CHAPTER 1:

1.0 INTRODUCTION

Cone-beam Computed Tomography (CBCT) is a leading-edge radiological diagnostic tool that is frequently used by South African dental practitioners is specialities such as oral and maxillofacial surgery, endodontics, implantology, orthodontics, temporomandibular joint disorders, periodontics and forensic dentistry (Alshehri, Alamri & Alshalhoob, 2010: 2; Noffke *et al.*, 2011: 262-266; Mah, 2010: 5). CBCT uses an innovative technology that offers a superior image quality compared to conventional radiological techniques (American Dental Association Council on Scientific Affairs, 2012: 899-902). But, South African dental practitioners that make use of this novel diagnostic procedure receive no formal theoretical or practical training pertaining to the safe and efficient use of this technology (Noffke *et al.*, 2011: 262-266).

Dental practitioners prefer to use this new technology due to the excellent quality of the images produced by this technique and because modern technology is considered a more sophisticated service. The rapid advancements in CBCT technology and aggressive marketing of the product have overtaken the rules and regulations available for this technique as well as training and competency levels required in using this new imaging system. Considerably higher radiation doses are being used with CBCT technology (Noffke *et al.*, 2011: 262-266). However, South African dental practitioners are using this new technology with the same safety precautions and clinical indications as previously used for lower radiation radiographic equipment (*op cit*). This is in the backdrop of increasing radiation safety concerns regarding this new technology. To this end, the American Dental Association Council on Scientific Affairs published guidelines that address the safe use of cone-beam

computed tomography in dentistry (Holroyd & Gulson: 2009: 1-10). Some of these pertinent guidelines to CBCT are:

- Imaging should be used only after a review of the patient's health and imaging history and completion of a thorough clinical examination.
- images of the oral and maxillofacial structures should be evaluated by a dentist with appropriate training and education in CBCT interpretation.
- dentists should use professional judgment in the prescription and performance of CBCT examinations by consulting recommendations from available CBCT guidelines and by considering the specific clinical situation and needs of the individual patient.

American Dental Association Council on Scientific Affairs (2012:2)

The Working Party convened by the Health Protection Agency's Radiation Protection Division and European Academy of Dental and Maxillofacial Radiology have also suggested similar guidelines (Holroyd & Gulson: 2009: 1-10). In contrast, South Africa lags behind America and Europe in that there are no specific guidelines pertinent to the use of CBCT.

Ethical and legal issues are raised by the fact that inappropriately trained dental practitioners are currently using a diagnostic technique that involves radiation risks for patients. The criteria for using CBCT technology as a diagnostic tool are far more complex than that for conventional radiographs in terms of selection criteria for patients that require CBCT examination, radiation dosage requirements, analysis of the image and diagnosis (Noffke *et al*., 2013: 256-9). "Avoiding or minimizing harm to patients is a fundamental obligation of all practitioners, and requires thorough, sound and rigorous training" (Moodley, 2011: 63).

Insufficient training in regards to the radiation risks associated with this technique and a lack of appropriate training for patient selection is ethically unjustifiable and as a result, may lead to the indiscriminate use of CBCT, thereby exposing patients to unnecessary risks.
A further ethical issue surfaces when dental practitioners arbitrarily make use of a diagnostic technique that exposes patients to a higher dosage of harmful radiation when, alternative lower dosage radiation techniques would yield sufficient diagnostic information.

1.1 The harm principle and radiation exposure

The harm principle was introduced by John Stuart Mill (Mill, 1863: 1-223). Although the original quote referred to state intervention in regards to preventing individuals from hurting themselves or others, it may also be applied in the healthcare context in respect to the use of CBCT by dental practitioners. Healthcare practitioners that cause harm to their patients can thus be held legally accountable according to the harm principle.

According to Marshall & Keen (2007: 2), no radiation dose can be considered safe due to the fact that ionizing radiation, like the type received from a CBCT scan, accumulates in the human body over time and has the potential to cause cancer. Furthermore they consider that in the new digital era of diagnostics, where radiation exposure is higher than in traditional radiography, healthcare practitioners that are disregarding basic radiation safety precautions are ultimately causing harm to their patients (Marshall & Keene, 2007:1-5).

Even though most dental surgeries have been using well-established radiation safety measures that have proven to be efficient in regards to conventional dental radiographs, these conventional protective measures cannot be applied adequately and safely to modern CBCT technology (Holroyd & Gulson, 2009: 9-10). To address these issues, the European Academy

of Dentomaxillofacial Radiology has published a set of twenty general guidelines pertaining to the safe and effective use of CBCT. These are, amongst others:

- CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks.
- all those involved with CBCT must have received adequate theoretical and practical training for the purpose of radiological practices and relevant competence in radiation protection.
- continuing education and training after qualification are required, particularly when new CBCT equipment or techniques are adopted.
- dentists responsible for CBCT facilities who have not previously received 'adequate theoretical and practical training' should undergo a period of additional theoretical and practical training that has been validated by an academic institution (University or equivalent).

(European Academy of Dentomaxillofacial Radiology, 2011: 28)

Serious ethical concerns are raised when young patients are regularly and indiscriminately exposed to ionizing radiation from CBCT (Lorenzoni *et al*., 2012: 1-10). CBCT technology is becoming increasingly more popular within the orthodontic specialty and the majority of orthodontic patients are represented by children and adolescents (*op cit*). These concerns arise from the fact that this age group is significantly more susceptible to the long term damaging effects of radiation than adults and due to the fact that they are in a growing phase with cells constantly being replicated and differentiated (Najjar *et al*., 2011: 784-792).

Additionally, children have smaller organs and their tissues are thinner than that of adults, allowing for more radiation to penetrate which is believed to lead to "increased internal scattered radiation " (*op cit*). "In practice, this might result in excessive radiation to children scanned with default adult setting" (*op cit*). The question is whether dental practitioners understand the risks of harm that they are exposing paediatric patients to when using CBCT.

In summary, even though the use of ionizing radiation in pediatric dentistry, with particular reference to orthodontics, is sometimes unavoidable, cautious justification should be sought before exposing young patients to CBCT diagnostic procedures due to the life-long associated risks of ionizing radiation (Lorenzoni *et al*., 2012:1-10).

Furthermore, dental practitioners need to be made aware of the differences in radiation safety requirements for modern radiological technology compared to traditional radiological technology. Exposing patients to a higher radiation dose can only be justified in cases where the additional information acquired through CBCT examinations is essential for an accurate diagnosis (*op cit*). It is evident that dental practitioners that do not have the relevant radiation safety knowledge will have difficulty in justifying which clinical cases warrant a higher dose of radiation and may therefore expose their patients to unnecessary risk and harm.

1.2 Problem statement

Guidelines and safety precautions that were once well established for traditional radiographic techniques are no longer applicable in regards to modern CBCT technology (Holroyd & Gulson, 2009: 1-10). In order to fill the competency based problems regarding professional use of CBCT, other countries such as England, America, and Germany have come up with certified training programs conducted by qualified specialists that address the various areas in

which dental practitioners require theoretical and practical training (Holroyd & Gulson, 2009: 1; Noffke *et al*., 2011: 262-266). A pertinent example of the type of specialized training required by dental professionals to safely make use of CBCT technology is offered by the training course developed by the American Academy of Oral and Maxillofacial Radiology (American Academy of Oral and Maxillofacial Radiology, n.d). This course is composed of two levels. In the first level, which is a one day course, dental practitioners are provided with an in-depth-knowledge of the principles behind CBCT technology, including:

- CBCT image and technique selection;
- reducing radiation risk;
- understanding 3D anatomical variations;
- recognizing key pathological processes; and
- the process of CBCT interpretation and reporting.

