

SEARCH MOP - Section 9
Case Registration
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9. Case Registration and Un-registration

9.1. OVERVIEW

Aim 1 of the SEARCH 3 Registry Study is to obtain estimates of the incidence of diabetes in subjects less than 20 years of age in defined populations. In order to achieve this aim, SEARCH centers will try to identify and obtain information on all persons who meet eligibility criteria for specific geographic or health plan based populations. General procedures for ascertaining/identifying all cases are discussed in Section 5A of the Protocol. A summary of the full eligibility criteria to be counted in the numerator for SEARCH include:

- *Diagnosed with any type of Diabetes except gestational*
 - on or after January 1, 2002 for incident cases
- *Less than 20 years of age*
 - Age less than 20 years on December 31 of the onset year for incident cases
- *Belonging to the center-specific defined population anytime during the index year (the index year for incident cases is the year of diagnosis)*
 - resident of defined geographic region for geographic based centers
 - is a member of the defined eligible health plan for membership-based centers

Ineligible if:

- *Active duty military*
 - At date of diagnosis for incident cases
- *Institutionalized (defined by the Census)*
 - At date of diagnosis for incident cases
- *Diabetes type is gestational diabetes*

9.2. CASE REGISTRATION

9.2.1. Case Registration Windows

Sites will use a 30 month ascertainment window from December 31st of each year for 2010- forward. Sites will continue to register cases if found outside the 30 month window. (04/2012)

For 2008 - 2009 re-ascertained cases

- Active solicitation of 2008 - 09 cases by sites to their clinical sources should end by **September 31, 2012.**

- Existing lists of possible 2008 - 09 cases that came from clinical sources should be examined, validated, and data entered through December 31, 2012, including (if available) date of birth, date of diagnosis, sex, race/ethnicity, and diabetes type. These should be entered on the extended core form for the 2008 - 2009 cohorts. IPS and other forms need not be obtained.
- Such cases should be considered 'late registered' for the tracking database upload, but not as 're-ascertained,' to reflect the incomplete re-ascertainment that was conducted.

For 2002 - 2009 cases

- All data entry for 2002 - 2009 cases (including initial data entry, registration of duplicates, un-registration, and late registration cases) should be completed by **December 31st, 2012** so that these data sets may be locked. No additional data entry for 2002 - 2009 cases should occur after Dec 31, 2012 (except data cleaning initiated by CoC).

Please note: Incident 2009 cases found during this period should not be flagged as Prevalent 2009 cases, as this work has already been completed.

Similarly, all data entry for each cohort (2010 - forward) will close as of the end of the 30-month window – and there will be no further new data entry (duplicates, un-registration, and late registered cases) after the close of the window. No additional data entry should occur after the end of each 30-month window for 2010-forward cohorts (except data cleaning initiated by CoC). (9/12)

9.2.2. Case Registration Criteria

Some validated cases will have one or more eligibility criteria unknown, e.g., residence or military status in the index year. Limiting registration only to validated cases for which residence in the geographic population of SEARCH can be confirmed, may selectively underestimate incidence. If allowed by the local Institutional Review Board, completion of the Initial Participant Survey (IPS) may be useful in establishing eligibility prior to registration.

To be eligible for registration, a person must have physician-diagnosed diabetes, be age eligible, not ineligible, and not known to be a duplicate.

9.2.2.1. Valid case

A case can be considered valid when there is information sufficient to believe the person has been diagnosed with diabetes by a physician. This determination can be made by provider report, self-report, or medical record review.

9.2.2.2. Age eligible

Meets age eligibility criteria if:

- Date of birth (DOB) and case eligibility status (year of diagnosis) are known:
 - DOB from 01/01/1991 to 12/31/2010 for 2010 incident cases (e.g., 1/1/1992 - 12/31/2011 for 2011 incident cases, 1/1/1993 - 12/31/2012 for 2012 incident cases, etc.)
- DOB is known but case eligibility status is unknown:
 - Cases identified in 2010 will be age eligible if the DOB is on or after 1/1/1991 (e.g., identified in 2011 and DOB on or after 1/1/1992). Case eligibility status must be determined, however, before the case can be registered.
 - Age eligibility for subsequent incident years will be based on age eligibility criteria as outlined once the case eligibility status has been established.
- DOB partially known:
 - If the year of birth but not day or month is known, information is sufficient to classify eligibility based on DOB criteria listed above.
 - If only the age in years on a certain date is known, information *may* be sufficient to classify participant as eligible or ineligible.

