### Project Deliverable

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<th>Project number:</th>
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<tr>
<td>Project Acronym:</td>
<td>SEDENTEXCT</td>
</tr>
<tr>
<td>Project title:</td>
<td>Safety and Efficacy of a New and Emerging Dental X-ray Modality</td>
</tr>
<tr>
<td>Instrument:</td>
<td>Collaborative Project (Small or medium-scale focused research project)</td>
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<tr>
<td>Activity code:</td>
<td>Fission-2007-3.2-01</td>
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<tr>
<td>Start date of project:</td>
<td>1 January 2008</td>
</tr>
<tr>
<td>Duration:</td>
<td>42 months</td>
</tr>
<tr>
<td>Title:</td>
<td>Systematic review complete</td>
</tr>
<tr>
<td>Contractual Delivery date:</td>
<td>30 September 2008</td>
</tr>
<tr>
<td>Actual Delivery date:</td>
<td>30 January 2009</td>
</tr>
<tr>
<td>Organisation name of lead beneficiary for this Deliverable:</td>
<td>UNIMAN (University of Manchester)</td>
</tr>
<tr>
<td>Document version:</td>
<td>V1.0</td>
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#### Dissemination level:

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<tr>
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<tr>
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</tr>
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Authors (organisations):

Keith Horner (UNIMAN): SEDENTEXCT Co-ordinator
Vivian E Rushton (UNIMAN): WP1 Lead

Abstract:

The aim of Work package 1 is to develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development uses systematic review and established methodology, involving stakeholder input.

As a first step in this process, a systematic review was conducted of scientific literature related to CBCT in dentistry. A multidisciplinary team was formed from individuals from all Partners who identified key topic areas for review. The protocol for the systematic review was further refined by setting a standard that each item of literature would be reviewed by at least two individuals, with a mix of specialists according to the topic area. Papers designated as “case reports/ case series”, that would clearly not satisfy inclusion criteria for diagnostic accuracy studies, would still be included in the review, undergoing a less rigorous review procedure.

A robust search strategy was eventually defined after repeated variations, yielding 241 papers (by September 2008). An ongoing update process of papers has been followed. Three proformas were devised to allow critical appraisal and grading of evidence obtained. Two scientists performed appraisal of each paper.

The systematic review has yielded the evidence required to allow the development of provisional evidence-based guidelines for CBCT, the next stage in Work package 1.
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1. The Context

1.1: SEDENTEXCT Aims and objectives

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

1. To develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development will use systematic review and established methodology, involving stakeholder input.

2. To determine the level of patient dose in dental CBCT, paying special attention to paediatric dosimetry, and personnel dose.

3. To perform diagnostic accuracy studies for CBCT for key clinical applications in dentistry by use of in vitro and clinical studies.

4. To develop a quality assurance programme, including a tool/tools for quality assurance work (including a marketable quality assurance phantom) and to define exposure protocols for specific clinical applications.

5. To measure cost-effectiveness of important clinical uses of CBCT compared with traditional methods.

6. To conduct valorisation, including dissemination and training, activities via an ‘open access’ website.

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

1.2: Work package 1 (WP1) objectives

- to perform a systematic review of CBCT based on ‘dose and risk’, ‘diagnostic accuracy’ and ‘quality assurance’
- to develop provisional guidelines to input into WP6.
- to incorporate knowledge obtained from the results of SEDENTEX CT study
- to develop definitive referral criteria and guidelines on quality assurance, optimization to input into WP6.

1.3: Deliverable 1.1

“Systematic review complete”. This Deliverable forms the basis of the WP1, being the acquisition of the information required to develop provisional guidelines on the use of CBCT in dentistry.
2. The Methodology

This section describes the work performed.

2.1: The establishment of the Guideline Development Panel (GDP)

A multidisciplinary team was formed from individuals from all Partners with the exception of Partner 4. The GDP includes a variety of stakeholders, including dentists, dental radiologists, medical physicists and oral and maxillofacial surgeons (from UNIMAN and beneficiaries NKUA, UMFCLUJ, KUL, MAHOD and VU), representing the many specialties that routinely work with CBCT. The membership was derived from colleagues attending the first SEDENTEXCT meeting held in Leuven in January, 2008. Following the Description of Work, key topic areas were confirmed as needing to be covered in the review. These are summarised below:

- Dose and Risk
- Diagnostic Reference Levels
- Optimisation
- Quality standards
- Cost/Benefit Analysis
- Diagnostic Accuracy Studies
- Case reports/ case series

The protocol for the systematic review was further refined at the Leuven meeting by setting a standard that each item of literature would be reviewed by at least two individuals, with a mix of specialists according to the topic area (i.e. two clinicians for diagnostic accuracy studies; physicists for dosimetry studies, etc.). A decision was made that papers designated as “case reports/ case series”, that would clearly not satisfy inclusion criteria for diagnostic accuracy studies, would still be included in the review, requiring a different assessment proforma.

2.2: Identification of the Literature

It was decided that the Panel would follow SIGN (2004) methodology. The WP1 Lead, in combination with a specialist in Evidence-based Oral Health Care performed an initial search for any existing guidelines. Searches were then performed in:

- the FDI guideline database (www.fdiworldental.org)
- the National Guidelines Clearing House (www.guideline.gov)
- Medline
- Embase
- Scopus
- Web Science.
The search strategy has been designed for use on MEDLINE (1950-) and adapted for use on the following:

- EMBASE (1980)
- Cochrane Oral Health Group’s Trials Register
- The Cochrane Central Register of Controlled Trials (Central)
- Web of Science
- Scopus
- UK Clinical Research Network
- Clinical Trials.gov
- Register of Controlled Trials (www.controlled-trials.com)
- NICE guidelines (www.nice.org.uk)

Also ‘grey literature’ has been evaluated using SIGLE (until 2005) (opensigle.inist.fr/) and FADE (www.fade.nhs.uk/).

