



EDITORIAL

“All that glitters is not gold”: standards for cone-beam computerized tomographic imaging

In the past few years, there have been increasing references in the dental literature to the utility of cone-beam computerized tomography (CBCT) in clinical dental practice. CBCT has been referred to as the “gold standard” and even the “standard of care” for diagnostic maxillofacial imaging.¹⁻⁴ However, as early as the 16th century, the Prince of Morocco in Act II, Scene vii of Shakespeare’s *The Merchant of Venice* warned, “all that glitters is not gold.” Others, in more contemporary publications, have also doubted the absolute value of CBCT imaging or the misrepresentation, by some, of the role of CBCT as the new universal imaging modality of choice.⁵⁻⁹ A recent front-page article in *The New York Times* has made the public aware of concerns about the use of CBCT in orthodontics and the associated radiation dose.¹⁰ Some may argue that representations within that article are biased. However, in his response, the President of the American Academy of Oral and Maxillofacial Radiology (AAOMR), Professor Allan G. Farman, applauds the efforts of the authors to draw attention to important radiation safety aspects related to the use of CBCT technology, especially on the most susceptible individuals, namely children.¹¹ Perhaps that article may even prompt some, enamored with the allure of 3-dimensional (3D) imaging, to reinstate radiation safety and considerations of the overall benefit of CBCT as a practice priority.

One aspect that has emerged from this discourse is a consideration of the concept of “standards” as applied to CBCT imaging. There are at least 5 “stakeholders” in the performance of CBCT imaging: 1) those for whom imaging is performed—patients; 2) those who perform the imaging—providers; 3) those who make, market and sell the equipment—the dental industry; 4) those involved in developing, monitoring and enforcing regulations associated with imaging—members of the health sciences professions, health physicists, state and federal regulators, the judicial system, and malpractice carriers; and 5) those who pay for the imaging—public,

patient or patient guardian, and third party payers. The concept of “standard” may well mean different things to different stakeholders. It is also quite likely that some stakeholders may be confused by discussions of standards by other stakeholders with whom they have less familiarity. The purpose of the present editorial is to frame this conversation, particularly regarding current and ongoing activities related to development of dental professional standards in CBCT imaging.

THE PATIENTS

When a patient is informed of the availability of CBCT to examine their specific condition, they often look toward their dentist/provider as to whether the image will be useful before consenting to have it performed. Is it needed? Is it worth it? Is there any harm from it? The practice of dentistry exposes practitioners at each patient encounter to an ethical obligation of beneficence—will the image “serve the patient’s best interests”? Some may equate this with applying state-of-the-art diagnostic options for each patient. Professional opinion, however, involves judgment. One of the elements that makes dentists professionals is the ability to balance the need for diagnostic information with the current scientific and technical reality of a particular modality to provide it while considering the costs and risks, both economic and actual. Practitioners are obliged ethically and morally to measure the benefit versus the risk. Dentists may also owe legal duties that overlap with ethical considerations to some degree.

For almost a decade, numerous authors, including myself, have expounded the diagnostic benefits of CBCT for specific applications. Most practitioners are therefore able to provide patients information regarding use of CBCT imaging from a technology assessment position, i.e., “It provides me with a 3D image of X, Y, or Z.” However a fundamental distinction exists between determining the overall benefits of CBCT imaging and relating it to specific patient outcomes. This is

because, unlike other areas of dentistry, such as surgery, there is a chain of events that separates the accuracy of the diagnosis from patient treatment outcome. In other words, should a CBCT image be taken in cases where a conventional panoramic view is diagnostically sufficient?

Fryback and Thornbury formalized a hierarchic framework for the links in this chain for diagnostic radiology.¹² Although CBCT is often able to separate abnormal from normal anatomy (level 1) and provides images capable of accurate diagnoses (level 2), assessments above these levels, resulting in changes to working diagnosis (level 3) and therapy (level 4), are not able to be readily determined by radiology studies alone.^{13,14} However, unlike many other disciplines, it is difficult to provide a patient with a data-based response that addresses specific questions, such as “is it useful?”

Emerging articles describing the clinical efficacy of CBCT imaging for specific patient clinical presentations, such as furcation involvements¹⁵ and impacted teeth¹⁶⁻¹⁸ certainly assist clinicians in presenting information to patients and quantifying the intrinsic value of diagnostic information provided by CBCT imaging. Such level 3 and 4 research would be welcome submissions to the Radiology section of *OOOOE*.

