SEARCH MOP - Section 8
Recruitment and Retention
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8. Recruitment and Retention

8.1. OVERVIEW

Participants are vital to the success of the study. Sites should strive to ensure that study participants have excellent experiences in the SEARCH study.

The goals of recruitment and retention in the SEARCH study are 1) to ensure complete ascertainment of all cases of diabetes in the eligible study population; 2) to maximize the number of registered children, adolescents, and young adults participating in study visits and completing study surveys and 3) to ensure continued contact with participants for long term follow-up. Study personnel need to emphasize the voluntary nature of participation throughout recruitment efforts. Recruitment should be broad-reaching to include participants, families, community organizations, schools, physicians, and other health care professionals that serve youth with diabetes. Study centers should both collaborate with physicians and other health care providers to identify potential participants, and where possible, approach eligible participants directly to request their participation in the study.

The following recruitment goals have been identified by the Steering Committee:

Initial Participant Survey
- ✓ 90% of registered cases in each incident year

Registry Study Visit
- ✓ 70% of eligible participants *(Eligibility described in Section 8.2.4)*

Cohort Study Visit
- ✓ 80% of eligible participants *(Eligibility described in Section 8.2.4)*

METHODS

Potential participants for the SEARCH study will be identified from a variety of sources. Once a potential participant has been identified as not ineligible study centers will collect core data, in a HIPAA compliant manner, register the case in the tracking database, and upload those data fields to the study Coordinating Center. Further details on case finding and registration are outlined in the case ascertainment section of the protocol.

Study personnel need to recognize the value of community and provider involvement in the study, and efforts to educate these groups regarding the study should be ongoing. Each center will access provider networks established during phase 1 of the study to identify potential participants. In addition, efforts to identify and establish reporting relationships with previously uninvolved or minimally involved providers and organizations should continue.

The centers will recruit eligible participants to complete study surveys and visits, where applicable. The time from case identification to recruitment to completion of the study survey and visit will vary from center to center based on participant availability and operational differences. The Coordinating Center will identify the deadlines for registering various cohorts of cases. Initial Participant Surveys should ideally be completed within 18 months of diagnosis. If an eligible case is identified after the ideal window has closed, sites should still register the case and attempt to complete an IPS. Initial study visits will need to be completed within 18 months of the date of diagnosis, or the participant will become ineligible for the visit component of the study.

8.2. PROCESS

Recruitment involves providing and promoting a level of awareness of the SEARCH study to potential participants and to physicians and other health care professionals caring for individuals with diabetes who are less than 20 years of age at the time of diagnosis. Because of the uniqueness of SEARCH sites, recruitment strategies will vary. The following are suggestions for recruitment efforts:

- Provide ongoing education of health care professionals about SEARCH including a "Dear Colleague" letter, a study brochure, individual meetings with physicians and other potential collaborators, and provider newsletters;
- Conduct presentations and Grand Rounds to physicians, school nurses, and other healthcare professionals;
- Make study brochures, surveys, and/or posters available in physicians' offices;
- Present information describing the SEARCH study in participating health plan and hospital newsletters, local medical and nursing newsletters, local chapters of diabetes associations' communications (e.g., the Juvenile Diabetes Foundation for Research), and in press releases to local newspapers.
- Recruit participants via inpatient and outpatient settings using a variety of methods

8.2.1. *Recruitment Aids*

8.2.1.1. Study Logo

The study logo has been designed to be culturally appealing to all potential participants and has been approved by the Steering Committee. The logo should be used for official SEARCH business and should not be used for any other purpose, including recruitment for ancillary studies, without the approval of the SEARCH Steering Committee.

8.2.1.2. Study Brochures

Study brochures can be distributed to participants and providers in a variety of ways. It may be mailed as stand-alone recruitment tools or sent in conjunction with an introductory letter. It can be made available to potential study candidates in doctors' offices or clinics. The study brochures are available in both English and Spanish. To ensure that all eligible individuals will be invited to participate, local sites may translate the brochure and other recruitment materials into additional languages as needed.

8.2.1.3.Introductory Letter

The Introductory Letter describes the purpose of the study to potential participants and/or their parent or guardian. Common information about the study will be provided across all centers but each center will customize the letter according to their local operational and IRB requirements. The letter informs that individual that they can complete the survey and return it by mail or they can wait until the study staff calls them and complete the IPS by telephone. Letters to participants 18 years of age and older should be addressed to the participant, and letters to those under the age of 18 should be addressed to the parent/guardian. The letter will be signed as dictated by local operational and IRB requirements, which may include a signature of the SEARCH study Principal Investigator for the study center and/or the primary diabetes provider. If approved by the local IRB, the introductory letter may contain the elements of informed consent and serve in lieu of a consent form for the IPS.

