

Department of Health and Human Services Public Health Services		LEAVE BLANK—FOR PHS USE ONLY.	
Grant Application <i>Do not exceed character length restrictions indicated.</i>		Type	Activity
		Review Group	Number
		Council/Board (Month, Year)	Formerly
		Date Received	
1. TITLE OF PROJECT (<i>Do not exceed 81 characters, including spaces and punctuation.</i>) DPBRN Study 4: Patient satisfaction with dental restorations			
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> YES (If "Yes," state number and title) Number: _____ Title: _____			
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		New Investigator <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	
3a. NAME (Last, first, middle) DPBRN c/o Riley, Joseph L. III		3b. DEGREE(S) PhD MS	
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4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
4b. Human Subjects Assurance No		5a. If "Yes," IACUC approval Date	
4c. Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		5b. Animal welfare assurance no.	
4d. NIH-defined Phase III Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes			
4a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes			
If "Yes," Exemption No. _____			
6. DATES OF PROPOSED PERIOD OF SUPPORT (<i>month, day, year—MM/DD/YY</i>) From _____ Through _____		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$)	
9. APPLICANT ORGANIZATION Name Address		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 7b. Total Costs (\$) 7c. Direct Costs (\$) 7d. Total Costs (\$)	
		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged	
		11. ENTITY IDENTIFICATION NUMBER	
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address Tel: _____ FAX: _____ E-Mail: _____		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address Tel: _____ FAX: _____ E-Mail: _____	
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PPD NAMED IN 3a. (<i>In ink. "Per" signature not acceptable.</i>)	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. (<i>In ink. "Per" signature not acceptable.</i>)	
		DATE	
		DATE	

DESCRIPTION: See instructions. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving these goals. Describe the rationale and techniques you will use to pursue these goals.

In addition, in two or three sentences, describe in plain, lay language the relevance of this research to public health. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

Patient satisfaction is important to practicing dentists because of links to regular return visits, caregiver trust, perception of technical competence, and treatment outcome. However, little is known about the satisfaction of dental patients, particularly as related to specific dental procedures. Dental restorations are one of the most commonly performed dental procedures, yet no study has documented patient satisfaction with a restoration-specific dental visit. There are many unique characteristics to a dental restoration visit, such as the dentist-patient communication about the restoration material, comfort during and following the procedure, and the patient's view of the quality of the restoration. How patients prioritize these characteristics or use them in decisions about satisfaction are unknown. It is known that patients make judgments of the technical competence of dentists, but whether these judgments have any association with immediate or long-term restoration quality and therefore the extent to which they are valid is undetermined. Studies of dental satisfaction have asked about satisfaction with dentists and dental care in general or a recent experience without distinguishing between the reason for the visit or the treatments received. The aims of this study are to determine the relative contribution and importance of characteristics of a restoration and restoration visit with overall patient satisfaction following a dental visit that involved a restoration replacement or repair; and to link patient's satisfaction and perception of the dentist's technical expertise with long-term objective outcomes of the dental restoration.

In a preliminary study we have developed an instrument for measuring dental patient's satisfaction with a restoration visit. This instrument assesses thoughts and feelings associated with restoration aesthetics, comfort level during and following the procedure, cost/value, perception of technical aspects, and the interpersonal experience. This study will involve approximately 6000 patients that have received at least one dental restoration repair/replacement. Patients will be recruited from practices participating in DPBRN Study 3 (replacement restorations), most of whom will be enrolled in Study 5 (restoration longevity). Participants will complete and mail the survey questionnaire the day following the dental visit to allow them to evaluate and respond to the short-term outcomes, such as comfort and function, as well as to the immediate aspects of the visit. DPBRN offers a unique opportunity to study patient satisfaction because it is a consortium of practicing dentists and not dental academics, and the network allows for the efficient recruitment of a large sample of patients. Additional strengths are that this study will assess a comprehensive range of determinants of dental patient satisfaction and the ability to relate patient satisfaction with longitudinal dental outcomes.

Relevance to public health: Links between patient satisfaction and regular dental visits, appointment keeping, overall patient compliance, and success of the treatment may indicate mechanisms to improve oral health.

	<i>Page Numbers</i>
Face Page	1
Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells	2
Table of Contents	3
Detailed Budget for Initial Budget Period (or Modular Budget)	_____
Budget for Entire Proposed Period of Support (not applicable with Modular Budget)	_____
Budgets Pertaining to Consortium/Contractual Arrangements (not applicable with Modular Budget)	_____
Biographical Sketch – Principal Investigator/Program Director (Not to exceed four pages)	_____
Other Biographical Sketches (Not to exceed four pages for each – See instructions)	_____
Resources	_____
Research Plan	4
Introduction to Revised Application (<i>Not to exceed 3 pages; SBIR/STTR Phase I not to exceed 1 page.</i>)	_____
Introduction to Supplemental Application (<i>Not to exceed one page</i>)	_____
A. Specific Aims	5
B. Background and Significance.....	6
C. Preliminary Studies/Progress Report/ Phase I Progress Report (SBIR/STTR Phase II ONLY)	10
D. Research Design and Methods	11
E. Human Subjects Research	17
Protection of Human Subjects (Required if Item 4 on the Face Page is marked "Yes").....	_____
Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked "Yes" <u>and</u> a Phase I, II, or III clinical trial is proposed)	_____
Inclusion of Women and Minorities (Required if Item 4 on the Face Page is marked "Yes" and is Clinical Research)	18
Targeted/Planned Enrollment Table (for new and continuing clinical research studies)	20
Inclusion of Children (Required if Item 4 on the Face Page is marked "Yes")	18
F. Vertebrate Animals	_____
G. Literature Cited	21
H. Consortium/Contractual Arrangements	_____
I. Resource Sharing	_____
J. Letters of Support (e.g., Consultants).....	_____
Commercialization Plan (SBIR/STTR Phase II and Fast-Track ONLY)	_____
Checklist	_____

(Items A-D: not to exceed 25 pages*)
* SBIR/STTR Phase I: Items A-D limited to 15 pages.

CONTEXT WITHIN WHICH THE STUDY WILL BE CONDUCTED

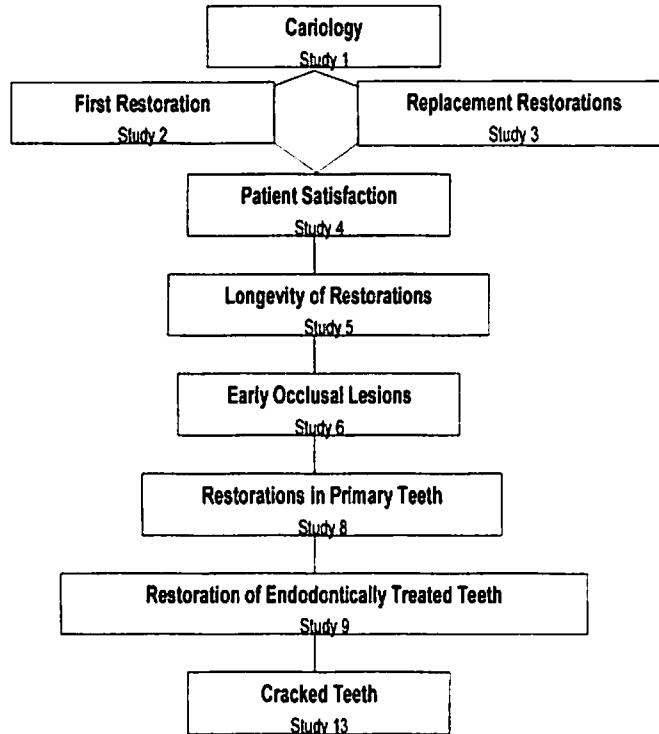
The Dental-Practice Based Research Network (DPBRN) is a group of dental practices that have joined together to investigate research questions and to share experience and expertise. DPBRN practitioner-investigators comprise dentists in Alabama, Florida, Georgia, Minnesota, Mississippi, Oregon, and Scandinavia. A comprehensive description of 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>. We refer to the DPBRN practitioner-investigators in the remainder of this protocol as "p-i's".

