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 www.DentalPBRN.org.

This study will be the DPBRN's third network-wide study, each of which has dealt with some aspect of restorative dentistry. Study 1 was a questionnaire related to DPBRN clinicians' practices regarding caries diagnosis and treatment. Study 2 focused on the reason(s) for placing the first restoration in any previously unrestored permanent tooth surface(s). This third study will deal with the reason(s) for replacement and repair of defective existing dental restorations. 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. Subsequent studies in the series on restorations in general dental practice will deal with the gradual degradation of restorations and development of defects on 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 and baseline for subsequent studies, but they will also form a foundation for monitoring changes that may occur in restorative therapy and treatment patterns over time.

The aims of the present study are to quantify the different reasons for replacement or repair of defective restorations in general dental practice and to record the restorative material of the failed restoration and the material used in the ‘replacement restorations’. The study is largely descriptive in nature and it provides cross- sectional information about the restorative treatment received by patients in DPBRN practices. Since this project is a practice-based study, restorative dentistry in a ‘real life’ situation will be recorded. The clinicians involved in these studies are referred to as practitioner-investigators (p-is).

Descriptions will be provided for common reasons for failure of the restorations, including secondary/recurrent caries, fracture and discoloration of restorations and ‘other reasons’. The terms employed in the descriptions are in common use in textbooks, teaching programs, and among practicing dentists. They have also been used in certain prior practice-based studies. The p-is will be given explanations of the classification terms used in this study.

The present study does not intend, in any way, to influence when or why restorations are replaced or repaired. It is recognized that some clinicians replace defective restorations without consideration of repair as an alternative treatment for defective restorations. Furthermore, the clinical technique and the selection of materials used to restore the teeth are entirely up to the clinicians involved. The information regarding treatment for defective restorations in general dental practice will provide the opportunity to record not only the diversity in the treatment provided, but also to generate information for subsequent hypothesis testing studies that the DPBRN envisions in the future. The results will also be related to the findings from Study 1 where the p-is’ practices regarding caries diagnosis and treatment were recorded.

A. Specific Aims:

Specific Aim 1: To quantify the prevalence of reason(s) for replacing existing restorations in DPBRN practices.

Specific Aim 2: To quantify the percentages and types of restorative materials of failed restorations that are being replaced in DPBRN practices.

Specific Aim 3: To quantify the percentages and types of restorative materials used to replace or repair failed restorations in DPBRN practices.

Specific Aim 4: To test the hypothesis that dentists who reported, in Study 1, that they treat enamel lesions operatively are more likely in a clinical scenario, as in this study, to replace entire restorations rather than do repairs, and are more likely to report the clinical diagnosis of secondary caries as a reason for replacement.

B. Background and Significance

B. 1. Understanding why restorations fail in DPBRN practices

Without a thorough understanding of the reasons for failure of restorations, it is unlikely that improvements in restorative therapy can be achieved. Because approximately half of all restorations placed on adults are done to replace failed restorations, it is important to analyze the reasons for replacements and to quantify this prevalence in DPBRN practices.

Restorations are replaced for a number of reasons, which may be divided into three major groups (Löe, 1995; Hickel and Manhart, 2001): 1. Clinician effects, 2. Material properties and 3. Patient factors. Each of these groups may be further subdivided, but irrespective of how the failure is categorized, it is often difficult to identify which factor plays the most important role in the failure. Sometimes a combination of factors may be the cause of the failure, although clinicians rarely record more than one reason for replacement of restorations.

B.2. It is important to quantify the prevalence of repair as well as total replacement among DPBRN practices.

Most failures of restorations occur gradually, but abrupt failures may also occur, e. g., bulk fracture of a restoration. The recognition of defects does not necessarily coincide with the failure of restorations to an extent that it will cause damage to the teeth involved and require immediate replacement of the restoration. Defects that develop gradually suggest that there may be treatments other than replacement of restorations at certain stages, including repair and refurbishing of defects (Mjör, 1993; Gordan, 2000, 2001; Gordan et al., 2003; Blum et al., 2003), especially if the defect is localized.

