Journal of the American College of Dentists

Taking a Product from Concept to Market

Summer 2006
Volume 73
Number 2
Mission

The Journal of the American College of Dentists shall identify and place before the Fellows, the profession, and other parties of interest those issues that affect dentistry and oral health. All readers should be challenged by the Journal to remain informed, inquire actively, and participate in the formulation of public policy and personal leadership to advance the purposes and objectives of the College. The Journal is not a political vehicle and does not intentionally promote specific views at the expense of others. The views and opinions expressed herein do not necessarily represent those of the American College of Dentists or its Fellows.

Objectives of the American College of Dentists

The American College of Dentists, in order to promote the highest ideals in health care, advance the standards and efficiency of dentistry, develop good human relations and understanding, and extend the benefits of dental health to the greatest number, declares and adopts the following principles and ideals as ways and means for the attainment of these goals.

A. To urge the extension and improvement of measures for the control and prevention of oral disorders;
B. To encourage qualified persons to consider a career in dentistry so that dental health services will be available to all, and to urge broad preparation for such a career at all educational levels;
C. To encourage graduate studies and continuing educational efforts by dentists and auxiliaries;
D. To encourage, stimulate and promote research;
E. To improve the public understanding and appreciation of oral health service and its importance to the optimum health of the patient;
F. To encourage the free exchange of ideas and experiences in the interest of better service to the patient;
G. To cooperate with other groups for the advancement of interprofessional relationships in the interest of the public;
H. To make visible to professional persons the extent of their responsibilities to the community as well as to the field of health service and to urge the acceptance of them;
I. To encourage individuals to further these objectives, and to recognize meritorious achievements and the potential for contributions to dental science, art, education, literature, human relations or other areas which contribute to human welfare—by conferring Fellowship in the College on those persons properly selected for such honor.


**Product Development to Practice**

10 From the Laboratory to the Operatory  
*Linda C. Niessen, DMD, MPH, FACD*

14 Is This Idea Worth Anything? Mechanics of Technology Transfer  
*J. Max Goodson, DDS, PhD*

18 Development of the Curvex Toothbrush  
*Stephen D. Harada, DDS*

21 Challenges to the Introduction of New Technologies to Dental Practice  
*Michael L. Barnett, DDS*

26 Clinical Trials and Oral Care R&D  
*Robert W. Gerlach, DDS, MPH*

32 The Dental Enterprise: Its Transition from Xenodontic to Biodontic Dentistry  
*Edward F. Rossomando, DDS, PhD, MS*

**Issues in Dental Ethics**

35 Why Our Ethics Curricula Don’t Work  
*Charles N. Bertolami, DDS, DMedSc, FACD*

**Study: Medical Visits for Dental Problems**

47 Adult Patient Visits to Physicians for Dental Problems  
*Leonard A. Cohen, DDS, MPH, MS, and P. Ann Cotten, DPA, CPA*

**Departments**

2 From the Editor  
Cornpone

4 Readers Respond  
Letters to the Editor

7 Forum: The Good Name  
*Steve Chan, DDS, FACD*

53 Leadership  
Mentoring

Cover Photograph: ©2006 Andrei Tchernov, iStockphoto.
Cornpone Opinions

In the 1890s, Mark Twain published a magazine article “Corn-pone Opinions.” The title comes from an imagined child orator friend of Clemens’s youth who holds, “You tell me whar a man gits his corn pone, en I'll tell you what his 'pinions is.” In Twain's words, “A man is not independent, and cannot afford views which might interfere with his bread and butter. If he would prosper, he must train with the majority; in matters of larger moment, like politics and religion, he must think and feel with the bulk of his neighbors, or suffer damage in his social standing and in his business prosperities.”

Twain ran through examples such as hoop skirts, tastes in literature, religion, and politics to demonstrate that the mass of humanity drifts in and out of views about what is proper with little or no formal thought. “It may be,” he says, “that such an [original, rational] opinion has been born somewhere, at some time or other, but I suppose it got away before they could catch it and stuff it and put it in the museum.” In a majestic sweep of his arm, he brushes all individual intelligence into the dust bin: “Broadly speaking, there are none but corn-pone opinions. And broadly speaking, corn-pone stands for self-approval. Self-approval is acquired mainly from the approval of other people. The result is conformity.” Of course, Twain was having his fun at our expense; are we really to believe that everything is based on “corn?”

I can see that some of you have gradually assumed a defensive posture in anticipation of Chambers beating you over the head with some dead guy concerning EBD, professional codes with “don’t criticize” clauses, and the tension between monopolies and access. Not I! Basically, Twain was right; at least he was on the money.

A pretty strong case can be made that medicine and dentistry are vigorously ignoring EBM and EBD. Practitioners are weighing what works in their offices and is approved by their colleagues on one hand and comparing it to what academic researchers are saying. Twain would have predicted the outcome of that one in a minute. I do have some misgivings about routine extraction of asymptomatic third molars, considering caries as a treatment opportunity rather than a disease process, and standing orders for bitewings. I also wonder why dentists push whitening and not nicotine patches. But professional opinion is the source of the standard of care. And if standards did not exist, the notion of a functioning profession would be unworkable. Such conformity is indispensable to the insurance industry that now pays for half the dental bill in America.

Twain anticipated by a good fifty years Abraham Maslow’s hierarchy of needs. This psychologist demonstrated that we first worry about survival, then security. If these are in hand, we direct our concern to being recognized as a valued member of various groups. That becomes, as Twain remarked, the basis for the fourth level of needs—self-esteem. Self-actualization, the highest level, is where original systems of thought thrive. This theory helps explain why non-patients, whose lives are dominated by getting by, generally view dentistry in terms of survival (pain relief) and why so many patients are motivated at the functional level of care. The general rise in prosperity and security in this country has also recently released a backlog avalanche of demand for good appearance (acceptance and self-esteem). Few patients ever make it to the preventive, systematic pro-health, self-actualization level. Or as Twain remarked, “I am persuaded that a coldly-thought-out and independent verdict…is a most rare thing—if it ever existed.”

Nowhere is the power of belonging to a community more clear than with regard to ethics. The number of original moral and religious thinkers is so small
that we can name them. I wouldn’t give you any odds on success if you wanted to convince me to behave as you do by attaching my ideas. It is much more probable that what passes for rational thought about the important things in life comes in the form of rationalizations of positions that have already been taken for other reasons—often for the sake of fitting in with a valued group such as one’s parents or colleagues. Ethics programs in dental schools that talk about what one ought to do wither before the lessons young practitioners master by watching the first dentist they associate with. We must have homilies on what is best in the profession. But the homilies do not make the profession.

Having walked so far in the good companionship of Mark Twain, I, for one, must part company for the rest of the journey. Samuel Clemens spent his life obsessing about both finding and losing his identity by playing to public opinion. He invented the humorous front of Mark Twain, but he was also Tom Sawyer—the guy who made a killing in the whitewash business, ran an insider trading scheme in bible verses to impress his girlfriend, and staged his own death so he could listen to the orations at his funeral. Dentistry is well stocked with individuals who are working through similar struggles by showing their cases on the CE circuit and becoming the president of every organization that will have them.

Like Clemens, some in dentistry today are trapped inside a false dichotomy—self-determination or interference, control or surrender, conformity or having a few original ideas. Really, we can have it both ways. We can choose, support, and create communities that value intelligent, reasoned progress that is open and not privately selfish. We can conform by fostering intelligent discussion. If conforming to professional norms means being prepared to discuss the reasons for doing something and supporting a common ethical set of values, we can have our cornpone and eat it too. Surely somebody else must have been thinking this way; dentistry has come a long way since Samuel Clemens’ time, and it wasn’t only because of conformity.

David W. Chambers, EdM, MBA, PhD, FACD
Editor
Dear Managing Editor:

Through your office, I would like to compliment the Editor of the College on the winter 2005, volume 72, number 4 (“Standards”) edition of the *Journal of the American College of Dentists*.

I have been anxiously awaiting an issue of the *Journal* that focused on standards. I found it even more exciting when it appeared that standards were being co-joined by some authors with evidence-based dental practice initiatives. The two subjects were sometimes discussed as being partners in a symbiotic relationship that would ultimately benefit patients and have a positive effect on treatment outcomes. But appearances can be deceiving, and on final reading of the “standards” edition, I found that the marriage of standards and evidence-based dental practice were two issues that the seven contributing authors could or would not find time or reason to connect.

Each of the contributing authors is recognized as an authority on at least one of the issues, and each is a significant stakeholder in promoting opinions and observations of his or her profession, school, company, or organization. As a result, the “standards” issue fails to provide a blueprint for the development of a scientifically-based method of patient treatment and treatment planning centered on mutually agreed clinical standards. There was no attempt at cross-fertilization between authors and different disciplines.

Dr. Chambers seems to point to this conclusion in his editorial, “How should dentists practice?” He offers yet another guidepost or opinion in his landmark #8 “outcomes-based practice,” wherein retrospective analysis of multiple practice outcomes would and should provide valuable insights into the development of proven treatment decisions for the offices where the care was provided. (I purposely use the words “would” and “should” because Dr. Chambers implies in his editorial that, as professionals, we studiously avoid words and phrases that seem to force compliance.)

On balance, Dr. Debora Matthews’ article, “What is a clinical pathway?” seems to come closest to satisfying my thirst for a process of integrating standards of care with best science in patient treatment and outcomes analysis. I suggest that the clinical pathways approach to the development of patient care algorithms is only deficient in that it ignores the importance of developing individual patient health indices against which the pathways algorithms would be applied.

I can wholeheartedly agree that the development of any sort of practice guidelines that were developed for application on a population basis are bound to be found inappropriate for some individuals in individual practices. Not being able to respond to the health profile and idiosyncrasies of individual patients is apparently a fatal flaw that has kept practice guidelines development at a standstill. As Dr. Armitage points out, “When it comes to standards, one size does not fit all.”

The answer seems obvious: develop and use a universal program that measures each patient’s health profile or wellness index. Do that and a major impediment to progress in this area of standards and practice guidelines development will have been overcome.

In Dr. Ellek’s article, “The ADA’s Practice Parameters,” she points out that “the parameters have served the needs of practicing dentists for fifteen years. And they describe a range of treatment options that dentists will want to consider in combination with particular clinical conditions and patient preferences.” The ADA cautions us that “the parameters not be used out of the context of individual professional judgment.”

I served in the ADA House of Delegates during the years when the *Practice Parameters* were being developed and adopted, and I was disheartened by the absence of “prescriptive direction” to dentists to embrace the parameters as a first step in formulating a universal language in treatment planning and a glossary of terms in patient care. As a result, the *Practice Parameters* became optional considerations for dentists,
and I fear that most dentists would not recognize the value of the parameters in their everyday practices or practices of the future. I do not remember ever receiving a list of the ADA's Practice Parameters. Neither would many dentists appreciate the benefit of weaving diagnostic codes (SNODENT) and Practice Parameters.

So the development of standards and practice guidelines languishes in that dark hole of indecision. Who will stand up and use his or her bully-pulpit to influence member dentists to place their professional egos aside and to adopt scientifically proven and legitimately developed standards and practice guidelines?

The Journal of the American College of Dentists, along with most other journals, has an obligation and mission to teach. The ACD Journal has a long-standing commitment to identifying and promoting ethics in dentistry. I can think of no better way than for the ACD to identify the benefits that are potential in patient care and treatment outcomes should standards and practice guidelines be developed and promulgated while the individual patient’s health profile is a primary concern.

Lawrence J, Singer, DDS, FACD
Wallingford, CT

Dear Dr. Chambers,

It is with great pleasure that I respond to the wonderful paper by Dr. Kenneth Jones in the fall 2005 issue of the Journal of the American College of Dentists. I agree with so much of what Dr. Jones so passionately professes. Dr. Jones correctly points out many of the flaws of the Medicaid system that make it so difficult for dentists to participate, especially the administrative burden and low reimbursement rates. I would suggest that dentists in Ohio take the course of dentists in many other states—assist in developing a lawsuit against the state Medicaid agency to improve fees and reduce administrative burdens. This has been successful in many states, and we hope it will work here in Florida where I live.

Dr. Jones clearly recognizes that the problem of access to dental care in the U.S. is complex. It is really a societal issue of immense magnitude and multiplicity of causes. Dentists alone will not fix the problem. While I can concur with Dr. Jones’ suggestion that maybe one solution is to require all dentists to see Medicaid patients, I think the numbers of underserved patients and the geographic misdistribution of dentists would make it unlikely that this is a sufficient response. We need more innovative solutions, more prevention, more education, more responsible parents and patients, better workforce models, etc. We need the profession to fight for these things, not resist them.

(A summary of dental education’s position can be found in Haden, N.K., et al., Improving the oral health status of all Americans: Roles and responsibilities of academic dental institutions. Report of the ADEA President’s Commission. Journal of Dental Education 2993, 67 (5), 563-583.)

I also agree that we need to improve the ethics education and commitment of our parishioners and students. Many of us in dental education and practice would applaud Dr. Jones’ suggestion that dental schools make better efforts to “find those prospective students that are not only bright and talented, but have the ethical commitment to make a difference from day one. We need less emphasis on who has the class with the highest GPA and a little more on whose class remains true to the personal statement that said ‘I want to help people.’”

However, I also believe that ethics education in dental school can show students model behaviors and actions that will improve their approaches to access to care issues. I think one wonderful teaching model is the participation of members of the American College of Dentists in predoctoral ethics and professional curricula in our schools. Students want to hear from the “wet fingered practitioners” that they have been fully involved in care for the poor
and underserved. I also applaud the recent efforts of the American Dental Association to initiate a review of the Code of Professional Conduct and Principles of Ethics with a partial focus on access issues. This should be of assistance to all practicing dentists in dealing with access dilemmas.

My only concern is with Dr. Jones’ suggestion that students from poor and disadvantaged backgrounds may not return to their roots. This misperception must be corrected, even if one of Dr. Jones’ sources is “more than one educator.” I would direct readers to a recent publication—Sullivan, L. et al. *Missing persons: Minorities in the health professions.* The Sullivan Commission, Washington, DC. 2004. The data and summary on page 24 seem to rebut and refute the fear that individuals from underprivileged backgrounds fail to assist those communities from which they arise.

Thanks to Ken Jones and others who understand and passionately believe that professionalism is more than being called “Doctor.” Instead, it is “knowing that I have done my best to fulfill my obligation to my profession, to my family upbringing, to my patients, and to a society that says that what I do matters.” This attitude makes me proud to be a member of this profession.

Sincerely,
Frank Catalanotto, DMD, FACD
Gainesville, FL

**Author’s Response**
Thank you, Dr. Catalanotto, for reading and understanding my wet-fingered viewpoint. Your cited reference to the *2004 Report of the Sullivan Commission on Diversity in the Healthcare Workforce* seems impressive. However, I believe my eyes and ears out here in the everyday practice of dentistry. Both as a dentist and as an attorney, I have faith in my own observations and discussions, and I know that one can interpret statistics and studies in many different ways. In fact, it happens every day, as expert witnesses arrive at diametrically opposed opinions on the exact same case facts. It would be interesting to read follow-ups that determine each one of these individual senior’s actual practice access parameters, two, five, and twenty years down the road from graduation. Are their promised “I’m going to’s” any different from their eventual “I did’s?” I look forward to a more long-term study on this subject and to seeing how the statistics compare with the individual practice realities. Until then, we’ll just have to “agree to disagree.”

Kenneth D. Jones, Jr., DDS, JD
Mansfield, Ohio
Mercedes. McDonald’s. Tiffany. Each is only a name. But as a brand, the name now brings a host of associations—and a reputation. The principles of branding apply not only to the commercial world, but to dental practices and professional associations. There are fundamental behaviors that drive choice in the marketplace. Branding tips choice in favor of the brand.

Branding is not advertising, nor marketing, nor commercialism. Branding is a continuous exercise to create and maintain a specific image in the marketplace.

When an early craftsman placed his distinctive mark on the underside of the vessel he created he made a declaration to the marketplace: “I made this.” His signature made a declaration to the marketplace. The act was just one element to differentiate his work from others in the market. The craftsman’s intent was to create a greater value beyond other similar works in the market. Those who would consume the work sought a greater value beyond merely possessing the object.

When a name is the first that one associates with a product or service, it is a brand. Kleenex is a facial tissue. Hallmark makes greeting cards. Yet, not all facial tissues are Kleenex, nor are all cards a Hallmark. Those who choose the brand expect more value.

When the vessel from that potter became the coveted “maker” in the market, the craftsman’s good name became the brand. In dentistry, when patients refer others, a doctor’s name becomes a brand. Current patients of a practice received something they valued more than just the filling or crown.

Fundamental behaviors drive consumption. Behaviors that drive consumption of name brands over others in the same business are the same for Fortune 1000 companies as well as dental practices. Brands alter the balance of choice. In highly competitive markets, brands can sustain a competitive edge.

- Brands differentiate—and they target.
- Brands beckon—and they promise.
- Brands are intellectual properties—yet you cannot touch, taste, smell, feel, or hear them.
- Brands satisfy—beyond touch, taste, smell, feel, and hearing.
- Brands command value—and they command loyalty.
- Brands create emotional responses—and they inspire apostles.

A rose is a rose is a rose, but a brand separates. The Apple iPod is not the fastest MP3 player, nor has the most capacity, or the most features, but it’s the most recognized and the market leader. Is it just the advertising?

Dr. Chan is a Past President of the Northern California Section of ACD and practices in Fremont, California.
Consider: In an experiment, subjects were asked how much they would pay for a pair of good quality diamond earrings. A second group was asked how much they would pay for the same earrings, but were told they are from Tiffany. A third group was asked what they would pay for the earrings, but were told they are from Wal-Mart. The average price for unbranded earrings was $550. With Tiffany branding, the average price subjects were willing to pay increased to $873. The increase was only due to the addition of the name, Tiffany. With the Wal-Mart name, the price expectation fell to $81, a decline of 85% from the unbranded earrings and decline of 91% from the Tiffany-branded earrings. Why was there a willingness to pay a premium for the same product? The money is just a marker, a measure, of how much they valued what they were willing to consume.

Branding is more than introducing products or services in the market and just seeing “what sticks.” It is a deliberate dissection of the market. It is an array of tactical choices to achieve an impression in the market. It is a series of conscious decisions on where a company wants to position itself in the market. Branding strategies create an emotional bond.

How do consumers choose a dentist? A filling is a filling is a filling. Yet, patients typically do not have expertise to evaluate what they purchase. Branding is the impression of the service, not the physical “filling.” When a soccer mom professes to other team moms: “My kid goes to Dr. Widget,” Dr. Widget’s name has become a de facto brand.

When a person identifies himself or herself as a patient of Dr. Widget, he or she expresses a quasi-membership with that practice. The law of exclusivity applies here. When something is perceived to be desirable yet limited in access, the drive is to want to be a part of those elite few.

Branding of goods is typically judged by tangible attributes. Goods can be physically compared. Services, in contrast, are typically judged by intangible qualities. In the case of practices, they look to other environmental cues such as professionalism, the staff, and the appearance of the office, the ease of performance, confidence. The cues may or may not correlate with the soundness of the service just purchased.

Judging goods are more often conducted using search qualities as opposed to services where experience qualities are determinates in judging services. Search qualities enable the consumer to evaluate features prior to purchase whereas experience qualities are judged after some trial or consumption.
this entire array uniquely characteristic or do others in the market offer the same things?

Are the features of value to the consumer where they are willing to pay more for it? Does the consumption merely satisfy or does it delight? Does the consumer perceive they are buying a service which is premium among other practices available to them? Does consumption create bonds of loyalty? Do they want to repeat the experiences?

