Impact of Dental Practice-Based Research Networks on Patient Care

DPBRN Study 16

1.0 ABSTRACT

The overarching goal of the practice-based dental research networks is to impact the practice of dentistry and improve patient care. A critical issue is assessing whether the research conducted is achieving this goal. The three NIDCR-funded PBRNs (DPBRN, PEARL, and PRECEDENT), collectively known as CONDOR, have developed a strategy for assessing the impact of practice-based dental research on the PBRN practices and on the practice of dentistry and dental hygiene in general. The strategy involves the development and use of a Core questionnaire that includes several questions from each PBRN that have been extracted from questionnaires previously administered as part of their initial research program activities.

This protocol is for the first administration of this Core Questionnaire with the purpose of assessing dental practice changes that may have occurred since the earlier administration of the individual questions within the separate networks. It will also collect baseline information for the others. The Core Questionnaire will be re-administered at later points in time including yearly and particularly following completion of studies and announcement of results. In this manner changes in practice over time and concurrent with research results dissemination can be measured.

2.0 BACKGROUND

Balas and Boren[1] estimate that it takes, on average, 17 years from reporting of a trial result to implementation into practice. In recent years, there has been increased emphasis on evidence based approaches to clinical and dental practice[2], however, dentistry is still at an early stage in accepting evidence-based practice guidelines. A number of overviews have provided insights into both barriers to acceptance and implementation of research findings and ways of better communicating research findings to practicing practitioner-investigators[3]. McGlone et al conclude that the most effective way to communicate research findings and effect changes in practice is through the use of multi-faceted and interactive educational meetings.

In 2005, the National Institute of Dental and Craniofacial Research (NIDCR) funded three practice-based research networks to plan, implement and maintain a general dental Practice-Based Research Network (PBRN). The mission of these networks is to conduct multiple clinical trials, prospective observational studies and retrospective case-control and chart review studies to address questions relevant to general practitioner-investigators in their routine care of patients. The PBRN model has been successfully implemented in medical-clinical settings. In a review of primary care PBRNs[4], the authors comment that PBRNs “are the best places to accomplish implementation [of research results] because they have representatives on both sides of the translational gap, researchers and clinicians.” When clinicians actually participate in a research project, the authors conjecture, they are more likely to implement the results.[5] In an observational study conducted in Denmark, however, the prescribing patterns of physicians treating asthma patients was not affected by their participation in industry-sponsored clinical trials of asthma drugs[6].

The three dental PBRNs have a unique opportunity to measure the impact of research participation on potential changes in practice based on the results of the research protocol. Further, by pooling the efforts across the three dental PBRNs, we will be able

to examine the effect of participation in research in general to the acceptance of research findings from other studies and the effect of association with but not participation in a research network.

2.1 Preliminary Data

Each of the three PBRNs have initiated studies that have resulted or may result in providing information that has the potential to impact practice patterns among practitioner-investigators.

- **PRECEDENT**

  Several procedures and products are available for pulp management in extensively decayed teeth. Pulp capping treatment is a conservative procedure that aims at maintaining the pulp viability. Pulp capping for permanent teeth is one of the most disputed topics in dentistry. Although many products have been suggested, a recent Cochrane Review found that evidence is lacking as to which pulp capping material is the most appropriate. None of the studies selected by the Cochrane reviewers used Mineral Trioxide Aggregate (MTA) as a pulp capping material. PRECEDENT, therefore, is conducting a randomized trial to evaluate treatment outcomes using MTA versus Calcium Hydroxide as direct pulp capping agents in extensively decayed permanent teeth.

- **DPBRN**

  The management of dental caries comprises a major part of the typical practitioner's time; however actual practice tendencies with respect to caries management have not been well characterized. The DPBRN study entitled "Assessment of Caries Diagnosis and Caries Treatment" examined how practitioner-investigators within the five regions of the network approached dental caries diagnosis and caries treatment. The study provided important information indicating substantial variation among the five regions within the network on issues such as the use of the dental explorer and use of caries risk assessment tools. There was substantial variation among the US practitioner-investigators within the network and especially between the US and Scandinavian members. These findings are guiding the development of further research, some of which will address the issues of the outcome for these different approaches.

