not expected for at least three months following changes to lifestyle or treatment.
- Longer observation periods for interventions with greater duration and/or higher frequency, like receipt of home-delivered meals five times a week for one year, provide more time for the intervention to decrease A1C and are more likely to show change in diabetes control.
- Longer observation periods for interventions with shorter duration and/or lower frequency, like home-delivered meals three times a week for two weeks, could provide a longer window after the intervention concludes for A1C to change based on factors unrelated to the intervention.
- If intervention start dates for selected participants span an extended time period (e.g., multiple years), interpretation of pre/post changes may be more difficult, especially if the intervention evolved over that time span.

4.3 Pre/Post A1C Selection

Based on the time components defined for the measurement period, users will select a pre-intervention A1C during the look-back period and an A1C during the observation period.

- **Pre-Intervention A1C**: A single A1C result is required during the look-back period. When there are multiple A1C results during the look-back period, this should be the A1C with a result date closest to the intervention start date (i.e., the latest A1C result in the look-back period).
    - Participants who do not have an A1C result in the look-back period cannot be assessed by the pre/post metrics.
    - Best practice is to select the A1C that occurs as close to the intervention date as possible during the look-back period.
    - Figure 2 illustrates this guidance and shows the potential impact of shorter look-back periods on inclusion.

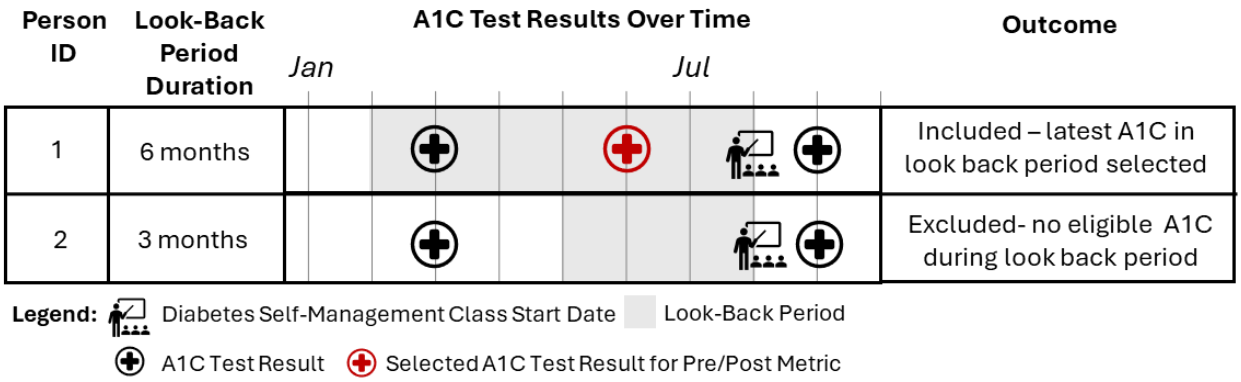


Figure 2. Pre-Intervention A1C Selection Example

- **Post-Intervention Observation Period A1C**: A single A1C result is required during the observation period. This should be the A1C with a result date furthest away from the intervention start date (i.e., the latest A1C result in the observation period).
  - Participants who do not have an A1C result in the observation period cannot be assessed by the pre/post metrics.
  - Participants who do not have an A1C result greater than or equal to 90 days after the intervention start date within the observation period cannot be assessed. This is because A1C results from days 1–89 following intervention start reflect pre-intervention diabetes control, and those A1C results should be excluded.
  - Figure 3 illustrates this guidance and shows the potential impact of shorter observation periods on inclusion.

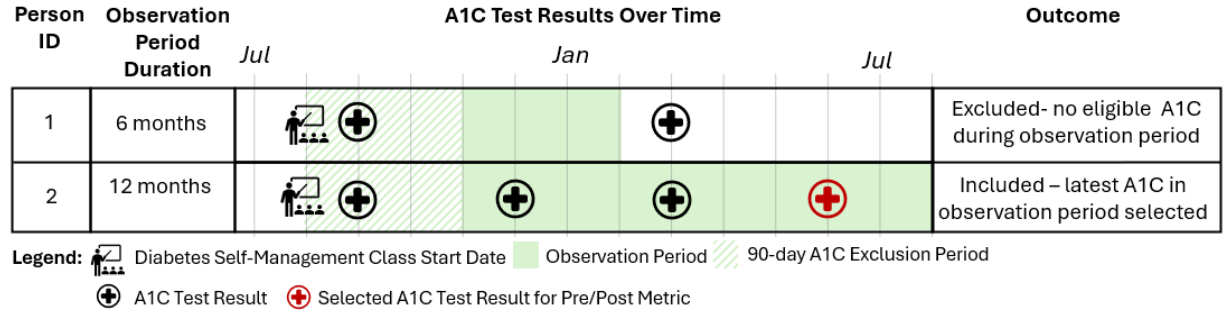


Figure 3. Post-Intervention A1C Selection Example

4.4 Population Selection

The population of interest should be defined based on the demographic, clinical, and/or intervention participation characteristics required for reporting. For instance, a defined population may be all participants that received home-delivered meals from MAC, Inc. Determination of which individuals in the population of interest will contribute data to the final metric calculation should be based on the calculation logic described below.

4.5 Age Calculation

Users must calculate individual age as part of this metric. Individuals must have only one age calculated based on a single date in the measurement period to determine if they meet the denominator's exclusion criteria. There are several ways that age can be calculated but a consistent approach should be used for all individuals.

