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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADJ</td>
<td>Amelodental junction</td>
</tr>
<tr>
<td>BMC</td>
<td>Bio-Medical Central</td>
</tr>
<tr>
<td>BASCD</td>
<td>British Association for the Study of Community Dentistry</td>
</tr>
<tr>
<td>CD ROM</td>
<td>Compact Disc, Read-Only-Memory</td>
</tr>
<tr>
<td>DiFOTI</td>
<td>Digital imaging Fibre-Optic Trans-illumination</td>
</tr>
<tr>
<td>DMFT/dmft</td>
<td>Decayed Missing Filled Teeth (PERMANENT/primary)</td>
</tr>
<tr>
<td>DMFS/dmfs</td>
<td>Decayed Missing Filled Surfaces (PERMANENT/primary)</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
</tr>
<tr>
<td>DPH</td>
<td>Dental Public Health</td>
</tr>
<tr>
<td>DT/dt</td>
<td>Decayed Teeth (PERMANENT/primary)</td>
</tr>
<tr>
<td>ECM</td>
<td>Electronic Caries Monitor</td>
</tr>
<tr>
<td>FDI</td>
<td>Fédération Dentaire Internationale</td>
</tr>
<tr>
<td>FOTI</td>
<td>Fibre-Optic Trans-illumination</td>
</tr>
<tr>
<td>FT/ft</td>
<td>Filled Teeth (PERMANENT/primary)</td>
</tr>
<tr>
<td>GDP</td>
<td>General Dental Practice/Practitioner</td>
</tr>
<tr>
<td>ICC</td>
<td>Intra-class Correlation Co-efficients</td>
</tr>
<tr>
<td>ICDAS</td>
<td>International Caries Detection and Assessment System</td>
</tr>
<tr>
<td>ID</td>
<td>Identity</td>
</tr>
<tr>
<td>IOTN</td>
<td>Index of Orthodontic Treatment Need</td>
</tr>
<tr>
<td>LED</td>
<td>Light Emitting Diode</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>MT/mt</td>
<td>Missing Teeth (PERMANENT/primary)</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
</tr>
</tbody>
</table>
PhD  Doctor of Philosophy
QLF  Quantitative Light-induced Fluorescence
RCT  Randomised Control Trial
SEDENTEXCT  Safety and Efficacy of a New and Emerging Dental X-ray Modality
SD  Standard Deviation
SiC  Significant Caries Index
SLR  Single Lens Reflex
SPSS  Statistical Package for Social Sciences
Stata  Data Analysis and Statistical Software
WHO  World Health Organisation
UK  United Kingdom
UniViSS  Universal Visual Scoring System
Epidemiological studies that conform to the highest possible standards of research design are required to provide good quality caries data necessary for disease surveillance, health needs assessments and the evaluation of oral health intervention strategies. Caries detection methods used in such studies should be suitable for “blinding” examiners collecting research data, to exposure or group allocation of participants in order to minimise the introduction of bias. The purpose of the studies in this thesis was therefore to assess the diagnostic performance and the pragmatic applicability of the use of intra-oral photographs as a caries detection method in epidemiological studies.

Phase I compared the caries detection performance of intra-oral photographic assessments with visual examination and histology as the reference standard. Extracted teeth were assessed for caries using visual examination and assessments of photographs. The diagnostic decisions made were compared to histology. The visual examination and photographic assessments method had median sensitivity values of 65.6% and 81.3%; and median specificity values of 82.4% and 82.4% respectively. The two methods both had good intra- and inter-examiner reliability.

The study in phase II compared the assessment of intra-oral photographs as means of detecting dental caries with visual dental examination in 5-year-olds and 10/11-year-olds in an epidemiological survey setting. 5-year-olds and 10/11-year-olds were visually examined. Intra-oral photographs taken of the children’s teeth were also assessed by the same examiners. There was good intra-examiner reliability for both the visual and the photographic methods for all the examiners. However the photographic method was found to be lengthier than visual examination.

Phase III compare caries data obtained from a full mouth visual examination with that obtained from eight, six and four intra-oral photographs of index teeth in two groups of children aged 5 years and 10/11 years. The views of users of the methods (examiners) as well as those on whom the methods were used (children) were also sought using focus group discussions. The examiners found it easier to make caries detection decisions on intra-oral photographs of primary teeth and they suggested that the use of other drying methods are required to improve the utility of photographic method. Generally, the intra-oral camera was well received by the children as a means of caries detection. Caries information obtained from the assessment of eight intra-oral photographs of the primary dentition was comparable to that from full mouth visual examination and may be used as an alternative caries detection method in situations where the visual examination method may not be applicable.
DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.
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Dr Tanya Walsh, for her statistical advice and support; and for her ability to instil clarity of purpose and her encouragement along the way.

Heywood Middleton and Rochdale Primary Care Trust for releasing me from some of my time commitment to them in order to undertake this academic journey; and also for providing me with the support staff I needed for the school based studies, especially Mrs Debra Ridding for facilitating the children’s focus group discussions; Miss Ruth Bardsley and Mrs Janet Dickinson, who helped to liaise with the schools.

Mrs Angela Willasey, the North West bench mark examiner for the NHS Epidemiology surveys, for the many months she spent tirelessly examining the children in all three phases of the studies as the bench mark visual method examiner.

All the examiners who gave their time generously to each examine hundreds of children and assess thousands of intra-oral photographs.
Dr Andrew Taylor who provided bespoke computer software and advice that was essential for the intra-oral photographic data collection.

The Dental Health Unit for providing resources such as toothpaste and tooth brushes for the children who took part in the studies.

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The members of staff of all the participating schools who worked hard to accommodate members of the research team within the demanding routines of busy school life.

The children who willingly participated in the studies.

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DEDICATION

I dedicate this thesis to my father, Joseph Adzah Laryea and my mother Ellen Okailey Laryea, who have taught me that all things are possible to them that believe. They have been an inspiration and a constant source of encouragement especially during this academic journey.
The Use of Intra-oral Photographs in Dental Epidemiology

Chapter 1

The Author and this Thesis
1.0. The Author and this Thesis

1.1. The Author

I completed my dental degree at the University of Manchester Dental School in 1991. After a short period working in the hospital setting to obtain the Fellowship in Dental Surgery (Royal College of Surgeons England), I spent the majority of my working life so far working in the then Community Dental Service. I have always had a keen interest in Dental Public Health (DPH), particularly oral health promotion and epidemiology. This was because even as a dental student, observing the distress of children and their families receiving treatment for caries under general anaesthesia was traumatic and the alternative of spending my working life in attempting to maintain disease free dentitions became more and more appealing. I also became aware and interested in the role played by epidemiology in DPH. I studied for a Masters degree in DPH and was given the opportunity to take on the responsibility for oral health promotion and undertake the NHS epidemiological surveys for Heywood, Middleton and Rochdale Primary Care Trust (PCT), a role I performed for over a decade. During this time I also became a trainer and a benchmark examiner for the NHS epidemiological survey. It was during this time that the York review and the MRC report prompted a focus on how future caries epidemiological studies could strengthen the robustness of data they produced. It was the desire to be a part of the quest for the solution to this, in my view, important question that led me to undertake this study. This study has therefore been undertaken while I have been working as a Senior Dental Officer for Heywood, Middleton and Rochdale PCT and more recently as a Specialist Trainee in DPH with The North Western Deanery.

The study was planned to be undertaken in three phases; an initial phase to validate the proposed caries examination method in an in-vitro study, a second phase in which to try the proposed caries examination method in an in-vivo study and a third phase in which to evaluate the method in different population groups in a trial. It was however identified during the initial in-vivo study that the approach used for the application of the method was too lengthy. The PhD had to evolve to determine ways of making the proposed caries examination method less protracted but still effective.
1.2. Introduction to the Thesis

This thesis is presented using the University of Manchester alternative thesis format sometimes referred to as the journal format. This format allows incorporation of sections that are in a format suitable for submission for publication in a peer-reviewed journal into the thesis. As developing the skills to present one’s work for publication in a peer-reviewed journal is an essential part of the PhD training, the use of the alternative format for the presentation of this thesis seems to have many advantages and few drawbacks.

This thesis has three main sections:

- The literature review
- The main body of the thesis including published and submitted papers
- A section summarising the findings, outlining the implications of the studies within this thesis for policy, service, practice and future research

The literature review covers aspects of dental caries which provide the rationale for the choice of caries detection methods, particularly for use in practice-based randomised controlled trials and dental epidemiology.

The main body of the thesis covers the studies that were undertaken to address the objectives of the thesis. These are presented as papers that have been published, accepted for publication or been submitted to peer-reviewed journals. These are:

- An in-vitro study (Paper 1)
- An in-vivo study (Paper 2)
- A qualitative study (Paper 3)
- A second qualitative study (Paper 4) and
- A second in-vivo study (Paper 5)

These five journal papers each form a separate chapter of the thesis. Although as part of my PhD training I have honed my skills to work in collaboration with others as reflected in the authorship of the papers, I have undertaken the bulk of the work that is presented.
Outlined below are the contributions made by the collaborators on each paper, and the stage of the paper on the route to publication.

### 1.2.1. Paper 1

*Paper 1: Comparison of photographic and visual assessment of occlusal caries with histology as the reference standard by Uriana Boye (UB), Tanya Walsh (TW), Iain A. Pretty (IAP) and Martin Tickle (MT)*

Authors' contributions

UB contributed to the protocol, undertook the coordination and management of the study, took the photographs and wrote the manuscript. TW gave statistical advice, assisted with data analysis and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript.


### 1.2.2. Paper 2

*Paper 2: Comparison of an intra-oral photographic caries assessment with an established visual caries assessment method for use in dental epidemiological studies of children by Uriana Boye (UB), Angela Willasey (AW), Tanya Walsh (TW), Martin Tickle (MT) and Iain A. Pretty (IAP)*
Authors' contributions

UB contributed to the protocol, undertook the coordination and management of the study, took the photographs, trained the examiners on the photographic assessments and wrote the manuscript. AW was the benchmark examiner. TW gave statistical advice, assisted with data analysis and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript.

This paper has been submitted to Community Dentistry and Oral Epidemiology.

1.2.3. Paper 3

*Paper 3: Children’s views on the experience of a visual examination and intra-oral photographs to detect dental caries in epidemiological studies by Uriana Boye (UB), Geraldine R.K. Foster (GF), Iain A. Pretty (IAP) and Martin Tickle (MT)*

Authors' contributions

UB contributed to the protocol, undertook the coordination and management of the study, facilitated some of the focus group discussions, contributed to the data coding analysis and wrote the manuscript. GF provided the required independent assistance with data analysis and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript.

This paper has been accepted for publication by Community Dental Health; September 2011: Boye, U., Foster, G.R.K., Pretty, I.A. and Tickle, M. (in press): Children’s views on the experience of a visual examination and intra-oral photographs to detect dental caries in epidemiological studies. Community Dental Health, doi:10.1922/CDH_2817Boye05 (Appendix 3)
1.2.4. Paper 4

*Paper 4: The views of examiners on the use of intra-oral photographs to detect dental caries in epidemiological studies by Uriana Boye (UB), Geraldine R.K. Foster (GF), Iain A. Pretty (IAP) and Martin Tickle (MT)*

Authors’ contributions

UB contributed to the protocol, undertook the coordination and management of the study, conducted the interviews, contributed to the data coding analysis and wrote the manuscript. GF provided the required independent assistance with data analysis and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript.

This paper has been accepted for publication by Community Dental Health June 2012: Boye, U., Foster, G.R.K., Pretty, I.A. and Tickle, M. (in press): The Views of Examiners on the Use of Intra-oral Photographs to Detect Dental Caries in Epidemiological Studies (Appendix 3)

1.2.5. Paper 5

*Paper 5: Comparison of varying numbers of intra-oral photographs with an established visual caries examination method for use in dental epidemiological studies of children by Uriana Boye (UB), Iain A. Pretty (IAP), Martin Tickle (MT) and Tanya Walsh (TW)*

Authors’ contributions

UB contributed to the protocol, undertook the coordination and management of the study; took the photographs and wrote the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript. TW gave statistical advice, assisted with data analysis and contributed to the manuscript.
This paper has been submitted to BMC Oral Health

A characteristic of the alternative format presentation is that although the individual papers report on different aspects and findings of the studies, the requirements of peer reviewed journals result in there being similarities in methodology and some of the supporting references. This is reflected in the repetitions to be found in the reporting of these sections of the main body of the thesis.

The final section of the thesis is a summary chapter which consists of a reflective exploration of the processes undertaken to deliver the studies within the thesis. It also outlines the implications of the findings of the studies within this thesis for policy, service and practice; and makes recommendations for future research.

Although the formatting of the manuscripts submitted to journals required tables and figures to be positioned at the end of the papers, the tables and figures for each of the papers as included in this thesis have been integrated within the text of each paper in order to facilitate ease of reading. However to avoid duplication in the presentation of references cited in this thesis, the references pertaining to each paper and section have all been collated and presented at the end of the thesis.
The Use of Intra-oral Photographs in Dental Epidemiology

Chapter 2

Literature Review
2.0. Comparison of Visual Dental Examination and the Assessment of Photographs for Caries Detection

2.1. Introduction

Despite the improvements observed and reported in the literature, poor oral health remains a significant public health problem even in high-income countries such as the UK (Petersen, 2009) particularly among disadvantaged population groups. A range of conditions are classed as oral diseases but the most common contributors to poor oral health are dental caries and periodontal disease. Dental caries and its consequence if not managed appropriately can be detrimental to general health and has a negative impact on quality of life (Shidara et al., 2007). As well as the impact on the individual, the prevention and treatment of dental caries requires a substantial allocation from state-funded health budgets. This resource is used by dental public health and related specialties to plan, fund, develop the workforce and deliver adequate dental health services for their populations.

A World Health Organisation (WHO) bulletin reported that estimated costs of treating caries is US$ 3513 per 1000 children in some countries (Sheiham, 2005). The most recent information available from the NHS Information Centre of the UK shows that in England, £1,977m was spent on the National Health Service (NHS) General Dental Services (GDS) in 2005/6.

To improve population oral health and plan dental services, dental public health specialists need to assess and monitor dental disease levels in populations. Dental epidemiological surveys are conducted in many countries to provide the data used for oral health needs assessments on which health planners and commissioners of dental services rely. These studies are also useful for the evaluation of oral health improvement strategies.

The reduction in caries that has occurred globally has been largely attributed to the use of fluoride, especially fluoride toothpaste (Davies et al., 1995). It could be argued that apart from water fluoridation the use of most of the other vehicles for fluoride delivery could actually increase dental health inequalities. This could be because access to and/or the use of these fluoride delivery systems may be dependent on some of the determinants of
oral health inequalities whereas water fluoridation does not require any effort on the part of the target population. Water consumption is universal, thus compliance with water fluoridation is automatic. This implies that to decrease dental health inequalities, particularly the unacceptable difference in levels of dental caries according to socio-economic status, water fluoridation would be the fluoride intervention of choice wherever possible.

To encourage the implementation of new water fluoridation schemes as a strategy to address poor dental health in the UK, the Water Act was revised 2003 to remove difficulties that had plagued the water fluoridation legislation. Leading up to the change in the legislation, the Department of Health, commissioned the Centre for Reviews and Disseminations, the University of York, to carry out an expert scientific review of fluoride and health. The resulting report: A systematic review of public water fluoridation, published in 2000 (McDonagh et al., 2000a) concluded that the available research weighing up the impact of water fluoridation needed to be strengthened. As a consequence the Department of Health requested a Medical Research Council (MRC) working group to make recommendations for further research in this field. The ensuing MRC report published in 2002 made a series of recommendations on how the quality of studies evaluating the impact of water fluoridation could be improved and emphasized the main issues to be addressed. This implied that any new studies of water fluoridation and by extension any studies designed to evaluate the effectiveness of other caries prevention and management interventions should conform to the highest possible standards of research design in order to produce an evaluation near the top of the hierarchy of scientific evidence. This usually necessitates that examiners collecting research data are “blind” to exposure of participants in order to minimise the introduction of examiner bias into the study, as in blinding examiners to group allocation in randomised controlled trials (RCT).

In addition to conventional visual examination, various methods of detecting and measuring dental caries are recorded in the literature. There are the traditional methods such as radiographs and more innovative techniques/technologies such as Quantitative Light-induced Fluorescence (QLF) (Pereira et al., 2009), fibre-optic trans-illumination
(FOTI) (Cleaton-Jones et al., 2001), electronic caries monitor (ECM) (Ashley, 2000) and DIAGNODent which could be considered for their suitability for use in dental caries epidemiological studies which require “blinding”.

Dental caries epidemiological studies have traditionally depended on visual examination. Using this method in ecological studies such as those involving pairing of fluoridated and non-fluoridated areas, the only method of ensuring that the examiners are blind to patients’ attributes such as of their place of residence, and therefore exposure, is probably by transporting the subjects to an examination site located outside the test and control areas (Milsom and Mitropoulos, 1990). Apart from the obvious logistical difficulties of transporting possibly thousands of participants, usually children, between examination posts and their schools in a large study, there would be various ethical considerations such as obtaining parental consent for the large scale transporting of children, and other issues that would be impossible to resolve. For example in studies to evaluate water fluoridation schemes, as water fluoridation is a population-based intervention, individuals cannot be randomly allocated to a test or control group.

There are also potential difficulties that could arise when visual examination methods are used for the assessment of teeth in other settings such as in caries detection when conducting epidemiological studies or dental practice based RCTs on caries prevention. Random allocation of patients to test or control groups, clinical assessment of caries status and collection of caries information could all be very time consuming for a busy general dental practitioner (GDP). To avoid using GDPs to monitor disease and manage the dental care of their patients which would be a potential source of bias for practice based RCTs on caries prevention, external examiners are usually engaged to undertake the examinations at additional cost and disruption to practice service. However GDPs can capture photographic images of their patients at the chair side. The photographs could be allocated to an independent remote “blind” examiner for assessment, thereby reducing disruption and costs as well as minimising bias.

The use of radiographs to ensure examiner “blinding” is a difficult proposition as it is fraught with ethical dilemmas and problems with validity in detecting occlusal caries (Shi
et al., 2000). QLF is more suited to lab based research and clinical work involving very precise measurement of changes in mineralization of tooth-tissue (Meller et al., 2012). ECM is a very technique sensitive caries detection method and its performance can be affected by factors such as the presence of water and tooth temperature and site of the carious lesion (Longbottom and Huysmans, 2004). A systematic review of the performance of laser fluorescence devices for detecting caries showed that commercially available DIAGNODent were prone to giving false positive results (Bader and Shugars, 2004). For such reasons these methods may not lend themselves easily to the requirements of clinical dental assessment in the field.

An alternative method of blinding examiners would be for examiners to inspect digital photographs of participants’ teeth rather than examine the subjects clinically. There is an increase in the use of intra-oral cameras in the clinical setting. A search of the literature showed that intra-oral video camera images (Forgie et al., 2003) as well as intra-oral camera images (Erten et al., 2005) have been used in in-vitro studies for caries detection. There is however little information on the evaluation of this method for use in clinical assessments for the purpose of dental epidemiology and practice based RCTs. There are potential applications if this procedure can produce valid and reliable results. Assessment of intra-oral photographs as a method of caries detection could offer dental epidemiologists and practice based RCT researchers a viable means of “blinding” examiners in the field as well as in practice based RCTs. This will assist with the production of evaluation studies near the top of the hierarchy of scientific evidence.

2.1.1. Search Strategy for the Literature Review

To aid the identification of the relevant publications to inform the ensuing literature review, the following search strategy was employed. Three broad areas of relevance to the research were defined. These areas were

- Caries pathogenesis and pathology
- Caries epidemiology and
Caries detection and diagnosis

Each of these areas was apportioned into sections from which search phrases and terms were identified. For caries pathology and pathology, terms such as causes, associations, risk factors as well as specific terms such as caries biofilm, caries bacteria were used for refining searching for publications. The search refining terms used for caries epidemiology included phrases such as caries trends, caries distribution, and caries impact. For caries detection and diagnosis phrases such as caries detection and diagnosis methods, caries detection and diagnosis techniques and technology, caries indices and indexes as well as specific terms such as visual, histology, radiographs, QLF, FOTI, ECM, DIAGNOdent, imaging and photographs were used. Related terms as well as synonyms were also identified using a database thesaurus and used; for example the synonym of microscopy was used for histology. During the searches the key terms were connected using Boolean Operators (“and”, “not” and “or”) to ensure that the database could properly interpret search queries and allow specifically defined data to be retrieved. The use of the Boolean operators also enabled search queries to be narrowed or broadened as necessary: for example searches were conducted using caries detection “and” caries epidemiology or combinations of terms or phrases from the three broad of relevance. The main database searched was the University of Manchester Library Online Access Catalogue.
2.2. Dental Caries

Dental caries is a disease that affects the dental hard tissue (enamel, dentine and cementum) (Frank, 1990). If not treated or halted caries results in a progressive destruction of the tooth. The biochemical mechanisms of the carious process have been well researched (Selwitz et al., 2007). This has greatly increased the understanding of the aetiology and pathogenesis of disease. This improvement in the knowledge about the disease has been important in informing the development and implementation of strategies to prevent the disease.

2.2.1. Aetiology and Pathogenesis

In the simplest of terms, dental caries is the localized destruction of susceptible, dental hard tissue(s) that occurs when acidogenic bacteria in the biofilm that covers tooth surfaces metabolise fermentable sugars in the mouth (Paes Leme et al., 2006). The acids produced in this process, if not neutralized, decrease the pH (Takahashi and Nyvad, 2008) at the tooth surface. This lowering of plaque pH encourages the loss of ions, mainly calcium and phosphates, from the dental hard tissues (ten Cate, 1992). This process of demineralization over time can result in the destruction of the structure of the dental hard tissues (Frank et al., 1989). The normal biochemical processes that occur in the mouth however ensure that demineralization is counteracted by re-mineralization, the deposition of mineral, mainly calcium compounds, within porous areas of the dental hard tissues at the tooth surface especially when surface organic material has been removed (Robinson et al., 1990). The degree to which the equilibrium is shifted between the processes of demineralization and re-mineralization (Figure 2.1.) determines how the carious process is controlled – its onset and rate of progression (Anderson et al., 1996).
Dental caries is however a complex disease (Fejerskov, 2004). Although the three essential elements i.e. cariogenic bacteria, fermentable carbohydrates and tooth surface have to be present simultaneously for caries to occur, the initiation and progression of the disease is dependent on a myriad of factors that influence these three prerequisites and interact with each other.

2.2.2. Factors Influencing the Development and Progression of Caries

Dental caries is a multi-factorial disease and is influenced by factors such as the bacterial composition of the biofilm, tooth factors, salivary flow rate and composition, consumption of dietary sugars, preventive behaviours and exposure to fluoride. The extent of the influence of factors affecting the caries process varies widely; some factors act directly and the effect of others are more remote. Research in this field continues to inform the prevention and management of the disease. The factors considered here are those that influence the prerequisites for caries within the oral cavity.
2.2.2.1. Bacterial Composition of the Biofilm

The bacterial composition of the oral biofilm is very diverse. Early studies using conventional culture methods implicated streptococcus mutans and lactobacillus species as the most common microorganisms involved in the initiation and progression of dental caries (Loesche, 1986). The results of a systematic review (Tanzer et al., 2001) conducted to assess the literature on microbiological involvement in dental caries, supported the view that streptococcus mutans play a major role in the initiation of coronal caries in both children and adults and also in the aetiology of root caries. The review also found that although its role in the initiation of dental caries was not clear, lactobacilli play an important contributory role. However with the development of advanced techniques for identifying bacteria, more is being revealed about the complexity of the oral micro-flora involved in the caries process. A study (Corby et al., 2005) using some of these newer bacteria identifying techniques compared the bacteria in the plaque of caries-free children to that in children with active caries. It found that, in addition to streptococcus mutans and lactobacillus species, the micro-flora traditionally associated with caries, there was an overabundance of other bacteria in caries-active mouths. These included actinomyces species, fusobacterium species, cardiobacterium species, selenomonas species, atopobium species, haemophilus parainfluenzae and bacteriodetes species. The specific role played by this micro-flora in the onset and the development of caries is not clear. The constituent bacteria within plaque are different depending on the site in the mouth (Aas et al., 2005). It also varies at different depths of a carious lesion (Munson et al., 2004). This probably reflects the role played by the different bacteria at various stages of the carious process. Abundance of these gram positive bacteria in the oral micro-flora is associated with an increased susceptibility to dental caries (Corby et al., 2005). Dental caries is initially reversible and can be arrested with sufficient removal of the oral biofilm (Selwitz et al., 2007).
2.2.2.2. Tooth Factors

The morphology of a tooth and its position in the mouth may affect that tooth’s resistance and susceptibility to caries. Factors prevailing at the time of the development of the tooth can determine its susceptibility to dental caries in the future. Congenital diseases and conditions that result in the malformation of enamel and/or dentine such as amelogenesis imperfecta, dentinogenesis imperfecta and syndromes affecting formation of hard tissues of the body such as osteogenesis imperfecta, predispose to caries (Li et al., 1996). Infant malnutrition has been associated with caries in the primary dentition (Psoter et al., 2005). This could be explained by the fact that infant malnutrition is associated with both enamel and dentine hypoplasia and poor salivary gland function all of which predispose to caries. On the other hand, factors such as the presence of optimum levels of fluoride ions during tooth formation, such as the levels present in those residing in an area with access to fluoridated water, enhances the tooth’s resistance to caries (Singh et al., 2007).

The position of the teeth in the mouth can contribute to their caries susceptibility (Martens et al., 1985). For instance lower primary incisors in infants are rarely affected by caries except in severe early childhood caries. This has been explained by the fact that the tongue largely covers them during feeding thus reducing their contact with dietary components (DenBesten, 2003). Also their position in the mouth ensures that these teeth are constantly bathed in saliva and so benefit from the protective effects of the saliva (Featherstone et al., 1993). Such knowledge could be used in the choice of teeth that could be monitored in an evaluation study of caries prevention interventions.

2.2.2.3. Saliva

The composition and properties of saliva has been widely studied to assess how it influences the caries process. Studies have shown that certain properties of saliva such as its buffering capacity (Llena-Puy, 2006) and composition (Bardow et al., 2005), its flow rate (Tenovuo, 1998) and its ability to inhibit or support the existence of selective microorganisms are very important factors affecting the caries process (Lenander-
Lumikari and Loimaranta, 2000). This is because the colonization of microbial flora on the tooth surface is modified by salivary proteins. High molecular weight salivary proteins bind with oral streptococci and therefore promote their adhesion to the tooth surface whereas low molecular weight salivary proteins promote the aggregation of these bacteria, preventing their adhesion to tooth surfaces and hence their clearance from the oral cavity.

These various properties of saliva are interdependent on each other. For example the composition of saliva is dependent on its flow rate. When the salivary flow rate changes, the concentration of some of its components such as bicarbonates, sodium, magnesium and proteins also change (Nagler and Nagler, 2001). Saliva composition especially its concentration of bicarbonate in turn affects its buffering capacity (Ligtenberg et al., 2006).

A high flow rate and a high buffering capacity enhance saliva’s ability to neutralize acids produced by cariogenic bacteria thus increasing resistance to caries susceptibility. Conditions that result in decreased flow rate e.g. drug induced xerostomia and radiotherapy to the head and neck region increases susceptibility to dental caries (Mese and Matsuo, 2007). Also saliva with a high content of certain ions especially fluoride, is associated with a decrease in caries risk (Kaneko et al., 2006). The widespread use of dental products containing fluoride such as toothpaste influences the concentration of fluoride. Total fluoride exposure is an important confounder that will have to be controlled for in studies evaluating preventive interventions as recommended by the Medical Research Council (2002).

2.2.2.4. Dietary Factors

The influence of diet on oral health cannot be over emphasised. This influence is usually classified as pre- and post-eruptive effects (Kargul et al., 2003). Pre-eruptive nutritional status could affect the caries susceptibility by influencing enamel and dentine formation; tooth eruption and exfoliation dates and formation and function of salivary glands. There are some differences in opinions as to the level of importance of the pre-eruptive effects
of diet on caries susceptibility. Some authors (Peres et al., 2005) have placed high importance on how much social and biological factors including diet in very early life, could influence susceptibility to dental caries later on in life. Biological factors relate to the management of individual caries risk and will not play a significant role in population caries management strategies. Due to the significance of social determinants of health, such findings are more likely to be found among populations in developing nations (Astrom and Okullo, 2003). This is supported by studies (Alvarez et al., 1990, Alvarez et al., 1993) that have reported an association between early nutritional status and increased susceptibility to dental caries. Others (Cleaton-Jones et al., 2000) however, report no such association and attach less importance to the pre-eruptive effect it has on caries susceptibility later on in life, especially in developed countries. Pre-eruptive dietary factors in developing countries where malnutrition is still prevalent could influence the resistance of the teeth to caries in later life (Enwonwu et al., 2004). This is less so in developed countries, where even among socially disadvantaged groups, malnutrition is rare.

The most significant dietary factor shown to have a pre-eruptive effect on resistance of teeth to caries in later life irrespective of socio-economic status is the consumption of fluoride (Groeneveld et al., 1990). Ingestion of fluoride that occurs mainly as a result of residing in an area with the optimal levels of fluoride in the water supply results in the deposition of hydroxyl-fluoroapatite during the formation of enamel, greatly increasing its resistance to caries. Ingestion of fluoride supplements by pregnant women however has not been found to have any beneficial effect on their children’s teeth (Leverett et al., 1997).

Of greater influence on caries susceptibility are the post eruptive effects of diet rather than the pre eruptive effects. The two most significant contributory factors are the frequency of the consumption of simple fermentable sugars and the exposure to fluoride containing substances.

Post eruptive effects of dietary sugars on caries susceptibility is very well established and supported by well-known classic studies and reports (Gustafsson et al., 1954, Wallis, 1962, Gamblen, 1962, Scheinin et al., 1976) and numerous recent studies (Kolker et al., 2007,
Lim et al., 2008, Burt et al., 2006). Frequent consumption of dietary sugars ensures an abundant supply of substrate for cariogenic bacteria to continuously generate acids. This ensures the shifting of the equilibrium between demineralization and re-mineralization in favour of demineralization. The association found between the choices of food and drink frequently consumed and the composition of the microorganism resident in the mouth has been variable. Frequent consumption of carbohydrates has been shown to encourage the proliferation of acidogenic bacteria in the mouth (Grindefjord et al., 1991) (Tinanoff and Palmer, 2000). A study by Burt (Burt et al., 1988) found that children who had a high sugary intake had a higher increment of approximal caries. The average number of daily eating occasions was found not to be related to caries increment, nor was the average number of sugary snacks consumed between meals, but the average consumption of between-meal sugars was related to the approximal caries increment.

Another study (Beighton et al., 1996) found no significant correlations between the types of food ingested and salivary levels of caries-associated micro-organisms except that the frequency of sugary intake was correlated with lactobacillus levels. The salivary levels of mutans streptococci, and lactobacilli have been significantly correlated with poor oral hygiene \( (r = 0.136, p < 0.01) \). Levels of lactobacilli in saliva and frequency of intake were independently and positively related to caries experience. This could be explained by the fact that the use of fluoride toothpaste is related to good oral hygiene.

Exposure to fluoride through various vehicles such as water, milk, salt and dentifrices and its effect on caries susceptibility has also been well researched (Marinho, 2009, Espelid, 2009, Yeung, 2008). The mechanism through which fluoride affects the resistance of the teeth to caries is better understood now and most experts in oral health promotion perceive fluoride as the most important factor in the prevention of dental decay (Kay and Locker, 1998).

In summary, caries is a multifactorial disease. Its inception and rate of progression as well as any effective prevention strategies are reliant on the interactions between the tooth factors, the bacterial biofilm and the environment.
Dental caries is a universal disease that can affect all ages, populations and diverse sections of society to varying degrees. Its effects are manifest in both the hard and soft dental tissues and ultimately the total wellbeing of the individual. In the distant past caries was a disease of the privileged as they had better access to sugar and related foods and drinks. In recent times, post-World War II however; caries has become a disease associated with social deprivation in developed nations (al-Mohammadi et al., 1997, Antoft et al., 1999, Ferreira et al., 2007). There are variations in the prevalence of dental decay according to countries. Globally however there has been a significant decrease in the levels of caries on the whole (Nithila et al., 1998, Narvai et al., 2006). Most authors attribute this decrease to access to and the widespread use of fluoride toothpaste (Cutress and Hunter, 1992). Other contributory factors such as dental health strategies and lifestyle choices such as changes in dietary patterns and improved oral hygiene are considered to have had an impact too (Holm, 1990). The distribution of the disease within a population is dependent on various risk factors. It is also dependent on the dental health measures and interventions that have been implemented within the population.

2.3.1. Distribution and Trends

Information from the WHO Oral Health Data Bank shows a trend of an overall decrease in the prevalence of caries globally. However there are variations in the distribution according to countries and regions as illustrated in the example shown in figure 2.2.

Numerous epidemiological studies have shown a reduction in caries in developed countries. The results of some oral health surveys carried out in the post war decades showed high levels of dental decay (Jackson, 1974, Heloe and Haugejorden, 1981). The increased availability and therefore presumed consumption of sugar among some population groups (Sreebny, 1982) was associated with the increased levels of caries. By the 1970s and 1980s however a decrease in the prevalence of caries was being widely reported in the literature (Downer, 1993, Gordon and Newbrun, 1986). Most of the
A decrease in caries reported was in developed countries with some reports indicating a rise in caries in developing countries. Recent studies conducted in some developing countries have indicated a rise in the levels of caries in these countries (Yabao et al., 2005, Uetani et al., 2006, David et al., 2005).

Figure 2.2: Changing Levels of Dental Caries Experience (DMFT) Among 12-year-olds in Developed and Developing Countries

![Diagram showing changing levels of dental caries experience (DMFT) among 12-year-olds in developed and developing countries.]  
Source: Dr. Poul Erik Petersen, World Health Organization

A systematic review of published data from 1967 to 1997 was conducted (Cleaton-Jones and Fatti, 1999) to establish trends in caries rates in sub Saharan Africa. This showed a primarily downward trend in caries levels. Another more recent systemic review by the same team looking at data from 1970 and 2004 confirmed their earlier finding and they concluded that the perception that dental caries rates are increasing in developing countries could not be supported (Cleaton-Jones et al., 2006).

A joint working group of the WHO and FDI (Fédération Dentaire Internationale) was formed in 1981 to explore the reasons for the marked decline in caries in children and young people that had been observed in a number of developed countries in the 1970s.
This group reported that the most probable explanation for the reduction in caries that had been observed was the exposure to fluoride in its various forms especially fluoride toothpaste (Renson, 1989). Several studies have since been conducted to further investigate this. The findings of these studies have been supportive (Al-Jundi et al., 2006, Jackson et al., 2005). Thus this view is now universally accepted (Ten Cate, 2004).

By the 1990s, a different type of caries distribution among children in developed countries was being reported in the literature. The majority of the disease in some populations was being assigned to a small high-risk group within the population (Pitts and Davies, 1992, Downer, 1994). This led to what became known as the 80-20 phenomenon. It is said according to this dictum, that 20% of the children had 80% of the caries in the population (Murray, 1994). Comparison of the outcomes of population segmentation analyses according to caries experience using the distribution of decayed, missing, filled teeth index scores and the Super Profiles geo-demographic classification (which uses demographical and small area such as post code social grade definitions) have been conducted (Tickle, 2002). The study reported that about half of the population disease was confined to a minority of the population but not to the extent of 80% of the disease in 20% of the population. The study also found that though high caries risk children were more likely to be found in areas of social deprivation, they did not live exclusively in a small number of such areas. Some authors have therefore called for the use of the 80-20 phenomenon phrase to be abandoned (Dugmore, 2006) and the use of this dictum within the literature had diminished. In common with other chronic diseases, dental caries is more common in deprived communities. This is supported by the Marmot Review (2010) which found that there is a social gradient in health: those living in the most deprived communities suffer more ill health than those living in the least deprived communities. Disease and ill health is however not solely confined to the most disadvantaged communities.

The direction of the caries trend especially in developed countries for the past two decades seems to have reached a plateau with no more significant decreases in disease levels. There are reports of increases in disease levels in some instances (Winter, 1990). The increase in caries prevalence according to Bagramian et al (2009) affects primary as well the permanent dentitions. Health organizations worldwide and regionally are
therefore seeking different and acceptable ways in which the knowledge about prevention of dental caries can be implemented to kick-start another downward movement in the direction of the trend of the disease. Knowledge about the distribution of the disease within a population is important in determining the dental health measures and interventions that could be implemented. This is in turn dependent on various risk factors. The role of dental public health specialists in assessing the caries risk of populations is thus an important facet of the process of planning and implementing effective preventive measures.

2.4. Risk Factors

Like all diseases with a complex aetiology, there are factors, particularly social determinants that increase populations’ caries risk. These risk factors are usually not found in isolation. They tend to have common characteristics and influence each other. Some of the most common risk factors associated with dental caries are the same risk factors associated with other chronic diseases (Maltz et al., 2010). This has led to the development of the “common risk factor approach” to health and oral health promotion (Petersen, 2005). This approach has been endorsed by various health organizations and oral health promotion experts (Sheiham and Watt, 2000).

2.4.1. Lifestyle Choices

As already mentioned above, the cause and effect relationship between frequent sugar consumption and dental caries is universally accepted. Therefore the choice of a diet comprising the frequent consumption of foods and drinks high in sugar increases one’s risk of developing dental caries. Children who report frequent consumption of sugary substances have been found to have more caries as compared those who do not (Levine et al., 2007).
Another lifestyle choice that has been identified as a risk factor for dental decay is the maintenance of oral hygiene. This risk factor is more significant for populations residing in areas supplied by non-fluoridated water. Those with poor oral hygiene are more likely to have higher levels of dental decay than those with good oral hygiene (Broadbent et al., 2011). The use of fluoride toothpaste in maintaining good oral hygiene has a topical protective effect against dental caries. Although it has been shown that oral hygiene instruction and frequently repeated professional tooth cleanings could prevent caries (Axelsson et al., 1976), this is very labour intensive and will not be viable as a dental public health intervention. Moreover this study was conducted prior to the widespread availability of fluoride toothpaste.

Cultural and life style choices regarding infant feeding practises are determinants of early childhood caries (Mohebbi et al., 2008). Differences in cultural practises reflected in the fact that in the UK, children from some ethnic minority groups, especially those of South Asian heritage, have a high caries experience in the deciduous dentition than their Caucasian counterparts. In a UK Department of Health national survey of infant feeding among the Asian community (Watt, 2000), overall 2-3% of mothers admitted to adding sugar to their babies’ bottle contents at the age of 9 months. By the time the age of the children reached 15 months, the figure had risen to 10%. This same survey also found that by the age of 15 months at least 90% of Asian children are still using a feeding bottle. This is not consistent with common advice given which states that children should be introduced to a feeding cup at about 6 months and discouraged from using a bottle by the age of 1 year. Children who had prolonged breast feeding were found to have greater risk of early childhood caries as compared to those who did not (van Palenstein Helderman et al., 2006). Other lifestyle choices related to weaning practices increase the susceptibility of Asian children’s deciduous teeth to dental caries. As many branded baby foods contain non-Halal meat products, they are unsuitable as weaning foods for Muslim children. The family diet may be considered too spicy and therefore inappropriate for weaning. Consequently, many young children are fed diets with high sugar content in preference to savoury foods (Bedi, 1989).
There is also a tendency among Asian parents to not use toothpaste when brushing infants’ teeth. A study that compared the effects of health related behaviour on dental health among young Asian children found that residing in a fluoridated area decreases susceptibility to dental caries (Williams and Hargreaves, 1990).

### 2.4.2. Use of Dental Services

The association between dental attendance and the prevalence of dental caries has been studied. There are differing views in the literature regarding the level of the contribution health services have made to the improvement in oral health. A study by Nadanovsky and Sheiham (1995) reported that dental services could account for only 3% to variations in caries levels in 12-year-olds in industrialised countries during the 1970s and early 1980s. This study however used the dentist: population ratio as the only indicator for dental services as other dental service indicators such as provision and coverage of preventive services were not available to use. Some of the reasons identified by other studies for the poor use of dental services and irregular attendance are fear, anxiety and the cost of dental treatment. This tendency is more prevalent among certain communities. For instance, Asian parents have been found to delay taking their children to a dentist until symptoms arise rather than by a child’s first birthday as recommended by the dental profession (Williams et al., 1991b, Williams et al., 1991a).

A study that examined the relationship between dental anxiety and dental attendance found a close association between asymptomatic, irregular attendance pattern, a history of extraction and having a dentally anxious parent (Milsom et al., 2003). Whatever the reasons for infrequent use of dental services, irregular attenders have been found to have higher experience of tooth decay than regular attenders. A strong inverse relationship has been reported between dental caries and contact with primary dental care services (Tickle et al., 2000). The designation of poor use of dental services as a risk factor for dental caries could be due to confounding and could be explained by the fact that regular attendance demonstrates an interest in oral health and good self/home care. Irregular and non-attenders may lose out on receiving oral health advice. Furthermore they may
miss out on any professionally applied preventive interventions such as fissure sealants or fluoride varnishes that are known to decrease the risk to dental caries.