(American Academy of Oral and Maxillofacial Radiology, n.d)

(http://www.aaomr.org)

After completion of level one of the training course, participants are required to complete an online examination to obtain a certificate of competency in CBCT application and safety (*op cit*).

Level two of the training consists of a 2 day training programme for those practitioners that have successfully completed part one of the training (American Academy of Oral and Maxillofacial Radiology, n.d). This two-day training session includes an in-depth analysis of the anatomy of the head-and-neck and interpretation of three-dimensional CBCT scan and

principles of enhancing patient safety as well as selection criteria (*op cit*). A practical component of the second sessions includes an exercise of image manipulation to improve clinical outcomes (*op cit*). Ethical and legal responsibilities when using CBCT technology are included in the training (*op cit*). Training is provided by board certified radiologists (*op cit*).

Similar detailed training courses are provided to dental professionals in Denmark, Germany and England, and though they vary in approach, they all emphasize the need for specialized training for those professionals that make use of CBCT technology (European Academy of Dentomaxillofacial Radiology, 2011: 122).

South Africa still needs to develop minimum requirements that need to be achieved for dental practitioner's certification for use of CBCT technology similar to the American guidelines. Some of which are:

- Understanding of the basic principles of CBCT
- Appreciation of the risks associated with ionizing radiation and how to minimize exposure
- Recognize when to prescribe CBCT scans based upon high-yield criteria and minimized radiation dose
- Review associated anatomy and the basics of pathology
- Provide basic interpretation to create a report of CBCT images and identify when to refer for a second opinion or over-read

(American Academy of Oral and Maxillofacial Radiology, n.d.)

Currently in South Africa, no such certification courses are available (Noffke *et al*., 2011: 263-266). Information regarding CBCT is available in the form of scientific articles and workshop presentations by international and local speakers and presented to healthcare practitioners including dentists. There are no practical components in these workshops.

Individual training is provided to the dentist purchasing the CBCT machine by the companies that provide the equipment (Noffke *et al*., 2011: 263-266). These companies give demonstrations on the different components of the machine, technical aspects such as imaging techniques in image acquisition and processing and positioning of the patient. The training excludes instructions on radiation safety, patient selection and justification criteria, normal anatomy on a three-dimensional image, radiological interpretation and diagnosis of pathology in the scanned area and legal responsibilities of the operator of CBCT machine (*op cit*).

Thus, dental practitioners who may not have received adequate training regarding the safe and effective use of this technology are currently using this diagnostic procedure (*op cit*). Presently, dental practitioners are making use of a new radiological technology but are still using traditional safety precautions, patient selection criteria and diagnostic criteria as well as rules and regulations. These local training gaps should thus be addressed in earnest by implementing certified training programs at universities around the country.

1.3 Research methodology

The study was designed as a descriptive analytic study using normative ethical and legal analysis. Data collection was web-based. Literature review for report was conducted systematically using search engines such as PubMed, J-STOR, EBSCO, Elsevier, Google Scholar, Medline Science Direct and other search engines.

1.4 Ethical considerations

As this study was normative and descriptive and as it does not involve human participants, a waiver to do this research was obtained from HREC of the University of Witwatersrand (Ref: W-CJ-130412-.

CHAPTER 2:

2.0 LITERATURE REVIEW

2.1 Biological effects of ionizing radiation

Radiation is a form of energy that travels through space and matter (Oak Ridge Institute for Science and Education, 2013:5-19). CBCT technology uses a type of radiation called ionizing radiation that has the capacity to generate charged particles called ions (*op cit*). Ionizing radiation interacts with individual atoms either directly or indirectly and this interaction can have a harmful biological effect on the cells of the human body (United States Nuclear Regulatory Commission Technical Training Centre, n.d: 3).

There are two important types of radiation induced biological changes that are detrimental to the human body, namely stochastic effects and deterministic effects (Marshall & Keene, 2007: 1). The stochastic effects of ionizing radiation are seen some time after the exposure and these include malignancies and genetic mutations (Little, 2003: 261). Stochastic effects are of concern where small repeated radiation doses are received (*op cit*). By contrast, the deterministic effects of ionizing radiation are noticed a short time after the exposure to radiation and these include toxicity of the kidneys and bone marrow suppression (*op cit*). Research that has been conducted on atomic bomb survivors has confirmed that, exposing individuals to small but repeated ionizing radiation is a causative agent for cancer (Inkret, Meinhold & Taschner, 1995: 123). The International Commission on Radiological Protection introduced the Principle of ALARA (As Low as Reasonably Achievable) as the basic guideline for radiation protection (Marshall & Keen, 2007: 2; Noffke & Snyman, 2007: 438). The principle of ALARA states that even small radiation doses can be detrimental to the

health of the human body and therefore radiation exposure should be maintained as low as possible without losing the information required for diagnostic purposes (*op cit*).

2.2 Brief history of CBCT

CBCT developed as a result of the discovery of X-rays in 1895 coupled with the recent advancements made in image processing technology (Friedland, 2009: 58; Sukovic, 2003: 36). The first CBCT machine was developed in 1982 and was used in angiography (Lofthag-Hansen, 2010: 7). The first CBCT machine was developed for use in the maxillofacial region in the 1990's and it was available commercially on the dental market in 2001, as a convenient lower dosage, compact, faster and safer version compared to the Computed Tomography (CT) that is used in Medicine (*op cit*). A typical CBCT scanner can fit into any dental practice and is easily accessible by patients (see figure 1).

CBCT machines provide a three-dimensional image in contrast to the two-dimensional image provided by conventional dental panoramic machines (see figure 2). The advantage of viewing the images in a three-dimensional plane is that greater detail can be achieved in the area of interest by reconstructing and manipulating the image using computer generated programmes (*op cit*) (see figure 3). The cost of a CBCT scan is considerably higher than the cost of a conventional panoramic radiograph, as indicated by the table below.

Table 1: Costs of CBCT scan compared to dental panoramic radiographs

Cost of CBCT examination (Rands)	Cost of dental panoramic radiograph (Rands)
1800-4500	350-900

This novel diagnostic technique was well received by the dental profession and some labelled it as the "gold-standard" in clinical diagnostics (Scarfe, 2011: 401-2). Aggressive marketing in the dental field by certain companies underrated radiation concerns by unscientifically equating a CBCT examination to a "whole-body scan at the airport" (Bogdanich & McGinty, 2010: 1). In South Africa, these claims are made in the backdrop of little or no training on CBCT use for dental practitioners. CBCT technology uses significantly higher radiation dosages compared to conventional radiographic techniques such as intraoral radiograph and panoramic radiograph.

The table below provides a brief comparison regarding the effective dose received from CBCT machine compared to conventional dental panoramic machine.

