Abstract

DESCRIPTION (provided by applicant): Dental caries and periodontal disease are two of the most common infection-based dental conditions in the United States. Most dental practice revolves around efforts to prevent these conditions or treatments to mitigate their effects. Ample evidence suggests that dentists often do not use the most effective treatment methods when treating caries and periodontal disease. We postulate that this is not because they have not been exposed to evidence-based guidelines but rather that they continue to express the practice patterns they learned in dental school - even if they are no longer considered best practices. This project will provide dentists with simulated patients posing evidence-based challenges of effective treatment and build in treatment-specific decision support. We will assign HealthPartners dentists into a usual-care and simulation group and measure their treatment-planning patterns after the simulation group is exposed to evidence-based simulations and feedback support. We expect to find that the dentists exposed to the simulation encounters will exhibit practice patterns more congruent with successful patterns practiced in the simulation. While conducting this project, we will also plan the distribution of the simulation tool to the broader dental community. PUBLIC HEALTH RELEVANCE: Dental caries and periodontal disease are two of the most common infection-based dental conditions dentists encounter in daily practice. Although there are evidence-based guidelines for prevention and treatment for these conditions, research shows that dentists often do not to use the most effective treatment methods. This study seeks to assess whether training dentists through simulated patient interaction and feedback rooted in evidence-based guidelines leads to better dental care.

Specific Aims

In the past, substantial efforts have been made to educate health care professionals about the most effective practices (i.e., evidence-based treatments). The National Institute of Dental and Craniofacial Research (NIDCR) awards more than $60 million annually, which has resulted in thousands of papers describing advances in dental education and research. Despite these efforts, it has become apparent that publication in scientific journals is, at best, a very slow method for translating current evidence into daily practice. Testing a way to bridge this gap between the most effective interventions and day-to-day dental clinical practice is this proposal's primary purpose. We will construct and test a dental care simulator using a case-based approach and tailored feedback to help dentists improve clinical decisions. This new approach will be evaluated using a randomized controlled trial design comparing the effectiveness of simulated treatment-planning exposure to a usual-care approach when rolling out the same evidence. This effort goes beyond the current approaches of didactic teaching of evidence-based guidelines and aims to change practice behavior, resulting in improved patient outcomes. We believe that health professionals need a non-critical environment in which to learn and practice new processes until they achieve optimal care in a real-world simulated environment, such as a Web-accessible, case-based patient simulation (Dental-SimCare, or D-SimCare).

This project takes advantage of the experience of our research team in building medical simulations and promoting evidence-based dentistry. We will use a set of accepted dental guidelines, published evidence-based reviews evaluated by our project personnel, and outcome measures available from HealthPartners Dental Group (HPDG) data sets.

The working hypothesis for this project is that the real-life treatment decisions of dentists exposed to the dental simulation will be closer to evidence-based guidelines than those of the dentists who will not use this learning system. We posit that the opportunity to plan and practice new treatment protocols in the simulated learning environment will help dentists incorporate new practice patterns into their daily clinical practices far more successfully than with knowledge acquisition alone.

Aim 1. Build a Web-based dental encounter simulation training tool that:

a. Will be online accessed via desktop and mobile devices (various operating system compatibility and browser support),
b. Will be easy to maintain, update, and expand, *and*
c. Can train dentists to apply the most effective guideline-based treatments to patients.

Aim 2. Demonstrate that the practice patterns of dentists who have used D-SimCare adhere more closely to evidence-based care than those who have not.

We will evaluate if use of D-SimCare training by dentists (study group) improves the use of evidence-based treatment protocols versus a usual-care control group over a follow-up period. Compliance with evidence-based treatment will be determined by appropriate documentation of treatment plan components in the electronic dental record (EDR). In order for this project to be evaluated (Aim 2), the follow-up data needs to contain diagnosis codes. While most dentists' offices in the United States do not have or use diagnosis coding, HealthPartners Dental Group has a history of diagnosis coding. After D-SimCare has been evaluated and found effective, dentists will not need to code diagnoses; they will need to only do what they are currently trained to do: recognize and treat problems.

This project is a new, innovative method for training practicing dentists in the protocols of best dental practice. It is innovative because case-based simulation of real-world patient scenarios for training dental providers to provide optimal and personalized care could greatly improve the delivery of oral health care and is not currently available. If this approach is shown to be effective, offering this learning tool to the broader dental community over the Web will be relatively straightforward. We will plan for the potential access and distribution of this dental simulation during the study so that, if it is successful, D-SimCare can be quickly offered to the broader dental community.

Research Strategy

Significance:

This project responds to PAR-10-038, "Dissemination and Implementation Research in Health (R01)." Creating and disseminating treatment guidelines for practitioners is a priority for the National Institutes of Health (NIH) and the American Dental Association (ADA), but very few of these guidelines are implemented by dentists in practice today[1-2]. Instead, dentists tend to use diagnostic and treatment approaches acquired during their primary dental education[3]. Moreover, if one considers that the median age of practicing dentists is 50 to 54 years, most patients conceivably receive care that was state of the art as long as 25 years ago.

In October 2006, as part of the NIH Roadmap for Medical Research, NIH initiated a broad re-engineering effort in clinical and basic sciences to create greater opportunity to catalyze the translation of scientific discoveries into practical applications and clinical care. NIH acknowledges that there are significant barriers between basic research and the clinical environment that make it difficult to translate the most effective methods into the clinic setting. One of the foci in the roadmap is to accelerate community engagement and research by "focusing on community and provider education and outreach and development of software to facilitate the collaboration and education of community practitioners." More work is needed to build and evaluate methods to change treatment behaviors of dental providers and bridge the gap between evidence-based research advances and improvement of day-to-day clinical practice.

