**CONTEXT WITHIN WHICH THE STUDY WILL BE CONDUCTED**

The Dental-Practice Based Research Network, the DPBRN, is a group of dental practices that have been linked together to investigate research questions and to share experiences and expertise. 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 second network-wide project dealing with restorative dentistry. Study 1 was a questionnaire related to caries diagnosis and treatment in DPBRN practices. This study focuses on the reasons for placing the first restoration on a previously unrestored tooth surface. Study 3 will deal with the reasons for replacement and repair of defective dental restorations. The DPBRN practitioner-investigators ("p-is") in this study and Study 3 will all have completed the questionnaire in Study 1.

Because the DPBRN is committed to being guided by the needs and desires of practitioners, the intent for its first series of studies is to address topics that are of direct relevance to general dentists in 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. Subsequent studies in the series on restorations in general dental practice will likely deal with the gradual degradation of restorations and development of defects in restorations over time and the longevity of different types of restorations. Apart from the data collected for each study, the initial three studies will not only form the basis for the subsequent studies, but they will also form a foundation for monitoring changes that may occur in restorative therapy in the future.

## A. SPECIFIC AIMS:

**Specific Aim 1**: To quantify DPBRN p-is' pre-operative and post-operative assessments of the depth of the caries lesion being treated.

**Specific Aim 2:** To quantify the prevalence of dental material types used in the first restoration in a permanent tooth surface.

**Specific Aim 3:** To test the hypothesis that p-is in Study 1 who stated that they wait until the caries lesions reach dentin before they place the first restoration are in fact more likely in this study to do restorations on caries lesions that have progressed into dentin.

**Rationale.** Because the main reason for placing the first restoration on a tooth surface is due to caries - referred to as primary caries - the results from this study will be correlated with answers provided by the same clinicians in Study 1 wherein they stated at what depth they typically intervene in the caries process by placing the tooth surface's first restoration.

In addition to being a potential major source of variation among DPBRN practices, the decision of when to place the first restoration on a tooth surface is a critical point in the life cycle of a tooth, as detailed in section B.3. Because this project is a practice-based study, restorative dentistry in ‘real life’ situations will be recorded. The present study does not intend in any way to influence when or why restorations should be placed. Furthermore, the clinical technique and the selection of materials used to restore the teeth are entirely up to the p-is.

## B. BACKGROUND AND SIGNIFICANCE:

### B.1. Caries diagnosis and treatment are associated with substantial variation and uncertainty

Diagnoses of dental caries, both primary and secondary/recurrent lesions, are common procedures in general dental practice. However, caries diagnosis and treatment planning are hampered by the lack of a “gold standard” due to insufficient research showing the short- and long-term outcomes of caries treatment (Elderton and Nuttall, 1983; Elderton, 1989; Espelid et al., 1994; Benn and Meltzer, 1996, Bader and Shugars, 1995a,b, 1997). Despite major advancements in caries prevention, the placement of restorations and extraction of teeth as a result of caries continues (Kaste et al., 1996; Winn et al., 1996; Virtanen, 2001). Clinical validations of the diagnoses of caries lesions and other types of defects are needed to secure a sound foundation for treatment planning in restorative dentistry.

The information in this study about the restorative treatment received by patients in DPBRN practices will provide the opportunity to record not only the diversity in the treatment provided, but also to generate basic information for hypothesis testing and for the design of future studies. The results will also be related to the findings from Study 1 wherein we measured p-is' attitudes and practices regarding caries diagnosis and preventive practices.

Restorations are needed to replace diseased and lost dental tissues. Limited information is available from general dental practice in the US about the stage in the development of caries lesions that is considered appropriate for operative intervention. Marked variations exist among clinicians and teachers of restorative dentistry in the diagnosis of caries lesions (Rytömaa et al., 1979; Kay et al., 1988; Noar and Smith, 1990; Bader and Shugars, 1995a, b, 1997) and in caries management and prevention (Bader et al., 2001; Kidd and Nyvad, 2003). Caries diagnosis as a topic is an extensive field of research that has been, and still is, the topic of ongoing detailed studies (Pitts, 1997; Pitts and Stamm, 2004).

**B.2. Progression of caries in modern society is slow**

Whenever caries lesions progress the results will be destruction of tooth tissues, with eventual cavitation, and dental pain. It has long been established that this progression is slow (Shwartz et al., 1984), and can be quite dependent on access to fluoride. In permanent teeth of adults with average oral hygiene based primarily on tooth brushing with fluoride toothpaste, caries lesions take about four years to pass through enamel and another four years until the lesion reaches the pulp. The teaching of Cariology in dental schools (Yorty and Brown, 1999; Clark and Mjör, 2001) is diverse regarding at which stage of development the caries lesion should be treated preventively, and at which stage it requires operative/restorative treatment. We also have preliminary data from general practitioners in Florida, referred to in Study 1, indicating that they treat primary caries lesions operatively at an earlier stage of development than that taught by most dental schools. This situation may be a remnant from the time when caries lesions were believed to, and in fact did, progress fast through the dental tissues.

