

CONTEXT WITHIN WHICH THE STUDY WILL BE CONDUCTED

This study will query dentist practitioner-investigators in the "Dental Practice-Based Research Network" ("Dental PBRN" and "DPBRN"). The DPBRN is a group of outpatient dental practices that have affiliated to investigate research questions and to share experiences and expertise. To date, 1,000+ dentists have completed a 101-item enrollment questionnaire. An additional 200+ have attended a three-four hour orientation session delivered in a Continuing Education format. DPBRN practitioner-investigators comprise dentists in Alabama, Florida, Georgia, Minnesota, Oregon, Washington, and Scandinavia. A comprehensive description of the DPBRN is provided in the "parent" U01 grant application, which has already been provided to the DPBRN Protocol Review Committee. An additional resource is the DPBRN's web site at <http://www.DentalPBRN.org>.

This study will be the DPBRN's first network-wide study, and consequently, in addition to being referred to by its title ("Assessment of caries diagnosis and caries treatment"), we also refer to it as "Study 1". Because the DPBRN is committed to being guided by the needs and desires of its practitioner-investigators, the intent for its first series of studies is to address topics that are of direct relevance to general dentistry daily clinical practice, to conduct studies that are simple in design and which require minimal training, and to conduct studies that do not unduly interrupt the busy flow of daily clinical practice. We refer to the DPBRN practitioner-investigators in the remainder of this protocol as "p-is".

A. SPECIFIC AIMS:

Specific Aim 1: To quantify the percentages of Dental PBRN dentists who report using selected methods for caries diagnosis.

Specific Aim 2: To quantify the percentage of Dental PBRN dentists who report using a caries-risk assessment protocol of any variety.

Specific Aim 3: To quantify the percentages of Dental PBRN dentists who report intervening surgically at the caries stages E1, E2, D1, D2, or D3.

Specific Aim 4: To test the hypothesis that reported use of a caries-risk assessment protocol is associated with a higher likelihood of reporting use of a preventive program.

B. BACKGROUND AND SIGNIFICANCE:

B.1. Caries continues to be prevalent, with substantial incidence among all age groups

Despite advancement in the prevention of dental caries, active dental caries still regularly leads to dental restorations and dental extractions (Kaste et al., 1996; Winn et al., 1996; Virtanen, 2001). Contrary to the assumption that caries is a prevalent disease primarily among children, new reports show that caries is a disease still prevalent in the middle-aged and older adult population with substantial incidence rates (Lawrence et al., 1995; Locker, 1996; Hawkins et al., 1997; Gilbert et al., 2000; Thomson, 2004). A prospective longitudinal cohort study in a diverse community-based population in Florida showed 67% incidence rate of caries disease in patients older than 45 years of age over a two-year period (Gilbert et al., 2000). Incidence rates over a three-year period of 57% for coronal caries increments and 27-39% of root caries increments have been reported in various populations over 50 years of age in North America (Lawrence et al., 1995; Locker, 1996; Hawkins et al., 1997).

B.2. The lack of a "gold standard" in clinical treatment planning

Treatment choices for dental caries are affected by a multitude of factors, including variations among dentists regarding caries diagnosis. The subjective assessment of each dentist when making the diagnosis of caries may be responsible for the greatest variation in treating the disease. The stage in caries development when operative intervention is indicated is not established or agreed upon (Yorty and Brown, 1999; Clark and Mjör, 2001). A major problem may be that dentists lack a "gold standard" in clinical treatment planning because there is a paucity of research assessing the short and long-term outcomes of treatment (Elderton and Nuttall, 1983; Elderton, 1989; Espelid et al., 1994; Bader and Shugars, 1996; Benn and Meltzer, 1996; Bader