This study will be DPBRN's fourth network-wide project dealing with restorative dentistry. Study 1 was a questionnaire related to caries diagnosis and treatment in DPBRN practices. Study 2 focused on the reasons for placing the first restoration on a previously-unrestored permanent tooth surface. Study 3 addressed the reasons for replacement and repair of defective dental restorations. A fifth study will quantify the annual and three-year incidence of defects in DPBRN Studies 2 and 3. Because 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.

This study will assess patient satisfaction with a restoration visit using patients recruited from practices participating in DPBRN Study 3 (replacement/repair restorations) with subjects recruited for Studies 3 and 4 simultaneously. This proposed study will assess a comprehensive range of determinants of patient satisfaction immediately following the restoration replacement or repair to study the relative contribution of each determinant towards overall patient satisfaction. In addition, objective measures of restoration quality will be assessed during recall visits at 1-, 2-, and 3-year post baseline for subjects who consent to participate in Study 5, allowing us to correlate dental satisfaction with objective restoration outcomes in a longitudinal model.

Following the provision of informed consent, subjects will be given the satisfaction questionnaire upon leaving the practice. Included will be a stamped envelope addressed to the DPBRN data collection site. Subjects will be asked to complete the questionnaire the following day, giving them time to reflect on the experience and make an initial evaluation of the filling(s). The Coordinating Center will then link restoration replacement/repair data collected as part of Study 3 and outcome data from Study 5 with satisfaction ratings. We propose collecting 6000 completed questionnaires from patients for this study.

DPBRN Restorative Studies



A. SPECIFIC AIMS:

Specific Aim #1: Quantify dental patient satisfaction with a recent dental visit where a restoration was placed or repaired using an instrument that adequately samples from the range of characteristics that are important to patients.

Specific Aim #2: Test the hypothesis that patients' ratings of the technical ability of their dentist, comfort during the visit, and having a pain-free visit will be the strongest predictors of overall patient satisfaction. To accomplish this, we will quantify the relative contribution and importance of characteristics of a restoration and restoration visit towards the overall patient satisfaction with that visit.

Specific Aim #3: Test the hypothesis that patient's satisfaction and perception of the dentists' technical expertise will be associated with the long-term outcomes of that restoration(s).

Rationale: Patient satisfaction is important to practicing dentists because of links to regular return visits, caregiver trust, perception of technical competence, and treatment outcome. However, little is known about the satisfaction of dental patients, particularly as satisfaction is related to specific dental procedures. Dental restorations are one of the most commonly performed dental procedures among general dentists, yet no study has documented patient satisfaction with a restoration-specific dental visit. There are many unique characteristics to a dental restoration visit, such as the dentist-patient communication about the restoration material, comfort during and following the procedure, and the patient's view of the quality of the restoration. How patients prioritize these characteristics or use them in decisions about satisfaction are unknown. It is known that patients make judgments of the technical competence of dentists, but whether these judgments have any association with immediate or long-term restoration quality and therefore the extent to which they are valid is undetermined. As dentistry becomes a more consumer-driven profession, better understanding of patient satisfaction with specific dental procedures will allow for improved management and promotion of

dental practices. Dental care is often driven by the perceived needs of patients and may be delayed longer than is optimal as patient's satisfaction is related to regular dental visits. The purpose of Specific Aim #1 of this project will be to administer a dental patient satisfaction questionnaire designed to assess patient satisfaction with a recent restoration replacement/repair procedure and the restorations placed. Specific Aim #2 will allow for inferences about the relative priority and importance of individual or common domain characteristics of the restoration or restoration visit. This project will also determine the strength of associations between a patient's satisfaction and restoration outcomes (Specific Aim #3). Patient satisfaction will be defined as the dental care recipient's cognitively- and affectively-based response to the structure, process, and results of the service that is experienced.

B. BACKGROUND AND SIGNIFICANCE:

Consumer satisfaction is central to marketing theory and based in the premise that a business prospers by meeting the needs of consumers. From this perspective, consumer satisfaction has been defined as a complex evaluation regarding whether the experience is at least as good as it was believed to be (Zeithaml, Bitner, and Gremler, 2005). The implication is that a customer's evaluation involves a balance between expectations and perceptions. The health care industry has embraced the importance of patient satisfaction and it is accepted as an important measure of the quality of the care provided (Donabedian, 1988). Of particular interest to dentists, oral health researchers, and public health officials are links between patient satisfaction and regular dental visits, appointment keeping, overall patient compliance and success of the treatment which leads to improved oral health (Newsome and Wright, 1999). However, most studies of patient satisfaction have been performed in medical rather than dental settings. Studies that have focused on dental care have tended to ask about satisfaction with dentists and dental care in general or assessed satisfaction with a recent experience, without distinguishing between the reason for the visit or the treatments received.

B.1. Theoretical perspective

The most common conceptualization of consumer satisfaction is the "disconfirmation theory" that proposes that a comparison between perception and experience and satisfaction is mediated by the direction and magnitude of the discrepancy (Oliver, 1997; Spreng, MacKenzie, and Olshavsky, 1996). This is based on the assumption that subjective qualities rather than objective performances are the attributes that are judged by the user (Ware and Davies, 1983). As applied to a dental visit, it is not the absolute time spent waiting for the dentist, but the evaluation of it as long or short. There is evidence that when performance differs only slightly, there is a tendency to compensate, with the service users adjusting their perceptions towards expectations (Newsome, 1999). A broader view suggests that consumers (patients) have a desired level of service hoped for, a minimum tolerable level, and a level of service they believe they probably will receive. Consumers have some range within which they will be willing to accept, and this range is likely to vary as a function of the particular attribute of the service and may be associated with the consumer's level of importance of the characteristic. The range of acceptability is thought to be greater for less important characteristics than more important ones (Zeithaml, Bitner, and Gremler, 2005). There is some evidence for a direct effect of expectations on perceived performance such that people tend to see what they expected to see, producing a positive effect of expectations, but most research has found that performance is the major determinant of satisfaction (Tse and Wilton, 1988).

B.2. Measuring dental patient satisfaction

B.2.1. Studies using standardized Instruments. There are two scales that have been developed for measuring dental satisfaction.

