

Appendix E. Subject retention plan

This Subject Retention Plan provides an outline of the issues associated with subject retention and the procedures for maximizing retention during the course of the Cracked Tooth Registry. For registries that involve longitudinal follow-up of study subjects, retention is a key requirement. High retention rates increase the validity and generalizability of registry data by ensuring that bias due to incomplete follow-up of subjects does not affect study findings.

Retention of study subjects is a multifaceted problem. Difficulties with maintaining complete follow-up can be due to a variety of causes. It is important to identify and delineate the different types of retention issues because the way to address them will depend on the type. The four types of retention issues are:

Lost: Subjects move and their new location cannot be found.

Missing Data: Subjects still within the practice but follow-up visit is missed or data are not collected during visit.

Refused: Subjects decide they no longer want to continue participating in study.

Unable: Subjects no longer seeing their original/enrolling practitioner.

Below the National Dental PBRN describes the plans for addressing each of these retention issues. Also provided are other administrative and design methods that will help to increase retention rates.

Methods to Minimize “Lost”

- 1) At subject enrollment, emphasize study requirements to subjects:
 - a. They are part of a long-term (4 year) follow-up study, and the importance of annual assessments.
 - b. RCs or the CC will contact them by telephone to arrange follow-up visits even if they change dentists.
 - c. Entry criteria will include the ability and likelihood of maintaining participation throughout the study.
 - d. Collect information on:
 - i. Home address
 - ii. Home telephone number
 - iii. Cell phone number
 - iv. E-mail address(es)
 - v. Contact information (including cellular telephone and email) of two persons who do not live in the same household as the subject and who will know of the subject's whereabouts.
- 2) During study visits, confirm contact information (of subject and the two contact persons).
- 3) Have only one recall per year rather than two. Cracks in teeth progress relatively slowly and so yearly evaluation will suffice. For those teeth that get worse in the interim and

require treatment, data will be collected at the treatment visits. Make contact with participating offices and subjects every six months to remind them of upcoming recall intervals. The subject's preferred method of contact (e.g., postal mail, email, telephone) will be ascertained at the baseline appointment. Experience has shown that it is personal relationships, both between the subjects and offices, and the offices and the RCs, that promote successful execution of PBRN studies. In other words, it will be more meaningful for subjects to hear from their personal dental offices regarding a reminder for a study recall appointment. In turn, it will be more meaningful for the office to hear from its RC that it is time for them to contact subjects. It seems reasonable that the interim six-month contact be used to set up the specific recall appointment, which requires that the office be the entity to contact the subject. Experience has also shown that it is beneficial for the network to relieve burden on the practices. To that end, the National Dental PBRN will request IRB approval for the RCs and for the CC to receive the subject contact information and the contact information of two persons who do not live in the same household as the subject, so that both can assist the practices with follow-up contacts (e.g. birthday cards, recall visit reminders, etc), particularly with subjects who have had difficulty attending visits. The regions will have some latitude in determining the best means for maintaining contact with study subjects and ensuring their ongoing participation.

- 4) Number of Subjects per Practitioner Considerations:
 - a. Ask practitioners to enroll at least 10 and no more than 20 subjects, preferably during an 8 week enrollment period. Recruiting in a limited time period will make it easier to recall and follow the patients. Previous work found that 'cracks' are common such that enrolling 10 in a six week period should be feasible for virtually all practitioners.
- 5) Given the above design features, subjects should not be "lost". However, if a subject moves and contact is lost, the CC has extensive experience with using tracing resources such as National Change of Address services, motor vehicle departments, and LexisNexis databases. In those cases, the CC will implement those tracking procedures.
- 6) The process for contacting patients for recall visits and reminders will be for the practice to make the initial contact attempts, then inform their RC if there was no response within three weeks of the first contact attempt. The RC will then inform the CC, and the CC will initiate tracking procedures to identify updated patient contact information. Initiating tracking procedures promptly when there is no patient response to contact attempts will minimize missed study visits and also minimize loss to follow-up.

Methods to Minimize "Missing Data"

- 1) Put all participating practitioners on the same study schedule. Have an enrollment phase, then a break, then another specific follow-up phase of a couple of weeks and continue this cycle over the course of the study. Offices in general do a good job enrolling subjects because they are focused on the study every day during the enrollment period. However, it is more challenging to remember to perform study procedures when the enrollment phase is over and they may only have a study patient in the office once every couple of weeks. The patient has come and gone before they remember to do the study follow-up, even with the reminders that were put in place. So, over an 8 week period the office enrolls eligible subjects, with a goal of 10, but the flexibility to enroll up to 20 subjects within the enrollment period. Then over the next 10

months the intensity is much less, periodic check-in calls by RCs to ascertain staff turnover, data collection for internal crack characterization on teeth requiring treatment, etc. At one year it ramps up again and patients are seen specifically for a brief study visit.