Well before the publication of the *New York Times* article, the increasing use of computerized tomography (CT) in medicine has been acknowledged, particularly in pediatric diagnosis and adult screening.¹⁹ This trend is most likely mirrored by the utilization of CBCT. The risk of CBCT imaging for the patient is related to radiation-induced carcinogenesis. Recently the calculation methods to derive estimates of this risk have been revised upwards.²⁰ In maxillofacial radiology, applications of these data have resulted in our appreciation of radiation effective dose being 32%-422% riskier than previously thought.²¹ The situation is worse for children, who are at much greater risk than adults from a given dose of radiation both because they are inherently more radiosensitive and because they have more remaining years of life during which a radiation-induced cancer could develop. There seems to be complacency demonstrated by some in equating CBCT examinations in the same light as other dental radiologic procedures for single procedures, especially for children. However radiation doses from specific CBCT units vary enormously, with some rivaling medical multislice CT. Specific CBCT manufacturers attempted to address some of these issues in press releases in response to the *New York Times* article.

Another flaw in this approach is related to a lack of appreciation of the potential impact of cumulative radiation dose. The concern is so great in the medical radiology community that at least 2 national initia-

tives—Image Gently²² and the National Children’s Dose Registry²³—have been established to raise awareness of the opportunities to lower radiation dose in the imaging of children. The AAOMR has recently joined the Image Gently alliance and in so doing has made 3 pledges on behalf of its members: 1) to significantly reduce, or “child-size,” the amount of radiation used; 2) to not overscan, by scanning only when necessary, only the indicated region, and only once; and 3) to be a team player, involving experts to monitor pediatric protocols and involving those who perform scans to optimize exposure parameters.

THE PROVIDERS

This group of stakeholders involves those who legally prescribe (dental practitioners), perform (practitioners, certified radiographers, qualified dental auxiliaries, imaging facilities), and interpret (practitioners, specialists, and oral and maxillofacial radiologists) CBCT images. All are accountable, either directly or vicariously, to various considerations in CBCT imaging. The designation of dentists as professionals implies that they are able to exercise judgment regarding all aspects of CBCT imaging by applying moral, ethical, and legal standards within a business environment. The interests of the latter, expediency and profit, should always be subservient to the former. CBCT technology applies ionizing radiation to produce a volumetric dataset. While this can be reconstructed to produce virtual surface, volumetric, and subsequent physical models that may negate optical (e.g., photographic) or chemical impressions, dental practitioners who perform CBCT examinations have a moral and ethical responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole. This concept is known as “as low as reasonably achievable.” Based on this overriding professional responsibility, a number of overseas organizations have published guidelines on various aspects of CBCT imaging. These include advice from the Health Protection Agency in the UK,²⁴ provisional radiation protection guidelines,²⁵ and basic principles of use of CBCT²⁶ from the European SedentexCT (Safety and Efficacy of a New and Emerging Dental X-Ray Modality) group. Although some may argue that standards expressed in these documents may not be appropriate in the USA, because of differences in the delivery of care, the AAOMR was the first to promulgate a position statement on performing and interpreting CBCT, and it remains current.²⁷

One of the specific missions of the AAOMR is to “improve quality of patient care,” and as such it is in the process of collaboratively developing and distributing patient selection criteria for CBCT imaging that are task and age dependent in a manner similar to

existing guidelines of the Food and Drug Administration–CDRH/American Dental Association for selection of dental imaging in the asymptomatic dental patient for dental caries, periodontal disease, and growth and development.^{28,29} These serve as professional guidance on the appropriate use of CBCT imaging in the USA. The first of these is a document jointly developed and approved by the American Association of Endodontists and the AAOMR and published simultaneously in the *Journal of Endodontics* and *OOOOE* in February 2010. Another joint position paper activity that is still in the works involves the American Association of Orthodontists and the AAOMR and is directed toward finding the best evidence for safe and effective use of all diagnostic imaging used in orthodontics, including, but not restricted to, CBCT. Additional guideline updates are being developed for temporomandibular joint evaluation and for imaging in dental implantology and dental caries diagnosis. Copyright of all guideline documents will be held jointly by the respective organizations, so they will remain open source and be updated every 3-5 years.