Dental Satisfaction Questionnaire (DSQ) is comprised of 19 items that ask about satisfaction with the dentist and dental care in general and is not appropriate for the evaluation of a specific visit. Items such as "Dentists should do more to reduce pain" or "Dentists are not as thorough as they should be" are scored on a 5-point scale anchored by strongly agree – strongly disagree. The DSQ can provide scores for 5 domains

(Access, Availability/Convenience, Cost, Pain, and Quality) and an overall dental satisfaction index by summing the items (Davies & Ware, 1981). A study by Golletz, Milgrom, and Mancl (1995) supports the internal structure and reliability of the DSQ. It has been translated into Norwegian (Skaret et al 2004) and a modified version has been translated into Chinese (Chu et al., 1999; 2001). The DSQ has been criticized as only considering dentists or dental care in general, without regard for the procedure performed, and concentrates only on cognitive factors (Newsome and Wright, 1999). This questionnaire does not actually ask about satisfaction; rather, satisfaction is inferred by the level of agreement with each of the statements. This scale has been used in other studies that have sampled low-income persons in the US (Golletz, Milgrom, and Mancl, 1995), a community sample in Norway (Skaret et al 2005), and older Finnish men (Tuominen and Tuominen 1998).

The Dental Visit Satisfaction Scale (DVSS, Corah, et al., 1984) is a scale that has been adapted from the **Medical Interview Satisfaction Scale (Wolfe et al., 1978)**, a scale developed to measure patients' perception of a specific visit to a physician. The DVSS has 10 items and asks general questions about a dentist and dental encounter as first-person statements about aspects of a dental visit (e.g., "I really felt understood by the dentist" or "The dentist is thorough in doing the procedure") and are rated on a 5-point scale anchored by strongly agree – strongly disagree. The items have been reported to reflect three factors; communication, acceptance by the dentist, and technical competence (Corah et al., 1984). Swedish (Hakeberg et al., 2000) and Dutch versions (Stouthard, Hartman and, Hoogstraten, 1992) have been developed with similar factor structures reported. Locker and Lidell (1991) and Stouthard et al. (1992) have criticized the use of past tense by the DVSS. The DVSS assesses a wider domain than the DSQ (Newsome and Wright, 1999), recognizing a broader range of influences on patient satisfaction. Similar to the DSQ, the DVSS infers satisfaction through agreement with each statement. The DVSS has been used to assess satisfaction following cranio-facial pain consultation (Murray et al., 1997), patients attending an emergency PDS clinic and an oral medicine clinic (Hakeberg et al., 2000), and among older adults (Liddell and Locker 1992).

B.2.2. Studies using ad hoc instruments

There are a number of studies that have used ad hoc measures of dental patient satisfaction as reviewed by Newsome and Wright (1999). These studies have generally asked questions that can be classified into one or more of the domains of technical competence, interpersonal factors, convenience, costs, and facilities (see section B.3. for additional discussion). However, there is no standardization of wording across the studies and scales or items are of undocumented reliability or validity. As with the DSQ and DVSS, many studies infer satisfaction, but most do not ask specifically about it. As examples, the satisfaction measures from several recent studies are briefly reviewed below.

Several studies have directly asked about dental patient satisfaction. Abrams et al. (1986) compared dental satisfaction with a restoration quality index. To measure patient satisfaction they asked 5 questions about satisfaction related to the time for the visit, comfort, explanation of the treatment, dentist competence, and quality of the treatment, with responses scaled from very satisfied to very dissatisfied. Calnan, Dickinson, and Manley (1999) compared the importance and satisfaction with dental care, and tested for differences between rural and inner-city dwelling adults using a postal survey. They collected ratings of satisfaction with 5 different aspects of dental care (access/availability, cost, facilities, technical skills, and interpersonal care) using a 5-point Likert scale anchored by very satisfied and not very satisfied. Tamaki et al. (2005) associated patient satisfaction with dental clinic credibility in 39 private dental clinics in Japan that provided check-ups and preventive care. They used 11 items that asked about the level or satisfaction with technical competence, cost, waiting time, communication, and cleanliness of the office, using a 4-point ordinal scale (very satisfied, fairly satisfied, not very satisfied, and dissatisfied). A number of studies related to oral health have asked a single question about patient satisfaction in the context of other more central themes (e.g., Unell et al., 1999) and are not reviewed here.

Other studies have not used the term "patient satisfaction" but have measured related attitudes and beliefs. A common method is to rate the importance of certain dentist or dental practice characteristics. A study by Goedhart et al. (1996) examined the importance of 56 possible quality aspects of dental treatment as judged by a sample of Dutch regular dental attenders. These aspects included accessibility of

dental care, cost, pain during the procedure, functionality of the treatment, esthetics, information provided, dentist as a person, and technical ability, rating them as unimportant to extremely important. None of the items included the word "satisfaction". Holt and McHugh (1997) inferred satisfaction by examining the importance of 18 factors to patients. These included the dentist's care and attention, pain control, explanation of treatments, value, waiting time, education provided, reputation of the dentist, and staff helpfulness.

Another method of assessing patient satisfaction is to make comparisons with characteristics that constitute the ideal dentist. Lahti et al. (1992) factor analyzed a pool of statements about the ideal dentist and identified five factors: mutual communication, fair support, personal appearance, preferred type of practice, and blaming. Subsequent studies using these questions found important differences between dentists' and patients' views of the ideal dentist (Lahti et al., 1996a) and discrepancies between patients' view of the ideal and their current dentist (Lahti et al., 1996b). Taking a similar approach, Burke and Croucher (1996) asked 30 patients to generate criteria which define a good dental practice. These preferences were subsequently ranked based on importance by another sample of 344 patients from London, England. The criteria were consistent with the important issues as defined by Newsome and Wright (1999), and included dentist's skills, caring dentist, general hygiene, understanding dentist, cost, appointment system, and explanation of treatment.

Other studies have asked patients to rate their experiences, with satisfaction implied by a positive response. For example, in testing for differences across dental practice settings, Handelman, Fan-Hsu, and Proskin (1990) and Handelman et al. (1996) used a 14-item survey that asked for ratings of the dentist's technical abilities, painless treatment, positive aspects of communication, promptness of the treatment, convenience/accessibility, and politeness of the staff. Five forced response choices related to the specific outcome were used (e.g., the staff was: very polite and helpful - very impolite and not at all helpful). Alvesalo and Uusi-Heikkila (1984) used 4 items that asked about the difficulty in getting an appointment, costs of care, comfort in the chair, and convenience in treatment to assess patient satisfaction among patients visiting the University of Connecticut dental clinics. They did ask one question about satisfaction, inquiring about agreement with; "I think that I am generally satisfied with the dental care of this clinic." A less structured approach was taken by Gurdal et al. (2000). They content analyzed responses by patients visiting a dental faculty outpatient clinic in Izmir, Turkey to open-ended questions about factors which they praised or had a complaint. The subjects were instructed to record their impressions regarding the dental services they had received and to comment on everything they thought was important. Patients were assigned to groups that were satisfied, dissatisfied, or both satisfied and dissatisfied by the authors. None of the studies using the DSQ or the DVSS have compared scores with overall ratings or satisfaction, importance, or priority.

No existing measure of patient satisfaction would be appropriate for evaluating satisfaction specific to a dental restoration and related visit, the purpose of this proposal.