**B.3. Placing the first restoration in any tooth is a crucial time in the life of that tooth**

Early stages of caries lesions may be arrested or "healed" (Kidd and Fejerskov, 2003). When preventive measures fail or are not attempted, dental restorations must be placed to avoid further destruction of the teeth. The decision to place the first restoration on a tooth surface is an important one because it often is the beginning of an unfortunate cycle of restoration replacement over subsequent decades in which each succeeding restoration is progressively larger, ultimately leading to a large restoration that places the tooth at substantially increased risk for dental extraction. Approaches that delay placement of the first restoration may be a key source of improving the long-term effectiveness of dental care.

The extent or depth of the caries lesions when restorations are placed in general dental practice has not been determined and the teaching in this area varies considerably (Yorty and Brown, 1999: Clark and Mjör, 2001). Requirements of suitable lesions for operative treatment for State Board Examinations indicate that caries lesions limited to enamel are preferred (Anusavice and Benn, 2001). This approach contradicts scientific evidence and it sends a message to dental students and to the dental community at large that early surgical intervention is desirable. In general dental practice routine restorative treatment of enamel lesions is usually not indicated, because these lesions may be arrested and they should be subjected to non-invasive, preventive treatment. The goal must be to inform the patients about caries prevention and how initial lesions may be arrested. However, the selection of a preventive, non-invasive approach to the treatment of caries versus placement of restorations is an unsettled issue, not only in general practice, but also in teaching programs and at state board examinations. Preliminary data from a study among clinicians in Florida referred to in Study 1 indicate that almost ⅔ of caries lesions treated operatively are enamel lesions, and many of these lesions may be arrested provided effective preventive programs are instituted.

**B.4. There is substantial diversity between teaching programs and what is done in daily clinical practice regarding when to treat caries lesions operatively**

According to a survey of the teaching of cariology in North American dental schools (Clark and Mjör, 2001), about two thirds of the schools advocated surgical intervention when lesions have reached dentin, mainly the D1 level - the outer third of dentin. The remaining one third of the schools taught the treatment of enamel lesions operatively, mainly E2 lesions. In Florida, where the clinicians are graduates from dental schools

across the US, almost 60% treated enamel lesions operatively, including 11% E1 lesions, and only about 40% waited until the caries lesions reached dentin. These differences have been illustrated in the protocol for Study 1. This diversity has no foundation in research. It may be based on tradition and uncertainty about caries progression among clinicians who may adopt the "better safe than sorry" option and operatively treat lesions that may be arrested by preventive measures.

The cooperation of the patient in the monitoring of incipient lesions is essential. Patients must be informed about the monitoring of lesions recommended by the clinician and the instructions must be documented in the patient's treatment record. The patient must have an explanation of the advantages and prognosis of caries preventive programs and he/she must be given responsibility for the follow-up of preventive regimens.

**B.5. DPBRN dentists' restorative treatment may be influenced by the characteristics of their patient populations and be linked to the dentists' use of preventive and caries risk assessment approaches**

Non-invasive treatment of caries involves education and encouragement of behavioral changes to the individual patient with emphasis on plaque control, the use of fluorides, and dietary modification (Kidd and Nyvad, 2003). The need for restorative dental treatment is to a large extent dependent on the oral hygiene, dietary habits, and access to fluorides. Toothpaste is a common source of fluoride. Monitoring of incipient primary enamel lesions to assess their development is a recognized clinical approach for primary caries lesions.

Many factors play a role in establishing a patient's risk for developing caries lesions (Stewart and Stamm, 1991). In a review of published data, it was indicated that the presence of active caries lesions and many restorations was a good measure of the risk for future lesions provided the oral environment is unchanged (Anusavice, 1995). Socioeconomic aspects and social class are strongly related to such preventive measures (Kelly et al., 2005). Treatment planning, including caries diagnosis, must take these factors into consideration, including the patient's condition and preferences (Ismail and Bader, 2004).

It is for these reasons that this study will be linked to Study 1. In Study 1, we queried DPBRN dentists about the characteristics of their patient populations, as well as if they use certain caries risk assessment and preventive dentistry approaches.

