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## SCIENTIFIC ARTICLE

# Conebeam Computed Tomography: Legal Considerations

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With the introduction of conebeam computed tomography (CBCT) in the early 2000s,<sup>1</sup> oral and maxillofacial radiology fully entered the modern world of 3-dimensional (3D) radiographic imaging. Although conventional or medical computed tomography (CT) had been available since the 1970s,<sup>2</sup> with few exceptions, it had not been widely used in dentistry. In the early days of conventional CT, the machines were limited in number, restricting their use to only the most beneficial of purposes—for example, imaging of the brain. The cost of a CT examination was also prohibitive. For these reasons, the modality in dentistry was used almost exclusively in oral and maxillofacial surgery and sparingly at that. Even as the limitations of access and cost disappeared, the cost–benefit ratio when the x-ray dose was compared in relation to the information to be gained was generally considered to be unfavorable for the use of CT scans in most dental applications.

CBCT, with its great decrease in dose compared to conventional CT<sup>3,4</sup> and the lower capital cost of a CBCT machine, making it affordable for the dental market, significantly changed the dental CT playing field. The exact role that CBCT will play in dentistry is yet to be fully determined, but the modality has already raised a number of medicolegal issues.

While some professional oral and maxillofacial radiology organizations have published guidelines on the use of CBCT,<sup>5,6</sup> the exact role that CBCT will play in all fields of dentistry is still in a state of flux. 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.

### **WHO MAY OWN AND OPERATE A CBCT MACHINE?**

As far as the taking of images is concerned, especially extraoral films, the practice of oral and maxillofacial radiology varies across the world. In some countries, most of the exposures are performed in individual dental offices, while in others dentists refer patients to dental radiology centers. The United States provides an example of both. While most dentists in the United States expose their own images, it is quite common practice in mostly west coast states (California, Washington, and Nevada) to refer patients to centers known as dental x-ray laboratories. When CBCT first appeared on the market in the United States, almost all of the machines were purchased by radiology centers or dental schools. There is an increasing trend, however, for individual offices to purchase CBCT

machines. This is in part because manufacturers are making “mini” machines, which are both smaller and cheaper than earlier CBCT machines, and marketing them to individual dentists. This raises the question of who may own and operate a CBCT machine. One of the legal issues concerns ownership of a CBCT machine—specifically, who may own and operate one.

In most American states, any licensed dentist may own and operate a CBCT machine. No training beyond that of dental school is required. In states that have dental x-ray laboratories, which are mostly owned by non-dentists, even they may own and operate CBCT machines provided that they have appropriate training and have passed an examination. Many American states and developed countries limit the number of CT, magnetic resonance imaging, positron emission tomography scanners, and other advanced imaging equipment in a particular geographic area. In the United States, the purchase is regulated through so-called certificates of need. For example, Michigan<sup>7</sup> and Connecticut<sup>8</sup> have such laws. In states or countries 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. The province of Ontario, Canada, restricts the purchase and operation of CBCT machines to radiologists.<sup>9</sup> In some countries, a dentist may not own and operate even a panoramic machine without special training. It goes without saying that these countries will not allow a dentist to own or operate a CBCT machine without special training.

In whatever country or jurisdiction a dentist practices, the dentist should be sure to clarify if there are any requirements that would prevent him or her from purchasing and operating a CBCT unit. It is not advisable to rely on the sellers of the equipment for this information. This is not because they are untruthful or trying to mislead, but they may not be aware of all the laws pertaining to having such equipment, and they may especially not be aware of any upcoming laws that may change existing laws. It is best to check with the state agency that licenses, inspects, and tests radiologic equipment.

In general, the legal requirements for ownership and use of a CBCT machine are generally not burdensome. This may not be true, however, if a dentist decides to buy a machine with a physician. Some dentists have considered doing this because the economics of buying their own machine do not make sense. If a dentist is considering buying a machine with a physician, he may become subject to laws that pertain to physicians. As such, the dentist must know not only the laws applicable to him or her, but also to physicians. In the United States, such laws include the Stark Law<sup>10</sup> and federal antikickback statute.<sup>11</sup> Dentists should also be aware of any medical board regulations that may pertain to physicians who have an ownership interest in a CBCT.