Effective branding is revealed.
Effective branding is often minimalist. The message should permeate throughout the organization with every touch point. People draw conclusions and make choices from watching. The object is to induce the targeted end user to sing the praises of the brand.

In developing a positioning statement for the brand, a conscious design maps out:
1. A description of the targeted consumer.
2. Identify the frame of reference.
3. Identify the point of difference, i.e. why consuming the brand is superior to alternatives. What are the concrete functional benefits? What are the abstract emotional benefits?
4. What is the supporting evidence for claims related to the frame of reference and point of difference, i.e., what are the reasons to believe in this company?

The principles of excellence, ethics, and professionalism are intimately linked to branding in dentistry as in the commercial world. Whenever there is human performance, there are flaws and faux pas. Beyond differences in opinion or taste, a brand’s promise of what it delivers is tested when there are mistakes. A brand’s promise is its bond with the consumer.

How a brand behaves in the face of challenge reveals more about a brand than its declarations to the market. Consider the examples of an event that challenged a maker’s reputation. Tylenol responded to contaminated products with an unprecedented scale of product recall and industry-changing packaging. Contrast the effect of Ford’s and Firestone Tire’s responses to incidents of tire blowouts on Ford Explorers. When words are inconsistent with behaviors, the brand’s image is in conflict. The whole world is watching.

Fortune 1000 companies spend millions designing, cultivating, and protecting their brands. They expend these resources for a more predictable outcome in the marketplace. The return on this investment of time is proportional to the detail taken in the design. Branding is not a series of random acts.

In the marketing wars, just believing you have a great product is naive. A successful brand continuously works at sustaining its position and its relationship with the consumer. The object is to “brand” the brand in the minds of the target consumers.

The object of becoming a brand is primary recognition in any specific market. It is not just constructing a better widget; it is the sum of actions to sustain your “good name.” At the end of the day, in dentistry, and indeed, in professional associations, you have become a brand, when those who consume your wares do so solely because of your “good name.”

Branding is not advertising, nor marketing, nor commercialism. Branding is a continuous exercise to create and maintain a specific image in the marketplace.
In 2004, the U.S. spent $1.9 trillion on health care, 16% of the GDP (Smith et al., 2006). The market for dental care rose to $80 billion, an increase of 6% over 2003. It is estimated that about 70% of the U.S. population sees a dentist in a given year. The aging of the population, increased demand for esthetic dental services, and retention of natural teeth are thought to be contributing to the growth of the dental care market.

Growth of the dental care market is also being fueled by new products and technologies that make dental care more comfortable for the patient and more efficient for dental professionals. Innovation is critical to the success of a modern dental manufacturer. In 1995, DENTSPLY International’s sales were $572 million. In 2005, DENTSPLY’s sales had grown to $1.7 billion. However, the 1995 product portfolio represented a little over half of the products sold in 2005. The new products came from acquisitions, new product development, and licensing agreements. New product development is critical to both the growth of dental practices and the dental industry.

This paper will provide an overview of the dental industry and discuss how manufacturers work with dental professionals, scientists, and inventors to bring new dental products and technologies to dentistry.

**Dental Market Overview**

The global dental supply and equipment market is estimated to be $13 billion, of which equipment accounts for $2 billion and dental consumable supplies account for the remaining $11 billion. The U.S., Europe (Germany is the largest market in Europe), and Japan are the three largest dental markets. Figure 1 shows the dental markets by continent as a pie chart. Dental market growth rates for the next five years are estimated to be 5% to 6% with some variability based on a country’s economic growth.

Industry growth drives vary by the stage of development in each country. An aging population, the retention of natural teeth, and the increased patient expectation of esthetic dentistry are serving to fuel the dental market in developed countries such as the U.S. In the developing world, the rising standard of living and large unmet need are driving demand for dental care.

The provision of dental care has evolved during the past century from one of extraction in the early twentieth century, to repair by the middle of the century, to prevention and esthetics recently. The twenty-first century will see the fruits of the molecular biology revolution bring new and emerging technologies to dentistry. These technologies have the ability to redefine how dental care is provided, how oral diseases are prevented, and how oral health is improved.

New salivary diagnostic tests for oral cancer or caries risk factors are being
developed. Genomics and proteomics are leading to new tests for caries and periodontal diseases. Salivary DNA tests are already commonly used in law enforcement. Microbiologic indicators are being developed for causative bacterial agents in caries and periodontal disease. “Smart” materials are being developed to repair lost tooth structure or prevent tooth structure from being lost initially.

Advancements in imaging technologies are changing how we diagnose and treat oral diseases. CT scans are improving implant placement and making the procedure even less invasive. Diagnosing caries using radiographs may become a technique of the past as electrical impedance improves our ability to diagnose caries at earlier stages prior to hard tissue loss. Ultrasound may be used for caries and calculus detection. Future preventive trends may include new methods to remineralize or strengthen teeth, novel delivery systems for fluorides and other remineralizing solutions, modifications to the disease-causing bacteria, and vaccines against caries and periodontal disease. How will these new technologies reach the dental operatory?

**New Product Development Process**

New product development requires a collaboration with scientists and inventors (who conceive the idea), academicians and clinicians (who conduct the clinical trials on the product), manufacturers (who make the product), and distributors (who distribute/sell the product).

New product ideas can be generated by individuals working on their own, within a university, or in industry. An academic-based scientist and the parent university may partner with a manufacturer to bring a new product to market. For example, Dr. Max Goodson’s efforts to identify a locally administered antibiotic agent led to the development of Actisite® fibers.

Many dental manufacturers invest significant resources in internal research and development teams that generate new product ideas. New product ideas and technology can also be acquired by a company or can be licensed from universities or another company.

New ideas (intellectual property) require patent protection. Once a new idea that has relevance to dentistry is identified, a patent search is conducted. For a company to invest in a new idea or technology, a critical component in the evaluation of the idea is the patent protection surrounding it. Bringing a new product to market requires a considerable investment, after the purchase or license of the technology. Patent protection enables a company to recoup the initial investment needed to bring the product to market without other companies immediately entering the marketplace with the same or similar “me too” product.

Clinical relevance is another critical component of the idea and technology evaluation. Does the idea meet a clinical or patient need? Does it solve a clinical problem? What does it replace? Does it make the delivery of dental care easier or more efficient for the patient or dental team? Is the potential technology or product easy to incorporate into a dental operatory or dental laboratory? Is it easy to learn the new technology?

Once clinical relevance is determined, a business plan is developed. The marketing team will identify the market size. In other words, who will buy the product and what will they be willing to pay for the product? What does the product compete with? The manufacturing team will evaluate the cost to manufacture...
the product. Are raw materials readily available? Can existing manufacturing facilities be used to make the product? Do manufacturing facilities have to be modified? Does the product require any specific handling such as refrigeration during shipping and storage?

The R&D team will determine the regulatory path for the program and the costs of any clinical trials necessary to bring the product to market. Is the product a drug, device, or combination? Like voting in Chicago, consultation with the FDA should occur early and often.

The costs to develop and manufacture the product are then weighed against the revenues that will be generated by the sales of the product. These costs versus revenues determine the return on investment to the company for this new product. It is important to recognize that the costs associated with developing and launching a product must be expended prior to any revenue generation. Occasionally, unforeseen expenses as a result of delays in the product launch that were not calculated in the original return on investment estimates do occur.

As part of this evaluation process, the R&D team will conduct internal testing to validate the initial claims made by the inventor. Professional testing for safety and effectiveness will be conducted. Clinical trials will be conducted under FDA guidelines. The product type (drug, device, biologic, or combination) will determine the clinical trial requirements. Most dental devices are approved by the FDA under the 510K process which takes advantage of research already conducted on similar products already approved for the market. If a similar (predicate) product does not exist, an NDA (New Device Application), with more extensive testing requirements, will be required prior to the clinical trials.

Clinical trials are usually conducted under contract to a university, with a contract research organization (CRO), or in-house. The National Institute of Dental and Craniofacial Research recently funded four large Practice Based Research Networks that may serve as potential sites for dental industry clinical trials.

The costs of clinical trials are an important component of the new product development process. Experienced clinical scientists are critical to the conduct of the clinical trials. University-based clinicians provide this pool of experienced investigators, because they understand the importance of patient informed consent, compliance with the clinical protocol, and completing the trial in the time frame outlined.

End-user testing or field testing will occur to assist the marketing departments in identifying the relevant benefits and features of the new product. After the product is launched, post-market surveillance occurs to ensure that the product is performing as expected.

**Technology Transfer**

Just because one builds a better mousetrap, such as a nickel-titanium rotary endodontic file or a zirconia material for crowns and bridges, does not mean dental professionals will use it. Adopting a new product or technology varies by dental professional. The most common theory on technology transfer is Rogers’ (1995) “diffusion of innovation theory.” Rogers identifies five types of innovation adopters, based on how quickly they incorporate new technologies:

- **Innovators (venturesome)**
- **Early Adopters (respectable)**
- **Early Majority (deliberate)**
- **Late Majority (skeptical)**
- **Laggards (traditional)**

Innovators are the first to adopt a new technology. If you are driving a hybrid car, consider yourself an innovator. If you have an 8-track tape player or Beta...
Since patient care requires consistent, reliable performance from the products or techniques, most dental professionals tend to be more deliberate in their adoption of new products and fall into the early majority category. Table 1 lists the differences between the early adopters and the early majority. Those who are not interested in change can fall into the late majority or laggard categories.

Malcolm Gladwell, in his book *The Tipping Point* (2000), described how ideas diffuse through society using the theory of social epidemics. He identified the “role of the few”—the connectors, mavens, and salesmen and saleswomen who serve as the messengers who bring the message of the new idea or technique to dental professionals. This role is often filled by the clinician or educator who provides continuing education programs and teaches dental professionals about new techniques and products, or the well respected specialist in a community that the general dentists look to for advice.

The “stickiness factor” refers to how salient the message is or how it connects with patients or dental professionals. Digital radiography immediately connected with (was not sticky for) dental professionals who were comfortable with computers and could not wait to get rid of the messy developing chemicals in the dental office. The “power of context” refers to the sensitivity of the message or the transmission of an idea in various settings. For example, during the advent of the HIV epidemic in America, one dentist was reported to have transmitted HIV/AIDS to a patient. Within a very short time, patients expected (and demanded) their dental professionals to wear gloves during dental procedures to ensure that they did not transmit HIV to patients. The fear of being infected by HIV/AIDS from one’s dentist served as a powerful context in which to transmit this new idea of wearing gloves during every dental procedure.

Roger Clarke (www.anu.edu.au/people.roger.clarke/sos/inndiff.html) summarizes the characteristics of innovations identified by Rogers (1995) that enable them to become readily adopted by society. If the new product or idea provided a relative advantage (performed better than the current product or technique), it would be more readily adopted. An innovation has a better chance of being adopted if it satisfies these criteria:

- It is compatible or consistent with existing values, experiences, or needs.
- It is easier to use (or less complex) than existing products or techniques.
- Its results can be observed.
- It can be tried on a limited basis.
- Some clinicians have hypothesized that the characteristics of dental innovations that enable easy adoption are those that:
  - Save the dental professional time and enable them to make more money.
  - Are demanded by patients.
  - Ensure compliance with medical-legal considerations.

Whatever the reasons for adopting innovations, it is clear that as the dental industry introduces new products and technology to dentistry, an understanding of the theories of technology transfer will assist in the adoption of these new ideas.

**Table 1. Differences between early adopters and early majority.**

<table>
<thead>
<tr>
<th>Early Adopters</th>
<th>Early Majority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology focused</td>
<td>Not technology focused</td>
</tr>
<tr>
<td>Revolutionary change</td>
<td>Evolutionary change</td>
</tr>
<tr>
<td>Visionary users</td>
<td>Pragmatic users</td>
</tr>
<tr>
<td>Willing to take risks</td>
<td>Risk averse</td>
</tr>
<tr>
<td>Willing to experiment</td>
<td>Proven applications</td>
</tr>
<tr>
<td>Tend to communicate across disciplines</td>
<td>Tend to communicate within disciplines</td>
</tr>
</tbody>
</table>

**Summary**

Stephen Jay Gould wrote, “Obsolescence is a fate devoutly to be wished for, lest science stagnant and die” (1989, p. 347). Given the innovations that we see entering the dental marketplace today, oral health science is very much alive and well. New science and technology will help achieve the movement of dentistry from a primarily surgical discipline to one that is medically and surgically oriented and practiced. Industry support is needed to provide products to achieve this type of dental practice. The future of the dental industry will move from primarily a device business to one based more on pharmaceutical and biologics principles. The characteristics of dental professionals must be understood to facilitate adoption of any new technology.

**References**


Abstract

The path from a proven scientific idea to a commercially viable product is seldom easy. It often requires ten or more years and millions of dollars. The essential elements include a creative concept that has been proven sound, identification of the commercial applicability of the concept, and financing and management of the development process.

Every year, scientists working in oral health research generate thousands of excellent new ideas. Most contribute to theory building; some are practical innovations that other scientists put to use to accelerate the research enterprise; a few have potential for application in healthcare delivery. These are product concepts—the breakthrough ideas behind a technology that may improve oral health. The stories of ideas in the laboratory making their developer famous, and perhaps financially blessed, are known. What is less well understood is the hard path from concept to viable product and the challenges that leave so many good ideas unrealized.

For a concept to travel to successful commercialization, it must meet three criteria: 1) it has to work, not only in controlled situations, but generally or practically; 2) it has to be of substantial economic advantage to those other than the researcher; and 3) the many formalized steps between conception and development must be successfully negotiated.

A Good Idea

Research is hard work. A breakthrough idea with commercial applications requires something more. Creativity is a precious blend of novelty and usefulness. Novelty can strike in the laboratory, but not in the normal way science is done. Observation, especially the knack of seeing something new in what others see in traditional ways is one source. For example, Horace Wells saw nitrous oxide used as a party pastime drug by the upper middle class and wondered why it could not be used with the same effects but for different purposes. Pasteur’s famous, but usually misquoted, remark is also to the point: “chance favors the prepared mind” (he actually said chance favors only the prepared mind). Einstein’s very fully mylenated brain was more powerful than others and struck the theories of relativity by a process that might be called “pure creativity.” For most of use, serendipity is a more realistic goal. The fortuitous pairing of luck and awareness that promoted Fleming to discover penicillin is a well-known example. Logical reasoning, working with predictable consequences over a range of situations, is yet another path to good ideas. It certainly worked for Crick in the case of triplet DNA. Yet another source is noting relationships, often consciously using analogy to rearrange things, as Mendeleyev did with the periodic tables.

Whether by these or other means novel ideas are generated, they must still meet the test of usefulness in order to qualify as creative. They must predictably solve a problem that someone else cares about. That kind of insight is more likely
to come at the edges where science and practice rub against each other than it is to be found in the lab.

**Commercial Viability**

Other people have to be able to make money off the researcher’s good idea if it is to go anywhere. Someone else must by able to turn more of a profit in prototyping, developing, protecting, financing, manufacturing, marketing, and distributing the new idea than they do with their current line in order to switch their interest to it. Because the idea is unproven, a premium is usually expected. Sometimes a single firm assumes responsibility for all these functions and needs only make a large profit on the aggregate. If development of the idea is distributed across several entities, each will expect to make a profit. It is a virtual certainty that the typical researcher is incapable of substituting his or her expertise for that of others in the development-to-market process, so the idea is still-born unless it offers enough profit potential to others to attract their attention.

The same logic applies to end users. Dentists, physicians, or others who might use the products flowing from a good idea can be counted on to apply their own personal profit logic to any innovation. It is natural for scientists to think in terms of effectiveness of patient health outcomes. While practitioners are aware of these metrics, they are also sensitive to ease of use, training, required changes in other parts of the practice routine, and their own opportunity for financial reward. Sometimes, as in Block Drug’s failure to engage dentists in prescribing nicotine patches or in bikers rejection of motorcycle helmets, effective products fail to match the users’ self-concept. The dental market is unusual in several respects. Many dentists see themselves as very inventive and prefer personal work-arounds. They are slow to innovate, depending heavily on professional word of mouth. They also buy almost everything they use in their offices on their personal credit cards. That means big-ticket changes and innovations spill over to other aspects of the practice and are in direct competition with the family vacation.

**Commercializing a Research Idea**

Now that the path that a good idea must travel to become a commercially viable product has been established, attention can turn to the process that transforms a concept into a product.

The first step (omitted at great risk) is the initial reality check. Is the trip worth taking? Here are some of the questions the researcher might want to ponder:

- When fully commercialized, will the product generate sufficient revenue to be self-sustaining in the market? Normally $10-20 million would be a safe ante. If you want a large company to sell it, we are talking $50 million and up.
- Will the fully commercialized product make a difference to people? Is it better and more likely to generate profit for others than what is available

Creativity is a precious blend of novelty and usefulness.
now? Is it safe from being overrun in a short period by other developing technology?

- Can one handle the competitive pressures of commercial life? These will include financial uncertainty, peer attacks, potential lawsuits, job loss, etc.
- Is it worth it personally? Can this become the most important thing in one’s life (rather than a dream) that one is prepared to spend ten or more years to achieve?

If the responses to this very challenging reality check are convincingly positive, the first and concrete step is to protect one’s opportunity to develop the idea. It is an absolute requirement that intellectual property be protected, because that is all one has at this point—an idea. A patent allows the inventor to stake a claim to the potential value that may arise out of the idea. A patent is a warrant from the government providing a right to prevent others (if one has the funds to procure legal services) from using an invention for some specified period of time, in essence the right to a monopoly for a time. It also converts the idea into a marketable entity, allowing one to sell or license it. In exchange for the exclusive use of an idea, the inventor must publicly and formally disclose the secrets of the invention. Patent applications can be denied if the inventor fails to demonstrate that the idea is novel and useful (the two criteria of creativity discussed above) and that the invention is nonobvious. The cost of obtaining a patent normally exceeds $10,000, and substantially exceeds this sum if international patents are obtained.

An alternative approach is to secure a provisional patent. The so-called “patent pending status” is simpler and less expensive. Costing less than $100 for some very simple forms, the extent of disclosure is minimal. Although the provisional patent establishes a filing date and serves to some degree as a deterrent to competitors, the maximum length of protection provided by this approach is one year.

As soon as the topic of “owning an idea that has commercial value” comes up, it is necessary to inquire about whether and how that ownership might be divided. There are two issues: 1) does the individual who first articulates a novel and useful idea have an opportunity to own it outright and completely, and 2) once ownership of an idea has been established, can it be sold or divided?

Individuals who work alone and receive no support from other interests might be able argue that their ideas are their own. But the many American scientists who are employees of research or commercial organizations will be governed by conditions in their terms of employment as to what proportion of intellectual property is theirs and how the organization may or may not help in developing a concept for market. Employees of the federal government are bound by similar and very restrictive terms. Currently, there is an ongoing debate as to whether employees of the National Institutes of Health should be allowed to profit from commercial spin-offs of their tax-supported work. Universities are especially affected by these issues because they focus on pure research and are funded, through tuition, state support, and private and federal grants and contracts, for knowledge creation and transmission through teaching and publication. In 1980, the United States government laid down the basic framework that governs the structure of commercializing research ideas flowing from federal funding. This is known as the Bayh-Dole Act, and the basic reasoning is that it is good for America when promising ideas are
sped to commercial application and that universities are in a better position to do this than the government. Universities are expected to develop research innovations arising from federal funding. Many universities have established offices for this purpose, and a typical arrangement is that the scientist receives one-third of the resulting revenue stream (sometimes net of development costs), while the remainder is plowed back into research. On occasion, a university may determine that an innovation lacks commercial potential, in which case the innovator may be offered the entire ownership of the innovation.

