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# Medicolegal Issues Related to Cone Beam CT

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**The introduction of cone beam computed tomography into dentistry, and particularly into private offices, has raised a number of medicolegal issues. Among the issues raised are who may own and operate the machines, for what purposes should the machines be used, how broadly or narrowly should the field be collimated, does the full volume need to be interpreted and, if so, by whom? For images interpreted over the Internet (teleradiology), where must the interpreting radiologist be licensed? For images interpreted by a nonradiologist, may patients legally sign a waiver of liability for a dentist's interpretation of the films? This article explores these and other issues related to the use of cone beam computed tomography in dentistry. (Semin Orthod 2009;15:77-84.) © 2009 Elsevier Inc. All rights reserved.**

The world of oral and maxillofacial radiology is undergoing not only rapid, but also remarkable change. After decades of being limited largely to two-dimensional intraoral, panoramic, and cephalometric (skull) radiographs, the discipline took a giant leap forward with the introduction of cone beam computed tomography (CBCT) with its three-dimensional (3D) capabilities. While traditional or medical computed tomography has been available since the 1970s,<sup>1</sup> with the exception of oral surgeons, it has not been widely used by dentists. Initially this was probably due to lack of access to the machines, as well as the dollar cost of an examination. Even as more machines became available and the problem of access was no longer an issue, and the cost of examinations dropped dramatically, concerns about the cost-benefit ratio when the x-ray dose was considered in relation to the information to be gained still pre-

vented the routine use of CT scans for most dental applications.

The advent of maxillofacial cone beam CT in the early 2000s<sup>2</sup> radically altered the oral and maxillofacial radiology landscape. Primary among the reasons for the change is the enormous decrease in dose compared with a comparable examination on a medical CT,<sup>3,4</sup> and the lower capital cost of a CBCT machine, making it affordable for the dental market. Additional advantages of all of the CBCT machines—with one exception—when compared with traditional CT is the “open” format of the CBCT machines, making claustrophobia a virtual nonissue, and the fact that the patient is seated rather than lying down, the latter position probably being undesirable for most orthodontic examinations. These attributes of CBCT machines can be seen at the Web sites of the various CBCT manufacturers (or at <http://www.conebeam.com/?q=cbct-clinician/manufacturers>). A further advantage of CBCT is that manufacturers have developed the scanners with a view primarily toward the dental market. This in turn has led to the development of dental-specific software applications by a variety of vendors, especially in the areas of implantology (NobelGuide, Nobel Biocare, Yorba Linda, CA; SimPlant, Materialise, Ann Arbor, MI; EasyGuide, Keystone Dental, Burlington, MA) and orthodontics (Dolphin 3D, Dolphin Imaging, Chatsworth, CA) and Quick Ceph (Quick Ceph Systems, San Diego, CA).

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The precise role that CBCT will play in all fields of dentistry is still in a state of flux. It is clear, however, that it will be used across all disciplines, more for some than for others, and certainly in orthodontics. In addition to the appropriate use of CBCT in diagnosis and treatment, a purely "medical" issue, the advent of CBCT has raised a number of medicolegal questions, among them issues of ownership, the image volume to be covered, interpretation, and licensure. Although this journal is directed primarily at orthodontists, as far as the medicolegal aspects of CBCT are concerned the same issues apply to all dentists. Hence, I will use the word dentist instead of the more specific word, orthodontist.