**HOW LARGE SHOULD THE FIELD OF VIEW BE?**

CBCT examinations raise the issue of just which area of the anatomy should be included in a study. For example, if one takes a CBCT scan of the maxilla for purposes of evaluating the jaw for implants, should one cover just the alveolar bone

and only a few millimeters superior to the sinus floor, or should one include most of or even the entire sinus? According to accepted radiologic principles, the indications for and the extent of imaging should be based on clinical indications.<sup>12,13</sup> The basis for these principles is to protect both the individual patient's and the public's health from unnecessary radiation. In the example given above, if the patient has no sinus symptoms and no sinus pathology is suspected upon clinical examination, there is little argument for including the whole sinus. The request of the treating clinician over how large an area to cover is a valid consideration, although it should not trump well accepted radiologic principles.

One can also collimate too narrowly, either accidentally or on purpose, and thereby exclude anatomy that ought to be covered. Some people deliberately collimate too narrowly to avoid including anatomic structures that they are uncomfortable interpreting. This issue will be discussed later in the article. As mentioned previously, there is an increasing trend for CBCT machines to be bought by dentists who are not oral and maxillofacial radiologists. Prime among this group of dentists are orthodontists and practitioners who perform implant surgery. These practitioners generally do not have the training to interpret the films beyond the anatomy that they see on a daily basis in their area of practice. In an attempt to avoid issues of interpretation of anatomy they are not comfortable with, some practitioners collimate the beam down to the smallest area possible. In doing this, however, one runs the risk of missing relevant information. For example, if one were to collimate too narrowly

when imaging the temporomandibular joint (TMJ), one could miss pathology that is not located on or in the condyle or glenoid fossa, but that is nevertheless contributing to the TMJ problem. To reiterate, the physical extent of the examination should be based on the patient's signs and symptoms.

**WHO SHOULD INTERPRET THE CT SCANS?**

One major problem that a non-radiologist dentist who acquires a CBCT machine faces relates to the interpretation of the images. That this is a matter of concern is recognized by specialties beyond that of oral and maxillofacial radiology.<sup>14,15</sup>

Dental x-ray laboratories with CBCTs and some medical radiology facilities in the United States that do so-called DentaScan imaging studies (with conventional CT machines) do not read the images. More than that, they include a specific disclaimer. This is especially true of the medical facilities. The disclaimer from the Massachusetts General Hospital provides a fairly characteristic example: "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..."

Dentists who take their own scans or who use the services of facilities that perform them and do not include a report should be concerned about liability for reading the scan. The dentist is responsible not only

for reading the scan as it pertains to their area of practice or the particular reason for which the image was taken, but also for reading all of the anatomy—that is, the entire image volume contained in the scan. Because of the concern over the interpretation of the scans, dentists have sought different ways to limit their liability. They have considered asking patients to sign a waiver of liability for the interpretation of the scans. Such a waiver of liability will, however, in no way in fact limit liability.<sup>16-18</sup> Malpractice carriers also will not allow dentists to require patients to sign a disclaimer.<sup>15</sup> Dentists have also thought about giving patients the choice of whether to have the images read by a radiologist. Dentists reason that because it is the patient's choice there should be no liability on their part for any non- or misdiagnosis. This tactic will also not work. While patients may make treatment decisions, their choices are limited by the bounds of accepted standards of care, and it is not acceptable to give a patient a choice that is below the standard of care.

**REFERRING OUT THE READING OF SCANS**

Dentists who take their own CT scans are not required to read the scans themselves. This is not unlike any other procedure—a dentist is not expected to perform a procedure that he is not competent to perform. Under these circumstances he is expected to refer the patient to a practitioner who is competent. Unless they have completed a formal program in oral and maxillofacial radiology, most dentists do not have the expertise to interpret CT scans. They are therefore obligated to refer the reading of the images.