A shift in the proportion of primary and replacement restorations has occurred over time. Replacement restorations reported in practice-based studies on adults in Scandinavia 25 years ago comprised about 75% of all restorations inserted (Mjör, 1981) while more recent studies show that about 50% were replacements (Mjör et al., 2000; 2002). Data from general dental practices in the US have shown that between 54% and 60% of all restorations were replacement restorations (Klausner et a., 1987; Pink et al., 1994; Mjör and Moorhead, 1998, McDaniel et al., 2000).

B. 3. "Age of restoration at replacement" and "longevity" must be distinguished when looking to make long-term improvements in dental care

The “age of restorations at replacement” and “longevity of restorations” are somewhat different parameters. Whenever a restoration is replaced, irrespective of the reason, and the patient’s treatment record is available to show the date when the restoration was originally placed, the age of the restoration to be replaced may be noted, irrespective of who placed the restoration. The longevity of restorations refers to the age of all restorations, including those that had not failed at a given time (Jokstad et al., 1994).

Conclusions about practices' restoration longevity might be strongly influenced by clinicians' threshold for replacing restorations that they consider "defective". The reasons for replacement of restorations are intimately linked to the longevity of restorations, which is a major component in estimates of the long-term cost of restorative treatment (Mjör, 1992), and that will have an effect on the longevity of the dentition as well because successively replaced restorations become larger and larger with each replacement.

If dentists have a low threshold for replacing a restoration, then the longevity of restorations will be shorter. Although dependent on the type of restoration, the short-term and long-term treatment costs vary considerably depending on the materials used. Variations in dentists’ treatment decisions also have marked cost implications (Shugars and Bader, 1996). A better understanding of the reasons for failure of restorations may lead to improvements in the longevity of restorations and, therefore, it may have an effect on the total cost for restorative work needed during the individuals’ lifetime. Alternative treatments to replacement of restorations will also be studied. Thus, repair of restorations has been made an option for the treatment of localized defects and refurbishing of surfaces, including polishing of margins, may be alternative treatments to replacement. The aim is not only to increase the longevity of restorations, but also to save tooth structure, especially if tooth-colored restorative materials have been employed (Gordan, 2000, 2001; Mjör and Gordan, 2002; Gordan et al., 2003, 2004; Moncado et al., 2005). Saving tooth structure is considered a major quality improvement in restorative dentistry.

B. 4. Techniques used to diagnose restoration defects are varied

The clinical techniques available to diagnose defects on restorations are limited. Visual examination and probing by an explorer are the two main techniques in common use, often supplemented by radiography. The advantages of radiography are hampered by the radiopacity of the restorative material, which may be either too much, resulting in a "shadowing" effect if the angulation of the x-rays is not favorable, or too little to give adequate contrast (Tveit and Espelid, 1992). However, under favorable conditions radiography may be useful in diagnosing secondary caries at the gingival cavosurface margins of proximal surfaces of restorations (Tveit et al., 1991). Pain and tooth sensitivity may also be associated with defective restorations, for example due to the presence of crevices between the tooth and the restoration. Stress on a tooth caused by contraction of a bonded resin based restorative material may also cause pain shortly after the restoration has been placed.

Some failures are easy to diagnose. For example, loss of a restoration or bulk fracture of a restoration where part of the restoration is lost, fracture of part of the tooth adjacent to a restoration, and poor anatomic form are easily diagnosed; in fact, bulk fracture and loss of part of or the entire restoration is often diagnosed by the patient and may be the reason for seeking dental treatment. Lack of optimal contacts with neighboring teeth and overhangs on restorations may be the result of the use of less-than-optimal clinical techniques and are often of iatrogenic origin. They may also lead to periodontal disease. It has long been recognized that operator faults are common (Healey and Phillips, 1949). It is likely that the more technique sensitive the restorative procedure, the higher the frequency of iatrogenic problems. The increasingly common and extended use of composite restorations may enhance the importance of these problems. Therefore, a large number of clinicians must be involved to obtain a full range of the potential defects.