**B.6. Non-carious defects should also be taken into account in a study of first restorations on permanent tooth surfaces**

Loss of tooth tissue is most often due to caries, but tissues lost because of abrasion, erosion, abfraction, attrition or trauma also require restoration. Additionally, restorations may be needed to replace congenitally malformed or inherently discolored tooth tissues in order to restore function and esthetics of the dentition. Abrasion of tissues due to physical wear, for example excessive or incorrect tooth brushing or using abrasive toothpaste, may result in wedge-shaped defects that require restoration. These defects are found in the cervical area of teeth and are predominant in adult populations with gingival recession. The exposures of cementum and root dentin, which are less abrasion-resistant than enamel, to the oral environment predisposes the tissue to wear. Abrasion defects represent restorative challenges, because the dentin, which comprises the main part of the defect, including the pulpal floor and most of the cavosurface margin, is sclerotic and difficult to treat with adhesive techniques (Duke and Lindemuth, 1990). Flexure of teeth, often associated with excessive biting forces or orthodontic problems, also predisposes the teeth to abrasive defects, and they are often referred to as abfraction lesions. These lesions are age dependent, being more common in older than in younger age groups. Erosion and chemical degradation of tooth tissues, for example by citrus fruit or by acidic soft drinks may also result in the need for restorations. Physical trauma may cause fracture of intact teeth - usually incisors - that calls for restoration of teeth. Incisor teeth are most prone to fracture due to external trauma, but metallic intraoral piercing devices may also cause tooth fractures and these typically occur on posterior teeth. All these causes may result in defects of various sizes that require restoration either to prevent further damage from occurring or for esthetic reasons.

A majority of patient contact time spent by DPBRN p-is in general dental practice deals with restorative dentistry and its associated diagnosis, as determined from the enrollment questionnaires completed by about 1,100 DPBRN p-is (www.DentalPBRN.org). Restorative dentistry is, therefore, the major workload in general dental practice and it covers most of the treatment performed on patients.

**B.7. The choice of restorative materials by DPBRN dentists is also relevant to the long-term effectiveness of dental care**

The materials used to restore teeth vary in physical and biological properties and in esthetic appearance. Some restorations are inserted in a soft, pliable state. These restorations harden in situ and are referred to as direct restorations. Others are manufactured on a model prepared from an impression or from a computer image of the prepared tooth. They are referred to as indirect restorations and they are more costly at the time of placement than directly placed restorations. Indirect restorations have an increased longevity (Mjör and Medina, 1993, Jokstad et al., 1994) compared to direct restorations. This increased longevity may actually make the long-term cost of these restorations equal to or lower than direct restorations (Mjör, 1992).

Amalgams and resin-based composites have, up until the present time, been the most commonly used restorative materials. The development of the adhesive resin-based restorative materials has resulted in smaller, less invasive cavity preparations than for metallic restorations. In addition, provided caries preventive programs are utilized by the patients, including some form of access to fluoride, there is no need for extension of the cavity preparation to allow for access of effective cleaning devices like the toothbrush, and the concept of minimally invasive dentistry has emerged (Ericson et al., 2003).

The selection of restorative materials depends on factors like the size of the restoration, the overall condition of the tooth, esthetic requirements, and the cost involved. However, many additional factors affect the selection of restorative materials, including the dentition treated, the age and gender of the patients, the type of practice, private or public health, socio-economic status, and the experience and gender of the clinician (Qvist et al., 1990a,b, Mjör et al., 2002). Third-party payment systems, including insurance coverage (Burke et al. 2001), and political restrictions on the use of certain materials, may also have an effect on the availability of restorative materials in some countries (Sundberg et al., 2000; Forss and Widström, 2001).

**The use of resin-based composites as the all-round restorative material is steadily increasing.** Marked changes have occurred in the selection of restorative materials over the last 30 years (Christensen, 1995; Leinfelder 1996; Mjör and Moorhead, 1998; Mjör et al., 1999; Forss and Widström, 2001); the major shift being from amalgam to resin-based composite materials. The reasons for this change are manifold. New operative procedures that allow the use of tooth-colored adhesive restorative materials evolved due to a change in the caries situation, resulting in smaller cavity preparations. Supported by strong marketing of tooth-colored restorations, the use of these materials has had an exponential effect on the demand for “white fillings” as all-round restorative materials because of their improved esthetics. The fact that more cariogenic plaque adheres to resin-based materials than to other materials (Svanberg et al., 1990) has received little attention. The quality of resin-based materials has also gradually improved over the last 30 years. The clinical teaching of restorations using resin-based composites in dental schools has also increased (Mjör and Wilson, 1998; Wilson and Mjör, 2000). In addition, a general biological awareness in society at large has turned against amalgam because of the “mercury issue”.

No recent data from the US are available on the selection of restorative materials in general dental practice, but the shift from amalgam to composite materials (Mjör and Moorhead, 1998) has occurred as in other developed countries. In some areas and practices amalgam is not in use any more. A recent report indicates that in some parts of Scandinavia the use of amalgam represents less than 10% of all restorations inserted (Grimmestad et al., 2004). The shift towards resin-based materials has had an impact on the short- and long-term cost of restorative dental care, but few attempts have been made to monitor the changes (Mjör, 1992; Mjör and Moorhead, 1998). Present-day resin-based restorative materials have clinical properties and problems similar to those of amalgam (Mjör et al., 2000), but present-day resin-based restorations have increased longevity compared to earlier generations of the materials. The greatly enhanced esthetic properties of resin-based composite restorations appear to overshadow any negative effect of these materials. Their main problem is that they are technique-sensitive and resin-based restorative materials require a more meticulous clinical technique. Therefore, they take longer to place, which makes them more expensive than amalgam restorations.

