

Safety and Efficacy of a New and Emerging Dental X-ray Modality



# **Project Deliverable**

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#### **Abstract**

**Objective**: The objectives were to analyse the costs of three interventions: intraoral and panoramic radiography and Cone Beam Computed Tomography (CBCT) in case of patients with retained maxillary canines and to investigate differences in cost between interventions and between four radiological clinics in four different countries.

**Material and method**: Model protocols for analysis of direct costs and indirect costs for the three interventions were established. The cost analysis was based on actual costs. Costs were subdivided according to categories of labour, equipment, technique, and overhead for the different interventions. Patient costs in terms of time spent in the clinic and travel were recorded. One hundred and thirteen patients with retained maxillary canines were examined in four radiological clinics in four countries.

**Results**: Valuation of costs per intraoral and panoramic image and volume with CBCT shows higher costs for CBCT compared to the others in combination. The difference is obvious for all countries as well as the difference between countries.

**Conclusion:** Examination with CBCT is more costly compared to examination with intraoral and panoramic radiography for patients with retained maxillary canines. The cost-effectiveness ratio will be calculated as the next step within this workpackage.

This is a public version of this Deliverable. Certain details of the work performed and results obtained have been withheld pending submission of manuscript(s) for publication in peer-reviewed journals.

A complete version of the Deliverable has been disclosed to the Commission and will be published publicly at the earliest opportunity.

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## 1. The Context

### 1.1 SEDENTEXCT Aims and objectives

The aim of this project is the acquisition of the key information necessary for sound and scientifically based clinical use of dental Cone Beam Computed Tomography (CBCT). In order that safety and efficacy are assured and enhanced in the 'real world', the parallel aim is to use the information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria and to provide a means of dissemination and training for users of CBCT. The objectives and methodology of the collaborative project are:

- 1. To develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development will use systematic review and established methodology, involving stakeholder input.
- 2. To determine the level of patient dose in dental CBCT, paying special attention to paediatric dosimetry, and personnel dose.
- 3. To perform diagnostic accuracy studies for CBCT for key clinical applications in dentistry by use of in vitro and clinical studies.
- 4. To develop a quality assurance programme, including a tool/tools for quality assurance work (including a marketable quality assurance phantom) and to define exposure protocols for specific clinical applications.
- 5. To measure cost-effectiveness of important clinical uses of CBCT compared with traditional methods.
- 6. To conduct valorisation, including dissemination and training, activities via an 'open access' website.

At all points, stakeholder involvement will be intrinsic to study design.

### 1.2 Work package 5 (WP5) objectives

The main objective is to analyse the cost-effectiveness of CBCT in different clinical situations, health care contexts and countries.

#### 1.3 Deliverable D5.1

The title of the deliverable is "Analysis of time and cost spent on different CBCT examinations in all participating radiology departments".

Examination with CBCT is currently asked for in a number of clinical conditions within oral health care. Information was obtained from partners on which clinical situations for which patients are most frequently referred for CBCT examinations. The most frequent referrals were found to be for 1) patients with retained maxillary canines, 2) patients with lower wisdom teeth that are planned to be extracted, 3)

patients with partly edentulous jaws in question for implant treatment and 4) patients with temporomandibular joint disorders.

Originally, the plan for the work in WP5 was to start patient examinations on the four listed clinical situations. However, as it was experienced that the development of protocols for analysis of costs was more complicated and time consuming than assumed, it was decided to start with one key paediatric use of CBCT, namely patients with retained maxillary canines. The constructed protocols were then to be used for the other clinical situations as well. This decision was approved by the Commission.

The departments where patient examinations have been performed are connected to the following Universities:

Oral Imaging Centre, Katholieke Universiteit Leuven, Belgium

Department of Oral and Maxillofacial Radiology, Malmö University, Sweden

Faculty of Dental Medicine. University of Medicine and Pharmacy in Cluj-Napoca, Romania

Vilnius University, Vilnius, Lithuania.

Examinations of patients with other clinical situations than retained maxillary canines have started and cost analysis is estimated to be finalised Month 27.

## 2. The Methodology

#### 2.1 Protocols

A model common to all types of economical evaluation was used for developing protocols for calculations of costs. This model is based on three steps:

Identification: What resources were used or released?

Measurement. How much was used or released?

Valuation: Expressed in common units (Drummond, 2005).

A cost analysis protocol based on the three above steps was developed to be used for economical evaluation of panoramic and intraoral radiography and examinations with CBCT (Appendix 1). With the set out from this protocol other protocols were constructed for calculations of *direct* (Appendix 2) and *indirect* costs (Appendix 3).

The protocol that was designed to be used during patient examinations for calculations of *indirect costs* was tested by all partners and after some corrections used when patient were examined. The work to develop protocols for calculations of *direct costs* started in a meeting in Malmö on 9 October 2008 with MAHOD together with UNIMAN. All protocols can subsequently be adapted to the other important clinical situations in which CBCT is used.