The use of guidelines to encourage behavior change in dentists: The existence of a new or revised clinical guideline does not ensure a change in clinical practice[4]. A review of 59 published evaluations of clinical guidelines in medicine concluded that guidelines could improve clinical practice, but the size of the improvements in performance varied considerably depending on the strategy for implementation[5]. Our own review of the dental literature (Table 1) found little effect of guidelines on clinical practice. Bero et al.[6] examined systematic reviews of strategies for the dissemination and implementation of research findings to identify evidence of the effectiveness of different strategies and to assess the quality of the systematic reviews. The reviews examined suggest that the passive dissemination of information (e.g., publication of consensus conferences in professional journals or the mailing of educational materials) is generally ineffective, resulting in only small changes. However, these passive approaches represent the most common ones adopted by researchers, professional organizations, and health care systems. The use of active strategies to implement evidence-based dentistry appear necessary to change practice[6].

Table1. Studies evaluating effectiveness of guidelines in dentistry

Author of randomized controlled trial	Topic	Guideline tested	Result
O'Brien, 2000[7]	Orthodontic referral	Locally developed	Nsd,* inappropriate referrals increase
Bahrami, 2004[8]	Third-molar extraction	Locally developed	Nsd, regardless of implementation
van der Sanden, 2005[9]	Lower third-molar extraction	SIGN 47	Nsd in percentage of appropriate referrals
Pre-post studies			
Worrall, 2001[10]	Third-molar referral	RCSE	Significant Improvement
Foley, 2003[11]	Caries prevention	SIGN 47	Some significant improvement, some nsd
Jamileh, 2003[12]	Lower third-molar extraction	NICE & SIGN	Some significant improvement, some nsd
Ryan, 2004	Third-molar extraction	NICE	No extra effect on existing trend
Rogers, 2005[13]	Third-molar extraction	NICE	No extra effect on existing trend
Sheldon, 2004	Third molar	NICE	No extra effect on existing trend

Nsd, No significant difference between experimental and control group or pre-post studies.

Case-based learning and simulation are not used as training, except in dental schools

While case-based dental simulation is not new to dental education, it does appear to have been used in the past almost exclusively in dental schools[14], as they are traditionally the site of most initial dental education. However, as most dentists can expect to practice for at least 40 years, the development of effective approaches to continuing education is imperative. The Internet offers the opportunity to bring simulated case-based learning into every dental office in the country. Simulations, both computer-based and process-based, have proven effective in training both physicians and dentists in the higher education environment[14-16]. A particularly fine example is in the work of the Karolinska Institute in Sweden. However, the main deficit of many case-based systems is that they are unable to actively simulate the patient and assess the provider's learning status to provide suitable successive cases of increasing complexity. They have also not been tested as a method to develop and reinforce the most effective knowledge to practicing dentists. This may be because, before the advent of the Internet, there was no way to provide a case-based simulation practice environment for ongoing learning. If we aim to reduce the delay in dentists' acquisition of the latest best practices, techniques need to be developed to encourage and support new practice patterns, such as a Web-based simulation environment.

Conceptual model for using case-based simulation to translate knowledge into practice

This project is based on the conceptual model developed by Green and Seifert[17] in their article "Translation of Research Into Practice: Why We Can't 'Just Do It'." The authors state that translation goes through three stages, starting with **awareness**. Awareness alone, while it may be necessary to understand and provide the appropriate presentation of the latest knowledge, does not lead to the incorporation of new knowledge into clinical practice. The development and problems in promulgation of guidelines have supported this point. Hundreds of guidelines incorporate the latest knowledge in both medicine and dentistry but, while most providers know they exist, few have taken the time to read the ones most relevant to their practice[18]. Studies have shown poor correlation between continuing medical education or clinical practice guideline dissemination and actual changes in clinical care[18]. The second stage, **acceptance**, involves becoming familiar with the new knowledge and understanding how to apply it in a clinical setting. However, acceptance alone will not change how health professionals practice. When the health care professional treats a patient, he or she relies on a body of well-practiced care patterns that they have developed during their training and subsequent practice. New clinical actions need to be practiced before they are adopted into a provider's skill set. For the third stage, **adoption**, to take place, the provider must become comfortable with the changes to clinical practice; we suggest that the most appropriate adoption mechanism is a realistic training situation with feedback in which the new knowledge can be incorporated into the standard repertoire of clinical skills.

Green and Seifert [17] suggest that, for adoption to occur, the provider needs what they call "*deliberate practice*" (i.e., a realistic directed simulation of the clinical processes). Such simulations should provide the user a series of related cases with the contextual cues of a clinic visit in which the provider is asked to make appropriate clinical decisions and is given feedback on the consequences of those decisions.

Innovation:

This is a highly innovative project because it takes an approach already tested in medicine, modifies it to fit the unique elements of the dental encounter, and validates it in a data-rich environment. Further, it seeks to shift current clinical practices on the basis of evidence-based guidelines. Of the150,000 dentists in the United States, 130,000 are general dentists. Because dentists provide about 20% of the health care encounters in the United States, we need to provide dentists training on the use of the most current and effective procedures. A Web-based system will allow the dentist freedom and independence to continue this education. Dentistry, unlike medicine, is composed of small practices spread across the country. This makes dentists difficult to reach using standard methods of continuing education. We hope that D-SimCare will fulfill part of this continuing education need.

While the initial project will be funded for only 4 years, we anticipate its use well beyond this development period. Therefore, D-SimCare will be constructed to have a standard, simple process for incorporating other effective dental protocols. An advisory governance council (stakeholders) will be formed to provide future direction for the expanded function. Support staff and further upgrades will be paid for with a reasonable yearly fee. D-SimCare will allow dentists to fulfill continuing education requirements over the Internet from their office or home.

