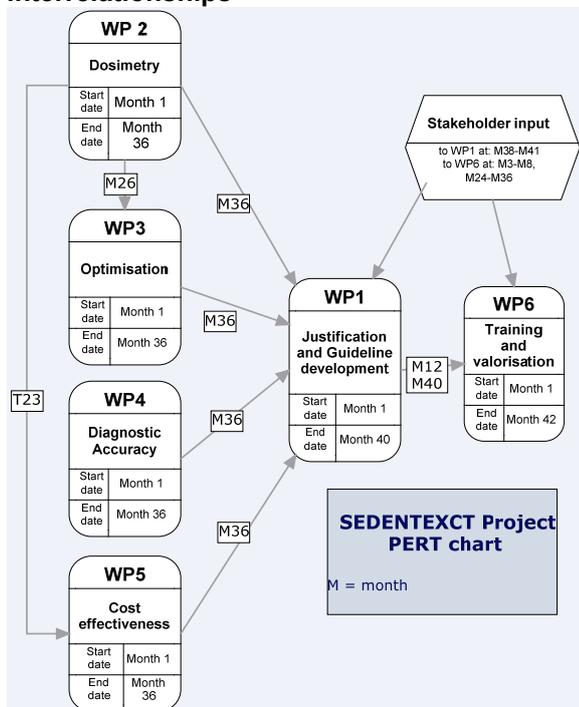


1. Publishable summary

1.1 Introduction

The SEDENTEXCT project (1 January 2008 – 30 June 2011) is focused on enhanced safety and efficacy in the use of Cone Beam Computed Tomography (CBCT) in dental and maxillofacial radiology. In particular, the work plan aims to find solutions to the challenge of this new x-ray imaging modality becoming available to the large community of dentists, medical physicists and other stakeholders in Europe. It is not only a collaboration of seven partner organisations, but also of experts from different disciplines, including radiologists, medical physicists, dentists, health economists, educationalists and other scientists.

Figure 1: Diagrammatic representation of the SEDENTEXCT workpackages and their interrelationships *Project objectives*



The project has a number of linked objectives:

- To develop evidence-based guidelines on the use of CBCT in dentistry, covering referral criteria, quality assurance and other optimisation strategies.
- To determine patient dose in CBCT, with an emphasis on paediatric dosimetry, and personnel dose.
- To perform diagnostic accuracy studies for CBCT in key clinical applications in dentistry.
- To develop a quality assurance (QA) programme, including the development of a tool/tools for QA and to define exposure protocols.
- To make an economic evaluation (“cost effectiveness” assessment) of CBCT compared with traditional methods of dental imaging.
- To conduct valorisation, both dissemination and training, activities via an open access website.

Each of these objectives is addressed by a work package (WP). In turn, these are planned to interact and feed into the cornerstone WPs of guideline development and valorisation, as shown in Figure 1.

1.2 Work performed and results

1.2.1 Management and coordination

The first aspect of any project is its management and coordination. The project has seven partners: the University of Manchester (UNIMAN) (Project Coordinator), the National and Kapodistrian University of Athens (NKUA), “Iuliu Hatieganu” University of Medicine and Pharmacy in Cluj-Napoca (CLUJ), Leeds Test Objects Ltd. (LTO), Katholieke Universiteit Leuven (KULeuven), Malmö University (MAHOD), and Vilnius University (VU).

Financial and administrative management, including quarterly project monitoring, information exchange between project partners and the Commission and implementation of the Consortium

Agreement and Communication Action Plan (CAP), has been performed by the Coordinator (Professor Keith Horner) and Project Manager (Dr. Gillian Armit) at the University of Manchester in an efficient manner. Communication between partners is primarily electronic (email or teleconferencing) or by telephone, supplemented by workshops and twice-yearly Consortium meetings. An independent Ethical Monitoring Committee was established to oversee ethical approvals and ensure that procedures are being followed. Over and above the financial and administrative management, we have enacted the scientific coordination of SEDENTEXCT as planned in the Description of Work (DoW).