and Shugars, 1997). A comparison of restorative treatment recommendations showed that dentists had remarkable differences related to the decision-making process (Rytomaa et al., 1979; Merrett and Elderton, 1984; Kay et al., 1988; Noar and Smith, 1990; Bader et al., 1994). Part of these inconsistencies are related to the marked variation that dentists have in correctly identifying caries, with sensitivity values ranging from .77 to 1, and specificity values ranging from .45 to .93 (Espelid et al., 1994). A more recent review reported poor evidence of the validity of all diagnostic methods (Bader et al., 2001A). In quantifying agreement among dentists' recommendations for restorative treatment, it was concluded that much of the variation in dental practice profiles is due to basic differences in decision-making (Bailit H, Clive J, 1981; Bader and Shugars, 1993). Lack of consistency in both dentists' decisions to intervene and dentists' selection of treatment can have a significant effect on cost of treatment (Shugars and Bader, 1996). Understanding the diagnosis and the clinical decision process is fundamental to determining normative treatment needs and to intervening to reduce over-treatment (Bader and Shugars, 1992) and consequently to reduce the cost of care. As pointed out over 10 years ago in a comprehensive review of the literature "the extent to which variation in dentists' detection of caries, evaluation of existing restorations, and identification of damaged teeth are associated with characteristics of the dentist, the practice, and the patient is completely unknown" (Bader and Shugars, 1992). This information remains unknown. It was also indicated that "the factors associated with variation in selection among treatment alternatives suggest that most dentists develop their principal treatment recommendations without considering many non-clinical patient factors" (Bader and Shugars, 1992). A retrospective analysis of caries risk assessment showed that dentists can classify their patients into groups that will experience different levels of need for restorative treatment that are caries-related (low, moderate, and high need) (Bader et al., 2005). This study confirmed the validity of dentists' subjective assessment of caries risk (Bader et al., 2005).

B.3. Caries risk assessment: an overlooked practice in treatment planning

Many factors play a role in establishing a patient's caries risk (Stewart and Stamm, 1991; Bratthall and Petersson, 2005). The presence of active caries lesions was reported as a good measure of the risk for future lesions (Anusavice, 1995). Socioeconomic aspects and education are also related to caries risk (Schou, 1998; Bratthall and Petersson, 2005). In addition, the caries experience of patients who have attended the practice for a minimum of 2 years allows a reliable caries risk assessment (Bader et al., 2005). Finally, the clinician's subjective assessment has been pointed to assessment of caries risk (Bader et al., 2005). About 65% of North American dental schools advocate caries risk assessments as part of treatment planning (Clark and Mjor, 2001). However, only about 27% of clinicians apply a caries risk assessment regimen during their treatment planning (Clark and Mjor, 2001). The discrepancy between what is taught in dental schools and what actually occurs in daily clinical practice among DPBRN dentists needs to be documented and the consequences understood in order to facilitate the DPBRN's long-range plans to speed dissemination of the latest scientific advances into daily clinical practice.

B.4. Treatment of the caries lesion: an issue without a strong consensus

No strong consensus exists within the dental profession regarding the use of a preventive versus surgical treatment to reduce and/or treat dental caries. The lack of consensus exists not only in general practice (Bader et al., 2001 B), but also in teaching programs (Anusavice and Benn, 2001). A review rated the evidence for efficacy of methods to manage non-cavitated lesions to be incomplete (Bader et al., 2001 A). Marked differences in treatment approach exist among different countries (Shwartz et al., 1984; Nuttall et al., 1993; Mileman and van der Weele, 1996; Lewis et al., 1997; Ratledge et al., 2001; Lith et al., 2002; Mejare et al., 2004). In Scandinavia, the majority of unfilled carious surfaces have caries lesions whose depth only extended into enamel (Lith et al., 2002). Restorative treatment has been predominant for proximal surfaces that involve dentin only (Lith et al., 1995). Caries experience seems to make a difference in the approach of treatment. On individuals with high caries experience, 50% of the lesions in the outer half of the dentin are restored, in contrast to 20% restored in individuals with lower caries experience (Lith et al., 1995). Patient age is also relevant, as adolescents (12-15 years of age) experience higher proportion of restorations at the occlusal surfaces compared to proximal surfaces (Mejare et al., 2004). On young adults (20-27 years of age), the proportion of occlusal and proximal surfaces restored were almost equal (Mejare et al., 2004).

B.5. Lack of evidence of effectiveness of professional intervention in caries prevention of high caries risk adults

The lack of evidence-based studies in the effectiveness of professional intervention for the prevention of carious lesions among caries-active adult individuals has been reported (Bader et al., 2001B; Twetman et al., 2004). As a result, two national reports stressed the need for rigorously designed studies and clinical trials to evaluate the efficacy of fluoride treatment in older adults at high risk for dental caries (NIH, Consensus Development Conference, 2001; CDC, 2001). Studies also showed the need to determine the effectiveness of other preventive interventions in adults, such as chlorhexidine varnish and rinse (Powell et al., 1999; Banting et al., 2000;) and calcium phosphate mouthrinse for patients with salivary gland dysfunction (Hay and Thomson, 2002).

