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A Clinician's Perspective

Implementation

Using Sealants

Fundamentals:
Part 2 of 2
Francesco Chiappelli, PhD

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DEPARTMENTS

FEATURES

Paolo Prolo, MD

Easy Evaluation of Research in Evidence-based Dentistry

The basic principle underlying evidence-based medicine or dentistry indicates that the recommended treatment for a given condition should be the one that the available scientific data suggest. What does a researcher comparing conditions want to know? Is the difference observed reliable? Is the observed difference large enough? What does a patient who faces a choice among treatments want to know? Would one particular option be better than the other?

Because any difference, however small, can yield a significant difference, when the sample size is large enough, those in applied fields have long sought a more intuitively appealing measure of a treatment's comparative effectiveness. One might rely upon "experts" to judge every case (How can we tell who is truly expert?). Or, we might use focus groups of relevant people (patients and possibly families or payers). Certainly, a valid and reliable system for grading published reports is important and necessary in order to assign some degree of ranking to the quality of individual studies, in terms of their effectiveness and efficacy.

The website askward.net has recently been introduced to assist the clinician in making wiser decisions with respect to the treatment of each patient using the best available evidence. The dentist is prompted to state the clinical question, such as, "What is the best treatment for patients with mucositis?" The question is translated into a PICO question, and the research is procured to generate the consensus statement following the stringent evidence-based principles outlined in this issue of the *Journal of the California Dental Association*. The output is generated within a short amount of time (generally one to 15 days, depending upon the complexity of the clinical question). It provides the dentist, for a minimal fee, with a critical evaluation of the available research by means not only of a score of research quality, which assists the dentist in accepting or rejecting the findings in clinical decision-making, and with a short qualitative grading. The output also proposes a consensus statement about the best available evidence.

The website does not seek to replace the clinical decision-making process by the dentist. Rather, it provides essential information so that the dentist can be fully informed to make decisions with respect to the optimal treatment for the each patient, based on the whole body of research. Furthermore, the website provides regular updates of the critiques and consensus statements.

In a slight modification of this approach, the website can provide the service of aiding in crafting better research reports. The author is queried with respect to research methodology, design, and data analysis. This directed guidance ensures that the manuscript follows CONSORT and any other standard of sound research reporting.

This is one example of the important steps now being made to actualize evidence-based dentistry a practical reality in the dental practice in California in the 21st century. It is a promising one because it places the onus of reading and critically assessing the research literature to individuals fully trained in oral biology and medicine, as well as in research methodology, design, and data analysis. Therefore, it frees the dentists from the gargantuan task of acquiring the skills for reading critically the entire body of research on every domain of research that pertains to their patients, and allows them to utilize the well-reviewed and succinctly synthesized bottom line in the clinical treatment of their patients. CDA

Authors / Paolo Prolo, MD, is an assistant research faculty, Division of Oral Biology and Medicine at the University of California Los Angeles School of Dentistry. David R. Moradi (not pictured) is a pre-dental student and Audrey M. Navarro (not pictured) is a graduate student and a pre-dental student.

The website askward.net has recently been introduced to assist the clinician in making wiser decisions with respect to the treatment of each patient using the best available evidence.

Informed Consent Not So Controversial in California

Educators and private practitioners should be aware that California is one of the states where the provision of informed consent apparently is not controversial.

A recent *Journal of the American Dental Association* article reporting the results of a survey about the number of dentists who provide informed consent for the provision of local anesthesia generated positive comments from several California dental educators.[1,2] However, one missive opined that California law, as the educator understood it, does not require consent for the administration of local anesthesia.[3]

Educators and private practitioners should be aware that California is one of the states where the provision of informed consent apparently is not controversial. This is evidenced in California by provisions such as California Jury Instruction 532, which includes the statement "The patient must be told about any risk of death or serious injury or significant potential complication that may occur if the procedure is performed."

It is well-documented that the administration of local anesthesia can result in death or serious injury.

Sincerely,

Daniel L. Orr, II, DDS, PhD, JD, MD
Clinical Professor of Surgery and
Anesthesiology for Dentistry
University of Nevada School of Medicine

References / 1. Orr DL, Curtis WJ, Obtaining written informed consent for the administration of local anesthetic in dentistry, *J Am Dent Assoc* 136(5):1568-71, November 2005.

2. Dower JS, Indresano AT, Peltier B, Letters to the Editor, *J Am Dent Assoc* 137(4):438, April 2006.

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Jeffrey P. Huston, DDS, MS

Preventing Dental Disease

Insanity has been defined as doing the same thing over and over and expecting a different result. Fifty-five percent of California children have untreated dental decay — twice the national average. It is time to change existing caries management methods. Scientific advancements in dentistry support a shift from the current "drill and fill" approach to a medical management model which is based on bacterial etiology. We can PREVENT dental disease.

Proactive practioners and parents can develop fresh mindsets to control the carious disease process *before* it manifests into cavities. We can learn and apply new methods in prevention and oral health behavior modification.

Risk assessments help us target who has the highest probability of carrying and transmitting virulent cariogenic bacteria. It is efficient and practical to focus our limited energy and resources on these individuals. Recent studies confirm that babies and toddlers are inoculated with acidogenic bacteria vertically from their primary caretakers, most likely their mother, and/or horizontally from peers, usually siblings or classmates. We can educate them about the deleterious processes going on in their mouths and how to control spreading the disease. The majority of child caretakers will be motivated to action upon realizing they are likely to transmit nasty cavity causing germs to their little loved ones if they don't alter their oral health habits. We must break the chain of infection.

Early visits, after the first tooth erupts or age 1 at the latest, are being recommended by the American Dental Association, American Academy of Pediatric Dentistry and American Academy of Pediatrics. Let's start seeing more babies and young children in our practices. Ninety percent of the first appointment is spent discussing risk assessment, prevention counseling, anticipatory guidance, and recommending specific interventions. We can share things they can be doing at home. In addition, we can make stronger efforts in reaching pregnant women and young mothers with this information. These are exciting ways for new and seasoned dentists to help the public and build or rejuvenate their practices at the same time.

Varnish with fluoride can be applied judiciously to the enamel of highly susceptible patients. Strengthening teeth by enhancing remineralization and repairing decalcified areas with fluoride is a highly desirable management modality because it is less invasive than traditional surgical dentistry and ultimately more effective. Incipient lesions can be arrested before they become cavities requiring treatment.

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Reducing transmission of cariogenic bacteria, incipient lesion detection and early interventions with various regimens in high and moderate risk adults and children promise to decrease dental problems and the need for surgical procedures.

It can't be repeated enough that patients, parents, and guardians "need to know we care before they care what we know."

Encouraging the use of xylitol as a sugar substitute gives patients an easy option to comply with. Finnish studies showing minimal dental problems in offspring of high-risk mothers who chewed five pieces for five minutes a day is astonishing. Xylitol products are taking over the gum market in Japan. Recently, Icebreakers Ice Cubes chewing gum has become available in the mainstream U.S. market. Xylitol can thwart the transmission of harmful microorganisms by decreasing their number in acquisition reservoirs. In some situations, it may be necessary to first prescribe an antibacterial mouthwash to decrease the bacterial load and get the buffering benefits of saliva in operation.

Nice and supportive professional attitudes are paramount when attempting to influence people. It can't be repeated enough that patients, parents, and guardians "need to know we care before they care what we know." Most importantly, young patients are not likely to remember the details of any procedures we perform. However, it is highly probable that they will remember our disposition. Don't forget the sticker and toy rewards.

Thank the parents or guardians for coming in and for bringing in their children. Express appreciation for allowing us to perform preventive dentistry. We can say, "Yes, the baby cried the entire exam, but thanks for letting me apply the new fluoride varnish to those chalky white spots. Along with your daily application of the other things we have discussed, it will minimize the need for invasive and costly treatment in the future."

In summary, reducing transmission of cariogenic bacteria, incipient lesion detection and early interventions with various regimens in high- and moderate-risk adults and children promise to decrease dental problems and the need for surgical procedures. First Smiles — Dental Health Begins at Birth courses have been promoting the prudent utilization of these and other new scientific findings in preventive oral health for the past two years. Thousands of California dental and medical healthcare providers have attended training sessions sponsored by the California Dental Association Foundation and Dental Health Foundation. Have you attended one of these continuing education classes yet?

Material for this report can be found in the February and March 2003 issues of the *Journal of the California Dental Association*. These journals, examples of caries risk assessment forms and information on continuing education opportunities, are online at www.first5oralhealth.org. CDA

Dan Hubig

Not Following the Law Can Cause Big Trouble

By Dell Richards

Like many small businesses, dental practices often get into trouble because they do not know or follow the law. Whether it is wages and hours, or discrimination and sexual harassment, ignoring the law can end up costing not only valuable time and hard-earned money, but reputation and patients.

Often the little things cause the biggest trouble — "little" things such as overtime, lunches, and breaks.

"Wages and hours is a huge issue," said Bette Robin, a Covina dentist, who also is a lawyer. "Overtime violations are the Number 1 issue. Lunch is a big issue. There are all sorts of problems that some dentists almost routinely violate."

Only one person has to file a complaint for the practice to have to pay through the nose.

Part of the problem is ignorance, Robin said. The law is complicated and getting more so all the time. But, small business owners sometimes think the law doesn't apply to them. "They think the law only applies to big businesses."

Being paid a salary, for instance, does not make employees exempt from regulations governing workers. The only exempt "employees" are associates. Even office managers don't always qualify.

Dentists often make agreements, as well as assumptions, about salaried employees that are illegal. If someone has to work overtime to do their job, but is not paid overtime, that is a violation of the law. Even if an employee agrees to disregard these laws, that also is illegal.

While it may not matter as long as everyone is happy, all it takes is one disgruntled employee to turn a dentist in.

Once an investigation opens, the California Labor Commissioner can go back three to four years, depending on the statute violated. "They can open the bag to look at all different issues," Robin said. "Then, it's not just a small, isolated problem with one employee. It becomes a much bigger issue with all employees."

Depending on the statute violated, commissioners can check timecards and other documents, which dentists have to supply and take the time to find.

In 2005, the California Division of Labor Standards Enforcement investigated more than 40,000 cases and held more than 30,000 conferences with employers about claims. Of these, nearly 9,000 went into formal hearings as a result of which employees were awarded nearly $60,000.

In addition to the time and inconvenience, penalties can be quite severe. "The labor commissioner does not have the authority to waive penalties as they did in the past," said Robin. "They must assess them — and they can add on. They can be substantial, many times the original amount owed."

Unfortunately, dentists sometimes think of their employees as a "family." This not only can cause problems with wages and hours, but can end up causing even larger problems with discrimination and sexual harassment. Practitioners may not understand that what is acceptable to them can be offensive to others.

Andrea Rosa, founder of The Rosa Law Group, cited the example of a firm that creates a sense of camaraderie by joking and teasing. The jokes could be off-color, racist, sexist, homophobic, or about certain religions.

While these antics may make the group more cohesive, if jokes go too far, it can cause problems. "The conduct can cause problems," Rosa said. "Joking and being too familiar can be problem, especially if the people don't know where to draw the line."

If a new person is hired, that person may not find any of it funny. People may be hired who could easily take offense to what others may consider commonly accepted dialogue in social settings, entertainment venues, or other situations.

Again, only one person has to file a complaint for the practice to have to pay through the nose. The cost of an investigation, the attorney to resolve or defend a lawsuit, the lawsuit itself can mount up fast. "One complaint can damage a business owner's resources and be an enormous financial burden," said Rosa.

The average cost of an age discrimination lawsuit award is more than $200,000. Race discrimination awards average $150,000. Sexual harassment awards have been in the millions.

If a lawsuit is filed, the damage to the dentist's reputation from being in the press can destroy years of credibility. "The damage to a person's reputation can be terrible," Rosa said. "Just being in the newspaper saying a suit was filed can stop people from going to the practice anymore."

That is why prevention is the key. Whether it's having a person who enforces strict rules about wages and hours — or trainings on discrimination and sexual harassment — money spent on prevention is money well-invested.

Even if no one ever files a complaint, an unhappy employee can cost a practice enormous sums of money over the long-run. "Patients are not loyal unless employees are committed and happy," said Kathleen Naganuma, owner of The Naganuma Consulting Group, which does employee and patient satisfaction training and consulting. "Employee interaction with patients directly impacts how the patient feels about the practice."

Because dental procedures are such an intimate experience, people often are anxious when they arrive. How they are treated the moment they walk in the door colors the whole experience. "Having the environment be friendly and calming is critical to the patient's comfort level," Naganuma said. "If the employees are not friendly and warm, it adds to the feeling of fear and isolation."

Because employees such as receptionists and treatment coordinators are the first and last people to handle the patient, it is crucial for them to shine. "There's definitely a correlation between patient growth and employee satisfaction," Naganuma said.

In a small office, one disgruntled employee has a much bigger impact than in a large worksite.

If a dentist has a team of five people and one is dissatisfied, 20 percent of the workforce is going to be fighting management. "One disgruntled employee can disrupt the whole team," said Naganuma. "Most dental practices need to be very careful to make sure that their employees are engaged in the business and committed to its success for the business to run as well as it should."

A practicing journalist, Dell Richards runs Dell Richards Publicity, a public relations firm specializing in dentistry and health care.

"One disgruntled employee can disrupt the whole team,"

KATHLEEN NAGANUMA

Phase 3 Studies Initiated for Novel Dental Anesthesia Reversal Agent

A San Diego-based pharmaceutical company has begun two pivotal Phase 3 studies for NV-101, a vasodilator that is being evaluated as a local dental anesthesia reversal agent.

"Following receipt of the FDA's written agreement in October 2005 of the design and planned analysis of our pivotal studies through the Agency's Special Protocol Assessment process, we have begun the Phase 3 studies in 24 study sites across the United States," said Donna Janson, president and chief executive officer of Novalar Pharmaceuticals, Inc., a privately held specialty pharmaceutical company. "These sites include leading dental schools, clinical research organizations and private clinics."

Working off the results from the Phase 2 study, which was presented at the American Association for Dental Research annual meeting, the two multicenter, blinded, randomized, controlled Phase 3 studies will assess the safety and efficacy of NV-101 in reversing soft-tissue anesthesia with four leading anesthetics commonly used in dental procedures. Additionally, one Phase 2 pediatric study also is underway in children between the ages of 4 and 11. The three clinical studies are expected to be completed by the end of this year.

"While local dental anesthesia is the most widely used anesthetic procedure, it frequently results in longer than necessary soft-tissue numbness due to vasoconstriction induced by local anesthetic solutions," explained Bruce Rutherford, DDS, PhD, Novalar's vice president, clinical development.

Study Shows Link Between Perio Treatment and Reduced Costs for Chronic Conditions

A study recently found that there is a relationship between treatment of the gums and the total cost of care for several chronic diseases.

The retrospective study of claims data — conducted by the Columbia University College of Dental Medicine and Aetna — included analyzing an estimated 145,000 Aetna members with uninterrupted medical and dental coverage over a two-year period (2001-2002). The results indicated that periodontal care appears to have a positive effect on medical care costs, with earlier treatment resulting in decreased medical costs for those with coronary artery and cerebrovascular diseases, and diabetes. Additionally, the medical costs of care for diabetics and coronary artery disease patients were found to be reduced if they, in the first year of the study, received periodontal care.

"The results of this study are encouraging because they show the connection between good oral health and overall well-being, as well as illustrating that the early treatment of periodontal disease can help reduce medical costs for these conditions," said Pat Farrell, head of Aetna Specialty Products. "We believe that in addition to lowering medical costs, we are also helping to improve members' quality of life. We will continue to work with Columbia to demonstrate ways that dental care can improve the overall health of our members."

David A. Albert, DDS, MPH, associate professor of dentistry at Columbia University said "Systemic health is often associated with the condition of the oral cavity in that many systemic diseases manifest in the mouth. However, less is known about the connection between a diseased periodontium and the impact it may have on systemic health. The association between periodontal infection and systemic health has important implications for the treatment and management of patients."

Bilingual DVD on Dental Health Available

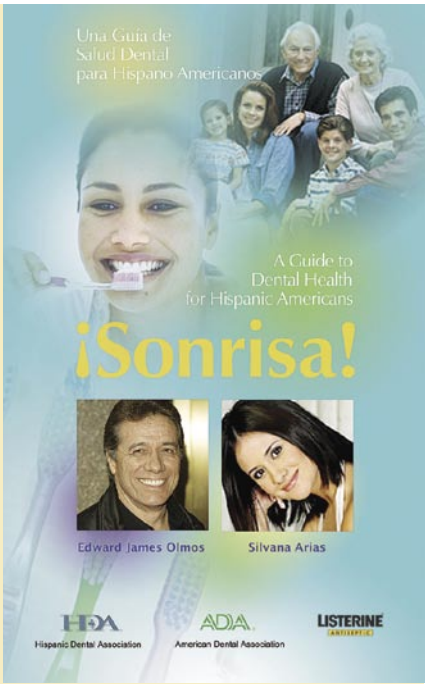
"Sonrisa: A Guide to Dental Health for Hispanic Americans," designed to assist families in locating affordable dental care and preventing oral health problems, is now available as a DVD and guidebook.

"As the fastest growing demographic group in this country, there is certainly a need to address the oral health care needs of Hispanic American patients," said David J. Farinacci, DDS, chair of the American Dental Association's Council on Communications.

The 30-minute program was the first-ever collaboration between that council and the Hispanic Dental Association. Sponsored by Pfizer Consumer Healthcare, Sonrisa, which is Spanish for "smile," also include tips for parents as well as encourage dental careers for Hispanic Americans. In the DVD, celebrities Edward James Olmos and Silvana Arias explain the significance of good oral health. Both the DVD and the 40-page guidebook are in Spanish and English.

"It's a thrill to work with the Hispanic Dental Association and see them involve us in educational programs like this," Farinacci said. "Collaboratively we can accomplish so much more."

To obtain a copy of the program while supplies last, call (800) 223-0182. For more information about the program, call (800) 621-8099, ext. 2806.



Review Commissioned to Assist in Understanding Lasers

In an effort to help clinicians better understand the clinical applications of the use of lasers in periodontics, the American Academy of Periodontology commissioned a review of the literature on the emerging technology. The paper, "Lasers in Periodontics: A Review of the Literature" appeared in the April issue of Journal of Periodontology.

"The increase in promotion of the use of lasers in periodontics has prompted many questions from periodontists, general practitioners and patients," said Kenneth A. Krebs, DMD, and president of the AAP. "This paper will help clinicians sort through the hype and identify the appropriate use of this technology in providing periodontal care."

Fellow member and author of the paper, Charles M. Cobb, DDS, said "The topic of lasers has been condensed to a 'to-use' or 'not-to-use' debate. The issue is really more complicated than that. Each laser has a different wavelength. These various wavelengths can accomplish different things, however, damage to periodontal tissues can result depending on the wavelength and power, and the periodontal procedure that the laser was used to perform. This paper will help clinicians develop an evidence-based approach to the use of lasers in periodontal treatment."

To view the paper online, go to: http://www.perio.org/resources-products/posppr3-5.html.

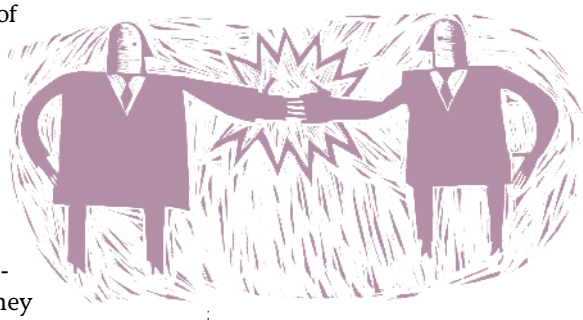
General Dentists Consider Endodontists Trusted Partners

A recent poll of general dentists revealed that unbiased education on the latest endodontic techniques and materials is important to their continued practice.

The American Association of Endodontists surveyed American general dentists last year regarding the realities and perceptions of continuing education of endodontics in the United States as part of its public awareness campaign: "Endodontists: The Root Canal Specialists." The goal of the campaign is to educate general dentists and the public about the value endodontists bring to the dental team.