  Six of the questionnaire items were used in the DPBRN study "Assessment of Caries Diagnosis and Caries Treatment." A test-retest validation of that questionnaire was undertaken using a total of 32 practitioners representing all 5 regions within the DPBRN. A summary of those results is displayed below in the table. Most measures have reliability as indicated by simple and weighted kappa statistics between 0.6 and 0.8, generally suggesting moderate to good reliability. It should be noted that the kappas were very sensitive to small differences in agreement rates: the item with the lowest kappa (0.24) still had 65% agreement while an item with a kappa of only 0.47 had 91% agreement. Nevertheless, special care will be taken when incorporating items with low reliability in analyses.

PIRG Question	DPBRN Question	Topic	DPBRN n test-retest	simple kappa	weighted kappa
1	3	Dental Explorer	32		0.74
2	6	Air Drying	31		0.63
2.1	6b	Air Drying	27		0.86
3	21	Caries Risk	28	0.73	--
4	30 case 2	Clinical Scenario	32	0.24 to 0.79*	--
5	30 case 3	Clinical Scenario	32	0.35 to 0.71*	--

**Note: PIRG #s 4 and 5 had 13 answer choices with multiple selections, for each, 6 of 13 had perfect agreement.*

- **PEARL**

  Based upon results of PEARL Study PRL0501 (Deep Caries Survey), 80% of PEARL Practitioner-Investigators (P-Is) reported removing all caries from deep lesions and 20% reported that they only partially remove caries. Based upon this survey's results, and the recent publication of a Cochrane Review reporting that treatment outcomes of both treatment approaches produces similar outcomes, a prospective PEARL study is being conducted to longitudinally assess treatment outcomes for both procedures in PEARL P-I practices. Treatment of deep caries is a prominent problem that has not been studied extensively, particularly the consequences of complete as compared to partial caries removal. If the longitudinal study provides supporting evidence of the effectiveness of partial caries removal within a dental PBRN setting, and that finding is followed by widespread dissemination, it may lead to wider adoption of these techniques by the profession.

2.2 Questionnaire Development

Each PBRN contributed questions related to areas currently being researched by that PBRN, including current practices for deep caries management, use of pulp capping materials, and caries diagnosis and risk assessment. Questions provided by DPBRN have been administered to members of that network providing information that can be used to test the sensitivity and reliability of the survey. Additional questions regarding how practitioner-investigators and dental hygiene obtain information that change their practice patterns also are included. The questionnaire was piloted among practitioner-investigators from each of the PBRNs and revised accordingly.

3.0 SPECIFIC AIMS

The ultimate goal of the dental PBRNs is to improve patient care and oral health through changes in clinical practice. This project seeks to address the following specific aims:

1) Is there evidence that members of the network changed their practice strategies during the time they have been in the network?

2) Is there evidence that those who have been more involved in meetings, studies, etc, changed their practice strategies more than those who have not?

3) Is there evidence that practitioner-investigators participating in a study have changed their practice strategies relevant to the topics addressed in that study?

4) Is there evidence that network members are more likely to change their practice strategies than non-members?

4.0 RESEARCH PLAN

4.1 Overview

The Core Questionnaire measures use of specific techniques and practice approaches and is designed to measure whether these practices and approaches change over time.

4.2 Schedule of Administration

The questionnaire will be administered to all DPBRN practitioner-investigators (including both dentists and dental hygienists) who:

(1) has completed a DPBRN Enrollment questionnaire and for whom DPBRN has a current active address and who is currently licensed to practice;
(2) reports on the Enrollment Questionnaire being a general dentist, pediatric dentist, or dental hygienist, or reports doing at least some restorative dentistry procedures;
(3) practices in one of the five DPBRN regions (AL/MS, FL/GA. MN, PDA, or SK).

The questionnaire will be administered on approximately an annual basis.

Following the first mailing, potential participants will be given four weeks to return a completed questionnaire. Those who have not returned a questionnaire by then will be mailed a second one. Those who have not returned a questionnaire by four weeks after the second mailing will receive a third and final mailing. After a final four-week waiting period, if a p-i has not returned the questionnaire, we will assume that he or she is not interested in participating.

