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Standards:
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excellence, ethics, professionalism,
and leadership in dentistry**

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- 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;
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Cover image There are many ways to measure up. See last quarter's issue.

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From the Editor

The Fine Art of Being Logical

One of the less popular branches of philosophy, logic, does not do much to tell dentists how to practice. But sometimes, when we get it wrong, it suggests to others that we are dealing off the bottom of deck.

Logic comes in three flavors: (a) deductive; (b) inductive; and (c) abductive.

The first category is about consistency in the things we say. Internal contradictions make others suspicious. The ADA Code of Professional Conduct says that ethical dentists must report continuous or gross faulty treatment. Dr. Overlook fails to do so. Therefore the dentist is unethical. Where deductive logic so often fails us is when the facts have not been determined or when there are hidden assumptions. “No individual

who perforates a tooth on a restoration should have a dental license” leaves a lot of wiggle room. The premise may be equivocal. It applies in initial licensure examinations but not necessarily in practice.

Mostly deductive logic is about the meaning of words. An argument that has the right form may nevertheless be meaningless. My brother cannot be an only child. “We should perform RCT rather than placing an implant where there is inadequate bone, and it does not look good to me, so I will do the endo” is logically sound. But it may be questionable dentistry since “It does not look good” may be a bad call. Wagging a righteous finger at colleagues for possible logical inconsistencies adds the insult of irrationality to a disagreement over cases. As the brilliant, Middle Ages logician Thomas Aquinas recommended, when in deductive difficulty, make a distinction.

The scientific base for dentistry is inductive (also known as inferential logic). We reason from multiple particulars to generalizations. We are warranted in maintaining that composites “generally” have a shorter longevity than amalgams because qualified people have carefully, and under controlled circumstances, reported that, on average, that is what one finds.

Deductive arguments often contain the word “all.” Inductive arguments “never” say that. Induction deals in probabilities. If an experiment produced similar outcomes in many

cases, it probably will in future cases as well. That is what the p-value measures. But probability means something different to researchers and to practitioners. Clinicians want to know the likelihood that a product, material, or method will fail. Graft A may be successful in 46% of the cases and graft B in 49%. With a large enough sample size, research could demonstrate the statistical superiority of graft B. Neither technique is promising. There is a movement in dental journalism to require that research studies report the measure of effect (what clinicians care about) as well as p-values (the concern of researchers).

Many are unfamiliar with abduction, the third form of logic. Here the inference is from observations to the best explanation. Findings can support multiple interpretations. Abductive statements contain the term “because,” or words to that effect. An RCT with a tiny p-value could be the second or third best explanation for what is happening. Most phenomena of interest in dentistry have multiple causes. One should not confuse “best evidence,” a term of art for methodological rigor, with best explanation.

There are five recognized criteria for abduction: (a) testability; (b) utility; (c) scope; (d) simplicity; and (e) conservatism.

Conspiracy theories are not *testable*. “The reason the patient did

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not respond well to my faith healing of her oral disease is that she did not believe strongly enough." There is no research that can say otherwise. A good explanation is *useful* in the sense of leading to meaningful intervention. Saying that some individuals do not value oral health because they do little to seek care sounds undeniable. But it is a bit circular and does not help fix any problems. A good explanation also accounts for more than one particular case; it *has scope*. *Simplicity*, or economy of theory, is also a characteristic of good explanations. Few moving parts, an

absence of *ad hoc* assertions, and parsimony are all good. A theory that *conserves* what people already believe and is consistent with related theory is better than one introducing novelty.

In 2004, I reviewed and advised against publishing a manuscript. All reviewers rejected it with prejudice (I know because I checked). It was published anyway "due to a clerical oversight." A newly reported toxic disorder was characterized by pain, depleted energy, memory loss, and sometimes worms crawling in the skin. It was identified in seven women, all of whom showed clinical improvement as a result of treatment at the author's clinic, which included general health practices such as diet and rest and removal of restorations containing calcium hydroxide.

Does this paper pass the logic test? It was claimed that "resolving the symptoms [the effect] by removing the material [the cause] confirms this cause-effect relationship." Technically this is not a valid deductive argument since affirming the consequent does not prove the antecedent. It hardly passes the test of inferential logic since the fact that seven women who went to a clinic got better does not prove that being a woman causes awful skin conditions. Finally, there are holes in the abduction. Although the hypothesis is testable it was not tested (and quite possibly there would be

objections to the standards of scientific testing). It is not useful to link a small number of cases to a private treatment, and little insight is afforded into other similar conditions. A lack of simplicity can be seen in eschewing established dermatological theory. The fact that the article three times mentions the location of the clinic violates the standard of using, where possible, existing explanations. Something new, which the author alone can provide, is said to be needed.

Logic in dentistry is about weaving together what we know and sharing it. Deductions should use terms unambiguously and consistently. Induction should be grounded on a sufficient number of clearly operationalized cases to project a pattern. Abduction, the tough one, means giving better explanations for the facts that all can use.



Readers Respond

Letters to the Editor

Is There Only One Standard of Care?

Letter to the Editor:

The “Defining the Standard of Care” article by Dr. Jerrold was entirely superlative. However, no matter how expertly the description is made, the difficulty in defining such an amorphous concept tends to lead to further confusion. I came across a particular area contradicting another particular area. Dr. Jerrold noted that “If a physician fails to keep current or fails to use current knowledge in the treatment of a patient, the physician is negligent.” However, the two schools of thought concept may offer a competing view to the “keeping current” standard.

An example would be the two schools of thought regarding the diagnosis and treatment of temporomandibular disorders (Brown & Greene, 2017). The old school of thought, with a relatively large group of clinical dentists, favors a dental occlusion model. While the new school of thought is based upon

Is the standard of keeping current more important than allowing another standard which is held by clinicians who refuse to accept the newer standards which have been developed through scientific research?

experimental data derived through randomized controlled trials and favors stress as a major disease factor. As the evidenced-based concept is the current accepted view by scholars, educated clinicians, and academic clinicians, and the occlusion-based concept has not held up to scientific scrutiny, but that both clinical concept groups are well-represented in numbers of clinicians, there appears to be competing standards of care.

So it appears to me that it is impossible to discern one standard of care for this issue. Here is my questions for Dr. Jerrold: Is one concept of the standard of care superior to another? Is the standard

of keeping current more important than allowing another standard which is held by clinicians who refuse to accept the newer standards which have been developed through scientific research? This issue was apparent in regard to the treatment of President Garfield, when his physicians did not believe in hand hygiene with regard to palpating the wound to find a bullet and resulted in the president’s painful death (Ehrhardt et al, 2018). The view of educated physicians at the time was that washing hands previous to operating was an important means of decreasing deaths due to sepsis. How does the law value evidenced-based medicine and dentistry compared to the two schools of thought concept?

Sincerely,

*Ronald S. Brown, DDS, MS, FACD
Washington, DC*

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Response

I want to thank Dr. Brown for bringing up a very important point: the numerous shades of gray inherent in our jurisprudential system.

One gray area is that the laws governing a variety of issues relating to professional negligence are not uniform among the 50 states. The quote he attributed to me is actually part of one of Pennsylvania's Jury Instructions. Other states may or may not hold similarly. The "two schools of thought" doctrine also varies among the states. Where the doctrine is applicable, the judge issues a jury instruction on how it is to be employed and the jury then decides how that relates to the defendant's conduct. This is based in large part on the testimony of the expert witnesses who have opined as to how much weight should be afforded each school of thought and why.

Dr. Brown is absolutely correct that it may be "...impossible to discern one standard of care for [a given] issue". But that is precisely what makes the law, as exercised in the United States, so wonderful. It is fluid, it is responsive, it is precise, and it allows for flexibility in application.

Today's science often rebukes yesterday's science. That is called

evolutionary learning. As a profession we have recognized that fact by defining evidence-based dentistry as incorporating the best evidence with a practitioner's clinical experience, giving due preference to input from the patient. We must accept that depending upon the patient's presentation, the differential diagnostic smorgasbord, and the myriad of therapeutic approaches available, there may not be only one way to address a particular problem. I applaud the grayness, it makes me human.

*Laurance Jerrold, DDS, JD, FACD
New York, New York*

Erratum

The editor apologizes for misidentifying in the spring quarter's editorial the author of the *Gies Report on Dental Education* and former editor of this journal. His name is William Gies.

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President-elect's Address

Light

Stephen A. Ralls, DDS, EdD,
MSD, FACD

September 5, 2019
San Francisco, California

Good morning. Fellows, guests—welcome to San Francisco, and congratulations to our incoming class. I am extremely honored to address you this morning. I welcome you to the last Annual Meeting and Convocation before the hundredth anniversary of our founding next August.

You will hear the term *ethics* used often at this meeting and other college events. We offer courses, materials, resources, and we tend to highlight ethics in our journal. And after years in the making, under the direction of Dr. David Chambers, our major *American College of Dentists Report on Ethics, New Professionalism*, will soon be released. In part, to prime the pump for that event, I want to give you a few things to ponder this morning, along with a few questions. The context is two very broad groups: habitually unethical dentists and the rest of dentistry.

I think we in this room would generally agree on what most of the problems in dentistry are, but maybe not so much on the answers. “If only we had more ethics,” some would say. Here’s a question: do any of you actually know *any* dentist who would admit to being unethical? “Who me? No way! Not my office!” The problem, of course, is that some actually are unethical, and trying to generate improvement where there are such distortions has obvious inherent difficulties. A sprinkling of ethics is not the answer. We need the light of ethics, but it must shine where it is most needed.

No, we don’t need more “cow bells.” Take the dentist who is disciplined for significant infractions. What do we do? Well, the prescription often includes having the offender take a course in ethics. Yes, that is right, please take a course just like the one that did not work the first time around back in dental school. Think about it for a minute. Will an unethical dentist even take one course in ethics if they are not forced to do so?

Here is another perspective. We have offered free online courses in ethics for almost 20 years, and these for CE credit. Before we added some protective measures, we actually had a few dentists who would rapidly take the tests on a bunch of courses, only to see what the answers were. They would then immediately retake the tests, answers in hand, and score 100% on all the retakes. With this rapid-fire approach, ten courses could be completed in about a half an hour, and there was obviously no attempt at reading the material. Ten hours of CE in 30 minutes is not bad. Mind you, these are courses in *ethics*! Unbelievable. Sickening, actually. I am sure you have your own stories to tell. The point is, sometimes we find ourselves trying to push our way through a door that says “pull.” Yes, I know, we take consolation because, it is said, the cream always rises to the top, but unfortunately, as we occasionally see, so does the pond scum.

Dr. Ralls is president and former executive director of the American College of Dentists; smugcod@gmail.com.



We cannot change anything unless we recognize there are problems that demand action. The issues are often so insidious they creep up without warning, and it is only over a longer period of time that you can stand back with some perspective and ask, “How did that happen?” Here’s a question. If everyone calls an orange a lemon, does the orange become a lemon? Look at our profession. Is it becoming a lemon that we still call an orange? Dentistry has changed and is changing. Yes, we need questions and dialogue, but we also need more.

We talk about commercialism, student debt, third-party influence, and other problems—and virtually all have ethics overtones or implications. I think we do agree that we cannot just sit there. Doing nothing is *not* an option. Nobody is thrilled to just stand by and watch another lug nut fall off the wheel. There is an old saying in the Navy, “You can’t steer a ship that isn’t moving.” Well, regarding ethics, we *are* moving. But are we going in the right direction? What I mean by that is, are we effective? Does our emphasis on ethics change anything, or does it merely assuage our professional guilt? After dealing with this subject for well over 20 years, I certainly recognize the outstanding progress made on some fronts. But I also know we do not need more ticket-punch approaches that are a hundred miles wide and one micron thick. Scratch, sniff, and poof—it is gone. Some of this stuff is really just ethics cosmetology...an ethics dust-off...ethics in name only.

A popular question in dental circles seems to be: can you teach ethics?

My answer is, yes, of course. It is a subject like math or biology. But that is not the real question is it? The real question is: Can you change behavior through an ethics course, or materials, or other resources? Well, I am confident there are some out there who would still act like frauds even if they have taken every single ethics course known to humanity. The mere knowledge of ethical values—veracity, justice, autonomy, you have heard the list—does not change anything for the good or bad. It is not the regurgitated profession of ethical values that is important. It is the possession of ethical values—the adoption of those values into a way of life, a way of practice. Adoption of values and standards can make a difference on outcomes, but of course, that is the challenge is it not?

And importantly, you *cannot* have an unethical outcome by accident. There has to be some level of intentionality. From a practical standpoint, every unethical act in a dental office is associated with an antecedent decision that led to the action—even when camouflaged by longstanding bad habit patterns. Obviously, unethical behavior has to be distinguished from unintentional missteps that are due to, for example, defective materials, poor treatment conditions, misdiagnosis, mistakes in judgment or treatment—even medical

Moral leadership shines a bright light that sets an example in a broader context.

issues and incompetence. That dynamic—that unethical actions stem from deliberate decisions—leads to another point.

Why do we do *anything*? That is another million-dollar question. It has been said that the reasons behind all *bad* actions fall into one of three general categories—at least for the sane person: greed, power, or sex. And I would throw in desperation as a fourth category. Jonathan Edwards, third president of Princeton and noted intellect of the eighteenth century, essentially put it this way: we always decide or choose based on the strongest inclination we have at the moment of the decision. We like to think that decisions are guided by ethical principles, but decisions are also shaped by various motivations and temptations. We may be on a diet, but then along comes a hot fudge sundae, and so much for that.

So, as Tom Peters said, “If you’re not confused, you’re not paying attention.” Let me be clear on one point so there is no confusion. Ethics courses, materials, publications, and dialogue are vital for those who want to improve and strengthen their knowledge and understanding of ethics. They are invaluable in exposing students to professional ideals and standards. And for the receptive

The point is this: People *affect* other people! People *shape* other people! We see how others act in different situations and conditions and we often follow their lead.

student and dentist, they can influence behavior. They also have considerable value in raising the visibility of ethics and associated issues to the profession and the public—keeping the topic on the front burner.

What can be questioned, however, is the ability of such courses and resources to convert behavior in the unethical—to change the unethical to the ethical. We hope for positive transformation, but we also silently acknowledge that CE and resources are not the secret elixir of conversion therapy. For the habitually unethical, educating a path to a higher plane of virtue is a very tall order indeed. So,

where does that leave us? The habitually unethical represent a fairly small and not-so-responsive group, estimated at 20% to 30% of the profession. And although we should not quit on them, we no doubt have greater impact when focusing on the more-receptive sector of dentistry using personal approaches that complement the courses and resources. And hopefully, over time, fewer and fewer bad apples emerge, or thrive.