So while general dentists may differ in how they handle root canals, nearly half of them reported they refer most to all of their root canal cases to specialists. On average, general dentists said they perform only two treatments for root canals per month. Additionally, close to 90 percent of those surveyed responded they are at least "somewhat comfortable" with their overall understanding and knowledge of endodontics, and admitted they would like to learn more.

"As any good practitioner, general dentists want to ensure they are providing the highest quality care to their patients," said Marc Balson, DDS, and AAE president. "With up to three additional years of specialized training, endodontists are uniquely trained to perform root canals. This gives us not only the experience to treat the most complex cases, but to serve general dentists as valuable members of the dental team."



Ninety-five percent of the respondents said they consulted with an endodontist in the year preceding the survey; this is in contrast to more than half of the general dentists who said they did not take any endodontic C.E. courses in the same time frame. The poll also revealed that the respondents viewed professional organizations, such as the AAE, and educational institutions as the most credible of C.E. courses.

Other interesting results include:

- The opinion among general dentists that endodontists are trusted partners in providing high-quality dental care;
- That 72 percent of general dentists believe endodontists are willing to help them learn more about endodontics;
- Roughly two-thirds of general dentists would like to learn from a local specialist; and
- Most interest topics range from endodontic diagnosis and troubleshooting, obturation techniques, and rotary instrumentation systems.

Honors

W. Patrick Naylor, DDS, MPH, MS, has been named

associate dean of Advanced Dental Education at Loma Linda University School of Dentistry. The appointment is effective Aug. 1 and he will be responsible for the organization and administration of the instructional and research activities connected with the program. Naylor is a retired colonel in the U.S. Air Force Dental Corps.

Proactive Approach Recommended for Boorish Behavior

Lee Ann Engle

A risk management expert believes dentists should regard their staff members as "front-line risk managers" and quickly deal with fears and grumblings from patients.

"Employees who know the warning signals can give their doctors a 'heads up' when patient comments or actions cross the boundaries of appropriate behavior," wrote Kathleen Roman, risk management expert, in an issue of the *KDA Today*, a publication of the Kentucky Dental Association.

Roman advised that role-playing and discussion helps staff become skilled at dealing with a patient's inappropriate behavior. Snarky comments about a dentist's pricing or abilities uttered within earshot of other patients in the waiting room can have a harmful effect on the practice. In most cases, staff either laugh it off, which they shouldn't do, or ignore the comments altogether. However, immediate response to these types of remarks can counteract the effects. For example, responding to a rude comment with "If you have any concerns or questions about the treatment plan, we need to make sure that you and doctor have a chance to talk before your next appointment," Roman said. Or, in the case of a payment concern, "If you have a minute, I know that our office manager will want to go over any aspects of the payment plan that are of concern to you."

A proactive approach has several good points. First and foremost, it stops the problem in its tracks and demonstrates to other patients who are listening that any statements are taken seriously. Secondly, it curtails the chances other patients who hear the complaints will make similar comments. And lastly, taking these statements seriously helps the rest of the staff and the dentist prevent potential problems such as stopped payments, lawsuits, or missed appointments.

Upcoming Meetings 2006

Sept. 15-17	CDA Fall Session, San Francisco, (866) CDA-MEMBER (232-6362).
Oct. 7-11	Pacific Coast Society of Orthodontists 70th Annual Session, Honolulu, Hawaii; Oct. 11-13 post-meeting program, Poipu Beach, Kauai; www.pcsortho.org, (415) 674-4500.
Oct. 16-19	ADA Annual Session, Las Vegas, (312) 440-2500.
Nov. 2-4	Hispanic Dental Association 14th Annual Meeting, Universal City, www.hdassoc.org or (217) 793-0035.
Dec. 3-6	International Workshop of the International Cleft Lip and Palate Foundation, Chennai, India, (91) 44-24331696.

To have an event included on this list of nonprofit association meetings, please send the information to Upcoming Meetings, *CDA Journal,* 1201 K St., 16th Floor, Sacramento, CA 95814 or fax the information to (916) 554-5962.

Clinician's PERSPECTIVE

Evidence-based Dentistry: A Clinician's Perspective

Janet Bauer, DDS, MSEd, MSPH, MBA; Sue Spackman, DDS; Francesco Chiappelli, PhD; Paolo Prolo, MD; and Richard Stevenson, DDS

ABSTRACT

Evidence-based dentistry is a discipline that provides best, explicit-based evidence to dentists and their patients in shared decision-making. Currently, dentists are being trained and directed to adopt the role of translational researchers in developing evidence-based dental practices. Practically, evidence-based dentistry is not usable in its current mode for the provision of labor-intensive services that characterize current dental practice. The purpose of this article is to introduce a model of evidence-based dental practice. This model conceptualizes a team approach in explaining problems and solutions to change current dental practice. These changes constitute an evidence-based dental practice that involves the electronic chart, centralized database, knowledge management software, and personnel in optimizing effective oral health care to dental patients.

Beginning with medicine, and by transference affecting dentistry, is the growing perception that dentists rely too heavily on conceptual knowledge and training, local clinical expertise, and experience in communicating what is best for patient care. These perceptions are vocalized by biomedical-dental researchers, responsible for producing new knowledge, and policy-makers, advocating decision-making behavioral changes in dentists. The goal of both is improving patient care



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Paolo Prolo, MD, is an assistant research faculty, Division of Oral Biology and Medicine at the UCLA School of Dentistry.

Richard Stevenson, DDS, (not pictured) clinical professor and chair, Division of Restorative Dentistry at the UCLA School of Dentistry.

Guest editor / Francesco Chiappelli, PhD, is an associate professor, Division of Oral Biology and Medicine at the UCLA School of Dentistry.

Patent Statement / The content, and any computer software program derived from said content, from this manuscript is covered by provisional patent pending.

with new advances in knowledge and technology. Practically, the argument reduces simplistically to who is the final arbiter of best evidence: those who create new knowledge, assuring its confidence in scientifically quantifying or qualifying outcomes, or those who apply evidence in patient care settings.

An arbiter is an individual or consensus manager who decides an issue for what is best and acceptable given the current standard of that issue. In this case, the arbiter determines best evidence in formulating a clinical practice guideline. A CPG provides decision, utility, and cost data for dentist-patient negotiations in arriving at an informed consent. Informed consent is shared decision-making. Shared decision-making is the daily negotiation that a dentist does with patients in arriving at a mutual understanding regarding needed dental services. Mutual understandings are developed when dentists explain treatment options, based on their understanding of what is best for the patient using conceptual knowledge, clinical expertise, and experiences in like-patient situations and conditions, determined by local practice norms. Patients communicate what is best for themselves in terms of their past experiences with dentistry, ability to comply with maintenance requirements, and economic constraints. Both express their personal utilities in making trade-offs in deciding what can and cannot be done, or selecting a choice where the risks of one outcome is offset by the benefits of another. A trade-off is basic to the clinical decision, choosing the treatment option that is best for dentist and patient in providing and accepting dental treatments. The outcome of shared decision-making is a treatment plan upon which both dentists and their patients can agree. In this traditional approach, the dentist is the final arbiter of best evidence, utilizing intuitive knowledge, clinical expertise and experience to communicate treatment options deemed appropriate to the individual patient. Conducted on a routine basis in current dental practices and in the past, this approach is termed the intuitive approach to decision-making, making practice-specific clinical decisions appropriate to individual patient care.

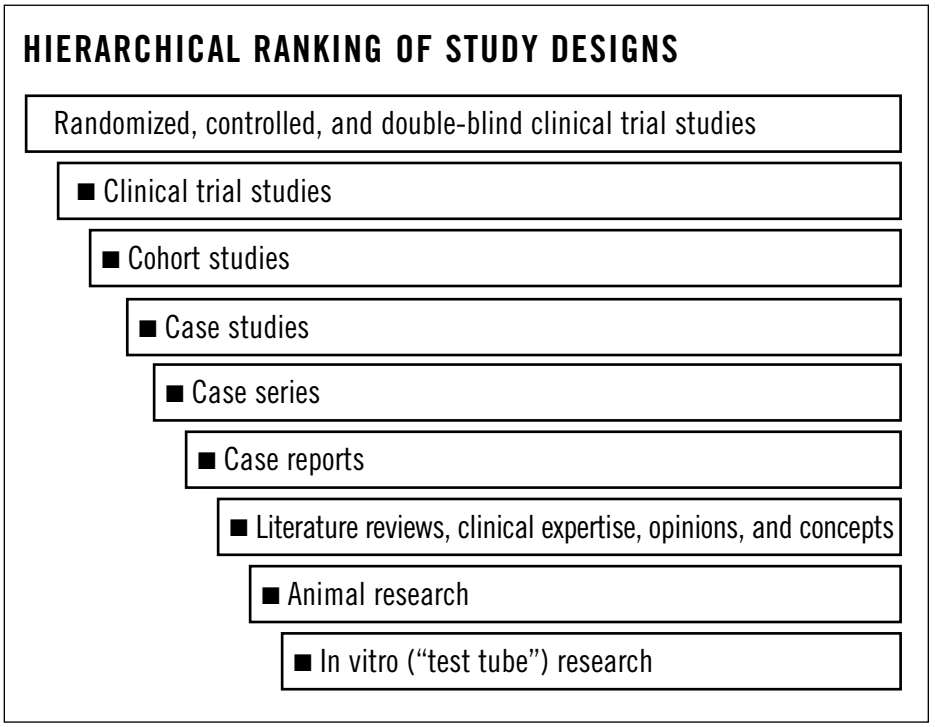

Figure 1. Hierarchical ranking of study designs: A randomized, controlled, and double-blind clinical trial study design being the highest and the standard of evidence quality.

Intuitive Approach

In the intuitive approach, evidence is derived from applying knowledge logically based on concepts learned during training and implicitly in rendering oral health services, based on experience and patient characteristics of well-being, and the judgment of clinical experts. This knowledge, or evidence, may have been determined from a long-term monitoring of patients under conditions and patient attributes that reflect the environs of the practice. In other words, evidence has been rendered best through the long-term, multifaceted monitoring of its implementation and compliance subject to patient (human) behaviors. In the intuitive approach to decision-making, shared decision-making communicates how this evidence will be applied to the individual patient for which a decision is needed. To this communication, the dentist and patient bring their personal utilities. The dentist may weight evidence, or render importance to the evidence, based on personal or professional experience, beliefs of its effectiveness or efficacy, and practice behavior, or practice profile. The patient may weight evidence based on risk behavior, costs, and personal or cultural preferences and values. These weightings are part of a dialogue that communicates trade-offs each party is willing to accept in reaching a mutually determined clinical decision. This dialogue is a process that occurs at the time of the dental examination of which the assessment, evaluation, and treatment planning are guided by the dentist's communication of best evidence and

filtered by the dentist's clinical knowledge, expertise, experience, and personal beliefs and values.

Analytical Approach

The analytic approach to decision-making, on the other hand, is based on a consensus of current research, filtered by the professional literature or consensus manager groups, organizations, or agencies. In the analytic approach, evidence is derived from basic researchers who explain and contribute to a body of knowledge using parametric, technological, animal, or human models. The variables studied are chosen to demonstrate rapid, dramatic effects. After the 1960s, clinical studies became pre-eminent in determining effective health care.[1] Evidence derived from clinical studies is categorized hierarchically based on the soundness of the study's methodology and findings (**Figure 1**). The highest explicit standard is the randomized, controlled, and double-blind clinical trial-study design. The clinical practice guideline is produced by the "conscientious, explicit, and judicious use" of quantitative and qualitative "clinically relevant scientific evidence" synthesized through systematic research.[2,3] Systematic reviews are conducted much like primary investigations, except that they identify and appraise all relevant studies from all sources in response to a specific clinical question.[4] The data from each study is synthesized according to explicit and reproducible criteria, limiting bias, and random error. In other words, best evidence developed against a scientifically determined standard is assessed, evaluated, and disseminated to the dentist who then applies this evidence to individual patients.

Thus, best evidence does not rely on local conceptual knowledge, training, clinical expertise, or experience to provide treatment options for shared decision-making. Instead, the dentist becomes the conduit for predetermined best evidence. The dentist's role is to consider the patient's utility and costs data in the context of his or her presenting conditions and chief complaints, assisting the patient in making a clinical decision appropriate to his or her situation. The context of the situation is where dentists apply their individualized conceptual knowledge, clinical experience, and expertise. Thus, knowledge, clinical expertise and experience is useful in converting "average patient" best evidence into "individual patient" evidence, discussing individual patient limitations that determine trade-offs between treatment options in reaching the clinical decision.

Shared decision-making is focused on the CPG. The dentist uses the CPG to communicate to the patient the various treatment options and their probabilities of reaching a desired outcome based on the "average patient." The dentist, then, uses clinical expertise and experience of the patient's utilities and costs to assist that patient in analyzing, through the CPG, the option that the patient decides is best for his or her situation, individualizing "average patient" data to the patient.

Criticism of the Intuitive Approach

In the dentist-patient relationship, the dentist is the final arbiter of evidence, responsible for its collection, evaluation of effectiveness and efficacy, implementation, and monitoring of long-term outcomes. Thus, evidence reflects the context, practice behavior, and bias of the clinician in an intuitive implementation of knowledge to individual patient care. Evidence, then, is a compilation and consensus of existing evidence derived from conceptual and learned treatment modalities, clinical experience, and the judgment of clinical experts in determining what is the current state-of-the-art of knowledge, or best evidence. However, current debate is critical of the clinician's proprietary status in determining what evidence is best evidence. The criticism is the same, the clinician's lack of using explicitly derived evidence in implementing standards of care to individual patients. An evidence shift is suggested, holding the analytical approach superior to the intuitive approach and evidence to an explicit standard of acceptance. The arbiter of this evidence is the translational researcher. Currently, the translational researcher-produced CPG is disseminated in a narrative format and appears in professional journals. The format may vary, reporting on one article or a systematic review. An article analysis and evaluation includes subjects and therapies used, the main outcome measures, results, and conclusions, followed by a commentary and analysis of a member of the editorial board.

The systematic review includes all data sources and study designs, data extraction and synthesis, results, and conclusions, followed by a commentary of a member of the editorial board.

Criticism of the Analytic Approach

The analytic approach, however, is not without controversy. In 2002, Marks was commissioned by The Health Development Agency (National Health Service, United Kingdom) to provide an analysis of the analytic approach to decision-making.[5] According to Marks, the analytic approach is as much flawed as the intuitive approach to clinical decision-making. Similar to the intuitive approach, the analytic approach in and of itself is opinioned-based. Best evidence results from a systematic process of filters that represent successive biases toward a state of knowledge influenced by the interests of those that fund discovery. In other words, translational researchers subject their findings to conforming processes that parallel those of the clinician: evidence supported by training, routines, and habits. Thus, the systematic review is neither objective nor hierarchical in its audit of clinical knowledge. To date, there exists no best evidence to sup-

port the researcher's claim that the systematic review is more rigorous and sound than other qualitatively derived evidence. Marks argued that the systematic review actually wastes valuable information and knowledge. Yet, the evidence derived from the systematic review is based on an explicit standard of developing new knowledge, the analytic approach, and confers less random error and bias as that evidence derived over a long period of time from the intuitive approach. It is population-based evidence that can be generalized.

Purpose

Despite the criticisms of either approach, dentists are being encouraged to change how decision-making is done in private practice, the basis of an evidence-based dental practice. The purpose of this article is to describe a conceptual model for an evidence-based dental practice. In this model, decision-making for the clinical decision, and ultimately the treatment plan, is emphasized. This model uses explicitly derived evidence and intuitive approaches in a process to communicate evidence on "average patients" in shared decision-making. The outcome is a clinical decision made by an individual patient during informed consent. However, the model may be inclusive of other practice decisions including patient behaviors, dental practice administration, equipment, and restorative, rehabilitative dental services. As a model that conceptualizes a process of decision-making, it does not possess the power to predict conditions and thus, does not include etiological factors or patient risk factors.

Evidence-based Dental Practice

The foundation of an evidence-based dental practice is best evidence. The arbiter of best evidence is the researcher, specifically the translational researcher. This represents a shift in the traditional paradigm that describes current dental practices. With this shift, dentists are no longer the arbiters of best evidence. This concept has been adopted by policy-makers in the public market of health care and third and fourth parties that operate in private markets. Evidence becomes a means of improving and monitoring health care delivery. In the public market, this is used to regulate health care inequalities, promote cost-effective treatments and practice, and provide greater accountability of public spending and resource allocation to health and health-care research. In private markets, this is used to define benefits based on cost/profit margins, regulate the mechanics and safety of practices, and control practice profiles. This paradigm shift is problematic for dentistry. Unlike medicine, dentistry has remained an independent profession seeking practice modes independent of third-party regulators and the public sector, influenced only when costs favor third-party benefit structures that may bear significantly on the patient's clinical decision. Fundamentally, the dentist-patient relationship is the metaphysical norm for dental practice in emphasizing personal responsibility for one's oral health. Thus, dentists are very suspicious of any attempt to undermine this tenet by government and private regulators.

DENTISTS ARE BEING ENCOURAGED TO CHANGE HOW DECISION-MAKING IS DONE IN PRIVATE PRACTICE, THE BASIS OF AN EVIDENCE-BASED DENTAL PRACTICE.

Reasons for a Paradigm Shift

There are two 21st century concerns that provide an imperative for the success of dental practice and the assurance of optimal oral health care for dental patients. One concern is the demographic and service shift to older adults, the other, an explosion in new knowledge.

Older Adults

Previously, practice dynamics centered on procedure-oriented care. Fluoridation and public awareness of healthy personal lifestyles have shifted the practice away from procedure-oriented care to patient-centered care. In patient-centered care, risk assessment and management goals include promoting compliance in following healthy behaviors and oral self-care. However, older adults are at greatest risk for changes in their health and functional status that adversely affect their abilities to meet these goals. The need for interdisciplinary (primary health care teams) and intradisciplinary (dental specialty care teams) -coordinated treatment plans to effect optimal therapies and treatments will change the dynamics of dental practice. Currently, practice management services understand this and are actively marketing dental practice in the model of "A Center for Dental Medicine."[6] In such a practice, dentists work in teams to include all needed health care and dental specialty services to meet the needs of older adults in developing treatment plans and implementing coordinated services. Thus, the arena of knowledge has increased to provide effective and efficacious dental care to older adults, including coordinated medical, dental, psychological, and social services. The dentist becomes a member of a team of health-care professionals whose knowledge must transcend the oral cavity and include evidence regarding reciprocal interactions in medicine, psychology, and social welfare in promoting oral health.

Knowledge Explosion

The second concern is the explosion of knowledge to advance dental care services and delivery. Since the 1990s, advances in computer technology, the worldwide web, and librarian resources has characterized the explosion of knowledge specifically in health care, the universal way that knowledge may be accessed, and the need for knowledge

management systems.[7] In the future, dentists and other health-care professionals may consult interactively using the Internet to discuss and monitor shared patient cases. Fundamental to this process will be the dentist's ability to provide best evidence to support dental interventions. As such, professional dentistry has defined evidence-based dentistry to be "an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical expertise and the patient's treatment needs and preferences."[8]

Model of Evidence-based Dental Practice

A model of evidence-based dental practice addresses both concerns in facilitating the profession's definition of evidence-based dentistry. The reality of this model is the use of knowledge management strategies mediated by interactive software to achieve shared decision-making within the dental examination appointment. This model is based on a definition of evidence-based dental practice: "Evidence-based Dental Practice is patient-centered care provided by dentists in optimizing interdisciplinary resources for promoting oral health and preventing disease in individual patients. The practice of evidence-based dental care means integrating researchers, clinical experience and expertise, and patients in clinical decision-making."

The Evidence-based Dental Practice Team

In evidence-based dental practice, basic researchers perform and produce evidence on the "average patient." Translational researchers systematically evaluate evidence produced by basic researchers and others. In shared decision-making, clinicians apply the product of translational researchers, the CPG, to individual patients. To initiate the CPG, translational researchers develop research questions with the assistance of the dentist.

Researchers

Basic researchers are concerned with the soundness and generalization of information; whether findings can be applied to similar patients in similar settings. Significance is statistical significance or the acceptance that some relationship exists between two variables or the acceptance of a measure of a variable. Results are rapid using large study populations to show dramatic differences. Concerns are stated in terms of validity and reliability of study design to express confidence in providing evidence.