B.6. Individualized preventive treatment plan for patients at high risk for caries

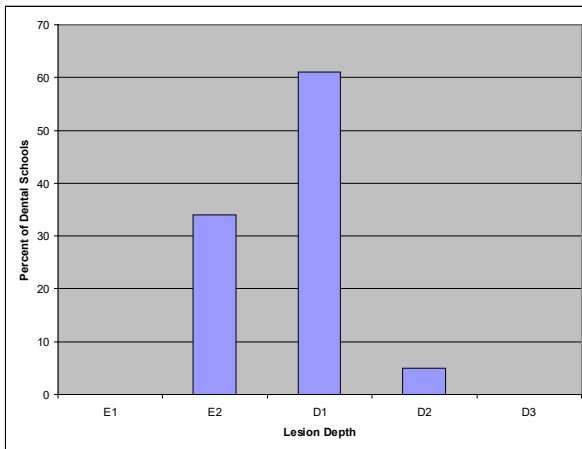
Even though the methods to identify caries-active adult patients are not agreed upon nor have a sufficient evidence base, studies have suggested that clinicians should individualize preventive treatment plan for patients at high risk for caries (Pitts, 1998; Powel, 1998). It is possible to recognize adults who may experience elevated caries increments (Bader et al., 1999; Bader et al., 2003; Bader et al., 2005). However, individualized preventive treatment has not been ideal, nor is it being commonly done for patients at high risk for caries (Bader et al., 1999 B; Bader et al., 2003).

C. PRELIMINARY STUDIES

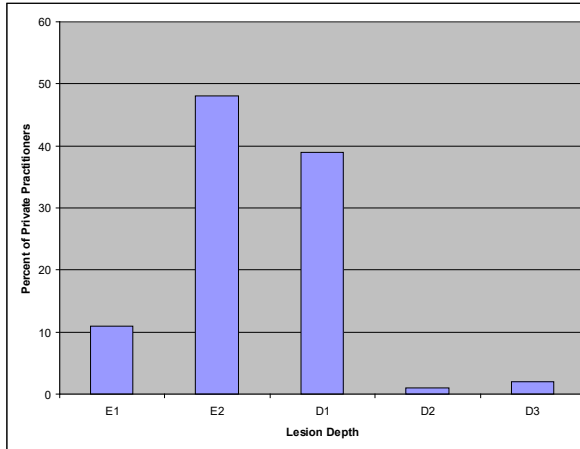
C.1. Teaching and practice of cariology

The bar graphs below illustrate the different depth of carious lesions selected for restorative treatment by North American Dental schools (Clark and Mjör, 2001) and by private practitioners in Florida. Reported depth of lesions that were treated by surgical intervention was as follows: E1 (outer 1/2 of the enamel), E2 (inner 1/2 of the enamel), D1 (outer 1/3 of dentin), D2 (middle 1/3 of dentin), and D3 (inner 1/3 of dentin).

North American dental schools



Private practitioners in Florida



Limited information is available from general dental practice about what lesion depth practitioners consider appropriate for operative (surgical) intervention. Marked variations exist among clinicians in the diagnosis of caries lesions (Rytömaa et al., 1979; Kay et al., 1988; Noar and Smith, 1990; Bader and Shugars, 1995, 1997) and in caries management and prevention (Bader, Shugars and Bonito, 2001; Kidd and Nyvad, 2003). Caries diagnosis as a topic is an extensive field of research that has been and is subjected to ongoing detailed studies for many years (Pitts, 1997; Pitts and Stamm, 2004), but dissemination into and adoption by practitioners in daily clinical practice has been very limited.

C.2. Preliminary studies in the dental practice-based context conducted by the DPBRN group

The "parent" U01 grant application describes numerous practice-based studies conducted by investigators in the DPBRN group. These studies have been conducted in Florida, the Kaiser Permanente organization, the HealthPartners organization, Alabama, and in Scandinavia. These studies have involved questionnaires

completed by dentists in full-time clinical practice, studies involving direct data collection by clinicians, and investigations that make use of data already being collected during the process of daily clinical care.

