HELENA CHRISTELL

COSTS AND BENEFITS OF CONE BEAM COMPUTED TOMOGRAPHY

For maxillary canines with eruption disturbance

MALMÖ UNIVERSITY

**COSTS AND BENEFITS OF
CONE BEAM COMPUTED TOMOGRAPHY**

Malmö University, Faculty of Odontology
Doctoral Dissertations 2017

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The image on the front page illustrates costs being outweighed by the benefits to the patient, created with inspiration from “Takeover” by Keith Haring.

ISBN 978-91-7104-724-3 (print)

ISBN 978-91-7104-725-0 (pdf)

Holmbergs, Malmö 2017

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Malmö University, 2017
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This publication is also available in electronic format at:
<http://dspace.mah.se/handle/2043/22147>

To you who supported and never doubted me

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LIST OF ARTICLES

This thesis is based on the following articles, referred to in the text by their Roman numerals. All articles are reprinted with permission from the copyright holders and appended to the end of the thesis.

I. Economic evaluation of diagnostic methods used in dentistry. A systematic review. Christell H, Birch S, Horner K, Lindh C, Rohlin M, The SEDENTEXCT consortium. *Journal of Dentistry*. 2014;42: 1361-71.

II. A framework for costing diagnostic methods in oral health care: An application comparing a new imaging technology with the conventional approach for maxillary canines with eruption disturbance. Christell H, Birch S, Horner K, Rohlin M, Lindh C, The SEDENTEXCT consortium. *Community Dentistry and Oral Epidemiology*. 2012;40:351-61.

III. Variations in costs of cone beam CT examinations among health care systems. Christell H, Birch S, Hedesiu M, Horner K, Ivanauskaitė D, Nackaerts O, Rohlin M, Lindh C, The SEDENTEXCT consortium. *Dentomaxillofacial Radiology*. 2012;41:571-7.

IV. The impact of Cone Beam CT on financial costs and orthodontists' treatment decisions in the management of maxillary canines with eruption disturbance. Christell H, Birch S, Bondemark L, Horner K, Lindh C, The SEDENTEXCT consortium.

Submitted for publication in *European Journal of Orthodontics* January 7, 2017.

ABBREVIATIONS AND GLOSSARY

CA	Cost Analysis
CBA	Cost Benefit Analysis
CEA	Cost Effectiveness Analysis
CUA	Cost Utility Analysis
CT	Computed Tomography
GDP	Gross Domestic Product
HTA	Health Technology Assessment
OHRQoL	Oral Health Related Quality of Life
QALY	Quality Adjusted Life Time
WTP	Willingness To Pay
RCT	Randomised Controlled Trial

ALARA (As Low As Reasonably Achievable): This phrase, deriving from the radiation protection principle of optimisation, means that (individual) doses should be as low as reasonably achievable, taking into account economic or social factors.

CBCT (Cone beam Computed Tomography): An X-ray imaging technique in which a volumetric image dataset is obtained by acquisition of multiple projectional sets of X-ray attenuation data by rotation around the object of interest of a divergent X-ray beam (conical or pyramidal), with subsequent computed reconstruction.

Maxillary canines with eruption disturbance: Clinical conditions where the maxillary canine has any eruption disturbance, also termed impaction, retention, ectopic eruption or displacement of maxillary canines.

Patients' preferences: The extent to which individuals appreciate different phenomena. The more something is appreciated by an individual, the higher the utility-level when the person receives the product or service. Patients' preferences represent the choices patients would make faced with alternative options. In order to compare between options that involve different costs (and hence different investments of scarce resources) the strength of preferences, not just choice, is required.

ABSTRACT

With a continuous influx of new imaging technologies, the question must be raised whether the use of new methods provides benefits for the patients justifying any additional costs incurred. There is a growing awareness of the need for economic evaluations in dentistry and further understanding in this field is needed. The use of Cone Beam Computed Tomography (CBCT) in dentistry has emerged during the last decades and it is important to investigate if it fulfils its purpose of forming a basis for treatment planning in a cost-effective way. *Evidence for the costs and benefits of CBCT is still scarce.*

In Study I, a systematic review of the literature regarding economic evaluations of diagnostic methods in dentistry was conducted according to international guidelines. Four databases were searched and relevant publications were retrieved and selected according to predetermined criteria for inclusion and exclusion. The methodological quality of the studies was assessed combining a protocol for diagnostic studies and a checklist for economic evaluations. **Key findings:** Of the 160 economic evaluations in dentistry, 12 concerned diagnostic methods. In general, the perspective of the study was not stated and the methods for costing varied. A need for improved quality of future economic evaluations was identified.

In Study II, a framework for analysing costs of diagnostic methods in dentistry was constructed. The framework was tested for costing of examination using intraoral and panoramic radiography compared with CBCT and panoramic radiography regarding patients with maxillary canines with eruption disturbance **Key findings:** The

framework demonstrated a feasibility of analysing relevant costs for capital, consumables, labour and patient-related costs. Examination with CBCT and panoramic radiography was associated with a significantly higher cost of 128.38€ compared with that of intraoral and panoramic radiography 81.80€ resulting in an incremental cost for CBCT and panoramic radiography of 46.58€.

In Study III the costs of CBCT-examinations were analysed comparing four different clinical conditions in four different settings in Leuven -Belgium, Cluj -Romania, Malmö -Sweden and Vilnius -Lithuania. **Key findings:** The estimates for clinic-related costs varied among the health care systems, being highest in Malmö and lowest in Cluj. This variation was mainly due to different purchase costs for the CBCT equipment (range 148 000–227 000€). The variation in examination fees (range 0–102.02€) was the principle reason for the differences in patient-related costs. Costing of a dental radiographic method cannot be generalised from one health care system to another, without considering their specific circumstances.

In Study IV, a web-based survey was constructed in order to measure the proportion of orthodontists' treatment decisions that were different when comparing CBCT and panoramic radiography with intraoral and panoramic radiography and to analyse the costs of producing different treatment plans, for patients with maxillary canines with eruption disturbance. The orthodontists were randomly assigned to denote treatment decisions for four patient cases presented with either intraoral and panoramic radiography or CBCT and panoramic radiography, respectively, at two occasions for the same patient case. **Key-findings:** Twenty-four percent of the treatment decisions were different when the orthodontists had access to CBCT and panoramic radiography instead of intraoral and panoramic radiography. The total diagnostic cost per examination was 99.84€ using intraoral and panoramic radiography and 134.37 using CBCT and panoramic radiography, resulting in an incremental cost per examination of 34.53€ for CBCT and panoramic radiography. This can be expressed in terms of an incremental cost-effectiveness ratio (ICER) which is a measure of the average additional cost per treatment decision that is different as a result of using CBCT imaging i.e. 143.88€.

Clinical implications and importance

This thesis will add to the knowledge in an area where technical development rather than patients' benefits tends to dominate the discussion. Currently there are no clear selection criteria for examination with CBCT regarding patients with a suspected eruption disturbance of maxillary canines. This condition is mostly detected and treated in younger patients to whom radiation exposure poses a greater risk than it does to adults. This makes the justification of radiographic examination particularly important.

The systematic review in Study I highlighted a need for standardised methods of economic evaluations in dentistry and confirmed that there is a knowledge gap regarding economic evaluations, in particular concerning diagnostic methods. To the best of our knowledge, the cost-analyses in Study II and III are the first performed in this field. Applications of the framework will support the development of a standardised methodology for conducting economic evaluations in dentistry and thereby promote the generalisability of future studies. Study IV is one of the first to compare the costs of dental radiographic examinations with the possible benefits for the patients. For a majority of the patients, CBCT is not beneficial in terms of a different treatment decision. For patients with severe space deficiency in the maxilla, indicating a need for tooth extractions, CBCT can provide additional information which may prevent the extraction of healthy and undamaged teeth.

This thesis provides no evidence to support routine use of CBCT for patients with maxillary canines with eruption disturbance. A sub-group of patients was identified for whom CBCT examination may be beneficial. The results of costs and effects for different imaging methods provided in this thesis can inform the development of clinical practice guidelines and support decision makers regarding investment decisions and prioritisation.

POPULÄRVETENSKAPLIG SAMMANFATTNING

I tandvården finns allt fler metoder för prevention, diagnostik och behandling. Eftersom resurserna är begränsade bör den metod väljas där nyttan uppväger kostnaden. *Idag saknas dock vetenskapliga belägg gällande kostnadseffektivitet för undersökning med Cone Beam Computed Tomography (CBCT).*

En systematisk översikt i **Studie I** identifierade 160 hälsoekonomiska utvärderingar inom tandvård varav 12 gällde diagnostiska metoder. Översikten kunde inte identifiera någon kostnadsanalys på patientnivå för diagnostiska metoder. Därför konstruerades i **Studie II** ett ramverk för analys av kostnader förknippade med diagnostiska metoder i tandvården. Applicering av ramverket visade att CBCT och panoramaröntgen hade en signifikant högre kostnad (128,38€) jämfört med intraoral och panoramaröntgen (81,80€). I **Studie III** jämfördes kostnader för CBCT undersökning av patienter med olika kliniska tillstånd på kliniker i Cluj -Rumänien, Leuven -Belgien, Malmö -Sverige och Vilnius -Litauen. Klinikrelaterade kostnader varierade mellan sjukvårdssystemen vilket främst berodde på olika höga inköpskostnader för CBCT-apparaterna medan skillnader i patientrelaterade kostnader främst berodde på variation i patientavgifter. I enkätundersökningen i **Studie IV** ombads specialister i tandreglering att ta behandlingsbeslut gällande patienter med eruptionsstörning av överkäkshörntanden. Majoriteten av behandlingsvalen var samma oavsett om specialisterna hade tillgång till röntgenbilder från CBCT och panoramaröntgenundersökning eller till bilder från intraoral- och panoramaröntgenundersökning. CBCT kan vara till nytta för en del av patienterna genom att i högre grad än intraoral röntgen och panoramaröntgen identifiera en resorptionsskada på granntänder till

hörntanden med eruptionsstörning, vilket kan göra att en skadad tand tas bort istället för en frisk tand.

Sammanfattningsvis kan sägas att det finns ett stort behov av hälsoekonomiska studier med god kvalitet gällande diagnostiska metoder inom tandvård. Undersökning med CBCT medför en högre kostnad än konventionella röntgenmetoder och för majoriteten av patienter med misstanke om eruptionsstörning av överkäkshörntänderna medför den ingen extra nytta avseende behandlingsbeslut.

Klinisk betydelse

Denna avhandling har ökat kunskapen inom ett område där den tekniska utvecklingen av diagnostiska metoder inom tandvård stundtals dominerar framför patientnyttan. För närvarande är det vetenskapliga underlaget bristfälligt för indikationer då det gäller CBCT undersökning av patienter där det finns misstanke om felaktig eruption av överkäkshörntänderna. Detta tillstånd upptäcks och behandlas oftast på unga patienter vilka är mer känsliga för röntgenstrålning än vuxna och det är därför särskilt viktigt att röntgenundersökningar av denna patientgrupp är berättigade.

Den systematiska översikten i Studie I belyste behovet av standardiserade metoder för hälsoekonomiska analyser inom tandvård, speciellt gällande diagnostiska metoder. Enligt vår kännedom är kostnadsanalysen i Studie II den första inom detta område. Det ramverk för kostnadsanalys som konstruerades i Studie II, kan bidra till utveckling av standardiserade metoder för hälsoekonomiska analyser inom tandvård. Studie III visar svårigheterna med att jämföra kostnader mellan olika länder om man inte beaktar specifika omständigheter i respektive land. Studie IV är en av de första studier som jämför kostnader för dentala röntgenmetoder med den associerade patientnyttan. Studien visar att CBCT undersökning i de flesta fall inte ändrar behandlingsbeslutet. För majoriteten av patienter där överkäkshörntänderna har en eruptionsstörning tillför CBCT undersökning sannolikt ingen extra nytta jämfört med undersökning med intraoral röntgen och panoramaröntgen. CBCT kan emellertid bidra med ökad information gällande identifiering av resorptionsskador på granntänder till överkäkshörntänderna vilket gör att man kan undvika borttagning av friska oskadade tänder.

Resultaten från denna avhandling visar att rutinmässigt användande av CBCT för patienter med eruptionsstörning av överkäkshörntänder inte kan tillrättas. De visar också att CBCT kan vara till nytta för en liten del av dessa patienter. Framtida studier bör formulera indikationer för CBCT undersökning som skiljer ut patienter för vilka denna undersökning kan medföra någon nytta. Resultaten kan bidra till utveckling av riktlinjer för klinisk praxis och ligga till grund för beslut om investering och prioritering inom tandvård.

BACKGROUND

General background

The rapid development of health technology in recent decades has provided exceptional possibilities for diagnosis and treatment, which has resulted in improvements in clinical outcomes for patients. The plethora of available methods in health care has consequently increased the demands on health care. Providers of health care now have to choose between an array of different health care methods for diagnosis, treatment and prognosis to ensure that resources are used in the best alternative manner. Thus, that the health benefits to the patients are maximised using available health care resources. There is a growing interest in the results of health economic evaluations among decision makers who are required to optimise resource allocation within health care as well as in dental care.

Dental Cone Beam Computed Tomography (CBCT) is an emerging technique for diagnostic imaging. It offers images in three planes with a high level of detail which makes it an attractive method for many dental applications. CBCT is currently requested for a number of dental conditions, one of which is to identify maxillary canines with a suspected eruption disturbance and any root resorption on the neighbouring teeth. CBCT-examination may however, be associated with a greater radiation dose as well as with higher costs compared with conventional dental imaging methods (1).

SedentexCT 2008-2011, was a project financed by the European Union (EU) aiming to improve the safety and efficacy of CBCT examinations (2). Within the project, methods for quality assurance and safety testing were developed, and studies on technical, diagnostic and therapeutic efficacy were performed by collaborators in Manchester

and Leeds (United Kingdom (UK)), Leuven (Belgium), Athens (Greece), Cluj (Romania), Vilnius (Lithuania) and Malmö (Sweden).

The aim of the collaborators in Malmö was to analyse the cost-effectiveness of CBCT compared with conventional imaging methods and these studies formed the basis of this thesis.

Health technology assessment

Health technology assessment (HTA) originated in the United States (US) in the early 1970s as a consequence of an increased influx of new medical technology. Among providers of health care and decision makers this raised the question of how to choose the most beneficial method, also with regard to the cost. Costly medical technology like computed tomography (CT) developed throughout the 1970s and 1980s. This resulted in an increased share of the state budget being devoted to health care, which might have provided a powerful incentive for a broadened technology assessment (3). This development led to a discussion in the US and in Europe of the effectiveness of the interventions used and of the inequity of health care (4).

In the last decades, the cost of health care, including public and private expenditures, has continued to increase and now constitutes a growing share of the gross domestic product (GDP) of European member countries in the Organisation for Economic Co-operation and Development (OECD) (5) as seen in Figure 1. The resources spent on health care differs however fundamentally between countries reflecting inequalities in the access to health care due to varying political systems. Also a substantial part of the health budget is spent on dental care in the OECD countries (6).

Figure 1. The increase of health care costs in percentage of the Gross Domestic Product (GDP) in 27 OECD countries from 1973 to 2012. The figure was constructed based on data from OECD health statistics (5).

Economic evaluation is an essential part of HTA forming a framework for assessment of evidence for clinical effects and the associated resource use. Economic evaluation always implies a comparison of alternative interventions often with a new intervention being compared with the one currently used. This evaluation can be performed using different perspectives i.e. that of the patient, the provider, or society. The perspective is important to consider when planning an economic evaluation, as an intervention can look appealing from one perspective but less appealing from another perspective (7). Furthermore, the perspective determines which effects and costs that are relevant to include.

There are four types of economic evaluations whereof cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA) are considered to be full economic evaluations as they assess both costs and effects of an intervention. The difference between these analyses is mainly the way the effects are measured and expressed. The fourth type of economic evaluation is cost-analysis

(CA) which analyses the additional cost of the different interventions being compared and does not include analysis of effects.

CA is useful when comparing interventions where the effects are considered equal. Drummond et al. (2005)(7) recommend that the analysis of costs be performed in three subsequent steps:

- Identification of relevant costs i.e. costs that are assumed to affect the outcome of the analysis. Costs can be defined as “resources denied other uses” (7).
- Measuring of the number of resources consumed and cost per unit. This step in the analysis answers the question of how many and how much.
- Valuation of each resource consumed to get a monetary cost which is summarised to a total cost of the intervention. Comparison of the total cost for the interventions being assessed will give the incremental cost i.e. the additional cost for the costlier intervention.

CEA is useful for comparing the costs and effects of different interventions aimed at serving the same patient group and/or producing the same type of outcome. It values effects measured in physical or natural units like additional life-years or clinical outcome measures like number of cases correctly diagnosed, or avoided decayed tooth-surfaces. CEA enables comparison of interventions with one single effect in common. The result is presented as the mean additional cost per additional unit of effect or an incremental cost-effectiveness ratio (ICER). ICER is a way to summarise the cost-effectiveness. It can be defined as the difference in cost between the methods being compared divided by the difference in their effect.

CUA is useful for comparison of interventions with multiple effects. CUA extends CEA to use preference-based units of outcome that support incorporating several different outcomes into a single outcome measure using e.g. quality adjusted life years (QALY) to measure the effects (7). QALY is based on utility i.e. patients’ preferences which is a measure that weights duration of a change (or difference) in health states by the relative preference of an individual between those health states. The weight is derived by comparing the particular health state with states of perfect health and death. The weighting of

a health state can be estimated using direct methods like Time Trade Off (TTO), Standard Gamble (SG), Visible Analogue Scale (VAS) or indirect methods like EQ-5D (8). QALY is a generic measure that allows comparison of different interventions of the same or different clinical conditions in terms of changes in the health related quality of life related to life-years. The result of CUA is presented as the mean additional cost per additional QALY or expressed as an incremental cost utility ratio (ICUR).

Finally, cost-benefit analysis (CBA) measures the effects and costs of interventions in the same units i.e. in monetary terms. CBA often uses willingness to pay (WTP) as outcome measure. WTP means that an intervention is evaluated by asking patients and/ or individuals in a population what they would be willing to pay for the intervention. Both costs and effects are expressed in monetary terms and the intervention for which the willingness to pay exceeds the costs should be chosen. The result is presented as the net gain to society.

The National Board of Health and Welfare was clear in their national guidelines that there is a knowledge gap regarding cost-effectiveness for the interventions used in dentistry and that the study quality of health economic evaluations had to be improved (9).

Diagnostic methods

The purpose of a diagnostic method is to distinguish the healthy from the diseased based on positive or negative findings. It can also predict a disease or be used to screen an entire population in order to prevent and/ or to diagnose disease. Diagnostic methods in dental care include clinical examinations, imaging methods and laboratory tests.

As HTA gained an increasingly important role in healthcare and with an amplified use of methods for diagnostic imaging, decision makers within health care demanded to see value for the cost involved. Consequently, there was a need for conceptual thinking regarding assessment of the outcome of diagnostic methods. In 1991 Fryback and Thornbury therefore presented a model for organising assessments of diagnostic methods in a six-level hierarchy (10). Efficacy can be defined as the probability of a test benefiting patients when applied under ideal conditions of use. An acceptable level of efficacy for a diagnostic method must exist at lower levels to assure efficacy at higher

levels. Diagnostic methods are often assessed regarding their efficacy concerning technical aspects or diagnostic accuracy. The choice to use an imaging method should however, be based on an understanding of its efficacy also on higher levels. Evidence of the aggregate benefits of a diagnostic method to society may constitute a more powerful influence on the allocation of resources in health care. An imaging method with no impact on treatment-planning cannot be expected to benefit the patient, except by means of 'clinician's reassurance'.

The different levels of assessment for efficacy of diagnostic methods correspond to cost-effectiveness analysis with the highest level concerning the consequences for society in terms of the cost to society and general health. Higher-level benefits with impact on the treatment decision regarding CBCT examination of maxillary canines in relation to the associated costs are still unknown.

Maxillary canines with eruption disturbance

With a prevalence of 0.9%-3% the maxillary canine is, after the third molar, the tooth most frequently found with impaction (11-13). A majority of impacted canines are unilateral and palatally positioned and occurs twice as frequently in females (14,15). The normal eruption time for permanent maxillary canines may vary from nine to 13 years (13). Clinical examination of patients aged eight to ten years showing a lack of a buccal bulge on palpation in the region of the maxillary canine in the age eight to ten years may indicate an eruption disturbance. In 7-10% of children the clinical findings must be supplemented with radiographic examination to determine the position of the canine (13,16).

The position of unerupted maxillary canines can be buccal, normal (i.e. central in the alveolar process and distal or bucco-distal to the lateral incisor) or palatal. Canines that are palatally displaced have the least tendency for eruption (12). The etiology of eruption disturbance of maxillary canines is still not clear (17).

Early treatment often involves extraction of primary canines, sometimes followed by limited appliance therapy (18,19). If no improvement occurs within 12 months after extraction of the primary canine, it can be assumed that the permanent canine will not self-correct. In cases without self-correction, an overall orthodontic

treatment plan is required which may include treatment aiming to creating space between the canine and the incisor root in order to prevent further resorption (20,21). Consideration of any extraction of the permanent teeth and whether any root resorption is present on the teeth neighboring the impacted maxillary canine, will be essential for the initiation of the treatment. Without diagnosis of resorbed incisor roots close to the impacted canine, there is a high risk that severely resorbed incisors are left in place and that healthy premolars are extracted (22).

Early extraction of the deciduous maxillary canine has been recommended in order to facilitate the eruption of permanent palatally displaced canines but a Cochrane review from 2009 showed no robust evidence to support this practice (23). Recent randomised controlled trials have however showed significantly higher success-rate for eruption of the maxillary canine after extraction of the primary canine compared with a control-group (24,25). If left undetected and untreated, maxillary canines could move further medially and thereby increasing the risk of causing root resorption on neighbouring teeth, notably lateral incisors (18). The prevalence of root resorption on teeth neighbouring the maxillary impacted canine is between 27-67% (26-28).

The position of palatally impacted maxillary canines on radiographs has been associated with a variation in prognosis for spontaneous eruption and with the success-rate of orthodontic treatment aiming to move the canine to the correct position in the dental arch (18). Less angulation to the midline, shorter distance of the canine cusp-tip to the dental arch plane and longer distance between the canine cusp-tip and the midline) is crucial to a good prognosis for spontaneous eruption (29). In addition, the canine position subsequently affects the duration of the treatment and the cost associated with the treatment (30) as well as the prevalence of root-resorption on teeth neighboring the canine. The best predictor of root resorption seems to be the location of the canine mesial in relation to the midline of the lateral incisor root (31,32).

Many patients with maxillary canines with eruption disturbance are referred for CBCT-examination but the question is whether CBCT-examination has impact on the treatment decision.

Imaging methods for localisation of maxillary canines

Already in 1910 Clark described *intraoral radiographic examination* of teeth “buried” in the incisor and canine region and the difficulties in deciding which tooth is in front of the other when depicted superimposed (33). He described a solution to the problem by taking periapical radiographs using different angles in the horizontal plane. This method was later called Clarks rule, parallax technique, or stereo-roentgenography (Figure 2).

Figure 2. Panoramic and two periapical intraoral radiographs (Patient case 2 in Study IV). The two intraoral radiographs illustrate the parallax technique identifying the right maxillary canine palatal to the lateral and central incisor.

Paatero presented the first dental application of *panoramic radiology* in 1949 as “a new tomographical method for radiographing curved outer surfaces” (34). Panoramic radiographs provide an overview of the maxillary and mandibular dental arches with the teeth and their supporting structures as well as the temporomandibular joints and maxillary sinus. Ericson and Kurol (1988) proposed an index based on the canine position in a panoramic radiograph; the angulation of the canine to the midline, the distance of the canine crown-tip to the occlusal line and the medial position of the crown in different degrees of overlap of the lateral and central incisors (18).

According to the magnification technique, impacted teeth located palatally are more enlarged in the panoramic radiograph than the adjacent normally located teeth. Palatally impacted maxillary canines was possible to correctly identify in 80-90% of the cases using the magnification technique (14,35). Compared with postero-anterior skull radiographs, there was a tendency for the canine angulation to

be increased and appearing to be further away from the midline in the panoramic radiograph (36). Intraoral and panoramic radiography are commonly used imaging methods for identification of maxillary canines with eruption disturbance (17). Only about 50% of the resorptions on the palatal or buccal aspects of incisor roots however, can be detected by intraoral or panoramic radiographs (37).

Computed Tomography (CT) provides images in three planes. The basic principle for CT is that the x-ray tube is connected to a detector on the opposite side synchronously rotate around the patient. CT uses a fan-shaped beam that is projected through the patient from several different angles. The radiation is attenuated (i.e. weakens) differently depending on the type of tissue that it passes through with high attenuation in high-density tissue such as bone tissue. A curved detector registers the intensity of the radiation and the linear attenuation-coefficient for each pixel in the detector is measured and re-calculated to Hounsfield values. With information of the angle for each measured data, a two-dimensional sectional image of the object is reconstructed. The two-dimensional images are combined in the computer to produce a volume of data that can be manipulated in order to demonstrate various anatomic structures with good detail reproduction. Modern scanners allow the volume of data to be reformatted in various planes or even as 3D volumetric representations of structures (38).