8.2.1.4.Incentives for Participation

Participants will receive incentives commensurate with level of involvement and effort. The specific incentive may vary across sites, and will be in accordance with local IRB regulations. Sites may give incentives in the form of cash or gift cards, in line with local policies.

The following monetary guidelines have been established by the Steering Committee.

Initial Participant Survey:
$10

Registry Visit:
$80 (may be split between the participant and the parent)

Cohort Visit:
$120 (may be split between the participant and the parent)
(An additional $20 incentive will be given to participants selected to repeat the heart function measures).

Travel Incentive:
Sites may provide additional incentive for travel to study visits as dictated by local site and IRB guidelines.

Participants may be offered a partial incentive for partial completion of a visit per site-specific procedures.

If a parent/guardian does not accompany the participant to the visit because the participant is age 18 or older, the participant will receive the parent/guardian's compensation.

If the participant comes for the visit and is not fasting (requiring a second visit for the fasting blood draw), providing an additional incentive is up to the local site and their IRB.

If a participant completes a partial visit or does not come for an in person visit, but does complete the forms, incentives may be provided as decided by the local site and their IRB. The recommendation is that incentives for partial visits be equitable to the level of effort put forth by the participant.

8.2.2. *Mailed Information*

Each site will develop procedures for mailing/distributing information and/or surveys to eligible individuals. The mailing might include an introductory letter, the IPS, the SEARCH study brochure, and a postage paid return envelope. Based on center-specific requirements, other documents such as a consent form, HIPAA authorization, or privacy protection information may be included as required. The envelope, and letter if applicable, will be addressed to the parent if the Participant is < 18 years of age and the Participant if they are 18 years of age or older. The return address on the mailing envelope and the postage paid return envelope should be the local study center and not the Coordinating Center. To be sensitive to confidentiality, the outside of the envelope

will not include any information that would identify the potential individual as having diabetes.

Some centers may include a refusal postcard with the mailing. The letter may inform the participant that the study staff will call them in a specified amount of time (for example 10 days) if they do not return the refusal postcard.

Any communication to participants (or parents/guardians) should be submitted to the local IRB for review and approval prior to mailing.

8.2.3. *Contact with the Participant after Mailing of IPS*

Where feasible (i.e., where the study center has the contact information and permission to contact the individual), study personnel will call and/or email the participant or parent/guardian unless the participant has returned the refusal letter/postcard.

8.2.3.1. Contact with the Participant after survey return

If the participant has completed and returned the IPS, they will be thanked for completing the survey via mail, email, or telephone call. Any blank spaces or unclear answers on the form will be reviewed with the participant to ensure completeness and accuracy. The responses to other key questions may also be reviewed. Then the remainder of the SEARCH study will be described to them in detail and they will be recruited for the study visit if they are in an eligible cohort. See recruitment script below.

8.2.3.2. Contact with the Participant without survey return

The amount of detail in this contact will be determined by whether or not the participant recalls reading the introductory letter that contains the basic information needed for informed consent for the IPS. If they do not recall the content of the introductory letter, the information in the introductory letter will be read to them. Then they will be invited to complete the IPS by telephone. If they decline to complete the form by telephone but are willing to participate in the study, the IPS form can be completed in another manner, including in person, through a re-mailing of the IPS, or online, if that is available. Sites should have study participants sign HIPAA authorization forms before the data from the survey is entered into the study website.

8.2.3.3. Participant Contact Information

Participants' names and contact information are confidential and should not be sent to the Coordinating Center. Participant contact information will be retained by the individual study site to facilitate tracking, follow-up, and participant identification should a problem arise with the linking system incorporated in the study ID number**. Under no circumstances should the Participant Contact Information be**

transmitted to the Coordinating Center or disclosed to any individual or group outside of the local research team.

8.2.4. *Recruitment for Study Visits*

After verifying eligibility criteria (e.g., age, residency or health plan membership, and diabetes diagnosis), study personnel will invite eligible participants and their parent/guardian (if the participant is under age 18) to participate in a study visit, if applicable.