With the increase in use of tooth-colored restorative materials, restoration discoloration may be an increasing reason for replacement and subsequent removal of additional tooth structure. Tooth-colored materials may become discolored either at the tooth/restoration margin or the bulk of the restoration becomes discolored causing a shade mismatch between the tooth and the restoration. Bulk discoloration may be by superficial extrinsic stains or it may be intrinsic, which is usually a material defect. The degree of discoloration is subjectively judged. Discoloration of deeper tissues, including carious dentin left behind during cavity preparation or amalgam staining may also be seen through the translucent enamel (Mjör and Toffenetti, 2000).

Degradation of restorative materials, which may be enhanced by wear and low pH in vivo, requires the attention of dental manufacturers to improve the quality of the material. Inadequate oral hygiene and habits like bruxism are patient factors that play a role in the failure of restorations. Provided the clinically diagnosed secondary caries is similar to primary caries, the patients' oral hygiene and access to fluorides, for example via toothpaste, is likely to be effective. Conversely, if the clinical diagnosis of secondary caries comprise restoration defects as well as caries (Mjör, 2005), it is unlikely that oral hygiene and access to fluorides will play the same role as it does for primary caries

B. 5. Monitoring defects at the margins of restorations may provide an opportunity to extend the longevity of a restoration

A number of different types of defects are located at the margin of restorations, including secondary caries, non-carious but degraded or "ditched" margins, marginal fractures and marginal discoloration of restorations. Some of these are found in specific locations. Thus, ditching is a characteristic of the occlusal part of restorations where secondary caries rarely develops. Secondary caries, on the other hand, is usually diagnosed gingivally (Mjör, 1985; Mjör and Qvist, 1997). These marginal defects are difficult to differentially diagnose on tooth-colored restorations (Tyas, 1991, Kidd et al., 1995; Kidd and Beighton, 1996).

It is recognized that while a few restorations may fail immediately after they were placed, most restorations last for some time prior to failure. Thus, stages prior to complete failure of restorations may allow some clinical action to be instituted to prevent further damage. It is also possible that some defects may reach a certain stage that does not compromise the tooth and no further degradation will occur. No investigations have focused on the monitoring of defects to study their ultimate fate, but such studies are in progress (Gordan et al., 2005; Moncado et al., 2005). Actions like repair, refurbishing and monitoring will, therefore, under well-defined conditions, be suggested as alternative treatments to complete

replacement of restorations that are failing. However, in this study it will be left entirely up to the clinicians to select the most appropriate treatment for failed and failing restorations.

B. 6. Preventive approaches have not targeted the clinical diagnosis of secondary ("recurrent") caries lesions

Preventive approaches are predominantly used to address primary caries. Early stages of caries lesions may be arrested or “healed”, but when preventive measures are not undertaken or fail and active caries develops, dental restorations may need to be placed to avoid further destruction of the tooth. However, such preventive measures have only been applied to primary caries lesions. 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). Toothpaste is a common source of fluoride. Monitoring incipient enamel lesions to assess their development is a recognized clinical approach for primary caries lesions, but this approach is not common for secondary caries lesions. Additionally, preliminary results from an unpublished study among general practitioners in Florida indicate that variations also exist among clinicians in practice and that they treat lesions operatively at an earlier stage in the development of the lesions than what is taught in the majority of dental schools.

Risk factors for primary caries have been identified. 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 the presence of 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). Again, these factors have only been associated with primary caries lesions and have not been related to secondary caries, despite the fact that the diagnosis of secondary caries is by far the most common reason for replacement of restorations in general dental practice.

B.7. The treatment of secondary caries is a salient issue in daily clinical practice, and therefore, for the DPBRN.

The diagnosis of secondary caries is vaguely described in textbooks and in teaching programs in cariology and in operative dentistry (Clark and Mjör, 2001). Treatment planning, including secondary caries diagnosis, must take several factors into consideration, including the patient’s condition and preferences (Ismail and Bader, 2004), although the clinical diagnosis of secondary caries has been challenged as it also comprises defects other than carious defects (Mjör, 2005).