The size and location of the restoration is also important for the long-term outcome of restorative treatment (Maryniuk, 1984). Traditionally five different types of restorations have been described based on their location. These are referred to as Classes I-V, but each class of restoration may differ considerably in size. A Class VI has also been described and it refers to restorations at the tip of a cusp. Some have extended Class VI to also include restorations limited to incisal edges.

### B.8. Data collection is affected by the importance of the short-term and long-term costs of restorative treatment

Published fee schedules in the US are largely based on the number of surfaces involved and the restorative materials used (Anderson, 1994; McCann, 2004). Therefore, the number of surfaces involved in the restoration will be recorded in the present study. Single crowns will be included in this study as a five-surface restoration. Tooth colored resin-based composite restorations are more expensive than similar-sized restorations in amalgam, and this is an additional reason to record the type of restorative material being used. A differentiation between direct and indirect restorations will also be made because of the difference in longevity of the two types of restorations and also in the short- and long-term cost of these treatments (Mjör, 1992).

## C. PRELIMINARY STUDIES

### C.1. Studies preceding this DPBRN study

Data from previous studies on dental restorations conducted by DPBRN investigators have been referred to in Section B of this protocol. First-hand data are therefore available for comparison with the data obtained in this study from DPBRN practices. In addition, unpublished data from a study of the practice of cariology among almost 300 clinicians in private practice in Florida are available. Some of the results will be used to substantiate the aims outlined in this protocol. The information from Study 1 will also be used to compare attitudes and opinions related to selected topics in cariology to what treatment is actually done in practice.

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

The "parent" U01 grant application describes 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. These investigators have now joined forces in a collaborative, well-integrated entity now called the DPBRN.

## D. RESEARCH DESIGN AND METHODS

### D.1. Inclusion criteria

To be eligible to participate in Study 2, practitioner-investigators must be enrolled in the DPBRN, do at least some restorative dentistry in their practices as reported on the enrollment questionnaire, and have completed DPBRN Study 1.

### D.2. Selection and recruitment process

A total of 100 DPBRN p-is will be enrolled in this study. The first phase of recruitment letters will be sent to 200 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. A p-i who has participated in Study 1 may elect to participate in this study, Study 3, or both studies at the same time.

### D.3. Discussion of this protocol with practices

Before any data collection begins by an individual practice, DPBRN Project Coordinating staff will have a face-to-face meeting with each participating practice to explain the protocol for this study. Our previous experience suggests that having this meeting during lunch (provided by the DPBRN) with all the practice's dentists and staff is the preferred method. Other possibilities may be if the practice has a pre-arranged time for meetings or when no patients are being treated. This mechanism provides an opportunity to address all questions that all staff members might have about the protocol. Human subjects/informed consent issues will be reviewed, as well as procedures specific to this study. It is important that the clinicians and their staff familiarize themselves with the Data Collection Form, including the definitions and criteria for data to be entered and the terms used. Proper completion of the Data Collection Form will be reviewed with all

practitioners and staff in the practice. A printed page that lists the criteria for classifying the reasons for placement will be provided to the practice. A number sufficient for each operatory will be provided, and the Project Coordinator staff will assist the practice in placing these water-resistant, plastic-sealed pages in each operatory on the day of training.

**D.4. Criteria for recording reasons for placing the first restoration**

Descriptions will be provided for the reasons to place the first restoration on any permanent tooth surface and the restorative materials employed. The terms used in the descriptions of the reasons for placing the restorations include primary caries, non-carious defects such as abrasion, abfraction, and erosion, as well as stained/unsightly areas and non-carious/traumatic fractures. These terms will be described in conformity with the terms in common use in textbooks, teaching programs and among practicing dentists. They have also been used in similar practice-based studies. In the presumably rare circumstance during the field phase in which the p-is are not clear as to which classification to use for a restoration, the p-is will be encouraged to contact the assigned Project Coordinator for further explanations. Data Collection Forms have been designed specifically for this study, and are attached in the Appendix.

***Primary caries*** is the first caries lesion on a tooth surface, which according to the p-i's diagnosis requires operative intervention and restoration. A variety of techniques are available to diagnose primary caries, including visual inspection, probing, transillumination, and radiographs. The p-is will be asked which technique(s) they used to diagnose the caries, and the estimated depth of the lesion preoperatively and postoperatively. The depth of the lesions will be estimated by the p-is to be in the outer ½ (E1) or inner ½ (E2) of enamel or in the outer ⅓ (D1), middle ⅓ (D2) or inner ⅓ (D3) of dentin.

***Restoration of a non-carious defect*** includes loss of tooth tissue due to abrasion, abfraction, erosion, unsightly area, or due to a fracture that requires restoration.

***Other reasons*** than those listed above should be pooled together under this heading.

**D.5. Criteria for determining which restorative materials to record**

All restorative materials employed will be recorded on the Data Collection Form for this study. The use of base, lining or bonding materials as well as materials used for the final restoration will be recorded. Only the type of material, not brand names, will be reported.

