Leveraging Electronic Dental Record (EDR) Data for Clinical Research

Practitioner Recruitment - Frequently Asked Questions (FAQ)

Why is this important to me as a dentist?

This research project is looking first at the effectiveness of specific treatment and the ability to identify relevant information from our electronic dental records. It potentially can help evaluate treatment effectiveness, providing dentists with improved decision support tools. It may also help with design and implementation of improved practice workflows.

What dentists or dental clinics can participate in this study?

Dental clinics that have used either Dentrix or EagleSoft for at least five years are eligible for this study.
Additionally, dental clinics must have either been doing posterior composites for their patients for at least three years AND/OR endodontic therapy for at least three years with up to 5 years, if the data is available.

What is required for dentists to participate?

Dentists should be members of the National Dental Practice Based Network and be at "full" participation level. Additionally, participating practices will need to complete Orientation training or attended an Annual meeting of practitioners and Human Subjects training.

How are my patients involved in this study?

Your patient's should have no direct involvement. They do not need to sign any forms, as the information transmitted to researchers is de-identified.

Will it interrupt any current treatment or patients?

No. The study is specifically designed to obtain data from a backup and not your "live" database. This eliminates any possibility of impacting your ongoing patient care.

What will the study research?

The study is looking at two procedures, posterior composites and endodontic therapy and their longevity. It will look at posterior composites that were placed and follow them for up to 5 years. It will identify endodontically treated teeth and find out how many of those teeth were removed over time.

Thus, the search of your backed up database will look for specific CDT codes where your electronic records system has documented that these procedures have been completed between 2-5 years ago. As an example, it will look for D2391, D2392 and D2393 procedures identify the tooth involved and the surfaces involved. It will then look to see if there has been any further treatment on this specific tooth and surfaces (obviously for this specific patient), identify the procedures completed and forward this information, without any patient identification, to the researchers.

The researchers will then look at the data from all participating practices and attempt to analyze the data and draw some conclusions on expected service for posterior composites (i.e. it may show that 80% of the restorations are still present after five years, information that may help both you and the patient decide on appropriate treatment on other teeth that may need similar restorations or even other patients that may need similar care). It

is the intention of the researchers to share this information with participating practices as well as publishing the aggregate (not the results from specific dental clinics) findings.

An additional goal of the study is to determine whether this data can be easily accessed and the methodology that can effectively access the information. This will assist researchers in designing future studies, based on the information already available in our electronic dental records systems.

How much of my time will my participation take?

The time it takes you to read through this information, obtain answers to any questions you may have, and sign the obligatory authorizations should complete your time commitment. Reviewing the research results would also take some time and hopefully prove valuable to you.

How will the data be obtained?

The one of the two vendors (Dentrix or EagleSoft) will extract data from a backup of your databases; this will be performed remotely with your approval. This method will not expose your database to any risks nor will it impact the performance of your live database.

How will my data be protected once it is extracted?

The vendors will extract the data utilizing secure remote methods; the data will then be stored in a secure, limited-access environment prior to be transferred to Regenstrief Institute. Regenstrief Institute will receive the data from the vendors in a secure manner. Regenstrief Institute security includes restricted access to Regenstrief Institute sites, system security procedures and passwords which limit access to the least privileged, backup procedures that ensure against data loss, and secure file transfer which encrypts the transmission of data between Regenstrief Institute and its clients.

What are the risks?

There is a minimal risk of loss of confidentiality. Regenstrief Institute and Indiana University personnel have been trained in the importance of protecting patients' confidentiality, and the Principal Investigator and Regenstrief personnel have completed appropriate training related to confidentiality of data. As such, the loss of confidentiality is felt to be extremely remote. All project team members have signed non-disclosure agreements with each vendor and with the National Dental PBRN.

What are the legal documents I will be asked to sign?

We will be asking study participants to review and/or sign documents regarding legal data protections. Those documents include:

- Master Services Agreement (MSA) – this is an agreement between you (practitioner) and the University of Alabama, Birmingham (UAB). UAB manages the parent grant that supports the National Dental PBRN. It assures that you will be properly reimbursed for your activity with the project.
- Terms of Access Agreement (TAA) – this is an agreement between you (practitioner) and Indiana University to ensure that the data recipient is committed to protecting the privacy and security of confidential patient information in accordance with HIPAA Privacy Regulations, other federal and state laws, and contractual obligations.
- Business Associate Agreement (BAA) or vendor-specific agreement – these would be agreement(s) between your practice and your EDR vendor that describe the permitted and required use of protected health information that allows the vendor to create de-identified data on your practices behalf.
- W-9 Form – this document will allow us to process your payment for study participation. It may already be on file with the University of Alabama if you have previously participated in a study, but will need to be signed if you are new to the NDPBRN network.

For more information about Regenstrief Institute, visit https://www.regenstrief.org/