2.4.3. Socio-economic Status

Socio-economic status is described in the literature as a significant risk factor for caries (Locker, 2000). Socio-economic status is closely linked with lifestyle risk factors previously mentioned. Although there are complex explanations for behaviour and lifestyle choices, those from lower socio-economic backgrounds, especially children, have been found in various studies to develop more caries (Pitts, 1998), have fewer fissure sealants placed (Tickle et al., 2007) and have more untreated lesions (Rizk and Christen, 1994) than their counterparts from less deprived backgrounds. A study conducted in Scotland found that increasing deprivation was associated with increasing caries experience. The children from the most deprived areas had significantly more untreated decay and missing teeth. There was however no association found between deprivation and restorative care in 5-year-olds in a population with low levels of restorative intervention (Sweeney et al., 1999).

Another study (Domínguez-Rojas et al., 1993) conducted to investigate possible associations between various factors and caries susceptibility established an interaction between socio-economic status, tooth brushing, and reception of dental care. These were found to be associated with the development of dental caries. Understanding the risk factors associated with dental caries can provide an indication of possible preventive oral health strategies and interventions suitable for specific communities (Grindelbjerg et al., 1995). For communities where inequalities in dental health exist, the use of fluoride, particularly water fluoridation, has been found to decrease inequalities (Brown et al., 1990).

In short, the extent to which the circumstances into which people are born as well as the conditions in which they have to grow and live are shaped by the availability and distribution of resources which determine their oral health. These social determinants of oral health are mainly responsible for inequities in oral health (Watt, 2002).
2.5. Impact of Caries

Even though there have been improvements in oral health worldwide, poor dental health, especially as a result of dental caries remains a problem, especially among communities in areas of social deprivation. The impact of dental caries is experienced by individuals in a variety of ways. There are also implications for society as a whole.

2.5.1. Impact on the Individual

Dental decay in children if left untreated can result in considerable morbidity: pain, infection with associated absenteeism from school (anonymous, 2008). The use of general anaesthesia for extraction of decayed teeth is the choice of treatment for particularly young children who have a number of teeth affected. This can be very distressing for the children involved and their parents (Bridgman et al., 1999). Gazal and Mackie (2007) reported that the level of distress suffered by children appears to be determined by the age of the child and the number of teeth extracted. The urgent treatment provided for children could affect their anxiety levels for potential dental care and could create the non-attenders or irregular users of dental services of the future (Armfield et al., 2006). These are usually the same individuals already disadvantaged in other ways because they are socially deprived further increasing the extent of their misery (Armfield et al., 2009). The effects of factors such as poor oral health, mainly operating early in life is associated with future poor health. This is particularly so in individuals from lower socio-economic backgrounds (Osler et al., 2009).

The association between socio-economic conditions and oral health appears to be a cause and consequence relationship. The experience of difficult socio-economic circumstances in childhood could be a predictor of future poor oral health in adults. This is supported by the conclusion of a longitudinal study (Poulton et al., 2002) that the burden of oral disease experienced by adults could be reduced by protecting children from the effects of socio-economic adversity. The impact of poor dental health including dental caries on the quality of life of adults has also been researched by various studies (Oscarson et al., 2007,
There seems to be an association between poor dental health and dissatisfaction with quality of life indicators. Untreated dental caries can result in pain, infection, loss of days from work, poor self-worth and low self-esteem resulting in the loss of interest in participation in social life.

2.5.2. Impact on Society

Some of the effects of caries experienced by individuals are translated into impact on the communities in which they reside and function. Days off work are lost as parents care for their children suffering the effects of dental pain such as taking their wards for teeth extractions under general anaesthesia. There is also an emotional impact on families when the need for general anaesthesia is identified (Amin et al., 2006) especially as parents become aware of the complications that could occur. Some parents also expressed feelings of guilt as they felt responsible for the caries experience of their children.

The financial burden on health care authorities/systems for the treatment of dental caries and the impact of dental caries can be huge. Conventional methods of managing dental caries can consume significant resource when a large proportion of the population is affected (Edelstein, 2002). In the UK, the main cost to the dental budget is the provision of routine care in the general dental service according to a recent report - the NHS Dental Statistics for England: 2011/12, Third quarterly report - from the NHS Information Centre for Health and Social Care. The gross expenditure increased by 53 per cent between 1997/98 and 2005/06 (£1,293m to £1,977m). The use of dental extractions under general anaesthesia for the management of dental caries is also expensive. Studies that have assessed the cost and effectiveness of preventive measures especially water fluoridation as compared to various ways of managing dental caries show that the former offers significant cost savings and lower caries increment (Kanellis et al., 2000, Griffin et al., 2001).
2.6. Caries Detection, Diagnosis and Measurement

Preceding sections of this review have established that dental caries is a chronic but preventable disease which can be costly to both individuals and health systems. Decisions about caries management in the individual or within a population; the introduction of caries prevention strategies and the evaluation of such interventions will all be dependent on being able to determine the presence of the disease and the ability to measure it at the required level for a particular purpose.

The terms caries diagnosis and caries detection are sometimes used interchangeably in the literature. There are those who believe that the two terms are distinct and should not be used interchangeably: caries diagnosis being defined as “the art or act of identifying a disease from its signs and symptoms” and caries detection is the signs and symptoms identified (Nyvad, 2004). Caries can be an active, progressive disease process in high risk individuals (Figure 2.3.). It starts from very early de-mineralization changes, signs of which are not visually detectable, through to the manifestations of gross dental hard tissue destruction and finally involvement of the pulp.

The pathogenesis of caries is however dynamic and is characterised by phases of activity and inactivity. Carious lesions are therefore described as active or inactive. Teeth have physical, chemical, electrical and optical properties. These properties are affected by the level of activity within a carious lesion. The presentation of the carious lesion can therefore be a reflection of the level of bacterial caries activity.

Variations that occur within the physical, chemical, electrical and optical properties as teeth make the transition from being sound through the different stages of the carious process have led to the development of techniques and technologies for the detection of the disease. These techniques and methodologies, some traditional and others novel, have been validated and are being validated for detecting dental caries along the continuum of tissue damage (Bader and Shugars, 2004, Kuhnisch et al., 2006, Pretty, 2006). The process of detecting and diagnosis of caries needs to be supported by a means of quantifying the detected-diagnosed disease.
2.6.1. Caries Measurement

Measuring is the process of quantifying and categorizing an entity in a standardised way. Caries is not just a single state of disease but a process resulting in a continuum of disease (Featherstone, 2004) starting from the microscopic loss of mineral content from the dental hard tissues that results from an established demineralisation process through to total destruction of the dental tissues including the pulp.

Figure 2.3: Clinical Caries Progression

This continuum of disease has been presented diagrammatically by the “iceberg of dental caries” by Pitts 2004 (Pitts, 2004b) shown in Figure 2.4. The apportioning of caries detections methods to specific levels of caries progression may emerge as being more of a continuum than the discrete manner in which they are depicted on this diagram as further research emerges.

All aspects of the prevention and management of dental caries require processes to determine the presence of the disease, ways of grading the stage along the continuum of disease as well as means of quantifying how much of the disease is present. The determination of all these parameters constitutes caries measurement. The requirements of a caries measurement method would be dependent on what the outcome of the caries assessment will be used for; the requirements of an outcome measure for clinical
management of caries will be different to that required for needs assessment for service planning, disease surveillance or clinical trials. Caries determination can be subjective; as such the importance of accurately assessing agreement within a group of assessors or a single assessor measuring consistently is vital. Whatever the objective for which the caries measurement is undertaken, the methods used should conform to generic acceptable criteria that allow standardisation.

Figure 2.4: Pitts’ “Iceberg of Dental Caries”: Diagnostic Thresholds in Clinical Trials and Practice (From Pitts 2004)

It is therefore necessary that in the consideration of caries measurement thought is given to the concepts of validity, accuracy, reliability, precision, responsiveness, agreement, sensitivity and specificity.
**Validity:**

Validity is the essence of measurement. It is the ability of a test or method to determine what it is intended to detect (Daly et al., 2002). The degree to which a test or method is valid is established by tried and tested research and an understanding of the entity it is supposed to measure. Validity determines the accuracy of the test or method being used for measuring. Methods used in clinical or epidemiological studies should be valid. Different types of validity have been described such as content, criterion, construct and external (Pine, 1997a).

- **Content validity:** is based on the extent to which a measure reflects the specific intended domain of content (of the entity)
- **Criterion validity:** is the extent to which a measure accurately determines an entity as compared to another measure already shown to be an accurate determination for the said entity
- **Construct validity:** is the extent to which there is agreement between a specific measure developed for determining an entity and the theoretical concept from which the measure was developed
- **External validity:** is the extent to which the findings of a study can be applied to other contexts

For the purposes of disease detection or diagnosis however, validation of a method could be considered as an on-going process of ensuring accurate determination of the disease which relates to the purpose (for example disease surveillance, needs assessment or clinical management) for which the measurements are being obtained by the test or method (Pretty and Maupome, 2004a).

**Reliability:**

Reliability is the ability of a test or method to give consistent measurements under consistent conditions (Daly et al., 2002). It determines the precision of the test or method being used for measuring and adds quality to validity. Reliability can be determined for an
individual rater (intra-rater) or within a group of raters (inter-rater) (Pine, 1997b). Intra-rater reliability determines the extent to which an individual consistently measures the same entity using the same method under the same conditions on different occasions. Inter-rater reliability measures the extent to which different people consistently measure an entity using the same methods. The concept of agreement is an expression of reliability. High inter-rater scores mean good agreement which implies that the group of raters are measuring the entity consistently. To allow aggregations and comparisons of data in epidemiological studies involving several examiners there must be high inter-rater reliability and is usually assured through a calibration exercise.

*Sensitivity and Specificity:*

Sensitivity and specificity relate to the accuracy of a detection test or method. The sensitivity of a test or method is the probability of that test to predict correctly the presence of a disease in a population whereas the specificity is the probability of the test to predict correctly the absence of the disease in a population (Pine, 1997a). The concepts of sensitivity and specificity are usually associated with the use of screening tests. When a test reports that a disease is present in an individual who is free of that disease, the result is said to be false positive (Pine, 1997a). A false negative result occurs when the test reports a negative result for an individual who has the disease (Pine, 1997a). False positive and false negative results can have implications. For example the inability of a test to find occult or hidden caries in a patient (giving a false negative result) could have implications for the management of the affected tooth and the care received by that patient. The ideal test should therefore have a high sensitivity and a high specificity. The sensitivity and specificity of a new caries detection test or method can be determined by comparing it to a universally accepted reference standard caries detection test. The reference standard caries detection method or test is the test that is best able to detect the true caries status (Pine, 1997a). In caries epidemiology studies that require the use of multiple examiners, to ensure good inter-examiner reliability, an examiner who has been proven to be accurate at detecting caries with consistently good intra-examiner reliability is nominated as a
bench mark examiner against whom all other examiners are measured or calibrated against (Assaf et al., 2004). For other examiners to calibrate, they are required to obtain high sensitivity and specificity values appropriate for a study using the bench mark examiner’s scores as the reference standard. Studies conducted to validate the caries detection ability of tools or methods tend to use histology as the standard against which the test tools or methods are tested. The use of histology as the reference standard is explored later on in this review.

Receiver Operating Characteristics

Receiver Operating Characteristics (ROC) analysis is a measure of a test’s accuracy that combines sensitivity and specificity but is independent of the prevalence of disease. It is based on a graphic representation of the reciprocal relation between sensitivity and specificity (sensitivity on the y axis and 1-specificity on the x axis). Threshold or cut-off points are computed at which disease is presumed to be present or absent. A set of data is generated of different threshold or cut-off points. This is used to generate the ROC curve which gives a summary of the range of decision thresholds for the test under consideration. The closer ROC curve is to the upper left corner of the plot the greater the overall accuracy of the test because both sensitivity and specificity of the test approaches perfection (Pretty and Maupome, 2004b). ROC analysis may however not show a statistically significant difference because there is little or no difference between the populations and cases studied or because the number of cases used in the study is too small to provide adequate statistical power (Metz, 2006).

2.6.2. Caries Indices

To enable comparisons within and between individuals as well as within and between populations, across time and space, detected caries must be quantified in a standardised way. Dental caries indices are the standardised measures that have been devised to quantify the disease. They measure the incidence, prevalence, and severity of the disease.
Caries indices tend to be numerical, have defined components by which they are indicated and are denoted on a progressing scale with definite upper and lower limits. An ideal caries index should have the following characteristics:

A caries index should be:

*Valid*; that is it should measure caries as an accurate representation and correspond to the different stages of the diseases (Lo, 2010).

*Reliable*; that is it should measure caries in a repeatable way, consistently whether used by the same or different examiners, under standardised conditions at different times (Lo, 2010).

*Sensitive and specific*; it should be able to give a true indication of the presence or absence of the disease. This characteristic of a caries index enables the detection of the disease (Lo, 2010).

*Responsive*; it should be able to detect small changes in caries status to determine either improvement or deterioration (Daly et al., 2002).

*Complete*; it should be able to estimate the number of existing cases of caries in a population or the proportion of the population with caries from a sample.

*Quantify caries*; it should be able to provide a measurement of how much caries there is (Daly et al., 2002). The scale of the measurement could be qualitative (nominal/categorical or ordinal/ordered categorical) or quantitative (interval or ratio).

- A caries index that uses a nominal scale simply lists the different states of caries for example arrested or active caries, and it does not attempt to rank the disease status in order of severity.

- A caries index that uses an ordinal scale of measurement would only classify the disease in order of, for example, progressive severity such as early, moderate and gross caries.
• A caries index that uses an interval or a ratio scale however is one in which numbers that bear a mathematical relation to each other, are used in quantifying caries in a ranked order. An interval scale uses discrete numbers whilst a ratio scale is one that uses a continuous number scale for example the dmft/DMFT index (section 2.6.2.1.).

The ideal index should be amenable to statistical manipulation to give an expression of the disease status of individual in a numerical expression and where required the incidence, prevalence, and severity of the disease in a population (Lo, 2010).

Pragmatic to apply; it should be relatively easy to employ and apply in the field and setting for which it is to be used. It should also be economically viable.

The choice of caries indices will be dependent on the caries detection process which an index needs to support, as well as the purpose for which detection is required. For example a detection method that has a high sensitivity for detecting the very early stages of the disease will be required in practice to promote re-mineralization and as such will need to be supported by an index that records early caries such as the ICDAS index (section 2.6.2.1.), whereas a different technique with both high sensitivity and specificity for detecting outer dentine caries is required to aid decision making about whether to restore a tooth or not and will require an index such as the caries severity index (section 2.6.2.1.).

2.6.2.1 Examples of Caries Indices

The DMFT/dmft Index

A number of caries indices have been developed for use in the clinical setting as well as for dental epidemiology. The best known of these indices which has been in use for over seven decades is the decayed missing filled teeth (DMFT/dmft) index (Jackson, 1950). As its name indicates it quantifies caries by computing the sum of the decayed, missing and filled teeth. It is therefore an expression of the cumulative caries experience. It is used for
caries in the primary dentition (dmft) as well as the permanent dentition (DMFT). A variation of this index, DMFS/dmfs which is more detailed, uses the assessment of tooth surfaces rather than whole teeth. The advantage of the DMFT/dmft index is that it is very simple to use. Also because its use is ubiquitous, it allows comparison of global caries databases. Another advantage of the DMFT/dmft index is that it allows other measures which give additional information such as the treatment index (proportion of a population requiring treatment) and care index (proportion of a population who have received treatment) to be computed (Daly et al., 2002).

The DMFT/dmft index however has some limitations (Sheiham et al., 1987). It assumes that all missing teeth are as a result of caries and does not account for teeth missing for other reasons such as periodontal disease or trauma. It may therefore over-estimate tooth loss as a result of caries. The filled component of the index does not differentiate between restorations placed for preventive reasons and those for restoring damage due to caries. The DMFT/dmft index is cumulative and historical and therefore unable to measure improvement in dental health. Also because the DMFT/dmft index assigns equal weight to all its component measures, it is unable to measure accurately the implications for dental health.

Although the caries diagnostic protocol used in the UK as well as many other countries means that DMFT/dmft index does not take into account early carious lesions, because it is simple to use, it has been the index of choice for numerous epidemiological studies. Some of these studies devised and used modifications of the DMFT/dmft index in an attempt to differentiate between early and late carious lesions (Anaise, 1984). Others (Slade and Caplan, 1999) have advocated that for longitudinal caries studies where more complex information such as cumulative incidence and incidence density, which quantify caries risk and caries rate respectively are required another outcome measure should be used in addition to DMFT/dmft as the latter is too simple for the all potential changes in caries status.
The Significant Caries Index

Another caries index, the Significant Caries index (SiC) was introduced by the WHO in its quest to set targets against which oral health could be improved for all (Bratthall, 2000). The SiC focuses attention on those with the most caries experience in a population. It uses the DMFT/dmft index to determine the third of a population under study with the highest caries experience. The mean DMFT/dmft value of this sub-population becomes the SiC index score of the population. The rationale for this index is that when the oral health of the third of a population with the worst oral health is improved, the oral health of the whole population improves and the “rule” of thirds can be used to continuously improve oral health. As the SiC index is based on the DMFT/dmft index, all the inherent limitations of the latter as an index will be translated into the former. A detailed analysis of caries data globally have showed large pockets of disease in populations with supposedly controlled caries (Nishi, 2002).

ICDAS Index

More recently the International Caries Detection and Assessment System index (ICDAS) has been developed (Ismail et al., 2007). This is an integration of several systems into one standard system for caries detection and assessment. It takes into account the stage of the carious process and an assessment is also made of disease activity at the time of examination. The ICDAS index takes into account very early carious lesions. The ICDAS index has been applied to both primary and secondary dentitions since its introduction to the dental community nearly a decade ago, there has been a proliferation in the literature of caries studies that have used it as one of their caries indices (Pitts, 2004a, Pitts, 2009, Shoaib et al., 2009). It has been reported to have good reproducibility and accuracy for detecting occlusal caries at different stages of the disease (Diniz et al., 2009). A study by the Translation Research into Dental Settings (TRiaDS) Collaboration however found that although most of dental practitioners in their study agreed with the rationale of the ICDAS system they found it difficult to use in practice (Cassie, 2009). The study report did not however elaborate on what the difficulties were.
The Universal Visual Scoring System (UniViSS)

The Universal Visual Scoring System (UniViSS) is one of the most recently developed caries detection methods. The architects of this system attribute its development to work based on publications by Ekstrand (Ekstrand et al., 1998) Nyvad (Nyvad et al., 1999) and the ICDAS criteria. The UniViSS was developed to improve the visual detection and diagnosis of caries. It incorporates assessments for a spectrum of carious lesions at differing stages of progression including both cavitated as well as non-cavitated lesions on all tooth surfaces in both primary and permanent teeth.

The criteria of UniViSS are applied in three systematic steps which are listed below:

1. Assessment of the tooth surface for the detection of a carious lesion and its severity

2. Assessment for discolouration/or colour of the lesion

3. Assessment and the analysis of lesion related factors such as location on the tooth surface and texture as well as patient related factors which reflect caries risk such as age, oral hygiene, nutritional habits and fluoride intake

Although the architects of this system have advocated its possible use in epidemiology, research and in the clinical setting, they acknowledge that the system requires further testing for validity and reproducibility (Kuhnisch et al., 2009a).

2.6.3. Caries Detection Methodologies/Methodological Approaches to Detecting and/or Assessing Caries

There are several processes, techniques and methods described in the literature used for the detection and diagnosis of caries. Just as described above in section 2.6.2. for the caries indices that support the process of caries detection, the ideal properties of a caries detection method or tool are

- validity
• reliability

• sensitivity and specificity

• responsiveness

• completeness

• pragmatic applicability, including:
  
  – *Acceptability*; that is the caries detection tool or method should not cause discomfort, any negative feelings or ill effect in the examined as well as examiners
  
  – *Simplicity* to use specially for epidemiological purposes with no undue associated lengthy procedures
  
  – *Affordability*; that the cost of the caries detection tool or method should reasonable providing maximum utility and benefits relative to amount of investment

2.6.4. Histology as the Reference Standard

The bulk of the structure of the tooth is made up of mineralised tissues consisting of hydroxyapatite crystals. When the equilibrium between the processes of demineralization and re-mineralization is shifted in continual favour of demineralization there is a progressive loss of the hydroxyapatite crystals. This results in the development of porosities within the affected areas starting with the subsurface region of the enamel. Assessment of these changes that occurs in the tooth structure as a result of its interactions with the dental biofilm at the microscopic level has been used by several studies as the reference standard in many studies for validating other caries detection methods (Baseren and Gokalp, 2003, Jablonski-Momeni et al., 2009).

There are various ways to prepare teeth for microscopic assessment. Tooth sections could be prepared either as calcified or decalcified. As there is total loss of both the enamel and
dentine in decalcified sections these tend not to be the specimens of choice for caries research. Traditionally, teeth in their natural state are used for caries studies. They are prepared for microscopy viewing by sectioning and grinding techniques to produce tooth sections of the desired thickness (usually in microns) to provide the required detailed resolution. Serial histological sections (Figure 2.5.), have been used as the reference standard in the validation of other caries detection methods (Manton and Messer, 2007).

Figure 2.5: Serial Histology Sections of a Carious Tooth

Depending on the stage of progression of the carious lesion, both enamel and dentine lesions show up as distinct zones that correspond to the developmental of stages of the lesion as well as the levels of extent of infiltration of carious bacteria (Kawasaki and Okuda, 1990). Histological assessments are aided by techniques that capture the histological images and store them for future reference. One such simple technique is to obtain magnified digital photographs of histological tissue sections by using a digital camera and anti-dazzle macro lens (Jablonski-Momeni et al., 2009).

The preparation and assessment of histological sections is labour intensive and requires complex equipment. Damage that may occur to teeth during the preparation of histological sections results in the loss of caries detection information. This loss of information coupled with difficulty experienced in assessing lesion depth could result in apparent variations in caries detection accuracy (Jablonski-Momeni et al., 2008). These
potential sources of error important particularly in studies concerned with validation of methods used for the detection of early enamel lesions.

2.6.5. Visual Examination

The most common and traditional method of detecting and diagnosing dental caries is by an unaided visual inspection of the tooth surfaces (Angmar-Mansson and ten Bosch, 1993). The tooth is examined for the identifiable signs usually pertaining to the disease such as shadowing that results from increase in enamel translucency, dark or white chalky areas of opacities and frank cavitation (Ekstrand et al., 2001). Visual examination on its own can be prone to detection imprecisions especially where early carious lesions on occlusal surfaces are concerned (Milicich, 2000). This could be explained by the fact that the morphology of pits and fissure where occlusal caries tends to start can make unaided visual caries detection difficult. These imprecisions are reflected in the varying sensitivity and specificity values found by different studies. Although specificity tends to be high with this method, sensitivity is low (Ewoldsen and Koka, 2010). For example in a study which compared visual examination to histology as the reference standard sensitivity and specificity values of 62% and 84% were reported (Lussi, 1991). These values were found to be 12% and 93% in another study that investigated the diagnosis of fissure caries without cavitation (Lussi, 1993). These inaccuracies can be reduced by the use of detection aids. The tactile information gained by running an instrument such as a probe across the lesion is thought to aid visual detection although Bader et al. (2001) found no evidence to suggest any advantage gained by using tactile aids to supplement visual detection. Inserting a probe into a cavity to check for stickiness as a way of diagnosing caries is considered to be outdated as it is believed to accelerate development of early caries (Neuhaus et al., 2009).

Magnifying implements such as loupes are now being employed more frequently by clinicians to aid detection (Mamoun, 2009). Some presentations of dental caries can be similar in appearance to other non-carious lesions. Early enamel carious lesions could present as white spots similar to enamel opacities resulting from mild fluorosis. In such
cases the experience of the examiner and the process of history taking help in making the diagnosis of dental caries. As technology advances novel aids and new systems are being developed and researched to compliment the visual detection of caries (Pretty, 2006).

2.6.6. Fibre-Optic Trans-illumination

There are references in the literature regarding the investigation of Fibre-Optic Trans-illumination (FOTI) as a means of caries detection (Mialhe et al., 2009a). FOTI is simply the use of very high intensity light shone on the teeth to enhance visual detection of caries. A sound tooth absorbs only a minimal amount of the light shone on it. A carious lesion in a tooth, because it has less mineral content, absorbs and scatters the light more. Thus a sound tooth appears translucent whilst a carious lesion appears dark with trans-illumination (Figure 2.6). FOTI has been used as an aid to visual detection of caries (Cortes et al., 2003). Various studies have compared the caries detection ability of FOTI with that of traditional methods (Wenzel and Fejerskov, 1992). The principal draw back to the original FOTI method as a caries detection aid to visual examination is that an image could not be captured and stored for future reference. Basic FOTI has been reported to have a high sensitivity (67%) and specificity (97%) for caries detection as compared to visual examination sensitivity (38%) and specificity (95%) against the reference standard of histology (Peers et al., 1993).

It has been reported as an especially quick method to use an aid in the detection of posterior approximal caries although its use in this capacity instead of radiographs has not been recommended as separation of the teeth by implements such as the placement of orthodontic rubber rings overnight is required (Mialhe et al., 2009a). It is also more dependent on examiner training and experience for accurate interpretation (Neuhaus et al., 2009).
There is now digital imaging FOTI (DiFOTI) available (Schneiderman et al., 1997). DiFOTI can produce images that can be stored for future reference. It requires two different camera heads to operate; one for obtaining information about occlusal surfaces and the other for smooth surfaces. This makes DiFOTI a cumbersome and time-consuming caries detection method to use. A study which evaluated DiFOTI against the reference standard of histology reported sensitivity and specificity valve for different tooth surfaces. Sensitivity and specificity values were 100% and 88%; 82% and 100%; 44% and 83% for smooth, occlusal and approximal surfaces respectively (Gutierrez, 2008). 44% of sites diagnosed by DiFOTI as having early caries could be detected visually within 2.5 years (Devlin, 2006). A limitation to DiFOTI is that like basic FOTI, it requires considerable amount of training to achieve the level of competence required for its use (Pretty, 2006). Another drawback to this technique is that intact white-spot lesions may appear dark and thus be wrongly diagnosed as requiring a restoration (Pretty and Maupome, 2004c). This newer technology is however not widely used as other caries detection methods.

2.6.7. Radiographs

The use of radiographs for caries detection have been available for over a century (Campbell, 1995). Over the years improvement in technology and legislation has enhanced
the safety of the radiograph. They are widely used in the clinical setting as one of the main aids to clinical caries detection and diagnosis.

The different components of the tooth have variable mineral content. Likewise as carious lesions develop, there is a progressive loss of mineral content. The differing mineral content present in the different parts of the tooth as well as the carious lesion absorb ionizing radiation to different levels. The resulting image produced (Figure 2.7.) after exposing the tooth to controlled burst of radiation is traditionally made up of an array of dark and light shades of grey. This image is viewed and interpreted to detect dental caries. Areas of the tooth with a high mineral content allow less penetration of the ionizing radiation rays and thus appear light whereas less mineral dense areas appear dark. The image is usually developed onto a film using chemicals.

Figure 2.7: Radiographs showing occlusal and approximal restorations and lesions

Technological advancements mean that, digital radiographs are becoming the norm. Instead of a chemically developed film, electronic sensors are used to create a good quality radiographic image. Although digital radiographs are more expensive than traditional ones, they require less irradiation and therefore safer for the patient. Digital
radiographic images are also obtained more quickly and less prone to errors (Ilguy et al., 2009) and have the advantage that they can be stored electronically.

There are numerous studies in the literature that compare radiographs to other caries detection methods (Hintze et al., 1998, Jacobsen et al., 2004). In fact because of the longevity of its use, radiographs tend to be used by some researchers as a reference standard in comparison studies involving caries detection methods. A systematic review (Bader et al., 2002) reported mean sensitivity and mean specificity values of 33% to 66% and 76% to 95% respectively comparing the caries detection performance of radiographs with histology. These values were dependent on the tooth surfaces examined as well as the stage of the disease. Studies in the literature that have compared approximal surfaces caries detection performance of radiology with that of visual examination have reported disparity between sensitivity values of the methods. One study (Baelum et al., 2012) reported sensitivity and specificity values of 34.2% and 80% for visual examination but sensitivity and specificity values of 74% and 70% for radiographs. There are however problems of validity when using radiographs for detecting occlusal caries (Shi et al., 2000) because of the morphology of the pits and fissures of the posterior teeth. Evidence based guidelines regarding radiation protection developed for dental and maxillofacial radiology by SEDENTEXCT project recommends that radiographs must not be carried out unless a history and clinical examination have been performed to justify and demonstrate for each patient that the benefits outweigh the risks (Horner, 2011). The fact that the health risk effects of ionising radiation are cumulative over a lifetime makes the choice of radiography as the caries detection method in situations where there is no direct benefit to the individual an unethical dilemma.

As with visual examination, caries detection using radiographs can be aided by the use of magnifying implements. As technology has evolved, there is software now available which allows manipulation and enhancement of digital images to improve their ability to detect dental caries. Stored digital radiographic images serve as reference for the future in longitudinal assessments.
2.6.8. Quantitative Light-induced Fluorescence

Quantitative Light-induced Fluorescence (QLF) is a method that uses the auto-fluorescence of teeth as a means of detecting caries (de Josselin de Jong et al., 1995). Compared to some of the traditional caries detection methods it is a relatively new technology. The QLF consists of a hand-piece, a control light box and a computer to which captured images of the teeth are displayed, stored and analysed (Figure 2.8.).

Objects with the ability to fluoresce have within them compounds known as fluorophores. When light of a particular wavelength is shone on these objects, their fluorophores absorb the initial photons. They then emit photons with a longer wavelength. This optical occurrence is known as fluorescence. Teeth are fluorescent objects and their fluorophores are said to be located at the amelo-dentinal junction (ADJ).

When the QLF light source is applied to the tooth surface, it passes through the enamel and on to the fluorophores at ADJ where the fluorescence emanates. The intensity of the fluorescence of any material depends on the size of its fluorophores and their surrounding chemical environment. As the carious process begins, the translucency of the enamel is modified changing the environment of the fluorophores. This in turn affects the scattering of photons reaching the ADJ as well as those of emitted photons. The mineral content of enamel therefore has a direct relationship with the level of fluorescence produced by the teeth.

Using software that is able to detect fluorescence, a series of complex analyses are conducted on QLF captured images to determine a calculated (quantifiable) de-mineralization level for the tooth in question. QFL can therefore be used to determine a number of factors about a carious lesion all related to the level of activity (that is the shift in equilibrium between de-mineralization and re-mineralization).
Studies comparing QLF to other caries detection methods have reported QLF to be sensitive in detecting carious lesions particularly smooth surface and early caries (Meller et al., 2006, Kühnisch et al., 2006). A sensitivity of 79% and a specificity of 75% have been reported as a histological validation of QLF caries detection performance of smooth surface carious lesions on primary teeth (Ten Cate JM et al., 2000). Heinrich-Weltzien et al., 2005 found in a study of 34 children that compared QLF and visual examination that of all the carious lesions detected in the study, 7.9% was detected by QLF alone and 4.9% was detected by visual examination alone (Heinrich-Weltzien et al., 2005). The majority of these reports however have been based mainly on the use of QLF for detecting smooth surface and early caries; its use in in-vitro research and clinical work involving measurement of small changes in mineralization of tooth-tissue (Yin et al.). It has also been proposed for use as a tool to monitor the lesions over a period of time (Pretty et al., 2002). Although its use in the detection of secondary caries has been tested in-vitro, research is required for in-vivo use (Pretty et al., 2003). Also the similarities between the presentation of the areas of hypo-mineralisation in dental fluorosis and caries could potentially result in false positive QLF measurement results (Pretty et al., 2006).
2.6.9. Electronic Caries Monitor

A sound tooth has a very high resistance to the flow of an electric current. When demineralization starts a carious lesion progresses, hydroxyapatite crystals are lost from the tooth structure. The resulting porosities within the tooth structure become filled with ions and fluid from the oral environment, particularly water. These are good conductors of electric current and therefore decrease the electrical resistance or impedance of the carious tooth. Increasing porosity implies decreasing electrical resistance or impedance. This difference in electric resistance between a sound tooth tissue and a carious lesion can be measured at specific sites (Figure 2.9.) or over the whole surface of a tooth (Longbottom and Huysmans, 2004).

Electronic Caries Monitor (ECM) is a tool that uses the ability of a tooth to allow the conductance of an electric current through it to varying degrees depending on its caries status (Ricketts et al., 1996). The evidence in the literature on the reliability of ECM is variable. A review of the caries detection performance of ECM by (Huysmans, 2000) reported sensitivity and specificity values of 74.8% (± 11.9) and 87.6% (± 10) – for site specific measurements and 63.0% (± 2.8) and 79.5% (± 9.2) - for surface measurements respectively. Other studies have reported ECM to be less reliable as compared to other caries detection methods (Wicht et al., 2002, Huysmans et al., 2005) with a tendency for producing false positive values. These could be explained by the fact that there are several factors that could affect the electrical measurements obtained. For instance factors such as the use of a single fixed-frequency alternating current or Electrical Impedance Spectroscopy as the means of measuring the tooth tissue electrical resistance or impedance, the presence or otherwise of water, the temperature of the tooth, the presence of cracks in the enamel and tooth thickness could all affect the value of readings obtained from ECM (Longbottom and Huysmans, 2004). The use of a disease detection method or tool that is prone to false positive results in caries epidemiology could provide inaccurate data upon which poor planning decisions could result with subsequent ineffective allocation and use of resources.
2.7. Caries Detection and Dental Epidemiology

Dental caries is a complex dynamic disease. Its presentation differs from site to site on the tooth and the location within the mouth. The level of activity within the lesion, caries staging and rate of progression of the lesion all make it improbable that one type of caries detection method will have all the properties to be the ideal method for every situation.

Dental epidemiological measurement provides data to support the evaluation of caries prevention interventions and also for disease surveillance and needs assessment to support service planning. Such evaluations involve population-based studies. The exhortation to strengthen the evidence base for caries prevention strategies as found in reviews, most notably the York Review (McDonagh et al., 2000a) and the MRC Report (2002) should be heeded. New studies for evaluating caries prevention interventions should be designed robustly to provide evidence at the top or near the top of the evidence hierarchy. Randomised controlled trials (RCTs) study design is the benchmark for producing evidence of the highest level. Ideally the evaluation of all caries prevention strategies should be set up as RCTs to comply with the recommendations of the reviews. It is however not possible to apply this study design to all such interventions. For instance it is impossible to randomly allocate individuals into either the intervention or the control
group in water fluoridation schemes, as by nature these are population-based interventions. This and other challenges of designing studies to evaluate community based interventions were identified and considered at a WHO Oral Health Programme workshop in 2003 (Petersen and Kwan, 2004).

Other study designs will have to be considered for population-based evaluation studies that will still produce evidence near the top of the scientific evidence hierarchy. Common to all these study designs, is the need to ‘blind’ outcome assessors collecting and interpreting the data to some attributes of the studies’ participants such as participants’ residential fluoride status in water fluoridation evaluation studies. “Blinding” is key when collecting base line data but even more important for the assessment of outcomes for the intervention. This will eliminate a key source of bias in such studies. In practice based RCTs, to reduce disruption to practices, patients attending the dentist, could as part of their routine dental visit, have images of their teeth taken by their GDP or a trained member of the dental team and stored. The database of stored images could then be assessed by “blind” assessors remote from the dental practice.

Thus an important factor to consider when choosing a method for caries detection in such epidemiological studies is the ability of that technique to ensure examiner “blinding”. The method should also be valid, reliable, have a high sensitivity and specificity to the detection of caries, be simple to use and be acceptable both to those to whom the method is applied as well as those who apply it.

2.7.1. Choice of Caries Detection Methods for Use in Epidemiology Studies

Large epidemiological studies have traditionally depended on the use of conventional visual clinical examination techniques as the caries detection method. Using this method of examination, the only method of ensuring that the examiners are unaware of the place of residence of the participants is by transporting the participants to an examination site located outside the test and control areas (Milsom and Mitropoulos, 1990). In addition to the enormous logistical difficulties that would arise, there would be various ethical
considerations and issues that would be insurmountable as such evaluation studies will involve numerous subjects including children and multiple sites.

If it is impossible to transport participants to achieve “blinding”, consideration will have to be given to the separation of the production of the entity for measurement from the process of assessment for measurement. The caries detection methods that can produce and store images will lend themselves well to this purpose. In effect those obtaining the images do not need to be “blinded”, only those assessing the images. Then rather than transport subjects, images obtained from the subjects can be assessed by examiners remote from the field work or study team who will be “blind” to various attributes of the subjects. This consideration will rule out the use of techniques such as ECM and basic FOTI in such studies for the evaluation of caries prevention strategies as they do not produce and store images.

As DiFOTI can produce and store images, it could be considered for ensuring examiner “blinding”. However features that make it a cumbersome and time-consuming caries detection method to use, as well as the considerable amount of training required to achieve the level of competence needed for its use, means DiFOTI fails the pragmatic applicability test and therefore not the tool of choice for use in public health applications.

Also despite improvements in radiographic technology, the use of radiographic images for this purpose is not feasible as it is governed by regulations and as such it is fraught with ethical problems as participants in the study may not benefit directly from any radiographs obtained for such studies. Although QLF has shown promise, it may be difficult to use commercially available equipment to make a distinction between dental caries and other lesions such as enamel fluorosis that could be present (Pretty et al., 2006). QLF may not lend itself easily to the most basic requirement of dental public health based research in the field; simplicity.

An alternative method of ensuring examiner “blinding” in studies to evaluate caries prevention interventions would be for examiners to inspect digital photographs of participants’ teeth rather than examine the subjects visually or clinically.
2.7.2. Use of Photographs and Camera vs. Clinical Diagnosis in Healthcare

The transmission of medical information in the form of photographs or other digital images away from the patient to a health professional in a remote location for the purposes of diagnosis, monitoring or the performance of procedures are the main principles of telemedicine. These functions have been greatly enhanced by the availability of fast and powerful information technology systems. The practice of telemedicine can be “real time” where the patient and health professional are present in their respective locations at the same time or as a “store and forward” process where the medical information is obtained from the patient, stored and transmitted to the health professional at a later time. “Store and forward” telemedicine involving photographs is commonly used in dermatology and ophthalmology (Karim et al., 2002, Jolliffe et al., 2001).

In the specialty of ophthalmology, the use of high quality clinical photographs is the reference standard for the diagnosis of common eye conditions that could result in blindness (Constable et al., 2000). The equipment needed to produce these high-resolution images was large, expensive and not easily accessible to patients in remote areas. With improvement in technology, cheaper and more compact systems have been developed that produce good quality images. This is allowing the increasing use of telemedicine in the remote screening of individuals at risk of certain eye diseases (Patton et al., 2006).

Studies conducted to compare “real time” and “store forward” tele-dermatology found the former to be clinically more effective. This is to be expected as the health professional making the assessment remotely can relay a diagnosis or opinion that can immediately influence patient management. “Store and forward” tele-dermatology has however been found to be the more cost effective (Loane et al., 2000). Various studies have been reported that have compared clinical visual examination to stored digital video images and still images. These have generally reported good agreement between the methods. Of the studies that have been uncertain of the reliability of photographs to diagnose some skin conditions, this has been due in part to the quality of the photographs and the fact that
sometimes the sense of touch may be important in the diagnosis of certain lesions (Tucker and Lewis, 2005). Of particular interest is a study that made a diagnostic comparison between clinical examinations and stored video images of pigmented lesions removed for histology (Jolliffe et al., 2001). Although the same examiner examined the lesions clinically as well as assessed the stored video images, time was allowed to lapse between the two examinations. The examiner had also examined a large number of other lesions between the two examinations thus reducing the potential source of recall bias. This study showed that diagnosis of an individual pigmented lesion by viewing stored video images is as accurate (47% agreement with histology) as the diagnosis made by conventional clinical examination (43% agreement with histology) when compared to the gold standard of histology.

Using the strategy indicated above in section 2.1.1., a search of the literature was undertaken to determine if these principles have been tested and applied to dentistry. The search showed a pilot study that investigated the use of intra-oral cameras in dental screening (Patterson and Botchway, 1998). The aim of this study was to determine whether the use of intra-oral cameras and “real time” tele-technology would be comparable to traditional visual examinations for completing visual oral health screenings in the traditional school setting. A total of 137 schoolchildren were screened by a dental hygienist using the traditional visual examination method. Two months later, 32 out of the 137 children were randomly selected and re-screened using the intra-oral camera and a tele-technology system. The images obtained were transmitted to a remote location where the same examiner who undertook the visual examinations assessed them. The caries indices of dmft/DMFT obtained using the two examination methods were then compared. Although this study showed that the use of intra-oral cameras and “real time” tele-technology is feasible for use in dental epidemiology, there are difficulties with the comparisons made between the two methods. The caries information obtained from the two methods was not comparable because the examinations were conducted two months apart to allow time for travel and equipment set up. To overcome this problem, intra-oral images could be obtained at the same time as the visual examination but archived for assessment later. Although the study reported that this was a reliable way of screening
children for dental disease there was no information provided to support this finding. The process of using intra-oral cameras and “real time” tele-technology was found to be costly as compared to traditional visual examination because of the amount of equipment and personnel required. In this study it included 2 monitors, communication equipment and intra-oral camera system. The personnel used on the day included 1 dentist, 3 hygienists and 2 dental students. This confirms the findings in other fields of medicine that “real time” telemedicine can be expensive (Fitzsimmons et al., 2011).