The recommended approach is to calculate an individuals' age on the selected intervention start date as follows: Intervention Start Date minus Date of Birth.

4.6 Denominator

Participants in the denominator are those 18 years or older who have an indication of diabetes unrelated to pregnancy, an intervention start date, at least one A1C result in the look-back period, and at least one A1C in the post-intervention observation period. An indication of diabetes is defined as individuals with one or more ICD-10 diagnostic codes indicating diabetes (E10, E11, and E13).[5] Participants who received an intervention with no recorded dates cannot be included in the denominator. Participants with only A1C result cannot be included in the denominator.

4.7 Denominator Exclusions

The following exclusions are applied to the denominator population described above:

- Individuals who had any ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24) during the measurement period are excluded as they are/were currently pregnant.
- Individuals who do not have at least one A1C result that is >4% and <15% during the look-back period are excluded from the denominator. Values outside of this range are considered biologically implausible.
- Individuals who do not have at least one A1C result that is >4% and <15% during the observation period are excluded from the denominator ("qualifying A1C result"). Values outside of this range are considered biologically implausible.
- Individuals who did not have at least one qualifying A1C result in the observation period over 90 days after the intervention start date are excluded from the denominator. Because A1Cs measure glycemic control over 90 days, A1C results in the post-intervention observation time period must be at least 90 days from the intervention start.

4.8 Numerators

Participants in the denominator are aggregated into three potential numerator categories based on the calculated difference between the most recent (latest) A1C result in the look-back period and first A1C result that occurred more than 90 days after the intervention start date. These categories are as follows:

[5] Individuals who had an ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24), malnutrition-related diabetes mellitus (Lontchi-Yimagou et al., 2022) (E12), diabetes due underlying conditions (E08), or drug-induced diabetes (E09) are not included in the denominator.

- **Improved A1C Control**: Latest Pre-Intervention A1C Result minus Latest Post-Intervention A1C Result equals ≥ 0.5%.
- **Maintained A1C Control**: [6] Latest Pre-Intervention A1C Result minus Latest Post-Intervention A1C Result equals <0.5% and >(-0.5%) (absolute difference <0.5%).
- **Degraded A1C Control**: Latest Pre-Intervention A1C Result minus Latest Post-Intervention A1C Result equals ≤ (-0.5%).

The population in each control category should be calculated as a proportion of the denominator (e.g., percent improved A1C control).

4.9 Calculation Logic

The Pre/Post Change in Individual A1C metric calculation logic is described below; see Appendix D for calculation logic diagram.

1. Did the participant have an intervention start date? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
2. Is the participant 18 years or older? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
3. Did the participant have at least one documented encounter that included at least one diagnostic code in the look-back period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
4. Did the participant have one or more ICD-10 diagnostic codes indicating diabetes (E10, E11, and E13) in the look-back period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
5. Did the participant have an ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24) during the look-back period? (Y/N)
    - If yes, exclude.
    - If no, proceed to next step.
6. Did the participant have one or more A1C results >4% and <15% constrained to codes in HbA1C Laboratory Test value set[4] in the look-back period (e.g., qualifying A1Cs)? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.

[6] The absolute difference in A1C must be greater than 0.5% to be considered medically relevant.

7. Did the participant have one or more A1C results >4% and <15% constrained to codes in HbA1C Laboratory Test value set[4] during the observation period(s) ("qualifying A1C result")? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
8. Did the participant have at least one qualifying A1C result in the observation period over 90 days after the intervention start date? (Y/N)
    - If no, exclude.
    - If yes, include the participant in the denominator.
9. What was the difference between the participant's latest pre-intervention A1C result and their latest post-intervention observation period A1C result?
    - If the difference was greater than or equal to 0.5%, this participant's pre/post change in individual A1C control is classified as "Improved A1C Control." Calculate as proportion of denominator.
    - If the absolute difference was less than 0.5% (<0.5% and >(-0.5%)), this participant's pre/post change in individual A1C is classified as "Maintained A1C Control." Calculate as proportion of denominator.
    - If the difference was less than or equal to -0.5%, this participant's pre/post change in individual A1C control is classified as "Degraded A1C." Calculate as proportion of denominator.

5 Metric 3: Pre/Post Change in Diabetes Control Status

5.1 Metric Description

This pre/post metric compares two A1C results among adult participants diagnosed with diabetes—selecting A1C results from before and after an intervention to determine if participants experienced a change in one of three diabetes control categories derived from the American Diabetes Association (ADA) diabetes guidance on diabetes management. The Post-Intervention period control categories are then compared to the Pre-Intervention control categories to assess change in diabetes control category among participants. A change in diabetes control category post-intervention may indicate improved control, maintenance of control, or degradation in control.

5.2 Measurement Period

The measurement period for this metric is the same as for Change in Individual A1C pre/post metric (See Section 4.2).

5.3 Pre/Post A1C Selection

The A1C selection guidance for this metric is the same as for Change in Individual A1C pre/post metric (See Section 4.3).

5.4 Population Selection

The population selection for this metric is the same as for Change in Individual A1C pre/post metric (See Section 4.4).

5.5 Age Calculation

The age calculation for this metric is the same as for Change in Individual A1C pre/post metric (See Section 4.5).

5.6 Denominator

The denominator for this metric is the same as for Change in Individual A1C pre/post metric (See Section 4.6).

5.7 Denominator Exclusions

The denominator exclusions for this metric are the same as for Change in Individual A1C pre/post metric (See Section 4.7).