**D.6. Data collection process**

Each p-i should record up to one hundred restorations consecutively placed in the treatment of previously unrestored surfaces of permanent teeth. A total of 100 restoration replacements will likely be done on less than 100 patients. Our estimate is a mean of 60 patients, based on previous studies.

It is realized that it will take some time to complete up to one hundred restorations, depending on the busyness and type of practice. Based on previous studies, we estimate that the typical DPBRN practice will take 4-16 weeks to complete 100 initial restorations on patients who have consented for the project. Our estimate based on previous studies is that about 95% of patients who need restorations will consent to be enrolled in the study. P-is will have up to 16 weeks to complete enrollment of 100 restorations, beginning from the date of the first restoration that is enrolled.

It is essential that ALL restorations placed on previously unrestored surfaces, from small one-surface restorations to single crowns, including temporary restorations, be recorded. This means that initial restorations will be recorded regardless of the reason for the patient's visit. That is, restorations will be recorded on regularly scheduled patients and on patients who show on an 'urgent care' or 'emergency' basis. The data on each patient with a qualifying restoration should be entered on a separate Data Collection Form.

After information on the first 100 restorations has been recorded, the data should be submitted to the DPBRN Regional Coordinator. If the requested number of restorations has not been reached after 16 weeks of enrollment, all data collection should be stopped and the data that have been collected should be sent to the Regional Coordinator. The p-is must keep copies of the forms sent to the Regional Coordinator, and these should become part of the patients' treatment records.

The Data Collection Form is designed in such a manner that a dental assistant may do the actual entry of information by asking the clinician questions. However, it is considered essential that the clinician placing the restoration check the information entered. It is important that the data be entered at the time the restoration is placed and with the patient still in the dental chair.

The Data Collection Form has been pre-tested by the six practitioner-investigator members of the Executive Committee and their staff members. An additional 10 DPBRN practices will finalize pre-testing of the form. Pre-testing is assessing the feasibility of the Data Collection Form in the flow of a busy practice environment, as well as the comprehension and intuitiveness of the classification criteria. The pre-testing phase for each of these groups 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 Data Collection Form.

The data will be sent to the Coordinating Center via two methods. Dental offices in the Permanente Dental Associates group and in the HealthPartners group will enter the data in a secure web-based portal. Dentists in Alabama, Florida, and Scandinavia will mail the completed forms to the Regional Coordinator who will process the forms and forward them to the Coordinating Center.

The signed Informed Consent Form and a copy of the Data Collection Form will be maintained in the patient's chart.

P-is will be remunerated when the forms for 100 qualified restorations have been submitted or at the termination of data collection for the study. Remuneration will be $50 for the first restoration per patient and $20 per restoration completed on the same patient at the same visit thereafter (pending final decision by the DPBRN Executive Committee). Queries from the Coordinating Center regarding illegible or unclear responses must be addressed before any payments will be made. We expect that payments will take up to 4 weeks for processing of paperwork

**D.7. Data management and quality assurance procedures**

Forms sent as hard copy to the Regional Coordinator will be scanned into electronic images and sent to the Coordinating Center. Staff at the Coordinating Center will take the electronic images and professional data entry staff will use a dual monitor system to view the electronic image on one monitor and enter data into a second. They will be organized into identifiable batches for data entry and two 10% samples of forms will be selected. The first will be re-entered by the original data entry technician to determine intra-rater reliability and the second by a different technician for inter-rater reliability. If the discrepancy rate for either re-entry sample is above 0.5%, then the full batch will be re-entered. Re-training may be necessary if unacceptable error rates continue to occur.

All electronic data stored for the study will be located on a secure network drive with severely restricted access. All personnel at the Coordinating Center are required to have current IRB and HIPAA training certification and all must sign confidentiality forms. All paper copies are stored in a secured room.

The data will be stored using the current version of ACCESS or SQL database software packages. The database programming staff will work with the Coordinating Center investigators and Network Chair to make sure that the required systems are available on time and function efficiently.

The final dataset and documentation will be prepared by members of the Coordinating Center statistical consulting unit (SCU). Data analysis will be performed by one member of the SCU and subsequently verified by another, using the SAS® statistical software system.

**D.8. Monitoring recruitment and data collection during the field phase**

A DPBRN Regional Coordinator will be assigned responsibility for the practice. Telephone contact will be initiated with each practice during the first week of their participation in the study with subsequent contact during week 2 and on a monthly basis thereafter. The Regional Coordinator will assess progress in each practice to that date and answer any questions the practice has. This monitoring will also involve asking the practice to FAX or email to the DPBRN Regional Coordinator or staff assigned to the practice a small number of initially completed forms. This will allow the DPBRN Regional Coordinator or staff member to review them for completeness and legibility. Following this review and any necessary discussion with the practice, these faxed or emailed forms will be immediately destroyed. Face-to-face meeting will be held with the practice staff at the discretion of the Regional Coordinator assigned to the practice.