Table 2: Comparison of effective doses

Radiographic technique	**Effective dose (µSv)**
Dental panoramic radiograph	24
Small Field of View (CBCT)	48-652
Large Field of View (CBCT)	68-1073

Holroyd & Gulson (2009:2)

2.3 Training and certification

In South Africa, the chief statute that oversees the medical profession is the Health Professions Act No. 56 of 1974 (Coetzee & Carstens, 2011: 1263). The functions of this Act, are to:

- Establish the Health Professions Council of South Africa and professional boards;

- to provide for control over the education, training and registration for and practicing of health professions registered under this Act and
- and to provide for matters incidental thereto

Health Professions Act (56 of 1974)

Through this Act, the Health Professions Council of South Africa (HPCSA) was thus established (Health Professions Act, 56 of 1974, 2 (1)). The objectives and functions of the HPCSA, amongst others, are:

- To coordinate the activities of the professional boards established in terms of this Act and to act as an advisory and communicatory body for such professional boards, and
- to promote and to regulate interprofessional liaison between health professions in the interest of the public

Health Professions Act, 56 of 1974, (3 (a)(b)

[Para. (b) substituted by s. 3 of Act 29/2007]

South African courts recognize the HPCSA as the "sole repository of the power to decide what is ethical and what is unethical in medical practice" (Coetzee & Carstens, 2011: 1265). The HPCSA is further considered as a:

> [T]ruly a statutory custos morum of the medical profession, the guardian of the prestige, status and dignity of the profession and the public interest in so far as

> members of the public are affected by the conduct of members of the profession to whom they have stood in a professional relationship
>
> *Veriava v. President of S. African Med & Dental Council* 1985 (2) SA 587

Under the Health Professions Act, the HPCSA is authorized to establish professional boards whose functions are, inter alia, to grant certificates and authorize training schools (Coetzee & Carstens, 2011: 1266). Twelve professional boards have been established under the Health Professions Act, including the Medical and Dental Professional Board (MDPB) (*op cit*). The MDPB is in control of the training of dental students as well as medical students and is responsible for all medical and dental practitioners that are registered with the HPCSA (*op cit*).

No healthcare practitioner is allowed to practice their profession in South Africa before being registered with the HPCSA under the Health Professions Act (Health Professions Act, 56 of 1974, 17(1)(a). Individuals that violate this provision may be fined and/or imprisoned for up to twelve months (Health Professions Act, 56 of 1974, 34(1)).

Twelve professional boards have been established under this Act that have the "power to institute an inquiry into any complaint, charge or allegation of unprofessional conduct against practitioners registered under [the Health Professions] Act" (Health Professions Act, 56 of 1974, 4(a) 41). Unprofessional conduct is defined as "improper or disgraceful or dishonourable or unworthy conduct" (Health Professions Act, 56 of 1974, 4(a) 1). If

healthcare practitioners are found guilty of unprofessional conduct the professional boards may impose one of the following penalties:

- A caution or a reprimand or a reprimand and a caution; or
- suspension for a specified period from practising or performing acts
- specially pertaining to his profession; or
- removal of his or her name from the register or
- a fine not exceeding R10 000 or
- a compulsory period of professional service as may be determined by the professional board or
- the payment of the costs of the proceedings or a restitution

Health Professions Act (56 of 1974, (42(1)(a)-(f))

With reference to CBCT, in depth knowledge is required by dental practitioners in order to accurately make use of CBCT technology for diagnostic purposes (Noffke *et al*., 2011: 263-265). This knowledge includes appropriate selection criteria for patients and selection of the correct anatomical area to be included in the scan, diagnosing pathology in and around the maxilla-facial area as well as knowledge regarding radiation protection measures (*op cit*). The following safety standards need to be complied with when using CBCT technology: "radiation protection in relation to CBCT equipment, including justification (referral/ selection criteria) and relevant aspects of optimization of exposures and staff protection" (European Academy of Dentomaxillofacial Radiology, 2011: 122).

In South Africa, instructions are received upon purchasing the equipment from the manufacturers on the use of CBCT (*op cit*). Some may argue that sufficient information is received in this manner as well as from reading scientific articles about CBCT. However due to the complex knowledge that is required in the use of CBCT for diagnostic purposes, the risks associated with ionizing radiation and in order to avoid the complications that may arise from incorrect diagnosis, it is an ethical requirement for dental practitioners to have reasonable knowledge and acceptable competency levels so that they can make use CBCT appropriately. This is not merely a requirement, but also a duty of the dental practitioner to learn these skills.

2.4 Duties of healthcare practitioners

"A duty is an obligation to do or refrain from doing something" (Health Professions Council of South Africa, 2008, Booklet 1, 4(1): 4). The fundamental ethical duty of all healthcare practitioners is to act, at all times, in the best interest of their patients (World Medical Association International Code of Medical Ethics and the Declaration of Geneva, 2006:1-2).

General duties of healthcare practitioners as stated by the World Medical Association International Code of Medical Ethics include, amongst others, the duty to:

- Be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity
- always exercise his/her independent professional judgment and maintain the highest standards of professional conduct.

World Medical Association International Code of Medical Ethics and the Declaration of Geneva (2006:1)

In South Africa, all healthcare practitioners are required to be registered with the Health Professions Council of South Africa and as such this registration grants healthcare practitioners "the right and privilege to practice" their chosen profession (Health Professions Council of South Africa, 2008, Booklet 1, 1(1):1). "Correspondingly, practitioners have moral or ethical duties to others and society" (*op cit*). These duties are expressed both as "natural duties" as individuals living in a society as well as "professional duties" that are acquired as a result of the profession that they entered into (Health Professions Council of South Africa, 2008, Booklet 1, 4(6)1; 4(6)2, :4). Natural duties included common duties to promote good and prevent harm and act in a fair and just manner as a member of society at large (*op cit*). Professional duties include duties to patients upon entering into a contractual relationship with them as well as specific duties that healthcare practitioners have towards the institution that they are employed by (Health Professions Council of South Africa, 2008, Booklet 1, 4(6) 3:4). Legal duties are " duties imposed by the common law and by statute law (for example, the National Health Act, No. 61 of 2003) that require health care practitioners to follow certain procedures and to use particular skill and care when dealing with patients" (Health Professions Council of South Africa, 2008, Booklet 1, 4(6)4 :4).

Further duties that healthcare practitioners have towards their patients include, but are not limited to:

- Be mindful that they are in a position of power over their patients and avoid abusing their position
- honour the trust of their patients

- apply their mind when making diagnoses and considering appropriate treatment.
- respect the privacy and dignity of patients
- respect the right of patients to be fully involved in decisions about their treatment and care even if they are not legally competent to give the necessary consent.

Health Professions Council of South Africa

(2008, Booklet 1, 5(1):5)

In addition, healthcare practitioners have duties to themselves to:

- Sustain their knowledge and skills by lifelong learning in their specific field of interest
- be aware that they may not be competent in all fields and admit the limits of their professional knowledge
- be well informed of the rules and regulations that govern their specific field

Health Professions Council of South Africa

(2008, Booklet 1, 8(1):9)

Concerning CBCT, dental practitioners have the general duty to heal and prevent harm to their patients. Furthermore, dental practitioners have the duty to use their professional skills and knowledge towards serving the best interest of the patients. This duty is extended to the use of CBCT as a diagnostic modality, only in those clinical circumstances in which it would be beneficial for the patient. Furthermore, it is the professional duty of every dental practitioner to keep abreast with technological and scientific advancements in their particular

specialty. "In particular they should regularly take part in educational activities that would enhance their provision of health services" (Health Professions Council of South Africa, 2008: Booklet 1, 8(1): 9). At the same time, healthcare practitioners have the duty to recognize the confines of their knowledge and skills and limit their practice only to those fields in which they are competent (*op cit*). This is pertinent to CBCT training as well.