The development/research team has considerable experience and knowledge addressing medical case-based learning, the evaluation of educational systems, the development of intelligent tutoring systems, conducting dental health services research, and investigating the use of the electronic medical record (EMR) and EDR for physician/dentist and patient interventions. HealthPartners Research Foundation (HPRF) is an ideal site for this project due to our past dental health services research, the interest in translating research results into dental practice, and our prior successful experience in developing a case-based simulation tool [19] to translate diabetes best practices into clinical practice. Several previous preliminary studies demonstrated the extensive experience of the investigators, the well-tested methodology to evaluate these hypotheses, and the adequacy of sample size of dentists and patients for this proposed project to be successful.

A number of factors make us confident that we will be able to construct and evaluate this innovative approach to transferring the most current dental care guidelines into dental practice. First, we have experience building a physician-oriented SimCare; HPRF researchers are currently evaluating the third version. Second, Dr. Friction will make freely available to the project the software and screens used in the Tirr, an EDR-like tool. This will give us a head start on screen development. Further, by using HPDG's EDR data, we will be able to find frequent examples of x-rays and dental descriptions to use in developing simulated patient profiles. (Preliminary discussions with our Institutional Review Board [IRB] staff have suggested that this will be acceptable.) Finally, for purposes of validating outcomes, we have the rich sets of data maintained in the HPDG's EDR. This data include diagnoses coding; caries and periodontal risk levels; decayed, missing, filled (DMF) status; periodontal measures of pocket depth, attachment loss and bleeding, and comprehensive electronic treatment plans.

HealthPartners leaders are committed to providing the highest quality dental care and enthusiastically endorse this project. To ensure availability and dissemination of results and interventions, Drs. James Fricton, Brad Rindal, and James Bader participate in the state and national Dental Practice-Based Research Network (DPBRN). Drs. Heiko Spallek and James Fricton are also part of the national Clinical and Translational Science Awards consortium. They and the research team members frequently speak at national meetings, which will also help ensure dissemination of results nationally and encourage use.

Another important point of distribution of newly found evidence will be the Dental Informatics Online Community (www.dentalinformatics.com), a National Library of Medicine (NLM)-funded project lead by one of the co-investigators on this proposal, Dr. Heiko Spallek. Through Dr. Spallek's involvement in the Dental Informatics Online Community, we will have access to this unique dissemination tool, which is a platform for sharing best practices in dental informatics.

Approach:

The overarching goal of D-SimCare is to develop and validate the effectiveness of a Web-accessible, case--based, simulated training tool based on the latest evidence that will, in turn, effectively change dentist behavior. This is a two-arm, 15-month, prospective, group-randomized clinical trial. We expect all 17 HPDG clinics to be block-randomized into either a usual-care arm or an intervention arm on the basis of proportion of patients covered by government programs. All dentists practicing at each individual clinic will have the same intervention assignment at their clinic to reduce the threat of contamination within clinics. The study dentists practicing at usual-care clinics will not receive any additional training until after the study is complete. The study dentists practicing at intervention-arm clinics will complete D-SimCare training. The treatment plans of the roughly1,700 patients linked to each dentist will be examined during an15-month follow-up period. Analysis will focus on the extent to which treatment plans completed for each patient are concordant with evidence-based guidelines and how this concordance varies by study arm.

The study will proceed in six phases:

1) Design, programming, and pilot testing of D-SimCare,

2) Recruitment and baseline assessment,

3) Randomization, implementation, and training on simulated cases,

4) Data collection, *and*

5) Analysis and dissemination of results

6) Planning and preparation for continued use and support

Phase 1 will consist of the construction of the D-SimCare training tool, a Web-accessible, java-based system with the backend data in an Oracle database. This phase will be informed by our study of dentists' usage of EDRs and experience gained in developing a Web-accessed, java-based, medical case-based learning tool. This phase will be guided by an ongoing formative evaluation. Our primary strategy will employ user-centered evaluation methods during various stages of system development. These techniques include heuristic evaluation, cognitive walkthrough, and user testing. Heuristic evaluation is a systematic inspection of the usability of a user interface design. A small number of evaluators examine the interface and judge its compliance with recognized usability principles ("heuristics").

The use of user-centered design principles is vital for our project because many dentists are not very proficient with technology. User testing begins with defining tasks for testing an interface. Dentists from outside HPDG who are not familiar with the system will be asked to complete the task(s) and to verbalize their thoughts in the process using a think-aloud-protocol that is considered the gold standard for measuring usability. Both user actions and utterances are recorded and provide clues to usability problems with the product. In summary, these formative evaluation methods are derived from so-called "discount" usability engineering methods developed in the field of human computer interaction. The design will be completed in an iterative approach applying these user-centered design methodologies to reduce the number of potential usability problems later on. Because of our participation in the DPBRN, we have a pool of non-HealthPartners dentists with research interests who will be recruited for pilot testing.

During *Phase 2*, dentists will be identified and recruited to participate in the study. We will invite eligible general dentists to participate if they provide regular dental care in HPDG clinics at least 4 days per week. Our experience in recruiting dentists into prior DPBRN studies leads us to believe that we will be able to recruit around 28 to 30 dentists from HPDG. At this point, we will firm up the final set of guidelines to be included in training. Currently, we intend to include the ADA guidelines on the use of pit and fissure sealants and on the application of topical fluorides and the American Heart Association (AHA) guideline on the prevention of infective endocarditis because they have well-researched guidelines and deal with serious dental conditions. Dental caries is the most common chronic health-related condition in the nation. We also expect that, by this point in the project, a number of other evidence-based guidelines will be included, and we will design and construct D-SimCare to make further guideline incorporation relatively simple.