The use of tele-health technology has become more established in North America in recent times (Demiris et al., 2006). The principles of “store and forward” image technology involving photographs as have been trialled in other fields of medicine are being applied to dental public health research (Kopycka-Kedzierawski et al., 2007). Dental teams in parts of the USA are employing the tele-health infra-structure already available for use in medicine for dental screenings to advise and provide referral and treatment recommendations for populations with limited access to dental services (Kopycka-Kedzierawski and Billings, 2006). Using the principles of “store and forward” image technology, a study could be designed to test the validity of using the viewing and assessment of intra-oral photographs to detect dental caries.

### 2.7.3. Use of Intra-Oral Cameras in Dentistry and Dental Epidemiology

Photographic images have been widely used for a long time in dentistry in a variety of ways. They have been employed as part of the patient records, used for patient education and communication (Akcam et al., 2010). They have also been used in treatment planning and patient monitoring. Cameras available for use in dentistry have evolved with the advancement in technology (Terry et al., 2008). Although extra-oral cameras are still being used in dental specialties such as orthodontics (Bister et al., 2006), various intra-oral cameras are now available on the market and their use in general dental practice has greatly increased. Intra-oral cameras have become smaller in size. They are mostly shaped like dental hand pieces and are ergonomically easy to handle (Figure 2.10.). All currently available intra-oral cameras have their own LED light source and the digital images these
cameras produce have improved in quality. There are now increasing reports in the literature of using the assessments of intra-oral photographs for various purposes in dentistry. Assessments of intra-oral photographs have been used in various specialties of dentistry. Tsuzuki et al. (2002) conducted a study to evaluate the use of an intraoral camera for dental examination in forensic inspection. Although they found the intra-oral camera images obtained to be useful for forensic inspections, these images were obtained on a dry skull. They found it was more difficult to obtain photographs which could provide adequate clinical information due to problems with the depth of field when the camera used in that study was in close proximity to teeth. Intra-oral cameras have however improved and they produce clearer images. The assessment of intra-oral photographs has also been used for determining plaque levels in clinical trials (Smith et al., 2006). Although the images obtained with the intra-oral camera were adequate for determining dental plaque surface area measurements, the study reported that images produced by a digital SLR camera were more reliable than those obtained using a digital intra-oral camera. This finding cannot however be taken on face value as poor performance of the intra-oral. The disparity in performance can be explained by the vast difference in size of the stored images for the two camera systems; the image files saved by the intraoral camera’s software were TIF format of size 650 kB, whereas the image files saved by the digital SLR camera were TIF format files of size 4.6 MB. The smaller size of the images produced by the intra-oral camera implies more of such images can be stored and sent through information technology communication methods.

Intra-oral photographs have been used in the evaluation and assessment of changes in oral mucosal pathology (Zadik et al., 2012). This study by Zadik et al. did not assess the validity of using intra-oral photographs for diagnosing mucosal pathology. Rather intra-oral photographs were used as a tool to assess the level of consistency of diagnosis of mucosal lesions between oral medicine specialists and other dental specialists though there is reference in their report to dermatology but not intra-oral photographs having been validated for such a purpose. In the specialty of oral medicine however, the size, colour and other visual features are important in the assessment of changes to a mucosal lesion. There good quality images will be required to make such assessment. The study
reported good agreement within the oral medicine specialists group for these lesion characteristics with the exception of changes to the colour of lesions.

There are several references in the literature regarding the use of photographs for quantifying developmental defects of enamel (Wong et al., 2005) including dental fluorosis (Soto-Rojas et al., 2008, Tavener et al., 2007) and hypo-mineralization (Elfrink et al., 2009) to list a few. The study by Elfrink et al. compared visual examination (used as the reference standard) and the assessments of intra-oral photographs in determination of caries prevalence as well as hypo-mineralization on primary molars in a clinical setting. The sensitivity of the assessment of intra-oral photographs for caries prevalence was 85.5% and the specificity was 83.6%. However there were difficulties in differentiating between enamel opacities due to caries and those due to developmental defects as well as changes in colour tone of obtained photographs as a result of teeth being exposed to excessive ambient light. Based on their findings, Elfrink et al. recommended that the assessment of intra-oral photographs could be considered for use in epidemiological studies.

To make the use of this technology in large-scale epidemiological surveys a possibility, small, light-weight intra-oral cameras can be connected to a laptop computer to store the captured photographs for future reference and assessments. Research is however required to determine if the assessment of photographic images produced this way can support the valid and reliable diagnosis of dental caries in such studies.

In the UK the National Health Service epidemiological surveys have been conducted regularly since their inception in 1985 by the British Association for the Study of Community Dentistry (BASCD). This nationally coordinated large scale epidemiological surveys involve children attending state funded schools. 5-, 12- and 14-year-olds have been the usual cohorts surveyed at regular intervals. These surveys are governed by standardised national protocols covering sampling, diagnostic standards and statistical handling of data.
The well documented visual examination method developed by BASCD (Pitts and Evans, 1997) has been the main method of caries detection in the UK National Health Service epidemiological surveys and accounts for the invaluable worth of caries data possessed by the UK. It is therefore prudent to test any new caries detection method to be considered for such surveys against the established BASCD visual examination method and assess its validity and reliability against the reference standard for caries diagnosis of histological section. In addition to understanding the performance of the method, it is also important to test the pragmatic applicability of the method in practice.

If this alternative method when tested can produce valid and reliable results, it would mean that assessment of the photographs of participants’ dentitions could be used as a means of detecting caries in studies evaluating caries prevention interventions where examiner “blinding” is required. This could mean that future evaluation of interventions could be conducted with suitably designed studies including “blinding” when necessary to produce evidence near the top of the evidence hierarchy.
2.8. Summary of the Literature Review

In summary, the impact of poor oral health, including dental caries, on individuals particularly children and their families can be distressing. Dental caries continues to use up significant health care resources. The dental public health functions of oral health needs assessments, planning of and implementation of dental services to meet the identified needs; monitoring of disease levels as well as evaluation of caries prevention strategies all form part of the armamentarium to improve oral health. The availability of good quality data is vital to support the delivery of all these dental public health functions. The required good quality data can only emanate from well designed and robustly conducted research. Therefore research exploring any aspects of dental caries should be well designed and conducted robustly employing the most appropriate methods and tools. Practice-based RCTs and well-designed epidemiological studies to evaluate population-based caries prevention interventions require assessors to examine participants “blind”.

This review has however showed that conventional visual examination methods for caries detection do not lend themselves to such study designs. Other methods of detecting and measuring dental caries recorded in the literature such as radiographs and more innovative techniques/technologies such as QLF, FOTI and ECM would not be suitable for use in such dental caries epidemiological studies where assessors examine participants “blind” because they are not pragmatically applicable.

An alternative caries detection method could be to assess the intra-photographs of study participants’ dentitions. If this alternative method when tested can produce valid and reliable results, it would mean that assessment of the intra-photographs of participants’ dentitions could potentially be used as a means of detecting caries in practice-based RCTs and epidemiological studies to evaluate population-based caries prevention interventions where examiner “blinding” is required.
2.9. Aims of the Study

The purpose of this study was therefore to compare the use of the production and assessment of intra-oral photographs as a means of caries detection with an established visual examination method (the visual examination method developed by BASCD) in epidemiological studies.

The study was undertaken in three discrete phases.

2.9.1. Phase I

As should be the case for any tool or method for measuring or ascertaining an entity, before using the assessment of photographs as a means of caries detection, it was important to test the validity of method using a reference criterion. An initial phase to compare the caries detection performance of the photographic assessments method and the established visual examination method with histology as the ultimate reference standard for caries detection was considered to be necessary (to enable an evaluation of the concurrent validity of the photographic assessment method).

Aim

The aim of the first phase of the study was to compare the caries detection performance of the photographic assessment method with the established BASCD visual examination method for detecting dental caries and histological section as the reference standard in-vitro.

The following hypotheses were tested to determine if:

1. There is a significant difference in visual examination scores for the extracted teeth recorded by a group of examiners (to test inter-examiner reliability for the visual examination)
2. There is significant difference in visual examination scores for the extracted teeth recorded by the same examiner on two different occasions (to test intra-examiner reliability for the visual examination method)

3. There is a significant difference in photographic assessments of the extracted teeth viewed by a group of assessors (to test inter-examiner reliability for the photographic assessments)

4. There is a significant difference in assessment scores of photographs of the extracted teeth viewed by the same assessor on two different occasions (to test intra-examiner reliability for the photographic assessments)

5. There is a significant difference in recorded dental caries between the visual, photographic and histological methods of detecting caries at “the caries into dentine” level.

2.9.2. Phase II

Children particularly those aged 5 years (for the primary dentition) and 10/11 years (secondary dentition) are the main population group involved in dental caries research and the NHS dental epidemiology programme in the UK. It was therefore logical for the study sample to be drawn from this population group for an in-vivo comparison of the photographic and visual methods in an epidemiology setting.

_Aim_

The main aim of this phase of the study was to test the performance of the intra-oral photographic assessment method as a caries detection method in 5-year-olds and 10-/11-year-olds in an epidemiological study.

The second phase of the study was therefore conducted to compare the intra-oral photographic assessment method with the established visual examination method.
developed by BASCD for detecting dental caries in two groups of children aged 5 years and 10/11 years.

The following hypotheses were tested to determine if:

1. There is a significant difference in dental caries experience (prevalence and severity) detected by the visual examinations of the same subjects by the same examiner on two different occasions (to test intra-examiner reliability for the visual examination)

2. There is a significant difference in dental caries experience detected by the same examiner assessing the same intra-oral photographs on two separate occasions (to test intra-examiner reliability for the photographic assessments)

3. There is a significant difference in the scores for dental caries experience between the photographic and visual methods of detecting caries.

2.9.3. Phase III

In addition to testing the validity, reliability and sensitivity of the assessment of the intra-oral photographic method as a caries detection method for use in dental epidemiology it was equally important to investigate its acceptability to those to whom the method was going to be applied to as well as those who would be using it. It was also important to investigate how simple the method could be made to enable its use for epidemiological purposes with minimal associated lengthy procedures.

Aims

The aims of this phase of the study were to

- Elicit children’s views on the established visual examination method and the intra-oral photographic assessment method (using a qualitative methodology),
• Obtain the views of examiners on their experience of using the established visual examination method and the intra-oral photographic assessment method (using a qualitative methodology) and

• Compare the visual examination method with the assessment of varying numbers (8, 6 and 4) of intra-oral photographs for use as a caries detection method. The following hypotheses were tested to determine if:

1. There is a significant difference in the detected dental caries information recorded by an examiner during the visual examinations of the same subjects on two different occasions (to test intra-examiner reliability for the visual exam)

2. There is a significant difference in the detected dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment of the “8” photographs)

3. There is a significant difference in the detected dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment of the “6” photographs)

4. There is a significant difference in the detected dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment of the “4” photographs)

5. There is a significant difference in the detected dental caries information recorded between the visual examination and “8” photographic assessments.

6. There is a significant difference in the detected dental caries information recorded between the visual examination and “6” photographic assessments.
7. There is a significant difference in the detected dental caries information recorded between the visual examination and “4” photographic assessments.

The third phase of the study therefore had three components:

1. The first component was conducted to elicit children’s views on the established visual examination method developed by BASCD and the intra-oral photographic examination method as a means for detecting caries in epidemiological studies.

2. The second component was conducted to obtain the views of examiners on their experience of using the established visual examination developed by BASCD and the assessment of intra-oral photographic assessment method as means of detecting caries in epidemiological studies and to explore how these experiences were influenced by some of the practical issues encountered during the examinations.

3. The third component was conducted to compare the detected caries data obtained from a full mouth visual examination using the method developed by BASCD in epidemiological surveys with the detected caries data obtained from eight, six and four intra-oral photographs of teeth liable to decay (index teeth) using the intra-oral photographic assessment method in two groups of children aged 5 years and 10/11 years to order to determine the least number of intra-oral photographs required to provide the most useful caries information in epidemiological surveys.
Rationale - Paper 1

Histology is considered the current absolute reference standard for caries detection (Jablonski-Momeni et al., 2009). It was therefore important at the outset of developing the intra-oral camera as a method of caries detection, to test the validity of the new method using histology. It was also necessary to compare the diagnostic performance of the new method to that of the current visual examination caries detection method traditionally used in caries epidemiological studies. Hence the need for the initial in vitro study reported in this chapter.
Comparison of Photographic and Visual Assessment of Occlusal Caries with Histology as the Reference Standard

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Abstract

Background: The purpose of this study was to compare diagnostic performance for the detection of caries using photographs with an established visual examination method and histological sections as the reference standard. Methods: 50 extracted permanent teeth were assessed for the presence of occlusal caries by 9 examiners using two methods; traditional visual examination developed by BASCD and photographs produced by an intra-oral camera. For both methods, diagnoses were made at “caries into dentine” level. The teeth were histologically sectioned and the diagnostic decisions using visual and photographic assessment were compared to the histological reference standard. Inter- and intra-examiner reliability for the methods was assessed and weighted kappa values were calculated. Results: The visual examination method had a median sensitivity value of 65.6% and a median specificity value of 82.4%. The photographic assessments method had a median sensitivity of 81.3% and a median specificity of 82.4%. Conclusions: The photographic assessments method had a higher sensitivity for caries detection than the visual examination. The two methods had comparable specificities and good intra- and inter-examiner reliability.
Background

Dental caries is still the principal challenge that occupies the efforts of clinical and public health dentists alike. Whether in the field of caries research, dental education and dental epidemiology or in the clinical decision making in dental practices, the appropriate means of caries detection and measurement is required. This has led to proliferation of literature about how best to detect and diagnose dental caries in various settings (Baelum, 2010). The most common and traditional method is by a visual inspection of the tooth surfaces. Great progress has been made in the development of novel techniques and technologies that aid the detection of dental caries. These caries detection aids aspire to increase the sensitivity of visual caries detection as well as maintaining a good level of specificity (Neuhaus et al., 2009). The majority of these systems were validated using visual caries determination methods (Sridhar et al., 2009, Karlsson et al., 2009, Kuhnisch et al., 2009b). The need for clinically reliable caries detection methods has however led to the development and refinement of visual systems such as the ICDAS (International Caries Detection and Assessment System) and the Universal Visual Scoring System (UniViSS) (Kuhnisch et al., 2009a, Kuhnisch et al., Kuhnisch et al., 2011).

Dental surveillance surveys and large epidemiological studies have traditionally depended on the use of visual dental examination techniques as the caries detection method. This is because for dental public health purposes, visual determination is simple, requires low technology and is easy to administer. This method of caries detection is however not appropriate in comparative studies where examiners collecting caries information need to be “blind” to various attributes of the different populations; for example the residential status of participants in the evaluation of water fluoridation schemes or to the allocation of participants in randomized control trials. Other caries detection methods such as radiographs, or more innovative techniques/technologies such as Quantitative Light-induced Fluorescence (QLF), fibre-optic trans-illumination (FOTI) and electronic caries monitoring (ECM) (Pretty, 2006) will not be suitable for use in such studies for a variety of reasons.
The use of radiographs to ensure examiner “blinding” is an unviable proposition as it is fraught with ethical dilemmas in terms of justifiable risks from exposure to ionizing radiation and problems with validity in detecting occlusal caries (Shi et al., 2000). Although dental caries and enamel fluorosis present as different lesions, it may be difficult to use the QLF techniques that are commercially available to make a distinction (Pretty et al., 2006). QLF is more suited to laboratory based research and clinical work involving precise measurement of changes in mineralization of tooth-tissue. ECM is a very sensitive caries detection method which can be affected by factors such as the presence of water and tooth temperature (Ricketts et al., 1996).

As digital imaging fibre-optic trans-illumination (DiFOTI) produces images that can be stored, it could be considered for ensuring examiner “blinding”. It is however very cumbersome to handle and time consuming to use. It also requires considerable amount of training to achieve the level of competence needed for it to be used as a caries detection method (Pretty, 2006). As such, none of the so called “novel” methods for caries detection appear appropriate for use in epidemiological studies where blinding is required.

However, a simple and economical method of “blinding” may be for examiners to inspect photographs of participants’ teeth rather than examine the subjects visually.

Photographic images have been used in dentistry in a variety of ways (Kupietzky et al., 2005, Serra and Otis, 2004, Meneghim et al., 2007) and intra- and extra- oral cameras have evolved rapidly over recent years with a commensurate decrease in cost and complexity of use. With the advancement in technology, there are various intra-oral cameras now in use in clinical dental practice. There are however very few studies in the literature that have investigated the use of intra-oral images and caries diagnosis. In a study by Elfrink et al (Elfrink et al., 2009), intra-oral photographs were used to score caries and hypo-mineralization on primary molars in a clinical setting and the results suggest that intra-oral photographs may be used in clinical practice and large epidemiological studies.
with some degree of confidence. The main method of caries determination in the UK National Health Service epidemiological surveys is via a visual examination method developed and described by the British Association for the Study of Community Dentistry (BASCD) (Pitts and Evans, 1997, Pine et al., 1997a, Pine et al., 1997b). Before intra-oral photographs can be recommended for use in epidemiological studies their performance must be assessed against the established BASCD visual examination method and the reference standard for caries diagnosis of histological section.

**Aim**

The purpose of this study was to compare the performance of photographs for the detection of caries into dentine with an established visual examination method and histological section as the reference standard. The following hypotheses were tested to determine if:

1. There is significant difference in visual examination scores for the extracted teeth recorded by a group of examiners (to test inter-examiner reliability for the visual examination)
2. There is significant difference in visual examination scores for the extracted teeth recorded by the same examiner on two different occasions (to test intra-examiner reliability for the visual examination method)
3. There is a significant difference in photographic assessments of the extracted teeth viewed by a group of assessors (to test inter-examiner reliability for the photographic assessments)
4. There is a significant difference in assessments scores of photographs of the extracted teeth viewed by the same assessor on two different occasions (to test intra-examiner reliability for the photographic assessments)
5. There is a significant difference in recorded dental caries between the visual, photographic and histological methods of detecting caries at “the caries into dentine” level.
Methods

Prior to undertaking the study, ethical approval was granted by the University of Manchester Committee on Ethics of Research on Human Beings (Reference Number 06306). Extracted permanent teeth, supplied by the University Of Indianapolis School Of Dentistry were used for the study. Patients from whom the teeth were obtained gave their consent for the teeth to be used in any non-DNA dental research. Teeth with lesions other than caries and teeth with restorations and/or fissure sealants were excluded from the study. The teeth were subsequently anonymised. The study was conducted to the Helsinki Declaration and local legislation as determined by the ethics committee whose approval was gained.

Fifty permanent extracted teeth, varying from sound to grossly carious teeth were used for this study. There were 32 molars (16 of which were sound) and 18 premolars (12 of which were sound). The teeth were examined visually for caries (without probing) using the method developed and described by BASCD [16]. The BASCD codes used for scoring, classified teeth as being sound (caries-free), having arrested caries, having caries into dentine or having caries extending into the pulp (Figure 3.1.). The teeth were also photographed using an intra-oral camera and the obtained images assessed for caries using the same BASCD codes as were used for the visual examination. The teeth were then sectioned for a histological assessment to detect the presence of dental caries.

Visual Examination

Nine examiners trained and calibrated to the BASCD caries examination protocol as members of the team who undertake the UK National Epidemiological Surveys convened to examine the extracted teeth visually for caries. They examined the teeth using the criteria and protocol developed by BASCD. Each examiner assessed the teeth on two separate occasions to test intra-examiner reliability.
The teeth were stored in thymol to prevent microbial contamination. Prior to the examination, two sets of randomly generated identity numbers (ID) were assigned to each tooth, one set for the first exam and the other set for the second examination. For the visual examination each tooth was placed in water within a dappen pot labelled with its assigned ID. The teeth were examined using Daray X100 Lamp with Pivot D desk mount (Daray Healthcare Products® Swadlincote, Derbyshire) as the source of light. Each tooth was dried with cotton wool rolls prior to the examination. Caries was diagnosed visually at the ‘caries into dentine’ level (enamel only caries was not recorded). Only the occlusal surfaces of the teeth were assessed and the assigned BASCD score recorded onto a paper pro-forma. The second examination was conducted 1 hour after the first.

**Photographic Procedure and Assessment**

Each tooth was photographed using an intra-oral camera, the Sopro 717 (The Acteon Group® Eaton Socon, Cambridgeshire), which has an integral LED light source. The teeth
were dried using cotton wool rolls prior to being photographed. Each tooth was held in place on an adjustable mount, the level of which was raised or lowered relative to the camera to obtain the best occlusal view photograph. The camera was held by a clamp in a fixed position pointing downwards onto the tooth surface. The digital image of each tooth generated was saved under a file name which was the same as the identity number allocated to that tooth. The photographs were presented as a Microsoft PowerPoint (2003 version) slide show for assessment.

The same 9 examiners who had examined the extracted teeth visually assessed the PowerPoint presentation of the photographs on two separate occasions. On the first occasion, the examiners convened to view the slide show of the teeth. This was to ensure that each examiner assessed the photographs under the same physical conditions. The examiners were seated behind tables and each had a view of one common screen that was 2.5 metres away in a room lit by ambient daylight. The PowerPoint slide show of the teeth was projected onto the screen. Each photograph remained on the screen for 15 seconds. Just as for the visual examination, only the occlusal surfaces of the teeth were assessed for caries using BASCD criteria. Caries was diagnosed at the “caries into dentine” level. Each examiner recorded the scores for each tooth onto a paper pro-forma, identical to the one used for the visual examination. The examiners were supervised and did not concur with each other during the process.

For viewing on the second occasion, each examiner was provided with a non-time limited version of the same PowerPoint presentation on a CD ROM. Each examiner viewed the photographs a minimum of 14 days after the first viewing. Each examiner viewed the slide show on either laptops or desktop computer screens at a time of day and room conditions of their choice. The purpose of the second viewing was to compare the caries detection performance when the photographs were viewed under standardized and varying physical conditions. Only the occlusal surfaces of the teeth were scored for caries using BASCD criteria. Caries was again diagnosed at the “caries into dentine” level. The examiners
recorded the scores for each tooth onto a paper pro-forma, identical to the one used for the visual examination.

**Histological Assessment**

The extracted teeth were then sectioned for histological assessments. To obtain the histological sections, each tooth was immersed in resin and allowed to set into blocks, with approximately 1.5cm to each side. Each block with an encased tooth was then pressed up against a model grinder, removing thin layers of resin at a time until initial exposure of tooth. The newly exposed tooth surface was polished, dried, and photographed with an extra-oral camera with a ring illuminator. The extra-oral camera with the ring illuminator was pointed upwards, with a small mount on top of it, to house the tooth. This ensured that the tooth was always in focus at the same zoom. The tooth was then returned to the grinder for a while to remove more resin and tooth. The process of alternative grinding and photographing was repeated about 50 times per tooth. The average distance between one photographed cross-section and the next was 0.16mm. (Figure 3.2.)

Figure 3.2: Examples of Tooth Sectioning Procedure

The histological section with the worst level of caries for each tooth was assessed by a trained and standardized examiner. The sections were scored from photographs that were at 10x magnification. The histological assessment was conducted on two separate occasions, one week apart, by the same examiner to test intra-examiner reliability.
Sections were scored as sound (caries-free), caries into outer dentine, caries into inner dentine and caries into pulp. These scores were used in the comparative analysis as the reference standard (Ricketts et al., 1998).

**Data Processing and Analysis**

Data from the visual examinations, photographic and histological assessments of the extracted teeth were collated for analysis. SPSS® version 15.0 (IBM Company, Chicago), was used to compute weighted kappa scores as a measure of agreement to test intra-examiner reliability for the visual examination and the photographic assessments using the Landis and Koch measurement of observer agreement for categorical data (Landis and Koch, 1977b). Inter-examiner reliability was also assessed to test the measure of agreement within the group for both the visual examinations and the photographic assessments using Stata® statistical software version 10 (Stata Corporation Texas).

McNemar test (p<0.05) was performed to compare the performance of the visual and photographic methods using SPSS® version 15.0. SPSS® version 15.0 was also used to compute sensitivity and specificity of the visual examinations using the first histological assessments as the reference standard and sensitivity and specificity of the photographic examinations using histological assessments as the reference standard. For these analyses, the teeth were grouped as sound or carious. All the teeth scored as having arrested caries, caries into inner/outer dentine or caries into pulp by all the examination types were grouped as carious.

**Results**

The frequency distribution of the codes/scores allocation to the teeth according to the examination type is presented in Table 3.1.
Table 3.1: Frequency distribution of tooth scores according to examination method

<table>
<thead>
<tr>
<th>Tooth condition</th>
<th>Histology Freq</th>
<th>Histology Percent</th>
<th>Mean Visual Scores Freq</th>
<th>Mean Visual Scores Percent</th>
<th>Mean Photo Scores Freq</th>
<th>Mean Photo Scores Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sound</td>
<td>18</td>
<td>36.7%</td>
<td>26</td>
<td>52.0%</td>
<td>22</td>
<td>44.0%</td>
</tr>
<tr>
<td>Caries into dentine</td>
<td>24</td>
<td>49.0%</td>
<td>22</td>
<td>44.0%</td>
<td>26</td>
<td>52.0%</td>
</tr>
<tr>
<td>Caries into pulp</td>
<td>7</td>
<td>14.3%</td>
<td>2</td>
<td>4.0%</td>
<td>2</td>
<td>4.0%</td>
</tr>
<tr>
<td>Missing data</td>
<td>1*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>50</td>
<td>100%</td>
<td>50</td>
<td>100%</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

* For histology: inner and outer dentine caries was combined into caries into dentine
* 1 tooth exploded during histological sectioning

Table 3.2 summaries the intra examiner agreement for both the visual examination and photographic assessments. The level of agreement between the first and second visual examination for the individual examiners ranged from substantial agreement to almost perfect agreement (weighted kappa from 0.67 to 0.92 with a median = 0.85) Landis and Koch (Landis and Koch, 1977b). The level of agreement between the first and second photographic assessment for the individual examiners (to compare standardized with varying physical conditions for viewing photographs) ranged from moderate agreement to almost perfect agreement with weighted kappa from 0.59 to 0.92 with a median = 0.74. (Landis and Koch, 1977b)
Table 3.2: Intra-examiner reliability for the Visual and Photographic Assessments

<table>
<thead>
<tr>
<th>Examiner</th>
<th>1st and 2nd Visual exams</th>
<th>1st* and 2nd** Photos assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0.87</td>
<td>0.74</td>
</tr>
<tr>
<td>B</td>
<td>0.85</td>
<td>0.59</td>
</tr>
<tr>
<td>C</td>
<td>0.87</td>
<td>0.69</td>
</tr>
<tr>
<td>D</td>
<td>0.79</td>
<td>0.92</td>
</tr>
<tr>
<td>E</td>
<td>0.67</td>
<td>0.59</td>
</tr>
<tr>
<td>F</td>
<td>0.88</td>
<td>0.78</td>
</tr>
<tr>
<td>G</td>
<td>0.74</td>
<td>0.68</td>
</tr>
<tr>
<td>H</td>
<td>0.92</td>
<td>0.75</td>
</tr>
<tr>
<td>I</td>
<td>0.79</td>
<td>0.84</td>
</tr>
<tr>
<td>Median</td>
<td><strong>0.85</strong></td>
<td><strong>0.74</strong></td>
</tr>
</tbody>
</table>

*Photographic assessments projected on screen  
**Photographic assessments on personal computers

The measure of inter-examiner reliability for the visual examinations was a multi-rater kappa of 0.66. This showed there was substantial agreement within the group for the visual scores. The measure of inter-examiner reliability within the group for the photographic assessment was a multi-rater kappa of 0.60. Again this showed a substantial agreement within the group. McNemar test (p<0.05) calculated to compare the performance of the visual and photographic methods showed no significant difference between the methods.

Sensitivity and specificity as a measure of the diagnostic performance of the visual examination and the photographic assessment methods as compared to the reference standard of histological section assessments are presented in Table 3.3.
Table 3.3: Sensitivity and Specificity

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Visual Examination</th>
<th></th>
<th>Photographic assessment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>1</td>
<td>62.5%</td>
<td>100.0%</td>
<td>78.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>2</td>
<td>62.5%</td>
<td>82.4%</td>
<td>68.8%</td>
<td>76.5%</td>
</tr>
<tr>
<td>3</td>
<td>68.8%</td>
<td>76.5%</td>
<td>78.1%</td>
<td>82.4%</td>
</tr>
<tr>
<td>4</td>
<td>71.9%</td>
<td>76.5%</td>
<td>90.6%</td>
<td>75.5%</td>
</tr>
<tr>
<td>5</td>
<td>68.8%</td>
<td>70.6%</td>
<td>81.3%</td>
<td>88.2%</td>
</tr>
<tr>
<td>6</td>
<td>71.9%</td>
<td>76.5%</td>
<td>84.4%</td>
<td>82.4%</td>
</tr>
<tr>
<td>7</td>
<td>62.5%</td>
<td>82.4%</td>
<td>71.9%</td>
<td>76.5%</td>
</tr>
<tr>
<td>8</td>
<td>65.6%</td>
<td>94.1%</td>
<td>78.1%</td>
<td>88.2%</td>
</tr>
<tr>
<td>9</td>
<td>65.6%</td>
<td>82.4%</td>
<td>78.15</td>
<td>70.6%</td>
</tr>
<tr>
<td>Median</td>
<td>65.5%</td>
<td>82.4%</td>
<td>81.3%</td>
<td>82.4%</td>
</tr>
</tbody>
</table>

Discussion

The main findings of this study showed substantial intra- and inter-examiner reliability for both the visual and photographic assessments. The median sensitivity and specificity values of the visual examinations and photographic assessments as compared to the gold standard of histology were 65.5% & 82.4% and 81.3.8% & 82.4% respectively. These showed that the photographic assessment method in this study has a caries detection capability that is comparable to that of the BASCD visual examination method.

The difficulty of convening examiners from a wide geographical area made a longer washout period for the visual examinations problematic in this study period. It had to be expected that a decision (one of 50) could not be recalled by the examiners after the washout time allowed in this study. In this study caries was only diagnosed when it was determined by the examiners to have reached dentine. This is because the established visual examination method developed by BASCD that was used for the comparisons determines caries at the caries into dentine level as part of its protocol. Although early caries is not accounted for, this method has provided the main epidemiological data on
the state of the dental health of the child population in the UK for almost 30 years (Mitropoulos et al., 1990, Pitts et al., 2007, Pitts and Palmer, 1994). Any other caries detection method to be used in dental public health studies in the UK should at least be comparable to the BASCD examination in ease of application, reliability and validity.

The detection of caries was restricted to only the occlusal surfaces of the teeth. The purpose of this approach was to minimize the number of photographs per tooth that had to be assessed by the examiners. This may be seen as limiting the external validity of the findings of this study. However majority of carious lesions occur in pits and fissures on occlusal surfaces (Weintraub, 2001) and moreover as lesions on occlusal surfaces are the most difficult to reliably diagnose (Lizarelli et al., 2004) the findings of this study will contribute to the available literature. Future research could include caries detection on other tooth surfaces in vivo. Also weighted kappa rather than non-weighted kappa values were computed and used for the reliability comparisons because the caries diagnosis was not just recorded as dichotomous scores (of caries present or absent) but rather as category of scores.

The physical conditions by which photographs are viewed and how they are presented could potentially influence assessment, reducing intra examiner reliability. However we found good agreement between the standardized and non-standardized presentation of the photographs, suggesting that the mode of presentation has little impact on diagnostic decision making from photographs.

Decisions about the introduction of caries prevention strategies such as water fluoridation and the evaluation of such interventions will depend on detecting the presence of the disease at the appropriate level. The requirements of a caries detection tool needed for such a task will not be the same as that required in, for example, general practice to aid management of the early stages of the disease. Examiners collecting data should however do so at a consistent level; the intra examiner reliability for both the visual and photographic methods was high.
Histology/microscopy is used as the reference standard in many comparison and validity studies (Ando et al., 2001, Wenzel and Hintze, 1999, Jacobsen et al., 2004, Jablonski-Momeni et al., 2009). Some researchers believe that there is tissue loss during sectioning of teeth and thus histology/microscopy cannot be said to be the ultimate reference standard. This may be important in studies concerning very early enamel lesions but not detecting caries into dentine used for dental public health purposes. The two methods in this study were compared to histology as the reference standard to determine their validity. The photographic assessments method had a higher sensitivity (median value 81.3%) for caries detection than the visual examination (median value 65.6%). The two methods however had the same specificity (82.4%) which was high. The photographic assessment method in this study has caries detection capability that is at least comparable to that of the BASCD visual examination method.

As well as the possible advantages concerning blinding in comparative studies, another benefit that the photographic method could provide for dental public health epidemiological research is the archiving of images. This is a concept which is already widely used in “Store and forward” telemedicine (Karim et al., 2002, Jolliffe et al., 2001). The use of intra-oral photographs would allow remote dental examination and screening as piloted by a previous study (Patterson and Botchway, 1998). In theory, trained dental nurses or other dental care professionals could take the intra-oral photographs for a single examiner to assess them all. The use of this approach in epidemiological studies will eliminate potential errors that could be introduced by using multiple assessors if potential logistical issues of using the system in the field can be mitigated.

Also archived photographic records would allow true comparative public health studies on the same cohort of population or different cohorts based on archived images in future research. This could include future water fluoridation evaluation studies. These could be conducted as prospective cohort studies where examiners assess the photographs of participants in both the test and control groups “blind” to participants’ exposure to water fluoridation thereby reducing the risk of bias.
The findings of this study relate to teeth in in-vitro condition. The next stage in the development of the use of intra oral photographs in dental public health epidemiological studies is to explore their performance in an in-vivo study comparing the two methods.

**Conclusions**

In summary, the comparisons in this study showed that the assessments of the photographs as a method of caries detection had a higher sensitivity than visual examination compared to the reference standard of histology. The two methods however had comparable specificities. There was also good intra examiner and inter examiner reliability for the examiners assessing the photographic images.

**Competing interests**

None of the authors are aware of any competing interests in the production of this manuscript.

**Authors' contributions**

UB contributed to the protocol, undertook the management of the study, took the photographs and wrote part of the manuscript. TW gave statistical advice, assisted with data analysis and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and wrote part of the manuscript. MT contributed to the protocol, undertook study monitoring and wrote part of the manuscript. All authors read and approved the final manuscript.

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**Disclaimer**

The views and opinions expressed are those of the authors and do not necessarily reflect those of the NHS.
The Use of Intra-oral Photographs in Dental Epidemiology

Chapter 4

Paper 2: Comparison of an Intra-oral Photographic Caries Assessment with an Established Visual Caries Assessment Method for use in Dental Epidemiological Studies of Children

Rationale – Paper 2

The in-vitro study reported in Paper 1 showed that the assessment of photographs of teeth taken with an intra-oral camera as a method of caries detection had a higher sensitivity than visual examination when compared to the reference standard of histology. The two methods, however, had comparable specificities. There was also good intra-examiner and inter-examiner reliability for the intra-oral photographic assessment method. These results indicated that further investigation of the use of intra-oral photographs for detecting caries in the field on live participants was required. This in-vivo testing was the next logical step to take after the in-vitro testing and this provides the rationale for Paper 2.
Comparison of an intra-oral photographic caries assessment with an established visual caries assessment method for use in dental epidemiological studies of children

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Children Blinding Visual examination
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Abstract

Objectives: A cross-sectional study was conducted to compare a visual dental examination method developed by the British Association for the Study of Community Dentistry with assessment of intra-oral photographs as means of detecting dental caries in 5-year-olds and 10/11-year-olds. Method: 150 5-year-olds and 140 10/11-year-olds were visually examined by 5 trained and calibrated examiners. The children also had intra-oral photographs of their teeth taken. The same 5 examiners assessed the photographs for caries. Both photographic and visual assessments were undertaken at “caries into dentine” level. Results: Weighted kappas for the outcome dmft/DMFT as a measure of intra-examiner reliability for the visual examinations ranged from 0.94 to 0.98 (median = 0.98) in the 5-year-olds and 0.80 to 1.00 (median = 0.93) in the 10-/11-year-olds. Weighted kappas as a measure of intra examiner reliability for the photographic assessments ranged from 0.83 to 1.00 (median = 0.93) in the 5-year-olds and 0.69 to 0.95 (median = 0.81) in the 10-/11-year-olds. Sensitivity values for the photographic assessment method as compared to the gold standard of the visual examination scores of a benchmark examiner ranged from 87.8% to 95.8% in the 5-year-olds and 58.5% to 71.7% in the 10/11-year-olds. Conclusion: There was good intra-examiner reliability for both the visual and the photographic methods for all the examiners. There are no clinically significant differences between the photographic scores and the visual assessments using any of the metrics described. The photographic approach is therefore equivalent in diagnostic utility to the visual system and confers considerable advantages in terms of examiner bias reduction, remote scoring and archiving. These advantages must be weighed against the (modest) costs of the cameras but the increased time required to acquire the images.
Introduction

Poor oral health has an impact on the wellbeing of individuals and ultimately affects the functioning of communities and populations. This is reflected in the World Health Organisation’s call for its members to re-orientate health policies to incorporate oral health (Sheiham, 2005). To improve population oral health dental public health specialists need to assess dental disease levels in populations. Dental epidemiological surveys are conducted in many countries to provide the data used for oral health needs assessments on which health planners and commissioners of dental services rely. These studies are also useful for the evaluation of oral health intervention strategies. There are a variety of methods, mostly visual examination methods such as the ICDAS (Cadavid et al., 2010) and caries indices such as the decayed missing filled (DMF) index used internationally for collection of caries data in these epidemiology studies. In the UK, the National Health Service (NHS) dental epidemiological surveys use the well documented clinical examination method developed by the British Association for the Study of Community Dentistry (BASCD) (Pitts et al., 1997) as the means of caries detection. Trained and calibrated examiners using a dental mirror and cotton wool rolls as diagnostic aids visually assess the dentition detecting caries at “caries into dentine” level. This method has the advantage that it has been developed to be simple and easy to use in the field in large epidemiology surveys. Although it has been used by the UK dental public health system to accumulate large amounts of very useful dental surveillance data over the years, visual examination is limited in some circumstances. It is not possible to blind examiners to certain characteristics of participants in comparative studies e.g. area of residence when assessing the impact of fluoridation or to the allocation of an intervention in some randomized controlled trials increasing the risk of bias. Alternative methods of assessment that enable “blinding” of examiners, must also comply with modern ethical standards as well as being simple and easy to use. This excludes methods such as radiographs and novel caries detection technologies which are dependent upon user expertise or the physical environment (Pretty, 2006). Assessment of intra-oral photographs of participants is an alternative. There are however few studies that have explored the use of intra-oral photographs in dental epidemiology. A pilot study by Patterson and Botchway (Patterson
and Botchway, 1998) investigated the use of intra-oral imaging in dental screenings. This study compared clinical examination to assessment of digitally generated images using “real time” tele-technology. Although the study reported that this was a reliable way of screening children for dental disease the process was found to be costly as compared to traditional clinical examination. Technology has since advanced and light-weight ergonomically easy to handle intra-oral cameras can be used to capture the images in the field and stored on a laptop computer, making the use of this technology in large scale epidemiological surveys a possibility. The results of a recent study in which intra-oral photographs were used to score caries and hypo-mineralization on primary molars in a clinical setting (Elfrink et al., 2009) and an in-vitro study that compared visual, photographic and assessments with a histological gold standard (Boye et al., in press) suggests that intraoral photographs may be used in large epidemiological studies with some degree of confidence. However further research is required to determine if intra-oral photographs can provide valid and reliable detection of dental caries in epidemiological surveys and studies in children. In the UK, the nationally coordinated NHS epidemiological surveys in children routinely assess the primary dentition in 5-year-old children and the permanent dentition in a range of older cohorts with up to and including 14-year-olds. These are therefore the most appropriate age groups to use for assessing the performance of this technology.

The aim of the study was to compare intra-oral photography with the established visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) for detecting dental caries in two groups of children aged 5 years and 10/11 years. Comparisons were made to determine whether:

1. There was a difference in dental caries prevalence detected by the visual examinations of the same subjects by the same examiner on two different occasions (to test intra-examiner reliability for the visual examination)
2. There was a difference in dental caries prevalence detected by the same examiner assessing the same intra-oral photographs on two separate occasions (to test intra-examiner reliability for the photographic assessments)

3. There was a difference in the scores for dental caries prevalence between the photographic and visual methods of detecting caries.

Materials and Methods

Ethical Approval
Ethical approval was obtained for this study from the University of Manchester Committee on Ethics of Research on Human Beings (reference number 06306) and confirmation of support for this ethical approval was given by the National Research Ethics Service in the UK.