### **Purchasing and Ownership of a CBCT Machine**

One of the legal issues concerns ownership of a CBCT machine, specifically who may own and operate one. As far as the taking of images, especially extraoral films, is concerned, the practice of oral and maxillofacial radiology varies across the country. In general, it is fair to state that in most of the country exposures are done in individual dental offices. On the West Coast, however, so-called dental x-ray laboratories take a significant number of films. It is quite common practice for orthodontists in states such as California, Washington, and Nevada, for example, to refer patients to such facilities. In states where x-ray laboratories exist, they do not have to be owned or run by a dentist. California, for instance, issues limited x-ray permits, one of which pertains to dentistry and which allows an individual who has taken an approved course and passed an examination to hold a limited dental x-ray permit.<sup>5</sup> It follows that under California law an individual who is not a dentist or physician or a full-fledged medical x-ray technician may own and operate certain x-ray equipment, including CBCT machines. This permit holder may expose patients only on a prescription from a licensed dentist. The x-ray laboratories provide only a technical service and images made in such facilities images are not reported on by the facility, although some of them may make arrangements with radiologists to read and report the cases.

Other states consider CBCT machines to be medical devices, which means that all state laws pertaining to medical radiologic devices apply to CBCT systems. Some states limit the acquisition of medical x-ray equipment, primarily CT, magnetic resonance imaging (MRI), and positron emission tomography (PET) scanners, based on the perceived need for the machines. To purchase a CT scanner, including a CBCT machine, in these states one must show that there is a need for such a machine. Among the states that have the so-called certificates of need (CON), the specifics of the laws vary, but the requirements may be quite onerous. Michigan is one state that has a CON requirement that was established in Public Act 256 of 1972.<sup>6</sup> In states that classify CBCT machines as a medical device, the law may also require that such machines be operated only by a registered medical radiology technician, radiologist, or other health care professional with specified training.

In summary, therefore, some states allow even nondentists to own and operate CBCT machines, while in others the laws make it difficult and sometimes practically impossible, due to the CON, for many fully licensed dentists or even radiologists to acquire a CBCT machine. Whether only radiologists, medical or oral and maxillofacial, should be allowed to own and operate CBCT machines is an issue that has been raised. In Ontario, Canada, precisely this matter is under discussion. The Ontario Ministry of Health set up an advisory committee (Diagnostic Imaging Safety Committee) to give advice on CT issues, including CBCT. The committee's recommendation to the Ministry of Health is that The Healing Arts Radiation Protection Act (HARP Act)<sup>7</sup> be amended to restrict the purchase of CBCT machines to oral and maxillofacial radiologists only. The ministry has yet to make any decision, but currently there is an effective moratorium on the approval of dental CBCT scanners by anyone (Dr. Michael Pharoah, Head, Oral Radiology Department, Faculty of Dentistry University of Toronto, personal communication, January 2008). At the present time it seems unlikely that any American state will explicitly limit the ownership of CBCT machines to radiologists, although other requirements, such as a

CON or a minimum number of annual examinations that must be done, may exclude many dentists. The purpose of requiring a minimum number of annual examinations is to assure that operators maintain a certain level of competency.

While in-office ownership of a CBCT machine by a dentist or group of dentists in a group practice may be subject to some of the restrictions above, the legal requirements for ownership and use are probably generally not too problematic. The situation is far more complex, however, if a dentist enters into a joint purchase of a machine with a physician. Due to the cost of a CBCT machine some dentists have considered this option. If a dentist is considering the latter option, he should be aware that he might run afoul of the Stark law.<sup>8</sup> The Stark law prohibits physicians from making referrals for a "designated health service," payable by Medicare or Medicaid, to any entity with which the physicians have a financial relationship. Designated health services include the taking and interpretation of a CT scan in a physician's office or freestanding facility. If a dentist were to enter into a business relationship with a physician, almost all of whom accept Medicare and/or Medicaid payments, the dentist, even though he does not himself accept such payments, might find himself under investigation together with the physician(s) for potential violations of the law. Even in the unlikely event that a physician is not subject to the provisions of the Stark law, he is still subject to the federal antikickback statute.<sup>9</sup> The antikickback statute provides for criminal penalties for certain acts impacting Medicare and Medicaid reimbursable services. The Stark and antikickback laws are extremely complicated and are well beyond both the scope of this article and the expertise of the author. The best advice that can be given to a dentist is to consult an attorney who specializes in the Stark and antikickback laws before embarking on any joint purchase with a physician or a dental care provider who accepts Medicare or Medicaid. Even in the case of physicians who are not subject to the Stark law, state medical boards may have regulations that have similar effects and prohibit self-referral by physicians to facilities in which they own an interest, in keeping with the Code of Ethics of the American Medical Association.<sup>10</sup>