During *Phase 3,* clinics having study-consented dentists will be stratified into like blocks on the basis of the proportion of patients covered by government programs. Within each block of clinics, each clinic will be randomly assigned to either a control or study group. Study dentists will be assigned to the control or study group on the basis of the random assignment of the clinic in which they work; the control group will provide usual care with a delayed option to use the D-SimCare tool after follow-up patient data has been collected. Training in tool usage will be provided through a number of venues: we will give demonstrations and training sessions at meetings at the intervention clinics; a manual of operation will be constructed and refined during pilot testing at the end of phase one; and an online video of D-SimCare operation will be available to study participants. Next, the study group will be given a series of simulated dental cases with evidence-based challenges. They will build treatment plans for successive cases until they are judged to be following evidence-based protocols. The feedback to the dentist about the congruence of their treatment plan with evidence-based guidelines will be provided after each treatment plan is submitted. Each feedback element will have its own unique code, which will allow the assessment of the dentist's treatment-planning success. As in dental practice, individual cases will present both treatment and diagnoses challenges and will often address more than one problem. In our experience with physicians, multiple cases are easily manageable; physicians completed up to a dozen simulated patients with multiple simulated encounters within a week while dealing with busy practices. We also found that, although not required, they often repeated cases until they achieved the greatest success. As further motivation towards simulated case completion, we will arrange continuing education credits for dentists in the intervention group and, subsequently, in the usual-care group.

Phase 4 will commence after the simulated cases are finished. It will consist of an 15-month follow-up period in which data is collected on the treatment of real dental patients within the study conditions. The presence of study conditions will be established through the use of HPDG's extensive set of diagnosis and finding codes and associated ADA treatment codes.

Phase 5 will be a 9-month analysis and reporting period. At this time results will be analyzed and disseminated at national conferences and submitted for publication.

Phase 6 involves planning and preparation for continued use and support. This phase will run concurrently with many of the other phases and will anticipate a significant result. We do not intend to conduct this study, publish some papers, and the move on to other research. If this system proves successful, we will support its use on a national scope. Planning for maintenance and dissemination will be conducted with 'Journey Well', a HealthPartners corporate entity that markets health products developed at HealthPartners.

Dentist and patient study subjects : Dentists participating in the study are general dentists practicing in HPDG; their treatment plans are recorded in and can be extracted from the EDR, which allows us to track data in a standardized way.

To be eligible for this study, HPDG dentists must be a general dentist who currently provides ongoing care at least 4 days per week. Eligible dentists will be personally contacted about the purpose of the study and invited to participate. There are currently about 50 eligible dentists in 17 clinics with a total of about 100,000 patients. Thus, each of the two study arms, control and intervention, could include up to 25 dentists, with a potential pool of about 50,000 patients in each arm. Prior recruiting experience leads us to expect a recruitment rate of 60%, which will realistically result in about 30 participating dentists with about 60,000 patients in both study arms.

Description of intervention: The intervention tested in this project will provide an entirely new learning and practice model that can be used in the future to improve dental care by training dentists to use the latest effective guidelines. It supplies the dentist with a case-based simulated environment to design treatment plans based on the latest evidence-based protocols while facilitating the introduction of these treatments into their practice repertoire.

This Web-based training tool will consist of a series of tabbed screens. First will be basic demographic information and health history. Next will be a diagrammatic depiction of teeth, their presence or absence, and any active caries and restorations. Third will be x-rays. Fourth will be a depiction of periodontal status. Last will be a treatment-planning screen where the dentist can create a treatment plan by choosing options. After indicating the end of the treatment-planning process, they will encounter a feedback screen. This screen will evaluate their treatment plan and make suggestions for improvement. An appropriate treatment approach will be considered mastered when the dentist has treatment-planned a particular situation in three simulated patients without an error. Because a patient may have multiple conditions, it will be possible for the dentist to plan one situation appropriately while missing it on others. The feedback coding system will allow us to track and analyze outcomes relative to specific conditions.

Table 2. Example elements from HealthPartners Dental Group electronic dental record for possible inclusion/exclusion in guideline development and evaluation

Included in guideline	Code	Description
Yes	D1203	Topical fluoride gel - child
Yes	D1204	Topical fluoride gel - adult
Yes	D1209	Fluoride varnish - child
Yes	D1211	Fluoride varnish - child
No	D1110	Prophylaxis - adult
No	D1120	Prophylaxis - child
No	D0425	Test - caries susceptibility

Currently, we intend to include the ADA guideline on the use of pit and fissure sealants, a highly effective yet underused caries preventive process [20]; the ADA guideline on the application of topical fluorides [21-22], which are often inappropriately used; and the AHA guideline on the use of prophylactic antibiotics, which have been shown to be problematic because it is inappropriately used [23-24]. By this point in the project, a number of further evidence-based guidelines will probably have been sufficiently developed, and we will design and construct D-SimCare so that we can make further guideline incorporation relatively simple. We want to be clear that the purpose of this project is not to test the validity of specific guidelines but rather to develop and test a method of translating an existing guideline into dental care.

The proposed intervention is based on both an established process-control conceptual model and current theories of behavior change. The intervention is simple, inexpensive, and congruent with primary dental care practice patterns; thus, its dissemination potential is high. It is also a methodology that we have shown to be effective in improving chronic disease care in medicine.

Simulated intervention: Dentists assigned to the study group will receive a feedback-based D-SimCare intervention on a set of patients who reflect the study set of interventions. Each simulated visit will be followed by feedback on the treatment plan proposed on the basis of the specific dental guidelines. D-SimCare will require the dentist to review all feedback before continuing to the next patient. Dentists will continue to treat simulated patients until they achieve congruence with the evidence-based guidelines across the differing cases. The adaptive character of the D-SimCare system will be represented by providing customized feedback to the dentist on the basis of treatment decisions and behavior patterns shown by individual dentists. We also plan to incorporate assessment functionality in D-SimCare to allow it to automatically identify knowledge gaps and present cases to train or update the dentist's practice patterns in those areas. We believe that only a learner-centered approach that takes individual learner characteristics into account can come close to the gold standard of educational systems, one-on-one tutoring [25].