Study Design
This was a cross sectional study which took a form similar to a calibration exercise prior to the BASCD nationally coordinated NHS epidemiological surveys of children in the UK (Pine et al., 1997b). These surveys are undertaken routinely in the school setting to collect data in a standardised way. The additional feature introduced in this study was the use of an intra-oral camera to obtain photographs of the dentitions of the children involved in the study.

Study Population
The study population was 5-year-old and 10-/11-year-old children attending primary schools in Rochdale Metropolitan Borough Council, an area in the North West of England characterized by poorer oral health than the English average. Before the data collection exercise, invitation letters, study information sheets and consent forms were sent to parents/legal guardians of eligible children via their children’s schools, informing them that a ‘dental inspection’ including the taking of photographs of the teeth, was going to take place on an appointed day in their children’s/wards’ school which could include their
child/ward. Parents/guardians were asked to provide informed consent to enable their child to participate in the study. Completed consent forms were returned to the study team via the schools. Only children whose parents/legal guardians gave positive consent were included.

A master list of consented children was assembled by the study team. From this list, unique identity numbers were allocated to each subject. All the children in the two age groups recruited into the study each had a visual dental examination according to BASCD diagnostic protocol (Pitts et al., 1997) and also had a set of photographs taken of their complete dentition.

**Visual Dental Examination**

The visual examinations of all consenting children were undertaken by five experienced examiners trained and calibrated in the BASCD diagnostic protocol including the regional bench mark examiner (an experienced examiner with a proven track record used as a reference standard for training purposes) for the NHS epidemiology programme. Five examination stations were set up to enable 5 children to be examined at a time. Each child lay supine on an examination table with an examiner seated behind their head. The children remained at the examination stations whilst the examiners moved round the stations, examining each child in turn until all the children had been assessed by all 5 examiners. At the end of each examination cycle another group of 5 children were brought to the stations to replace those already assessed for a new examination cycle to begin. The source of light used was Daray X100 Lamps with Pivot D desk mount (Daray Healthcare Products® Swadlincote, Derbyshire). The examination for dental caries prevalence and experience was carried out according to the method, criteria and coding system employed in the BASCD coordinated NHS Epidemiology Programme, using the recommended instrumentation and equipment (a hand mirror, cotton wool rolls and a blunt probe for the removal of debris), sterilization/disinfection precautions and data collection and data validating methods (Dental Survey Plus 2® The Dental Health Services Research Unit, University of Dundee). The primary teeth were examined in the 5-year-olds
and only the erupted permanent teeth were examined in the 10/11-year-olds. All surfaces of each eligible tooth examined were scored. Caries was diagnosed visually at the ‘caries into dentine’ level. The scores for each subject were recorded by a scribe on to a pro-forma bearing the identity number allocated to that subject generated from the master list. 15% of the children in each age group were re-examined to test intra examiner reliability.

*Photographic Procedures and Assessments*

Prior to taking the photographs, folders carrying the same identity numbers as those assigned to the subjects for the visual examinations were created on a password protected computer. This was to enable matching of the clinical and photographic assessment scores later.

An intra-oral camera, the Sopro 717 (The Acteon Group® Eaton Socon, Cambridgeshire), with its own integral LED light source, was used to take photographs of each tooth in each subject. The intra-oral camera system was connected to a laptop with a bespoke developed “Super” software programme to allow each captured image to be viewed before accepting to save to the subject’s allocated file or rejected and another image captured. The children lay supine on an examination table with the examiner/photographer seated behind them at the head end. All the teeth were dried with cotton wool rolls prior to taking the photographs. A set of photographs showing the surfaces of all the eligible teeth, were obtained for each subject. Between subjects, the infection control procedures specified by the manufacturer of the intra-oral camera’s user guide was followed.

The same five examiners, trained and calibrated in the BASCD NHS epidemiology diagnostic protocol, examined the children visually and the photographs of their dentition. No additional training and calibration in assessing the photographs was provided. This was because the training and calibration provided for the visual examination was deemed to be an adequate proxy for the photographic assessment using the same BASCD criteria.
Each examiner was provided with USB flash drive loaded with the labelled folders containing the photographs of the subjects’ teeth. Each examiner viewed the photographs on either laptops or desktop computer screens at a time of day and room conditions of their choice. As was the case for the clinical examination, caries was diagnosed at the “caries into dentine” level using the BASCD diagnostic criteria. The examiners recorded the photographic scores for each subject on to a paper pro-forma, identical to the one used for the visual examination. 15% of the subjects in each age group’s photographs were assessed again to test intra examiner reliability.

**Statistical Analysis**

The data collated from the visual examinations and photographic assessments of the subjects’ teeth were entered into Dental Survey Plus 2® (The Dental Health Services Research Unit, University of Dundee) software. The software was used to analyse the data and generate mean caries experience indices (dmft, dt, ft, mt; DMFT, DT, FT and MT). Weighted kappa statistics as a measure to test intra-examiner reliability for both the visual examinations and the photographic assessments in both age groups were computed and the Landis and Koch measurement of observer agreement for categorical data (Landis and Koch, 1977b) was used. The size and direction of the deviation of mean caries indices recorded by all the examiners for the photographic assessments from the visual assessments by the benchmark examiner was measured.

Using the benchmark examiner’s visual examination as the gold standard for both the deciduous and permanent dentitions, SPSS® version 15.0 (IBM Company, Chicago) was also used to compute estimates of sensitivity and specificity of the photographic method for each examiner. For this analysis, the teeth were classed as either sound or carious; teeth scored as having arrested caries, primary or secondary caries into dentine with or without pulpal involvement were all classified as carious.

The total number of photographs required to collate full mouth images of each child’s teeth and the time required for the visual and photographic assessments were recorded.
Results

A total of 130 5-year-olds and 140 10-/11-year-olds were recruited into the study. As the intra-oral photographs required a longer time to complete than the visual examination, the study team had to return later in the school day or the next day to obtain intra-oral photographs for a few of the participants. Of these seven 5-year-olds and five 10/11-year-olds were not available to have intra-oral photographs taken of their dentition although they had been examined visually and were therefore excluded from the data analysis. Each subject in the study had up to 24 intra-oral photographs taken. Taking intra-oral photographs required a mean time of 8.78 minutes (with a standard deviation of 2.76).

The prevalence of caries (using the visual examinations method) was 41.60% in the 5-year-olds and 40.60% in the 10-/11-year-olds; and using the photographic assessment method, 41.32% in the 5-year-olds and 42.75% in the 10-/11-year-olds.

The weighted kappas computed as a measure of intra examiner reliability for each examiner and for each method is shown in Table 4.1.

<table>
<thead>
<tr>
<th>Examiner</th>
<th>5-yr-olds’ Wt kappas</th>
<th>10-/11-yr olds’ Wt kappas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Visual Examinations</td>
<td>Photo Assessments</td>
</tr>
<tr>
<td>Bench Mark</td>
<td>0.98</td>
<td>0.93</td>
</tr>
<tr>
<td>1</td>
<td>0.98</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>0.94</td>
<td>0.83</td>
</tr>
<tr>
<td>3</td>
<td>0.98</td>
<td>0.92</td>
</tr>
<tr>
<td>4</td>
<td>0.95</td>
<td>0.93</td>
</tr>
</tbody>
</table>

The dmft and DMFT indices computed from the photographic assessments for Examiner 4 were much higher than those for the other examiners, with the greatest contribution from the dt and DT components. Examiner 4 re-assessed and scored all the photographs in both
cohorts one year later after the initial assessments. The mean dmft scores for two photographic assessments (1 year apart) was 3.31 and 3.65 for the 5-year-olds (compared to a mean dmft score for the other examiners of 1.82 with a standard deviation of 0.20) and mean DMFT scores of 4.56 and 4.61 for the 10/11-year-olds (compared to a mean DMFT score for the other examiners of 0.98 with a standard deviation of 0.17); Examiner 4 therefore remained an outlier.

**Training of Examiner 4**

Examiner 4 was given training on detecting caries at caries into dentine level using intra-oral photographs alone. The training comprised reiteration of the BASCD caries codes and the viewing and discussion of intra-oral photographs showing examples of the codes. Examiner 4 then viewed and scored intra-oral photographs of twenty-five 5-year-olds and twenty-five 10/11-year-olds. The resulting scores were compared with the scores assigned to these photographs by the trainer.

There was very good agreement between the scores of the trainer and Examiner 4 for both cohorts. The sensitivity was 0.94 and the specificity was 0.99 for the 5-year-olds scores and the valves were 0.88 and 0.99 for 10/11-year-old children’s scores as compared to the BASCD acceptable values of at least 0.75 sensitivity and 0.90 specificity (Pine et al., 1997b). Four weeks following training, Examiner 4 re-assessed all of the study photographs and the scores obtained were included in the analyses.

Tables 4.2 and 4.3 summarize the differences between the mean caries indices of the visual examination as compared to those of the photographic assessments in the 5-year-olds and 10/-11-year-olds respectively. Excluding the outlier pre-training assessments scores of Examiner 4, there was good agreement between individual examiner’s visual examination caries indices and those of the photographic assessments with weighted kappa values ranging from 0.84 to 0.88 with a median value of 0.85 for the 5-year-olds and weighted kappa values ranging from 0.69 to 0.81 with a median value of 0.78 for the 10/11-year-olds.
Table 4.2: The mean indices (with standard deviations) of the visual examination as compared to those of the photographic assessments in the 5-year olds

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Mean dt</th>
<th>Mean mt</th>
<th>Mean ft</th>
<th>Mean dmft</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>V</td>
<td>P</td>
<td>V</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>V</td>
<td>P</td>
<td>V</td>
<td>P</td>
</tr>
<tr>
<td>V</td>
<td>1.44 ± 2.52</td>
<td>1.75 ± 2.68</td>
<td>0.15 ± 0.89</td>
<td>0.15 ± 0.89</td>
</tr>
<tr>
<td>P</td>
<td>0.07 ± 0.34</td>
<td>0.10 ± 0.45</td>
<td>1.66 ± 2.79</td>
<td>1.99 ± 3.02</td>
</tr>
<tr>
<td>Bench Mark</td>
<td>1.71 ± 2.35</td>
<td>0.15 ± 0.89</td>
<td>1.59 ± 2.74</td>
<td>1.54 ± 2.72</td>
</tr>
<tr>
<td>1</td>
<td>1.44 ± 2.44</td>
<td>1.71 ± 2.64</td>
<td>0.15 ± 0.89</td>
<td>0.15 ± 0.89</td>
</tr>
<tr>
<td></td>
<td>1.57 ± 0.38</td>
<td>0.09 ± 0.41</td>
<td>1.67 ± 2.72</td>
<td>1.94 ± 2.94</td>
</tr>
<tr>
<td>2</td>
<td>1.56 ± 2.57</td>
<td>1.57 ± 2.67</td>
<td>0.15 ± 0.89</td>
<td>0.15 ± 0.89</td>
</tr>
<tr>
<td></td>
<td>0.07 ± 0.37</td>
<td>0.09 ± 0.41</td>
<td>1.78 ± 2.91</td>
<td>1.80 ± 2.97</td>
</tr>
<tr>
<td>3</td>
<td>1.35 ± 2.53</td>
<td>2.95 ± 3.10</td>
<td>0.15 ± 0.89</td>
<td>0.15 ± 0.89</td>
</tr>
<tr>
<td></td>
<td>0.10 ± 0.39</td>
<td>0.21 ± 0.62</td>
<td>1.60 ± 2.84</td>
<td>3.31 ± 3.43</td>
</tr>
<tr>
<td>4 (A)</td>
<td>3.46 ± 3.19</td>
<td>0.15 ± 0.89</td>
<td>0.10 ± 0.39</td>
<td>0.04 ± 0.20</td>
</tr>
<tr>
<td></td>
<td>1.60 ± 2.84</td>
<td>3.65 ± 3.46</td>
<td>1.60 ± 2.84</td>
<td>1.59 ± 2.69</td>
</tr>
<tr>
<td>4 (B)</td>
<td>1.35 ± 2.53</td>
<td>1.34 ± 2.34</td>
<td>0.15 ± 0.89</td>
<td>0.10 ± 0.39</td>
</tr>
<tr>
<td></td>
<td>0.11 ± 0.46</td>
<td>1.60 ± 2.84</td>
<td>1.59 ± 2.69</td>
<td>1.60 ± 2.84</td>
</tr>
<tr>
<td>4 (C)</td>
<td>1.35 ± 2.53</td>
<td>1.34 ± 2.34</td>
<td>0.15 ± 0.89</td>
<td>0.10 ± 0.39</td>
</tr>
<tr>
<td></td>
<td>0.11 ± 0.46</td>
<td>1.60 ± 2.84</td>
<td>1.59 ± 2.69</td>
<td>1.60 ± 2.84</td>
</tr>
</tbody>
</table>

V = Visual Examinations
P = Photographic Assessments
4(A) = Examiner 4’s initial photographic assessments score pre-training
4 (B) = Examiner 4’s photographic assessments score 1 year after initial assessments
4 (C) = Examiner 4’s photographic assessments score post-training
Table 4.3: The mean indices (with standard deviations) of the visual examination as compared to those of the photographic assessments in the 10-/11-y-rolds

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Mean DT</th>
<th>Mean MT</th>
<th>Mean FT</th>
<th>Mean DMFT</th>
</tr>
</thead>
<tbody>
<tr>
<td>V</td>
<td>P</td>
<td>V</td>
<td>P</td>
<td>V</td>
</tr>
<tr>
<td>Bench Mark</td>
<td>0.69 ± 1.37</td>
<td>0.73 ± 1.32</td>
<td>0.03 ± 0.22</td>
<td>0.27 ± 0.70</td>
</tr>
<tr>
<td>1</td>
<td>0.60 ± 1.26</td>
<td>0.48 ± 1.10</td>
<td>0.03 ± 0.22</td>
<td>0.27 ± 0.70</td>
</tr>
<tr>
<td>2</td>
<td>0.70 ± 1.25</td>
<td>0.90 ± 0.40</td>
<td>0.02 ± 0.22</td>
<td>0.26 ± 0.69</td>
</tr>
<tr>
<td>3</td>
<td>0.55 ± 1.12</td>
<td>0.85 ± 1.38</td>
<td>0.03 ± 0.22</td>
<td>0.25 ± 0.60</td>
</tr>
<tr>
<td>4 (A)</td>
<td>0.77 ± 1.24</td>
<td>4.33 ± 2.80</td>
<td>0.03 ± 0.22</td>
<td>0.24 ± 0.64</td>
</tr>
<tr>
<td>4 (B)</td>
<td>0.77 ± 1.24</td>
<td>4.45 ± 2.86</td>
<td>0.03 ± 0.22</td>
<td>0.24 ± 0.64</td>
</tr>
<tr>
<td>4 (C)</td>
<td>0.77 ± 1.24</td>
<td>0.68 ± 1.34</td>
<td>0.03 ± 0.22</td>
<td>0.24 ± 0.64</td>
</tr>
</tbody>
</table>

V = Visual Examinations
P = Photographic Assessments
4(A) = Examiner 4’s initial photographic assessments score pre-training
4 (B) = Examiner 4’s photographic assessments score 1 year after initial assessments
4 (C) = Examiner 4’s photographic assessments score post-training
Table 4.4: Size and direction of the deviation of each examiner’s **photographic** assessments dmft /DMFT score from the bench mark’s **visual** dmft/DMFT score

<table>
<thead>
<tr>
<th>Examiner</th>
<th>5-yr-olds</th>
<th>10-/11-yr olds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean dmft</td>
<td>Deviation from Bench Mark’s visual score</td>
</tr>
<tr>
<td>BM (visual scores)</td>
<td>1.66</td>
<td>0.00</td>
</tr>
<tr>
<td>BM* (photo scores)</td>
<td>1.99</td>
<td>0.33</td>
</tr>
<tr>
<td>1</td>
<td>1.54</td>
<td>0.12</td>
</tr>
<tr>
<td>2</td>
<td>1.94</td>
<td>0.28</td>
</tr>
<tr>
<td>3</td>
<td>1.80</td>
<td>0.14</td>
</tr>
<tr>
<td>4 (photo score pre-training)</td>
<td>3.31</td>
<td>1.65</td>
</tr>
<tr>
<td>4 (photo score one year later)</td>
<td>3.65</td>
<td>1.99</td>
</tr>
<tr>
<td>4 (photo score post-training)</td>
<td>1.59</td>
<td>0.07</td>
</tr>
</tbody>
</table>

* The photographic assessments of the visual examination bench mark (BM) examiner are undertaken as one of the group of examiners and not as a bench mark photographic assessor.
Table 4.5: Sensitivity and Specificity

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Reference Standard: Visual Examination scores of the Bench Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
</tr>
<tr>
<td>5-year-olds Photograph assessment</td>
<td></td>
</tr>
<tr>
<td>BM*</td>
<td>95.9%</td>
</tr>
<tr>
<td>1</td>
<td>87.8%</td>
</tr>
<tr>
<td>2</td>
<td>93.9%</td>
</tr>
<tr>
<td>3</td>
<td>91.8%</td>
</tr>
<tr>
<td>4</td>
<td>93.9%</td>
</tr>
<tr>
<td>10/11-year-olds Photograph assessment</td>
<td></td>
</tr>
<tr>
<td>BM*</td>
<td>66.0%</td>
</tr>
<tr>
<td>1</td>
<td>58.5%</td>
</tr>
<tr>
<td>2</td>
<td>71.7%</td>
</tr>
<tr>
<td>3</td>
<td>66.0%</td>
</tr>
<tr>
<td>4</td>
<td>66.0%</td>
</tr>
</tbody>
</table>

*BM is the visual examination benchmark examiner whose photographic assessments are undertaken as one of the group of examiners and not as a benchmark photographic assessor.
Table 4.4 depicts the size and direction of the deviation of each examiner’s photographic assessments dmft/DMFT score from the benchmark examiner’s visual dmft/DMFT scores. Sensitivity and specificity as a measure of the caries detection performance of the photographic assessment methods as compared to the visual scores of the benchmark examiner are shown in Table 4.5.

**Discussion**

The main findings of the study were that there was very good intra-examiner reliability for both the visual examination and photographic assessments in both cohorts for each examiner (Landis and Koch, 1977a). Comparison of the photographic assessments mean caries indices of dt, dmft, DT and DMFT within the group of examiners identified Examiner 4 as an outlier as indicated in tables 1, 2 and 3. The status of Examiner 4 as an outlier was confirmed by repeating the photographic assessments after one year. Specific training in the use of intra-oral photographs for detecting caries at the caries into dentine level brought photographic scores of Examiner 4 into an acceptable range of the trainer’s photograph assessment scores with sensitivity and specificity values of 0.94 and 0.99 for the 5-year-olds and values of 0.88 and 0.99 for 10/11-year-old children as compared to the BASCD acceptable values of at least 0.75 sensitivity and 0.90 specificity (Pine et al., 1997b).

Computed weighted kappa was used as the measure for the level of agreement because the caries indices were categorical and a weighted kappa assigns less weight to agreement between categories as the categories move further apart and vice versa. The examiners in the study were very experienced in the use of the visual examination method and as expected the intra-examiner reliability for this method was very high for all the examiners including Examiner 4. This is comparable to the findings in other visual caries detection. It is important that the intra-examiner reliability for the photographic assessments is comparable to that of other caries detection examination methods used in epidemiological studies. The intra-examiner reliability for the photographic assessments
was high for each examiner. This showed that each examiner, including Examiner 4, was consistent in the way they obtained caries information from the photographs.

Although Examiner 4 had almost perfect agreement between the 1\textsuperscript{st} and 2\textsuperscript{nd} photographic scores, the much higher average dmft and DMFT values compared to the rest of the examiners, suggests that Examiner 4 appeared to have a systematically lower threshold of identifying lesions as carious on the intra-oral photographs compared to the other examiners.

The training that the examiners have received prior to the visual examination was used as proxy training for the photographic assessments because both photographs as well as clinical examples of caries were used. The examiners however are very experienced in examining children and not photographs as reflected by the sensitivity and specificity values. This coupled with the discrepancy with Examiner 4’s initial photographic scores and subsequent conformation after specific training using photographs alone suggests that a different approach may be required to assess caries using intra-oral photographs. If this method is to be used in future epidemiological studies our experiences strongly suggest that is necessary to train and calibrate examiners specifically using photographs of teeth.

Various studies have found that there is variable inter-examiner reliability in the detection of occlusal caries in permanent posterior teeth (Mialhe et al., 2009b, Pereira et al., 2009) mainly as a result of the fissure morphology and staining. This uncertainty could explain the lower sensitivity in the permanent dentition as compared to the deciduous dentition found in this study (with the occurrence of frank cavitation being observed more commonly in primary teeth). Other potential reasons include the difficulty of imaging the much larger permanent teeth and also the loss of context when the tooth surface fills the entire image space. The presence of a “greying” or shadowing of the occlusal surface often indicates the presence of caries into dentine in permanent teeth. The high level of
illumination and flat image perspective may well make such assessment more complex. The presence of saliva or debris in fissures can also confound analysis.

Specific training developed for examiners to use for this method of caries detection may increase the sensitivity. Although the two methods are different, the high intra-examiner reliability for both implies that either method could be used in epidemiological studies, the choice of method dependent on the purpose of the study. In essence – both systems lack sensitivity in relation to occlusal caries. The data support the view that neither method is superior.

A key advantage of using the intra-oral photographic method is the capability to archive the images generated. This capability can give rise to a number of benefits. Using information and communication technologies archived intra-oral photographs can be used to provide remote training and calibration for individuals or groups of examiners. Archiving would also allow remote assessment and scoring of intra-oral photographs in epidemiological studies that may require blinding. Improvement in intra-examiner reliability of remote examiner(s) and the sensitivity of the method could be explored by including random “pop up” test intra-oral photographs which allows comparison with reference standard set of scores to which the examiner must achieve a set kappa level in order to be allowed to carry on with the assessment.

There are however practicality issues regarding obtaining the intra-oral photographs that should be considered. In order to provide the photographic assessors with the opportunity to assess all surfaces of all the teeth just as they would have if they were examining the teeth visually, all surfaces of the teeth had to be photographed. This meant that each subject in the study had up to 24 intra-oral photographs taken depending on the number of teeth present in their mouths. This required a mean time of 8.78 minutes per subject as compared to an average time of 3 minutes needed for the visual examination per subject. Although the teeth were dried with cotton wool rolls, as according to the BASCD protocol, maintaining moisture control as the intra-oral photograph were obtained was difficult.
especially for the 5-year-old children. This contributed to the increase in the time taken to obtain the intra-oral photographs. The additional time taken and therefore the costs versus the benefits the intra-oral photograph method provides needs to be assessed and deductions made dependent on the aims of the study for which the method is to be employed.

Development of a method to reduce the time required to obtain the intra-oral photographs that would also provide comparable diagnostic performance to visual examination would enhance the use and acceptance of the photographic method. Further research is required to determine how this could be achieved.

The comparisons in this study showed there was good intra-examiner reliability for the visual examinations and the photographic assessments for all the examiners. Training and calibration improved the diagnostic performance of an outlying examiner. Sensitivity of the photographic assessment methods as compared to the benchmark examiner’s visual examination method scores was much higher for the deciduous dentition than the permanent dentition.

**Conclusion**

With reference to the study’s three objectives, it is possible to state that there are no clinically significant differences between the photographic scores and the visual assessments using any of the metrics described. The photographic approach is therefore equivalent in diagnostic utility to the visual system and confers considerable advantages in terms of examiner bias reduction, remote scoring and archiving. These advantages must be weighed against the (modest) costs of the cameras but the increased time required to acquire the images.
Acknowledgments

The authors would like to acknowledge the assistance received from the examiners who took part in the study and the Dental Observatory, Preston which trains and calibrates examiners in the visual examination method. They would also like to thank the examiners and all the children who participated in the study. Dr. I Pretty is supported by an NIHR Clinician Scientist Award.
The Use of Intra-oral Photographs in Dental Epidemiology

Chapter 5

Paper 3: The Views of Children on the Experience of a Visual Examination and Intra-oral Photographs to Detect Dental Caries in Epidemiological Studies

Rationale - Paper 3

The results of the in-vivo study comparing the intra-oral photographic assessment method with an established visual examination as a means of caries detection in an epidemiological setting demonstrated that the new method continued to show promise. However, before a new caries detection method or tool can be recommended for widespread use in dental caries studies, it should be tested not only for validity and reliability but also for acceptability by the group(s) on whom it is intended for use. In the UK, as the dental epidemiology surveys regularly involve 5-, 10-, 11- and 12-year-olds, it was necessary as part of this thesis to seek the views of children in these groups on the intra-oral photographic method as compared to the current visual examination method. Hence the need to conduct the study reported in this chapter.
The views of children on the experience of a visual examination and intra-oral photographs to detect dental caries in epidemiological studies

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**Aim** The aim of this study was to elicit children’s views on the established visual examination method used for the epidemiological surveillance of dental caries and an experimental intra-oral photographic examination method. **Method** Focus group interviews were conducted with 5-year-olds (with the aid of a puppet) and 10-/11-year-olds (without a puppet) after they had experienced both methods. 10 focus groups were interviewed in each cohort. **Results** The children’s views on the methods related to the level of acceptability of their experience. The key factors affecting acceptability and children’s preferences related to the combined effects of contextual factors prior to the examination and experiences during the examination. These included communication and children’s expectations. These factors influenced the examination experience along with their feelings about the environment and the tactile sensation from instruments in the mouth. The majority of children preferred the experimental photographic method as a means of caries detection rather than the traditional visual examination. They also wanted feedback on their oral health and more communication on what was happening during the examination. **Conclusion** Appropriate communication, attention to the examination environment and handling of instruments can enhance the dental examination experience for children in the school setting. The children’s preferences indicated that generally, the intra-oral camera was well received as a means of caries detection for epidemiological studies within the school setting. These results may have implications for seeking ethical approval and conducting epidemiological studies on children in the future.

**Key words:** Children’s views, caries detection, dental epidemiology, qualitative, intra-oral photographs, visual dental examination

**Word Count:** 3387
Introduction

Children are examined in dental caries research and surveillance programmes and yet we know little about their views on participation in these studies. Children are not miniature adults therefore undertaking research involving children using adults’ perceptions of what they suppose are children’s views is at best inadequate. Organisations like the Medical Research Council and UK Medicines for Children Research Network have developed guidance to inform research involving children (Alderson, 2007, Baston, 2008).

In the UK dental caries remains the disease most commonly affecting children, especially those from disadvantaged socio-economic backgrounds. National Health Service (NHS) epidemiological dental health surveys of children provide data for monitoring caries trends and commissioning dental services. These nationally coordinated surveys use dentists, trained and calibrated in the use of a visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) (Pitts et al., 1997) as the means of detecting dental caries. The dentists visit schools to examine participating children.

To produce top level evidence, studies evaluating the effectiveness of caries interventions require that examiners collecting research data are “blind” to certain attributes of participants e.g. area of residence. Using traditional visual examination methods, the only way to “blind” examiners to participants’ place of residence is by transporting them to examination sites outside the test and control areas (Milsom and Mitropoulos, 1990). Ethically and logistically this is impractical in studies involving thousands of children. Although the use of radiographs in epidemiological surveys has been advocated (Gowda et al., 2009), their use may be more appropriate in longitudinal studies to monitor interproximal caries progression in permanent teeth (Arrow, 2007). Other novel caries detection methods may not be suitable for epidemiological studies because they are cumbersome to use in the field on children or are dependent on user expertise or the physical environment (Pretty, 2006). An alternative method of “blinding” examiners would be for examiners to inspect intra-oral photographs of participants’ teeth.
Before this alternative method can be recommended for use in research and surveillance programmes, it ought to be tested for acceptability, validity and reliability as a caries detection method. There is little information available on children’s views on the NHS epidemiological surveys. Although the literature records how challenging it can be to obtain accurate reflections of children’s views on issues that affect them, evaluation of therapies and/or services for children would be incomplete without inclusion of their views. Attempts should be made to understand what children truly think of the dental health surveys they participate in. These surveys regularly involve 5-, 10-, 11- and 12-year-olds to allow regional, national and international comparisons. Therefore the development of new caries detection methods for use in these surveys should involve the same or similar age groups.

Methods used to appraise children’s views and experiences originated from research assessing pain experienced by children. These included simple visual analogue scales like the Oucher scale and the Children’s Hospital of Eastern Ontario Pain Scale (CHEOPS) (Beyer et al., 1992, Lyon and Dawson, 2003). Their core feature is the use of facial expressions as a response scale to indirectly measure subjective attitudes. Applying these scales to elicit children’s views can be simplistic. Other techniques have been used to elicit the views of young children across a wide range of themes. These include the use of focus groups and semi-structured interviews, storytelling, art/drawing, writing, role play and the use of puppets (Chapparo and Hooper, 2005, Fredman et al., 2007, Heary and Hennessy, 2002).

To obtain the children’s views on both the intra-oral photographic and the visual examination methods, an age-appropriate technique should be employed. Very young children find it easier to communicate with and through puppets in role plays (Hay et al., 1992, Lewis et al., 1992). If this is carried out in small groups, children feel more at ease than having their views sought in isolation. The aim of the study was therefore to elicit children’s views on the visual examination developed by BASCD and an intra-oral
photographic assessment examination method for detecting caries in epidemiological studies.

**Method**
Ethical approval was obtained for the study from the National Research Ethics Service, UK (Reference Number: North West 10 09/H1011/57).

The study population comprised two groups of children, one of children aged 5 years and the other of children aged 10/11 years, attending primary schools in Rochdale, a town in the North West of England. These age groups were chosen for the study because they are the ages at which national and international caries data is collected. Five primary schools took part in the study.

Study information sheets and letters were sent to parents of eligible children via the schools, inviting them to give their consent for their children to take part in the study. The 10/11-year-olds were also given study information sheets. Only children whose parents gave explicit consent were included in the study. Also a child’s decision not to participate in the study was respected.

Only children who had recently (less than 1 week) experienced both the visual and photographic examination methods were included. In each of the 5 participating schools, the research team liaised closely with teachers to determine a purposive sample comprising two groups of five 5-year-olds and two groups of five 10/11-year-olds, a total of 20 groups. There were 5 children in each focus group. Interviews were conducted separately with each focus group. The children gave their views on the two examination methods with or without the aid of a puppet, according to their age. The interviews were conducted in the children’s respective schools and audio recorded onto Sony Digital Voice Editor 3® (San Diego USA).
For the 5-year-olds’ interviews, the children and the interviewer (with the puppet) sat in a circle in a quiet room familiar to the children. Before starting each interview, the children were familiarised with the recording equipment, the puppet and the rules of engagement for the interview.

At the start of each interview, visual prompts were used to help the children recall their experiences of having the two methods of examinations. The children were told that the puppet was going to have the two examination methods that they had experienced. Using an interview guide the children discussed what in their view the puppet could expect and how it might feel about the experience. Each interview was on average about 30 minutes long.

The 10-/11-year-olds’ interviews were conducted in a similar fashion to those of the 5-year-olds but without the use of the puppet. They were asked directly their views on the two examination methods they had experienced.

The audio recordings of the interviews were transcribed and analysed. A grounded theory approach using the constant comparative method outlined by Green & Thorogood (2009) was used. After each batch of four interviews, the transcripts were analysed using line-by-line open coding. The words and short phrases generated were used to sum up the substance of the text. The principles outlined by (Corbin, 1998) for coding data was used to develop the grounded theory. Data collection and analysis proceeded concurrently allowing the emerging hypothesis to be developed (Pope et al., 2000). Themes emerging from the analysis of initial interviews were used to adjust the interview guide for subsequent interviews in order to refine and clarify the data being captured. Data within categories were scrutinized for deviant cases and confirming views across the range of children. Further data collection and analysis of interview transcripts proceeded in this manner until there was little new data emerging from the analysis.

To enhance validity of the process, a clear account of the method and data analysis has
been provided to allow reproducibility (Mays and Pope, 1995). Also the transcripts were scrutinized by an independent reader who was not otherwise involved in the study to provide a measure of trustworthiness and validity of the interpretation (Van Til et al., 2003). Quotes indicative of the children’s views have been reported to show that the analysis is fully grounded in the children’s accounts.

Findings
A total of 100 children participated in the study. There were fifty 5-year-olds and fifty 10-/11-year-olds. The male to female ratio was 1:1. There were no drop-outs as the sample was purposefully obtained.

The following categories emerged from the grounded theory analysis:
The communication category comprises the children’s recollection of what information they received prior to both examination methods. It also includes the children’s expressed opinions on what they would have liked to have been said to them by the dentist by way of explanation or reassurance.

The expectation category covers the positive and negative views of what the children thought would happen during both examination methods.

The initial impressions category relates to responses about the children’s feelings when they entered the examination room for both methods. These were expressed as positive or negative.

The experiences category encompasses the whole experience of dental examinations and comprises the following sub-categories: dental examinations in general, examination with the mirror, the camera, and seeing pictures of the teeth taken by the camera. The dental examinations had properties relating to the environment and children’s feelings about the experience. The camera and mirror had properties relating to sensations in the mouth and the children’s feelings about their experience. Each property had a positive and negative dimension. The children also expressed negative or positive feelings about seeing images
of their teeth captured by the intra-oral camera.

The preferences category summarises the children’s preferences for the visual examination or the photographic examination method. These were expressed as a preference for either, both or neither method.

The improvements category encompasses the children’s ideas on how the experience of both examination methods could be improved.

The overarching category which held the other categories together to form an explanatory whole was acceptability of the dental examination. The main categories and sub-categories were constructed to present a preliminary model of a grounded theory of what happens in the dental examination in the school setting and how this contributes to children’s acceptability of the intra-oral camera and mirror as caries diagnostic tools.

A summary of the preliminary model depicting the children’s acceptability of the visual and photographic dental examination methods is presented in Figure 5.1.

The model acknowledges the influence of all these factors on the level of acceptability of the dental examination and in determining children’s views on their preferences for the visual and the photographic examination.

Majority of the children preferred the photographic method and preferred the visual method. A third was equally happy with both examination methods. A minority expressed negative views on both methods.
Figure 5.1: A grounded theory of children’s acceptability of the dental examination in the school setting
Discussion

The main finding of this study was that the children’s views on the methods of examination related to the level of acceptability of their experience. Factors affecting acceptability and the children’s preferences related to the combined effects of contextual factors prior to the examination and experiences during the examination. These included communication and children’s expectations. These factors influenced the examination experience along with their feelings about the environment and the tactile sensation in their mouths from instruments. The children also wanted more communication during the examination and feedback on their oral health.

The responses about communication indicated that in general the examiners gave directive instructions and brief information to the children about what was happening and in some cases this was child focused. The level of fear, nervousness and lack of understanding, in some cases however, suggests that those children had not been fully informed about the dental examination or misunderstood the information given. The responses about the communication they would have liked revealed a discontinuity with the communication actually received. The children also wanted feedback on their oral health and more communication in the form of explanation during the examinations.

“They could have given us more information on what they were actually like doing and how the teeth were. Not just say they are OK, like tell us” Child 15-1

The children in this study considered communication between the dental epidemiology team and themselves to be a factor which contributed to their level of acceptability of the examination methods. This was emphasised in the improvements suggested by children for the examinations.

Past dental experiences and preconceived ideas shaped the children’s expectations of dental examination which in turn seemed to affect their initial impressions of the examination room in both examination methods. This is not surprising as generally dentistry produces anxiety and fear in a number of children (Tickle et al., 2009). Although some children were not daunted by the dental examination and had resilience to what
was a new experience, the responses showed that for others, their expectations were negative, dominated by fear, uncertainty and nervousness.

“When we first walked in we were all scared and nervous because I didn’t know what we were going to do...” Child 4-2

Some of those who coped well described their experiences of the examination methods as happy, fun and exciting.

“At first before I walked in to the room, I felt really happy and excited”. Child 4-4

It was apparent from the children’s responses that the environment in which the examinations were performed played a part in determining the acceptability of both methods as did sensations in the mouth from instruments and items such as cotton wool used for the examinations.

“When they put the light on and I put my sunglasses on, you know that mirror thing, it looks like a knife but, then I took my glasses off and it was, it didn’t look like a knife so I just put them back on while they counted my teeth” Child 8-3

This is consistent with findings in the literature that the environment in which dental care is provided and the manner in which care is received influences how patients perceive the experience. A supportive dental environment in which strategies to make patients feel relaxed and in control are employed increases the patient’s acceptability of the dental care provided (Law and Blain, 2003). An important part of these strategies is communication between the dental team and the patients.

A frequency count of responses indicated that fewer participants preferred the visual examination method as compared to the photographic method. Of those children who preferred the visual examination method, familiarity with the process and the fact that they could keep the disposable examination mirrors used contributed considerably to its acceptability. Others complained of a dry mouth and disliked the taste of the examination gloves used. Although gloves were also worn for the intra-oral camera examination method, the children did not comment on the taste of gloves in their responses about
method. This could be explained by the fact that the children may have been distracted by their interest in the images of their teeth produced by the intra-oral camera.

The children’s preferences indicated that generally the intra-oral camera was well received. Predilection for technology was cited as the reason for their preference by some. Also being able to see images of their teeth on a screen was a positive experience for many and was the most common reason given by the children for their acceptability of the experimental method.

“I liked it when I saw my teeth because naturally humans don’t get to actually look inside their mouth, because of the positioning of their eyes, and except looking at them in the mirror when you are brushing your teeth, there is a brush in the way so you can’t actually see right at the back, where ever the photo was took so quite interesting actually, to see what they actually looked like”. Child 7-5

Some children expressed disappointment that they were unable to see the images of their teeth on the screen throughout the examination period.

“Do you know on the camera when you lie down you can’t see because they take the pictures and like when you look up the pictures you don’t get to see them” and “It would have been better if they put the screen on top of your head, so you could see it” Child 20-4

This was however set against the difficulty for some of the shock of seeing their teeth on a screen. They found the size of their teeth worrying and some children disliked the yellow appearance of their teeth

“It felt horrible because it’s like you could see the gums and everything and the teeth had like yellow stuff on. Well I know everyone has yellow teeth but again I really hate yellow so when I grow up I might get my teeth whitened” Child 8-2

Another characteristic of the experimental method commented on by participants was warmth/heat from the camera. The camera warms up when it has been in use for a while. Although the warmth was seen as a positive attribute by some, others expressed negative feelings of pain and discomfort. Having a spare camera available to use when the first is
warm could be a way to overcome this in those participants for whom the sensation of warmth is a difficulty.

The frequency count of responses showed that very few children were happy with both examination methods and even fewer expressed negative views on both. The latter group were generally those who had negative experiences and expectations of dental examinations.

Although children may consent by their conduct to partake in epidemiological studies, dental epidemiological teams could enhance the experience for child participants by conducting the dental examinations in conducive environments with more explanatory and effective communication.

Other improvements suggested by the older children related to privacy and confidentiality issues. Peer victimisation, teasing and bully among school children are still major issues (Lunde et al., 2007) even though most schools have policies to control these problems. Physical appearance such as malocclusion has been listed as one of the characteristics for which children are bullied (DiBiase and Sandler, 2001). A few of the children in the study were worried by other children seeing or hearing what the examiners had to say about their teeth. For dental examinations that take place in the school setting, the environment that dental epidemiology teams have to work in is often dictated by the space schools can spare. This can result in children being examined in a non-confidential manner. Other children especially those with negative experiences and preconceived ideas about dentistry however requested reassurance from the presence of a friend or teacher if required.

As far as we can discover, this is the first study to use a grounded theory to explore children’s views and experiences of the established visual examination method and obtaining intra-oral photographs for the dental examination in the school setting. The findings demonstrate that children should not be seen as passive participants in the dental examination but rather as a group able to express their views on their experiences and exercise discernment in their attitude regarding what happens to them. Dental
epidemiology teams need to be sensitive to children’s needs and improve the acceptability of the dental examination experience by managing the contextual factors including communication, the examination environment and handling instruments in the mouth.

Intra-oral photographs enable archiving of images which can be revisited for a number of purposes, for example longitudinal studies; enable examiner blinding in research studies; offer the possibility of remote dental examination and screening; and support the use of a single examiner to assess all participants in epidemiological studies thus eliminating concerns about inter-examiner reliability.

In order to progress the development of the use of intra-oral photographs as a means of detecting caries in dental public health epidemiological studies, as well as the children’s views, the views of other stake-holders especially those of the dental epidemiology team should be sought on how user-friendly and cost effective the experimental method is compared to the established method.

**Conclusion**

Children’s views on the examination methods related to the level of acceptability of their experience. The key factors affecting acceptability and children’s preferences related to the combined effects of contextual factors prior to the examination and experiences during the examination. Appropriate communication, attention to the examination environment and sensitivity in handling instruments could enhance the dental examination experience for children in the school setting. The children’s preferences indicated that generally the intra-oral camera was well received as a means of caries detection for epidemiological studies within the school setting.