The Real Thing

Let me illustrate one of these approaches with a short story. J.T. was born in 1913 in central Maine, the youngest daughter of four children. Her middle-class family soon moved to Oakland where not long after, her mother died of cancer. J.T. persevered and went on to graduate from high school at the age of 16 as valedictorian. In the midst of earning a certificate to teach junior high school, her father died suddenly of a heart attack. She regrouped and went back to earn a bachelor’s degree, then eventually found herself enrolled at Forsyth Dental Infirmary in Boston as a dental hygiene student. There she was class president and graduated second in her class. J.T. was teaching at Forsyth in the early 40s when war broke out. In support of the effort she joined the WAVES and was commissioned an ensign in the Hospital Corps, which in itself was a very rare distinction. She was promptly sent to San Diego where she was put in charge of about 70 hygienists. Soon thereafter she met another young officer, got married, and had a family of three.

Things were going along in story-book fashion until one hot summer day. It was a Monday afternoon in the San Joaquin Valley, August 24th, 1964. The family was about to change

significantly and indelibly. J.T.’s only daughter, Chris, was pushed into the shallow end of a swimming pool, her head hit bottom, and she was instantly paralyzed from the neck down—one minute an active 13-year-old, the next minute a quadriplegic. As one might expect, it was the type of tragedy that can tear a family to shreds—total chaos, extreme stress, and throw in a suffocating feeling of despair to boot.

But through all this there was one very bright light that shined. From day one, over the good days and bad, J.T. was a steady beacon of love, hope, and resolve. Little did J.T. know, she would not have one good night’s sleep for almost 30 years. It did not matter, she just got stronger attending to the business at hand, taking care of her daughter, dealing with the situation in the only way she knew how. There was no whining, no crying, no complaining, no pity parties. In time, and with the ship steadied, Chris went on to graduate from college, and even earn graduate degrees. J.T.? Well, she lived to be 100, faculties intact, still making her own meals, then dying in her sleep, never having experienced significant hospitalization or the thrill of assisted care.

Okay, I know what you are thinking. That is a tragic story and all, but what does it have to do with the college and ethics? Maybe you need to go hug a cactus. Let me answer this way. One way that behavior is changed is by modeling other people we respect: a family member, a colleague, a teacher, a friend, clergy, or someone else. Sometimes it is conscious, sometimes subconscious.

And as you probably figured out, J.T. was my mother, Chris was my sister. I was a young teenager when I lived through that horror show. I only

made it through by following the unquenchable light given off by my mother. I saw firsthand how to deal with adversity through her example. The point is this: People *affect* other people! People shape other people! We see how others act in different situations and conditions and we often follow their lead. And let us be clear, it does not take a tragedy for an influential light to shine. It can simply be a dentist modeling another dentist's way of practice. I could just as easily have used a less-dramatic example from my own dental mentors and colleagues, or my wife Laura, or my father, or others. Think back to the people in your own career who influenced you, who shaped you, those you modeled, as well as those who took you under their wing and mentored you. Those were your beacons of light. The modeling-mentoring approach is one way. But I have to caution, although anyone can change, that approach only works insofar as someone is receptive to it, which typically excludes the habitually unethical, but often includes students, new dentists, and younger dentists.

Spread the Light

Another way to shine light is through ethical leadership. I have mentioned the problem of reaching the unethical or less-than-ethical dentists. As you know, some practice on the extreme fringe of "acceptable" behavior, or beyond it. Others hide behind a cloak of respectability. It is a challenge. If we do nothing, we are rightfully criticized for tacit approval. It is not a situation where we can just kerosene the ant hill. But we are not powerless either. You are all leaders in different areas, such as organized dentistry, education, specialties, state boards, military, industry, and more. And you interface with dentists from different sectors.

Moral leadership shines a bright light that sets an example in a broader context. A profession is supposed to be largely self-regulating, but I'm not talking the ethics police here. I'm talking leading by example, by leaders with standards, who embody standards, who radiate standards. This larger-scale approach is accomplished through your influence in organizations, boards, councils, committees, presentations, publications, and communications.

In the end, a profession is only as ethical as its tolerance for low standards and unethical behavior allows it to be. Infections of lower standards should concern all of us, and could end up defining us. I do not think we can wait for bureaucracies to solve this issue. I do not think they can. They can help, but keeping dentistry strong as a profession is really up to us. We will shape the future of dentistry. The question is the direction. Yes, the road can be bumpy and there can be frustration with obstacles and circumstances. It's our responsibility, not something for others to do.

This afternoon you will see a torch leading the procession into the Convocation. Metaphorically, the torch lights the way for the profession. If you think about it, light is a funny thing. Light erases dark, but not the other way around. Dark does nothing to light. We do not assess levels of darkness, we use light meters. When faced with darkness, we instinctively look for light. Light reveals. Light exposes. Light can harden materials, or melt snow. Light can disinfect, but it can also repair, renew, and bring life. As fellows, we have a light to

carry into *all* corners of the profession. We can be a transforming influence. That was essentially the basis for fellowship in the first place—recognizing dentists with high standards who could serve as models to a struggling profession that was mired in problems. I sincerely and respectfully ask—urge—each of you to act on the opportunities you have to shape others in the profession as a mentor, a model, a guide, a teacher, and as a person of influence, as a policy maker, and as a leader.

The profession does have challenges, and those can lead to fragmentation. And, as Vance Havner put it, "When the tide's low, every shrimp has its own puddle." Yes, some feel we are beginning to face an ebb tide, but this is a time for strength and determination and unity. Encourage and reinforce the good, confront the negative, and correct the correctable. It is something each of us can do, and should do.

Fellows, I can't state this any clearer, the profession needs you and your influence...and your leadership. You lead...you *lead*. You can change the direction. You can change the scenery. You carry a torch. Light a path to a better, stronger profession. We need a profession, not a lemon. Light works. Shine brightly. ■

Convocation Address

Lifelong Excellence and Ethical Leadership in Service of the Public

Mary Jo White, MA, JD

September 5, 2019
San Francisco, California

To begin, let me heartily congratulate the some 300 new fellows who today join the American College of Dentists, which constitutes only 3.5% of your profession. You are a diverse group and hail from 47 of the 50 states, Canada, Europe, Australia, Jordan, and New Zealand. The armed services are well-represented and you are graduates of all 66 U.S. dental schools and schools in every province of Canada. It is also great to see all of the women...but who's counting.

The American College of Dentists is rightly regarded as "the conscience" of dentistry and you have been chosen for your integrity, unselfishness, high professional ideals, and ethical leadership. You are expected to represent these ideals for the rest of your lives. These traits will appear as energy, deep commitment to enhancing oral health standards, selflessly helping your communities, and by being leaders, role models, and mentors. Most importantly, this will be reflected through serving your patients with excellence, honesty, and respect. And, here you thought you had already made it when the heavy-lifting is just beginning.

The title of my remarks is "Lifelong Excellence and Ethical Leadership in Service of the Public." Don't worry, this will not be a long philosophical dissertation. I am the practical type and just want to sound a couple of themes.

First, I want to pause briefly on what it means to be "a professional" in society today, whether it be as an oral health professional like you are, a lawyer like I am, or a teacher, a physician, or a handful of other callings that are preceded by extensive learning and training followed by a work life dedicated to skilled and critical public service.

Second, as the title of my remarks foreshadows, I do want to urge that all professionals strive for lifelong excellence and ethical leadership in everything we do, demanding most from those of us who have had the good fortune to rise to the top and to be recognized as leaders.

What Is a Professional?

So, what does it mean to be a professional? Although we have each spent most of our adult lives working to be one and then working as one, it is always worth a brief reminder. Two quick definitions:

The first comes from the National Labor Relations Act, which defines a professional as someone "engaged in work, predominately intellectual and varied in character, as opposed to routine or menial, involving the consistent exercise of discretion, and judgment in its performance, requiring knowledge of an advanced type acquired by a prolonged course of specialized intellectual study, in an institution of higher learning." Not bad, but a bit dry and incomplete.

We do better by looking for definitions of "professional" as an

Mary Jo White served as the 31st chair of the Securities and Exchange Commission from 2013 to 2017 and was the first and only woman to be the United States Attorney for the Southern District of New York.



adjective rather than a noun. There, we find these attributes: accomplished, adept, expert, skilled, admirable, excellent, highest quality, model, leader, and ethical. That's more like it; now, we recognize ourselves.

But, just to be sure we fully appreciate our station in life, a word about what it does *not* mean to be a professional. It does not mean an easy life, becoming rich, or receiving universal acclaim or praise. In fact, your profession shares with mine the dubious distinction of being number one or two—or thereabouts—in some surveys of the ten most hated and least respected professions. Must be “fake news.” I hasten to add that other surveys show that the public's trust in dentists, along with other health professionals, remains very high. Still, we both attract more than our share of unflattering jokes.

You have your Orin Scrivello and lawyers have our Donald Gennaro. Who are Orin Scrivello and Donald Gennaro? Well, Orin is the sadistic dentist who enjoys inflicting pain on his patients and who, to very loud audience applause, is eaten by Audrey II, the gigantic Venus fly trap in “Little Shop of Horrors.” Donald Gennaro is the nerdy, greedy, children-disliking attorney in Jurassic Park, who is eaten by the T-Rex while hiding in the port-o-john to the absolute glee of movie goers across the country. At least these are dated stereotypes and yours is a clearly exaggerated caricature of a

What is harder is to always act upon what we know to be ethical, irrespective of criticism, negative financial or personal consequences, or disappointing some people you care about.

dentist, while the lawyer in Jurassic Park is, I fear, much closer to the mark.

I think that the reasons for our common fate in some of the surveys are probably quite different. You, again come out better and, by the way, those of you in military service rank at the top across the boards and are highly valued. Your service of country seems to eliminate any negatives.

In the case of oral health professionals generally, you may be underappreciated at times because your work comes (or at least is perceived to come) with some invariable discomfort and pain. No one likes pain, and our universal aversion to it spills over to you, the service providing professional. Although a lot has been done to make dentistry less painful and to alleviate the public's fears, the poll numbers persist. So, too, for the legal profession, and for more troubling reasons.

For lawyers, the low rankings appear to go beyond the work we do to essential character flaws. Much of the American public seems to think that most lawyers are dishonest, arrogant, and care only about making money. Pretty bleak. Those kinds of negatives

require major surgery if not a whole rethink by the legal profession of who we let join our ranks, how we train young lawyers and how we behave once we are admitted to the bar. Like you, lawyers practice for a long time (40-50 years on average) so we have an extended period of countless interactions with the public we serve. That translates into a lot of opportunities to be on our best behavior. And importantly, it also means sufficient time to learn from our mistakes and to improve.

Being a Strong Professional

With that dose of humility, let me pivot to how great it is to be a professional and, in particular, a dentist or lawyer. First and foremost, it is because we are not just merchants in the marketplace; we have a higher calling to serve the

public's best interests. We have the opportunity to not only practice the profession we have chosen everyday, but also to be positive, indeed, critical, even life-saving forces for our clients and patients.

There are many attributes of a strong professional. I will talk about only two: excellence and ethical leadership. My pitch is that we can best elevate our professions, in fact and in the public's eyes, by a commitment to excellence in every interaction we have and by demonstrating ethical leadership in every decision we make. This is also known as "doing the right thing." And, of course, mentoring and teaching others to do the same is part of the program.

Excellence

Excellence is one of the four core values of the college. It is also the lodestar for how to deliver lifelong public service at its best. It is an attribute that applies to how well we do in school and training and to each crown, implant, or legal argument we make. It is an aspirational standard by which we should measure every job we do and how well we have served each client. As President Connolly said at your 2018 annual meeting, the ACD has "made the choice to push ourselves to be the best we can be."

An esteemed federal judge in New York, Edward Weinfeld, once said that

he treated every case—big and small, simple and complex, high-profile and routine—exactly the same because it was his duty to give each matter his all. He also rightly observed that, to the litigant in his courtroom, their matter was the most important case in the world and how the judge acts, talks, and rules each time will be the basis on which permanent judgments are made about the entire judiciary.

Judge Weinfeld was known for arriving at court at 6:00 am six days a week for his entire 40-year career. Upon arriving at the courthouse on his last day, at the age of 86, he declared, "I do so with the same enthusiasm and excitement that was mine on the very first day of my judicial career." He said something else I very much agree with. "What one enjoys is not work, but rather joy." I venture to say that Judge Weinfeld regarded his life of hard work as joy because of how high he set his lifelong

What one enjoys
is not work, but
rather joy.

bar for excellent performance. There is indeed pride and a lot of personal and professional satisfaction in doing the best job we can on everything we touch. That kind of striving for excellence is also apparent to the public we serve.

I have been practicing law for over 40 years, about half as a government official and half as a lawyer in the private sector. Despite some misconceptions, there is an obligation to deliver excellence in both places.

Emory Buckner, a famous U.S. Attorney in New York in the 1920s

and an esteemed private practitioner as well, said the following about public service. "A private lawyer is always in session. He takes his client's troubles home with him, sleeps with them, breakfasts with them, never loses sight of them. The United States which honors and trusts us is entitled to receive at least as much as a merchant who buys legal services over the counter. Let us give to Uncle Sam everything we have. When we leave government service, we want to be able to say that we have given to the public all that was in us—all the intelligence that we have, all the brains that we have, all the judgment and loyal service that we had to give."

So, too, for all professionals. We should demand of ourselves a lifelong commitment to excellence. We will do a lot of good if we do, both for our clients and our professions, not to mention ourselves.

Ethical Leadership

Let me turn to the most important thing I want to say to the 2019 class of fellows. Live and breathe ethical leadership. Despite trying as we might, we will invariably not get a grade of "excellent" on every job we do. But we can, without fail, always do the right thing, as we see it. And when the opportunities present themselves, we can also teach ethical leadership to others.

In my experience in leadership positions, frankly I have found that it is not usually hard to figure out what the right thing to do is. After a little study and thinking, we know. What is harder is to act consistently upon what we know to be ethical, irrespective of criticism, negative financial or personal consequences, or disappointing some people you care about.

It is important when we identify unprofessional behavior to use the deviation from our standards, not only as a teaching moment for peers, but also as the occasion to explain to our clients and patients how unacceptable such behavior is.

David Ozar, an honorary fellow of the college, tells us that we in professions that should regard ourselves as operating on a “normative” model that prioritizes serving our communities and clients’ best interests, rather than following a business model that maximizes our own personal and financial interests. Very good advice and the key to ethical leadership.

There are daily choices we all make, which require that we consider the ethical and right thing to do. Lawyers often have to decide, for example, whether we can represent multiple clients in the same or related matters or whether doing so would create a conflict of interest. If one client could avoid being sued by the government by providing evidence against another client, you can’t do right by both of them, as much as you might try to rationalize it. In the end, you have to say no to one of them, even though you would like to take on the extra business.

Dentists, like lawyers, have to decide every day on the range of work they will recommend to patients. Should it be confined only to work that is needed for oral health or can it

appropriately include discretionary, cosmetic work as well? If so, what do you need to explain to patients about what is needed versus what may be desirable and the expense of both, so that they can make informed decisions? There are many other kinds of daily ethical choices involving, for example, treating elderly clients, prescribing pain medications, providing access to our services to those who cannot afford them, third-party payer questions, deciding whether we can decline to serve certain clients.