The initial ‘scoping’ search strategy was found to be unhelpful as it was not specific in identifying papers relating to the dental uses of CBCT. Numerous publications relating to non-dental use/ radiotherapy were included. The refinement of the search strategy to derive those papers related to dental cone beam computed tomography contributed to a loss of four weeks overall. However, the Work Package lead was able to derive a small number of dental papers from each of the eleven ‘scoping’ searches undertaken. The search strategy was finally refined using controlled vocabulary e.g. MeSH and free text words. This (Table 1) proved successful in including all papers related to the use of CBCT.

**Table 1: Search strategy developed for use in the SEDENTEXCT project**

<table>
<thead>
<tr>
<th>1</th>
<th>cone beam computed tomography .mp</th>
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<tbody>
<tr>
<td>2</td>
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<td>3</td>
<td>volumetric tomography.mp</td>
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<tr>
<td>4</td>
<td>digital volumetric tomography.mp</td>
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<tr>
<td>9</td>
<td>cone-beam ct.mp</td>
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<tr>
<td>10</td>
<td>cone beam imaging .mp</td>
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<td>or/1-13</td>
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<tr>
<td>16</td>
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<tr>
<td>17</td>
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</tr>
<tr>
<td>19</td>
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</tbody>
</table>

6 SEDENTEXCT D1.1 Report
The results of searches were imported into Endnote (version 9) and coded according to the key topic areas.

The initial search strategy was completed one month late (M1.2), but the search itself was completed on time (M1.3). Searches have been repeated each month to provide an update on the literature. The screening of relevant papers has provided the Guideline Development Group with a total of 241 papers as of the end September 2008. These papers have been categorised as detailed in Table 2:

<table>
<thead>
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<th>Category of paper</th>
<th>Number</th>
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<td>Diagnostic Accuracy</td>
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<tr>
<td>Dose and Risk</td>
<td>16</td>
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<tr>
<td>Quality Assurance</td>
<td>26</td>
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<tr>
<td>Optimisation</td>
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<tr>
<td>Case reports, case series</td>
<td>146</td>
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</table>

2.3: Data extraction/quality assessment

Papers for review were posted as PDF files on the website intranet in batches, allocated to the Guideline Development Panel members (1 and 2).

Figure 1: Page from SEDENTEXCT intranet showing reviewers in WP1
Proformas for data extraction were developed and piloted by members of the Manchester team. These were also downloadable from the project intranet (http://www.sedentexct.eu/intranet).

In the “Description of Work”, the completion of the systematic review (D1.1) was planned for Month 9 (30 September 2008). In view of the delays detailed in the Annual Report of the project, the actual Delivery date was at the end of Month 13 (31 January 2009).

2.4: Forthcoming work and input to the project

The systematic review has now been fed into the process of Provisional Guideline Development, as described in the “Description of Work”. A two day meeting has been arranged of the Guideline Development Panel in March 2009, at which Provisional Guidelines will be formulated, leading to Deliverable 1.2 of the project.
Appendix 1: Review proforma for Diagnostic Accuracy studies
Appendix 2: Review proforma for general use

<table>
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<tr>
<th>Study Details</th>
<th>Study Design</th>
<th>Aims and methods</th>
<th>Results and Author’s Conclusions</th>
<th>Comments</th>
<th>Suggested Grader: A-E</th>
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<tr>
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<td>Aim:</td>
<td>Method:</td>
<td>Results:</td>
<td>Strengths:</td>
<td></td>
</tr>
<tr>
<td>First author/year</td>
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<td></td>
<td>Conclusions:</td>
<td>Weaknesses:</td>
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GENERAL ASSESSMENT FORM FOR SEDENTEXCT PUBLICATIONS
Appendix 3: Review proforma for Case studies and case reports

### CASE REPORT AND CASE SERIES REVIEW

<table>
<thead>
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<th>Paper No:</th>
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<tbody>
<tr>
<td>First author and year of publication:</td>
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</tr>
<tr>
<td>Clinical area:</td>
<td></td>
</tr>
<tr>
<td>Number of cases presented:</td>
<td></td>
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</table>

**Case selection:**
1. Consecutive
2. Non-consecutive
3. Unknown/unclear

- Implications of the case are important?
  - Yes
  - No

- Uniqueness of case(s):

- Implications of the case are clearly delineated?

- Literature review is adequate?

- Important addition to the literature?
  - Yes
  - No

**Key points:**

**Overall assessment:**
A. Valuable information from consecutive case series
B. Valuable information from case series where selection process is unclear
C. Equivocal value (small series/ unclear or no apparent systematic selection process)
D. Adds little or nothing to existing knowledge
Appendix 4: reviewed papers


Araki, M., S. Kameoka, et al. (2007). "Usefulness of cone beam computed tomography for


Howerton, W. B., Jr. and M. A. Mora "Use of conebeam computed tomography in dentistry." General Dentistry 55(1): 54-7; quiz 58.


Nakajima, A., M. Murata, et al. (2007). "Development of three-dimensional FE modeling system from