Examples (2010 Incident Cases)

- If it is known a Participant was 12 years old in 2005,
 - The Participant is then known to be less than 20 years old on 12/31/2010 and therefore *eligible* in all circumstances.
- If it is known a Participant attended a camp for 12-16 year olds in 2010,
 - Sufficient information is known to classify them as *eligible*.
- If it is known a Participant was 19 years old in 2009,
 - Sufficient information is available to classify them as *ineligible*.

9.2.2.3. Not ineligible

A case is considered not ineligible if no information is available indicating the participant is ineligible based on geography, health plan, institutionalization, military or gestational diabetes eligibility/ineligibility requirement.

Note: There are no requirements to obtain information on institutional status. If information is not readily available from existing databases indicating the participant is ineligible, the participant should be coded as eligible.

9.2.2.4. Duplication

Data available for duplicate checking and the procedures and patterns used for duplicate checking are center specific, but may include use of any of the following data; full name, initials, date of birth, zip code of residence, or date of diagnosis. It may be impossible to be certain that the case is NOT a duplicate. Registration should occur when you have concluded that reasonable efforts have been made to identify duplicates.

9.2.2.5. Issues Pertaining to Cases with “Cured” Diabetes

The SEARCH Steering Committee has agreed that for purposes of the SEARCH Study, “once a case, always a case.” A participant may report a past history of diabetes but no current diabetes. For example, an incident participant, enrolled in SEARCH in 2012, reported that he had bariatric surgery. During his registry study visit after the surgery the participant reported the diabetes was “cured” (because his blood sugars had returned to “normal”). In this example, the participant definitely had diabetes in 2012 and was registered as a valid, incident case. For SEARCH purposes, this participant will always remain a case and should be invited for a study visit, if they meet eligibility for a study visit according to the protocol (e.g., diagnosis in the incident year for which registry study visits are being completed).

9.2.3. Case Registration Procedure

Once an individual has been determined to be eligible for registration, the participant’s record in the local tracking database system (TDDBS) should be flagged as registered. On a regular basis, each center will upload new data to the Coordinating Center. The following is a list of information that, if available, will be uploaded from a center’s local TDDBS to the Coordinating Center:

- ID
- Age
- DOB
- Gender
- Race/ethnicity
- County of residence
- Zip Code
- Diabetes validated (yes)

- Method of validation (Medical record review/Direct verification by a physician/Clinically verified database/Death certificate/Self-report)
- Presumed Diabetes Type
- Case Status (Incident Year)
- Date of Diagnosis
- Secondary Diabetes [diabetes caused by another source e.g., illness or medication] (Yes/No)
- Residence Eligibility (Eligible/Pending/Not Applicable)
- Health Plan Eligibility (Eligible/Pending/Not Applicable)
- Military Eligibility (Eligible, Unknown)
- Institutional Eligibility (Eligible, Unknown)
- Date registered/unregistered

NOTE: All identifying information remains solely within the local tracking databases of the five participating centers. Only the above list of minimal information about the participant will be forwarded to the Coordinating Center. This will allow estimation of incidence rates by diabetes type, age, gender, race/ethnicity, and will assist with evaluation of typology. To protect participant health information in accordance with HIPAA guidelines, a Limited Data Use Agreement between each HIPAA-covered center and the Coordinating Center will be in place prior to the uploading of any data to the Coordinating Center. Centers that are not a HIPAA-covered entity may not require a data use agreement.

In the future, if more complete or accurate information becomes available that confirms the participant to be ineligible, the participant will be unregistered (Section 9.3).

The Coordinating Center will work with each center to provide methods for ID generation, registering participants, and procedures for uploading registration information. Section 9.2.3 describes specific procedures available to check eligibility and register participants using the ACCESS tracking system developed by the Coordinating Center.

9.2.4. Case Registration Using ACCESS TDBS

When a unique (unduplicated) case is validated, eligible, and NOT ineligible based on current information, the case should be registered. When the local center receives and enters adequate information in the TDBS, that center will register the case by clicking the Register button on the Case information screen on the TDBS. This screen is opened from the Patient menu and the Case Tab.

