Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL No 8705

Dental Cone Beam Computed Tomography

2 February 2011

1. INTRODUCTION AND ISSUE

The Superior Health Council (SHC) has received an urgent request for an advisory report on dental Cone Beam Computed Tomography (dCBCT) from the Minister of Social Affairs and Health, Mrs. Onkelinx, who is tasked with social integration.

More precisely, the following specific questions have been asked:

1. How safe is this technology in terms of the ionising radiation burden compared to other medical imaging techniques used for the maxillofacial region, including teeth and prostheses, especially but not only with regard to traditional panoramic X-rays?
2. What are the aspects in which this technology differs from conventional radiographic CT-scanning with an electronic, computerised counting system?
3. What are the indications for and what is the place of this technology compared to other imaging techniques of the dental and maxillofacial region?
4. Does the use of such a device require specific training and particular precautionary measures in terms of need assessment, operation, supervision, and interpreting the images? What are the requirements that such training should meet? What are the basic qualifications that the healthcare professional concerned must possess?

In order to respond to the request, an ad hoc working group was set up with experts in dentistry, oral and maxillofacial surgery, radiology, medical physics and radiation protection.

2. ADVICE

2.1 Safety of the technology

In comparison with traditional, conventional (2D) dental radiology techniques, dental cone beam-CT (dCBCT) is characterised by the use of higher radiation energies and by more extensive anatomic regions visualised in 3D. On the whole, it can be said that the radiation dose to which the patient is exposed during a dCBCT examination is considerably higher than for all the traditional types of maxillofacial radiography, especially intra-oral and panoramic X-rays. The dose also greatly depends on the type of equipment used (especially the extent of the scan

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volume) and the different scan settings selected by the operator. The effective dose values reported (E) range from 19 to 1073 µSv per scan.[1]

The dose generated by a dCBCT-scan is therefore many times higher than that of a traditional panoramic image (PAN), which ranges between 4 and 30 µSv. Given the significant number of dental X-rays made in this country, it can be expected that this dental imaging application will lead to a further increase in the population dose from medical exposure. From the viewpoint of radiation protection there is therefore every reason to pay close attention to the justification for this technique and to its meticulous implementation. We should also note that there are enormous variations in quality between the different dCBCT systems. It follows that the patient should be protected against suboptimal quality examinations. An additional consequence of the high radiation energy produced by dCBCT is its implications for staff protection and the protection of other individuals in the adjoining rooms. Whereas the use of intra-oral and panoramic devices involves relatively few requirements as far as the lay-out of the rooms is concerned, this is not the case for dCBCT. Consequently, the design of rooms in which dCBCT equipment is to be installed should be assessed carefully. Also, routine personal dosimetry is advisable for the operators. Given the higher dose associated with dCBCT, it is advisable to apply legal principles equivalent to those that hold for conventional CT, paying close attention to the operator's expertise, the availability of a quality assurance programme under the supervision of an accredited nuclear physics expert, the availability of equipment for patient dosimetry, appropriate regulations to carry out the dosimetry and measures to protect the staff (involving the implementation of article 25 of the general regulations regarding the protection of the population, workers and environment against the danger of ionising radiation (RGPRI), in particular) and providing the patient with sufficient information.

2.2 Differences with conventional radiographic tomodensitometry involving a computerised electronic counting system

dCBCT is a medical imaging technique that uses X-rays and is closely related to conventional CT-scans. The basic difference between dCBCT devices and conventional CT-scanners has to do with the fact that it no longer works with a fan-shaped ray bundle that hits a linear detector system (1D), but with a conic ray bundle that hits a flat detector (2D). This technological characteristic provides the basis for the two major advantages of the technique: (1) a relatively weak dosimetry compared with conventional CT-scans (the dose range of a traditional CT-scanner amounts to 534-2100 µSv, compared to 48 – 1073 µSv for dCBCT for the same anatomic region) and (2) the fact that the information is volumetric, which allows easy three-dimensional processing. The empirical clinical trials available that use dCBCT show an image quality which is comparable to that of a CT-scan for the morphological analysis of mineralised structures, i.e. the bones and teeth, and which is even potentially superior to it with regard to spatial resolution. Another advantage of dCBCT is that it is less sensitive than "traditional" CT to the artifacts generated by the presence of metal dental material. The attendant drawbacks of CBCT as compared with CT result from the fact that it produces a poorer image quality for the soft tissues. The scan volume (as regards both diameter and length) is more restricted for dCBCT than it is for CT. With most devices it is possible to measure an FOV of 15 x 15 cm and thus to include both the upper and lower jawbone in the same image. Two images can also be combined so as to visualise a full skull. Even a 12 x 12 cm FOV (routine setting for a single image of the jaw) and therefore a fortiori larger dCBCT scan volumes make it possible to visualise numerous structures and lesions which do not form part of the oral and dentoalveolar region (incidentalomes). Each structure visualised by means of dCBCT can also be potentially affected

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[1] It may be stated that these doses can be compared to the annual exposure to ionising radiation, which is about 2500 µSv in Belgium.

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by a lesion. These lesions need to be examined carefully and have to be reported by a radiologist.
For the sake of completeness, it should be pointed out that a recently developed CBCT device even makes it possible to examine the knees, ankles, wrists, elbows and cervical vertebrae. These implementations go beyond the scope of this advisory report and are not gone into below.