**D.9. Post-baseline plan**

The Specific Aims of this study will be addressed by making use of the cross-sectional nature of the data from this study and Study 1. However, we ultimately envision a longitudinal data collection component from the data from this study. We also envision subsequent DPBRN studies having to do with the longevity of dental restorations placed in Study 2 and Study 3. That is, the restorations placed in this study may comprise

part of the baseline for longevity studies. Patients in this study will understand as part of the Informed Consent process that their restorations may be followed longitudinally in subsequent studies.

**D.10. Study design and statistical analysis**

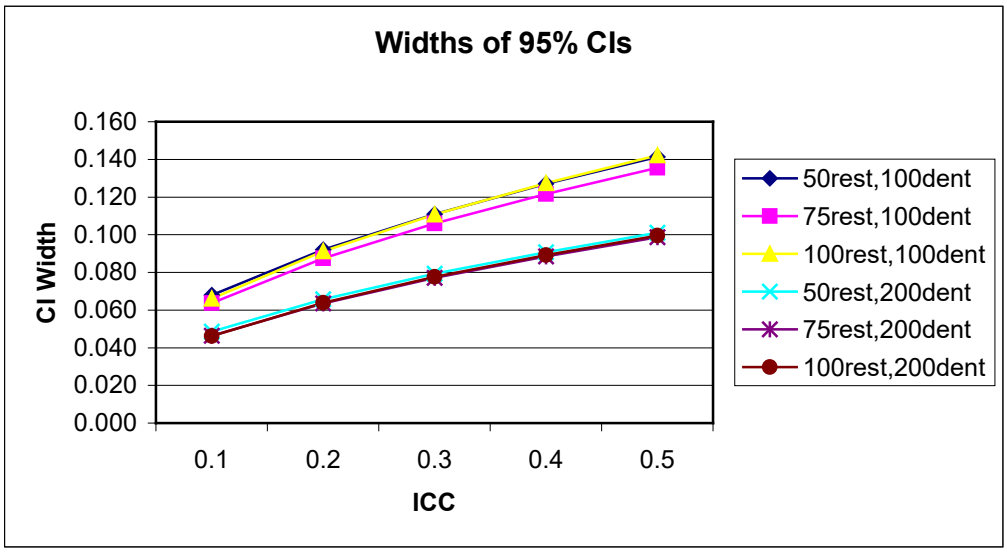
The study design is cross-sectional, with data consisting of responses to questions regarding treatment and material choices made by the participating dentist-practitioners based on 100 consecutive restorations for each of the dentists. A total of 100 dentist-practitioners will be recruited to participate in the study, based on a stratified convenience sampling scheme that will encourage representation of minority dentists, those who serve patient populations with a large number of racial/ethnic minorities, female dentists, and dentists who are geographically proximate to the DPBRN administrative sites.

The statistical analysis for Aims 1 and 2 will consist of calculating point estimates and 95% confidence intervals (CI) for the percentages of lesions and materials, respectively, in each category. Lesion depth will be classified into five categories based on the extent of penetration into the enamel or dentin. The sample size for each percentage and CI will be the number of restorations for lesions at each depth for Aim 1, and the number of restorations using each type of restorative material for Aim 2. The sample size for Aim 3 will be the number of p-i's participating in the study. The lengths of confidence intervals will be adjusted to account for the correlation among multiple observations made by the same dentists by incorporating a variance inflation factor (VIF) into the calculation of the standard error of the estimated percentage. The VIF is calculated as 1 + (average number of observations per dentist) x (intraclass correlation). For calculation of confidence intervals, the variance of the observations is multiplied by the VIF in order to reflect the effect of the clustered observations.

For Aim 3, the proportions of dentists who choose to place a restoration for a lesion that extends into dentin will be compared between the two groups defined by the dentists' response in Study 1 as to whether they wait until caries lesions reach dentin before they place a first restoration. For each dentist, an outcome variable will be calculated reflecting the proportion of restorations that are placed for lesions that reach dentin. This outcome measure will be compared between the two groups defined by the dentists' Study 1 response by means of analysis of variance (ANOVA). Gender and ethnicity will be included in the model to reflect the stratified sampling design. An arcsine transformation may be used to normalize the outcome measures.