B.3. Dimensions of patient satisfaction with dental care

Consistent with consumer satisfaction theory, as reviewed in section B.1., it is important to consider the patients' evaluations of the importance of the characteristic as the greater the importance - the larger its role in predicting overall satisfaction. Prediction studies that would test for dentist and dental visit characteristics as predictors or ratings of satisfaction or importance would allow for the determination of relative importance. However, few studies have done this. Gopalakrishna and Munnaleneeni (1993) examined factors that predicted a single-item measure of dental patient satisfaction. They found that waiting time, followed by pain management, were the strongest predictors. Weaknesses of this study are the limited measure of satisfaction and the lack of interpersonal or technical factors among the independent variables. The study by Tamaki et al. (2005) considered a more comprehensive list of characteristics. They reported that technical competence and communication were the characteristics most associated with ratings of clinic credibility.

As an alternative, mean scores for importance can be compared to determine the most important characteristics of dental care. Burke and Croucher (1996) reported that the three highest-ranked criteria associated with a "good dental practice" in southern England were explanation of procedures, sterilization / hygiene, and the dentist's skills. In another study from England that involved ratings of importance, Holt

and McHugh (1997) found that dentist care and attention and pain control were the two most important. The lowest ratings were opening hours and office décor. A weakness of this comparison is that there were no questions about technical competence. Comparing Dutch patient ratings of the importance of various aspects of dental care, Goedhart et al. (1996) concluded technical aspects and communication to be the most important. The lowest priority ratings were for office environmental variables. Calnan, Dickinson, Manley (1999) found that perceived technical skills were evaluated as the most important components of dental care by approximately 50% of respondents living in England. Using their open-ended questions, Gurdal et al. (2000) found Turkish patients reported that interpersonal relationships, office organization, and scientific ability were the most important satisfaction factors.

From the above studies, we can see that technical skills, followed by communication skills and pain control, are identified most often as important to dental patients. It is interesting that in oral health care settings, patients typically lack the capacity to adequately evaluate the technical performance of the dentist. This assertion is supported by a study by Abrams and Ayers (1986) that failed to find an association between an objective index of restoration quality and patient ratings of the competency of the dentist and quality of the treatment received.

Satisfaction with a dental visit is the result of a complex set of attitudes and beliefs that are applied to a number of characteristics of the dental visit. This is supported by the above studies of dental patients and those reviewed by Newsome and Wright (1999). Newsome and Wright concluded that five generic issues affect dental patient satisfaction: 1) Technical quality of care, which could include knowledge, technical skills, and the patients' perception of the overall quality of the work; 2) The domain of interpersonal factors is very broad and would include communication related to assessment or treatment (explanations or choices), patients' views of the provider (trust worthy; patient's perception of the dentist's behaviors or attitudes (friendly, courteous); 3) Convenience includes factors involved in receiving or arranging for care such as getting an appointment, waiting time during the visit, clinic accessibility; 4) Financial issues are factors involved in the cost and value of the services; and 5) The office environment, which includes modern equipment, décor, and cleanliness. We argue that one set of issues important to dental patients that does not precisely fit Newsome and Wright's definition of technical competence relate to patient comfort and includes such variables as a pain- or anxiety-free visit; therefore we will consider this the sixth domain of important characteristics. The inconsistency of the satisfaction-related issues assessed and the patient or community populations sampled across studies make strong inferences about relative importance difficult.

B.4. Specificity of the clinical population studied

It is logical that important differences in levels of satisfaction or in the priority given components of satisfaction are likely to exist as a function of the clinical populations or the dental procedures performed. Unfortunately, most studies of dental patient satisfaction have focused on dental visits in general (i.e., Calnan et al., 1999; Goedhart et al., 1996; or all studies using the DSQ) and have sampled from the community without regard to time lag or the nature of the dental care the subjects have received (i.e., Holt and McHugh, 1997; Gopalakrishna and Nummalaneni, 1993; Burke and Croucher, 1996). Many studies of clinical samples have assessed patient satisfaction in university dental clinics, a setting where generalizability to private practice settings may be questionable (i.e., Handelman et al., 1996; Chu, Yeung, and Lo, 2001; Gurdal et al., 2000; Alvesalo and Heikkila, 1984). Consequently, there is little information about dental patient satisfaction among patients who have received a homogenous set of dental procedures.

B.5. Satisfaction with restoration visit

We are able to find two studies that have measured patient satisfaction with any direct relationship to dental restoration visits. Goedhart et al. (1996) investigated the importance of 56 aspects of the quality of dental care. The subjects were 1328 regular dental attenders that were recruited as part of a nationwide dental study in Holland. Among the top-rated 10 of the 56 quality characteristics, three were related to a dental restoration: "Your teeth close well after a filling has been made, so the filling is not too high"; "The filling in a front tooth is invisible"; and "Dental restorations should hold out for at least four years". No restoration-related characteristic was among the 10 with the lowest priority. Unfortunately, it is unclear

whether or how many of the respondents in this study had received restorations or the time from placement to the survey.

Another study compared the technical competency of a previous dentist with the patient's perception of the quality of past dental care. Abrams et al (1997) recruited 117 patients before an initial examination in a university dental clinic and compared their satisfaction ratings of previous dental care with a standardized index of restoration quality of their old restorations. Neither the summary score from the 5-item measure of patient satisfaction nor the item asking about satisfaction with the quality of past treatment were significantly associated with the restoration index score. This finding can be interpreted to mean that patients are unable to evaluate the technical competency of dental care. Weaknesses of this study include that the restoration index considered all restorations regardless of the time lag, many of the patients were scheduled because of problems with older restorations – consequently a greater number of problem restorations existed, and recent visits were more likely to have influenced their recall of past satisfaction with dental treatment.

It should be apparent that, although relating to dental restorations, these two studies do not appropriately address the specific aims of this proposal. The restoration-specific items, as asked by Goedhart and colleagues, will be important to ask of patients who have received a restoration as they directly assess patient's perception of the restoration quality. The value of this technical assessment as it related to overall satisfaction with the visit is not known, nor are there any quality data to suggest that this evaluation has a basis in fact. This study will collect a comprehensive range of data on patient satisfaction and test how various aspects of patient satisfaction contribute to overall satisfaction and whether these ratings correlate with the actual technical quality of the restoration.

B.6. Implications for dental practitioners

The findings of the project have several direct implications for dental practices. The importance of patient satisfaction is consistent with the recent emphasis on patient-centered oral health care that is defined as care that minimizes the current and future experience of illness and the negative experience of oral health care provision (Newsome and McGrath, 2006).

Related to improved management and promotion of dental practices, patient satisfaction is important to practicing dentists because patient satisfaction results in increased caregiver trust (Yamalick., 2005) and return visits (Newsome, 2003). Taking a consumer-driven approach, practicing dentists are motivated to understand how patients evaluate the dental service provided so that practice promotion can focus on what patients appreciate and value in the services provided. For example, we do know that a dentist's technical competence is a high priority for patients (Goedhart et al., 1996; Tamaka e al., 2005), but patients are likely to use non-technical aspects of the visit in this appraisal (Newsome and McGrath, 2006). Should we find that patient judgments of technical competence are based on the office environment, the clarity of the explanation of the procedure, the level of comfort during the visit, and post-treatment temperature sensitivity of the tooth; there are direct implications for patient management before, during and after the procedure. Corrective steps could include changes in office policies or procedures, patient education, or even changes in the dentist's interpersonal approach.