These results may have implications for seeking ethical approval and conducting epidemiological studies on children in the future.
Rationale - Paper 4

Pragmatic applicability is an essential requirement of any caries detection method or tool that is used in the field to collect epidemiological data. The views of users of the method or tool in the field are therefore very important. These views are useful for shaping further developments of the method and devising ways of improving application of the method in the field. An important part of this thesis was therefore to elicit the views of examiners on using the methods developed and tested in Papers 1 and 2. Hence the need to conduct the study reported in this chapter and publish Paper 4.
The views of examiners on the use of intra-oral photographs to detect dental caries in epidemiological studies

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Aim: The aim of the study was to obtain the views of examiners on their experience of using intra-oral photographs as a means of detecting caries in epidemiological studies compared to an established visual examination method. Method: A focus group discussion was conducted with five examiners experienced in an established visual examination method after they had performed visual dental examinations of a sample of children as well as assessed intra-oral photographs of the same children. Results: The time taken by examiners to assess intra-oral photographs becomes extended when compared to performing a visual examination. The ability to assess intra-oral photographs on a screen at a convenient time and place was considered advantageous. The examiners found it easier to make caries detection decisions on intra-oral photographs of primary teeth than permanent teeth. Adequate removal of debris and moisture control prior to obtaining the photographs were viewed as important. Conclusion: The views of examiners in this study suggest that to improve the utility of photographic method, further research is needed to determine adequate drying methods for use in the field. Consideration should be given to a time-limited, standardised presentation of the photographs including the size and resolution. Specific training on caries detection from photographs is also required.
Introduction

Despite a decline in the prevalence of dental caries in many countries, it still remains the most significant disease in children (Marthaler, 2004). The prevention and treatment of dental caries consumes most of the dental resource allocation of state-funded health budgets. Data collated through dental epidemiological studies to inform the allocation of these resources should provide dental public health planners with appropriate information to complete this task efficiently. Different caries detection methods of varying sensitivity and specificity dependent on the degree of progression of lesions have been described in the literature (Bader et al., 2001). The choice of caries detection method for such studies is dependent on a numbers of factors. Validated caries detection methods with high sensitivity for identifying early carious lesions are useful in longitudinal caries progression studies and in the clinical management of the disease (Ismail, 1997). Epidemiological assessment of caries traditionally relies on visual assessments. Many countries including the United Kingdom (UK) use traditional visual examination methods for their national epidemiological studies and record caries at the dentinal level. The visual examination method used in the UK National Health Service (NHS) epidemiological surveys was developed by the British Association for the Study of Community Dentistry (BASCD) (Pine et al., 1997b). This method is however unsuitable for comparative studies where examiner “blinding” to some attributes of participants is required to reduce the risk of bias. An alternative inexpensive and simple method of “blinding” suggested by Boye et al., (2012) is for examiners to assess intra-oral photographs of participants’ teeth instead of a visual examination. An additional benefit of this method is the ability to archive the obtained photographs, undertake repeated and remote analysis and the possibility of using a differently skilled workforce such as hygienists to acquire the images which may reduce the costs of such surveys.

This method has been shown to be a valid and reliable means of assessing caries (Boye et al., 2012). It has also been shown to be acceptable to children, the main participants of the caries epidemiological surveys (Boye et al., in press). The experiences and views of examiners on diagnosing caries from the intra-oral photographs in epidemiological surveys
has however not been reported in the literature. This is an important aspect of the implementation of such systems. While they may be scientifically and philosophically ideal, unexplored barriers to their effective and efficient use in the field could hinder their uptake. By understanding the views of the users such barriers can be explored, and often reduced or eliminated.

The aim of this study was to obtain the views of examiners on their experience of using the established visual examination developed by BASCD and the assessment of intra-oral photographs as means of detecting caries in epidemiological studies and explore how these experiences were influenced by some of the practical issues encountered during the examinations.

**Method**

Ethical approval was obtained for this study from the National Research Ethics Service (Reference Number: North West 10 09/H1011/57).

The examiners used in the study had been trained and calibrated to the BASCD caries examination protocol as members of the UK National Epidemiological Surveys team (outside the current study). Completion of this national training and calibration in the BASCD caries examination protocol was used as the main selection criterion for recruitment of the examiners into this study. Five examiners, who were dentists trained, calibrated and experienced in the use of the visual examination method developed by BASCD for use in the UK NHS dental epidemiology programme, took part in the study. These examiners had each participated in the visual examination of more than 200 5-year-olds and 200 10/11-year-olds in schools. The same dentists (after appropriate training) had also assessed intra-oral photographs of the same children as a means of detecting caries. The intra-oral photographs were obtained by a single examiner (not one of the 5) at the time when the visual examinations were carried out. For the photographic assessments, each of the five examiners was provided with a Universal Serial Bus (USB)
flash drive loaded with labelled folders containing a set of intra-oral photographs of each participant’s teeth at least two months after the visual examinations. Each examiner viewed the photographs on either laptop or desktop computer screens at a time of day and room conditions of their choice. Caries was diagnosed at the “caries into dentine” level. Examiners recorded their diagnosis on score sheets.

The examiners convened three weeks after they had carried out both the visual examination and photographic assessments for a focus group discussion to explore their views on their experiences of using the two methods and also to clarify any issues that needed further explanation.

All five examiners were invited to attend the focus group and they were given the topic areas that would be covered in the discussion. A member of the research team facilitated the discussion. Another individual was present solely to take additional notes about the group interactions. Before the start of the focus group discussion the facilitator informed the participants of the ground rules and established the guiding principles of the discussion. Confidentiality was also assured.

The areas discussed by the group included the participants’ views on the following topics:

- The conditions for conducting the examinations
- Their experiences of the two examination methods
- The differences between the use of intra-oral photographs and visual examination as means of detecting caries
- Their perceived advantages of assessing intra-oral photographs to detect caries instead of performing a visual examination using BASCD criteria
- Their perceived advantages of performing a visual examination using BASCD criteria instead of assessing intra-oral photographs to detect caries
- How the intra-oral photographic method could be used for future epidemiology work
• Their views on how the intra-oral photograph method could be improved.

The focus group discussion was audio recorded digitally and lasted for 50 minutes.

An audio typist transcribed the focus group discussion recording verbatim. Thematic analysis identified the common themes from the focus group discussion transcripts by first assigning codes to the emergent themes then, using an inductive process for constructing interpretations, the codes were used to develop an overall classification of themes. Transcripts were then closely examined for sections that did not fit the emergent framework. The overall classification of themes was assured by an independent researcher’s analysis of the transcripts and the notes taken during the focus group discussion (Barbour, 2001). To add to the credibility and trustworthiness of the research process, a protocol for the method and data analysis used in the study was produced to create an audit trail to enable reproducibility (Jootun et al., 2009). In the presentation of the study findings, selected quotes from the focus group discussions are used to illustrate how analysis of the data reflects the views of the examiners (Gill et al., 2008).

Findings

All the five examiners contributed to the focus group discussion. As they were experienced in the use of the visual examination method, in their discussions, the characteristics of the intra-oral photographic assessments method were compared to the former. The following are the main themes that emerged from the focus group discussion:

Viewing/Examination Conditions

This theme relates to the participants’ responses about the environments in which the photographic assessments were carried out. This included type of lighting, time of day, and type of screen used for viewing photographs as these examples show with the examiner’s identification number appended:

“when I was doing it in work it was just natural light through the window, but at home our computer is on the landing, we don’t have a window there, so that was artificial light” #2

“I did mine day and night, on a desk top and it was either with natural light or with just a
normal light bulb.” #1

“... but I used one (desktop) in work and one (laptop) at home so I was using different computers and I didn’t find any difference there”. #5

and “I did try doing them on my laptop but I felt that was too, the screen was too small, so I ended up doing it on one with a full size you know” #2

Viewing/Assessment Process

This theme comprised the participants’ views on their experiences of assessing the intra-oral photographs and the associated demands on the examiners as compared to the visual examination method. The following sub-categories were identified: duration of viewing which consists of time taken to view an intra-oral photograph, time taken to view all the intra-oral photographs of a patient and the total length of time participants spent “sitting” carrying out all the assessments. Some of them spent whole days on this activity or described it as taking “an awfully long time” #1 but acknowledged that it “got easier towards the end” #2.

“I think I took longer over the photographs because if I was in doubt at all, I was staring at the photographs for a long, long time, whereas if you have got a wriggly child you do just, go in, have a quick look you have got your epidemiology head on so you know it’s a quick look, score low and that is what we are used to doing, but when there is a photo on the screen and you think, there might be a shadow there, you can spend a long, long time and you look at it from different angles, you know, so I think the photographs probably took me longer.” #5

the mental and physical demands of the viewing process;

“I tried to just do one school per evening, so that’s 30 / 40 children, well I never really managed 40 and so it was basically an hour and then, I had lost concentration really”. #2

“I think I tried to limit it actually because I started getting very sharp pains down my side of the neck, so I limited it to about an hour, and then went off and did something else for 10 minutes and then came back at it fresh”. #1
and any additional support required such as a scribe.

“I actually used (dental nurse) as a scribe, so I have them (paperwork) and she did as we do in when we are out in the field and that was actually very good. We got through it very quickly then. …” #3

Utility

This category relates to the participants’ views on the utility of the two examination methods. They expressed views on the advantages and problems of each method. They found it difficult to make decisions about the presence of tooth coloured restorations and the extent of carious lesions especially when assessing the intra-oral photographs of the permanent dentition

“Because of my greatest uncertainty when assessing early lesions and tooth coloured fillings I found it easier to assess the 5-year-olds’ photographs than the older children’s”. #5

The use of a zoom facility to enlarge the view of the photograph was suggested by one participant as a way to aid caries detection decisions when there is doubt.

“it would be great if you could zoom in, and have a look at the images” #4

The rest of the participants however voiced concerns about altered perceptions of the magnified tooth and questioned whether that would be helpful as in their opinions photographs needed to be viewed in a standardised way in studies involving multiple examiners.

“I didn’t think that is the right thing to be doing in that situation. Because you are not having a standard examination, you know you are looking at one patient, with it at one magnification and another patient with something completely different so your results are going to be, quite dramatically different…” #1

The examiners said that the tactile sense derived from touching the teeth with a probe was a valuable aid in detecting caries, restorations, fissure sealants and malformations of enamel or dentine; hypoplastic teeth could be mistaken for caries on a photograph.
“I suppose that you can look, you can move the child, you can move your light, you can move your mirror and it’s what we are used to, that’s more what we are trained in, the photographs are still very new to us, aren’t they so?” #3

“Not being able to touch it (the tooth) with a probe; that was difficult. I think the ones that were obviously healthy or obviously carious that was quite easy and quite quick but it was the doubtful ones, that was where I was having difficulty and spending a lot of time, and still not resolving it at the end you just wanted to poke them really, didn’t you?” #5

The examiners reported that saliva and debris on teeth were problematic when assessing the photographs.

“I think they were very good photographs but saliva is still a problem. Saliva definitely yes, It only needs a tiny amount of saliva and the light shines off it doesn’t it, and you can’t tell if there is a cavity.” #3

Despite the drawback of extended viewing experienced by some examiners, being able to look at an intra-oral photograph of a tooth on a screen at any time “examining the subjects from the comfort of your arm chair!” without “fighting a tongue, cheek and a wriggly child” #4, was considered advantageous.

This theme also includes the participants’ expressions of further applications for the photographic method in dental epidemiology studies. These were the use of intra-oral photographs for remote training and calibration of examiners in epidemiological skills and in longitudinal caries progression studies.

**Improvements**

This theme sums up the participants’ views on how the intra-oral photographs examination method could be improved to enhance its usefulness. The main improvement they suggested for the photographic method was the use of more efficient means of moisture and debris removal such as compressed air instead of cotton wool prior to taking the intra-oral photographs.

“… yes, dry with air, if you were just doing photographs then you might be able to get a
Also more training on assessing intra-oral photographs for caries was requested by the group

“we are trained to look at the teeth and score them in a clinical situation, but I think, to have a training exercise looking at the photograph and as we do to be able to discuss with other people because it is slightly different and to get your head round this scoring ... on photographs I think you do need a bit more training about that”. #2

Discussion

The study explored the views of a number of experienced examiners trained and calibrated in the visual examination method developed by BASCD for use in the UK NHS dental epidemiology programme on their experiences of assessing intra-oral photographs as a means of detecting caries as compared to the BASCD developed visual method. The main findings of the study are that the time taken by examiners to assess intra-oral photographs becomes extended when compared to performing a visual examination. The ability to assess intra-oral photographs on a screen at a convenient time and place was considered advantageous. The examiners found it easier to make caries detection decisions on intra-oral photographs of primary teeth than permanent teeth.

In common with other qualitative research, a limitation of this study is that in its pursuance of an in-depth understanding of the subject under investigation, a small number of participants who may not be representative of all examiners were engaged in the study. This makes it less easy to generalise the findings from the study to the population (Allen et al., 2010). However the purpose of this method of enquiry is to uncover all the issues pertinent to the subject matter not their prevalence or frequency distribution (Green and Thorogood, 2009).

As experienced examiners in the visual examination method, the participants
Acknowledged and expressed the need for and requested further training in the assessment of intra-oral photographs as a means of detecting caries. This is similar to the finding by Assaf et al. (Assaf et al., 2006) that although the use of new methodology may be possible in epidemiological surveys, strategies to improve training in diagnosis and calibration of examiners are necessary. The use of photographs enables such calibrations to be undertaken with ease. A standard portfolio of photographs can be prepared and presented to examiners for such purposes. It is also possible for this calibration to be undertaken online, with real time responses to decisions and immediate feedback. Such calibration can be undertaken at the examiners’ convenience and does not require access to schools or children. The use of a standardised validated and calibration set of photographs that can be used across multiple examiners, in multiple sites over multiple years is advantageous.

The examiners’ familiarity with the visual examination method could explain why most of them reported spending less time making a diagnosis during the visual examination method while the photographic method took time to get used to. This is because in the examiners’ experiences the whole mouth is in sight and can be viewed as part of the person during the visual examination. Also the child being examined as well as any equipment and the instruments e.g. light source and hand mirror can be repositioned to aid the examiner. All these options were not available to the examiners in the photographic method. The ability of those collecting data to be able to view the teeth and mouth as an extension of the person and his/her environment as part of the diagnosis decision making process however could be a potential source of bias in epidemiology studies evaluating oral health interventions (Milsom and Mitropoulos, 1990).

The participants reported that sitting for an extended time in front of a computer screen, interpreting photographs, made physical and mental demands on them. The participants expressed that they experienced tiredness, physical strains and loss of concentration. Physical symptoms included sharp pains down the side of the neck, dry eyes, eye strain.
and wrist strain. As in studies of those working with visual display units (Korhonen et al., 2003) has shown, these factors made it more difficult to make a diagnosis. The examiners however had ways of overcoming these difficulties that included working for shorter periods, taking breaks away from the computer and “coming at it fresh”. A way around this is to standardise the process by ensuring time limited viewing of images and the standardisation of the size and resolution of images. There is however no consensus in the literature currently, whether the photographs of teeth should be viewed as life sized or magnified.

The examiners described how they spent time deliberating over the interpretation and scoring of questionable carious lesions. While some examiners saw the ability to view the intra-oral photographs again at a later time as an opportunity to affirm their diagnosis (an opportunity not available with the visual examination method) others felt it extended the time for indecision. This could be mitigated by time limited access to photographs (Langer et al., 2006).

The accompanying paperwork for recording diagnostic decisions was seen by the examiners as exacerbating the duration for viewing photographs and they felt this could be reduced by preparing the paperwork prior to the photographic assessments and the use of a scribe as occurs when undertaking the visual examination method. This may reduce the potential cost savings of using the photographic method. Alternatively an electronic on screen recording system synchronised to the images could be developed.

The examiners reported experiencing more difficulty interpreting and scoring photographs of the permanent teeth than those of the primary teeth, similar to the findings in other studies. Costa et al. (Costa et al., 2007) found that diagnostic methods for occlusal caries were more efficient in primary teeth than permanent teeth.
The examiners also expressed experiencing problems associated with identifying the presence of tooth coloured restorations, clear fissure sealants and non-curious lesions and attributed this to the lack of tactile sensation. Bader et al. (2001) found no evidence to suggest the superiority of tactile methods. Factors which obscured the tooth surface such as saliva, food debris, plaque and stains were problematic. Some of these factors can be more easily eradicated in the visual examination method; however any moisture or debris that remains on the tooth when the intra-oral photograph is captured is in effect a permanent obstruction which will always impair caries detection from that image. Moisture control in children can however be challenging (Tran and Messer, 2003) and even more so when obtaining intra-oral photographs. In the view of the examiners, using more efficient means of moisture control such as compressed air when obtaining intra-oral photographs rather than using cotton wool rolls as stipulated for use in the visual examination method developed by BASCD will improve their utility. The use of a camera with an inbuilt drying nozzle could also assist.

The use of the photographic method could support epidemiological surveys as part of the training, calibration and data collection processes. It allows multiple examiners to inspect a tooth without the difficulties often encountered when a child experiences multiple examinations. Participants identified that this feature will lend itself to e-learning training and calibrating examiners in caries epidemiology skills remotely or by convening. Examination of archived intra-oral photographs in a longitudinal study of caries progression was identified as more likely to allow accurate and reliable comparisons than the comparisons of visual and written records.

As the debate continues about the level at which caries should be recorded in dental epidemiology surveys there is increasing support for the use of intra-oral photographs in this field (Elfrink et al., 2009). The examiners in this study were optimistic about the possible use of the photographic method for remote training and calibration of examiners in epidemiological skills with improved utility.
Conclusion

The views of examiners in this study suggest that to improve the utility of photographic method, further research is needed to determine adequate drying methods for use in the field. Consideration should be given to a time-limited, standardised presentation of the photographs including the size and resolution. Specific training on caries detection from photographs is also required.
Paper 5: Comparison of Varying Numbers of Intra-oral Photographs with an Established Visual Caries Examination Method for Use in Dental Epidemiological Studies of Children

Rationale - Paper 5

The testing of the intra-oral photographic assessment method as a caries detection method in both the in-vitro (Paper 1) and in-vivo (Paper 2) studies showed promise. The qualitative studies showed that the method was acceptable to children however, obtaining full mouth intra-oral photographs was found to be time consuming. The caries detection information may be available from fewer intra-oral photographs thus reducing the time taken to obtain the photographs, costs and inconvenience and therefore this approach using reduced numbers of images needed to be tested in the field, hence the need to conduct the study reported in this chapter.
Comparison of varying numbers of intra-oral photographs with an established visual caries examination method for use in dental epidemiological studies of children

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MESH Keywords
Caries detection  Intra-oral photographs  Dental epidemiology
Method comparison  Visual examination  Children

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Abstract

Aim A cross-sectional study was conducted to compare caries data obtained from a full mouth visual examination using the method developed by the British Association for the Study of Community Dentistry (BASCD) in epidemiological surveys with caries data obtained from eight, six and four intra-oral photographs of index teeth in two groups of children aged 5 years and 10/-11 years.

Method Five trained and calibrated examiners visually examined the whole mouth of 240 5-year-olds and 250 10/-11-year-olds using the BASCD method. The children also had intra-oral photographs taken of index teeth. The same 5 examiners assessed the intra-oral photographs (in groups of eight, six and four intra-oral photographs) for caries using the BASCD criteria; dmft/DMFT were used to compute Weighted Kappa Statistic as a measure of intra-examiner reliability and intra-class correlation coefficients as a measure of inter-examiner reliability for each method. A method comparison analysis was performed to determine the 95% limits of agreement for all five examiners, comparing the visual examination method with the photographic assessment method using 8, 6 and 4 intra-oral photographs.

Results The intra-rater reliability for the visual examinations ranged from 0.81 to 0.94 in the 5-year-olds and 0.90 to 0.97 in the 10/-11-year-olds. Those for the photographic assessments in the 5-year-olds were for 8 intra-oral photographs, 0.86 to 0.94, 6 intra-oral photographs, 0.85 to 0.98 and for 4 intra-oral photographs, 0.80 to 0.96; for the 10/-11-year-olds were for 8 intra-oral photographs 0.84 to 1.00, 6 intra-oral photographs 0.82 to 1.00 and for 4 intra-oral photographs 0.72 to 0.98. The 95% limits of agreement were -1.997 to 1.967, -2.375 to 2.735 and -2.250 to 2.921 respectively for the 5-year-olds and -2.614 to 2.027, -2.179 to 3.887 and -2.594 to 2.163 respectively for the 10/-11-year-olds.

Conclusions The photographic assessment method, particularly assessment of 8 intra-oral photographs with the additional benefits of archiving, remote scoring, allowing multiple scorers to score images and enabling longitudinal analysis, may be used as an alternative caries detection method in the primary dentition in situations where the visual examination method may not be applicable.
Introduction

Although there has been an improvement in oral health, levels of dental caries remain high in some sections of society and caries is still the most significant cause of poor oral health in children (Arora et al., 2012). Dental caries epidemiological surveys, as well as studies designed to evaluate the effectiveness of interventions for caries prevention and management are therefore mainly, although not exclusively, conducted in children. Having the appropriate tools to support the delivery of reliable dental epidemiological surveys and enable robustly designed studies to be conducted is therefore important.

In the UK the National Health Service (NHS) dental epidemiological surveys which are regularly undertaken have ensured that the UK has one of the most respected caries surveillance programmes for children. These UK surveys use the well documented visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) (Pitts and Evans, 1997). However visual dental examinations by their nature can introduce assessment bias into dental epidemiological studies and therefore limit their robustness. This is particularly relevant when examiner blinding is required in studies undertaken to evaluate oral health intervention strategies or community water fluoridation schemes (McDonagh et al., 2000b). Having considered the barriers to using other methods of caries detection as an alternative to the visual examination method, a study by Boye et al. (2012) showed that assessments of intra-oral photographs has promise. Intra-oral photographs have been used in the clinical setting to record caries and hypo-mineralization in primary molars (Elfrink et al., 2009) and to score caries on primary and permanent teeth in the epidemiological setting by Boye et al. The use of intra-oral cameras in the epidemiological setting has been shown to be acceptable to children, the main population involved in caries epidemiological and intervention studies [Boye et al. in press]. An advantage that the use of intra-oral photographs has over visual examination methods in such studies is the ability to archive intra-oral photographs. This permits multiple scorers to score the images as well as remote scoring and longitudinal analysis.
There are however surmountable practical challenges to more widespread use of this method of data capture. Examiners who trialled this photographic assessment method were found to be optimistic about the use of this method in dental epidemiology with improved utility [Boye et al. in press]. One of the key challenges relates to the number of intra-oral photographs required to provide adequate information to undertake a caries assessment. To enable the assessment of all surfaces of the teeth as they would be in a visual examination of the mouth, examiners have to be provided with intra-photographs showing all surfaces of all the teeth. This approach makes the photographic assessment method a much longer and therefore more costly process as compared to visual examination methods.

The evidence from the UK NHS dental epidemiological surveys data (The Dental Observatory, Preston UK) show that caries in the primary dentition is usually located in the molars, upper incisors and lower canines and caries in the permanent dentition is usually found in the first molars and so it would make sense pragmatically and financially to limit the data capture to these teeth assuming there is no loss of information required to support assessment. These teeth are henceforth referred to as the index teeth. Use of index teeth or sites is common in other epidemiological and clinical assessments, for example in periodontal studies (Leroy et al., 2010).

**Aim**

The aim of this study was to compare the visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) with a photographic assessment method (assessment of information provided from caries assessment with varying numbers of intra-oral photographs) for use in epidemiological surveys.

**Objectives:**

To compare the mean caries indices obtained from a full mouth examination using the visual method with
• the mean caries indices obtained from the assessment of eight intra-oral photographs of identified teeth liable to decay (index teeth) in the same subjects
• the mean caries indices obtained from the assessment of six intra-oral photographs of index teeth in the same subjects
• the mean caries indices obtained from the assessment of four intra-oral photographs of index teeth in the same subjects

in two groups of children aged 5 years and 10/11 years; the two main cohorts examined in the UK NHS epidemiological surveys.

**Method**

Ethical approval was obtained for the study from the National Research Ethics Service, UK (Reference Number: North West 10 09/H1011/57).

This was a cross-sectional, method comparison study comparing an established visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) for the nationally coordinated NHS epidemiological surveys of children in the UK with a photographic assessment method in a sample of 5-year-old and 10/11-year-old children.

**Study Population**

Five-year-old and 10-/11-year-old children attending state primary schools in Rochdale an area in the North West of England, with a 5-year-olds population dmft of 2.08, dt of 1.79, mt of 0.17 and ft of 0.12 in 2007/2008 and 12-year-old population DMFT of 0.95, DT of 0.40, MT of 0.09 and FT of 0.45 (The Dental Observatory, Preston UK), was the study population. Before data was collected, study invitation letters, study information sheets and consent forms were sent to parents/legal guardians of eligible children via their children’s schools, informing them about the study. Parents/guardians were asked to provide informed consent to enable their child to participate. Completed consent forms were returned to the study team via the schools. For the 5-year-olds, only children whose parents or legal guardians gave positive consent were included in the study. For the 10-
/11-year-olds in accordance with the guidance from the UK Department of Health (CDO, 2008) regarding consent for this age group, only those children who gave informed consent in addition to their parent’s compliance to let them participate were included in the study. Each child recruited into the study was assigned a unique study identification number (ID).

Examination and Assessment

The children in each age group had a visual dental examination according to BASCD diagnostic protocol (Pitts et al., 1997) and also had 8 intra-oral photographs taken of their dentition on the same day as the visual examinations. All the examiners involved in the study were experienced epidemiological examiners (with a minimum of 10 years’ experience) and had been trained and calibrated to the BASCD caries examination protocol as members of the UK National Epidemiological Surveys team (Mitropoulos et al., 1990). Completion of this national training and calibration based on a minimum sensitivity of 0.75 a specificity of 0.90 for the primary teeth and a minimum sensitivity of 0.80 a specificity of 0.90 for the permanent teeth was used as the main selection criterion for the examiners used in this study.

Visual Dental Examinations

The visual examinations were performed by 5 dentists one of whom was a bench mark examiner for the UK NHS epidemiology programme. All the dental examinations took place in the children’s schools. During the visit to each school five examination stations were set up to enable 5 children to be examined at a time in each examination cycle. The children lay supine on each of five examination tables with an examiner seated at the head end. The children remained at the examination stations whilst the examiners moved round the stations, examining each child in turn until all the children had been assessed by all 5 examiners. At the end of each examination cycle another group of 5 children were brought to the stations to replace those already examined for a new examination cycle to begin. The examination for dental caries was carried out according to the method, criteria
and coding system employed in the BASCD coordinated NHS Epidemiology Programme (Pitts et al., 1997), using the recommended instrumentation and equipment:

- Daray X100 Lamps with Pivot D desk mount (Daray Healthcare Products® Swadlincote, Derbyshire) as light source, a hand mirror, cotton wool rolls and a blunt probe for the removal of debris sterilization/disinfection precautions
- data collection and data validating methods (Pine et al., 1997b) using Dental Survey Plus (Dental Survey Plus 2® The Dental Health Services Research Unit, University of Dundee).

The primary teeth were examined in the 5-year-olds and only the erupted permanent teeth were examined in the 10/11-year-olds. All surfaces of each eligible tooth examined were scored. Caries was diagnosed visually at the ‘caries into dentine’ level. 15% of the children in each age group were re-examined to test intra-examiner reliability. The scores for each subject were recorded by a scribe on to a pro-forma labelled with the unique ID of that subject and inputted into Dental Survey Plus 2® software programme.

Photographic Procedures and Assessments

Prior to taking the intra-oral photographs, folders carrying the same unique IDs as those assigned to the subjects for the visual examinations were created on a password protected computer. This was to enable matching of the visual examination and photographic assessment scores during analysis.

An intra-oral camera, the Sopro 717 (The Acteon Group® Eaton Socon, Cambridgeshire), with its own integral light-emitting diode (LED) light source, was used to take 8 intra-oral photographs of the index teeth for each subject. The index teeth for the 5-year-olds were all first and second primary molars, the upper central and lateral primary incisors and the lower primary canines. The index teeth for the 10/11-year-olds were all the four first permanent molars (intra-oral photographs were obtained of the occlusal with buccal surfaces and occlusal with lingual surfaces of the lower first permanent molars; occlusal with buccal surfaces and occlusal with palatal surfaces of the upper first permanent molars).
The intra-oral camera system was connected to a laptop computer with bespoke software package. This system allowed each captured intra-oral photograph to be previewed before saving it to specified tooth labelled slots in the subject’s allocated folder. The intra-oral photographs (Figures 7.1a. and 7.1b.) were obtained on the same day as the visual examinations. Each child lay supine on an examination table with the examiner/photographer seated behind them at the head end. The teeth were dried with cotton wool rolls (following the same procedure as the visual examinations) prior to taking the intra-oral photographs. Between subjects, the infection control procedures specified by the manufacturer of the intra-oral camera’s user guide was followed.

Figure 7.1a: Example of 8 Intra-oral Photographs of a 5-year-old

Figure 7.1b: Example of 8 Intra-oral Photographs of a 10/-11-year-old
Using the labelled folders containing the 8 intra-oral photographs for each subject, two new folders were created containing 6 and 4 intra-oral photographs respectively by selectively removing photographs in a standardized way. Two intra-oral photographs of the upper central and lateral incisors were removed and the resulting folder with 6 intra-oral photographs was renamed with the ID label of the subject but with the suffix 6 added. The same process was used to create the folders with 4 intra-oral photographs. Starting with the folder containing the 6 intra-oral photographs, the two intra-oral photographs showing the lower left and lower right primary canines were removed leaving 4 intra-oral photographs showing all the primary molars. For the permanent teeth, two intra-oral photographs showing the occlusal with buccal surfaces of the upper first permanent molars were removed for each child to produce the folders with 6 intra-oral photographs. Then a further two intra-oral photographs showing occlusal with lingual surfaces of the lower first permanent molars were removed for each child to produce the folders with 4 intra-oral photographs. When the compilation of the folders was completed, there were three folders for each subject: ID labelled (8), ID labelled (6) and ID labelled (4) containing 8, 6 and 4 intra-oral photographs respectively.

In total 6 photographic presentation folders (5-year-olds: 8 intra-oral photographs per subject, 5-year-olds: 6 intra-oral photographs per subject and 5-year-olds: 4 intra-oral photographs per subject; 10-/11-year olds: 8 intra-oral photographs per subject, 10-/11-year-olds: 6 intra-oral photographs per subject and 10-/11-year-olds: 4 intra-oral photographs per subject) were prepared for assessment and loaded onto USB flash drives. For each of the presentations, 15% of the ID labelled folders were assigned new ID numbers and added to the presentations. This was to test intra-examiner reliability of the photographic assessments. The key to the original identity numbers and the new identity numbers (for those added to test intra-examiner reliability) were retained by the study administrator.
The same 5 examiners who had examined the children visually assessed the intra-oral photographic presentations of the children’s dentitions, blinded to the results of their visual assessment. Before undertaking the photographic assessments all the examiners convened to receive training on the process of viewing the intra-oral photographs and navigating through the folders but were not calibrated in assessing the intra-oral photographs. Each examiner was provided with a USB flash drive with the photographic presentations four weeks after the visual examinations. Each examiner viewed the intra-oral photographs on computer screens at a time of day and room conditions of their choice. As was the case for the visual examination, caries was diagnosed using the BASCD diagnostic criteria. The examiners recorded the scores from their intra-oral photographic assessments for each subject on to a paper pro-forma, identical to the one used for the visual examination.

**Statistical Analysis**

The data collated from the visual examinations and intra-oral photographic assessments of the subjects’ teeth were entered into Dental Survey Plus 2® (DSP2) software programme (The Dental Health Services Research Unit, University of Dundee). The software was used to analyse the data and generate mean caries experience indices at tooth level i.e. dmft and components (dt, mt, ft) and DMFT and components (DT, MT, FT) for the deciduous and permanent dentition respectively. The Weighted Kappa statistic was used as a measure of intra-rater reliability for both the visual examinations and the photographic assessments in both age groups and the Landis and Koch measurement of observer agreement for categorical data [Landis and Koch, 1977b] was used to determine the level of agreement.

The mean caries indices data generated by DSP2 software was exported into Stata® statistical software version 11 (Stata Corporation, Texas) to compute intra-class correlation coefficients as a measure of inter-examiner reliability for each method. A method comparison analysis was performed using Stata® version 11 to determine the 95% limits of agreement for all five examiners, comparing the visual examination method with
the photographic assessment method using 8, 6 and 4 intra-oral photographs (Bland, 2007).

Using the difference in mean dmft/DMFT values as a measure to determine the bias between the methods, a priori estimate of mean dmft/DMFT value within ± 0.3 was set as an acceptable difference for the samples overall.

**Results**

A total of 240 5-year-olds and 250 10-/11-year-olds were recruited into the study. Of these, 39 5-year-olds and 19 10-/11-year-olds did not have both visual examination and intra-oral photographs taken of their dentition. Their data were therefore excluded from analysis.

The weighted kappa statistic computed as a measure of intra-rater reliability showed almost perfect agreement for all the examiners using the different examination and assessment methods. The weighted kappa statistic for the visual examinations ranged from 0.81 to 0.94 with a median value of 0.93 in the 5-year-olds and 0.90 to 0.97 with a median value of 0.92 in the 10-/11-year-olds. The weighted kappa statistic for the photographic assessments in the 5-year-olds were for 8 intra-oral photographs, 0.86 to 0.94 (median 0.94), 6 intra-oral photographs, 0.85 to 0.98 (median 0.94) and for 4 intra-oral photographs, 0.80 to 0.96 (median 0.93). The weighted kappa statistic for the photographic assessments in the 10-/11-year-olds were for 8 intra-oral photographs 0.84 to 1.00 (median 0.91), 6 intra-oral photographs 0.82 to 1.00 (median 0.91) and for 4 intra-oral photographs 0.72 to 0.98 (median 0.92).

Table 7.1. shows the computed intra-class correlation coefficients (ICC) as a measure of inter-rater reliability of the methods. The agreement within the group of examiners for the 5-year-olds’ assessments was high for all methods. In the 10-/11-year-olds the ICC was higher within the group of examiners for the visual examination method as compared to the intra-oral photographic assessment methods.
Table 7.1: Intra-Class Correlation Coefficient as a Measure of Inter-examiner reliability

<table>
<thead>
<tr>
<th>Population</th>
<th>Visual</th>
<th>8 Photos</th>
<th>6 Photos</th>
<th>4 Photos</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-year-olds dmft</td>
<td>0.963 (0.954 to 0.970)</td>
<td>0.964 (0.956 to 0.971)</td>
<td>0.870 (0.817 to 0.906)</td>
<td>0.958 (0.948 to 0.967)</td>
</tr>
<tr>
<td>10/11-year-olds DMFT</td>
<td>0.896 (0.875 to 0.914)</td>
<td>0.584 (0.525 to 0.642)</td>
<td>0.764 (0.710 to 0.809)</td>
<td>0.531 (0.470 to 0.592)</td>
</tr>
</tbody>
</table>

Tables 7.2. and 7.3. show the summary of the mean indices with standard deviations computed from the scores of the individual examiners for all the examination and assessment methods for the 5-year-olds and the 10-/11-year-olds respectively.

The 95% limits of agreement comparing the visual examination method with the photographic assessment method using 8, 6 and 4 intra-oral photographs were -1.997 to 1.967, -2.375 to 2.735 and -2.250 to 2.921 respectively for the 5-year-olds and -2.614 to 2.027, -2.179 to 3.887 and -2.594 to 2.163 respectively for the 10-/11-year-olds. Bland-Altman plots were also generated to aid visualization of the limits of agreement between the methods. The corresponding Bland-Altman plots showing the limits of agreement between the methods are shown in figure 7.2. for the 5-year-olds and in figure 7.3. for the 10-/11-year-olds. Increasing size of the circles on the Bland-Altman plots denotes increasing concentration of observations at the particular points on the plots.
Table 7.2: The mean caries indices with standard deviations according to examination method in 5-year-olds

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Mean dt</th>
<th>Mean mt</th>
<th>Mean ft</th>
<th>Mean dmft</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>V</td>
<td>8P</td>
<td>6P</td>
<td>4P</td>
</tr>
<tr>
<td>Bench Mark</td>
<td>1.69</td>
<td>1.75</td>
<td>1.72</td>
<td>1.33</td>
</tr>
<tr>
<td></td>
<td>±</td>
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<td>1.85</td>
<td>1.69</td>
<td>1.69</td>
<td>1.36</td>
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<td>±</td>
<td>±</td>
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<tr>
<td>2</td>
<td>1.92</td>
<td>2.00</td>
<td>2.12</td>
<td>1.69</td>
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<td></td>
<td>±</td>
<td>±</td>
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<td>3</td>
<td>1.70</td>
<td>1.77</td>
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<td>4</td>
<td>1.84</td>
<td>1.90</td>
<td>1.81</td>
<td>1.54</td>
</tr>
<tr>
<td></td>
<td>±</td>
<td>±</td>
<td>±</td>
<td>±</td>
</tr>
</tbody>
</table>

V = Visual Examinations  P = Photographic Assessments
Table 7.3: The mean caries indices with standard deviations according to examination method in 10-/11-year-olds

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Mean DT</th>
<th>Mean MT</th>
<th>Mean FT</th>
<th>Mean DMFT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>V 8P 6P 4P</td>
<td>V 8P 6P 4P</td>
<td>V 8P 6P 4P</td>
<td>V 8P 6P 4P</td>
</tr>
<tr>
<td>Bench Mark</td>
<td>0.50 0.69 0.66 0.61</td>
<td>0.12 0.10 0.10 0.10</td>
<td>0.24 0.20 0.22 0.21</td>
<td>0.87 0.99 0.98 0.92</td>
</tr>
<tr>
<td></td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
</tr>
<tr>
<td></td>
<td>1.00 1.07 1.05 1.01</td>
<td>0.58 0.54 0.54 0.53</td>
<td>0.68 0.60 0.62 0.61</td>
<td>1.30 1.30 1.28 1.27</td>
</tr>
<tr>
<td>1</td>
<td>0.47 0.50 0.34 0.43</td>
<td>0.12 0.11 0.10 0.10</td>
<td>0.26 0.26 0.27 0.26</td>
<td>0.85 0.88 0.71 0.79</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>0.93 0.94 0.81 0.87</td>
<td>0.60 0.57 0.57 0.53</td>
<td>0.66 0.68 0.70 0.68</td>
<td>1.26 1.23 1.16 1.19</td>
</tr>
<tr>
<td>2</td>
<td>0.40 1.19 1.08 0.97</td>
<td>0.12 0.10 0.09 0.09</td>
<td>0.23 0.13 0.15 0.16</td>
<td>0.74 1.42 1.32 1.21</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>0.85 1.39 1.28 1.24</td>
<td>0.58 0.55 0.55 0.55</td>
<td>0.58 0.48 0.51 0.55</td>
<td>1.19 1.50 1.43 1.38</td>
</tr>
<tr>
<td>3</td>
<td>0.48 0.94 0.89 0.82</td>
<td>0.12 0.09 0.09 0.09</td>
<td>0.23 0.19 0.19 0.19</td>
<td>0.82 1.22 1.18 1.11</td>
</tr>
<tr>
<td></td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
</tr>
<tr>
<td></td>
<td>0.92 1.22 1.18 1.18</td>
<td>0.58 0.55 0.55 0.55</td>
<td>0.58 0.58 0.60 0.60</td>
<td>1.25 1.39 1.35 1.35</td>
</tr>
<tr>
<td>4</td>
<td>0.55 0.87 0.89 1.00</td>
<td>0.12 0.10 0.10 0.10</td>
<td>0.25 0.19 0.20 0.16</td>
<td>0.92 1.17 1.19 1.25</td>
</tr>
<tr>
<td></td>
<td>± ± ± ±</td>
<td>± ± ± ±</td>
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<td>± ± ± ±</td>
</tr>
<tr>
<td></td>
<td>1.11 1.23 1.31 1.37</td>
<td>0.58 0.55 0.55 0.55</td>
<td>0.58 0.59 0.60 0.54</td>
<td>1.39 1.41 1.46 1.52</td>
</tr>
</tbody>
</table>

V = Visual Examinations P = Photographic Assessments
Figure 7.2:

Bland-Altman Plots – 5-yr-olds data

No obvious variation in agreement across the range of measurements
No obvious variation in agreement across the range of measurements
Discussion

This study was a method comparison study comparing the caries detection performance of an established visual examination method developed by BASCD with a photographic assessment method, assessing 8, 6 and 4 intra-oral photographs, in a sample of 5-year-old and 10/11-year-old children in an epidemiological setting. The main findings of the study are that there was very good intra- and inter-examiner reliability for all examination and assessment types in the 5-year-old children with the intra-class correlation coefficient, a measure of inter-examiner reliability for the visual examination method (0.963) similar to that of the assessment of 8 intra-oral photographs (0.964). There was however weaker agreement within the group of examiners when using the photographic assessment method in the 10-/11-year-olds. The populations’ summary mean caries indices of the study showed comparable mean dmft/DMFT values between the visual and the photographic assessment methods, especially between the visual examination method and 8 intra-oral photographic assessments in the 5-year-olds. The narrowest limits of agreement for the 5year-olds, -1.997 to 1.967, was found between the visual examination and the assessment of 8 intra-oral photographs whereas that for the 10-/11-year-olds, -2.594 to 2.163, was between the visual examination and the assessment of 4 intra-oral photographs.