Thus, D-SimCare moves away from the traditional broadcast, one-size-fits-all approach and employs various concepts from educational adaptive hypermedia — an emerging field in educational research. This paradigm shift focuses on evaluating the learner's abilities, pre-existing knowledge, and interactions with the learning system to most efficiently structure and tailor the presented curriculum material. D-SimCare will adapt the suggestions on the basis of the user model developed during interaction with the system.

Guidelines contain a set of suggested actions based on the patient state and the most effective approaches developed by research and expert judgment. These actions represent the set (often ordered) of procedures that, based on current evidence, will provide the patient with the best result. They also identify exclusion processes that may have been felt in the past to be necessary but that evidence has shown to have a neutral or negative effect on treatment success.

Usual care for the control group. The patients in the control group will continue to receive their regular care. Usual-care dentists will not have the opportunity to experience D-SimCare until completion of the follow-up period. To reduce contamination between dentists, dentists will be randomly assigned at the clinic level. All dentists agreeing to participate in the study within the same clinic will be randomly assigned to the same group. Data required to measure the outcomes is incorporated in the EDR for both the intervention and control groups and will be collected on all participating dentists at HealthPartners. The same algorithms that are used to score and access the elements of the treatment plans in D-SimCare will be used to evaluate the treatment plans in the EDR.

D-SimCare operational process

The dentist will access D-SimCare by logging into a specific Web site, which will explain D-SimCare and how to use it. New users will be able to register and receive a logon and password. Registered users simply enter their logon and password. Having entered the system, they will encounter the general interface screen, which will have a set of functionality tabs in a row. When a tab is selected, the functions associated with the tab will appear in the area below the tabs on the screen. These tabs contain the core components of the collection of patient's dental data as well as treatment-planning options. When the user finishes the treatment plan and schedules the next encounter, this window will be replaced by a window critiquing the user's actions and making suggestions for further treatment actions. Each simulated patient's situation will represent a case space of learning points. If D-SimCare determines by the dentist's actions with multiple patients that he or she has acquired particular learning points, congratulations will be offered and treatment of patients representing that evidence-based domain will end. Dentists will be able to log out of the system and pick up where they left off the next time they log in. All a user's interactions will be captured so that their treatment patterns can be analyzed to improve D-SimCare and to better understand the dentist's learning processes.

Variable definition, measurement definition, and measurement of outcomes: Each of the treatment plan procedures associated with study guidelines will be mapped by study personnel to the treatment plan procedures found in the HPDG EDR. These possible treatments will then be incorporated with other possible treatments that the dentists on our study team feel are not evidence-based alternatives into the treatment-planning options in D-SimCare (See Table 2 for examples).

Each simulated case will give the dentist sufficient information (i.e., x-rays, periodontal status, tooth status chart, patient complaints, and past notes) to make an accurate diagnosis and design an appropriate treatment plan. We will pilot test D-SimCare using dentists from outside HPDG to ensure that the system works, is easily understood, that appropriate diagnoses are made on a straightforward basis, and that the sets of possible actions for treatment planning map to the diagnoses.

We expect that once a dentist is trained to recognize and treat training situations appropriately, he or she will change his or her chairside procedures to maximize effectiveness. The EDR allows us to track the diagnoses through findings codes and elements of the treatment plan. Our main dependent variables are binary measures of whether treatment plans adequately reflect guideline-based care.

Dependent variables for Aim 2; Hypotheses 1-3: The principal dependent variables for Hypotheses 1-3 are the proportion of eligible treatment plans in the 15-month post-intervention follow-up period with fluoride varnish or gel application (H1), the proportion of eligible treatment plans with sealant application (H2), and the proportion of treatment plans with inappropriate use of antibiotics (H3). ADA guidelines for fluoride and sealant application and AHA guidelines for the use of antibiotic prophylaxis define the suggested treatment to use on appropriate individuals. We will focus on aspects of the guidelines that have the strongest evidence and recommendations for defining the dependent variable and the sample on which it will be computed. For H1 (fluoride application), care will be considered consistent with guidelines when i) patients younger than 18 years, ii) at moderate or high caries risk, iii) who have not had fluoride applied to their teeth in the past 6 months, and iv) have a varnish application or fluoride gel application in their treatment plan. For H2 (sealant placement), care will be considered consistent with guidelines when i) patients younger than age 18 years, ii) are at elevated caries risk or who have teeth at elevated risk, iii) have not had sealants applied to permanent teeth, iv) and the treatment plan indicates the use of sealants on pits and fissures on permanent teeth. In addition, treatment plans that include pit and fissure sealants for noncavitated carious lesions in children, adolescents, and young adults will be considered consistent with guidelines. For H3 (avoiding non–guideline-based use of antibiotic prophylaxis), care will be considered inconsistent with guidelines when i) treatment plans for patients contain use of prophylactic antibiotics, ii) and the patient does not have any of the conditions indicated for use of prophylactic antibiotics per AHA guidelines. While outcomes are all planned procedures, we feel that, as dentists become familiar with the evidence-based procedures, the main challenge in dentistry is helping dentists plan for the most effective treatments for a given situation.

Additional dependent variables for Hypotheses 1-3: Publication of new guidelines may result in other conditions and treatment plan elements for consideration. D-SimCare will be designed so that new areas and treatments can be easily integrated.

<u>Other secondary outcome measures</u> This project will also measure and report on the following outcomes in addition to the specific project aims:

- Exit surveys: Dentists' satisfaction with the case-based learning system. Perceived usefulness by dentists as a measure for acceptance rate can be used for adoption estimates when rolled out in a larger community.
- Performance on the D-SimCare system will be tracked to evaluate whether it is more difficult to achieve mastery with some guidelines than others.
- The proportion of treatment plans that inappropriately include sealant application among those with a low caries risk score.