Apart from the physical and technical differences with CT, there are a number of inherent differences in the regulations that are likely to affect patient safety. The main conditions that do not apply to dCBCT are the following:

- CT examinations can only be carried out if the patient was specifically referred (justification at the level of the patient).
- CT devices require a measuring and registration system for patient dosimetry.
- CT devices require that conformity tests be carried out annually by a radiophysicist; that an updated and sufficiently detailed protocol be available with which the device and its settings can be checked.
- CT devices require routine personal dosimetry for their users.
- The Belgian CT fleet (used almost exclusively in hospitals) is known by the FANC (verification) but, on the other hand, the dCBCT fleet is as yet insufficiently known and/or inventoried.

The SHC takes the view that it is advisable that the FANC should propose amended regulations in the near future so as to define a legal framework for dCBCT on the basis of the framework that currently applies to CT-scanners. This framework should, above all, lay down the following issues: the licence for the equipment, for its operator and for the dedicated room, the acceptance criteria, the standards for quality checks and control, continued training, etc. The SHC will, in any case, support any such initiative from the FANC and remains available to verify and formally assess a possible adaptation of the RGPRI.

2.3 Indications for and part played by dCBCT in imaging the dental and maxillofacial region

A distinction should be made between primary panoramic devices with a dCBCT option (with an effective dose under 100 µSv) and devices that are specifically dCBCT oriented with an effective dose between 10 and 1200 µSv. The justification for making a dCBCT image according to the indication therefore also depends on the device.

The Council takes the view that, if 2D images do not provide sufficient information, a dCBCT image can be made of the dental and maxillofacial region by experienced operators for diagnostic purposes and/or pre-operative surgical planning in the event of

- pre-operative planning for autologous transplantations and the placing of implants;
- the carrying out of a diagnosis after endodontic failure in view of providing care and/or applying a new treatment;
- dental anomalies;
- suspected dentoalveolar trauma and/or the follow-up for this trauma;
- suspected interrelations between the mandibular channel and a wisdom tooth, if it turns out to be necessary to remove the latter surgically;
- a dental eruption problem with impaction of definitive, supernumerary and supplementary teeth;
- a bone-related dysfunction of the temporomaxillary articulation;
- diagnostic and/or therapeutic treatment of benign tumours and cysts of the maxillary bone;
- maxillofacial surgery.

Summing up, there should be guarantees that (i) every image is justified for the patient concerned and that (ii) the radioactive burden is kept as low as possible by selecting optimal settings for the device and ensuring that it is used by experienced operators.

2.4 Training and precautions

The use of dCBCT requires skills which most dentists and stomatologists currently lack. There is no specialisation in dental and maxillofacial radiology available in Belgium, in contrast to what is the case in some of our neighbouring countries. Specialists in radiodiagnostics do have these skills, but they do not have a high level of practical experience in using dCBCT. They should therefore be asked to broaden their skills through continued training.

The training should be adapted to the level of involvement:

1. Specific training is essential for all dentists who wish to carry out dCBCT-scans themselves. This should include both acquiring the technical and diagnostic skills as well as handling radiation protection, especially as regards the justification principle and ALARA for all patients.

2. The creation of a real certificate or speciality in dental and maxillofacial radiology following a model proposed by the EADMFR and summarised by Horner et al. (2009). Like radiologists, these specialists would be authorised to carry out and interpret all medical imaging examinations in dental and maxillofacial pathology themselves.

3. For all dentists, it is important that the basic curriculum should contain theoretical and practical teaching about new techniques in radiology so as to enable them to make the right choices regarding dental and maxillofacial imaging in their clinical practice, thus optimising patient exposure to ionising radiation.

4. In future, it is essential that, if they are not carried out by the dentists themselves, these examinations should be performed by technologists who have the necessary training in dental and maxillofacial radiology rather than by dental assistants whose level of training currently varies too much because there is no proper definition, nor any recognition for this profession.

3. ELABORATION AND ARGUMENTATION

<u>List of abbreviations used</u>

ALARA	*As low as is reasonably achievable*
CBCT	*Cone Beam Computed Tomography*
CT	conventional CT-scan, also called traditional CT-scan
dCBCT	dental CBCT-scan
DRL	*Diagnostic Reference Level*
E	Effective dose
FOV	*Field of View*
MRI	*Magnetic Resonance Imaging* (formerly called functional MRI)
MSCT	*MultiSlice* CT-scan
OMF	Oral and maxillofacial surgery
PAN	Panoramic radiographic record of the maxillary arches
SHC	Superior Health Council

3.1 Methodology

In order to respond to the request, an ad hoc working group was set up with experts in dentistry, oral and maxillofacial surgery, radiology, medical physics and radiation protection. The advisory report is based on the scientific literature and the experts' points of view. As is pointed out in the Minister's precise questions, this advisory report is restricted to the scientific aspects, which are also based on previous recommendations by expert committees, especially SEDENTEXCT (2009) and EADMFR (Horner, 2009). The part of the report that deals with the aspects of radiation protection is also based on documents from the British Health Protection Agency (HPA, 2009; 2010) and the European Commission (EC, 2004). Moreover, the advisory report is restricted to the use of CBCT in the dental and maxillofacial region (dCBCT) and can certainly not be taken to apply to the use of this technology in other pathologies or by practitioners of other specialities. Finally, on account of the short time given for responding to this request for advice, it has not been possible to consult the professional and scientific associations of the physicians concerned.

3.2 Further details

Dental Cone Beam Computed Tomography (dCBCT) is a technology used in radiodiagnostics that makes it possible to visualise anatomic bone structures in the dental and maxillofacial region in 3D with a high contrast between the respective structures.

Before drawing up the answers to the Minister's four questions, we shall first give some explanation about dCBCT technology and the principles of radiation protection.

