Nordic survey on national requirements and regulatory management for dental Cone Beam CT

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Abstract. Cone Beam CT (CBCT) has become a very attractive imaging tool within dental radiology, mainly because of its capability of providing cross sectional images and three dimensional reconstructions. CBCT are associated with higher doses and risks compared to traditional dental radiographic methods. Countries with lack of regulatory control of CBCT have experienced a rapid increase in the number of CBCT being purchased. The majority of dentists taking CBCT in clinical use have often no postgraduate qualifications or special expertise in radiology and radiation protection. Vendors claim that it is difficult and frustrating to deal with the different requirements and regulatory management for CBCT provided by the national authorities. The aim of this work was to compare national requirements, regulatory management and guidelines for dental CBCT among the Nordic countries to identify differences and similarities and to evaluate the need for harmonization of national requirements and common Nordic recommendations for dental CBCT. Differences in national requirements, regulatory management and guidelines were revealed. Main discrepancies were obtained within classification of workplace, requirements associated with competence and profession, professions allowed for image interpretation and requirements towards vendors of CBCT. This study indicates a need for a harmonization of requirements and regulatory managements together with establishment of common Nordic recommendations for CBCT.

KEYWORDS: Cone Beam CT, regulatory management, guidelines, quality control, competence, radiation protection

INTRODUCTION

Cone Beam CT (CBCT) has become a very attractive imaging tool within dental radiology, mainly because of its capability of providing cross sectional images and three dimensional reconstructions. However, CBCT are associated with higher doses and risks compared to traditional dental radiographic methods (SEDENTEX CT 2011). Numerous manufacturers are now producing CBCT equipment and many vendors have started intensive and often quite aggressive sales campaigns, yet the evidence-base for appropriate use is not yet strong. Different models of CBCTs are available on the market with a huge variation in complexity, available scan field of views (FOVs), adjustable exposure parameters and patient doses. Simple CBCT are almost comparable to conventional OPG equipment while the most complex CBCT are more comparable to medical CT scanners. Some vendors appears as unserious, due to insufficient knowledge regarding quality control, dosimetry, doses and risks associated with their CBCTs. Countries with weak or no regulations for use of dental CBCT have experienced a rapid increase in the number of CBCT being purchased, mainly among dentists with no postgraduate qualifications or special expertise in radiology and radiation protection. There is evidence in the literature of inappropriate and excessive use of CBCT together with evidence of poor image quality because of insufficient attention to quality assurance and inadequate training of users. In some clinics in the United States, CBCT imaging has even become a routine examination regardless if it is justified or not (Bogdanich and McGinty 2010).

In 2008 the European SEDENTEX CT project was launched. One of the aims of this project was to establish evidence-based guidelines for radiation protection for CBCT within dental and maxillofacial radiology. This guideline was published in 2011 and has been the basis for the establishment of national regulations and guidelines for CBCT in many European countries (SEDENTEX CT 2011). The guideline provides valuable information about referral criteria, patient and staff doses and establishment of a quality assurance system including quality control of the equipment.

The Nordic radiation protection authorities have experienced an increasing frustration among the vendors, claiming they have to comply with different requirements and regulatory management within the Nordic countries. The aim of this work was therefore to compare national requirements and management for dental CBCT among the Nordic countries to identify differences and similarities and to evaluate the need for harmonization of national requirements and regulatory management and the establishment of common Nordic recommendations for dental CBCT.

METHOD

Detailed information on national requirements and regulatory management of dental CBCT among the Nordic countries were obtained through review of national radiation protection regulations and available guidelines for dental CBCT (Friberg 2010, Waltenburg 2009, STUK 2011, Guðlaugur Einarsson 2011). In addition, more systematic and comparable data about regulatory management were collected by use of a questionnaire distributed to all national radiation protection authorities. The questionnaire was based on the European guidelines for CBCT in dental and maxillofacial radiology (SEDENTEX CT 2011). Differences and similarities in requirements, regulatory management and guidelines for use of CBCT within the Nordic countries were identified and analyzed.

RESULTS

Review of national regulations and guidelines revealed both differences and similarities within national regulatory management for CBCT between the Nordic countries.

Authorization and notification

Use of CBCT within dental clinics is subjected to authorization in all the Nordic countries and all purchased CBCT equipment must be notified to the local authority.