Some decisions are relatively trivial in consequence, others have significant impact. Doesn’t matter. Every one requires doing the right thing and often also requires of leaders that they also teach others, by word and example, about the importance of adhering to their moral compass in every encounter they have throughout their careers. The ethical dilemma videos that the college co-produces with the Indiana University School of Dentistry are very thoughtful, practical tools that can broadly teach every dental student and practitioner about ethical choices and professionalism. They help raise the bar for everyone.

When one of our own violates the duty to ethically serve the best interests of a client or patient, it hurts the entire profession. It is important when we identify unprofessional behavior to use the deviation from our standards, not only as a teaching moment for peers, but also as the occasion to explain to our clients and patients how unacceptable such

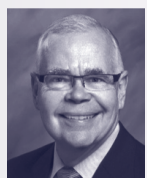
behavior is. The college’s website currently features just such a discussion and engagement tool involving a dentist who sparked unwelcome publicity when he was charged with insurance violations for repeatedly misleading patients to consent to extensive unnecessary work. The college’s openness and active engagement about this case and the importance of scientifically based oral healthcare is the conscience of your profession on display and ethical leadership at its very best. All professions should do the same.

Conclusion

Let me close as I began, by congratulating every new fellow. You have achieved much and are the leaders of your profession. Enjoy and celebrate your well-deserved recognition and success. But also always remember that, as fellows of the American College of Dentists, you now have new responsibilities to fulfill. Embrace and celebrate those too. ■

2019 ACD Awards

William John Gies Award



The highest honor the college can bestow upon a fellow is the William John Gies Award.

This award recognizes fellows who have made broad, exceptional, and distinguished contributions to the profession and society while upholding a level of leadership and professionalism that exemplifies fellowship. The impact and magnitude of such contributions must be extraordinary. The recipient of the William John Gies Award for 2019 is **Dr. Charles J. Goodacre**.

For more than five decades, Dr. Goodacre has motivated, educated, and inspired us to embrace lifelong learning and imbue the tenets of professionalism. He is regarded by many as the “educator’s educator” and he has earned the reputation as clinician-scholar of the highest caliber.

Dr. Goodacre earned his DDS degree from Loma Linda University School of Dentistry in 1971. Subsequently he completed a three-year combined program in prosthodontics and dental materials at Indiana University School of Dentistry and in 1974 earned his MSD degree. Charlie began teaching in 1974, and more than 40 years later he continues to find time for teaching dental students and advanced education students. He codirected the implant dentistry course for dental

students at Loma Linda University for more than ten years and each year provides national board reviews in tooth morphology and occlusion for dental students. He has maintained a part-time private practice limited to prosthodontics since 1974.

His teaching style is worthy of emulation and, not surprisingly, he routinely received awards from senior dental classes at Indiana University as the outstanding clinical instructor or outstanding lecturer. He received the Educator of the Year Award from the American College of Prosthodontists in 2003, the George H. Moulton Award from the American Academy of Fixed Prosthodontics in 2005, the Jerome M. and Dorothy Schweitzer Research Award from the Greater New York Academy of Prosthodontics in 2007, the William J. Gies Award in 2008 from the American Dental Education Association (ADEA) for Outstanding Innovation as a Dental Educator, and the Gold Medallion Award from the American Prosthodontic Society in 2010. In 2011 he was awarded honorary fellowship in the Faculty of Dentistry of the Royal College of Surgeons in Ireland and also the Distinguished Service Award from the American College of Prosthodontists. In 2012 the American College of Prosthodontists acknowledged him with the Distinguished Lecturer Award.

Dr. Goodacre was appointed as chair of the Department of Prosthodontics at Indiana University and as dean of the Loma Linda

University School of Dentistry from 1994 to 2013. He is a diplomate of the American Board of Prosthodontics and past-president of the American Board of Prosthodontics, the American College of Prosthodontists, and the Academy of Prosthodontics. More recently, Dr. Goodacre was honored by Loma Linda University as Distinguished Professor at the school of dentistry. The special merit rank is awarded to a full-time faculty member who has made distinguished contributions in teaching, research, publication, or creative work.

Dr. Goodacre served as an editor of the *International Journal of Prosthodontics* for ten years, has over 220 publications, and has delivered more than 500 invited presentations. His more recent educational activities have focused on the development of interactive, navigable electronic education programs with particular emphasis on 3D formatting, applications, and effectiveness. He continues to motivate, educate, and elevate his students to pursue professionalism not as a destination but rather as a journey.

The American College of Dentists acknowledges the enormous contributions in education, research, and leadership that Dr. Goodacre has made to the profession and to the public we serve and recognizes his efforts with the 2019 William John Gies Award.

Ethics and Professionalism Award



The Ethics and Professionalism Award recognizes exceptional contributions by individuals or organizations

for effectively promoting ethics and professionalism in dentistry through leadership, education, training, journalism, or research. This award is the highest honor given by the college in the area of ethics. This award is made possible by a generous contribution from the Jerome B. Miller Family Foundation. The American College of Dentists recognizes **Dr. Karl Haden** for his continuous promotion of ethical leadership through the Academy for Academic Leadership (AAL) training portal.

N. Karl Haden, PhD, is the founder and president of the AAL, a consulting and professional development firm focused on health professions education and the healthcare industry. His organization developed the ADEA Leadership Institute, which is designed for mid-career faculty members who desire to attain administrative roles within their own or other institutions or enhance their effectiveness in these roles. This year-long program, conducted in four phases, is ADEA's flagship career enhancement program and provides dental educators with perspectives about oral health policy and legislation, organization and financing of higher education, the dental

school's role within the parent institution, financial management, legal issues, recruiting faculty, and opportunities to acquire and practice skills associated with effective leadership. ADEA Leadership Institute fellows also explore team building, personality preferences, leadership styles, emotional intelligence, stress management, work-life balance, strategies for leading change, and giving and receiving feedback, as well as engaging in self- and peer-assessment throughout the year.

Dr. Haden's formal education is in religious studies, the humanities, and philosophy, studies to which he credits many of his perspectives on leadership. Dr. Haden has authored numerous articles and monographs in educational leadership and policy and is a frequent speaker at national and international conferences. Dr. Haden is president and CEO of AAL. Since AAL's founding in 2005, Dr. Haden and AAL have worked with more than 150 U.S. and international higher education institutions, associations, and businesses through AAL's professional development programs and consulting services. Dr. Haden oversees ongoing leadership development initiatives for numerous organizations, including the American Association of Colleges of Osteopathic Medicine, the American Association of Oral and Maxillofacial Surgeons, the American Dental Education Association, the Dental Trade Alliance,

and the Interprofessional Education Collaborative. His areas of expertise include leadership, organizational change, team building, strategic planning, and curriculum development.

Dr. Haden has authored or coauthored more than 80 articles and monographs. He is the author, along with AAL Senior Fellow Rob Jenkins, of *The 9 Virtues of Exceptional Leaders: Unlocking Your Leadership Potential*. Dr. Haden is an honorary fellow of the American College of Dentists and a fellow of the Center for the Study of the Great Ideas. In 2017, Dr. Haden was honored by the ADEA Gies Foundation as recipient of the Gies Award for Achievement—Public or Private Partner.

Outstanding Service Award



The Outstanding Service Award, given since 1995, recognizes fellows for specific, outstanding service

to dentistry, the community, or humanity. This award is presented through a special recommendation of the Board of Regents, and the 2019 recipient is **Dr. Guy N. Minoli**.

Activist and social reformer Jane Addams famously opined that "action is the sole medium for the expression

of ethics” and action is precisely what Dr. Minoli took in the development and maturation of his highly acclaimed dental ethics program.

Dr. Minoli earned his baccalaureate degree from Fordham University and his DDS degree from the State University of New York, Buffalo School of Dentistry. Subsequent to graduation from dental school in 1983, he completed a general practice residency from New York Presbyterian Hospital/Cornell Medical Center, where he later worked as the supervisor of that program. He has also served as the chief consulting dentist at Mary Manning Walsh Nursing Home, president of the Eastchester Dental Society, chair of the New York Section of the American College of Dentists, and president of the New York Academy of Dentists.

Dr. Minoli is currently an assistant professor at Cornell Weill Medical College, where he is a faculty member of the General Practice Dental Residency Program. He is also a member of the American Dental Association, the New York State Dental Association, the First District Dental Society, the American College of Dentists, and the New York Academy of Dentists. Dr. Minoli helped to create a nationally awarded mentorship program for young dentists. As a fellow of the American College of Dentists and chair of the New York Section, Dr. Minoli recognized the need for the deliberate commitment to future fellows of ACD.

Through his vision and support he founded the ACD Mentoring Program, which started in 2013 and which now invites all 17 New York metropolitan postgraduate programs to a lecture series that promotes a culture of leadership, ethics, and mentoring.

This landmark program, which received the Section Achievement Award from the American College of Dentists, serves as a national example for all sections of ACD. The program introduces young dentists to the tenets and principles of professionalism upon which the college was founded. Dr. Minoli has been an ethics facilitator at New York University, Columbia, and Stony Brook dental programs for more than 20 years.

Throughout his long and distinguished career, Dr. Minoli has sought to foster and encourage ethics education and active participation in organized dentistry with the many residents that he has trained and continues to train. Dr. Minoli understands that the responsibility of professionals extends well beyond the treatment room into the community at large.

Honorary Fellowship

Honorary fellowship is a means to bestow fellowship on deserving non-dentists. This status is awarded to individuals who would otherwise be candidates for fellowship by virtue of demonstrated leadership and achievements in dentistry or the community except that they are not dentists. Honorary fellows have all the rights and privileges of fellowship except they cannot vote or hold elected office. This year there are four recipients of honorary fellowship.



The first recipient of honorary fellowship is **Karen M. Fischer**. For the past seven years, Ms. Fischer has served

with distinction as the executive officer for the Dental Board of California. She has considerable administrative skill, which she brings to her executive position on the board, and is regarded as a champion for ensuring that the protection of the public is the primary focus on all issues that come before the board. While the licensing and regulatory functions are primarily legislative in nature, the disciplinary functions for the “protection of the public” are a primary responsibility of the executive officer, and Ms. Fischer is masterful in the management of this responsibility. She is widely regarded as a process person and an adroit administrator who implements board-approved policies and actions in real time. Under the direction of the board, she and her staff rolled out the first portfolio examination for initial dental licensure pathway for California in 2013. This process consumed more than three years from development to implementation.

Ms. Fischer graduated from the University of California, Davis, where she received a bachelor of arts degree in German. She continued her education by taking evening classes at California State University, Sacramento, where she earned a master’s in public administration.

Prior to selection as the executive officer for the Dental Board of California, Ms. Fischer enjoyed a diverse professional background that included executive and administrative positions in health care, labor unions, consulting firms, and the California State Senate. These experiences have helped shape her world view and prepare her for the unique challenges

of motivating, evaluating, and training of 79 staff members and managing a \$16 million budget in the execution of the mission of the Dental Board of California. Her curriculum vitae reveals a level of dedication and commitment to the public good that is in keeping with the finest traditions of public service.



The second recipient of honorary fellowship is **LaVette C. Henderson, CMP, CVEP, HMCC.**

Ms. Henderson began her professional career in accounting and included hospitality in 2001, when she joined the National Dental Association (NDA) team full time. She was promoted through the ranks to chief operating officer of the NDA and presently serves as the deputy executive director. The NDA represents more than 7,000 committed oral healthcare professionals providing outreach, advocacy, and leader development both nationally and abroad. Ms. Henderson's passion is advocating for vulnerable and underserved populations and she has worked tirelessly to identify populations at risk and to promote both access and equity in the healthcare system. She has fostered a close professional relationship with the Congressional Black Caucus in Washington, DC, and she is well known and respected on the Hill.

Ms. Henderson holds a bachelor of science degree in management (magna cum laude) and an associate's degree in accounting, and is a certified meeting professional. She is a veteran, having served five years in the DC Air National Guard as a medical technician. With more than 30 years of experience, this citizen-soldier

commands a diverse skill set that includes critical thinking, project management, leadership skills, contract negotiation, event programming, content development, resolution-focused team building, and strong logistical and analytical skills. She is accomplished in association, conference, and financial management. Ms. Henderson also serves as the executive liaison to the NDA Corporate Round Table and reinforces impactful partnerships and collaborations that are essential to operationalizing the missions of the NDA.



The third recipient of honorary fellowship is **Christopher Scott Litch.** Mr. Litch is chief operating officer and

general counsel for the American Academy of Pediatric Dentistry (AAPD). He coordinates AAPD's internal operations and planning; directs the AAPD's government relations and public policy agenda; and manages legal issues affecting the AAPD and pediatric dentistry. He serves as secretary to the AAPD Political Action Committee, member of the AAPD Constitution and Bylaws Committee, and staff liaison to the AAPD Council on Government Affairs. Mr. Litch organizes the annual Pediatric Oral Health Advocacy Conference in Washington, DC, and manages the state Public Policy Advocates program.

Prior to his 20-year tenure with the AAPD, Mr. Litch worked on legislative and regulatory issues at the American Dental Education Association in Washington, DC, for 11 years, ultimately as general counsel and associate executive director for government and institutional relations. He received a juris doctor degree from the University of Maryland Francis King Carey School of Law, a master's degree from the

Sanford School of Public Policy at Duke University, and a bachelor's degree from the University of Maryland, Baltimore County. He is a licensed attorney in three jurisdictions (District of Columbia, Illinois, and Maryland) and certified association executive. He received the 2012 Association Professional Achievement Award from the Association Forum.



The fourth recipient of honorary fellowship is **Kay Mosley Miller.** Ms. Miller began her relationship with the

profession of dentistry nearly 40 years ago after completing undergraduate studies in nursing at Oklahoma State University. Her commitment to healthcare outcomes and continuing education led her to ambulatory outpatient care with a keen interest in dentistry. Subsequently, she became a board-certified dental assistant with considerable savvy in business and practice management. Her policy expertise was forged in academic dentistry during the many years she served with distinction as the executive assistant to the dean of the University of Oklahoma School of Dentistry.

Ms. Miller's service to the Oklahoma Dental Association is the stuff of legends and she, more than most, understands the importance of healthcare equity. Her "access to care" advocacy platform was developed during her tenure with Delta Dental of Oklahoma from which she retired in 2012. Ms. Miller has spent the balance of her professional life working for the profession for the expressed benefit of the public we

Congratulations to all ACD award winners.

serve. She has championed access to care initiatives and healthcare reimbursement incentives for the most vulnerable members of society.