Practitioners have a moral obligation to maintain and improve their professional skills through life-long learning; this applies to the adoption of new technologies. The educational standard is, therefore, that professionals not only become familiar with the technical and operational aspects of CBCT, but also understand the scientific validity and health risks of its use. This can be a daunting task at a time when information and evidence-based consensus is still evolving. This ethical standard has been translated into a legal requirement in many states which require that dental practitioners attend continuing education courses. In many states, the use of lasers and various sedation techniques in dentistry requires specific training; however, as yet, most states do not require formal training in the use of CBCT imaging before operation in clinical practice. There is an enormous need and desire from practitioners for education on all aspects of CBCT imaging, including the appropriate use of the modality, technical parameters associated with scanning, practitioner and patient responsibilities, documentation, quality assurance, interpretation of resulting images, and dose considerations. Although many educational activities are provided by organizations recognized by the ADA Continuing Education Recognition Program, it is important to recognize that this group does not approve the specific courses and educational activities offered by these organizations.³⁰ Some courses are specifically underwritten by commercial vendors, and therefore it is sometimes difficult for practitioners to validate information delivered under these circumstances. Shortcomings of this approach regarding real or at least apparent conflict of interest

were recently divulged to the public in the *New York Times* article.¹⁰

As part of its vision statement to serve health professionals, the AAOMR anticipates that a generic non-vendor basic certification training in CBCT use will be initiated in 2011 and presented in various venues. This would be similar in scope to that suggested in the UK,²⁴ and already in place in Greece, Denmark, and Germany.

Inherent to the process of CBCT imaging is interpretation of the resulting images. This is an ethical responsibility of the individual who prescribes the imaging and either an implied or a specifically described legal requirement when using American Medical Association Current Procedural Terminology or American Dental Association Council Dental Procedures and Nomenclature codes. The AAOMR has indicated that the practice standard for performing CBCT imaging regarding interpretation is that “the practitioner who operates a CBCT unit, or requests a CBCT study, must examine the entire image dataset.”²⁷ Furthermore, the AAOMR states that “qualified specialist oral and maxillofacial radiologists may be able to assist diagnostically when practitioners are unwilling to accept the responsibility to review the whole exposed tissue volume.” This opinion has been supported by many in the literature.³¹⁻³³

THE DENTAL INDUSTRY

Understandably, recent economic events in the USA have tainted various divisions of commerce, notably the banking, mortgage, and insurance industries, as being profit-hungry conglomerates led by executives without standards. However it would be a mischaracterization to assume that such behavior exists in much of the dental trade industry. In fact, it is this industry that pioneered and commercially introduced CBCT technology and continues to facilitate much of the technically based research and development within this field. Dental manufacturers and distributors have a unique relationship with the dental profession; for the most part, the value of establishing and maintaining relationships with their clients is understood as most will likely remaining so for 20-30 years. Corporate viability is dependent on strong long-term relationships. Therefore, it is in the best interests of the dental trades to expand and consolidate this base. Commercial vendors of CBCT units must assure that such units satisfy certain minimal mandated operational performance standards associated with equipment capable of ionizing radiation at the federal (typically federal Food, Drug, and Cosmetic Act [FFDCA], chapter V, Subchapter C—Electronic Product Radiation Control; and Title 21 Code of Federal Regulations [Subchapter J,

Radiological Health] Part 1020.30 21) and local levels. Other standards include safety issues related to construction (International Electrotechnical Commission—IEC 86 B, including subcommittee 46) and manufacture (with Section 510k of FFDC A). There are also Underwriters Laboratories, CE (European Community for all electrical and electronic equipment), and Institute of Electrical and Electronics Engineers specifications for certain components. In addition, industry has entered into collaborative partnerships with the dental profession to ensure imaging standards for interoperability, including establishment of a universal file format and standards for image display and e-mail transport through DICOM (Digital Image and Communications in Medicine) Standards Committee activities and Integrating the Healthcare Enterprise.

There is a vested commercial interest in the dental trades seeing judicious and appropriate use of their products on many levels, including marketing leverage, establishment of after-sales maintenance contracts, reduced after-sales support activity, and word of mouth referral. However, commercial vendors are inherently dependent on endorsements by current users. Much of the latter half of the *New York Times* article examines this dilemma, particularly as it relates to “sponsored” provision of continuing dental education.¹⁰ One approach is to provide unrestricted support for other specific professional bodies or to partner with these associations to establish independent academic-based foundations through which educational activities and opportunities can be facilitated.

THE LEGAL SYSTEM

There are 2 components of the legal system that offer minimal compliance guidelines, which some refer to as standards. These are equipment regulations (administered through state and federal statutes) and private civil actions based on professional negligence (malpractice/tort actions in court).

Operating and performing CBCT imaging in dental practice involves compliance with regulations related to the installation and operation of x-ray generating equipment. As described above, federal regulations are usually concerned with essential elements of equipment manufacture and the monitoring of radiation output periodically. Although not currently required, it is conceivable that standards in this domain may evolve to include demonstration of image quality assurance as a method of minimizing radiation dose and optimizing image quality. This certainly seems to be the direction in which a number of other countries are responding to the increased use of CBCT.²⁴ Such quality control would most likely involve the use of a quality phantom as a method of demonstrating compliance with an im-

aging standard and periodic assurance of exposure compliance.