Description of dCBCT technology

Cone beam computed tomography (CBCT) is a medical imaging technique that uses X-rays. It is closely related to the conventional CT-scan. Thus, this device reconstructs, by computer, digital matrix images that represent anatomic cross-sections on the basis of data collected by a fixed mechanical instrument that rotates around the patient. This instrument consists of a device that generates X rays on one side and another that detects them on the other. The dental CBCT (dCBCT) units have been especially developed for use in dental and maxillofacial imaging (Arai et al.,1999; Araki et al., 1994). These dCBCT units use a relatively narrow cone beam which results in a scan area with a limited scan volume or field of view (FOV) in the axial dimension compared to the scan area of conventional CT or MultiSlice CT (MSCT) devices. A broad range of devices are currently available (more than 50 types) with highly different image outputs, medical/physical as well as dosimetric characteristics (Vandenberghe et al., 2010). The great diversity of the dCBCT systems makes it more difficult to make the right choice for use in dentistry. That is why it is preferable to make the following distinction (Loubele et al. ,2007; 2008; 2009; Pauwels et al., 2011; Vandenberghe et al., 2010):

- primary panoramic devices with cone beam option (effective dose E < 100 µSv) and
- primary specialised dCBCT devices, which can be subdivided into two subcategories:
    - dCBCT devices with a small field of view and a weak dose (E < 100 µSv);
    - specialised dCBCT devices with a large field of view and a higher dose (E < 1200 µSv);

On the basis of this distinction, user categories can be defined who, depending on their training and the indication, can use one or several of these devices.

Principles of radiation protection

The use of ionising radiation not only confers social advantages, it also entails health risks. Since the discovery of ionisation sources (just over a century ago), a set of principles has been worked out to prevent, or at least minimise, health risks. These principles have been drawn up for various fields and certainly not in the least within the framework of healthcare, where radiation sources are used extensively. The radiation protection is grounded on two principles, viz. justification and optimisation. Moreover, the dose limits and the reference levels (DRL) play a part in the protection system (ICRP, 2007). The diagnostic reference level is defined as the dose value which, in principle, should not be exceeded during a routine examination of a patient with a normal (standard) stature.

Justification

The notion of justification implies that a medical technology or a medical treatment should offer more advantages than disadvantages. This concerns advantages and disadvantages in the broad sense. The use of ionising radiation sources during medical diagnostics and therapy, including dental surgery (with which we are concerned here) is, as a general rule, considered to be justified.

This does not mean, however, that the use of any source of radiation is justified in all situations. Rather, this will require striking a balance between its diagnostic or therapeutic value on the one hand, and its disadvantages on the other, with the health risks involved in exposure to radiation being predominant. The Minister's questions imply that one should be critical about the justification for using dental cone beam computed tomography (dCBCT) in the context of dental diagnostics.

Finally, radiological treatment should be justified for each patient individually. This not only implies knowledge about the patient but also of the possibilities and limits of the technology, which requires radiological as well as medical knowledge and experience (in this instance in dental medicine).

Optimisation or ALARA

Optimisation focuses next on reducing the attendant health risk from exposure to radiation without losing the advantages of this application – in the case at hand: obtaining dental diagnostic information. This principle is also described as aimed at keeping the exposure to radiation as low as reasonably achievable (ALARA). Included in what is reasonably possible is balancing this risk against the quality of the intended result of this application. Optimisation should be concerned with preventing unnecessary exposure not only for the patient but also for other people.

Exposed individuals, dose limits and diagnostic reference levels (DRL)

During the evaluation of radiation exposure in dental medicine, a distinction should be made between three groups of persons, viz. (1) the patients, (2) the physicians and the medical auxiliary staff who handle the radiation equipment and (3) the remaining individuals. The latter include those who accompany the patients to assist them and persons in areas in the vicinity of the treatment rooms (staff or others) who have no connection with the treatment. As regards the last two groups, the basic principle is that the general rules set by law apply, including the threshold values for the radiation dose. Threshold values of this type do not apply to the patient. However, so-called diagnostic reference levels (DRL) are being set for an ever-increasing number of medical acts that use radiation sources. These can be used as a criterion for abiding by the ALARA principle in a series of patient treatments.

3.2.1 Question 1: Safety of the technology

dCBCT devices can, to some extent, be classified according to the scan volume or field of view (FOV) that they allow and the dose linked to it. The scan volume or FOV is connected to the size and shape of the reconstructed field and is generally cylindrical. The currently available devices offer FOVs that range from a few centimetres in height and diameter to over 20 cm

(SEDENTEXCT, 2009). Figure 1 shows 3D reconstructions of the prevailing FOVs in dCBCT (from Roberts et al., 2009).

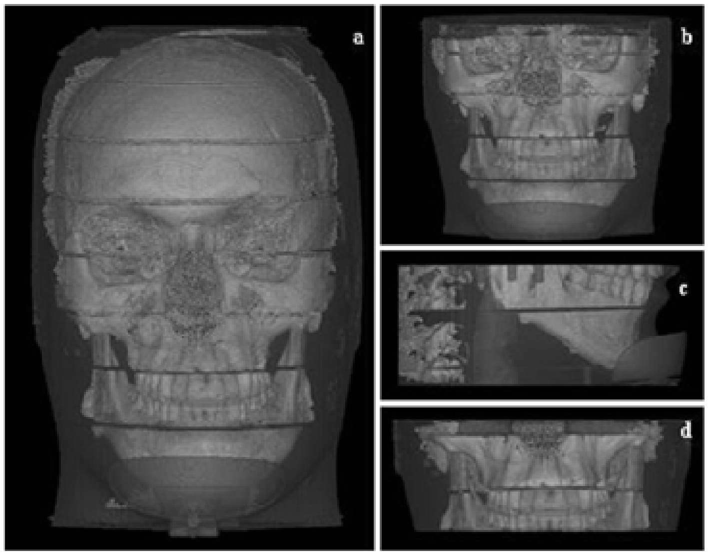

Figure 1. Typical FOVs in dCBCT: (a) full skull; (b) view of the two jawbones over 13 cm in height; (c) lower jawbone over 6 cm in height; (d) upper jawbone over 6 cm in height (from Roberts et al., 2009).