The Registry Visit will be completed for eligible cases diagnosed in 2012. Those with a Secondary form of diabetes are not eligible for a visit. The following 2012 incident cases will be eligible for a Registry visit: all minority cases, all cases age 10 and over at diagnosis, all non-Type 1 diabetes, and a 50% sample of the non-Hispanic white (NHW) cases with Type 1 diabetes diagnosed under age 10.

The following is the decision rule for determining whether to invite a potential participant to attend a SEARCH 3 Registry visit.

Is the child known to be non-Hispanic White (NHW)?

If NO: Invite the child to attend a Registry Visit

If YES:

Was the child under 10 years of age at diagnosis?

If NO: Invite the child to attend a Registry Visit

If YES:

Is the child known to have Type 1 diabetes?

If NO: Invite the child to attend a Registry Visit

If YES:

Can you determine the day of the month that the child was born?

If NO: Invite the child to attend a Registry Visit

If YES:

Is the child born on a day of the month that is an odd number (1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, or 31)?

If YES: Invite the child to attend a Registry Visit

If NO: Do not invite the child to attend a Registry Visit. Record in the tracking database and on the web report that this child was NOT invited to attend a Registry Visit.

If at any point in this decision process you are unsure of the answer to any of these questions (age at diagnosis, type, birthday, etc.), then you can invite the child for a Registry Visit.

In summary, the goal is to invite all eligible 2012 participants EXCEPT those that are known to be NHW, less than 10 years old, have Type 1 diabetes AND are born on an even numbered day of the month. (02/12) See Table 12.1 for specific data collection to be done at the Registry Visit.

The Cohort study visit will be offered to eligible participants diagnosed in 2002-2006 and 2008. To be eligible, participants must have completed a previous study visit (baseline in-person visit or typology visit), have had diabetes for a minimum of five years, and completed their most recent SEARCH visit more than 2 years ago. The Coordinating Center will assist sites in developing reports to manage recruitment of participants. The Cohort study visits will also implement a recruitment pilot with three different recruitment strategies to be performed from February 2012 until June 2012. See Appendix A for additional description. (2/12) When assigning earliest recommended visit dates, consideration was given to visit intervals such that for 2002 - 2006 cases the recommended date for the opening of the cohort visit window was set to the later of EITHER the baseline visit plus five years OR the last in person visit plus two years. However, for 2008 incident cases additional consideration was given to the overall timeframe of SEARCH 3 and the criteria for the earliest recommended visit date is the later of the diagnosis date plus 5 years or the last SEARCH visit plus 2 years (see section 1). Sites should mark a case as Do Not Contact or Refusal on the website in any of the following instances: participant is deceased; participant completed a baseline visit in error (was never eligible for a visit); or the participant has refused any further contact with SEARCH. An individual may be scheduled for a Cohort Visit starting up to 1 month prior to when their visit window opens, and anytime thereafter.

8.2.4.1. Participant Visits

Local sites should schedule visits at times and locations that are convenient for study participants. Once scheduled for a visit, several pieces of information about the upcoming visit should be clearly described and communicated to the participant, via mail, email, telephone, and/or in-person as local procedures allow. Examples of information are:

- A map or directions on how to get to the location where the study visit will be conducted and parking instructions.
- Instructions on the importance of coming to the visit fasting. Provide instructions that the participant should fast for no less than 8 hours prior to their visit. Describe circumstances under which fasting should be discontinued.
- Instructions for the use of insulin and other diabetes medications prior to the study visit.
- Request the participant bring the following items to their visit: glucose meter and glucose records, diabetes medication(s) and associated administration tools, other prescribed medications, and family history information.
- Instruct participants who are completing a cohort visit to wear or bring loose fitting shorts; bring in overnight urine collection; bring in completed forms, if applicable.
- Inform the participant that they will able to select from breakfast or snack items after their blood is drawn.
- Give the participant an estimate of the amount of time that will be needed to complete the visit.

8.2.5. *SEARCH Public Website*

A public website with information for participants and providers is available: www.searchfordiabetes.org. The website will be kept updated by Coordinating Center personnel Local sites are encouraged to develop local websites to recruit study participants, within the guidelines of local IRB and organizational policies.

8.2.6 *Social Media*

The Coordinating Center and/or local sites may develop additional methods to recruit study participants. Some of these might include for example Facebook, Twitter, and the like.