Patient satisfaction is associated with a number of positive oral health outcomes that are important to practicing dentists. Patients with the highest dental satisfaction are known to be the most likely to have regular preventive visits and to have restorative work performed rather than an extraction (Riley, Gilbert, Heft, 2006). Dissatisfied patients delay needed dental services longer than is optimal, and one study found that delaying needed care increases the probability of oral pain and further dissatisfaction (Riley, Gilbert, Heft, 2005). There is some evidence that dentists believe they know patients' desires and priorities rather than finding out what they do want (Rao and Rosenberg, 1986) and our pilot data partially support this conclusion. As few studies have examined dental patient satisfaction for specific dental procedures, it is possible that dentists err in their assumptions. More specific information will identify the correct targets and maximize the benefit to dentists and patients.

The strongest evidence for the importance of patient satisfaction in potentially improving daily clinical practice is the strong interest of DPBRN dentists in this study, as judged by their responses and reactions at DPBRN regional meetings.

There are many unique characteristics to a dental restoration visit. How patients prioritize these characteristics or use them in decisions about satisfaction are unknown. Specific Aim #2 will test hypotheses about the relative priority and importance of individual or common domain characteristics of the restoration or restoration visit. Examining the determinants of patient perceptions of technical competence is new and innovative. Patients make this judgment, but how this inference is made is unclear. In addition, whether these judgments have any association with immediate or long-term restoration quality and therefore the extent to which they are valid is also undetermined. Specific Aim #3 will address the questions related to real and perceived technical competence. The findings of this study will be published in clinical journals read by clinical dentists.

C. PRELIMINARY STUDIES:

C.1 Qualitative interview with dentists and recent patients

Based on the above literature review, we have concluded that we would be unable to adapt an existing survey instrument for use in meeting the Specific Aims of this proposal. The first step in the development of a new questionnaire was therefore to identify the determinants of patient satisfaction with a restoration visit. As the extant literature on dental satisfaction was broadly focused, we interviewed 15 patients and 16 practicing dentist to learn the specific characteristics of tooth restoration and related visits that are important to patients. The interviews lasted from 20-60 minutes.

The results supported the limited literature on patient satisfaction with a dental visit, but other factors were also identified. The dental literature suggests that personal interactions between patients and dentists, technical ability of dental personnel, and communication were the most important issues relating to patient satisfaction. A consistent theme during the interviews was that many patients and dentists felt the most important factor in patient satisfaction was a pain-free procedure. In general, patients and dentists felt that satisfaction with the restoration visit was a three-fold process, although they did not agree on the specific components. First, it is important for the dentist to explain the procedure step by step, answering all questions and letting the patient know when each step is to take place. Second, it is important to anesthetize the patient fully the first time so that they do not experience any discomfort other than the injection. Third, patients want the tooth to be natural looking, regardless of the cost of the procedure. To them, aesthetics was very important. Dentists are aware of this; however, they felt that longevity of the restoration should take precedence in the decision whether to use composite or amalgam; amalgam was perceived to last longer compared to tooth-colored resin-based composite materials.

Integrity of the dentist, rapport with patients, and trust were also factors of importance mentioned by patients. Dentists perceived their patients to be unconcerned with and/or not value their level of technical expertise or materials used. Many of the dentists felt that it was very important to have headphones, music, murals, for the patients to feel more relaxed during a procedure. Patients, on the other hand, felt as long as they were properly anesthetized, educated on what was happening step by step, and had a choice in the restoration materials, the physical environment was of little importance in alleviating anxiety about the restoration. The patients also expressed a concern with the level of their comfort being influenced by how the dentist and staff treated them. A number of patients mentioned the importance of having the restoration done right the first time so the procedure would not have to be repeated.

Some issues that both patients and dentists felt were important were the level of communication that the dentist and staff provided. Educating the patient was important because it alleviated a lot of the anxiety that patients felt coming in for the restoration. Dentists interviewed, for the most part, were aware of this and make an effort to provide extra time to explain the procedure and give the patient informed choices. Trust was also a mutual factor in patient satisfaction both in patient interviews and dentist's interviews.

Patients expressed that if they trusted the dentist, their comfort level would rise and the anxiety and/or fear of the restoration procedure would lessen. Most of the patients wanted a clean environment but didn't think it was important to have headphones or murals to be satisfied with the procedure. Both dentists and patients mentioned the noise of the drill to be bothersome to the patient.

C.2. Quantitative assessment of importance to satisfaction

The characteristics reported during the qualitative interviews along with those identified during the comprehensive literature review were used to construct a 40-item preliminary instrument. Its purpose was to determine the relative importance of each characteristic towards patient satisfaction during a restoration visit. A patient and dentist version were designed which used the same questionnaire items, but the instructions asked about patient's satisfaction from the patient's viewpoint or dentist perceptions of patients' viewpoints. The initial draft was evaluated and modified following comments provided by several experts in the dental restoration field (see supplemental materials for a copy of the questionnaire). As the purpose was to reduce the overall length of the survey to approximately 15 questions, this process allowed us to select the range of characteristics associated with the restoration or experience of the visit which are rated as important to satisfaction by patients. This preliminary version was administered to 19 dentists and 39 persons with a restoration-related dental visit within the previous year.

Satisfaction item scores ranged from 9.5 - 3.5 for the patients and 9.7 - 2.8 for the dentists. We found from the patient's perspective; perception of the dentist's skills, comfort during the procedure, and having a pain-free visit were the most important towards satisfaction. For the dentists, they indicated the dentist having a trusting and caring relationship with the patients, being friendly and respectful towards the patients, and having a pain-free visit were the most important for patients. Items with the lowest ratings for both groups had to do with office décor. The ratings of patients and dentists were significantly different for 9 of the 40 items. Patients rated the following as more important than did dentists: cost of the visit, the dentist having a gentle touch, the fee was reasonable for the work done, and technical skills of the dentist. Dentists, on the other hand, rated questions related to having a trusting and caring relationship with the patients, being friendly and respectful towards the patients, and office décor as more important than did patients.

C.3. Construction of the questionnaire

The original 40-item pool was divided into common domains of: 1) Relationship with the dentist, 2) Technical ability of the dentist, 3) Comfort/Pain free visit, 4) Restoration material, 5) Communication - treatment, 6) Office environment, 7) Communication - Interpersonal, 8) Waiting at the office, and 9) Cost. The identification of these nine domains and item assignment was based on independent recommendations by four health care experts (two dentists, psychologist, and medical anthropologist) and in consideration of the five domains suggested by Newsome and Wright (1999), plus additional items specific to restoration materials. The goal for selecting items for the final survey was to have items highly rated as important towards patient satisfaction and broad content. When three or four items within a domain were highly rated, we attempted to select items with lower inter-domain correlations to reduce redundancy. A single item was selected from the waiting time, cost-benefit, and office environment domains because of the relatively lower ratings. The proposed survey items are presented in section D.8.1.

D. RESEARCH DESIGN AND METHODS:

D.1. DPBRN practices

A total of up to 200 DPBRN p-i's will be recruited for this study from p-i's participating in Study 3. To be eligible to participate in Study 4, the practitioners must also be participating in Study 3.

D.2. Discussion of study with practices

Before any data collection begins by a p-i, DPBRN Project Coordinating staff will go over the procedures by telephone or in person with that participating p-i and their staff to explain the protocol for this study. Human subjects/informed consent issues will be reviewed as needed, as well as procedures specific to this study. It is important that the participating clinicians and their staff familiarize themselves with the materials and instructions for patients. Printed material on the survey protocol will also be provided.