With modern technology, it is a simple matter to refer the reading

of images to an oral and maxillofacial or medical radiologist. Today, this is usually accomplished by uploading the cases to a server from which the radiologist downloads them, interprets them, and sends back a report. It is also possible for a radiologist to log on directly to the dentist's computer and to read the images in that manner. While there are few technological hurdles to reading the CT scans, licensing laws have not kept pace with the changes in technology.<sup>19</sup> In countries with a national dental license, or at least a de facto national license, licensing laws do not present any impediment to the reading of scans by a radiologist situated anywhere in the country. In countries like the United States, Canada, and others that have state-by-state or province-by-province licensing, the laws may present a significant problem. In order to practice in a state, a dentist must have a valid license in that state. Typically, "...it is the location of the patient that defines where the care has been delivered and the jurisdiction of applicable regulations."<sup>20</sup> It further states that "...whether the out-of-state practitioner is reimbursed is irrelevant."

State-by-state licensing laws present a problem for a dentist in one state who wants to have his CT scans read by a radiologist in another state. The general rule is that a dentist needs to be licensed in the state in which he is practicing. For centuries this has meant that the dentist needs to be licensed in the state where his practice is physically located. With reading images over the Internet, also known as teleradiology, the radiologist can be located anywhere he or she can access the Web. The purpose of licensing laws is to protect the health and welfare of the citizens of a state,<sup>21</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 working physically out of state. However, can the state where the radiologist is physically located when he reads the films require him to be licensed there too? While the answer in America is “almost certainly,” there are no reliable data on American licensing requirements for out-of-state dentists who read films of the citizens of their state.

Some American medical boards have weighed in on the issue of telemedicine. Among the boards that have considered the matter, there is an exceptional lack of uniformity. A few medical boards have enacted forms of limited licenses that apply in cases of telemedicine, but many require a full license in that state for an out-of-state radiologist to read images taken of its citizens in-state. The Federation of State Medical Boards maintains an updated list of state telemedicine licensing laws.<sup>22</sup>

Dentists have sought to circumvent the state-by-state licensing problem by phrasing the radiologist’s interpretation as being only a “second opinion.” The argument then becomes that the out-of-state radiologist does not need a license in the state where the dentist and his patients reside. This tack will not work, because 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>23</sup> In order for the radiologist’s interpretation to constitute a true second opinion, the dentist would in fact have had to make a diagnosis and then seek the radiologist’s opinion. Some states have a licensing exception for an out-of-state

physician who is providing a second opinion. In Massachusetts, for example, “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” provides a second opinion, does not need a Massachusetts license (emphasis added).<sup>24</sup> 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 for a second opinion, the licensing exception does not apply (Debra Stoller, Senior Board Counsel, Massachusetts Board of Registration in Medicine, personal communication, January 2010).

The issues that arise as a result of state-by-state licensing within a country would of course apply even more so between countries when a dentist uses an out-of-country radiologist.

**INSURANCE CONSIDERATIONS**

If a radiologist’s malpractice carrier covers the radiologist only for the state in which he took out the malpractice coverage and/or in which he is licensed, the carrier may not cover him for reading the images of patients whose scans were taken in a state in which he is not licensed. If a dentist refers the reading of a CT scan to such an out-of-state or out-of-country radiologist, and the patient later sues the radiologist, the dentist may find that the patient sues him because there is simply no money to be had from the radiologist. This is even more likely if the state in which the patient resides requires the radiologist to be licensed there and he is not. In the United States, there is also potential liability for referring a patient to a practitioner that the dentist knows or should know is

not competent. This legal action is known as negligent referral.<sup>25</sup> A patient could argue that the referring of the reading to an unlicensed radiologist means that it was a negligent referral, making the dentist primarily liable. It should be pointed out, however, that such suits are rare.

**CONCLUSION**

With so much uncertainty surrounding the issues discussed above, what advice can one give to a dentist seeking to acquire a CBCT machine? The dentist should make sure that the law of the jurisdiction in which he or she practices—whether state, provincial, regional, or national law—imposes no impediments to the acquisition and operation of a CBCT unit. It is essential that he or she reads the entire image volume or has it read by someone who is competent to do so. If the dentist chooses to do the latter, he or she should be sure to check with the appropriate dental board or boards as to where the radiologist is required to be licensed. Referral to a radiologist who is not licensed in the appropriate jurisdiction(s) might make the dentist vulnerable to disciplinary action by the dental board and may also make the dentist guilty of the crime of aiding and abetting the unlicensed practice of dentistry.<sup>26</sup> Finally, the dentist should confirm that the radiologist carries malpractice coverage and that the dentist’s carrier will cover him or her for out-of-state practice.

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