The clinical diagnosis of secondary caries is ill defined and prone to practitioner variation due to differences in dentist thresholds for replacing a restoration. The diversity in clinical diagnosis of secondary caries is astounding (Merrett and Elderton, 1984; Espelid and Tveit, 1991; Bader and Shugars, 1992; Özer and Thylstrup, 1995). The great variations noted may be an indication not only that the diagnosis is ill defined, but also that what is clinically diagnosed as secondary caries, may not actually be caries lesions. Some of the lesions may not call for any immediate clinical action. It is important to recognize possible misdiagnoses in the large number of clinically diagnosed secondary caries lesions as shown in cross-sectional practice-based studies. Secondary caries has been the major reason for replacement of restorations in adults ever since the early days of operative dentistry (Black, 1918), but its nature, possible prevention and treatment has largely remained uninvestigated.

Studies of the location of secondary caries indicate that it is primarily diagnosed gingivally, and it is rarely diagnosed occlusally (Mjör, 1985; Mjör and Qvist, 1997). Both the location and the diagnostic technique may be important for the analysis of the nature or mechanism of how the defect was initiated and progressed, e.g., even minute gingival proximal overhangs may also be associated with plaque accumulation at the gingival cavosurface margin of restorations and may lead to secondary caries lesions because it predisposes to plaque accumulation (Özer, 1997).

The clinical diagnosis of secondary caries is the most common reason for replacement of restorations as recorded in cross-sectional studies in general dental practice (Dahl and Eriksen, 1978; Mjör, 1981; Klausner et al., 1987; Qvist et al., 1990a,b; Pink et al, 1994; Mjör et al., 2000). Traditionally, this diagnosis invariably leads to replacement of restorations. Practice-based observations suggest that the diagnosis of secondary caries is ill defined (Mjör and Toffenetti, 2000; Mjör, 2005) and numerous studies have shown great variations between clinicians in diagnosing secondary caries (Merrett and Elderton, 1984; Espelid

and Tveit, 1991; Tveit and Espelid, 1992; Bader and Shugars, 1992; Clark and Mjör, 2001; Setcos et al., 2004). Teaching programs in cariology in North America are equally diverse in their teaching related to the clinical diagnosis of secondary caries (Yorty and Brown, 1999; Clark and Mjör, 2001).

Secondary caries must be differentiated from remaining caries (Fitzgerald et al. 1994). Remaining caries represents caries left behind during the previous restorative procedure. It is usually not found until the restoration has been removed, but if it becomes active and grows in size or if it is fairly extensive from the onset, it may be detected radiographically. It may be discolored and if it is located close to the enamel, the area of the tooth may take on a bluish-gray hue (Mjör and Toffenetti, 2000). Initial, sub-clinical lesions left at the margin of a cavity preparation, e. g., a white spot lesion, may also continue to develop and be the start of a lesion that may be recorded as a secondary lesion while it is, in fact, a primary lesion. Considerations to the prevention of secondary caries were at the center of attention during the early development of restorative dentistry and it led to Black's "extension for prevention" principle for cavity preparation. This principle is still widely taught and practiced today. However, characterization of secondary caries diagnosed clinically has received little attention (Mjör, 2005).

Surveys of the teaching and practice of the clinical diagnosis of secondary caries at dental schools is inconsistent and confusing (Yorty and Brown, 1999; Clark and Mjör, 2001). Furthermore, this diagnosis has been linked to "microleakage" with minimal clinical data and no relevant scientific evidence. The diagnosis appears to be used whenever a defect at the margin of a restoration results in an "explorer catch" (Mjör & Toffenetti, 2000; Mjör, 2005). The suggested misdiagnosis of marginal defects as secondary caries is substantiated by findings that fluorides leaching from restorative materials have no effect on the clinical diagnosis of secondary caries in general dental practice contrary to expectations (Mjör, 1997; Mjör et al., 2000), although the fluoride does have an effect on primary caries on the adjacent teeth (Qvist et al., 1997). This issue has been further confused by in vitro studies where a fluoride effect was demonstrated on "secondary caries" (Swift, 1989), which is demineralized dental tissue rather than caries lesions. Not even in xerostomic patients could the prevention of secondary caries be demonstrated in patients that were categorized as fluoride users, i. e., those that showed greater than 50% compliance to the fluoride regimen prescribed, since the fluoride non-users showed some improvements from materials leaching fluorides (McComb et al., 2002).