CHAPTER 3

3.1. LEGAL ISSUES PERTAINING TO CBCT

3.1.1 Legal measure that control the use of X-ray equipment

In South Africa, there are legal and control measures that regulate the safe use of equipment that uses ionizing radiation (Department of Health Directorate: Radiation Control 2010; Hazardous Substance Act 15 of 1973). The Department of Health Directorate of Radiation Control has the function, amongst others, of ensuring that radiation control measures are in place according to The Hazardous Substances Act 15 of 1973. To this end the Department of Health has established guidelines pertaining to the safe use of radiation (Department of Health: Radiation Control, 2010). According to these guidelines, radiological examinations should only be performed when the "benefit outweighs the associated risk" and radiation exposures should at all times respect the Principle of ALARA which is to keep the radiation dose as low as reasonably achievable (*op cit*).

In terms of protection of patients, the guidelines specify that: "all medical exposures should be subject to the principle of justification and optimization" and that "diagnostic procedures that use ionizing radiation should only be performed if validated by a clinical examination" (*op cit*).

Radiographic equipment purchased in South Africa needs to be licensed with the Directorate of Radiation Control; CBCT falls under this Act. The dental practitioner who owns the CBCT machine must apply for a license in order to be allowed to operate the machine (Noffke & Snyman, 2007: 438). Once the licence is granted, it becomes the responsibility of the owner

of the machine to comply with radiation safety standards set by the Hazardous Substance Act (Act 15 of 1973).

The same laws can arguably be applied to CBCT machines where the dental practitioner holds the responsibility in terms of maintaining radiation safety standards set by the Act (Noffke & Snyman, 2007: 438).

3.1.2 The right to a safe environment

According to the Bill of Rights of the Constitution of the Republic of South Africa, which is the supreme law of the land, every individual has the right to "an environment that is not harmful to their health and well-being"(1996, Section 24(a)). This is not only a legal right but a human right as well. When patients are exposed to radiation for diagnostic purposes, they are being exposed to a harmful environment. Dental practitioners need to ensure that they protect and promote a healthy environment by only exposing patients to radiation when the clinical benefit outweighs the risks. The indiscriminate use of CBCT for reasons other than clinical benefit would be harmful to the health and wellbeing of patients and thus unwarranted. Although it is not always possible to completely prevent radiation exposure, it should be kept as low as possible and only with specific clinical indications and justification. Anyone who infringes upon this right by arbitrarily exposing patients to a harmful environment can be held accountable for negligence or found guilty of medical malpractice and even be struck off the register of the Health Professions Council of South Africa.

3.1.3 Professional negligence and medical malpractice in South Africa

Negligence is defined as "intentionally imposing risks that are unreasonable, as well as unintentionally but carelessly imposing risks" (Moodley, 2011: 66). Professional negligence is regarded in those instances where "health practitioners *negligently* fail to exercise the degree of skill and care of a reasonably skilled practitioner in their field of practice" (Dhai & McQuoid-Mason, 2011: 92). In the case of *Mitchell v. Dixon* (1914 AD 519), it was noted that "a medical practitioner is not expected to bring to bear upon the case entrusted to him the highest possible degree of professional skill and care, he is bound to employ reasonable skill and care; and he is liable for the consequences if he does not." The courts in South Africa decide whether or not the healthcare practitioner was negligent by considering the degree of skill that a reasonable healthcare practitioner would generally display (*Van Wyk v Lewis,* 1924 AD 438). Standard of care is determined by whether a "reasonably competent healthcare practitioner in the same field would have been able to foresee the likelihood of harm and would have been able to take adequate steps to guard against it" (*Buls v Tsatsarolakis,* 1976 (2) SA).

"Imperitia culpae adnumeratur —lack of skill is reckoned as a fault!" (Otto, 2004: 20). "A practitioner is always negligent if he performs a procedure knowing that he does not have the necessary skill, knowledge or experience" (*op cit*). The fact that lack of skill is considered a form of negligence is extremely significant to dental practitioners that are currently using CBCT technology without adequate expertise and knowledge. Dental practitioners can thus be held accountable for professional negligence if they fail to use CBCT technology with the degree of competence that a reasonably skilled dental practitioner would demonstrate. Furthermore dental practitioners could be considered negligent if they carry out diagnostic assessments which they are not appropriately trained to diagnose, leading to a misdiagnosis

or a failure to diagnose pathology (Pepper & Slabbert, 2011: 29-35). Those dental practitioners that use CBCT negligently and indiscriminately for each and every patient without clear clinical justification could be held responsible for medical malpractice.

Medical malpractice is the "negligent or intentional unlawful conduct on the part of the healthcare practitioners that causes injury or damage to their patients or their patient's property" (Dhai & McQuoid-Mason, 2011: 92). Medical malpractice is thus a form of negligence but "goes further than professional negligence because it includes negligent or intentional acts" *(op cit).* Patients in South Africa are becoming increasingly more aware of their rights in regards to their healthcare, and, as a result, medical malpractice litigation cases have also drastically increased in the last few years (Naidoo, 2010:1-4). These malpractice cases include, amongst others, misdiagnosis and practising outside of scope of competence (Pepper & Slabbert, 2011: 29-35). Between April 2008 and March 2009, approximately 90 South African healthcare practitioners were found culpable of "unprofessional conduct" and 44 healthcare practitioners were permanently removed from the roll for "unethical and unprofessional conduct" (Naidoo, 2010:1-4).

The Consumer Protection Act came into effect in 2011 in order to prevent vulnerable individuals from being exploited (Consumer Protection Act, 68 of 2008). The establishment of this Act has direct implications for dental practitioners as it stipulated that the person that supplies the goods to patients is liable for any harm that may be caused (Pepper & Slabbert, 2011: 29-35). This extends to giving insufficient caution regarding the risks "associated with the use of any goods" and means that patients may claim damages from the dental practitioner if they were not made aware of the risks associated with the diagnostic procedure (*op cit*).

In summary, dental practitioners that make use of CBCT technology indiscriminately for all patients without clinical justification could be held accountable in a court of law. Similarly, dental practitioners could be held liable for damages to the patient if they fail to inform them of all the risks that are associated with the CBCT procedure.

3.2 CODES OF ETHICS

"Codes of ethics have been a longstanding element in the professional control of the behaviour of doctors, and indicate a commitment to act with integrity in extreme circumstances" (Limentani, 1999: 394). The International Code of Medical Ethics was adopted at the General assembly of the World Medical Association in 1949 in London and was last amended in 2006 (World Medical Association International Code of Medical Ethics and the Declaration of Geneva, 2006:1-2). These Ethical Codes are relevant to all healthcare practitioners and stipulate the general duties that are expected from healthcare practitioners, such as to:

- Be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity.
- always exercise his/her independent professional judgment and maintain the highest standards of professional conduct.
- respect the local and national codes of ethics.

World Medical Association International Code of Medical Ethics and the Declaration of Geneva (2006:1-2)

Specific duties that healthcare practitioners have towards their patient and colleagues in the International Code of Ethics include, among others, to:

- Always bear in mind the obligation to respect human life
- owe his/her patients complete loyalty and all the scientific resources available to him/her. Whenever an examination or treatment is beyond the physician's capacity, he/she should consult with or refer to another physician who has the necessary ability.

World Medical Association International Code of Medical Ethics and the Declaration of Geneva (2006:1-2)

Dental practitioners must comply with the laws and regulations specified in the national and international codes of ethics as they are binding to all healthcare practitioners.