Prior to enactment of Bayh-Dole, the average annual number of university patents on research was approximately two hundred; in 2003, the number has swelled to almost five thousand. In that year, $41 million were invested in research sponsorship. At the same time there were four hundred thirty-two startup companies associated with this type of activity; over eight thousand patent applications, and just over four thousand patents issued from related activity. This costs out at about $10 million invested per patent issued.

Intellectual property has most of the same characteristics as does real property. It can be bought and sold, divided, bequeathed, and even rented out for use. The latter is called licensing, and as with rental agreements, conditions can be attached to licensing the use of intellectual property. They may be exclusive or non-exclusive and can be limited to certain uses, certain markets, and specific time periods. They may even contain clauses requiring the partner to develop the product within a specific period of time or relinquish interests. Licensing arrangements may be sold for a lump sum or for future royalties. Although intellectual property, unlike real property, is not taxable, it is subject to governmental restrictions on use and requires substantial investment to bring out its potential value.

The normal means by which a researcher’s good idea, protected as intellectual capital, is commercialized is by selling and licensing portions of it to those who ensure its development.

Commercialization costs money. Some of the alternative approaches to capitalization include university development, starting one’s own business, and working with industry partners, including consultants, stockholders, collaborators, and contractors. Those who generate ideas will face a trade-off between control and economic return. Moving toward established commercial firms for product development will tend to compromise what inventors regard as the purity of their ideas. Retaining independence requires large infusions of cash that may diminish future earnings and force eventual loss of control or even of the company. Venture-capital funders are normally interested in short-term payback, may require the innovator to put up a large initial investment (often bigger than one’s house), and may insist on further protections of their funds through testing, licenses, or employment of experts.

The Food and Drug Administration regulates drugs, devices, medical equipment, and so forth prior to and during marketing. The filing for FDA approval alone can be expensive and time-consuming. Phase I and II trials will be required for any novel idea in order to establish safety, efficacy, and dosage-response relationships. Prior to marketing, novel products must undergo a Phase III clinical trial, normally consuming three to five years and costing hundreds of thousands to millions of dollars.

Innovators who come from the academic ranks must also weigh the culture clash they are about to experience. Academic tradition emphasizes the values of abstract ideas, inquiry, long time horizons, open work and publication, and societal good. By contrast, in commercial development these values take the form of concrete products, goal-directed development, short horizons, confidentiality, and corporate profit in industry.

Decisions about these fundamental values and the path most appropriate for developing an idea must be worked out in the innovator’s mind before accepting partners. They are the bedrock for the contracts that must be negotiated. A well-negotiated contract is fair to all parties; it must consider the partnership based on the differing needs each brings to the table. It is natural for the person with the idea to overestimate the rewards of the idea while underestimating both its cost and time to development. Normally the researcher with the good idea is at a disadvantage, even following thorough preparation. Scientists negotiate few such contracts over a lifetime.

The road from a good idea to a useful product in the hands of dentists is difficult. The work necessary to ensure sound science, commercial viability, protection of creative interests, and regulatory compliance is substantial. Fortunately for the dental profession, there are those individuals and organizations prepared and qualified to make that journey.
Abstract
This is a first-hand narrative of the steps in developing a new toothbrush from concept through initial marketing. The design seeks to provide the softest bristles consistent with effective plaque removal. Patent protection, incremental design and testing, and accurate market analysis have been essential steps in the process.

From the middle of 1998 to the end of 2003, the Curvex toothbrush and its derivatives, were developed to offer an innovative manual toothbrush with a bristle array that would not only geometrically fit the most difficult areas of the mouth to clean, but also try to use the softest bristle filaments in the industry range of “soft” toothbrushes without a loss of plaque removal efficacy. The industry standard for a “soft” toothbrush is a .007 mil diameter bristle filament (most commonly used), to a high of .008 mil diameter, (also the start of the “medium” range) to a .006 mil diameter filament (the softest of the range). From the onset, it was recognized that there were three main considerations: 1) the softer the bristle, the more likely to encounter bristle deformation when brushing in the customary to and fro motion; 2) a softer bristle must achieve an adequate level of plaque removal; and 3) if a softer bristle could be successfully integrated in toothbrush head design, there could be benefits to the gingival health of the user. The Curvex was the result of these efforts.

The head of the toothbrush would incorporate a tapering bristle array at each end of a larger planar mid-section group of bristles. The mid-section planar array would serve to clean the most easily reached areas (i.e., buccal surfaces of teeth). The tapering end groups at both ends would result in an innovative geometric fit for closer contact with the lingual anterior curve of the upper and lower arches. When brushing in the usual to and fro motion, the end groups of bristles would support the larger mid-section group of bristles to reduce bristle “splaying” when brushing in the longitudinal to and fro direction and allow use of a softer .006 mil diameter filament and still maintain adequate plaque removal efficacy.

To complement this unique bristle array, a convex head was devised. This would not only allow the toothbrush to reach further back on the palate (when brushing the lingual of upper molars) by curving away from the roof of the mouth, but also allow the end groups of bristles to engage behind any terminal molar with ease. This configuration would also avoid hitting the mandible when reaching the lingual surfaces of lower molars.

The neck and handle were reversed curved, as opposed to most conventional toothbrushes, to allow a reach further back without hitting the tips of the upper and lower anterior teeth.

Initial Development and Testing
The first prototypes were made by modifying commercially available toothbrushes to our specifications and design. These prototypes were provided to a limited number of dental professionals for evaluation. This took place over a

Stephen D. Harada, DDS

Dr. Harada is President and Founder of Ergonomic Dental Technologies, Inc. (EDT). www.edit-curvex.com
three- to six-month period. The first reports from dental professionals were very encouraging.

**Patent Counsel**

Following preliminary design work, the services of a patent counsel were sought. This was the single most important step in the entire project, and remains so today. The intense collaboration between inventor and counsel cannot be over emphasized. One must engage the services of the absolute best—not the best that can be afforded, but the best. A poorly drafted patent is no better than none at all.

After counsel was engaged and reviewed the design, a patent search of prior designs, or, as it is called, “prior art” was done to verify originality or inventive novelty. The inventor and counsel then reviewed all materials to determine if there was enough novelty to proceed with a patent application and how to word it. For us, this entire process involved three to four months. To protect intellectual property, all feasible variations to the basic concept should be applied for. This also allows for future product differentiation. The application process can and does take years, but is crucial to protect the invention. Once submitted, the United States Patent Office does its own search; in my case, prior art dating from as far back as the 1860s was cited and had to be addressed.

As it was felt that the oral hygiene device market was expanding worldwide, international patents would be sought in Europe and Asia. These involved separate applications on the part of the patent counsel. It should be emphasized that there are no guarantees of success even if a United States patent has been issued. Japan, as a world economic power, was of primary interest and importance even though it was known that their patent procedures were very difficult. It was determined that due to the differing nature of marketing in foreign countries, I would pursue a retail position in Japan, although it is very difficult for most American companies to penetrate the Japanese packaged-goods market.

At the same time production was being initiated, patent counsel was involved in various trademark searches. This had to be done not only for the U.S., but also individually for any other country in which sales might result. Each country had to be searched, and then a trademark filed for. The Curvex name was in fact the result of no less than eight searches internationally and domestically. Following consultation with the FDA, and prior to any sales, requirements for registration were met.

**Proof of Concept/Additional Testing**

After further trials to determine optimum dimensions for strength, aesthetics, ergonomic engineering and potential commercial engineering, design engineers were recruited to construct computer assisted drawings (CAD) with which to
create a mold for additional tests. A rubber mold was created that could produce fifty samples of the toothbrush, sans bristling. These in turn were bristled by another source.

It had been previously decided that the fifty toothbrush samples would be sent to selected members of the dental profession, and if a 75% positive response was received I would proceed to the next step. These trials extended over a six-month to one-year period. This goal was met.

**Manufacturing**

A decision was made to manufacture entirely in the continental United States, as opposed to outsourcing or assembly of components in the U.S. The manufacturer was selected and large capacity molds were fabricated for commercial production. Even though costs were higher, it was also decided to use the best materials that would lend themselves toward ease of recyclibility.

**Marketing and Distribution**

It was decided that for the United States, I would approach the dental professional market. Data showed that over 20% of Americans received toothbrushes from their dentist, and that 80% of all Americans use a manual toothbrush. Additionally, it was felt that the dental healthcare professionals would be most appreciative and receptive to an innovative product that was not just a “me too” copy or variation of existing designs.

In making the decision to market Curvex in the United States first to the dental profession, in fact to colleagues, I felt the need for a valid clinical study, not just a “focus group” evaluation. To this end a clinical study was done comparing plaque removal of the Curvex with its .006 mil diameter filament with the Oral-B Indicator, which uses a .008 mil diameter filament. This was conducted at the University of the Pacific, Arthur A. Dugoni School of Dentistry Dental Hygiene Program, under the auspices of the Department of Periodontics. The Curvex was found to remove plaque as effectively as the Indicator. These results were presented at the IADR/AADR meeting in March 2005. ADA Certification was also sought for Curvex and achieved.

Currently Curvex is sold to the dental professional market through major American dental distributors. Institutional sales have been achieved and the domestic retail market is in the planning stages. Internationally, Curvex is sold retail in Japan’s largest GSM.
Challenges to the Introduction of New Technologies to Dental Practice

Michael L. Barnett, DDS

Abstract

Despite promising breakthroughs in basic biomedical science, the pace at which innovative and disruptive new technologies are developed and introduced into dental practice lags behind that of medicine. This is largely a result of resource issues, both financial and human, as well as determinants in the marketplace. For example, the cost of developing a new drug or technology for dentistry and bringing it to market is often disproportionately high relative to the size of the dental market, thereby making it commercially unfeasible to pursue development. When a new technology is commercialized, its successful introduction can be facilitated by research that makes a compelling case for effective use. As our understanding of mechanisms of disease pathogenesis progresses, identifying compounds and technologies with applicability to both oral and systemic diseases could change the economics of dental product development and lead to additional innovative advances in our field.

In 1997, in a guest editorial in the Journal of Dental Research entitled “Molecular approaches to oral therapeutics: Dentistry in the next millennium?” I discussed, perhaps with a bit of naive optimism, what I envisioned as a future change in the paradigm of dental treatment. At that time, I spoke of the evolution of a mechanical/surgical paradigm to a pharmaceutical/regenerative one. Implicit in this view was the expectation that a steady stream of discoveries would be commercialized leading to significant innovations in the management of oral diseases. Clearly, this has not been occurring at the rate at which it may have been envisioned, and certainly nowhere near the speed at which new technologies have been introduced in medicine.

Why has this been the case? I believe that part of the answer, at least, can be found in a consideration of three aspects of the technology transfer process: the discovery phase (in which basic discoveries are made with potential application to clinical practice), the development/commercialization phase (a major effort in which the practicality of the discoveries is determined and the necessary formulation and preclinical and clinical studies are conducted), and the application phase (in which new technologies are integrated into routine clinical practice).

Some would limit the definition of technology transfer to the first two phases; that is, they define it as the mechanism by which research discoveries are transferred from the academic research lab to companies in order for them to be developed and commercialized. However, if clinicians or consumers cannot be convinced to use the new products, all that has come before will have been futile. This paper will consider some of the issues that may facilitate or inhibit the development and introduction of truly innovative new products to dental practice. In this paper, my frame of reference will be primarily that of drug development, whether prescription or over-the-counter. I should note at the outset that opinions expressed are solely my own, and may not reflect the opinions or experiences of others in the oral care pharmaceutical industry.

The Discovery Phase

With regard to discovery, it is important to note that most of the basic biomedical research relevant to dentistry is conducted in academic institutions. There is relatively little basic dental research conducted by
industry. So it is reasonable to assume that the pace of discovery will be significantly impacted by the availability of adequate resources in the schools, both human and financial. The vast majority of basic research in dentistry is funded by the National Institute of Dental and Craniofacial Research (NIDCR). Consider two numbers: 389 and 7.4. If the score of a game were 389 to 7.4, there would be no question about which side won. However, in this case the score is $389 million to $7.4 billion. Put another way, $389 million is approximately the annual fiscal year 2006 NIDCR budget covering a variety of activities, only some of which include basic research, while $7.4 billion is the approximate annual budget for drug discovery, research, and development from only one pharmaceutical company. (See www.nidcr.nih.gov/NewsAndReports/ReportsPresentation/DirectorReportJanuary2006.htm and www.pfizer.com/pfizer/are/investors_reports/index.jsp.)

Given this great disparity in financial resources alone, it is not surprising that a disparity exists between advances in medicine and those in dentistry.

The question is often asked, why doesn’t the dental industry support significant research and development (R&D) spending for basic research? The answer is found in the dynamics of the marketplace, in particular, the level of anticipated sales compared to the cost of developing and launching a truly new product, especially a drug product. The dental market, especially that portion that does not involve over-the-counter products, is relatively small, and the cost of developing and commercializing new chemical entities and other new technologies is rather large. Therefore, the economics preclude widespread investment by large established companies in products that would have sales which could be considered quite modest by large company standards. Thus, even though a pharmaceutical company that markets oral care products might spend $7 billion annually on R&D, the allocation of resources will depend upon the relative size of the market for prescription drug products for systemic diseases and that, say, for over-the-counter oral care products. As an example, in a company with total annual sales of approximately $50 billion, oral care products may constitute only about $1 billion of the total and, as a result, be allocated a commensurate (relatively small) share of R&D funds.

In addition to adequate funding, there is a need for an adequate number of talented, active investigators in both basic and clinical areas. With regard to new technology development, a significant driver has been the encouragement of an entrepreneurial mindset among academic investigators largely as a result of the Bayh-Dole Act of 1980. This act allowed the patenting of discoveries funded by federal grants and contracts, and enabled the research institutions and inventors to share in the proceeds from their inventions. Academicians have discovered that the licensing of technologies and the establishment of start-up companies to leverage these can be lucrative, and universities have discovered that significant income can be derived from research findings on their campuses and have established an infrastructure to foster relationships leading to commercialization. To give some idea of the magnitude of the income that can accrue to a university, in fiscal year 2001 the number one institution, Columbia University, earned...
approximately $129.9 million from the licensing of technologies. Given the new entrepreneurial spirit developing in academia, this should have the potential to be a more powerful force driving the discovery of new clinically relevant technologies in the years to come.

However, in recent years, it has been increasingly challenging to attract talented dental scientists to pursue academic careers that will allow them to maximize their scientific development. Economic considerations are clearly a factor in that the majority of students graduate with considerable debt and, faced with the choice between a lucrative private practice or an academic career, will generally choose the former. This is especially true in an environment where faculty shortages often preclude the luxury of sufficient time for research to allow one to be competitive in the quest for funds and where federal funding of research through such agencies as NIH/NIHCR is being effectively reduced by competing budget priorities in Congress.

**The Development/Commercialization Phase**

What has to occur between that “eureka” moment in the laboratory and the availability in the marketplace of a product based on a new discovery? A headline in the New York Times several years ago proclaimed, “Despite billions for discoveries, pipeline of drugs is far from full.” The gist of this article was that while intuition suggests that the application of new knowledge and enhanced methods (exemplified, for example, by advances in genomics and proteomics and by the use of combinatorial chemistry to create and evaluate new compounds) should dramatically facilitate the rate of new drug discovery, in fact many of the “traditional” considerations, such as drug toxicity and the ability to successfully produce and formulate a drug product for human use, remain rate-limiting steps. The process of developing and commercializing a new drug or technology is quite expensive and lengthy, taking approximately ten or more years. In fact, it has been estimated that only one of every two hundred fifty drugs that enter preclinical testing is ultimately approved by the FDA. Moreover, a recent study from Tufts University estimates that the average total cost of developing a new prescription drug is upwards of $800 million after the cost of failures and other costs are factored in. (See http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6.)

In the case of dental technologies, this figure can be a bit misleading, since oftentimes a product is developed not by a major pharmaceutical company but by a new, start-up company financed with venture capital or working in partnership with a larger company. In such cases, the actual cost may be only tens of millions of dollars, but the odds of success may decrease because there is often only one egg in the basket. The major players in the dental products world are consumer products companies that rarely pursue compounds or products requiring an NDA (New Drug/Device Application) but that modify existing products or develop new therapeutic products that are governed by an OTC Monograph. (Notable exceptions are successful products that have been marketed under an NDA such as triclosan-containing dentifrices and chlorhexidine-containing mouth rinses.)

What does it take to get venture capitalists or large corporations willing to take on a new technology? At a minimum, the technology should provide some breakthrough in the management of a disease or offer clear advantages over existing treatment or diagnostic methods, and it should be patent protected. The latter is a key consideration as any company investing considerable sums to commercialize a discovery will need to have exclusivity over a reasonable period of time. However, innovativeness and intellectual property protection are, in themselves, not sufficient. As noted above, companies are also interested in the size of the prospective market for a new product.

In the case of dentistry, the potential markets are small compared to many for pharmaceutical products. For example, the entire U.S. dentifrice market in 2005 was $2.5 billion, which was divided among a number of different companies, while blockbuster drugs might have sales of several billion dollars each. Additionally, since the cost of developing and launching new products is considerable, decisions regarding whether to pursue products, especially consumer products, are often made by companies not on the basis of projected needs or demographics, but rather on the basis of focus group results and the size of an existing market, in order to provide some assurance that the product is likely to be a success. So it is clear that a variety of hurdles must be surmounted in order for the development/commercialization stage to be successfully navigated.

**The Application Phase**

Finally, in considering therapeutic products that are used in dental practice, what does it take for a product that has received FDA approval to be accepted for widespread use in dental practice? Or, to put it another way, what are some of the challenges to accomplishing this? Why is it that products that are initially success-
ful to some degree are unable to sustain a significant market presence and eventually are discontinued? As I pointed out in a 2002 Journal of Dental Research editorial, “Decisions, decisions,” there seems to be two issues involved. Since these are often very new technologies and may represent new approaches to disease management, that is, the pharmaceutical/regenerative rather than the mechanical/surgical, many dentists may not be up-to-date with the pathogenic mechanisms of disease on which these new technologies are based and therefore do not feel comfortable adopting them for their patients. This is not to be construed as a criticism of the practicing dentist since it is very difficult for any of us to keep current with every new scientific advance. Therefore, the effective introduction of a new technology should incorporate some aspect of education and preparation of dental practitioners by the company.

In addition, product claims and supporting data should provide a compelling argument for utilizing a product, especially in this age of evidence-based practice. Unfortunately, the clinical data supporting product launches may not always be the most compelling. This can result from the fact that studies submitted to demonstrate a product’s effectiveness generally use the most inclusive patient populations and results are generally expressed as means of the patient groups studied. To use as an example a site-specific treatment for periodontitis, it is possible that this can underestimate a product’s true potential. This happens because the distribution of severely involved and lesser involved sites cause the differences between the new technology and controls to not be overly impressive (often in the range of tenths of millimeters when expressed as group means) because results in the relatively few more severely involved sites are “diluted out” by shallower sites. Despite this, it is likely that the new technology could have greater effectiveness in certain subsets of patients or sites. Thus, information concerning specific patient populations for which the technology would be especially indicated and the proper place for incorporating the technology in the course of therapy would not only be more persuasive but also result in a higher probability of successful outcomes when the product is actually employed in practice. The paradox is that while studies providing such information could be instrumental in helping to assure the ultimate success of the product, there are frequently cost and time inhibitions which preclude their being conducted prior to product launch. As a result, potentially effective products can be commercial failures because practitioners are not provided enough information to help ensure clearly beneficial therapeutic outcomes. While the statistical significance of study results is usually presented, the clinical significance is often not adequately addressed.