All data required for registration is entered and stored in the TDBS. The process and source of information used to enter data on potential participants is center specific. These data may be gathered locally from secondary data sources (e.g., database searches, clinician referrals, chart reviews, death certificate reviews) and primary data sources (e.g., participant self referral, participant and/or parent/guardian survey, and/or the Initial Participant Survey [IPS]). Primary and secondary source definitions may differ by center. Some centers may choose to administer the IPS prior to registration as part of their case ascertainment efforts.

Information regarding the TDBS is described in Section 6. The following figure illustrates the CASE TAB of the TDBS.

The screenshot shows the 'CASE' tab of the TDBS registration interface. At the top, there are navigation buttons and search fields. The search criteria are: Search By PID: 99900165, First Name: Ken, Search By Acrostic: GRIKEM, and Last Name: Griffey. Below the search fields are tabs for 'Pat Info', 'Case', 'Address', 'Phone', 'Guardian', and 'Consents'. The main form area is divided into several sections:

- Local Medical Number 1:** [Empty], **Local Medical Number 2:** [Empty], **Diagnosis Date:** 1/1/01. Below this is a date picker with MM: 1, DD: 1, YYYY: 2001.
- Case Status:** A dropdown menu showing 'Prevalent case in the year 2001:Corresponds to a birth date: 1/1/82-12/31/2001'.
- Data Source:** Primary (dropdown), **General Case Source:** Administrative Source (dropdown), **Source Provider ID:** [Empty].
- Validated:** Valid (dropdown), **Validation Method:** Clinically Verified Database Search (dropdown).
- Duplicate:** No (dropdown), **Duplicate PID:** [Empty].
- Age:** Eligible (dropdown), **Geography:** Pending (dropdown), **Health Plan:** Pending (dropdown).
- Institutionalized:** Pending (dropdown), **Military:** Pending (dropdown), **Gestational Diabetes:** Pending (dropdown).
- Notes on Ineligibility:** [Empty text area].
- Unregistration Number:** [Empty text field].
- Unregistration Reason:** [Empty text area].

 At the bottom center of the form is a 'Register' button.

When the Register Button is ‘clicked,’ the TDBS will evaluate if the information entered meets the eligibility criteria and provide a message indicating 1) registration is completed or 2) provide information regarding information that makes the participant not eligible to be registered. If the case is registered, the ‘Register’ button will be replaced by an un-register button.

On a regular basis, each center will upload new registration and un-registration data to the Coordinating Center using the TOOLS menu and clicking on the export routine. The new data is then made available to the Coordinating Center via the data upload utilities on the SEARCH website. These utilities are provided based on security rights assigned.

9.3. CASE UNREGISTRATION

During the process of data collection and participant contacts, a case may be discovered to be ineligible or duplicated. When an already registered case is later found not to meet one or more of the eligibility criteria (see section 8.1), or is shown to be a duplicate case, the case will be un-registered, will not be counted for incidence estimates and will not be invited to further participate in data collection. Unregistration information will be collected using the Unregistration Form.

9.3.1. *The Unregistration Form*

The unregistration process is a multi-step task. This task includes the completion of the Un-registration Form, data entry into the web-based data management system and ending with data entry into the local Tracking Database. The intent of this form is to document the reason(s) the case is not eligible and request it to be un-registered.

Reason to Unregister *(check all that apply)*

1 Duplicate case: → **Please provide PATIENT ID number of matching case:**

2 Patient does not have a diagnosis of diabetes. Check all that apply: →

Error in validation

Not validated on Initial Patient Survey

Other *(please specify)* →

3 Patient does not meet residency requirement

4 Patient is not a member of health plan in the relevant year

5 Patient was in the military in the relevant year

6 Patient was institutionalized in the relevant year

7 Other *(please explain)* →

Item 1: Refers to the case being a **duplicate**.

- Check this box if this Participant is determined to be a duplicate case and place the matching Participant's assigned identification number in the boxes provided. The Participant identification affixed to the top of the Unregistration Form is the identification number of the Participant to be unregistered. The matching identification number is that of the Participant to be retained in the SEARCH study.