B. 8. Understanding which restorative materials are being used in DPBRN practices is salient to designing subsequent interventions to improve restoration longevity

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. They 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 than directly placed restorations at the time of placement, but the long term cost may not be much different from that of tooth-colored direct restorations (Mjör, 1992). Amalgams and resin-based composites have, up until the present time, been the most commonly used restorative materials.

The selection of restorative materials depends on factors like the size of the restoration, the over-all 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, Qvist and Mjör, 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).

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 quality of resin-based materials has also gradually improved over the last 30 years. In addition, a general biological awareness in society at large has turned against amalgam because of the “mercury issue”. In addition the teaching of resin-based restorations, which lagged behind the use of the materials in general practice, has improved (Mjör and Wilson, 1998; Wilson and Mjör, 2000).

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 has occurred as in other developed countries (Mjör and Moorhead, 1998). In some parts of Scandinavia the use of amalgam represents less than 10% of all restorations inserted (Grimmestad et al., 2004) and in some areas and practices amalgam is not in use any more. The shift towards resin-based materials has had an impact on the short and long term cost of restorative dental care, but little information is available to monitor the changes (Mjör, 1992; Mjör and Moorhead, 1998).

The size and location of the restoration is also important for the long-term outcome of restorative treatment (Maryniuk, 1984) and “replacement restorations” are generally larger than the failed restoration. Large, complex amalgam restorations tend to fail more readily due to fracture, especially tooth fracture, than due to secondary caries (McDaniel et al., 2000).

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. Published fee schedules in the US are largely based on the number of surfaces involved and the restorative materials used (Anderson, 1994; McCann, 2004). 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 the treatments (Mjör, 1992). 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.

C. PRELIMINARY STUDIES

C.1. Studies preceding this DPBRN Study

Data from previous studies on dental restorations authored by the faculty of the DPBRN have been referred to in this protocol. First-hand data are therefore available for comparison with the data obtained in this study from DPBRN practices. In addition, preliminary data from a study of the practice of cariology among almost 300 clinicians in private practice in Florida is available. These results and the data from Study 1, which will be available by the time of data collection for Study 2 and this study, will allow comparison with the clinically recorded data.

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. These investigators have now joined forces in a collaborative, well-integrated entity now called the DPBRN.

D. Research Plan

D.1. Study population

This study will involve p-is enrolled in the DPBRN and having additional education and training in human subjects protection.

D.2. Selection process

A total of 200 DPBRN p-i's will be enrolled in this study. They must all have completed Study 1 and may or may not have participated in Study 2. Based on information that the DPBRN dentists provided in their enrollment questionnaires, only dentists who reported that they do at least some restorative dentistry will have participated in Study 1.

Two hundred dentists will be selected for participation based on participation in Study 2 or other targeted criteria: (1) they are racial/ethnic minority dentists or they serve patient populations with a substantial proportion of racial/ethnic minorities; (2) they are female dentists; or (3) they are geographically proximate to the administrative sites for each of the DPBRN regions.

D.3. Discussion of study protocol with practices

Before any data collection begins by a p-i, DPBRN Project Coordinating staff will have a face-to-face meeting with that participating p-i and their staff 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 there is 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 participating 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 participating practitioners and staff in the practice. Printed material on filling out the forms will also be provided. If a p-i participated in Study 2, this in-office meeting may be omitted, since an in-office training was provided for Study 2.

D.4. Criteria for classifying the treatment of the failed restoration

This section describes definitions of terms that will be used as part of the data collection process.

Replacement of complete restoration denotes removal of the existing restoration and any adjacent pathologically altered and discolored tooth tissue that is esthetically unacceptable.