Cone beam computed tomography was introduced in the early 1980s for angiography, but has since then become the most significant advance in dental- and maxillofacial imaging. The development of specialised CBCT scanners for use in dentistry begun in the late 1990s (39). CBCT uses a cone-shaped source of ionising radiation, similar in shape to the divergent beam of conventional 2D imaging. The cone-shaped beam is directed through the centre of the depicted object i.e. centre of rotation, and the attenuated radiation is projected on a detector on the opposite side. The x-ray source and detector rotate around the centre of rotation where the image volume is acquired. Most CBCT systems use a fixed source-to-object distance and object-to-detector distance and a flat panel detector with a layer of scintillator material used to convert the x-ray photon into light photons. The light is absorbed allowing formation of electric charges that are converted to

a digital signal. During one rotation of 180° to 360° (in some cases two rotations of 360°), multiple sequential planar projection images are acquired covering the field of view (FOV). The single projection transmission images constitute raw data that are reconstructed by computer algorithm to generate cross-sectional images (38).

The image quality characteristics can be described using four fundamental parameters, spatial resolution and contrast, noise and artefacts. Increased spatial resolution (sharpness) and contrast provides improved reproduction of details but also results in more noise. Hence, image quality should be assessed relative to the imaging task detection of bone fracture or visualisation of a soft-tissue abnormality (38). CBCT imaging has been suggested for localisation of maxillary canines with eruption disturbance as well as for detection of root resorption on adjacent teeth (40).

The diagnostic accuracy of CBCT regarding identification of maxillary canines with eruption disturbance as well as identification of any root-resorption on adjacent teeth seems to be higher compared with conventional 2D technique (27). The question is however, whether the information from CBCT-examination will change treatment planning compared with conventional imaging methods.

Radiation dose

The effective dose (sievert (μSv)) of CT for maxillofacial imaging has been reported to have a range of 280-1 210 μSv (41) which is usually higher than that of CBCT. The effective dose for CBCT varied for different machines and different field of views (FOV) with a range of 9.7-197 μSv for a small FOV (≤ 5 cm height), a range of 3.9-674 μSv for medium FOV (5.1-10 cm height), whereas the range was 8.8-1 073 μSv for a large FOV (>10 cm height) (41). The effective dose for CBCT is however considerably higher than that of conventional imaging methods with <1.5 μSv for one single intraoral radiograph, and range of 2.7-24.3 μSv for one panoramic radiograph (42).

For medical CT there are diagnostic reference levels with recommendations of the maximum dose for different procedures (43) but for CBCT there are no such reference levels. The SEDENTEXCT guidelines recommend an 'Achievable Dose' level of 250 mGy.cm² for CBCT appropriate for examination prior to implant treatment in adults (42).

GENERAL AIM

A general aim of the SEDENTEXCT project was to acquire key information necessary for scientifically based clinical use of CBCT in dental- and maxillofacial imaging. Economic evaluation, weighing costs and benefits of alternative interventions, provides information that is necessary to achieve complete evaluation of a new imaging method and its contingent benefits in terms of patients' health.

The general aims of the present thesis, based on four studies referred to by their roman numerals (I-IV), were to assess any benefits of CBCT as well as the costs for producing these benefits in the context of maxillary canines with eruption disturbance.

SPECIFIC AIMS

The specific aims of the studies on which the present thesis are based were to:

- Elucidate scientific information on economic evaluations in oral health care with emphasis on diagnostic methods (Study I).
- Propose a framework for costing diagnostic methods in oral health care and to illustrate the application of the framework to the radiographic examination of maxillary canines with eruption disturbance (Study II).
- Analyse the costs of Cone Beam Computed Tomography (CBCT) in different health care systems for patients with different clinical conditions (Study III).
- Measure the proportion of orthodontists' treatment decisions that were different based on CBCT and panoramic radiography compared with intraoral and panoramic radiography and the costs of producing different treatment plans, regarding patients with maxillary canines with eruption disturbance (Study IV).

METHODS

Systematic review (Study I)

The literature review was performed according to the PRISMA Statement (44) and CRD's guidance for undertaking reviews in health care (45). The subsequent steps that were defined in order to conduct a systematic review are presented in Table 1.

Table 1. The subsequent four steps defined to conduct a systematic review; (i) specification of problem, (ii) formulation of a plan for the literature search, (iii) literature search and retrieval of records, and (iv) extraction and quality assessment of data.

Specification of problem	Which diagnostic methods in dentistry have been analysed? What types of economic evaluations have been conducted?
Formulation of a plan for the literature search	Consulting librarian for guidance. Construction of search strategies.
Literature search and retrieval of records	Searches for literature in four electronic data-bases; MEDLINE (PubMed), the Web of Science, the Cochrane Library and the NHS Economic Evaluation Database. Retrieval of records and subtraction of duplicate publications. Identification of relevant studies according to abstract and/ or title by independent assessment of two reviewers. independently using protocol with criteria for inclusion and exclusion. Selection of original studies reporting economic evaluations in dentistry with abstract in English. Summary of the selection process in a PRISMA Flowdiagram (44). The flow diagram can be seen in Study I, Figure I.
Extraction and quality assessment of data	Critical appraisal of economic evaluations of diagnostic methods in dentistry using a second protocol.** Data was captured of the type of economic evaluations, the perspective, time horizon, discounting and outcome. Study design of included studies was “decision model (simulation)-based analyses and empirical economic evaluations, which collect patient-level data on costs and outcomes” as defined by Anderson (2010) (46).
**Protocol constructed based on the QUADAS tool (47), for assessment of the diagnostic methods and the checklist by Drummond et al. (2005) (7) for assessing economic evaluations.	

Cost-analysis (Study II, III and IV)

Framework for costing

The framework for costing diagnostic methods in dentistry incorporated three consecutive steps as presented in Table 2; i) identification of resources believed to have any impact on the results, ii) measuring the amount of resources consumed and finally iii) valuation of the used in monetary terms to get a cost per intervention. The framework included costs for the health care system in delivering the service from a *providers' perspective*. Patient-related costs for using the service were included to enable a *societal perspective* according to Drummond et al. (2005) (7).

Data collection was aided using four forms constructed for i) apportioning the cost of capital equipment for each radiographic examination and ii) to measure consumable items to report the time spent on the intervention by health care providers and iv) to measure the cost for the patients and accompanying persons.

Table 2. The three consecutive steps of: (i) identification (ii) measurement and (iii) valuation of costs comprised in the framework for costing of diagnostic methods in dentistry based on recommendations by Drummond et al. (2005) (7). The example is described for diagnostic imaging methods.

	Identification (what)	Measurement (how much/ many)	Valuation (unit-cost)
Cost to the provider:			
Capital costs	Equipment Maintenance	No of: Examinations per year Images per examination Equipment time	Purchase cost for the equipment Cost per examination for: Equipment Maintenance
Rental costs	Accommodation Patient record Image archive	No of: Square meters Patient record Images stored	Cost per examination for: Accommodation Patient record Image archive
Labour costs	Specialist Dental nurse/ assistant	No of worked clinical hours	Annual labour cost Labour cost per examination
Cost to the patient:			
Cost for time spent	Transport Waiting Examination	Minutes for: Transport Waiting Examination	Average gross annual earning Minimum wage cost per hour Cost per examination: Transport Waiting Examination
'Out of pocket' cost	Cost per km Parking	Cost per km No of km Parking	Out of pocket cost per examination

Direct costs included costs for *capital equipment* i.e. radiographic machines, computers, maintenance and repair of the equipment, costs for accommodation i.e. clinic and office space as well as cost for labour. The annual cost for the radiographic apparatus was calculated by dividing the purchase costs with the expected lifetime. The cost for maintenance was based on the average annual cost for a defined period of time. Cost for *accommodation* for the clinic and office space was calculated as cost per square metre and included overhead costs (e.g. cleaning, lighting and heating).

The clinic and office space was estimated based on the construction map of the clinic. The costs for capital, maintenance, and accommodation for one year was divided by the total number of images/volumes taken during one year to get the mean cost per image/volume. The cost per image/volume was then multiplied by the mean number of images/volumes recorded per examination to get the mean cost per examination. The total number of images/volumes per year was retrieved from the billing codes for a radiographic examination. The calculations were based on an observed average number of radiographs per examination. Scrap value or scrap cost of old equipment was not included as it was assumed not to differ between the radiographic machines. Hence it would not affect the incremental cost. Cost for *consumables* was based on the actual units consumed and the unit price.

Labour cost included valuation of the actual time spent on administrative work, patient contact, and for interpretation of images and report writing. The quantity of time was valued according to the full employment costs i.e. salary plus employment ‘overheads’ or benefits. See example of calculation of labour cost in Table 3. Other aspects of overhead costs (e.g. management and administration) were not included as these are assumed not to differ between the interventions being compared. Hence, they would not affect the incremental cost.

Table 3. Example of calculation of labour cost per hour for a specialist and a dental assistant.

Calculation of labour cost	
Specialist	
Annual gross labour cost for a specialist including on-costs (51% in Sweden 2008). Based on the valuation of wage and salary structures (general practice dentist) according to official statistics in Sweden 2008 (48).	74 340€
Annual labour cost for worked clinic hours (20% of annual gross labour cost)	14 870€
Worked clinic hours – hours worked in clinic according to schedule (350h) minus time for sick and parental leave (7h), and ‘downtime’ (43h)	300h
Labour cost per hour = $\frac{\text{Labour cost for worked clinic hours (14 870€)}}{\text{Total annual worked clinic hours (300 h)}}$	49.60€
Dental assistant	
Annual gross labour cost for a dental assistant including on-costs (51% in Sweden 2008). Based on the valuation of wage and salary structures (dental nurse) according to official statistics in Sweden 2008 (48). (Full-time employment in Sweden is 1980h)	39 115€
Labour cost for worked clinic hours (100% of annual gross employment cost)	39 115€
Worked clinic hours – hours worked in clinic according to schedule (1265h) minus time for sick and parental leave (114h) and ‘downtime’ (125h)	1 026h
Labour cost per hour = $\frac{\text{Labour cost for worked clinic hours (39 115€)}}{\text{Total annual worked clinic hours (1 026h)}}$	38.10€

Patient-related costs included valuation of the time spent by patients and accompanying persons on transport to and from the clinic and the time spent on the actual examination as well as outlays for travelling and parking. Time spent by the patient and accompanying persons over 18 years of age was valued according to the national average wage cost per hour and the time spent by patients below 18 years is valued according to minimum wage. “Out-of-pocket” expenses implied cost for driving a private car and parking or fares for taxi, train, or bus. An analysis from a users’ perspective would also include fees or co-payments for the examinations.

Empirical test of the framework

The framework for costing was tested in Study II and III. Cost data from Study II (cost year 2008) was updated in Study IV (cost year 2014). Study II estimated the costs associated with examination using intraoral and panoramic radiography compared with CBCT and panoramic radiography regarding maxillary canines with eruption disturbance in one clinic (Malmö). In Study III the framework was applied for calculation of the costs associated with CBCT examinations comparing four different health care systems (clinics in Cluj -Romania, Leuven -Belgium, Malmö -Sweden and Vilnius -Lithuania) regarding three different clinical conditions i) maxillary canine with eruption disturbance, ii) tooth loss prior to implant treatment and iii) lower wisdom tooth planned for removal.

Calculation of *capital costs* was based on data regarding the expected working life of the equipment. In the clinic in Malmö this was estimated to be 10 years for the three radiological apparatus. In Study IV, the working life of the panoramic machine was adjusted to 12 years corresponding to its actual working life, and the working life of the equipment for intraoral radiography was changed to 20 years. Study IV also included the opportunity cost and depreciation of the radiographic equipment using a rate of 3% and 5% according to recommendations by Drummond et al. (2005) (7).

Cost data for *maintenance* was based on either the actual average cost for repair and service during a 3-year period or on the pre-paid maintenance contracts with the costs for 2008. In Malmö, the cost for *accommodation* was valued in accordance with local market rental prices whereas for the other centres included in Study III the cost per m² by hospital finance was used. Valuation of the cost for access to the digital system for patient records and the image archive was based on the total amount of radiographs according to billing codes and for image storing, the cost per digital space expressed in terabyte.

Calculation of *labour cost* (Table 3) regarding the clinic in Malmö was based on data on wage and salary structures of a dentist and a dental assistant according to national statistics in 2008 (48)(Study II, III) and 2014 (49) (Study IV). For the centres in Cluj, Leuven and Vilnius involved in Study III, labour cost was based on the reported annual salary of the radiologists and radiographers. The clinic hours worked for a dental assistant, dental assistant or a radiographer included the imaging procedure in the radiographic examinations as

well as the administrative time spent on taking care of the patients when booking appointments. The working time for a specialist in oral and maxillofacial radiology included time for quality control of images, review and interpretation of CBCT-images as well as writing the radiological report. The estimation was based on observation of one radiologist performing these tasks for a subsample of 20 patients in Malmö.

Patient-related costs were retrieved using self-reported data for each patient. For several patients in the clinics in Cluj, Leuven and Vilnius, the appointment at the radiological clinic was combined with a visit at a nearby clinic and therefore no cost for travelling were recorded for these visits. The value of time for adult patients and accompanying persons in Study II and III was based on the average gross annual earnings for 2007 from Eurostat Statistics (50) for Romania, Belgium and Sweden and for Lithuania on the gross average monthly earnings for 2007 according to Statistics Lithuania (51). In Study IV it was based on official statistics from Sweden (52). The figures for annual earnings were divided by the number of working days (holidays and vacations excluded) in 2008 (Study II and III) and in 2014 (Study IV) to determine the average earnings per worked day. The average earning per day was then divided by eight (the number of working hours per day) to get an estimate of the average wage rate per hour. The data were used as a measure of the value of adults' time in each system.

The value of the time for patients under 18 years of age was based on the minimum wage rates for Belgium, Lithuania and Romania according to Eurostat statistics of gross earnings (53). For 2008 there was no national minimum wage recorded for Sweden. Instead the last reported national minimum wage for 2004 according to a report from The Institute for Labour Market Policy Evaluation 2004 (IFAU) (54) was used. Transport cost per kilometer for patients using private transport was based on rates used by Rotary International for 2008 (55) Study I and II) and the European Commission for 2014 (56) (Study IV). When the patients walked or cycled, the cost was limited to the valuation of their time.

All costs were adjusted to 2008 (Study II, III) or to 2014 (Study IV) values. In Study II and III at the 2008 average rate of one Euro = SEK 9.60, and at the 2014 average rate of one Euro = SEK 9.00. See Study II, III and IV for presentation of the radiographic equipment used.

Web-based survey (Study IV)

A web-based survey was created in association with a web developer. All members of the Swedish Orthodontic Society (n= 314) were invited by e-mail, in an attempt to find specialists in orthodontics with at least one year of experience in treating orthodontic patients.

Twelve patient cases were constructed for the survey. For further information of patient characteristics see Study IV, Table 1 and 2.

Parameters common to all cases:

- A subjective treatment need
- One maxillary canine with eruption disturbance and no likelihood for spontaneous eruption
- A complete permanent dentition including the second molars
- Normal sagittal molar relation (Class I)
- Normal skeletal relations between the maxilla and the mandible
- Cephalometric analysis showed normal maxillary incisor inclination
- No subjective need for correction of the maxillary dental midline
- Good oral hygiene

Parameters varying between cases:

- Age and gender
- Left or right maxillary canine with eruption disturbance
- Any maxillary centreline displacement
- Any space deficiency in the maxilla

For each case there were two intraoral periapical radiographs at different horizontal angles, one panoramic radiograph and CBCT images (Figure 3,4). There was also a radiological report describing the position of the maxillary canine, the distance of the canine crown in relation to the marginal bone, root morphology and any resorption of teeth neighbouring the maxillary canine. Intraoral and panoramic radiographs as well as CBCT-images from patients already examined in Study II, were reviewed, and all patients with unilateral eruption disturbance of the maxillary canine with otherwise no, or minor, need for orthodontic treatment were included in Study IV. A specialist in oral radiology interpreted the images and wrote the report.

The orthodontists were randomly assigned to four of the 12 patient cases. In part one of the survey two cases were presented with intraoral and panoramic radiography and two cases with CBCT and panoramic radiography. In part two the cases presented with intraoral and panoramic radiography in the first round were instead presented with CBCT and panoramic radiography, whereas cases presented with CBCT and panoramic radiography were presented with intraoral and panoramic radiography.

In the survey, the participants were asked to denote;

- their age, gender and years of experience,
- a treatment for four cases choosing from the following alternatives;
 - 1) no treatment, 2) nonextraction treatment, 3) orthodontic treatment and extraction of the first premolar, 4) orthodontic treatment and extraction of the maxillary lateral incisor, 5) orthodontic treatment and extraction of the maxillary canine with eruption disturbance.
- the level of confidence in their decision on a five-point scale; 1) very confident, 2) fairly confident, 3) neither confident – nor unconfident, 4) fairly unconfident or 5) very unconfident.

Intraoral radiographs

Panoramic radiograph

CBCT images

Figure 3. An example showing the radiographs presented in the survey for one (case 8) of the 12 patient cases.

Intraoral radiographs

Panoramic radiograph

CBCT images

Figure 4. An example showing the radiographs presented in the survey for one (case 10) of the 12 patient cases.

In the survey a viewer program for the CBCT images (i-Dixel One Data Viewer Plus software, J. Morita®, Kyoto, Japan) was available enabling the orthodontists to view the CBCT images in all planes (the axial, coronal and sagittal) dynamically by scrolling through the consecutive orthogonal image stack (Figure 5).

The survey was open from May 2016 to November 2016. The original e-mail invitation to participate was followed by four reminder e-mails sent via MailChimp® (The Rocket Science Group, Atlanta, US). Finally, an attempt was made to contact all non-respondents by telephone. A group of three orthodontists, one specialist in periodontology, one trainee in oral radiology and one external web-developer evaluated the web-based survey before implementation. The orthodontists in the evaluation group were not included as subjects in the study.

Figure 5. Image of the viewer program for the CBCT images (i-Dixel One Data Viewer Plus software, J. Morita®, Kyoto, Japan) available in the survey.

Study II, III and IV were conducted in accordance with the ethical principles of the World Medical Association Declaration of Helsinki (2008 version) and approved by the Iuliu Hatieganu University of Medicine and Pharmacy in Cluj-Napoca Ethics Committee, Romania (18514/4.09.2008), the Commission for Medical Ethics of the Faculty of Medicine of the Katholieke Universiteit Leuven, Belgium (B32220083749), the Regional Ethical Review Board, Lund,

Sweden (H15606/2008) and Vilnius regional committee for biomedical research ethics, Lithuania (2010-05-05 No. 158200-01-138-39).

Statistical analyses

Intrarater agreement for treatment decisions based on observations of the same patient case using the same imaging method was estimated in terms of percent agreement per patient case. Kappa statistics and percent agreement was used to analyse the treatment decision of the different imaging methods. Fisher's Exact Test was used to compare treatment decisions and associated confidence levels when using the different imaging methods. IBM SPSS Statistics (Version 23, Chicago, Illinois, USA) was used for all calculations. Statistical significance was set at a p -value less than 0.01.

RESULTS

Systematic review

A total of 3 708 records were retrieved with 3 380 remaining after subtraction of duplicates whereof 159 were considered to be economic evaluations in the field of dental care (Figure 6). Full-text publications were excluded if they were; not comparing two alternative methods in terms of the costs, non-systematic reviews or concerning other topics than economic evaluations of methods in dental care. For further information of the characteristics of the 12 included economic evaluations on diagnostic methods see Study I, Table 2.

Figure 6. The distribution of all studies identified as economic evaluations in dentistry from 1973 to February 5, 2013.

The 12 included economic evaluations of diagnostic methods:

Empirical economic evaluations:

- Perry et al. (1994) (57)
- Scaf et al. (1997) (58)
- Xia et al. (2006) (59)
- Subramanian et al. (2009) (60)
- Christell et al. (2012) (61)

Decision model-based analyses:

- Taylor-Weetman et al. (2002) (62)
- Gray et al. (2000) (63)
- Zavras et al. (2000) (64)
- Van der Meij et al. (2002) (65)
- Speight et al. (2006) (66)
- Norlund et al. (2009) (67)
- Dedhia et al. (2011) (68)

The different types of diagnostic methods being analysed were tests for diagnosis described by five studies using imaging methods (58,59,61,62,67) and one using probes for examination of periodontal health (57). Tests for screening a population were describing five studies regarding oral cancer (60,63,65,66,68) and risk of caries (64). The outcome measures of the diagnostic methods were described as values of sensitivity and specificity by six studies whereof one regarding imaging methods (67) and five regarding tests for screening (63-66,68). One study described the correlation of agreement between probing instruments (57) and one presented difference in radiation dosages (58).

All but two studies presented a rationale for the diagnostic methods and the methods were described in a transparent way permitting replication. One of the studies with a non-transparent description of the rationale was based on a pre-doctoral thesis not possible to retrieve (64) and in the other study the data was based on expert opinion (59).

The type of economic evaluation performed was cost-effectiveness analysis in three studies (60,63,67), CUA was performed by three studies (65,66,68) and CA was performed by six studies ((57-59,61,62,64). In three studies the type of economic evaluation was

not stated (57,58,67). The study perspectives stated in four studies, wereof a societal perspective was stated in three studies (60,61,68) and patients' perspective was stated in one study (66).

Presentation of costs based on identification and measurements of the resources used and valuation of these resources in monetary terms were presented in four studies (57,60,61,64). Six studies presented cost-estimations based on fees, expenditures and/or other estimations of payments made or received (58,62,65-68). Incremental cost was presented by two studies (61,64) and ICER was presented in five studies (60,65-68). For further information of the characteristics of the 12 included economic evaluations on diagnostic methods see Study I, Table 2.

Cost-analysis

The *framework* for cost-analysis facilitated the costing with its three subsequent steps of identification, measurement and validation with the different costs separately described in detail.

Empirical test of the framework

In the clinic in Malmö, for maxillary canines with eruption disturbance, CBCT and panoramic radiography had a mean total cost per examination of 128.38€ and for intraoral and panoramic radiography the cost was 81.80€, resulting in an incremental cost for CBCT and panoramic radiography of 46.58€. In the up-dated cost-analysis (in 2014) the mean total cost per examination for using CBCT and panoramic radiography was 134.37€ and for using intraoral and panoramic radiography it was 99.84€ (Table 4). Hence, the resulting incremental cost of 34.53€ was 26% lower compared with that of 2008. When also including equipment depreciation and opportunity cost of funds using a rate of 3% the incremental cost per examination increased by 2.79€ (7%) whereas a rate of 5% resulted in an increase of 4.75€ (12%).

The comparison between different health care systems showed that the cost for CBCT-examinations varied, being the highest in Malmö irrespective of the clinical condition examined (maxillary canine with eruption disturbance, tooth loss prior to implant treatment and lower wisdom tooth planned for removal). The lowest provider-related costs were seen in Cluj whereas the lowest patient-related costs were seen in Leuven. Variation in direct costs was mainly owing to different

capital costs for the CBCT equipment arising from differences in purchase prices (range 148 000–227 000€). Compared with the cost of 147 880€ in Cluj (year 2006), the purchase cost was 37% higher in Malmö (year 2003), 52% higher in Vilnius (year 2002) and 8% higher in Leuven (year 2008) (Table 5).

Capital costs for equipment per examination for CBCT per examination varied between 10.67€ in Leuven to 52.14€ in Vilnius. This was due to the number of images taken during 2008 that in Malmö was 4 009 intraoral radiographs, 1 765 panoramic radiographs and 948 CBCT volumes. The average number of CBCT volumes per examination was 450 in Cluj, 1500 in Leuven and 435 in Vilnius.

There was a variation of the *cost for accommodation* per examination across systems (1.29€ in Cluj, 1.60€ in Leuven, 6.14€ in Malmö and 1.82€ in Vilnius) which was due to differences in the space for accommodation (19m² in Cluj, 6m² in Leuven, 16m² in Malmö, 28m² in Vilnius) and the cost per m² (30.49€ in Cluj, 400.00€ in Leuven, 215.00€ in Malmö, 20.29€ in Vilnius).

Table 4. Distribution of direct costs per examination based on CBCT and panoramic radiography compared with intraoral and panoramic radiography. Costs were estimated using 2014 prices (Euro).

Identified direct costs		Cost per examination		
		CBCT + panoramic radiography	Intraoral + panoramic radiography	Incremental cost for CBCT + panoramic radiography
Cost to the provider				
Capital costs	Equipment	24.42	6.48	17.94
	Maintenance	4.96	0.83	4.13
Rental costs	Accommodation	10.78	6.28	4.50
	Image archive	4.01	2.90	1.11
	Patient record			
Labour costs	Specialist	7.31	5.17	2.14
	Dental nurse	26.75	23.18	3.57
Total provider-related costs		78.23	44.84	33.39
Costs to the patient				
Cost for time spent:	Transport	28.98	28.98	-
	Waiting	7.63	7.63	-
	Examination	9.02	7.88	1.14
'Out of pocket' cost	Cost per km	10.51	10.51	-
	Parking			
Total patient-related costs		56.14	55.00	1.14
Total cost -societal perspective		134.37	99.84	34.53
Total cost including opportunity cost and cost for equipment depreciation using 3% rate		138.74	101.41	37.33
Total cost including opportunity cost and cost for equipment depreciation using 5% rate		141.86	102.57	39.29

Labour cost per examination in Malmö for a specialist was 5.37€ for CBCT and panoramic radiography and 3.80€ for intraoral and panoramic radiography. The average gross labour cost per worked clinic hour for a specialist was 49.60€ and for a dental assistant it was 38.10 (Table 3). In the up-dated costing (for 2014) the corresponding cost for a specialist was 67.44€ whereas for a dental assistant it was 51.12€.