Ms. Miller has received numerous awards and honors, including the inaugural Kay Mosley Distinguished Service Award of Excellence, the highest award given by the American Dental Assistants Association Foundation. She was also awarded the United States Army Dental Command Certificate of Training from the American Dental Assistants Association. She has been a member, board member, chair, and president of many organizations throughout her storied professional career, including the president of the American Dental Assistants Association.

Ms. Miller is deeply committed to the mission of the college, and every

year she volunteers time and talent to champion its expressed initiatives. Her career is characterized by lifelong service with impactful contributions to the fields of dental advocacy and education as evidenced by scholarship, volunteerism, and community service.

Section Newsletter Award

Effective communication is a prerequisite for a healthy section. The Section Newsletter Award is presented to an ACD section in recognition of outstanding achievement in the publication of a section newsletter. The award is based on overall quality, design, content, and technical excellence of the newsletter. The **British Columbia Section** is the winner of the Section Newsletter Award for 2019.

Model Section Designation

The purpose of the Model Section Program is to encourage section improvement by recognizing sections that meet standards of performance in four areas: membership, section projects, ACD Foundation support, and commitment and communication. This year the **Arkansas Section**, the **Kentucky Section**, the **Nebraska Section**, and the **Wisconsin Section** earned the Model Section designation.

Lifetime Achievement Award

The American College of Dentists Foundation honors fellows who have completed 50 years of fellowship in the American College of Dentists. The individuals named below were inducted in 1969 and were honored for their achievement during the Annual Meeting Business Meeting

of the College in San Francisco on September 5, 2019. This award consists of a medal and certificate and is supported by the Samuel D. Harris Fund.

Edward B. Armstrong
Boca Raton, Florida

Earl M. Behning
Minneapolis, Minnesota

Charles L. Bolender
Lake Forest Park, Washington

John B. Burns
Cheyenne, Wyoming

Arden G. Christen
Indianapolis, Indiana

Patrick D. Crowe
Honolulu, Hawaii

Ted L. Harper, Jr.
Palm Desert, California

John G. Kramer
Martins Ferry, Ohio

Sidney LaPook
New York, New York

J. Wendell Lotz
Cincinnati, Ohio

Richard A. Shick
Grand Blanc, Michigan

Heber S. Simmons, Jr.
Jackson, Mississippi

Richard S. Youngs
Adrian, Michigan

2019 Fellowship Class

Regency 1

Hannah Ahn
Fairfield, Connecticut

Hemali M. Ajmera
Bayside, New York

Shelly M. Anderson
Halifax, Nova Scotia

Peter R. Auster
Pomona, New York

Meredith A. Bailey
Boston, Massachusetts

Stephen N. Bakios
Portsmouth, Rhode Island

Leonard J. Brenner
Brooklyn, New York

Samuel P. Carocci
Orchard Park, New York

Theresa A. Casper-Klock
Auburn, New York

Dolores A. Cottrell
Albany, New York

Benjamin R. Davis
Halifax, Nova Scotia

Lucretia A. DePaola-Cefola
Wilton, Connecticut

Thomas G. Duplinsky
Orange, Connecticut

David L. Fried
Wallingford, Connecticut

Geraldine C. Garcia-Rogers
Chelmsford, Massachusetts

Peter M. Gershenson
New York, New York

Gary S. Goldstein
Niskayuna, New York

Matthew Hall
Syracuse, New York

Richard A. Holden
Breadalbane, Prince Edward Island

Nadeem Y. Karimbux
Boston, Massachusetts

Douglas B. Keck
Guilford, Connecticut

Mina C. Kim
New York, New York

Sylvain Laforte
Saint-Lambert, Quebec

Constantinos G. Laskarides
Boston, Massachusetts

Rebekah Lucier-Pryles
White River Junction, Vermont

Stuart A. MacDonald
Glace Bay, Nova Scotia

Kenneth S. Magid
Harrison, New York

Jean-Francois Masse
Quebec City, Quebec

Michael J. McGarvey
Syracuse, New York

Thanh-De Nguyen
Town of Mount Royal, Quebec

Richard Raftus
Halifax, Nova Scotia

Kadambari Rawal
Brookline, Massachusetts

Paul C. Schoenbeck
Shelburne, New Hampshire

Pasquale Scutari, Jr.
North Syracuse, New York

Gina M. Terenzi
Boston, Massachusetts

Carroll-Ann Trotman
Boston, Massachusetts

Regency 2

Edward C. Adlesic
Allison Park, Pennsylvania

John L. Alonge
Erie, Pennsylvania

Shan K. Bagby
San Antonio, Texas

Caitlin S. Batchelor
Harrisonburg, Virginia

Cheryl B. Billingsley
Manakin Sabot, Virginia

James M. Boyle III
York, Pennsylvania

Karin D. Brian
Coatesville, Pennsylvania

Sandra J. Catchings
Staunton, Virginia

Sayward Edwards Duggan
Yorktown, Virginia

Steven A. Guttenberg
Washington, DC

Daniel Hammer
Virginia Beach, Virginia

Andrew I. Horng
North Potomac, Maryland

Elizabeth D. T. Hunnt
Poquoson, Virginia

William S. Hunt
Poquoson, Virginia

Harry Jackson
Kailua, Hawaii

David M. Kaffey
Lansdale, Pennsylvania

Marcel G. Lambrechts, Jr.
Sandston, Virginia

Kim A. Menhinick
Bethesda, Maryland

Amanda R. Nelson
Fairbanks, Alaska

David D. Nelson
Fairbanks, Alaska

Dustin Reynolds
Lynchburg, Virginia

Harold B. Snyder III
Frederick, Maryland

David A. Sullivan
Pittsburgh, Pennsylvania

Melissa Tucker
Fort Polk, Louisiana

James W. Willis
Burke, Virginia

Mark S. Wolff
Philadelphia, Pennsylvania

Lisa N. Yarbrough
Mililani, Hawaii

Regency 3

Ferdinand V. Allison III
Durham, North Carolina

Robert J. Beall
Mount Pleasant, South Carolina

Stanley R. Beard
Jackson, Alabama

Angela M. Broome
Chapel Hill, North Carolina

John T. Carlson
Tuscaloosa, Alabama

William Davie Cranford, Jr.
Rock Hill, South Carolina

Isaiah L. Davis, Sr.
Columbia, South Carolina

Jennifer D. Davis
Vestavia Hills, Alabama

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Adel S. Khalil
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Voluntary Consensus Standards

A Pathway for Constructive Solutions

Beverly Oviedo, MS

Abstract

Standards are voluntary guidelines that coordinate actions in related activities. Thus they promote predictability, coordination, efficiency, and cost-savings. Standards organizations include an international coordinating body, the International Organization for Standardization, and national and industry groups. In the United States, the American National Standards Institute has designated the American Dental Association as the responsible party for dental standards in the areas of information and products. An example is given of how standards work in dentistry and how a standard for environmental sustainability was developed in dentistry.

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Standards make things work, not just consistently, but better. The standards to be discussed here provide world-class specifications for products, services, and systems to ensure quality, safety, and efficiency. Almost all industries develop and apply standards to their products and services. Firms within industries such as manufacturing, technology, agriculture, and health care agree to common standards rather than compete against each other with diverse standards. This is win-win logic.

Standards are criteria for materials, processes, and outcomes that make it easier for those involved in collaborative activities to coordinate what they do. If specialists can count on the referring general practitioners having performed a work-up using a generally accepted protocol and agreed-upon calibration of diagnostic equipment, the hand-off is faster, smoother, more accurate, and less expensive than would be the case where practitioners all followed their own rules. If practitioners purchase arch wires or impression material or invest in expensive equipment such as CBCT or CEREC, they save time, avoid unexpected outcomes, and improve predictability of outcomes.

Thus it is in the interest of organizations representing groups that regularly interact, as well as the members of those groups, to voluntarily agree to standards. Virtually all involved in oral health belong to multiple groups that participate in standards setting. This includes being aware of relevant

standards, sometimes participating in standard setting, and an ethical obligation to maintain standards—all for the common good.

It will probably not come as a surprise to learn that there are standards for setting standards. There is a worldwide recognized structure for this. At the top level is the ISO, the International Organization for Standardization, based in Geneva. The ISO structure is organized around countries rather than industries. So the ISO provides overall guidance, establishes standards at the highest level, and recognizes technical advisory groups (TAGs). Dentistry is TAG 106. The ISO also recognizes national groups concerned with developing standards.

In the United States, the ISO recognizes the American National Standards Institute (ANSI). ANSI is one of the 164 organizations representing countries at ISO. This group, a non-profit headquartered in New York, recognizes the American Dental Association (ADA) as the group responsible for TAG 106. The ADA has two standards groups or standards committees: SCDI, which is concerned with dental informatics hardware and software selection, digital photography, interoperability, and data security, for example; and SCDP, which sets standards for products such as arch wires and composite restoration materials.

ASTM International, formerly the American Society for Testing and

Materials, is a separate organization that researches and publishes standards. ASTM is one of the largest standards development organizations in the world. It develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. ASTM currently has more than 12,800 published voluntary consensus standards in use around the world.

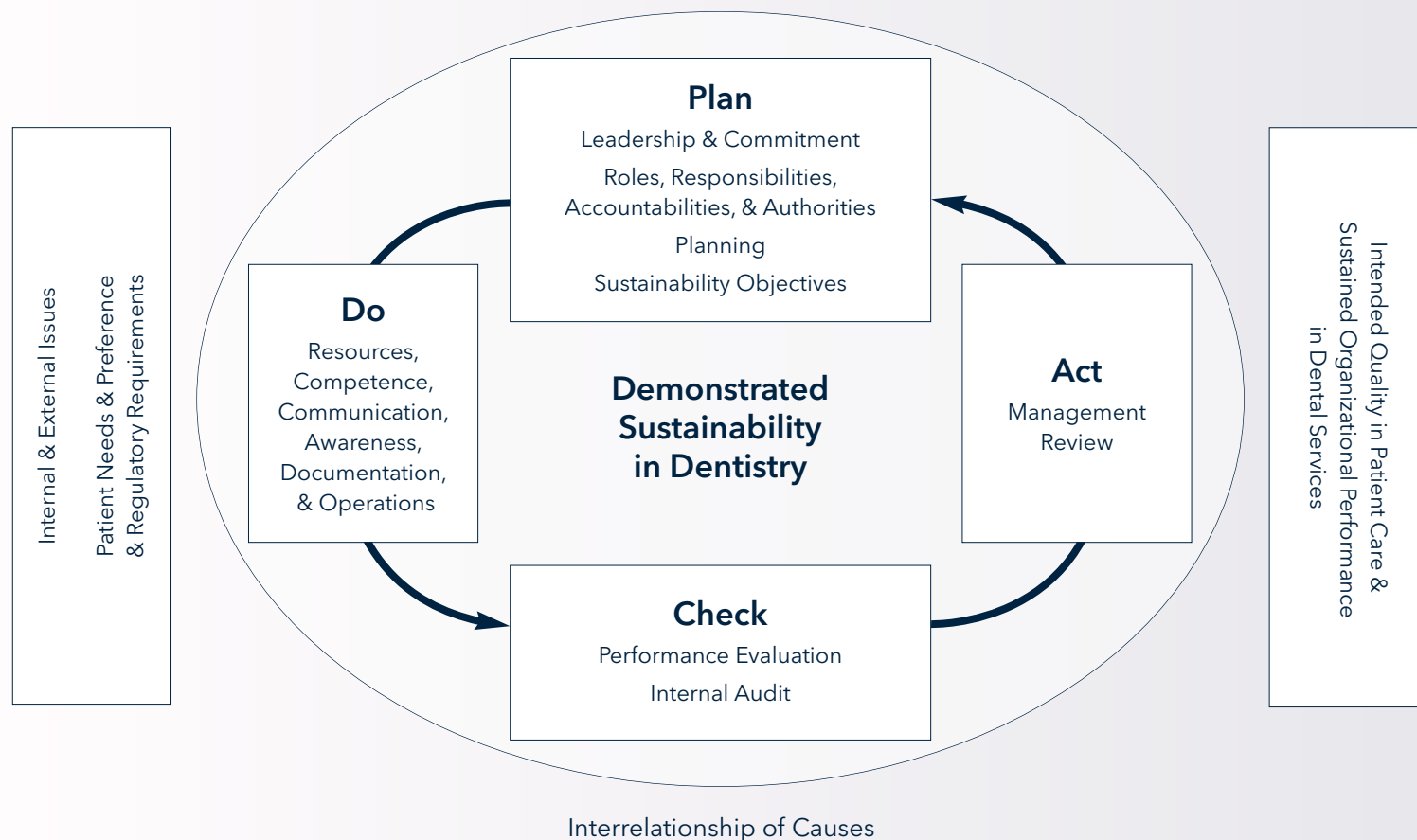
The National Institute for Standards and Technology is a branch of the U.S. Department of Commerce, with a campus in Gaithersburg, Maryland, and is a research institute devoted to increasing technology competitiveness through research.

All of the organizations mentioned above are not-for-profit. All develop or recognize other organizations or standards. Use of standards is voluntary and none of these organizations monitors or polices adherence. Standards organizations are funded principally through the sale of standards. For example, the ADA sells ISO 7787-2:2000 (Dental rotary instruments, Cutters Part 2: Carbide laboratory cutters), which specifies the dimensional and other characteristics for the 11 most common carbide cutters, which are predominantly used in the dental laboratory. ISO 10477:2018 (Dentistry, Polymer-based crown and veneering materials)

classifies polymer-based crown and veneering materials used in dentistry and specifies their requirements. It also specifies the test methods to be used to determine conformity to these requirements. This document is applicable to polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns. It also applies to polymer-based dental crown and veneering materials for which the manufacturer claims adhesion to the substructure without macro-mechanical retention such as beads or wires. The first standard is offered for sale at \$70; the second for \$138.

FIGURE 1. Context of Dental Service Organization; Management System for Sustainability in Dentistry

Example of an approach for integrating sustainability into the culture of a dental service organization



An Example

Putting dental standards into a real-world perspective, ADA published in *ADA News* an article titled “3D Printing in Dentistry Focus of Ahlstrom Award Recipient’s Projects.” The article outlines how Dr. Suvendra Vijayan, an assistant professor in oral and maxillofacial radiology at the University of Pittsburgh School of Dental Medicine, won an award for putting together a “well-designed and executed paper that incorporated standards-based informatics research,” said Dr. Greg Zeller, chair of the ADA Standards Committee on Dental Informatics and a member of the award selection committee.

Dr. Vijayan’s project was the perfect example of the practical application of dental standards. According to *ADA News*, “Dr.

Vijayan used a 3D printer to create 30 different virtual models of ten mandibles, using CBCT DICOM images. The virtualization was done using a fixed standardized protocol, and he measured them using 24 linear cephalometric measurements. Dr. Vijayan found no difference in reliability across models made from different voxel sizes, thus concluding that the study ‘successfully showed that the reliability of measurements made on 3D printed models of dry skull mandibles...are valid, reproducible and reliable and can be used for diagnostic and clinical purposes.’”