In the following paragraphs the SHC examines aspects of radiation protection in dCBCT, both as regards patient protection as well as the protection of the staff and public.

3.2.1.1. Patient protection

Various studies have been published that contain information on the radiation dose (effective dose) to which the patient is exposed during typical dCBCT examinations (Iwai et al., 2000; Loubele et al., 2009; Ludlow et al., 2003; Ludlow et al., 2006; Pauwels et al., 2011 ; Roberts et al., 2009; Tsiklakis et al., 2005). To determine the effective dose, it is important to stress that, in 2007, the International Commission on Radiological Protection (ICRP) recommended modified tissue weight factors (ICRP, 2007) compared to its previous recommendations of 1991(ICRP, 1991). Most relevant for radiation exposure in dental imaging is the inclusion of the salivary glands and, possibly, also of the brain as distinct tissue and the contribution of the mouth mucosa in the "remainder organs". One of the consequences is that the value of the effective dose for dental examinations is significantly higher on the basis of the ICRP's most recent recommendations as compared with the values published earlier, i.e. there is typically a 2-fold variation (Martin, 2007 ; Roberts et al., 2009). The figures mentioned in this advisory report have always been calculated according to the most recent recommendations.
Table 1 gives a survey of the effective radiation dose (µSv) from a dental radiographic examination, including dCBCT and conventional CT. For dCBCT, a distinction has been drawn between images with a small FOV, where the field is smaller than the facial area, and images with a large FOV, where the field includes at least the two jawbones. The typical effective dose values (E) range from 48 to 1073 µSv per dCBCT image. The dose for local small fields of view up to 5 x 5 cm is not mentioned in the table. The relevant data range from 19 to 44 µSv (Pauwels, 2010). The considerable variation between the dose values for dCBCT is mainly due to technical differences between the devices, the differences as regards the scan settings selected (operation) and differences between the dose calculation models. The dosimetric advantage of dCBCT is both relative and potentially highly variable depending on the use made of the device. It is true that the dose released by a dCBCT scanner is clearly inferior to that delivered by a

conventional CT-scanner (average ratio of 1/10 at equal quality and for a comparable type of examination, with potential fluctuation between 1/2 and 1/30), it nevertheless remains clearly superior to the dose released in conventional, intra-oral and even panoramic dental radiology. The main organs exposed during a dCBCT examination with an FOV of the entire skull are the following: red bone marrow (irradiated fraction: 16.5 %), thyroid (100 %), trachea (10 %), salivary glands (100 %), brain (100 %), mouth mucosa (100 %), hypophysis (100 %) and eyes (100 %) (Roberts et al., 2009). A study by Pauwels et al. (2011) assessing the dose delivered by 14 different dCBCT scanners shows that the “remainder organs” contribute most to the effective dose (with a proportion of 37 %). Other organs that contribute to a significant extent are the salivary glands (24 %), the thyroid (21 %) and red bone marrow (14 %). The contribution of the brain, bones and skin to the effective dose is next to negligible.
Moreover, the Council stresses that, depending on the imaging geometry, the dose received by the salivary glands and the thyroid can exceed 1 mGy. Although these values are relatively low, there are indications in the literature of an increased incidence in tumours for both organs as well as the brain as a result of dental radiography (EC, 2004). Epidemiological studies into the long-term effects of dCBCT are not available to date, but the SHC takes the view that, considering the uncertainty over the attendant risk from radiation to the crystalline lens, it is advisable to apply the precautionary principle in this context and to ensure no potential risk is neglected.
The dose from a dCBCT scan can be 2 to 45 times higher than that from a traditional panoramic image (PAN), and up to 130 times higher than the dose from an intra-oral image. Given the implementation of the principles of radiation protection, this implies that a dCBCT scanner can on no account be directly substituted for traditional 2D imaging, especially as far as panoramic and cephalometric devices are concerned.

Radiographic examination	Effective dose (µSv)	Dose as a multiple of the dose from a panoramic image
Intra-oral	1 – 8 [1]	-
Cephalometrics	2 – 3 [1]	-
Panoramic (PAN)	24 [2]	1
dCBCT (small FOV: dentoalveolar)	48 – 652 [2]	2 – 27
dCBCT (large FOV: craniofacial)	68 – 1073 [2]	3 – 45
CT-scan 2 jawbones	180 – 2100 [3]	8 – 88
CT-scan upper jawbone	1400 [3]	58

Table 1. Effective dose reported for dCBTC compared to other forms of dental imagery

[1] IAEA, 2010;
[2] HPA, 2010;
[3] SEDENTEXCT, 2009.

In its 2007 recommendations, the ICRP suggests that there is a nominal risk coefficient of 5 % per sievert for all forms of radiation induced fatal cancer (ICRP). This coefficient is an average for the total population (all ages included). However, in the field of application of dCBCT, a large proportion of the patients are children (especially in orthodontology) in whom the risk is more significant. In paediatric patients, the risk is about twice as high as in adults.