Patient-related costs per CBCT-examination (not including patient-fee) varied between health care systems and between different clinical situations with a range of 16.15€-59.44€. The cost was the highest in Malmö irrespective of clinical condition. Also the average patient-related cost per examination including patient-fee, was the highest in Malmö where it varied between 59.44€ and 147.48€ depending on clinical condition. It was the second highest in Vilnius (21.73-100.09€), the third highest in Cluj (90.43–96.30€) and the lowest in Leuven (21.76-41.96€).

Table 5. The patient-related costs from a societal perspective and from a users' perspective (including patient fee) in different settings regarding CBCT-examination of maxillary canines with eruption disturbance (Costs in Euro).

	Cluj	Leuven	Malmö	Vilnius
Transport	23,68	12,66	23,32	12,35
Patients' time value	4,57	8,49	12,51	8,04
Accompanying persons time value	4,17	15,20	23,61	4,89
Total patient-related cost -societal perspective	32,42	36,35	59,44	25,28
Patient fee	58,06	5,61	0	4,18
Total patient-related cost -users' perspective	90,48	41,96	59,44	29,46

The valuation of the time spent by the patients and, where applicable, by the accompanying person resulted in the highest cost in Malmö, second highest in Leuven, third highest in Vilnius and lowest in Cluj. In Malmö all visits to the radiological clinic represented separate trips for the patients. In the other settings however, the visit to the radiological clinic was added to the visit to another clinic in 30–50% of the

patients in Cluj, 23–61% in Leuven and 34–66% of the patients in Vilnius. The average travel distance to and from the radiology clinic for the three clinical conditions was shortest in Malmö (23–28 km), followed by Leuven (21–30 km) and Vilnius (15–47 km), and longest in Cluj (72–126 km).

Web-based survey

A total of 314 members of the Swedish Orthodontic Society were invited to participate in the study.

Exclusion was made of orthodontists (n=93);	
• not active within orthodontics	(n=30)
• being orthodontic resident	(n=20)
• not working in Sweden	(n=17)
• with insufficient contact information	(n=10)
• on parental or sick leave	(n=9)
• not working with this patient group	(n=7)

Of the 221 remaining orthodontists, 154 accepted to participate.

Responses were not used when orthodontists had not (n=42);	
• answered the second part of the survey	(n=17)
• responded after four reminders	(n=12)
• been able to open the CBCT files/survey	(n=7)
• been able to save the answers	(n=3)
• approved of the study design	(n=2)
• other reasons	(n=1)

When the survey closed, 112 orthodontists had answered both parts of the survey with 445 assessments based on CBCT and panoramic radiography and intraoral and panoramic radiography respectively.

Intrarater agreement

Intrarater agreement based on 30 orthodontist’s assessment regarding the treatment alternative varied from 50% to 100% using intraoral and panoramic radiography. Full agreement was observed for eight cases. Based on CBCT and panoramic radiography, the agreement

varied between 0% for one case and 100% for seven cases. The number of assessments varied between 3 to 7 per case.

Comparison between imaging methods

The number of assessments varied between 31 to 44 per case. Agreement between imaging methods, intraoral and panoramic radiography compared with CBCT and panoramic radiography regarding the treatment alternatives chosen, varied between 100% and 12.8% for different cases κ -values varied from 1.0 to 0.018.

Figure 7. Treatment decisions (%) per patient case by 112 orthodontists based on intraoral and panoramic radiography or CBCT and panoramic radiography at two occasions for the same patient cases. The difference between case 10 and all other cases was significant ($p < 0.01$).

Orthodontic treatment not including tooth-extraction was the most frequently denoted treatment alternative, chosen in 66% of the assessments based on intraoral and panoramic radiography and in 64% of the assessments based on CBCT and panoramic radiography.

Overall 24% (107 of 445) of the treatment decisions were different when based on CBCT and panoramic radiography compared with intraoral and panoramic radiography. One case (number 10) differed

significantly from all other cases ($p < 0.01$) (Figure 7). For this case, 87.2% (34 of 39) of the treatment decisions differed depending on imaging method. For this case, based on intraoral and panoramic radiography, orthodontic treatment and extraction of the permanent canine was denoted in 51.5% (20 of 39) of the assessments. Orthodontic treatment and extraction of the first premolar constituted 38.5%, extraction of the lateral incisor made up 5% whereas nonextraction constituted 5%. Based on CBCT and panoramic radiography, the majority (79%) denoted orthodontic treatment and extraction of the lateral incisor with root resorption.

Pairwise comparisons between cases showed no significant difference regarding confidence level specified according to the five-point scale, except for some cases.

Using CBCT as a routine procedure for all patients with maxillary canines would imply a probability of 0.24 different treatment decisions. This can be explained in terms of a cost-effectiveness-ratio (ICER) as an average additional cost of 143.88€ per different treatment decision using CBCT imaging.

DISCUSSION

Main results

The systematic review showed that among the economic evaluations of interventions in dental health care, only a small part concerned diagnostic methods. The review identified a need for an improved study quality of economic evaluations on diagnostic methods in dental care. The variation in methodology revealed a need for standardised methods for conducting and reporting economic evaluations.

The framework for cost-analysis of diagnostic methods provided a detailed description of the different costs. With its three subsequent steps for identification, measurement and valuation it facilitated the process of analysing costs associated with imaging methods in dentistry. The framework also supported a transparent and complete reporting which will facilitate future comparisons with other studies. The costs for using CBCT and panoramic radiography were significantly higher than those of intraoral and panoramic radiography regarding patients with maxillary canine with eruption disturbance. This was mainly due to a significantly higher purchase cost for CBCT compared with the cost for the equipment needed for intraoral and panoramic radiography.

The costs for CBCT-examination varied among different health care systems. The difference in costs for the different centres did not correspond to the level of gross domestic product (GDP) in the respective countries with higher costs in countries with higher GDP. The variation in costs between different settings were mainly due to the fact that dental care was organised differently in different health care settings with regards to availability of the service, dental staff,

referral process and patient flow. These circumstances make it difficult to compare costs between different health care systems.

The web-based survey showed that for a majority of the patients CBCT- examination is not beneficial in terms of producing a different treatment decision. The potential benefits of using CBCT was defined as attaining a different treatment decision assuming that a different decision can result in an improved treatment and thereby enhance the health of some of the patients. Hence, patients with severe space deficiency with a need of tooth-extraction may benefit from a CBCT examination as this can lead to extraction of a damaged tooth instead of a healthy tooth. The small probability of the treatment decision being different, means that CBCT is a relatively costly imaging technique for this patient group.

Systematic literature review

It is perhaps not unexpected that preventive methods like water fluoridation have been of particular interest in studies of cost-effectiveness in the dental context. Such interventions have a relatively high initial cost that must be justified by health authorities and politicians prior to implementation, but they also can be anticipated to be beneficial in the long-term perspective for a large group of people. Several economic evaluations, however, also concerned therapeutic interventions. Patient outcomes comparing alternative therapeutic methods is attractive for researchers as the impact on the patient is explicit and it deals with the “big picture” of healthcare. In contrast, diagnostic methods and their impact on costs and benefits are easy to overlook as they contribute only a component to the treatment pathway of patients. It is possible that clinicians may trivialize the contribution of diagnostic methods and the impact of diagnosis might be underestimated.

Considering the fact that the introduction of costly diagnostic methods like CT and magnetic resonance imaging (MRI), which are also used in dental care, has been a potent driving force behind the development of HTA (3), the number of economic evaluations in this area should be higher. The number of publications of economic evaluations in dentistry has increased gradually since 1972 with a notable increase in 1999. The increasing possibilities to provide health care and the increasing costs of provision of services meant

that governments and other decision makers required efficient and equitable ways to allocate the resources. Therefore, HTA organisations were founded in several countries (4) demanding that the decisions in health care should be based on economic evaluations. Despite this, although notable changes have occurred in the organisation and governance of HTA in European countries during the last 12 years (69) the number of economic evaluations in dentistry decreased in 2007 and then plateaued. This may reflect a relatively lower priority given to dentistry in healthcare, or possibly the increasingly private funding of dental care in many countries. Dentistry is, however, not a cheap form of healthcare; many treatments are expensive and technology-intensive so economic evaluations should be important in planning services. For example, CBCT is a potentially high cost diagnostic method which should not be introduced without some consideration of its impact in terms of economic costs and clinical benefits.

A review of the literature is an integral part of the research process and the planning of a study always includes a compilation of the research in the field (70). Systematic reviews have gained increasing importance in health care as a way for clinicians to keep themselves up-to-date, to identify knowledge gaps and they often form the basis for practice guidelines. The review in Study I was performed according to international guidelines for conducting and reporting systematic reviews (44,45). To assess potential bias in the included studies of diagnostic accuracy studies, the QUADAS tool was implemented (47). The economic evaluations were assessed according to the checklist recommended by Drummond et al. (2005) (7). The guidelines and associated checklists enables standardised conductance regarding retrieval, assessment and reporting of data that improves the transparency and validity of a systematic review.

Cost-analysis

The systematic review (Study 1) did not identify any publication presenting an analysis of costs on patient-level regarding imaging methods. To the best of our knowledge, the cost-analysis in Study II is the first in this field. The methods for economic evaluation are often developed in the context of decision making regarding pricing and reimbursement for interventions, and therefore tend to be specific to local decision problems. Drummond et al. (2015) (71) therefore

recommends that the reporting of economic evaluations should be standardised to promote a consistent decision-making process. Using the framework for costing, presented in Study II, can encourage the development of more unified methods for conducting economic evaluations of diagnostic methods in dentistry. Also, it may improve the external validity, which will facilitate comparisons with other scientific studies.

Investing in costly machines means that the money is tied up for some years and that the opportunity to spend this money on something else is lost. This additional cost, the opportunity cost, usually corresponds to the interest rate you would get if the money were saved in a bank account. Investing in capital equipment will involve depreciation cost as the resale value of the asset decreases over time. This corresponds to the cost for depreciation. The costing in Study IV included the opportunity cost of capital and cost for depreciation but the effect on the incremental cost was relatively low with an increase of only 7% (2.79€) using an interest rate of 3%.

The costing process was facilitated by the framework but it was still time consuming to analyse costs on micro-level. To also enable a cost-effective approach regarding the performance of costing, it is therefore important to avoid spending time and effort on measuring and valuing resources that would not affect the incremental cost or the total cost to a great extent. Hence, Study II aimed to estimate the difference in cost for the imaging methods intraoral and panoramic radiography and CBCT and panoramic radiography, thus the incremental cost, rather than the actual total cost of the imaging methods. Overhead costs in the hospital for administration were assumed not to affect the incremental cost and were therefore not included in the costing. Nor was the value of the old radiographic devices included in the cost-analysis as this was assumed to be proportionate to the purchase price for each machine. Consumable items were registered, measured, and valued in Study II but not in Study III and IV as this cost was very low and thus considered negligible.

The framework for costing incorporated comparisons of different perspectives, which enabled considerations of whether any costs saved by the health care system would be at the expense of higher costs for the patients or if higher costs for the health care system would lower the costs for the patients. A societal perspective is preferred

in economic evaluations (72). The main argument for performing a cost-analysis from a societal perspective is that it considers all relevant benefits and costs to society including patient-related costs and productivity changes.

Costs defined as resources consumed does not include pure transfers of money such as patient fee or social insurance costs for sickness benefits as these would reduce the direct costs (71). From a users' perspective however, the patient-fee is a net cost to the health care system, and reduces the funds available to spend on other (utility generating) goods and services. This means that separate evaluations from the perspective of patients are important as an intervention that is deemed cost-effective from the system perspective may not be cost effective from a patient's perspective because of the user fee charged. In this case, interventions adopted in the health care system as a result of a cost-effective result to the system based on broad patient uptake of the intervention, may result in poor levels of uptake because of higher costs to patients to use the service. A separate presentation of patient-fees in economic evaluations of interventions in dentistry could be considered an important evaluation of the expected demand for the service. Because the intervention is based on high cost capital equipment, any such reduction in demand would affect the cost-effectiveness results from a system perspective, as the capital cost per test increases as the volume of tests falls.

A study by Petersen et al. (2014) (73) analysed the costs of imaging methods regarding examination with CBCT compared with panoramic radiography prior to extraction of impacted mandibular third molars. They estimated the average cost per examination with CBCT to 184.44€ which is considerably higher than the range of costs reported in Study III that varied between 21.73€ and 142.05€. The purchase price for the CBCT-machine reported in the study by Petersen et al. (2014) (73) was however lower than the purchase prices of the CBCT-machines included in Study III. The main reason for the differences in cost per examination between Petersen et al. (2014) (73) and Study III, seems to be a higher number of images per year in all settings in Study III.

Web-based survey

Study IV investigated whether radiographic examinations using either conventional imaging methods i.e. intraoral and panoramic radiography or CBCT and panoramic radiography had any impact on the orthodontists' treatment decision regarding patients with maxillary canines with eruption disturbance. The outcome measure was defined as the proportion of treatment decisions differing for the two methods. Our results from this study showed that 24% of the treatment decisions were different depending on the imaging method. There were significant differences between several cases with regards to the number of different treatment decisions depending on the imaging method, but only one case differed significantly from all other cases. Two previous studies indicated significant differences between the imaging methods with 27% (74) and 29.5% (75) of the treatment decisions being different. The results of two other studies showed no significant differences between radiological examinations of this patient group (76,77).

The different results from our study and previous studies may be due to methodological heterogeneity regarding sample (number of patient-cases, age of the patients, diagnoses uni- or bilateral maxillary canines with eruption disturbance), the imaging methods and different sizes of field of view (FOV) of CBCT and observers (number, dentists/specialists). Previous studies (74,77) included between 18-40 cases while our study included 12 cases whereof each orthodontist only assessed four patient cases. The age of the patients in previous studies varied between 11-34 years while all patients in Study IV were 13-14 years old. Patients included in other studies had a uni- as well as bilateral maxillary canines with eruption disturbance while only patients with uni-lateral maxillary canines were included in Study IV. Other studies included 4-26 observers being orthodontists, general dental practitioners or a mixture of specialists in different fields whereas in Study IV all 112 observers were orthodontists. The conventional methods in other studies implied panoramic radiographs alone (76,77) or panoramic radiographs together with intraoral radiographs (74), whereas one study also included lateral cephalography (75). In Study IV intraoral and panoramic radiography was compared with CBCT and panoramic radiography. The two studies that showed significant differences between the imaging methods were the only studies that

included intraoral radiography in their conventional methods. All studies but one (76) used a large FOV while a small FOV was used in Study IV.

The decisive factor regarding the treatment alternatives in Study IV was whether or not any tooth needed to be extracted and if so, which tooth. Tooth-extraction is an invasive, non-reversible intervention and the clinical decision-making is therefore important. The choice of which tooth to extract depends on factors related to anatomic differences as well as the patient's attitude towards orthodontic treatment (17). Botticelli et al. (2011) (75), showed that using CBCT led to a more invasive treatment with fewer non-treatment alternatives compared with panoramic radiography and a higher number of extractions of the permanent maxillary canine. The conclusion by Wriedt et al. (2012) (76) on the other hand, was that many maxillary canines recommended for extraction using panoramic radiography were instead recommended for orthodontic alignment when CBCT was used. Study IV showed that the number of non-extraction treatments was similar for CBCT and panoramic radiography compared with intraoral and panoramic radiography. Also the number of extractions of the maxillary canines was similar for the two radiographic methods regarding all cases but one. For this case, extractions of the maxillary canine were denoted by 17 orthodontists based on intraoral and panoramic radiography, whereas when basing their decisions on CBCT, the orthodontists denoted extraction of the lateral incisor. Thus, it is not possible to draw any general conclusions regarding whether or not CBCT is beneficial for the patients in terms of leading to a less invasive treatment.

When considering tooth extraction as part of the orthodontic treatment it is important to evaluate any space deficiency (78). Based on the sum of the mesio-distal widths of the permanent teeth, a space deficiency of more than four millimeters is considered as crowding (79). One of the cases was described in the survey as having a space deficiency of more than eight millimeters, which indicated a need for tooth extraction. The report for this case, based on CBCT, described a root resorption half way to the pulp on the lateral incisor. The report based on intraoral and panoramic radiography for the same case stated however, that there was no indication of root-resorption. This case was the only case presented with a combination of severe

space deficiency and a moderate root resorption on the lateral incisor. This is probably the reason why a majority of the treatment decisions for this case differed depending on the imaging technique.

Outcome of imaging method in orthodontics

According to the model described by Fryback & Thornbury (10) efficacy of a diagnostic method can be assessed at different levels: 1) technical efficacy, 2) diagnostic accuracy efficacy, 3) diagnostic thinking efficacy, 4) therapeutic efficacy, 5) patient outcome efficacy and finally 6) societal efficacy (Figure 8). An imaging technique must be effective on lower levels to enable efficacy on higher levels (10). Efficacy on lower levels however, does not ensure efficacy on higher levels. It is therefore essential to assess imaging methods for maxillary canines with eruption disturbance on all levels of efficacy. An application of the model by Fryback and Thornbury (1991) (10) for CBCT of maxillary canines with eruption disturbance is presented in Figure 8.

The first level concern technical aspects like resolution and sharpness. Not only does the spatial resolution measured in line-pairs differ for different CBCT devices as shown by Pauwels et al. (2012) (80), but also the radiation dosage (41). High image quality might result in fewer retakes, which could minimise unnecessary radiation. This is important from the perspective of ALARA (as low as reasonably achievable) (81) meaning that an examination should result in as low a radiation dose as possible.

The second level concerning diagnostic accuracy efficacy was assessed by e.g. Algerban et al. (2011) (82) comparing six CBCT-systems with an in-vitro reference standard - i.e. a child cadaver skull in the early mixed dentition phase. Eight maxillary lateral incisors with simulated root-resorption and two maxillary lateral incisors with no root-resorption were used to estimate sensitivity and specificity for detection of root resorption for different CBCT-units. For the group of 12 observers (eight postgraduate orthodontists, two orthodontic instructors and two dental radiologists) the sensitivity ranged between 85-98% and the specificity between 58-95%. A separate evaluation of two radiologists showed a higher range for the sensitivity 93-100% and for the specificity 50-100%.

Figure 8. Different levels of efficacy for imaging methods and examples of outcome measures related to CBCT maxillary canines with eruption disturbance. The figure is modified from the hierarchical model by Fryback & Thornbury (1991)(10).

Diagnostic accuracy is considered to be of intermediate character as it does not measure the health impact for the patients and this makes the evaluation of diagnostic tests more challenging than for treatment methods (83). Therefore, economic evaluations of diagnostic methods often use intermediate outcomes. This practice assumes that the achieved outcome will result in cost-effectiveness in the long run provided that the resulting treatment is cost-effective (71). The results of cost-effectiveness using intermediate measures could however be misleading. Regarding CBCT-examination, the additional cases of root-resorption that were detected compared with intraoral and panoramic radiography, would include patients with a less severe degree of resorption. Treating these patients might not be as valuable as treating those with more severe root resorption. It can only be assumed that a treatment decision that is different when using CBCT

instead of intraoral and panoramic radiography will result in an improved treatment outcome for some of the patients.

The third level applies to diagnostic thinking efficacy which has been assessed by e.g. Botticelli et al. (2010) (75) using conventional imaging methods; panoramic radiography, lateral cephalogram and two periapical radiographs compared with CBCT for localisation of the maxillary canine position and presence of root resorption. Their results showed an agreement between the conventional methods and CBCT varying between 65-74% regarding the canine position and an agreement for root-resorption being 82%. In the context of economic evaluation, costs may be analysed on this level.

The fourth level concern therapeutic efficacy. Study IV assessed efficacy on this level in terms of the proportion of treatment decisions being different depending on the imaging technique used. Comparison of intraoral and panoramic radiography with CBCT and panoramic radiography resulted in 24% of treatment decisions being different. The economic evaluations used on this level are cost-analysis or cost-minimisation analysis.

The fifth level applies to patient outcome efficacy. To the best of our knowledge, no studies have assessed the efficacy on this level regarding maxillary canines with eruption disturbance. Outcome measures that can be used on this level are quality adjusted life years (QALYs) or willingness to pay (WTP).

The sixth level applies to the effectiveness from a societal perspective concerning the general health of the population and the cost to society. As far as the author is aware, no study regarding patients with maxillary canines has been performed on this level.

It is not yet clear whether or not CBCT-examination has any impact on the wellbeing of patients with maxillary canines with eruption disturbance (42). “A definitive answer concerning whether a radiologic examination is efficacious with respect to patients’ outcomes requires a prospective, randomised controlled trial I (RCT)” Fryback & Thornbury (1991) (10). Petersen et al. (2016) (84) performed such a trial in order to analyse the frequency of neurosensory disturbances after removal of lower wisdom teeth. Their trial included 230 patients undergoing either CBCT or panoramic radiography. No significant differences in the number of neurosensory disturbances were observed between the different imaging methods. An RCT regarding patients

with maxillary canines with eruption disturbance may be difficult to perform. As the orthodontic treatment is a lengthy process and its effects are long-lasting, long-term follow-up would be necessary in order to determine whether or not the use of CBCT is beneficial for the patient. Furthermore, information of the imaging method is not the only basis for planning the management the patient.

According to the results of Study IV, there are probably few patients that would benefit from CBCT-examination. The fact that it can be difficult to determine the unique contribution of an imaging method means that very large sample sizes are required. The prevalence is low, between 0.9-3% (11-13) and even lower for patients with a severe space deficiency in need of tooth extraction who also have severe root-resorption on the lateral incisor adjacent to the maxillary canine with eruption disturbance. This will limit the possibility to do an RCT. Furthermore, patients in a need of tooth-extraction due to severe space deficiency, would be at risk of having a healthy tooth extracted instead of a tooth with root-resorption if not examined with CBCT. This would be an ethical problem.

The outcome measure for Study IV, the proportion of treatment decisions that were different, must be regarded as an intermediate outcome measure since there is no direct link to the health of the patient. Preferably, a measure of effectiveness relating to a final output like life-years gained should be used in economic evaluations, but more important is that the outcome is relevant (71).

Maxillary canines with eruption disturbance are regarded as a malocclusion. Several studies have investigated the impact of malocclusion and the need for orthodontic treatment on individuals' self-perception of oral health related quality-of-life (OHRQoL). The correlation between quality of life (QoL) and malocclusion or orthodontic treatment need has been found to be weak (85,86). A recent systematic review regarding OHRQoL however, showed that the scientific evidence was considered strong regarding negative effects of malocclusions on OHRQoL (87).

Measures of OHRQoL provide information about the individuals' self-perception of e.g. malocclusion. For an outcome measure to be useful for decision makers in dentistry however, it should reflect some aspect of the patients' preferences. Measuring utility means that all aspects of the interventions that can have an impact on the wellbeing

of the patient is recognised (88). Few studies seem to have assessed the consequences of orthodontic treatment in terms of utility and the question remains whether or not orthodontic treatment have any long-term impact on the quality of life in general according to patients' preferences.

Societal cost

According to national statistics, there were 937 122 children aged 9-17 years in Sweden in 2014 (89) and 17 805 of these children had maxillary canines with eruption disturbance based on a prevalence of 0.9-3% (11-13). The relatively low prevalence of this condition means that the children for whom CBCT-examination is beneficial would represent a small proportion of the population eligible for this radiographic examination. The incremental cost per examination using CBCT and panoramic radiography was 34.54€ based on prices from 2014 (Study IV).

Modelling the aggregated diagnostic cost using CBCT as a routine procedure for this population however, results in an additional cost to society of around 0.9 million Euro over a 10-year period as well as in unnecessary radiation exposure in the population (Table 6). The calculation of modelled aggregated costs is based on the following assumptions;

- that the annual rate of reduction in population size (-1%) remains constant over the next 10 years according to official statistics of population per year in Sweden (89),
- that the future population, based on official government demographic projections (89), includes children leaving the population as they age and children entering the population as they age, as well as children in this age range entering the population from outside Sweden i.e. immigrants,
- that each child is examined once,
- that the demand for CBCT-examination is spread over a 10- year period using an estimate of the incidence for children with a maxillary canine with eruption disturbance based on the figure for prevalence (1.9%) resulting in an average of 3 740 children per year that would be examined during a 10-year period,

- that the estimation of incidence includes 1.9% of children 9-year old each year for 10 years, as well as 1.9% of the children that in the first year were aged 10-17 years divided by ten and thus distributed over 10 years,
- that the incremental cost per examination continues to fall at the average annual rate observed over the period 2008-2014 (4.3%) (Study II, IV),
- that the inflation rate remains around zero as seen from recent years according to official statistics for Sweden (90).

Table 6. The modelled aggregated diagnostic cost to society over a 10-year period using CBCT as routine procedure for the population in the age range 9-17 with eruption disturbance of the maxillary canines.

Aggregated cost to society over a 10-year period	
Total no of children aged 9-17 yrs. during a 10-year period	1 968 610
Children with maxillary canines with eruption disturbance (1.9% prevalence*)	37 404
Estimated incidence based on the prevalence (1.9%)*	3 740
Incremental cost per examination using CBCT and panoramic radiography (2008)	46.58 €
Incremental cost per examination using CBCT and panoramic radiography (2014)	34.53 €
Decrease in incremental cost during 2008-2014	12.05 €
Annual decrease of incremental cost	4.3%
Average incremental cost per examination using CBCT and panoramic radiography	23.30 €
Incremental cost per year using CBCT and panoramic radiography (23.30 € x 3 740)	87 150 €
Total incremental cost using CBCT and panoramic radiography over a 10-year period**	871 504 €
* Dachi et al. 1961; Thilander et al. 1973; Ericson et al. 1986 (11-13)	
** Assuming an inflation rate that stays around zero and not including cost for depreciation of capital equipment.	