. Pre-printed survey form packages will be sent by the Coordinating Center to each regional office. These forms will have the p-i self-checking identification number preprinted on each page of each form. The regional center will then communicate with individual p-is and forward their packages to them. P-is will be asked to complete the questionnaires by hand and return to their assigned regional coordinators in a pre-addressed envelope. Upon receipt, the regional coordinator will review the questionnaire for completeness and then forward to the CC. The p-is will be remunerated $50 after they have returned a completed questionnaire and responded to a possible query from the regional coordinator having to do with verifying illegible or unclear responses.

Information about the practitioners will be provided by each network. This information will include their level of involvement in PBRN studies, attendance at annual meetings and whether they participated in a particular PBRN study addressing a topic covered in the Core Questionnaire. Any compensation provided to the practitioners for their participation in this study will be the responsibility of the individual network; however, at

the recommendation of the CONDOR Directors and the PIRG group, practitioners will be compensated $50 each time they complete the questionnaire.

4.3 Definitions

To address Aim 1) and 4), practitioner-investigators who are not formally participating in one of the CONDOR PBRNs will provide a comparative population and will be asked to complete the Core Questionnaire at similar time points. These would include “Friends of PRECEDENT,” practitioner-investigators from METLIFE or HealthPartners, for example.

Aim 2) will be addressed by identifying practitioner-investigators who attend network annual meetings frequently versus those who do not attend or attend infrequently (once or twice over a 7 year period) and comparing change in practice patterns between these two groups. This will be combined with information about participation in studies to construct an indicator for level of involvement in the PBRN. Study involvement will be defined as those participating in at least one study requiring patient consent.

Aim 3) will be addressed by identifying practitioners who participated in the particular PBRN study which addresses the practice issue covered by the Core Questionnaire section and comparing their questionnaire responses pre- and post-study publication with those of practitioner-investigators who did not participate in the PBRN study.

4.4 Statistical Considerations

The data collected from these surveys will be used to track changes over time in practice patterns. As studies are completed and results disseminated, the Core Questionnaire provides an opportunity to track changes that may be attributable to the dissemination of research results. For these analyses, four analytic groups will be distinguished:

1. Practitioners who participated in the study
2. Practitioners who did not participate in the study but who are part of the Network performing the study
3. Practitioners from the other Networks
4. A sample of practitioners outside the networks (e.g., METLIFE, HealthPartners).

Summary statistics will be presented overall and within the four subgroups defined above. As these analyses are considered exploratory, no adjustment for multiple comparisons will be made. Any non-pre-specified analyses will be clearly identified.

Most of the questions in the Core Questionnaire have continuous, ordinal or binary responses. These questions include items 1, 2, 2.1, 3, 3.1, 6, 7, and 12a through 12f. In addition, while items 4 and 5 are categorical and allow multiple responses per question the overall response pattern can readily be placed in ordinal categories as, for example, no intervention, prevention/additional diagnostics, minimal intervention, and full intervention. Items 8 though 11 have nominal responses that do not lend themselves to ordinal categorization. For the purposes of analysis, each answer choice can be considered as a separate item with a binary response. For each of these items, a three-valued change score can be constructed for each item between administrations by taking the value 0 where there has been no change, 1 if the change is from a lower category to a higher category, and -1 if the change was from a higher to lower category.

For binary outcomes, this is equivalent to the difference of the measure for each item between administrations while for the ordinal outcomes this amounts to categorizing the observed difference into 0, positive and negative.

Each administration after the baseline will result in two change scores, one measuring change from baseline, the other measuring change since the most recent administration. Change scores from individual items will be combined into an omnibus change score for each practitioner that can be taken as a measure of overall rather than item-specific change. This approach will provide great flexibility for longitudinal modeling on changes in practice patterns over time with adjustment for covariates while also allowing the use of simple unadjusted tests to directly address the specific aims. Summary scores will be created for groups of questions related by the following themes: 1) approaches to diagnosis, 2) approaches to therapy, and 3) sources of information. Unless stated otherwise, all statistical tests will use a type-one error rate of 0.05 unadjusted for multiple comparisons.

The first specific aim will examine whether practice patterns change over time as represented by the mean change from baseline for each item within each analytical group. A t-test will be used to test the observed mean score against the null hypothesis that the mean is zero, indicating no mean change. Chi-square tests will be used to test for differences in change patterns between and among groups. Confounders such as PBRN, years in practice, region within network, foreign versus US practice, gender and age will be examined using multivariate models as appropriate (e.g. ANCOVA or logistic regression, using mixed models or generalized estimating equations (GEE) to account for clustering). Where there are sufficient data, we will compare practice type (individual versus group) and practice area (rural versus city). If the distribution of mean score is not normally distributed, non-parametric models will be used.