Given the specific nature of dCBCT scanners and the higher dose associated with them compared to traditional (2D) dental radiology techniques, it is advisable to abide by legal principles that are equivalent to those that apply to conventional CT-scanners in order to protect the patient. Special attention should be paid to the justification for the examination, the user’s expertise, the optimisation of the examination, the availability of a quality assurance programme under the supervision of an accredited medical radiophysics expert and the availability of a measuring and registration system for routine patient dosimetry.

Influence of the scan settings – optimisation of the examination

dCBCT devices allow the operator to select the scan settings according to the image quality required. The main scan settings that affect the patient dose are (1) the scan volume or FOV, (2) the exposure settings and (3) the image quality, especially its resolution. Thus, there can be a 16 to 350-fold variation in the effective dose (E) delivered by a dCBCT unit, depending on the options chosen for the field of view and image quality. The risks are the following: on the one hand, the volume explored can be greater than the region of clinical interest and, on the other, the image quality prescribed can be superior to what is necessary to solve the clinical case. Guidelines for the appropriate use of dCBCT equipment have been issued by the members of the SEDENTEXCT (SEDENTEXCT, 2009) project and by the British Health Protection Agency (HPA, 2009 ; 2010). The users can take into account these recommendations as well as the advice provided by the accredited medical radiophysics expert.

1. Influence of the scan volume or field of view (FOV)

The choice of field of view and the patient dose are directly related (the larger the field of view, the higher the radiation). The dose is at its highest when making a full image of the skull (relative E = 100 %) and at its lowest when making an image of the upper jawbone (relative E= 10 %). It follows that it is important to choose the smallest possible field of view that can provide all the relevant clinical information about the patient. dCBCT equipment with a fixed large field of view is not appropriate for visualising small anatomic regions (HPA, 2010).

2. Influence of the exposure settings: Peak voltage (kVp) and tube current - scan time product (mA-s)

dCBCT units use higher peak voltages than conventional 2D dental radiography devices. A large number of the current dCBCT units generally use a peak voltage of 120 kVp, although some of them can also operate with a lower voltage ranging from 70 to 110 kVp (Pauwels et al., 2011). Conventional (intra-oral and panoramic) dental radiography units generally use a peak voltage ranging from 50 to 70 kVp. 3D dCBCT imaging requires higher radiation intensities than 2D radiography. The two settings, viz. peak voltage (kVp) and tube current - scan time product (mA-s) have a direct influence on the dose. The user should always select optimal exposure settings by taking into account the diagnostic requirements and striving towards keeping patient exposure to radiation as low as possible. Thus, increasing the exposure time (expressed in s) or tube current (mA) produces images with a higher resolution but will also result in a higher dose to the patient.

3. Influence of the image quality: Image resolution – voxel size

A dCBCT scanner can usually provide images with different voxel sizes or resolutions. A voxel (volume element) is a picture element used in three-dimensional imaging. This term is a contraction of *volume* and *pixel.* The user can select a voxel size between 0.075 and 0.4 mm (Vandenberghe et al., 2010). A smaller voxel size produces an image with a higher resolution and is usually chosen for dental imaging, as the standard resolution may be insufficient. However, a higher resolution involves a higher radiation dose because of the stronger radiation intensity and the number of projections during the rotation of the tube. A study by Roberts et al. shows that reducing the voxel size (thus increasing the resolution) from 0.4 mm to 0.2 mm doubles the effective dose (Roberts et al., 2009). As a result, carrying out a dCBCT scan with a resolution that is needlessly high for the medical aim pursued results in an unnecessary increase in the dose to the patient.

Quality assurance programmes and patient dosimetry

The acceptability and conformity tests carried out by an accredited expert in medical radiophysics form a large panel of the quality assurance programme for radiography systems. For X-ray devices used in dentistry, a measurement protocol setting out acceptability criteria was published in the FANC decree of 12.12.2008 (FANC, 2008). However, compared with the recent recommendations by the HPA for dCBCT (HPA, 2010), this decree only contains minimal test criteria for dCBCT.
These limited criteria do not suffice to ensure that X-ray devices can be used without any major risk to carry out exposures that have no diagnostic value, and they do not make it possible to guarantee the protection of the patient and of the staff that operates the device. Therefore, the Council takes the view that a revision of the acceptability criteria for dCBCT is urgently needed.
An important factor in equipment quality assurance is the testing frequency. At the moment, X-ray equipment used for dental diagnostics is tested on an annual basis. As regards the revision of the RGPRI, a proposal was made to change the testing frequency to once every three years for intra-oral, panoramic and cephalometric radiography units. However, in its recently published advisory report No. 8674 (SHC, 2010), the Superior Health Council states that, because of their greater technological complexity, dCBCT and other tomographic techniques should receive the same attention as similar devices used for traditional X-ray diagnostics. The SEDENTEXCT project (SedentexCT, 2009) and the HPA (HPA, 2010) both recommend that dCBCT units should be tested on an annual basis. The Council also takes this view and therefore recommends that dCBCT units should be tested annually.

Another important part of quality control in X-ray diagnostics is assessing the patient dose, which requires using the most adequate diagnostic reference levels (DRL) (RGPRI). The person in charge should determine the average patient dose for all types of examinations by means of triennial dose-rate studies so as to allow for a comparison to be made with these diagnostic reference levels. The FANC has made available specific guidelines on patient dosimetry in general and on (1) the frequency with which dose-rate studies must be carried out, (2) the procedures to follow and (3) types of examinations for which they are required on a regular basis. (FANC, 2010). Yet, these guidelines do not contain any recommendations for dental radiography examinations and therefore no recommendation for dCBCT either. This goes against the recommendations made for dCBCT by the SEDENTEXCT project (SedentexCT, 2009, see **www.sedentexCT.eu**) and the HPA (2010), which advocate a system in which the patient dose is routinely measured at least once every three years, in agreement with the current Belgian guideline for X-ray equipment in general .