Item 2: Refers to the Participant not having a **diagnosis of diabetes**.

- Check this box if you determine the Participant has not been diagnosed with diabetes, and
 - Check the corresponding box(es) determining where the error in diagnosis occurred.

Note: If IPS question 3 is checked “No” and there is reliable information indicating the Participant actually has diabetes, the Participant SHOULD NOT be un-registered allowing the Participant to remain registered. Note within the local TDBS, this Participant should not be contacted further. The reason should be documented in the TDBS as the Participant believes they do not have diabetes.

Item 3: Refers to the Participant not meeting the **residency** requirement.

- Check this box if the Participant did not meet the residency requirement - specifically, if they were not a resident of the county and state.

Item 4: Refers to the Participant’s non-membership of a **health plan member**.

- Check this box if the Participant is not a member of a health plan in the relevant year.

Item 5: Refers to the Participant being in the military.

- Check this box if the Participant was a member of the military at date of diabetes diagnosis for incident cases.

Item 6: Refers to the Participant being institutionalized.

- Check this box if the Participant was institutionalized at date of diabetes diagnosis for incident cases.

Note: There are no SEARCH questions or uploaded fields that refer to information relating to Participant institutionalization. If this information becomes known from available records or anecdotal information, the Participant should be unregistered and the reason for un-registration should be noted in the TDBS.

Item 7 Refers to **Other** reasons the Participant may not be eligible.

- If there are other reasons the Participant is not eligible for the SEARCH study, check this box and specify the reason.

The Unregistration ID Number box is provided to record the un-registration number provided by the web-based data management system as explained below.

9.3.2. Unregistering the case

Once a participant is determined to be ineligible and the Case Un- registration Form is completed, the subject will be unregistered from the web-based data management system **and** the tracking database.

- The information on the Case Un-registration Form will be entered on the appropriate screen of the web-based data management system.
- When finished, click on the button at the bottom of the screen labeled **Unregistered**.
- The computer will respond with a confirmation message and **unregistration number**. This number must be written on the bottom of the Un-Registration Form.
- After the Participant has been unregistered on the web-based data management system, the Participant should be unregistered in a center's local TDBS by flagging the Participant's record as un-registered.

To un-register the participant using the ACCESS TDBS

- Access the Patient Information screen and click the Case tab.
- Enter the **Unregistration** number. This will confirm the participant has already been unregistered from the central database.
- Click on the button on the bottom of the screen labeled unregister.
- The program will ask for confirmation that you wish to unregister the participant. Click on the appropriate response.
- Enter the reason the participant was unregistered in the box provided.