A limitation of this study is that although the examiners were trained and calibrated in the visual examination method, and they received training on the process of viewing the intra-oral photographs, they were not calibrated in assessing the intra-oral photographs. The use of intra-oral photographs however forms part of the standard BASCD training for the visual examination method. Another limitation of the study is that the assessments of the intra-oral photographs were carried out under non-standardised viewing conditions. An in-vitro study that compared assessment of intra-oral photographs under standardised and non-standardised viewing conditions however found no significant difference in outcomes between the two methods (Boye et al., 2012). To enable the use the photographic assessment method in the field, it is
necessary for the method to lend itself to pragmatism without detrimental effects on its reliability and validity. Despite the customized viewing conditions, the results of this study show good intra- and inter-examiner reliability for the photographic assessment method especially in the 5-year-olds.

In addition to measures of reliability, other studies in the literature that have compared utility of different caries detection methods have tended to use sensitivity and specificity valves as the measures for the comparison (Erten et al., 2006, Zhang et al., 2009, Rechmann et al., 2012). Sensitivity and specificity for the photographic method as compared to the visual examination method have been reported (Boye et al., 2012) to be comparable to or higher than the findings of other caries detection studies (Sheehy et al., 2001, Lussi et al., 2001) although there was variation in the stages of caries progression assessed by the different studies. Sensitivity and specificity values as the measures for the comparison of caries detection methods is acceptable when caries prevalence is the only aspect of caries experience that is to be determined. When caries severity is also to be determined as part of such comparisons other measures rather than sensitivity and specificity valves may have to be considered for the comparisons.

The determination of limits of agreement is used widely in the medical literature to make comparisons between methods of quantifying entities (Bland and Altman, 2012). The limits of agreement between the methods found in the study were wider than the priori estimate of mean dmft/DMFT value to be within ± 0.3 for the samples overall. Solely based on the priori estimate of mean dmft/DMFT value to be within ± 0.3 for the samples overall as the acceptable difference between the visual and photographic methods by this study, the visual examination and photographic assessment method may not be used interchangeably. A detailed examination of the standard deviations from which the limits of agreement were computed however shows that both the visual examination and photographic assessment method showed comparable wide
variations in their mean caries indices with relatively large standard deviations (figures 7.4a. and 7.4b.). This shows that the established visual method was variable in its caries detection ability in this study and the photographic method was no worse than the visual examination method.

The size of the circles on the Bland-Altman plots depicts the number of observations that lie on that point on the plot. The closeness of the largest circles to zero indicates that majority of the DMFT/dmft scores for the individual observations were within the a priori limits. For all pairwise method comparisons however there were many observations which would fall out-with these limits. One possible explanation for this is transcription errors. For example entering the code for “extraction as a result of caries: code 6” instead of the code for “caries-free: code 0” for the molars in all four quadrants of the mouth because of illegible writing would significantly alter the resultant dmft/DMFT value. An electronically integrated formatted pro-forma which allows direct entry of assessment scores coupled with the double entry of data to allow the checking of disagreements, would minimize such transcription errors.

When limits of agreement have been determined it is important to decide whether the difference found between the methods being compared is small enough for the particular purpose for which it is intended in practice (Bland, 2008). As dmft/DMFT is scored per child as whole values it may be tolerable to accept a difference of ±1 dmft/DMFT for each individual observation. This would however depend on whether the caries detection method is being used to collect data for needs assessments, clinical trial outcomes or disease surveillance. The low systematic errors indicated by the majority of the mean differences approaching zero may make the methods suitable for needs assessments. The magnitude of differences found in this study for some of the individual observations would however make it an unacceptable outcome measure for determining the need for individual dental attention.
Figure 7.4a: Scatter plot of standard deviation against mean for all 201 5-yr-olds
Figure 7.4b: Scatter plot of standard deviation against mean for all 231 10-11-yr-olds
The advantages of the photographic assessment method such as archiving, allowing the use of dental skill mix and its use to support training and calibration in dental epidemiology have been well rehearsed. Although solely based on the limits of agreement found in this study the two methods cannot be used interchangeably, the comparability of the population summary measures: the computed mean caries indices for the visual examination and photographic assessment method as well as the consistent high levels of both intra- and inter-reliability of the photographic assessment particularly the assessment of the 8 intra-oral photographs in the deciduous dentition is promising and merits further refinement, Boye et al., (in press) to promote its use as a potential alternative but not a replacement caries detection method for use in the primary dentition in situations where the visual examination method may not be applicable such as when examiner blinding is required and in practice based RCTs. This should be done with a clear awareness of the differences between the visual examination method and the photographic assessment method.

**Conclusion**

The photographic assessment method, particularly assessment of 8 intra-oral photographs, was shown to have consistently high levels of intra- and inter-reliability comparable to the visual examination method in the primary dentition. The limits of agreement were however wider for the permanent dentition. With the additional benefits of archiving, remote scoring, allowing multiple scorers to score images and enabling longitudinal analysis, this method may be used as an alternative caries detection method in the primary dentition in situations where the visual examination method may not be applicable such as when examiner blinding is required and in practice based RCTs. This should be done with a clear awareness of the differences between the two methods.
Competing Interests
None of the authors are aware of any competing interests in the production of this manuscript.

Authors' Contributions
UB contributed to the protocol, undertook the management of the study, took the photographs and wrote the manuscript. IAP contributed to the protocol, undertook study monitoring and contributed to the manuscript. MT contributed to the protocol, undertook study monitoring and contributed to the manuscript. TW gave statistical advice, assisted with the data analysis and contributed to the manuscript. All authors read and approved the final manuscript.

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The Use of Intra-oral Photographs in Dental Epidemiology

Chapter 8

The Use of Intra-oral Photographs as a Means of Caries Detection in Dental Epidemiology – Discussion
The Use of Intra-oral Photographs as a Means of Caries Detection in Dental Epidemiology – Discussion

8.1. Introduction

Dental caries remains a significant oral health problem particularly among disadvantaged population groups (Petersen, 2009). Dental caries and its consequences can be detrimental to general health and the quality of life (Shidara et al., 2007). The appropriate level of the detection of the disease is required to inform decisions about its prevention and clinical management in the population. Epidemiological studies provide the data required for caries surveillance and health needs assessment. Well-designed practice-based randomised controlled trials (RCTs) are useful for the evaluation of health technologies including caries prevention interventions. Practice-based and epidemiological studies have traditionally employed visual examination as the caries detection method. The Medical Research Council (MRC) was however critical of the robustness of some of these studies and the methods used to assess caries particularly those pertaining to the evaluation of water fluoridation (2002). The traditional visual examination methods used in these studies do not lend themselves for use in large epidemiological studies where “blinding” is required to minimise potential sources of bias. They would also be very expensive to undertake in practice-based RCTs as they require external examiners to visit dental practices to collect data. Conducting studies this way would cause disruption to busy dental practice routines and would make participation in such trials unattractive for dental practitioners (Hopper et al., 2011). Other caries detection methods such as Quantitative Light-induced Fluorescence, fibre-optic trans-illumination and electronic caries monitors are not suitable for use in large epidemiological studies because they require complex equipment or are very technique sensitive (Neuhaus et al., 2009). There are also associated ethical issues with the use of radiographs (Horner, 2011). An alternative caries detection method evaluated by this thesis for use in practice-based RCTs and epidemiological studies where blinding is required is the assessment of intra-oral photographs by trained examiners (Boye et al., 2012).

The studies presented in this thesis have therefore focused on testing the validity and the reliability of the intra-oral photographic assessment method as a means of caries
detection compared to the reference standard of histology as well as comparison to an established visual examination method developed by the British Association for the Study of Community Dentistry (BASCD) (Pine et al., 1997b). The pragmatic applicability: the acceptability, feasibility and practical aspects to the utility of the intra-oral photographs assessment method were also investigated. This was undertaken by seeking the views of users of the method as well as the views of those on whom the method was used. The studies were conducted in three phases.

**8.2. The Main Findings**

*Phase I*

This was an in-vitro study which compared the caries detection performance of the photographic assessment method with the established visual examination method developed by BASCD and with histological sections as the reference standard. The main findings of this study showed that there was substantial intra- and inter-examiner reliability for both the visual examination and the photographic assessments. The median sensitivity and specificity values of the visual examinations and photographic assessments as compared to the gold standard of histology were 65.5% & 82.4% and 81.3% & 82.4% respectively. These show that the photographic assessment method in this study has a caries detection capability that is comparable to that of the visual examination method. The next step in the process for determining the suitability of the use of intra oral photographs in dental epidemiological studies and practice based RCTs was to explore their performance in an in-vivo study.

*Phase II*

This study was a cross sectional study which compared the intra-oral photographic assessment method with the BASCD visual examination method as a means of detecting dental caries in two groups of children aged 5 years (to test capability in the primary dentition) and 10/11 years (to test capability in the secondary dentition) in an epidemiology (school) setting. The main findings of the study were that there was very good intra-examiner reliability for both the visual examination and photographic assessments in both groups of children for each examiner. Comparison of the
photographic assessments mean caries indices of dt, dmft, DT and DMFT within the
group of examiners identified one of the examiners, E₄, as an outlier. Although E₄ had
good intra-examiner reliability (weighted kappa statistic of 0.93 and 0.81 for the 5-
year-olds and 10-/11-year-olds respectively), E₄’s photographic scores were much
higher than any of the other examiners. E₄’s mean dmft and DMFT scores for the
photographic assessments were 3.31 and 4.56 as compared to mean dmft and DMFT
scores of 1.82 and 0.98 for the rest of the group of examiners. The status of E₄ as an
outlier was confirmed by repeating the photographic assessments one year later. E₄’s
mean dmft and DMFT scores after one year were 3.65 and 4.61. This showcased a
strength of the photographic method – the ability to archive allows photographs to be
revisited and assessed several times over many years if required. This can have several
applications which are discussed later on. The experience of E₄ however identified the
importance of ensuring robust training and calibration. This could be provided by using
sets of training photographs which was what happened in case of E₄. Specific training
in the use of intra-oral photographic assessment method for detecting caries brought
the scores of this examiner into an acceptable range of the trainer’s photograph
assessment scores with sensitivity and specificity values of 0.94 and 0.99 for the 5-
year-olds and values of 0.88 and 0.99 for 10/11-year-old children; and the mean caries
indices scores of the group of examiners.

The sensitivity and specificity values obtained for the permanent teeth in this study
were lower than those obtained for the primary teeth. Other studies have reported
variability in the detection of occlusal caries in permanent posterior teeth as a result of
fissure morphology and staining. (Mialhe et al., 2009b, Pereira et al., 2009). This could
explain the lower sensitivity and specificity values in the permanent teeth in this study
as the occurrence of frank cavitation occurs more commonly in the primary teeth.
Other potential reasons include the difficulty of imaging the much larger permanent
teeth and also the loss of context when the tooth surface fills the entire image space.
The presence of a “greying” or shadowing of the occlusal surface often indicates the
presence of caries into dentine in permanent teeth. The high level of illumination and
flat image perspective may well make such assessment more complex.
This study also identified practical issues associated with obtaining intra-oral photographs of all surfaces of all teeth present in a mouth which made that a lengthier process than conducting a traditional full mouth visual examination. For the intra-oral photographic assessment method to be suitable for use in epidemiological studies its pragmatic applicability needed to be assessed and developed. It was necessary to explore the possibility of using fewer intra-oral photographs without the loss of utility. The method’s user friendliness as well as its acceptability by those on whom it would be used needed to be assessed. The next phase in the process was used to explore these issues.

Phase III
This phase required both quantitative and qualitative methodologies to address the objectives identified.

Quantitative Methodology
Evidence from the NHS dental epidemiological data from surveys conducted between 2000 and 2006 (The Dental Observatory, Preston UK) show that caries in the primary dentition is usually located in the molars, upper incisors and lower canines and caries in the permanent dentition is usually found in the first molars - referred to as the index teeth. To consider the use of fewer intra-oral photographs, it was necessary to investigate the extent of caries that could be determined by assessing intra-oral photographs of the index teeth as compared to the assessment of full mouth intra-oral photographs and full mouth visual examination. A quantitative methodology was required to test this. This was a cross-sectional study conducted to compare caries data obtained from a full mouth visual examination using the BASCD method with caries data obtained from eight, six and four intra-oral photographs of index teeth in two groups of children aged 5 years and 10/11 years in an epidemiology (school) setting.

The main findings of the study were that there was very good intra- and inter-examiner reliability for all examination and assessment types in the 5-year-old children with the intra-class correlation coefficient, a measure of inter-examiner reliability for the visual examination method (0.963) similar to that of the assessment of 8 intra-oral
photographs (0.964). There was however weaker agreement within the group of examiners when using the photographic assessment method in the 10-/11-year-olds. The population summary mean caries indices of the study showed comparable mean dmft/DMFT values between the visual and the photographic assessment methods, especially between the visual examination method and 8 intra-oral photographic assessments in the 5-year-olds. The narrowest limit of agreement for the 5-year-olds (the primary teeth) was found between the visual examination and the assessment of 8 intra-oral photographs whereas that for the 10-/11-year-olds (the permanent teeth) was between the visual examination and the assessment of 4 intra-oral photographs. However a detailed examination of the standard deviations from which the limits of agreement were computed shows that both the visual examination and photographic assessment method showed comparable wide variations in their mean caries indices with relatively large standard deviations. A secondary analysis of NHS dental epidemiological survey data for both primary and permanent teeth, collected between 1996 and 2011 using visual examination, (The Dental Observatory, Preston UK) showed similar standard deviations. This shows that the established visual method exhibits variability in its caries detection ability and in this study the photographic assessment method was no worse than the visual examination method.

Qualitative Methodology

The thesis also investigated the acceptability, feasibility and practical aspects of the utility of the intra-oral photographs assessment method from the points of view of the dentists who used the method as well as the children on whom the method was used. Qualitative methodology was required to elicit their views and obtain an in-depth understanding of the issues that informed these views.

For eliciting the examiners’ and the children’s views, group discussions rather than “one to one” interviews were used. For the examiners, the interactions produced between the participants during the group discussions allowed them to further explore their views on their experiences of using the two methods. The discussions also helped to clarify issues that needed further explanation. For the children, group discussions were used to allow them to feel comfortable (safety in numbers) to express their views; and to make the group discussions even more age appropriate in the case of the
5-year-old children, a puppet was used in the facilitation of the discussions. The numbers of children in each focus group was also kept to a maximum of five to allow each child in the group the opportunity to be involved in the discussions.

The main findings of the qualitative elements of the thesis in relation to the acceptability, feasibility and practical aspects of the utility of the intra-oral photographs assessment method was that the views expressed by the children on whom both methods of examination were used related to the level of acceptability of their experience. Factors affecting acceptability and their preferences were associated with the combined effects of contextual factors prior to the examination and experiences during the examination. These included the communication (both information content and the way that content was communicated) they received and their expectations. These factors influenced the examination experience along with their feelings about the environment and the tactile sensation in their mouths from instruments and equipment. The responses from the study indicated that generally the intra-oral camera was well received by the children in both age groups on whom it was used as a means of obtaining images for caries detection in epidemiological studies within the school setting. They were particularly fascinated and interested to see and discover more about what was present in their mouths.

The dentists who used the method found the ability to be able to assess intra-oral photographs on a screen at a convenient time and place (from the comfort of their armchair) as a means of detecting caries rather than examine subjects visually advantageous. They however found that without a time restriction on the length of viewing, the time they took to assess the intra-oral photographs become extended when compared to performing a visual examination. It may therefore be necessary to consider putting time restriction on viewing of photographs. The examiners also found it easier to make caries detection decisions on intra-oral photographs of primary teeth than those of permanent teeth. This could be addressed with specific training tailored for assessing primary and permanent teeth.
8.3. Strengths and Weakness

**Strengths**

A strength of the thesis as a whole is the methodical approach taken in addressing the objectives set out to test the diagnostic accuracy of the photographic assessment method as a potential caries detection tool. This approach to the studies in this thesis allowed the photographic method to be tested for its compliance with what would be considered as ideal properties of a caries detection method (Kuhnisch et al., 2009a). This is similar to the approach taken to develop some of the familiar indices in use today such as the Index of Orthodontic Treatment Need (IOTN) (Brook and Shaw, 1989).

An additional strength of this thesis is its use of mixed methodology. In the past, epidemiological studies have mainly employed quantitative methodology (Daly et al., 2002) taking the biomedical approach to answering research questions. Quantitative methods are however unable to adequately collect and analyse sociological data which pertain to understanding human behaviour and choices to which qualitative research methodology is better suited (Green and Thorogood, 2009). The mixed method approach allowed the thesis to play to the strengths of both quantitative and qualitative in the collection and handling of the data required.

Also the use of histology, the currently known absolute reference standard for caries diagnosis in the validation of photographic assessment method as a means of caries detection is an additional strength of this thesis.

The use of experienced examiners who regularly trained and calibrated as part of the UK NHS epidemiological surveys was advantageous and pragmatic. These examiners had a firm understanding of the important aspects of data collection for epidemiological purposes such as the importance of good reliability values. They were also familiar with examining children within the school setting.
Weaknesses

The studies in this thesis used just one intra-oral camera system, the Sopro 717 (The Acteon Group® Eaton Socon, Cambridgeshire), for obtaining the intra-oral photographs. This camera was used for the studies because it is small and lightweight, has an integral LED light source and it is simple and easy to use. The use of other intra-oral camera systems in dental epidemiology could however be tested in future research when there are further advancements in technology.

A limitation of the studies presented in this thesis is that although the assessors were experienced examiners trained and calibrated in the visual examination method, and they received training on the process of viewing the intra-oral photographs, they were not calibrated in assessing the intra-oral photographs. The use of intra-oral photographs however forms part of the standard BASCD training for the visual examination method. The experience of the outlier examiner in phase II shows that training and calibration for caries detection on intra-oral photographs is possible and effective.

The difficulty of convening examiners from a wide geographical area made a longer washout period than optimal between the visual examinations and the photographic assessments problematic in the in-vitro study. It therefore had to be presumed that a decision - one of 50 - could not be recalled by the examiners after the washout time allowed in this study which meant that the visual examinations and standardized photographic assessments were carried out on the same day. This was however mitigated by carrying out repeat photographic assessments for comparison after a suitable washout period of over 14 days.

During the in-vivo studies the examiners were not required to view and assess the intra-oral photographs under standardised conditions such as time of day for viewing, the use of ambient or additional artificial lighting, the use of specified computer screen types and size and the length of viewing time. This approach was taken to replicate the use of the photographic assessment method in the field, and to how the method lent itself to pragmatism without detrimental effects on its reliability and validity. The in-vitro study compared the assessment of intra-oral photographs under standardised and non-standardised viewing conditions and found no significant difference in
outcomes between the two methods. In view of that finding the assessments of the in-vivo intra-oral photographs in the subsequent in-vivo studies were carried out under non-standardised viewing conditions. Despite the customized viewing conditions, the results of these studies show good intra- and inter-examiner reliability for the photographic assessment method especially in the 5-year-olds.

A limitation of using qualitative methodology is that in its attempt to achieve an in-depth understanding of the subject under investigation, a small number of participants who may not be representative of all examiners or all children were engaged in the qualitative studies as saturation was reached. This makes it less easy to generalise the findings from the study to the population (Allen et al., 2010). The rationale for using of this method of enquiry is however to uncover the issues relevant to the subject matter and not to discover their prevalence or frequency distribution (Green and Thorogood, 2009).

The studies in this thesis were conducted on children within schools, which can be a more challenging environment than the dental surgery due to lack of optimal examining conditions. The use of the intra-oral photographic assessment methods can however be tested in future research within various other contexts.

8.4. Reflections on the Process

Challenges encountered

Logistics and organization of the data collection

Ten examiners were recruited into the in-vitro study. Coordinating and selecting convenient timings for all the examiners to convene from a wide geographical area to conduct the visual examinations and photographic assessments at the same time under standardized conditions was challenging. When unforeseen circumstances prevented one of the examiners from conducting the visual examinations alongside the other nine examiners, that examiner had to be excluded from the study.
The logistics of organizing the in-vivo studies was further compounded by the involvement of schools. As well as selecting convenient times for all the five examiners and their recorders to convene from a wide geographical area to conduct the visual examinations on children in 16 schools and obtain the intra-oral photographs at the same time as the visual examinations; these timings also had to accommodate the schools’ opening times and activities over many months. In order not to have to exclude the data of any of the examiners from the study, if an examiner could not examine children on any chosen day, all the other examiners were prevented from examining any children on that day. To have used more than five examiners for the in-vivo studies would have required a much larger study administration support and more time at a much greater cost. Also parents, schools and ethical committees may not have agreed to have that many examiners examine a child on one occasion.

Consent Rates for the in-vivo studies

The use of negative consent, where participates are included in a study unless they actively refuse to partake, although it leads to very high consent rates, is no longer acceptable for the NHS epidemiological surveys. The method used for obtaining informed consent for the study followed the Department of Health guidance for the NHS epidemiological surveys (CDO, 2008). For the 5-year-olds, parents/guardians had to give positive consent i.e. actively agree for their children to take part and for the 10-/11-year-olds it was of combination of parents/guardians not actively refusing their children’s involvement as well as children giving their positive consent. The consent rates for the studies were similar to that found for NHS epidemiological surveys conducted over the past five years. For the 5-year-olds the consent rate was 64.2% as compared to the North West Regional average of 65.1% and England average of 66.8% (2007/2008 5-year-olds survey, information obtained from The Dental Observatory, Preston) and for the 10-/11-year-olds it was 78% as compared to North West Regional average of 74% and England average of 74.1% (2008/2009 12-year-olds survey, information obtained from The Dental Observatory, Preston). The use of positive consent, although viewed as more ethical, may result in self-selected samples that could result in potential selection bias. Disadvantaged groups with higher diseases levels are less likely to give positive consent (Tickle et al., 2003).
Obtaining the intra-oral photographs

Attempting to obtain the intra-oral photographs in a standardized manner was a great challenge. The differences in the participants’ ability to open their mouths, differences in tooth size and morphology were the main contributory factors to this challenge as well as the fact that the available camera systems at the time of the studies did not have any positioning implements to aid standardization of image capture. The availability of such a positioning tool or implement would have decreased the time required for obtaining the intra-oral photographs and may have improved the experience for both the photographer and the participants.

The use of a foot switch to control the on/off and “capture” functions of the camera in addition to having the use of bespoke software that allowed the captured photographs to be previewed on a screen before a decision to be made to store or discard and re-capture helped immensely with the studies.

Number of intra-oral photographs required

To enable the assessment of all surfaces of the teeth as they would be assessed in a visual examination of the mouth, examiners have to be provided with intra-oral photographs showing all surfaces of all the teeth. This meant that during the in-vivo study in phase II, each child had up to 24 intra-oral photographs taken depending on how many teeth were present in their mouths requiring a mean time of 8.78 minutes (with a standard deviation of 2.76). This was particularly challenging for some of the 5-year-olds. This approach also makes the photographic assessment method a more costly process as compared to visual examination method. The second in-vivo study was therefore conducted to investigate whether fewer photographs would be a viable solution. The study showed that caries information obtained from the assessment of 8 intra-oral photographs of the primary teeth was comparable to that from a whole mouth visual examination.

Moisture Control

To obtain intra-oral photographs of reasonable quality for assessment, the teeth had to be clear of debris and saliva as any moisture or debris not removed before the
photograph of the teeth is captured was in effect a permanent obstruction on archived images which would always affect caries detection. The same moisture control protocol for the BASCD visual examination method was followed for the photographic method. Using this method however, moisture control was difficult to achieve in some children. Although the teeth were dried with cotton wool rolls, as according to the BASCD protocol, prior to taking the intra-oral photographs, the sequence of events in the process meant that in some quadrants of the mouth, the operator had to retract the tongue using one hand and remove saliva and debris off the teeth with the other hand. The operator then had to put the cotton wool rolls down and with that hand operate the intra oral camera. In some of the children, this time of exchange allowed them to swallow causing moisture contamination of the teeth. An attempt to keep the teeth dry in these children was almost an impossible task.

Obtaining the photographs was also found to be technique sensitive. The children’s heads had to be located within a narrow limit of positions. Very small deviations from these positions produced poor images. Keeping some of the younger children still in the required position long enough to obtain the photographs was a challenging task. Any movement by a child at the time of exposure, as expected, affected the quality of photographs and those photographs had to be re-taken adding to the length of the procedure. The experiences gained from the first in-vivo study such as the optimal positioning of the children as well as the intra-oral camera to obtain the photographs and use of the bespoke software for previewing and storing the captured images helped to inform the photographic procedure in the 2nd in-vivo study. Future improvements in technology such the availability of cameras with a greater depth of fields, so that focusing is not as critical may also be of help.

The children observed and were fascinated by the images of their mouths and contents as displayed on the computer screen. This prompted interesting questions from them which helped to facilitate the photographic procedures.

**Qualitative methodology**

As the purpose of the qualitative research with the examiners within this thesis was to elicit and report the views of the participants rather than undertaken a theoretical
analysis that would result in the development and synthesis of conceptual definitions that takes no account of subjective views, the approach taken with the data analysis was thematic content analysis style. This allowed key elements of accounts of the examiners’ views and experience of using both methods to be captured.

The grounded theory approach (the constant comparative method) was used to analyse the children’s qualitative research data. This was feasible because of the number of group discussions conducted and it provided a systematic approach to the management of the data analysis. Emerging themes from preliminary analysis of the initial batch of group discussions were used to inform how subsequent discussions were conducted in order to pursue new emerging themes as well as allow the exploration of the relationships between themes and scrutiny of disconfirming and confirming views across the range of participants.

*Children’s views - the use of puppets to elicit children's view*

Although the literature records how challenging it can be to obtain accurate reflections of children’s views on issues that affect them, as most of the caries studies involve children, it was important for this thesis to elicit children’s views on the caries detection methods involved. Very young children have been shown to find it easier to communicate with and through the use of age-appropriate puppets in role plays (Hay et al., 1992). This technique was therefore employed in this study to obtain the views of the 5-year-olds. It was interesting to note that a few of the 5-year-olds in the study expressed the views that communicating with them via a puppet was infantile and silly. This demonstrates the importance of understanding how to relate to children in research to obtain accurate data from them. Age-appropriateness may have to be qualified by intellectual and emotional appropriateness.

*Children’s views - communication and confidentiality*

The importance that the children in the studies attached to the quality of communication they received prior to and during their involvement in the studies was striking. They were generally very articulate in expressing their opinions on what they would have liked to have been communicated to them by the examiners by way of explanation or reassurance as well as receiving feedback on their oral health. They
were also keen to express their views on the importance to them of being examined
and communicated with in a confidential manner. This suggests that children should
not be seen as passive participants in the dental epidemiology studies but rather as
individuals who are interested in what happens to them and should be managed with
dignity and respect.

8.5. The Finding of this Thesis in the Context of the Literature

Although there are very few studies on the use of intra-oral photographs and images in
dental epidemiology, the intra- and inter-examiner reliability levels found in the
studies of this thesis for the intra-oral photographic assessment method is similar to
those reported for other caries epidemiology studies, particularly where visual
examination methods have been used coupled with training and calibration (Assaf et
al., 2007). This is an important aspect of study design methodology which ensures
robustness of the findings of epidemiological studies and RCTs. The good intra- and
inter-examiner reliability found for the intra-oral photographic assessment method
satisfies a criteria for an ideal caries detection method (Daly et al., 2002) and strongly
suggest that this method can be used in epidemiological studies in children where
“blinding” of assessors is important.

The sensitivity and specificity of 65.5% and 82.4% respectively found in this thesis for
the visual examination method, using the reference standard of histology, is very
similar to the values reported elsewhere in the literature (Lussi, 1991). The sensitivity
and specificity of 81.3% and 82.4% respectively of the intra-oral photographic
assessment method, using the reference standard of histology, compare favourably
with the findings of other studies that used other methods of caries detection: the
mean sensitivity and mean specificity values of 33% to 66% and 76% to 95%
respectively reported for radiographs (Bader et al., 2002); sensitivity of 79% and a
specificity of 75% reported for QLF (Heinrich-Weltzien et al., 2005); sensitivity and
specificity values of 82% and 100% for DiFOTI detecting caries on occlusal surfaces
(Gutierrez, 2008) and sensitivity and specificity values of 74.8% and 87.6% reported for
ECM (Huysmans, 2000). The use sensitivity and specificity values as the measures for
the comparison between caries detection methods are adequate for determining caries prevalence. However when the comparisons also involve caries severity, as was the case in this thesis, other measures such as ROC and limits of agreements analysis are more appropriate. The Bland and Altman method for multiple observations analysis was used in this thesis for the caries severity comparisons because it allowed illustration of the caries severity (DMFT/dmft scores) as evaluated by the five examiners whilst respecting their individual differences; rather than a single numeric value it provided the 95% limits of agreement for the methods. The Bland and Altman method is also of value particularly when determining whether a new method could be used instead of an established one (Bland and Altman, 2012). The large standard deviations around the study population mean DMFT/dmft found for both the visual and intra-oral photographic assessment methods from which the limits of agreements between the two methods reported in this thesis were computed exposed the variability of caries detection ability of both methods (Agbaje et al., 2012). If levels of caries continue to fall in the population, this variability will continue to widen. This could have implications for standardisation in future epidemiological surveys and the validity of any results obtained.

The examiners in this study were optimistic about the potential use of the intra-oral photographic assessment method for remote training and calibration of examiners in epidemiological skills with improved utility. Similar to the findings of other studies (Assaf et al., 2006), they identified the need for examiners to receive further training to become better at detecting caries when using the intra-oral photographic assessment method especially on permanent teeth (Costa et al., 2007).

Although there are reports in literature of the use of intra-oral cameras and photographs in children, a search of those studies did not reveal any reports on the views of the children on these methods or tools. The views of the children in this thesis showed that on the whole the intra-oral camera was well received as a means of caries detection for epidemiological studies within the school setting. This is advantageous as an ideal caries detection method should be acceptable to those on whom it is used.
8.6. Implications of the Findings of this Thesis for Policy, Service, Practice and Further Research

The main findings of this thesis that:

- Compared to the reference standard of histology the photographic assessment method had better sensitivity and comparable specificity to the visual examination method.
- The population summary mean caries indices values for the photographic assessment methods, are comparable to those of visual examination method in the 5-year-olds with comparable intra- and inter-examiner reliability.
- The limits of agreement between the photographic and visual examination methods was wide because the standard deviations from which the limits of agreement were computed were wide for both methods of assessments depicting wide variations in their mean caries indices. This shows that the established visual method was variable in its caries detection ability in this thesis and the photographic method was not inferior to the visual examination method.
- The use of fewer photographs in the primary dentition is acceptable and has comparable outcome to the visual examination method.
- The responses from the qualitative studies indicated that generally the intra-oral camera was well received by children within the school setting. Their acceptance was associated with factors such as the communication they received prior to the examination, their expectations, their feelings about the environment and the tactile sensation in their mouths from instruments and equipment.
- Features of the photographic assessment method such as the archiving facility was viewed as an advantage by examiners.

could have implications for policy, the design and conduct of future caries epidemiological studies as well as areas for future research regarding the use of intra-oral photographs.
The use of the intra-oral photographic assessment method as a caries detection in epidemiological studies

Although the population mean caries indices were comparable for the two methods, they were both variable in their caries detection ability as indicated by their relatively large standard deviations. The two methods cannot be used interchangeably. The photographic assessment method may however be used as an alternative to the visual examination method for use in the primary dentition in situations where the visual examination method may not be applicable, such as when examiner blinding in require e.g. water fluoridation studies. This should be done with a clear awareness of the differences between the visual examination method and the photographic assessment method. This method could be tested in further research for use in practice based RCTs for caries as an outcome measure but also potentially for other outcome measures such as restoration survival. Intra-oral photographs could be obtained during a routine dental visit in general practice and then archived for assessment by “blind” external assessor(s).

Archiving

The archiving facility of the photographic method is an additional benefit with many potential applications. Dental skill mix could be used to capture the photographs in the field. Dental skill mix could also be employed in the assessment of caries in epidemiological studies using the intra-oral photographic assessment method (Brocklehurst and Tickle, 2011). This however needs to be tested in further research. Such research could involve members of the dental team other than the dentist such as dental therapists and hygienists being trained to capture the intra-oral photographs and archive them. The archived photographs could then be assessed by:

- A single trained reliable assessor assessing all the obtained intra-oral photographs, eliminating potential errors that could arise from poor inter-examiner reliability in caries detection studies
- Multiple examiners remotely from multiple sites using information and communication technologies without the need to convene in a single geographical location. This could facilitate large multi-centre caries studies
• Multiple examiners many times without worry of patient fatigue

• Single or multiple assessors for the purpose of training and calibration to support the undertaking of practice-based caries RCTs and epidemiological studies

• Single or multiple assessors for analysis in longitudinal studies, enabling the sequential assessment of caries progression in individual teeth

• Single or multiple assessors for assessment and elimination of diagnostic reversal between baseline and outcome in clinical trials and longitudinal studies

• “Blind” single or multiple assessors in RCTs or prospective cohort studies to reduce a potential source of bias

• Multiple assessors when the intra-oral photographs have been taken in general dental practice. If representative samples of the population including those hard to reach groups could be obtained, this may serve as a potential replacement for the current UK NHS epidemiological surveys.

*Training and calibration of examiners in the use of the photographic assessment method*

Although all of the examiners involved in the studies were experienced epidemiological examiners (each with a minimum of 10 years’ experience) and had been trained and calibrated to the BASCD caries visual examination protocol as members of the UK National Epidemiological Surveys team many times, the outlying scores of one of the examiners which improved after specific training in the photographic assessment method suggests that although the use of intra-oral photographs form a key part of the training and calibration of the visual examination method, this may not be sufficient as proxy training and calibration for the photographic assessment method. Specific training and calibration for caries detection from intra-oral photographs is also required. Further research will be required to optimize the process and content of such training and calibration. The research
regarding training should address the difficulties encountered by examiners when making caries detection decisions on intra-oral photographs such as:

- Distinguishing between caries and non-carious lesions such as hypoplasia and fluorosis
- Identifying tooth-coloured restorations
- Orientating and viewing teeth intuitively
- Examiners dependency on tactile sensations that can be derived from the use of instruments such as dental probes to aid caries detection

In addition to training and calibration, improvement in intra-examiner reliability of remote examiner(s) and the sensitivity of the method could be tested and explored by including random “pop up” test intra-oral photographs which allow comparison with reference standard set of scores to which the examiner(s) must achieve a set kappa level in order to be allowed to carry on with the assessment.

Assessment of the intra-oral photographs

An advantage of the intra-oral photographic assessment method is that once the photographs have been captured and archived, measures to control cross infection between examiners or assessor and the examined are no longer a concern. Inadequate removal of moisture, food debris or plaque prior to obtaining intra-oral photographs is however problematic. They serve as a permanent obstruction on tooth surfaces and hamper the photographic assessment method. Moisture control in children can however be challenging and even more so when obtaining intra-oral photographs. Using more efficient means of moisture control when obtaining intra-oral photographs rather than using cotton wool rolls as stipulated for use by BASCD protocol will improve their utility. Further research is needed to determine adequate drying methods that could be used with the photographic method in the field. This could incorporate the use of the newly developed intra-oral camera with an in-built drying nozzle.
Standardised viewing

Although the application of non-standardised viewing conditions such as non-specified computer screen size, time of day and the presence of ambient natural or artificial light in these studies were not found to be detrimental but rather enhanced the pragmatism of approach required for the use of the photographic assessment method in the field, assessment of intra-oral photographs that were not time limited were found to prolong the assessment times. Depending on the requirements for which the photographic assessment method is to be employed, consideration may have to be given to a time-limited, standardised presentation of the intra-oral photographs including the size and resolution. These however need to be tested in further research to determine optimal viewing conditions.

Data handling

Data recording and transcription errors may not always be easily detectable but affect the determined values of the outcome measures. For example when using the BASCD criteria coding, entering the code for “extraction as a result of caries: code 6” instead of the code for “caries-free: code 0” for the molars in all four quadrants of the mouth because of illegible writing would significantly alter the resultant dmft/DMFT value. In addition to the usual safeguards of data entry practices in research, further research is needed to consider the development of an automatic electronic system integrated with the photographic system to be used for recording and checking tooth score to minimize such errors.

Children’s views

Although parents may give consent for their children and children may consent by their conduct to partake in epidemiological studies, the children involved in this research have demonstrated that communication with the children themselves is important. There may be the need to have a specified communication strategy for research involving children. This may have implications for seeking ethical approval and conducting epidemiological studies on children in the future.
For dental examinations that take place in the school setting, the environment that dental epidemiology teams and researchers have to work in is often dictated by the space schools can spare. This can result in children being examined in a non-confidential manner. The concerns expressed by the children in this study about others seeing or hearing what the examiners had to say about their oral health should be heeded. Dental epidemiology teams and researchers need to be sensitive to children’s needs and enhance the research experience for child participants by conducting the dental epidemiology studies in environments that are conducive.

8.7. Summary of Recommendations for Future Research

The studies in this thesis have tested the validity, reliability and some aspects of the pragmatic applicability of the intra-oral photographic assessments method which may be applied to further studies as the caries detection means. The following is a summary of the recommendations for further research:

- A methodological study, designed to use the intra-oral photographic assessment method as an outcome measure in a trial alongside the visual examination method, would be an opportunity for further development.
- The visual examination method developed by BASCD against which the intra-oral photographic assessment method has been evaluated in this thesis is one of many. Evaluation of the intra-oral photographic assessment method’s ability to detect various levels of caries against another caries detection method for example ICDAS system could be tested in further research.
- Further research to test the use of the intra-oral photographic assessment method in other settings such as in general dental practices, in other groupings such in adults and the use of the method for other dental conditions other than caries, for example restoration failure, could provide alternative ways of assessing various dental outcome measures.
- Further research to test the use of dental skill mix in the application of the intra-oral photographic method will provide additional opportunity to expand the use of the method.
• Further research is needed to optimise the process and content of training and calibration for the intra-oral photographic method.

• Further research to determine adequate drying methods that could be used with the intra-oral photographic method in the field will improve the utility of the method.

• Further research to determine optimal viewing conditions, particularly the length of viewing time which allows pragmatic applicability of the method in the field will contribute to the strength of the photographic assessment method.

• Further research to determine methods of minimising potential data recording and transcription errors that could affect outcome measures obtained using the photographic assessment method or fully automated software assessment eliminating the need to use a human assessor is desirable.

• Further research to investigate the costs-benefits of the photographic assessment method will be beneficial in the decisions about the choice of caries detection methods fit for the purpose for which it is to be used for.

8.8. Conclusions

In conclusion, the comparisons made in the in-vitro study showed that the assessment of intra-oral photographs as a method of caries detection had a higher sensitivity than visual examination when compared to the reference standard of histology. The two methods however had comparable specificities. There was also good intra-examiner and inter-examiner reliability for the examiners assessing the intra-oral photographs.

The findings of the in-vivo studies in this thesis show that the intra-oral photographic assessment method is not inferior to the visual examination method using the metrics described. The intra-oral photographic assessment method, particularly assessment of 8 intra-oral photographs, was shown to have consistently high levels of intra- and inter-reliability which were comparable to that found in the visual examination method in the primary dentition. Although the intra-examiner reliability for the two methods was comparable in the permanent dentition, the limits of agreement were
wider. The examiners also found it much easier to make caries detection decisions on the intra-oral photographs of the primary dentitions than those of the permanent dentitions.

The views of the children who participated in the qualitative studies indicated that the intra-oral camera was acceptable as a means of caries detection for epidemiological studies within the school setting. They suggested that appropriate communication, attention to the examination environment and sensitivity in handling instruments should be considered in order to enhance the dental examination experience of children in the school setting.

The intra-oral photographic assessment method was also well received by the examiners in the studies. They however suggested that further research is needed to determine adequate drying methods for use in the field. They also suggested that specific training on caries detection from photographs should be provided and consideration should be given to a time-limited, standardised presentation of the intra-oral photographs.

The intra-oral photographic assessment method is therefore comparable in diagnostic utility to the visual examination method in the primary dentition and offers numerous advantages over the visual examination such as the ability to ensure examiner “blinding” to reduce the risk of bias, archiving of source clinical images and remote scoring. These benefits must be weighed against the (modest) costs of the cameras but the increased time required to acquire the intra-oral photographs. Such costs may be offset by the use of skill mix to acquire the images; dental nurses and therapists for example.
The Use of Intra-oral Photographs in Dental Epidemiology

References
References

London: UCL.


AGBAJE, J. O., MUTSVARI, T., LESAFFRE, E. & DECLERCK, D. 2012. Measurement,  
analysis and interpretation of examiner reliability in caries experience surveys:  

AKCAM, M. O., EVIRGEN, S., USLU, O. & MEMIKOGLU, U. T. 2010. Dental anomalies in  


boys aged 2, 4 and 6 years according to socio-economic status in Riyadh, Saudi  


ALLEN, S., CHIARELLA, M. & HOMER, C. S. 2010. Lessons learned from measuring safety  
culture: an Australian case study. Midwifery, 26, 497-503.