D.3. Subjects

The study will involve approximately 6000 patients (200 practices x 30 patients) that have received a dental restoration repair/replacement as part of Study 3. Children 12 years of age and younger will be excluded because of issues related to comprehension and validity of responses. A total of 50 restorations are done in Study 3, which typically will involve 30 different patients.

D.4. Limit of subjects per practice

Each p-i should recruit all the patients with replaced or repaired restorations placed in the treatment of permanent teeth that are also enrolled in Study 3. It is realized that it will take some time to enroll up these patients, depending on the type of practice. Based on previous studies, we estimate that the typical DPBRN p-i will take 3-8 weeks to enroll the 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. Because this study is linked to a consecutive patient/restoration study, enrollment for this study will continue until the p-i has met the recruitment goal, it has been determined that enrollment 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.

D.5 Recruitment and data collection

Subjects recruited for Study 3 will also be asked to participate in Study 4 by filling out a post-treatment survey. For ease of administration, Study 4 materials will be included with Study 3 forms. Initial approach will be made by office staff. Once the subjects have had the studies explained to them and have given informed consent (explicitly for Study 3) they will be provided with the study materials. Subjects will be given the Satisfaction Survey Form – along with a stamped envelope – and instructed to complete the survey the next day. The first page of the Satisfaction Survey Form will be an information sheet that provides the elements of informed consent. Should an IRB require written consent, it will be obtained in conjunction with consent for Study 3. We anticipate some variability in requirements from one IRB to the next. The subjects will mail the completed satisfaction survey directly to the Regional Coordinators, thus ensuring that dentists remain blind to patient satisfaction ratings. Study 4 will use the same subject numbering system as Study 3 (clinical parameters of the restoration) and Study 5 (ratings of defects) so that the information for studies can be linked. Immediately following the dental visit, a reminder card will be mailed to each subject from the DPBRN office thanking them for participating and reminding them to complete and mail the satisfaction survey. This reminder card will be part of the study materials packet and will be addressed and placed in outgoing mail by office staff at the time of the patient's visit. It is anticipated the reminder letter would be received by the subject in approximately one day, consistent with the targeted time lag for completing the satisfaction survey. The signed Informed Consent Form will be maintained in a secure research folder according to HIPAA regulations (should they be required). Patients will be assured that no identifiable patient satisfaction information will be shared with the DPBRN practitioner or staff.

D.6. Data management and quality assurance procedures

Patient Satisfaction Surveys will be sent by the subjects directly to the Regional Coordinators for quality control purposes before being forwarded to the Coordinating Center. At the Coordinating Center professional data entry staff will enter data into a secure database. 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.7. Monitoring recruitment and data collection during the field phase

A DPBRN Regional Coordinator will be assigned responsibility for each p-i and his/her practice. Telephone contact will be initiated with p-is and their practices 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 of each p-i to that date and answer any questions they may have. Face-to-face meetings will be held with the p-i and their practice staff at the discretion of the Regional Coordinator assigned to the practice.

D.8. Measures

D.8.1. Satisfaction Survey Form

Table of Satisfaction Survey items.

Each item will be scored using a Likert scale with strongly agree and strongly disagree as the anchors. The overall satisfaction item will use the anchors "extremely satisfied – extremely dissatisfied". The technical ability item will use the anchors "poor – excellent".

<u>Satisfaction domains</u>	<u>Item wording</u>
Relationship with the dentist	I was satisfied because I have a lot of trust in my dentist.
	I was satisfied that the dentist cared about me as a person.
Technical ability of the dentist	I was satisfied that the dentist was gentle when working in my mouth.
	I was satisfied with the quality of the dental work.
	I was satisfied with the skill of the dentist.
Comfort – pain free	I was satisfied that the filling feels smooth when I touch it with my tongue.
	I was satisfied that the dentist minimized pain during the procedure.
	I was satisfied because the filling was not sensitive when I bit down.
	I was satisfied with how the filling feels with hot or cold foods or drink.
Restoration material	I was satisfied with the way the dentist minimized my fear and anxiety.
	I was satisfied because I expect the filling to last a long time
Communication - treatment	I was satisfied because the dentist gave me a choice between a silver or white filling.
	I was satisfied that I was able to ask questions about the dental procedure.
Communication - Interpersonal	I was satisfied with how the dental procedure was explained before it was started.
	I was satisfied with the friendliness of the dentist.
Waiting at the office	I was satisfied with the friendly and courteous staff.
	I was satisfied with the short amount of time I spent in the waiting

	room.
Cost	I was satisfied that the dentist's fee was reasonable for the work done.
Office environment	I was satisfied with the clean and organized office
Overall evaluation	Overall, how satisfied were you with all aspects of your dental treatment and visit?
	Overall, how would you rate the technical abilities of the dentist?

D.8.2. Criteria for recording why a restoration is being replaced or repaired

The main reason for replacement or repair of a restoration, as described below, will be available from Study 3.

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 any reason for replacement of a restoration deemed acceptable by the practitioner.

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

D.8.3. Objective follow-up assessment of restoration

As described in Study 5, upon recall examination of the restoration, each restoration should be rated according to the following two criteria:

Acceptable: The restoration is of satisfactory quality and is expected to protect the tooth and the surrounding structures or has one or more features that deviate from ideal conditions, but it does not need to be replaced or repaired.

Replace or repair: Not acceptable because future damage to the tooth and/or surrounding tissues is likely to occur or is occurring. Not acceptable to the patient who has asked for repair or replacement.

D.8.4. Dentist's perception of patient satisfaction

A brief single-page form will be included in the Study 3 packet for the dentist to evaluate the patient and visit. It will include an overall rating of patient satisfaction, comfort and anxiety of the patient during the procedure, level of rapport established, the extent to which the patient was interested in information about the procedure, whether the patient felt strongly about the choice of restoration material, and the level of complications during the procedure. In exploratory analyses, we will use these variables as covariates (individually or by calculating scores for dentist-patient concordance). These data may help explain differences in patient satisfaction and improve our subsequent ability to make recommendations to improve daily clinical practice. Dentists who choose will receive anonymous feedback about the aggregated results of patient satisfaction in their practice and how it compared to their own ratings of the visit.

D.9. Study design and statistical analysis

The study uses a descriptive cross-sectional design, consisting of a single administration of a questionnaire-based survey to a convenience sample of dental patients receiving treatment at members of DPBRN. A subset of the subjects will participate in a 3-year longitudinal panel (Study 5). As the questionnaire will be administered to each patient and does not specifically ask about each restoration, the subject will be the unit of measure. Should a tooth fail in a subject with multiple restorations, we score that subject as "failure".

Specific Aim #1: Quantify dental patient satisfaction with a recent dental visit where a restoration was placed or repaired using an instrument that adequately samples from the range of characteristics that are important to patients.

This aim is primarily descriptive in nature. Summary statistics will be provided for each questionnaire item including mean, standard deviation, median and quartiles. Summary statistics will also be provided for an aggregate score for each of the satisfaction domains discussed above. Each domain's score will be constructed as the sum of responses to each survey item within that domain. Scores will also be calculated for the three levels of repair/replacement: subjects: 1) only repairs, 2) repair and replacement, 3) only replacement.

Specific Aim #2: Test the hypothesis that patients' ratings of the technical ability of their dentist, comfort during the visit, and having a pain-free visit will be the strongest predictors of overall patient satisfaction.