The total aggregated diagnostic cost of 0.9 million Euro for using CBCT as a routine procedure is relatively low compared with the total additional cost for CBCT-examination prior to removal of impacted lower wisdom teeth presented by Petersen et al. (2015) (91). They showed that using CBCT as a routine procedure instead of panoramic radiography for this condition would cost 6.6 million Euro per year.

The calculation by Petersen et al. 2015 (91), was based on an annual incidence of nearly 37 000 removals of impacted mandibular third molars whereas the estimated incidence of maxillary canines was around 10 times lower ($n=3\,740$). Hence, the aggregated cost to society for using CBCT as routine procedure for different clinical conditions depends on the degree of utilisation by the patients. The cost for a specific condition would differ between different countries as the number of patients undergoing CBCT-examination probably would be much higher in countries where the patients can afford this examination and where the government subsidises this, as is the case in Sweden. With an increasing number of technologies available in healthcare, those paying for it will probably require information also on cost-effectiveness of technologies that have a relatively low impact on a constrained budget.

Radiation exposure

One aspect of the economic evaluation that was left out in the studies was the impact on costs associated with the stochastic effects related to the x-ray exposure using the imaging methods. Some studies have estimated the cancer-risk from radiation exposure using CBCT based on effective dose (91,92).

A significant problem when applying the concept of effective dose to CBCT examinations is that the *individual weighted tissue contributions are small*, either due to that the fraction of tissue irradiated is small (e.g. red bone marrow), or the weight factor is small (e.g. parotid glands) or both (e.g. bone surfaces). The value of the effective dose can therefore be several orders of magnitude lower than the mean dose in the irradiated tissue types, which limits its validity for risk estimations (93-96).

For the population with maxillary canines with eruption disturbance, the additional cost in terms of excess cancers for an examination with CBCT and panoramic radiography as compared with intraoral and

panoramic radiography would be exceedingly small. The individual risk of cancer is very small and may be acceptable for a patient as long as the examination is justified and optimised, but the risk of long-term public health problems cannot be neglected (96).

Ethical aspects

Ethical aspects in dental care concerns potential benefits and adverse effects to the patient, the autonomy and integrity of the patient as well as equity in terms of who should be offered treatment (97). In health economics, ethical aspects also considers questions relating to funding of health care (98,99). The World Health Organisation (WHO) have stated that health care should be distributed according to the individual's needs, "equity in health", and that the financing of health care should be equitably distributed – "equity in finance" (100). Ethical principles for good health care forming the 'ethical platform', should according to The National board of Health and Welfare in Sweden (Socialstyrelsen) (101) be prioritised in the following order:

- I. The principle of humanity stating that people have equal value and equal rights regardless of personal characteristics and functions in society.
- II. The principle of need and solidarity stating that resources primarily should be allocated to areas where the need is the greatest. The concept of solidarity includes awareness that groups who are not aware of their human dignity, are less able than others to exercise their rights.
- III. The third principle of cost-effectiveness stating that the choice between various sectors or interventions should aim at a reasonable relationship between cost and effects in terms of improved health and quality of life.

Since 2010, the ethical assessment of new methods is statutory before they are introduced in health care (102). A short analysis of the four studies in this thesis was therefore performed based on the protocol recommended by the Swedish agency for health technology assessment and assessment of social science (97) concerning ethical aspects of health impact, resource use, organisation, global perspective of equity as well as long-term ethical consequences of CBCT examination:

- *Health impact:* Current evidence of the health impact of CBCT is weak. Study IV gives an initial indication that CBCT might be beneficial for a subgroup of patients. Using CBCT and panoramic radiography instead of intraoral and panoramic radiography means however, a significantly higher monetary cost and radiation dose.
- *Resources, organisation and a global perspective of equity:* The dental care was organised differently in the four health care systems compared in Study III which resulted in a variation of the resources used. The main reason to the difference in costs between health care systems was however the varying patient-related costs which in turn was due to difference in patient charges and the distances to the radiological clinics. In one of the health care settings there was only two CBCT-units, and for some patients the travel to the clinic included taking a plane ride. High patient-related costs and patient charges appears to have an impact on the utilisation of health care (103-105). From a global perspective, this indicates that there is an inequity in the provision of CBCT-examinations among the health care settings being compared. In 2014, there was an unmet need for dental examinations or treatments for 8% of the population in the countries in the European Union. This was in most cases related to the organisation of the service (106). The distribution of dental care will be inequitable as long as the patients pay a share of the cost for care.
- *Long-term ethical consequences:* The life-time risk of cancer is 2 to 3 times greater from exposure during childhood than from exposure during adulthood (107). Patients with maxillary canines examined with CBCT are often very young and it is therefore of outmost importance that the examination is justified.

There has been a debate in Sweden about whether the three ethical principles should be equivalent and that the principle of cost-effectiveness should be given more weight. Recently the National Centre for Priority Setting in Health suggested a review of the ethical platform as the gap between the medical and technical opportunities

and the resources available to provide such care is growing (108). Applying the principle of cost-effectiveness could ensure that benefits are produced at least cost, avoiding waste of health care resources which in turn releases resources that are inefficiently developed to be used in more productive ways.

Many providers of dental care may however, find it difficult to base their decisions on the principle of cost-effectiveness if this conflicts with other values associated with providing health care. Hence, for the cost-effectiveness principle to gain more weight in dentistry, further studies of economic evaluations are needed to narrow the gap between the directives of cost-effectiveness and evidence-based results of cost-effectiveness. The decisions regarding what interventions that are considered to be cost-effective should be transparent and be delivered along with an ethical analysis. Furthermore, a users' perspective should be incorporated in the methodology of economic evaluation as well as in prioritisation of dental interventions. In economic evaluations, a societal perspective is recommended, meaning that effectiveness is a measure of patients' preferences. The costs estimated on a societal level however, does not include all aspects of a users' perspective, as patient fees included in patient-related costs are offset by revenues from patient fees at the system level. The fact that this aspect of the user's perspective is not considered in the prioritisation of interventions in oral health care assigns the patient merely the role of a tax payer. This may increase inequalities in the access to dental care as the distribution of service becomes increasingly dominated by considerations of patients' ability to pay as opposed to patients' need for care.

FUTURE RESEARCH

Future research should identify patients for whom CBCT examination is beneficial and where the additional costs in terms of radiation dose and monetary cost are justified. The resulting evidence should be used to develop robust referral criteria that can segregate the patients for whom CBCT is more likely to be beneficial from those patients who are less likely to benefit from this imaging technique. A multicentre HTA approach should be considered, using guidelines for conducting and reporting high quality studies. Use of standardised methods for costing alongside the analysis of diagnostic methods would increase the study quality and validity and the transparency of future studies. An important part of this would be a common framework with a systematic approach for costing including identification, measurement, and valuation of the costs.

The outcome of CBCT should be measured at higher levels of efficacy to measure the impact on the general health of the patients. The RCT would be designed with the intervention group assigned for CBCT and panoramic radiography and a control group using intraoral and panoramic radiography.

For an outcome measure to be useful in a health economic evaluation it should include some aspect of patients' preference. A search on PubMed showed few studies that have assessed the consequences of orthodontic treatment seem to have measured patients' preferences. Quality adjusted life time (QALYs) is considered to be an attractive outcome measure of health care as it combines quantitative (life-years) and qualitative aspects (quality of life). The use of Willingness to pay (WTP) for assessments in health care has been controversial from an ethical perspective as it values health in monetary terms. The scenario asking patients about their willingness to pay for an intervention is however very similar to the reality in a dental clinic and could be a valuable tool for future studies assessing the benefits of interventions in dentistry.

CONCLUSIONS

- There is a paucity of research on economic evaluation in dentistry and fewer still on diagnostic methods. High quality economic evaluations of diagnostic methods in dental care is needed, performed according to guidelines for conducting and reporting HTA. Further research, using a combination of RCT with economic evaluation in a HTA design is needed.
- The framework for costing of diagnostic methods facilitated the costing with its subsequent steps and detailed description of the costs. It could be of use for future studies.
- Comparing costs of interventions in dentistry between countries and health care systems is difficult without considering specific circumstances.
- Minor part of patients with maxillary canines with eruption disturbance may benefit from CBCT in terms of a changed treatment plan. It remains to be determined for this sub-group whether the change in treatment plan would lead to better treatment outcomes and patient wellbeing.
- Limited treatment decisions were different when the orthodontists had access to CBCT and panoramic radiography instead of intraoral and panoramic radiography, which makes CBCT a relatively costly imaging method for patients with maxillary canines with eruption disturbance.
- The studies presented here raise the possibility of identifying high yield selection criteria for CBCT in the context of patients with maxillary canines with eruption disturbance.

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ACKNOWLEDGEMENTS

I want to thank my head supervisor Professor Christina Lindh for giving me the opportunity to do this thesis. You have shared your knowledge and invited me into your network of researchers. The possibilities to learn and do research that you offered when you invited me to participate in workpackage 5 in SEDENTEXCT is priceless. It was a joy to get to know you.

I also want to thank my supervisor Professor Madeleine Rohlin for your invaluable input regarding all steps of conducting research with an exceptional fingertip feeling for quality and unwavering accuracy.

I want to thank my co-author Professor Keith Horner for making this thesis possible by initiating and coordinating SEDENTEXCT. Your understanding and overview of all aspects of radiology and knowledge of what research is at the forefront meant invaluable input.

I also want to thank my supervisor Professor Stephen Birch for your forthright and encouraging tutoring as well as your generous sharing of knowledge and time.

I want to thank my supervisor Professor Lars Bondemark for sharing your knowledge and ideas of orthodontics that enabled clinical implications of the results of this thesis.

I want to thank DDS Anna Senneby, my colleague and dear friend for your support and encouragement through these years regarding all

aspects of research and life. Your knowledge and quick understanding and respons have been important, challenging and joyful.

I would also like to thank my dear friends and collaborators in the SEDENTECXT team.

I want to thank all the staff at the department of oral radiology for invaluable help and support throughout the work with this thesis.

I want to thank Mats Melkersson for your love and support. For believing in me from the start, coaching me to higher levels and for allowing me to freely express my creativity.

Thanks to my beloved family and to Chippen – the best dog and research assistant in the world.

This thesis was supported by the European Atomic Energy Community's Seventh Framework Programme FP7/2007–2011 under grant agreement no 212246 (SEDENTEXCT: Safety and Efficacy of a New and Emerging Dental X-ray Modality), The Swedish Dental Association, The C-O Henriksson Foundation, and the Faculty of Odontology at Malmo University.

APPENDICES

I

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Review

Economic evaluation of diagnostic methods used in dentistry. A systematic review

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ARTICLE INFO

Article history:

Received 27 March 2014

Received in revised form

25 July 2014

Accepted 30 July 2014

Keywords:

Economics

Health care costs

Dentistry

Diagnosis

Systematic review

ABSTRACT

Objectives: To review the literature of economic evaluations regarding diagnostic methods used in dentistry.

Data sources: Four databases (MEDLINE, Web of Science, The Cochrane library, the NHS Economic Evaluation Database) were searched for studies, complemented by hand search, until February 2013.

Study selection: Two authors independently screened all titles or abstracts and then applied inclusion and exclusion criteria to select full-text publications published in English, which reported an economic evaluation comparing at least two alternative methods. Studies of diagnostic methods were assessed by four reviewers using a protocol based on the QUADAS tool regarding diagnostic methods and a check-list for economic evaluations. The results of the data extraction were summarized in a structured table and as a narrative description. **Results:** From 476 identified full-text publications, 160 were considered to be economic evaluations. Only 12 studies (7%) were on diagnostic methods, whilst 78 studies (49%) were on prevention and 70 (40%) on treatment. Among studies on diagnostic methods, there was between-study heterogeneity methodologically, regarding the diagnostic method analysed and type of economic evaluation addressed. Generally, the choice of economic evaluation method was not justified and the perspective of the study not stated. Costing of diagnostic methods varied.

Conclusions: A small body of literature addresses economic evaluation of diagnostic methods in dentistry. Thus, there is a need for studies from various perspectives with well-defined research questions and measures of the cost and effectiveness.

Clinical significance: Economic resources in healthcare are finite. For diagnostic methods, an understanding of efficacy provides only part of the information needed for evidence-based practice. This study highlighted a paucity of economic evaluations of diagnostic methods used in dentistry, indicating that much of what we practise lacks sufficient evidence.

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¹ Listing of partners on www.sedentext.eu.

<http://dx.doi.org/10.1016/j.jdent.2014.07.018>

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1. Introduction

Diagnostic methods used in dentistry include clinical visual examinations and radiography while screening methods are used to discover those among the apparently well who are in fact suffering from disease. These services, however, are produced using resources that could otherwise be employed in delivering other types of care or serving other patients. In order to ensure that whatever level of resources we commit to delivering care are used in ways that provide the greatest health gain, health care interventions must be assessed in terms of both effectiveness and costs.¹

Only through such comparisons can the opportunity cost of possible new interventions (what other uses of the same resources have to be forgone in order to support a new intervention) be identified and hence the impact of the new intervention on total health gains be considered. The need for economic evaluation applies to all methods used in health care i.e. preventive, diagnostic, and treatment methods.

Different types of economic evaluation have been developed, which are aimed at addressing fundamentally different questions. Cost-analysis (CA) addresses questions about the additional cost of new interventions. This approach is generally used where the aim is to compare different ways of producing the same level of outcome. Cost-effectiveness analysis (CEA) builds on CA by also considering comparisons between interventions where the outcome need not be the same. The additional effects of the new intervention are measured in terms of the intended clinical outcome of the intervention (e.g., reducing rates of mortality, morbidity or the level of a clinical risk factor such as blood pressure). In this way CEA addresses questions about the additional (or incremental) costs of producing the additional (or incremental) effects produced by the new intervention (compared to the current way of serving the same patients) based on the incremental cost-effectiveness ratio (or ICER), i.e. the ratio of incremental costs to incremental effects. Cost-utility analysis (CUA) addresses similar questions to CEA and uses the same ratio (ICER) but expresses effectiveness using a preference based measures (mostly Quality Adjusted Life Years/QALYs) that measure what the outcomes of the intervention mean to patients. Through this approach, questions can be addressed about the additional costs of producing comparable improvements in health related quality of life among interventions aimed at serving different patient groups and/or producing different types of clinical outcomes (e.g., reducing mortality among infants versus palliative care for the elderly). Finally, cost-benefit analysis (CBA) addresses questions about whether a new intervention represents a net gain to society by answering questions about whether the additional effects of the intervention exceed the additional costs of the intervention, by expressing additional costs and additional effects of a new intervention in the same units.

There is a growing awareness regarding the need for economic evaluations in dentistry. An initial survey of the scientific literature indicates that economic evaluation in dentistry mainly concerns methods used for prevention and

treatment but few studies deal with diagnostic methods.² As the results of a diagnostic examination provide the basis for treatment planning and for the evaluation of treatment outcomes it is of importance that a diagnostic method serves its purpose and is cost-effective. To further our understanding in this field, this paper aims to elucidate economic evaluation of diagnostic methods in dentistry, using a systematic review approach.

2. Material and methods

To achieve a systematic approach, we conducted the literature review in accordance with the PRISMA Statement³ and CRD's guidance for undertaking reviews in health care.⁴ The following steps were defined: (i) problem specification, (ii) formulation of a plan for the literature search, (iii) literature search and publication retrieval, and (iv) data extraction, quality assessment, and data synthesis.

2.1. Problem specification

The review of the literature on economic evaluation of diagnostic methods in dentistry aimed to address the following questions:

- Which diagnostic methods have been analysed?
- What types of economic evaluation have been conducted?

The following elements were defined prior to the literature search:

- Dentistry: defined according to Medical Subject Heading term (MeSH) in PubMed: "The profession concerned with the teeth, oral cavity, and associated structures, and the diagnosis and treatment of their diseases including prevention and the restoration of defective and missing tissue."
- Diagnostic method: a test included in the process of attempting to distinguish one disease from another or from no disease, such as clinical, imaging or laboratory tests.
- Economic evaluation: defined according to Drummond et al.¹ as the comparative analysis of alternative courses of action in terms of costs and consequences.

2.2. Formulation of a plan for the literature search

Searches were conducted in four electronic databases MEDLINE using PubMed as search engine, the Web of Science (WSci), the Cochrane Library (Cochrane) and the NHS Economic Evaluation Database (NHS EED) under the guidance of librarians. The selection of search terms was based on the MeSH terms used in eight studies on economic evaluation.^{5–12} The search strategies are presented in Table 1.

2.3. Literature search and retrieval of records

The records retrieved were imported to RefWorks® and duplicates from searches in WSci, Cochrane and NHS EED in relation to the MEDLINE search were subtracted. Relevant records were selected via a two-stage process. First, two

Table 1 – Search strategy in MEDLINE 01.01.1965–05.02.2013, Web of Science 01.01.1986–05.02.2013, the Cochrane Library 01.01.1898–05.02.2013, the National Institute for Health Research Economic Evaluation Database (NHS EED) 01.01.1968–05.02.2013.

Database	Index terms
MEDLINE	<p>("Delivery of Health Care" [MeSH] OR "Economics" [MeSH] OR "Health Resources/economics" [MeSH] OR "Health Services Research/economic" [MeSH] OR "Dental Health Services" [MeSH] OR "Models, Economic" [MeSH] OR "Outcome and Process Assessment" [Health Care] [MeSH] OR "Quality-Adjusted Life Years" [MeSH] OR "Quality of Life" [MeSH] OR "Dentistry" [MeSH] OR "Decision making" [MeSH] OR "Diagnosis" [MeSH] OR "Oral Health" [MeSH] OR "Radiology" [MeSH] OR "QALY" OR "Willingness to pay" OR "Diagnosis" OR "Radiography" OR "Radiology") AND ("Cost" OR "Cost-benefit" OR "CEA" OR "Cost-effective" OR "Cost-effectiveness" OR "Cost-utility" OR "Cost-minimization" OR "Economic evaluation" OR "Health-economy") AND ("Dent" OR "Dentistry" OR "Oral Health")</p> <p>Included</p> <p>Humans, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Clinical Trial Phase I, Clinical Trial Phase II, Clinical Trial Phase III, Clinical Trial Phase IV, Comparative Study, Controlled Clinical Trial, Evaluation Studies and English</p>
Web of Science	<p>("Cost and Cost analysis" OR "Delivery of Health Care" OR "Outcome Assessment" OR "Quality-Adjusted Life Years" OR "Dentistry" OR "Decision making" OR "Diagnosis" OR "Diagnostic imaging" OR "Oral Health" OR "Radiology") AND ("Cost-benefit" OR "CEA" OR "Cost-effective" OR "Cost-effectiveness" OR "Cost-utility" OR "Health-economy" OR "Willingness to pay") AND ("Dent")</p>
The Cochrane Library	<p>("Delivery of Health Care" [MeSH] OR "Health Care Economics and Organizations" [MeSH] OR "Outcome Assessment (health care)" [MeSH] OR "Quality-Adjusted Life Years" [MeSH] OR "Dentistry" [MeSH] OR "Decision making" [MeSH] OR "Diagnosis" [MeSH] OR "Diagnostic imaging" [MeSH] OR "Oral Health" [MeSH] OR "Radiology" [MeSH] OR "Dentistry" OR "Diagnosis" OR "Oral Health" OR "Radiology") AND ("Cost-benefit" OR "CEA" OR "Cost-effective" OR "Cost-effectiveness" OR "Cost-utility" OR "Health-economy" OR "QALY" OR "Willingness to pay" OR "Dent" OR "Oral Health")</p>
NHS EED	<p>("Economic evaluation" OR "Cost-analysis" OR "Cost-effectiveness" OR "Cost-utility" OR "Cost-benefit") AND ("Dentistry" OR "Oral health")</p>

reviewers (HC/CL or MR) identified records by assessing the titles and abstracts independently with focus on economic evaluation in dentistry. Then, the reviewers independently read selected available full-text articles applying inclusion and exclusion criteria as presented in a protocol (Appendix A). The studies selected were original studies (analyses of primary or secondary data, systematic reviews), which reported an economic evaluation comparing at least two alternative interventions used in dentistry, with an abstract in English. A study was excluded if it described the development of a protocol for study design or described other interventions e.g. antibiotic strategies or general anaesthesia. The reference lists of included studies of diagnostic methods were hand searched to identify additional studies not captured by the electronic searches. The PRISMA³ flow diagram was used to summarize the study selection process.

2.4. Data extraction and interpretation of data of studies of diagnostic methods in dental care

The studies of economic evaluations on diagnostic methods in dental care were further analysed and a critical appraisal was made by all authors using a second protocol (Appendix B). Items from the QUADAS tool¹³ regarding the diagnostic methods and from the checklist presented by Drummond et al.¹ for assessing economic evaluations were included in the protocol. Besides the type of economic evaluation, data on the perspective, time horizon, discounting and outcomes were captured.⁴ The study design of the included studies was defined as "decision model (simulation)-based analyses and empirical economic evaluations, which collect patient-level data on costs and outcomes".¹⁴

3. Results

3.1. Literature identification

The number of retrieved records and the records excluded and included in different phases are presented in a flow diagram (Fig. 1). A total of 3708 citations were retrieved with 3380 remaining after removal of duplicates of which 159 were found to report an economic evaluation of interventional methods used in dentistry. Of these studies, 11 studies (7%) involved economic evaluations of diagnostic methods and were included for further analysis. The search in reference lists of included studies on diagnostic methods resulted in one additional study. The principal reasons for exclusion are presented in Fig. 1.

3.2. Interpretation of data of economic evaluation on diagnostic methods in dentistry

3.2.1. Which diagnostic methods have been analysed?

Table 2 summarizes salient features of 12 studies on economic evaluations of diagnostic methods in dentistry. Five studies comprised empirical economic evaluations and seven studies were designed as a decision model (simulation)-based analyses. Six studies described tests used to diagnose conditions of which five evaluated imaging methods^{15–19} and one evaluated probes used to examine periodontal health.²⁰ Five studies analysed tests used to screen a population for oral cancer^{21–25} or for caries risk.²⁶ The outcomes of the diagnostic methods under comparison were presented as values for sensitivity and specificity in one study

Fig. 1 – Flow diagram according to PRISMA Statement³ presenting the study selection process with number of publications retrieved, included and excluded for systematic review of economic evaluations of diagnostic methods in dentistry.

of diagnostic methods,¹⁸ and five studies of screening.^{21–23,25,26} In one study, the outcome of the diagnostic methods was presented as correlation of agreement between probing instruments²⁰ and in another study as radiation dosages.¹⁵ In four studies, no value was presented on diagnostic accuracy.

A rationale for the diagnostic methods under comparison was presented in all studies and the methods were described in a way to permit replication except in two studies. In one of these, the data on outcomes was based on a pre-doctoral thesis not possible to retrieve.²⁶ In the other study, data were based on expert opinion.¹⁷

3.2.2. What types of economic evaluation have been conducted?

The type of economic evaluation is presented in Table 2. In seven studies it was stated that the type of economic evaluation was CEA.^{16,20–25} As no end outcomes were presented in the study by Taylor-Weetman et al.¹⁶ this study

may rather be defined as a cost-analysis. The type of evaluation in three other studies^{22,23,25} may also be redefined as a CUA instead of a CEA as outcomes were presented in terms of QALYs. Two studies were presented as cost-analyses.^{19,26} The type of economic evaluation was not stated in four studies.^{15,17,18,20}

In four studies the perspective of the analysis was stated, with three being from a societal perspective^{19,24,25} and one from the patients' perspective.²³ In general, the studies stating the perspective included costs relevant to the stated perspective. In the remaining studies, where no perspective was stated, costs were limited to health care system costs. Cost estimates based on the identification and quantification of different resources used and valuation of these resources in monetary units were presented in four studies.^{19,20,24,26} In other studies, the cost-analyses were based on fees, expenditures and/or other estimations of payments made or received as opposed to resources used.^{15,16,18,22,23,25} In two

TESTS USED TO DIAGNOSE PATIENTS						
First author Country Reference number Study design	Population	Diagnostic methods [Interventions]		Economic evaluation		Weaknesses
		Clinical condition Methods compared	Outcome expressed as	Type of evaluation -stated by authors -as defined according to Drummond et al. ¹⁴	Results/conclusions by authors	
Perry USA ²⁰ Empirical	Ten patients with periodontitis	Periodontal pocket depth	Correlation of agreement between probes	NA	No differences of clinical significance between probes in measurement of pocket depth Electronic probes more time- consuming with higher cost per examination	Diagnostic methods Only 2 examiners and 10 patients No outcome measured, surrogate outcome in terms of correlation between methods Economic evaluation with physical units Perspective not stated Year value of money not presented
		a. Conventional b. Manual pressure regulated c. Electronic pressure regulated (2 mm) d. Electronic pressure regulated (0.5 mm)		Cost-analysis	Cost per examination (US\$) a. 4.29 b. 5.28 c. 12.78 d. 8.65	
Scaf USA ¹⁵ Empirical	One Alderson- Rando phantom	Pre-surgical implant assessment	Mean absorbed doses (μGy)	NA	Radiation doses higher with CT Mean cost higher with CT	Diagnostic methods In vitro study Film not current approach No outcome measured, surrogate outcome in terms of radiation dose Economic evaluation Perspective not stated Year value of money not presented
		a. Film-based multidirectional tomography b. Computed tomography (CT)	Effective doses (μSv)	Cost-analysis	Mean cost per examination (1995 US\$) a. 286 b. 679	
Taylor- Weirman UK ⁴⁶ Model-based analysis	Patients with primary and permanent dentition	Dental occlusal and proximal caries	None	Cost-effectiveness analysis Cost-analysis	Diagnostic methods Imaging protocols described to permit replication Economic evaluation Cost based on information from eight institutions Diagnostic methods Based on review of five studies Economic evaluation No strengths	Diagnostic methods Panoramic radiography not current approach No data on caries prevalence or exact accuracy Economic evaluation Perspective not stated Costs based on fees according to Statement of dental numeration
		a. Panoramic radiography b. Bitewing radiography		Cost per examination (2002 £) a. 10.15 b. 4.55	Bitewing likely to be more accurate than panoramic radiography Not possible to determine which method is most cost- effective as sensitivity but not specificity could be calculated	
Xia USA ¹⁷ Empirical	No sample	Deformities of skull and face	None	Cost-effectiveness analysis Cost-analysis	Costs lower for computer aided surgical simulation with virtual surgery	Diagnostic methods Novel method Economic evaluation Calculation of costs presented Diagnostic methods No sample No outcome measures Not described to permit replication Economic evaluation Perspective not stated Year value of money not presented Costs based on authors' experience
		a. Computer aided surgical simulation with virtual surgery b. Clinical and radiographic examination		Cost per examination (US\$) a. 1.900 b. 3.510	Costs for computer aided surgical simulation with virtual surgery could be calculated	

Table 2 – Characteristics of included studies on economic evaluation of methods used in dentistry. Strengths and weaknesses assessed with a protocol (Appendix B) based on items from QUADAS¹⁸ on diagnostic methods and a checklist on economic evaluation (Drummond et al.¹⁴). QALY = quality-adjusted life-year; ICER = incremental cost-effectiveness ratio; NA = not available.