BEST EVIDENCE BEGINS WITH THE CLINICAL QUESTION REGARDING SOME ASPECT OF THE INDIVIDUAL PATIENT'S CARE.

The translational researcher has the primary responsibility of the systematic review, and rightly so, because translational researchers are most qualified in this discipline. These responsibilities involve producing, disseminating, and measuring outcomes of best evidence.

Dentists

Dentists perform assessments, evaluate services needed, and develop plans for treatments and therapies. Dentists are concerned with clinical significance; whether differences in research findings have meaning in care delivery. Dentists make judgments that may weight best evidence differently from the researcher. Personal and professional experiences, values and preferences, and appropriate practices, as well as patient well-being and quality of life issues weigh heavily on how best evidence is used in clinical decisions.

Dentists have primary responsibility for the completion of the treatment plan and quality assurance of every aspect of practice that involves the patient care and care delivery. Dentists may work with translational researchers to record the long-term monitoring of best evidence as applied to individual patients for subsequent outcome analysis. This long-term monitoring may come from the dentist's clinical experience and from experts in the dental field.

Patients

Lastly, patients provide individual characteristics and health circumstances, or factual data. This information is used to modify best evidence on the "average patient," individualizing it to the presenting patient. Patient compliance with treatment outcomes determines the meaning, or importance, of best evidence in practice.

The outcome of this shared decision-making team is the clinical decision. Best evidence begins with the clinical question regarding some aspect of the individual patient's care. All resources with their varying degrees of weighting best evidence achieve a consensus for an aspect of the patient's dental care. The process ends with the translational researcher analyzing the outcomes provided by the dentist in monitoring long-term outcomes of best evidence.

Central Repository of Best Evidence

The organization and infrastructure of the evidence-based dental practice requires knowledge management strategies under control of a centralized repository. This central repository is suggested as the American Dental Association. The ADA is the ethical, regulatory, and community advocate for patient oral health and personal self-care. Knowledge management starts with the patient's electronic chart being integrated with the central repository of the primary network. The primary network controls all aspects of the central repository of best evidence. Being the central processing

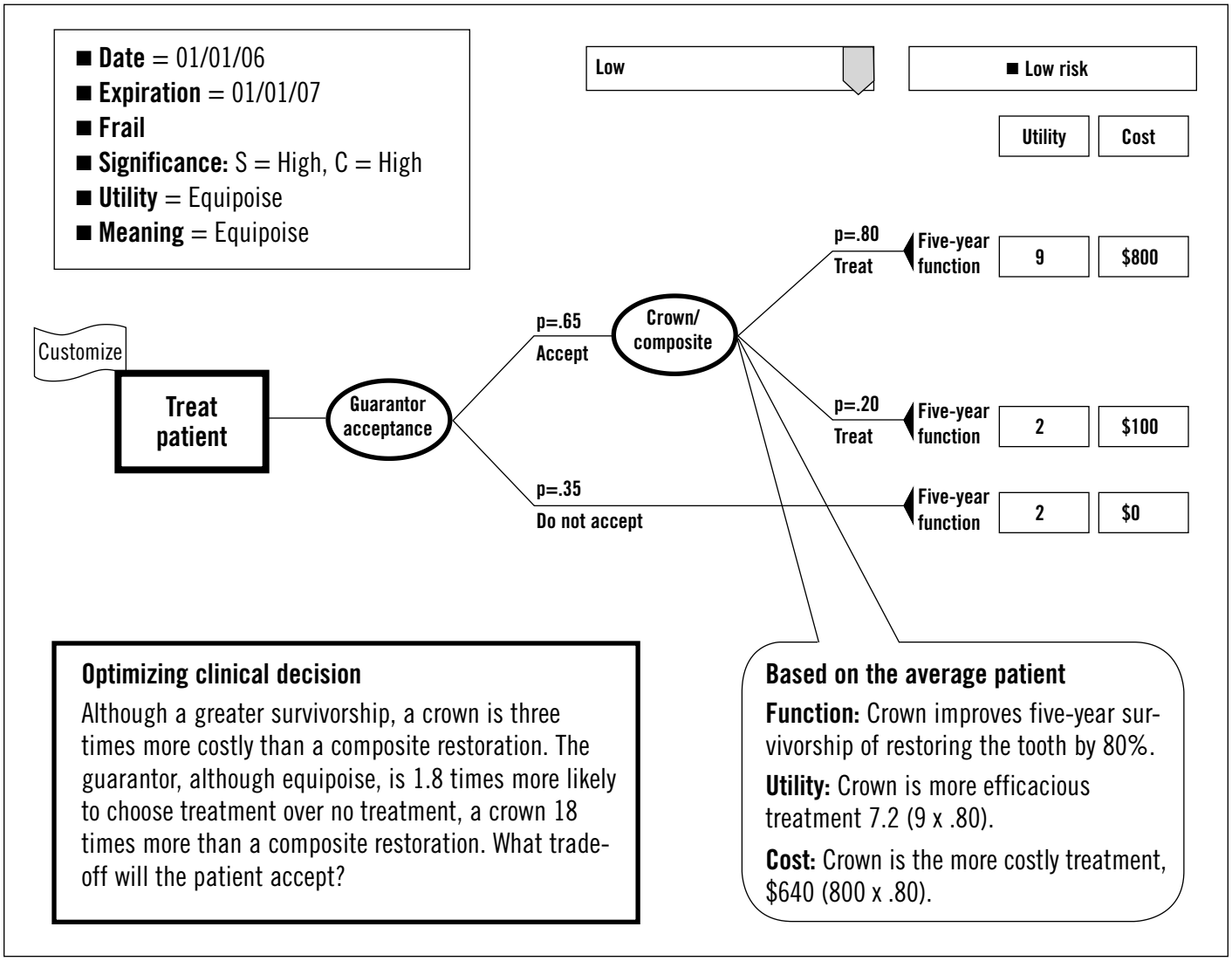

Figure 2. An example of a clinical practice guideline with treatment options, associated probabilities, utilities, and costs in determining the optimum clinical decision.

agency, the ADA is responsible for managing researchers, clinicians, and patient data in the production, storage, monitoring, and dissemination of best evidence. Evidence in this database is based on the "average patient." The product and knowledge management format of the primary network is the CPG. Using the CPG integrated with the patient's electronic chart provides a transfer of information from and to the central repository. This is important to understand because it is the basis by which best evidence is analyzed and updated.

Implementation of the Evidence-based Dental Practice

Through the electronic chart, the dentist accesses the knowledge management, decision-making software by clicking on its icon. The software is accessed only when there is uncertainty about a decision that has to be made. Routine decision-making does not warrant accessing evidence-based dentistry databases. For example, a tooth with caries into the dentin does not require new research to determine that it needs rehabilitation either with an indirect or direct restorative material to restore tooth health.

Dentist Inputs

Once the icon is clicked, the dentist is presented with a form with which the clinical question is inputted. The input template structures the inputs to form a research question from which best evidence may be extracted and delivered to the dentist (**Figure 2**). Once the inputs are completed, the dentist clicks the "Continue" button. From this submission, a CPG is provided that is

retained within the patient's chart for subsequent retrieval. With this CPG, the dentist may discuss with the patient treatment options and the probabilities of related outcomes. These estimates are based on the "average patient." The information for the CPG resides in the database having been developed by researchers with or without the assistance of a dentist. Utility data is also provided categorized, based on three risk levels: high, moderate, and low. For example, a patient who is a high-risk taker (risk-seeker) may value a procedure that conservatively removes suspected cancerous tissue to reduce scarring and decrements in appearance; the low-risk taker (risk-adverse) values total removal of the suspected cancerous tissue with a periphery of healthy tissue regardless of postsurgical scarring. Utility data is provided as a ranking on a value scale from zero to nine. For the conservative procedure, the high-risk taker may value this procedure an eight, the low-risk taker a two. Finally, cost data is available and may be limited to practice schedules (delineated by insurance coverage benefits specific to the patient) or include national, regional, and local data, if so desired by the dentist.

Shared Decision-making

Using the CPG based on the "average patient," the dentist and presenting patient discuss options, utilities, and costs that meet the patient's expectations and goals. Patients can manipulate preferences because different scenarios are made instantaneous using the CPG and knowledge management software. This is done by the dentist who merely changes the numbers in the CPG, the software updating the values and decision analysis instantaneously.

Informed Consent

The patient becomes an informed consumer responsible for his or her decision and, ultimately, its outcome. With the clinical decision having been made, the dentist inputs the patient's scoring and preferences. At follow-up, the dentist may input the patient's actual outcome and utility scores, submitting the results through the CPG individualized to the patient.

Reciprocation of Knowledge

Concurrently, the dentist may do the same in rating clinical significance of the evidence from a link within the CPG. Thus, the process is twofold. One component of the process is shared decision-making. The second component is reciprocation of knowledge with the central repository. In the second component of the process, the dentist provides feedback from patients who have experienced the treatment under consideration. Translational researchers, then, may use this reciprocal evidence in evaluating the developed CPG for updating or revising best evidence.

Conclusion

Understandably, the evidence-based dental practice concept is unlike current modes of integrating research findings into patient care in which there are proprietors of independent domains of knowledge development and management, seeking credence in the uncertainty and multifaceted nature of human behaviors that is health care. In the 21st century, the mode is toward real-time, interactive, cooperation and coordination of resources over distances to best meet the needs and challenges of a differing demographic and economic world. A conceptual model of evidence-based dental practice is described that integrates best evidence from systematic reviews with shared decision-making. The basis for this model is knowledge management software that allows dentists and their patients to view and analyze clinical decisions that are made under uncertainty. This process has two components: one that assists patients in becoming informed consumers, and the second, reciprocating knowledge between private practice and research development. Utilizing advances in computer technology and the assets of each domain in a team approach to oral health will assure our patients effective and efficacious care in meeting their needs: trust, value, and goals for optimum oral health. CDA

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Making Clinical Decisions Using a Clinical Practice Guideline

Janet Bauer, DDS, MSEd, MSPH, MBA; Sue Spackman, DDS; Francesco Chiappelli, PhD; Paolo Prolo, MD; and Richard Stevenson, DDS

ABSTRACT

Clinical practice guidelines are statements developed from best evidence about clinically relevant appropriate care. A simulated patient case is presented to demonstrate how to use a CPG in decision-making in determining a clinical decision. Conceptualized knowledge management software templates are provided to explain a process by which best evidence is retrieved from a primary, centralized network database. Templates describe the process of converting a clinical question into a research question, retrieving best evidence, and performing data analysis for the outcome of individualizing and optimizing a clinical decision. Templates also describe the reciprocation of information to update CPGs by translational researchers who manage and build the primary, centralized network database.

Clinical practice guidelines are statements developed from best evidence about clinically relevant appropriate care. These statements may be about protocols, standards or practice patterns.[1] CPGs are important to the clinician to improve process and health outcomes, whether they are created locally or nationally. CPGs, and the algorithm in which they are contained, organize and sequence care outcomes



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Patent Statement / The content, and any computer software program derived from said content, from this manuscript is covered by provisional patent pending.

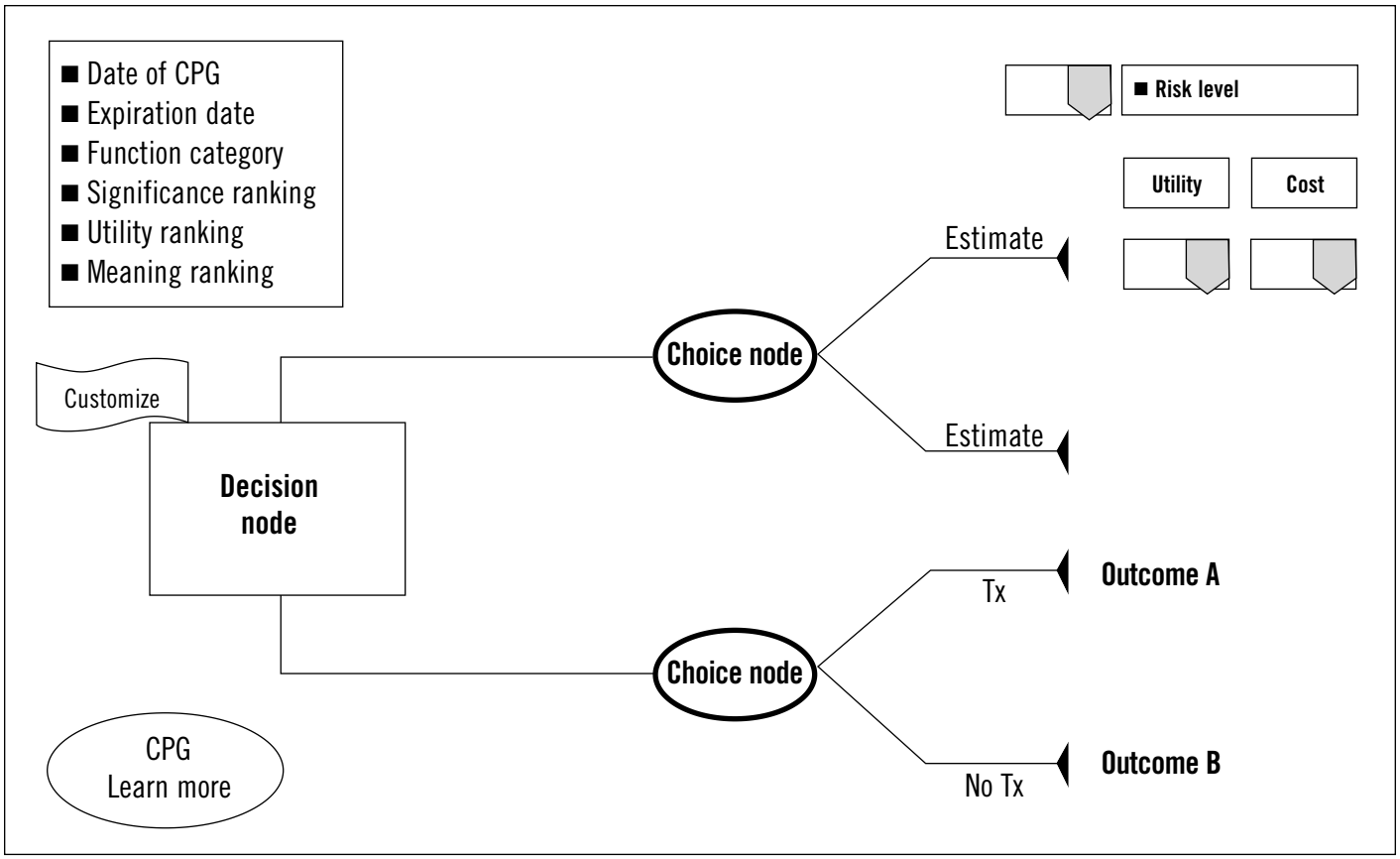

Figure 1. An example of a clinical practice guideline conceptualized for the knowledge management software showing two options and their related outcomes. From the CPG template, the dentist accesses the Customize Clinical Practice Guideline form through the "Customize" (flag) button.

for specific conditions. Thus, the dentist uses the CPG to address specific and narrowly defined patient care issues. CPGs, have been shown to be effective in producing behavioral change in clinicians' practices and care delivery.[2-5]

The purpose of this article is to simulate clinical decision-making processes using a CPG and a conceptualized, knowledge management software for making clinical decisions.

Patient Case

An 87-year-old woman presented for a routine dental examination. The patient's chief complaint was "a loose bridge." The history was that the fixed-partial denture was placed several years ago and had been serviceable until two months ago when it became mobile. On the day of the appointment, it was quite loose and seemingly on the verge of coming out. The patient's last dental visit was six months ago for a dental prophylaxis. The patient's last dental examination with bite-wings radiographs was a year ago. The past medical history included a periodic examination with the internist six months ago, a record of no emergency room visits, hospitalizations, or serious illnesses. The current medical condition was osteoarthritis, for which an over-the-counter pain medication is taken on as-needed basis. The patient had no known allergies to drugs, metals, or environmental allergens. The past dental history revealed a near-complete dentition with the removal of all third molars, without incident, and the loss of tooth No. 3, the maxillary right first molar, due to a failed root canal treatment following crowning procedures. The area was rehabilitated with a three-unit fixed-partial denture extending from tooth No. 2, the right maxillary second molar, to tooth No. 4, the right maxillary second bicuspid.

Other past dental services have been limited to maintenance care, tooth prophylaxis every six months and dental examination every year. The extra and intraoral examinations were noncontributory and all assessments were within normal limits, except for the fracture of both abutments of the right maxillary three-unit fixed prosthesis. The patient managed her own oral self-care twice a day with a regimen that included oral rinses, flossing, and toothbrushing. The social history revealed the patient had recently moved from her primary residence in another state to be closer to her older brother and sister who will celebrate her 98th birthday next month.

Anecdotally, their brother, who is 100 years old, planned the party at

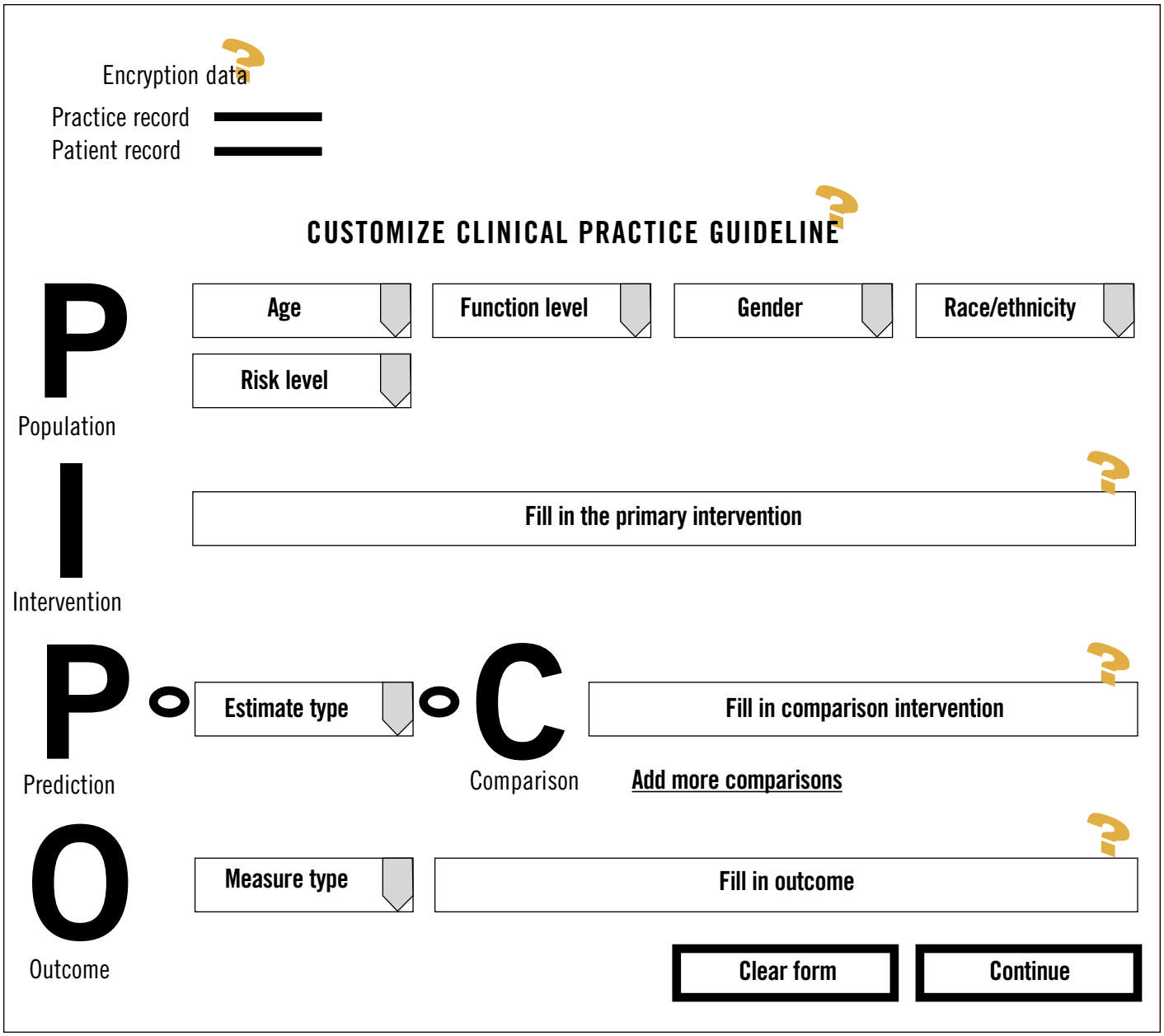

Figure 2. The Customize Clinical Practice Guideline form.

the local botanical gardens where his sister works as a docent. The patient is functionally independent, a nonsmoker, and a nonalcohol user with no history of substance abuse. The patient presented with a low-risk for dental caries, gingivitis, periodontal disease, and oral tissue dysplasia. The patient demonstrated excellent oral and medical health behaviors. The patient stated: "I want to be buried with all my teeth!"