Considering the arguments mentioned above, it is advisable to apply to all dCBCT scanners the same regulations concerning quality assurance and patient dosimetry as those that hold for conventional CT-scanners. In particular, this involves: (1) extensive annual quality checks carried out by a medical radiophysics expert and (2) a patient dosimetry system with a triennial assessment of the results.

3.2.1.2. Protection of the staff and other individuals

The recent report entitled *Guidance on the Safe Use of Dental Cone Beam CT* by the British Health Protection Agency (HPA, 2010) provides recommendations concerning the radiation protection of staff and other persons (except patients) when using dCBCT.

Rooms
Whilst there are few requirements for the equipment of rooms in which intra-oral and panoramic radiography devices are used, matters are rather different for dCBCT. Therefore the design of the rooms in which dCBCT units will be installed has to be studied very carefully, in consultation with the accredited physical inspection service, though the basic principles for their design can be borrowed from conventional CT.

The exposure to scattered radiation is more significant with these units than it is with conventional ones because they use beams that are more loaded with energy and more intense. As a result, there should be additional community as well as personal protection measures. Nevertheless, the exposure of the staff and other individuals can be controlled efficiently by using isodose cards, establishing a maximal work load, carefully conceiving the lay-out of the facilities and establishing specific procedures.

Personal dosimetry

According to the *European Guidelines on Radiation Protection in Dental Radiology* (RP 136), routine personal dosimetry is desirable but not necessary when using intra-oral and panoramic radiography equipment (EC, 2004). However, the RP 136 recommendations do not mention the use of dCBCT.

The HPA document states that personal dosimetry is appropriate for the operators, the service-engineers and the physicists; it must be carried out on a routine basis or at least for a sufficiently long trial period (HPA, 2010). It has been found that, on a yearly basis, dCBCT can cause the staff to be exposed to an effective dose that exceeds the limit set for the public (1mSv/year)

At present the literature offers few, if any, data concerning (potential) staff exposure due to dCBCT. In addition, given the nature of the equipment used, routine personal dosimetry currently does not prevail in dental care in Belgium. Consequently, the use of dCBCT will have to be assessed in detail and the results of this assessment may have consequences for personal dosimetry provided for the staff. On account of the arguments mentioned above, the Council recommends routine personal dosimetry when using dCBCT.

3.2.2 Question 2: What are the differences with conventional tomodensitometry involving a computerised electronic counting system?

General considerations

The basic difference between dCBCT and conventional CT-scanners has to do with the fact that it no longer works with a fan-shaped ray bundle that hits a linear detector system (1D) but with a conic ray bundle that hits a flat detector (2D**).** This technological characteristic provides the basis for the two main advantages of the technique: (1) a weak dosimetry (dose range traditional CT-scanner or MSCT: 534 µSv – 2100 µSv) and (2) that fact that the information is volumetric, which allows easy three-dimensional processing. In spite of the image quality being subjective and difficult to quantify, currently available empirical clinical studies that use CBCT show an image quality that is comparable to that of a conventional CT-scanner for the morphological analysis of the mineralised structures that we are concerned with, i.e. bones and teeth. The disadvantage of CBCT over conventional CT-scanners is, on the one hand, the fact that it offers a poorer image quality for the soft tissues and, on the other, that it does not really allow to measure densities. However, these issues are not essential in dental care. The indications for dCBCT-scans of the dental and maxillary region would, on the one hand, be the replacing of a conventional CT- scan when this is clinically justified and a detailed analysis of the soft tissues is not required, and, on the other, the resorting to more effective 3D imaging when conventional intra-oral or panoramic dental imaging has not yielded all the necessary information for treatment. On no account should dCBCT be used as a primary imaging technique and even less as a general means for managing all clinical situations.

Image quality

The spatial resolution that can be obtained with dCBCT ranges from 0.4 to 0.075 mm, which is considerably higher than what is possible with most conventional CT-scanners. Metal also usually generates far less artifacts (which is important in the dental region). As a result, most images obtained through dCBCT are much better quality than those obtained by means of conventional CT. Nonetheless, the image quality strongly depends on the experience of the practitioner who carries out the examination. Indeed, apart from the ability to select the appropriate technical settings, patient immobilisation and positioning as well as processing the images are crucial factors. Experience with dCBCT suggests that the daily patient flow has to be sufficiently strong (between 10 and 15) in order to gain the required routine and experience, thus guaranteeing quality.

Interpretation of the images – Field of view (FOV) – Incidentalomes (De Vos et al., 2009)

With most devices allowing a 15 x 15 cm field of view, a single image suffices for visualising the upper and lower jawbones. Some devices make it possible to combine images taken at different heights (lower half of the skull and upper half of the skull), thus visualising the skull as a whole. Traditional 2D teleradiographs or lateral skull radiographs (cephalometrics) are being replaced by these dCBCT images of the entire skull. They are typically requested by orthodontists as well as by doctors specialised in oral and maxillofacial (OMF) surgery who provide treatment for cleft lips and palates and facial defects. We can perhaps expect that, in the years to come, larger detectors for broader fields of view will come into existence. But even a field of view of 12 x 12 cm (traditional setting for an image of a single jawbone) already makes it possible to obtain an image of many structures and lesions which are not part of the dental region or the region dealt with by oral and maxillofacial surgery (incidentalomes): vertebrae, skull base, eye-sockets, central skull base and the region of the hypophysis, etc. Each structure X-rayed by dCBCT may potentially present a lesion. If dCBCT users are only trained in the anatomy and pathology of dental structures, they could fail to detect any pathology affecting one of these adjacent regions and not be able to identify it either. That is why they should have enjoyed sufficient or more general training (radiologist) in order to be able to interpret such images. The users should have received enough training to be able to assess the limits of dCBCT (traumatism with a potential subdural haematoma, abscess, tumour, …) and to realize when a CT-scan or a traditional MRI is required.