“With the progress in 3D printing, it is a matter of time before it becomes mainstream,” Dr. Vijayan told *ADA News*. “The major idea behind my

research was to prove that cone beam CT images can be used to accurately print human anatomy structures.”

Developing Standards—Sustainability in Dentistry

Since October 2008, ASTM International Technical Committee E60: Committee on Sustainability has been actively developing standards focused on sustainability in areas such as building and construction, water use and conservation, manufacturing, and more. As a result, dental sustainability currently falls under the jurisdiction of the E60.80 Subcommittee on General Sustainability Standards.

E60 recognizes mainstream adoption of sustainability standards in the dental industry, relying on building consensus industry standards. Technical experts from industry, government, trade associations, and academia work collaboratively to create a framework for standards related to sustainability that can be integrated into the organizational culture to facilitate decisions. These decisions give equal consideration to people, planet, and profit.

ASTM E3014-15 (Standard Practice for Managing Sustainability in Dentistry) provides comprehensive guidance on managing sustainability issues in dental practices. It also creates a systematic approach to assist with identifying, prioritizing, supporting, and addressing relevant sustainable development issues in a dental service provider’s practice.

In 2011 Eve Cuny, then-director of environmental health and safety at the University of the Pacific Arthur A. Dugoni School of Dentistry, identified the need to create a standard for managing sustainability in dentistry.

The industry’s size and scope represents a significant environmental and social footprint that can be managed in ways that reduce costs, mitigate risks, and capture opportunities for dental providers. The steps in this process are listed below.

- On June 30, 2011, a proposal for the concept submitted to ASTM.
- On December 11, 2012, ASTM International News Release announced the approval for development of the proposed new standard.
- A working group of stakeholders was formed that included experts in the dental, business, and sustainability industries. The working group was developed under E60.80 General Sustainability Standards, part of the ASTM structure, as work item WK34710.
- On September 15, 2013, working group activities were initiated.
- Over the following one and a half years, the working group met with interested stakeholders to share information and gain a consensus necessary for adoption of the standard. ASTM members were requested to comment on the proposed standard. It was necessary for the working group to address any negative comments. A standard cannot be adopted unless it receives 100% approval from ASTM members.
- The standard, *Practice for Managing Sustainability in Dentistry*, was

Standards make coordination among practitioners... faster, smoother, more accurate, and less expensive and save time, avoid unexpected outcomes, and improve predictability of outcomes.

adopted in 2015 by ASTM International's 30,000 members, including representation from 140 countries.

ASTM E3014-15 starts by outlining a specific approach to integrating the value of corporate social responsibility throughout the organizational culture. This begins with dental leadership championing the standard in organizations where it is to be implemented. The success of the management system depends on commitment from all parts of the organization as well as identifying and engaging stakeholders.

ASTM E3014-15 includes such a framework (Figure 1). The standard is applicable to all sizes of organizations. It is based on the PDCA Cycle of Plan-Do-Check-Act, which represents the management processes for implementing sustainability in the organizational culture and is based on continual improvement. A first step is the development of a sustainability policy, which outlines the organization's commitment to decision making that ensures ethical and environmentally friendly practices. Following the standard's step-by-step approach ensures that the dental service organization can operate in a more sustainable way. This includes reducing its carbon footprint, adopting "green" practices, and considering the well-being of all stakeholders in its business decisions.

This same thought process can be applied to dental standards developed to advance sustainability in the dental industry. With enough

commitment to the integration and application of these standards in everyday dentistry, the overall changes can have positive impacts on dental providers, their patients, and, ultimately, society at large.

In order to advance further standards resources, E60.80 is forming a task group to develop another new standard for General Requirements for Dental Facilities, Equipment, Consumables, and Staffing for Managing Sustainability in Dentistry. Anyone with subject matter expertise or other material interests in this topic is welcome and encouraged to join the task group and aid in the development and approval of this and any additional future ASTM International standards. ■

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Evidence-Based Dentistry and Clinical Guidelines

Carlos Flores-Mir, DDS, DSc

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Abstract

Evidence-based dentistry is defined as the integration of clinicians' judgment from experience, the best research evidence from the literature, and relevant patient values. Although there are various reasons offered for not fully adopting EBD, it should be realized that research evidence need not be comprehensive and conclusive to be of value. Systematic reviews and clinical guidelines are often useful summaries of available evidence. The practice of shared decision making where both dentists and patients consider the relevant evidence has much to recommend it.

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Historically, clinical decisions in dental practices have been characterized by an emphasis on the professionals' training and prior experiences. A new paradigm, evidence-based dentistry (EBD), has been increasingly advanced by various stakeholders. (See the theme issue on EBD in the fourth issue, 2010, of this journal.) EBD is considered a clinically practical method for using available, even imperfect, scientific evidence to inform and manage clinical problems, along with the consideration of patients' values and preferences and clinical expertise or informed clinical judgment (Glick, 2019; Guyatt, 1991).

Inconsistencies exist between available scientific evidence, but its uses chairside are common in all healthcare fields (Norton et al, 2014). Several perceived barriers to its use have been identified. Awareness or knowledge by itself does not change behavior. Simply suggesting that clinicians use available evidence has not been a satisfactory approach. It has been established that a blend of knowledge translation strategies is required to deliberately overcome specific and pre-identified barriers to influence clinicians' behavior (Oliver et al, 2014).

EBD has been misunderstood for several years. There is the misconception and oversimplification suggesting that EBD is mostly about published dental literature. Further, some feel that if a paper has not been read before a clinical decision is made,

the clinician is not practicing sound dentistry. Even worse, it is believed that if there is a clinical practice guideline (CPG) that applies, the clinician may face lawsuits if the recommendations contained in the CPG are not followed to the letter. Like everything in life, the truth is neither black nor white.

The purpose of this paper is to succinctly explain why practice based on evidence, when available and properly used, can benefit clinicians and patients. The intention is to also emphasize that even in the absence of high-certainty evidence, clinicians can still practice EBD day to day.

Why Bother with EBD?

EBD is a tool that includes three important components: (a) the clinician's experience and knowledge; (b) the patient's values and preferences related to the set of outcomes for the alternative interventions under evaluation; and (c) the desirable and undesirable consequences (outcomes) for each intervention as identified in the best literature (Zhang et al, 2017). See also the ADA statement on EBD.¹

It is important to understand what is meant by "best available evidence." First, it is impossible that there is no evidence whatsoever. There is always some evidence that specifically applies to each clinical situation. If it is severely limited, that does not prevent

The purpose of this paper is to succinctly explain why practice based on evidence, when available and properly used, can benefit clinicians and patients.

us from proceeding with treatment. Clinicians' experience still allows them to identify the patients who would benefit the most from the interventions under consideration. Respect for patients' beliefs and preferences in specific clinical situations is the next consideration. Even those clinicians who think they are not using scientific evidence are still using some form of evidence that they learned from dental school or from interactions with colleagues or notes taken during scientific conferences. That in itself is the application of some level of evidence every time a clinician makes a clinical decision.

The recent explosion of published science has increased the challenge of finding best evidence. First there has to be time for searching built into what it means to be a clinician. In addition, access to time-efficient and reliable sources may not be as easy as it sounds. There is an increased number of websites to guide clinicians.

If the evidence indeed exists and we have access to it, the next step is to critically appraise it since not all

evidence is created equal. Acquiring the skills to screen multiple papers, select the most efficient to answer our clinical question, and finally synthesize the findings in a reliable and accurate way is the next step. Time constraints on learning and routinely applying these skills is a realistic consideration. It is hypothesized that some preconceived views of EBD might result from lack of awareness of EBD basics. To the extent this is the case, practitioners should be encouraged to seek and attend educational programs specifically focused on EBD, so potential biased views of EBD are confronted and elucidated.

One significant problem in the daily use of EBD concepts is confusion over the role evidence plays in practice. Among some of the inaccurate views reported in studies are suggestions that dentists struggle to see value in using evidence to inform their practice, consider EBD impractical, or even regard it as a complicating factor in daily operations (Hannes et al, 2008; Wårdh et al, 2009). Further, some dentists perceive CPGs as restrictive to their freedom and research literature to be somewhat unreliable or inapplicable (Guncu et al, 2018; Hannes et al, 2018).

Barriers involved in the application of EBD principles have been identified by dentists. Among these, the most

commonly mentioned are financial constraints and a shortage of time, hence the necessity of creating and implementing initiatives to increase access and to turn traditional scientific formats into more straightforward presentations. Therefore it has been proposed that systematic reviews (SRs) should be more accessible. It is also recommended that plain-language summaries and infographics would make them more approachable (Buljan et al, 2018). Finally, summarized versions, critical summaries, or CPGs associated with evidence identified by the SRs should be produced (Abt et al, 2012; Chambers et al, 2011). These formats, if properly presented, might represent useful alternatives for practitioners to access, since findings are expected to be presented in a more synthesized and contextualized way. If they are also easily accessed and at a minimal cost, we may have a winner.

Systematic Reviews

These highly stylized reviews follow a specific, detailed methodology to synthesize available evidence. A key component of SRs is the application of tools to grade the methodological rigor of the evidence associated with the desirable and undesirable outcomes for a given intervention. A widely used format is the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) (Guyatt et al, 2008).

Basic components of a well-conducted SR include a(n):

1. well-defined clinically relevant explicit question
2. comprehensive and explicit search strategy
3. broad approach to the literature using multiple electronic databases
4. selection of articles conducted in duplicate and independently
5. critical appraisal of the risk of bias

- of each included study individually
6. assessment of the certainty of the evidence (e.g., GRADE approach) for each outcome across included studies

Although all the criteria stated above are indispensable components of a well-conducted SR, the last one is the one that it could be argued every practitioner needs to fully understand as it implies the direct application of the synthesized evidence into clinical practice.

Clinical Practice Guidelines

Clinical practice guidelines are “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” (Institute of Medicine, 2011). A summary is available.²

Such CPGs are developed by several healthcare agencies and stakeholders with the purpose of assisting clinicians and patients with healthcare decisions. They are usually developed through consensus meeting and take a long time and many resources to be finished and published (Djulfbegovic & Guyatt, 2019).

CPGs are not fixed rules that must be followed at any cost but are proposed for practitioners and patients to ponder. While they recognize and describe generally recommended intervention sequences, they are not offered as a substitute for the direct opinion of the practitioner. Clinical guidelines inform but do not dictate, and guide but do not enforce.

Finally, CPGs do present management suggestions, called recommendations. Guideline panels gather evidence regarding a variety

of factors to weigh when producing these recommendations using the systematic review methodology described above. The evidence-to-decision framework, one of the most frequently used frameworks by guideline panels, considers the presentation of explicit judgments about: (a) the balance between desirable and undesirable consequences associated with the different treatment options; (b) the certainty of the evidence; (c) patients’ values and preferences; (d) resource utilization; and (e) health system-related equity, feasibility, and applicability (Alonso-Coello et al, 2016a; Alonso-Coello et al, 2016b).

Certainty of the Evidence and Clinical Decisions

Practitioners are often exposed to different clinical recommendations about the potential effect of a number of interventions on specific clinical scenarios. As important as the underlying evidence is the potential net benefit expected when these interventions are implemented. This can be shared and communicated to patients when implementing shared decision making (Légaré & Thompson-Leduc, 2014). Finally, the certainty of the evidence is a cornerstone piece as clinicians also need to know how much trust they can place in those recommendations. There is no such thing as an uncertainty-free world.

The certainty of the evidence in the context of CPGs represents how confident we are that the true effect lies within a particular range or on one side of a defined threshold (cut-off or decision line) (Hultcrantz et al, 2017). Another way to present this is to think about how confident we are that the reported effect estimate (amount of the expected response to treatment, either positively or negatively) is

similar to the likely actual effect of an intervention. When the certainty of the evidence is high or moderate, clinicians and patients can be confident that the estimates are supported by reasonable literature and evidence enough for direct clinical application. On the other hand, when the assessment is low or very low, clinicians and patients should be cautious when applying the reported estimate into their clinical treatment decisions as the actual or true effect value may be quite different. Also, in cases of low or very low certainty of the evidence, any well-conducted related study can change not only the magnitude but also the direction of the portrayed effect. The rules of the game can change quickly in these scenarios. Continuous monitoring of new related studies is required.

Summary

Practitioners and their patients need to delineate what are the most important outcomes that influence final clinical decisions. EBD provides to the involved parties the underlying body of evidence informing each outcome—in that sense, establishing the balance between the desirable and undesirable consequences among all interventions, assessing the certainty of the evidence across all outcomes, and accounting for the always limited resources in an attempt to determine whether the incremental benefit

expected from implementing a management approach is worthy of the additional costs (e.g., additional visits, possibility of progression of lesions to a more severe stage requiring more invasive means, additional radiographic testing). ■

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Ethics and the Law

The Merger

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LLM, FACD

Abstract

In addition to the ethics of how dentists treat patients, there are standards for what dentists owe each other and organizations that support the profession. Although these standards are usually expressed in legal terms, they all have a foundation in ethics. Examples are given of unjustifiable criticism, confidentiality and staff management, proper delegation of duties, transfer of records, cooperating with patients to defraud benefits carriers, and relationships with state dental boards.

While practicing law and dentistry over the last 20 years, consulting and defending dentists and other members of the healthcare professions in lawsuits and disciplinary matters, I have rarely, if ever, seen an allegation or cause of action that did not begin with an ethical violation. These actions include serious legal issues resulting in malpractice and other types of lawsuits, disciplinary actions by state dental boards, and Medicare and Medicaid violations with penalties. It has become apparent that ethics and the law are necessarily linked. The following are descriptions of actual cases confirming the merger of ethics and the law. The future of dentistry will be directly influenced by and dependent on how well each component of the profession—dentists, auxiliaries, management organizations, and governing bodies—manages, respects, and complies with basic ethical and legal principles.

Unjustified Criticism

I have often said that if it were not for dentists saying things they should not say—one dentist unjustifiably criticizing the work of another, fee issues, and record keeping among others—I could spend a lot more time on the golf course. I recently received a call from a dentist asking for advice and telling me that he was being sued by a patient. The patient had an old upper anterior bridge that would not stay in. The dentist had repeatedly

recemented it, each time telling the patient that the bridge was worn out and should be replaced. All of this was carefully documented. The last time the dentist recemented the bridge, the patient promised that when she returned from an out-of-town trip, she would have the bridge replaced. While on her trip the bridge came out again and she went to a dentist to have it put back in. This dentist told her that the bridge was terrible and that recementing it is a violation of the standard of care. Furthermore, he should make her a new bridge right now and she should file a malpractice suit against the original dentist.