8.3. ADDITIONAL METHODS OF RECRUITMENT AND RETENTION

The methods that will be used to foster recruitment and retention in SEARCH are:

- Provide lab results, and retinopathy results, along with clinical feedback about SEARCH test results to participants and their physicians
- A study newsletter which will provide information about diabetes and study progress on a regular basis
- Provision of periodic information about the results of SEARCH either as part of the newsletter or as a separate communication
- Combine study visits with regular visits for clinical care, including combining research and clinical labs in one blood draw

- Coordinate SEARCH visits with visits for other studies
- Send reminder cards or letters to participants
- Staff participation in diabetes events

8.3.1. *Updating Contact Information*

SEARCH staff should verify or update participant contact information at least annually in order to maintain accurate contact information. Contact information should be verified or updated each time a participant attends any SEARCH visit. If no visit occurs in a given year, contact information may be verified in-person, by telephone, email, online, or through the mail. Other methods to update information might include reviewing medical or billing records, or utilizing online search engines.

Whenever possible, updated information should include both the participant/parent's information, as well as those people identified by the participant as alternate contacts.

SEARCH staff can utilize the Contact Information Update form to document updated information. In addition to contact information, this form also collects social security number. As with all data collection, the participant may opt to not provide the social security number. Collection of the social security number on this form is being used as a means to assist in mortality tracking and overall tracking of the SEARCH participant.

8.3.2. *Lost to Follow-up*

Even with regular contacts, centers may lose touch with some participants.

If the participant moves out of the area and does not leave a forwarding address, special efforts should be made to locate the participant by contacting the people on the contact information sheet. The following other sources may be helpful in locating the participant; voter registration offices, public housing and relocation authorities, health and welfare agencies, public record search databases (i.e., LexisNexis), Medical records, and clinical or billing databases (as allowed by the institution).

If the participant cannot be located either through the contacts listed on the contact information sheet and all attempts to locate him/her have failed, the participant may be considered lost-to-follow up. Periodic attempts should still be made to re-locate the participant as long as they are still eligible to participate in a study visit.

8.3.3. *Permanent Refusals*

If an individual informs SEARCH that he/she is no longer interested in SEARCH and does not want to be contacted again, SEARCH staff should mark these individuals as permanent refusals or 'do not contacts'. This should be noted both in the local tracking system and on the study website. Study staff will no longer attempt to contact these individuals for SEARCH or related ancillary studies, unless the participant contacts SEARCH again to indicate renewed interest in the study.

Appendix A - Protocol: Testing the Effectiveness of Three Recruitment Strategies for the SEARCH for Diabetes in Youth Cohort Study

February 20, 2012

Summary: The proposed validation study is designed to test the effectiveness of three recruitment strategies for participants in the SEARCH for Diabetes in Youth Cohort Study. Four of the five SEARCH clinical sites (Colorado, California, Ohio, Carolinas) will participate in this study. Participants eligible for the SEARCH Cohort Study will be contacted using one of three ways: (1) Through the recruitment strategies that were being used by the study clinical sites (phone calls, letters, invitation cards) during SEARCH Phase 2; or, through the enhancement of these strategies by the addition of: (2) a mailed DVD with a video designed by the SEARCH study; or, (3) a post card mailed to study participants with a link to the video clip posted on YouTube that had been on the DVD. The study will be conducted from February – July 2012 (or until 423 total participants have been contacted (141 with each method). Data will be collected on the rates of participants that respond and attend the study visit according to each of the three recruitment strategies.

Introduction: Pediatric clinical research studies are presented with numerous challenges in achieving the highest recruitment and retention rates possible. This is especially true for studies that include adolescents, persons from racial and ethnic minority groups, and persons who are low income. The SEARCH study conducted an analysis of participation in the Initial Participant Survey (IPS) and the In-Person Visit (IPV) during the first phase of SEARCH study, and found that older age, having type 2 (vs. type 1 diabetes), and being African American (vs. non-Hispanic white) was associated with lower participation rates in the study visit (Liese et al, 2008).

The third phase of the SEARCH for Diabetes in Youth Study (SEARCH Phase 3) began on September 30, 2010, with participant recruitment for the Cohort Visits to begin in November 2011. For the Cohort Study, participants in the incident 2002 - 2005 cohorts who had participated in a baseline visit in the first two phases of SEARCH and have at least five years duration of diabetes will be invited to participate in a Cohort study visit to assess diabetes complications and processes of care. This validation study is designed to assess the effectiveness of various recruitment strategies for eligible participants in the SEARCH Cohort Study. Data from this validation study will be used to inform future recruitment efforts for SEARCH as well as add the literature on effective recruitment strategies for pediatric clinical research studies.