Repair of restoration involves removal of part of the restoration and any adjacent pathologically altered as well as discolored tooth tissue that is esthetically unacceptable followed by placement of restorative material in the prepared site. Repair can also include light grinding and polishing, removal of overhangs, polishing discolored tooth-colored restorations, or sealing margins. Functioning restorations that have not failed but are replaced to become part of a larger restoration are not recorded as replacements.

D. 5. Criteria for recording why a restoration is being replaced or repaired

Only the main reason for replacement or repair of a restoration will be noted.

Secondary/recurrent caries is a lesion detected at the margin of an existing restoration. The lesion should have the same characteristics as primary caries lesions. At the pre-cavitation stage it may appear as a “white spot lesion“ if the cavosurface margin is in enamel. More advanced lesions will show variable discoloration from white to dark and the margin may have crumbled leading to frank cavitation. If the lesion may be visually inspected and reaches into dentin, it will, in its active stage, be soft, have a yellow/light brown discoloration, and present a wet appearance. Inactive/arrested dentin lesions are hard, discolored brown/dark brown, and appear dry. Secondary caries must be differentiated from caries left behind during the previous restorative procedure. This “remaining caries” is usually diagnosed after the restoration is removed and, if discolored, it may appear as a bluish-gray hue through the transparent enamel. It may also be seen radiographically as a demineralized zone under a restoration. If it is located at the margin it may be misdiagnosed as a secondary caries lesion even though it may have been left behind during a cavity preparation.

Bulk fracture of a restoration includes isthmus fracture or any fracture through the body of the restoration or the marginal ridge, but with the restoration still in place.

Restoration marginal fracture is often referred to as “ditching” of restorations. Only those restorations with marginal fractures or degraded margins, but without caries, should be recorded in this category of failure.

Bulk discoloration includes any mismatch between the color of the body of a tooth-colored restoration and the tooth that leads to replacement of the restoration.

Marginal discoloration leading to replacement of a restoration is found at the tooth/restoration interface. Stained margins must be differentiated from carious margins by not having the characteristics listed for active caries.

Lost restoration is recorded when either all of the restoration or a major part of it is missing due to lack of retention

***Tooth fracture** is* any kind of tooth fracture adjacent to a restoration, for example the fracture of a cusp or of an enamel margin. This classification allows tooth fractures to be distinguished from restoration fractures.

Poor anatomic form as a diagnosis for replacement of a restoration includes any inadequate morphology such as improper contact to neighboring or opposing teeth or restorations and loss of restorative material due to degradation and/or functional wear.

Pain/sensitivity of any kind requiring replacement of a restoration is listed under this category. It may be the sole reason for replacement or it may occur in addition to other reasons, such as secondary caries lesions or fractured tooth or restoration, in which case both reasons should be recorded.

Change material is used to denote replacement of serviceable and functional restorations where the change of the restorative material was the reason for the replacement, not because the restoration failed.

Patient request includes replacement of a restoration, which the practitioner feels is at least in the range of acceptability, due to color, morphology, restorative material, or other reasons leading to patient dissatisfaction with the restoration.

Other reasons include any other reasons for replacement / repair of restorations than those listed above.

If a serviceable or intact restoration is replaced because it is incorporated into a larger restoration, this is not recorded as a failure. An example would be the removal of an intact occlusal Class I restoration so that it can become part of a Class II restoration.

D.6. Data collection process

Each p-i should record up to fifty consecutive replaced/ repaired restorations. A total of 50 restoration replacements/ repairs will likely be done on less than 50 patients. Our estimate is a mean of 30 patients, based on previous studies.

It is realized that it will take some time to complete up to fifty replaced / repaired 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 50 replaced/ repaired restorations on patients who have consented to participate in the project. Our estimate, based on previous studies, is that about 95% of patients who need restoration replacement / repair will consent to be enrolled in the study. It is realized that it will take some time to complete up to 50 restorations, depending on the busyness and type of practice. Because this is a consecutive restoration study, enrollment will continue for each p-i until data collection on 50 eligible restorations has been completed, it has been determined that data collection should end because of the p-i's lack of full compliance with the study protocol, or because the DPBRN at large has met its recruitment goal.