Definition and measurement of key independent variables: The main independent variable is a clinic-randomized indicator for study arm (D-SimCare intervention or control). Patient independent variables such as age, gender, and racial/ethnic group, are available in the membership data sets. A caries risk assessment score is gathered at 95% of exam visits and is available through claims data. Geocoding of patient addresses and linking to U.S. Census data yields potential community-level measures of socioeconomic status (e.g., median household income, proportion of households living in poverty). Patient DMF scores are recorded at each encounter, along with average periodontal measures such as probing depth, attachment loss, and bleeding.

Dentist-level independent variables include dentist age, gender, years of practice experience, years of work with a computer, and practice clinic. These measures are derived from administrative and clinical databases in the dental group. Variables such as referral rates and rates of certain procedures or tests are calculated for each dentist on the basis of proportion of all patients with the targeted diagnoses. Clinic-level independent variables include staff size, number of patient visits, and location and are available from summaries of claims data.

Analysis plan and sample size justification

Analytic approach. Hypotheses 1-3 posit that dentists who receive the D-SimCare intervention will have a

higher proportion of patient treatment plans with guideline-suggested use of fluoride applications (H1) and sealant applications (H2) and a lower proportion of inappropriate use of antibiotic prophylaxis in the treatment plans of those receiving antibiotic prophylaxis (H3) than dentists assigned to usual care. Each dependent variable will be measured as a binary outcome at the patient's treatment plan level. The data structure is hierarchical, with clinics assigned to study arm, dentists nested within clinics, and patient treatment plans nested within dentists and patients. We will test against the null hypothesis that the D-SimCare intervention will not affect rates of guideline-suggested care using generalized linear mixed-model (GzLMM) regression with a logit link where appropriate. Use of fluoride, sealants, and prophylactic antibiotics will be dependent variables in three separate regression models, and study arm (D-SimCare vs. no control) will be the primary independent variable.

Analytic model for omnibus test of Hypotheses 1-3. The form of our proposed analytic model is:

$Plan\_Met_{ijk} = \gamma_{000} + \gamma_{001}DSIM + [v_{00k} + u_{0jk} + e_{ijk}]$

where Plan Met_{ijk} represents a binary indicator of a particular treatment plan meeting evidence-based criteria for patient i, seen by dentist j, in clinic k,

γ_{000} is the model intercept,

γ_{001}DSIM represents D-SimCare training vs. usual care control, correspond to the arm into which the clinic is randomized,

v_{00k}, u_{0jk}, and e_{ijk} represent random clinic and dentist intercepts and patient error terms.

Hypotheses 1-3 will be supported if in the regression model testing each hypothesis, the fixed parameter representing the D-SimCare intervention, γ_{001}DSIM, is significantly different from zero (e.g., parameter estimate/SE > 2.0) and indicative of a higher rate of the presence of guideline-suggested elements in the treatment plan, while controlling for patient and dentist characteristics that are not evenly distributed by randomization)

Sample size and power analysis for Hypotheses 1-2.

The parameter γ_{001} testing hypotheses 1-2 will be treated as a fixed effect in the context of random clinic and provider intercepts but no random slopes. Power was estimated using an effective sample size (n_{eff}), adjusted from the clustered sample size (n), the average number of patients per unit of randomization – the clinic (n_{clus}), and the anticipated intraclass correlation coefficient (ICC) (ρ).

We anticipate that all 17 clinics will permit their dentists to participate in the study. These clinics have about 50 eligible general dentists. Based on prior work in the dental group, we anticipate a study consent rate of 60% among dentists, yielding about 28 participating dentists (14 per study arm). The 17 dental clinics will be randomly assigned to the D-SimCare or usual-care arm, and dentists in these clinics will follow the study arm assignment of their clinic to prevent contamination. Each dentist has, on average, 1,700 patients having treatment plans in a 1-year period. For H1 and H2, we are focusing on the roughly 25% (425 patients per dentist) younger than age 18 years. To best match with guidelines, the patient sample is further restricted to the 39% (166 per dentist) with moderate or high caries risk measured by a routinely gathered caries risk assessment (available on nearly all patients). With 14 dentists per arm and 166 treatment plans for patients younger than age 18 years at moderate or high caries risk per dentist, the patient sample size (number of treatment plans) is 2,324 per study arm. To be conservative, we estimate the ICC using an ICC range of ρ=0.01-0.05 for patients nested within clinics. However, in numerous clinic-randomized studies in our organization using a variety of endpoints, clinic ICCs have been in the lower range of ρ=0.005-

Table 3. Minimum detectable proportion and corresponding odds ratios of treatment plans with guideline-suggested use of fluoride in H1 or sealants in H2 in the D-SimCare arm relative to the usual-care arm when P_{UC} = .50-.80, using effective sample sizes per arm based on possible clinic ICC=.01-.05 and eight clinics per study arm.