## The Field of View

One of the issues raised by CBCT is just which anatomical area of the jaws and head or neck should be included in a study. For example, assume one takes a CBCT scan of the fully edentulous maxilla for purposes of evaluating the feasibility of placing implants. Does the image provide sufficient coverage if the beam is collimated (in the vertical) to include just the alveolar bone and only 2 to 3 mm superior to the sinus floor? Or is it necessary to include more of or perhaps even the entire sinus? The general principles of radiology dictate that the taking of films be based on clinical indications and that examinations not be done as part of "a fishing expedition."<sup>11,12</sup> The rationale for this is to protect both the individual patient's and the public health from unnecessary radiation. Thus, in the example above, if the patient has no sinus symptoms and no sinus pathology is suspected on clinical examination, there is not a strong argument for including the whole sinus. The answer to how large an area to cover also includes, however, the desires of the treating clinician, although this should not generally override well-accepted principles of radiation hygiene. In the above example, some clinicians may insist on seeing all the way to the orbital floor. Further, some software programs require that certain anatomic landmarks be included since the program uses them as (anatomical) fiduciary markers.

It is also possible to collimate too narrowly, either accidentally or by design, and thus to exclude structures that reasonably ought to be included. The issue of purposely collimating too narrowly is closely related to the reading or interpretation of the films, an issue discussed in depth below. CBCT machines are increasingly being marketed to private practitioners who are not oral and maxillofacial radiologists. Companies' target market is especially orthodontists and practitioners who place dental implants. These practitioners typically do not have sufficient training to interpret the films beyond the confines of their specialty or daily area of practice. Some practitioners believe that one way to overcome the issue of interpretation is to collimate down to the smallest area possible. For example, if an orthodontist does a CT to evaluate an impacted maxillary canine, the idea

would be to collimate the beam to include just the tooth and nothing superior or inferior to it. The danger with this approach, however, is that one may miss pathology that is contributing to the noneruption or impaction of the tooth. Similarly, when radiographing the temporomandibular joint (TMJ), if one were to collimate too narrowly, one could potentially miss pathology that is not located directly on or in the condyle or glenoid fossa, but that is contributing to the TMJ problem. In principle, the anatomical area covered by a CT scan should be no different than would have been covered by a plain-film examination. The extent of the examination should be based on the patient's symptoms and the findings on clinical examination.

### Responsibility for Interpreting CT Images

While there are many reasons that a dentist or practice may not acquire a CBCT machine—including issues of space, recovering the cost of the machine, having to learn and maintain additional software and hardware—probably the major reason that is emerging as a barrier to acquiring a machine relates to the interpretation of the images. This is a quite common concern expressed by dentists. Indeed, I am aware of practitioners who have actually ordered CBCT machines, only to put the order on hold based solely on their concerns about liability related to interpreting the images.

Facilities such as dental x-ray laboratories and medical radiology facilities, including hospitals that do so-called dental CT scans (eg, for implant planning, to locate an impacted tooth or for orthodontic purposes), do not read and write a report of the case. In fact, medical facilities typically include a specific disclaimer such as the one from the Massachusetts General Hospital, which states: "These images were NOT reviewed by a Mass General radiologist for diagnostic purposes, and NO radiological review, report, or professional bill was generated. These images are intended for review by dental care professionals to aid in dental implant or extraction surgical planning. Mass General Imaging makes no diagnostic claims regarding these images. If there are concerns regarding pathology and a radiological consult is desired, please contact . . ." Whether dentists have the CT scans

performed by such facilities or whether they take them in their own offices, they are concerned that they will assume liability for reading the scan. This concern is well placed. Not only will they be responsible for reading the scan as it pertains to their area of practice or the particular reason for which the image was taken, but they will also be responsible for reading the entire image volume.