ALVAREZ, J. O., CACEDA, J., WOOLLEY, T. W., CARLEY, K. W., BAIOCCHI, N., CARAVEDO,  

status on the age distribution of dental caries in the primary teeth. J Dent Res,  
69, 1564-6.

AMIN, M. S., HARRISON, R. L. & WEINSTEIN, P. 2006. A qualitative look at parents'  
experience of their child's dental general anaesthesia. International Journal of  
Paediatric Dentistry, 16, 309–319.

DMFT index. Community Dent Oral Epidemiol, 12, 43-6.


*Journal of the California Dental Association.*


APPENDICES
APPENDIX 1: Information Related to Ethical Approval

Ethics Application Form
Study Protocol (with Study Information Sheets and Consent Forms)
Ethical Approval Letters
Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Comparison of a photographic and a clinical dental examination: Phase 3

1. Is your project research?
   - Yes  
   - No

2. Select one category from the list below:
   - Clinical trial of an investigational medicinal product
   - Clinical investigation or other study of a medical device
   - Combined trial of an investigational medicinal product and an investigational medical device
   - Other clinical trial or clinical investigation
   - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
   - Study involving qualitative methods only
   - Study limited to working with human tissue samples, other human biological samples and/or data (specific project only)
   - Research tissue bank
   - Research database
   - Other study

If your work does not fit any of these categories, select the option below:

2a. Please answer the following question(s):

   a) Does the study involve the use of any ionising radiation?
      - Yes  
      - No
   b) Will you be taking new human tissue samples (or other human biological samples)?
      - Yes  
      - No
   c) Will you be using existing human tissue samples (or other human biological samples)?
      - Yes  
      - No

3. In which countries of the UK will the research sites be located? (Tick all that apply)
   - England
   - Scotland
   - Wales
   - Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:
   - England
   - Scotland
4. Which review bodies are you applying to?
- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- Ministry of Justice (MoJ)

5. Will any research sites in this study be NHS organisations?
- Yes
- No

5a. Do you want your application to be processed through the NIHR Coordinated System for gaining NHS Permission?
- Yes
- No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?
- Yes
- No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? The guidance notes explain how an adult is defined for this purpose.
- Yes
- No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?
- Yes
- No

9. Is the study, or any part of the study, being undertaken as an educational project?
- Yes
- No

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?
- Yes
- No

10. Is this project financially supported by the United States Department for Health and Human Services?
- Yes
- No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?
- Yes
- No
The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Comparison of a photographic and a clinical dental examination: Phase 3

Please complete these details after you have booked the REC application for review.

REC Name:
North West 10 Research Ethics Committee

REC Reference Number: 09/H1011/57
Submission date: 02/10/2009

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:
Comparison of a photographic and a clinical dental examination: Phase 3

A2-1. Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/degree:
PhD

Name of educational establishment:
The University of Manchester

Name and contact details of academic supervisor:

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<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<td></td>
<td>Professor</td>
<td>Martin</td>
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<td>Tickle</td>
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Address
School of Dentistry
The University of Manchester
Oxford Road, Manchester

Post Code: M13 9PL
E-mail: martin.tickle@manchester.ac.uk

Date: 02/10/2009
Name and contact details of student:

Title  Forename/Initials  Surname  
Mrs  Uriana  Boye  

Address  
Oral Health Promotion Unit  
1st Floor, London House  
Oldham Road, Middleton  

Post Code  M24 1AY  
E-mail  uriana.boye@hmrpct.nhs.uk  
Telephone  01616551455  
Fax  

A copy of a current CV for the student (maximum 2 pages of A4) must be submitted with the application.

A2.2. Who will act as Chief Investigator for this study?  

☐ Student  
☐ Academic supervisor  
☐ Other  

A3. Chief Investigator:  

Title  Forename/Initials  Surname  
Mrs  Uriana  Boye  

Post  Senior Dental Officer  
Qualifications  BDS, FDS RCS, MSc  
Employer  Heywood, Middleton and Rochdale NHS Trust  
Work Address  1st Floor, London House  
Oldham Road  
Middleton  

Post Code  M24 1AY  
Work E-mail  uriana.boye@hmrpct.nhs.uk  
* Personal E-mail  
Work Telephone  01616551456  
* Personal Telephone/Mobile  01616551456  
Fax  

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?  

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

Title  Forename/Initials  Surname  

Date: 02/10/2009  

5  

30751/65399/1/372
A5-1. Research reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version: 05
Protocol Date:
Funder's reference number: not applicable
International Standard Randomised Controlled Trial Number (ISRCTN):
ClinicalTrials.gov Identifier (NCT number):
European Clinical Trials Database (EudraCT) number:
Project website:

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A5-2. Is this application linked to a previous study or another current application?

☐ Yes   ☐ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.

Primary Care Trust Dental Services regularly conduct surveys in schools as part of Department of Health requirements. These surveys help to monitor the dental health of children and assist in the planning of future dental services. Caries data collected this way can be used for evaluating water fluoridation schemes. However dental teams could be influenced in the way they collect the data if they are aware of the fluoridation status of the residence of subjects. This could potentially create bias. If dental teams could examine photographs of subjects, rather than perform clinical examination of subjects it could overcome the problem of bias.

This study will help to find out whether examining photographs of children's teeth gives the same results as examining the children themselves.

Two groups of children, one aged 5 years and the other 10/11 (Year 6), attending primary schools in Rochdale will be eligible to take part in the study. These age groups have been selected as they are internationally recognised as the ages at which information about dental decay is usually collected.

The children will have a clinical examination of their teeth (a "dental inspection") at school by 5 dentists. They will also have up to 8 photographs taken of of their teeth at the same time. (There will be no photographs of the face taken.)
Some of the participating children, in both age groups, and on a separate occasion, will be selected at random to say what they thought of the inspection method and the photographic method of obtaining information about their teeth. These children will meet in small groups and will give their views with or without the aid of a puppet, according to age group.

A6-2. Summary of main issues. Please summarise the main ethical and design issues arising from the study and say how you have addressed them.

Age of children:

The specific age groups were chosen because they are internationally recognized cohorts on who caries data is usually collected. This will allow comparison of research findings with other retrospective and prospective caries data.

Parental opt out as part of the consent process for the Year 6 children

The research team recognises that positive parental consent is the most ethical system of consent where feasible. However, previous research has demonstrated this is not practical in the school setting. For example a study very similar to the current study reviewed by the University of Manchester Research Ethics Committee, involving obtaining photographs of teeth, clinical dental examinations and a number of computer based questionnaires used positive parental consent initially. The consent rate with positive parental consent after all of the steps taken to try and improve consent was in the region of 55%. This prompted a return to the ethics committee as the low consent rate was going to jeopardize the outcome of the study. An alternative system involving parental opt out was outlined to the ethics committee and it was accepted. This system forms the basis of that within this current study and it also relates to a similar age group.

There have been a number of research projects in which parental opt out with child positive consent have taken place. These have often been questionnaires and similar examinations in schools where the risk of the procedure has been defined as minimal or none.

Also to address the low consent rate of the 12 year old NHS Dental Epidemiology a parental optout system has been approved for the national epidemiological surveys and also research. This is aligned with the Department of Health's aim of including children in the decision making process regarding research study participation.

Clinical and Photographic examinations

The clinical examination is an established examination method developed by British Association for the Study of Community Dentistry (BASCD) and has used for almost 3 decades now during the nationally coordinated NHS epidemiological dental health survey in the same age groups. The only additional component to be introduced in this study is the use of the intra-oral camera. Parents and subjects will be reassured in the study information leaflets and any further contact if they wish that the photographs taken will not show subjects faces or have any patient identifiable features

Interviews

Although it can be challenging to obtain an accurate reflection of children's views on various issues that affect them, children's views on the two examination methods are an important part of the study. This is because any future use of the experimental method will be in children. Views were sought from child psychology experts, schools and the literature as to the most appropriate way to elicit the views of the children.

The use of puppets to interview the younger children (and the older ones if they wish) will help to bring the experience of the interviews to a level that the children can relate to. It was also felt children would feel more at ease in a group situation rather than being interviewed on their own. Therefore instead of one to one interviews, group interviews with a maximum of five children in each group will be conducted. The group interview will be on average about 20 minutes long.

Schools' administration and time commitment

The study will generate a small extra administrative load for schools in sending out letters to parents and collating parental consent for pupils to participate. The schools will also need to host the research team during the clinical and photographic examinations as well as the interviews. In acknowledgement and appreciation of each school's participation, £1 will be donated to the schools' funds for every consent form returned (whether to give or refuse
A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To compare the use of a photographic method for the detection of dental decay with an established clinical examination method.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

To elicit children's views on both the established clinical examination and the experimental photographic method of examination.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The purpose of this study is to compare the use of a photographic method for the detection of dental decay with an established clinical examination method.

In 2005 the Water Act was revised, this change removed flawed legislation which had been the key obstacle preventing the implementation of new water fluoridation programmes in the UK. Following the change in legislation several areas in England are actively exploring the possibility of new water fluoridation schemes. The York systematic review of public water fluoridation, 2000, was critical of the quality of research evaluating the impact of water fluoridation. As a consequence the Department of Health (DH) asked a Medical Research Council (MRC) working group to make recommendations for further research in this field.

The MRC published a report in 2002 making a series of recommendations on how the quality of studies could be improved and highlighting the main issues to be addressed. One of the key problems to resolve in any evaluation of water fluoridation programmes is the 'blinding' of examiners measuring outcome, to the residential (fluoridated or non-fluoridated) status of participants. This is a key source of bias in any study.

Using conventional clinical examination techniques, the only method of ensuring that the examiners are unaware of the place of residence of the subjects is probably by transporting them to an examination site located outside the test and control areas. Apart from the obvious logistical difficulties in a large fluoridation study with possibly thousands of children involved, there would be various considerations and issues that would be impossible to resolve.

An alternative method of blinding examiners would be for examiners to inspect digital photographs of participants' teeth rather than examine the subjects clinically. If this process can produce valid and reliable results it would mean that in theory a single examiner could examine photographs of all participants, blind to their exposure to water fluoridation. The raw source data could also be archived to enable other researchers to undertake new analyses.

Little work has been done in this field. As technology has progressed cameras have become smaller in size and the digital images they produce have improved in quality. Now small, light-weight intra-oral cameras are available which can be connected to a laptop computer, making use of this technology in large scale epidemiological surveys a possibility. Research is required to determine if the images produced this way can support the valid and reliable diagnosis of dental caries in the field of dental public health.

Conclusion from earlier work reveal that the level of agreement between the experimental and established methods are good. However for the experimental procedure to provide examiners with photographs of all the teeth surfaces they had already examined clinically, implied that the experimental method took considerably longer. If a reduced number of photographs that can provide similar caries information as can be obtained from a full mouth clinical examination can be determined, it would increase the ease of use of the new method.

The experimental method if used in the future to evaluate water fluoridation schemes will involve mainly children. Although it can be challenging to obtain an accurate reflection of children's views on various issues that affect them and the impact of those issues on their lives, evaluation of such a tool for use in children will be incomplete without inclusion of what they think about it.

This part of the project will test the possibility of obtaining similar caries information from fewer photographs (fewer than taken in previous work) as compared to full mouth clinical examination. Retrospective caries data obtained from the Dental Observatory, Preston, indicates that generally certain teeth are the most liable to decay in the two cohorts being investigated. Subjects will have a full mouth clinical examination (generally there is not a substantial difference in time needed to conduct a clinical partial mouth examination as compared with a full mouth examination). Each subject will also have a maximum of 8 photographs taken of the identified teeth that are liable to decay (indexed teeth).
Semi structured interviews using a puppet will be used to on a number of focus groups to elicit the children’s views on both the established and experimental methods.

A13. Please give a full summary of your design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

The study will be a cross-sectional comparison between the chosen experimental photographic method of detecting dental caries and the established clinical examination developed by the British Association for the Study of Community Dentistry (BASCD). Before the study, invitation letters and study information sheets will be sent to parents of eligible children (aged 5 and 10/11) in the chosen schools via their children’s schools, informing them that a dental inspection, including the taking of photographs of the teeth, will take place on an appointed day. Parents of the 5 year olds will also receive consent forms and will have to give or refuse consent by returning completed and signed consent forms to the school. Only 5 year olds whose parents give positive consent will be included in the study. Parents of the Year 6 children (aged 10/11) will receive a parent opt-out form which they can complete if they do not want their child to be included. Consent will be obtained from Year 6 children whose parents have not withdrawn them from the study. Consent by conduct will also be used during the study; therefore a child’s decision not to participate will be respected.

All children will receive a clinical examination (a “dental inspection”) by a panel of 5 dentists trained and calibrated by BASCD coordinated NHS Epidemiology Programme to undertake the national surveys. The children will also have 8 photographs of their teeth taken by one of these dentists. For both the clinical and photographic examinations, the children will recline on an examination couch (or equivalent) with the examiner seated behind them. The examination for dental caries will be carried out according to the method, criteria and coding system employed in the BASCD coordinated NHS Epidemiology Programme, using the recommended instrumentation and equipment (a hand mirror and cotton wool rolls), sterilisation/disinfection precautions (the use of non latex gloves), and data collection and data validating methods (Dental Survey Plus 2). Caries will be diagnosed visually at the ‘caries into dentine’ (obvious caries) level. BASCD conventions (Pitts et al. 1997) will be adhered to. Only the deciduous teeth of 5-year-olds will be scored and in Year 6 only permanent teeth will be scored. The photographs will be assessed “blind” at a later date by the same dentists who examine the children clinically.

No treatment will be carried out during the study.

Some participants (who would have had both the clinical and photographic examinations) will be selected to join small focus groups in which semi-structured interviews with or without the use of puppet(s) will be used to elicit the children’s views on both the established and experimental methods. These interviews will take about 20 minutes to complete.

The study will be carried out between December 2009 and May 2010, in primary schools in Rochdale.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

☐ Design of the research
☐ Management of the research
☑ Undertaking the research
☐ Analysis of results
☐ Dissemination of findings
☑ None of the above

Give details of involvement, or if none please justify the absence of involvement. Advice has been sought from schools regarding how best to conduct the focus group interviews with the children to ensure that the children are at ease.

The research team will liaise with schools to make sure that visits to the schools to conduct the study cause as little disruption as possible to the daily activities of the schools.
4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Male and female subjects aged 5 years and 10-11 years
2. Informed consent obtained from parents/guardians
3. Subject in attendance at school on the day of visit by research team
4. Subject willing to be examined and have photographs of his/her teeth taken
5. For the focus groups semi-structured interviews, subjects who have been examined and had photographs of their teeth taken and willing to be interviewed

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. 5 year olds whose parents/guardians do not give informed consent
2. Year 6 children whose parents opt to withdraw them from the study
3. Children who refuse to be examined or have photographs taken of their teeth
4. Children who refuse to be interviewed

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:
1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

<table>
<thead>
<tr>
<th>Intervention or procedure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seeking and obtaining informed consent/parental opt-out</td>
<td>1/n/a</td>
<td>30 minutes</td>
<td>Parents of potential participants aged 5 years will receive, via their child's school, a letter of invitation, an information sheet and consent form to read and consider, and will be invited to complete and return consent forms to the child's school. Parents of older children (aged 10/11) will receive an opt-out form to complete if they do not want their child to be included in the study. The older children will also be invited to consent to their participation.</td>
<td></td>
</tr>
<tr>
<td>Semi-structured interviews</td>
<td>1/n/a</td>
<td>20 minutes</td>
<td>Some of the children participating in the clinical and photographic examinations will take part in small focus groups, where they will be invited to give their views on both examination methods. These will take place in school, in an appropriate room, and will be conducted by members of the research team.</td>
<td></td>
</tr>
</tbody>
</table>

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.

Please complete the columns for each intervention/procedure as follows:
1. Total number of interventions/procedures to be received by each participant as part of the research protocol.

Date: 02/10/2009
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

<table>
<thead>
<tr>
<th>Intervention or procedure</th>
<th>1</th>
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<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental examination</td>
<td>1</td>
<td>1</td>
<td>10 minutes</td>
<td>The oral examinations will take place in the participant's school and will be carried out by one of 5 trained and calibrated examiners (dentists)</td>
</tr>
<tr>
<td>Photographing of indexed teeth</td>
<td>1</td>
<td>n/a</td>
<td>10 minutes</td>
<td>Up to 8 photographs will be taken, in school and on the same occasion as the clinical examination, by the Chief Investigator. A reserve examiner will also be available if necessary.</td>
</tr>
</tbody>
</table>

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

☐ Yes ☐ No

A21. How long do you expect each participant to be in the study in total?

A total of 50 minutes: 10 minutes for the clinical examination, 10 minutes for the photographs, up to 10 minutes to familiarise children with the interview process and up to 20 minutes for the interviews.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Sterilization and infection control procedures as per the BASCD coordinated NHS epidemiological surveys’ protocol. Also the manufacturer’s infection control instructions for the intra-oral camera will be followed to safeguard participants.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

☐ Yes ☐ No

A24. What is the potential for benefit to research participants?

Although there will not be a direct benefit to the research participants, they will contribute to the development of a tool that could enhance the robustness of future evidence on water fluoridation schemes, a public health measure that is aimed at improving dental health, particularly that of children. This study will also enable the views of children to be considered in the development of a tool that is mainly aimed towards them.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.

Those who have participated in the trial will continue to receive dental inspections at school as part of epidemiological surveys and following the BASCD guidelines. There will be no continued provision of examination by intra-oral camera or participation in focus groups.

A26. What are the potential risks for the researchers themselves? (if any)
**RECRUITMENT AND INFORMED CONSENT**

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

**A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?**

For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).

The research team will liaise with participating schools to select eligible children - ie children who will be 5 years old but not 6 years old on the date of the planned visit to school to conduct the clinical and photographic examination and also the children in Year 6. The parents/guardians of these children will receive invitation letters with study information sheets and the relevant consent or parental opt-out forms.

**A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?**

- [ ] Yes
- [ ] No

*Please give details below.*

Class lists with children's date of birth will allow the study administration to identify eligible children.

**A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?**

- [ ] Yes
- [ ] No

**A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?**

- [ ] Yes
- [ ] No

*If Yes, please give details below.*

Apart from the members of the research team only representatives of the sponsor organisation and regulatory bodies will be allowed access for monitoring purposes. The following clause will be part of the consent form to ensure that participants give or refuse consent for this:

“I understand that relevant sections of my personal data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.”

**A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?**

- [ ] Yes
- [ ] No

**A29. How and by whom will potential participants first be approached?**

Invitation letters, study information sheets and consent/parental opt out forms will be sent to parents of eligible children in the chosen schools, via the schools, informing them that a dental inspection, including the taking of photographs of the teeth, will take place on an appointed day. Parents will also be informed that a number of children, selected randomly from those who have already received both clinical and photographic examinations, will be interviewed in focus groups to elicit the children’s views on both the clinical examination and the photographic procedure.
A30.1. Will you obtain informed consent from or on behalf of research participants?

- Yes
- No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

See Part B, Section 7

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30.2. Will you record informed consent (or advice from consultees) in writing?

- Yes
- No

A31. How long will you allow potential participants to decide whether or not to take part?

Potential participants will be given advance notice of the study in a letter (via parents) which will include an information sheet. They will have at least 48 hours in which to decide whether or not to participate.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

- Yes
- No
- Not Known

A33.1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? (e.g. translation, use of interpreters)

For those whose first language is not English, the study team will follow the procedures already used by each school to get information across to pupils, parents and guardians whose first language is not English.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

If information becomes available during the course of the research which could have a bearing on continued participation, that information will be sent to the child’s parents/guardian, via their school.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.

Date: 02/10/2009
Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:
  - Manual files including X-rays
  - NHS computers
  - Home or other personal computers
  - University computers
  - Private company computers
  - Laptop computers

Further details:

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

When participants are recruited to the study, each will be allocated a unique identification number. The study manager, (the CI, Mrs Uriana Boye, based at the University of Manchester), will retain a master list of all participants and their unique identification numbers. This will be stored on a password protected PC and as a backup hard copy which will be kept in a fireproof locked safe. Names of participants will not appear on pro-formas for collecting data; only their allocated ID numbers. No identifiable information will be used when reporting findings from the study.

The master list of all participants and their unique identification numbers will be destroyed when study findings have been published. The anonymous data will be stored on the password protected PC of the Chief Investigator and back up copies in a locked cabinet at the University of Manchester. The data will be stored for a minimum of 10 years according to the guidelines of the Medical Research Council.

A40. Who will have access to participants’ personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

Members of the study team and, in addition, representatives of the sponsor will require access to data collected during the conduct of the study for the purpose of monitoring and audit.
A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

If longer than 12 months, please justify:
We will follow the University of Manchester Code of Good Research Conduct which requires trial documents to be held for five years after the last publication from the study or for 10 years, whichever is the longer.

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- Yes
- No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Study participants will receive no direct payment, but may receive stickers or dental health resources (tooth brushes and/or toothpaste) to thank them for taking part. Participating schools will receive £1 per completed consent form returned, whether giving consent or declining participation on behalf of the child.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes
- No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- Yes
- No

A49-1. Will you inform the participants’ General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

- Yes
- No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A50. Will the research be registered on a public database?

- Yes
- No
A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [ ] Peer reviewed scientific journals
- [ ] Internal report
- [ ] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A53. Will you inform participants of the results?

- [ ] Yes  
- [ ] No

*Please give details of how you will inform participants or justify if not doing so. Participants or their parents will be sent a summary of the trial results written in terms understandable to a lay person.*

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi-centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

*Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:*

The study methodology is almost a replica of the methodology for the established BASCD coordinated national NHS epidemiological surveys, the only addition being the introduction of the use of the intra-oral camera. Dr Iain Pretty, who is involved with the supervision of the study, has expertise in dental research using imaging technologies and he has worked within international collaborations in this field.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [ ] Review by a statistician within the Chief Investigator’s institution
Review by a statistician within the research team or multi–centre group
☑ Review by educational supervisor
□ Other review by individual with relevant statistical expertise
□ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title  Forename/Initials  Surname
Dr  Tanya  Walsh

Department  School of Dentistry
Institution  The University of Manchester
Work Address  Oxford Road
Manchester

Post Code  M13 9PL
Telephone  01612757817
Fax
Mobile  01612757817
E-mail  tanya.walsh@manchester.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?
Dental caries detection capability of the experimental method as compared with the established clinical examination method.

A58. What are the secondary outcome measures? (if any)
The views of the children on both the established clinical examination method and the experimental method.

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size:  600
Total international sample size (including UK):
Total in European Economic Area:

Further details:
Please see A60 below

A60. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

Advice was obtained from the study statistician. The study is a method comparison study and it has been decided that a sample size of 300 participants in each of the two age groups should be adequate for the purposes if the study . There will therefore be a total of 600 participants.

Small focus groups have been chosen as the method of eliciting the children's views because advice from experts who work with children indicated that the children will be better at ease in a small group than on their own. Also a group with more than 5 children could result in more extrovert ones taking over.

Date: 02/10/2009

17

30751/65399/1/372
A61. Will participants be allocated to groups at random?

- Yes
- No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Data from the clinical examinations and the photographic assessments will be collected by the examiners on to paper proformas with grids for dental charting identical to the standard BASCD caries chart field grid. The caries status of each tooth surface examined will be recorded. The data will then be collated and entered into a PC or lap top by the study administration for processing by means of Dental Survey Plus 2 software, identical to those used in the BASCD coordinated NHS Dental Epidemiology Programme (Pitts et al 1997). Summary sheets for the deciduous and permanent dentitions will be generated. Indices of mean caries prevalence and experience (the summary outcome measures) will include dmft and components (dt, mt, ft) and DMFT and components (DT, MT, FT). The clinical and photographic data of each subject will be matched together for the purposes of the later data analysis.

Summary statistics and comparative analysis will be undertaken
1. Kappa statistics as a measure of agreement between the test and re-test by the same examiner for the clinical examination carried out for both the deciduous and permanent dentitions (for intra examiner reliability)
2. Kappa statistics as a measure of group agreement for the clinical examination carried out for both the deciduous and permanent dentitions
3. Kappa statistics as a measure of intra examiner reliability for the 8, 6 and 4 folder photographic assessments carried out by the same examiner (for both the deciduous and permanent dentitions)
4. The size and direction of the deviation of mean indices (dmft, dt; DMFT and components) recorded clinically by the assessors from the indices obtained clinically by the benchmark examiner
5. The size and direction of the deviation of mean indices (dmft, dt; DMFT and components) recorded photographically by the assessors from the indices obtained clinically by the benchmark examiner.

Analysis of interviews
An initial analysis of transcripts will be made after each interview using a constant comparative method which will identify information that has already been identified. The interview pro-forma will be modified accordingly to pursue new categories that emerge. Each category emerging from interviews will be assigned a code. The coding of themes will generate an initial coding framework which is added to and refined through discussions between the research team and applied to further data. Further sampling of schools (up to 5 schools) and analysis of interview transcripts will be conducted concurrently until no new categories emerge. The major categories will be integrated and refined to generate findings from the data.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.

<table>
<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<tbody>
<tr>
<td>Dr</td>
<td>Iain</td>
<td>Pretty</td>
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<table>
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<tr>
<th>Post</th>
<th>Senior Lecturer</th>
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<tr>
<th>Qualifications</th>
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<table>
<thead>
<tr>
<th>Employer</th>
<th>Dental Health Unit, Skelton House</th>
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<tbody>
<tr>
<td>Work Address</td>
<td>Manchester Science Park, Lloyd St N</td>
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<td>Manchester</td>
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<tr>
<th>Telephone</th>
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<tr>
<th>Work Email</th>
<th><a href="mailto:lain.A.Pretty@manchester.ac.uk">lain.A.Pretty@manchester.ac.uk</a></th>
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</thead>
</table>

Date: 02/10/2009
Title Forename/Initials Surname  
Mrs  Angela  Willasey  

Post  North West Bench Mark Examiner for BASCD coordinated NHS surveys  

Qualifications  BDS  

Employer  Warrington PCT  

Work Address  Garven Place Dental Department  
Sankey Street  
Warrington  

Post Code  WA1 1GP  

Telephone  Fax  

Mobile  

Work Email  angela.willasey@warringtonpct.nhs.uk  

A64. Details of research sponsor(s)  

A64-1. Sponsor  

Lead Sponsor  

Status:  
- NHS or HSC care organisation  
- Corporate  
- Pharmaceutical industry  
- Medical device industry  
- Local Authority  
- Other social care provider (including voluntary sector or private organisation)  
- Other  

Commercial status:  
- Non-Commercial  

If Other, please specify:  

Contact person  

Name of organisation  The University of Manchester  
Given name  Dr  Karen  
Family name  Shaw  
Address  Head of the University Research Office, The University of Manchester  
Town/city  Oxford Road, Manchester  
Post code  M13 9PL  
Country  UNITED KINGDOM  
Telephone  01612758795  
Fax  
E-mail  research-governance@manchester.ac.uk  

Is the sponsor based outside the UK?  
- Yes  
- No  

Where the lead sponsor is not established within the UK, a legal representative in the UK may need to be appointed. Please consult the guidance notes.
A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

☐ Yes  ☐ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68. Give details of the lead NHS R&D contact for this research:

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<thead>
<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<tbody>
<tr>
<td></td>
<td>Mrs</td>
<td>Rachel Georgiou</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Heywood, Middleton &amp; Rochdale PCT</th>
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<tbody>
<tr>
<td>Address</td>
<td>GM PCT ReGrouP, c/o R &amp; D</td>
</tr>
<tr>
<td></td>
<td>Clinical Sciences Bldg,</td>
</tr>
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<td></td>
<td>Stott Lane, Salford</td>
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<th>Post Code</th>
<th>M6 8HD</th>
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<tr>
<td>Work Email</td>
<td><a href="mailto:rachel.georgiou@manchester.ac.uk">rachel.georgiou@manchester.ac.uk</a></td>
</tr>
<tr>
<td>Telephone</td>
<td>0161 206 0475</td>
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<tr>
<td>Fax</td>
<td>0161 206 4205</td>
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<tr>
<td>Mobile</td>
<td>0161 206 0475</td>
</tr>
</tbody>
</table>

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/12/2009
Planned end date: 31/05/2010

Total duration:
 Years: 0  Months: 6  Days:

A71-1. Is this study?

Date: 02/10/2009
A71.2. Where will the research take place? (Tick as appropriate)

- England
- Scotland
- Wales
- Northern Ireland
- Other countries in European Economic Area

Total UK sites in study 10

Does this trial involve countries outside the EU?
- Yes
- No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England
- NHS organisations in Wales
- NHS organisations in Scotland
- HSC organisations in Northern Ireland
- GP practices in England
- GP practices in Wales
- GP practices in Scotland
- GP practices in Northern Ireland
- Social care organisations
- Phase 1 trial units
- Prison establishments
- Probation areas
- Independent hospitals
- Educational establishments: 10
- Independent research units
- Other (give details)

Total UK sites in study: 10

A75-1. Will a data monitoring committee (DMC) be convened?

- Yes
- No

If Yes, please forward details of the membership of the DMC, its standard operating procedures and summary reports of interim analyses to the Research Ethics Committee which gives a favourable opinion of the study (or to GTAC if applicable).

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

Failure to recruit sufficient participants
### A76. Insurance/ indemnity to meet potential legal liabilities

<table>
<thead>
<tr>
<th>Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland</th>
</tr>
</thead>
</table>

#### A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

**Note:** Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (NHS sponsors only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

The University of Manchester will be covered by its Public, Products and Employer's liability policy.

**Please enclose a copy of relevant documents.**

#### A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

**Note:** Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- [ ] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [ ] Other insurance or indemnity arrangements will apply (give details below)

The University of Manchester will be covered by its Public, Products and Employer's liability policy.

**Please enclose a copy of relevant documents.**

#### A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

**Note:** Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [ ] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The University of Manchester will be covered by its Public, Products and Employer's liability policy.

**Please enclose a copy of relevant documents.**

#### A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

- [ ] Yes
- [ ] No

If Yes, please give details of the compensation policy:
The University of Manchester has Clinical Trials cover which encompasses provision of No Fault compensation.

Please enclose a copy of relevant documents.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Participants will be recruited from two different age groups: 5 year olds and 10/11 year olds (Year 6 at primary school). The specific age groups were chosen because they are internationally recognized cohorts on whom caries data is usually collected. This will allow comparison of research findings with other retrospective and prospective caries data.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No controls will be recruited.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

The 5 year old children will be too young to receive information or give consent, therefore potential participants will be approached via their parents or person with parental responsibility. Informed positive consent will be required before a child in this age group can take part in the study. Children in the older age group (age 10/11) will be invited to consent themselves into the study. Their parents will be sent information leaflets in the same way, and will also be sent an opt-out form to complete if they do not wish their child to take part in the study.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

The 5 year old children will be too young to receive information or give consent, therefore potential participants will be approached via their parents or person with parental responsibility. Informed positive consent will be required before a child in this age group can take part in the study. Children in the older age group (age 10/11) will be invited to consent themselves into the study. Their parents will be sent information leaflets in the same way, and will also be sent an opt-out form to complete if they do not wish their child to take part in the study.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.
**PART C: Overview of research sites**

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

<table>
<thead>
<tr>
<th>Research site</th>
<th>Investigator/ Collaborator/ Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution name</td>
<td>NHS Heywood, Middleton and Rochdale Primary Care Trust</td>
</tr>
<tr>
<td>Department name</td>
<td>Oral Health Promotion</td>
</tr>
<tr>
<td>Street address</td>
<td>Telegraph House, Baillie Street</td>
</tr>
<tr>
<td>Town/city</td>
<td>Rochdale</td>
</tr>
<tr>
<td>Post Code</td>
<td>OL16 1JA</td>
</tr>
<tr>
<td>Title</td>
<td>First name/ Initials</td>
</tr>
<tr>
<td></td>
<td>Surname</td>
</tr>
</tbody>
</table>
**PART D: Declarations**

**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs.
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee’s final opinion or the withdrawal of the application.

**Contact point for publication**

*NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.*

- [x] Chief Investigator
- [ ] Sponsor’s UK contact point
- [ ] Study co-ordinator

Date: 02/10/2009
Access to application for training purposes

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .................................................................

Print Name: Uriana Boye

Date: (dd/mm/yyyy)
D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature: .....................................................

Print Name: ............................................................

Date: (dd/mm/yyyy)
# D3. Declaration for student projects by academic supervisor

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the Chief Investigator and the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

**Signature:** ..............................................................

**Print Name:** Martin Tickle

**Date:** (dd/mm/yyyy)

**Post:** Professor of Dental Public Health

**Organisation:** The University of Manchester
Study Protocol for Phase III

Study Title: Comparison of a photographic and a clinical dental examination: Phase III

Chief Investigator (PhD student) Uriana Boye
Senior Dental officer
Oral Health Promotion Unit
NHS Heywood, Middleton & Rochdale
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Middleton
M24 1AY

Co-investigator (PhD supervisor) Professor Martin Tickle
Professor of Dental Public Health
University of Manchester School of Dentistry
Higher Cambridge Street
Manchester M15 6FH

Co-investigator (co-supervisor) Dr Iain Pretty
Senior Lecturer
The Dental Health Unit
Skelton House
Manchester Science Park
Lloyd Street North
Manchester M15 6SH

Statistician to the study Dr. Tanya Walsh
Lecturer in Dental Statistics
University of Manchester School of Dentistry
Higher Cambridge Street
Manchester M15 6FH
1.0 Introduction

1.1 Background

Randomised controlled trials (RCTs) robustly designed and properly conducted produce the highest hierarchy of evidence upon which practice can be based. In order to avoid one source of bias in RCTs, one of the requirements is that, ideally, the administrators of the trial, as well as both field investigators and participants, should be unaware of the experimental group to which individual subjects have been randomly allocated. This is known as a ‘double blind’ design. It is relatively easy to achieve double blind conditions in RCTs where a drug or therapeutic agent is being tested against an active or passive placebo control. Both test and control agents being administered to subjects, can be made identical in appearance, taste and texture. ‘Blinding’ is however, far more difficult to achieve in RCTs of public health measures - water fluoridation being a prime example - where it is difficult to disguise from investigators collecting outcome measures, the locality - fluoridated or non-fluoridated - in which participating subjects live. In spite of this potential difficulty, the Department of Health (DH) in its response to the Medical Research Council’s (2002) recommendations outlining ‘a programme of research that would substantially increase our understanding of the impact of water fluoridation on health’ called for the development of a robust design for the evaluation of any new fluoridation schemes. This implied that any new studies of water fluoridation should conform to the highest standards of clinical trial design in order to produce an evaluation near the top of the hierarchy of scientific evidence. As subjects can not be randomly allocated to the intervention group in any new water fluoridation schemes, their evaluation studies can not be set up as RCTs. They could however be designed as prospective Cohort studies, the next level down from RCTs but should still produce scientific evidence near the top of the hierarchy. This type of study design, as in RCTs would also require ‘blinding’, at least, of those administering the trial on a day to day basis and investigators collecting and interpreting the data.

Using conventional clinical examination techniques, the only method of ensuring that the examiners are unaware of the place of residence of the subjects is probably by transporting them to an examination site located outside both the test and control areas. The place of residence of child participants could be hidden from the examiners
providing the children were not wearing school uniforms (Jackson et al. 1975). This was feasible up until the 1980s (Milsom and Mitropoulos 1990). However, today, taking a large number of children out of school and transporting them to a remote location, possibly 40 miles or more from their homes, would be now virtually out of the question. Apart from the obvious logistical difficulties in a large fluoridation study with possibly thousands of children involved, there would be ethical and safety considerations. There would also be issues of parental consent and attrition of the sample that would probably be impossible to resolve.

An alternative method of blinding examiners would be to use an imaging technique, with photography, a non-invasive procedure, being the method of choice. Photographs of the dentition of participants would be taken and coded to ensure anonymity. Examiners could assess these photographs for caries rather than examine the subjects clinically.

With a view to investigating a suitable non-clinical method of examining child participants, the evaluation of a potentially useful photographic method is therefore the subject of this protocol. The protocol in itself forms part of a broader, more comprehensive protocol for the design of an evaluation of possible water fluoridation programmes.

1.2 Aims

The purpose of this project is to devise a protocol aimed at comparing the dental caries detection performance of a photographic method in children aged 5 and 10/11 years with an established clinical examination method as reference criterion, thereby enabling an evaluation of the concurrent validity of the photographic method. An additional dimension to this project is to also compare the diagnostic performance of the chosen non-invasive imaging technique and clinical diagnosis with histology, the ultimate diagnostic tool for caries.

The project has been designed to be undertaken as three discrete studies:
1.3 Work already undertaken

1.3.1 Phase I

The first part of the project compared the clinical, photographic and histological examination of extracted teeth.

After obtaining ethical approval from the University of Manchester Committee on Ethics of Research on Human Beings, 50 pre-selected, extracted teeth, some sound and others with carious lesions of various degrees of severity were photographed using an intra oral camera.

The teeth were then examined clinically by a panel of experienced and calibrated dental examiners using the method developed by the British Association for the Study of Community Dentistry (BASCD protocol, Pitts et al. 1997). The photographs of the extracted teeth were then assessed by the same examiners who conducted the clinical examination (using the BASCD criteria). The teeth were then sectioned for histological assessment. The resulting histological section with the worst level of caries for each tooth was used in the comparative analysis. Scores from the histological assessments were used as the gold standard against which the clinical examination and photographic assessments scores were compared.

1.3.2 Main Results of Phase I

Evaluation of the outcomes of each examination method showed substantial agreement for the clinical examination with intra-rater kappas ranging from 0.67 to 0.92 (median = 0.55) with multi-rater kappa of 0.66. Agreement for the photographic method ranged from 0.59 to 0.88 (median = 0.74) with a multi-rater kappa of 0.60. There was also a moderate level of agreement between the clinical and photographic assessments (intra-rater kappas from 0.45 to 0.73; median = 0.53), histology and photographic assessment (0.45 to 0.56 median = 0.54), and histology and clinical examination (0.38 to 0.55 median = 0.46).
1.3.3 Conclusion from Results of Phase I

The comparisons showed a moderate level of agreement between the clinical and photographic examinations. The level of agreement between the gold standard and test method was better than the agreement between the gold standard and the established method. It is therefore concluded that it was worth considering the use of photographs for detecting caries to overcome the problem of blinding.

1.4 Phase II

This part of the study consisted of a comparison of the experimental photographic method of detecting dental caries, with the established clinical examination method developed by BASCD (as above). The concurrent validity of the photographic method was evaluated using the established clinical method as the benchmark.

This took a form similar to the calibration exercises undertaken prior to NHS epidemiological surveys of children. These surveys are coordinated nationally by BASCD and are undertaken routinely in the school setting to provide surveillance data on population levels of dental caries.

The study took place in 8 primary schools in Rochdale Metropolitan Borough. Subsequent to obtaining ethical approval from the University of Manchester Committee on Ethics of Research on Human Beings and informing the relevant local research governance group, children aged 5 years and those aged 10-11 years were recruited to take part. Only children whose parents gave positive consent were included in the study. During the study any child’s decision not to participate was respected.

The children were clinically examined by a panel of 5 trained and calibrated dentists using BASCD criteria. The children also had photographs of their teeth taken. The photographs were assessed “blind” at a later date by the same dentists who examined the children clinically.
1.4.1 Main Results of Phase II

There was almost perfect agreement between the caries scores obtained by the experimental photographic method and those obtained by the established clinical examination in the 5 year olds group for majority of the examiners (4 out of the 5). Their computed weighted kappa statistics were 0.88, 0.87, 0.85, 0.84, and 0.50. The level of agreement between the two methods for the 10 – 11 year olds was substantial for majority of the examiners (4 out of 5) with weighted kappas of 0.81, 0.78, 0.78, 0.69, and -0.01.

1.4.2 Conclusion from Results of Phase II

The level of agreement computed between the experimental and established methods was good. However for the experimental procedure to provide examiners with photographs of all the teeth surfaces they had already examined clinically implied that the experimental method took considerably longer (the clinical examination took on average 5 minutes whereas the photographic method took on average 15 minutes). If a reduced number of photographs that can provide similar caries information as that which can be obtained from a full mouth clinical examination could be determined, it would enhance the ease of use of the new method.

Also the photographic method if used in the future in the evaluation of water fluoridation schemes will involve mainly children. Although it can be challenging to obtain an accurate reflection of children’s views on various issues that affect them and the impact of those issues on their lives, the development and evaluation of a new tool for use in children will be incomplete without inclusion of what they think about it.

1.5 Phase III

Retrospective BASCD caries data obtained from the Dental Observatory, Preston, indicates that generally certain identified teeth are the most liable to decay in 5 year olds
and 10/11 year olds. To seek out ways in which to enhance the usability of the test method, it is necessary to test the possibility of obtaining similar caries information from fewer photographs (fewer than taken in phase II) as compared to full mouth clinical examination. There is generally not a substantial difference in time between performing a clinical full mouth examination and a partial mouth examination.

1.6 Aims

This aim of the study will be to compare caries data obtained from a clinical full mouth examination with caries data obtained from 8, 6 and 4 photographs taken of the identified teeth that are liable to decay (indexed teeth).