**D.11. Power considerations**

Precision of estimation for the percentages defined in Aims 1 and 2 were based on widths of 95% CIs for a percentage of 50%, based on normal approximation, and adjusted for clusters of size 50, 75 and 100, corresponding to the number of restorations per dentist. An estimated percentage of 50% was used for these calculations, as this yields the widest CI, and thus the most conservative estimate of precision. The figure shows the widths of CIs for sample sizes of 100 and 200 dentists, with 50, 75 or 100 restorations observed per dentist, and ICC values of 0.10 to 0.50. With a sample size of 50 restorations for each of 100 dentists, the CI width for an estimated percentage of 50% ranges from 6.8% for ICC = 0.10 to 14.1% for ICC = 0.50. If each of 100 dentists contributes 100 restorations to the sample, then the CI width ranges from 6.6% to 14.2% for ICC values of 0.10 to 0.50. Increasing the number of dentists to 200 yields higher precision for the same total number of observations. With ICC = 0.10, and using 50 restorations per dentist and 200 dentists, the resulting 10,000 observations yields a CI of width 4.9%, compared to the width of 6.6% that results from the same total number of observations, but using 100 restorations from each of 100 dentists. The following graph illustrates the available precision for sample sizes of 100 and 200 dentists, with 50, 75 and 100 restorations observed per dentist, and ICC values of 0.10 to 0.50. As is clear from the graph, the precision depends more strongly on the number of dentists and the ICC than on the number of restorations per dentist.




Power for the hypothesis test specified in Aim 3 was estimated based on a t test comparing the average proportions of restorations placed by each dentist, assuming equal allocation of respondents between the two categories (whether or not they state in Study 1 that they wait until lesions reach dentin before restoration) and estimating power to detect a difference from 50% in one of the categories of the other variable. Alpha was set at 0.05. The sample size for this hypothesis test is the number of dentists. The average proportions for the individual dentists were assumed to be distributed uniformly between 0 and 1 in order to obtain a conservative power estimate. Thus, the standard deviation assumed for these power estimates is 0.29. A sample size of 100 dentists would yield 80% power to detect a difference in mean proportions of approximately 0.182, or 18.2%. A sample size of 200 dentists would yield 80% power to detect a difference of approximately 0.128, or 12.8%. More generally, fifty dentists per group (N = 100) would provide 80% power to detect a difference equal to 0.625 times the standard deviation of the observations, and 100 dentists per group (N = 200) would provide 80% power to detect a difference equal to 0.439 times the standard deviation.

## E. HUMAN SUBJECTS RESEARCH

### E.1. Risks to the patients and health care providers

**Human subjects' involvement and characteristics**. This protocol involves human subjects. The human subjects directly involved in this study are the patients who have sought dental treatment in the p-is' practices. The p-i's will be recruited from the clinicians enrolled in the Dental PBRN who have completed Study 1 and meet the eligibility criteria specific to this protocol. The p-is will consecutively record the restorative treatment they provide to the patients who provide informed consent and who thereby become subjects in this study. Because restoration data will be linked to characteristics of the p-is and their practices, comparisons will be made across practices and by practice characteristics. Participating in the data collection and returning Data Collection Forms will constitute consent by the p-is.

**Sources of materials.** Data will be obtained from the Data Collection Forms that each p-i completes. These forms represent 100 consecutive restorations, which may or may not derive from 100 consecutive patients. Data on restorations will also be linked to responses that practitioners provided in the Study 1 questionnaire, as well as data that practitioners completed for the DPBRN enrollment questionnaire.

**Potential risks.** The only risk to the p-is and their patients will be the highly unlikely accidental disclosure of health care provider and patients' dental restorative information. However, every precaution will be taken to prevent such disclosures and the DPBRN has an unblemished track record in this regard. No experimental techniques or materials will be used and the burden on the patients, clinicians and dental office staff, will be the same as that experienced as part of regular dental treatment, except that an Informed Consent Form and Data Collection Form will be completed for each patient/subject in the study. Information on the restorations placed will be entered on a Data Collection Form specially designed for this study. The treatment sessions will, therefore, be slightly longer in order to record on these forms the treatment that was provided.

The Data Collection Forms will be coded, kept confidential, and will be stored in a secure place. The Dental PBRN Executive Committee has closely reviewed the research protocol at each stage of its development, has closely reviewed and pre-tested the data collection forms, and has provided its unanimous endorsement of the study, the protocol text, and the data collection forms. The Dental PBRN Executive Committee voting members comprise six representative dentists in full-time private practice from across the DPBRN, the NIDCR representative (Dr. Bruce Pihlstrom), the Network co-Chair (Dr. Gregg Gilbert), and the Coordinating Center Principal Investigator (Dr. Dale Williams). The other Network co-Chair (Dr. Ivar Mjör) serves as a non-voting president of the Executive Committee.

**E.2. Adequacy of protection against risk**

**Recruitment and informed consent.** We will provide the p-is and their patients 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. A specially designed Informed Consent Form will be explained to the patient by the p-is. After assurance that the information provided is understood by the patient the patient and p-i both sign the form, which then becomes part of the patient's treatment record.

**Protection against risks.** Records 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. All personnel with access to this information have been certified in human subjects research and HIPAA regulations. This information will not be sold or used for any reason other than research. Results will 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**

P-is will benefit from the opportunity to reflect their views on caries treatment and gain information on the practice methods of their peers. The p-is will also benefit from a better understanding of how the diagnosis and treatment of dental caries may influence patients' long-term treatment. The indirect benefit to the patients may be the ultimate improvements in dental restorative treatment in daily clinical practice. The potential benefits to the p-is and indirectly to their patients will far exceed the risk involved with the participation. The p-is will charge their normal fees for the treatment provided.