A project website address (www.sedentexct.eu) was established and a logo (with colour scheme) (Figure 2) developed to define a project identity:

Figure 2: SEDENTEXCT project logo



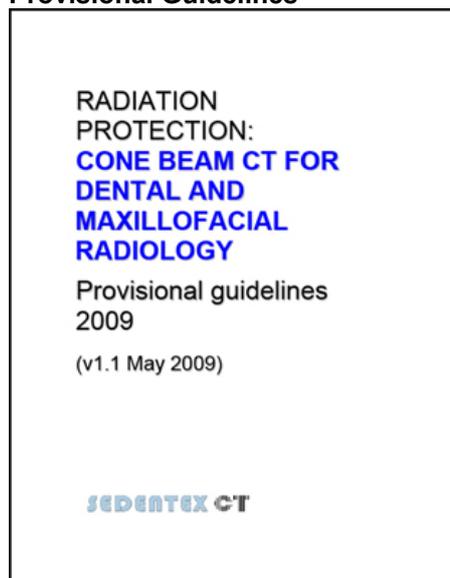
During Year 2, the project's publicly accessible website was enhanced, providing a new home page and additional material and functionality. The SEDENTEXCT Provisional Guidelines for use of CBCT in dental and maxillofacial radiology was published on the project website in May 2009. The site also includes links to the Basic Principles of CBCT Use and some EU countries' national guidance on CBCT. Partners are now able to upload publicly available information about CBCT themselves, as well as upload documents to the project intranet. Apart from acting as a repository for project documentation and material for the WP1 systematic review, the wiki facilities are enabling partners to brainstorm by contributing to shared web pages.

Other dissemination activities have been performed as a means of improving project visibility. The twice-yearly project newsletters, the Basic Principles of CBCT Use and the SEDENTEXCT Provisional Guidelines have been circulated to national and international professional bodies in dentistry and medical physics, and a circulation list has been drawn up to support systematic dissemination in the latter part of the project. The project has generated 14 academic papers and presentations to date, including eight presentations at the 17th International Congress of Dentomaxillofacial Radiology in June/July 2009.

1.2.2 Research activities

WP1 of SEDENTEXCT deals with evidence-based guideline development using systematic review. Its first externally visible output was the development of Provisional Guidelines on CBCT use in dentistry. In the first year, a Guideline Development Panel (GDP) was set up, key topic areas identified for review (Dose and Risk, Diagnostic Reference Levels, Optimisation, Quality standards, Cost/Benefit Analysis, Diagnostic Accuracy Studies and Case reports/ case series) and a protocol refined for critical appraisal of literature. Several search strategies were tested and a final strategy was identified. The initial systematic reviews, performed by pairs of appraisers, were completed in early 2009 and the GDP met in March 2009 to finalise the Provisional Guideline document. A set of 53 preliminary recommendations were generated and graded according to the strength of the evidence base. Following internal and confidential external review, the Provisional Guidelines document was released to the public in May 2009. The Provisional Guidelines have been disseminated widely, including to the European Academy for Dental and Maxillofacial Radiology, the European Federation of Organisations for Medical Physics, and the Article 31 Group of Experts. UNIMAN is continuing to conduct literature searches in preparation for work on the Definitive Guidelines to be produced by the end of the project.

**Figure 3: SEDENTEXCT
Provisional Guidelines**



A major output from the CBCT dosimetry work in Year 2 was the development of standardised dose indices for characterising dose distribution for CBCTs and hence allowing simple conversion to the effective dose to the patient. In association with a dosimetry phantom being developed by the SME partner, this will allow the effective dose to the patient to be established for any CBCT machine. Based on experimental results involving a wide range of CBCT devices and different dosimetry methods and phantoms (i.e. test objects), three different dose indices were defined. Due to the relatively complicated exposure geometry of dental CBCT, there is still a need for an extensive validation of the proposed indices to evaluate their practical applicability and significance as an estimation of patient dose.

As part of the dosimetry work, *in vivo* measurements of the skin dose measurements of about 200 patients has taken place, and work has commenced on scatter dose measurements for personnel and helpers.

A further strand of the dosimetry work is the development of mathematical models using the Monte Carlo N-Particle Transport Code (MCNP), the use of which may offer a less time-consuming alternative to phantoms for determining effective dose. The computational framework has been set up and the simulations have started.

A Quality Assurance (QA) phantom and associated software are being developed for use on all CBCT units and for an extensive range of image quality assessments. The 1st prototype QA phantom has been tested by scanning it on a wide variety of CBCT devices, using multiple exposure protocols where possible. From the analysis of these scans, improvements to the phantom and insert design were identified. The 2nd prototype phantom has been manufactured and implements all improvements in the design that were deemed necessary following the testing of 1st prototype QA phantom. The first version of the QA software has been tested and a number of improvements are being made.