Another well-established code of ethics is the Hippocratic Oath (Limentani, 1999: 394-398), which is currently used by all the four medical universities in South Africa. This Oath expects healthcare practitioners to always take into consideration the health and wellbeing of their patients as their first priority (*op cit*). It expresses both duties of nonmaleficence and beneficence as these two duties are strongly interconnected (Beauchamp & Childress, 1994: 194).

Every graduate student of the University of the Witwatersrand, for instance, makes the following public pledge, inter alia:

> That I will exercise my profession to the best of my knowledge and ability for the safety and welfare of all persons entrusted to my care and for the health and well-being of the community.

Ethical codes thus provide standards that regulate the collaboration between healthcare practitioners and their patients (Dhai & McQuoid-Mason, 2011: 16). Healthcare practitioners need to use these ethical codes as "guidelines for morality in healthcare and health practice" (*op cit*). The healthcare profession is self-regulated and ethical codes thus serve as important guidelines for healthcare practitioners and are essential in upholding societies' expectations of the profession (Cruess, Johnston & Cruess, 2004: 209).

3.2.1 Professionalism and competence in healthcare

Professionalism

"Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners" (Health Professions Council of South Africa, 2008, Booklet 10: i).

A profession is a "dedication, promise or commitment" affirmed publicly (Pellegrino, 2000: 148). A healthcare profession can be defined as "an occupation that is characterized by high moral standards, including a strong commitment to the well-being of others, mastery of a body of knowledge and skills, and a high level of autonomy" (Williams, 2009: 48). This commitment is underpinned by a social contract between the profession and society (Cruess & Cruess, 2008:579). This social contract implies that particular obligations and expectations must be met by both parties (*op cit*).

Healthcare practitioners are viewed by society in the dual role of healer and professional and thus society expects healthcare practitioners to treat their patients with dignity and compassion and to respect the confidentiality and privacy of their patients (*op cit*). As part of the contract, healthcare practitioners also have certain obligations towards the profession (*op cit*). These obligations include adherence to codes of ethics in order to protect the trust in the profession. According to Cruess "the recognition of these expectations is important as they serve as the basis of a series of obligations which are necessary for the maintenance of medicine as a profession"(2006:170-6). "Mutual trust and reasonable demands are required of both parties to the contract" (*op cit*).

Therefore, being regarded as a professional implies that high levels of competence will be expected from healthcare practitioners; these standards of competence can be ensured by "setting and maintaining standards for education, training, and practice-and by disciplining incompetent, unethical, or unprofessional conduct" (*op cit*).

Codes of ethics in healthcare therefore provide the framework and guidelines for the ethical behaviour of healthcare practitioners and serve as an important component of societies' expectations of the profession (Cruess *et al*., 2004: 209) "For the ideal of professionalism to survive, physicians must understand it and its role in the social contract" (*op cit*).

The dental practitioner-patient relationship is unique due to the fact that dental practitioners are afforded special access to knowledge both regarding the patient as well as regarding the various diagnostic and treatment options available for the patient (American College of Dentists, 2012: 5). Patients trust that dental practitioners possess the necessary knowledge and skills to offer them the best diagnostic and treatment options (American College of Dentists, 2012:8). As such, dental practitioners are obligated to comply with ethical codes of ethics in all aspects of their profession, including diagnostic procedures (Scarfe, 2011: 403).

In summary, healthcare practitioners are required to demonstrate clinical and technical competence together with empathy and kindness towards their patients (Dhai & McQuoid-Mason, 2011:61). It cannot therefore be said that dental practitioners are treating their patients with dignity when they lack the competence to use CBCT appropriately.

Competence

The Oxford Dictionary defines competence as the "ability to do something successfully or efficiently" (Oxford University Press, 2013). "Competence builds on a foundation of basic clinical skills, scientific knowledge, and moral development" (Epstein & Hundert, 2002: 227).

Competence is a key feature that a professional must demonstrate in order to protect the status of the profession (Swich, 2000: 612-616). Epstein & Hundert, further describe professional competence as "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served" (2002:228).

"A crucial aspect of healthcare practice is the application of scientific knowledge to human health, thereby bridging the gap between science and society" (Dhai, 2008b: 174).

Maintaining competency levels in healthcare is not only an ethical requirement but also a legal requirement. In South Africa, continued professional development (CPD) is an initiative that is endorsed by Section 26 of the Health Professions Act No 56 of 1974, as a means of ensuring that healthcare practitioners maintain high standards of professional competence. The Health Professions Council of South Africa provides the following motivation for introducing compulsory CPD initiative:

- The knowledge, information and skills acquired by healthcare professionals as students and or interns become obsolete at some point in time
- the acquisition of new knowledge and skills for any field is advancing constantly and this new knowledge is not easily communicated to healthcare professionals; and
- in order to protect the public by ensuring the promotion of health of the society of the Republic, healthcare professionals are required to commit themselves to lifelong learning (CPD) and to keep abreast by improving their knowledge, skills and ethical attitudes.

Health Professions Council of South Africa

2008 (Booklet 4, (1): 5)

Indeed, rapid technological advances in diagnostic modalities such as those seen in CBCT, make it increasingly more difficult for dental practitioners to keep up to date with their competency levels. Great expertise and skill is needed to determine the specific anatomical region that should be included in the CBCT examination, called the Field of View (FOV) (Friedland, 2009: 58-60). The FOV could be chosen to be too large, in which case the radiological principle of ALARA (as low as reasonably achievable) is not respected, or the FOV could be chosen to be too small thereby missing out on important anatomical landmarks and/or pathology (*op cit*). Reports indicate that some dental professionals intentionally make use of a smaller FOV in order to avoid having to interpret anatomical structures that they do not feel competent interpreting (*op cit*). This practice is not ethically acceptable as it is clearly not in the best interest of the patient to receive a radiation dose that is unnecessarily high or to risk important pathology being missed due to a smaller than required area being imaged. Furthermore, dental practitioners that do not have the required expertise may not be equipped to diagnose pathology outside the clinical concern of the dental practitioner; this may have

serious health consequences for the patient if left undiagnosed and hence untreated (Noffke *et al*., 2013:256-9). The most recent guidelines published by the American Dental Association, specify that dental practitioners have the responsibility to interpret the entire image that was scanned, including the regions outside the maxillofacial region (American Dental Association, 2012: 900). It is unjustifiable for dental practitioners to make use of CBCT technology without an in-depth knowledge of anatomy and pathology in the maxillofacial region.

In my view, due to the complexities of using CBCT as a diagnostic technique compared to traditional radiographic techniques, competency levels regarding this technology should be regulated by means of certified courses offered by qualified professionals in South Africa. Ensuring competency levels regarding CBCT merely through CPD is insufficient, as these courses are often offered by companies whose primary goal is to promote their products and as such may undermine the radiation risks associated with the technology they are endorsing (Bogdanich & McGinty, 2010: 9).

Briefly, competence protects patients from harm. The use of CBCT by incompetent dental practitioners is considered unethical practice and might lead to the unwarranted use of this technique at each patient encounter which would be considered an over-service.

3.2.2 Overservicing

Overservicing is one of the key concerns regarding the use of CBCT. The issue of overservicing has been addressed by the Health Professionals Council of South Africa, which has published guidelines pertaining to overservicing and perverse incentives in healthcare (Health Professionals Council of South Africa, 2008: Booklet 5). Overservicing is defined as "the supply, provision, administration, use or prescription of any treatment or care…which is

medically and clinically not indicated, unnecessary or inappropriate" (Health Professionals Council of South Africa, 2008: Booklet 5, 3(1): 4).