The process of developing and commercializing a new drug or technology is quite expensive and lengthy, taking approximately ten or more years. In fact, it has been estimated that only one of every two hundred and fifty drugs that enter preclinical testing is ultimately approved by the FDA.
Conclusion
It is clear, therefore, that there are a number of significant challenges to be overcome in the development and marketing of truly innovative products in dentistry. Nevertheless, while the challenges discussed in this paper have been largely related to drug products, it should be recognized that, in fact, there have been significant advances in dental practice over the years, particularly in the areas of materials, devices, and diagnostics. Some examples are the development of new composite restorative materials, the widespread use of dental implants, and the introduction of digital radiography and, more recently, cone beam radiographic techniques. In addition, there are always ongoing efforts to develop and commercialize new products with a number of small companies working on innovative approaches to the development of new therapies and diagnostics, for example, biomimetic materials for regenerating tooth and bone, novel therapies and preventive agents for dental caries, chemotherapeutic approaches to treating periodontitis, saliva-based diagnostics, and methods for early detection of dental caries and oral mucosal lesions. Also, larger, more established consumer product companies are constantly developing new products to satisfy consumer needs.

However, the pace at which new technologies and quantum leaps are introduced into dental practice lags behind that of medicine, largely as a result of resource issues, both financial and human, as well as determinants in the market place. Perhaps in addition to the “usual suspects,” we should look outside the dental research community for potential therapies. As noted, the high cost of bringing new chemical entities through the FDA process, coupled with the relatively small size of the dental market, is a considerable barrier to the development of technologies, especially new drugs or drug-based combination products. However, technologies with potential applicability to dentistry are sometimes being investigated for other, wider indications by companies which have not considered dental applications. Given that a large percentage of the cost of developing new chemical entities is in the preclinical phase of development, the cost of conducting clinical studies for dental diseases can be a comparatively modest incremental cost over and above studies for the primary indication. Of course, the flip side to this is to identify applications of products developed for dentistry to other diseases, and seek ways to facilitate their development for the additional indications. This would be a means of easing the financial burden of developing dental products as the overall potential market for all indications could potentially justify the development costs. Finally, as a professional community we need to be informed about the scientific rationale, indications, and evidence-base for new technologies in order to best utilize new advances and assure their ultimate success.

The major players in the dental products world are consumer products companies that rarely pursue compounds or products requiring an NDA but, rather, modify existing products or develop new therapeutic products that are governed by an OTC Monograph.
Robert W. Gerlach, DDS, MPH

Abstract

The introduction of hydrogen peroxide whitening strips in 2000 has contributed to new paradigms for treatment and expanded interest in tooth whitening. Clinical trials played a prominent role in the whitening strip research and development process. Four case studies from the whitening strip development program are used to review the fundamentals of clinical trials design, conduct, analysis, and interpretation as part of new product development in oral care.

“Do you have any ‘clinicals’?” This is perhaps the most common question from clinicians, researchers, reporters, and even consumers when a new product or service is introduced to dentistry.

Clinical trials play a prominent role in research and development (R&D) leading to these innovative oral care products and treatments. Critical elements in the design, conduct, analysis, and interpretation of clinical trials are described, with reference to new product development in oral care. The case studies were part of R&D for hydrogen peroxide whitening strips. Introduced in 2000, this so-called “easy-to-use” tooth whitening system represented a significant departure from contemporary treatment (Gerlach, 2000). Four examples early in that program typify the strengths and limitations associated with clinical trials and new dental product development and how oral care R&D differs from the classic pharmaceutical model.

Clinical trials are a class of prospective, designed medical studies. Eligibility, treatment, and evaluation may be closely controlled via specific entrance criteria, prescribed usage, calibration, or other factors. Human studies typically follow nonclinical research in order to confirm or refute findings from bench experiments or patient observation. In classic drug development, clinical research is categorized in phases, where phase I is early safety testing among healthy volunteers to assess drug pharmacokinetics and pharmacodynamics, phase II is initial efficacy testing in a population suffering from the disease or condition of interest, and phase III is the broad scale clinical safety and efficacy testing used by regulators for approval and labeling.

New pharmaceutical development has often focused on the “blockbuster” approach—R&D in pursuit of the rare billion dollar proposition—a virtual unknown in oral care. With little promise of the return on investment that enables lengthy development, there has been relatively little new drug development in dentistry. Over the past twenty years, fewer than a dozen dentistry-specific drugs have gained U.S. Food and Drug Administration (FDA) approval. Only one area, locally delivered antimicrobials for periodontitis, has at least three new drug approvals and none of these could readily be classified as a “blockbuster.” Instead, oral care R&D has more typically focused on FDA “monograph” actives (such as fluorides for caries, where safety and efficacy were previously established), devices (such as implants, toothbrushes, and restorative materials that may leverage a preexisting or “predicate” device approval), and increasingly, cosmetics such as the hydrogen peroxide gel on
whitening strips. Unlike new drug development, clinical trials are not typically required as part of R&D for monograph actives, devices, or cosmetics, so most clinical research is voluntary.

**Types of Studies Used in Testing New Products**

The randomized controlled trial (RCT) is generally thought to represent the gold standard test of efficacy and safety in biomedical research. Participants in an RCT receive either the experimental product or technique of interest (the unknown) or a control product or technique (the known). In oral care, most controlled clinical trials are sponsored by industry as part of the lengthy R&D process leading to a new product. In general, these industry-sponsored clinical trials are undertaken to 1) aid in development and decision making (for example, which product iteration to advance for safety, efficacy or cost purposes); 2) address explicit or implicit regulatory or credentialing requirements (recommended or mandated by government, professional associations, or reviewing bodies); or 3) support marketing, claims, or communications (directly or indirectly to consumers, professionals, or reviewing organizations).

Four early studies with different controls are used to characterize the design, conduct, analysis, and interpretation of oral care clinical trials and the unique contributions of this research to new product development.

**The Proof of Concept Study—The Basis for Interest**

A fourteen-day study was conducted to assess clinical response with an experimental hydrogen peroxide whitening strip. Thirty-six healthy adults were randomly assigned to the experimental strip or three other professional, tray-based products at different peroxide concentrations. Results for all four systems showed significant ($p < 0.001$) whitening relative to baseline, with no significant ($p > 0.56$) differences between the experimental strips and the lowest concentration professional whitening tray (Gerlach, Gibb, & Sagel, 2000).

With monograph actives, devices, and cosmetics, first clinical research in oral care often begins with “proof of concept” to assess potential activity relative to baseline, historical controls, or head-to-head comparisons. The first comparative clinical trial evaluated an early whitening strip formulation versus a professional tray-based carbamide peroxide system. The tray control was selected because of limited clinical trials evidence under different usage conditions, market share, and personal experience. The design simply paired the experimental whitening strips at twice the peroxide concentration and half the contact time versus the daytime tray system. Two higher peroxide concentration tray systems from the same manufacturer were selected as additional controls.

Although large multi-center RCTs provide additional complexity in recruitment, training, standardization, and analysis, these trials are somewhat uncommon in dentistry.
Prior to this clinical trial, there were a number of unknowns associated with the new-to-the-world strips. While strips relied on conventional oxidative chemistry, there was no efficacy precedent with low levels of total peroxide used for short periods (custom trays were typically filled with large volumes of gel and then worn overnight). There was no assurance that individuals could and would reapply strips twice daily over a few weeks, and safety with the unconventional strip delivery was generally limited to a few case studies or uncontrolled clinical trials. The objective instrumental method (digital imaging) was largely untested, and clinical response with the controls (daytime tray use at rising concentrations) was unknown. Failure at this early stage could have been attributed to inadequacies associated with the experimental strip, the method, the benchmark controls, or a number of other factors associated with study design, conduct, and analysis.

Experts have long cautioned interpretation of RCTs that show non-inferiority (Burns & Elswick). Even with controls, clinical outcomes such as those seen in this first whitening strip comparative trial may be readily misinterpreted, as variability, sample size, and other factors may contribute to between-group differences or lack thereof. Absence of significant between-group differences did not mean the groups were necessarily equivalent. The use of two additional control groups, while contributing to overall complexity, aided in study interpretation, since the peroxide concentration effect seen with the professional tray systems suggested adequate measurement sensitivity in this clinical trial to detect a treatment effect. While the primary comparison (experimental whitening strip to lowest concentration professional tray) was multivariable in nature, the experimental strips had approximately twice the peroxide concentration for half the time compared to the tray. Since concentration and time empirically contributed to whitening, outcomes from this first RCT made sense. We interpreted the outcomes to mean that whitening strips could provide a whitening benefit with less time and lower total peroxide than contemporary professional tray systems, and planned further research.

The Placebo-Controlled Trial—Causal Efficacy and Safety

A randomized, double-blind, placebo-controlled clinical trial with fifty-seven adults evaluated response after two weeks strip daily use and six months post-treatment. Results demonstrated that the peroxide strip group experienced significant ($p < 0.0001$) initial color improvement relative to baseline and placebo, with most of the whitening sustained over six months. Tooth sensitivity and oral irritation, the most common adverse events during strip use, resolved and there were no new treatment-related adverse events during the post-treatment period (Gerlach, Gibb, & Sagel, 2002).

Clinical research commonly involves comparisons to a negative control, such as untreated, inactive therapy, or in this circumstance, placebo. Placebos play a critical role in R&D, since this is the only negative control that allows for the direct assumption of causality. The use of controls, one of the cornerstones of the RCT, helps blind evaluation and aids in study interpretation. Randomization, the other cornerstone of the RCT, limits introduction of unknown bias. Adverse events are collected in a standard manner irrespective of causality. Test products are dispensed in common blinded packaging with unique subject numbers. Data are generally recorded electronically, and evaluability is determined after data finalization, but prior to treatment unblinding.

The research also demonstrates the important contribution of methods to the RCT. Whitening strip clinical research started with no preconception of product efficacy or safety. One important early research objective was to objectively measure clinical response in order to guide formulation, since variables relating to materials, concentration, thickness, retention, and manufacturing could all be manipulated, and any of these could impact favorably or unfavorably on clinical responses. To assure unbiased evaluation during the formulation phase, early whitening strip clinical trials used a novel, instrumental evaluation of whitening via standardized digital images of tooth surfaces to assess color change over time. The digital imaging method offered appreciable advantages over the contemporary approach (shading), which has historically yielded ambiguous results for various oral care products. Images were collected blind to treatment assignment, time, and study design, using endpoints that have been shown to be relevant to self-perception of tooth color. Safety was assessed using pharmaceutical standard practices from interview and clinical examination to ascertain signs and symptoms that may possibly be associated with treatment.

Results from the placebo-controlled trial were consistent with the earlier proof of concept study. Despite differences relating to sites, populations, and time, two-week use of whitening strips yielded similar color improvement. Comparisons to placebo helped confirm that a
durable whitening effect, with 70-80% of initial color improvement, was still evident after six months. The method also demonstrated a serendipitous finding—age was inversely related to whitening response. Like other experiments, clinical trials offer the opportunity for discovery. In this study, younger subjects experienced more whitening during the two-week treatment period. Whether this unanticipated outcome was attributed to chance or some biological or behavioral factors was unknown.

Clinical-trials experts have long recognized the ethical and practical limitations associated with placebo-controlled trials (Lasagna, 1979). Except for some medical evaluation, there may be little in return for the study volunteer who is randomly assigned to the placebo. In oral care RCTs, subjects are often compensated for participation in placebo-controlled studies, and such compensation could impact recruitment, compliance, or other factors. It can be difficult to identify volunteers for placebo-controlled testing and limit dropout from a lengthy clinical trial. When treatment effect is notable (such as the visible whitening seen when peroxide is delivered using a tray or strip barrier), subjects and researchers may discern treatment assignment despite blinding. Perhaps surprisingly, placebos may necessitate specific R&D, since these may be difficult to formulate and use may contribute to measurable clinical response.

Alternatives to placebos include dose-ranging studies or comparisons to an active therapy or positive control. Studies without experimental controls may make comparisons to baseline or historical data from other studies. These studies provide less evidence of safety and efficacy compared to controlled trials, so caution should be used in interpreting outcomes from such uncontrolled research. Despite these limitations, placebo-controlled trials play an important role in R&D with respect to formulation, safety, and other factors. We interpreted the findings of this placebo-controlled trial to indicate that it was the peroxide on strips led to measurable initial and sustained whitening without persistent side effects, and that age might contribute to response.

The Positive Control—Extended Evidence of Efficacy and Safety

A randomized clinical trial evaluated whitening safety and efficacy in thirty adolescents who completed orthodontia. Subjects were assigned to whitening strips or an overnight professional tray-based whitening system, and arches were each treated sequentially for four continuous weeks. Results for each group exhibited significant (p < 0.0001) mean color improvement by arch at Week 2, and increasing through Week 4. Groups did not differ on whitening after four weeks, and the adverse event profile was generally similar in occurrence and severity to earlier research in adults (Donly & Gerlach, 2002).

The first adolescent study was undertaken after the discovery in the placebo-controlled RCT of a statistical relationship between decreasing age and increasing tooth whitening. Treatment followed institutional review, parental consent, and child assent. This was a positive controlled study, as the experimental strip to the professional tray system used in the original proof of concept study, with the latter used overnight according to convention. Arches were treated separately over a four week period to limit use, and clinical response was carefully monitored throughout over eight weeks. Results demonstrated the viability of strip or tray tooth whitening in this age group. Measured whitening among children exceeded that seen in previous studies among adults, without untoward safety findings.

In recent years, the pharmaceutical research community has recognized the need for RCTs in children (Caldwell, Murphy, Butow, & Craig, 2004). These studies pose specific challenges with respect to ethics, conduct, and interpretation, and are rarely indicated as part of new adult drug marketing plans, so most use in that age class comes in the absence of RCT evidence. To spur child testing, U.S. drug approval now incorporates limited marketing incentives for RCTs in children. There are no similar incentives for monograph, device, or cosmetics research, and at the time of this testing, virtually no high quality evidence on tooth whitening practices in children existed. Use by children was possible, so clinical research was conducted to assess safety and efficacy of whitening strips among this population. The first RCT evaluated children after...
completion of orthodontics where esthetics may be of particular personal concern.

This first adolescent strip RCT was followed by other studies involving presumptively “vulnerable” populations, including the elderly, xerostomics, and others. Such research provided important evidence of safety. Other safety evidence came from RCTs involving extended usage, up to twice daily use over a six-month period among individuals with tetracycline-associated tooth stain, and long-term post-treatment follow-up. Such research can be controversial, as there are disincentives to test “outside of the norm.” If an untoward outcome were observed under extraordinary usage conditions, an extraneous population, or extended monitoring, then adverse findings could impact R&D and marketing plans. Because whitening strips represented a new-to-the-world approach to treatment, numerous RCTs were conducted to evaluate extended use and post-treatment monitoring relative to active controls and placebo. While the composite research now represents the largest body of controlled testing in this age group, the first RCT involved thirty adolescents, and individually, fifty-six hours of strip use—four hundred and forty-eight hours of tray use. We interpreted the first adolescent study to demonstrate the viability of tooth whitening among younger age groups, with potentially better efficacy and comparable side effects to those seen in adults.

**Integrated Research—Expanding Clinical Trials Evidence**

An integrated analysis was conducted on thirteen whitening-strip clinical trials. The research involved six hundred seven subjects, ranging from ten to seventy-four years of age. In the pooled sample, twice-daily use of whitening strips resulted in significant ($p < 0.0001$) whitening (color or shade), with age and starting tooth color significantly ($p < 0.0001$) impacting on whitening response. Safety findings were unremarkable (Gerlach & Zhou, 2001).

This integrated analysis has been a part of longer-term R&D, even contributing to marketing decisions. One discovery in meta-analysis was the effect of age and starting tooth color on whitening clinical response. While contemporary research had typically enrolled thirty-to forty-year-olds with certain starting tooth shades, the larger sample size in the meta-analysis and the broader population allowed for assessment of response among younger individuals. Results demonstrated that meaningful whitening could be achieved among younger age groups with mild discoloration.

The composite research provided important evidence of safety. Although individual RCTs showed no meaningful safety findings in the absolute or relative to controls, sample size in any single trial was relatively small. The integrated analysis of thirteen reported clinical trials involved over six hundred subjects assigned to whitening strips over fourteen to twenty-four days. Increased sample size provides important evidence of safety, especially with respect to uncommon events. Sample sizes of three hundred or more are generally thought to be needed to detect infrequent events with some certainty (less than 1% occurrence). In pharmaceutical R&D, multi-center studies are often conducted as part of phase IV, where such post-marketing studies have a role in increasing sample size and promoting professional experience. Although large multi-center RCTs provide additional complexity in recruitment, training, standardization, and analysis,
Dentistry has seen considerable recent interest in cross-study integration via a meta-analysis of multiple clinical trials, and systematic review (a critical integration of the available research, particularly RCTs) (Ismail & Bader, 2004). The resulting integrated evidence, which generally increases study power (discrimination), may provide the highest evidence of efficacy and safety. In this regard, integrated analysis may serve as an alternative to multi-center testing for the purposes of safety assessment. Care must be taken with such research, particularly when the integrated analysis is limited to the published literature, as with the first meta-analysis on whitening strips. Publication bias may limit the quality of available evidence from RCTs. Three types of outcomes are particularly vulnerable to publication bias: trade secrets, no effect or negative findings, and repetitive trials. The role of integrated analysis and systematic review in oral care R&D is uncertain, as the approach is relatively new, and there are few examples of such assessment during R&D (versus afterwards). For whitening strips, the integrated analysis demonstrated efficacy and safety across a broad population and different conditions of use, with age and color contributing to clinical response. These findings contributed to marketing targeting a younger demographic group, a group that continues to be at the forefront of whitening strip use, and a primary participant in subsequent whitening-strip RCTs.

Summary

Monograph actives, devices, and cosmetics—along with foods or new techniques—carry little to no requirement for clinical testing, and in fact, most of the thousands of oral care products and many techniques have never been subject to rigorous evaluation via clinical trials. In contrast, the clinical development program with whitening strips has been particularly complex in number and scope, with clinical research contributing a variety of discoveries and six variants (approximately one per year) since the original system in 2000, along with extensive scientific exchange. Whitening-strip RCTs have been conducted in collaboration with various academic and contract research groups within and outside the U.S. The clinical program remains incomplete, particularly in the area of practice-based research, which has gained in interest in recent years (Philstrom & Tabak, 2005). In-office studies, which are commonplace in dermatology, urology, orthopedics, and other medical disciplines, are relatively rare in dentistry. The multi-center, multi-examiner, practice-based approach conflicts with some of the basic premises of RCTs on standardization and analysis, while combination treatment, concomitant medications, fees, ethical issues, and other factors make such research difficult to plan, conduct, and interpret. Nonetheless, such research is believed to help model clinical practice experience and promote technology transfer from RCTs to contemporary practice. Further research may be indicated to extend whitening-strip RCT findings to the practice environment.

Whitening strips continue to be a market leader and demonstrable business success. The clinical trials program leading to this novel product has been unusually comprehensive, with respect to the number and types of RCTs. In hindsight, it is not easy to state whether market success enabled comprehensive clinical testing or whether the clinical testing resulted in the evident market success.