5.8 Numerators

Participants included in the denominator are aggregated into three potential numerator categories based on the comparison of the diabetes control status category of the last A1C result in the pre-intervention look-back period to the diabetes control status category of the last A1C result that occurred more than 90 days after the intervention start date during the observation period. Selected pre and post intervention A1C results are first categorized into the following diabetes control status categories:

- **Diabetes Control Status Categories:**
    - **Well Controlled:** A1C results <7%
    - **Moderately Controlled:** A1C results ≥7% <9%
    - **Not Controlled:** A1C results ≥9%

The change in a participant's diabetes control status is then categorized as follows:

- **Improved Diabetes Control Status**: Participants whose post-intervention A1C diabetes control status category (post) was in an improved diabetes control status category compared to their pre-intervention A1C (pre). This includes:
    - Not Controlled (pre) to Moderately Controlled (post)
    - Not Controlled (pre) to Well Controlled (post)
    - Moderately Controlled (pre) to Well Controlled (post)
- **Maintained Diabetes Control Status**: Participants whose post-intervention A1C diabetes control status category (post) was in the same diabetes control status category as their pre-intervention A1C (pre). This includes:
    - Not Controlled (pre) to Not Controlled (post)
    - Moderately Controlled (pre) to Moderately Controlled (post)
    - Well Controlled (pre) to Well Controlled (post)

- **Degraded Diabetes Control Status**: Participants whose post-intervention A1C diabetes control status category (post) was in a worse control status category compared their pre-intervention A1C (pre). This includes:
    - Well Controlled (pre) to Moderately Controlled (post)
    - Well Controlled (pre) to Not Controlled (post)
    - Moderately Controlled (pre) to Not Controlled (post)

The population in each control status category should be calculated as a proportion of the denominator (e.g., percent improved diabetes control status).

5.9 Calculation Logic

The Pre/Post Change in Diabetes Control Status metric calculation logic is described below; see Appendix E for calculation logic diagram.

1. Did the participant have an intervention start date? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
2. Is the participant 18 years or older? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
3. Did the participant have at least one documented encounter that included at least one diagnostic code in the look-back period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
4. Did the participant have one or more ICD-10 diagnostic codes indicating diabetes (E10, E11, and E13) in the look-back period? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
5. Did the participant have an ICD-10 code indicating diabetes mellitus during or due to pregnancy (O24) during the look-back period? (Y/N)
    - If yes, exclude.
    - If no, proceed to next step.
6. Did the participant have one or more A1C results >4% and <15% constrained to codes in HbA1C Laboratory Test value set[4] in the look-back period (e.g., qualifying A1Cs)? (Y/N)
    - If no, exclude.
    - If yes, proceed to next step.
7. Did the participant have one or more A1C results >4% and <15% constrained to codes in HbA1C Laboratory Test value set[4] during the observation period(s) (“qualifying A1C result”)? (Y/N)

- If no, exclude.
- If yes, proceed to next step.

8. Did the participant have at least one qualifying A1C result in the observation period over 90 days after the intervention start date? (Y/N)
   - If no, exclude.
   - If yes, include the participant in the denominator.
9. What was the individual's last A1C result in the look-back period?
   - If the A1C result was <7%, this individual's pre-intervention diabetes control status is classified as "Well Controlled."
   - If the A1C result was ≥7% and <9%, this individual's pre-intervention diabetes control status is classified as "Moderately Controlled."
   - If the A1C result was ≥9%, this individual's pre-intervention diabetes control status is classified as "Not Controlled."
10. What was the individual's last A1C result in the observation period?
    - If the A1C result was <7%, this individual's post-intervention diabetes control status is classified as "Well Controlled."
    - If the A1C result was ≥7% and <9%, this individual's post-intervention diabetes control status is classified as "Moderately Controlled."
    - If the A1C result was ≥9%, this individual's post-intervention diabetes control status is classified as "Not Controlled."
11. What was the difference between the participant's pre-intervention diabetes control status and their post-intervention diabetes control status?
    - If better, this participant is identified as having "Improved Diabetes Control Status." Calculate as proportion of denominator.
    - If the same, this participant is identified as having "Maintained Diabetes Control Status." Calculate as proportion of denominator.
    - If worse, this participant is identified as having a "Degraded Diabetes Control Status." Calculate as proportion of denominator.

Appendix A Background Research Findings

This appendix summarizes findings from relevant diabetes literature, which provided measurement thresholds, intervals, and analytic approaches that informed measure development