Room shielding, classification of workplace and staff protection

All the Nordic countries have implemented a dose limit to the public from ionizing radiation (0.25 mSv/year or 0.3 mSv/year) in their national radiation protection regulation. This dose limit defines the need for additional shielding of the examination room. Necessary amount of shielding (given in lead equivalence thickness [mm Pb]), can either be obtained by detailed shielding calculations or by following general national shielding recommendations. No countries have requirements for use of personal protective equipment or personal dosimetry. However, if staff has to be inside the examination room during exposure, use of a lead apron is recommended and need for personal dosimetry must be evaluated. Major differences in classification of workplace were observed among the Nordic countries. Differences and similarities regarding recommendations for room shielding and classification of workplace are summarized in table 1.

Patient dose, DRLs and radiosensitive organs

All national regulations has requirements for patient dose monitoring and hence the CBCT has to provide an indication of patient dose, either in the dosimetric quantity dose area product (DAP) or computed tomography dose index (CTDI). No countries have yet established national diagnostic reference levels

(DRLs), but will most likely be established in the near future. Only Norway and Finland impose the clinics to establish local DRLs for typical CBCT examinations. Shielding of radiosensitive organs are recommended in all countries, but only when use of shielding devices do not affect the clinical information.

Table 1: Summary of recommendations for room shielding and classification of workplace in the Nordic countries.

	Norway	Sweden	Denmark	Finland	Iceland
Room shielding recommendations					
1 mm Pb – all kVp			X [1)]		
1 mm Pb < 100 kVp and 2 mm Pb > 100 kVp	X	X			X
mm Pb as function of mAs/week				X	
Classification of workplace					
Controlled area	X			X	X
Supervised area		X			
No classification of area			X		

[1)] Providing built-in shielding behind the detector (1 mm Pb @ ≤ 100 kVp, 1.5 mm Pb @ > 100 kVp).

Justification, optimization and image interpretation

General requirements on justification and optimization are implemented in all the national radiation protection regulations. No national referral criteria are established yet and most countries refer to the European referral criteria published by the SEDENTEX CT project (SEDENTEX CT 2011). Clinics in all the Nordic countries have to establish local referral criteria to justify their use of CBCT. Further, in most countries clinics can only perform CBCT examinations of patients having a referral from a physician or dentist. In addition, justification of the referred CBCT examination must be evaluated by the person having the clinical responsibility in the clinic. However, written referrals to own clinic is not necessary in most of the countries, but the justification of the examination together with the radiological report has to be included in the patient records.

The main elements in the process to obtain an optimized exposure for individual patients is: 1) the CBCT equipment must be able to provide a scan field of view (FOV) that fits the necessary examination volume, 2) established optimized standard examination protocols and 3) the CBCT equipment must have the possibilities for adjustment of exposure parameters to meet the needs for each individual patient. All Nordic countries have requirements that covere item 2) and 3). The Norwegian, Finnish and Swedish requirements covers also item 1). Differences among the professions allowed for CBCT image interpretation were observed between the Nordic countries, see table 2. In all countries, dental and maxillofacial radiologists and medical radiologist are allowed to interpret all CBCT images while dental hygienists are not allowed to interpret any CBCT images. The role of the dentist in CBCT images interpretation varied among the Nordic countries and is summarized in table 2.

Professions, competence and education

The presence of a radiation protection officer (RPO) and a person possessing radiological competence are required in all Nordic countries, but only Norway, Sweden and Finland requires the presence of a medical physicist. The person with radiological competence also operate as the clinical responsible within the CBCT clinic. All countries also have requirements to the competence necessary to be allowed to operate the CBCT equipment. However, differences in the level of competence to qualify for the required professions and the competence required to operate the CBCT, were revealed. Required professions and level of competence among the Nordic countries are summarized in table 3. Norway, Sweden and Finland provide specialization in Dental and Maxillofacial radiology and Denmark is the only

Nordic country that offers a CBCT course for dentists (table 3). For those countries requiring a medical physicist, he/she is involved in purchase, quality control, calibration of dose indicators, education and training of staff in radiation protection, establishment of local DRLs (except Sweden), optimization, evaluation of room shielding, doses and risks. Those countries with no demand for a medical physicist have to rely on the competence and service provided by the CBCT vendors.

Table 2: Summary of professions allowed for CBCT image interpretation together with any special restrictions to image interpretation in the Nordic countries.

	Norway	Sweden	Denmark	Finland	Iceland
DM[1)]/medical radiologist	**X**	**X**	**X**	**X**	**X**
Dentist with additional course	**X**		**X**	**X**	**X**
Only small FOVs (dento-aveolar)	X				
All FOVs (dento-aveolar and craniofacial)			X	X	X
Dental hygienist					

[1)] DM = Dental and Maxillofacial

Vendors of CBCT

The vendors are also subjected to requirements by all the Nordic radiation protection authorities and the requirements are summarized in table 4.