References


The Dental Enterprise: Its Transition from Xenodontic to Biodontic Dentistry

When patients visit a dental office, they expect a diagnosis and resolution of the problem. They expect to leave the office with their problems solved completely, with minimum physical and psychological discomfort, and at a reasonable cost. The success of a dentist in providing oral health care quickly, completely, painlessly, and at a reasonable cost requires the collaborative effort of what can be referred to as the dental enterprise. In the United States, the dental enterprise includes the dental industry, dental schools, dental provider associations and organizations, and a number of dental government agencies. It is through cooperation in this enterprise that dentistry is able to provide oral health care to the American people. The necessity for cooperation among the components of this enterprise cannot be overemphasized, since good oral health is vital to the quality of life of each citizen. Similarly, the good oral health of citizens is vital to our nation’s economy. In addition, maintaining the oral health of our armed forces is an absolute for national defense.

During the twentieth century, the dental enterprise cooperated on developing methods, techniques, and materials for the repair and restoration of lost tooth structure and for the replacement of lost teeth. For most of that century, repair, restoration, and replacement (the 3Rs of dental practice) were accomplished using metals of various types (gold and amalgam), plastics (acrylics), ceramics, and rubber for dentures. These materials are nonbiological, or foreign to the body, and because the Greek word for foreign is xeno, I will refer to the practice of dentistry during this period as the practice of xenodontic dentistry.

Xenodontic Dentistry

The components of the dental enterprise cooperated in the development of xenodontic dentistry during the twentieth century. Dental schools taught it, the dental industry manufactured and distributed products for it to function, and dentists used these products to provide care to patients. The National Institute of Dental and Craniofacial Research (NIDCR), the research component of the dental enterprise, provided financial support for research, which developed new and improved products, equipment, and procedures to enhance xenodontic dentistry. In addition, the NIDCR funded clinical trials and programs to train the next generation of scientists and teachers for our dental schools.

During the second half of the twentieth century, a series of discoveries from basic science laboratories suggested that the era of xenodontic dentistry might end. One of the first papers to support this was in 1953 when the structure of DNA, the hereditary material of life, was
elucidated (Watson & Crick). Additional support came about fifty years later when the sequence of the human genome was published in 2000 (National Institutes of Health, 2000; Venter et al., 2001).

As this milestone was reached, many in the dental enterprise began to envision a new era in dentistry: one in which xeno-materials were replaced by bio-based materials to repair and restore tooth structure and replace teeth lost to disease. I will refer to the practice of dentistry during this as the practice of biodontic dentistry. The introduction of bio-based materials into dentistry was more difficult than anticipated. Some segments of the dental enterprise were so invested in xenodontic dentistry, that the introduction of biodontic dentistry would be disruptive, in that it would require displacing elements supportive of xenodontic dentistry.

THE DENTAL ENTERPRISE AND TECHNOLOGIES

Mapping the sequence of the human genome, though a milestone for the scientific establishment, appears to have had little or no effect on the dental industry, dental education, or dental practices. To understand why it did not result in the mobilization or unification of these components of the dental enterprise, it is helpful to appreciate the difference between revolutionary and evolutionary innovations.

A clear example of a revolutionary innovation is the flight of the Wright brothers’ 1903 Flyer, an event that ushered in a new industry. This innovation was accepted so rapidly that in fewer than one hundred years, that original flight of about forty yards at Kitty Hawk evolved into a spacecraft, a flight that brought us hundreds of thousands of miles into space. One reason this innovation was accepted so readily and evolved so rapidly was that it was revolutionary. There was no preexisting aviation enterprise; therefore, acceptance of the Wright Flyer did not require the displacement of a preexisting form of flight. The acceptance of an innovation becomes more difficult if it must displace an existing enterprise.

Did mapping the sequence of the human genome represent a revolutionary event? And did its acceptance by the dental enterprise require the displacement of preexisting manufacturing, educational, and oral health delivery activities? Not necessarily. Although it is true that this event represented what is, without argument, the first step in what will eventually become biodontic dental practices, and the displacement of xenodontic dental practices, the acceptance of this innovation should be described as an evolutionary step, one of many the dental enterprise took as the twentieth century was traversed.

Like any evolutionary step, adaptation will be required of the dental enterprise. Manufacturers must recognize the need to adjust their products and educators...
must redo their curricula. As a result of the transition from xenodontic to biodontic dentistry, dental offices will not have to change the services they provide in any drastic way. Their responsibility will remain to repair, restore, and replace teeth and tooth structure lost to disease. What will change is how they do this. Instead of using xenodontic materials like metals, plastics, and ceramics, they will use biodontic materials like those derived from stem cells or other biologically obtained materials. Ease of use, opportunities for greater success, and enhanced patient satisfaction will drive the transition from xenodontic to biodontic dental practice.

Transition from a Xenodontic to Biodontic Dental Practice

Most evolutionary changes take time. The amount of time depends on what is evolving. In the case of mammals, evolution can take many generations. In the case of bacteria or viruses, changes can occur in one generation. Based on historical trends of acceptance time for innovations in dentistry, the transition from xenodontic to biodontic dental practices might be expected to take several generations. This would be true if not for one critical factor: the intellectual level of the students entering dental schools today. Today’s dental students are not only more “cyber savvy” than previous generations, but they enter dental school with a better biological background than before, and they are taught more biological science in dental school than ever before. As a result, the use of biodontic products for repair, restoration, and replacement is more acceptable to them than the use of xenodontic products.

Fortunately, there are those in the dental enterprise who have recognized this change. Several schools have already altered their curricula to increase the number of basic science hours. Some dental manufacturers have acquired biotech start-ups, recognizing that the need for biodontic materials will increase as soon as these students graduate. Some manufacturers, recognizing the rapid rate of change, have joined with dental schools in ventures that promote the use of new biodontic products and equipment by the students.

For example, at the University of Connecticut School of Dental Medicine, the dental students in the Connecticut chapter of the Biodontic Society have set up an interest group for exploring the use of new equipment and products. With the support of the dental school’s administration and dental companies, these students have acquired space and solicited products and equipment to be tested. In addition, student chapters of the Biodontic Society are being formed at other dental schools with the expectation that Product Evaluation and Research Laboratories (PERLs) will be formed.

Given the role of dental students as agents of change and the support of all components of the dental enterprise, it should come as no surprise that the transition from xenodontic to biodontic dental practice may take less than one generation.

References


Charles N. Bertolami, DDS, DMedSc, FACD

**ABSTRACT**

The impact our ethics curricula have on students seems marginal at best. Students take the ethics courses we offer and pass the tests we give, but no one’s behavior changes as a result. We fundamentally see ourselves teaching about ethics, which is slightly different than teaching ethics—and expecting behavior to change as a result of what is taught. The premise of this article is that our ethics courses are inadequate in content and form to the extent that they do not cultivate an introspective orientation to professional life. In some cases, they amount to little more than a study of various state dental practice acts or the Code of Ethics of the American Dental Association. Three specific weaknesses are identified in a typical ethics curriculum: 1) failure to recognize that more education is not the answer to everything; 2) ethics is boring; and 3) course content is qualitatively inadequate because it does not foster an introspective basis for true behavioral change. A fourth element, an innovation, is directed to this third weakness and entails implementing a precurriculum very early in the dental educational experience to address the disconnect between knowledge and action.

Dr. Bertolami is Professor and Dean, School of Dentistry, University of California, San Francisco. He may be contacted at bertolamiC@dentistry.ucsf.edu. This paper is the 2005 winner of the Journalism Prize in Excellence, Ethics, and Professionalism of the American College of Dentists and the American Association of Dental Editors. The essay appeared in the April 2004 issue of the Journal of Dental Education and appears by permission of the American Association for Dental Education.

**Why Our Ethics Curricula Don’t Work**

No one has ever done the right thing because of taking an ethics course in dental school. Can I prove this with scientific certainty? No, but the impact our courses have on students seems marginal, as is surely evident to anyone who has spent much time in dental schools or dealing with dental students. Cheating is common, as any dental educator or administrator can attest. At the very least, if our ethics curricula were working, wouldn’t such dishonesty be relatively uncommon? As it is, our students take the ethics courses we offer and pass the tests we give, but no one’s behavior changes as a result. Unfortunately, most educators seem just fine with that. After all, it’s unimaginable that after an outbreak of cheating, we should call our ethics professors to account for their failing.

We fundamentally see ourselves teaching about ethics, which is slightly different from teaching ethics—in the sense of expecting behavior to change as a result of what is taught. But in professional education, is it all that unreasonable to expect ethics curricula to positively and beneficially influence the behavioral choices students and practitioners actually make in life? When it comes to ethics, I doubt the disparity could be greater between what we teach in professional schools and what the public thinks we teach. The selection process for admitting future doctors to dental or medical school combined with
some special wisdom purportedly imparted somewhere along the way is just assumed to guarantee graduates who hold themselves to a higher standard. Higher at least than what might be expected from some alternative educational process: one driven, for instance, by the purely bottom line mentality of market-driven capitalism. An example of the latter might be one in which applicants bid on open slots, with the seat going to the highest bidder; or in which professors augment income by agreeing to grade only selected students' tests or to write only selected students' letters of recommendation based on additional personal financial consideration (Easterbrook, 2002; MacWilliams, 2001). Thankfully, in the United States such abuses are uncommon; nevertheless, the public might still be surprised by the minimal consideration given to ethics as an admissions criterion, despite availability of some rather creative approaches to discerning this most elusive of attributes (Galdwell, 2002).

This difference between perception and reality is all too evident in periodic calls for increasing exposure of students to courses on ethics, usually right after some public disclosure of wrongdoing by a practitioner captures the attention of the media and then fosters a demand for action. The negligent death or injury of a patient, misconduct of a financial or sexual nature, or simply the suspicion that practitioners are placing their own interests ahead of the people they’re supposed to be serving, all lead to demands for something to be done: for universities to do a better job inculcating ethical values in the minds of students.

The scenario is by no means unique to professional education, just starker because the standards are higher and the failings more obvious. When scaled up to the societal level, we end up with an all too familiar litany of malfeasance and scandal. Examples abound: collusion between corporate leaders and the accounting firms that were supposed to be auditing them; university research scientists fabricating data in order to publish papers for promotion and tenure; theft of donated money by leaders of charitable organizations; egregious misbehavior by priests; presidential impeachments with attendant undermining of public confidence in elected officials and in government; greed driving collapse of the savings and loan industry—all examples of systemic corruption, corruption by professionals, that enhanced understanding of the principles of ethics is supposed, somehow, to correct. If only it were that easy.

To make the argument more forcefully: when a dentist is caught in wrongdoing and his or her license is revoked, he or she is usually entered into a “diversion” program to be rehabilitated. This typically involves referring the dentist to the local dental school for re-education. But, what are we in the schools supposed to do with them? Enroll them in a continuing education course and then test them on the definition of the word “beneficence”? No one’s behavior changes as a result. The mistake is that it’s just assumed that the guilty can be slotted into some preexisting and suitably convincing curriculum on good behavior. While the term “re-education” is sometimes used as a humorous euphemism for coercive persuasion, in this context, the difference between knowing the answers to questions on a test and assimilating the meaning of those answers into one’s professional and personal identity is crucial. State dental boards, dental associations, legislatures, and the universities themselves should know better. It just doesn’t work that way, but we pretend it does (which is an ethical issue in itself). Oxford philosopher and ethicist Simon
Blackburn makes this point when he paraphrases Aristotle: “It takes education and practice [emphasis added] in order to become virtuous. It does not just happen, like growing taller or hairier... [and] education is a matter of drawing out a ‘latent’ potential, at least in the best people” (Blackburn, 2001). Alain de Botton underscores the notion that things don’t just happen with an analogy that compares living without thinking systematically to practicing “an activity like pottery or shoemaking without following or even knowing of technical procedures. One would never imagine that a good pot or shoe could result from intuition alone; why then assume that the more complex task of directing one’s life could be undertaken without any sustained reflection on premises or goals?... Perhaps because we don’t believe that directing our lives is in fact complicated. Certain difficult activities look very difficult from the outside, while other, equally difficult activities look very easy. Arriving at sound views on how to live falls into the second category, making a pot or a shoe into the first” (deBotton, 2000).

Is any of this appropriate matter for discussion during the education of one entering a health profession? I contend that it is. For one thing, according to former Harvard president Derek Bok, “most of the sources that transmit moral standards have declined in importance. Churches, families, and local communities no longer seem to have the influence they once enjoyed in a simpler, more rural society. While no one can be certain that ethical standards have declined as a result, most people seem to think that they have, and this belief in itself can erode trust and spread suspicion in ways that sap the willingness to behave morally toward others” (Bok, 1976). It does seem that universities and professional schools have a role to play.

My premise is that our ethics courses are inadequate in content and form to the extent that they do not cultivate an introspective orientation to professional life. In some cases they amount to little more than a study of various state dental practice acts or the Code of Ethics of the American Dental Association; or, even worse, they offer a set of abstractions: formal definitions for terms like justice, respect, responsibility, caring, virtue, trustworthiness, beneficence or the memorizing of such desiccated notions as “the four components of a moral life.” Students catch on fast. They realize that the assumption underlying these definitions is unstated—namely, that they already buy into the behaviors that the definitions describe, that all they really need is catchier phraseology to cement their commitment to good behavior. While such information should certainly be included somewhere in the dental curriculum, it is just that, information—nothing potentially life-altering or, more to the point, potentially convincing. While the ethics courses do succeed in telling students what our expectations of them are, that’s about all they do. Knowing our expectations is all that’s needed to pass the test. What the courses fail to address is the one question everyone really wants the answer to: Why? Why be good? Why be ethical? Only the answers to those questions have any hope of convincing anyone to actually do anything differently. Our prevailing ethical curricula pretend that everyone already knows and accepts the answers, so we can move on, having laid the flimsiest of foundations. The result? No one is convinced of anything, lives and behaviors do not change, and only the most ruminating of students is likely to pose the questions, “Why should I do what you say is the right thing? Why should I be even remotely interested in any of this?” At their best, our ethics curricula offer sputteringly apoplectic answers. At their worst, they offer only silence. The courses make assumptions about what students know and what they value, but such assumptions may not be grounded in reality and thereby render much of the ethics curriculum incoherent to increasing numbers of students.

This article considers three specific weaknesses in a typical ethics curriculum as a starting point for creative thinking about ways to improve. It also proposes one innovation to help remediate students (and I argue that all students require such remediation) not only to make ethics intelligible, but with the sincere aim of positively influencing behavior both in dental school and beyond.

The weaknesses are: 1) failure to recognize that more education is not the answer to everything; 2) ethics is boring; and 3) course content is qualitatively inadequate because it does not foster an introspective basis for true behavioral change. A fourth element, an innovation, is directed to this third weakness and entails implementing a precurriculum very early in the dental educational experience to address the disconnect between knowledge and action. By very early, I mean at the beginning of the first year and possibly, under certain circumstances, even before formal matriculation into dental school. By precurriculum, I mean prior to undertaking our current set of ethics courses.

Weakness One: Failure to Acknowledge the Limits of Education

Yale psychologist Robert Sternberg (2002) argues that we act as if there are no social problems for which more or better education isn’t the answer. He
asserts that the value of education is so convincing that it is sometimes the only solution considered, and he points to the endemic belief that education is offered as the answer to virtually every problem. By way of illustration he gives the case of one South American country that appointed in the 1980s a minister for the development of intelligence, believing that higher intelligence would, somehow, create better, more humane people. It strikes us oddly discordant that there are some problems—perhaps the most important problems—for which more education, more knowledge is not the answer. Here’s a sobering fact: of the one hundred fifty people convicted at the Nuremberg war crimes tribunals that followed World War II, twenty were physicians (No author, 1997)—presumably intelligent and educated people. Among the Nuremberg war criminals, it is doubtful that any single profession was as well represented as medicine, unless twenty-two convicted SS officers are counted as all sharing a “profession.” Whatever benefits go along with increased intelligence, says Sternberg, wisdom is not one of them. Further, if wisdom is defined in terms of seeing the world as it truly is and acting on that accurate vision, then a key insight follows: it is ethics and wisdom that go hand in hand, not intelligence and wisdom. He also points out that focusing exclusively on the development of academic skills may actually take away from the kinds of activities that could help students develop wisdom. Nowhere is this truer than in professional education. While “increased academic skills may be necessary for many kinds of success,” Sternberg asserts, “they are not sufficient. Students need something more.” In the long run, success in practice depends on acquiring the kind of practical wisdom Sternberg refers to. Yet this is seldom discussed let alone formally taught in professional school. In fact, Bok asserts, “Professional schools have never shown much interest in providing lectures on moral conduct or surveys of ethical theory. Many of them have simply ignored moral education altogether” (1997). This is especially unfortunate inasmuch as “higher education occupies such strategic ground from which to make a contribution,” says Bok. “Every businessman and lawyer, every public servant and doctor will pass through our colleges, and most will attend our professional schools as well. If other sources of ethical values have declined in influence, educators have a responsibility to contribute in any way they can to the moral development of their students.”

Knowledge-based ethics courses accomplish little by way of ensuring exemplary conduct because there is an enormous disconnect between knowing what’s right and doing it, between understanding the principles of ethics at an intellectual level and applying them in daily life. Simply put, people do not necessarily do wrong because they do not know what is right. There is something much deeper than simple knowledge at the root of ethical behavior.

Weakness Two: Ethics Is Boring
As to the courses we give, most ethical principles are simply too abstract, dry, and off-putting to have any practical effect. In a word, they’re boring. They capture neither a student’s attention nor interest, much less make any difference in real life. Thomas Merton saw no value to a person struggling to obtain virtue in the abstract, that is, as a quality for which a person has no direct experience. Such a person, he observed, will never prefer virtue to the corresponding vice that, by comparison, will inevitably seem the more lively, inviting, and exciting (Merton, 1993). The difference between living ethically and studying ethics is the difference between playing a sport and reading the rulebook.

Furthermore, “poor instruction can harm any class. But it is devastating to a course on ethics, for it confirms the prejudices of those students and faculty who suspect that moral reasoning is inherently inconclusive and that courses on moral issues will soon become vehicles for transmitting the private prejudices of the instructor” (Bok, 1997). Ethics courses taught by dentists can rapidly degenerate to moralizing in preachy little sermonettes or, even worse, to a self-indulgent self-righteousness reminiscent of Adam Smith’s famous observation that “virtue is more to be feared than vice, for its excesses are not subject to the constraint of conscience.” But even when taught by professional ethicists, such curricula can prove grindingly dull, recounting only various ethical theories ad seriatim—empiricism, epicureanism, logical positivism, materialism, rationalism, skepticism, stoicism, utilitarianism, whatever—and again cannot fail to deliver. “To the extent that these courses are simply surveys of ethical theory,” writes Bok, “they…do little to help the student cope with the practical moral dilemmas he may encounter in his own life” (Bok, 1997). Such ethics courses do not help students capture the exciting vision of “who I could be”; he continues, they do not “help students clarify their moral aspirations…to define their identity and to establish the level of integrity at which they will lead their professional lives.” “Many individuals who are disposed to act morally,” he says, “will often fail to do so because they are simply unaware of the ethical problems that lie hidden in the situations they confront. Others will not discover a moral problem until they have gotten too deeply enmeshed to extricate themselves.” Bok concludes that “students [need to]
become more alert in discovering the moral issues that arise in their own lives,” but, even when they do, that knowledge has to somehow change behavior.

**Weakness Three: Qualitative Inadequacy**

Something more is needed than learning about dental practice acts, codes of ethics, and various historical ethical theories. Something different is needed, something that helps students identify their core belief structure—possibly modifying those beliefs in light of a new learning experience—and then reconnecting the student’s central machinery for action with that set of beliefs, newly discovered and embraced as his or her own. This entails personalizing the curriculum: making it honest and introspective, and coming before formal dental ethics courses. Thus, an innovative precurriculum in ethics must be personalized; it must be honest; and it must be appropriately sequenced.