Table A-1. Glycemic Control Studies and Measurement Methods of Interest

	Title	Summary	Measurement
1	Glycemic Targets: Standards of Medical Care in Diabetes—2023	The American Diabetes Association (ADA) recommends assessing glycemic status at least twice a year for patients with stable control and quarterly for those with recently changed therapy or unmet glycemic goals. A1C continuous glucose monitoring (CGM), and self-monitoring of blood glucose (SMBG) are used for this assessment. For nonpregnant adults, an A1C goal of <7% is recommended, and if using CGM, a time in range of more than 70% with time below range less than 4% is the goal. Individual patient factors may necessitate more or less stringent A1C goals.	**Threshold:** A1C of <7% (53 mmol/mol) **Baselined:** NA **Measurement Interval:** Biannual **Measurement Type:** Categorical attainment of threshold.
2	Type 2 Diabetes in the Real World: The Elusive Nature of Glycemic Control	This review examines published findings about diabetes treatment and resulting glycemic control rates. Despite the approval of 40 new treatment options for type 2 diabetes since 2005, only about half of patients with the condition are meeting their glycemic goals. There has been little change in the percentage of individuals achieving their target goals over the last decade.	**Threshold:** A1C of <7% (53 mmol/mol) **Baselined:** No **Measurement Interval:** Annual **Measurement Type:** Categorical attainment of threshold.
3	Glycemic Response and Attainment of A1C Goals Following Newly Initiated Insulin Therapy for Type 2 Diabetes	The study identified characteristics associated with glycemic response to newly initiated insulin therapy in 1,139 type 2 diabetic patients. The outcomes of interest were the proportion of patients achieving A1C <7% and mean change in A1C within 3-9 months. The mean A1C at insulin initiation was 8.2 vs. 9.2% among those who did and did not attain A1C <7%. Within a mean of 5 months, 464 (40.7%) patients attained A1C <7%. In multivariable analyses, pre-insulin A1C was responsible for nearly all the explained variance in A1C change. Each one percentage point of pre-insulin A1C reduced the probability of attaining <7% by 26% - suggesting that insulin initiation at lower A1C levels improves goal attainment and independently increases glycemic response.	**Threshold:** A1C of <7% (53 mmol/mol) **Baselined:** Yes **Measurement Interval:** 3-9 Months post baseline **Measurement Type:** Measured HbA1c change and attainment of threshold.

	Title	Summary	Measurement
4	Hemoglobin A1C testing frequency among patients with type 2 diabetes within a US payer system: a retrospective observational study	This study examined A1C testing frequency among type 2 diabetes patients within a US payer system and found many patients were not tested as per American Diabetes Association guidelines. More frequent A1C testing was associated with a higher likelihood of achieving glycemic control, but these findings were inconsistent and modest. The authors suggest that testing frequency alone is not driving these outcomes, but rather a combination of factors including baseline A1C levels, comorbidities, and age. Of the patients with both measures available, 71.0% had glycemic control at both baseline and combined follow-up.	**Threshold:** A1C of <8% (64 mmol/mol) **Baselined:** Yes **Measurement Interval:** Study variables of interest were measured over the following time periods: • follow-up period 1 (first 12 months post-index date) • follow-up period 2 (12–24 months following follow-up period 1) **Measurement Type:** Categorical attainment of threshold. Correlational Regression analysis (Unadjusted and multivariable logistic regression)
5	Nutritional Intervention in Patients with Type 2 Diabetes who are Hyperglycemic Despite Drug Treatment - Lifestyle Over and Above Drugs in Diabetes (LOADD) Study: Randomized Controlled Trial	This randomized control trail aimed to determine the extent to which intensive dietary intervention can influence glycemic control and risk factors for cardiovascular disease in patients with type 2 diabetes who are hyperglycemic despite optimized drug treatment. Participants received intensive individualized dietary advice (according to the nutritional recommendations of the European Association for the Study of Diabetes) for six months. The primary outcome measure was A1C and secondary outcomes included measures of adiposity, blood pressure, and lipid profile.	**Threshold:** A1C of <7% (53 mmol/mol) **Baselined:** Yes **Measurement Interval:** 6 Months post baseline **Measurement Type:** Measured HbA1c change and attainment of threshold. Analysis: Comparative (ANCOVA)

	Title	Summary	Measurement
6	Medically Tailored Meal Delivery for Diabetes Patients with Food Insecurity: a Randomized Cross-over Trial	This study tested whether a medically tailored meal delivery program could improve dietary quality in individuals with type 2 diabetes and food insecurity. Participants received home delivery of 10 meals per week for 12 weeks by a non-profit organization, Community Servings. The primary outcome was the Healthy Eating Index 2010 score (HEI), which represents dietary quality. Participants reported lower food insecurity, less hypoglycemia, and fewer days where mental health interfered with quality of life during the "on-meal" period.	**Threshold:** A1C of <8% (64 mmol/mol) **Baselined:** Yes **Measurement Interval:** 12 weeks post baseline or post intervention **Measurement Type:** Measured the individual HbA1c of participants on intervention and off intervention The study used linear mixed models to analyze HEI scores and generalized estimating equations to analyze secondary outcomes.
7	Healthy People 2030: Reduce the proportion of adults with diabetes who have an A1c value above 9 percent — D-03	Healthy People 2030 recommends that when people with diabetes have an A1C level above 9%, they may need more care and treatment. Clinical trials have shown that having A1C levels above 9% increases the risk of complications.	**Threshold:** 11.6% of adults with A1C of >9% **Baselined:** Yes (18.7%) **Measurement Interval:** 10 years **Measurement Type:** Percentage point improvement
8	eCQM Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%) | eCQI Resource Center (healthit.gov)	The Electronic Clinical Quality Measures (eCQM) program provides a measure definition for a diabetes control measure, calculated as the percentage of patients 18-75 years of age with diabetes who had an A1C>9% during the measurement period.	**Threshold:** Percent of diabetic adults with an encounter during the measurement period whose most recent A1C level (performed during the measurement period) is >9.0% or is missing or was not performed during the measurement period. **Baselined:** No **Measurement Interval:** Annual **Measurement Type:** Categorical attainment of threshold.

Appendix B ACL CODI Data Model Attributes Required to Compute Diabetes Control

This appendix defines the data attributes needed to compute the diabetes control measure organized by the CODI Data Model tables; attributes are identified in ALL CAPS as they are defined in the CODI Data Model Data Dictionary.[7] If you are not using the CODI Data Model, you will need to map the fields from your source system to the attributes defined below.