Providing patients with a diagnostic procedure which is not clinically indicated and not necessary is also considered an overservice (*op cit*). It follows that the routine use of CBCT examinations on every patient without a specific clinical indication is ethically unjustified, as it is not in the best interest of the patient to perform examinations that carry a much higher health risk due to higher radiation doses, in cases where conventional examinations would provide sufficient diagnostic information.

3.3 ETHICAL PRINCIPLES

3.3.1 Principlism

Beauchamp and Childress introduced the four principled approach to medical ethics. Their intention was to offer healthcare practitioners a framework for practicing ethically and guiding the behaviour of healthcare practitioners. These principles form the core of teachings in ethics classes as they are helpful in introducing health professionals to ethics. This research report is focused on the utility of these principles whilst acknowledging that there are weaknesses to this approach. The four fundamental moral principles are autonomy, beneficence, non-maleficence and justice (Beauchamp & Childress, 1994: 9). All of these four principles are "prima-facie" principle, which means that they are binding and must be fulfilled unless they clash with an equivalent or stronger principle (Dhai & McQuoid-Mason, 2011: 14).

3.3.2 The ethical principles of autonomy and beneficence

The first two principles advanced by Beauchamp and Childress, are the principle of autonomy and the principle of beneficence. The principle of autonomy refers to "a set of diverse notions including self-governance, liberty rights, privacy, individual choice, liberty to allow ones will, causing one's own behaviour, and being one's own person" (Beauchamp & Childress, 1994: 67). In the healthcare context, this principle signifies that every rational person has the right to make their own decisions regarding medical treatment. On the issue of CBCT, autonomy refers to respect for persons and links to the principle of beneficence. Use of CBCT without competence therefore undermines the autonomy of the patient.

The principle of beneficence can be defined as an "action that is done for the benefit of others" (Pantilat, 2008: 1-2). The main duty of the dental practitioner, according to this principle, is to always serve in the best interest of the patient by maximizing benefits and minimizing harm.

These two ethical principles will be discussed in further detail later in this research report.

3.3.3 The ethical principle of non-maleficence

Nonmaleficence has been defined using the term harm which includes injury, injustice and violations of an individual's rights (Pantilat, 2008: 1-2). "Obligations of nonmaleficence are obligations of not inflicting harms and not imposing risks of harm" (*op cit*).The principle of non-maleficence otherwise known as *"primum non nocere"* translates to" first do no harm". (*op cit*).The principle of nonmaleficence imposes a duty on the healthcare practitioner to refrain from intentionally causing harm to their patients (Beauchamp & Childress, 1994: 189).

According to this principle, dental practitioners thus have the responsibility to protect their patients from harm. This includes protecting them from unnecessary radiation risks when other alternative diagnostic options are available. This principle is very valuable when dental practitioners have to weigh the net clinical benefit offered by the CBCT examination against the radiation risks associated with the procedure. CBCT in incompetent hands imposes risks of harm and is therefore unethical and unjustified.

3.3.4 The ethical principle of justice

Justice can be defined as "the quality of being fair and reasonable" (Oxford University Press, 2013). "Justice imposes an ethical obligation to treat each person in accordance with what is right and proper" (Health Professions Council of South Africa, 2008, Booklet 6, 4(1)3:3). In healthcare, the principle of justice is equated to fairness and integrity (Beauchamp & Childress, 1994: 257-301).

According to Gillon (1994: 184), the principle of justice includes, amongst others: "respect for people's rights (rights based justice)" and "respect for morally acceptable laws (legal justice)".

The principle of justice compels healthcare practitioners to always treat their patients in a fair and just manner (McQuoid-Mason & Dada, 2011: 249). Healthcare practitioners must also be conscious of the fact that they must treat all their patients in an impartial manner while taking cognisance of the "rights and laws concerning unfair discrimination in the management of patient and their families "(Health Professions Council of South Africa, 2008, Booklet 1, 5(6):7).

Thus, dental practitioners have the obligations to treat their patients fairly. Considering that patients are dependent on the knowledge and expertise of the dental practitioner regarding the diagnostic technique that would be most beneficial in their case, the obligation of the dental practitioner is to ensure that they provide their patients with informed and justifiable diagnostic options. Therefore, it cannot be said that dental practitioners are treating their patients justly if they are causing harm to their patients. This is especially so if dental practitioners do not have adequate competency levels regarding CBCT and if patients are not provided with sufficient information in the form of informed consent.

3.4 INFORMED CONSENT IN HEALTHCARE

Traditionally, healthcare practitioners had a paternalistic approach towards their patients and were considered to be the protectors of the health and wellbeing of their patients (Oluchi, 2013:1). Patients granted healthcare practitioners the status of protector and accepted the inequalities of the healthcare practitioner-patient relationship, trusting that the physician always knew best (*op cit*).

Informed consent in healthcare is a considerably new concept that was initially established for research purposes, but has since been widely applied in clinical healthcare as well (*op cit*).

The notion of informed consent came into prominence with the Nuremberg Code as a result of research that was done on patients without informed consent by the Nazi's during the Second World War (Wood, Friedland & McGrory, 2001: 1-36). The Nuremberg Code was established in 1947 and specified that "the voluntary consent of the human subject is absolutely essential" (Oluchi, 2013: 10). The Belmont Report was subsequently created as a means of protecting human beings from being exploited during research and focused on three

main principles that are fundamental norms in regard to research involving human subjects, namely, respect for persons, beneficence and justice (Oluchi, 2013: 12).

In the healthcare setting, informed consent implies that the patient agrees to a certain medical service "after being informed about the nature, effect and consequences of such service" (McQuoid-Mason & Dada, 2011: 93). The process of informed consent " involves a constant exchange of information between patient and healthcare provider as well as autonomous decision making that is founded on respect and participation of both parties in the process" (Dhai, 2008a: 27).

3.4.1 Informed consent and autonomy

"Informed consent and autonomy are the major ethical principles that define the relationship between health workers and the patient "(Tsotsi & Rudolph, 2005: 216-20).

In the healthcare context, the principle of autonomy lies at the centre of informed consent and refers to the fact that based on adequate information, each competent patient is permitted to make their own decisions regarding their medical treatment (Dhai & McQuoid-Mason, 2011: 14). The principle of respect for autonomy regards patients as autonomous individuals and as such "takes into consideration self determination as the basis for informed consent "(*op cit*). Through this principle, every patient is afforded the right to "be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and the risks associated therewith" (Dhai & McQuoid-Mason, 2011: 70). Healthcare practitioners thus have the obligation to recognise and respect this right regarding their patients; "not to do so would not only violate their patients' autonomy, but would also be synonymous with treating them as less than persons" (Dhai & McQuoid-Mason, 2011: 68).

Autonomy should be respected by healthcare practitioners by allowing patients the right to "self-determination or to make their own informed choices and to live their lives by their own beliefs, values and preferences" (Health Professions Council of South Africa, 2008: Booklet 1, 2(3)5: 2).

3.4.2 Informed consent and beneficence

Beneficence is considered as a general obligation of doing what is right for others (Pantilat, 2008: 1; Kinsinger, 2009: 44). In the healthcare content, the principle of beneficence compels healthcare practitioners to always provide the treatment that is most beneficial for their patients while ensuring that they minimize harms (Moodley, 2011: 57). This principle refers not only to physical benefit but also refers to information sharing between the healthcare practitioner and the patient. The principle of beneficence is essential to the process of informed consent. In order to provide net clinical benefit with minimal harm, the information that healthcare practitioners give their patients must be adequate in helping the patient make the best choice regarding their treatment (Dhai & McQuoid-Mason, 2011: 70).