#### 2.2 Patient selection and examination

Following institutional ethical approval, patients above the age of 9 years, referred for examination of one or two maxillary retained canines, were selected to be included in the study. Patients and parents signed an informed consent to give their approval to the patient being included in the study.

Intraoral and panoramic radiography was performed for each retained canine as well as an examination with CBCT. Indirect costs were recorded according to the pre established protocol. Time spent for radiographers for each examination was recorded in the same protocol.

Data were collected in four centres as described in the protocols. Costs were reported in the currency of the country and translated into EUR. For costs in Lithuania, Sweden and Romania the exchange rate of the 22/6/09 was used.

#### 2.3 Valuation of costs

Valuation of *direct costs* was done according to the following:

1) purchase cost and cost for annual maintenance for the three different radiographic machines were divided by the expected lifetime. This annual cost was then divided by the total amount of billing-codes done in the clinic during one year.

- 2) Every clinic valuated the cost per square meter for the accommodation that is based on the cost to set up the whole entity today. This cost was divided between equipments for intra oral and panoramic radiography and CBCT, respectively.
- 3) All disposable items used less than 100 times in clinic examination, were listed by the dental assistants in four occasions during interventions with intra oral and panoramic radiography as well as with CBCT.
- 4) Labour costs were calculated according to <u>Total employment-cost</u>

Total wage-cost per hour = Total paid hours

Total employment cost= overhead employment cost + wage.

Total paid hours = Total worked hours minus benefit hours not paid for; sick leave, vacation and other such as parental leave.

Valuation of *indirect costs* (paid by the patient) were done based on patients' or accompanying persons' answers of questions on transport time and distance, type of transport and cost for parking as well as loss of income for visiting the clinic.

### 3. Results

#### 3.1 Patients

One hundred and thirteen patients has so far been examined, 50 in Malmö, Sweden, 32 in Vilnius, Lithuania, 24 in Leuven, Belgium and 7 in Cluj, Romania.

### 3.2 Direct and indirect costs

The summary of cost per intraoral and panoramic image and CBCT volume for examinations of patients with retained maxillary canines in four countries is presented in Table 1.

Table 1. Valuation of cost per image of intraoral and panoramic radiographs and volumes of CBCT. Costs in terms of time for radiologists writing reports are not included in the calculations.

	Intra-oral (EUR)	Panoramic (EUR)	CBCT (EUR)
Malmö	4,02	16,12	105,42
Cluj	2,42	3,79	36,44
Leuven	1,26	1,45	24,28
Vilnius	1,95	2,25	68,26
Average	2,41	5,90	58,6

All costs are presented in the attached Appendix 4 (cost analysis) which is currently confidential pending publication.

## 4. Conclusions

Examination with CBCT is more costly than examinations with intraoral and panoramic radiographs, both separately and in combination, for patients with retained maxillary canines in the four participating clinics from different European countries. There is also a difference in costs of interventions between countries. The main factor for the difference in costs is due to the time spent. Time spent for examinations with CBCT exceeds time spent for panoramic and intraoral radiography. In Malmö cost is based on wage-cost for two dental assistants, since they always work two by two, which make the examinations more expensive. Cluj reports the longest working-time per intervention.

The valuation of costs that has been performed will form the ground for costeffectiveness analysis where the actual impact of CBCT on diagnosis and treatment of patients with retained maxillary canines will be explored.

Assessment of radiographs for the retained canines has commenced and will be finalised in March 2010. Time for assessing radiographs as well as the confidence of the radiologist in his/her decision will be recorded in order to explore the full costs of every examination as well as the diagnostic thinking efficacy of CBCT and panoramic radiography compared to intra-oral and panoramic radiography (Fryback and Thornbury, 1991)

Examinations of patients with other clinical situations (lower wisdom teeth, before implant treatment) are ongoing and are planned to be finalised in Month 27.

## 6. References

Drummond M. F. Drummond MF, Sculpher MJ, Torrance GW, O'Brian BJ, Stoddart GL. Methods for the economic evaluation of health care programmes, Oxford, 2005, Oxford Medical Publications, 3rd ed

Fryback D. G., Thornbury J. R. The efficacy of diagnostic imaging. Med.Decis.Making 1991;11:88-94.