3.2.3 Question 3: What are the indications for and part played by CBCT in imaging the dental and maxillofacial region?

Principles for a justified use of dental volumetric tomography

In order to justify this use, it is essential to take into account the existence of a broad range of devices. Thus, depending on the user and the indication, the individual balance (see rule 2 below) between the information needed (patient benefit) and the exposure to radiation linked to making the image is determined on the basis of the type of equipment used, thus allowing for the ALARA principle to be complied with.

Justification principles (Horner et al., 2009; EC, 2004)

What are the indications for and what is the place of this technology compared to other imaging techniques for the dental and maxillofacial region?

1. dCBCT should only be resorted to after a medical history has been taken and clinical examination performed.

2. Each dCBCT examination should be justified: the immediate medical benefit for the person concerned should be weighted against the individual damage that exposure to ionising radiation could result in.

3. In addition, the dCBCT examination must be expected to provide new (diagnostic or therapeutic) information that may help to determine the type of treatment the patient requires.

4. dCBCT cannot be routinely repeated with the same patient, except if it can be shown that the benefits for the patient of a new image outweigh the attendant risks of dCBCT.

5. The letter of referral that medical practitioners provide their patients with should contain enough information on their medical history and clinical examination so as to enable the licensed dCBCT user to justify the examination.

6. The images can only be taken with dCBCT if other means that do not produce any radiation burden or a significantly lower radiation burden do not make it possible to solve the diagnostic or therapeutic case.

7. The dCBCT images have to undergo a careful clinical evaluation (analysis of all the data provided by the image), the results of which will be recorded in a radiological report.

8. A dCBCT image can be sufficient when information is needed on the hard tissue structures and when it is necessary to make out the general outline of the soft tissues. Conversely, if, in addition to the information on the hard tissue structures, detailed and differentiated information is required on the present soft tissue structures, it may be advisable to use a CT scan (MSCT) or an MRI.

Definition of the indications for a justified use in accordance with the justification principles defined under point 1 # 8

9. Provided that the principles of radiation protection are complied with, especially by adjusting the size of the field to the indication, selecting the mA(s) settings according to individual cases and potentially adapting other optimisation means, dCBCT technology can be used by certified users for, amongst others, the following dental and maxillofacial purposes (yet note that this list may not be complete: Alqerban et al. (2009); Guerrero et al. (2010); Liang et al. (2010a; 2010b); Loubele et al. (2007; 2008); Shahbazian et al. (2010); Van Assche et al. (2010); Vandenberghe et al. (2008; 2010); Vercruyssen et al. (2008)):

    a. Pre-surgical planning for the placement of implants;

    b. Pre-surgical planning for autologous transplantations;

    c. Making a diagnosis after failed endodontic treatment to shed light on the aetiology of the failure and potentially decide whether new treatment is necessary;

    d. Dental anomalies (dens in dente, mesiodens, supernumerary tooth,…) for which additional three-dimensional information is necessary to determine what treatment to give;

    e. Suspected dentoalveolar trauma that cannot be viewed with conventional 2D imaging (root fracture, tooth luxation, tooth avulsion and root resorption after dentoalveolar trauma);

    f. Strong interrelation between the mandibular channel and the wisdom teeth when it is necessary to surgically remove the wisdom teeth;

g. A dental eruption problem with impaction of definitive, supernumerary or supplementary teeth;

h. Bone-related dysfunction of the temporomaxillary articulation;

i. A diagnostic and/or therapeutic approach to benign tumours and cysts of the maxillary bone;

j. Maxillofacial surgery (diagnosis and/or need for 3D images).

This list is based on the knowledge that is currently available and may be extended at a later stage.

3.2.4 Question 4: Training and precautionary measures

1. Specialist physicians in radiodiagnostics

Accredited radiodiagnostics specialists have the necessary skills for carrying out and interpreting dental and maxillofacial radiology examinations, except for those that concern intra-oral radiography, which continue to be carried out by dentists only. During their specialist training, they receive adequate instruction in anatomy, radiological techniques and diagnostics, as well as radiation protection, both in actual practice and in university or interuniversity courses. Therefore, they should have the necessary skills for carrying out and interpreting CBCT examinations. When a CBCT unit is first installed in a hospital, the radiologists should familiarise themselves with the technique through appropriate training in the framework of their continued training. There is no need to provide a specific certificate for this technique.

2. Dentists and stomatologists specialised in dental and maxillofacial radiology

Basic training in dental and maxillofacial radiology makes all dentists, including stomatologists (who are essentially dentists) fit to practice intra-oral and panoramic, including computerised, radiology. Radiation protection forms just a small part of this training programme.

At this stage it appears that basic radiodiagnostics training for dentists and stomatologists does not suffice to allow all practitioners to carry out and interpret CBCT scans, as they induce a higher exposure to ionising radiation. Additional training is essential and should be organised in terms of a model such as that currently offered by the universities of Louvain (UCL and KUL) and Ghent. Minimal terms and conditions that include the technical and diagnostic aspects, as well as those that concern radiation protection must be established among those involved, i.e. the universities, the FANC and the professional dentist and stomatologist associations. Taking into account the doses of ionising radiation and the potential exposure of children and teenagers, the various aspects of radiation protection need to be gone into carefully.