On the subject of CBCT, when healthcare practitioners provide full information to their patients regarding their treatment options and the risks and benefits associated with each option, they are facilitating their patients to make informed decisions, thereby maximising the benefits of treatment and giving effect to the principle of beneficence.

3.4.3 Elements of informed consent

Certain ethical and legal elements are attributed to informed consent (Oluchi, 2013: 1-26). These elements are:

- disclosure,
- understanding
- capacity and
- voluntariness.

(Dhai, 2008a: 27).

Disclosure refers to the obligation of the healthcare practitioner to "reveal all the therapeutic and diagnostic options available as well any benefits, risks, costs and any other outcomes associated with every option" (National Health Act, 61 of 2003, 7(1)(b)). Healthcare practitioners have the obligation to inform their patients regarding any "material risks" associated with the medical procedure and also to inform them that they are entitled to refuse any therapeutic or diagnostic procedure after being made aware of the risks and obligations of the informed refusal (Dhai, 2008a: 27).

A material risk is in one that:

- A reasonable patient, if warned of the risk or danger, would probably attach significance to it
- the healthcare practitioner would be aware that the individual patient, if warned of the danger, would probably attach significance to it.

Castell v De Greef (1994 (4) SA)

An example of a material risk is found in the case of *Esterhuizen v. Administrator Transvaal* , in which a minor suffering from a Kaposi's sarcoma was treated with superficial radiation with her parents' consent (1957 (3) SA). Following the reappearance of the tumour, the medical team decided to expose the patient to a more radical type of radiation without further consenting with the parents and this resulted in acute burns on her limbs which had to be amputated (*op cit*). The Court held that the radical type of radiation was performed without adequate informed consent from the child's parents and noted that the parents would have probably attached significance to the risk of radiation had they been informed of such risks (*op cit*).

Vis-à-vis disclosure in CBCT examinations, in my opinion, the risk associated with radiation exposure, especially those associated with the stochastic effects of radiation would constitute a material risk and healthcare practitioners are obligated to disclose this information to their patients.

Understanding suggests that the patient fully appreciates the nature of the disease and is able to fully comprehend the information exposed to him or her (Dhai, 2008a: 28). It remains the obligation of the healthcare practitioner to determine the mental competence of the patient (*op cit*). Capacity refers to the capability of the patient to understand the information that is given to him or her (*op cit*). If healthcare practitioners have difficulty determining whether or not their patients are competent to understand the implications of a diagnostic procedure, a psychiatric consult should be sought and it is advisable to seek the consult of an ethicist (Schenker *et al*., 2007:294-9).

Voluntariness denotes that patients are allowed to make their own decisions based on the information that they have received without being coerced or manipulated into doing so (*op cit*). Lastly the principle of informed consent should be regarded as an "on-going process"

which means that it should not be a solitary occurrence but should be a continuing dialogue between health care practitioners and their patients which keeps them abreast of changes in the condition of patients and the treatment or investigation the practitioners propose (Health Professions Council of South Africa, 2007, Booklet 9: 3(4)1: 4)

In a culturally varied country such as South Africa, dental practitioners need to acknowledge that all the different cultural views need to be respected by allowing individuals to make informed decisions regarding the type of diagnostic assessment that would be most beneficial (Schenker *et al*., 2007: 294-9).

3.4.4 Legal aspects of informed consent

Not only is informed consent important from an ethical perspective but it is also a constitutionally protected right in South Africa. Informed consent safeguards the right of bodily integrity that is enshrined in the Bill of Rights of the Constitution of the Republic of South Africa which affirms that "everyone has the right to bodily and psychological integrity, which includes the right to security and control over their body as well as the right "not to be subjected to medical or scientific experiments without their informed consent" (Section 12 (2) b,c).

Although the Bill of Rights of the Constitution of the Republic of South Africa refers specifically to scientific and medical experiments, this right is also applicable in the healthcare context. By bodily integrity, it is understood that:

> Every human being's right to life carries with it, as an intrinsic part of it, rights of bodily integrity and autonomy – the right to have one's own body whole and intact and (upon reaching an age of understanding) to take decisions about one's body.
>
> *Walker RLJ* (2000, in Re A Minors)

The right to bodily and psychological integrity translates into the "inviolability of the person" which is considered together with the right to life as the most important of human rights declaration (Kalupner, n.d:1).

Informed consent in South Africa has been implemented into the healthcare practice setting under the following principles following the judgement in the case of *Castell v. DeGreef* **:**

- A shift from medical paternalism to patient autonomy
- a shift from the 'reasonable doctor' standard to the 'prudent patient' standard
- a shift in disclosure to the 'material risk' standard, where the level of disclosure required is what a reasonable patient would consider pertinent before making a decision

Castell v. DeGreef , 1994 (4) SA

Informed consent needs to be given by an individual with legal capacity based on the following information:

- The user's health status
- the range of diagnostic procedures and treatment options generally available to the user

- the benefits, risks and consequences associated with each option and
- the user's right to refuse health services and explain the implications, risks and obligations of such refusal.

National Health Act 61 of 2003 (s 7(3))

"The South African courts have held that legally for a proper informed consent the patient must have: knowledge of the nature or extent of the harm or risk; appreciated and understood the nature of the harm or risk; consented to the harm or assumed risk; and the consent must have been comprehensive, (i.e.: extended to the entire transaction, inclusive of its consequences)" (Health Professions Council of South Africa, Booklet 9, 4(1): 5).

In cases where patients do not have the mental capacity to give informed consent, the National Health Act stipulates that decision may be made on their behalf by:

- An individual that is mandated by the patient, in writing
- an individual authorised by a court order
- the spouse/ partner of the patient, parent, grandparent, an adult child, brother/sister (in the specific order).

National Health Act 61 of 2003, Section 7(1)(b).

3.4.5 Informed consent and CBCT

Informed consent should be obtained from every patient before a diagnostic procedure such as CBCT can be performed as the process of "informed consent is central to the practice of ethical, safe, legal, and patient-centred health care" (Schenker *et al.*, 2007: 294).

The informed consent process presents unique challenges in diagnostic procedures involving ionizing radiation such as CBCT (Brink, Goske, & Patti, 2012: 11-14). This is due to the fact that estimating the general stochastic effects of ionizing radiation cannot be achieved precisely and also due to the fact that the risk is dependent on several variables, such as age, number of CBCT scans received in the past, etcetera (*op cit*). According to them, risks associated with "repeated low levels of ionizing radiation" are so difficult to quantify and clearly explain to patients that a different approach is needed to help the patient clearly understand the risks and weight them against any foreseeable benefits (Brink *et al*., 2012:11). This approach should focus on patient education and evaluating the risks associated with radiation for each patient according to their specific risk factors and not merely a standard document that all patients read and sign (Brink *et al*., 2012: 11-14).

In modern practice, control over therapeutic and diagnostic choices are no longer the decision of the healthcare practitioner, but of the patient (Oluchi, 2013:26). Dental practitioners need to assist their patients in the decision making process regarding CBCT examinations, by means of a collaboration between the dental practitioner and patient and this decision making process should be specific to each patient. Informed refusal should be respected and valued just as much as informed consent (Dhai & McQuoid-Mason, 2011: 70).