The second specific aim examines whether observed changes in practice patterns differ by categories of “involvement.” After categorizing the practitioners, the question is easily tested for each item by cross-tabulating change scores and categories of involvement and applying a chi-square test to the resulting table. Regression models for change, using the ordinal involvement categories as independent variables, that incorporate covariates such as age, gender, years in practice and region will also be used.

The third specific aim addresses the question of whether practitioner-investigators participating in a study change their practice in that study area. This will be very similar to the first specific aim except that the analytical cohort will consist of those practitioners who participated in the respective network studies related to each of items 1 through 8.

The fourth specific aim addresses the question of whether participation in one of the Networks has an effect on practices compared to practitioners not involved directly in network activities. This will be examined by testing for a difference in change scores between those who are in the CONDOR network versus those who are not involved in CONDOR using the same approach as for specific aim 2.

The analyses described above are simple and, without adjustment for covariates, cannot address confounding factors such as underlying differences between practitioners who attend annual meetings vs. those who do not. However, all the analyses described above can be repeated using generalized linear and mixed models that will allow for

longitudinal modeling and adjustment for important covariates such as practitioner demographics, practice type, baseline responses and study participation as well as accounting for clustering within regions and multiple observations per practitioner.

Statistical Power: The analyses discussed above rely on t-tests and chi-square tests. Because there is considerable variability in the number of enrolled practitioners among the three networks, basic power calculations are presented for a range of sample sizes. All power calculations assume 80% power and a type-1 error rate of 0.05 for a two-sided test. For the t-test, conservatively assuming the maximum variance of 1.0 for the change score gives power to detect as significant a mean change of 0.13 for a sample size of 500, 0.20 for n=200, 0.28 for n=100, and 0.40 for n=50. For chi-square tests, the most conservative assumption is that one of the proportions is 50%. With this assumption, and assuming equal sample sizes, there is power to detect as different a proportion of 0.41 for n=500, 0.36 for n=200, 0.30 for n=100 and 0.22 for n=50.

Because each change score can assume values -1, 0 or 1, their theoretical maximum variance (and standard deviation) is 1.0. For the power calculations involving t-tests we made the conservative assumption that the observed variance would equal the maximum. Under this assumption, detectable differences can be considered either as effect sizes or absolute differences interchangeably. The intention is that they represent absolute differences in means. In the likely event that the observed variances will be less than 1.0, the differences detectable with 80% power will be smaller than those presented in the power calculations. For both the t-tests and chi-square tests power calculations were done for detecting non-zero change in practice for a range of sample sizes from 50 to 500. This range was intended to demonstrate the available power for network-wide and multi-network groups down to comparing groups of specialists among all three networks or even specific regions within the DPBRN.

4.5 Data Collection

The majority of the questions on the Core Questionnaire have had common data elements defined as part of an earlier study. For those data elements that have not been curated, common data elements will be defined for each question and used across the Networks so data can be pooled for analyses. A Data Definition document will be drafted and circulated to each PBRN defining the data elements, their variable type and coding. All data elements will be curated as for other PBRN studies.

Because the Core Questionnaire includes pictures of teeth with specific dental conditions, particular care will be taken to assure adequate resolution of these pictures in paper.

The Core Questionnaire should be administered the same way at each time point within PBRN (e.g., if by electronic data capture or eDC, the Core Questionnaire will always be administered via eDC in that network). The method of administration will be recorded for possible sensitivity analyses.

Within PBRN, the practitioner-investigators may be identified by name in order to link information about study and meeting participation; however, all data used for analysis will substitute a participant ID for any identifying information about the practitioner-investigator. Each PBRN will be responsible for assigning this participant ID. The ID will

consist of an identifier for the network (PEARL, PREC, DPBRN, CROWN) followed by a numeric ID (e.g., 001, 002, 003, etc). Each network will be responsible for maintaining the security surrounding any link between the practitioner ID and his/her identity. All data will be presented in the aggregate and we will review results to make sure that there are no "small cells" in the output that could potentially identify a survey participant.

Each PBRN will be responsible for applying data cleaning procedures to the questionnaire data.