Difficulty in making the transition between theory and practice is a problem we are very well acquainted with in professional education: between understanding the principles of, say, physiology and applying that knowledge in a practical clinical setting. The same goes for ethics. Recognizing when you’re at an ethical decision point and then acting in accord with what you’ve learned—giving life to the abstract—must be one of the goals of a curriculum in professional ethics. How to make this happen is the question.

**An Innovation: An Introspective Precurriculum**

If the problem lies in the disconnect between theory and practice, then what may be missing is a preamble, offering antecedent—even remedial—ways of thinking with the aim of making subsequent formal courses in ethics more intelligible and more relevant, letting students decide for themselves whether what they have been taught fits with their own personal conception of an ethical life, a moral life, a good life.

Before formal ethics courses can make much sense, students have to come to terms with who they really are, what they really want, and what they really believe and why. The personal odyssey by which a student successfully negotiates the arduous path toward professional school does not encourage facing such questions. Instead, they float—reading the signs of the times and circumstances, responding to the pressures and preferences emanating from parents, peers, and professors. They certainly know how they are supposed to act, what they are supposed to say, and what they are supposed to believe. This is especially evident on the day candidates are interviewed for admission. Even in the case-based problem-solving scenarios offered in our ethics courses, students clearly know the answers we’re looking for. But, whether they really buy into any of the behaviors that the answers speak to we don’t really know, nor—if the truth is told—do they. The question seldom enters consciousness of most professional school students. This is not surprising.

They have been so focused on succeeding in a highly competitive environment to gain admission that serious introspection is a luxury that just never arises, or even worse, is interpreted as a sign of weakness. Yet such introspection—coming to terms with one’s own true feelings and beliefs—is essential. It is the foundation for long-term compatibility with one’s chosen occupation and for happiness in professional and personal life.

The premise of the precurriculum is that courses on professional ethics, even very well done and engaging ones, are effective in explaining to us what it means to be good, but much less effective in convincing us to be good, that is, to act on that understanding. What does it take to act? What kind of intellectual matter can we present to students that, were their brains to marinate in it for a period of time, would lead to positive changes in action? The answer is: matter that provokes meaningful introspection so that students are continually incubating insights that they have discerned for themselves. This is something currently missing from dental education, maybe because we just presume students are naturally introspective. If they are, nothing in the dental curriculum promotes that orientation.

Apart from the decline in influence of the traditional vehicles for transmitting moral standards in our society, considering such matters before embarking on the formal study of professional ethics has added importance in light of the increasing diversity of society and the professions. An increasingly diverse social, cultural, ethnic, racial, and gender composition of the professions means that students do not necessarily share any single cultural heritage or belief structure. Finding common ground between students and faculty, indeed between groups of students themselves, is not easy. Counterintuitively, the increasing diversity of the people who

“It takes education and practice in order to become virtuous. It does not just happen, like growing taller or hairier…[and] education is a matter of drawing out a ‘latent’ potential, at least in the best people”
Knowledge-based ethics courses accomplish little by way of ensuring exemplary conduct because there is an enormous disconnect between knowing what’s right and doing it, between understanding the principles of ethics at an intellectual level and applying them in daily life.

The premise of a precurriculum is that professional school students are fundamentally idealistic, or they were when first attracted to the health professions. That idealism bespeaks a spark of introspection to begin with. This residual idealism has to be captured, cultivated, and maintained. As Bok writes, “We should be willing to assume that most students will have sufficient desire to live a moral life that they will profit from instruction that helps them to become more alert to ethical issues, and to apply their moral values more carefully and rigorously to the ethical dilemmas they encounter in their professional lives” (Bok, 1997).

Such a precurriculum would almost certainly necessitate curricular materials (de Mello, 1995) that by current standards would be unconventional, at least until appropriate adaptations could be devised. But the content itself would be aimed at three central tenets that, though rife with my own personal opinions, are at least worth discussing.

**Doing Well, Doing Good**

Dental students admittedly want to do well, in the financial and material sense; but they also want to do good, in the sense of serving others, adhering to the idealism that motivated them to become doctors in the first place. Is it possible to do well in all the ways so valued by a materialistic society, while at the same time not giving up on a life of altruism? This first central idea of the precurriculum says that there is no intrinsic conflict between doing well and doing good, between personal material benefit and helping meet the needs of other people. In fact, when things work right, these two aspects of personal behavior can be mutually reinforcing, reflective of a life in overall balance. It also assumes that we must be completely honest with ourselves and with others. Fundamental to such honesty is a recognition and acceptance of our own secret motives. This is essential for professional do-gooders, which includes doctors. To paraphrase Thomas Merton, the desire...
for virtue is frustrated in many people of
good will by the distaste they instinctively
feel for the false virtues of those who
are supposed to be good but who do not
live up to their own stated ideals. He
contends that persistent wrongdoers
actually have a very keen eye for false
virtues and a very exacting idea of what
virtue should be in a good person. If
individuals who are supposed to be good
only “see a ‘virtue’ which is effectively
less vital and less interesting than their
own vices, they will conclude that virtue
has no meaning, and they will cling to
what they have although they hate it”
(de Mello, 1995). The same point is
made more directly by Blackburn, who
insists that we “confront what really
bothers people about the subject.”
Namely, “the many causes [students]
have to fear that ethical claims are a
kind of sham” (Blackburn, 2001)—that
is, that even we the professors don’t
really believe what we’re teaching.

In the health professions the senti-
ment is commonly expressed that the
patient’s welfare always comes first, that
the patient’s needs must come before the
needs of the practitioner. This is a noble
sentiment; it is also untrue. No serious
effort at fostering ethical behavior in
professional practice can be based on a
principle, however hallowed, that is on
its face, false. Physicians and dentists do
not place the patient’s welfare before
their own. The platitude that they do so
is only passably credible to the extent
that the patient’s and the practitioner’s
interests are not usually in conflict. On
those occasions when the patient’s and
the practitioner’s interests do conflict,
each person—patient as well as practi-
tioner—can be reliably counted on to
place themselves first (as most conspicu-
ously displayed in all malpractice
litigation). Practitioners do indeed often
place the patient’s welfare above their
own convenience, but this is a different
thing entirely. The purpose of much of
the educational, social, cultural, and
economic environment that society has
created around health care is to prevent
conflicts between the welfare of the
deliverer and the welfare of the recipient
of care from ever arising. It sounds dis-
cordant to doctors and patients alike, but
each person is either overtly or secretly
pursuing their own interests. Society
has shrewdly concocted an arrangement
wherein most health professionals are
 accorded highly privileged lives and
thus, by helping others, help themselves
—most of the time. This unspoken social
contract between health care providers
and the public simply reflects the impor-
tance society places on its own health.
The precurriculum proposed in this
article acknowledges that there is nothing
wrong with individuals (including
doctors) pursuing their own enlightened
self-interest. The trick is to structure
professional practice (and one’s entire
life) in a way that allows one’s own best
interests to be pursued while concomi-
tantly furthering the interests of others
and of society and to learn to recognize
and avoid situations in which one’s own
best interests and those of others are in
conflict. In other words, dental educators
need to help students learn how to maxi-
mize win/win situations while minimizing
win/lose situations that inevitably
deteriorate toward lose/lose scenarios in
which both patient and provider lose.

**Being Bad—Being Blind**
The second central idea is “being bad—
being blind.” The essence is that people
who engage in unethical conduct do so
not because they actually want to be
bad, but because they choose to be blind.
In other words, the fundamental error of
the criminal (or the unethical practi-
tioner) is that they misconstrue where their
own true interests lie. Once one accepts
that there is nothing wrong with pursu-
ing one’s own best interests, it becomes
important to know what, exactly, those
interests are. What appears to be in one’s
self-interest over the short term can be
manifestly disastrous over the longer term.

As Blackburn notes, clearly recogniz-
ing one’s true interests is not all that
easy, after all, when considering what
“is required for a life of reason or a life of
true flourishing, we will find people are
perfectly ready to settle for a good fake”
(Blackburn, 2001). Many forces cloud
the issue, aiming to get us to think
and act in particular ways: to make us
productive, controllable, a good citizen,
and a hard worker. The message is often
subliminal but is powerful nonetheless,
exerting hidden influence and frequently
coming from the people in our lives
we trust the most—parents, teachers,
friends, spouses, pastors—people who
really do have our best interests at heart
but who can themselves be deluded.
Not to mention others who do not
necessarily have our interests at heart:
corporate advertisers and the media,
for instance. Blackburn describes the
problem of “thinking poisoned by an
enveloping climate of ideas, many of
which may not even [be] conscious. For
we may not be aware of our ideas. An
idea in this sense is a tendency to accept
routes of thought and feeling that we
may not recognize in ourselves, or even
be able to articulate. Yet such dispositions
rule the social and political world”
(Blackburn, 2001). Hidden influences
affect everyone in society, including
students entering dental school. The
difference is that we are trying to get
dental students to adopt a code of behav-
ior that is higher than the societal norm,
a task made impossible if we never talk
about those influences and their effects
on decision making.
Meekly accepting others’ decisions—call it a Code of Ethics—is precisely what we faculty devoutly hope students will do. But the point is that there can be no ethical decision-making if students have no experience making decisions for themselves, weighing the evidence for themselves, and drawing their own conclusions—inventing for themselves principles they can live by with comfort and confidence. This entails questioning everyone and everything, including our own most cherished and firmly held beliefs, developing the attitude that such beliefs, however revered, are always held only contingently. Are our beliefs based on what others have told us and that we have mindlessly accepted without close examination, or have we questioned what we have been told? Have we discovered for ourselves what we genuinely hold to be true, what we actually believe, not what we say we believe in order to keep peace with everyone else? Are dental students ever stimulated to consider their attachments, their beliefs, and their fears? Typically students consider their beliefs to be what makes them who they are: their fears, what keeps them safe, their attachments, what makes life exciting—in a nutshell, what got them into dental school in the first place (de Mello, 1995). But, conscious and formal consideration of these deeply held and personal qualities can expose them as decisive filters of the incoming stream of reality upon which the student is making life decisions: a highly filtered view that can engender biases, prejudices, and most importantly, misconstrual of one’s own true interests.

Allied to the matter of blindness and the misconstrual of one’s own best interest is the misery factor. Unethical people are extremely unhappy. They are not unhappy because they are unethical; rather, they are unethical because they are unhappy. They conceive of one or another unethical act as a means of overcoming their misery—a seemingly small price to pay for achieving happiness. They have given up seeking a cure for their unhappiness; what they want is relief: “a good fake.” True criminals are a case in point. They want what someone else has. Why? It is a question I ask students during my ethics lectures. I pose the question: What do you want in life? We then play the game of “Five Whys.” Whatever they say they want, I ask why—doing so five consecutive times. Before the fifth why, the answer almost always ends up being “because I want to be happy.” In this sense they—all of us—are not all that different from the criminal; we all want the same thing: to be happy. Only our means differ. Happiness and ethics are inseparable. Moreover, ethical practice is just a part of an ethical life, and an ethical life is just a part of a broader, healthier, and more robust experience of life itself.

Beyond the matter of ethics (and as part of it), misery is also worth talking about in professional education because it may manifest not only in unethical behavior but also in other maladaptive schemas. Dentists in particular have a well-known reputation for a high incidence of suicide. Why is this never discussed in dental school? Whether it’s true is arguable; nevertheless, even if dentists and physicians have no higher rate of suicide (or depression, anxiety, anger, addiction, divorce, etc.) than the population in general, what kind of accomplishment is that? How is it that educated people with impressive credentials, degrees, and titles who have near certitude of financial security, prestige, and recognition—all things we’ve been told to work toward—are not protected from the same hazards that attend the lives of others who, in most ways, are much worse off? These questions are seldom asked in professional school and are therefore never answered. A cycle of maladaptive behavior can begin long before professional school. It can persist and, significantly, be rewarded in dental school and practice. But it culminates eventually in a feeling of being trapped: a feeling that engenders unhappiness and counterproductive behaviors both in professional practice and in life. When it does, it can lead in turn to unethical activity—activities the practitioner, in a delusional fog, is convinced will bring happiness. The tragedy of such behavior is that the doctor, desensitized, living “a good fake,” no longer sees life the way it truly is (or can be).

Trained to Be Bad

The third central idea of a possible precurriculum is honestly acknowledging and confronting the truth that in the professions we are almost trained to be bad. Professional people can be uniquely vulnerable—unintentionally trained to be unethical. People who go to dental, medical, law school, etc. are accustomed to competing to get what they want. Competition entails winners and losers. Professionals are at the top of a highly competitive pyramid and have become acclimated to (even acquired a taste for) being the winner. Professionals such as dentists are equally accustomed to seeing a lot of losers along the way and become hardened to the notion that there are always going to be losers. Unfortunately, the stance that “what I want is what’s right” easily becomes “what’s right is whatever I want.” As stated earlier, there is nothing wrong with pursuing one’s own best interest. Knowing one’s own legitimate needs, pursuing them, even aggressively, is fine provided what we want is really in our best interest and balanced by the legitimate needs of others. You winning does not mean I have to lose. In fact, from a purely pragmatic perspective, to construct a life wherein
you consistently win, often at the cost of others, is to create for yourself an intrinsically unstable situation, like the successful mobster who is fabulously wealthy but installs bars on the windows of his home and is afraid to go outside. Or, as expressed by Harvard Law Professor Mary Ann Glendon, “people remember, and they get back—with interest” (Glendon, 1994).

Most of us make the assumption that most people are honest most of the time. This is almost certainly true. But it’s also true that most people are dishonest some of the time. Herein lies a conflict. There is throughout professional education a subtle, almost subliminal, and unjustifiable assumption that professionals are honest and ethical all of the time; in other words, people like us never do wrong. We know it isn’t true, but we pretend it is, and we teach our ethics courses as if it’s simply a lack of knowledge that leads professionals to wrongdoing. Based on this false foundation, the rest of our ethics curricula become a house of cards. The truth is we are exactly the kind of people who commit unethical acts. We could not possibly be better trained, cultivated, and rewarded for doing so. Any assumption that academic credentials or high test scores immunize us against wrongdoing is imaginary and dangerous.

Why are highly intelligent people almost uniquely vulnerable to certain kinds of mistakes and wrongdoing? Perhaps because the intrinsically subjective nature of our own intellects causes us to overvalue what we know and to undervalue what everyone else knows. Down deep, we think we’re smarter than others—even in the face of evidence to the contrary (Sternberg, 2002).

Perhaps the most important aspect of a precurriculum would be to help students understand that there are no real gurus. No one can teach you anything when it comes to learning the truth of an ethical life. Whatever you learn, you have to teach yourself. Regrettably, the language of good behavior can sound terribly clichéd. “Professors are often reluctant even to talk about this subject,” says Bok, “it is so easy to seem censorious or banal” (Bok, 1997). It is why, despite Sternberg’s urging that we teach wisdom as part of an academic curriculum (2002), Herman Hesse’s Govinda asserts that “wisdom is not communicable. The wisdom which a wise man tries to communicate always sounds foolish. Knowledge can be communicated, but not wisdom. One can find it, live it, be fortified by it, do wonders through it, but one cannot communicate and teach it” (Hesse, 1957). Whatever the body of wisdom that informs one’s life, it cannot be procured in a package. Mentors and guides can help point the way—the purpose of the precurriculum—but in the last analysis, the discoveries have to be the student’s alone. Thus, this is not about teaching values; rather, it is about encouraging each student to develop his or her own values while understanding multiple points of view and considering even his or her most firmly held beliefs in a strictly contingent way, open always to change in the face of new evidence.

Regarding the exact structure of such a course, I envisage an approach similar to one used at the University of California, San Francisco (UCSF) for the past four years. This one-quarter, one-hour per week course titled “Leadership and Values” is for all practical purposes identical in content to the precurriculum described in this article with its focus on the three central ideas discussed here and with emphasis on the student’s attachments, beliefs, and fears. It is, however, somewhat different in form, inasmuch as the present course is an elective not a requirement (and therefore consists of students self-selected on the basis of their own preexisting interest in the subject matter). It has been open to all students regardless of year, rather than coming at the very beginning of dental school. But, like the proposed precurriculum, the format is small-group, seminar-style. Some years a waiting list of more than fifty students has been generated—more than could be accommodated, reflecting a high level of interest among students when the course content became known among students generally. Specified readings are distributed to students prior to class, and two students self-identify as discussion leaders for that session. Classes consist of a brief oral introduction by the instructor to frame the kinds of questions addressed by the readings, followed by both student-led and instructor-led discussion. Classes conclude with general scenarios that are quite likely to arise in the life of a dental student before the
issues in dental ethics

next class session. Most predictable are those scenarios that involve anxiety, depression, or anger and the misconstrual of one’s own true interests under the sway of these highly charged emotional states. The subsequent class session includes a discussion of these actual events during the intervening week before moving on to new material. There are no examinations or assignments apart from the readings and participation in discussion. The content of the proposed precurriculum would be the same, but adapted and possibly intensified by a more concentrated experience during orientation week or, conceivably, as a self-study program prior to beginning dental school.

Do I think implementation of such a curriculum would really work, that is, would it influence behavior? I do, at least for some students, and over time. Why? Because the intent of the precurriculum is not to provide information; rather it is to cultivate a beneficial way of thinking, one to which the student will become habituated if it is reinforced throughout the dental school experience. The intent is not to teach the student to see everyone and everything in the light of an oppressing morality, but rather to see everyone and everything in the light of their own true interests. To place themselves at the center of the universe, which everyone does anyway, but to do so consciously and from the honest perspective of their own well-ordered life. Seeing the world in this way will promote professional standards if we really do believe that living an ethical life is not only best for the world, but best for us. Further, the potential impact of such a precurriculum has to be assessed with the understanding that attaining an ethical life does not occur overnight. It is literally a whole-life project, occurring in fits and starts, two steps forward, one step back. It requires that students and practitioners, who do on occasion fail to do the right thing, learn from the experience. This can only happen after the event, when the dust settles, provided they are introspective enough to perceive the occurrence as a failure in the first place; a failure having an ethical dimension; and a failure that offers an opportunity for behaving differently next time—an opportunity for growth.

How will continual reinforcement occur? It presumes faculty members capable of modeling a “reflective practitioner” mode of introspection and accustomed to exercising critical appraisal in their own lives. Having faculty members undergo a precurriculum experience themselves could be an important faculty development activity. There is some anecdotal evidence that such retreat-format experiences can make a difference in people’s lives (de Mello, 1995). But even if well-run faculty development retreats are not possible, it would still be a big help if faculty could simply understand that when it comes to teaching, there is a difference between the information they give to students and the information they give off to students (Postman, 1994); that the content of what we teach is one thing, but the form in which we teach it is another (Bertolami, 2001; O’Donnell, 1998); and that “the content of a lesson may be the least important part about learning” (Postman, 1986). All of this is expressed most succinctly by the great nineteenth-century educational theorist John Dewey, who said, “The greatest of all pedagogical fallacies is the notion that a person learns only what he is studying at the time. Collateral learning in the way of formation of enduring attitudes...may be and often is more important than the intended content of what is taught” (Postman, 1986). At the very least, sensitivity to these issues may help prevent faculty from unintentionally undoing whatever is accomplished for students through a precurriculum.

Such an approach could create a climate of opinion within dental schools where introspection could be discussed without embarrassment as an important part of one’s professional education: a climate that helps students understand that it isn’t enough just to do the right thing, that what is also required is to want to do the right thing. The difference is as subtle as it is immense. The effect could be to re-sensitize students and faculty to the truth that some problems for which we as a profession do not now have answers are, at their root, ethical in nature. It involves perceiving subtleties that, upon reflection, become glaring truths that students would never detect without a more introspective approach to professional life.