My advice to the calling dentist was that he should let the one who made the replacement know that his actions appeared to be a violation of the American Dental Association (ADA) Principles of Ethics and Code of Professional Conduct, Section 4.C and 4.C.1. If he actually said what the patient reported, he may be guilty of slander and libel. I advised him that in the interest of full disclosure, he should inform the dentist, incidentally, that he is a member of the State Board of Dental Examiners. He followed my advice, and the offending dentist was very contrite and apologized. The situation between these professionals is fine now, but based on what the offending dentist told the patient, she

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may still pursue the lawsuit. The original dentist is still waiting for the statute of limitations to expire. Had the second dentist observed proper ethical protocol by merely contacting the first one, the entire issue could have been avoided.

Confidentiality

Ethical violations involving records and record keeping are very common and can result in severe consequences. Consider a recent case in which a patient came for extensive restorations involving implants and reconstructive procedures. A well-meaning dental office staff member was at a cocktail party some time after the diagnosis and treatment planning. The staff member made a casual comment that Ms. X is a patient, and she is having \$60,000 of work done. The comment got back to Ms. X, who was understandingly upset. She filed a suit, complained to the dental board, and notified HIPAA authorities. The lawsuit was settled for a six-figure amount, the staff member was terminated, and the dentist was disciplined by the dental board and the U.S. Department of Health and Human Services.

According to current law, employers are responsible for the actions of their staff, who in this case failed to follow ethical principles involving patient records and protecting patient confidentiality.

Delegation within the Scope of Practice

I received a call from a dentist who was facing revocation of his license for improper delegation. When asked what duties were involved, he told me that his assistants were allowed to take final impressions, seat crowns and bridges, and cut crown preparations. When asked where he got the idea that his assistants were allowed to do those things, he said he learned it at a seminar that taught how to make \$2 million a year in dentistry. Apparently the seminar was premised on maximizing the productivity of dental assistants and hygienists. It is possible that some of the delegation discussed in the seminar is allowed in some jurisdictions, while being prohibited in other states.

I asked as a matter of curiosity, “What do patients think about the assistants and hygienists cutting crown preps?” He replied somewhat defensively, “The patients sometimes say they are doing a better job than I was doing.” The dentist ultimately was allowed to keep his license, but he was severely fined and sanctioned. Adherence to the ethical guidelines and legal requirements of delegation would have avoided the consequences. It occurred to me that this practitioner also must face the challenge of improving his technical skills.

What Is in the Records When a Practice Is Sold

The transition process will include a transfer of ownership or maintenance of the patient records. There is an ethical responsibility to know what one is “buying.” After assuming ownership of the practice and beginning to treat patients, the buyer in a case I am familiar with found

numerous ethical violations. These included upcoding, charges for services that were not provided, missing consent forms, faulty treatment plans, solicitation, and dental treatment records that did not comply with ethical principles and dental board rules. In each case the unethical and illegal activity resulted in ample amounts to significantly affect the purchase price. In each case lawsuits ensued.

I have rarely, if ever, seen an allegation or cause of action that did not begin with an ethical violation.

In another case, a buyer purchased a practice and did not examine the financial records and business practices of the seller, who had a long history of improper marketing. The impropriety consisted of unethically soliciting patients by rewarding or directly paying others to refer patients to the office or paying individuals directly to become patients. As in the case above, the impact of these actions was large enough to dramatically affect the purchase price. As a result, the buyer decided (unwisely) that in order to make ends meet he would have to continue the illicit marketing process and gradually decrease it as his production grew. Unfortunately for this dentist, before he could cease the activity completely, he was confronted by the Attorney General’s Office with

a notice containing recoupment, fines, and penalties potentially totaling in excess of \$1 million. In this case, while the buyer did not examine the records and business practices and complete an adequate due process examination, the attorney general was very thorough. Evidence was presented that included statements from patients who received payments, statements from employees and marketers who presented the payments to the patients, bank statements, cancelled checks, and invoices from entities where gifts were purchased.

In both of the above cases, the buyers assumed that the sellers had been ethical in their business dealings, so they did not seek professional advice prior to executing the purchase contracts. In each case, because of the unethical infractions, the purchase price was grossly inflated, making it very difficult for the purchaser to meet the practice overhead and even make the loan payments.

A better result was achieved in another case. The dentist considered purchasing a practice with financial records indicating a significant amount of production. The buyer in this case obtained the advice of a professional who found irregular insurance claims, including unethical upcoding, billing for services not provided, and a policy of not charging or forgiving copay. Interviews with patients of the practice revealed that if a purchaser of the practice did not continue these unethical business practices the patients would cease coming to the practice. With these findings considered, the analysis concluded that the purchase price was grossly inflated. The purchase was declined, and the buyer avoided a potential disaster. The matter of the potential buyer's responsibility to inform the appropriate authorities

of a manifest pattern of gross or continuous faulty treatment as required by the ADA Principles of Ethics and Code of Professional Conduct in 3.C is an ethical one, but perhaps not a legal obligation.

Another consideration is ownership of the patient records. The owner of a dental practice filed suit against his associate of ten years when she left his practice and took the files of all the patients she had treated, including patients of the owner. In this case there was no contract including employment of the associate, no contract relative to termination of employment, and no restrictive covenant limiting the distance from her former office where she would be allowed to locate a practice. According to the dental board rules, patient records are owned by the treating dentist. In this case there would be dual ownership of the records since both dentists had treated most of the patients over the years.

The answer to the legal question is clear. Both dentists are entitled to ownership of the records. The solution to the problem then becomes an ethical issue, particularly for the associate. Even though she is legally entitled to the records, does she ethically want to take all the records from the office that had provided her employment and a professional home for over ten years? The two parties mutually decided on a procedure fair to all. An expensive litigation was avoided.

Bending Insurance Claims

Virtually all practitioners have encountered patients who want to alter the treatment date on an insurance claim or reduce or eliminate a copay. In a recent case, a patient

sought care under an assumed name and paid cash to get a discount and then filed an insurance claim under her real name in order to receive the insurance benefit. When the dentist refused to participate in this, the patient filed a complaint with the dental board. The State Board of Insurance is interested in this patient's unethical activities.

In another recent case a patient who had been severely injured in an automobile accident required extensive dental reconstruction. The patient convinced the dentist to radically inflate her fees. The result was excessive overbilling in violation of ethical principles and dental board rules. The insurance company spotted the excessive fees and notified the State Board of Insurance and the dental board. By complying with the patient's unethical requests, the dentist has not only engaged in unethical behavior but licensure and potential fraud legal issues as well.

The Noncompliant Patient

This problem is often encountered when orthodontic patients refuse to practice good oral hygiene, wear their elastics, or return regularly for adjustments and professional oral hygiene care. Occasionally when all else fails, the dentist chooses to terminate the doctor-patient relationship to avoid being held responsible for the consequences of neglect. When appropriate procedures are followed, this is legal. If good-faith

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and fully informed discussion is part of the decision, this may be the most ethical course of action as well.

Also in the noncompliant category is the adult patient who refuses to return as required and directed for necessary follow-up care. In a malpractice case, the patient came in with nondescript pain in the upper bicuspid area. The dentist obtained one periapical radiograph in the upper bicuspid area and four bitewings. He placed a couple of restorations in the lower molar area, but found no indications, clinically or radiographically, for treatment in the upper bicuspid area. He instructed the patient to return for observation in three months, or sooner if the pain persisted, for a follow-up exam. Despite repeated phone calls and attempts to reach patient, the patient did not return in the recommended three months. The office continued for two years (all documented) to try to reach the patient. Finally, after two and a half years, the patient returned, this time with severe pain and swelling in the same upper bicuspid area. The dentist attempted, but could not relieve the pain, so he referred the patient to an oral surgeon who extracted the bicuspid and first molar. In the process, the surgeon performed a biopsy that revealed a rare squamous cell carcinoma in the maxillary sinus. Ultimately, the patient had extensive radical surgery resulting in the loss of an eye and disfigurement.

A lawsuit for failure to diagnose was filed against the original treating dentist. During the discovery phase of the suit it was revealed that the patient had been examined during the two and a half years since the original dental treatment by an ENT physician

who made sinus radiographs. The physician did not diagnose, either radiographically or clinically, the malignancy or any other disease. Experts examined the dentist's records and could find no fault with the treatment the dentist provided nor any basis for him to diagnose a malignancy. The experts agreed that the documentation of the dentist's attempts to persuade the patient to return was exceptional and persuasive that he was acting in the best interest of the patient.

Patients in these types of cases, where they refuse to comply with a doctor's instructions, must be responsible to a large degree for their own well-being. All the evidence added up to a good defense for the dentist. The insurance company, though, decided not to go to trial, basically because of the appearance of the patient, and ultimately paid a large six-figure settlement. The dentist acted ethically all through the process in compliance with Section 1.A and Section 2.B of the ADA Principles of Ethics and Code of Professional Conduct regarding consultation and referral and attempting to allow the patient to be involved, but the patient did not respond in time.

The Ethical Standards of Organizations

It seems clear in the case just discussed that the dentist acted appropriately, even though the patient eventually suffered a significant medical problem. Some would want to know more about the actions of the malpractice carrier that paid out a large settlement that presumably increased the premium of all ethical dentists. Organizations have ethical and legal responsibilities.

Managing entities, or dental service organizations, are becoming

commonplace. They employ large numbers of recent graduates, often paying “signing bonuses” and requiring long-term contracts with severe penalties for breaches and premature terminations. In a recent case a young dentist accepted a large signing bonus and then terminated his employment after only six months in practice. He left his office of employment with no notice and abandoned his patients. He is now facing a large lawsuit from the dental service organization, which is seeking enforcement of the contract that stipulates returning the signing bonus and damages resulting from his premature termination, as well as allegations from the dental board for patient abandonment.

Dental boards generally are granted, by state legislatures, absolute authority over who is allowed to practice dentistry, rulemaking for the practice of dentistry, and punishment of those licensees who violate rules of the boards. Recently a state dental board deleted the requirement of high moral character (an ethical consideration) as a standard for licensure and substituted the authority of the dental board to require a mental and/or physical examination (a legal issue) for licensure. As a result of this change, cases of “suspected” mental disorder and “physical impairment” have begun to appear. In one case a dentist was accused of being mentally incapable and was prohibited from practicing until he completed evaluation and treatment for substance abuse and mental disorders. He was required to undergo psychological testing by doctors employed by a state agency. The first test was inconclusive for mental disorders but did show that the practitioner was not a substance

abuser. Still not allowed to practice, the dentist convinced the dental board to allow a second evaluation, this time with a different psychologist approved by the state. The result was the same. The board declared the inconclusive tests as positive for cognitive impairment and continued the practice prohibition.

The board was finally convinced to allow testing by a nationally known independent psychiatrist who was also an expert in diagnosing addictions. An agreement was made that both the board and the dentist would accept the decision of this psychiatrist. After two examinations, the psychiatrist disagreed with both state-sponsored psychologists and concluded that the dentist had no cognitive disorder. The expert explained that the dentist did not give the customary answers to the mental tests administered by the two psychologists because he had a different thought process due to an unusually high IQ. The evaluation further concluded that the dentist had no mental cognitive issues or substance abuse issues, was not a danger to the public, and could safely return to practice. The dental board dismissed the case and the dentist was able to resume his practice, but the process took 18 months and cost thousands of dollars in lost income and legal expenses.

A second dentist under the same circumstances had the case against him dismissed as well. But in the process this dentist lost his practice and his office building, and his license to practice dentistry was retired.

In each of these cases the allegations were anonymous, and the dentists were basically denied due process. It would appear that along with the primary duty of dental boards to protect the public from unethical practitioners, they themselves could apply the ethical duty of fairness to due process in investigating allegations against dentists.

Conclusion

The illustrations above confirm that the principles of ethics and the law are inseparably joined. This has been illustrated by examples of justifiable criticism, fair dealing, duty to refer, including patients in treatment decisions, and billing practices, and of the actions of organizations representing dentists or overseeing dental practice. The successful future of the profession will ultimately depend on how well each constituent of the profession manages, respects, and complies with the basic ethical and legal principles. ■

Organizations have ethical and legal responsibilities.

Dental Insurance

What Can I Expect?

Robert G. Sherman, DMD, FACD

Abstract

Not all practitioners, such as employees or those in residencies or community clinics, have the opportunity to participate in dental benefits programs, and some may, after weighing the options, decide not to participate. The process of applying and qualifying to participate are discussed. The key standards include which services are covered, what documentation is needed, and how claims are reviewed. These may differ from plan to plan, but benefits providers work to ensure that payments are timely and accurate, given the standards agreed to by the provider and the funder of the benefits program.

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Most dentists at some point in their professional careers are faced with a business decision of whether to participate with a dental benefits plan or a dental insurance company. This decision is usually personal and may be influenced by a variety of factors, often based on how long the individual has been a dentist and when the dentist graduated from dental school.

New dental school graduates may enter the dentist workforce as associates in private practice, group practice or a dental service organization. These newly graduated dentists may not be afforded any options as they are essentially required by the practice owner to participate with a dental benefits plan or dental insurance company as a condition of employment. Other dental school graduates may enter a residency program or may elect to join the armed forces, public health, Indian health, community health, or other state and federal services. These graduates may not face the question of participation until their initial service obligation or residency is completed and they enter the world of private practice.

An experienced dentist in private or group practice may decide on joining as a “participating dentist” after considering several business questions.

- How many new patients per month will this bring into my practice?
- Am I willing and able to accept a contracted (maximum allowable) fee for all covered procedures?
- How much revenue can I expect to produce?

- Can I make a profit despite my services being offered at a negotiated discount?
- Do I have a clear understanding of both the administrative rules and regulations and the clinical rules of the plan? Am I subject to a future audit?
- Do the local demographics and numbers of patients in my community participating with the dental plan ensure a widespread and adequate source of new patients?

Credentialing/Application Process

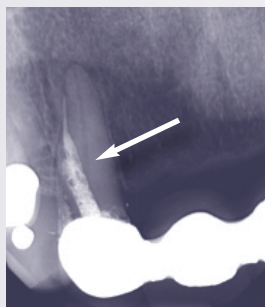
When a decision is made to become a participating dentist with a dental benefits plan or dental insurance company, the next step is to seek an application for membership/participation from the respective benefits plan or insurance company. The application would be expected to include information and questions such as:

- Dates of college and dental school attended and degrees earned.
- Are you a specialist? Proof of completion of specialty residency will be required.
- Prior work experiences as a dentist or specialist.
- Do you have current hospital privileges?
- What is your National Provider Identification Number (NPI)?

- Do you have a Drug Enforcement Administration license?
- Do you hold a current and active dental license in the state you practice dentistry in? If so, in what states are your licenses current?
- Have you ever been fined or disciplined by any State Board of Dentistry?
- Have you ever been suspended, fined, disciplined, or sanctioned by the Office of Inspector General, Medicare, or Medicaid?
- Have you had any felony convictions?
- Do you have current Professional Liability (malpractice) insurance coverage? Have you ever been sued for dental malpractice or paid a settlement as a result of purported malpractice?
- Are you addicted to or do you excessively use alcohol, drugs, toxic or foreign agents that may limit or adversely affect the performance of your professional duties and responsibilities?
- Do you have any medical, physical, or psychological problems that could possibly interfere in the provision of high-quality dental care?