While there are no legal cases specifically concerning the matter of the scope of interpreting a CBCT scan, the issue can fairly be regarded as settled. A CT is no different than any other image—a dentist cannot read only part of a panoramic film, or only part of a lateral cephalogram. For example, should an orthodontist miss an enlarged sella turcica resulting from a tumor on a lateral cephalogram,<sup>13</sup> the dentist reading the cephalogram cannot offer as an excuse in any legal proceeding that "I read only part of the film" or "I read the film only as it relates to the orthodontic diagnosis and treatment." The dentist is obligated to read all of the film. That this is accepted to be the standard within the profession is borne out by a recent editorial in the orthodontic literature.<sup>14</sup> Moreover, in determining the standard of care, courts look to what the practice in the profession is,<sup>15,16</sup> and as is evident from the editorial referenced above, the practice is to read all of the film. Courts are not likely to allow a lower standard of care than the profession demands of itself. Malpractice carriers have expressed similar sentiments.<sup>17</sup>

Dentists have given consideration to limiting their liability for reading CT scans by having patients sign a waiver of liability for their interpretation of the films. Such a waiver of liability carries no legal weight and will be null and void in any legal proceeding.<sup>18-20</sup> This is simply an affirmation of the fact that the profession as a whole, and not an individual practitioner, sets the standard of care. Further, malpractice carriers will not permit a dentist to write such a disclaimer nor will they honor it.<sup>17</sup> Another variation of the theme that dentists have considered is to give patients the choice of whether to have the films read by a radiologist. According to this line of reasoning, since the decision is entirely up to the patient there should be no liability on the part of the practitioner for any non- or misdiagnosis. This approach too will not work.

While patients may make treatment decisions, their choices are limited by the bounds of accepted standards of care. No dentist would permit a patient to agree to fill only two canals on a molar tooth undergoing endodontic treatment and then to place a crown because the dentist is unable to navigate the third canal or because the patient can only afford to have two canals filled. Such a scenario would call for a referral to an endodontist or foregoing the crown. The same principles apply to the interpretation of films.

### Issues Related to Referring Out the Interpretation of CT Scans

It is not uncommon nowadays to hear practitioners who are considering getting a CBCT machine complain that it is not fair that they should be required to read all of a CT scan. The short answer is that they are not required to read it themselves, just as they are not required to perform any other procedure that they are not competent to perform. Neither the law nor ethics requires that a dentist be able to do everything—only that if he is unable to undertake the work that he should refer the patient to an appropriately qualified individual. It is probably fair to state that, with the exception of individuals who have completed a formal program in oral and maxillofacial radiology, most orthodontists, and dentists in general, do not have the expertise to interpret CT scans, nor do they feel comfortable doing so. Thus, they are obligated to refer the reading of the images.

While modern technology has made the referral of the reading of images a simple matter, the law has not caught up with these changes. On the technical side, it is a simple matter for a dentist to have the images, which are all digital, read remotely by a radiologist. Cases can be burned to a CD that is mailed to the radiologist, who interprets the case and sends back a written report, whether by fax, e-mail, or traditional mail. Faster, more efficient, and more likely to be done nowadays is for dentists to upload cases from their computer to a file transfer protocol (FTP) server. FTP is a method of transferring data over a network or the Internet. An FTP server is a Web server to which one can log onto and upload or download files.<sup>21</sup> Typically, the radiologist will have set up an FTP site to which the dentist simply connects over the Internet

using his browser. From the referring dentist's perspective, no special software is required. If the dentist uploads the raw data in Digital Imaging and Communications in Medicine (DICOM) format, the radiologist can view the case using any number of commercially available software packages. DICOM is a standard developed by American College of Radiology–National Electrical Manufacturer's Association (ACR-NEMA) for communications between medical imaging devices.<sup>22</sup> Once he has read the case, the radiologist writes a report and sends it in one of the aforementioned ways or uploads it to the FTP server from which the dentist downloads it.