By way of example, in dentistry, our failure to see certain problems as fundamentally ethical in nature frustrates attempts at workable solutions. The shortage of faculty in dental schools (and all public sector careers) might be a case in point. This problem is almost never cast in an ethical light, but it could be: we still act in universities as if entering a profession is a noble calling for which students do not usually enter professional school expecting to reconstruct for themselves a whole new way of thinking and behaving. It’s hard for all of us.
some sacrifice is expected. The problem is that society as a whole has moved on. “The Victorian ideal of a life devoted to duty, or a calling,” says Blackburn, “is substantially lost to us. So a greater proportion of our moral energy goes to protecting claims against each other” (Blackburn, 2001). No one feels this change more directly than dentists in practice who see first-hand how the world works and what it values. Thus, the usual argument runs something like this: students have high debts and practitioners make a lot of money—depending on the specialty, perhaps three times what a typical faculty member earns (Lindauer et al., 2003). Therefore, dental graduates are justified in avoiding faculty jobs in favor of practice in order to do the right thing by paying off their debts. But consider an alternative view, one that recognizes that as a profession, dentistry is accorded an extraordinary degree of self-governance on the grounds that it is party to a binding social contract based on service to the public.

Has dentistry delivered on its part of the bargain? The Surgeon General’s report on oral health in America offers rather dramatic evidence of a positive correlation between a population’s per capita income and the number of dentists in a community (No author, 2000). In other words, dentists have gone where the money is, establishing isolated conclave of what O’Neil calls freestanding suburban bungalow practices (futurehealth.ucsf.edu/from_the_director_1003.html).

They have avoided practicing in both rural areas and the inner city just as they have avoided faculty positions or public sector careers. Many dentists also refuse patients on public assistance, patients under the age of three, patients over the age of eighty, patients with serious illnesses, or patients who are in nursing homes. If dentists distributed themselves more equitably among all different types of communities (and accepted all kinds of patients) as required by dentistry’s social contract (the basis of its autonomy), the net income of dentists, though still high, would not be as high as it is. In this light, the problem is not only that faculty salaries are too low; it is also that private practice incomes are too high—achieved at the social cost of taking care of only those who can pay, but not those who need care and are unable to pay. In other words, market-based capitalism rules. Were we to extrapolate this principle to academic life, we would be back to the notion of selling seats in dental schools to the highest bidders and offering letters of recommendation at a price. Under those circumstances, the problem of paying faculty enough to compete with private practice would dissolve overnight.

Have dental educators themselves contributed to the problem of student debt by failing to control costs and by encouraging everyone and anyone to assume however much debt is needed to pay for their education? Do faculty concern themselves with the compromises the new dentist will make in order to relieve the fiscal burden we’ve talked them into taking on? Have faculty been fixated obsessively on maintaining outdated teaching technologies that continue to make dental education among the most expensive in the university? Do state dental licensing boards insist on testing students on technical procedures having little relevance to contemporary practice and that require faculty to teach students not what they need to know but what they need to pass—and at enormous expense? Do dental license examiners argue that only live patient examinations prove competence, but at the same time excuse themselves from periodic re-examination under the same terms? All these questions have an ethical dimension.

It’s been said that the only Zen you find on mountaintops is the Zen you bring up there with you (Pirsig, 1984). Correspondingly, the only ethics students generally find in professional school is the ethics they bring in with them. Our earliest childhood notions of doing right by others can hold us in astonishingly good stead throughout life. But for professional school students who will routinely have the life and welfare of other human beings in their hands, wouldn’t a more mature and conscious understanding of one’s own code of life and behavior, including the beliefs underpinning them, constitute a worthwhile goal? Isn’t an important opportunity lost for the professions by not helping students deliberate such matters for themselves in a very practical way?

Perhaps in the process students could discover an approach to living they can subscribe to not only intellectually but also at the deepest emotional levels—an approach that is continually modified or reinforced by faculty throughout the clinical experience of dental school. Something that casts ethics in a vibrant and positive light rather than obsessing over what one is not supposed to do—a continuing project, robust and person-building.

Perhaps a professional ethicist would argue that the content of the precurriculum discussed in this article isn’t really ethics at all; it is actually a course on introspection. I concede the point. However, cultivating as a matter of habit the thought patterns such a curriculum could foster is badly needed in professional education, whatever it is called. It does involve taking risks, but the
objective is simply to become as sensitive to the ethical environment as we have become of the physical environment. “We know that we depend upon [the physical environment], that it is fragile, and that we have the power to ruin it, thereby ruining our own lives,” says Blackburn. “Perhaps fewer of us are sensitive to what we might call the moral or ethical environment. This is the surrounding climate of ideas about how to live. It determines what we find acceptable or unacceptable, admirable or contemptible. It determines our conception of when things are going well and when things are going badly. It determines our conception of what is due to us, and what is due from us, as we relate to others. It shapes our emotional responses, determining what is a cause of pride or shame, or anger or gratitude, or what can be forgiven and what cannot. It gives us our standards—our standards of behavior. In the eyes of some thinkers...it shapes our very identities” (Blackburn, 2001). This seems something worth taking some risks for. ■

References
de Mello, A. The way to love. New York: Image Doubleday.
Adult Patient Visits to Physicians for Dental Problems

Leonard A. Cohen, DDS, MPH, MS, and P. Ann Cotten, DPA, CPA

Abstract

Background and Objectives: Most physicians lack substantive training in dentistry and are usually not capable of providing definitive dental care. Therefore, physician offices are generally not the most appropriate site for the management of most dental problems. This study was conducted to examine the rate with which patients visit physician offices for the treatment of dental problems and their satisfaction with the treatment received.

Methods: Data on dental related problems were collected through a random telephone survey of English-speaking Maryland residents over the age of 20. A random digit dial methodology was used to generate the sampling frame. A total of 811 interviews were conducted. The overall survey has a margin of error of +/- 3.44% at the 95% confidence level.

Results: 5.6% of respondents reported seeing a physician for a dental problem during the prior year. Almost 80% reported being satisfied with the treatment received, while 36.4% reported needing follow-up care with a dentist for treatment of the same problem. Respondents expressing greater satisfaction with their visit to the physician were less likely to report needing to see a dentist for follow-up care (p<.05).

Conclusions: Additional studies are needed to assess the quality and appropriateness of physician management of dental problems.

Orofacial pain represents a significant public health problem affecting approximately 39 million adults during any six-month period in the United States (Lipton, Ship, & Larach-Robinson, 1993). Dental problems in general may result in days lost from work and school, as well as bed rest days (National Center for Health Statistics, 1996), and may significantly diminish the quality of life and disrupt the activities of daily living until resolved (Rosenberg, Kaplan, Senie, & Badner, 1988; Kressin, Spiro, Bosse, Gracia, & Kazis, 1996). While seeking professional dental services to address oral health problems may be an ordinary occurrence for most persons, for some individuals having access to dental care is anything but usual. Individuals without access to dentists in private practice are disproportionately poor and of minority backgrounds. In general, these groups experience greater frequency and severity of oral disease, and most frequently face cost and other barriers to access (National Institute of Dental Research, 1987; Green, Person, Crowther, Frison, Shipp, Lee, & Martin, 2003; Manski, Moeller, & Maas, 2001; Brown, Wall, & Lazar, 2002; U.S. Department of Health and Human Services, 2000; Stewart, Ortega, Dausey, & Rosenheck, 2002).

Individuals who lack access to private practice or community dental services may utilize hospital emergency departments (EDs) (Lewis, Lynch, & Johnston, 2003; Burt, & Schappert, 2004; Graham, Webb, & Seale, 2000; Waldrop, Ho, & Reed, 2000; Cohen, Manski, Magder, & Mullins, 2002) or physician offices (Burt, & Schappert, 2004; Riley, Gilbert, & Heft, 1999; Cohen, Manski, Magder, & Mullins, 2003) as alternative sources for the management of toothaches and related conditions. During the period 1997-2000, dental problems represented 0.7% of all ED visits (Lewis, Lynch, & Johnston, 2003). During a similar period (1999-2000), dental-related problems accounted for approximately 0.3% of all physician office visits (Burt, & Schappert, 2004).

Unfortunately, EDs and physician offices are generally not the most appropriate site for the management of most dental problems. Many EDs do not generally provide dental services, and therefore, are usually not capable of providing definitive dental care. The same is generally true of physicians, most of whom lack substantive training in dentistry. When definitive treatment is not available, patients may have to return for re-treatment of the same condition (Pennycook, Makower, Brewer, Moulton, & Crawford, 1993; Burgess, Byers, &
Thus, although the use of EDs and physician offices for the treatment of dental problems is well documented, major gaps in our understanding of these treatment patterns remain. “Oral Health in America: A Report of the Surgeon General” commented on the lack of data on physician-based services for oral and craniofacial conditions (U.S. Department of Health and Human Services, 2000). Furthermore, few, if any, studies have examined patient satisfaction with the treatment received in physicians’ offices for dental problems nor the need for follow-up care by a dentist. The current study was undertaken to explore these issues.

**Methods**

Data for this research project were collected via telephone surveys with Maryland residents over the age of twenty conducted from November 27 through December 16, 2004. Questions related to dental problems were part of a larger general population survey. The sample of potential respondents was generated using random digit dialing techniques. The sample was selected from all of the blocks of potential working phone numbers in Maryland drawn from all listed and unlisted phone numbers, excluding cell phones. A total of eight hundred eleven people were interviewed. The overall survey has a margin of error of ±3.44% at the 95% confidence level.

The question about the source of the dental problem was unprompted and open-ended. Responses were later recoded into appropriate categories to facilitate analysis. The analysis contained in this report only reflects the responses of those individuals who responded to the questions about dental problems. Statistics are calculated on the number of respondents to each question. Pearson chi-square was used to test for significance, when appropriate, except when cell size was less than five where a Fisher’s Exact Test was used. Where necessary, response categories were collapsed due to small cell size. The research protocol was reviewed by the University of Maryland Baltimore Office for Research Studies and judged exempt from IRB review.

**Results**

Among all survey respondents, 5.6% (45/803) reported that they had seen a physician or a medical doctor other than a dentist for a dental-related problem during the prior twelve months. Table 1 presents the demographic composition of those respondents with dental-related medical visits. The majority of these respondents were female (71.1%) and White (69.8%). The largest percentage possessed a graduate or professional education (29.5%), were in the $50,000-$100,000 income range (32.4%), and were in the age range 46-64 years of age (46.7%). Table 2 presents the percentage of all respondents who visited a medical provider for a dental-related problem by demographic characteristics. No statistically significant differences were noted in the rate of visits to physicians for dental problems based on the respondent’s demographic background.

Respondents with dental-related physician visits were asked to describe the nature of their dental problem. The most frequent problem mentioned was “toothache” (26.7%). A surprisingly large percentage of the respondents (26.7%) reported that they did not know or were not sure of the nature of their dental problem. Next most frequently, “jaw joint pain,” was mentioned by 13.3%

<table>
<thead>
<tr>
<th>Gender:</th>
<th>Medical Visits (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male .</td>
<td>28.9</td>
</tr>
<tr>
<td>Female</td>
<td>71.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race:</th>
<th>Medical Visits (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White, non-Hispanic</td>
<td>69.8</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>20.9</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2.3</td>
</tr>
<tr>
<td>Other</td>
<td>7.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education:</th>
<th>Medical Visits (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;High School</td>
<td>2.3</td>
</tr>
<tr>
<td>High School/GED</td>
<td>27.3</td>
</tr>
<tr>
<td>Some College/Technical School</td>
<td>20.5</td>
</tr>
<tr>
<td>College</td>
<td>20.5</td>
</tr>
<tr>
<td>Graduate/Professional Education</td>
<td>29.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Income:</th>
<th>Medical Visits (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$25,000</td>
<td>27.0</td>
</tr>
<tr>
<td>$25,000–$50,000</td>
<td>29.7</td>
</tr>
<tr>
<td>$50,000–$100,000</td>
<td>32.4</td>
</tr>
<tr>
<td>&gt;$100,000</td>
<td>10.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age:</th>
<th>Medical Visits (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
<td>8.9</td>
</tr>
<tr>
<td>31-45</td>
<td>24.4</td>
</tr>
<tr>
<td>46-64</td>
<td>46.7</td>
</tr>
<tr>
<td>&gt;64</td>
<td>20.0</td>
</tr>
</tbody>
</table>
of the respondents followed by “other problem” (8.9%), “painful oral sores” (6.7%), “face/cheek pain” (6.7%), “gingival problems” (6.7%), and “burning mouth” (4.4%).

Respondents with dental-problem-related physician visits next were asked to describe their level of satisfaction with the treatment or advice they were given (Table 3). Only 20.4% indicated that they were somewhat/very dissatisfied, while 79.6% reported that they were somewhat/very satisfied with the treatment received. Respondent level of satisfaction was not related to gender, education, or age. However, there was a definite trend toward Whites reporting higher levels of satisfaction (somewhat/very satisfied 89.7%) than Blacks (somewhat/very satisfied 57.1%, p=.07). Another trend showed satisfaction appearing to be related to respondent income with individuals reporting annual incomes less than $25,000 expressing a higher level of satisfaction (somewhat/very satisfied 100%) compared to individuals earning greater than $25,000 (somewhat/very satisfied 70.4%, p=.07). Slightly more than one-third (36.4%) of the respondents who saw a physician or medical doctor for a dental problem reported that following their visit to the physician they had to see a dentist for treatment of the same problem. Respondents who expressed no need for follow-up with a dentist were more likely to report being satisfied with the visit to the physician (92.9% versus 64.3%, p<.05) (Table 3). The natures of the respondents’ dental problems were not related to the need for follow-up with a dentist. A comparison of the demographic characteristics of these respondents revealed no association with respondent gender, education, or income. Blacks, however, exhibited a trend toward being

Table 2. Percentage of Respondents Who Visited a Medical Provider for a Dental Problem by Demographic Characteristics

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Dental Visits</th>
<th>No Dental Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>5.6</td>
<td>94.4</td>
</tr>
<tr>
<td>Gender: Male</td>
<td>4.7</td>
<td>95.3</td>
</tr>
<tr>
<td>Female</td>
<td>6.1</td>
<td>93.9</td>
</tr>
<tr>
<td>Race: White, non-Hispanic</td>
<td>5.4</td>
<td>94.6</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>5.0</td>
<td>95.0</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6.3</td>
<td>93.7</td>
</tr>
<tr>
<td>Other</td>
<td>8.6</td>
<td>91.4</td>
</tr>
<tr>
<td>Education: &lt;High School</td>
<td>2.5</td>
<td>97.5</td>
</tr>
<tr>
<td>High School/GED</td>
<td>5.7</td>
<td>94.3</td>
</tr>
<tr>
<td>Some College/Technical School</td>
<td>4.1</td>
<td>95.9</td>
</tr>
<tr>
<td>College</td>
<td>4.9</td>
<td>95.1</td>
</tr>
<tr>
<td>Graduate/Professional Education</td>
<td>9.2</td>
<td>90.8</td>
</tr>
<tr>
<td>Income: &lt;$25,000</td>
<td>7.0</td>
<td>93.0</td>
</tr>
<tr>
<td>$25,000 - $50,000</td>
<td>6.8</td>
<td>93.2</td>
</tr>
<tr>
<td>$50,000 - $100,000</td>
<td>4.9</td>
<td>95.1</td>
</tr>
<tr>
<td>&gt;$100,00.</td>
<td>3.0</td>
<td>97.0</td>
</tr>
<tr>
<td>Age: 21-30</td>
<td>6.0</td>
<td>94.0</td>
</tr>
<tr>
<td>31-45</td>
<td>5.2</td>
<td>94.8</td>
</tr>
<tr>
<td>46-64</td>
<td>6.2</td>
<td>93.8</td>
</tr>
<tr>
<td>&gt;64</td>
<td>4.9</td>
<td>95.1</td>
</tr>
</tbody>
</table>

Table 3. Percentage of Respondents With a Dental-Related Visit to a Physician Who Were Satisfied With the Visit by Demographic Characteristics and Need for Dental Follow-up

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Somewhat/Very Satisfied</th>
<th>Somewhat/Very Dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>79.6</td>
<td>20.4</td>
</tr>
<tr>
<td>Gender: Male</td>
<td>83.3</td>
<td>16.7</td>
</tr>
<tr>
<td>Female</td>
<td>76.0</td>
<td>24.0</td>
</tr>
<tr>
<td>Race: White, non-Hispanic</td>
<td>89.7</td>
<td>10.3</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>57.1</td>
<td>42.9</td>
</tr>
<tr>
<td>Education: High School or less</td>
<td>84.6</td>
<td>15.4</td>
</tr>
<tr>
<td>Some College or more</td>
<td>76.7</td>
<td>23.3</td>
</tr>
<tr>
<td>Income: &lt;$25,000</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>&gt;$25,000</td>
<td>70.4</td>
<td>29.6</td>
</tr>
<tr>
<td>Age: 21-45</td>
<td>73.3</td>
<td>26.7</td>
</tr>
<tr>
<td>&gt;45</td>
<td>82.1</td>
<td>17.9</td>
</tr>
<tr>
<td>Need for Dental Followup:*</td>
<td>64.3</td>
<td>35.7</td>
</tr>
<tr>
<td>No</td>
<td>92.9</td>
<td>7.1</td>
</tr>
</tbody>
</table>

*p<.05
more likely to report needing a follow-up visit with a dentist for their problem than did Whites (71.4% versus 26.7%, p=.07). Finally, younger respondents (ages 21-45) were significantly more likely to report needing a follow-up visit with a dentist than were those over the age of 45 (53.3% versus 21.4%, p<.05).

Discussion
This study had several limitations. Although the survey sample was drawn from all potential working phone numbers in Maryland, people without a telephone and people who only use cell phones were excluded from the sample population. In addition, the relatively small sample size limited the ability to explore demographic correlates of visits to physicians for dental problems, patient satisfaction with the services received, as well as the need for follow-up care with a dentist. As such, the statistical analyses examining these relationships should be interpreted with caution. The study does, however, present new findings documenting the frequency of dental-problem-related patient visits to physicians as well as previously unreported overall findings concerning patient satisfaction and need for follow-up services from a dentist.

In the United States during 1995, there were approximately seven hundred million total patient visits to physician offices which represented 81% of all ambulatory visits (Schappert, 1997). This figure had increased to eight hundred ninety million visits by 2002 (Woodwell & Cherry, 2004), with visits for dental-related problems representing approximately 0.3% of all physician office visits (Burt & Schappert, 2004). In the present study, approximately 5.6% of the respondents reported that they had visited a physician for a dental problem during the prior twelve months. This compares to the much larger approximately 40% of the U.S. population that visits a dentist during the year (Manski, Moeller, & Maas, 2001). Data from the 1989 National Health Interview Study (NIH) indicated that 21.8% of individuals over the age of seventeen in the U.S. civilian population experienced orofacial pain symptoms over a six-month period (Lipton, Ship, & Larach-Robinson, 1993). Although the findings from the NHIS survey obviously are not directly comparable to the present study, they suggest that approximately 10% of individuals suffering from acute dental symptoms may seek assistance from a physician for their dental problem. As was the case in the NHIS study, toothaches represented the most frequently cited problem among Maryland respondents (26.7% versus 12.2% in NHIS). Also similar to the findings in the NHIS study, where females experienced the highest prevalence of orofacial pain, females in the present study were most likely to report visiting a physician for dental problems.