Subjects will not be paid for their participation. DPBRN p-is will be remunerated $50 for the first restoration per subject enrolled and $20 for each additional restoration completed on the same patient at the same visit (pending final decision by the DPBRN Executive Committee), after having returned completed forms for 100 restorations and after having responded to a possible query from the Regional Coordinator or Coordinating Center to verify illegible or unclear responses. P-is in the PDA and HP organizations will not receive payment directly. Instead, a single lump sum payment will be paid to their organizations and this payment will indirectly contribute to remuneration.

**E.4. Importance of the knowledge to be gained**

The knowledge to be gained from the current study will quantify the reasons that restorations are done on previously un-restored permanent tooth surfaces. When the results of this study become available, comparisons can be made with responses provided for Study 1.

**E.5. Inclusion of women**

Both genders will be eligible to enroll. The percentage of practicing dentists in 2003 by gender was 18% female and 82% male (ADA 2003). In Scandinavia the ratio of female: male clinician is about 50:50. Based on the enrollment questionnaires completed by US DPBRN dentists, 14% are females. We anticipate that our targeting of this group during recruitment will yield a sample of 20% female dentists for this study. We anticipate that approximately 55% of the patients enrolled will be female.

**E.6. Inclusion of minorities**

Racial and ethnic minorities will be included in the study at least 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 the first Targeted/Planned Enrollment table later in this application. Because minority practitioners and practices that serve high percentages of minority patients will be targeted in Alabama and Florida, we anticipate that approximately 20% of the subjects in this study will be of a racial/ethnic minority group.

**E.7. Information to be provided for all clinical research studies**

The p-is who participate in this study will be dental practitioners who participated in Study 1 and meet the other eligibility criteria. The patients will be given an explanation of what the study entails and they will also sign an informed consent to participate. No gender or racial/ethnic group will be excluded. Our anticipated enrollment for patients is shown in the Targeted/Planned Enrollment table later in this application.

**E.8. Inclusion of children**

This study is designed to investigate the reasons for placement of the first restoration on a permanent tooth surface by DPBRN p-is. The age of the patients will depend on the dental practice; some p-is restrict their practices to the treatment of adults only, some have ‘family type’ practices, and some practices treat children and adolescents only. Because recruitment will be limited to permanent teeth, patients will need to have at least one permanent tooth in need of an initial restoration to be eligible. This means that subjects will be at least 6 years old because that is when the permanent first molar typically erupts. Parents/guardians of child subjects will provide the informed consent, although study participation also requires the child's assent.

## *Targeted/Planned Enrollment Table (for the dentist participants)*

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

**Study Title:** Reasons for placing the first restoration on permanent tooth surface(s)

**Total Planned Enrollment:** 100 DPBRN dentists (who treat 6,000 patients) †

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 2 | 3 | 5 |
| Not Hispanic or Latino | 18 | 77 | 95 |
| **Ethnic Category: Total of All Subjects *** | 20 | 80 | 100 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 1 | 1 | 2 |
| Asian | 1 | 1 | 2 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 2 | 8 | 10 |
| White | 17 | 69 | 86 |
| **Racial Categories: Total of All Subjects *** | 20 | 80 | 100 |

† We project that the 10,000 restorations (100 dentists each doing 100 restorations) will comprise 100 dentists performing treatment on 6,000 different patients.

The gender and racial and ethnic distribution of dental practitioners expected to participate in the study reflects the proportional distribution shown in the Targeted/Planned Enrollment for DPBRN Study 1 and the result of planned Study 2 targeting of dentists who are female and/or of a racial/ethnic minority.

## *Targeted/Planned Enrollment Table (for the patients participating)*

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

**Study Title:** Reasons for placing the first restoration on permanent tooth surface(s)

**Total Planned Enrollment:** 6,000 patients (treated by 100 dentists) †

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 330 | 270 | 600 |
| Not Hispanic or Latino | 2970 | 2430 | 5400 |
| **Ethnic Category: Total of All Subjects *** | 3300 | 2700 | 6000 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 33 | 27 | 60 |
| Asian | 66 | 54 | 120 |
| Native Hawaiian or Other Pacific Islander | 33 | 27 | 60 |
| Black or African American | 528 | 432 | 960 |
| White | 2640 | 2160 | 4800 |
| **Racial Categories: Total of All Subjects *** | 3300 | 2700 | 6000 |

† We project that the 10,000 restorations (100 dentists each doing 100 restorations) will comprise 100 dentists performing treatment on 6,000 different patients.

Because minority practitioners and practices that serve high percentages of minority patients will be targeted in Alabama and Florida, we anticipate that approximately 20% of the subjects in this study will be of a racial/ethnic minority group.

## F. VERTEBRATE ANIMALS

N/A

## G. LITERATURE CITED

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