It is advisable that, in the long run, there should be a much more specialised type of training in the form of an additional degree or a master-after-master in dental and maxillofacial radiology. This type of training is already available in neighbouring countries and should require about 12 months fulltime to complete. This training should, ideally, lead to a fully fledged speciality, so that those holding that degree devote a significant part of their time to specialised radiology techniques, thus enhancing their experience and skills. The training curriculum can be based on the EADMFR document *Framework for Specialist Training in Dental and Maxillofacial Radiology*. It should include the following aspects:

- Radiophysics, foundations of X-ray techniques and underlying technology;
- General principles of radiation protection and applied principles;
- Legislation in connection with radiation protection;

- Diagnostic techniques: Radiography, CT-scanning (including dCBCT), ultrasonography , MRI, SPECT and PET, interventional techniques.

This broad training should convey skills in all fields of dental and maxillofacial pathology, including the soft tissues and salivary glands, reconstructive surgery and implantology. It is essential that it should also cover the neighbouring structures which do not form part of the region of interest but could still be in the region imaged, e.g. the sinuses or the sella turcica. The aim is to be able, if necessary, to refer the patients or their radiology file to a general radiologist trained in interpreting all cephalic anomalies that lie outside the dentoalveolar region.
Of course, this theoretical training should be accompanied by practical training in close cooperation with dental practice and maxillofacial surgery. As is the case for medical and dental specialities or specific professional titles, the accreditation should, ideally, be awarded by the FPS Public Health through an ad hoc commission that has yet to be created. The FANC would then grant the accreditation de facto on the basis of previously approved terms and conditions, which clearly specify the radiation protection requirements in the licensing criteria[2]. Finally, whatever the path chosen, it is necessary to determine the licensing criteria for the departments and internship supervisors in dental and maxillofacial radiology.

This type of training should not, however, be considered as an essential requirement for the practice of CBCT, but as a means of promoting a practice that specialises in the many aspects of dental and maxillofacial imaging. The terms according to which practitioners with different levels of training would use the various techniques can be based on those proposed by Horner et al (2009). It is up to the scientific societies and universities to define the boundaries between conventional practice, which should be accessible to as many as possible (provided that certain conditions are met) on the one hand, and the practice of a real speciality that may come into existence in the future but cannot be created in the short term, on the other.

Finally, whatever the skill level or specialisation achieved, it is important to point out again that continued training is essential in a field with very rapid technological development. The universities and the scientific societies should co-operate to set up this training, which should receive the approval of the FANC for the radiation protection issues.

3. Dentists

Dentists are trained to carry out intra-oral and panoramic radiology. But even if they do not wish to specialise in dCBCT, it is important that minimal training should be provided as part of their university education, so as to enable them to make the right choices with respect to imaging in their daily practice. For example, it is not advisable to systematically start each radiological examination with a dCBCT-scan. Conversely, in very complex cases, it may be preferable to avoid dentoalveolar and even panoramic scans and to propose a dCBCT examination with a three-dimensional reconstruction from the start. What matters most is to optimise the radiation doses by refraining from needlessly resorting to multiple imaging techniques.
It should be pointed out that the accreditation process of the INAMI (National Institute of Health and Disability Insurance) already explicitly requires a minimal number of accreditation points in dental radiology, viz. 20 points over a five-year period and out of a total of 500. This is a good thing. However, accreditation is not mandatory. Given the expansion and the increasing complexity of dental and maxillofacial radiology techniques, this part of continued training should ideally be increased, taking into account the importance of radiation protection. For non-accredited dentists, an alternative system of continued training is essential for aspects of radiation protection in the broad sense.

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[2] It is advisable that the accreditation should not be granted by the FANC only. Indeed, the latter is competent in matters relating to radiation protection, but not medical training, which means that, comparatively, the radiation protection aspects would inevitably receive too much weight.

4. Dental assistant or dental hygienist

At the moment there is no access to this profession, which, moreover, is not defined by law. Some schools and dental associations grant a degree of dental assistant (this does not concern dentists in training).

This degree does not have any legal value, in contrast to the title of dental hygienist found in other European countries.

As far as dental radiology is concerned, with no higher ad hoc education available, the law allows dentists to carry out their own radiographs (RD of 20 July 2001). The concept of medical auxiliaries, defined in section 53.2 of this RD, therefore does not apply to dental assistants. This situation can be maintained as far as CBCT-scans carried out by dentists are concerned. In future, if the dCBCT examination is carried out by a third party, it is essential that it be done by well-trained auxiliaries. This sort of practice fits well within the qualification of medical imaging technologists, but dental and maxillofacial imaging is only taught to a very limited extent in many training colleges. A specialised certificate would be a good solution and could be organised by one or several training colleges as an addition to the bachelor degree in medical imaging technology (e.g. 20 to 30 credit units). In so far as this should become a specific requirement, it is necessary to provide public financing for this sort of training, either as an extension to the three-year vocational education or as a subsidised educational leave, accessible to active medical imaging technologists.

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5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group **in a private capacity**. The names of the experts of the Superior Health Council are indicated with an asterisk*.

The following experts took part in drawing up the advisory report:

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About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does so on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, a referring committee) and 4) the final endorsement of the advisory reports by the Board (ultimate decision-making body). This coherent set of procedures aims at allowing the SHC to issue advisory reports based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

These advisory reports are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

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