Table 2 (Continued)

TESTS USED TO DIAGNOSE PATIENTS						
First author Country Reference number Study design	Population	Diagnostic methods [Interventions]		Economic evaluation		Weaknesses
		Clinical condition Methods compared	Outcome expressed as	Type of evaluation -stated by authors -as defined according to Drummond et al. ¹	Cost expressed as	
Norlund Sweden ¹⁸ Model-based analysis	Patients with different caries prevalence	Denial occlusal dentine caries in permanent molars Different examinations a. Visual-tactile b. Visual-tactile and bitewing radiography c. Selective bitewing radiography of patients with positive finding by visual-tactile examination	a. Sensitivity (0.44) specificity (0.91) b. Sensitivity (0.57) specificity (0.80) c. Sensitivity (0.58) specificity (0.85)	NA Cost-effectiveness analysis	Cost per examination (2006 €) for true-positive findings at mean caries occurrence of accuracy estimates of 0.5% or 3% a. 160 or 25 b. 160 or 25 c. 395 or 75	Diagnostic methods Not described to permit replication Economic evaluation Perspective not stated Costs based on fees according to Swedish public dental service
Christell Sweden ¹⁹ Empirical	Patients 14-yr with maxillary canines with eruption disturbances	Maxillary canines with eruption disturbances a. Cone beam computed tomography (CBCT) and panoramic radiography b. Intraoral and panoramic radiography	None	Cost-analysis Cost-analysis	Mean cost per examination (2008 €) a. 128.38 b. 81.80	Diagnostic methods CBCT performed on only one clinic Described to permit replication No outcome measures Economic evaluation Based on 47 consecutive patients Societal perspective Calculation of costs with physical units
Gray Urzi ²¹ Model-based analysis	General dental population in primary care	Oral cancer a. Visual examination with examination with toluidine blue as an adjunct b. Visual examination with toluidine blue as an adjunct	Additional number of lesions detected by visual examination with toluidine blue as an adjunct	Cost-effectiveness analysis Cost-effectiveness analysis	Cost per additional case of oral cancer (1999– 2000 £) by screening in a population of 100,000 861,700	Diagnostic methods No generalizable to primary care Economic evaluation Perspective not stated Costs based on fees according to Walsall & Wolverhampton Health Authorities 1999–2000 Method not described to permit replication

Zavras USA ⁴⁸ Model-based analysis	Patients 1–3 yrs with caries prevalence 15%	Dental occlusal and proximal caries a. Microbiological screening of salivary mutans streptococci b. No screening	Sensitivity (0.34–0.72) Specificity (0.81–0.96)	Cost-analysis Cost-analysis	Total cost per child (US\$) a. 367.90 b. 356.70	Cumulative dental treatment costs for child aged 4 yrs: lower if the child has been screened Cost savings increase significantly when caries prevalence increases	Diagnostic method No strengths Economic evaluation Discounting at different rates Sensitivity analysis	Diagnostic methods Estimates of effectiveness based on one study not possible to retrieve Accuracy overestimated Regarding specificity and based on high prevalence Economic evaluation Perspective not stated Year value of money not presented Costs based on fees with no references Method not described to permit replication
van der Meij The Netherlands ⁴⁹ Model-based analysis	Patients >15 yrs with oral lichen planus prevalence 1%	a. No screening b. Screening with clinical examination by oral surgeons	Sensitivity (0.91) Specificity (0.92) Equivalent lives saved (£15) QALY	Cost-effective analysis Cost-utility analysis	Cost per case detected (US\$) by screening a population of 100,000 23.88 lives saved costed 1.28 US\$ One £15 costed 53,430	Health gain from screening was 592 QALY	Diagnostic methods Prevalence of lesions presented Economic evaluation Method described to permit replication Sensitivity analysis	Diagnostic methods No description to permit replication Economic evaluation Perspective not stated Year value of money not presented Costs based on estimations with no references Results not generalizable to primary care
Speight UK ⁵⁰ Model-based analysis	General population 49– 79 yrs	Oral cancer Types of screening a. No screening b. Invitational in general medical practice c. Invitational in general dental practice d. Opportunistic in general medical practice e. Opportunistic in general dental practice f. Opportunistic high- risk in general medical practice g. Opportunistic high- risk in general dental practice h. Invitational in specialist clinic	Sensitivity (0.85) Specificity (0.96) QALY	Cost-effectiveness analysis Cost-utility analysis	ICER and cost per QALY (2003 £) for eight different strategies a–h and for 3 scenarios I. No treatment effect II. 10% treatment effect III. 20% treatment effect in different age- groups	ICER for screening the whole population ranged from £15,790 to £25,961 per QALY Opportunistic high- risk screening by a general practitioner, in particular by a general dental practitioner may be cost-effective	Diagnostic methods Meta-analysis to calculate test performances Economic evaluation Perspective stated Authors from different HRA agencies world- wide Method described to permit replication Discounting at 3.5% of both costs and benefits Probabilistic sensitivity analysis results generalizable to primary care	Diagnostic methods No description to permit replication Economic evaluation Costs based on fees as well as a retrospective analysis of 147 cases and of actual annual costs over a 5-year period according to published statistics and NHS resources

Table 2 (Continued)

TESTS USED TO DIAGNOSE PATIENTS					
First author Country Reference Number Study design	Population	Diagnostic methods [Interventions]		Economic evaluation	
		Clinical condition Methods compared	Outcome expressed as	Type of evaluation -stated by authors -as defined according to Drummond et al. ¹	Cost expressed as
Subramanian USA/India ²⁴ Empirical	General population ≥35 yrs	Oral cancer Different types of screening a. Visual inspection of high-risk individuals (using tobacco and/ or alcohol) b. No screening (n = 80,086) (n = 87,829)	Life-years saved per 100,000 individuals in general population and per 100,000 high- risk individuals	Cost-effectiveness analysis Cost-effectiveness analysis	Cost per 100,000 individuals (2004 US\$) a. 478,742 b. 260,351
					Diagnostic methods High prevalence of oral cancer Economic evaluation Costs based on cost-analysis with no physical units presented Results not generalizable to other countries or to general dental practice
Dedhia USA ²⁵ Model-based analysis	High-risk males >40 yrs (using tobacco and/or alcohol)	Types of screening a. Yearly, community- based by health- workers b. No screening	Sensitivity (0.70) Specificity (0.99) QALY	Cost-effectiveness analysis Cost-utility analysis	Diagnostic methods Prevalence Described to permit replication Economic evaluation Societal perspective Calculation of costs presented with physical units including patient- related costs Sensitivity analysis
					Diagnostic methods No description to permit replication Economic evaluation Costs based on three studies and Medicare payment to Pennsylvania based on 2009 Current Procedural Terminology Codes, and Federal Register analysis for all variables

studies, the results were presented as incremental costs.^{19,26} Incremental costs and effects in an aggregated form as an incremental cost-effectiveness ratio (ICER) were presented in some studies,^{18,22–25} which enables direct comparisons of the average cost per additional unit of health gain between different interventions/studies. Effects and costs occurring in future periods were discounted in order to allow for time preference using annual discount rates of 3.5% in Speight et al.²⁵ and of 3% in Dedhia et al.²⁵ Zavras et al.²⁶ used a range of discount rates as part of the sensitivity analysis. Six studies presented sensitivity analyses to test the impact of changing the values of some variables on the result of the evaluation^{18,22,24,26} or of all variables of the model²⁵ to explore the impact of uncertainty in these variables. Speight et al.²³ performed a probabilistic sensitivity analysis (using distributions of the expected values of the variables that were considered to be uncertain).

3.2.3. Evaluation of evidence

There was between-study heterogeneity, in particular methodologically, in the diagnostic methods analysed and type of economic evaluation used limiting the capacity to synthesize results. Moreover the choice of economic evaluation method was generally not justified either directly or in relation to the identification of specific research questions. The perspective of the study was stated in half of the studies and the approaches used for costing diagnostic methods varied with some studies focusing attention on expenditures as opposed to the costs of resources used. Consequently, there was no scope for synthesis of results, even where studies addressed similar clinical issues.

4. Discussion

Diagnostic methods have the potential to provide more accurate information about patients' oral health status and earlier intervention in disease processes thus reducing the severity of conditions and the quantity and complexity of treatment needs. From an economics perspective such interventions can result in reductions in future costs of care as well as avoiding or reducing the future burden of oral disease. It is therefore important that new developments in diagnostic methods be considered within a systematic economic framework.

4.1. Methodological considerations

As the search could not be based on topic-specific terms, MeSH-terms listed in studies on economic evaluations in dentistry were used when the plan for the literature search was formulated. In accord with CDR's guidance,⁴ the search strategy combined economic terms with subject terms. This resulted in a comprehensive search. Furthermore, as recommended in AMSTAR – a measurement tool to assess the methodological quality of systematic reviews,²⁷ several electronic sources were searched, which resulted in a large number of citations not meeting the inclusion criteria. Many excluded studies presented only assumptions of cost-effectiveness without any analysis. Another frequent reason for

exclusion was that there was no comparative analysis of alternative courses as opposed to the definition of economic evaluation by Drummond et al.¹ applied in this review. The reference lists of studies on diagnostic methods were hand searched – a more reliable method compared with performing searches in additional electronic sources.^{9,28}

Despite the comprehensive nature of the search, it is unlikely that all studies on economic evaluations of diagnostic methods in dentistry were identified. Limitations of our review included the exclusion of non-English language studies and any grey literature. Evaluations performed by governmental advisory bodies and agencies as part of health service planning may not be published in the scientific literature and it is uncertain whether such studies are identifiable by searches in the databases used for this review.

4.2. Discussion of results

As expected, there were few studies presenting economic evaluations of diagnostic methods in dentistry, out of which half of the studies elucidated methods to establish a diagnosis and the other half methods used for screening. Methods used to diagnose or screen dental caries^{16,18,26} and periodontal disease,²⁰ which are common diagnostic procedures in dentistry, were analysed in only four studies. The outcomes of the methods varied across the included studies, but were mostly expressed as sensitivity and specificity of the diagnostic methods. In two studies of methods used to diagnose a lesion, the outcomes were defined differently. The study by Perry et al.,²⁰ which was based on examinations of the periodontal tissue using two different probes made by two observers of ten patients, were presented only as correlation between the examination techniques. Scaf et al.¹⁵ estimated the radiation dosages of two radiographic techniques under comparison, which is not valid as an outcome of a diagnostic method. This is not to say that radiation exposure is an insignificant component alongside the monetary costs, a fact presented in a recent systematic review of imaging systems used to monitor orthopaedic conditions.²⁹ To evaluate the long-term cost-effectiveness of these imaging systems, a framework for the synthesis of data from the review of clinical effectiveness and adverse effects of radiation exposure was provided.²⁹

The outcome of a diagnostic method can be expressed on six hierarchical levels where diagnostic accuracy expressed as sensitivity and specificity represents a lower level and the impact on patient's health and on society expressed as life years gained or QALY represent higher levels.³⁰ Although both patients and providers of health care could be assured by a correct diagnosis, they often require an outcome that expresses an impact on patients' health. This was estimated in three studies of screening of oral cancer, where diagnostic accuracy of the methods presented an interim outcome that underpinned the calculation of equivalent lives saved²² or QALYs.^{22,23,25}

The type of economic evaluation was not stated in one third of the studies. Although CEA was stated to be implemented in six studies, three of them could be defined as other types (CA or CUA) of evaluations. CEA is of most use for comparing interventions that are aimed at producing the same outcome (e.g., different ways of dealing with the same

patient group or condition). The interest of organizing a screening program would be in maximizing for example the number of cases detected and to find out the incremental cost per additional case detected by alternative screening programs. CUA involves measuring outcomes using metrics that incorporate both the length and quality of life, as expressed in QALYs, and is becoming used more frequently. Intermediate outcome measures can be linked to health-related quality of life using a decision model e.g. the Markov model. However, although studies using preference-based measures of outcomes are categorized as CUA in the methods literature, this is often viewed as a part of CEA broadly defined. The analytical approach is the same, only the nature of the outcome measure differs.

Five studies were empirical;^{15,17,19,20,24} the other studies were model analyses.^{16,18,21–23,25,26} Empirical studies using patient-level data and decision model-based analyses based on assumptions are not comparable and therefore data should not be combined in a synthesized analysis.¹⁴ The methods for analysing costs in the diagnostic studies were divergent. Three studies presented patient-level cost data^{19,20,24} whereas in the model analyses^{18,22,23,25,26} data on costs were based on assumptions or expenditures (fee levels or charges paid or received). Charges may differ from the actual resource consumption³¹ and simply measuring expenditures cannot substitute well conducted original costing that involves measuring quantities of resources required to deliver the intervention.¹ Comparisons between different studies and different health care systems are complicated if different methods for costing are used.³² Discounting future costs and benefits is needed if the study period lasts more than a year.¹ This was not performed by Van der Meij et al.²² and Norlund et al.¹⁸ where costs and effects were modelled without a long-term perspective or by Subramanian et al.²⁴ as no calculation of life-time costs was done, or by Christell et al.¹⁹ who presented a frame-work for costing for diagnostic methods in dentistry and an application of this where all costs and effects occur in the first year, thus avoiding any problems of discounting.

Sensitivity analyses can be included in the case of missing information or where the measurement of particular variables is subject to uncertainty. If sensitivity analyses reveal that outcomes are dependent on the value of such variables, priorities for future research should include collecting better information on this parameter. The results were robust to uncertainties in the variables in three of six studies^{24–26} presenting sensitivity analyses but non-robust in three other studies,^{18,22,23} where this uncertainty was presented in the conclusions of the studies. The data in model analyses are to different extents based on assumptions and thus more comprehensive analyses like probabilistic sensitivity analyses should be performed. A sensitivity analysis where two or more variables were changed to test the robustness was performed in three of four studies based on model analyses.^{22,23,25}

In economic evaluations, a societal perspective is recommended i.e., the evaluation should include all relevant costs to society (direct service delivery costs and patient-related costs).¹ Three studies adopted a societal perspective and included patient-related costs.^{19,24,26} Speight et al.²³ used a providers' perspective (NHS) and argued that they could not use a societal perspective with inclusion of patient-related costs or impact on

productivity since it was a retrospective analysis. The effect of an intervention is affected by the disease in a population and the underlying determinants of health.^{33,34} The cost-effectiveness of the same intervention in two places may be different even in circumstances where the incremental resource use and health effects are identical, due to factors relating to the decision context. The opportunity cost of the intervention is the value of the resources used for the intervention in their most preferred alternative use. The opportunity cost will therefore be influenced by whether the implementation of the new intervention will supplement or replace the current intervention and whether the current intervention, if replaced would free up enough resources to support the new intervention. If not, the relevant comparison is between the new intervention on the one hand and a combination of the current intervention and whatever other interventions will be reduced in order to free up enough resources to support the new intervention.

Analysis of the specific outcomes of included studies was not the primary aim of this review, which was rather focused on a broader assessment of the breadth, volume and methodology of economic evaluations of diagnostic methods. Nonetheless, some consideration of the results of included studies is worthwhile. Early detection of oral cancer through screening seems to be important in reducing the morbidity and mortality from oral cancer²² and is cost-effective in high-risk populations.^{24,25} As screening was evaluated in different populations (general and high-risk) and in different health care settings (general dental practice, general medical practice, specialist care, by health workers during household visits) no synthesis of the results was performed.

5. Conclusions

Among the few studies on diagnostic methods there was a vast heterogeneity, both in the diagnostic modalities and the evaluation methods used. Furthermore, the quantity and value of resources associated with the characteristics and contexts of different health care systems and populations in which the services are delivered may differ,⁸ adding to this heterogeneity. In order to improve the quality of future studies of economic evaluations of diagnostic methods used in dentistry and facilitate comparisons between results of studies there is a need for consistency in the application of the guidelines for economic evaluation of diagnostic methods. One important element of this is a common framework for the systematic identification, measurement and valuation of incremental costs¹⁹ that can be analysed alongside measures of incremental effects measured in accordance with the stated purpose, goals or objectives of the diagnostic method. Such analyses would support decision-makers searching for ways to increase and eventually maximize the health gains produced from the resources made available to health care systems.

Appendix A and B. Supplementary data

Supplementary material related to this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.jdent.2014.07.018>.

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II

A framework for costing diagnostic methods in oral health care: An application comparing a new imaging technology with the conventional approach for maxillary canines with eruption disturbances

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Christell H, Birch S, Horner K, Rohlin M, Lindh C, SEDENTEXCT consortium. A framework for costing diagnostic methods in oral health care: An application comparing a new imaging technology with the conventional approach for maxillary canines with eruption disturbances. Community Dent Oral Epidemiol 2012; 40: 351–361. © 2012 John Wiley & Sons A/S

Abstract – Objectives: The aims were (i) to propose a framework for costing diagnostic methods in oral health care and (ii) to illustrate the application of the framework to the radiographic examination of maxillary canines with eruption disturbances. **Methods:** The framework for costing, following Drummond et al. (2005), includes three elements: (i) identification of different resources used in producing and delivering the service, (ii) measurement of the amount of each resource required and (iii) valuation of the resources in monetary terms. Four data collection instruments were designed – a protocol for apportioning the cost of capital equipment to each diagnostic procedure, separate forms for recording consumable items, for the time of different health care providers used for a diagnostic examination and a patient survey for calculation of the total cost to the patient associated with the examination. The framework was applied to the radiographic examination of maxillary canines with eruption disturbances comparing two imaging methods: (i) a new method with cone beam computed tomography and panoramic radiography and (ii) a conventional method using intraoral and panoramic radiography. The primary analysis was performed from the perspective of the health care system. A separate analysis included patient costs with health care system costs to provide a societal perspective. Comparison of the two perspectives allows consideration of whether any costs savings to the health care system are generated at the expense of greater costs for patients and their families. Data for the cost-analysis were retrieved from 47 patients (mean age 14 years) referred to a department of radiology for examination of maxillary canines. **Results:** Application of the framework for costing allowed us to compare the resources used to perform examinations of the two methods. The mean total cost per examination for the new method was 128.38€ and 81.80€ for the conventional method, resulting in an incremental cost per examination of the new method of 46.58€. **Conclusions:** The application of the framework demonstrates the feasibility of measuring and comparing the total costs as well as the distribution of total costs between providers and patients for different approaches to this common examination.

Key words: clinical research; diagnostic research; economics; oral health

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Submitted 14 October 2010
accepted 13 January 2012

Today we face a continuous inflow of new health care technology. The question is not simply what the most effective technology to choose is, but whether the additional benefits justify any additional costs incurred. Economic evaluation is a set of formal quantitative methods to compare resource use and expected outcomes of alternative interventions for examination, prevention or treatment of patients to inform decision-makers about health care investments (1). Information on the costs of different interventions (inputs of capital equipment, consumables and the time of providers and patients) is therefore an important input to economic evaluation. In addition, information on costs is required to plan for the implementation of interventions. Finally, information on the distribution of costs between the health care system and patients is important in assessing expected levels of demand for services.

In oral health care, studies of economic evaluation are scarce and have predominantly been performed on prevention, for example, Birch (2), Marino et al. (3), and treatment, for example, van der Wijk et al. (4), Glendor et al. (5), Gjermo and Grytten (6). In these studies, cost considerations were presented in general terms, and the values were 'only indicative and illustrate principles rather than true costs' (7). A few studies of cost-effectiveness, for example, Sköld et al. (8), Oscarson et al. (9) and Liedholm et al. (10), presented more detailed analyses of the costs. To our knowledge, there is only one study on the economic evaluation of diagnostic methods used in oral health care rated to be of moderate study quality (7). To facilitate economic evaluations of diagnostic methods in oral health care, there is a need to identify key steps of costing diagnostic services and to identify resources used in the diagnostic process.

To illustrate application of the costing framework and test the feasibility of the framework, we apply it to a new diagnostic technology, the cone beam computed tomography (CBCT). This radiographic method is attractive for many clinical situations in oral health care such as the examination of the maxillary canines with eruption disturbances (11). This clinical situation might lead to displacement with the possible consequence of retention and root resorption of neighbouring teeth. Root resorption is detected in about 50% more teeth by computed tomography (CT) as compared with the commonly used radiographic examination with intraoral and panoramic radiography (12). However, CT, a three-dimensional imaging method, will result in a higher

radiation dosage than intraoral and panoramic radiography (13), a fact that makes it less appropriate especially when examining children and adolescents. CBCT produces a lower radiation dosage than that of conventional CT (14) and provides, at the same time, through a scanned volume, images in three dimensions with a high level of detail. However, decisions about the adoption of the new technology as a routine diagnostic procedure need to be informed by the additional costs of providing that enhanced diagnostic information from the technology.

The aims of the present study were:

- to propose a framework for estimating the cost of diagnostic methods in oral health care;
- to apply the framework to the radiographic examination of patients with maxillary canines with eruption disturbances using a new method, that is, CBCT and panoramic radiography and a conventional method, that is, intraoral radiography and panoramic radiography.

Materials and methods

Framework for costing

The cost-analysis of diagnostic methods, presented in Table 1, includes three parts (i) identification of different resources used, (ii) measurement of the amount of each of these resources required and (iii) valuation of each resource used in monetary terms. The framework comprises direct costs (the costs incurred by the health care system in delivering the service) and indirect costs (the costs incurred by patients in using the service) and follows the method proposed by Drummond et al. (1) for medical care interventions. The primary analysis was performed from the perspective of the health care system, that is, attention was focused on costs incurred by the system associated with the use of the new method (CBCT together with panoramic) according to a defined protocol. A separate analysis from a societal perspective was also performed which included costs to patients. Comparison of the results of the different study perspectives allows us to consider whether any costs savings to the health care system are generated at the expense of greater costs for patients, or whether increased costs to the health care system are offset (in part or full) by savings to patients.

Four data collection instruments were designed:

- a protocol for apportioning the cost of capital equipment to each procedure;

Table 1. Framework for cost-analysis of diagnostic methods in oral health care based on three steps: (i) identification (ii) measurement and (iii) valuation of costs based on recommendations by Drummond et al. (1). The example is described for diagnostic imaging methods

	Identification (what)	Measurement (how much/ many)	Valuation (unit-cost)
Direct costs			
Capital	Equipment Maintenance Accommodation	Hours of equipment time Hours of maintenance Number of m ²	Purchase cost for the equipment Equipment cost per examination Maintenance cost per examination Accommodation cost per examination
Consumables	Patient record Image archive	Number of patients Number of images stored Number of images per examination Consumables	Cost for patient record per examination Cost for consumables per examination
Labour	Consumables Specialist Dental assistant	Number of worked clinic hours	Annual labour cost Labour cost per examination
Indirect costs	Patient Accompanying person	Time per examination Time per examination spent on: Transport Waiting Examination 'Out-of-pocket cost' Cost for fee	Average gross annual earning Minimum wage cost per hour Cost for time spent per examination on: Transport Waiting Examination 'Out-of-pocket cost' per examination Cost for fee per examination

- a form for measuring consumable items (Appendix 1);
- forms for measuring the time that different health care providers used for the examinations;
- survey for measuring the time and cost for the patients and accompanying persons (Appendix 2).

Direct costs cover cost for the capital equipment such as apparatus, computers and digital screens, maintenance and repairs, costs of accommodation, that is, clinic and office space as well as cost for consumables and labour. To get the cost per examination, the different costs for equipment are divided by the number of images taken during a year. This cost per image is then multiplied with the number of images taken per examination.

Because the expected life of radiographic equipment is expected to be similar for the different types of equipment, capital costs are 'spread' across the same number of years. Because there is no difference between programmes in the distribution of programme costs over time, the cost-analysis can be based on an estimate of the incremental annual cost with the annual cost for the radiographic apparatus being calculated by dividing the purchase costs with the expected lifetime.

Any scrap value and/or scrap costs of old equipment should also be included where this differs between the programmes under consideration. The

scrap value or costs should be discounted to produce a present value of scrap, which is then deducted from or added to the purchase costs, before allocating this net present value equipment cost over the lifetime of the equipment. However, because there was no basis for assuming that the scrap value of the different radiographic apparatus would differ, this would not affect the incremental cost of the new programme.