The primary analysis for this aim will use linear regression with the patient's overall satisfaction as the dependent variable (Item #20: Overall, how satisfied were you with all aspects of your dental treatment and visit?), and other survey items as the independent variables. Generalized estimating equations will be used to adjust for the clustering of patients within dentists. By incorporating data gathered by DPBRN study 3 we will also be able to examine the effect of patient-level demographics on overall satisfaction. A secondary analysis will pursue an identical strategy to identify survey items related to the patient's assessment of the dentist's technical skill (Item #21: Overall, how would you rate the technical abilities of the dentist?).

Specific Aim #3: Test the hypothesis that patient's satisfaction and perception of the dentists' technical expertise will be associated with the long-term outcomes of that restoration(s).

The primary analytical strategy will be to use logistic regression with a binary outcome indicating whether or not each documented restoration failed within the 3-year monitoring period of Study 5. Two definitions of failure will be used: replacement or repair by the dentist due to the condition of the restoration, and repair or replacement for any reason regardless of the restoration's condition, including patient request. The independent variables will be the survey items assessing overall satisfaction and the assessment of the dentist's technical skill, as discussed in Aim 2. Generalized estimating equations will be used in this analysis as well to adjust for clustering within dentists. A secondary approach will use survival analysis with Cox proportional-hazards models to examine the relationship between the outcome of restoration failure and the patient's satisfaction and rating of the dentist's skill. This analysis will likely be less robust than the logistic regression due to the expected rarity of restoration failures within 3 years. Both analytical strategies will also explore the association between the outcome and each satisfaction domain. A comprehensive model will be constructed by including the most highly correlated item within each domain and then removing terms that are not statistically significant.

D.10. Power considerations

Each study aim will use patient-level data. The patients are not selected completely at random but are clustered within dentists. Patients who share the same dentist are likely to be more similar to one another than two people chosen completely at random. This similarity within dentists is represented by the intraclass correlation coefficient and it must be taken into account to avoid biased parameter estimates in statistical analyses. One of the simplest ways to consider this is to incorporate a design factor $D = (1 + (m - 1)\rho)$, where ρ is the intraclass correlation, and m is the average number of patients per dentist. In this case we expect to have approximately 30 patients per dentist and we can reasonably assume $\rho=0.05$, which results in a design factor of 1.85. In practical terms, this means that while we expect that approximately 6000 patients will be enrolled, the effective sample size will be given by $6000/1.85$ which is approximately equal to 3783. Adjusting power calculations to account for the clustering within dentists then requires only that calculations employ the effective sample size of 3783 rather than the nominal sample size of approximately 6000.

Aim 1. This aim is descriptive. However, the precision of the mean of any single survey item can be described by the width of a confidence interval around that mean. In this case the largest possible standard deviation for a single item would be 5 and thus the upper bound for the SD of the mean of a single item is $5/\sqrt{3783}=0.081$. It follows then that with 95% confidence the sample mean is within $1.96*0.081=0.16$ of its estimate and will likely be much closer.

Aim 2. This aim will rely on linear regression, which essentially estimates the correlation between two variables. An effective sample size of 3783 patients will result in 80% power to detect a correlation coefficient as small as 0.05 using a two sided test with a type-1 error rate of 0.05. There will clearly be enough power to detect correlations strong enough to be practically meaningful.

Aim 3. Very little data exist to allow for reasonable power calculations for this aim. The crux of the issue is uncertainty as to just how rare restoration failures will be. Nevertheless, it can be said with

confidence that an effective sample size of 3783 should be sufficient to detect meaningful relationships if any exist within a 3-year follow-up.

E. Human subjects research

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

E.1.1. 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-i's' practices and the p-i's themselves. The p-i's will be recruited from the clinicians enrolled in DPBRN and meet the eligibility criteria specific to this protocol. These subjects will have provided informed consent. Children 12 years of age and younger will be excluded because of issues related to comprehension and validity of responses.

E.1.2. Sources of materials: Data will be obtained from the Patient Satisfaction Surveys that are mailed to the Regional Coordinators before they are forwarded to the Coordinating Center. Data from these surveys will also be linked to responses on the replaced/repaid restoration (Study 3) and restoration defect ratings (Study 5).

E.1.3. Potential risks: The only risk to the p-i's 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. 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 a Satisfaction Survey Form and related forms will be completed by each patient/subject in the study. The Satisfaction Survey Forms will be coded, kept confidential, and will be stored in a secure place.

E.2. Adequacy of protection against risk

Recruitment and informed consent: We will provide the p-i's 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. The first page of the Satisfaction Survey Form will be an information sheet that provides the elements of informed consent. Should an IRB require written consent, a specially designed Informed Consent Form will be explained to the patient by the p-i's or human subject protection trained staff of the p-i. After assurance that the information provided is understood by the patient, the patient and p-i, or human subject protection-trained staff of the p-i, both sign the form, which then becomes part of the patient's chart or is stored in a secure research folder.

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 participant 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-i's will benefit from the opportunity to learn about patient satisfaction over-all and patient satisfaction in their practice compared to that of their peers. 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-i's and indirectly to their patients will far exceed the risk involved with the participation. Subjects will not be paid nor charged a fee for completing the survey. P-i's will not be paid for distribution of the survey to patients or for mailing the reminder letter.

E.4. Importance of the knowledge to be gained

The knowledge to be gained from the current study will increase our understanding of the determinants of patient satisfaction, which may have implications for interventions that promote compliance, increase return dental visits, and improvement in oral health.

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 on page 19 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.

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

The p-i's who participate in this study will be dental practitioners who participated in Study 1, meet the other eligibility criteria, and are participating in Study 3. 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. Children 12 years of age and younger will be excluded because of issues related to comprehension and validity of responses. Our anticipated enrollment for patients is shown in the Targeted/Planned Enrollment table on page 20 of this application.

E.8. Inclusion of children

This study is designed to investigate patient satisfaction associated with a dental visit in which a restoration repair or replacement is performed on a permanent tooth surface by DPBRN p-i's. The age of the patients will depend on the dental practice; some p-i's restrict their practices to the treatment of adults only, some have 'family type' practices, and some practices treat children and adolescents only. Children 12 years of age and younger will be excluded because of issues related to comprehension and validity of responses. 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

Study Title: Patient satisfaction with dental restorations

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 in Study 3 and therefore up to 6,000 patients will be participating in Study 4.

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.

Targeted/Planned Enrollment Table (for the patients participating)**This report format should NOT be used for data collection from study****Study Title: Patient satisfaction with dental restorations****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 in Study 3 and therefore up to 6,000 patients will be participating in Study 4.

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.

REFERENCES

- Abrams RA, Ayers CS, Vogt Petterson M. Quality assessment of dental restorations: a comparison by dentists and patients. *Community Dent Oral Epidemiol.* 1986 Dec;14(6):317-9.
- Alvesalo I, Uusi-Heikkila Y. Use of services, care-seeking behavior and satisfaction among university dental clinic patients in Finland. *Community Dent Oral Epidemiol.* 1984 Oct;12(5):297-302.
- Burke L, Croucher R. Criteria of good dental practice generated by general dental practitioners and patients. *Int Dent J.* 1996 Feb;46(1):3-9.
- Calnan M, Dickinson M, Manley G. The quality of general dental care: public and users' perceptions. *Qual Health Care.* 1999 Sep;8(3):149-53.