Clinical Question

The dentist assessed that the fractures to teeth Nos. 2 and 4 were catastrophic. The evaluation was to extract both abutments with the loss of the three-unit prosthesis. To rehabilitate the resultant edentulous area presented several options. The options were to do nothing, rehabilitate with a removable partial denture, or place an implant abutted fixed-partial denture. Clinical judgment recommended rehabilitation with the placement of two implants and a fixed-partial denture. This treatment would provide optimum chewing effectiveness and efficacy, convenience, and esthetics. However, the dentist was unsure if this rehabilitation was a realistic treatment for a patient who is 87-years old. The clinical question became: Are dental implants in comparison to a removable partial denture more effective in achieving optimum chewing effectiveness and efficacy in an 87-year-old woman?

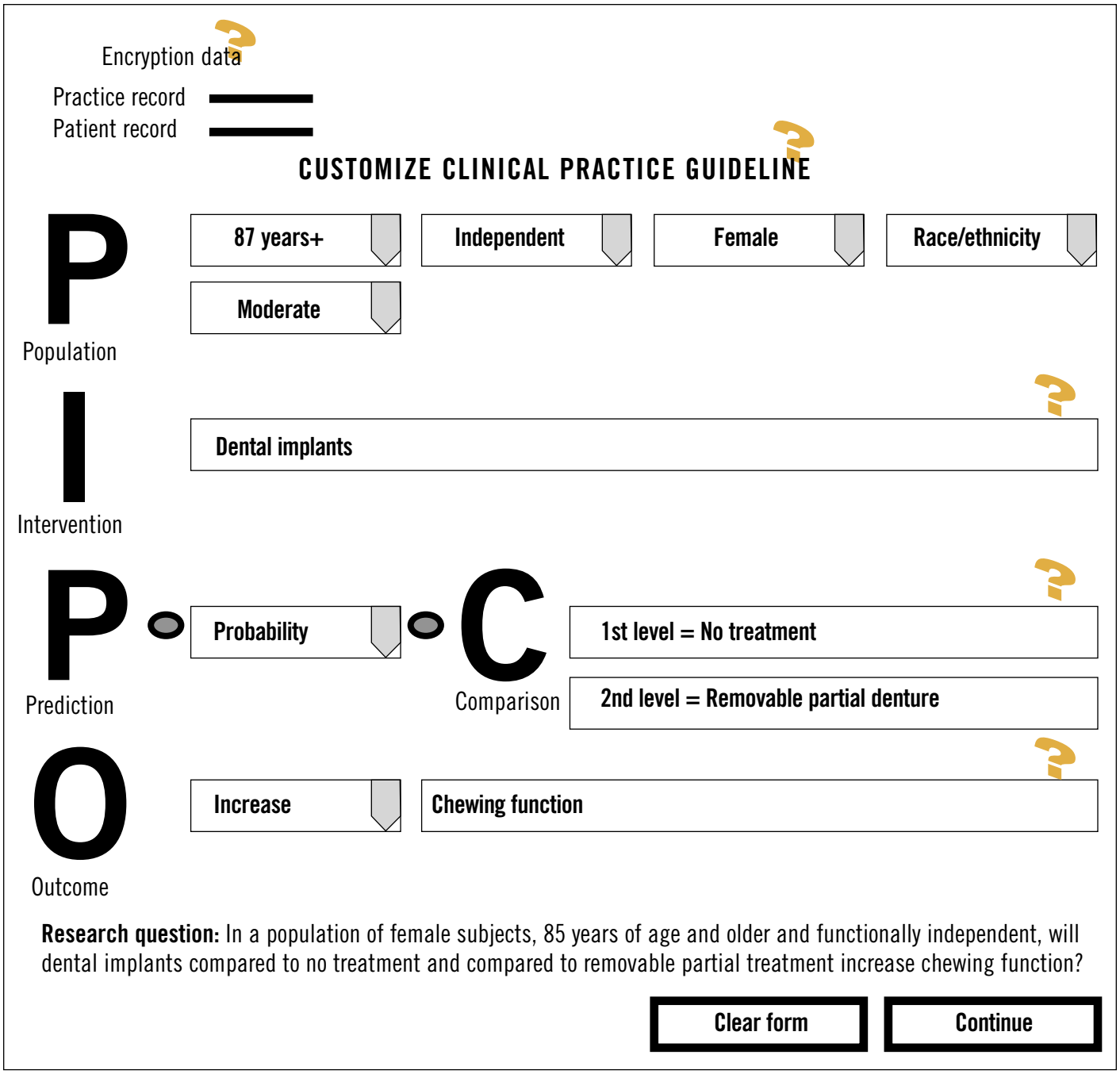

Figure 3. The clinical inputs to form a clinical question into a research question and create a CPG for the patient case.

Clinical Practice Guideline

A conceptualized knowledge management software using a primary, centralized network database of stored best evidence provides the CPG template with which the dentist will use to initiate the clinical question. In the background, the CPG template will access the patient's electronic chart, extracting all patient attributes, including those derived from the dental interview of past and present histories, intra- and extraoral examinations, and functional assessments.

In the event a CPG addressees the clinical question, this CPG provides baseline probabilities of the treatment outcomes and utility data under consideration. This data is based on the "average patient." Economic data is accessed from computerized practice schedules. In shared decision-making, the CPG is used as a decision aid with which the dentist and patient may change baseline data in individualizing the CPG to the patient. The revised CPG

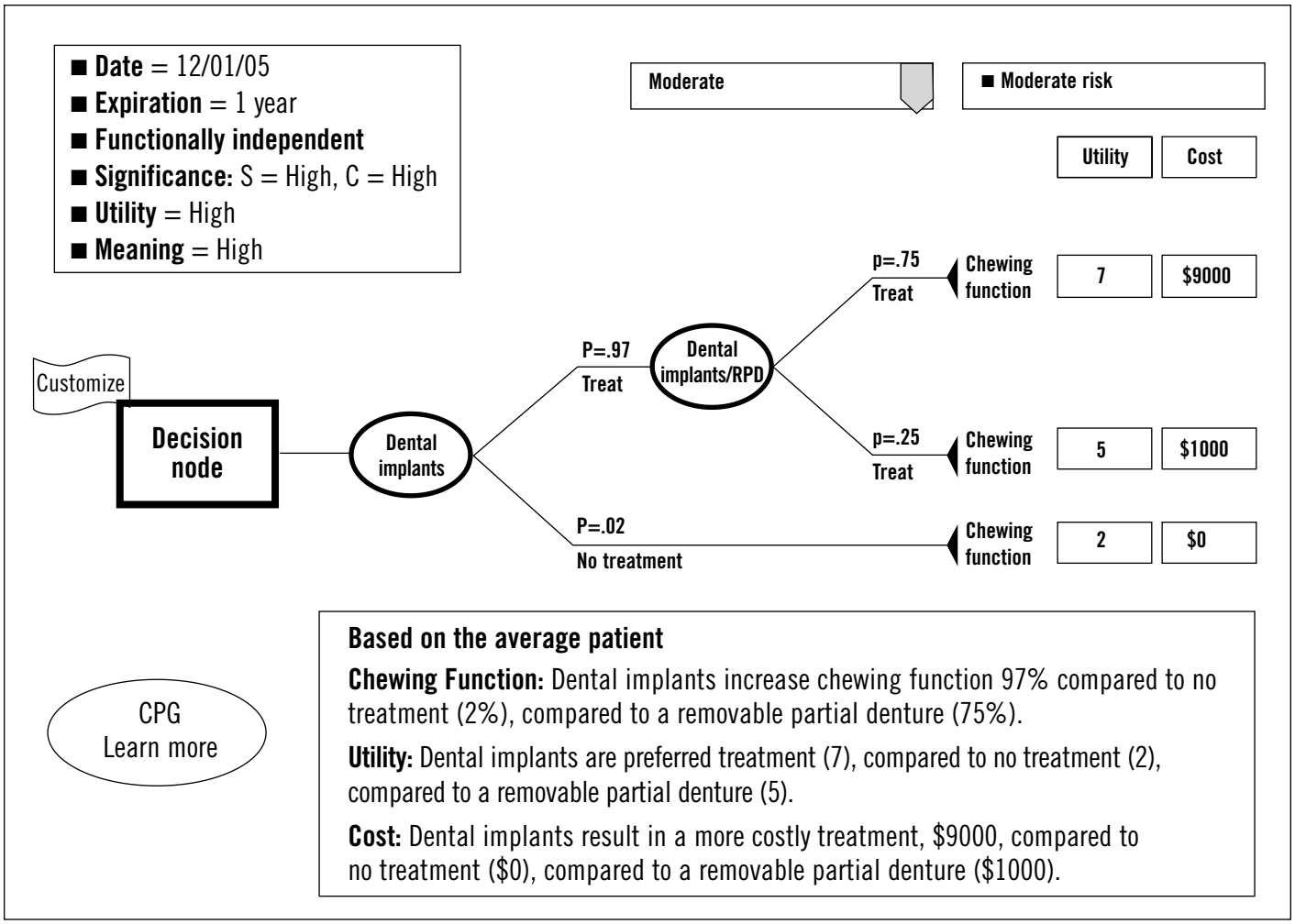

Figure 4. The patient case CPG containing decision data, utilities, and costs in response to the PIC/PO query.

is sent back to the primary network. Along with inputs from other practices and their patients on the same question, the information from the revised CPGs may be gathered along with this patient's inputs. Thus, there is a reciprocation of knowledge that may be used to update the CPG and/or advance new research. The exchange of patient information from the electronic chart to accomplish these responsibilities must abide by Health Insurance Portability and Accountability Act standards. The data ought to be encrypted such that patient identification is protected. Databases, in particular, are obligated to be especially diligent in optimally safeguarding such information. Password protection and user-access methods must be secured and security controls enforced. This has great importance if researchers are to access information to further study changes in practice, behaviors, and oral health trends.

Dentist Role

From the electronic chart, the dentist assesses the CPG template by clicking on an icon located in the patient's electronic chart. After which the dentist clicks on the flag icon link "Customize" and the Customize Clinical Practice Guideline form appears (**Figures 1 and 2**). The form assists the dentist in accessing the evidence-based dentistry database of the primary network. The form is organized to structure the clinical question into a research question. This structure is in the form of a PIC/PO question. PIC/PO is an abbreviation for population (P), intervention (I), comparison (C) or prediction (P), and outcome (O). As such, the research question includes the population studied, the interventions that are compared or the intervention to be predicted, and the outcome that is to be measured. If there are multiple comparisons, a link "Add more comparisons" may be assessed to specify levels of comparisons. Each level has its link to the place in the CPG where the comparison is to be made. For this patient case, the dentist accesses the "P" dropdown menus to choose those attributes that apply to the clinical question. The population is inclusive of that data for female, age 87 and older, functionally independent, and a moderate risk-taker (**Figure 3**).

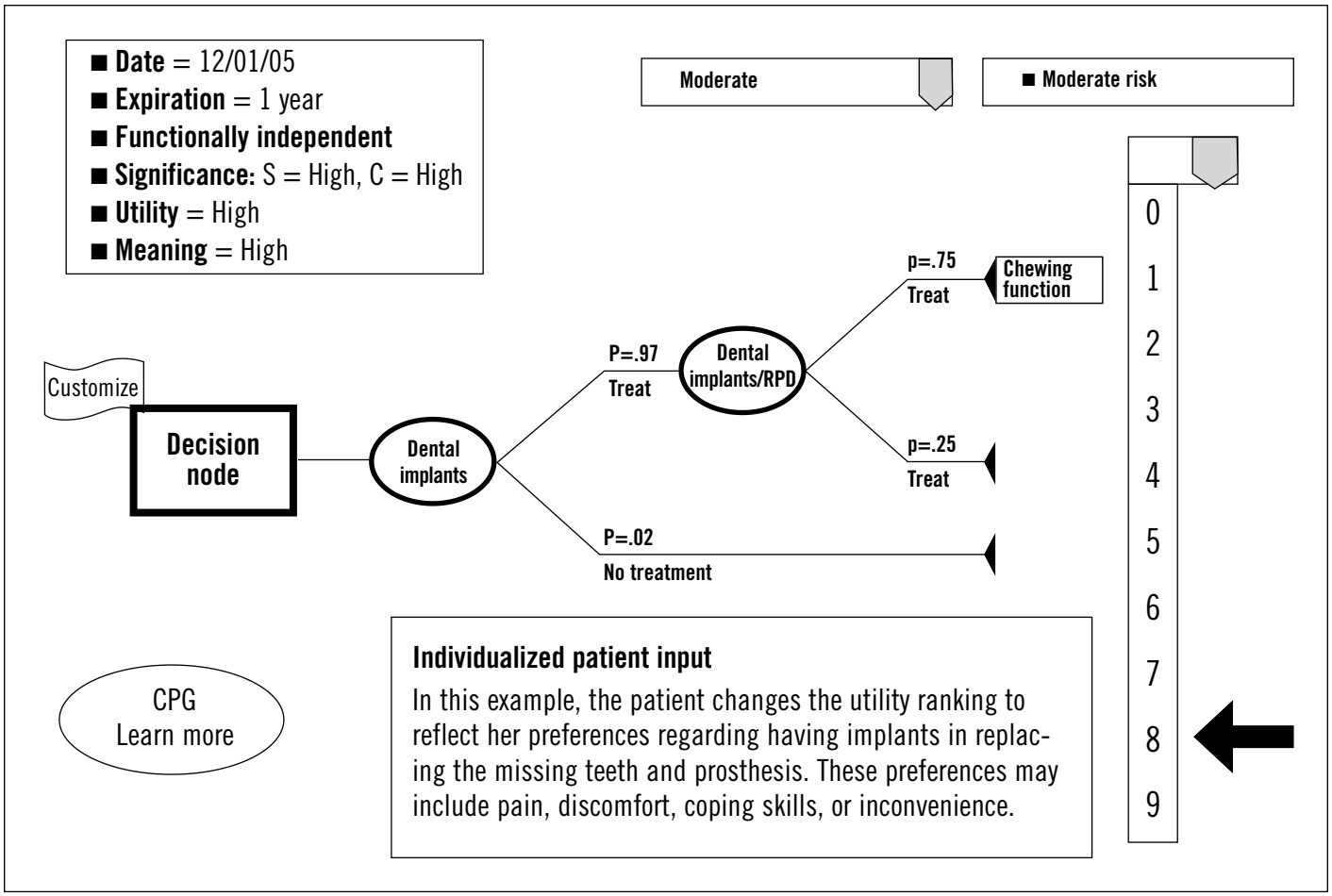

Figure 5. An example of the patient changing "average patient" utility ranking to individualize the CPG to the patient.

For the "I" menu text box, the dentist types the primary intervention, or in this case, the primary option dental implants. From the "P/C" menu, the dentist selects the radio button next to the "Estimate" dropdown menu from which she or he selects probability. The dentist also selects the radio button next to "Comparison." Since there are multiple comparisons, the dentist selects the primary comparison, no treatment, and the secondary comparison, removable partial denture. If the clinical question queries a prediction for outcomes of independent interventions, then the "Comparison" radio button is left unselected. Lastly, for the "O" menu, the dentist selects the measure type and types in the text box the outcome to be measured. In this patient's case, the measure is "increase" and the outcome is "chewing function." From these inputs, the research question developed from the clinical question appears at the bottom of the form. The question mark provides access to a description box to help dentists with his or her input. Once the research question is acceptable, the dentist clicks the "Continue" button. When the dentist sends a CPG request using the PIC/PO form, a search is conducted using the centralized database to link best evidence to the resultant CPG. The CPG is then displayed with the requested information (**Figure 4**).

For the dentist, the left upper corner box provides data on the quality of the CPG. By clicking on the link in the lower left corner, the dentist accesses the systematic review(s) that developed best evidence. This link accesses the CPG's original data, published articles, abstracts, or other user defined formats. Then, the dentist may investigate the evidence that produced this quality assessment.

Patient Role

The CPG presents the probabilities of increased chewing function in comparison to dental implants and no treatment and in comparison to dental implants and a removable partial denture. Additionally, the CPG provides the utilities for both comparisons and total costs for each treatment. These values are for the "average patient." The patient may input his or her preference of one procedure compared to another, or consider his or her preferences in the context of the "average patient" (**Figure 5**). The risk level relates to the patient's willingness to accept that the rehabilitation may not be

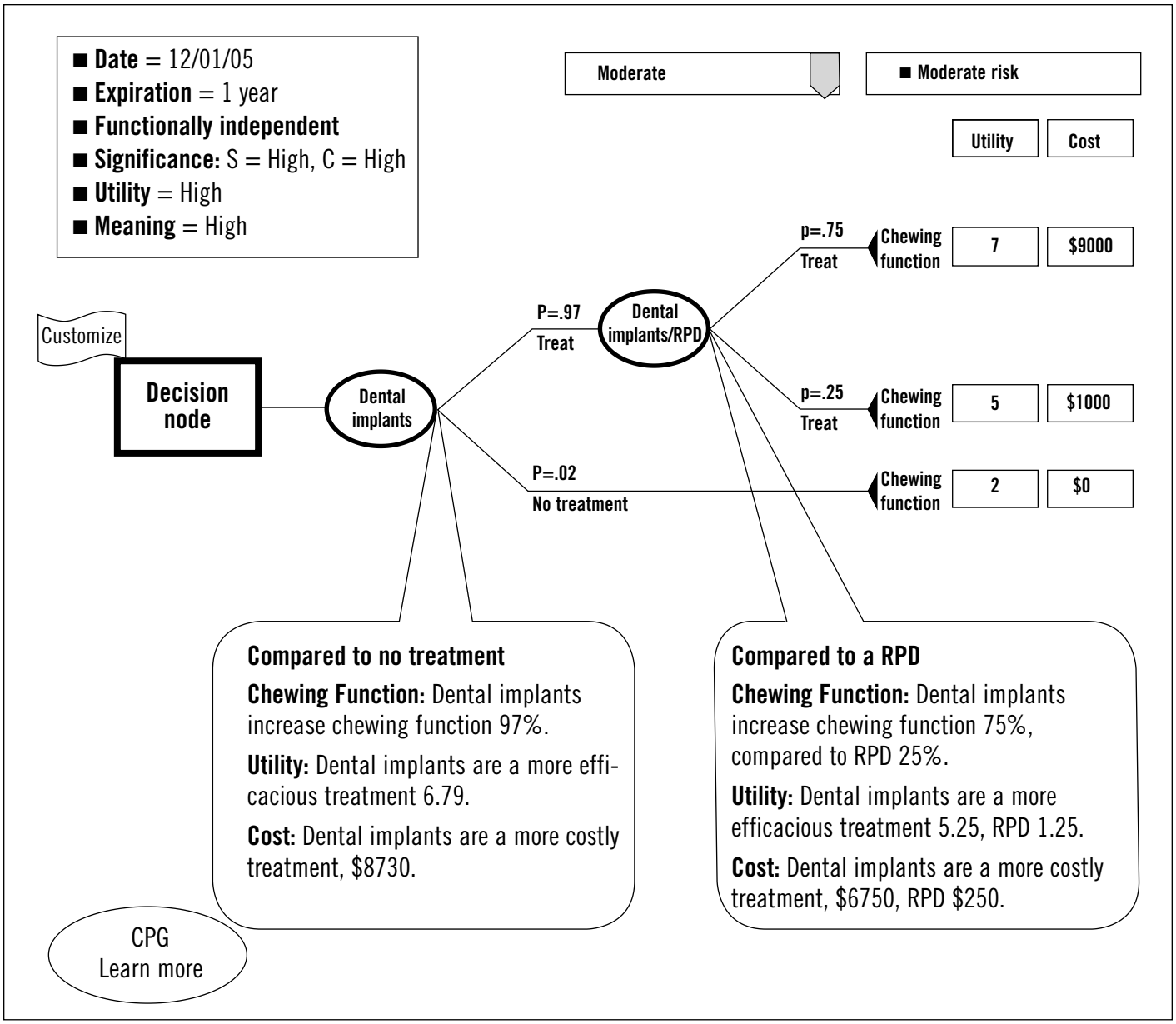

Figure 6. The patient case CPG showing the data analysis for the two options.

successful; high-risk tolerance indicates that the patient would accept a treatment with uncertain outcomes, a high risk of failure or short-term prognostications; a moderate-risk tolerance (risk-neutral) indicates a patient who is equipoised or will accept treatments that have a reasonable and acceptable range of uncertainty; and a low-risk tolerance indicates a patient who will not accept uncertain outcomes and chooses options with low variability. The patient may adjust risk tolerance levels or change utility inputs to test personal preferences or expand on the dentist-patient relationship dialogue in developing the informed consent leading to the treatment decision.