Methods: Four of the five SEARCH sites (California, Carolinas, Ohio, and Colorado) will participate in the recruitment study. Participants for this study will be selected from lists of eligible participants in the SEARCH Cohort(s) Study. Participants will be randomized to receive one of three recruitment options: (1) recruitment efforts currently being used by the study clinical sites (phone calls, letters, invitation cards); (2) supplemented recruitment with a mailed DVD with a video designed by the SEARCH study; (3) supplemented recruitment with a mailed post

card with a link to the video on YouTube. The video and postcard were developed by WellComm, Incorporated, a marketing company based in Denver, Colorado.

A total of 423 participants will be selected to be assigned to one of the three recruitment strategies (California, n = 72; Carolinas, n = 105; Ohio, n = 105; Colorado, n = 141). Equal random assignment to one of the three recruitment strategies will be conducted by the SEARCH Coordinating Center at the Wake Forest School of Medicine. Site project coordinators will be notified of the strategy to be used for each participant. It is anticipated that this validation study will occur from February - July 2012.

The Coordinating Center will conduct statistical analyses to determine which approach is most effective in recruiting participants into the SEARCH Cohort study visit. Logistic regression will be performed with the outcome variable being completion of the study visit (yes, no), and the primary predictor variable being recruitment strategy (usual strategy, mailed DVD, mailed postcard). Covariates to be included in the regression model include: participant age, gender, race/ethnicity, diabetes type, study site and prior participation in SEARCH follow-up visits.

Power/Sample size considerations. To determine the adequate sample size for this validation study we have examined several scenarios with different assumptions. These calculations were performed using nQuery 7.0 software for estimating sample sizes. Our estimates of effect sizes are based on what is reasonable and optimal regarding added benefit to the study to enhance recruitment. These estimates are more ambitious than those of a recent study conducted by TEDDY study investigators (7% increase in study enrollment) (Baxter et al, 2010).

The first calculation considers comparing the three groups using a single Chi-square test: With this scenario, when the sample size in each of the 3 groups is 141, a 0.050 level Chi-square test will have 80% power to distinguish between the groups when the proportions in the 2 categories are characterized by an Effect size, $\square^2$ = ij-□j)4/(β),of 0.0229. Since this calculation describes a detectable difference in terms of an effect size which depends on the cell probabilities within the 3 x 2 table and may not be intuitive since numerous scenarios could achieve a particular effect size, we examined several other possible comparisons.

The first comparison is to test whether the DVD approach is better than the other two approaches. Here, a two group Chi-square test with a 0.050 two-sided significance level will have 84% power to detect the difference between a phone call/post card group proportion of 0.800 (assumed proportion for “standard recruitment”) and a DVD group proportion, of 0.910 (odds ratio of 2.528) when the sample sizes are 282 and 141, respectively (a total sample size of 423). We chose 80% for the “post card/phone call groups” since that is what the grant proposes as the recruitment rate.

The second comparison is to compare the Search 2 approach (phone call) with the new approach (DVD or post card with weblink). Here, a two group Chi-square test with a 0.050 two-sided significance level will have 82% power to detect the difference between a SEARCH 2 (phone call) proportion of 0.700 and a new approach (DVD or post card) proportion of 0.825 (odds ratio of 2.020) when the sample sizes are 141 and 282, respectively (a total sample size of 423). This could be plausible since the 80% recruitment rate described in the grant did suppose that recruitment efforts would be enhanced during SEARCH 3. Thus, if no enhancement took place one could expect a lower recruitment rate (70%).

Finally, with 141 participants per group, we can make pair-wise comparisons as follows: A two group Chi-square test with a 0.050 two-sided significance level will have 82% power to detect the difference between a Group 1 proportion of 0.800 and a Group 2 proportion, of 0.920 (odds ratio of 2.875) when the sample size in each group is 141.

In addition, a two group Chi-square test with a 0.050 two-sided significance level will have 80% power to detect the difference between a Group 1 proportion of 0.800 and a Group 2 proportion of 0.650 (odds ratio of 0.464) when the sample size in each group is 141.

For each of these we set one group at an 80% success rate, with the assumption that either the new approach will allow recruitment rates to exceed that percent (92% or greater) or that the recruitment rates would only achieve that level if they were enhanced (i.e., by DVD) and otherwise would be lower (i.e. 65% or less).

It should be noted that when we perform our comparisons we will use more than simple Chi-square tests, but will also fit logistic regression models. In this way, when we add participant level characteristics to the model we may reduce variability and therefore be able to detect smaller group differences with this added precision.

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