If it is not possible to recruit 200 dentists, fewer than 200 dentists will be recruited, with each dentist enrolling more than 50 restorations in the study, such that the total number of restorations enrolled would still be 10,000 (e.g., 200 times 50, or 100 times 100).

It is essential that ALL restorations replaced/ repaired, from small one-surface restorations to single crowns, including temporary restorations, be recorded. This means that replaced/ repaired 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 participating patient should be entered on a separate Data Collection Form.

As information on the 50 restorations has been completed, the Data Collection Forms will be submitted to the DPBRN Regional Coordinator. If the requested number of restorations has not been reached after 16 weeks of enrollment, an evaluation will be made, by the Regional Coordinator, of the compliance by the p-I to determine if collection should continue or be terminated for that p-i.

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 or repaired and with the patient still in the dental chair.

The Data Collection Form has been pilot-tested by the practitioner-investigator members of the Executive Committee and their staff members. Pilot-testing will consist of assessing the feasibility of the form in the flow a busy practice environment, as well as the comprehension and intuitiveness of the

classification criteria. The data will be sent to the CC 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 CC.

The signed Informed Consent Form will be maintained in a secure research folder. The Data Collection Form will be sent to the Regional Coordinator for transmission to the Data Management Center. Both forms will be stored according to HIPAA regulations.

P-is will be remunerated when the forms for 50 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 $25 per restoration placement or repair completed on the same patient at the same visit. 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. 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 access progress in that 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.8. Post-baseline plan

There is a longitudinal data collection component from the data from this study. That is, the patients will consent to have the restorations replaced or repaired in this study considered to be baseline restorations for longevity studies. Patients in this study will understand as part of the Informed Consent process that their restorations will be followed longitudinally in DPBRN Study 5.

D.9. Study design and statistical analysis

The study design is a cross-sectional study, with data consisting of responses to questions regarding treatment and material choices made by the participating dentist-practitioners based on 50 consecutive replaced / repaired restorations for each of the dentists. Approximately 200 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.

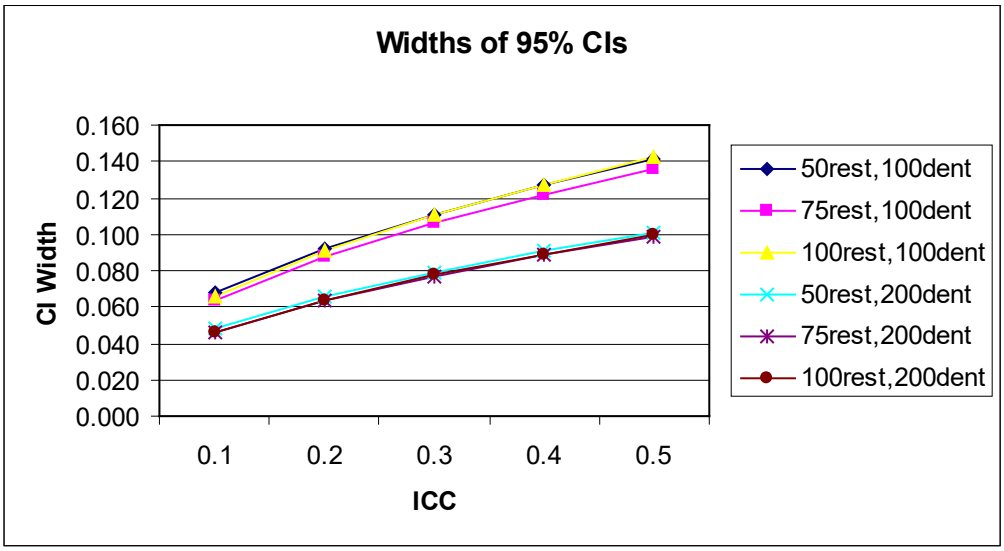
The statistical analysis for Aims 1, 2, and 3 will consist of calculating point estimates and 95% confidence intervals (CI) for the percentages of restorations in each category. The sample size for each percentage and CI will be the number of restorations for the specific type of restorative material. The lengths of the 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 4, the proportions of dentists who choose to (a) replace the entire restoration and (b) report the clinical diagnosis of secondary caries will be compared between the two groups defined by the