Unfortunately, while technology has developed apace, dental licensing laws remain firmly entrenched in centuries past and place barriers to the use of this technology.<sup>23</sup> Little or no progress has ensued at the federal level on the telemedicine front and legislation introduced<sup>24</sup> to address has not passed. There is no national dental (or medical) license, nor does one state automatically recognize a license granted by another state. This means that to practice in a state, a dentist must have a valid license in that state. New York law exemplifies the general rule in that: "It is the location of the patient that defines where the care has been delivered and the jurisdiction of applicable regulations."<sup>25</sup> It further states: "Whether the out-of-state practitioner is reimbursed is irrelevant."<sup>25</sup>

The licensing laws present a problem for a dentist in, for example, North Dakota, who wishes to have his radiographs read by an oral and maxillofacial radiologist in Iowa. Under current law, a dentist needs to be licensed in the state in which he is practicing. Traditionally, a dentist sees patients in the state in which his practice is located. This means that a dentist who is seeing patients in North Dakota must be licensed in that state. The purpose of licensing laws is to protect the health and welfare of the citizens of a state.<sup>26</sup> With teleradiology the radiologist can be located anywhere where he can obtain access to the images, usually over the Web. Based on the underlying reason for licensure, and assuming it to be the true purpose of licensing—as opposed to using licensure for economic protectionist purposes,<sup>27,28</sup>—it is reasonable for a state to require that radiologists reading the images of its citizens be licensed in that state, even though the radiologists may be living

and practicing out of state. The counter-argument is that if the radiologist residing in Iowa is licensed there, then North Dakota should not require him to be licensed in North Dakota. Sending the images to Iowa, the argument goes, is akin to the patient traveling to Iowa to see a dentist. If a North Dakotan traveled to Iowa to see a dentist, North Dakota does not require that the Iowa dentist be licensed in North Dakota, and would lack any constitutional basis for requiring it. The problem with comparing the reading of images over the Internet with the patient traveling to an out-of-state dentist is that when the patient travels out of state, he is doing so knowingly and of his own free will, whereas when the images are sent out of state, the dentist and not the patient makes that choice. One might argue that by informing the patient that the images will be read by a nonlicensed and out-of-state radiologist and getting the patient's consent, the patient is agreeing "to go" out of state, much as the patient above who travels from North Dakota to Iowa. While arguments can be made pro and con in support of this line of reasoning, the simple fact of the matter is that, to date, no state has explicitly adopted a law or policy that would permit the out-of-state and nonlicensed dentist to read films of its citizens. There is no reliable study, and certainly none published, that has surveyed state dental boards as to their licensing requirements for out-of-state dentists who read films of the citizens of their state. The issue is obviously one that concerns not only the referring dentist, but the radiologist as well. That the matter is one that should be taken seriously by the radiologist is borne out by a case where California is pursuing a criminal case against a physician who prescribed medication for a California resident over the Internet where the physician did not have a California license.<sup>29</sup>

A further wrinkle in the licensing scenario used above is that the radiologist may be required to be licensed in both North Dakota and Iowa, even if the radiologist is reporting only on North Dakota cases. This is because the constitutional standard that a state has to meet to justify requiring licensure is extremely low<sup>30</sup> and both states could credibly argue that the radiologist is practicing in its state. To further complicate matters, assume that the Iowa radiologist rents server space in Arizona, it may even be possible for Arizona to require him to be li-

censed there on the basis that the virtual patient is located in that state, although this would likely be a close constitutional call. There are, as yet, no decided cases on this issue. Even if it were to be held by a court that a state where the server is located may constitutionally require licensure, one would hope that no state would exercise such authority.