Upon receipt of the membership application, a query will be made to the National Practitioner Data Bank to verify and corroborate the accuracy of the membership application. If there is a noted discrepancy, the dentist applicant will be asked to address it. Additionally, the state boards of dentistry where the dentist

FIGURE 1. Sample of a Declined Claim



In this claim for payment of completed root canal treatment, the dental office has obviously perforated and damaged the tooth. As a participating network dentist, the completed dental care is expected to be within the accepted Endodontic standards of care. This claim was not paid as the endodontic treatment is clearly not within the accepted standard of care.

has previously practiced will also be queried to validate the licensure status of the dentist and to verify the veracity of the application. Once these hurdles have been completed, an approval or denial of membership will often be made by either the Credentialing Committee of the dental insurance company or the Board of Directors.

Administrative/Clinical Rules, Policies, Regulations

Upon receipt of the approval letter, the dentist must agree as a participating dentist to abide by the administrative rules and regulations as well as the clinical policies. Most dental provider contracts stipulate that the dentist is required to provide high-quality dental care, adhere to the accepted standards of care, and maintain thorough documentation for each clinical encounter. It is highly recommended that each dentist actually read and understand the provider agreement as these agreements may vary widely among dental benefits plans and insurance companies.

Prior to signing the agreement, the dentist should receive an advance copy of the plan's rules and regulations as well as a clinical policy manual that details those dental procedures that are covered by the plan and those procedures that may be denied. Since many dental plans vary in rules, policy benefits, and exclusions, it is critical for the dentist to know what procedures are covered and what procedures are not.

Most dental plans do not cover the placement of restorations and crowns for patients exhibiting wear, abrasion, and abfractions or changing/restoring the vertical dimension of occlusion. In these particular cases, it is not a matter of clinical necessity for the patient but essentially a benefit decision that was rendered by the patient's employer group, often for financial and utilization reasons.

The dentist must also be aware that some dental plans may have waiting periods where the patient must be an employee for a specified period of time determined by the employer prior to qualifying for select major high-cost procedures, such as crowns, bridges, implants, etc. Some plans may have certain exclusions for preexisting dental conditions, such as prior missing teeth and congenital conditions (e.g., peg laterals, diastemas), and for cosmetic procedures, such as bleaching, veneers, and cosmetic crowns.

The clinical policy manual should also detail the clinical criteria for each dental procedure code that is a benefit as well as any stipulated attachments, such as x-ray images, narratives, or clinical chart notes, that may be necessary for submission to support a claim request. With a full understanding of the benefits, exclusions, clinical policies, and administrative rules prior to commencing patient treatment, the dentist can minimize

any misunderstandings that may develop between the dentist and patient and decrease the likelihood of receiving future claim denials.

Claims Submission Process

Once cleared to submit claims to the dental plan or insurance company, the dentist must take responsibility for each claim whether it is submitted via hard copy or by digital signature from the dental office under the dentist’s name. In fact in Block 53 of the 2019 ADA claim form, the dentist certifies “that the procedures as indicated by date are in progress (for procedures that require multiple visits) or have been completed.” The dentist is responsible for the accuracy of each dental procedure code submitted on the claim line regardless of whether someone other than the dentist completed and submitted the claim. If fraudulent billings on a claim form and inaccurate submission of procedure codes have occurred, the

submitting dentist could be criminally liable and charged by authorities.

Dentists should always remember and become knowledgeable of the American Dental Association Principles of Ethics and Code of Professional Conduct. The principle of veracity states that “the dentist has a duty to communicate truthfully” and that dentists have a duty to be honest and trustworthy. In the Code of Professional Conduct, there are two specific sections that state that (5.A) “dentists shall not misrepresent the care being provided to a patient in a false or misleading manner” and that (5.B) “dentists shall not represent the fees charged for providing care in a false or misleading manner.”

The corresponding advisory opinions based on the Code of Professional Conduct address ethical issues in dental coding, such as waiving patient copayments, overbilling a patient or dental insurance company, altering treatment dates in an effort to increase benefits for the patient or the dentist, incorrectly describing dental care on a third-party claim form, and performing unnecessary dental treatments. In addition, other types of unethical and illegal activity include billing for treatment that was never performed and “upcoding,” which is the practice of billing for a more complex and higher-paying procedure than what was actually completed (e.g., billing for D7210 surgical extraction when a D7140 extraction of erupted tooth was performed). Another activity to avoid is “unbundling,” which is the process of separating a distinct procedure code into various component parts with separate fees that results in a total charge exceeding the global fee for the original completed procedure.

Most dental insurance companies prefer that a dental office submit its

FIGURE 2. Sample of a Submission Form

TREATING DENTIST AND TREATMENT LOCATION INFORMATION	
53. I hereby certify that the procedures as indicated by date are in progress (for procedures that require multiple visits) or have been completed.	
X _____	
Signed (Treating Dentist)	Date
54. NPI	55. License Number
56. Address, City, State, Zip Code	56a. Provider Specialty Code

dental claims online, usually using a proprietary computerized software system. A small percentage of dental offices continue to submit their claims, x-ray images, and other attachments in hard copy. When submitting these hard copy documents, dental offices should understand that the dental insurance company must scan or transcribe the contents of the documents into its proprietary electronic claims submission system. Electronic submissions of claims and attachments to the dental insurance company will usually expedite and ensure quicker payment to the dental office.

Electronic claims for basic procedures such as dental examinations (D0150, D0120, D0140), dental prophylaxis (D1110, D1120), or basic restorative procedures such as composite or amalgam restorations typically do not undergo review by a dental consultant or a dental claims processor (a nondentist lay person). These types of claims essentially get paid on an “honor system” that is based on frequency limitations over a predetermined time period (e.g., twice per year for dental prophylaxis) or a more rigid time period for restoration surfaces, which are usually paid once per 24 months. If a frequency limitation has been exceeded, the dentist may (based on provider contract) have the payment denied. As mentioned earlier, it behooves dentists to be well-versed in the clinical and administrative rules of the dental plan in which they participate.

Submission of dental claims for high-cost procedures, such as prosthodontic crowns, implants, periodontal surgery, complex surgical procedures and extractions (D7210,

D7220, D7230, D7240, D7241), endodontic treatments, and other frequently abused procedure codes, may undergo professional review by the dental insurance company. Some companies employ dental hygienists or trained claims processors to provide a first line of review for these high-cost and complex dental procedures. This initial review may only allow reimbursement of a specific claim based on the submitted procedure code and the accompanying supporting documentation (e.g., periodontal chart, x-ray images). This level of review usually is not empowered to deny a claim. When uncertainty or questions exist regarding the claim in question, it should be referred to a dental consultant who represents the next level of review. Most dental consultants are licensed dentists with more than ten years of clinical experience who often maintain licenses in multiple states.

Documentation Requirements

The dental consultant will review the submitted procedure codes on the digitized claim form and review the provided documentation, such as x-ray images, clinical notes (when indicated), narratives, and clinical photographs (when submitted). The consultant will attempt to determine whether the submitted procedure codes and the accompanying documentation correlate properly. Submission of incorrect CDT procedure codes, nondiagnostic x-ray images with cone cuts, positional errors, foreshortening and elongation, and improper patient positioning for panoramic images will absolutely result in a delay in adjudication and ultimate payment. Improper

Most dental provider contracts stipulate that the dentist is required to provide high-quality dental care, adhere to the accepted standards of care, and maintain thorough documentation for each clinical encounter.

It is highly recommended that each dentist actually read and understand the provider agreement as these agreements may vary widely among dental benefits plans and insurance companies.

Most dental plans and insurance companies actively try to expedite the claims review process and attempt to reduce turnaround time and unnecessary attachment requests that can slow down the adjudication process.

imposition of anatomic structures on the x-ray image, coupled with the incorrect teeth on the submitted x-ray image, along with missing or scant patient chart notes will result in a denial and a probable request for additional information from the dental consultant.

A narrative when requested is not a substitute for chart notes since it is usually composed after the date of service and often submitted after a claim has been denied. Some dental insurance companies will only accept a copy of the clinical notes and will not accept a narrative because of this. The narrative should be concise, accurate, not embellished, composed in proper dental terminology, and should include an accepted clinical diagnosis.

Clinical chart notes should be thorough, include a valid clinical diagnosis, and accurately describe the treatment that was performed and why it was done. The notes should ideally be constructed using the SOAP methodology and should not be written using copy-paste auto-notes. An outside auditor or reviewer of the chart notes should easily be able to determine what the dentist did and the clinical reasons why the procedure was done. Copy-paste auto-notes essentially all read the same for each tooth and an outside auditor may have difficulty in determining what actually was performed on the date in question. The routine use of copy-paste auto-notes should be avoided as they will often delay payment and may result in a significant time expense during the course of an audit.

Processing of Dental Claims

Upon final receipt of an appropriate x-ray image or other supporting documentation, the dental consultant can then adjudicate and make an objective benefit decision based on the patient's dental benefits contract as determined by the patient's employer group. Once again with a thorough understanding of the patient's dental benefits plan, the dental office can navigate more easily through a maze of what can appear to be overly complicated and burdensome administrative and clinical requirements.

In my experience of more than 13 years in the dental benefits industry, most dental plans and insurance companies actively try to expedite the claims review process and attempt to reduce turnaround time and unnecessary attachment requests that can slow down the adjudication process. Similar to any private practice, time is money for benefits carriers and most dental insurers do

not have sufficient dental consultants or resources to review every claim for major or costly procedures. Therefore attempts to auto-adjudicate claims have increased. This involves computerized system algorithms that match patterns of claims. To assist in this endeavor to expedite payments, it is imperative that dentists take charge of the claims submitted under their names, understand each CDT procedure code, and ensure the claim form accurately reflects what was done. When required, dentists are also responsible for ensuring that each claim contains accurate and appropriate x-ray images and other supporting attachments as requested.

Conclusion

Understanding the administrative and clinical rules of the dental benefits plan coupled with proper coding, thorough and complete supporting documentation, and accurate claims submission will produce quicker reimbursements and a more satisfied participating dentist and patient. Dentists and benefits carriers both have the same goal in mind: expediting reimbursement for appropriate care to maximize the care patients receive. ■

Disclaimer

The opinions and information stated in this article solely represent the views of the author and do not represent the opinion and views of the American College of Dentists or the Hawaii Dental Service.

Industry and the Dental Profession

Partners in the Technological Age

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Abstract

As the dental profession and industry evolve in the technology age, the opportunities for partnerships in the service of oral health increase. This paper sketches the regulatory environment for dental products, which includes both internal and external standards. There are industry-wide standards for efficacy, safety, labeling, manufacturing, and tracking of marketing statistics. Industry collaborates with organized dentistry, the research community, and education to develop standards.

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The dental “industry,” referring to companies that develop, manufacture, and distribute oral care products to dentists, hygienists, patients, and consumers, is in a partnership relationship to the profession. Innovation and technology have transformed twenty-first century dental education, research and development, and practice from a cottage industry to one guided by computerized learning, big data predictive analytics, and artificial intelligence to improve patient care (Joda et al, 2018).¹ The resources and services needed to address ever-changing demands to continuously move the profession forward increase, and the profession often looks to corporate partners for guidance and collaboration. Industry relies on the internal and externally based scientists who perform research to develop and test new products, clinicians who use these products, and patients and consumers who are the end-users. All of these provide valuable feedback. How does the industry navigate this evolving landscape while adhering to the highest ethical standards of service and clinical outcomes?

In 2017, Klaus Schwab, president of the World Economic Forum, argued in the book *The Fourth Industrial Revolution* that a technological revolution is under way “that is blurring the lines between the physical, digital, and biological spheres.” Schwab argued these technological changes are drastically altering how individuals, companies,

and governments operate, ultimately leading to a societal transformation similar to previous industrial revolutions (Schwab, 2017). Such changes are permeating all industries from finance to manufacturing to health care. The recognition that dentistry is affected by this fourth industrial revolution has recently been clearly recognized (Joda et al, 2018).^{2,3}

Historically, the dental profession’s adoption of new technology has been very slow. Edward Rossomando reported it took 57 years from Charles Goodyear’s 1839 discovery of vulcanization to Charles Essig’s 1896 chapter describing the use of rubber for denture bases (Rossomando, 2010). Dentists had improved methods to deliver care, but dentistry remained a trade industry throughout most of the twentieth century. This, along with slow adoption by professionals and a reluctance to change their behaviors, has also traditionally hindered innovations in the delivery of dental care, particularly to the populations who need it most. For example, the Centers for Disease Control and Prevention and the American Dental Association’s (ADA) Council on Scientific Affairs have cited a number of studies that recognize sealants as one of the most effective dental caries preventive strategies.⁴ While dental sealants were introduced in school-based programs in 1980, only about 26% of poor children and 34% of children from

families at higher income levels had received sealants by 2010 (Kitchens, 2005).⁵ Bioactive sealants, developed through new technologies, add hydrophilic properties to improve adaptation to pits and fissures, making sealants less technique-sensitive and easier to place than traditional materials (Cannon & Comisi, 2013).

As the first industrial revolution took place (around 1760), dentists worked independently through apprenticeships in an unregulated environment, primarily addressing tooth pain. Mass production defined the second industrial revolution, also known as the “technological revolution,” in the late nineteenth century. Companies like Colgate-Palmolive commercialized toothpaste in jars in 1873, making preventive products commercially available. The Dentist’s Supply Company of New York (later called Dentsply International) was chartered in 1899 and one of its initial commercial successes was a patented method of manufacturing denture teeth to prevent breakage during wear. These two examples illustrate how the industry worked collaboratively with scientists and clinicians to address oral health, successfully bringing consumer and professional products to the marketplace. Despite these collaborative successes, dental practices continued to work independently during this era.

The 1960s marked the beginning of the third revolution, the “Digital Revolution,” with the invention of the semi-conductor, development of personal computers, and widespread adoption of the Internet. For the first time, dentistry started to focus on

technology and efficiency: four-handed dentistry, lasers, the application of CAD-CAM technology in restorative dentistry, the first commercial electric toothbrush. All of these required a new way of thinking and presented new opportunities to address oral health issues. These advances required further collaboration between industry, academia, and clinical experts to support the development and adoption of emerging technologies. However, the profession continued to view industry generally as a supplier of goods and services, rather than a partner in the goal to advance oral health and dental care delivery.

Dental training and education have also made great strides, moving from archaic operative procedures such as hand instrumentation for caries removal and messy impression materials to transformational opportunities now possible. E-learning and virtual reality simulators in dental education (Bridges & Burrow, 2015) improve student training, workflow, and end product development, all benefitting students and faculty. CAD-CAM (Davidowitz & Kotick, 2011) employs 3D scanning, digital milling, and additive manufacturing to transform restorative and orthodontic therapies. These advances require collaboration between industry and the profession. Health care in the computer age must also balance innovation with the human factor of patient-dentist interaction and never lose sight of the fact that both dentists and patients are affected by changes in technology.