A number of studies have taken place concerning the diagnostic accuracy of CBCT. The *in vitro* segmentation accuracy studies on the surface and trabecular structures have collected data on the deviations of the three dimensional CBCT images from gold standard images from other imaging techniques. The linear accuracy studies measured distances between the teeth cement-enamel junction and bone in CBCT images and compared this with measurements in skulls. In the diagnostic accuracy studies, observers assessed the sensitivity of CBCT for detecting the presence of bone and root lesions.

Recruitment of patients is underway for the *in vivo* diagnostic accuracy studies for the following clinical conditions: implants, impacted canines and impacted third molars. Pre-, peri- and postoperative data have been collected for implant patients.

The first results for the analysis of the monetary costs of CBCT examinations show widely differing costs in four different centres for the use of CBCT for retained canines. The results also show the much higher cost of CBCT compared with conventional imaging approaches. The work is being extended to assess the costs associated with implants and impacted lower wisdom teeth.

Work on quantifying the benefits of CBCT in terms of additional diagnostic information has started. Patient recruitment is complete for the three clinical situations (retained canines, implants and

impacted lower wisdom teeth), and assessment of radiographs for diagnostic accuracy and diagnostic thinking efficacy has commenced.

With respect to the training website development, a Needs Analysis was performed amongst stakeholders (dentists, medical physicists, equipment manufacturers and suppliers) to determine website content and methods of user assessment. This work has informed the development of the prototype website, based on the Drupal Content Management System, providing discussion forums and wiki functionality. Partners are developing website content providing information on CBCT, according to the results of the Needs Analysis. Work is under way to develop on-line training materials and to 'seed' the discussion forum with issues related to the use of CBCT for diagnosis. Ten training modules have been specified and learning outcomes are being developed for each of them. The training website will be formally launched in June 2010, and an awareness-raising campaign is being planned.

1.3 Expected final project results and impact

The end-point of the SEDENTEXCT project is the development, valorisation and dissemination of evidence-based guidelines and the provision of training for stakeholders in the use of CBCT in dentistry using an internet resource, thereby enhancing the safety and efficacy of CBCT. To this end, the work plan is also intended to enhance the necessary evidence base. WP2 provides important dosimetry data for a range of CBCT equipment, with a priority for paediatric dose measurement. A method has been developed for characterisation of dose distribution, using measurements that will be performable in the field, to allow a simple way of effective dose estimation that may be adopted by medical physicists. Such dosimetry data will also be a driver to manufacturers to reduce doses. As such it coordinates with WP3, dealing with optimisation (including aspects of quality assurance and dose limitation). WP2 is also measuring personnel dose. This should be of importance to workers and in setting standards. By the end of the project, a QA programme that is generally applicable to CBCT will be developed. A key part of this will be the production of a marketable phantom for CBCT. A dose reduction strategy for CBCT will be developed. In terms of diagnostic accuracy, the project final results will give clinicians an accurate understanding of the diagnostic capabilities of CBCT compared with traditional techniques for key uses of the technique. This information will have an impact on referral criteria and, it is hoped, will reduce inappropriate examinations of patients. In this respect, the economic evaluation being performed in SEDENTEXCT is also important. We are developing, for the first time in dental imaging, a methodology for economic evaluation of a radiographic technique. At the end of the project, the results will inform dentists, health care providers and third party payment agencies with a better understanding that will reduce inappropriate use of CBCT. All these outputs from SEDENTEXCT will be used to develop and refine a set of Definitive Guidelines on CBCT for dentistry. We anticipate that these guidelines will be seen as authoritative and objective. We also anticipate, because of the involvement of key stakeholder groups at all points, that their impact will be significant upon individual users of CBCT and upon policy-makers nationally and at a European level. The 'valorisation' of the project results, through a process of web-based dissemination and design of a training programme aimed at all stakeholders (dentists, medical physicists, industry and the public), will be the lasting impact of the SEDENTEXCT project. The achievement of "adequate theoretical and practical training" for CBCT has been highlighted as important in raising standards; the freely accessible source of training that will be developed in SEDENTEXCT will make a significant contribution to this.

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