State regulations involve statutes that relate to 2 activities at the local level. The first pertains to the licensing and monitoring of CBCT equipment to ensure compliance with federal radiation output regulations. The second involves regulation of those operating CBCT units (1 state, Michigan, still requires a certificate of need before a dentist can even purchase a CBCT unit). CBCT units are registered as either a dental or, in some jurisdictions, a medical x-ray generator. Certification requirements vary according to equipment designation. This may necessitate specific training for CBCT licensing of “dental” radiographers, as is currently the case in at least 2 states in Australia (New South Wales and Queensland) and a number of other countries, including Germany, Greece, and Denmark. States, influenced by concerns from various stakeholders, may rigorously apply (e.g., certificate of need approving purchase and installation of CBCT equipment) or enact legislation to further regulate CBCT operation. For example, in Canada, the Healing Arts Radiation Protection Commission within the Ontario Ministry of Health currently does not grant access to CT equipment of any kind to dentists, unless they are certified oral radiologists. A suggested amendment would create 2 new subcategories of CT equipment, specifically small- and large-field dental CBCT. The use of small-field dental CBCT would be allowed for all dental specialties (not only oral radiologists) subject to the practitioner completing a multiday certification course. Large-field dental CBCT would be available to all dental specialties subject to the practitioner interpreting 50 cases with an oral radiologist.

In September of this year, Governor Schwarzenegger of California signed SB 1237 into law, specifically targeting concerns of cumulative radiation exposure from CT scans.³⁴ Commencing July 1, 2012, the law requires a radiation exposure measure to be on both printed materials and digitally stored with the patient’s historical records for all CT procedures. In addition the law requires physicians or other practitioners, including dentists, and their facilities that furnish CT services to be accredited. The applicability of this law to in-office CBCT equipment is yet to be determined.

The “standard of care” is one of the most important legal constructs of professional liability in dental care. However, there is still confusion among many as to how it relates to the provision of care in general dental practice. The standard of care applicable to dentists in professional tort cases is defined by state law and derived from numerous elements, including state statutes, licensing board regulations, case law, ethical codes of professional organizations, and professional

and community consensus.³⁵ Although all state laws differ slightly, most states define the standard of care as that which a reasonably skilled, educated, and experienced dentist would do in similar circumstances. If the dentist is a specialist, some states recognize a “national” standard of care in terms of what a reasonable or ordinary “specialist” would do, because most dental speciality residencies require consistent education and testing standards in core speciality areas. It is a term that derives from the legal process in which the patient has the burden of proving the 4 elements of a tort claim,³⁶ including what the standard of care requires, that the dentist violated this standard, and that the violation caused an injury. In CBCT imaging, this would most likely consist of a failure to identify, diagnose, and document a condition that led to an absence or delay in treatment for which damages can be quantified. More importantly, the plaintiff will hire an “expert” to establish a breach of the standard of care. Any time lawyers and paid experts get involved in defining standards, some unpredictable results are likely. This is even more true and problematic when there is a lack of consensus within the dental community on many of the issues discussed here, and also whether the same high standard of care required of a dental radiologist will be applied to other dentists who are allowed to take and interpret the same image, but with a different knowledge, skill, and training base. Various interpretations of the concept have been proposed, particularly as it relates to dentistry³⁶ and, more recently, to CBCT imaging in particular.^{2,3}

Malpractice carriers for at least 2 speciality organizations have identified failure to diagnose CBCT images as a potential liability issue. Oral and Maxillofacial Surgeons National Insurance Company (OMSNIC), the principle insurer for oral and maxillofacial surgeons (OMSs) in the USA, clearly states that an “OMS has a responsibility to read the entire film or have it read by a radiologist.”³⁷ Furthermore, acknowledging that OMSs may perform CT imaging services in a variety of circumstances, OMSNIC revised its position in April 2010 and offers insurance for 3 categories of risk, covering OMSs who: 1) take CT images for their own patients; 2) take these images for patients specifically referred by other providers who are not oral surgery patients of record; and 3) set up free-standing imaging facilities independent of their practices. Oral surgeons who wish to be underwritten must consider who will interpret the images, even though most have the necessary training to do so. As a precondition for coverage, OMSNIC requires their OMSs to send the image to a dental or medical radiologist for an interpretation or have the referring provider obtain it. OMSNIC does not set the standard of care, but it can

set the requirements for coverage that may in turn diverge from the standard of care, or it may influence it. There are many unsettled questions that can only be resolved on a case-by-case basis as to what the standard of care may require.