Dental Industry Standards

Approximately 2,600 major registered dental companies that manufacture products support the 200,000 practicing dentists and 210,000 dental hygienists in the United States. These

companies develop, manufacture, and distribute cosmetics, drugs, medical devices, and biologics, or a combination of them, that prevent, diagnose, and treat oral diseases and address demands dictated by the dental market. They are highly controlled by regulatory and government agencies (the Food and Drug Administration [FDA] in the United States and the European Medicines Agency [EMA] in Europe) to ensure patient and consumer safety and efficacy of marketed products. Industry must adhere to the same regulatory, legal, professional compliance, and high ethical standards as the medical industry.

The FDA’s modern regulatory oversight began with the passage of the 1906 Pure Food and Drugs Act, which prohibited interstate commerce of adulterated and misbranded food and drugs. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation’s food supply, cosmetics, and products that emit radiation. The agency also supports advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. At the FDA, dentistry falls under the Division of Dermatology and Dental Products.

The process to product approval usually begins with a technology or an idea, supported by science, that responds to or addresses a market need. Product development includes establishing formulation, dosing, product quality, and clinical safety

Food and Drug Administration Regulatory Scope

<i>Classification</i>	<i>Definition</i>	<i>Example</i>	<i>Requirement for approval</i>
Prescription drugs (both brand-name and generic and nonprescription, or over-the-counter (OTC))	A prescription drug is a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, prescribed by a doctor, intended to be used by one person, available in a pharmacy or through a pharmacy program.	Antibiotics	Regulated by the FDA through the New Drug Application (NDA) process. This is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured. Usually requires Phase I-III trials to market.
OTC Drug	OTC drugs are drugs that do NOT require a doctor's prescription. These can be purchased off-the-shelf in stores.	Toothpastes	Regulated by the FDA through OTC Drug monographs. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.
Medical Device	A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and that does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes. Medical devices are classified based on the risks associated with the use of the device (Class I, Class II, or Class III, with Class I being the lowest risk and Class III the highest risk). Most dental devices are Class I or II. Ninety-three percent of Class I devices are exempt from premarket review. Class II devices generally present a moderate risk of harm to the user, and most require FDA review through premarket notification (510(k)).	Tongue depressors, dental implants, prosthetics, CAD-CAM	Premarket Notification (510(k))—submission required to demonstrate that the device is substantially equivalent to a device already placed into one of the three device classifications before it is marketed. Premarket Approval (PMA)—application required to demonstrate that the device is safe and effective when used. It is the most stringent type of device marketing application and is required for Class III devices.
Cosmetics	Cosmetics are articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.	Dental whitening products	Under the Federal Food, Drug, and Cosmetic Act, cosmetic products and ingredients, with the exception of color additives, do not require FDA approval before they go on the market.
Biologics	Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small-molecule drugs. There are many types of biological products approved for use in the United States, including therapeutic proteins including monoclonal antibodies and vaccines (such as those for influenza and tetanus).	Vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, allergenics	The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2).

Examples of Food and Drug Administration Regulatory Tools

Investigational New Drug Application	A request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application.
New Drug Application	The formal final step taken by a drug sponsor, which involves applying to the FDA to get approval required to market a new drug in the U.S.
FDA Monograph	A monograph is a regulatory standard for ingredients. It is a kind of “recipe book” covering acceptable ingredients, doses, formulations, indications, and labeling. Any OTC medicine that conforms to the monograph may be manufactured and sold without an individual product license.

Regular reporting to FDA through safety surveillance or pharmacovigilance and product quality or quality assurance and quality control ensures oversight of adverse events or side effects.

and efficacy. Proposed methods for innovations that meet these requirements are compared either to currently marketed products or other comparators. Scientists, including microbiologists, engineers, chemists, and physicists, perform research in laboratories (in-vitro) to develop evidence-based support that will be used to support and test product claims. Once early safety and efficacy is established in the laboratory setting, products are tested in animal models (if needed) and human trials (in-vivo). FDA human clinical studies are conducted in a phased program (Phases I-IV) required for approval for drugs and clearance of medical devices. A major goal for the manufacturer is to establish new products as “standard of care” (a diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance). Some U.S. trials and most European trials require non-inferiority trials.⁶ A level of support aims to demonstrate that the test product is not worse than the

comparator by more than a pre-specified, small amount. This amount is known as the noninferiority margin, or delta (Δ), for most products.

As Curro and Burrell (2014) explained regarding the new drug approval process, “Phase I consists of pharmacology and pharmacokinetic studies, outlining the evidence for safety and early evidence of activity. These studies are often done to determine the initial dosing for the next series of studies. Phase II evaluates the drug in patients with the target disease to determine the level of efficacy and the doses to be used in follow-up trials. In Phase III, the drug is evaluated in larger patient populations with the target disease to further establish and confirm safety and efficacy. Phase IV is for post-marketing surveillance to continue the safety program of the marketed drug beyond the controlled clinical trials data established in the earlier phases of development.”

Regular reporting to FDA through safety surveillance or pharmaco-vigilance (PV) and product quality or quality assurance (QA) and quality control ensures oversight of adverse events or side effects. QA monitors product stability and oversight of product complaints. Companies are required to have formal, documented standard operating procedures and regular employee training throughout all parts of the process from product development through manufacturing, supply chain/distribution/logistics/packaging, promotional claims, and technical support to be in compliance with internal and FDA/EMA standards. Within the industry, compliance, regulatory, PV, marketing, and legal departments are tasked to monitor the accuracy of information about products, PV, and QA, as well as availability of products online. This includes monitoring expired and counterfeit products that may flood the market from a global source. Partnership between industry, regulatory agencies, the profession, consumers, and patients helps ensure product safety. The FDA has an online system for reporting suspected product failures and the ADA Code of Professional Conduct requires that its members use this system.

To remain competitive and respond to market demands and feedback from the profession and patients, companies develop short-term and long-term product research and development and marketing plans called “pipelines.” It takes time to bring products to market—often years to decades—and this can cost millions of dollars. Big data and innovation are being employed to use large sets of data and information to help decrease the time and costs associated with the development of innovative products.

Professional Agencies and Industry in the Age of the Fourth Industrial Revolution

While regulatory agencies mandate standards to ensure safety and efficacy, professional organizations like the ADA, through its standards program, are the driving force behind establishing how dental products and technologies are defined. Local agencies such as state dental associations maintain more regional oversight and interaction with Industry and the profession.

Professional organizations work to power the profession of dentistry on the national, state, and local levels. They advocate for their members with payers, collaborate with Industry, and provide educational resources to the profession to help the professional be successful. They provide resources to inform policymakers, healthcare advocates, and providers on topics relevant to the U.S. dental care system. From time to time, professional organization panels of experts publish position statements intended to be recommendations on various courses of action. These are not intended to be guidelines or official regulations. For example, in a 1977 position paper of the ADA Ad Hoc Committee on Trace Anesthetics as a Potential Health Hazard in Dentistry, complex issues surrounding nitrous oxide delivery were weighed, risk benefit ratios were discussed, and recommendations were offered to help dentists make informed decisions in practice (Jones & Greenfield, 1977).

More than 200 over-the-counter dental products carry the ADA Seal of Acceptance. The ADA’s Council on Scientific Affairs and other subject matter experts set forth guidelines and

perform critical reviews of therapeutic agents, drugs, chemicals, materials, instruments, cosmetics, and equipment that are employed in the treatment or prevention of dental disease. According to the guidelines set forth by the council, accepted products are required to display the ADA seal logo on product packaging in accordance with the ADA seal brand standards to help dental professionals make informed recommendations and consumers make informed decisions. Participating companies commit significant resources to test and market products in the seal program. The council coordinates with related regulatory, research, and professional organizations and encourages coordinated efforts for development and improvement of over-the-counter dental devices by national and international standardization programs. Market research has shown that the ADA seal on a product directly affects the purchase decisions of consumers.

Federal government agencies, including the National Institute of Dental and Craniofacial Research, support scientific research on dental, oral, and craniofacial health and disease and support industry growth and collaboration with the dental profession. The Small Business Innovation Research and Small Business Technology Transfer research programs were established to stimulate technological innovation in the private sector with research institutions, strengthen the role of small business in meeting federal research and development needs,

Features of the ADA Standards Program

- Setting expectations on how certain products and technologies should perform
- Understanding the big picture of how these products and technologies work together
- Setting the standards for dental materials
- Products and technologies, including digital technologies that improve the safety and health of both patients and professionals
- Many of these voluntary standards go on to become the backbone of governmental regulatory documents, not just nationally but also on the international stage.
- The American Dental Association currently sponsors two separate standards committees: one for dental products and one for dental informatics.
 - The Dental Products Committee addresses standards for dental materials, instruments, equipment, digital devices, and oral hygiene products. The Dental Informatics Committee develops standards and technical reports for electronic health records; interoperability and other issues involving the secure storage and exchange of digital images and patient data; and dental education and research systems.
 - ADA standards committees include volunteer technical experts who serve as representatives of organizations.
 - The ADA seal is recognized as the gold standard for evaluating the safety and efficacy of dental products.

All promotional messaging to the public by sales and marketing members of the industry must include a “fair-balance” of information on risks, warnings, and potential side effects.

increase the commercial application of federally supported research results, foster and encourage participation by socially and economically disadvantaged small business concerns and women-owned business concerns, and improve the return on investment from federally funded research for economic and social benefits to the nation.

Industry And Academia

According to Gillis and McNally (2010), “One of the primary purposes for industry to partner with dental institutions is to foster growth in capacity for delivering innovative

learning experiences, carrying out research, and taking a leadership role in professional development for both faculty members and practitioners. And motivation for growth resulting from industry partnerships must continuously be balanced with goals that are consistent with an institution’s mission.” Collaborations in innovative research, fostered by the industry’s use of the expertise found in dental academia, including expert faculty, facilities, and large patient pools, are designed to further science and develop new therapies. Companies sponsor research and can provide resources such as regulatory expertise needed to bring great ideas to market. Dental education has gone through its own revolution, integrating technology and innovation in learning. Haptic virtual reality clinical simulators have recently been integrated into dental training to improve efficiency and provide sensory feedback (Roy et al, 2017). These systems require an ongoing relationship between the institutions and the technology companies that manufacture and maintain the hardware and software.

Industry Accountability

The sales and marketing arm of the industry promotes and sells products and must communicate the risks and benefits in accordance with very strict ethical and legal requirements. Certain promotional materials created by the industry are submitted to the FDA for review to ensure compliant messaging. Prescription drugs are commercialized only within their FDA-approved “on-label” indications, based on efficacy endpoints and safety results from clinical trials. Medical devices must be marketed according to their approved clearance and accompanied by relevant instructions for use. All promotional messaging to the public

by sales and marketing members of the industry must include a “fair-balance” of information on risks, warnings, and potential side effects.⁷

Social media message platforms provide consumers and the profession access to information on products. E-commerce provides access to purchase some products, sometimes with global reach. In 2014, the FDA developed “Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices” as guidance on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues.

Social media is being employed by the industry and professional agencies as a powerful tool to bring awareness and education to consumers. In 2018, the ADA showcased an initiative on benefits and evolution of the ADA seal with its first-ever 360 video to be used by both professional and consumer audiences. It provides dental professionals with an educational tool to reinforce product recommendations and information to drive consumer awareness through video pre-roll on social media, coupled with paid search. The 2018 ADA consumer survey found 17% of respondents learned about the seal on BuzzFeed.⁸

The Path Forward

In this ever-changing environment, the role of the industry as partner and collaborator with the dental profession is critical to address the complex issues that accompany a technological revolution and provide solutions to improve oral health care. Partnerships are based upon commonly accepted rules, regulations, and ethics. In a dental ethics primer, Peltier and Jenson raise the question “Who determines what counts as right or wrong behavior in the practice of dentistry?”⁹ They assert what counts as right or wrong behavior is determined by all of the people who hold an interest (“stakeholders”) in health care. This includes providers, patients, and society. Building on the guiding principles of earlier ages and throughout the continuum of the field of dental medicine, namely to make patients comfortable and improve oral health, the industry and the dental profession will continue to be successful if we navigate through the Age of Technology together. ■

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Submitting Manuscripts for Potential Publication in JACD

Manuscripts for potential publication in the *Journal of the American College of Dentists* should be sent as attachments via e-mail to the editor, Dr. David W. Chambers, at dchambers@pacific.edu. The transmittal message should affirm that the manuscript or substantial portions of it or prior analyses of the data upon which it is based have not been previously published and that the manuscript is not currently under review by any other journal.

Authors are strongly urged to review several recent volumes of *JACD*. These can be found on the ACD website under “publications.” In conducting this review, authors should pay particular attention to the type of paper we focus on. For example, we normally do not publish clinical case reports or articles that describe dental techniques. The communication policy of the college

is to “identify and place before the fellows, the profession, and other parties of interest those issues that affect dentistry and oral health. The goal is to stimulate this community to remain informed, inquire actively, and participate in the formation of public policy and personal leadership to advance the purpose and objectives of the college.”

There is no style sheet for the *Journal of the American College of Dentists*. Authors are expected to be familiar with previously published material and to model the style of former publications as nearly as possible.

A “desk review” is normally provided within one week of receiving a manuscript to determine whether it suits the general content and quality criteria for publication. Papers that hold potential are often sent directly for peer review. Usually there are six anonymous reviewers, representing subject matter experts, boards of the college, and typical readers. In certain cases, a manuscript will be returned to the author with suggestions for improvements and directions about conformity with the style of work published in this journal. The peer-review process typically takes four to five weeks.

Authors whose submissions are peer-reviewed receive feedback from this process. A copy of the guidelines used by reviewers is found on the ACD website under “How to Review a Manuscript for the *Journal of the American College of Dentists*.”

An annual report of the peer-review process for *JACD* is printed in the fourth issue of each volume. Typically, this journal accepts about a quarter of the manuscripts reviewed, and the consistency of the reviewers is in the $\phi = .60$ to $.80$ range.

Letters from readers concerning any material appearing in this journal are welcome at dchambers@pacific.edu. They should be no longer than 500 words and will not be considered after other letters have already been published on the same topic. [The editor reserves the right to refer submitted letters to the Editorial Board for review.] Where a letter to the editor refers specifically to authors of previously published material or other specific individuals, they are given an opportunity to reply.

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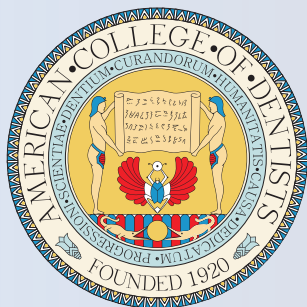
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