D. RESEARCH PLAN

D.1. Study population

This study will query dentist p-is in the DPBRN. DPBRN p-is comprise dentists in Alabama, Florida, Georgia, Minnesota, Oregon, Washington, and Scandinavia. A comprehensive description of the DPBRN is provided in the "parent" U01 grant application, which has already been provided to the DPBRN Protocol Review Committee. Because the two DPBRN Network co-Chairs and the Principal Investigator of the DPBRN Coordinating Center will be in attendance at the Protocol Review Committee meeting, further details regarding the structure and operations of the DPBRN can also be addressed at that meeting if further clarification is needed.

D.2. How Specific Aims will be met

The Specific Aims will be met by having DPBRN dentists complete a questionnaire (attached as Appendix 1) that queries the following key components:

1. Which technique(s) is (are) currently in use to diagnose caries lesions (SA 1).
Rationale. Studies have demonstrated substantial differences among dentists regarding the clinical decision-making process, in part due to the lack of sensitivity and specificity provided by some caries diagnostic methods. This component is addressed by questions #1-8 in the questionnaire.
2. Whether caries risk assessment is part of the p-is' treatment planning process (SA 2).
Rationale. Understanding the diagnostic and clinical decision-making processes that DPBRN dentists use is fundamental to determining normative treatment needs in the patient populations that they serve, in determining if over-treatment is common in DPBRN practices, and in designing interventions in DPBRN practices to reduce over-treatment, if over-treatment is being done. This component is addressed by questions #21-34 in the questionnaire
3. What is the most commonly used approach by the p-is to treat existing restorations that may or may not have recurrent caries (SA 2).
Rationale. Clinicians with less experience clinically diagnose more secondary caries than experienced clinicians (Burke et al., 1999; Mjör et al., 2002). In addition, replacement of restorations is more commonly indicated by dentists who have not placed the initial restoration (Elderton, 1977; Davies, 1984; Elderton, 1984; Boyd, 1989; Bader and Shugars, 1992). This component is addressed by questions #27-29 in the questionnaire.
4. Whether enamel or dentin lesions are intervened operatively (SA 3).
Rationale. The stage in the caries development process when operative intervention is indicated is not commonly agreed on. However, it can have a significant impact on the health of the tooth structure as well as on the cost of treatment. This component is addressed by questions #30-34 in the questionnaire.
5. Whether caries preventive agents are used in the participating practice (SA 4).
Rationale. Despite the lack of carefully designed studies that confirm the efficacy of preventive methods in high caries risk individuals (Bader *et al.*, 2001 A, B), a strong correlation has been demonstrated between various fluoride preventive agents and caries reduction in children and in older adult populations. This component is addressed by questions #9-20 in the questionnaire.

D.3. Inclusion criteria

To be eligible to participate in Study 1, practitioner-investigators must be enrolled in the DPBRN and do at least some restorative dentistry in their practices as reported on the enrollment questionnaire.

D.4. Selection and recruitment process

The number of practitioner-investigators currently enrolled in the DPBRN is more than 1,000 (please see the attached Target/Planned Enrollment Form for gender, racial, and ethnic characteristics of the enrollees). To meet the Specific Aims of this study, a minimum of 200 DPBRN practitioner-investigators will be enrolled in Study 1. However, an overall objective for the NIDCR RFA on dental PBRNs is to foster translation of scientific advances into daily clinical practice. Therefore, we anticipate repeating this questionnaire at a later point to quantify any changes in caries diagnostic and treatment methods used by DPBRN dentists. To meet this overall RFA objective, we will therefore mail the Study 1 questionnaire to all DPBRN enrollees who reported on the enrollment questionnaire that they do at least some restorative dentistry, such that the anticipated total number of dentists who complete the Study 1 questionnaire will be much larger than the 200 required to meet the Specific Aims for Study 1.

An introductory letter explaining the study will be mailed to each targeted practice, along with a printed copy of the questionnaire (attached in the Appendix). The questionnaire will be sent to all the participating dentists in the Permanente Dental Associates, the HealthPartners group, and Scandinavia (a total of more than 100). For Alabama and Florida DPBRN enrollees, the mailing will be done in two stages. The first phase of recruitment letters will be sent to practices that have been pre-selected because they meet one or more targeted criteria: (1) they have racial/ethnic minority dentists or they serve patient populations with a substantial proportion of racial/ethnic minorities; (2) they have female dentists; or (3) they are geographically proximate to the administrative sites for each of the DPBRN regions. Because Study 2 will be limited to dentists who have completed a Study 1 questionnaire, we want to have early identification of the 'targeted' practices so that we can more readily proceed to Study 2 recruitment with these practices. One month after the first phase mailing is done, a phase 2 mailing will be done to all the remaining DPBRN practices in Alabama and Florida.