The following attributes from the DEMOGRAPHICS table are required to calculate age. Notably, patient identifiers needed to match or link patients are stored in the DEMOGRAPHICS table but are not listed below. This measure definition assumes that patient matching or linkage has already occurred.

Table B-1. DEMOGRAPHICS Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
PATID	Char	None	Arbitrary person-level identifier. Used to link across tables.		Primary Key
BIRTH_DATE	MM/DD/YYYY	None	Date of birth. Needed for the calculation of age.	12/09/1949	Age Calculation (all)

[7] Available at https://mitre.github.io/CODI/

The ENCOUNTER table stores information about clinical encounters. The following attributes can provide evidence of a documented clinical encounter.

Table B-2. ENCOUNTER Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
ENCOUNTERID	Char	None	Arbitrary encounter-level identifier used to link across tables.		Primary Key
PATID	Char	None	Arbitrary person-level identifier used to link across tables.		Foreign Key
ADMIT_DATE	MM/DD/YYYY	None	Encounter or admission date.	02/24/2024	Denominator (all): Evidence of documented clinical services
DISCHARGE_DATE	MM/DD/YYYY	None	Discharge date.	02/24/2024	Denominator (all): Evidence of documented clinical services

The CONDITION table stores information about a patient's diagnosed and self-reported health conditions and diseases. The patient's medical history and current state may both be represented. The following attributes may provide evidence of a diabetes diagnosis.

Table B-3. CONDITION Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
CONDITIONID	Char	None	Arbitrary identifier used to link across tables.		Primary Key
PATID	Char	None	Arbitrary person-level identifier used to link across tables.		Foreign Key
CONDITION	seven-character, alphanumeric	ICD-10	Some codes will contain leading zeroes, and different levels of decimal precision may also be present. This field is a character field, not numeric, to accommodate these coding conventions. Please populate the exact value of this diagnosis code, but remove any source-specific suffixes and prefixes. (Description updated in v3.1.)	E10.42	Denominator (all): Evidence of diabetes diagnosis
CONDITION_TYPE	CHAR	CONDITION_TYPE_TYPE	Condition code type.	10 for ICD-10	Denominator (all): Evidence of diabetes diagnosis

The DIAGNOSIS table stores diagnosis codes that indicate the results of diagnostic processes and medical coding within healthcare delivery. The following attributes may provide evidence of a diabetes diagnosis.

Table B-4. DIAGNOSIS Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
DIAGNOSISID	Char	None	Arbitrary identifier used to link across tables.		Primary Key
PATID	Char	None	Arbitrary person-level identifier used to link across tables.		Foreign Key
DX	seven-character, alphanumeric	ICD-10	Some codes will contain leading zeroes, and different levels of decimal precision may also be present. This field is a character field, not numeric, to accommodate these coding conventions. Please populate the exact value of this diagnosis code, but remove any source-specific suffixes and prefixes. (Description updated in v3.1.)	E10.42	Denominator (all): Evidence of diabetes diagnosis
DX_TYPE	Char	DX_TYPE	Diagnostic code type.	10 for ICD-10	Denominator (all): Evidence of diabetes diagnosis

The PROGRAM_ENROLLMENT table contains one record for each person who enrolls in a program. The following attributes may provide evidence of intervention start date.

Table B-5. PROGRAM_ENROLLMENT Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
PROGRAM_ENROLLMENT_ID	Char	None	A primary key that uniquely identifies a row in the table.		Primary Key
PATID	Char	None	Arbitrary person-level identifier. Used to link across tables.	MRAG8308	Foreign Key
PROGRAMID	Char	None	A link back to the program this enrollment belongs to.	CTC	Foreign Key
ORGANIZATIONID	Char	None	A link back to the non-clinical organization that this enrollment belongs to.	MAC	Foreign Key
ENROLLMENT_DATE	MM/DD/YYYY	None	A date on which the enrollment was performed.	01/03/2024	May be used as Intervention Start Date (pre/post metrics 2 and 3)

The ASSET_ENROLLMENT table contains information for each unique asset enrollment for a person. The following attributes may provide evidence of intervention start date.

Table B-6. ASSET_ENROLLMENT Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
ASSET_ENROLLMENT_ID	Char	None	A primary key that uniquely identifies a row in the table.		Primary Key
PATID	Char	None	A link back to the demographic table.	MRAG8308	Foreign Key
ENROLLMENT_DATE	MM/DD/YYYY	None	A date on which the enrollment was performed.	01/03/2024	May be used as Intervention Start Date (pre/post metrics 2 and 3)
DELIVERY_START_DATE	MM/DD/YYYY	None	A date on which the individual who enrolled will start receiving asset. (ACL CODI note: CRISP prefers MM/DD/YYYY format)	01/03/2024	May be used as Intervention Start Date (pre/post metrics 2 and 3)
DELIVERY_END_DATE	MM/DD/YYYY	None	A date on which the individual who enrolled will stop receiving asset. This field may be blank if there is not a planned end to the service.	05/03/2024	
ASSET_ORANIZATIONID	Char	None	A link back to the organization that enrolled a person to receive assets	MAC	Foreign Key

The ASSET_DELIVERY table contains information about the delivery of assets associated with an asset enrollment; assets are resources transferred to an individual, like home-delivered meals. The following attributes may provide evidence of intervention start date.