DISCUSSION

This survey demonstrates that there exist some major differences within national regulations, regulatory management and guidelines for CBCT in dental radiology. The introduction of CBCT to dental clinics has introduced the need for a higher level of knowledge and competence available within the clinic. Increased complexity and the deliverance of higher patient and staff doses also introduce the need for stricter and more detailed requirements for quality control and understanding of doses and risks associated with CBCT examinations. Many differences in national regulatory management can be explained by the lack of legal basis provided by the already existing national radiation protection regulations in the Nordic countries. Some countries regulations do not fully meet the legal basis needed for establishment of the desired regulatory management, while other countries regulations are more general and manage to provide the necessary legal basis for this new radiological modality. Other differences may be a result of different interpretation and understanding, together with different priorities and focus within radiation protection at the national radiation protection authorities.

The differences in national regulatory management that really have important impact on the clinics who wants to purchase a CBCT are the requirements regarding involvement of professions, competence and image interpretation. The most striking difference is that only some Nordic countries demand for the involvement of a radiologist (dental and maxillofacial or medical) and a medical physicist. Dental clinics in those countries face a real challenging, since there are not many radiologists or medical physicists available to employ. Another important difference is the national requirements regarding professions allowed for CBCT image interpretation, where again only some countries allow dentist with supplementary course in CBCT to interpret some or all CBCT images. Lack of education of dentists with specialization within dental and maxillofacial radiology have forced through the need for allowance of dentists without specialization to interpret the images in some countries. There are also ongoing discussions between the professions regarding image interpretation. Some radiologists have the opinion that every CBCT image must be screened for pathology by a radiologist even if the clinical indication for the examination is solely for treatment planning for implant dentistry or similar and performed with

small scan FOVs. On the other hand, there is no doubt that a radiologist should be the preferred profession to interpret all CBCT images with large and medium scan FOVs.

Table 3: Summary of required professions and level of competence to qualify for the required professions and to operate the CBCT equipment in the Nordic countries. Available national education and training is also included in the table.

	Norway	Sweden	Denmark	Finland	Iceland
Radiation protection officer (RPO)	**X**	**X**	**X**	**X**	**X**
Qualified RPO by exam [1)]				X	
Dentist with supplementary course	X		X		X
Medical physicist		X			
Radiological competence	**X**	**X**	**X**	**X**	**X**
Dental and Maxillofacial radiologist	X	X		X	
Medical radiologist	X			X	
Dentist with supplementary course			X		X
Physician or dentist having a specialization				X	
Medical physicist	**X**	**X**		**X**	
Operation of CBCT	**X**	**X**	**X**	**X**	**X**
Dental and Maxillofacial/medical radiologist	X	X	X	X	X
Radiographer	X	X	X	X	X
Dentist with supplementary course	X	X	X	X	X
Dental hygienist with supplementary course		X	X		X
Available national education/training					
Specialization in DM radiology [2)]	X	X		X	
CBCT course for dentist			X		

[1)] Can be a dentist, physician or a medical physicist
[2)] DM = Dental and Maxillofacial

Table 4: Summary of national requirements to vendors of CBCT.

	Norway	Sweden	Denmark	Finland	Iceland
Authorization	X	X	X		
Inform customer of national requirements	X			X	X
Provide sales lists to the authority	X	X	X		X
Provide information of patient doses	X		X	X	
Provide information of isodose curves	X				

Another question is if some CBCTs should more or less be treated equivalent as a conventional OPG and not be subjected to authorization. Many new CBCTs have only the possibilities to provide small scan FOVs and the doses are comparable with a few OPG scans. It is maybe not desirable to treat these simple CBCTs at the same regulatory level as complex CBCTs providing large scan FOVs and high doses only because they fall under the definition of a CBCT, especially not from a radiation protection point of view.

The fact that most Nordic countries don't provide a proper training course for dentists in CBCT give rise to major concern. This makes it also very difficult for the authorities to evaluate if the dentists knowledge and competence is sufficient enough to comply with the requirements. The revealed conditions reflects an urgent need for establishment of training courses in CBCT for dentists and the learning outcomes associated with these courses should be harmonized between the Nordic countries.

This survey also supports some off the criticism raised by the CBCT vendors against the national radiation protection authorities. It is true that vendors have to deal with different regulatory management within the Nordic countries, which again affect the possibilities to market and sell their CBCTs. It is important to have in mind that the main task of the regulatory authorities is to ensure justified and optimized use of CBCT, not to prevent dentist from taking an important radiological tool in use.

CONCLUSION

This survey demonstrates the importance of regulatory management of CBCT to prevent inappropriate use of CBCT and indicates the need for a harmonization of requirements and regulatory managements together with establishment of common Nordic recommendations for CBCT.

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