Decision Analysis

Decision analysis combines probability data with utility and cost data.[6,7] The use of probability data is to show which choice is better. Utility and cost data integrate personal realities into the analysis. While probability data determines effectiveness, utility data determines efficacy. Utility data is quantified on a scale from zero to nine. Utility data indicates that treatments may cause pain, discomfort, challenge coping skills, or inconvenience. Patients may just not value treatment benefits. Thus, combining utility with probability data will indicate the value the "average patient" places on the treatment option. The resultant combined data informs patients of their options and allows them to weigh evidence to come up with a decision that is best and sensitive to their needs and goals. This has

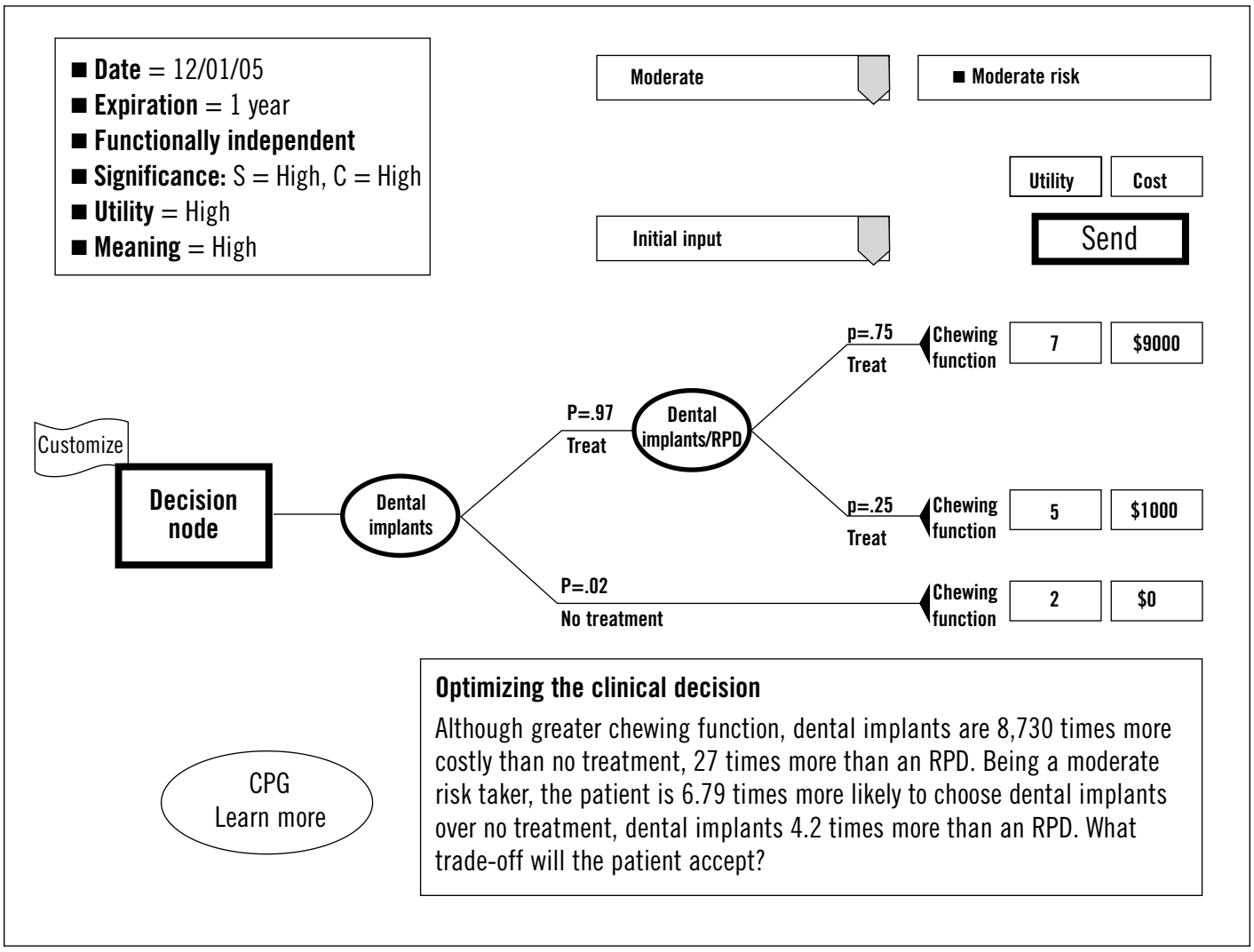

Figure 7. Summarizing the decision and utility data in optimizing the CPG in arriving at the clinical decision.

the additional advantage of identifying for both the dentist and patient sensitive aspects of particular importance to the patient in decision-making. Flexibility is also important because patients may vary in their risk-taking behaviors over time.

In this patient's case, the CPG provides two choices: Accept or deny treatment. If the choice is to accept treatment, there are two options: a dental implant or a removable partial denture. Decision data indicates that a dental implant increases chewing function (97 percent) compared to a removable partial denture (25 percent). Utility data indicates that a dental implant is preferred, 7, higher than a RPD, 5. Cost data, however, indicates that a dental implant is more expensive, $9,000 than a RPD, $1,000. If the choice is to not accept treatment, there is no cost, no real expected value. In analyzing between a dental implant and RPD, a dental implant has a greater expected utility (0.75 x 7 = 5.25), or is preferred, to a RPD (0.25 x 5 = 1.25); a dental implant has a greater expected value (0.75 x $9,000 = $6,750), or the most valuable option, to a RPD (0.25 x $1,000 = $250) (**Figure 6**). Thus, a dental implant provides the best weighted benefit; it is the optimized choice for tooth replacement. When comparing treatment with a dental implant to no treatment, the weighted expected utility of treatment is 7 (5.75 + 1.25), the weighted expected costs is $7,400 ($6,750 + $250). For no treatment, the weighted expected utility is 0.04, the weighted expected cost is zero. Thus, for the "average patient" who has a moderate risk tolerance, the optimal clinical decision is to select treatment, restoring the tooth with a dental implant (**Figure 7**).

The results are printable for patient retrieval and study. This patient, or dentist, may change the inputs, risk tolerance level and, within seconds, the new resultant analysis is displayed for discussion, the calculation and analyses of

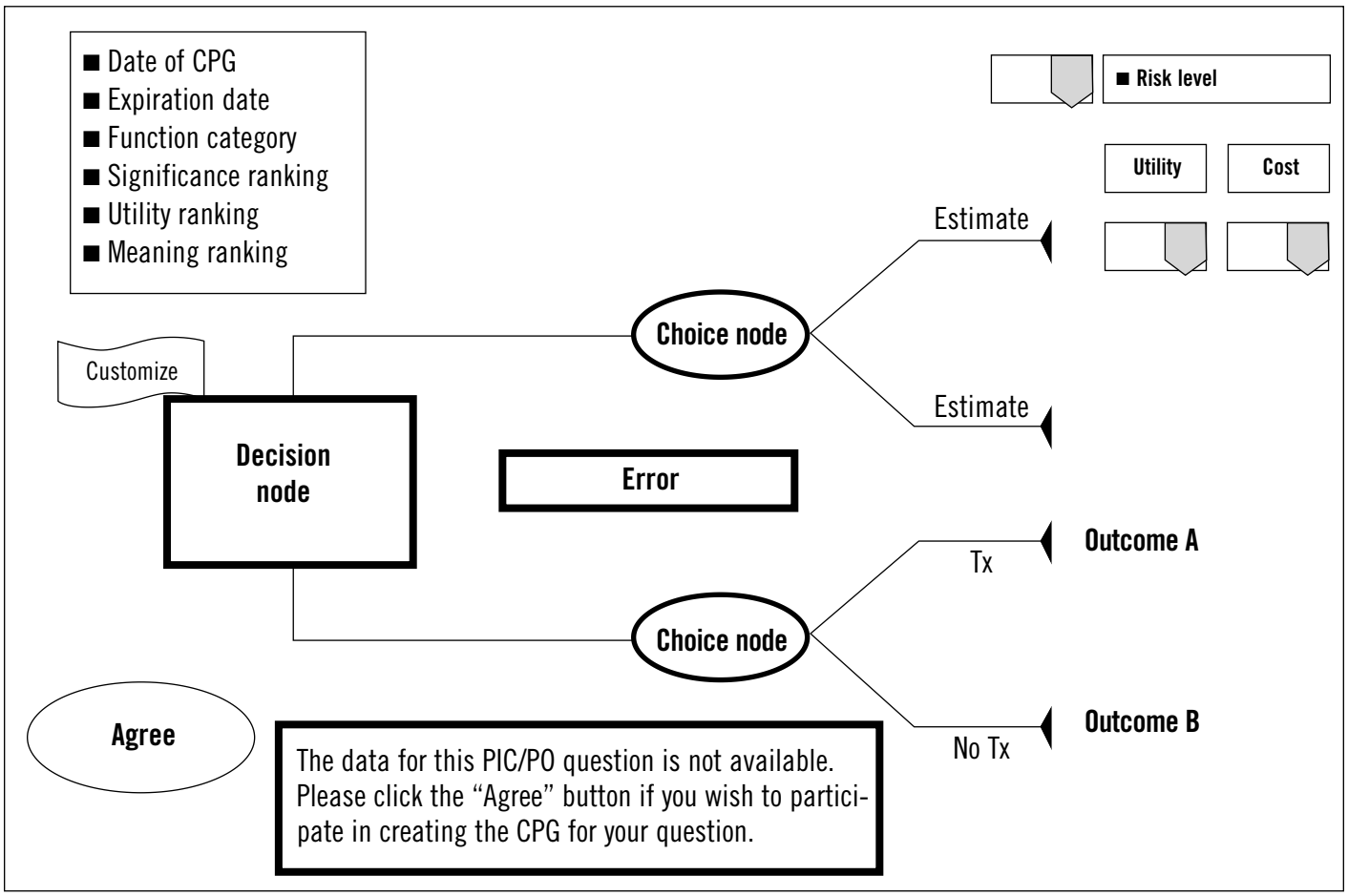

Figure 8. The CPG template when no best evidence is available from the centralized database in response to a PIC/PO query.

which takes place in the background. The clinical decision is finalized when data is individualized to this patient and the trade-off between costs and preferences are made. Once the clinical decision has been finalized, patient changes to the utility data are inputted and the "Send" button is clicked. On follow-up at the next yearly periodic dental examination, the dentist monitors patient compliance or success with treatment and changes this patient's previously determined probabilities, if needed. The new data is sent to the primary network by again clicking on the "Send" button. Next to the "Send" button is a dropdown menu to indicate if the analysis is a result of the initial analysis or the analysis at first, second, etc., or follow-up. This revised data may be used to update the CPG and/or advance new research.

The Translational Researcher

In the event that probability and/or utility data is not available, the dentist is presented with an error message that requests his or her participation in developing the CPG (**Figure 8**). The dentist's participation regards the research question and the clinical significance of the data subsequently determined from the systematic review using the dentist's PIC/PO question (**Figure 9**). With or without the dentist's agreement, the translational researcher conducts a systematic review to supply the needed information.

The translational researcher may produce quantitative and/or qualitative best evidence. Quantitative research provides parametric estimates of treatments, therapies, and other practice components and processes. Qualitative research provides measures of attitudes, beliefs, and preferences (utilities) of both practitioners and patients. Understanding behaviors brings an efficacy of care component to the clinical decision. In other words, patients may perceive the effectiveness of care differently depending on their life processes, and this meaning may change over time. Costs are specific to the practice's schedules. Because data is collected nationally, regionally, and locally, the CPG may present data based on the level of locale.

Once the systematic review has been completed, the evidence is inputted into the database of the primary network. Best evidence is associated with a date of the CPG, expiration date determined by the translational researcher, function and risk levels, utility rankings, and statistical, clinical, and meaning in practice significance. Finally, publication of the systematic review is linked to the CPG.

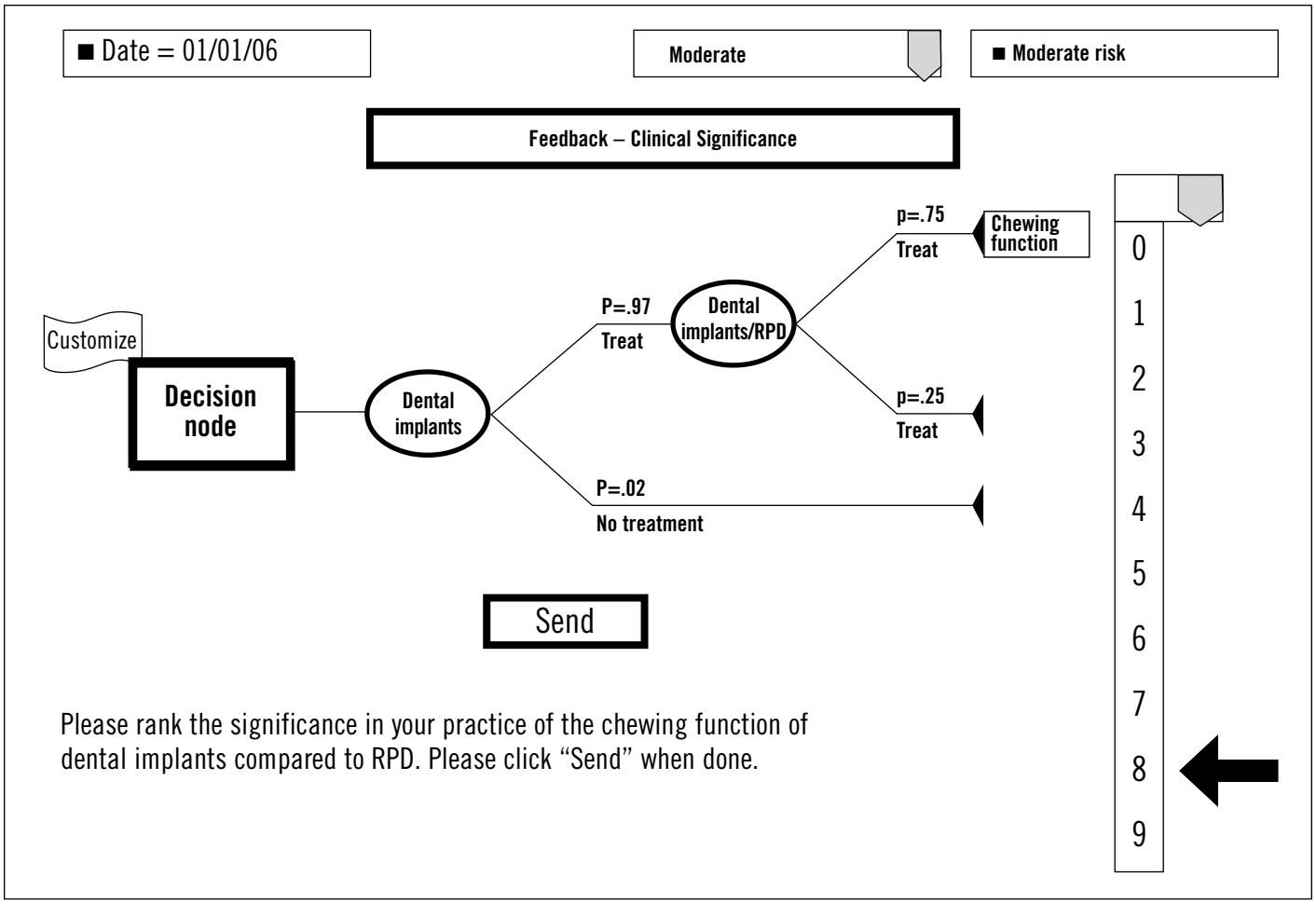

Figure 9. The form that queries the dentist in response evaluating the clinical significance of a CPG.

Conclusion

An example patient case provided a foundation upon which to illustrate how to use a CPG. Conceptual knowledge management software templates are used to demonstrate queries and responses to queries for information needed in decision-making. The information included decision and utility data from a primary, centralized network database and cost data from the practice cost schedule. When best evidence was not available, forms were explained to guide the dentist's participation in validating the clinical significance of a new CPG. From the patient case, decision analysis was presented in arriving at an individualized and optimized clinical decision. CDA

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Implementation

The Translational Clinical Practice System: A Way to Implement the Evidence-based Approach in the Dental Office

George K. Merijohn, DDS, and Michael G. Newman, DDS

ABSTRACT

Evidence-based decision-making in dental practice is challenging and rewarding. But for many clinicians, the evidence-based approach is an abstract and even theoretical idea that sounds good, but is not very practical. The Translational Clinical Practice System provides an overriding domain and a system within which the evidence-based approach may be more effectively utilized in clinical practice. Most would agree that using good evidence, information, and data as the basis for decisions are the starting points toward reaching the best results for the patient. However, there are clearly insufficiencies in the currently available best scientific evidence for many of the procedures patients need. The good news is that the evidence environment is improving and better quality information is becoming available in the office where it is needed. This article describes a logical and straightforward approach for clinicians to use in order to put together complex and often interwoven factors involved with patient care. Specific clinical examples are provided.

Four years ago, the National Institutes of Health determined there was a definitive need to translate the remarkable scientific innovations being witnessed into usable information by the clinician, and thus into improved health gains for the nation. The question asked was "What novel approaches can be developed that have the potential to be truly transforming for human health?" This query led to the development of the NIH Roadmap for Medical Research.[1] This initiative encourages fundamental changes in research, as well as in education. Among many initiatives, the roadmap wants to accelerate advances in the understanding of biologic systems and it wants to integrate powerful new tools that can be used at both the bench and

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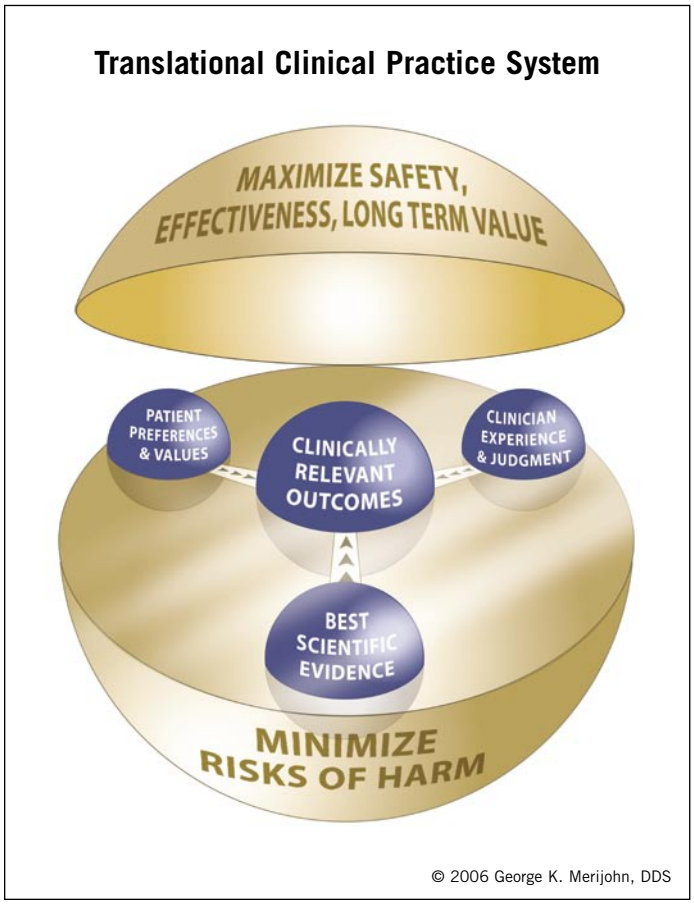

Diagram A. The large sphere in **Diagram A** represents the context which overrides clinical decision-making. The key to the TCPS approach is to recognize that there is a balance between maximizing safety, effectiveness and value and minimizing risk of harm. The four basic fundamentals of evidence-based decision-making are represented by the interconnected spheres. Clinicians should seek the highest level available in each sphere. The weighted emphasis of each sphere will vary depending upon individual circumstances.