Some medical boards have considered the issue of telemedicine. However, even among the boards that have fully considered the matter, lack of uniformity of the laws across states is still a marked feature. Some medical boards require a full license in that state for an out-of-state radiologist to read images taken of its citizens in-state, but some have enacted forms of limited licenses that apply in cases of telemedicine. The Federation of State Medical Boards maintains an updated list of state telemedicine licensing laws.<sup>31</sup>

Another idea that dentists have floated in an attempt to overcome the licensing dilemma is to couch the radiologist's interpretation as merely being a "second opinion" and that, therefore, even an out-of-state radiologist does not need a license to read the films. A true second opinion is the process of seeking an evaluation by another doctor or surgeon to confirm the diagnosis and treatment plan of a primary physician, or to offer an alternative diagnosis and/or treatment approach.<sup>32</sup> A second opinion only applies when the primary dentist has in fact made a diagnosis and then seeks another dentist's opinion. Massachusetts has a licensing exception for an out-of-state physician who is providing a second opinion. The exception applies to "a physician or surgeon resident in another state who is a legal practitioner therein, when in *actual consultation* with a legal practitioner of the commonwealth" (emphasis added).<sup>33</sup> Even then, as interpreted by the Massachusetts Board of Registration in Medicine, the licensing exception applies only when such consultation is made on a one-time or occasional basis. If a physician regularly consults a non-Massachusetts licensed physician, the licensing exception does not apply (Debra Stoller, Senior Board Counsel, Massachusetts Board of Registration in Medicine, personal communication, January, 2008). In states that do not explicitly allow for second opinions by unlicensed physicians, it is likely that in practice they probably follow very much the same principles. Given the definition and pur-

pose of a second opinion, a dentist who is seeking the services of a radiologist to read CT scans that he is unable to read himself cannot credibly claim that he is seeking a second opinion, the more so when such consultation is sought on an ongoing or routine basis.

### Insurance Considerations

If a dentist refers the reading of a CT scan to an out-of-state radiologist and the patient sues the radiologist for negligence, it is possible that the dentist may find himself on the financial hook. If the radiologist's malpractice carrier covers the radiologist only for the state in which he took out the malpractice coverage, the carrier may refuse to provide coverage for what it considers out-of-state practice, leading the patient to sue the dentist instead. This is even more likely if the state in which the patient resides requires the radiologist to be licensed there and he is not. While it is possible for the radiologist or the referring dentist to, in turn, sue the radiologist's malpractice carrier to provide coverage, it soon becomes evident just how complicated the legal process can become. As the expression goes, "one does not want to buy a lawsuit," even if the odds of winning are great. It is preferable by far to avoid any kind of suit. Referral to an unlicensed radiologist probably may also put the referring dentist at a slightly higher risk of a suit for negligent referral, although such suits are rare to begin with.<sup>34</sup>

### Conclusion

What advice then can currently be given to a dentist or orthodontist who is considering acquiring a CBCT machine? He should be certain that state law imposes no impediments to the acquisition and operation of a CTCT unit by him. It is incumbent on him to read the entire image volume or to have it read by someone who is competent to do so. To do this, he may have to become competent to read the images or, as is more likely, he may refer the reading of the images to a radiologist. If he chooses the latter path, at a minimum he should be sure that the radiologist is licensed in the state in which the referring dentist practices. Referral to a radiologist who is not licensed in the state might make the dentist vulnerable to disciplinary action by

the dental board and may also make him guilty of the crime of aiding and abetting the unlicensed practice of dentistry (California Business and Professions Code §2264). Some states where the radiologist is physically located may require that he also be licensed there as well and if the radiologist is not licensed there the dentist should ascertain if a license is needed. This can be done by directing an inquiry to the dental board. The dentist should ensure that the radiologist carries malpractice coverage and that his carrier will cover him for out-of-state practice.

Cone beam CT holds great promise for both patients and dentists, but it comes with potential pitfalls. With careful planning and the use of appropriately qualified individuals to aid in interpretation, dentists can enhance their practice and best serve the interests of their patients.

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