	ICC = .01 N eff=616	ICC = .02 N eff=349	ICC = .03 N eff=243	ICC = .04 N eff=187	ICC = .05 N eff=151
P_{UC} = .50	.579	.605	.626	.643	.659
P_{UC} = .60	.677	.701	.720	.736	.750
P_{UC} = .70	.770	.792	.809	.823	.836
P_{UC} = .80	.860	.878	.892	.903	.913
OR range	1.4-1.5	1.5-1.8	1.7-2.1	1.8-2.3	1.9-2.6

.0.015. Using the more conservative ICC range of ρ=0.01-.0.05 yields effective treatment plan per arm sample sizes of 616 (when ICC=.01), 349 (ICC=.02), 243 (ICC=.03), 187 (ICC=.04), and 151 (ICC=.05). Using these effective sample sizes, power analyses estimated the minimum detectable proportion (and corresponding odds ratios) of patients with guideline-suggested use of fluoride (H1) or sealant (H2) applications in the D-SimCare group ($P_{D\text{-}Simcare} > P_{UsualCare}$; 1-β=.80, α_2=.05) when P_{UC} = .50-.80, and the squared multiple correlation between γ_{001} and the remaining predictors is ρ^2=.00. The minimum detectable differences in Table 3 were derived using PASS 2002 sample size software. The range of expected rates for sealant application starts at 50% based on a prior study conducted at HPDG in which 50% of children ages 6 to 15 had one or more sealant applications over 18 months. Fluoride application rates are expected to be higher, hence the expected usual-care rates in the table range up to 0.80.

Under assumptions involving smaller ICCs (0.01 - 0.03), detectable differences in proportions and detectable odds ratios are in reasonable ranges in terms of a potential and clinically meaningful effect of the intervention on treatment plans. For example, if 70% of eligible usual-care patient treatment plans include fluoride application, and ICC=.02, the analysis will be powered (80%, α=.05, 2-tailed) to detect a significant effect if the proportion of D-SimCare patient treatment plans is greater than 79.27%, a difference of 9.2%. For higher ICCs, a substantial effect size would be required to be detected with high power.

Table 4. Minimum detectable proportion and corresponding odds ratios of inappropriate use of antibiotic prophylaxis in the D-SimCare arm relative to the usual-care arm when P_{UC} = .10-.40, using effective sample sizes per arm based on possible clinic ICC=.01-.05 and eight clinics per study arm.

	ICC = .01 N eff=539	ICC = .02 N eff=323	ICC = .03 N eff=230	ICC = .04 N eff=179	ICC = .05 N eff=146
P_{UC} = .10	.054	.043	.035	.028	.022
P_{UC} = .20	.136	.019	.106	.095	.086
P_{UC} = .30	.225	.204	.188	.174	.162
P_{UC} = .40	.318	.295	.277	.261	.247
OR range	.52-.70	.41-63	.32-.57	.26-.53	.20-.49

Sample size and power analysis for Hypothesis 3.
For H3, we are focusing on the roughly 6% (102 patients per dentist) with a treatment plan containing use of prophylactic antibiotics. With 14 dentists per arm and 102 patient treatment plans containing use of prophylactic antibiotics, the patient sample size (number of treatment plans) is 1,428 per study arm. Using an ICC range of ρ=0.01-0.05 for patients nested within clinics yields effective treatment plan per arm sample sizes of 539 (when ICC=.01), 323 (ICC=.02), 230 (ICC=.03), 179 (ICC=.04), and 146 (ICC=.05). Using these effective sample sizes, power analyses estimated the minimum detectable proportion (and corresponding odds ratios) of patients with inappropriate use of antibiotics (H3) in the D-SimCare group ($P_{D\text{-}Simcare} < P_{UsualCare}$; 1-β=.80, α_2=.05) when P_{UC} = .10-.40, and the squared multiple correlation between γ_{001} and the remaining predictors is ρ^2 = .00.

For example, if 20% of usual-care treatment plans containing prophylactic antibiotics use antibiotics inappropriately, and ICC=.01, the analysis will be powered (80%, α=.05, 2-tailed) to detect a significant effect if the proportion of D-SimCare patient treatment plans is less than 13.6%, a difference of 6.4%.

Limitations of the study

1. It might be suggested that no simulation can properly capture the true complexity of the dental encounter. This is true. However, we are not trying to simulate the entire dental visit but only the decision challenges the dentist faces when encountering one of the study situations. By having independent study situations, we are testing whether this form of active learning is effective in changing dentists' behavior in adhering to the most effective dental practices.
2. Dentist recruitment and contamination are threats to the study. To maximize dentist recruitment, we have minimized the burden of the intervention by making D-SimCare a Web-based tool. We will also arrange to provide dentists completing the study cases with continuing education credits. By making D-SimCare a Web-based system, we can quickly expand its utility to other populations while seamlessly updating the software and patient profiles without needing to ship new versions to current users. To further reduce the risk of contamination, we will randomize at the clinic level so that all dentists in a particular clinic will be in the same study arm.
3. While HPDG is unique in its size and scope compared to most dental practices in the United States, it

is an ideal environment for testing this approach because it is a more homogenous environment with rich clinical data and dentists accepting of research because of their participation in the DPBRN funded through the University of Alabama Birmingham.

It might be suggested that there is little variation in treatment protocols in the larger dental community and even less in a unified system such as HPDG. While we have no direct evidence to address this issue, we do not believe it to be true. First, at the ADA Champions Conference in Spring 2008, the discussion of specific treatment paradigms appeared to generate almost as many strategies as there were dentists. We also recently completed a series of observations of dentists; exams within HPDG and saw frequent variation in treatment plan construction.

Study timetable and sequence of events.

	Year 1				Year 2				Year 3				Year 4			
Task & Quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Phase I																
Design																
Programming																
Pilot testing																
Phase II																
Recruitment																
Baseline Assessment																
Phase III																
Randomization																
Implementation																
Training																
Phase IV																
Follow-up data collection																
Phase V																
Analysis																
Dissemination																
Phase VI																
Continual use planning																

In Phase 1, the research team will finalize the design of D-SimCare, which will be programmed as a Web-based simulation package. Formative evaluation using user-centered design principles as described will occur. During Phase 2, dentists will be recruited and a baseline assessment conducted to ensure comparability of study and control groups. Phase 3 will start with consent and randomization into either the intervention or control groups. Training materials will be developed, and D-SimCare will be implemented in the intervention group. Dentists will have up to 1 month to complete simulated cases. Multiple guideline-based situations will be generated as long as the dentist does not achieve mastery. They will do specific cases only once. When mastery of a particular guideline has not been achieved, cases with yet unmastered guidelines will be presented. New cases will continue to be generated with similar evidence-based requirements. We will be able to draw on the large library of digitized x-rays in the HPDG EDR for case materials. In Phase 4, subjects will be followed for 15 months and relevant data collected. During this period, we will also make modifications to D-SimCare suggested by the intervention process. With Phase 5, we will review preliminary analysis and establish the process for final analysis and publication of results. Dentists in the control group will be given access, which will cautiously be made available to other dentists, probably initially through the dental PBRNs. Phase 6, which will occur concurrently with many of the others, will involve planning the expanded use of D-SimCare.