There were no statistically significant differences in the rate of visits to physicians based on the respondent’s demographic background. An association might have been expected because, as previously mentioned, the poor and minorities experience a higher level of oral disease (Green, Person, Crowther, Frison, Shipp, Lee, & Martin, 2003; Manski, Moeller, & Maas, 2001; Brown, Wall, & Lazar, 2002), and frequently face cost and other access barriers (National Institute of Dental Research, 1987; U.S. Department of Health and Human Services, 2000; Stewart, Ortega, Dausey, & Rosenheck, 2002). Differences in physician utilization associated with respondent race and income may have been obfuscated by the small sample size. Nevertheless, a general comparison of the frequency of visits to physicians for dental problems with that of visits to dentists in general (U.S. Department of Health and Human Services, 2000) revealed, as would be expected, a much lower rate of visits for all demographic groups, but a similar pattern as regards higher visit rates for females, those better educated, and the non-elderly. However, unlike the general pattern of dental services utilization, Hispanics as compared to Whites, and those with lower incomes as compared to those with higher incomes, exhibited higher rates of visits to physicians for dental problems. Inasmuch as income and education are generally directly correlated, the paradox of a seemingly higher rate of visits to physicians by respondents with both greater education and low income was unexpected.

Over three-quarters of the respondents (79.6%) reported satisfaction with the treatment they had received. Although no comparative studies are available, empirically this level of satisfaction appears quite high. The trend suggesting that Whites were more satisfied than Blacks with the care received is consistent with national data reflecting patient satisfaction. However, the trend showing lower income individuals to be more satisfied than higher income individuals contradicts national reports (U.S. Department of Health and Human Services, 2004). Patient satisfaction with treatment is closely associated with the patient’s perception of the quality of the doctor-patient relationship (Speedling & Rose, 1985; Mataka, 2000; Kress & Shulman, 1997). Inasmuch as the quality of the relationship has been linked with the quality of the communication between the physician and patient (Mellor & Milgrom, 1995; Newsome & Wright, 1999), it appears that these patients were generally approving of their communications with their physicians.
Approximately one-third of the respondents sought follow-up care for their dental problem from a dentist following their physician visit. Thus, it appears that approximately two-thirds of the respondents may have received effective treatment for their problem or the problem resolved itself. It might have been expected that respondents seeking follow-up would have disproportionately represented patients presenting with toothaches, since these individuals might be thought to be most likely to need the services of a dentist to achieve resolution of their dental problem (Pennycook, Makower, Brewer, Moulton, & Crawford, 1993; Burgess, Byers, & Dworkin, 1990). This, however, was not the case. The higher rates of dentist follow-up experienced by Black respondents appear to be consistent with national data that reflect greater dental morbidity and higher toothache rates among Blacks (U.S. Department of Health and Human Services, 2000). As might be expected, respondents seeking follow-up care were more likely to have been dissatisfied with the care received from their physician. This dissatisfaction may have resulted from the fact that their expectations for obtaining relief for their dental problem were not met (Newsome & Wright, 1999).

Although physicians can provide care for dental problems, they often are not capable of providing definitive treatment. As such, physician offices are not generally considered the most appropriate setting for the treatment of dental problems. Most physicians have received only minimal training in the management of dental-related problems (Pennycook, Makower, Brewer, Moulton, & Crawford, 1993; Burgess, Byers, & Dworkin, 1990). Nevertheless, the respondents in the present study were overwhelmingly satisfied with the care they received. Several authors have provided guidance to physicians in the management of dental problems (Comer, Caughman, Fitchie, & Gilbert, 1989; Clark, Album, & Lloyd, 1995; Pyle & Terezhalmy, 1995; Venugopal, Kulkarni, Neruker, & Pannekar, 1998; Drum, Chen, & Duffy, 1998). In recognition of this need, the General Medical Services Committee of the British Medical Association published guidelines on the management of dental problems (General Medical Services Committee, 1994). Guidelines have been shown to assist physicians in dealing with dental problems in the hospital emergency room setting (Ma, Lindsell, Jauch, & Pancholi, 2004). Further studies are needed to assess the quality and appropriateness of physician’s management of dental problems.

REFERENCES


Technical Glossary

Editor's Note:
In an effort to make research papers that contain technical concepts more “user friendly,” the Journal will attach a technical glossary to those papers where it seems useful.

The Margin of Error is X%.

Wherever surveys are conducted there is an opportunity for error. When it is reported that 60% of individuals surveyed favor this policy or that, the actual proportion might be a bit higher or a bit lower. It is customary for public pollsters and the media to simply state a percentage error—\( \pm X\% \). The actual situation is a bit more complicated that this. First, the margin of error statement is understood as shorthand for the statement, “If you say that the average response was X%, with a margin of error of Y% you will be correct about X% of the time.” It is convention to set Y at 95%.

There is a simple formula for calculating this value, and it depends on three things: 1) how large the sample is, 2) whether the proportions tend to be close to 50:50 or at extreme values (such as 5% versus 95%), and 3) how confident one wants to be.

Larger samples produce smaller error ranges. Suppose a sample of four individuals was evenly split between two alternatives. The reported probability would be .50 ± .49. That is a huge margin of error and not much help. If the sample size is increased to 20 (keeping the proportion at .50), the margin or error drops to 22%. With sample sizes of 150, the error is 8%; and with a sample of 1000, the error rate drops to less than 1%.

This example was based on an assumption that the proportion favoring a statement is roughly equal to the proportion taking the opposite view. When the proportions are unequal (almost all in favor or almost all opposed), the error range decreases. Using the sample sizes of 4, 20, 150, and 1000, the error on a 95% versus 5% split would be 21%, 10%, 3%, and almost nothing. Of course the errors are not symmetrical, despite the tradition to treat them as such. A proportion of 95% with a 10% plus error rate is nonsense. If situations such as this arise, there are sophisticated methods for getting around the problem. In practical terms, it is unwise to use this kind of data for making decisions.

If one can live with greater than 95% certainty in making claims about survey results, the error ranges can be shortened. At a 90% chance of reporting a correct value, the error range is only 75% as wide. If more confidence is desired, say 99%, the error ranges are about half again as large.


Let me begin with a story. In a place called Ithaca, some three thousand years ago, a lad named Telemachus came of age while his father was absent. In the process of becoming a young man he had help and he had detractors. Most simply ignored him in their own eagerness to get ahead. A few felt virtuous and lectured him about what they might have done themselves if they had been as good as their word. There were some who sought his economic harm and spread rumors to damage his reputation. This latter group knew that the day would soon come when Telemachus would be old enough to challenge them. There was also an old family friend who showed the boy what it meant to be strong, wise, and virtuous. When Odysseus, the boy’s father, returned from the Trojan wars, the careers of the detractors were terminated violently. History failed to record the names of those who ignored or lectured Telemachus—which is really all they deserve. Homer named the detractors who stood in the way in his epic Odyssey, but they are not recalled fondly today. Only the more mature man who showed the young boy how to become a king is remembered through the ages. His name was Mentor, and he alone touched the future.

This is a contemporaneous story, and every professional today has an opportunity to make the timeless choice. Many will be too busy with their own affairs to give much thought to how the young men and women coming into dentistry will matter. Some will preach at them a little and expect that schools or parents should do their duties. There will always be a handful who badmouth the coming generations as being undertrained and improperly respectful of traditional values. These are the ones who will fight their younger colleagues for the future of the profession—and the smart money is always on youth. There are also dentists who encourage, work with, guide, nurture, reveal secrets to, earn the privilege of scolding, and want to see the success of their junior colleagues. Perhaps they share a few patients when new dentists move to town, introduce them at professional meetings, answer a question late one evening about a difficult case, or suggest a trustworthy accountant. The older practitioners may not know all the newest materials or pharmacology, but they can teach a level of quality that is far above the standard of care. They want the new guy or gal in town to succeed because he or she will thus blend the best of the emerging discipline of dentistry with the deep traditions of professionalism that cannot be learned from a few years in dental school or a CE course. These dentists who touch the future are called mentors.

What and Why of Mentoring
Mentoring is a long-term relationship that permits the professional growth of both an experienced individual and a
junior colleague. The bond matters, but its purpose is not social; both parties are expected to be transformed. And the process takes place in a professional context—it is for a purpose that colleagues would approve. Johnson and Riles capture the essence of the relationship: “Mentors provide protégés with knowledge, advice, counsel, support, and opportunity in the protégé’s pursuit of full membership in a particular profession. Mentoring is an act of generativity—a process of bringing into existence and passing on a professional legacy.” Some additional characteristics that help identify true mentoring include voluntary engagement (in both directions), mutuality, reflection, regular and prolonged (but generally informal) interaction, empowerment and development of both parties, absolute individuality and customization, and absence of a curriculum or generic path to be followed.

As valuable as a quick appearance before students might be, teaching is not mentoring. Teaching aims to provide knowledge and the instructor is assured protection from being changed by his or her students. CE gurus are seldom mistaken for mentors; if dental school faculty members are mentioned in this way, it is always because of a relationship that existed outside of the lecture hall. Coaching, often used as a synonym, differs from mentoring because the goal is group performance, not individual development. Personal trainers come closest to mentors, but they engage in hopes of financial return and seldom share a common professional identification with those they train. Consultants are also unlikely to be confused with mentors.

Research has shown that protégés can expect to benefit from mentoring in the following ways: accelerated career mobility, improved professional identity, greater professional competence, increased career satisfaction, more financial success, greater acceptance within the profession, and decreased career and life stress. They are also more likely to become mentors themselves. The mutuality of mentoring is supported in research demonstrating internal satisfaction and fulfillment, enhanced creativity and professional synergy, career and personal rejuvenation, development of a loyal support base, esteem from peers, and the pleasure of shaping the future of the profession for mentors. Mentoring is professionally sanctioned because it leads to greater productivity and competence, enhanced commitment to the profession, and early identification and development of future leaders.

**How Mentoring Works**

On the Greek island of Cos, just miles from present-day Turkey, two schools of medicine flourished in the fifth century B.C. At one end of the island, the Cnidian School believed that medicine involved identifying and treating diseases. Patients were the medium in which disease manifested itself, and patients were treated only in a secondary sense.
At the other end of the island, those in the Hippocratic School argued that the job of the healer is to assist in reestablishing the natural balances in patients that allow them to heal themselves.

Understanding this fundamental difference in the approach to a helping profession is critical to getting a grip on mentoring. Cnidians and their descendants prefer an approach based on telling others what to do—very rational, very arms-length and uninvolved. Those in the Hippocratic tradition understand what it means to say that mentoring is based on establishing a relationship in which others can grow. In fact, the Hippocratic Oath contains the sentence, “If any son of my colleague will come to me I will teach him the Art.” These words should cause some on the CE circuit to blush.

The essence of mentoring is captured in the Irish saying, “It doesn’t matter how tall your father is, you have to do your own growing.” Mentoring is creating the conditions that support maximal professional growth. On that basis, we can develop some of the approaches to good mentoring. Knowing the answers and being persuasive will not appear on the list.

Matching Up
Mentors are almost never one’s boss; that is a complicating dual relationship. Spontaneous pairings of mentors and protégés work better than assigned pairings. The protégé must recognize a blend of competence, power, openness, and safety in the mentor. The mentor must be perceived to have already taken the journal that the protégé proposes, or at least to have taken parts of it. But he or she must also be a good traveling companion, demonstrating warmth, good listening skills, trustworthiness, interpersonal sensitivity, respect for values, and even humor. From the mentor’s side, an ideal protégé has potential that can be developed. They are a promising investment in the future of the profession. The mentor must be able to say with conviction, “The profession will be better when I retire if I work with this young man or women than if I work with others or if I work with none.” Note that the investment is in the profession; when mentors seek to clone themselves, mentoring becomes hideous.

The early stages of a mentoring relationship should include exploration and discussion. One of the best means for determining compatibility is to talk about dreams. Without significant overlap in a common future, the mentoring project will come unraveled. If there is harmony at this level, the means for realizing these dreams should be discussed. How often the meetings should take place and where, what each party should do, which topics are on the table and which are not, how progress will be measured, a mutual commitment to honesty and candor, and an expectation to work at the project for about four or five years should all be part of the conversation. Although mentoring is always custom work, it is inviting unnecessary surprises not to have these frank discussions up front. If either party finds this too awkward, ending before starting might be the wise move. Research has shown that parties feel more comfortable in mentor-protégé relationships that are of the same sex or ethnic mix but they are not necessarily more effective. The critical determinant of a good relationship is squaring the expectations at the outset.

The Protégé’s Journey
Anyone who has ever been a parent, or perhaps taught in a residency program, understands the delicate balance required to support another’s growth. Some of the required skills are discussed below.

Acceptance and support are essential. A mentor helps the protégé articulate his or her dream and then blesses it. The support should be unconditional. That doesn’t mean that the protégé is praised for every action, including the goofs and vapid moves. It does mean that through it all the protégé can count on the mentor to attentive and affirming of his or her younger colleague as a person.

Sponsor the protégé. Be seen with them at important events and with important people. Recommend them to those who can help and open doors for them. Broadcast their triumphs. Give
them important assignments in the profession. Guide them to the resources they need. Point out which prizes are worth pursuing and show them who can be trusted and who might not be trustworthy—and teach them how to determine these things for themselves.

Protégés, especially as they begin to hit their stride, deserve to be challenged. By matching challenges to the level of the protégé’s competence, mentors guide development. It is a gradual process that may call for a scaffolding of safety from time to time. Challenges should be matched with high expectations for excellence. Protégés should not have to guess what constitutes excellence, whether excellence is expected of them, or whether their mentor believes they are capable of achieving excellence.

Mentors should model the behaviors protégés need to learn. They can demonstrate both dental and interpersonal accomplishment. They should also go beyond and reveal the complexity and balance they have achieved in their own lives. A single-dimension mentor is quickly recognized as shallow and has to resort to “do as I say and not as I do.” It helps if protégés can hear reflections from the mentor on why they are doing the things they do, what the critical cues are to monitor, what counts as success, and even that all outcomes may not be successful but each provides an opportunity to learn.

There is a difference between judging (seldom helpful) and providing feedback (very necessary). In the first case, one is expressing a personal point of view; in the second, information is provided that will help the protégé perform better in future. Feedback involves calling attention to gaps in performance outcomes and standards and invites a discussion of how this came about. Occasionally, a mentor will misunderstand the importance of immediately, clearly, and forcefully confronting career-damaging, unprofessional, or destructive habits on the part of the protégé. “That is personal,” they say to themselves. Wrong; the mentor-protégé relationship sanctioned by a professional group makes questionable personal behavior a central concern. There is no part of mentoring that is more important than challenging a protégé to build sound values.

Managing the Relationship
Mentoring relationships are complex; they do not always run true. Of course, they require time, and one of the vulnerabilities to which any process that unfolds over four or five years is subject is loss of interest or inconsistency in meetings and follow-through, especially on the part of the busy mentor.

But it is the emotional aspects of managing a relationship that are typically most challenging. On occasion, romantic or sexual or pathological involvements develop in mentor-protégé relationships, just as they do in other close pairings. It even happens that mentors are accused of these when they are quite innocent of everything except the need to document unusual behavior and seek outside professional help at the earliest
warnings. When the protégé fails conspicuously or commits some self-defeating or unethical gaff, the mentor suffers guilt by association.

Some degree of idealization is to be expected in the healthiest of processes. It is best to expect it, but not comment on it. It is also to be expected that the mentor will grow initially to a very strong power position with respect to the protégé. Again, this can be expected, but should be recognized tacitly and nothing more. Emotional attachment and friendship, on the other hand are normal and healthy. If the mentor is not joyous over the protégé’s accomplishments and if a mutual frankness and interest in small details of each other’s personal life fail to emerge, it is a warning that the relationship is souring.

One of the sayings engraved at the Delphic oracle in ancient Greece is generally translated as “know yourself.” A preferred translation would be “know your place.” Mentoring is not for everyone. The essential trait is self-awareness or authenticity, in the sense that mentoring only makes sense as a natural extension of who one really is. If indulged in as a form of ego aggrandizement, it will spill failure and perhaps disgrace. Mentors must be able to “walk the talk.” Their actions, their descriptions, and their motives must all be congruent. When they say, “I believe you will make a difference to the profession some day and I am willing to work with you on that,” they had better mean it all the way through.

**Concluding the Relationships**

The mentoring relationship is like an airplane trip. It must come to an end, it is hoped, just at and not before its planned time. There is a built-in mechanism in mentoring that brings most of them to conclusion in four or five years. It happens because the protégé grows faster then the mentor and because their world changes around them. A longer relationship should be viewed as suspicious of pathology. The goal of mentoring is to create a peer, not a dependent.

It is unfortunate when successful mentor-protégé relationships just drift apart. They should be celebrated. A dinner or other formal occasion would be nice. The mentor should summarize the accomplishments of the protégé—a grand reflective narrative—and should officially recognize the colleague as a fully-fledged peer. The former protégé should say thank you. At that point the profession will stand higher than it did previously. That is worth celebrating.

**A Suggestion**

Perhaps the American College of Dentists can take a leadership role in supporting mentors among its Fellows who will infuse the values of the College into the young men and women entering the profession. We know the value of this activity; we know how to do it; and no one could do it better.

Here is how it might work. Interested Sections would ask schools in their areas to provide the names of graduates with the highest potential for future leadership and would recruit from among Fellows those willing to consider becoming mentors. Perhaps the young men and women could be invited to a Section dinner meeting to facilitate possible pairings.

The Central Office would provide a manual for mentors, outlining the goals of mentoring, suggestions such as those that appear in this essay, and suggested activities. Examples might include visits to each others’ offices, sponsorship at College meetings, attending professional meetings together, and an occasional breakfast or lunch. Each activity would carry a predetermined point value.

As Fellows accumulate points for their work, they would receive recognition from the College, culminating at some point in awarding of a pen of recognition and confirming of the formal designation “Mentor of the College.” In the meantime the professional would have been enriched and there would be a cadre of emerging leaders from which to recruit new Fellows to the College.

The mentor must be able to say with conviction, “the profession will be better when I retire if I work with this young man or women.”
Recommended Reading

Summaries are available for the three recommended readings marked by asterisks. Each is about eight pages long and conveys both the tone and content of the original source through extensive quotations. These summaries are designed for busy readers who want the essence of these references in fifteen minutes rather than five hours. Summaries are available from the ACD Executive Offices in Gaithersburg. A donation to the ACD Foundation of $15 is suggested for the set of summaries on generations; a donation of $50 would bring you summaries for all the 2006 leadership topics.


Coaching is defined as the sum of all the skills that develop others; mentoring is the one of these that focuses on self-development of others. Shift from manager as a doer to manager as a coach. Full of practical ideas, this book is easy to follow—it is essentially a fat outline.


Mentoring is a multi-year relationship designed to promote professional growth, for both the protégé and the mentor. The book is modeled on Strunk and White’s classic, *The Elements of Style,* that has taught generations of students to write clearly. Each of the fifty-seven “elements” of mentoring is prefaced with a short case, followed by two or three pages of narrative and three to six actionable recommendations.

Johnson teaches at the U.S. Naval Academy and Johns Hopkins University; Ridley teaches at Indiana University and works as a consultant. The book is short, clear, and rich. It would make a nice gift.


Mentoring is defined with a twist—to be centered on personal learning of the mentee, with a specific nod toward the personal growth of the mentor. Filled with lots of “nice sounding words” and worksheets, the text seldom goes beyond the surface. Perhaps this is intended as a workbook for a course. The author is a consultant and trainer, specializing in leadership development and coaching.