The cost for maintenance is based on the average annual cost for a defined time period. Cost for accommodation for the clinic and office space is calculated as cost per square metre and includes overhead costs (e.g. cleaning, lighting and heating). The clinic and office space is estimated from the construction map of the clinic. The information of costs for consumables is based on the quantities of consumables consumed and the unit price (Appendix 1). The method for valuation of labour cost per hour is presented in Table 2. A protocol was also used to record the actual time spent on administrative work, in patient contact, and for interpretation of images and report writing.

The quantity of time was valued according to the full employment costs (i.e. salary plus employment 'overheads' or benefits). Other aspects of overhead costs (e.g. management and administration) were not included because there is no basis for assuming that these differ systematically between the programmes which involve serving the same client

populations. As a result, they would not affect incremental costs.

The *indirect costs* include patients' and accompanying persons' expenditure for travel and a valuation of the time spent travelling to and from the clinic and undergoing examination (Appendix 2). Time spent by the patient and accompanying persons is valued according to the national average wage cost per hour (15). The 'out-of-pocket' cost is paid directly by the patient and/or the accompanying person and implies cost for driving a private car and parking or fares for taxi, train or bus as well as any user fees or co-payments for the examinations.

Empirical test of the framework

The costing framework was tested on the radiographic examination of maxillary canines with eruption disturbances using either a new method, that is, CBCT and panoramic radiography or the conventional method, that is, intraoral radiography and panoramic radiography. The calculations were based on the anticipation that once providers are more experienced with the new technology (CBCT), there will be no need to use intraoral radiography for patients examined with CBCT. We therefore based the cost of using the CBCT according to the protocol of panoramic radiography and CBCT procedures alone versus the existing protocol of the panoramic and intraoral radiography.

The study was conducted in accordance with the ethical principles of the World Medical Association Declaration of Helsinki (2008 version) and approved by the Regional Ethical Review Board, Lund, Sweden (H15 606/2008).

Patients

Data for the cost-analysis were retrieved from the protocols (Appendix 2) used for patients referred for examination of maxillary canines with eruption disturbances to the Department of Oral and Maxillofacial Radiology Malmö University Hospital, Sweden. Seventy-one consecutive patients (mean age 14 years; range 10–19) were asked to participate in the study during March 2009 – March 2010. 47 patients (mean age 14 years; range 10–19) and/or their parents gave their informed consent to participate, while 24 (mean age 15 years; range 10–19 years) declined participation. Each patient was examined with intraoral and panoramic radiography as well as with CBCT, and the examinations were performed during one single visit. The time for each of the three elements of examinations was recorded separately.

Cost-analysis

The calculations were based upon the observed average service use per patient to reflect the likelihood that it would require different numbers of radiographs and volumes between patients to achieve images of acceptable quality.

Table 2. Example of calculation of labour cost per hour for a specialist and a dental assistant. Data are presented in Euro unless otherwise stated

Specialist		
Annual gross labour cost for a specialist including on-costs (51% in Sweden 2008). Based on the valuation of wage and salary structures (general practice dentist) according to official statistics (16).		74 340
Annual labour cost for worked clinic hours (20% of annual gross labour cost)		14 870
Worked clinic hours – hours worked in clinic according to schedule (350h) minus time for sick and parental leave (7h), and 'downtime' (43h)		300 h
Labour cost per hour = $\frac{\text{Labour cost for worked clinic hours}(14\,860\text{€})}{\text{Total annual worked clinic hours (300 h)}}$		49.60
Dental assistant		
Annual gross labour cost for a dental assistant including on-costs (51% in Sweden 2008). Based on the valuation of wage and salary structures (dental nurse) according to official statistics (16). (Full-time employment in Sweden is 1980h)		39 115
Labour cost for worked clinic hours (100% of annual gross employment cost)		39 115
Worked clinic hours – hours worked in clinic according to schedule (1265h) minus time for sick and parental leave (114h) and 'downtime' (125h)		1026 h
Labour cost per hour = $\frac{\text{Labour cost for worked clinic hours}(15\,500\text{€})}{\text{Total annual worked clinic hours (487 h)}}$		38.10

Direct costs. Capital costs—The radiographic equipment used for CBCT was Accuitomo (Morita, Kyoto, Japan) (75 kV, 6–8 mA, 17 s), for panoramic radiography Planmeca Pro Max (Helsinki, Finland) (72 kV, 16 mA, 17 s, magnification 1.2×) and for intraoral radiography Planmeca Intra (Helsinki, Finland) (60 kV, 8 mA, 0.10–0.20 s). All radiographic equipment was purchased in 2003. The expected working life of the equipment prior to its replacement was estimated to be 10 years for CBCT, panoramic radiography and intraoral radiography. The valuation of cost for maintenance was based on the average cost for repair and service per year in 2005–2008.

The total direct costs for 1 year were divided by the total number of images/volumes taken during 1 year to get the mean cost per image/volume. The cost per image/volume was then multiplied by the mean number of images/volumes recorded per examination to get the mean cost per examination for the new and conventional methods, respectively. The total number of images/volumes per year was retrieved from the billing codes for examinations with CBCT, panoramic and intraoral radiography.

The cost for accommodation was valued using the local market rental price in 2008. The cost for office space was divided in equal parts between CBCT, panoramic radiography and intraoral radiography, respectively.

Costs for consumables—Valuation of the cost for access to the digital system for patient records and the image archive was based on the total amount of radiographs in 2008 according to billing codes and for image storing, the cost per digital space expressed in terabyte. Information of the cost for disposable items was based on data recorded by four dental assistants for four patients each with the aid of Appendix 1. The items were valued according to actual costs paid in 2008 to get mean costs per image/volume and per examination.

Labour costs—The labour cost per hour presented in Table 2 was valued for a general service 'dentist' and a 'dental nurse' according to official statistics from 2008 (16). The calculation includes an employment overhead cost of 51% covering management, administration and social benefits such as pension and health insurance. The labour cost per hour was valued by dividing the annual gross salary for clinic work by the total annual number of worked clinic hours (Table 2). The annual num-

ber of worked clinic hours was measured according to the time schedules of the clinic excluding time for administration, 'downtime', vacation and absence like sick and parental leave. The amount of working time for the new and conventional method, respectively, was recorded. The labour cost per examination was valued by multiplying the labour cost per minute with number of minutes worked per examination.

The worked clinic hours for a specialist in maxillofacial and oral radiology (radiologists) included time for quality control of images and for interpretation and writing the radiological report. The worked clinic hours for a dental assistant included the imaging procedure in the radiographic examinations as well as the administrative time for taking care of the patients in booking appointments.

Indirect costs. In the patient survey (Appendix 2), patients and accompanying persons were asked to report time and money spent for transport to the clinic. Time spent by patients under 18 years was valued to 7.84€ per hour, based on the minimum wage in Sweden 2004 according to The Institute for Labour Market Policy Evaluation (17). For patients and accompanying persons over 18 years, the time spent was valued at 16.80€ per hour based on the national average wage rate in Sweden 2006 (15).

Transport costs were valued at 0.28€/km for private cars based on allowances for private vehicle use of the official tax authority (Swedish Tax Agency, 2008 regulation). When the patients walked or cycled, the cost was limited to the valuation of their time.

All costs were calculated in SEK, adjusted to 2008 values and converted to Euros at the 2008 average rate of one Euro = SEK 9.60.

Results

Cost-analysis

The cost-analysis is transparent with calculations described in detail, with the direct and indirect costs for the different resources presented separately. This facilitates identification, measurement and valuation of the different elements of costs and supports comparisons with other studies of costing. The mean total cost per examination was 128.38€ for the new method and 81.80€ for the conventional method, resulting in an incremental

cost for the new method of 46.58€ (Table 3). The incremental cost for the new method was mainly because of the higher direct costs, in particular the capital costs that comprised 43% for the new method and 17% for the conventional method of the total cost per examination. The indirect costs of the new and conventional method were comparable. However, this is largely the result of costs for the separate treatment protocols being modelled from patients who in practice received both intraoral radiography and CBCT. As a result, we did not have separate groups of CBCT patients and intraoral patients. Hence, in this application of the framework, average patient costs were the same for both interventions for all elements of patients' costs except the time taken to perform the examinations. Average examination time differed largely because of differences in the number of images per examination between CBCT and intra oral (see below). We might have expected more differences in patient costs if separate patients groups had been available.

Direct costs. Capital costs—The cost for equipment per examination for the new method was 34.54€ and 7.51€ for the conventional method (Table 3). The purchase cost for the CBCT equipment was

double that of the panoramic equipment and over five times higher than that for intraoral radiography.

The cost for maintenance was 6.61€ for the new method and 0.75€ for the conventional method. The total number of images taken during 2008 was 948 for CBCT, 1765 for panoramic radiography and 4009 for intraoral radiography. The new method was based on a recorded mean of 1.4 volumes of CBCT and one panoramic radiograph per examination. The conventional method was based on a recorded mean of 2.9 intraoral radiographs and one panoramic radiograph per examination.

Total cost for accommodation of the new method was 2.4 times that of the conventional method (Table 3). The cost was based on a hospital cost for accommodation of 215€ per m². The clinic space for the panoramic equipment and CBCT was measured at 28 m² each and at 9 m² for the intraoral equipment. The office space was 10 m² resulting in 3.3 m² for CBCT, panoramic and intraoral radiography, respectively.

Cost for consumables—This includes the cost for disposable items, access to the digital image archive and the system of patient records. This cost was low and comparable for the new and the conventional method (Table 3).

Table 3. Distribution of direct and indirect costs per examination for patients with maxillary canines with eruption disturbances using two diagnostic imaging methods: a new method (cone beam computed tomography – CBCT and panoramic radiography) and a conventional method (intraoral and panoramic radiography). All costs were calculated in SEK, adjusted to 2008 values and converted to Euros at the 2008 average rate of one Euro = SEK 9.60

Identified costs	Cost per examination new method	Cost per examination conventional method	Incremental cost of the new method
Direct costs			
Capital			
Equipment	34.54	7.51	27.03
Maintenance	6.61	0.75	5.86
Accommodation	13.77	5.73	8.04
Consumables	2.78	2.23	0.55
Labour			
Specialist	5.37	3.80	1.57
Dental assistant	19.95	17.28	2.67
Total direct costs	83.02	37.30	45.72
Indirect costs			
Patients' and accompanying persons' time spent on			
Transport	20.80	20.80	–
Waiting	5.46	5.46	–
Examination	6.51	5.65	0.86
'Out-of-pocket' cost			
Cost per km, parking, fare	12.59	12.59	–
Fee	n/a	n/a	n/a
Total indirect costs	45.36	44.50	0.86
Total cost	128.38	81.80	46.58

Labour costs—The calculation of labour costs per hour is presented in Table 2. The specialists worked on average 300 h in clinic in 2008 after allowing for vacation, administration time, sick leave and downtime, that is, 15% of a full-time employment. The average gross labour cost per worked clinic hour for a specialist was 49.60€. For a specialist, the recorded mean time per examination was 6.5 min for the new method and 4.5 min for the conventional method resulting in a mean labour cost per examination of 5.37€ for the new method and 3.80€ for the conventional method (Table 3).

A dental assistant worked an average of 1026 h in the clinic during 2008, that is, 58% of the total paid hours. The average gross labour cost per hour for a dental assistant was 38.12€. As two dental assistants performed the examination, the labour cost was 76.25€ per hour. The recorded mean time per examination for a dental assistant was 16 min for the new method and 14 min for the conventional method resulting in a cost of 19.95€ for the new method and 17.28€ for the conventional method (Table 3).

Indirect costs. The total indirect cost per examination for the patient and the accompanying person was 45.36€ for the new method and 44.50€ for the conventional method (Table 3). The analysis is based on costing a defined protocol for use of the new method in which decisions about treatment for maxillary canines with eruption disturbances are taken based on the results of an examination using CBCT together with panoramic radiography. This is compared with the diagnostic protocol of the conventional method using intraoral and panoramic radiography.

The indirect costs represented 35% of the total cost for the new method and 54% of the conventional method. The cost for the accompanying person comprised 75% of the indirect cost for the new method with a cost of 34.13€ and 76% for the conventional method with 33.73€.

The patient and the accompanying person spent an average of 14 min in the waiting room. The mean time for undergoing the examination was 16 min for the new method and 14 min for the conventional method. Most patients (91%) came to the clinic with an accompanying person. The majority of patients (79%) and accompanying persons (88%) travelled to the clinic by car. The mean travelled distance was 42 km including return and the mean time spent for travel was 48 min. The mean total

'out-of-pocket' cost for transport, parking and bus or train tickets per examination was 12.88€.

Patient charges were zero because no charges are made to patients younger than 19 years in Sweden for oral radiographic examinations. In other systems where charges are made to patients, these would need to be measured and included as an additional element of indirect costs. Once we consider a societal perspective, patient charges are not included because they represent a transfer of funds from one party (the patient) to another party (the health care system). Hence, there is no net change in resources used – the additional cost to the patient of the charge accrues as revenue to the provider and hence reduces direct costs by the same amount.

Discussion

Costings of interventions used to inform economic evaluations often use estimates of cost from previous studies or indicators such as provider fee levels that are unrelated to the opportunity costs of resource use. However, the validity of the results of economic evaluations depends crucially on the validity of the cost estimates being used (1). We present a framework for costing diagnostic methods in oral health care to provide a more complete understanding of incremental costs of new diagnostic methods. The design and content of the costing framework follows the recommendations by Drummond et al. (1) for medical care interventions.

We adopted a 'bottom-up' or micro-costing approach based on three coherent steps where each component of resource used is identified, measured and valued. Because the distribution of costs over time, including capital equipment purchase and disposal, was expected to be similar between the two programmes, the incremental cost could be calculated on the basis of the difference in average annual costs without the need to discount future costs (1). For programme comparisons where this is not the case (e.g. comparing a capital intensive programme with a predominantly labour intensive programme), the comparison would need to be based on the incremental net present value of cost based on discounting future costs (1). The different costs of the capital equipment, however, do give rise to different opportunity costs because the funds required to purchase capital equipment alternatively could have been invested in ways that

earned interest payments. Hence, higher costs of capital equipment imply higher (potential) interest payments forgone. Using a 5% interest rate, the new imaging method would involve an additional incremental cost, in terms of opportunity cost of capital, of 1.35 Euros per examination (given by the difference in capital costs per examination in Table 3 multiplied by the forgone interest rate of 5%) compared with the conventional method thus increasing the total incremental cost per examination of the new method to around 50 Euros.

Drummond et al. (1) note that there is no unambiguously right way to apportion overheads (p 68). We chose to include overhead costs that related to aspects of service provision that differed between the two programmes being compared (in particular accommodation and labour). But for all other aspects of overheads (e.g. general hospital management and administration), there was no reason to believe that these would differ between the programmes under consideration and hence inclusion of these would not affect the difference in costs between programmes (i.e. the incremental cost). It is difficult to see how replacing the traditional diagnostic protocol by the CBCT protocol would impact on these costs.

The feasibility of the framework was analysed by application to radiographic methods. However, the framework provides a generic methodology that can be applicable to costing other diagnostic methods in oral health care. Evaluations of the costs of diagnostic examinations in oral health care are important as many examinations are performed routinely and frequently. The distribution of the costs of clinical examinations, such as probing the periodontal tissue or visual-tactile examination of tooth surfaces, will be different as the costs for the equipment will be lower as compared to radiographic equipment. However, the costing framework has the capacity to support cost estimations for interventions with different levels of capital equipment costs.

Although the framework provided a structure for cost-analysis, the implementation of the framework provided some challenges. For example, it was difficult to obtain consistent information of direct costs of equipment maintenance and labour costs. To value the labour cost, information was taken from the finance department of the university, the hospital, the registry for the general dental clinics in Sweden as well as in agencies for statistics in Sweden (16) and in Europe (15). Comparisons of the results between different studies will be

facilitated if the sources of information are described in detail.

There are very few studies of costing diagnostic methods in oral health care and it was difficult to compare the results from the cost-analysis in the present study with results from other studies. A large part of the total cost for the new method was because of high capital cost for equipment, maintenance and accommodation being 43% of the total cost per examination as compared for the conventional method being only 17% of the total cost.

The capital cost of the equipment is allocated on the basis of the number of examinations performed per year. As with many new technologies, we might expect an increase in the use of CBCT over time as more providers become aware of the technology and trained for its use. Regarding the Malmö clinic, the annual number of CBCT examinations increased from 342 in the first full year of use in 2005 to 677 in 2008. Data for 2009, however, have shown that use has 'plateaued' with 649 examinations performed in 2009. There will be a maximum volume of examinations that can be performed beyond which further increases would require use of an additional apparatus. At present, CBCT is used for between 70% and 80% of clinic hours.

In principle, hours of use could be increased by up to 25% assuming a sufficient number of additional patients with the clinical condition and the availability of relevant staff. We therefore re-estimated the cost per examination for CBCT with a 25% increase in number of examinations, all other things constant. This resulted in a reduction in cost per examination for the new method of 7%. Although this would also increase provider time required, there is no reason why the average provider time per examination would change. Of course we cannot simply assume a constant stream of patients in need of this intervention. It may be that current levels of use represent prevailing levels of need in the community or catchment population. Hence, the estimated equipment costs per patient would be an accurate estimate of the opportunity cost of the equipment use. In such cases, we may want to consider changing catchment populations to utilize the equipment more efficiently. However, this will have implications for patient costs, and hence demand for the investigation, as a larger catchment population is likely to involve increased patient costs because of longer distances to the clinic.

Increasing the use of CBCT may also increase the average annual costs of maintenance and repair. For the period 2005–2008, the average annual costs was 4476.42€. It is difficult to analyse the trend in maintenance costs over such a limited period of time because a single item of repair can lead to 'spikes' in the pattern of maintenance costs. For example, in the 4-year period of 2005–2008, maintenance cost was zero in 2005 and 2007, but was over 17 000€ in 2008. Unlike the level of use of the new technology, there is no physical limitation on repairs and maintenance, and we might expect the average annual cost to increase with the age of the equipment. We therefore re-estimated the average cost per examination based on a 25% increase in the average cost of maintenance and repair over the 2005–2008 period. This resulted in an increase in the average direct cost per examination of the new method of 2%.

It remains important to analyse whether the clinical and patient outcomes of the new technology warrant the increased cost (14) in line with the ALARA principle 'As Low As Reasonably Achievable', that is, to identify the most cost-effective solution (18).

Because indirect costs affect the demand for services, and that they sometimes may be higher than the direct costs, they are important to measure and value (19). For the radiographic examination of maxillary canines with eruption disturbances, the indirect cost was similar for the new and for the conventional method. As already mentioned, this is partly because of the design of the study. There should, however, be reasonable approximations of indirect costs for the different interventions. Indirect costs represented 31% of the total costs for the new method and 54% for the conventional method in the present study. This is comparable with the results of two other studies on children and adolescents, one study of caries preventive measures Oscarson et al. (9) and one study of treatment of dental trauma Glendor et al. (5). The indirect costs presented by Liedholm et al. (10) on mandibular third molar removal were even higher being 61% of the total cost.

In conclusion, the use of the framework presented in this study should assist researchers to understand the determinants of costs and to provide a 'roadmap' to performing costing of diagnostic methods. The development of a standard framework for cost-analysis in oral health care would facilitate the performance of future studies

on costs as well as comparisons between results of cost-effectiveness studies.

Acknowledgements

The research leading to these results has received funding from the European Atomic Energy Community's Seventh Framework Programme FP7/2007–2011 under grant agreement no 212246 (SEDENTEXT: Safety and Efficacy of a New and Emerging Dental X-ray Modality). We thank Professor Mats Nilsson, Department of Radiophysics, Malmö University Hospital, for information and valuation of capital costs and the referees for their constructive and helpful comments on successive versions of this manuscript.

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Appendix 1

List of disposable items used in radiographic examination with intraoral radiography, panoramic radiography and cone beam computed tomography (CBCT)

Disposable items used in radiographic examination

Number of radiographs/volumes per examination (patient)
X-ray film (analogue)
Disposable holders for intraoral radiographs
Plastic protection for sensors
Plastic protection for phosphor-plate
Plastic protection for panoramic radiograph
Cotton rolls
Gloves
Mask
Paper for wiping
Serviette

Appendix 2

Patient survey for measurement and valuation of indirect costs

To be filled in by dental assistant/radiographer or other staff

1. Register date:.....
2. Patient name.....Birth date.....
3. Any cancellation or failure to arrive so that the time was not used.....min
4. Time when the patient arrives to the clinic.....
5. Waiting time in the clinic before the examination begins.....min
6. Time when the patient leaves the clinic.....
7. Total time for the patient spent at the clinic.....min(Time when the radiographic examination and interview is completed, minus the time when the patient arrives to the clinic)
8. Is this a parallel visit? Does the patient come directly from another clinic, for example, oral and maxillofacial surgery clinic in the hospital/university? ☐ yes ☐ no
If yes, what is the distance between the other clinic and the clinic of radiology?.....km
9. Fee for the examination paid by the patient.....

For the patient to answer:

If the patient is a child or adolescent travelling with an accompanying person to the clinic and will return home/to school together with the same person: Then go directly to question 15.

10. How did you come to the clinic today?
☐ car ☐ bicycle ☐ train ☐ walked ☐ taxi ☐ bus ☐ other, which is.....
11. How do you intend to return home/to school from the clinic today?
☐ car ☐ bicycle ☐ train ☐ walked ☐ taxi ☐ bus ☐ other, which is.....
12. If you got here by car – did you buy a parking ticket?
 If you got here by bus or train did you pay fare? ☐ yes ☐ no
 In case of yes – how much did you pay?.....

13. Approximately how far did you travel to come to the clinic today?km
14. Approximately how long did it take for you to come to the clinic?.....min
15. What is your employment status?
☐ employed ☐ self-employed ☐ homemaker ☐ looking for job ☐ retired ☐ not working because of ill health
☐ student ☐ other.....

16. Did you lose wage or vacation time to come to the clinic today?
☐ yes ☐ no In case of yes, how long time did you lose?.....min

For accompanying person to answer:

17. What is your relationship to the patient?
☐ parent ☐ brother/sister ☐ grandparent ☐ other relative ☐ friend ☐ other, which is

18. How did you get to the clinic today?
☐ car ☐ bicycle ☐ train ☐ walked ☐ taxi ☐ bus ☐ other, which is.....
19. If you got here by car – did you buy a parking ticket?
☐ yes ☐ no In case of yes – how much did you pay?
20. Did you pick up the patient at home/at school?
☐ yes ☐ no In case of yes, how long time did that take?min
21. How do you intend to return home/to school from the clinic today?
☐ car ☐ bicycle ☐ train ☐ walked ☐ taxi ☐ bus ☐ other, which is.....
22. Approximately how far did you travel to come to the clinic today?km
23. Approximately how long time did it take for you to come to the clinic today?.....min
24. What is your employment status?
☐ employed ☐ self-employed ☐ homemaker ☐ looking for job ☐ retired ☐ not working because of ill health
☐ student ☐ other.....

25. Did you lose pay or vacation time to come to the clinic today?
☐ yes ☐ no In case of yes – how much did you pay?

III

RESEARCH

Variation in costs of cone beam CT examinations among healthcare systems

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Objectives: To analyse the costs of cone beam CT (CBCT) in different healthcare systems for patients with different clinical conditions.

Methods: Costs were calculated for CBCT performed in Cluj (Romania), Leuven (Belgium), Malmö (Sweden) and Vilnius (Lithuania) on patients with (i) a maxillary canine with eruption disturbance, (ii) an area with tooth loss prior to implant treatment or (iii) a lower wisdom tooth planned for removal. The costs were calculated using an approach based on the identification, measurement and valuation of all resources used in the delivery of the service that combined direct costs (capital equipment, accommodation, labour) with indirect costs (patients' and accompanying persons' time, "out of pocket" costs for examination fee and visits).

Results: The estimates for direct and indirect costs varied among the healthcare systems, being highest in Malmö and lowest in Leuven. Variation in direct costs was mainly owing to different capital costs for the CBCT equipment arising from differences in purchase prices (range €148 000–227 000). Variation in indirect costs were mainly owing to examination fees (range €0–102.02).

Conclusions: Cost analysis provides an important input for economic evaluations of diagnostic methods in different healthcare systems and for planning of service delivery. Additionally, it enables decision-makers to separate variations in costs between systems into those due to external influences and those due to policy decisions. A cost evaluation of a dental radiographic method cannot be generalized from one healthcare system to another, but must take into account these specific circumstances.

Dentomaxillofacial Radiology (2012) **41**, 571–577. doi: 10.1259/dmfr/22131776

Keywords: cone beam computed tomography; costs and cost analysis; diagnostic; oral health

Introduction

The use of cone beam CT (CBCT) in clinical dental practice has increased rapidly over the last decade. Examinations with CBCT are currently used in the diagnosis of various maxillofacial conditions, either as

an addition to or as a substitute for previously used imaging methods. The diagnostic accuracy of CBCT has been reported as higher than that of conventional imaging methods in *in vitro* studies on furcation involvements,^{1,2} periapical lesions^{3,4} and teeth with eruption disturbances.⁵ However, for healthcare systems faced with limited resources, the question that decision-makers need to address is whether the additional benefits of CBCT imaging justify any additional costs incurred. Economic evaluations are therefore important when establishing selection criteria and guidelines of a new imaging method.⁶

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The research leading to these results has received funding from the European Atomic Energy Community's Seventh Framework Programme FP7/2007–2011 under grant agreement no. 212246 (SEDENTEXCT: Safety and Efficacy of a New and Emerging Dental X-ray Modality).