Table B-7. ASSET_DELIVERY Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
ASSET_DELIVERY_ID	Char	None	A primary key that uniquely identifies a row in the table.	PL33472MC	Primary Key
PATID	Char	None	Arbitrary person-level identifier. Used to link across tables.	MRAG8308	Foreign Key
PROGRAM_ENROLLMENT_ ID	Char	None	A link back to the program enrollment that this asset delivery belongs to. An asset delivery should be linked to either a program or asset enrollment.	CTC	Foreign Key
ASSET_ENROLLMENT_ID	Char	None	A link back to the asset enrollment that this asset delivery belongs to. An asset delivery should be linked to either a program or asset enrollment.		Foreign Key
DELIVERY_START_ DATE	date	None	The first date the asset(s) was delivered.		May be used as Intervention Start Date (pre/post metrics 2 and 3)
DELIVERY_END_ DATE	date	None	The end date the asset(s) was delivered. For a single day, the entry may populate the same date for start and end.		

The LAB_RESULT_CM table contains quantitative and qualitative measurements. The following attributes may provide evidence of eligible A1C test results.

Table B-8. LAB_RESULT Table Data Elements for Measure Calculations

Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
LAB_RESULT_CM _ID	Char	None	A primary key that uniquely identifies a row in the table.	PL334MC	Primary Key
PATID	Char	None	Arbitrary person-level identifier. Used to link across tables.	MA8308	Foreign Key
ENCOUNTERID	Char	None	A link back to the program this enrollment belongs to.	CTC	Foreign Key
LAB_LOINC	Char	LOINC	A date on which the enrollment was performed.	01/03/2024	Denominator (all): Evidence of eligible A1C result; Numerators (all): Eligible A1C results used to calculate control categories and change in control
SPECIMEN_DATE	MM/DD/ YYYY	None	Date specimen was collected.		Select labs that fall within the Measurement Period (all)
RESULT_DATE	MM/DD/ YYYY	None	Result date.		Select labs that fall within the Measurement Period (all)
RESULT_UNIT	Char	None	Converted/standardized units for the quantitative result.		Denominator (all): Evidence of eligible A1C result; Numerators (all): Eligible A1C results used to calculate control categories and change in control
RESULT_NUM			Standardized/converted result for quantitative results.		Denominator (all): Evidence of eligible A1C result; Numerators (all): Eligible A1C results used to calculate control categories and change in control

The ORGANIZATION table contains information for each organization sending or receiving referrals, collecting patient-reported outcomes, offering programs (e.g., diabetes prevention program) or assets (e.g., home-delivered meals). The attributes below can help define the population of interest based on participation in a particular organization's intervention.

Table B-9. ORGANIZATION Table Data Elements for Measure Calculations

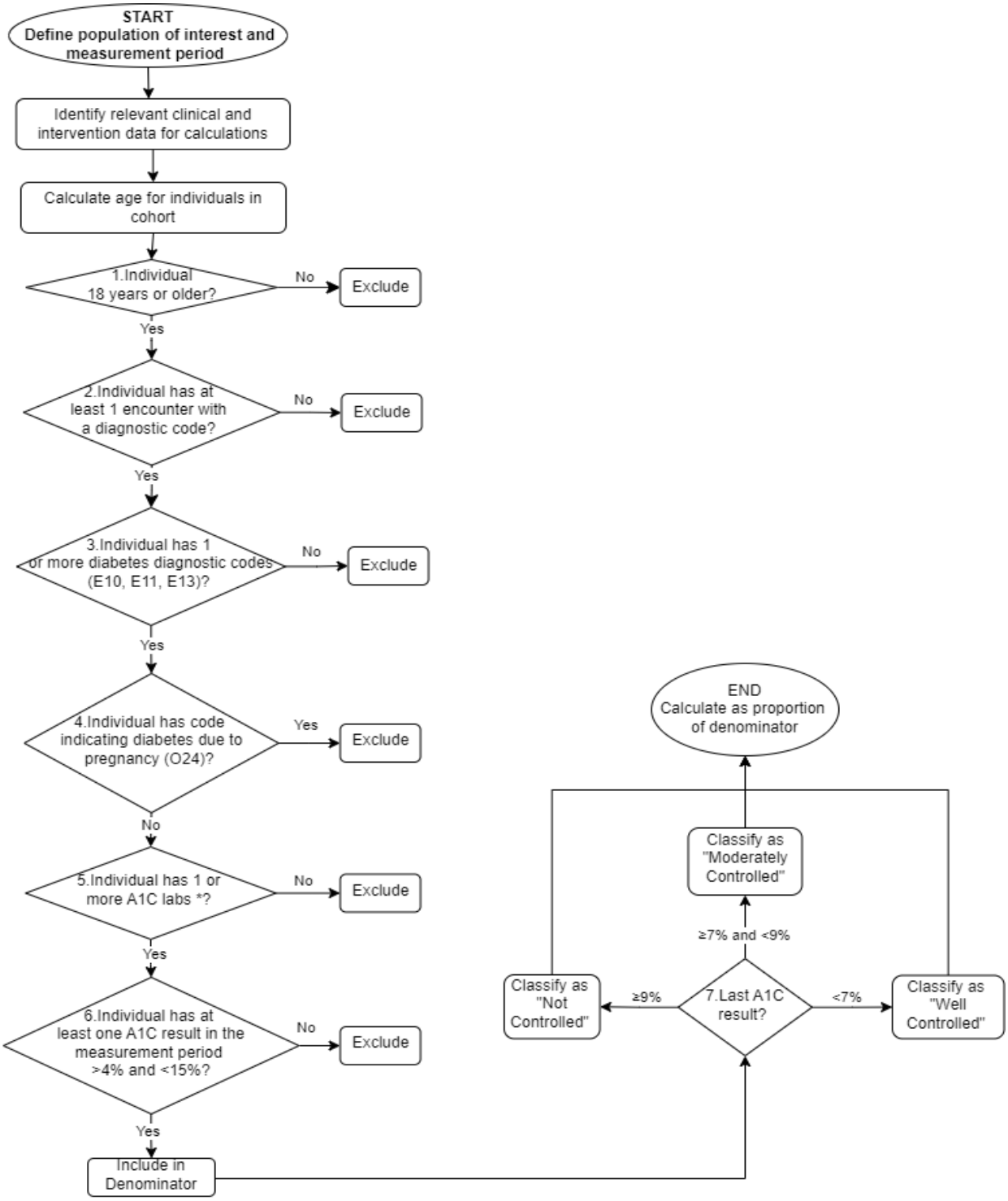
Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
ORGANIZATIONID	Char	None	A primary key that uniquely identifies a row in the table.	PL33472MC	Primary Key
ORGANIZATION_NAME	Char	None	Name of organization.	01/03/2024	May help define population of interest (all)