9.4. UN-REGISTERING PARTICIPANTS IDENTIFIED AS NOT HAVING DIABETES

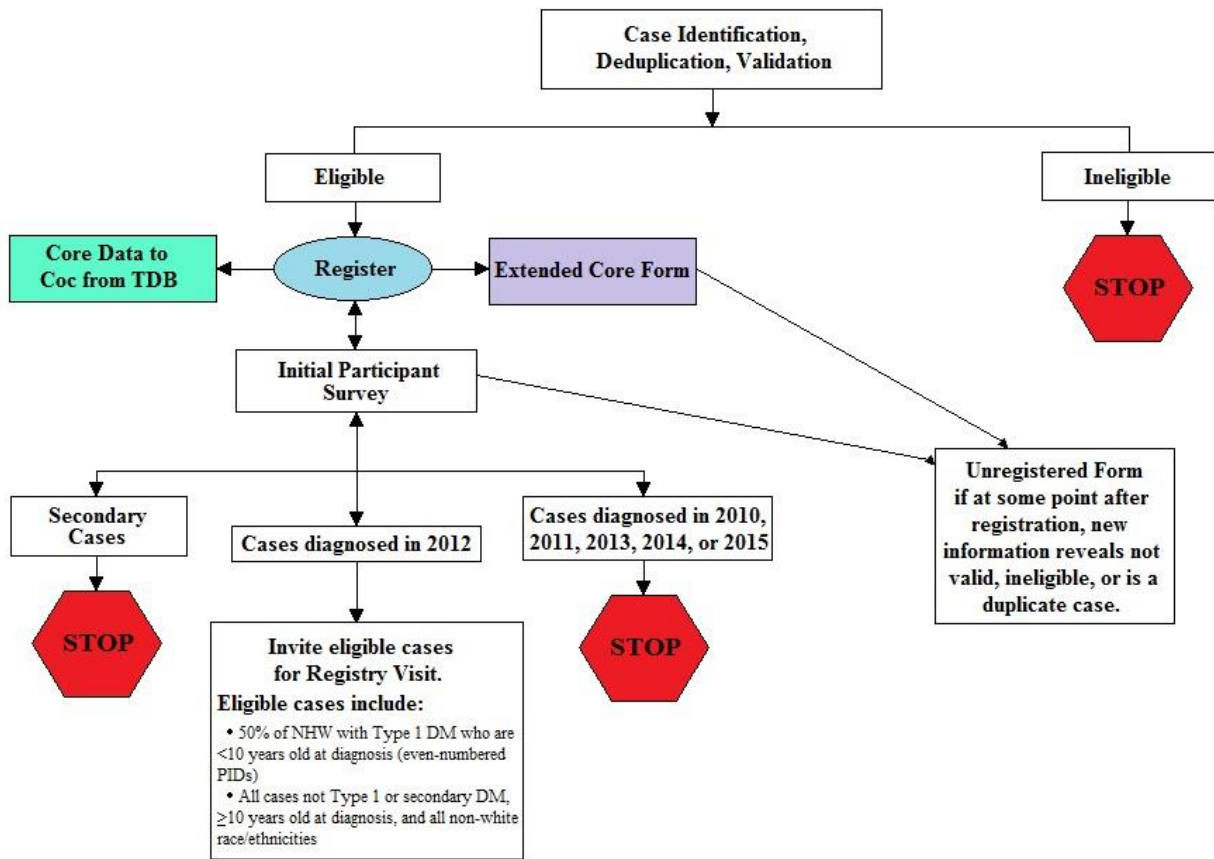
In some situations, cases originally registered in SEARCH may be determined later on to actually not have diabetes. This may occur as a result of a short-term elevation in blood glucose resulting in an inappropriate diagnosis of diabetes by a health care provider. If after the clinic site has reviewed the available data on this participant, including a confirmatory assessment by a pediatric endocrinologist, and determined that it is not a true case of diabetes, the study site should go through the un-registration procedures for this participant in the SEARCH database.

9.5. LATE REGISTERED CASES

Systematic re-ascertainment of cases was undertaken in SEARCH 2 (October 2009) for cases including 2002-2007 incident cases as well as 2001 prevalent cases in California. This was done to ensure the highest reliability of case ascertainment in the SEARCH study. The coordinating center modified the tracking data base to identify the late registered cases.

Systematic re-ascertainment will NOT continue in SEARCH 3. However, cases identified after the close of the primary 30 month (from 12/31/XX) ascertainment window may be registered as late registered cases whenever identified. (4/12)

Appendix 9-1 - Case Registration Flow



9.6 Case Ascertainment

The completeness of ascertainment for each site will be estimated by dividing the number of identified cases by the estimated total number obtained from the capture-recapture analysis. The capture-recapture corrected estimate will be computed by dividing the observed incidence rate by the estimated capture-recapture rate. This corrected estimate can be seen as a ratio of 2 random variables. Pooled estimates that borrow information across site, sex and age groups will be used to guarantee that the capture-recapture rate and its associated standard error can be computed for all combinations of the variables considered in the analysis. Stratification by site, diabetes type, race/ethnicity, sex and age group can sometimes lead to small cell count causing convergence failures in the maximum likelihood estimation routines. Pooled estimation performed assuming a log-linear model 84 makes it possible to obtain the maximum likelihood estimates in these cases and simplifies the derivation of the standard error associated with the estimated percentage completeness. We will consider models that include site, diabetes type, race/ethnicity, sex and age group and all relevant interaction effects between them as covariates. The standard error associated with the incidence rates can also be derived in a similar fashion within the log-linear model framework, such that the delta method can be used to derive the standard error associated with capture-recapture corrected incidence rate. We will consider both first – and second order Taylor expansions, and compare the accuracy of each set of estimates. This approach is similar

to that as applied to derive capture-recapture corrected incidence estimates in Dabelea et al 4. More information is provided in the technical report which is attached in Appendix X.