dentists' response in Study 1 as to whether they treat enamel lesions operatively. For each dentist, two outcome variables will be calculating reflecting (1) the proportion of restorations that they completely replace in this study, and (2) the proportion of restorations to which they assign the diagnosis of secondary caries in this study. These outcome measures 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. The initial analysis will be a multivariate ANOVA in order to appropriately incorporate the correlation between the two outcome measures. Univariate-outcome ANOVA models will follow this analysis for each of the two dependent variables. An arcsine transformation may be used to normalize the outcome measures.

D.10. Power considerations

Precision of estimation for the percentages defined in Aims 1, 2, and 3 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 treated 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 restorations treated. 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 4 was estimated based on a t test comparing the average proportions of restorations replaced by each dentist, assuming equal allocation of respondents between the two categories (whether or not they state in Study 1 that they treat enamel lesions operatively) and estimating power to detect a difference from 50% in one of the categories of the other variable. Alpha was set at 0.025 to account for the use of two dependent variables. The sample size for this hypothesis test is the number of dentists. Since no estimates of the standard deviation of the average

proportion of restorations replaced are available, 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 and they need to meet the eligibility criteria specific to this protocol. The p-is will consecutively record the restorative treatment they provide to patients with qualified restorative needs who provide informed consent and who thereby become subjects. 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. Practitioner-investigators may be asked to sign an Informed Consent prior to the initiation of data collection or returning Data Collection Forms will constitute consent by the p-is.

Sources of materials. Data will be obtained from up to 50 Data Collection Forms that each p-i completes. These forms represent 50 consecutive replaced/repaired restorations, which may or may not derive from 50 consecutive patients. Data on the replaced/repaired 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 replaced/repaired 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 reviewed the research protocol and these forms.

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 or a staff member trained in Human Subjects Protection. After assurance that the information provided is understood by the patient, he/she signs the form, which then becomes part of the patient's research 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 practitioner investigators

P-is will benefit from the opportunity to reflect their views on the current diagnosis of restoration defects used in their practices and gain information on the practice methods of their peers. The p-is will also benefit from a better understanding of how the diagnosis of restoration defects may influence patients' 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 $25 for each additional restoration completed on the same patient at the same visit, after having returned completed forms for 50 restorations and after having responded to a possible query from the RC or CC 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 identify and quantify the various diagnoses of defects on restorations and the alternative treatments provided. When the results of this study become available, comparisons can be made with responses provided for Study 1.

E.5. Inclusion of women practitioner investigators and subjects

Practitioners of 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 clinicians is about 50:50 and the female component is steadily increasing 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. Subjects will be enrolled regardless of gender.

E.6. Inclusion of minority practitioner investigators and subjects

Practitioners of 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 Targeted/Planned Enrollment table on page 16 of 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. Subjects will be enrolled without respect to racial or ethnic minority status.

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 informed of what the study entails and their questions will be answered before they sign an informed consent to participate. No gender or racial/ethnic group will be targeted or excluded. Our anticipated enrollment is shown in the Targeted/Planned Enrollment table on page 17 of this application

E.8. Inclusion of children

This study is designed to investigate the reasons for restoration defects diagnosed by DPBRN p-is that lead to replacement or repair of restoration in permanent teeth. The age of the patients will depend on the dental practice; some p-is may have restricted 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 a restoration replacement /repair 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: 200 DPBRN dentists (who treat 6,000 patients) †

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	4	6	10
Not Hispanic or Latino	36	154	190
Ethnic Category: Total of All Subjects *	40	160	200
Racial Categories			
American Indian/Alaska Native	2	2	4
Asian	2	2	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	16	20
White	34	138	172
Racial Categories: Total of All Subjects *	42	158	200

† We project that the 10,000 restorations (200 dentists each doing 50 restorations) will comprise 200 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 200 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 (200 dentists each doing 50 restorations) will comprise 200 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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