The PROGRAM table contains information for each distinct program. A program comprises a collection of interventions intended to produce a particular outcome. The attributes below can help define the population of interest based on participation in a particular program.

Table B-10. PROGRAM Table Data Elements for Measure Calculations

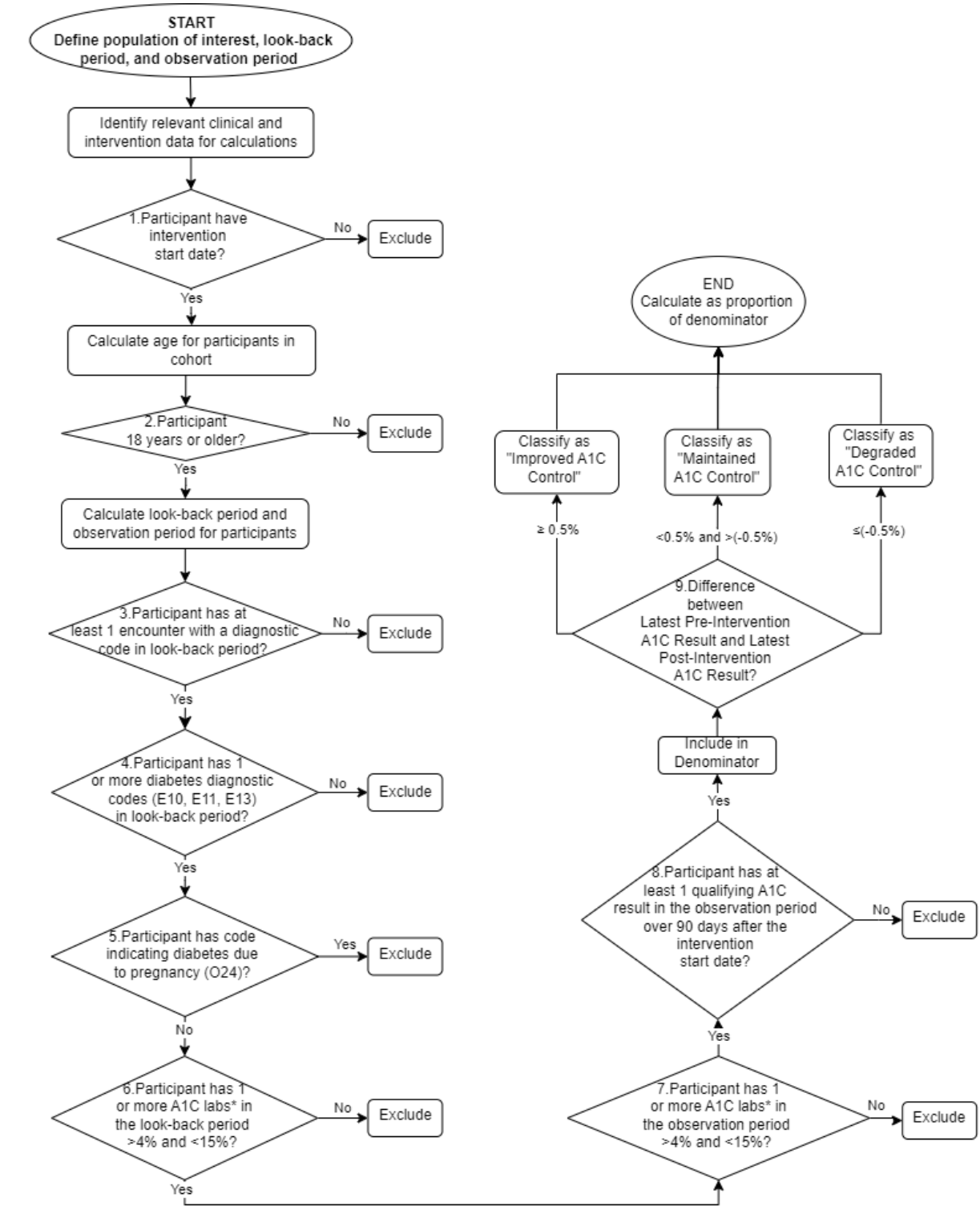
Attribute Name	Format	Value Set	Definition	Example Inputs	Measure Calculation Use (Metric)
PROGRAMID	Char	None	A primary key that uniquely identifies a row in the table.	PL33472MC	Primary Key
PROGRAM_NAME	Char	None	A name of the program (e.g., Congregate meal program).	Diabetes Self-Management Program	May help define population of interest (all)
PROGRAM_ORGANIZATIONID	Char	None	A link back to the organization that is offering the program..	MAC	Foreign Key