Received 31 July 2011; accepted 28 September 2011

To our knowledge there is only one study of the economic costs of different diagnostic methods used in oral healthcare.⁷ This study models the costs of true-positive occlusal dentine caries detection for (i) visual–tactile examination, (ii) visual–tactile examination combined with bitewing radiographs and (iii) selective radiographic examination of patients with lesions detected clinically by applying the prevailing charges per item of service in the public healthcare system in Sweden to assumptions about specificity and sensitivity of alternative approaches.⁷ As Drummond *et al*⁶ note, there is probably no substitute for a well-conducted original costing study based on primary data collection. Cost calculations based on patient-level data will give more valid results than those of a model analysis based on assumptions. We anticipate that difference in cost between CBCT and conventional imaging methods may vary both within and among different healthcare systems. Within a healthcare system examinations of patients with different clinical conditions may require a varying number of CBCT volumes, whereas among different healthcare systems the configuration of services, distribution of facilities and healthcare policies concerning access to care may differ. The aim of this study was, therefore, to analyse the costs of CBCT in different healthcare systems for patients with different clinical conditions.

Materials and methods

The healthcare systems selected were four departments using the following CBCT machines:

- NewTom® 3G [Quantitative Radiology (QR), Verona, Italy] purchased 2006 in the Faculty of Dental Medicine, University of Medicine and Pharmacy in Cluj-Napoca, Romania.
- Scanora® (Soredex, Helsinki, Finland), purchased 2008 in the Oral Imaging Centre, Katholieke Universiteit Leuven, Belgium.
- Accuitomo® MCT-1 (Morita, Kyoto, Japan), purchased 2003 in the Department of Oral and Maxillofacial Radiology, Malmö University, Sweden.
- NewTom CVT 9000 (QR), purchased 2002 in the Vilnius University, Vilnius, Lithuania.

CBCT examinations were performed on three different patient groups: patients with (i) a maxillary canines with eruption disturbance, (ii) an area of tooth loss prior to implant treatment and (iii) a lower wisdom tooth planned for removal. All patients referred for a CBCT examination during the period March 2009 to March 2010 were included in the study. Table 1 presents the number and age of study patients with different clinical conditions.

Cost calculations

The costs of the CBCT examinations were calculated using an approach for costing diagnostic methods described by Christell *et al*.⁸ Table 2 presents an overview of the approach, which consists of three steps:

- identification of different resources used
- measurement of the quantity used of each resource
- monetary valuation of the total resources used.

This approach calculates an average cost per CBCT examination based on the sum of direct costs (costs of delivering the service) and indirect costs (costs incurred by patients in using the service).⁸ Data for the cost calculations were collected using three data collection instruments:

- a protocol for apportioning the cost of capital equipment to each procedure
- a form for measuring the time of healthcare providers devoted to the examinations
- a patient survey to measure the time and other costs for patients and accompanying persons.

Direct costs

The direct costs cover the costs of capital equipment (radiographic apparatus, computers, digital screens), accommodation (clinic and office space) and provider time (radiologist, radiographer, imaging technician, dental nurse *etc*) in each of the healthcare systems. The annual cost for the radiographic apparatus was calculated by dividing the purchase cost by the expected lifetime. The annual cost of equipment was divided by the number of CBCT volumes taken during 2008 (450 in Cluj, 1500 in Leuven, 948 in Malmö, 435 in Vilnius)

Table 1 Number and age (mean age and range) of patients with different clinical conditions examined with CBCT in four radiology departments representing different healthcare systems

Radiology department	Clinical conditions					
	Maxillary canine with eruption disturbance		Tooth loss prior to implant treatment		Lower wisdom tooth planned for removal	
	Number	Mean age (range), years	Number	Mean age (range), years	Number	Mean age (range), years
Cluj	20	24 (13–55)	50	48 (30–70)	39	22 (9–36)
Leuven	50	15 (8–44)	38	54 (24–88)	46	29 (11–71)
Malmö	47	14 (10–19)	50	53 (18–83)	47	32 (13–74)
Vilnius	50	22 (9–60)	50	44 (22–68)	50	25 (17–51)

Table 2 Overview of the steps performed in cost analysis of the CBCT examinations of patients in different healthcare systems

Identification	Measurement	Valuation
What resources are used for the CBCT examination?	How much of each resource is used for the CBCT examination?	What is the unit-cost for each resource used for one CBCT examination?
Radiographic apparatus	Units used	Purchase cost
Maintenance	Hours of equipment time	Cost per square metre
Accommodation	Number of square metres	Labour cost per hour
Personnel	Time spent	
Patients	Patient and accompanying persons time spent	Valuation of time spent by patients and accompanying persons

The overview is based on the framework for cost-analysis of diagnostic methods presented by Christell *et al*.⁸

to produce the average cost per volume. This was then multiplied by the average number of volumes taken per examination of each clinical condition to give an average cost per examination.

Costs associated with maintenance and repairs were based on a mixture of costs for pre-paid maintenance contracts and actual repair costs. For service contracts, the contract cost for 2008 was used. For repair costs an average annual figure for the period 2005–2008 was calculated in order to smooth out fluctuations in actual repair costs over time. The cost for the clinic and office accommodation was calculated by applying the cost per m² used by the hospital finance department (including costs for services such as cleaning and utilities such as lighting and heating) to the area of accommodation used. The area was estimated from the construction maps of the clinics. Where the hospital finance department was unable to provide a cost per m² for office accommodation, the rental cost in the local property market for equivalent (size and location) office space was used.

The calculation of the cost of providers' time is based on the annual salary together with the overhead cost of employment. The total annual employment cost is divided by the total working hours of the providers to produce an employment cost per worked hour. Estimation of the working time spent by the specialists or the radiographers for the imaging process was based on direct observation and recorded on the data collection form. In Cluj and Vilnius, the examinations were performed by radiologists, in Leuven by radiographers and in Malmö by dental nurses. Provider time included time for patient-related administration, the actual examination, the imaging process and post-imaging procedures. Estimation of the time spent by the radiologists for interpreting the CBCT images and writing the radiological report was based on direct observation of one radiologist performing these tasks for a subsample of 20 patient images in Malmö.

Indirect costs

The indirect costs included the time spent by the patients (and where applicable an accompanying person), for travelling to, waiting for and undergoing the examination, as well as "out of pocket cost" for transport (fares) and services (patient charges). Information on travel time, distances and out of pocket costs were collected in

the patient survey using self-reported data for each patient and accompanying person.

For several patients in Cluj, Leuven and Vilnius, the visit to the radiology department was added on to a visit to another clinic, *e.g.* the orthodontic clinic or the maxillofacial surgery clinic at the same facility. Hence, for these patients no additional travel costs were incurred. Patients' costs were limited to time spent waiting for and undergoing the examination and any examination fees.

For patients and accompanying persons aged 18 years or over, the value of time was based on an average gross annual earnings for 2007 from Eurostat Statistics⁹ for Romania, Belgium and Sweden and on the gross average monthly earnings for 2007 taken from Statistics Lithuania¹⁰ multiplied by 12 for Lithuania. These annual earnings figures were then divided by the number of working days (holidays and vacations excluded) in 2008 to get the average earnings per worked day and then divided by eight (the number of working hours per day) to get an estimate of the average wage rate per hour of €1.96 in Cluj, €16.85 in Leuven, €16.80 in Malmö and €2.84 in Vilnius. These data were used as a measure of the value of adults' time in each system.

For patients aged below 18 years, the value of time (per hour) was valued at €0.40 in Cluj, €6.72 in Leuven, €7.84 in Malmö and €0.72 in Vilnius. These values were based on the minimum wage rates for Belgium, Lithuania and Romania.¹¹ For 2008 there was no national minimum wage for Sweden. We therefore used the last reported national minimum wage for 2004¹² and increased this by 2.5% per year based on increases reported for collective bargaining agreements.

The transport cost per kilometre for patients using private transport was based on rates used by Rotary International for 2008.¹³ Average parking cost per patient was estimated using survey responses for a subsample of patients. Public transport fares were not included because most patients using public transport were holders of pre-paid fixed price public transit passes.

The study was conducted in accordance with the ethical principles of the World Medical Association Declaration of Helsinki (2008 version) and approved by the Iuliu Hatieganu University of Medicine and Pharmacy in Cluj-Napoca Ethics Committee, Romania

Table 3 Direct and indirect costs of a cone beam CT (CBCT) examination of a patient with a maxillary canine with eruption disturbance in different healthcare systems. Costs in Euros

<i>Maxillary canine with eruption disturbances</i>				
<i>Direct costs</i>	<i>Cluj</i>	<i>Leuven</i>	<i>Malmö</i>	<i>Vilnius</i>
CBCT equipment	25.28	10.67	29.81	52.14
Maintenance	0	1.00	6.61	9.34
Accommodation	1.29	1.60	6.14	1.82
Labour				
Specialist	3.17 ^a	29.95	17.43	6.09 ^a
Radiographer/dental nurse	0	7.54	9.33	0
Total direct costs excluding maintenance costs	29.73	49.05	62.70	60.05
Total direct costs including maintenance costs	29.73	50.05	69.32	69.39
<i>Indirect costs</i>				
Examination fee paid by patient	58.06	5.61	0	4.18
Transport cost for patient or accompanying person	23.68	12.66	23.32	12.35
Patient's time value	4.57	8.49	12.51	8.04
Accompanying person's time value	4.17	15.20	23.61	4.89
Total indirect costs	90.48	41.96	59.44	29.46

^aThe specialist performed both the examination and the report.

(18514/4.09.2008), the Commission for Medical Ethics of the Faculty of Medicine of the Katholieke Universiteit Leuven, Belgium (B32220083749), the Regional Ethical Review Board, Lund, Sweden (H15606/2008) and Vilnius regional committee for biomedical research ethics, Lithuania (2010-05-05 Nr. 158200-01-138-39).

Results

Costs of CBCT examinations in different healthcare systems

The estimates of direct costs and indirect costs of CBCT examinations varied among the healthcare systems (Tables 3–5), being highest in Malmö and lowest in Leuven, irrespective of clinical condition examined. The variation among systems in *direct costs* was mainly due to different capital costs for the CBCT equipment arising from differences in the purchase price of the equipment. Compared with the cost of €147 880 in Cluj (year 2006), the purchase cost was

37% higher in Malmö (year 2003), 52% higher in Vilnius (year 2002) and 8% higher in Leuven (year 2008). As a result of the different age of equipment and local purchasing policy relating to maintenance costs, the costs of repairs and maintenance also differed between the healthcare systems.

The accommodation cost per examination varied across systems (€1.29 in Cluj, €1.60 in Leuven, €6.14 in Malmö and €1.82 in Vilnius) as a result of differences in the space for accommodation (19 m² in Cluj, 6 m² in Leuven, 16 m² in Malmö, 28 m² in Vilnius) and the cost per m² (€30.49 in Cluj, €400.00 in Leuven, €215.00 in Malmö, €20.29 in Vilnius).

Indirect costs also varied among systems (Tables 3–5), with average indirect costs per patient being highest in Malmö (between €59.44 and €147.48 according to clinical condition), second highest in Vilnius (€21.73–100.09), third highest in Cluj (€90.43–96.30) and lowest in Leuven (€21.76–41.96). Overall, where examination fees were charged, these constituted the major part of the indirect costs.

Table 4 Direct and indirect costs of a cone beam CT (CBCT) examination of a patient with tooth loss prior to implant treatment in different healthcare systems. Costs in Euro

<i>Patient with tooth loss prior to implant treatment</i>				
<i>Direct costs</i>	<i>Cluj</i>	<i>Leuven</i>	<i>Malmö</i>	<i>Vilnius</i>
CBCT equipment	25.28	10.67	29.81	52.14
Maintenance	0	1.00	6.61	9.34
Accommodation	1.29	1.60	6.14	1.82
Labour				
Specialists	3.36 ^a	29.25	17.43	5.92 ^a
Radiographer/dental nurse	0	3.17	9.33	0
Total direct costs excluding maintenance costs	29.93	44.69	62.70	59.89
Total direct costs including maintenance costs	29.93	45.69	69.32	69.23
<i>Indirect costs</i>				
Examination fee paid by patient	58.06	5.61	102.02	78.55
Transport cost for patient or accompanying person	28.06	7.84	15.85	9.55
Patient's time value	4.24	14.97	29.39	11.99
Accompanying person's time value	0.07	0.00	0.22	0.00
Total indirect costs	90.43	28.42	147.48	100.09

^aThe specialist performed both the examination and the report.

Table 5 Direct and indirect costs for a cone beam CT (CBCT) examination of a patient with a lower wisdom tooth planned for removal in different healthcare systems. Costs in Euros

<i>Lower wisdom tooth planned for removal</i>					
<i>Direct costs</i>		<i>Cluj</i>	<i>Leuven</i>	<i>Malmö</i>	<i>Vilnius</i>
CBCT equipment		25.28	10.67	29.81	52.14
Maintenance		0	1.00	6.61	9.34
Accommodation		1.29	1.60	6.14	1.82
Labour	Specialist	3.25 ^a	17.43	17.43	6.01 ^a
	Radiographer/dental nurse	0	9.33	9.33	0
Total direct costs excluding maintenance costs		29.81	44.18	62.70	59.97
Total direct costs including maintenance costs		29.81	45.18	69.32	69.31
<i>Indirect costs</i>					
Examination fee paid by patient		58.06	5.61	102.02	3.01
Transport cost for patient or accompanying person		32.77	2.51	16.17	9.11
Patient's time value		4.74	13.09	23.66	9.42
Accompanying person's time value		0.73	0.55	0.20	0.19
Total indirect costs		96.30	21.76	142.05	21.73

^aThe specialist performed both the examination and the report.

The visit to the radiology department for examination was added on to a visit to another clinic in 30–50% of the patients in Cluj, 23–61% in Leuven and 34–66% of the patients in Vilnius. In Malmö all visits to the radiology department represented separate trips for the patient.

The valuation of the time spent by the patients and, where applicable, by the accompanying person resulted in the highest cost in Malmö, second highest in Leuven, third highest in Vilnius and lowest in Cluj. The range for the average travel distance to and from the radiology clinic for the three clinical conditions was shortest in Malmö (23–28 km), followed by Leuven (21–30 km) and Vilnius (15–47 km), and longest in Cluj (72–126 km).

The average waiting time (in min) per visit in the clinic was estimated to be 25 in Cluj, 19 in Malmö and 10 in both Leuven and Vilnius.

Costs of CBCT examinations of patients with different clinical conditions

The direct and indirect costs of examinations of patients with different clinical conditions within the same healthcare systems varied somewhat except for in Cluj, where the costs were similar for all clinical conditions examined (Tables 3–5). In Leuven, the indirect costs for examinations of maxillary canines with eruption disturbances were higher than those for the two other clinical conditions, arising from cost for the accompanying person's time. In Malmö, the indirect cost for examination of maxillary canines was around half the cost of those of the other clinical conditions, since most patients with maxillary canines were aged below 19 years, the threshold for exemption from examination fees. In Vilnius, the fee for examination prior to implant treatment was much higher than for the other conditions.

Discussion

Little is known of how differences between healthcare systems affect the costs of a diagnostic method. One

reason for this is that there is a considerable variation in the methodology of the cost analysis and the range of costs included in published studies.¹⁴ Thus, the results of different studies are difficult to compare. The approach used in this study was based on three clearly defined steps: identification, measurement and valuation of resources used for a diagnostic examination in oral healthcare. The three steps provide a coherent overview of the calculations and facilitate analyses of different direct and indirect costs that comprise the unit cost of a diagnostic examination and were applied to the three most common clinical conditions giving rise to referral for CBCT examination.¹⁵

Even when using this explicit, transparent costing approach, the measurement and valuation of resources underpinning the calculation of direct and indirect costs is complex and time consuming. Data collection often requires a range of different sources for the required information and the particular sources may differ between systems. In this study, the primary data collection, *e.g.* the provider time by different providers, was performed by different individuals in each system. This may introduce problems with the accuracy of data collected in the separate systems resulting from pressures of work, and other system-specific conditions.

The radiology clinics in Cluj (Romania), Leuven (Belgium), Malmö (Sweden) and Vilnius (Lithuania) were selected to participate as they represent different healthcare systems. The countries constitute different institutional structures and political contexts. The percentage of the gross domestic product (GDP) spent on healthcare is around 5% in Romania and Lithuania, approximately half of the corresponding share of GDP in Belgium. Similarly, the government share of healthcare expenditure ranges from 66% in Romania to 85% in Sweden.¹⁶

There are few published studies on cost comparisons among healthcare systems in general,⁶ and to our knowledge no studies exist on imaging methods in different oral healthcare systems. Therefore, a compar-

ison of our results of a multicentre study using the same methodology for costing was not possible. We might expect differences in costs associated with different "costs of living" and levels of wealth in the countries being compared, which would lie outside the control of healthcare managers and policy makers. There was, however, no clear association between the estimated costs and the economic well-being of the country as measured by GDP per capita population. So although Belgium had a GDP per capita of €32 091 in 2008¹⁷ it had the lowest average cost per CBCT examination. Hence, in this study variations in cost could not be explained simply by the differences in economic well-being. Instead we need to consider the configuration of service delivery in terms of the equipment used, the staff employed, the integration of the service into existing service delivery, the location of service and healthcare policies relating to direct patient payments.

The estimated direct costs of CBCT varied among the healthcare systems. Differences were due to different prices (price of the CBCT equipment, wage rates) and differences in the types of staff used. Prices of equipment and labour are generally outside the control of decision makers. For example, wage rates are often set through broad collective bargaining mechanisms whereas new technology tends to be most expensive when it is first introduced, with prices falling, often substantially, as the technology is disseminated. Hence early adopters such as Vilnius (purchased in 2002) paid a higher price than Cluj (purchased in 2006) for equipment from the same manufacturer. Paying a "higher price" is, however, not without some corresponding benefit, since the CBCT service has been available for use with patients in "early adopting" centres for several years prior to access being made available to patients in "late adopting" centres.

Decision makers may have control over the number of CBCT volumes being performed and the types of staff used. This provides decision makers with opportunities to consider whether similar levels and quality of service could be provided using different configurations of service delivery. More CBCT volumes per machine were performed in Leuven than in Cluj with a similar equipment cost, thus reducing the average equipment cost per volume. Higher volumes per year may represent a wider range of conditions for which CBCT is used, higher need populations, different thresholds for referral, different catchment populations or a combination of these factors. In terms of staff used, the examinations were performed by nurses in Malmö, radiographers in Leuven and radiologists in Cluj and Vilnius. Moreover, Malmö used two nurses per patient while the other centres delivered care using a single provider. Consideration might therefore be given to alternate staff configurations as ways of influencing service costs. For example if the CBCT examination could be performed safely using only one dental nurse, the cost per examination would be reduced by almost €5 assuming no reduction in examination time.

Substituting the specialist in Cluj or in Vilnius with a radiographer for the examination would reduce the cost per examination by €1–1.5.

The accommodation cost per square metre and the space required for the CBCT equipment varied among the healthcare systems, which may be the result of existing physical structure of clinic space. Although the cost per square metre was almost twice as high in Leuven than in Malmö and about ten times higher than those in Cluj and Vilnius, the average cost for accommodation in Leuven was about the same as in Cluj and Vilnius because of the minimal amount of space partitioned off to the CBCT equipment.

Indirect costs

The most significant part of the indirect costs was the examination fee paid by the patients. Patient charges were relatively low in Leuven, but relatively high in Cluj and Malmö. The examination fee paid by the patient also varied according to the clinical condition examined. In Malmö, there was no patient charge for CBCT examinations of maxillary canines with eruption disturbances. In Vilnius, the fee was high for patients with tooth loss examined prior to implant treatment, but low for other clinical conditions. Because patient charges lie outside the control of those responsible for delivering the service, they represent external influences on the observed cost differences between systems and conditions. However, patient charges are likely to influence the volume of examinations performed, and hence the direct cost per examination, unless patients have some form of insurance through which such costs can be recovered. Policy makers at the higher level may need to be engaged in order to understand the impact of patient charges on indirect costs and hence utilization and the impact this may have on direct costs.

The transport cost for the patient was highest in Cluj because of the longer travel distances for patients. The clinic in Cluj serves a large geographic catchment population as the clinic is home to one of only two CBCT machines in Romania. A further factor influencing indirect costs is the patient's (and accompanying person's) time, which is highly dependent on the organization of the service. In Cluj, Leuven, and Vilnius, between 23% and 66% of the patients arrived at the radiology clinic directly from another clinic in the same facility, resulting in a lower average time per patient than in Malmö, where no patients came directly from another clinic. Every patient in Malmö was required to make a separate trip to the radiology clinic for a CBCT examination. Clearly the definition of catchment populations and the integration of services into care episodes provide further opportunities for finding cost savings in the delivery of CBCT examinations.

In conclusion, a cost evaluation of a dental radiographic method cannot be generalized from one healthcare system to another but must take into account the specific circumstances. The estimated cost of a CBCT examination

of patients with different clinical conditions—maxillary canine with eruption disturbance, tooth loss prior to implant treatment and lower wisdom tooth planned for removal—vary considerably across the four healthcare systems studied. In the same way, because costs might differ among systems, an intervention or procedure that is cost-effective in one system might not be cost-effective in

another system, even though the effectiveness of the intervention or procedure is the same in both settings.¹⁸ The cost analysis provides an important input for economic evaluations in comparing costs and consequences of diagnostic methods in different healthcare systems, and for planning service delivery in both public and private sectors.

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IV

The impact of Cone Beam CT on financial costs and orthodontists' treatment decisions in the management of maxillary canines with eruption disturbance

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Running title: Cost and impact of Cone Beam CT

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Summary

Background Examination with Cone Beam CT (CBCT) is common for localizing maxillary canines with eruption disturbance. The benefits and costs of these examinations are unclear.

Objectives To measure i) the proportion of orthodontists' treatment decisions that were different based on intraoral and panoramic radiography (M1) compared with CBCT and panoramic radiography (M2) ii) the costs of producing different treatment plans, regarding patients with maxillary canines with eruption disturbance.

Subjects and methods Orthodontists participated in a web-based survey and were randomly assigned to denote treatment decisions and the level of confidence in this decision for four patient cases presented with M1 or M2 at two occasions for the same patient case.

Results One hundred and twelve orthodontists made 445 assessments based on M1 and M2, respectively. Twenty-four percent of the treatment decisions were different depending on which method the raters had access to, whereof one case differed significantly from all other cases. The mean total cost per examination was €99.84 using M1 and €134.37 using M2, resulting in an incremental cost per examination of €34.53 for M2.

Limitations Benefits in terms of number of different treatment decisions must be considered as an intermediate outcome for the effectiveness of a diagnostic method and should be interpreted with caution.

Conclusions For the patient cases presented in this study, most treatment decisions were the same irrespective of radiological method. Accordingly, this study does not support routine use of CBCT regarding patients with maxillary canine with eruption disturbance.

Introduction

After the third molar, the maxillary canine is the tooth most often affected by eruption disturbance impaction, with a prevalence of between 0.9-3.0% (1-3). If left untreated, maxillary canines with eruption disturbance can cause root resorption on neighbouring teeth, notably lateral incisors, with a prevalence of between 7.7 to 67.6% (4-6). Root resorption occurs when the predentin or precementum becomes mineralized or, in case of the precementum, is mechanically damaged or scraped off (7), which can be the case when an ectopically erupting or retained maxillary canines is present (8). Consequently, patients with this condition frequently receive orthodontic treatment with a range of treatment options being available. The decision on management for these patients requires adequate understanding of the position of the canine and its relation to the rest of the dentition. Such information can only be comprehensively obtained by radiographic imaging. Maxillary canines with eruption disturbance is mostly detected and treated in younger individuals and, as risk from radiation exposure is higher in this age group, it is particularly important that the radiographic examination is justified (9).

Localisation of maxillary canines with eruption disturbance and detection of root resorption of teeth adjacent to the canine is a common indication for examination with Cone Beam Computed Tomography (CBCT) (10,11). This imaging method is, however, associated with a

higher cost (12,13) and involves a higher radiation dose than conventional imaging techniques (14,15), which may include panoramic, cephalometric, occlusal and periapical radiographs. These imaging methods have limitations due to two-dimensionality, superimpositions of anatomy and image distortion. Many of these problems were overcome with the introduction of CBCT. Regarding maxillary canines with eruption disturbance some previous studies found that the use of CBCT led to significantly different treatment plans (16,17) whereas other studies showed no such significant differences (18,19), compared with conventional radiography. In the SEDENTEXCT guidelines for evidence based use of CBCT it was concluded that there was no strong evidence to support using CBCT as the “first line” imaging method in the context of root resorption diagnosis (14).

Currently, there is no available evidence on cost-effectiveness of CBCT imaging of patients with maxillary canines with eruption disturbance. With increasing demands on decision makers to allocate resources efficiently in ways that produce most health gain for available health care technologies (20), this knowledge gap is problematic. Hence, there is a need for well-designed comprehensive studies on the possible benefits of CBCT examinations and their relation to the associated costs. Therefore, the aim of this study was to measure i) the proportion of orthodontists who denoted a different treatment decision based on intraoral and panoramic radiography compared with CBCT and panoramic radiography and ii) the costs of producing different treatment plans, regarding patients with maxillary canines with eruption disturbance.