3.4.6 Informed consent and vulnerable groups

Informed consent is particularly important in cases of vulnerable groups. According to the Council of International Organizations of Medical Sciences, vulnerability is the "substantial incapacity to protect one's own interests owing to such impediments as":

- Lack of capability to give informed consent,

- lack of alternative means of obtaining medical care or other necessities,
- or being a junior or subordinate member of a hierarchical group.

Council of International Organizations of Medical Sciences (2002)

Kipnis categorizes vulnerability, amongst others, in the following manner:

- Cognitive vulnerability refers to the person's ability to understand and give informed consent
- medical vulnerability medical vulnerability refers to patients that may be desperate for treatment
- allocational vulnerability refers to individuals that come from disadvantaged backgrounds and that are lacking in financial, medical, housing and other such benefits
- infrastructural vulnerability refers to those patients that come from disadvantaged social, organizational, political background

Kipnis (2001: 4-9)

Some of the categories of vulnerable groups include: patients, those with diminished capacity, those that are economically and socially disadvantaged as well as minority groups and refugees (*op cit*). Although CBCT is mainly used in the private sector, dental practitioners in the public sector may also use this technology and will encounter these vulnerable patients on a "day-to-day basis" (Schenker *et al*., 2007: 294-9). Patients that seek dental care at public health facilities are often vulnerable in more than one aspect, for example patients might be both medically and cognitively vulnerable. Since the process of

informed consent is dependent on communication, in cases where language barriers exist, the process of informed consent becomes extremely complex (*op cit*). This process is further complicated by low literary levels of many patients, making understanding of risks and implications even more difficult (*op cit*). This implies that even though the patient might have consented to the CBCT examination, it does not necessarily mean that they have also understood the information that was communicated to them regarding the risks involved and the fact that they may choose an alternative diagnostic technique.

In spite of all these challenges, dental practitioners have the ethical and legal duty to provide informed consent for diagnostic purposes fairly and justly to all patients, no matter how complex the process may be (*op cit*). Section 6 (2) of the National Health Act states that when possible, healthcare practitioners should "inform a user in a language that he or she understands and in a manner which takes into account the patient's level of literacy" (61 of 2003).

3.4.7 Informed consent with regard to children

The Constitution of the Republic of South Africa 1996, also protects the rights of children as it is recognises that children are vulnerable. The Children's Act, No 38 of 2005 was thus established and, according to this Act, children may consent to medical treatment if they are over 12 years of age and if they have the adequate level of maturity and mental capacity to understand the risks as well as the benefits associated with the treatment (Children's Act, 38 of 2005, Section 129 (2)). Healthcare practitioners should be mindful of the fact that children that do not fit the criteria mentioned above should be assisted by a parent or guardian in providing informed consent for CBCT (McQuoid-Mason & Dada, 2011: 67-9). If the parent or guardian is not available, informed consent or refusal should be sought from the

superintendent of the hospital, the Minister of Health or a high court (*op cit*). On the other hand, individuals over 18 years of age are considered to have full legal capacity and capable of providing informed consent or informed refusal to medical treatment (*op cit*). Still, healthcare practitioners have the obligation to ensure that young patients that are considered legally capable of providing informed consent are adequately equipped to understand the information that is provided to them regarding the risks and consequences of the diagnostic procedure (*op cit*).

CHAPTER 4

4.1 CONCLUSION

With the introduction of CBCT technology to the dental office, several unique ethical and legal issues have been created for the dental profession. Due to the many advantages that this innovative technique offers compared to conventional radiographic equipment, more and more South African dental practitioners are making use of CBCT technology (Noffke *et al*., 2013: 4). Serious concerns have been raised in regards to the level of expertise and training that is required of dental practitioners, in order for them to be able to safely and efficiently make us of CBCT technology (The American Dental Association Council on Scientific Affairs, 2012: 899-902).

While ionizing radiation is a convenient method of diagnosing dental pathology, unnecessary radiation exposure can be harmful to patients. With the introduction of CBCT technology to the dental practice, dental practitioners need to keep in mind that safe radiation practices should not be overlooked when using modern technology. It is essential that dental practitioner's diagnostic knowledge progresses at the same pace as technology.

The majority of the ethical and legal challenges highlighted in this research report would be resolved by providing South African dental practitioners with specialised training courses comparable to the training courses offered in the United Kingdom and the United States of America. Theoretical and practical training course that are validated by an academic organisation should be made available to dental practitioners who have not previously received training but are using this new technology. Furthermore, these courses should include the various ethical issues that dental practitioners may be faced with. Dental practitioners would also benefit if specific guidelines to the safe and effective use of this

technology would be available in South Africa similar to the guidelines available internationally.

From a bioethical perspective, the highest priority of healthcare practitioners is to act, at all times, in the best interest of the patient. This priority extends to treatment options as well as diagnostic procedures. Dental practitioners need to constantly evaluate the risks of a diagnostic procedure, such as CBCT against the benefits for each patient. This risk-benefit analysis can only be achieved successfully by ensuring that those practitioners that make use of this technology are adequately trained.

4.2 RECOMMENDATIONS:

- Formal training programmes ought to be implemented in South Africa so that dental practitioners may conduct radiological differential diagnosis safely and proficiently. These programmes should include:
    - Fundamental principles of radiation and principles of three-dimensional imaging for CBCT.
    - Principles of radiation safety and radiation protection regarding CBCT technology coupled with referral and selection criteria.
    - Radiation dose, including risks associated with ionizing radiation and optimization of radiation dose for patients and staff.
    - Normal anatomy interpretation on a three-dimensional CBCT image including artefacts and radiological interpretation of pathology in the maxilla-facial region on a CBCT image.
    - These training programmes should also address the relevant ethical and legal issues concerning CBCT examinations that are essential for dentists.

- Certification for dentists who have undergone CBCT training ought to be advocated for by the Health Professions Council of South Africa (HPCSA).

- Suitable guidelines should be provided to South African dental practitioners. A working group, similar to those established in the United Kingdom and the United States of American ought to be established in South Africa under the guidance of the Health Professions Council of South Africa (HPCSA) to formulate guidelines for using CBCT technology.

- In a culturally diverse country such as South Africa, dental practitioners need to be adequately trained in regards to ways of obtaining valid informed consent from patients who are often vulnerable. Dental practitioners ought to be provided with facilities that would aid in obtaining informed consent such as registered translators.

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APPENDICES

Waiver letter from University of Witwatersrand Human Research Ethics Committee (medical)

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-0706
Private Bag 3, Wits 2050, South Africa

Ref: W-CJ-130412-1

12/04/2013

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Hilde Doris Hendrik (student no: 585666)**

Project title: **The use of Cone-Beam Computed Tomography (CBCT) by dentists for diagnostic purposes in South Africa. Ethical and legal issues.**

Reason: This study is an analysis of information in the public domain. No humans are involved.

UNIVERSITY OF THE WITWATERSRAND
2013 -04- 12
JOHANNESBURG

Professor Peter Cleaton-Jones
Chair: Human Research Ethics Committee (Medical)

copy: Anisa Keshav / Zanele Ndlovu, Research Office, Senate House, Wits

Figure 1: showing an image of a Cone Beam Computed Tomography apparatus: ‘Carestream 9300’ from Carestream Health Inc., 2012 pamphlet, available from: https://www.carestream.com/cs-9300.html.

Figure 2: showing a conventional panoramic view of a salivary stone (Sialolith) in the left mandibular region.

Figure 3: The same salivary stone (Sialolith) as in figure 2, viewed on a CBCT image depicting the exact location of the salivary stone in the left mandibular region.