D.5. Length of field phase

The p-is will be requested to return the questionnaire within three weeks. A reminder letter will be sent after the third week to clinicians who have not returned the questionnaire. After an additional three weeks, a second reminder will be sent. After a final three-week waiting period, if a p-i has not returned the questionnaire, we will assume that he or she is not interested in participating.

D.6. Data collection process

At this evolutionary stage of the DPBRN development, p-is will have the option of completing the questionnaire by hand (followed by returning a pre-addressed envelope to the DPBRN Coordinating Center) or by answering the questionnaire within a secure data entry portal at our DPBRN Operations web site (a secure website administered by the DPBRN Coordinating Center and located at <http://share1.dopm.uab.edu/sites/dentalpbrn/default.aspx>).

The p-is will be remunerated \$100 after they have returned a completed questionnaire and responded to a possible query from the Coordinating Center having to do with verifying illegible or unclear responses.

D.7. Pre-testing of questionnaire

The questionnaire will be pre-tested by the six p-i members of the Executive Committee and another 10 p-is throughout the network. Pre-testing will assess the feasibility and comprehension of each questionnaire item.

A subsequent pre-testing phase will finalize documentation of comprehension of questionnaire items and quantify test-retest reliability of questionnaire items, which will involve 30 DPBRN dentists. Items must meet a test-retest reliability of $\kappa > 0.70$ or ICC > 0.70 to be considered sufficiently reliable for inclusion in the final version of the questionnaire. The anticipated lapse in time between test and retest will be one week. Pre-testing and documentation of adequate test-retest reliability will be completed before the Study 1 questionnaires are mailed to the remaining DPBRN enrollees.

D.8. Study design and statistical analysis

The study design is cross-sectional, consisting of a single administration of a questionnaire-based survey to a convenience sample of dental practitioners who are members of the DPBRN.

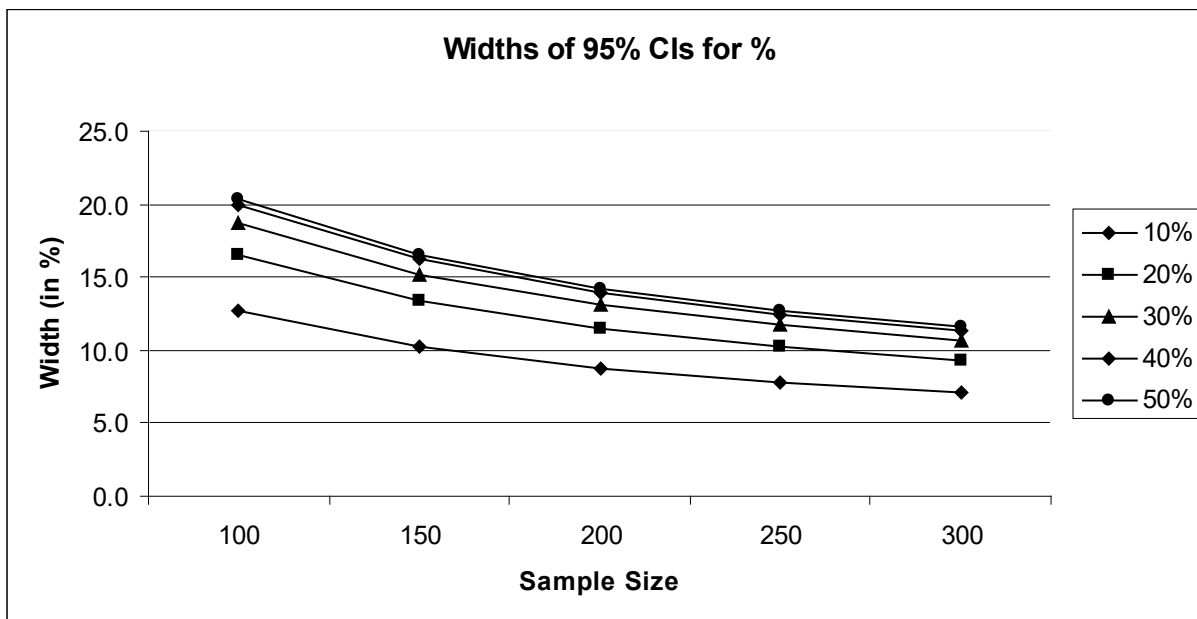
The statistical analysis for Aims 1, 2, and 3 will consist of calculating point estimates and 95% confidence intervals (CI) for the percentages of practitioners in each category. These categories are not mutually exclusive, so the sample size for each percentage and CI will be the number of p-is who respond to the question.