Appendix C Diabetes Control Surveillance Metric Calculation Logic Flow Chart



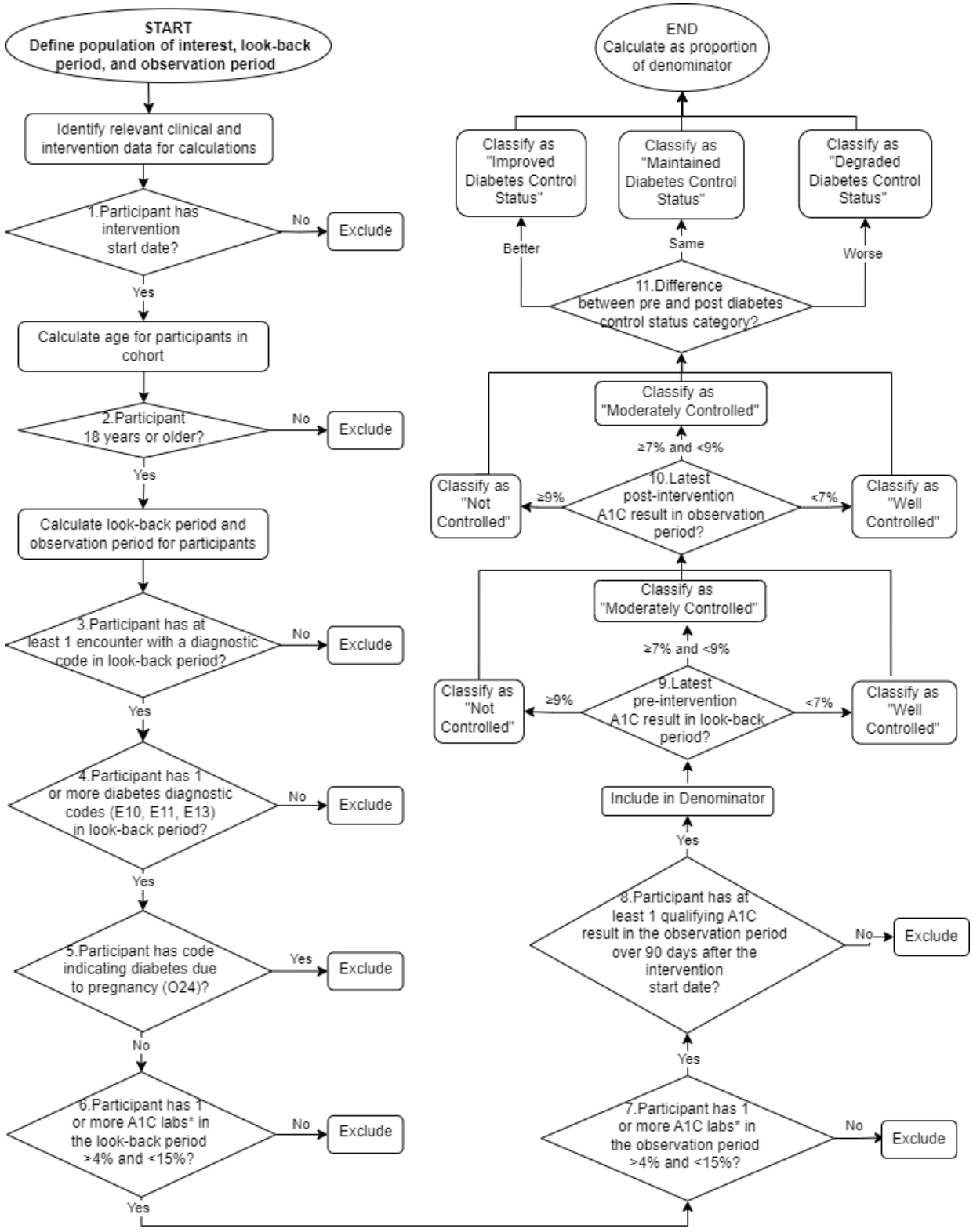
*A1C labs constrained to code in HbA1C Laboratory Test value set: VSAC OID 2.16.840.1.113883.3.464.1003.198.12.1013

Appendix D Pre/Post Change in Individual A1C Metric Calculation Logic Flow Chart



*A1C labs constrained to code in HbA1C Laboratory Test value set: VSAC OID 2.16.840.1.113883.3.464.1003.198.12.1013

Appendix E Pre/Post Change in Diabetes Control Status Metric Calculation Logic Flow Chart



*A1C labs constrained to code in HbA1C Laboratory Test value set: VSAC OID 2.16.840.1.113883.3.464.1003.198.12.1013

Appendix F Acronyms and Abbreviations

Term	Definition
ACL	Administration for Community Living
ADA	American Diabetes Association
CODI	Community and Clinical Data Initiative
CRISP	Chesapeake Regional Information System for our Patients
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act
LOINC	Logical Observation Identifiers, Names, and Codes