# Appendix 1

The model for economical evaluation applied on evaluation of diagnostic methods in oral health care

## Cost for intervention with intra-oral and panoramic radiography and CBCT

	Identification	Measurements	Valuation
Direct costs: Capital costs	Equipments for Io Panoramic CBCT Clinic space Office space	Number of images retrospectively in one year	Cost per image/volume for Io Panoramic CBCT
Consumables	Things used in the interventions that are disposable	Number of items per intervention	Unit price – total cost per intervention
Labour	Radiologists Radiographers Dental assistants specialised in oral radiology	Amount of working hours with radiography	Total wage-cost per hour
Indirect costs: Patients Accompanying person	Patients, carers, parents	Time for intervention Waiting time Travel timex2 Type of transport parking	Cost for loss of income Cost for transport Cost for parking

# Appendix 2

# Protocols for calculations of direct costs

# Capital costs

Capital costs: equipment, office and clinic space							
	Intra-oral radiography	Panoramic radiography	СВСТ				
Purchase price							
Expected lifetime							
Residual value							
Mean annual cost – straight depreciation (Alt. fixed annual instalment)							
Cost for office-, and clinic-space							
Access to digital journal system							
Access to image archive							

Capital costs: running costs - Maintenance cost for X-ray machines						
	Intra-oral radiography	Panoramic radiography	CBCT			
Cost for full service contract per year –also including vacuum parts						
Cost for cooperation service contract 60%						
Number of X-ray tube replacements during lifetime						
Number of detector replacements during lifetime						
Cost for detector replacements						
Alt.: Cost for service without service contract, call out costs - emergency						

Cost for preventive maintenance only		
Computer upgrade during lifetime		
Software upgrade alone		
Replacement of storage phosphor plates - Panoramic		

## Consumables

	Consu	mables	
		Radiographic	examination
Amount of	Intraoral radiography	Panoramic radiography	CBCT
Images/volumes per examination (nor retakes that are not saved)			
Time per examination			
Filmholders: apical			
apical			
bitwing			
other			
Plastic bags-sensor protection			
Tape			
Cotton rolls			
Tweezers			
Mirro			
Gloves			
Masks			
Napkins			
Desinfection			
Soap			
Surface desinfection			
Paper fro wiping			
Battery, data media, monitors, etc.			
Other			

## Labour costs

Labour							
	Radiologists	Radiographers	Dental assistants				
Total wage per year incl. overhead employment cost for							
Total amount worked hours per year for							

Average wage per		
hour for		

# Appendix 3

# Protocol for calculations of indirect costs

# SEDENTEX CT - protocol for health economy in WP 5

car	nines	wise	dom te	eth	impla	nts											
Pat	tient pro	tocol	to be f	illed in b	y radi	ograpl	ner,	den	tist c	or de	ental	assi	stant	: <b>.</b>			
2.	Register date: Patient name: Birth date: Patient name: Pat																
4.	Any ca				to arr	ive so	tha	t the	time	е со	uld n	ot be	e use	ed			
5.	Time w			ent arriv						-							
6.	Time w			ent leav													
7.	(The tir	 me wh	 en the	catient s radiogient arriv	aphic	exami	m nati	inute	es. Ind ir		view	were	e cor	nple	ted, <i>n</i>	ninus	the
8.	Is this a			it? Mea urgery)											r clini	C - OI	ral
lf tl clir	or the he pation nic and estion	ent is will r	a chile	d or you	ung ad												
9.	How di car bi			the clin walked			oth	ner, v	whic	h is.							
10.	How do	•		to retur walked								-					
11.	•	o l	n case	ar - did of yes -	- how	much	did	you									
12.				far did					the	clir	ic to	day?	,				

13.	Approximately how long did it take for you to come to the clinicminutes.
14.	What is your employment status? employed self-employed homemaker looking for job retired not working because of ill health student other
15.	Did you lose wage or vacation time to come to the clinic today?  yes no In case of yes, how long time? minutes.
Fo	or accompanying person to answer:
16.	What is your relationship to the patient? parent brother/sister grandparent other relative friend other, which is
17.	How did you get to the clinic today? car bicycle train walked taxi bus other, which is
18.	If you got here by car - did you buy a parking ticket? yes no In case of yes – how much did you pay?
19.	Did you pick up the patient at home/at school? yes no In case of yes, how long time did that take?minutes.
20.	How do you intend to return home/to school from the clinic today? car bicycle train walk taxi bus other, which is
21.	Approximately how far did you travel to come to the clinic today?km.
22.	Approximately how long time did it take for you to come to the clinic today?minutes.
23.	What is your employment status? employed self-employed homemaker looking for job retired not working because of ill health student other which is
24.	Did you lose pay or vacation time to come to the clinic today? yes no In case of yes, how much?
	diographer/dental assistant (name)
•	Number of intraoral periapical radiographs taken(retakes incl).

•	How long time did you spend taking the intraoral periapical radiographs?minutes.
•	Number of panoramic radiographs(retakes incl).
•	How long time did you spend taking the panoramic radiograph?minutes.
•	Number of volumes with CBCT taken?(retakes incl).
•	How long time did you spend taking the CBCT volume?minutes.
•	Number of volumes with medical CT taken?(retakes incl).
•	How long time did you spend taking the medical CT volume?minutes.
Cc	omments:

The report was finalised before the patient left the radiology clinic. yes no