Counsel for the American Association of Orthodontists Insurance Company suggests that orthodontists who interpret CBCT have accepted a greater duty to the patient than that to which they would otherwise be obligated, and that failure to detect any condition within the dataset would result in a breach of this duty.³⁸ Orthodontists are advised to use the services of someone trained to properly interpret the information revealed by CBCT.

The use of a specific technology, despite its legal admissibility as evidence,^{39,40} does not necessarily constitute the standard of care and moreover does not require that the dentist provide the highest possible level of care; it is a minimum standard.³⁶ Therefore, regarding 3D diagnostic imaging technology, such as CBCT imaging to be a standard of care may be a misrepresentation.⁸ Rather it is the judicious and timely selection of appropriate diagnostic modalities that is in the best interest of the patient that forms the standard of care. Unfortunately, confusion continues to prevail as some blur the concepts of state-of-the-art technology as being a replacement for traditional imaging rather than being a task-specific supplemental modality.

THE PAYER

There are 4 potential payment sources to providers for CBCT services: the patient, a third party (either private or government based), a combination of patient/third party payer, and the public through taxation.

Reimbursement for imaging procedures when third party payers are involved is geared toward reduction of their financial liability. These societies operate in a cost-conscious environment and are concerned with cost containment—reducing the general cost of health care and minimizing financial risk. The standard used here is cost-effectiveness analysis, an objective technique used to assess whether a new or more effective test or treatment is worth the additional cost.⁴¹ Such analysis is highly complex and relies on considerations of not only the cost associated with correct diagnosis using the new modality, but also costs involved with failure to diagnose by not using the test. Currently, there are no readily available studies on the economic impact of CBCT imaging for dental conditions. This concept comprises one of the 6 specific areas of focus of the SedentexCT Project, a 7-partner European collaborative effort that aims to acquire the key information necessary for sound and scientifically based CBCT in dental and maxillofacial imaging.⁴²

Third party payers, those with whom patients contract to assist in the payment of health services, are understandably concerned about utilization rates and costs. Some contend that specific marketing efforts directed toward practitioners, especially those touting the use of CBCT imaging as a method of increasing practice revenues or improving workflow efficiency, may serve to increase these concerns and actually be counterproductive at efforts directed toward acceptance for payment of CBCT services. Commercial responses at this stage have been varied and range from specific noninclusion clauses, financial limitations on payment, or gatekeeper mechanisms, such as “precertification” or payment related to specific disease entities. In some countries accreditation of CBCT imaging facilities is either currently required or proposed as a prerequisite for reimbursement by government entities. In the USA, United Healthcare and Medicare have both proposed CT facility accreditation as a reimbursement requirement for CT facilities used by clients within their respective systems. United Healthcare’s proposal has already required point-of-care imaging sites (i.e., in-office scanners) and providers to have completed and submitted an application to obtain accreditation as a condition for reimbursement as of September 1, 2009. United Healthcare recognizes the American College of Radiology⁴³ and the Intersocietal Accreditation Commission⁴⁴ standards and has enlisted their expertise in facilitating accreditation. In addition, Section 135 of Senate Bill 3,101 that halted the proposed physician pay cut for 2008 and 2009 also requires physicians (including dentists) who have CT scanners in their offices and bill Medicare to be accredited by January 1, 2012. The applicability of these legislative proposals as a standard for CBCT imaging is yet to be determined. The application of such standards to CBCT facilities would have numerous ramifications, particularly because this would be akin to “closing the stable door after the horse has bolted.” If the interpretation of the intent of this legislation is to restrict dentists to providing CBCT imaging only at accredited facilities, then accrediting a private office or dental clinic may become burdensome and expensive. And by whom is the office to be “accredited”? No doubt efforts would be rallied by many stakeholders to “exempt” dental imaging on the premise that these applications pose significantly less health and safety risks. In fact, some dentists who have been reimbursed for certain CBCT images have recently been audited, resulting in a refund request for previously paid fees as cost-containment mechanisms evolve. This provides no comfort to those who have invested in CBCT units based on a business model that assumes a certain level of reimbursement.

CONCLUSIONS

There are many “standards” to be considered with CBCT imaging. However the standard to which the dental profession is held, both by the public and among ourselves, transcends legal (standard-of-care) and technical (gold standard) definitions. The professional standard for CBCT is *appropriate* care: to choose CBCT imaging for each patient “wisely” based on selection criteria derived from the best available evidence. In this expanding era of 3D imaging, the apparent urgency of adopting glittering new technology should be balanced with diligent discovery and patience. The standard, therefore, for all stakeholders is *festina lente*—to “make haste slowly.”⁴⁵

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