Diagram B. Levels of Evidence Used to Determine Validity and Applicability of Clinical Research

The levels provide a better understanding of the quality and strength of the study and are based on the studies ability to control for bias and to demonstrate cause and effect.

the bedside in order to shorten the traditionally long lag time between discovery and clinical use. Genomics, proteomics, transgenic animal models, structural biology, biochemistry, and imaging technologies offer unprecedented prospects for advancing knowledge of human disorders in a translational context.[2]

The NIH is also encouraging fundamental change in how we train the new generation of clinicians for the health care challenges of this century. Its aim is to stimulate the development of a brighter vision through innovation and experimentation. It encourages a multiplicity of transformational tactics, since it is clear that no one model can be successful in all health care environments.

The Translational Clinical Practice System

The objective of the Translational Clinical Practice System Model is to lower the barriers to complex clinical decision-making in order to improve patient care. It provides a logical and straightforward way of putting together all of the complex and often interwoven decision components involved with patient care. The TCPS is designed to facilitate the clinicians' skills in translating the multifaceted interrelationship of scientific evidence, patient preferences and values, clinician experience and judgment, clinically relevant outcomes and ethical practice parameters into substantial health care improvements for their patients (**Diagram A**). The TCPS challenges conventional thought by encouraging a fundamental change or transformation in how clinicians decide upon treatment.

The focus of this article is to introduce the reader to the TCPS and to illustrate its use as an innovative vehicle with which to implement the evidence-based approach in clinical practice. It is written in the first-person narrative, because it describes our own experiences and views. As will be illustrated, implementation of the TCPS approach by the clinician is not dependent upon bureaucratic legislation or mandates. It just requires understanding of a few fundamental beliefs that put the patient's welfare at the foremost front of our clinical decision-making. Although

many of the examples used here are periodontal, the concept is applicable to all aspects of dental clinical practice.

The Evidence-based Approach

The movement toward actively incorporating evidence-based decision-making in dental practice is exciting and enriching. It is also challenging. For example, with a given clinical question, what is the clinician to do when there exists only flawed evidence or no evidence at all?

Evidence-based practice has been defined as combining best research evidence, along with clinical experience and patient preferences to improve treatment outcomes.[3] However, a large amount of published scientific research provides inadequate information, and that lack of good data significantly impairs the clinicians ability to translate these resources as high-level evidence when advising patients and providing treatment (**Diagram B**).

Fletcher and Sackett described "levels of evidence" to rank the validity of research evidence and then correlate these levels to different grades of recommendations.[4] These evidence levels have evolved over the years and have found their way into mainstream dental literature. For example, *The Journal of Evidence-Based Dental Practice* uses a modification of the levels of evidence developed by the Centre for Evidence-based Medicine at Oxford University, a portion of which is depicted in **Table 1** and graphically represented in **Diagram B**.[5]

The levels (grades) give the reader a better understanding of the quality and strength of the study. The grades are based on the studies' ability to control for bias and to demonstrate cause and effect. Although each level of evidence contributes to our body of knowledge, it behooves the clinician to always utilize the best available evidence for each clinical question. However, not all clinical questions can be answered by the gold standard (level 1a) of evidence: the systematic review of high quality, randomized controlled trials.

Ethical Practice Parameters

Because of the scarceness of high-level scientific evidence and the complexity of many clinical decisions, implementing the evidence-based approach in dental clinical practice is challenging. By establishing an overriding context of ethical practice parameters, the TCPS is designed to manage dilemmas of evidence and to facilitate the challenging task of translating best available scientific into appropriate clinical care. The framework of TCPS can help answer questions such as:

- Are diagnostic and treatment decisions guided mostly by limitations such as clinician experience, low-level evidence (e.g., expert opinion, case reports), and/or third-party benefit plans?
- Does the clinician have in place a higher level "operating system" which guides how he or she will advise and treat patients?

Utilizing ethical practice parameters is not a new way of framing decision-making. In medicine, it can be traced back to the phrase "First do no harm" originated by Hippocrates in his work, *"Of the Epidemics"* Book I, Section XI (400 BCE).[6] From the authors' point of view, the two core ethical practice parameters that override all clinical care delivery are:

- **Maximize** safety, effectiveness and long-term value
- **Minimize** risks of harm

In dentistry, the TCPS has evolved from its predecessor, the Precautionary Context Clinical Practice Model.[7] The essence of this framework is captured in commonsense aphorisms such as "Better safe than sorry," "An ounce of prevention is worth a pound of cure" and "Look before you leap." The TCPS shares its core philosophy of minimizing the risk of harm with a framework used by many governmental regulatory agencies, the Precautionary Principle (PP). However, as it is instituted on the government and large organization level, the PP does not readily appear to be applicable to dental clinical practice on the local level.

Emerging in European environmental policies in the late 1970s, the PP has been enshrined in numerous international treaties and declarations. It is, by the Treaty on European Union in 1992, the basis for European environmental law and plays an increasing role in developing environmental health policies as well.[8]

The PP recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm. Utilizing the PP, the government of Canada developed a framework which outlines the guiding principles for the application of precaution to science-based decision-making in areas of federal regulatory activity for the protection of health and safety and the environment and the conservation of natural resources.[9]

The TCPS, the PP and the Precautionary Context Clinical Practice Model are distinctive within science-based risk management.[7] Making choices based on the least harmful alternatives challenges conventional risk management strategies. These are often guided by entirely different principles perhaps best reflected in the aphorism, "Nothing ventured, nothing gained."

How the TCPS Improves Clinical Decision-Making and Patient Care

Adopting the TCPS facilitates the opportunity to improve the way decisions are made in dental clinical practice. Instead of asking "How much risk will be allowed?" the TCPS asks a very different question: "How little harm is possible?"

Although dental care can never be completely risk-free, a risk that is unnecessary, and not freely chosen, is never acceptable. Adopting the TCPS facilitates integration and translation of the varied and potentially conflicting elements affecting the clinical decision-making process.

The TCPS provides a domain within which clinical decision-making is based on the best available scientific evidence – science that is explicit about what is known, what is not known, and what may never be known about potential hazards (**Diagrams A and B**).

The TCPS was designed to prevent harm, not to prevent progress. Applying

Table 1

Levels of Evidence*

Level	Study Category: Therapy/Prevention, Etiology/Harm
1a.	Systematic review of randomized controlled trials
1b.	Individual randomized, controlled trial (with narrow-confidence intervals)
2a.	Systematic review of cohort studies
2b.	Individual cohort study (including low-quality randomized controlled trial; e.g., <80% follow-up)
2c.	"Outcomes" research; ecologic studies
3a.	Systematic review of case-control studies
3b.	Individual case-control study
4.	Case series (and poor quality cohort and case-control studies)
5.	Expert opinion without explicit critical appraisal, or based on physiology, bench result research, or "proof of principle study"

* Ref. The *Journal of Evidence-Based Dental Practice*

the TCPS fosters innovation in producing better materials, safer products and alternative dental care delivery processes. The ultimate goal of the TCPS is to enhance the clinician's stewardship of patient care.

Unfortunately, the reality of today's regulatory system in the United States is that a lack of proof of harm is often misinterpreted as proof of safety. While this system has been successful in approving drugs that may help manage many problems, it has also been less effective in identifying long-term side effects, toxic properties and/or disease transmission risks for many therapeutic agents. Adopting the TCPS better enables the clinician to take action despite scientific uncertainty about the magnitude of risk of harm. This new framework removes excuses for inaction on the grounds of scientific uncertainty ("paralysis by analysis").

The Evolution of the TCPS in Clinical Practice

For many years, the patient care philosophy used by the authors was to "passionately provide excellence in therapy with exceptional patient service and care." Although satisfied that these objectives were being achieved, there was a desire to provide even better service by refining the clinical practice model (what kinds of treatments were provided and the outcomes patients received). During the 1980s and 1990s, in each of our practices, we put in motion philosophies based on the guiding principles:

- Deliver treatment that provides the highest degree of safety, effectiveness, long-term value and patient comfort, and
- Ask always, "How little harm is possible?"

It was always considered an investment in both the patients' welfare and the dentists' practices to take the additional consultation time needed to review in-depth treatment alternatives and their risks/benefits as well as the patients' individual preferences and circumstances.

Putting our guiding principles into action on a daily basis in clinical practice was both exhilarating and demanding as it necessitated rethinking and revisiting some of the literature that guided decision-making. The TCPS evolved from these philosophies and has been serving our patients on a daily basis (**Diagram A**).

As we continue to do today, the revised questions we sought answers for always contained a component of asking, "How little harm is possible and which treatments provide the highest degree of safety, effectiveness, and long-term value based on the quality of evidence available?"

At that time, and even today, it became evident that classic narrative literature reviews, specialty position papers and the publishing criteria of the vast majority of journals left much to be desired. Sifting through the volume of research publications and then translating it continues to be fairly difficult and time-consuming.

However, the situation markedly improved in dentistry toward the end of the last century with the recognition of the evidence-based approach. In 1998 and 2001, respectively, the *Journal of Evidence-Based Dentistry* and the *Journal of Evidence-Based Dental Practice* began publication. Since then, utilization of those publications as well as PubMed, Science Direct, Scopus and the Cochrane Collaboration Oral Health Group Reviews and Protocols have significantly contributed to the ability to have sound scientific footing for the TCPS (**Diagram A**) utilized in our private practices, research, and teaching. These resources enable an improved clinical decision-making process, as well as effectively increasing our ability to add, eliminate, or modify existing treatment protocols in order to meet the criteria set forth by the TCPS. Importantly, these resources are available at the point of care, in the office, where patients are treated.

The *Absence* of Evidence: How it Fosters Improved Clinical Care Changes

As a result of reviewing the scientific literature as well as product and procedure information, it became clear that the old admonition, "The absence of evidence is not evidence of absence" would become an important clinical decision-making tool. We found that there was a lack of reasonably strong scientific evidence to support the continuation of certain procedures and protocols that exposed our patients to unnecessary risks when assessed through the TCPS.

The following examples describe how the TCPS was used and how it can

be used to direct clinical decision-making, especially when high-quality scientific evidence is not available.

Using Sterile Water During Dental Surgery

It has been clearly demonstrated that the risk of disease transmission increases during surgical procedures with the use of nonsterile output irrigant/coolant.[10-16] Also, due to the presence of a biofilm, the use of conventional dental unit waterlines (with or without filters) for surgical procedures increases the risk of disease transmission.[11-13,15,16]

Although at the time there was an absence of evidence to establish a direct disease transmission cause-and-effect relationship, specifically in dental surgery, in 1993 the Centers for Disease Control and Prevention recommendations for dentistry advised that "sterile saline or sterile water should be used as coolant/irrigant when surgical procedures involved the cutting of bone are performed."[14]

However, routine periodontal surgical practice continued to deliver potentially contaminated output irrigation water to the surgery site whether or not the source water was tap, bottled, or sterile – filtered or nonfiltered. This was because the irrigant was delivered by way of contaminated conventional dental unit waterlines. Even before 1993, the dental profession was aware of the risk problem, but no implementation guidance was provided at the organized dentistry level. By 1995, there still were no California or federal regulations enacted to enforce the 1993 CDC recommendation. The approach adopted was the more conventional risk-management strategy of waiting for disease transmission cases to become a public health concern before enacting change.

When the clinician is faced with identified dental treatment risks, controversies, or issues not yet resolved at the larger agency level of government or organized dentistry, making clinical decisions by way of the TCPS enables taking action, despite scientific uncertainty about the magnitude of risk of harm. The overriding guiding principle of the TCPS states that the clinician delivers treatment that provides the highest degree of safety, effectiveness and long-term value while exposing the patient to the least risk of harm. This puts the patient's welfare at the foremost front of our clinical decision-making.

As an example of TCPS decision-making, in 1995, one of the authors, (Merijohn) eliminated all traditional dental unit waterlines from his practice

Table 2

Examples of Periodontal Surgical Clinical Care Changes Resulting From the *Absence* of Evidence

Procedure/protocol	Before evidence-based approach	After evidence-based approach
Output irrigation solution for periodontal surgical procedures (excluding endosseous implant placement surgery)	Contaminated irrigation solution: tap water, filtered tap water, filtered bottled water *Risk of harm: Disease transmission*[10-17,8-15]	USP sterile saline output irrigation
Dental unit waterlines (DUWLs)	■ Use of nonsterilizable traditional DUWLs with in-dwelling filters ■ Use of air-water syringes attached to DUWLs *Risks of harm: Disease transmission*[11-13,9-11,15-17,13-15]	■ Use of detachable irrigation tubing sterilized for each procedure ■ Use of sterile irrigation syringes
Rotary drill utilization for surgical bone recontouring and root surface modification	■ Use of conventional high-speed, air-driven dental handpieces (sterilized) ■ Use of sterilized multiuse burs *Risks of harm: Introduction of air emboli into surgical spaces; heat trauma to, and excessive reduction of, bone and tooth structure*[18,19,16,17]	■ Use of low-speed variable torque electric motor handpieces (sterilized) ■ Use of single-use sterile burs for bone recontouring
Grafting material	■ Allogenic (human cadaver) ■ Xenogenic (animal source material) ■ Autogenous (patient tissue) *Risks of harm with allogenic and xenogenic tissues: Disease transmission*[20-24,18-22]	Autogenous tissues
Resorbable suture material	Xenogenic (gut) *Risks of harm: Disease transmission; autoimmune inflammatory reaction at surgical site*	Synthetic

and exclusively used USP sterile saline for output surgical irrigant/coolant. Sterile irrigant/coolant was, and continues to be, delivered via detachable irrigation tubing sterilized for each procedure or by sterile irrigation syringes (**Table 2**).[7]

In 2003, 10 years after its initial recommendation, CDC utilized an evidence-based approach to establish its updated Infection Control Guidelines. It recommended the following: "use sterile saline or sterile water as a coolant/irrigant when performing oral surgical procedures. Use devices specifically designed for delivering sterile irrigating fluids." The level of evidence cited was Grade 1B: "strongly recommended for implementation and supported by experimental, clinical, or epidemiologic studies and a strong theoretical rationale."[15]

Finally, 12 years after the initial 1993 CDC recommendation and effective April 2005, the Dental Board of California updated the Infection Control Regulations of the Dental Practice Act (Section 1005, Section C 15: Irrigation) mandating that "sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolant/irrigants are deemed to be sterile when delivered using a device or process that has a Federal Drug Administration marketing clearance for delivery of sterile coolant/irrigants to the patient. Delivery of sterile coolant/irrigants shall be in accordance with the manufacturer's directions."[16]

As demonstrated in this example, utilizing the TCPS can enable practitioners to take action and decrease the potential risks of harm for patients well before mandated regulations go into effect.

Utilizing Human Cadaver and Animal Tissue Grafts in Dental Surgery

Are they safe and effective, providing patients with long-term value?

In this example of clinical care decision-making in the absence of evidence, the flexibility and adaptability of TCPS is illustrated. Raising and examining this question within the context of the TCPS allows for two different conclusions to be drawn.

Table 3

Key Dental Restorative and Caries Questions to Address Within the TCPS Context

1. For a given clinical situation, are there greater tooth longevity risks associated with restorative intervention than with nonintervention?
2. What are the best methods for detecting early enamel caries and early dentinal caries?[35]
3. What are the best indicators for an increased risk of dental caries?[32]
4. What are the best methods available for the primary prevention of dental caries initiation throughout life?[36]
5. What are the best treatments available for reversing or arresting the progression of early dental caries?[37]
6. What are the most accurate methods available for distinguishing between the different stages of caries (e.g., cavitated/noncavitated; active/inactive; progressive/remineralizing; enamel only/dentin involvement)?

Table 4

Point of Care Clinical Questions to Answer Within the TCPS Context

- Wait and watch, or treat?
- If treating, what is the best approach?
- Which approach decreases tooth loss risk and maximizes tooth longevity?

Common restorative clinical situations where there exists an absence of strong scientific evidence to guide clinical decision-making

1. Noncavitated pits and fissures
2. Enamel craze lines
3. "Leaky" restorations
4. Cracks in existing restorations
5. Tooth surface – restorative margin interface discrepancies (gaps, openings)
6. Abfraction sites

While strong scientific evidence has not demonstrated that cadaver and animal tissue graft materials are the safest, most effective and best long-term value approach in elective dental surgery, neither has it determined that there exists a proven cause-effect relationship routinely implicating these materials in disease transmission and patient morbidity.

However, although approved by the FDA, these grafting materials do carry warnings as they are not guaranteed risk-free from transmitting diseases to patients. Further, the best scientific evidence has not definitively established that these materials provide significantly improved long-term, clinically relevant outcomes with respect to therapeutic effectiveness or improving tooth longevity, but high-quality evidence does exist that demonstrates allograft usefulness in clinical practice.

There are reported cases of disease transmission from the use of allograft materials in medical procedures. Although to date there are no published reports of definitive evidence of disease transmission cases resulting from their use in dental procedures, allograft tissue recall alerts have been published because of recently discovered higher-than-normal disease transmission risks associated with some allograft tissue material used in dental surgery.[25]

As is the case in the majority of treatment options in dentistry, relying strictly upon the currently available best scientific evidence and/or the absence of evidence can hamper clinical decision-making. In this example of whether or not to use cadaver and/or animal tissue grafts, both choices have reasonable scientific support but offer different risk exposures.

Using the TCPS enhances the clinicians' decision-making ability. It provides an ethical parameters framework or "operating system" within which the clinician applies not only the best scientific evidence (**Diagram B**) and/or absence of evidence, but also factors in their clinical experience and judgment, as well as respects patient preferences/values in order to provide clinically relevant outcomes (**Diagram A**).

For example, utilizing the available evidence and assessing it using the TCPS, Merijohn in 1995 chose to eliminate the use of all human cadaver and animal tissue graft materials from treatment protocols (**Table 2**).[7] Newman, utilizing the same available evidence, chose to continue to use autografts, allografts, xenografts and alloplastic materials in his treatment protocols. When they examined the scientific evidence within the context of the TCPS, the results provided these clinicians with an enhanced ability to make two different, yet appropriate clinical decisions.

Clinicians should always invest the time to educate patients of treatment alternative risks and benefits in order to foster a greater ability within each patient to make appropriate choices for themselves. Additionally, patient preferences and values should always be recognized and respected. It is the practice and recommendation of the authors that if the patient elects treatment procedures not provided by the clinician, that the patient be referred to others for further consultation and treatment.

Diagnosis and Management of Dental Caries and Common Restorative Clinical Issues in the Absence of Strong Evidence

In the evolution of caries treatment, dentistry has moved historically from extraction to decay removal and restoration (surgical intervention). Identification of early carious lesions and treatment with nonsurgical methods, including remineralization, represent the next era in dental care. In 1995, a supplement to the *Journal of the American Dental Association* first publicized this more conservative approach for worldwide dissemination.[26] However, the dental profession is only slowly progressing from "finding and filling" (surgical intervention) to "early detection and management."[27]

The stopping and reversing of caries is dependent on early and accurate diagnosis, which remains a developing field. If maximum benefits are to be obtained, improved diagnosis is essential.[28] Currently available evidence suggests that a large segment of the dental profession does not employ recommended conservative, noninvasive strategies to manage early occlusal lesions.[29-31]

As dentistry moves toward early detection of lesions and a more preventive philosophy rather than a restorative orientation, improved dental caries risk assessment throughout life is needed.[32]

How strong is the dental profession's evidence regarding the diagnosis and management of dental caries? As was concluded at the 2001 "National Institutes of Health Consensus Development Panel Conference on Diagnosis and Management of Dental Caries Throughout Life," the diagnosis and management of dental caries is an evolving area in dentistry, many aspects of which are beleaguered by the absence of strong scientific evidence.