Subjects and methods

A web-based survey for specialists in orthodontics was constructed in association with a web developer. Invitations to participate were sent by e-mail to all members of the Swedish Orthodontic Society (n= 314) according to the society’s membership directory, with the intention to reach specialists in orthodontics who had at minimum of one-year experience in treating orthodontic patients.

Patient cases

Twelve different patient cases were constructed, describing patients with unilateral eruption disturbance of the maxillary canine with otherwise no, or minor, need for orthodontic treatment, were constructed and included in the survey (Table 1). Each case was based on the following characteristics:

- A subjective treatment need
- One maxillary canine with eruption disturbance and no likelihood for spontaneous eruption
- A complete permanent dentition including the second molars
- Normal sagittal molar relation (Class I)
- Normal skeletal relations between the maxilla and the mandible
- Cephalometric analysis showed normal maxillary incisor inclination

- No subjective need for correction of the maxillary dental midline
- Good oral hygiene

Individual parameters that varied between the cases were; age, gender, left or right maxillary canine with eruption disturbance and any maxillary centreline displacement, are presented in Table 1. In ten of the cases the space deficiency was less than 4 mm in the maxilla indicating no need for tooth extractions. For two cases the space deficiency was at least 8 mm expressing an obvious need for tooth extractions. The assessment of space deficiency and centre line displacement was based on the panoramic radiographs. To do these assessments based on panoramic radiographs is not normal practice but was considered to have small impact on the results of this study.

The cases were presented with two intraoral periapical radiographs obtained at different horizontal angles, panoramic radiographs and CBCT images (see examples in Figure 1) as well as a written report describing the position of the maxillary canine, the distance of the canine crown in relation to the marginal bone, root morphology and any resorption of teeth neighbouring the maxillary canine. Intraoral and panoramic radiographs as well as CBCT-images from patients already examined in a previous study (12) were reviewed, and all patients with unilateral eruption disturbance of the maxillary canine with otherwise no, or minor, need for orthodontic treatment were included in present study. One of the authors (C.L.) a specialist in oral- and maxillofacial radiology assessed the radiographs and wrote the reports. The reports were written for intraoral and panoramic radiographs at one occasion and 1-2 weeks after, the reports on panoramic and CBCT images were written, without knowledge of the first report (Table 2).

Web-based survey

Informed consent to participate in the study was obtained from all orthodontists. Those that agreed to participate received an e-mail with a link to the first part of the online survey. After a further two weeks, they received another e-mail with a link to the second part of the survey. Each orthodontist was randomly assigned to four of the 12 patient cases by the use of digital random function allocating randomized combinations of sequences of four cases with either intraoral and panoramic radiographs or CBCT and panoramic radiographs. Each orthodontist was presented with only four of the twelve cases as this strategy was believed to increase the response-rate. In the first part of the survey two patient cases were presented with intraoral and panoramic radiographs (Method 1=M1) and two patient cases were presented with CBCT images and panoramic radiographs (Method 2=M2). In the second part of the survey there was a switch in the presentation of images which meant that the same patient case was presented with the other imaging methods. To estimate intrarater agreement, 30 of the 112 orthodontists were randomly assigned to answer the survey a third time with the same imaging methods as the first occasion for the same patient case.

The orthodontists were asked about their age, gender and years of experience. They were also asked to make a treatment decision for the four cases they were assigned by selecting one of

following alternatives; 1) no treatment, 2) nonextraction orthodontic treatment, 3) orthodontic treatment including extraction of the first premolar, 4) orthodontic treatment including extraction of the maxillary lateral incisor, 5) orthodontic treatment including extraction of the maxillary canine with eruption disturbance. In addition, the orthodontists had to denote the level of confidence in their decision on a five-point scale; 1) very confident, 2) fairly confident, 3) neither confident – nor unconfident, 4) fairly unconfident or 5) very unconfident.

The viewer program for the CBCT images (i-Dixel One Data Viewer Plus software, J. Morita®, Kyoto, Japan) was available in the online survey enabling the orthodontists to view all CBCT images in all planes (the axial, coronal and sagittal) dynamically by scrolling through the consecutive orthogonal image stack (Figure 2). The CBCT images and the viewer program as well as the responses of the orthodontists were stored on a remote server. The responses were downloaded onto a personal computer for analysis.

The survey started in May 2016 and continued until November 2016. The original e-mail invitation to participate was followed by four reminder e-mails sent via MailChimp® (The Rocket Science Group, Atlanta, US). Some respondents informed us that the e-mails were classified as having low priority, therefore an additional one to four ordinary e-mails were sent (not using MailChimp®). Finally, an attempt was made to contact all non-responders by telephone.

Prior to full implementation of the study, an evaluation group of three orthodontists, one specialist in periodontology, one trainee in dental-and maxillofacial radiology and one external web-developer evaluated the online survey and the associated survey procedures with respect to entering the survey via a link, filling in and saving the answers as well as downloading and viewing the CBCT-images. The orthodontists in the evaluation group also evaluated the relevance of the cases and were not included as subjects in the study.

Cost-analysis

Costing for the radiological methods M1 and M2 was based on the framework for cost-analysis as previously reported (10) with unit costs updated to 2014 (Table 3).

Radiography

The radiographic equipment used for CBCT was; 3D Accuitomo (Morita®, Kyoto, Japan) (90 kV, 5-6.5mA, 1/ 2PI, 9/ 17.5s., 4x4 cm field of view (FOV)) and Verawiew epocs (Morita®, Kyoto, Japan) (80kv, 5mA, IPI, 9.4s, 4x4 cm FOV), for panoramic radiography; Planmeca Pro Max (Planmeca® Helsinki, Finland) (72 kV, 16 mA, 17 s., MAG 1.2) and Verawiew epocs (Morita®, Kyoto, Japan) (65kv, 5mA, IPI, 6.5s, MAG 1.2), and for intraoral radiography Planmeca Intra (Planmeca®, Helsinki, Finland) (60 kV, 8 mA, 0.10-0.20 sec).

Statistical analyses

Intrarater agreement for treatment decisions based on observations of the same patient case using the same imaging methods was estimated in terms of percent agreement per patient case. Kappa statistics (κ) (22) and percent agreement was used to analyse the treatment decision under the different imaging methods. Fisher's Exact Test was used to compare treatment decisions and associated confidence levels when using the different imaging methods. IBM SPSS Statistics (Version 23, Chicago, Illinois, USA) was used for all calculations. Statistical significance was set at a p -value less than 0.01.

Radiographs and CBCT scans included in the survey were anonymised and the responses from orthodontists were recorded anonymously, using a study code number for each orthodontist. The study was conducted in accordance with the ethical principles of the World Medical Association Declaration of Helsinki (2008 version) and approved by the Regional Ethical Review Board, Lund, Sweden (H15606/2008).

Results

Three hundred and fourteen members of the Swedish Orthodontic society were invited to participate in the study. Ninety-three orthodontists were excluded due to following reasons;

- not active as orthodontist (n=30)
- orthodontic resident (n=20)
- not working in Sweden (n=17)
- insufficient contact information (n=10)
- on parental or sick leave (n=9)
- not working with this patient group (n=7)

Of the remaining 221 orthodontists, participation was accepted by 154.

Responses from 42 orthodontists could not be used due to the following reasons: 1) only answered one part of the survey (n=17), 2) no response after four reminders (n=12), 3) could not open the CBCT files / survey (n=7), 4) could not save the answers (n=3), 5) did not approve of the study design (n=2), 6) other reasons (n=1). Downloading and opening the CBCT images, save the answers or open the survey were problematic for some of the orthodontists and this was according to the web-developer due to local factors like the internet connection and virus programmes. Some of the orthodontists that had these problems received the CBCT-images on a USB-memory and a Word-document to fill in their questions.

When the survey closed, 112 orthodontists had answered both parts of the survey with altogether 445 assessments based on M1 and M2, respectively, for the same patient case. Of the 112 participants 64 (57.1%) were women and 48 (42.9%) were men whereof 88 (78.6%) worked in a public dental clinic, 22 (19.6%) in private practice and 2 (1.8%) were university employees. The highest number of participants were found in the age group 36-45, as well as among participants having 1-10 years of experience (Table 4).

Intrarater agreement based on 30 orthodontist's assessments regarding the choice of treatment varied from 50% to 100% using M1 with the lowest level of agreement being for case 10. Full agreement was observed for eight cases (case 2, 3, 4, 5, 8, 9, 11 and 12). Based on M2, the agreement varied between 0% (case 11) and 100% for seven cases (case 1, 2, 3, 4, 5, 8 and 12).

Comparison between imaging methods

The number of assessments varied between 31-44 per case (Table 5). There was 100% agreement regarding assessments for case 8 based on M1 and for case 3 based on M2. The lowest consistency was seen for case 10 based on M1 and for case 2 based on M2 (Figure 3).

The most frequent treatment decision was orthodontic nonextraction treatment, chosen in 66% of the assessments based on M1 and in 64% of the assessments based on M2 (Figure 3). Overall 107 of 445 (24%) treatment decisions were different when based on M2 instead of M1 and case 10 differed statistically significant in from all other cases (Figure 4). Treatment decisions showed a variability in agreement from 100% (case 1) to 12.8% (case 10). For case 10, 34 of 39 (87.2%) treatment decisions were different depending on which imaging method orthodontists had access to (Table 5). κ -values also varied from 1.0 for case 1 to 0.018 for case 10. For two cases (case 3 and 8) no κ -value could be calculated as the same treatment alternative was chosen by all raters but one which means that the percent agreement was high with 97.0% for case 3 and 97.7% for case 8 (Table 5).

The treatment alternatives chosen for case 10 based on M1 were to do orthodontic treatment and to extract the permanent canine in 51% (20 of 39) of the assessments, the first premolar 38%, the lateral incisor in 5% and nonextraction in 5%. In comparison, based on M2 the majority (79%) chose to do orthodontic treatment and extract the lateral incisor with root resorption. In four cases (1, 3, 5, 8) no, or at most two of the treatment decisions were different irrespective of radiological method and these cases had no space deficiency for the teeth or a space deficiency less than 4mm and no root resorption of any tooth adjacent to the maxillary canine.

In six of 445 (1%) assessments based on M1 and in 14 of 445 (3%) assessments based on M2 the orthodontists stated that they lacked information such as clinical photographs, dental casts or examining the patient clinically. In five (1%) assessments based on M1 they stated that they lacked information from CBCT and in eight (2%) assessments that they were uncertain of the presence of any root resorption. Two (0.4%) orthodontists stated that they were unfamiliar with interpretation of the CBTC-images.

The confidence level in the treatment decisions specified according to the five-point scale for the different cases comparing the two radiological methods is illustrated in Figure 5. Pairwise comparisons between cases showed no significant difference regarding confidence level, except for case 2 compared with case 3 and for case 10 compared with case 11.

Cost analysis

The mean total cost per examination was €99.84 using M1 and €134.37 using M2, resulting in an incremental diagnostic cost per examination of €34.53 using M2 (Table 3). Taking into account opportunity cost and depreciation for the radiographic equipment the incremental cost was higher. Using a rate of 3% for both equipment depreciation and opportunity cost of funds increased the incremental cost per examination by €2.79 (7%) whereas a rate of 5% resulted in an increase of €4.75 (12%). Part of the treatment decisions were different (24%) when based on M2 instead of M1. This can be considered a potential benefit for CBCT provided that the additional information is worthwhile for some of the patients and thus, leading to an improved treatment decision. The choice of using M2 implies a probability of 0.24 that the treatment decision will be different compared with using M1. This can be expressed in terms of an incremental cost-effectiveness ratio (ICER) which is a measure of the average additional cost per treatment decision that is different as a result of using CBCT imaging i.e. €143.88.

Discussion

For most of the patient cases the orthodontists chose the same treatment alternative irrespective of imaging method. For one case (number ten) however, a majority of the treatment decisions were different depending on the radiological method which was a significant difference compared with all other cases. This case was the only one exhibiting severe space deficiency in the maxilla and also had root resorption on the lateral incisor adjacent to the canine that was visible only on the CBCT images. This indicates that examination with CBCT and panoramic radiography is may be more beneficial than that of intraoral and panoramic radiography for patients with characteristics like those in case 10. For the majority of the cases however, CBCT examination does not seem to be beneficial in terms of influencing the treatment decision. Furthermore, for most pairwise comparisons between

Provided that the information from CBCT is worthwhile, hence leading to improved treatment decisions, this could be interpreted as a potential benefit to some of the patients. Few treatment decisions however, were different when the orthodontists had access to CBCT and panoramic radiography which makes this method relatively costly.

The choice of an imaging method should be based on a complete understanding of its efficacy, which can be defined as the probability of a test benefiting patients, applied under ideal conditions of use. Diagnostic efficacy can be described as a six-level hierarchy where an acceptable level of efficacy must exist at lower levels to assure efficacy at higher levels (23). Recently two studies evaluated costs and effects regarding radiographic examinations prior to removal of wisdom teeth (13,24). According to our knowledge, this study is the first to assess efficacy related to the costs of radiographic examination of maxillary canines with eruption disturbance. Therapeutic thinking efficacy can be assessed in terms of number of different treatment decisions when comparing different diagnostic methods. This measure must

however be considered as an intermediate outcome for the benefits of an imaging method and should be interpreted with caution (25). Diagnostic methods often tend to focus on the specific impact of the intervention as opposed to the broader health of the patient. Achieving intermediate outcome may, however, lead to cost-effectiveness in the long run and these results could be helpful for decision-makers choosing between methods for the same condition (25).

The radiographic methods frequently used for localisation of maxillary canines with eruption disturbance are intraoral and panoramic radiography using the principle of horizontal or vertical parallax (26). The accuracy of detection of root resorption has been shown to be superior using CBCT compared with intraoral radiography (27,28). A higher diagnostic accuracy in detecting resorption may, however, not be of clinical interest as the long-term prognosis even for severe root resorption is relatively good (29). Furthermore, root resorption of different degrees of severity was found in up to 68% of teeth adjacent to maxillary canines with eruption disturbance, but also on teeth adjacent to normally erupting canines, with a prevalence of over 30% (6). This raises the question whether it is necessary or justified to use imaging methods to identify all teeth with root resorption considering the radiation exposure and financial cost.

Radiological decision-making is a complex process affected by several factors like the properties of the diagnostic method, the diagnostic information, clinicians' perception and experience as well as the anamnesis (30). In this study, patient cases representing typical patients frequently encountered in clinical orthodontic practice were constructed containing information relevant to make a treatment decision. In order to have few variables that would have impact on the treatment decision, only patients with unilateral maxillary canines with otherwise no or minor malocclusion were selected. The assumption was that the information supplied for each case, other than that of the imaging methods, would have little impact on the treatment decision. This approach was supported by the orthodontists with only two dropping out of the study because they did not understand or approve of the cases.

In this study the management chosen by the orthodontists differed markedly for several of the cases when the orthodontists had access to different imaging methods but this did not result in an overall change in the frequency of different types of treatment. Only two cases (2 and 10) showed a profound difference in management with dramatically increased number of extractions of the lateral incisor. For both of these cases the lateral incisor had root resorption only visible on CBCT-images and they were the only cases with severe space deficiency. A study by Bjerklín and Bondemark (2008) (31), showed that a substantial proportion of the orthodontists suggested the first premolar or the permanent canine to be extracted regarding a case with severe space deficiency, even though computed tomography showed root resorption half way to the pulp on the maxillary lateral incisor. In this study however, when receiving information from CBCT about root resorption on the lateral incisor, most orthodontists chose to extract this tooth instead of another healthy or undamaged tooth.

Early management of patients with maxillary canines with suspected eruption disturbance has been shown to have better prognosis compared with that of adult patients (32). The patients included in this study were 13-14 years old with unilateral maxillary canine with eruption disturbance whereas previous studies also included adult patients with a mixture of uni- and bilateral maxillary canines with eruption disturbance (16-19). Furthermore, only two other studies used intraoral radiographs as part of their conventional imaging (14,15). Due to these differences, the results of the present study is difficult to compare with that of previous studies.

Previous studies have shown significantly higher confidence level in the treatment planning based on CBCT compared with panoramic radiography (19,33,34). This study, with considerably more raters, showed no clear evidence that the confidence was improved by CBCT. A reason for that could be that all orthodontists were well-trained and confident in their decisions irrespective of imaging method. Hodges et al. (2013) (34) found that there was a greater increase in confidence when the observers already used CBCT frequently in practice and it could be that the orthodontists in this study did not frequently use CBCT. Only two orthodontists however, stated that they were unfamiliar with interpreting CBCT-images. Another study on endodontic diagnosis found no clear evidence that confidence was improved by CBCT (35) but these results may be due to the observers being general dentists rather than specialists. Clinicians often place great value on results of a diagnostic method that does nothing more than reassure them (23) but it is questionable whether this should be an indication for radiographic examination of young patients with maxillary canines with eruption disturbance. Indeed, the definition of “justification” in radiation protection explicitly requires benefits to the patient or society in general, but does not include benefits to the clinician (36).

Cost-analysis

The mean incremental cost per examination for M2 in the present cost-analysis was lower than that in a previous cost-analysis from 2012 (12). The main reasons for this is the lower purchase price of the new CBCT machine, and the increased volume of tests performed using the machine. Although the cost-analysis in this study included opportunity cost of funds and the depreciation of capital equipment, which resulted in an increase of the incremental cost per examination, this was more than offset by the reductions arising from the lower purchase price and increased volume of patients.

The cost-analysis included opportunity cost of funds and cost for depreciation of capital equipment which involved an adjustment to the figure obtained in a previous cost-analysis (12). The incremental cost per examination of €34.53 was lower than the €46.58 reported in the cost-analysis from 2012. The main reasons for that is the 12% reduction of the purchase price of the CBCT machine and the 30% increase in the number of CBCT examinations, thus spreading the capital costs of the machine's purchase among a higher number of examinations. The increase in number of CBCT examinations may be due to an increase in

the catchment area and/ or to increased capacity of clinical staff to operate the technology, as well as an increased demand from referring clinicians.

Conclusions

Only a proportion of patients might benefit from CBCT in terms of a changed treatment plan. It remains to be determined whether for this sub-group the change in treatment plan would lead to better outcomes. Furthermore, the study presented here raises the possibility of identifying high yield selection criteria for CBCT in the context of patients with maxillary canines with eruption disturbance. Accordingly, this study does not support routine use of CBCT regarding patients with maxillary canine with eruption disturbance.

Acknowledgements

The authors gratefully acknowledge all orthodontists that participated in the study as well as the persons who were part of the evaluation group.

This study was supported by the European Atomic Energy Community's Seventh Framework Programme FP7/2007–2011 under grant agreement no 212246 (SEDENTEXCT: Safety and Efficacy of a New and Emerging Dental X-ray Modality).

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Table 1 Characteristics of the 12 patient cases included in the survey. Assessment of space deficiency in the maxilla, centre line displacement, angulation of the canine to the midline and the overlap of the canine in relation to the adjacent incisor/ -s was based on the panoramic radiographs.

Case	Age	Gender	Canine	Space deficiency in the maxilla	Centre line displacement in the maxilla	Angulation of the canine to the midline	Overlap of the canine with adjacent incisor/ -s
1	14	M	13	Small <4mm	1-2 mm to the right	40°	Lateral
2	13	M	13	Severe >8mm	2 mm to the right	40°	½ central
3	13	F	23	No	-	40°	Lateral
4	13	F	23	No	-	53°	Lateral
5	13	M	13	No	-	42°	Central
6	14	M	23	No	-	62°	Central
7	14	M	23	Small <4mm	1 mm to the left	11°	No
8	13	F	13	No	-	30°	½ central
9	13	F	23	No	-	56°	½ lateral
10	13	F	23	Severe >8mm	-	38°	½ central
11	14	F	23	Small <4mm	1-2 mm to the right	21°	½ lateral
12	14	F	23	Small <4mm	-	38°	Lateral

Table 2 Report based on images from the 12 patient cases using intraoral and panoramic radiography or (M1) or CBCT and panoramic radiography (M2). Estimation of the amount of resorption was based on the index suggested by Ericson and Kurol (2000)(21).

Case	Horizontal position of the canine		Bucco-palatal position of the canine		Vertical level of the canine crown-tip- distance from the bone crest		Displacement of the canine root		Resorption of teeth adjacent to the canine	
	M1	M2	M1	M2	M1	M2	M1	M2	M1	M2
1	Mesioangular	Mesioangular	Palatal	Palatal	Broken through marginal bone	Broken through marginal bone	No	No	No	No
2	Mesioangular	Mesioangular	Palatal	Palatal	In level with marginal bone	In level with marginal bone	No	No	No	Slight
3	Mesioangular	Mesioangular	Palatal	Palatal	3mm	1mm	No	No	No	Slight
4	Mesioangular	Mesioangular	Palatal	Palatal	3mm	1mm	No	Mesially in the apical part	No	Slight
5	Mesioangular	Mesioangular	Palatal	Palatal	2mm	Broken through marginal bone	No	No	No	No
6	Mesioangular	Mesioangular	Palatal	Palatal	10mm	8mm	Superiorly in the apical part	Superiorly in the apical part	No	Slight
7	Vertical	Vertical	Central	Central	In level with marginal bone	In level with marginal bone	No	No	No	Slight
8	Mesioangular	Mesioangular	Palatal	Palatal	3mm	1mm	No	No	No	No
9	Mesioangular	Mesioangular	Palatal	Palatal	5mm	3mm	No	No	Probably severe	Severe
10	Mesioangular	Mesioangular	Palatal	Palatal	5mm	2mm	No	No	No	Moderate
11	Vertical	Vertical	Central	Central	3mm	1mm	Mesial direction in the apical part	Buccal direction in the apical part	No	No
12	Mesioangular	Mesioangular	Palatal	Palatal	1mm	Broken through marginal bone	Mesially along the entire root	Mesially along the entire root	No	No

Table 3 Distribution of direct costs per examination based on CBCT and panoramic radiography (M2) compared with intraoral and panoramic radiography (M1). Cost to the provider is presented with no opportunity cost or cost for depreciation as well as with opportunity cost and cost for equipment depreciation using 3 and 5% rate. Costs were estimated using 2014 prices (Euro).

Identified direct costs		Cost per examination		
		M2	M1	Incremental cost for M2
<i>Provider-related costs</i>				
Capital costs	Equipment	24.42	6.48	17.94
	Maintenance	4.96	0.83	4.13
Rental costs	Accommodation	10.78	6.28	4.50
	Image archive			
	Patient record	4.01	2.90	1.11
Labour costs	Specialist	7.31	5.17	2.14
	Dental nurse	26.75	23.18	3.57
Total provider-related costs		78.23	44.84	33.39
<i>Patient-related costs</i>				
Cost for time spent on:	Transport	28.98	28.98	-
	Waiting	7.63	7.63	-
	Examination	9.02	7.88	1.14
'Out of pocket' cost	Cost per km, parking	10.51	10.51	-
Total patient-related costs		56.14	55.00	1.14
Total costs from a societal view		134.37	99.83	34.54
Total cost including opportunity cost and cost for equipment depreciation using 3% rate		138.74	101.41	37.33
Total cost including opportunity cost and cost for equipment depreciation using 5% rate		141.86	102.57	39.29

Table 4 Characteristics of orthodontists (n=112) that answered the survey at two occasions.

Gender	
Women	64 (57.1%)
Men	48 (42.9%)
Working place	
Public dental clinic	88 (78.6%)
Private practice	22 (19.6%)
University	2 (1.8%)
Age (years)	
25-35	7 (6.3%)
36-45	39 (34.8%)
46-55	23 (20.5%)
56-65	33 (29.5%)
>65	10 (8.9%)
Years of practice	
1-10	49 (43.8%)
11-20	38 (33.9%)
21-30	13 (11.6%)
31-40	10 (8.9%)
>40	2 (1.8%)

Table 5 Agreement between imaging methods, intraoral and panoramic radiography (M1) and CBCT and panoramic radiography (M2), regarding treatment alternatives chosen when having access to either M1 or M2 at two different occasions for the same patient case, presented as κ -values and percent agreement (%) for the number of assessments per case (n).

Patient case	K-value	Agreement between M1 and M2 (%)	Number of assessment per patent case (n)
1	1	100	35
2	0.323	64.7	34
3	-	97.0	33
4	-0.053	86.1	36
5	0.479	94.6	37
6	0.632	83.9	31
7	0.253	63.4	41
8	-	97.7	44
9	0.273	69.8	43
10	0.018	12.8	39
11	0.314	66.7	36
12	0.339	80.6	36

Figure 1 Examples of the radiographs presented in the survey for two of the 12 patient cases.

Case 8

Panoramic radiograph

Intraoral radiographs

CBCT images

Case 10

Panoramic radiograph

Intraoral radiographs

CBCT images

Figure 3 Number of treatment decisions (%) per patient case based on 445 assessments using intraoral and panoramic radiography (M1) and 445 assessments using CBCT and panoramic radiography (M2) at two occasions for the same patient cases, distributed per case (1 to 12).

Figure 4 Treatment decisions (%) per patient case by 112 orthodontists based on intraoral and panoramic radiography (M1) or CBCT and panoramic radiography (M2) at two occasions for the same patient cases. The difference between case 10 and all other cases was significant ($p < 0.01$).

Figure 5 Number of treatment decisions (%) per patient case with a different level of confidence rated on a five-point scale. Based on 112 orthodontists’ assessments using intraoral and panoramic radiography (M1) or CBCT and panoramic radiography (M2) at two occasions for the same patient cases. In most (62 of 66) pairwise comparisons between cases no significant differences were seen ($p < 0.01$).

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ISBN 978-91-7104-724-3 (print)

ISBN 978-91-7104-725-0 (pdf)

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