Data Sharing Agreement

The CONDOR PBRNs are establishing a data sharing agreement for this study. Once this has been finalized, this will be submitted as an amendment to the IRB protocol. No data will be released from the DPBRN until after this agreement has been approved by the IRBs of all the CONDOR PBRNs.

4.6 Human Subjects Protection

Because this study targets practitioner-investigators and not specific patients, this study is considered to have minimal risk to dental patients. Practitioner-investigators will not be identified by name in any dataset, but instead by network-provided codes so specific changes within practitioner can be tracked.

Human subjects involvement and characteristics. This protocol involves human subjects. The only human subjects directly involved in this study are the p-is who will be answering a questionnaire. Subjects will be recruited from the Dental PBRN and need to meet the eligibility criteria specific to this protocol and provide informed consent to participate. The Informed Consent form comprises part of the Introductory letter that will accompany the questionnaire. Returning a completed questionnaire constitutes verification of consent.

Sources of materials. Data will be obtained from the responses given by the practitioner-investigators who will be answering the questionnaire. Information about the Dental PBRN practitioner-investigators and their practices have been already gathered as part of the enrollment process.

Potential risks. The only risk to the participating subjects will be the highly unlikely accidental disclosure of health care provider information. However, every precaution will be taken to prevent this. No additional exposure is expected from this protocol.

Recruitment and informed consent. We will provide the study participants information that explains the nature of the study, time commitment involved, any risks involved, and compensation information. We will also answer any questions they may have in a telephone conversation or in face-to-face discussion with them.

Protection against risks. Records of participation will be kept confidential to the extent permitted by law. Only authorized personnel will have access to the data, and all information, whether electronic or in paper form, will be stored in a secure manner. This information will not be sold or used for any reason other than research. Results may be published for scientific purposes, but participant identities will not be revealed.

Potential benefits of the proposed research to the subjects and others
Subjects may benefit from the opportunity to reflect their views and gain information on the practice methods of their peers. The indirect benefit to the patients of the subjects answering the questionnaire may be ultimate improvements in dental treatment in daily clinical practice. Subjects may also benefit from a better understanding of how the risk characteristics of patients may influence patients' treatment. The potential benefits to the subjects and indirectly to their patients will far exceed the risk involved with the participation.

Importance of the knowledge to be gained
The knowledge to be gained from the current study will be to identify the various methods used for caries diagnosis and caries treatment and the potential impact that participating in a dental PBRN has on clinical practice.

Inclusion of women
Dentistry is a profession performed by both men and women; therefore, both genders will be eligible to enroll. Based on the enrollment questionnaires completed by DPBRN practitioner-investigators, 14% are female.

Inclusion of minorities
Racial and ethnic minorities will be included in the study proportional to their composition in the dental community. The racial and ethnic distribution of dental practitioners expected to participate in the study is approximately 10% of the subjects will be of a racial/ethnic minority group.

Information to be provided for all clinical research studies
Subjects who participate in the studies will be dental practitioners who meet eligibility criteria and who provide tacit informed consent to participate. No gender or racial/ethnic group will be excluded.

Inclusion of children
This study is designed to investigate the impact on clinical practice of participation by DPBRN p-is, all of whom are adults. Therefore, no children will be study participants.

5.0 REFERENCES

[1]Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of Medical informatics*. 2000:65-70.

[2]Ismail AI, Bader JD. Evidence-based dentistry in clinical practice. *JADA*. January 2004; 135:78-83.

[3]McGlone P, Watt R, Sheiham A. Evidence-based dentistry: an overview of the challenges in changing professional practice. *British Dental Journal*. June 23, 2001; 190:12 636-639.

[4]Mold JW, Peterson KA. Primary care practice-based research networks: Working at the interface between research and quality improvement. *Ann Fam Med*. 2005; 3 Suppl 1:S12-20.

[5]Frelick RW. The Community Clinical Oncology Program (CCOP) Story: Review of community oncologists' experiences with clinical research trials in cancer with an emphasis on the CCOP of the National Cancer Institute between 1982 and 1987. *Journal of Clinical Oncology*. 1994; Vol 12, no 8:1718-1723.

[6]Andersen M, Kragstrup J, Sondergaard J. How conducting a clinical trial affects physicians' guideline adherence and drug preferences. *JAMA 295*. June 21, 2006; 23: 2759-2764.