For Aim 4, the odds ratio (OR) will be calculated as a measure of association between the two dichotomous variables representing use of a caries assessment method and use of a preventive program. Pearson's chi-square statistic will be used to test the hypothesis of association between the variables; that is, that the OR is significantly different from the null value, 1.0. A 95% CI for the OR will be calculated, using the logit method.

D.9. Power considerations

The 95% confidence level and two-sided CIs and hypothesis tests were assumed for all power calculations. Precision of estimation for the percentages defined in Aims 1, 2, and 3 were based on widths of exact 95% CIs for binomial proportions corresponding to percentages ranging from 10% to 50%. An estimated percentage of 50% yields the widest CI, and thus the most conservative estimate of precision. The figure shows the widths of CIs for sample sizes of 100 to 300 responding practitioners. The CI width for an estimated percentage of 50% ranges from 20.3 for a sample size of 100, to 11.6 for a sample size of 300. That is, given an estimated percentage of 50%, for a sample size of 100, the 95% CI would be (39.85, 60.15), and for a sample size of 300, the corresponding CI would be (44.2, 55.8).

Power for the hypothesis test specified in Aim 4 was based on a chi-square test of equal proportions (OR = 1.0), assuming equal allocation of respondents between the two categories of one usage variable (caries assessment or preventive program), and estimating power to detect a difference from 50% in one of the categories of the other variable. A sample size of 100 practitioners would provide 80% power to detect an OR of 3.3 (50% versus 77% in the categories of the second variable). Sample sizes of 200 and 300 would provide 80% power to detect ORs of 2.3 (50% vs 70%) and 1.95 (50% vs 66%), respectively.



E. HUMAN SUBJECTS RESEARCH

E.1. Risks to the subjects and health care providers

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 that inquires mainly about the various methods used to diagnose caries and the stages of the caries process that requires

intervention. 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 dentists 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 and the DPBRN has an unblemished track record in this regard. No additional exposure is expected from this protocol.

E.2. Adequacy of protection against risk

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.

E.3. Potential benefits of the proposed research to the subjects and others

Subjects may benefit from the opportunity to reflect their views on the current caries diagnosis and caries risk assessment plans used in their practice 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.

E.4. 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. When the results of Study 2 become available (a study that documents at what caries lesion depth new dental restorations are actually being done in individual DPBRN practices), comparisons can be made with responses provide for Study 1.

E.5. 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 dentists, 14% are female. We anticipated that our targeting of this group during recruitment will yield a sample of 20% female dentists for Study 1.

E.6. 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 shown in Targeted/Planned Enrollment table. We anticipate that approximately 10% of the subjects in Study 1 will be of a racial/ethnic minority group.

E.7. 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 written informed consent to participate. No gender or racial/ethnic group will be excluded. Our anticipated enrollment for a hypothetical study is shown in the Targeted/Planned Enrollment table of this application.

E.8. Inclusion of children

This study is designed to investigate caries diagnosis and caries treatment used by DPBRN dentist p-is, all of whom are adults. Therefore, no children will be study participants.

Please see the following page for the Targeted/Planned Enrollment Form.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Assessment of caries diagnosis and caries treatment

Total Planned Enrollment: 1,116

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	9	17	26
Not Hispanic or Latino	176	914	1,090
Ethnic Category: Total of All Subjects *	185	931	1,116
Racial Categories			
American Indian/Alaska Native	1	2	3
Asian	6	11	17
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	17	23	40
White	161	895	1,056
Racial Categories: Total of All Subjects *	185	931	1,116

The "Ethnic Category: Total of All Subjects: must be equal to the "Racial Categories: Total of All Subjects."

F. VERTEBRATE ANIMALS

Not applicable.

G. LITERATURE CITED

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H. CONSORTIUM/CONTRACTUAL ARRANGEMENTS

These arrangements are discussed in the original Dental PBRN U01 grant application.

I. CONSULTANTS

These arrangements are discussed in the original Dental PBRN U01 grant application.

J. APPENDIX

DPBRN Study Questionnaire