- 2) Ask participating offices to develop a system to flag records of patients in their practices who are participating as subjects in the study, as well as to flag study patients in the office schedule. In this way, study personnel will be alerted to the fact that the subject is at the office, and can ensure that data collection takes place if indicated. Flagging the patient in the schedule will help to ensure that patients are not inadvertently scheduled when the practitioner will not be in the office. In the same way, if a subject's record is requested by another office, study personnel can inform the RC and attempts made to maintain the subject in the study.
- 3) Streamline follow-up data collection, so it won't be an involved recall exam.
- 4) Ask the practitioners to set aside specific time for follow-up assessments, perhaps 10 minutes, so they aren't trying to squeeze the recalls in with all their routine hygiene checks. With fewer subjects per practitioner, it seems like this might be more feasible.
- 5) Emphasize to practitioners as part of their initial study packages that the dentist has to be the motivational director of the study, especially regarding follow-up appointments, and make sure that the staff understands that the office is committed to taking the study on and seeing it through to completion.

Methods to Minimize “Refused”

- 1) The method described in the 1st point above under “Lost” will also help reduce the number of subjects who refuse to continue participating. At enrollment, subjects are informed that they are agreeing/consenting to participate in a long-term follow-up study. Subjects who enroll are required to state a willingness to participate throughout the study.
- 2) The method described in the 3rd point above under “Lost” (making contact between visits) should also help reduce refusals. The CC has found that retention is increased if subjects are kept engaged and interested in the study through the use of periodic newsletters and other study updates, postcards, birthday cards, phone calls, using the patient's preferred mode of contact. Additionally, follow-up involvement will be kept as light and convenient for the subject as possible.

Methods to Minimize “Unable”

- 1) There are several scenarios in which a subject stops seeing the original/enrolling practitioner:
 - a. Subject does not move, but:
 - i. Subject changes dentists- in same practice
 - ii. Subject changes dentists- in different practice
 - iii. Subject stops seeing any dentist
 - b. Subject moves
 - i. Subject sees new dentist

- ii. Subject stops seeing any dentist
 - c. Dentist retires or dies
 - d. Dentist moves
 - e. Dentist refuses to continue participating (shouldn't happen)
- 2) The operational impact of all of the above scenarios can be summarized by two scenarios:
 - a. Subject has a new dentist (not a National Dental PBRN member)
 - b. Subject stops seeing any dentist
 - 3) Locating the subject should not be a problem (see Methods to Minimize "Lost"), and having the subject agree to continue participating should not be a problem (see Methods to Minimize "Refused").
 - 4) The main operational issue is: How to get study follow-up visit information from subjects seeing a non-National Dental PBRN dentist or not seeing any dentist.
 - a. Actively recruit the new dentist into the Network so the subject can continue to be followed by the new dentist.
 - b. Send the subject who is not seeing any dentist, or who is seeing a non-Network dentist who refuses to become a Network dentist, to a Network dentist in the area just for study follow-up visits (and have study pay for the visit).
 - c. Request permission from the new office and the patient to complete a chart abstraction to obtain data.

Other Administrative and Design Methods To Increase Retention Rates

- 1) IRB/Informed Consent Considerations to Reduce Attrition
 - a. Incorporate into the informed consent form permission for all relevant study personnel, both in the dentist's office as well as the study investigators, and RCs to contact the subject. This will allow communications with the subject by study personnel without having to go through the dental office.
 - b. Incorporate into the informed consent form permission to see a National Dental PBRN provider other than the initial provider for the purpose of data collection. This will expedite data collection in those instances where a National Dental PBRN dentist retires or sells his/her practice, or where a subject goes to a different non-National Dental PBRN provider, or stops seeing a dentist for routine care.
- 2) Financial, but non-coercive incentive to patients to encourage continuing participation.

Additional Methods for Subjects who Have Missed a Recall Visit

- 1) If an enrolled patient misses the recall window for a visit, his or her contact information will be confirmed through the CC tracking procedures prior to the practice initiating contact attempts for the recall visit scheduling and the recall reminder for the next recall visit.
- 2) The practitioner's office will use the confirmed contact information to attempt to contact the patient by telephone (or other preferred means of contact) to schedule the next recall visit in a timely fashion, or remind the patient of the recall visit.

- 3) If successful in contacting the patient, there will be special emphasis on reminding the patient of the importance of his/her participation in the study and the importance of complying with the study visits.
- 4) If the patient cannot be reached, the two individuals designated as additional connections to the patient will be contacted to confirm the patient's contact information and/or determine the patient's whereabouts and additional attempts will be made to make contact with the patient.
- 5) If their designees cannot be contacted, CC tracing resources will be used in an attempt to locate the patient to schedule the visit, or remind them of the visit.