Visual and tactile diagnostic modalities appear to have satisfactory sensitivity and specificity in diagnosing substantial, cavitated, dental caries as does radiographic diagnosis of interproximal lesions. However, current diagnostic practices do not have sufficient sensitivity or specificity to efficaciously diagnose noncavitating caries (early caries), root surface caries, or secondary caries. There is currently no diagnostic modality that can differentiate between microbiologically active caries and demineralized dentin without caries beneath a restoration.

The NIH panel was disappointed in the overall quality of the clinical data set that it reviewed. Far too many studies used weak research designs or were small or poorly described and, consequently, had questionable validity. Several systematic reviews of the literature presented at the CDC concluded that the majority of the studies were inadequate. At present, the dental profession is unable to accurately identify early lesions or lesions that are actively progressing.

These are major weaknesses in dentistry, especially in view of the significant percentage of restorations inserted to replace existing restorations.[32] The absence of evidence to support routine, everyday restorative procedures is clearly a serious clinical problem.

The NIH panel concluded there was an absence of objective diagnostic methodology.[33] Although additional diagnostic devices have become commercially available since the 2001 NIH panel, as recently as 2005, it has been determined that identification methods for early occlusal caries are not yet accurate.[27]

For example, the DIAGNOdent (KaVo America, Lake Zurich, IL) laser fluorescence device for detecting caries had just become commercially available at the time of the NIH conference. A recent systematic review of the performance of the DIAGNOdent in detecting caries found the device of limited value as a principal diagnostic tool because of its high false-positive diagnosis compared with those with visual methods. Further assessment of the DIAGNOdent in clinical and in vivo applications to detect caries activity or progression is needed if this tool is to be considered efficacious in the detection and hence treatment of caries.[34]

As was illustrated in the previous examples regarding surgical irrigation and bone grafting decision-making, utilizing the TCPS improves the ability to make appropriate restorative treatment decisions especially when strong scientific evidence is lacking. The TCPS provides the clinician with an overriding context within which to utilize the best available scientific evidence, clinician experience and judgment, and the preferences of the patient.

The TCPS is a very effective and practical method to examine the issues presented in **Tables 3 and 4**. A few examples of restorative and caries questions to answer within the context of the TCPS follow.

- Which is the more appropriate recommendation: "Wait and watch" or treat?
- If treating, what it the best approach?
- Which approach decreases tooth loss risk and maximizes tooth longevity?

Clinicians investing the necessary time and resources for patient education will realize long-term gains both for their patients as well as their practices. The clinicians' goal is not only to recognize and respect patient preferences and values but to better enable the patients' decision-making process (**Diagram A**). In order for patients to make appropriate choices for themselves at the point of care, they need to be exposed to the best available evidence regarding therapeutic risks and benefits, long-term value, potential harm, safety, comfort, as well as esthetics. As dentistry progresses from "finding and filling" to early caries detection and management, the role of the dental professional as diagnostician, adviser, and consultant will become increasingly valued by both patient and dental care provider as well.

When the scientific evidence, or lack thereof, is assessed using the TCPS, the clinician can improve the way decisions are made (**Diagram B**). The strongest as well as the weakest evidence is critically assessed within a tangible framework. This helps simplify the decision-making process, enabling the clinician to choose the best available evidence based upon

which procedure(s) satisfy the two core ethical practice parameters of the TCPS that override all clinical care delivery:

- **Maximize** safety, effectiveness and long-term value
- **Minimize** risks of harm

Examples of Clinical Care Changes Resulting From the *Presence* of Evidence

The *Journal of Evidence-Based Dental Practice, Journal of Evidence-Based Dentistry*, PubMed, Science Direct, Scopus and the Cochrane Collaboration Oral Health Group Reviews and Protocols are examples of evidence-based resources which provide sound scientific footing for the TCPS way of thinking. The TCPS was designed for utilization in many settings, including private practice and teaching. **Table 5** outlines some of the positive changes adopted based on sound scientific evidence.

Practice Benefits Form Adopting the TCPS

The clinical care changes adopted in our practices by utilizing the TCPS have resulted in improved patient outcomes. From a practice management perspective, our practices benefit from incorporating the TCPS. Amongst other benefits, including providing a better level of care for our patients, it has facilitated the broadening of our scope of care. Educating our patients within the framework of the TCPS places demands upon our communication skills and time, but ultimately is very rewarding for both the patient and the practice.

For clinicians planning to incorporate the TCPS into their practices, it is important to note that all practice employees should participate in the process of adopting the TCPS. This creates a shared vision and an empowerment of the dental team through knowledge, thus enabling greater employee satisfaction.[7]

Conclusion

The TCPS provides an effective and systematic way to incorporate evidence-based decision-making at the point of care in clinical practice. Evidence-based decision-making in dental practice is rewarding and challenging. Although there will always be insufficiencies in the currently available best scientific evidence, this state continually improves over time.

For the private practice clinician, learning and sharing translational and evidence-based skills is a career-long enrichment process. As developments continue to evolve at the larger professional organization and agency level, transformational efforts

Table 5

Examples of Clinical Care Changes Resulting From the *Presence* of Evidence

Procedure / protocol	Before evidence-based approach	After evidence-based approach
In-office caries-prevention procedures immediately following all periodontal flap surgery suturing and at postop appointments	No treatment	Fluoride varnish application[38,27]
In-office caries-prevention procedures at dental hygiene maintenance appointments for higher-caries risk patients and root-sensitivity patients	Fluoride gel application	■ Fluoride varnish application[38,42] ■ Caries-risk assessment and prevention and dietary counseling[38]
At-home caries-prevention recommendations	■ Fluoride gel ■ Fluoride toothpaste (1,100 ppm) ■ Fluoride rinse ■ Occasional dietary counseling	■ Fluoride toothpaste (5,000 ppm)[38-40] ■ Xylitol-based chewing gum and candy[38,41] ■ Fluoride rinse[38] ■ Fluoride toothpaste (1,100 ppm)[38,40]
Root-form endosseous implant (titanium screw) brands/ manufacturers	Single	Multiple[43,44]
Toothbrush recommendations	Manual soft toothbrush	■ Manual soft toothbrush ■ Powered toothbrush with rotation oscillation[45,46]
Perio-systemic links	Cursory discussion with diabetic patients and people who smoke	In-depth counseling, education, referral and/or treatment ■ Diabetic patients[49] ■ People who smoke[47,48,51] ■ Moderate- to higher-risk pregnancy and pre-pregnancy patients with moderate to advanced periodontitis[50] ■ Moderate- to higher-risk cardiac patients with moderate to advanced periodontitis[52-54]

made at the local level will more rapidly facilitate substantive health care gains for patients. The TCPS provides an effective means by which to achieve this goal. CDA

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USING

sealants

Evidence-based Recommendations for the Use of Sealants

Anne Reeves, MPH; Francesco Chiappelli, PhD; and Olivia S. Cajulis, DDS

ABSTRACT

In traditional research, the "level of significance" refers to the probability value used to reject the null hypothesis. In evidence-based research, a similar term, "the level of evidence" refers to the quality of the published report that is analyzed critically in the context of a systematic review.[1] A systematic review, the principal research tool of evidence-based dentistry, is distinct from a classical narrative literature review in that it is focused to examine the strengths and weaknesses of the research methodology, design and data analysis of each report included in the review. A systematic review is very clearly defined, and sets out to find what evidence there is for prescribing a particular intervention for a given patient. Evidence-based recommendations are grounded on systematic reviews, and the evaluation of systematic reviews in a given domain of dentistry is critical for the successful implementation of evidence-based dental practice.

In the context of sealants, the evidence indicates that the intervention is effective in preventing dental decay on the molars and premolars of susceptible children and adolescents (Level of evidence: II-1). The preventive effect for second-generation sealants ranges from 33 percent to 71 percent. The median preventive effect is higher when sealants are reapplied, compared to a single application, because sealant effectiveness decreases over time. The majority of studies have focused on molars, and fewer studies have examined the preventive effect of sealants on premolars.

In this paper, the authors have developed evidence-based recommendations for the use of sealants by discussing the level of evidence and, when applicable, the number needed to treat (NNT) and the prevented fraction (PF), two fundamental criteria in evidence-based dental practice.[2]

The American Dental Association defines evidence-based dentistry as the process of incorporating the best available evidence from the entire body of available research into clinical decision-making. The intent of evidence-based dental practice is to optimize the specific treatment intervention to fit best the needs and desires of each individual patient. To actualize evidence-based dentistry, it is essential to develop and characterize fundamental standards for the evaluation of the "best available" research, which can be achieved utilizing the levels of evidence.[1] Here, the authors discuss critically the available evidence for the use of sealants in the development of evidence-based recommendation for clinical practice.

Taken together, the evidence suggests that once a tooth has erupted into the mouth and is free from gingival tissue, a sealant should be placed on that tooth as soon as possible (and up to four years). Because children receive their permanent molars and premolars during specific developmental periods, sealant placement between the ages of 6

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to 8 and 10 to 13 years would likely yield the most cost-effective program (Level of evidence: II-1).[3] Limited data suggests that molars are the most susceptible to attack within two to four years of eruption. However, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood (Level: II-2).[4] If risk assessment does not deem an individual to be at risk for caries, the practitioner may observe the patient over time and place sealants when the risk for caries becomes more apparent. The authors attempted to examine the number needed to treat (NNT) and the prevented fraction (PF) of sealants for differences in underlying caries risk.[2]

Methods

PICO Question:[3]

I. How great of a reduction in caries do pit and fissure sealants achieve, compared to identical populations without sealants in both molars and premolars?

II. In what age groups are sealants most effective in reducing caries based on the parameters of a) cost, b) number needed to treat (NNT) for various caries rates, and c) prevented fraction (PF)?

Protocol

In order to answer these questions, the Medline and Cochrane databases were searched to locate review articles using the keywords "pit and fissure sealants" and "pit and fissure sealant effectiveness." MeSH headings "cost-effectiveness," "age," and "preventive effect" were also used to locate articles. Abstracts were examined to identify systematic review articles on the topic. Eight review articles were selected and provide the basis for the analysis described below. Reference lists of the selected review articles were examined for additional studies that would assist in answering the proposed questions. Key oral health reports were also reviewed.[4,7]

Studies were evaluated in accordance with the "scale for evaluating evidence and making recommendations" Tables 4 and 5.[8] Although split-mouth randomized control trials (RCT) could potentially be evaluated as Level I evidence, in this paper they are classified as Level II-I evidence because of inherent biases in these designs. Since the inclusion of children into a split-mouth design generally requires at least one pair of caries-free molars, a caries-active child would be excluded. Therefore, not all children have the same chance of being selected for participation. Moreover, the longer the period of time after the tooth has erupted into the mouth, the higher the likelihood that a high-risk child would be excluded from the study.[9]

THE EVIDENCE IS STRONG THAT PIT AND FISSURE SEALANTS PLACED ON THE OCCLUSAL SURFACES OF PERMANENT TEETH DO PREVENT CARIES AMONG SUSCEPTIBLE CHILDREN AND ADOLESCENTS.

Results and Inferences

Sealants and the Best Available Evidence

The evidence is strong that pit and fissure sealants placed on the occlusal surfaces of permanent teeth do prevent caries among susceptible children and adolescents (Level II-I). However, there is little evidence on sealant efficacy among adults. The classic meta-analysis by Llodra examined the effectiveness of autopolymerized pit and fissure sealants in preventing caries.[10] A search of the MEDLINE database from January 1975 to December 1990 was conducted to locate studies on sealant effectiveness. To be included into the meta-analysis, studies had to contain original data, examine sealants as the sole preventive intervention, be published in English, Spanish, or French, and include data which could be used to derive PF. All studies used a half-mouth design (Level II-I). Publication bias was considered analytically. Results were stratified by sealant type, length of follow-up, tooth treated, water fluoridation, and operator. Reports on visible light sealants were excluded because the PF could be not calculated. The final analysis included results from a single application of autopolymerized sealants. Eighty-one percent of studies examined sealant efficacy for the first molars. Pooled data from Llodra's meta-analysis yielded a PF among the exposed group of 71 percent (CI^{95}: 69, 72) among children 5 to 13 years old.[4]

As part of an independent review, a nonfederal task force conducted a systematic review to evaluate the effectiveness, applicability, and cost-effectiveness of school-based and school-linked sealant programs. School-based programs are carried out in schools, while school-linked programs can be conducted in schools, private dental practices, and clinic settings. In general, these delivery programs target children at risk for caries based on their eligibility for free- and reduced-price lunch services throughout second to sixth grades. Experts have recommended that school-based and school-linked sealant programs target the first and second permanent molars of high-risk children.[4]

Ten out of 37 studies were retained for the final analysis on the effectiveness of school-based and school-linked sealant delivery programs in preventing caries (Level II-I, 2). The primary reasons for exclusion were insufficient data for quality scoring, limitations in execution or design, and lack of an appropriate effect measure. Seven studies reported on the effect of using sealant bisphenol-glycidal methacrylate (bis-GMA) as the only preventive intervention, and three reported using both bis-GMA sealants in

combination with other caries-preventive interventions.

The authors abstracted 22 estimates from the 10 studies that compared the caries experience of children who received sealants through a school-based or -linked program with children who did not. Exposure to a school-based or school-linked sealant program was associated with a median decrease in caries of 60 percent (range, 5 percent to 93 percent). School-based programs had a higher median effect (65 percent, range 23 percent to 93 percent) when compared to school-linked sealant delivery programs (37 percent, range 5 percent to 93 percent). Programs that provided sealant reapplication showed a higher median effect (65 percent vs. 35 percent).

The task force assessed the applicability of these findings to a variety of circumstances. The evidence encompassed studies that varied by time, place, population, the number of times sealant was applied to the same tooth surface, and duration of follow-up between sealant-caries status. The studies spanned from 1970 to the 1990s and included children and adolescents six to 17 years old from the United States, Guam, United Kingdom, Australia, Spain, Thailand, and Columbia. The effect size for studies in the United States (four studies) were similar to studies conducted outside of the country (six studies). The task force concluded that the findings should "apply broadly to populations of school-age children in a variety of school settings."[11]

Locker et al. cited Llodra et al. PF of 71 percent, and agreed with others that there was good evidence to support that sealants do prevent pit and fissure caries among susceptible children and adolescents (assuming the sealant is retained) (Level II-I).[3,10,12,13]

On the other hand, in their meta-analysis, Majare et al. found the evidence limited for assessing the caries-preventive effect in first molars and incomplete for assessing the preventive effect on primary molars, premolars and second molars (Level II-I, 2).[9] The sample included children age five to 14. Potential factors which might modify the effectiveness of pit and fissure sealants were also examined. Criteria for inclusion into their analysis were stricter than those used by Llodra et al.[10]

Of 113 studies assessed by Majare et al., nine met their criteria and were retained for the final analysis.[9] None of the studies were classified as strong evidence; two were evaluated as moderate, and 11 as limited evidence (c.f., Majare et al., Table 5).[9] Eight studies were used for the pooled estimate effect because they all used resin-based materials and a single application on permanent first molars. All but one study included in the pooled estimate were evaluated by Majare as limited evidence. Three studies yielded nonsignificant results.[14-16]

THE AUTHORS CONCLUDED THAT THE LITERATURE WAS INSUFFICIENT TO EXAMINE HOW SEALANT EFFECTIVENESS VARIES IN LOW-RISK VERSUS HIGH-RISK POPULATIONS.

For single applications, the relative risk ranged from 4 percent to 54 percent, and for repeated applications, the reduction in caries ranged from 69 percent to 93 percent. The pooled estimate for subjects with a single application of resin sealants on permanent first molars (compared to those without) showed a relative risk reduction (RR) of 33 percent (RR, 0.67 CI^{95}: 0.55, 0.83). The test of heterogeneity was highly significant at $p<0.001$, so the assumption that the studies were taken from the same population was rejected. The authors concluded that the literature was insufficient to examine how sealant effectiveness varies in low-risk versus high-risk populations.

In a Cochrane systematic review, Ahovuo-Saloranta et al. evaluated the caries preventive effect of resin-based pit and fissure sealants and glass ionomer sealants among subjects under 20 years old.[17] Studies included in the analysis were either randomized or quasi-randomized control trials with at least 12 months duration (Level II-1). Of 297 reports, 16 met Ahovuo-Saloranta et al. criterion. Of the 16 eligible studies, eight were retained for the final analysis, one parallel group design, and seven split-mouth designs. Five of seven split-mouth designs provided data on sealant versus a control group; two studies reported the difference between resin sealants and glass ionomer. The parallel design study compared resin sealant with a control group, glass ionomer with a control group, and resin sealant with glass ionomer. Incidence of caries was expressed as caries or no caries on the occlusal surfaces of permanent molars. Caries was defined as dentin, and enamel lesions were considered sound surfaces.[17]

The mean sample of children was 230 with approximately 300 tooth pairs. The parallel group study included 752 children in total. The combined analysis included children five to 13 years old from the United States, Australia, Columbia, Thailand, and the Syrian Arab Republic. Three studies were included in the meta-analysis for 12, 24 and 36 months, and two studies in the 48- to 54-month meta-analysis.[17]

The results comparing second-generation resin sealant with no sealant at follow-up months 12, 24, 36 were highly significant in support of the preventive effect of sealants to prevent decay. Compared to the control group, the reduction in caries rates among the sealant group ranged from 86 percent at 12 months to 57 percent at 48 to 54 months. The 24-month parallel group study found that among 12 to 13 year olds, there was significantly more caries in the control group with DFS = 0.65

(CI[95] 0.47, 0.83). Retention rates were considered good across all studies.[17]

Since few studies report the baseline caries prevalence in the population, it was not possible to examine the relationship between sealant effectiveness and baseline caries risk. Ahovuo-Saloranta et al. concluded that although sealants are shown as effective in caries prevention, it is impossible to infer the magnitude at each level of caries risk. Clinicians should consider local factors and follow specified guidelines for sealant placement.[17]

Tooth surface and type are important factors that influence levels of caries attack, and the pits and fissures of first and second molars are at highest risk.[3,18,19] Sealant application to the occlusal surfaces of first molars yielded the highest percentage of caries-free teeth for the least amount of resources.[18] Brown noted these findings are understandable because permanent first molars are at greatest risk of attack, and have the highest sealant retention rates.[18] However, Rozier concluded that "for the purposes of sealant use decisions, the evidence suggests that first and second molars are at equal risk of caries for pit and fissure caries, and together are at the highest risk of any tooth types."[19]

As discussed by Soderholm, epidemiologic studies suggest that targeting the first and second molars of children would reach 85 percent of all surfaces expected to develop caries.[20] By including premolars into a sealant program, 99 percent of tooth surfaces among schoolchildren expected to develop caries would be reached. Therefore, Soderholm suggested that including premolars in a sealant program would improve the outcome by only 14 percent, but would require significantly more resources. Including only first and second molars (and not premolars) into sealant delivery programs would yield the most cost-effective program. Additionally, he stated "If limited resources are available, targeted education about dental disease should have a higher priority than placing preventive sealants on low-risk patients." However, to adequately assess these issues, randomized control trials in populations with varying caries rates are needed.[20]

Of interest is a recent analysis of more than 500,000 children, which found an 85 percent reduction in overall restoration rates among children ages of seven to 15 with pit and fissure sealants compared to children without. This study was unique in that it used an outcome measure of "restorations on all surfaces," which included smooth surface caries rather than only looking at pit and fissure caries. These data indicated that sealants can confer protective effects on smooth surfaces, even though the sealant was not applied to that area. The authors proposed that limiting the favored niches for growth of caries causing bacteria in pit and fissure surfaces through sealant placement may lead to a change in the bacterial growth patterns on the teeth, thus reducing overall caries rates. This study utilized a retrospective cohort study design in an insured population with continuous eligibility for the Delta Dental insurance plan (Level II-b).[21]

EPIDEMIOLOGIC STUDIES SUGGEST THAT TARGETING THE FIRST AND SECOND MOLARS OF CHILDREN WOULD REACH 85 PERCENT OF ALL SURFACES EXPECTED TO DEVELOP CARIES.