- Chu CH, Lo EC. Patients' satisfaction with dental services provided by a university in Hong Kong. *Int Dent J*. 1999 Feb;49(1):53-9.
- Chu CH, Yeung CY, Lo EC. Monitoring patient satisfaction with university dental services under two fee-paying systems. *Community Dent Oral Epidemiol*. 2001 Oct;29(5):390-8.
- Corah NL, O'Shea RM, Pace LF, Seyrek SK. Development of a patient measure of satisfaction with the dentist: the Dental Visit Satisfaction Scale. *J Behav Med*. 1984 Dec;7(4):367-73.
- Davies AR, Ware JE, Jr. Measuring patient satisfaction with dental care. *Soc Sci Med* 1981;15: 751-60.
- Donabedian A. The quality of care. How can it be assessed? *JAMA*. 1988 Sep 23-30;260(12):1743-8.
- Freeman R. Communicating effectively: some practical suggestions. *Br Dent J* 1999;187:240-4.
- Goedhart H, Eijkman MA, ter Horst G. Quality of dental care: the view of regular attenders. *Community Dent Oral Epidemiol*. 1996 Feb;24(1):28-31.
- Golletz D, Milgrom P, Mancl L. Dental care satisfaction: the reliability and validity of the DSQ in a low-income population. *J Public Health Dent*. 1995 Fall;55(4):210-7.
- Gopalakrishna P, Munnaleneeni V. Influencing satisfaction for dental services. *J Health Care Mark*. 1993 Winter;13(1):16-22.
- Gurdal P, Cankaya H, Onem E, Dincer S, Yilmaz T. Factors of patient satisfaction/dissatisfaction in a dental faculty outpatient clinic in Turkey. *Community Dent Oral Epidemiol*. 2000 Dec;28(6):461-9.
- Hakeberg M, Heidari E, Norinder M, Berggren U. A Swedish version of the Dental Visit Satisfaction Scale. *Acta Odontol Scand*. 2000 Feb;58(1):19-24.
- Handelman SL, Fan-Hsu J, Proskin HM. Patient satisfaction in four types of dental practice. *J Am Dent Assoc*. 1990 Nov;121(5):624-30.
- Handelman SL, Jensen OE, Jensen P, Black PM. Patient satisfaction in a regular and after-hours dental clinic. *Spec Care Dentist*. 1996 Sep-Oct;16(5):194-8.
- Holt VP, McHugh K. Factors influencing patient loyalty to dentist and dental practice. *Br Dent J*. 1997 Nov 22;183(10):365-70.
- Lahti S, Tuutti H, Hausen H, Kaariainen R. Dentist and patient opinions about the ideal dentist and patient--developing a compact questionnaire. *Community Dent Oral Epidemiol*. 1992 Aug;20(4):229-34.
- Lahti S, Tuutti H, Hausen H, Kaarlanen R. Patients' expectations of an ideal dentist and their views concerning the dentist they visited: do the views conform to the expectations and what determines how well they conform? *Community Dent Oral Epidemiol*. 1996b Aug;24(4):240-4.
- Lahti S, Verkasalo M, Hausen H, Tuutti H. Ideal role behaviours as seen by dentists and patients themselves and by their role partners: do they differ? *Community Dent Oral Epidemiol*. 1996a Aug;24(4):245-8.
- Liddell A, Locker D. Dental visit satisfaction in a group of adults aged 50 years and over. *J Behav Med*. 1992 Aug;15(4):415-27.
- Locker D, Lidell AM. Correlates of dental anxiety among older adults. *J Dent Res* 1991;70:198-203.
- Murray H, Locker D, Mock D, Tenenbaum H. Patient satisfaction with a consultation at a cranio-facial pain unit. *Community Dent Health*. 1997 Jun;14(2):69-73.
- Newsome PR, McGrath C. Patient-centered measures in dental practice: 1. An overview. *Dent Update*. 2006 Dec;33(10):596-8, 600.
- Newsome PR, Wright GH. A review of patient satisfaction: 2. Dental patient satisfaction: an appraisal of recent literature. *Br Dent J*. 1999 Feb 27;186(4):166-70.
- Newsome PR. Current issues in dental practice management. Part 3. Attracting and keeping patients. *Prim Dent Care*. 2003 Oct;10(4):109-12.
- Oliver RL. *Satisfaction: A Behavioral Perspective on the Consumer*. NewYok: McGraw-Hill, 1997
- Rao CP, Rosenberg LJ. Consumer behavior analysis for improved dental services marketing. *Health Mark Q*. 1986 Summer;3(4):83-96.
- Riley JL 3rd, Gilbert GH, Heft MW. Dental attitudes: proximal basis for oral health disparities in adults. *Community Dent Oral Epidemiol*. 2006 Aug;34(4):289-98.
- Riley JL 3rd, Gilbert GH, Heft MW. Orofacial pain: patient satisfaction and delay of urgent care. *Public Health Rep*. 2005 Mar-Apr;120(2):140-9.
- Sitzia J, Wood N. Patient satisfaction: a review of issues and concepts. *Soc Sci Med*. 1997 Dec;45(12):1829-43.

- Skaret E, Berg E, Raadal M, Kvale G. Reliability and validity of the Dental Satisfaction Questionnaire in a population of 23-year-olds in Norway. *Community Dent Oral Epidemiol.* 2004 Feb;32(1):25-30.
- Skaret E, Berg E, Raadal M, Kvale G. Factors related to satisfaction with dental care among 23-year olds in Norway. *Community Dent Oral Epidemiol.* 2005 Apr;33(2):150-7.
- Spreng RA, MacKenzie SB, Olshavsky RW. "A reexamination of the determinants of consumer satisfaction," *Journal of Marketing*, 1996 60(3):15.
- Stouthard ME, Hartman CA, Hoogstraten J. Development of a Dutch version of the Dental Visit Satisfaction Scale. *Community Dent Oral Epidemiol.* 1992 Dec;20(6):351-3.
- Tamaki Y, Nomura Y, Nishikawara F, Motegi M, Teraoka K, Arakawa H, Tsurumoto A, Hanada N. Correlation between patient satisfaction and dental clinic credibility in regular dental check-ups in Japan. *J Oral Sci.* 2005 Jun;47(2):97-103.
- Tse DK, Wilton PC. Models of consumer satisfaction formation: an extension. *J Marketing Res* 1988;25:204-212.
- Tuominen R, Tuominen M. Satisfaction with dental care among elderly Finnish men. *Community Dent Oral Epidemiol.* 1998 Apr;26(2):95-100.
- Unell L, Soderfeldt B, Halling A, Birkhed D. Explanatory models for clinically determined and symptom-reported caries indicators in an adult population. *Acta Odontologica Scandinavica* 1999;57:132-8.
- Ware JE, Davies AR. Defining and measuring patient satisfaction with medical care. *Evaluation and Program Planning* 1983;6:247-263.
- Wolf MH, Putnam SM, James SA, Stiles WB. The medical Interview Satisfaction Scale: development of a scale to measure patients' perceptions of physician behaviour. *J Behav Med* 1978;1:391.
- Yamalik N. Dentist-patient relationship and quality care 2. *Trust. Int Dent J.* 2005 Jun;55(3):168-70.
- Zeithaml VA, Bitner, MJ, Gremer DD. *Services Marketing*. 4thrd edition. New York: McGraw-Hill, 2005.