EDITORIAL

Marketing versus science: a call for evidence-based advertising in dentistry

The health care industry is experiencing an explosion of research, which promises to shift the paradigm in the detection, diagnosis, and management of oral diseases. Some new diagnostic methods, such as individual molecular and genomic testing, adjunctive visual aids, cytology, and salivary diagnostics, are being, or will be, actively marketed. These products are often promoted as advanced "must have" products for the contemporary dental practice. Although we firmly believe in the future of technologic advances, we must objectively scrutinize their putative benefits and assess the potential risks in their use before incorporating them into clinical practice. We can recall the proclamation made in 1969 during the so-called golden age of antibiotics and vaccination: "It is time to close the book on infectious diseases, and declare the war against pestilence won." Fast forward 46 years, and we now know that not only was that proclamation grossly overoptimistic, buts its attribution to the then United States Surgeon General, Dr. William H. Stewart, has never been confirmed.[1] Whoever the true originator was, this proclamation serves as a classic cautionary reminder to the health care community to avoid hubris.

One of the primary methods employed by the dental profession to avoid making unsubstantiated proclamations is to thoroughly and objectively vet the available science before issuing clinical guidelines or recommendations. The American Dental Association Clinical Practice Guidelines are developed by a panel of experts, who critically appraise, summarize, and interpret the clinical relevance of the total body of evidence of a given topic to develop practical recommendations.[2] In the hierarchy of evidence levels, systematic reviews are the highest-level evidence, preferable to narrative reviews, for answering focused clinical questions. Evidence-based guidelines and recommendations addressing dental products or procedures are typically published in peer-reviewed professional journals. Although evidence-based guidelines or recommendations can be developed to address dental products or procedures based on a disciplined consideration of the totality of the best evidence available, there are no such constraints to the actual marketing of dental devices or products. By its very nature, the marketing of dental products may embellish their positive attributes, but this must be balanced by knowledge of the level and veracity of the evidence, the potential for conflicting evidence, and the nature of the data on which marketing is based.[3] As a consequence, the marketing claims for a given product may conflict with some or even the majority of the accumulated available evidence, or the evidence may be insufficient to support the marketing claim.

As an example, let us consider the recently marketed light-based adjunctive devices (e.g., chemiluminescence, fluorescence, ultraviolet detector),[4-18] which claim to markedly improve the practitioner's ability to discover mucosal abnormalities that might be missed while performing a routine oral examination, especially oral premalignant or malignant lesions. In reality, such claims are essentially based on "proof of concept" case assessment type studies or case series, which cannot be arbitrarily translated to real-world clinical practice.[19-21] To address this apparent contradiction, a brief explanation of the U.S. Food and Drug Administration (FDA) regulatory device clearance process is necessary.

With the signing into law of the Medical Device Amendments of 1976, the FDA was assigned, on May 28, 1976, the authority to regulate medical devices.[22] Today, the FDA's Center for Devices and Radiological Health regulates medical devices sold in the United States, and any therapeutic device that enters the oral cavity is regulated by the FDA. Examples include powered toothbrushes, caries detection devices, cements, mercury, implants, and saliva substitutes.[23] Devices are classified into one of three regulatory classes (I, II, III), based on the level of control necessary to ensure the safety and effectiveness of the device.[24] The FDA neither develops nor tests new devices but gives advice and evaluates the data submitted by manufacturers. There are basically two options for the manufacturer of a medical device when applying for clearance by the FDA. The Premarket Approval application option requires a manufacturer to submit valid clinical data to support the claims made for the submitted device.[25] In contrast, the Premarket Notification 510(k) process (also known as 510(k)) establishes a much less stringent path to obtain marketing approval. In submitting a 510(k), the manufacturer of the device in question need only show that the submitted device is at least as safe and effective as—that is, substantially equivalent to—a device that was legally marketed

Table I. Parameters of an ideal diagnostic device[31]

1. Simple, inexpensive, safe, and acceptable to the public
2. Detect early disease
3. Detect lesions likely to progress
4. Detect lesions that are manageable
5. Have a high positive predictive value and a low false-negative value

before May 28, 1976.[26] The legally marketed device to which equivalence is drawn is commonly referred to as the "predicate device." Any legally marketed device, regardless of its clearance date, may serve as a predicate for another device deemed substantially equivalent.

Currently available light-based visual adjuncts have been cleared as illumination devices, for which the original predicate was a nonmetal fiberoptic vaginal speculum used to illuminate the interior of the vagina.[27-29] Simply put, the FDA considers these adjunctive devices as illumination aids. Furthermore, while the FDA regulates the manufacturer's ability to market a given product, ascertaining the voracity and accuracy of the marketing claim falls under the purview of the Federal Trade Commission (FTC).[30] Thus, when assessing the marketing claims for adjunctive examination devices, the old caution "caveat emptor," or buyer beware, still applies. Given the huge impact that health care spending has on the nation's economy, we believe a case can be made for the FTC to ensure that medical device advertising is based on the totality of the evidence to support the marketing claims.

Fully understanding that increased FTC oversight is unlikely to occur in the foreseeable future, there are some straightforward questions the clinician can ask the manufacturer while considering whether or not to use a diagnostic method as an adjunct in clinical practice. The clinician can also look to the American Dental Association Council on Scientific Affairs when assessing a category of devices.[21] Table I lists the general criteria to consider when evaluating adjunctive detection or diagnostic devices.[31]

Most studies assessing the light-based adjuncts have been conducted by experts in high-risk populations and high-risk clinics, and these findings cannot be generalized to low-prevalence diseases and low-risk populations often served by general clinicians. Therefore, the majority of clinical evaluation of devices may not apply to the general dental practice environment. In a study assessing the value of using autofluorescence in the examination of 130 general population patients, the investigators determined that the conventional oral examination was more valid than autofluorescence in discriminating benign mucosal alterations from premalignancy.[32] Also, a recent review of 25 available studies addressing the light-based adjunctive devices reported sensitivity and specificity values ranging from 0.0% to 100%,[33] making any conclusions regarding their use in clinical practice impossible.

Ultimately, the attainment of a complete history and the accomplishment of a thorough and disciplined conventional oral examination remains the bedrock upon which the practitioner bases his assessment of the patient for any mucosal abnormality. Findings deemed suspicious or equivocal should be referred to an expert for further assessment or biopsied and sent to a laboratory for tissue evaluation, and findings deemed innocuous should be re-evaluated within 2 weeks and referred to an expert for further assessment, or a biopsy should be performed if the findings are still present.

Moving forward, we would strongly recommend that practitioners carefully scrutinize the marketing of the just-released or soon-to-be released salivary adjuncts being marketed to the dental profession.[34-37] How do the marketing claims for these products stack up against the evidence? What are their sensitivity and specificity? Do they detect early disease? Do they detect lesions likely to progress? Do they detect lesions which are manageable? It should also be noted that the FDA is in the process of developing an appropriate regulatory approach to address in vitro diagnostic testing.[38] It is our hope and desire to shift the marketing paradigm from "caveat emptor" to "caveat venditor."

Michaell A. Huber, DDS, DABOM, Professor
Department of Comprehensive Dentistry
University of Texas Health Science Center
at San Antonio School of Dentistry
San Antonio, TX

Joel B. Epstein, DMD
MSD FRCD(C), FDS RCS(E), DABOM
Consulting Staff
City of Hope National Medical Center
Duarte, CA
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center
Los Angeles, CA

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