Effectiveness of Sealants as a Function of the Patient's Age

According to Brown and Selwitz, the declining rates of caries experienced by most segments of the population, slower rates of disease progression, and disproportionate impact of caries among low-income and minority groups have enormous implications for sealant programs.[18] Since caries rates have declined (overall), and disease progression has slowed, cavitation appears to manifest later in the course of the caries process. This suggests that the accepted standard: that sealants should be placed as soon as possible once the tooth has erupted and is free from gingival tissue (and up to four years), may not hold true as individuals remain at-risk for caries into adolescence and adulthood (Level II-I).[3]

This is contrary to the belief that teeth are only susceptible to decay for a few years after eruption, and if a tooth does not develop a carious lesion within several years, it will remain caries-free.[18] While molars are most susceptible to attack within two to four years of eruption, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood.[4,22] Thus, the risk for primary caries in the pit and fissures of molars can continue across the life span.[3,4,18]

In one of the few studies including young adults, Arthur and Swango reported that an "appreciable amount" of pit and fissure decay occurred in subjects during the ages of 17 to 25, and suggested that the selective application of sealants to susceptible tooth surfaces could prevent disease.[23] Two studies reported a relatively constant rate of caries attack over time on the molars of schoolchildren between the ages of 5 to 15.[24,25] Thus, it was noted by Brown and Selwitz that the post-eruptive age of a tooth should "not be the major criterion of whether a tooth should be sealed." Rather, it is the "conditional probability of developing caries in a sound surface given the number of years after eruption."[18] Nevertheless, several comprehensive literature reviews have concluded that sealants should be placed shortly after eruption, but can be applied across a wide range of ages.[3,12]

Solderholm noted that sealant retention rates are higher among older children compared to younger children.[20] In his analysis, he argued that sealant application may be delayed until the child is older and caries risk can be more

easily determined. He suggested that "by accepting this approach, sealants become restorative materials rather than preventive materials shifting the time spent on traditional restorative methods, to time spent restoring incipient lesions would improve cost-effectiveness by reducing unnecessary sealant use" (by only treating individuals who are truly at risk for caries). He also noted that by delaying sealant placement until a child is older, it would be easier to keep the tooth dry, which would improve sealant retention, a primary ingredient of sealant effectiveness. However, this argument assumes in part, that sealants placed in younger children are not correctly done. There is no evidence to support that sealant retention rates for permanent molars differ between younger and older children when the procedure is correctly done.[20]

In contrast, Weintraub found it cost-effective when children received sealants before the age of 8, especially among children with previous caries experience (Level II-2).[26] This large retrospective cohort study included children living in North Carolina between the ages of 5 to 13 who were enrolled in Medicaid around the time of first molar eruption (between the ages of 5 and 7). To estimate sealant effectiveness among children with various levels of caries risk, data on caries-related services were examined. The service variable enabled the stratification of subjects based on caries risk (low-, middle-, and high-risk). Demographic factors, geographic characteristics, and sealant status were accounted for using multivariate analysis.[26]

Among low-risk children (66 percent of sample), sealants were effective in reducing the likelihood of a restoration in the sealed molars for up to four years, but sealants did not save cost expenditures within the eight-year follow-up period. For children classified as middle- and high-risk, sealants substantially lowered the odds of having a restoration for six and seven years, respectively. Restoration rates for high-risk children peaked at eight years old for unsealed teeth, and at nine years for sealed teeth (18 percent vs. 8 percent). The age when sealants had their greatest effect was eight years old, but both sealant effectiveness and restoration rates declined after this time. The effect on the level of expenditures was greatest for high-risk children at nine years, but declined over subsequent years as sealant effectiveness decreased. Expenditure savings for high-risk children occurred as early as seven years old, but the observed effect of sealant effectiveness dissipated these savings in subsequent years. Weintraub concluded that although sealants were effective overall, the savings to the Medicaid program from 1984 to 1992 for placing sealants in high-risk children (22 percent) were not adequate to offset the cost of placing sealants in the first permanent molars of all Medicaid-eligible children who received them. No conclusions can be made about cost-effectiveness beyond the time of the follow-up period. But, a similar study found increasing cost-benefit ratios over time (Level II-2).[27] It may be noteworthy that although this was a Medicaid population (and assumed to be at high-risk for caries); the overall disease burden was fairly low. A sealant program would be more cost-effective in a population with a higher underlying caries risk.[19,27]

THE AGE WHEN SEALANTS HAD THEIR GREATEST EFFECT WAS EIGHT-YEARS-OLD, BUT BOTH SEALANT EFFECTIVENESS AND RESTORATION RATES DECLINED AFTER THIS TIME.

Weintraub specifically examined the effectiveness of sealants among high-risk children and adolescents (Level II-I, 2).[13] Outcome measures included percent sealant retention, caries rates, changes in salivary mutans streptococci levels, cost-effectiveness, or cost-benefit analyses. Nine studies were randomized, half-mouth designs, and seven were cohort studies. Four split-mouth studies excluded children with no previous caries history or restricted the sample to children with caries. Five of the studies included a mixture of potentially low- and high-risk children. Studies varied across sealant type, application technique, age groups, selection criteria, sample size, and study duration.[13]

Retention began high, and declined over time regardless of risk status. Results showed that sealants are "more effective from a cost and time perspective if placed on high-risk rather than low-risk children, though it may take several years for savings to accrue."[13] It is widely accepted that limiting sealant application to high-risk children/teeth/sites is critical for achieving cost-effectiveness in any sealant program.[3,4,12,19,27] Although many studies use prior caries history or current caries status as an indicator of risk, ideal risk assessment should identify high-risk children before clinical caries is detectable.[13]

Bader examined the efficacy of caries preventive methods in high-risk individuals.[28] The study population included caries-active or high caries-risk children and adults, which was defined as any combination of decayed, filled and/or missing primary and/or permanent surface or tooth scores. He noted a number of limitations within the literature including the lack of studies including adult subjects, inconsistency in the identification of caries-active and at-risk subjects, and study design weaknesses. The literature focuses heavily on the permanent teeth of children and adolescents. Bader concluded that it is unknown whether the results from studies on children are applicable to adult populations with the same underlying caries risk.[28]

As demonstrated by Ahovuo-Saloranta et al. and Majare et al., few studies have

reported the baseline caries risk. Therefore, it was not possible to examine the NNT for the various caries rates.[17,9]

In 2001, Rozier updated Llodra et al. meta-analysis with a review of the preventive effects of pit and fissure sealants in the permanent teeth of children and adolescents.[12,10] Rozier presented the treatment effect as two measures: the NNT and the prevented fraction (PF). The pooled estimate for the caries preventive effect of sealants revealed that sealing 28 tooth surfaces would avert one DMFS in a low-risk patient. The mean PF ranged from 62 percent to 92 percent. These estimates were based on an annual increment of decay-affected pit and fissure-tooth surfaces of 50 per 1,000, or 5 percent per year. The American Dental Association, Canadian Medical Association, and expert opinion have all recommended that sealants be used selectively for high-risk individuals in clinical settings.[12] Clinical data suggest that sealants have a greater benefit when placed on teeth with incipient decay or in molars of individuals with a history of caries experience (Level III). If the underlying disease burden is low (i.e. there is less disease to prevent) within a population, the procedure will be more costly per surface of caries prevented, unless susceptible individuals and/or surfaces can be identified. In a population with a greater disease burden, one would expect the NNT to decrease. Balanced randomized control studies are needed to assess sealant effectiveness in light of individual caries risk.

Relevance to Clinical Decision-making

Sealants are effective in preventing dental decay on the molars and premolars of susceptible children and adolescents (Level II-I). The preventive effect for second-generation sealants ranges from 33 percent to 71 percent. However, new data shows a decrease in caries rates of 85 percent, and indicates that sealants may confer protective effects to smooth surfaces, as well as pit and fissure surfaces.[21] The median preventive effect is higher when sealants are reapplied, compared to a single application. This is because sealant effectiveness decreases over time. The majority of studies have focused on molars; while fewer studies have examined the preventive effect of sealants on premolars.

The majority of studies regarding sealant effectiveness involve a mix of children and adolescents. Rather than focusing on discrete age groups, the literature tends to classify individuals based on their risk for caries. For the most part, caries risk was assessed by a child's previous or existing caries experience, the presence or absence of deep pit and fissure grooves, and demographic factors. That being said, age is still considered one component of risk. The evidence suggests that once a tooth has erupted into the mouth and is free from gingival tissue, a sealant should be placed on that tooth as soon as possible (and up to four years). Because children receive their permanent molars and premolars during specific developmental periods, sealant placement between the ages of six to eight, and 10 to 13 years would likely yield the most cost-effective program (Level II-1).[3] Limited data suggests that molars are the most susceptible to attack within two to four years of eruption. However, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood (Level II-2).[4] If risk assessment does not deem an individual to be at risk for caries, the practitioner may observe the patient over time and place sealants when the risk for caries becomes more apparent (Level II-2).

THE UNDERLYING CARIES RISK OF THE POPULATION REMAINS THE MOST IMPORTANT CONSIDERATION FOR DETERMINING COST-EFFECTIVENESS OF SEALANT PROGRAMS.

Few studies have reported the baseline caries rate in the population. At this time, it is not possible to examine the NNT for various caries rates. Rozier reported a NNT of 28, but noted that this number reflects data from a low-risk population.[12] He concluded "estimates for the NNT suggest that the effects of sealants are low in patients who are at reduced risk for dental caries." If the underlying disease burden is low (i.e., there is less disease to prevent) within a population, the procedure will be more costly per surface of caries prevented, unless susceptible individuals and/or surfaces can be identified. In a population with a greater disease burden, one would expect the NNT to decrease.

In conclusion, data from balanced randomized control trials provide critical and timely new information. However, the underlying caries risk of the population remains the most important consideration for determining cost-effectiveness of sealant programs.

Appendices

1. Standards have been established for rating the level of evidence based on the nature of the study (e.g., fundamental vs. clinical), and of the design (e.g., observational vs. clinical trail) (c.f., *Journal of Evidence-Based Dental Practice*, and 2).

2. Systematic reviews of randomized controlled trials provide the highest level of evidence of efficacy of treatments, though in other circumstances, like adverse events, randomized trials may not always provide the best evidence. Systematic examination of the research evidence generates information that can be used to quantify the number of patients needed to treat (NNT) to obtain the beneficial outcome of the intervention, or to avoid the undesired side effect. NNT is considered to be a good measure of the absolute risk, an estimate of the average number of patients that the dentist would need to treat in order to have one additional event occur. NNT

refers in fact to the number of individuals or surfaces needed to treat per year to prevent one carious event.[5,6]

The prevented fraction represents the proportion of disease occurrence in a population averted due to a protective risk factor or a clinical intervention. PF is not equivalent to the absolute, but rather directly measures the impact of the treatment intervention. PF refers quantitatively to the proportional reduction in dental caries between experimental and control, expressed as a percentage: PF= I_0 -$I_{1/}$ I_1, where I1 is the incidence of dental caries in the group treated with pit and fissure sealants, and I_0 is the incidence of dental caries in the control group.[3]

3. Systematic reviews are research endeavors that follow the scientific process. They start with the research question, "PICO," for "population of patients to be examined," "interventions to be evaluated," "evaluation by means of a comparison of the treatment interventions under study," and "outcome under scrutiny."

4. The data of a systematic review are generally analyzed by two principal techniques. Acceptable sampling analysis provides the investigator with a quantification of the strength and the weaknesses with respect to the methodology, design and data analysis aspects of each report included in the systematic review. Meta-analysis is an overarching statistical analysis of the level of significance of the reports in the systematic review. A meta-analysis is a summary estimate of the effects, reported as rates, relative risks or odds ratio, in each report. It requires that every report included in the meta-analysis have similar methods, design, and data analysis, lest the comparison across reports be spurious. A fixed-model meta-analysis is one whose conclusions apply stringently and only to the reports examined. A random model meta-analysis refers to one whose conclusions were derived presumably from a random sample of reports in a given domain, and which may apply to the entire population of such reports. Whereas the acceptable sampling analysis is grounded on an analysis of variance approach, with the applicable parametric statistical inferences, meta-analysis are typically based on a chi-square analysis (either Mantel-Haenzel in the case of strict stratification, or Peto for looser stratification designs), with the associated limitations in parametric inferences.[2,29] CDA

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Robert E. Horseman, DDS

What's Super About the Market?

For many years my wife and I have enjoyed an amicable division of labor that has contributed to our connubial bliss. As the titular head of the household, I am assigned all the really important decisions such as whether we should go to war or if the acquisition of hog futures is in the best interest of our gross national product. She willingly assumes all the other decisions in our marriage. The only shoal that ever surfaced on our Sea of Domestic Tranquility concerned shopping.

It took a million years to develop man's ability to reason, but only a few minutes of feminine logic to destroy it. Time is money, my wife is fond of telling me, so when you go shopping take plenty of time. Samuel Butler had it right. "Logic is like the sword," he wrote. "Those who appeal to it shall perish by it."

It took a million years to develop man's ability to reason, but only a few minutes of feminine logic to destroy it.

That's why I find myself entered in the Saturday afternoon Grand Prix for shopping carts at the neighborhood Safeway.

Being a typical male, I never learned to shop properly. For example, if I like the first pair of shoes I try on, I buy them simply because they fit. I would never go in a store in the first place unless I knew exactly what I wanted, where it was and how much it was likely to cost. Feminine logic may be irrational, irrelevant and irresponsible, but it is also irrefutable.

So I have *The List* with me in the form of a Post-it note stuck to the handle of my shopping cart. Women believe that a man should never be sent to the market without *The List*. He will fetch home a cornucopia of imported malt beverages, pretzels, and hot rod magazines, they aver, conveniently forgetting the essentials he was sent for such as triple-size cotton balls, a box of Biz and some Cuddles fabric softener. I might as well be wearing a sign stating:

CAUTION!
MALE IMPULSE SHOPPER
Watch for sudden stops!

Over the years, battalions of MBAs, demographic experts, human behaviorists and marketing gurus have evolved the present-day layout of supermarkets, killing off the little mom-and-pop markets where you knew where everything was in the process. Your average market today covers an area slightly larger than Rhode Island. All competing chains have agreed on the following:

■ Now that we are in the banking business, no two stores shall have identical cus-

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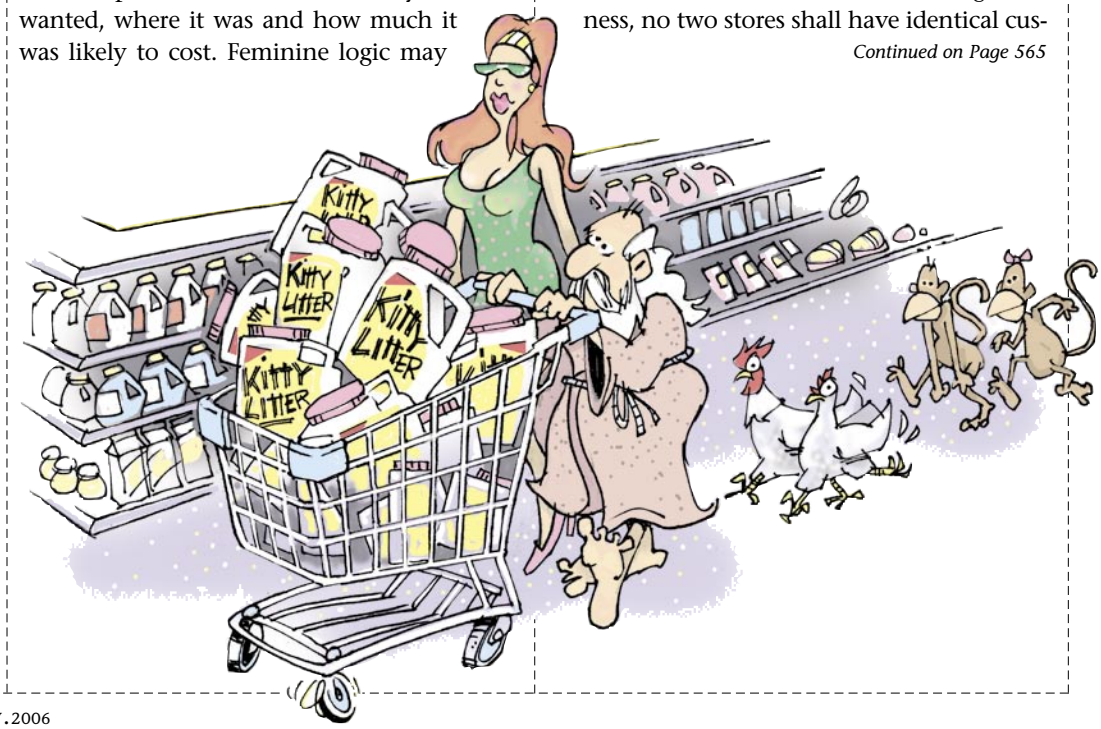

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tomer scanners for their ATM and credit cards. Intimidated customers, not willing to stumble through a competing system, will stabilize your customer base.

■ Those stores without an in-house Bank of America, should implement one ASAP. Equity loans processed on the premises enable a family of four to purchase a week's grocery needs at one visit.

■ Shopping carts shall be large enough to hold at least $200 worth of goods and a minimum of one unwilling child not to exceed 49 pounds in weight.

■ All carts shall consist of a wire construction that allows them to be nested with a hundred other carts. They can be separated from each other easily by any shopper currently on anabolic steroids.

■ At least two of the four wheels should be incapable of tracking in a straight line, but should chatter noisily or assume an out-of-round configuration. In the market parking lot, these carts must be easily steerable into the sides of parked cars and capable of accelerating by themselves when left unattended.

■ The standard width of a cart shall be 24 inches. The standard width of market aisles shall not exceed 40 inches. In the case of older markets, if the aisle is wide enough for two carts to pass, portable displays shall be placed every 20 feet to inhibit rapid transit past the store's own name-brands. No product should be beyond the grasp of a child riding in the cart.

■ Products consumed by the child to placate his screaming during his mother's tour of the market and not reported at the checkout station, shall be scanned as "Doing business, cost of."

■ On weekends and other busy times, at least four of the nine checkout registers shall be closed. A barrier placed across the entrance will prevent impatient customers from scanning their own groceries and departing before worried families put out an APB on them.

■ Checkout personnel at the "10 Items or Less, No Checks" register are reminded that the penalty for killing a customer presenting with 20 items and/or a check is the loss of two (2) break periods.

■ When a survey of regular customers indicates they have mastered the store's layout to the point where they can complete their shopping in a single day, managers are required to change the position of all products on the shelves in a random manner to other areas at least 50 yards distant. This must be accomplished in a single night and no explanation shall be offered.

It was a dark day in the history of commerce when the concept of manufacturers' coupons was first offered. One can only suppose that the idea was born during a night of heavy drinking or substance abuse by executives too addled to realize what they were doing. The session must have gone something like this:

Head Man: "Why don't we take a hundred million dollars of the company's money, print up a carload of coupons offering 'cents off' on bunch of stuff that isn't moving too swift like Grandpa's Pine Tar Soap. Then we put great batches of these coupons in every mailbox in the nation, in every newspaper and magazine in existence; slip 'em under every windshield and every doorstep until we run out of trees to make the paper from."

Underling No. 1: "Great idea, chief! I bet there are millions of tiny-brained folks out there willing to spend hours cutting out these coupons so they can save a buck or two, not realizing what it costs to run the program, thus canceling the perceived savings."

Underling No. 2: "But, chief, wouldn't it be more cost-effective and better business to simply lower the prices on all these things so that even the people who won't bother with the coupons will buy the products?"

Head Man: "That's why you'll always be Number 2, Number 2. The scanners were a big mistake. People were leaving the store too quickly; we don't make any money in the parking lot except for the body and fender concessions. Keep them in the store, lined up for miles behind some person with a fist full of coupons. Then they are forced to buy the Snickers and the Breath Savers while they sneak a look at the tabloid featuring the return of Noah to claim Debra Messing as his bride in Miami next month. Get it?"

I got it. I got a store card that will reduce the price of selected items by a few cents, provided my list reminded me to bring it. Everybody has the same card. Why not just reduce the price, save the scanning and bookkeeping time and the cost of setting up and maintaining the program? But that would be logical and logic will never learn that life seldom follows the script. CDA