Protection of Human Subjects

Risks to human subjects

a. *Human subjects involvement and characteristics.* The study sample will be drawn from the roughly 50 dentists practicing in HPDG and 100,000 patients receiving care at HPDG clinics. Base on our previous experience, we expect to recruit 30 dentists to participate in this study, approximately half of whom will receive the intervention. Of those dentists, we also expect to examine the patient records of somewhat less than 60,000 patients presenting with the dental Issues to be trained and evaluated. Only patients of dentists who agree to participate will be assessed.

   All dentists will be given the opportunity to participate. Dentists in the **intervention arm of the study** will be asked to complete a simulated dental training tool. Patient charts will be reviewed for diagnosis and treatment plan data used to evaluate congruence of dental practice with evidence-based guidelines in the 12-month follow-up period. Patient diagnosis and treatment information will be collected and linked with a specific dentist, but personal identifiers will not be extracted.

b. *Source of materials.* Research material: Data sources will include the database of simulated encounter results, the EDR, and the dental scheduling system. Results of the simulated encounters and actual patient diagnosis and treatment plan data previously described will be recorded in research databases. This study does not involve collection or handling of any biological specimens. The materials needed include records of dentist treatment plans. No patient identifiers will be captured or maintained.

   - Linkages to subjects: While diagnosis and treatment plan details will need to be linked to participating dentists, there will be no need to maintain any type of patient identifiers.

c. *Potential risks.* At its core, this project involves providing the tools to facilitate what is currently the standard of care in HPDG and to encourage the use of best-practice guidelines. Therefore, the level of risk to the patient should not be any greater than that experienced in current practice.

Potential Risks

There are two areas of risk. First is the release of patient-specific information. The second is to the dentists and hygienists, as the information collected could, theoretically, be used by the dental group to evaluate performance.

Adequacy of protection against risks

Recruitment and informed consent

The study subjects for this investigation are the dentists in HPDG. HPDG patients will contribute data that will be used both to develop the simulated cases and to evaluate the impact of the intervention. Dentist subjects will be recruited and consented with an IRB-approved consent form. Because we are not collecting patient-specific information and we expect patients to receive the normal standard of care, we will seek a waiver of consent from the IRB for patient subjects to collect data on their diagnosis and treatment.

Protection against risk

The project will be submitted to the HealthPartners IRB for review and consideration for approval according to federal grant regulations.

Information collected on the behaviors of dentists will have coded identifiers with a locked crosswalk table that will be available only to the study programmer and the PI. No information that could be used to identify the dental professionals will be maintained, and only summary information will be reported.

We will not include any patient identifying information in the study data files. No communication of any kind with patients or providers is planned other than what is detailed in the proposal. All published reports of results will use aggregated data.

Potential benefits of the proposed research to the subjects and others

Dentists enrolled in this research project will have the opportunity to experience a simulated training program designed to improve their skills in developing and implementing evidence-based treatment plans for which they will receive continuing education credits. There is no further benefit to them. There is no benefit to the dental patients other than potentially better care.

Importance of the knowledge to be gained

One of the most important issues we currently face as dental researchers is how to quickly and accurately translate the knowledge obtained from research to the broader dental community. This study is aimed at testing the use of a case-based simulation environment to improve the translation of dental evidence-based research into practice.

Inclusion of Women

We will recruit all general-practice dentists in HPDG for this research project; therefore, we assume that they will reflect the gender makeup of the dental group. All members of HPDG who receive care from participating HPDG dentists have the potential to participate, and we assume that they will reflect the dental makeup of dental patients.

Inclusion of Minorities

We will recruit all general-practice dentists in the HPDG for this research project; therefore, we assume that they will reflect the racial makeup of the dental group. All members of the HPDG who receive care from participating HPDG dentists have the potential to participate, and we assume that they will reflect the racial makeup of dental patients.

Planned/ Targeted Enrollment Table

Study Participants: Dentists			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	13	17	30
Ethnic Category Total of All Subjects*	13	17	30
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	13	15	28
Racial Categories: Total of All Subjects *	13	17	30

Study Participants: Patients			
	Sex/Gender		
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	690	468	1,158
Not Hispanic or Latino	34,626	24,216	58,842
Ethnic Category Total of All Subjects*	35,316	24,684	60,000
Racial Categories			
American Indian/Alaska Native	216	114	330
Asian	1,397	931	2,328
Native Hawaiian or Other Pacific Islander	43	29	72
Black or African American	2,328	1,554	3,882
White	31,335	22,053	53,388
Racial Categories: Total of All Subjects *	35,319	24,681	60,000

*The “Ethnic Category Total of All Subjects” must be equal to the “Racial Categories Total of All Subjects.”

Inclusion of Children

No children will be included in the population of dentist subjects; however, the patient population does include children who seek dental care with HPDG providers who agree to participate in the study. One of the primary outcomes of interest for this study is based on the ADA guidelines for fluoride and sealant application in children. Therefore, procedural and outcome information will be collected from child dental records, but this study will have no direct patient contact with children participants.