



Leveraging Electronic Dental Record (EDR) Data for Clinical Research

A Proof-of-Concept Study of Outcomes of Posterior Composite Restorations and Root Canal Treatments

Study Objective

Like other areas of healthcare, dentistry has made significant investments in adopting electronic dental record systems to manage both administrative and clinical data. Electronic dental record use is growing, making a rapidly growing corpus of EDR data available for research and quality assurance. Of the dentists enrolled in the National Dental Practice-Based Research Network (PBRN), more than 75% report using an electronic dental record (EDR) to document their patients' care. This data presents a potential rich opportunity for learning if used for research that is clinically meaningful to practitioners. Therefore, this proof-of-concept study is designed to test the feasibility of using prior-recorded EDR data to answer two important clinical questions:

- What factors are associated with the longevity of posterior composite restorations?
- What are the long term outcomes of tooth loss on permanent teeth receiving root canal treatment (RCT), regardless of whether the tooth received dental restorations following RCT?

Additionally, it is hoped that this study can help Network researchers and practitioners to identify other potential topics that can be explored using EDR data to help improve patient care.

Anticipated study launch date is: **Mid 2016**

How do I participate?

In order to be eligible to participate in this study, a dental practitioner enrolled in the National Dental PBRN must meet the following criteria:

- Have been using Dentrix or EagleSoft for at least 5 years to manage clinical data
- Be willing/able to authorize the secure extraction of EDR data by the system vendor for approved use by qualified researchers.
- Have the following treatment history captured in the practice's current version of the record:
 - At least **1 posterior composite restorations** on at least **100 patients** since 2000
 - **AND/OR** at least **1 root canal treatment on a permanent tooth** in at least **50 patients** since 2000.
- Have follow-up electronic data available for at least 2 years

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EDR Data Study Overview:

Practitioner Involvement

- As this study is primarily looking at historical data, there is very little time or direct involvement required of the practitioner. What is needed is permission to access your historical data, in a secure, de-identified fashion, through your current practice EDR vendor.
- Once the practitioner has enrolled in the study, a Regional Coordinator (RC) will provide the practitioner with additional study information and documentation.
- The practitioner will work with the vendor to set up a mutually convenient date/time for data extraction.

EDR Vendor Involvement

- Representatives from Dentrax or EagleSoft (hereafter referred to as “the vendors”) will remotely access the practitioner’s system at the time of the set appointment and begin the data extraction.
- Dentrax and EagleSoft technical personnel will run the queries on archived or copied databases and perform pseudonymization on necessary data elements. This process will have three benefits: (1) reduce technical overhead for the practice in participating; (2) reduce the probability of security and/or confidentiality breaches; and (3) increase practice acceptance minimizing impact on their live production systems.
- There are no foreseeable risks to the patients in this study since we propose to create a limited data set using existing data in EDR. The data gathered will be in compliance with the Health Insurance Portability and Accountability Act Privacy and Security rules <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>.
- Data identified for extraction will be de-identified during the extraction process and a data set with limited identifiers such as dates of treatment and birthdate will be generated.
- Data extracted from practices will generate individual data sets, one data set per practice.
- During the data extraction process from dental practices, the vendors will assign unique identification (ID) numbers to individual patient records. A document linking the unique ID number with patient record number used by practices will be shared with the regional administrative sites and utilized as needed.
- In the event, the study team has questions on patient level data, the RC will use the unique ID number to contact practices, and the practices will be able to retrieve the appropriate patient records by referring to the document linking the unique ID numbers.
- The vendors will securely transmit data from the EDR vendor to Indiana University/Regenstrief Institute.

Research Institution Involvement

Appropriate precautions will be taken and procedures will be followed to maintain confidentiality.

- These include use of unique study codes for participants, de-identification or obfuscating of protected health information (PHI), encryption of electronic data for transmission to Indiana University (IU)/Regenstrief Institute (RI) and password-protected computers for data storage.
- Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed.
- RI, a non-profit organization, will clean and process the data for data analysis. RI personnel have been trained in the importance of protecting participant confidentiality and the investigators and staff has completed appropriate training in this area, as such the loss of confidentiality is felt

to be extremely remote. Regenstrief employs best practice systems, service, and architectures to protect its network from internal and external threats.

Maintaining Study Data Privacy

Information obtained for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the University of Alabama, Birmingham IRB and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of National Institutes of Health; the U.S. Food and Drug Administration (FDA); and the Office for Human Research Protections (OHRP). The results of the research may be published for scientific purposes. However, your identity will not be revealed.

Benefits

This retrospective data analysis will not benefit the individual patients whose data is included in the study. A potential benefit of this study (for the clinicians and investigators) is to determine the extent to which EDR data may support obtaining reliable study outcomes for clinical research. Your involvement in this project may provide valuable information about the extent to which EDR data may support obtaining reliable study outcomes for National Dental PBRN. In addition, you will receive individual reports on your EDR documentation and a report showing your practice data status in the context of data from other practices in aggregate without any identifiers.

Practitioner Payment

You or your institution will be compensated for the time required to do the research, receiving \$500.00. Payment will be made via a check after data extraction. .