The following null hypotheses will be tested:

H011 There is no significant difference in dental caries information recorded by an examiner during the clinical examinations of the same subjects on two different occasions (to test intra-examiner reliability for the clinical exam)

H012 There is no significant difference in dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment the “8” photographs)

H013 There is no significant difference in dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment the “6” photographs)

H014 There is no significant difference in dental caries information recorded by an examiner assessing two randomised sequences of the same intra-oral photographs (to test intra-examiner reliability for assessment the “4” photographs)

H015 There is no significant difference in dental caries information recorded between the clinical examination and “8” photographic assessments.

H016 There is no significant difference in dental caries information recorded between the clinical examination and “6” photographic assessments.

H017 There is no significant difference in dental caries information recorded between the clinical examination and “4” photographic assessments.
An associated aim will be to elicit the children’s views on both the established clinical examination and the experimental photographic method of examination.

2.0 Method

2.1 Study design of Phase III
This part of the study will be conducted as a cross-sectional comparison involving the chosen experimental photographic method of detecting dental caries, with an established clinical examination method developed by the British Association for the Study of Community Dentistry (BASCD). This will take a form equivalent to a calibration exercise undertaken prior to NHS epidemiological surveys of children. These surveys are undertaken routinely in the school setting to collect data in a standardised way and are coordinated nationally by BASCD; the only additional feature proposed in the present study is the use of an intra-oral camera, as part of the exercise.

The BASCD bench mark examiner for the North West and 4 other BASCD trained examiners will clinically examine a sample of 5 and 10/11 year old children, in chosen schools. Each participating child will also have 8 photographs taken of specific teeth in their mouths using an intra oral camera. The photographs will be assessed later at a study day by the same BASCD trained examiners.

The chief investigator who already has experience in using the intra-oral camera on children (in Phase II) will obtain the photographs. A reserve or back up examiner, also trained in the photographic method, will be available to meet any unforeseen contingencies arising.

2.2 Subjects
The subjects will comprise a total of three hundred 5-year-old (Reception and Year 1), and three hundred 10- and 11-year-old (Year 6) school children. All children whose parents give consent in these age groups within the chosen schools will be regarded as eligible for the study. A master list of these children showing their gender and birth dates will be retained by the study administration from which identity numbers will be allocated to the subjects. All the children in the two age groups will each receive a clinical dental examination as well as have 8 photographs of their dentition taken.
Before the study, for the 5 year olds invitation letters (Appendix - 1), study information sheets (Appendix - 2) and consent forms (Appendix - 3) will be sent to parents of eligible children in the chosen schools, via the schools, informing them that a ‘dental inspection’, including the taking of photographs of the teeth, will take place on the appointed day which will include their child. Parents will also be informed that of the children who have both the clinical and photographic examinations, a selected number will be interviewed in focus groups to elicit their views on both the clinical examination and the photographic procedure. Parents will have to give or refuse consent by returning completed and signed consent forms to the school. Only children whose parents give positive consent will be included in the survey.

For the Year 6 children in accordance with guidance from the Department of Health reading consent for this age group (Appendix 8), invitation letters (Appendix - 1), study information sheets (Appendix - 2) and parental opt out forms (Appendix - 4) will be sent to parents of eligible children in the chosen schools, via the schools, informing them that a ‘dental inspection’, including the taking of photographs of the teeth, will take place on the appointed day which will include their child. Parents will also be informed that of the children who have both the clinical and photographic examinations, a selected number will be interviewed in focus groups to elicit their views on both the clinical examination and the photographic procedure. Parents can refuse to let their children take part in the study by returning completed and signed parental opt out forms to the school. Study information sheets (Appendix - 5) will also be provided for the Year 6 children. For those whose parents have not opted to exclude them from the study consent forms (Appendix – 6) will be provided. Only children who give informed consent will be included in the survey.

2.3 Oral Examination

The clinical examinations of all consenting children will be undertaken by 5 of the North West trained and calibrated examiners including the regional trainer for the BASCD epidemiology programme. For both the clinical and photographic examinations, the children will recline on an examination couch (or equivalent) with the examiner seated
behind them using a Daray Lamp as a source of light. The examination for dental caries prevalence and experience will be carried out according to the method, criteria and coding system employed in the BASCD co-ordinated NHS Epidemiology Programme (Pitts et al. 1997) using the recommended instrumentation and equipment (a hand mirror and cotton wool rolls), sterilisation/disinfection precautions (the use of non latex gloves), and data collection and data validating methods (Dental Survey Plus 2). Caries will be diagnosed visually at the ‘caries into dentine’ (obvious caries) level. BASCD conventions (Pitts et al. 1997) will be adhered to. Only the deciduous teeth of 5-year-olds will be scored and in 10- and 11-year-olds only permanent teeth will be scored. All surfaces of each tooth examined will be scored.

10% of the children in each age group will be clinically examined again to test intra examiner reliability and collectively for the group of examiners.

2.4.1 Photographic equipment and procedures
For the photographic procedures, an intra oral camera, which has an integral LED light source, will be used to take 8 photographs of each child’s indexed teeth. The indexed teeth for the 5 year olds will be the first and second deciduous molars, the upper central and lateral deciduous incisors and the lower deciduous canines. The indexed teeth for the 10/11 year olds will be all 4 first permanent molars. The children will be able to follow the photographic imaging on a computer screen.

Between subjects the infection control procedures specified by the manufacturer of the chosen intra oral camera user guide will be followed. The set of photographs taken for each child will be stored in a folder carrying the allocated identification number (ID) to that child. The ID label for each subject’s set of photographs will be the same as that assigned to their clinical records to enable matching later.

The ID numbers originally allocated to consenting children in the classes in the sampling frame, who are not examined on the appointed day, including absentees, will be retained as blank records in the archives.
2.4.2 Photographic Assessment

Using the ID labelled folders containing the 8 photographs for each subject, two new folders will be created containing 6 and 4 photographs respectively. To create the folder with 6 folders the ID labelled folder with 8 photographs will be used as the starting point. Two of the photographs of the indexed teeth will be deleted. The resulting folder with 6 photographs will be renamed with the ID label of the subject but with the number 6 in brackets added. The same principle will be used to create the folders with 4 photographs using the folder with 6 photographs as the basis. When the compilation of the folders is completed, there will three folders for subject: ID labelled (8), ID labelled (6) and ID labelled (4) containing 8, 6 and 4 photographs respectively.

Six photographic presentations (5 year olds - 8 photographs per subject, 5 year olds - 6 photographs per subject and 5 year olds- 4 photographs per subject; 10/11 year olds - 8 photographs per subject, 10/11 year olds - 6 photographs per subject and 10/11 year olds - 4 photographs per subject) will be prepared for assessing. For each of the presentations, 10% of the ID labelled folders will be assigned new ID numbers and added to the presentations. This will test intra-examiner reliability of the photographic assessments. The key to the original identity numbered sequences (the definitive identity numbers) and the new identity numbers (for those added to test intra-examiner reliability) will be known only to, and retained by, the study administrator.

The photographic assessments will be carried out by the same examiners who carried out the clinical examination. Before the viewings of the photographs, the study administrator will demonstrate the photographic technique to the assessors to familiarise them with what is involved. The purpose of the assessment exercise will also be fully explained to the assessors. The assessors will view the photographic presentations on desktop or laptop screens. They will record their visual diagnostic findings in association with the relevant identity number of each subject. The method for scoring the photographs will be identical to the clinical method and recorded on the same score sheet (Appendix – 8) as the clinical examination.
2.5 Semi structured interviews
The research team will work closely with schools to determine the best time to interview children. Arrangement will also be made for a suitable room in which to conduct the focus group interviews.

Semi-structured, audio taped interviews will be conducted using a puppet. Up to 5 children will be chosen randomly from the children who have had clinical and photographic examinations for each age group in each school for the focus groups. The interviews will be no longer than 20 minutes. No identifiable data other than the consent form will be collected. The confidentiality of participants and their views in focus groups and interviews will be maintained.

A draft interview pro-forma as shown in Appendix 7 will be used as a guide for the interviews. Audio recordings of interviews will be numbered for anonymity, transcribed verbatim by an audio typist and emerging themes and categories identified. The audio tapes will be securely stored and destroyed at the end of the study.

2.6 Location
The study will be administered from the School of Dentistry in Manchester University. The clinical examinations, photographic examinations and focus group interviews will take place in chosen schools within Rochdale Metropolitan Borough Council. Assessment of the photographs will take place during study days at the School of Dentistry, University of Manchester.

2.7 Personnel
Apart from members of the research team, the personnel will consist of the North West regional trainer for the BASCD epidemiology programme (the bench mark examiner), BASCD survey trained and calibrated examiners in the North West region to act as assessors, and a study administrator.
3.0 Data Processing and Analysis

3.1 Data Processing and Analysis of the clinical and photographic examinations
Data from the clinical examinations and the photographic assessments will be collected by the examiners on to paper proformas with grids for dental charting identical to the standard BASCD caries chart field grid (Appendix - 8). The caries status of each tooth surface examined will be recorded. The data will be collated and entered into a PC or lap top by the study administration for processing by means of Dental Survey Plus 2 software, identical to those used in the BASCD coordinated NHS Dental Epidemiology Programme (Pitts et al 1997). Summary sheets for the deciduous and permanent dentitions will be generated. Indices of mean caries prevalence and experience (the summary outcome measures) will include dmft and components (dt, mt, ft) and DMFT and components (DT, MT, FT). The clinical and photographic data of each subject will be matched together for the purposes of later data analysis.

Summary statistics and comparative analysis will be undertaken

1. Kappa statistics as a measure of agreement between the test and re-test by the same examiner for the clinical examination carried out for both the deciduous and permanent dentitions (for intra examiner reliability)
2. Kappa statistics as a measure of group agreement for the clinical examination carried out for both the deciduous and permanent dentitions
3. Kappa statistics as a measure of intra examiner reliability for the 8, 6 and 4 folder photographic assessments carried out by the same examiner (for both the deciduous and permanent dentitions)
4. The size and direction of the deviation of mean indices (dmft for the deciduous teeth and DMFT for the permanent teeth) recorded clinically by the assessors from the indices obtained clinically by the benchmark examiner
5. The size and direction of the deviation of mean indices (dmft for the deciduous teeth and DMFT for the permanent teeth) recorded photographically by the assessors from the indices obtained clinically by the benchmark examiner
3.2 Analysis of interviews

An initial analysis of transcripts will be made after each interview using a constant comparative method which will categorize information that has already been identified. The interview pro-forma will be modified accordingly to pursue new categories that emerge. Each category emerging from interviews will be assigned a code. The coding of themes will generate an initial coding framework which is added to and refined through discussions between the research team and applied to further data. Further sampling of schools (up to 5 schools) and analysis of interview transcripts will be conducted concurrently until no new categories emerge. The major categories will be integrated and refined to generate findings from the data.

4.0 Data Management

The master list of all the subjects in the study with their allocated identification numbers will be held by the study administrator. This will be stored on a password protected PC and as a backup hard copy which will be kept in a fireproof locked safe. Subjects’ names will not appear on proformas for collecting data only their allocated numbers. Subjects will not be identifiable in any reporting of data. As per BASCD, data from both the study will be backed up and each copy stored on a password protected computer.

5.0 Concluding remarks

The choice of age groups was driven by two main considerations. Eleven years is one of the age cohorts examined in surveys conducted under the BASCD coordinated Dental Epidemiology Programme. At the same time, eleven years of age is the probable upper age limit for following cohorts of children in the proposed RCT of water fluoridation. For ease of administration however, BASCD surveys draw samples children from Year 6 (a mixture of 10 and 11 year olds). 5-year-olds remain the other main group in BASCD surveys and also represents the probable baseline age group for the fluoridation RCT. Devising a technique for blinding examiners in the RCT is the main purpose for conducting the photographic assessment. In view of these various determining factors, it
would seem desirable to include, 5-, 10- and 11-year-olds, in this photographic validation study.

If the photographic method performs well, it might be adopted as the method of choice in the studies to evaluate future water fluoridation schemes. This would have the advantage that dental health professionals other than dentists could undertake the field work then trained and calibrated dental epidemiologists would interpret the photographs away from the field.
References


Dear Parent/Guardian

Re: Letter of Invitation for Your Child to Take Part in a Study to Monitor the Dental Health of Children

We are contacting you to invite your child to take part in a dental health study that is being conducted by the University of Manchester in conjunction with Heywood Middleton & Rochdale Primary Care Trust Dental Service.

The study will help develop a better and more scientific way of evaluating dental health initiatives and schemes as well as monitoring the dental health of children.

It is entirely your decision if you want your child to take part. Please find enclosed an information sheet that will help answer questions or concerns that you may have. If you require further information please contact Uriana Boye on 0161 655 1455.

Please sign the enclosed consent form indicating whether you would like your child to take part or not and return the form to your child’s school.

Thank you for your time

Yours sincerely

[Signature]

Professor Martin Tickle
Professor of Dental Public Health and Primary Care
INFORMATION FOR PARENTS/GUARDIANS OF POTENTIAL PARTICIPANTS IN DENTAL HEALTH STUDY OF CHILDREN

We are about to do a Dental Health Survey and would like to invite your child to take part.

Please read the following information carefully.

If you need help in understanding the purpose of the study and how much participation is required please ring Uriana Boye on 0161 6551455 and she will be happy to answer your questions and explain the study in further detail.

Title of the Study: Photographic vs. Clinical Diagnosis

What is the purpose of undertaking this Dental Health Study?

Heywood, Middleton & Rochdale Primary Care Trust Dental Service regularly carries out surveys in schools as part of its requirements from the Department of Health. The results of these surveys help to monitor the state of dental health of children in the area and assists health professionals in the planning of future dental services.

The methods by which health professionals have tried to improve dental health in the borough can also be evaluated by using these surveys to determine whether they have been effective. Such surveys have to be done in a very fair and accurate way. Examining photographs of teeth (without seeing the face as part of the photograph) can be a fair way of doing such a survey. This study will help find out if examining photographs of children’s teeth gives the same results as examining the children themselves. So alongside a simple dental health inspection, photographs (not X rays) will also need to be taken of your child’s teeth (this will not include a picture of his or her face).

What will take place on the day of the survey?

On the agreed date each child whose parent has given consent will receive a simple dental inspection similar to that carried out regularly by your local NHS Primary Care Trust Dental Service in schools as part of its requirements from the Department of Health. The only additional thing to be done as part of this survey is that the children will also have photographs taken of their teeth. This will be done with a mouth camera which is about the size of a toothbrush. No treatment will be carried out.
In order to determine the views of children on the survey, personnel experienced in working with children will have discussions with small groups of children. The discussions will be similar to “circle time” at school when children discuss what has happened in school that day. Not all children will form part of the small groups.

What will happen to the information gathered?

Only the study team will know which children are taking part in the study and this information will be kept safe and secure and treated in the strictest of confidence. To ensure the survey is fair and represents children in the area, the study will not make use any personal details such as your child’s name and which school they attend in reporting what is found. All information will be recorded confidentially.

Why has your child been selected to take part in this study?

This health study is concerned with studying the teeth of children who are 5 years old and those who are 10 – 11 years old (Year 6) and live in and/or attend schools in the Rochdale Borough area. Your child is of the appropriate age to participate in the study and lives and/or attends school in the area.

What if there is a problem?

Complaints
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Coordinator on 0161 2757583 or 0161 2758093 or by email to research-governance@manchester.ac.uk.

For parents/guardian of 5 year olds - If you wish to let your child take part in the study you must sign a consent form confirming your permission. Please complete the enclosed consent form indicating whether you wish your child to part in the study or not and return the form to your child’s school.  

For parents/guardian of Year 6 children – if you wish to withdraw your child from the survey please complete the parental opt out form and return it to your child’s school.

You can withdraw your child from the study at any time without having to give a reason. To withdraw your child from the study, please contact your child’s school.

If you require more information about any part of the study please contact Uriana Boye on 0161 6551455.

THANK YOU
CONSENT FORM

Title of Study: Photographic vs. Clinical Diagnosis

Survey Date: 

On the above date, a member of a research team from the University of Manchester and staff from Heywood, Middleton & Rochdale Primary Care Trust Dental Service will be visiting your child’s school to carry out a dental health survey.

Please put your initials in each box below which applies to you, print and sign your name and write the date at the bottom of the form.

1. I confirm that I have read and understand the information about the study. I have also had opportunity to ask questions

2. I understand that I have a choice about my child taking part in this study. I am free to withdraw my child at any time from the study without having to give a reason

3. I agree to my child taking part in the dental health study

4. I understand that relevant sections of my child's personal data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my child’s taking part in this research. I give permission for these individuals to have access to my child’s data.

4. If selected, I agree for my child to be included in the interviews

5. I do not want my child to take part in the dental health study

-------------------------------------
Print name of your child
-------------------------------------

-------------------------------------
Child’s class

-------------------------------------
Print name of Parent/Guardian

-------------------------------------
Signature

-------------------------------------
Date
PARENTAL OPT OUT FORM

Title of Study: Photographic vs. Clinical Diagnosis

If you do not want your child to take part in the dental study please sign below and return it to your child’s school.

“I do not want my child to take part in the dental Study”

-------------------------------------  -------------------------------------
Print name of your child             Child’s class

-------------------------------------  -----------------------------  -------------
Print name of Parent/Guardian        Signature                     Date

-------------------------------------
Relationship to child
Patient identification for the study

Y6 PUPIL STUDY INFORMATION SHEET

Dear Pupil

Title of Study: Photographic vs. Clinical Diagnosis

I am writing to ask you if you would like to take part in a survey that University of Manchester is doing in schools in Heywood, Middleton and Rochdale. I have also written to your parents or guardian to inform them about the survey.

We would like you to help us find out if what dentists see when they do a check up is similar to what they see when they have a look at photos of that mouth in children your age.

We will visit your school to carry out the survey. We will look in your mouth like a normal check-up at the dentist. We will also use a very small special camera to take photos of your teeth – which you will be able to see on a computer screen. It will not take photos of your face.

We will also have a chat with some of you in small groups to find out what you thought about having the check-up and the photos of your mouth taken. If you are chosen to take part in the chat, you can decide to do so by speaking directly to a person (our research team member) or through our special puppet.

When we finish the survey, we will give you a toothbrush and toothpaste to say thank you for helping us.

If you have any questions please ask us, if you do not want to take part, you do not have to. It is up to you!

Thank you

Professor Martin Tickle
Professor of Dental Public Health and Primary Care
Y6 CONSENT FORM

Title of Study: Photographic vs. Clinical Diagnosis

Survey Date:

Please put your initials by the following sentences you agree with:

<table>
<thead>
<tr>
<th>Sentence</th>
<th>Initials</th>
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<tbody>
<tr>
<td>I have read (or had read to me) about this survey</td>
<td></td>
</tr>
<tr>
<td>Someone else has explained the survey to me</td>
<td></td>
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<tr>
<td>I understand what this survey is about</td>
<td></td>
</tr>
<tr>
<td>I have asked all the questions I want</td>
<td></td>
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<tr>
<td>My questions been answered in a way that I understand</td>
<td></td>
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<tr>
<td>I understand it’s OK to stop taking part at any time</td>
<td></td>
</tr>
<tr>
<td>I am happy to take part</td>
<td></td>
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</tbody>
</table>

If you **don’t** want to take part, don’t sign your name!

If you **do** want to take part, you can write your name below

---------------------------------   ----------------------   ------------
Your name                                                   Date                     Thank you

---------------------------------   ----------------------   ------------
Name of research team                          Signature                     Date
Title of Study: Photographic vs. Clinical Diagnosis

Eliciting the children’s views on the established clinical examination and the photographic method

In order to elicit the views of the children on the established clinical examination and the photographic method, semi structured interviews will be conducted with a group of children rather than individuals. Each focus group will consist of a maximum of 5 children. There will be a total of 10 focus groups - 5 groups of 5 year olds and 5 groups of Y6 children. An oral health promotion officer used to working with children in schools using puppets will facilitate the “interviews” with a member of the research team (UB) present. The idea of using is a puppet is help the children relax and feel at ease to express their views. The Y6 children will be given the choice of using the puppet or speaking directly to the facilitator.

Only children who have had both the clinical examination and photographs of their mouths taken and whose parents have given their consent for the interviews (5 year olds) or whose parents/guardians have not opted to withdraw them from the study and the children given their consent (Y6) – and pupils willing to take part in the interviews - will be included in the focus groups.

Setting for Interviews

The interviews will be conducted in schools using the “circle time” approach. “Circle time” is a time at school when children relax usually sat together for example on the carpet and talk about what has happened during the day, how they felt about it or/and how it has affected them.

Prior to the interviews the research team will liaise with the class teachers to ensure that the puppet(s) is acceptable to the children.

Prior to starting the interview proper the research team will ensure that

- The children are familiar with the recording equipment
- The rules of engagement for the discussion are established. Examples of rules will be
  - They put up their hand to indicate they would like to say something and they will be asked to speak.
  - They should not all shout out answers at once.
  - That everyone has to listen to each other.
  - Give time for the shy ones to put up their hands too giving time to ensure their views are captured
  - The label of “in a while” topics. Explain to the children that for the duration of the interview, some things they may want to talk about
will have to be put in the “in a while box” to be talked about after the interview. This will be the way to gently handle the child who wants to talk about something unrelated to the discussion during the interview.

- Some visual prompts such as pictures of the clinical and the photographic examination they had will be used as triggers to help the children recall their experience of having the dentist look at their teeth in school. Hopefully this will help to focus their ideas of what they might have to contribute to the discussion.

The interviews will be recorded and then transcribed for analysis

The interviews

Working with a maximum of 5 children at a time, the facilitator will introduce the puppet to the children by name e.g. Tag.

Facilitator: “This is Tag. Tag is 5 years old. Say hello to Tag”… with slight modification of phrase for Y6 children

Children: Hopefully will say “Hello Tag”

Facilitator: (for 5 year olds) “Tag is from another school and has come to visit you today and Tag would like a chat. Are you ready to speak to Tag?”

Children:

Facilitator (depending on children’s response): Go on then Tag the boys and girls are ready to speak to you!”

Tag: “Hello boys and girls I have come to see you today because I need your help. I know the dentist has been to your school to count your teeth and take pictures of your teeth. The dentist is coming to my school too tomorrow but I don’t know what it will be like. I have to see you today so you can tell me what it going to me like. What will happen when the dentist counts my teeth?”

Children: …

*Interjections from Tag to develop themes when necessary*

Tag: “How will I feel when my teeth are counted by the dentist?”

Children: …

*Interjections from Tag to develop themes when necessary*
Tag: “What will I like about having my teeth counted?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “What will I not like about having my teeth counted?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “Thank you. Now I know about what will happen when the dentist comes to my school. Can you now tell me what will happen when I have pictures of my teeth taken?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “How will I feel when the dentist takes pictures of my teeth?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “What will I like about having pictures of my teeth taken?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “What will I not like about having pictures of my teeth taken?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “Is there anything else you would like to tell me?”

Children: …

Interjections from Tag to develop themes when necessary

Tag: “Thank you all for helping me. I am very glad I came to see you because I now know what will happen when the dentist comes.”
Facilitator: “Thank you boys and girls for being so helpful today”

Tag and Facilitator: “Bye-bye”

For Y6 focus groups who choose to speak directly to the facilitator, the questions will be posed to them directly.
Protocol: APPENDIX 8

Consent for School Dental Inspections and Dental Epidemiological Surveys

We have had reason to consider the issue of consent for both school dental inspections and dental surveys. Guidance was issued by the former NHS Management Executive in May 1992 which implied that it is acceptable to rely on negative consent for dental surveys. We are aware that PCTs are relying on this previous guidance to support the use of negative consent. This guidance should no longer be followed.

As both of the above stated processes inevitably involve physical contact between a dentist and a child, it is necessary to obtain consent from the child (if he/she is competent to give consent) or from a person with parental responsibility for the child, in accordance with the Department’s guidance on consent to treatment. Whilst the risk of any proceedings being brought against a dentist or PCT in relation to a school dental inspection or epidemiological survey might be considered low, in the event that there was, a dentist may not be able to prove that consent had been obtained simply on the basis that letter had been sent out to parents and no objection had been received.

We are aware of concerns about the impact that obtaining positive consent might have on the NHS oral health epidemiology programmes within England. Where programmes are surveying older children eg 10-11 year olds it is likely that a child of this age would be competent to consent to the dental examination, provided it is explained to them what the process involves, for what purpose the information obtained will be used, and that they can refuse to take part if they wish. If the competent 10-11 year old child consents, this will be sufficient.

In relation to younger children, we have been exploring whether positive consent to dental inspections/surveys obtained from the child’s parent (or relevant person with parental responsibility) when their child begins school would be sufficient proof of consent.

We consider that a dentist performing these inspections and surveys might be able to rely on such consent, as long as sufficient information is provided to the parent at the time that consent is obtained to enable their consent to be fully informed. It would be good practice to inform parents how many times the procedures would take place and in which school years, and that they may withdraw their consent at any time. It would also be good practice to write to parents to inform them when examinations/surveys are about to be carried out and reminding them that they may withdraw consent if they wish.

As this will be additional information that will need to be obtained from parents at school entry, we will need to discuss with colleagues in DfES how this might be incorporated into the school entry procedures prior to our issuing further formal guidance.

---

1 Good practice in Consent (HSC 2001/023)
http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceCirculars/HealthServiceCircularsArticleServlet?CONTENT_ID=4003790&crlk=CigZrc


2 for battery/assault or negligence, or disciplinary proceedings
SURVEY RECORDING FORM - DECIDUOUS DENTITION

1. PCT/HA/DHA codes

2. Examiner

3. School name

4. School postcode

5. Date of examination

6. School subject number

7. Child identity number

8. Month/Year of birth

9. Postcode

10. Examination type

11. Ethnicity

12. Oral Cleanliness

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<th>Tooth Codes</th>
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<tr>
<td>Extracted caries</td>
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<tr>
<td>Extracted ortho</td>
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<td>Unerupted or missing other</td>
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<th>Surface Codes</th>
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<td>Decayed</td>
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<td>Decayed + pulpal involvement</td>
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<td>Filled</td>
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<td>Obvious sealant rest'n</td>
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<td>Sealed surface</td>
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<td>Crown</td>
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<td>Trauma</td>
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Secretary to the Ethics Committee
Room 2.005 John Owens Building
Tel: 0161 275 2206/2046
Fax: 0161 275 5697
Email: timothy.stibbs@manchester.ac.uk

ref: TPCS/ethics/06306

Professor Martin Tickle,
University of Manchester School of Dentistry

16th March 2007

Dear Martin,

Committee on the Ethics of Research on Human Beings
Tickle: Comparison of a photographic and clinical dental examination (ref 06306)

I write to thank you and Uriana for coming to meet the Committee yesterday and to confirm that the Committee gave ethical approval to the above project, subject to:

- Toning down the information sheet top a more neutral language
- Asking participants to initial rather than tick the consent form boxes.

This approval is effective for a period of five years and if the project continues beyond that period it must be submitted for review. It is the Committee's practice to warn investigators that they should not depart from the agreed protocol without seeking the approval of the Committee, as any significant deviation could invalidate the insurance arrangements. We also ask that any information sheet should carry a University logo or other indication of where it came from.

Finally, I would be grateful if you could complete and return the attached form at the end of the project or by March 2008, whichever is earlier.

We hope the research goes well.

Yours sincerely

Timothy Stibbs
Dr T P C Stibbs
Secretary to the Committee
Acting NHS SalfoR+D Director: Dr Stephen Waldek
NHS SalfoR+D Associate Director: Dr Lloyd Gregory
ReGrouP Manager: Rachel Georgiou

Email: Salford-Regroup-RD@manchester.ac.uk
Tele: 0161 206 8343
Fax: 0161 206 4205

SalfoR+D web address:
ReGrouP web address: http://www.nhssalfordrd.org.uk/
http://www.gmregroup.nhs.uk/index.html

10\textsuperscript{th} December 2009

Mrs Uriana Boye
Senior Dental Officer
Heywood, Middleton and Rochdale NHS Trust
1st Floor, London House
Oldham Road
Middleton
M24 1AY

Dear Uriana,

Study Title: Comparison of a photographic and a clinical dental examination: Phase 3
REC Reference No: 09/H1011/57
R&D Reference No: 2009/223

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with NHS SalfoR+D and has gained NHS R&D approval from the following NHS Trusts:

- Tameside & Glossop PCT


It is a legal requirement for Principal Investigators involved in Clinical Trials to have completed accredited ICH GCP training within the last 2 years. Please ensure that you provide the R&D Department with evidence of this (certificate for completing the course). A list of GCP training courses can be obtained from the R&D Office.

All researchers who do not hold a substantive contract with the Trust must hold an honorary research contract before commencing any study activities related to this approval. The ‘Research Passport Application Form’.

This can be obtained from web addresses: http://www.gmregroup.nhs.uk/researchers/passports.html and http://www.hope-academic.org.uk/academic/salford/R&D/Research%20Passports.html This form should be completed and returned, with a summary C.V and recent (within 6 months) CRB to the address shown above.
It is a condition of both NRES and NHS R&D approval that participant recruitment data should be forwarded on a regular basis. Therefore, progress reports must be submitted annually to the main REC and copied to the R&D office until the end of the study. 
http://www.nres.npsa.nhs.uk/applicants/review/after/progress.htm#annual.

Any amendments to the study should also be notified and approval sought by Ethics Committee and R&D Department. On completion of the study you are required to submit a 'Declaration of End of Study' form to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Any serious adverse events or governance issues related to the research must be notified to the R&D office.

Yours sincerely,

Rachel Georgiou
ReGroup Manager

Cc Martin Tickle
Sponsor’s representative
APPENDIX 2: Information Related to Interviews and Focus Group Discussions

Interview Schedules

Example of Children’s Interview Transcripts with Coding for Data Analysis

Example of the Examiners’ Interview Transcripts with Coding for Data Analysis
**Prompts**  
(pictures of examination, mirror, camera etc)

| Think about the time that the dentists came to your school last week (give them time to remember). **Tell me what happened when they came to your school** |

**Environment**  
(e.g. noise, waiting, lying down, smells, cotton wool rolls – all peripheral things out the mirror and the camera)

| **Tell me what it was like to go into the room where the dentists were**  
**Tell me how it felt being in the room.**  
Paper plate faces – ask children to explain their choice of face  
**What would you like to tell Douggie about being in the room** |

**Mirror**

| **Tell me what it feels like to have your teeth checked/counted by the dentist**  
**What would you like to tell Douggie about it**  
**Tell Douggie what you think he might like about having his teeth counted**  
**Now tell him anything he might not like about it**  
**Think about the dentists who checked your teeth. Tell me what they said to you before they counted your teeth**  
**What would you like them to say to Douggie before they start counting his teeth** |

**Camera**

| **Tell me what it feels like when the dentist takes pictures of your teeth with the camera**  
**What would you like to tell Douggie about having pictures of his teeth taken with the camera**  
**Tell Douggie what you think he might like about having pictures of his teeth taken**  
**Now tell him anything he might not like about it**  
**Think about the dentist who took the pictures of your teeth. Tell me what she said to you before she took the pictures**  
**What would you like her to say to Douggie before she starts taking pictures of his teeth**  
**Tell me about the pictures of the teeth you saw on the laptop/computer**  
**Tell me if there is anything else about the pictures that you want to tell Douggie** |
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<td>The camera better than the mirror</td>
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<td>Both the same or</td>
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<td>You did not like both</td>
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<td></td>
<td>?Use paper plate faces)</td>
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<thead>
<tr>
<th>How can improvements be made</th>
<th>Pretend you are all dentists. You are going to check Douggie’s teeth. Tell me what kind of things you would do and say to Douggie to make him comfortable and happy to have his teeth checked.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Now you are going to take pictures of Douggie’s teeth. Tell me what kind of things you would do and say to Douggie to make him comfortable and happy to have pictures of his teeth taken with the camera</td>
</tr>
</tbody>
</table>

<p>| Final thoughts | Tell me anything else you would like to say about when the dentists came to your school last week |</p>
<table>
<thead>
<tr>
<th>Prompts (pictures of examination, mirror, camera etc)</th>
<th>Think about the time that the dentists came to your school last week (give them time to remember). Tell me what happened when they came to your school</th>
</tr>
</thead>
</table>
| **Environment** (e.g. noise, waiting, lying down, smells, cotton wool rolls – all peripheral things out the mirror and the camera) | Tell me what it was like to go into the room where the dentists were  
Tell me how it felt being in the room. |
| **Mirror** | Tell me what it felt like to have your teeth checked by the dentists using the mirror  
What did you like about having your teeth checked with the mirror  
Now tell me what you did not like about it  
Think about the dentists who checked your teeth. Tell me what they said to you before they started checking your teeth  
What more would you have like them to say to you before they started checking your teeth |
| **Camera** | Tell me what it felt like when the dentist took pictures of your teeth with the camera  
What did you like about having pictures of your teeth taken with the camera  
Now tell me what you did not like about it  
Think about the dentist who took the pictures of your teeth. Tell me what she said to you before she took the pictures  
What more would you have liked her to say to you about using the before she starts taking pictures of your teeth  
Tell me about the pictures of the teeth you saw on the laptop/computer |
| **Comparisons between the mirror and the camera** | Did you like/prefer  
The mirror better than the camera  
The camera better than the mirror  
Both them same or  
You did not like both |
| **How can improvements be made** | What would you have liked to know before coming to see the dentists?  
What would you like to tell the dentists to change to make things better next time |
| Final thoughts | Is there anything else you would like to say / what else would you like to say about the mirror/camera/or both |
## EXAMINERS’ FOCUS GROUP TOPIC SCHEDULE

| Conditions for viewing photographs | • time of the day  
| • type of lighting  
| • type of screen  
| • approximate time for viewing each photo  
| • taking breaks  
| • any other comments about the viewing conditions |

| Experience of the photographic assessments | • Ease  
| • Difficulty  
| • Other |

| Advantages of assessing PHOTOGRAPHS to provide caries information over performing a Bascd clinical exam |

| Advantages of performing a BASCD CLINICAL exam over assessing photographs to provide caries information |

| Any other comments on the differences between the use of photographs and clinical examination for the detection of caries. |

| Uses | How do you envisage using the photo method in epidemiological surveys in the future  
| Other uses |

| Final thoughts | How the photo method could be improved to enhance its use  
| Any other comments and final thoughts |
Example of Children’s Interview Transcripts with Coding for Data Analysis

I: I would like you to be able to tell me about some of the things that happened on Friday when the dentist came into your school.

Lilly: They put a picture in our mouth when I look on the computer it was showing them.

And [0.23]

I: Sydney can you remember on Friday? Can you remember what happened on Friday?

Sydney: Put glasses on people,

I: So you remember the glasses? William can you remember anything from Friday?

William: Yes, [0.47] one of the dentists took us down to look at our teeth.

I: And you can remember that, you can remember all that. You all remember Friday now don’t you? All the dentists coming in. Shall I show you a picture did it look a little bit like this with all those dentists?

It was like that, yes, it was like that but there wasn’t too much room, it was in a smaller room. In the music room.

I: Right so you all remember you went into the music room,

And that, and you put that in my mouth didn’t you?

I: Can you tell me William what am I holding, what is this picture of?

William: A camera

I: Oh so you remember a camera.

William: That is a camera and [1.36] teeth when they were taking those pictures of my teeth.

I: Sydney can you remember this picture?

It will come up on a computer.

I: Do you remember that Sydney? You are nodding, do you agree that, do you remember that that was the camera? Melanie would you like to tell me what it was like?

Lilly: It was like it had a light, there they put in our mouth and then there was a picture showing you.
Sydney: And we looked at it.

I: do you remember what it was like? What was it like?

Sydney: It was like

William: Had fun

I: William thinks it was fun.

? I did

? I did too.

I: Right can anyone tell me when you went into the music room what did it feel like when you walked into the music room?

? I like doing music.

I: On Friday when you went in the music room with all the dentists? Do you know what it felt like?

? Yes, I think it was like fun. Everyone was smiling.

I: Melanie what did it feel like?

Lilly: It felt like a bit strange.

I: It felt a bit strange. Why did it feel strange Lilly?

Lilly: Because I never went in it.

? I know [3.37]

I: It looked

? Cool

I: You thought it felt cool? Sydney, how did it feel when you went in there?

Sydney: It feels like having no friends.

I: I have got Dougie today, Dougie the dog have you ever met Dougie before?

? No

I: Because he sometimes goes round to different schools,

? I have

I: And he talks about,
I have seen him

He talks all about looking after his teeth, because he is very good at looking after his teeth. But Dougie he goes to school but he has never had all those dentists go into his school and have a look at this teeth, he has never had that before. Is there anything you would like to tell Dougie about what is going to happen when all the dentists come, what would you like to say to Dougie Lilly?

It was really fun.

I: tell him it is going to be fun. Anything else, why is it going to be fun?

Because you open your mouth and say ahh.

Anything else you we could tell him?

He will have to wear sunglasses and pretending you are being silly.

Ok, can you think of anything else?

and they make you open your mouth and say make sure you don’t close it.

Open his mouth and not close it. Anything else? Sydney can you tell Dougie what is going to happen when the dentists come into school.

He will feel a bit scary.

So tell him it could be a bit scary. Why might it be scary?

Because erm, don’t know.

You don’t know, that’s Ok. Anything else, William can you think what should we tell Dougie is going to happen when all the dentists come?

He is going to be really cool, excited.

Why should we tell him it will be excited?

Because its all fun, get to take a picture of the mouth.

Got to open his mouth?

Yes

And that will be exciting anything else, why it would be exciting?

Because you get to lie down and wear glasses, and he gets your own tooth brush and tooth paste.
I: Right so you get a prize at the end. Is there anything he might not like can you think, is there anything he might not like?

William: I think he will not like lying down, I lie down and then think I was going to fall off.

I: Right, so shall we tell him that.

? I did too

? I did.

I: What else do you think? Is there anything he might not like?

Sydney: Falling off

I; Off the table, so he might feel like he is going to fall off, did you feel like you were going to fall off the table?

Sydney: [7.25] and it’s [7.30] we were worried that it might fall, that I might fall off.

William: Might fall off

I; Off the table

? Its quite thin

I: The table is quite thin

? I think that

I: So he might not like that Dougie but what will he really like, is there anything?

? He will like opening his mouth.

I: He will like that. Did you like that? William your hand is up.

William: I like when I wore those cool sunglasses.

I: Right,

William: It’s like being on holidays sunbathing on the bench.

I: When the dentist come and see Dougie what do you think a dentist could say to Dougie when they come to see him, to help him feel happy? What could they say

? Having nice teeth.

? Make him lie down.
I: They could say lie down.

? And sit up sometimes

? You can sit up sometimes, loads of dentists coming. All of the dentists.

I: Lots of dentists. And what could they say to make him feel happy?

? Not getting bad teeth.

I: so they could tell him that. William?

William: Well, sometimes the dentist [9.20]

I: And William if you were a dentist, you imagine if you were a dentist, and you were going to a school, how would you make the boys and girls in your school feel happy?


I: Sydney what would you say, can you imagine if you was the dentist Sydney and you was going into the school, how would you make the boys and girls in the school feel happy? Can you think of anything? That’s ok, shall we ask Lilly.

Lilly: I would tickle them

I: You would tickle them to make them happy. Is there anything else you could say to them to make them feel happy?

Lilly: Let them dance.

I: Ok, shall we look again at the picture. Do you remember the camera, can you all remember the mirror as well?

? yes

I: Which do you think is Dougie going to prefer, which is he going to like best?

Sydney: the mirror

I: You think Dougie will like the mirror.

? He won’t like that because they will have to hold his mouth.

I: Sydney said he will like the mirror first, why do you think Dougie will like the mirror?

? [11.28] and you can use them.

I: So Dougie is going to like the mirror best. Or which did you say, Lilly. You think he will like the mirror. Why do you think he might like the mirror then?
Lilly: Because it gets put in your mouth and it gets all funny in your mouth.

I: Why else might he like the mirror?

Lilly: It gets cold in your mouth.

I: Ok,

Lilly: The mirror is really cold.

? I didn’t cry

I: Do you think Dougie will prefer this mirror or the camera?

William: Camera

I: You think he will like the camera. Why do you think he will like the camera?

William: Because I don’t like mirrors I use, I lost my toothbrush

I: So the mirror or the camera, for Dougie, which do you think he might prefer? Or could it be that he is not going to bother which one he likes, he will them both, could he like them both?

? Yes, both.

? Guess what sometimes, I have my tooth and it is automatic so you turn it on and you put toothpaste on you put a little ball and it goes round and you put it in your teeth and it goes like that open wide.

I: Ok, everybody. Now before Dougie goes in to school and sees all the dentists, if there anything you would like to tell him before he sees the dentist, what would you like to tell him?

William: That its so nice.

I: Right tell him it’s going to be nice.

William: They are going to be nice. He looks cute, he looks well nice.

I: Dougie is well nice?

William: And his teeth look nice and shiny.

I: Do you think the dentist will tell him that? What do you think the dentists will say? Do you think the dentist will comment on his teeth?

? Yes
I: Is that nice if the dentist comments do you think? Is that nice if the dentist comments on your teeth?

When I went to [14.29] I got all these days off, and one day I went [14.42]

I: Yes Lily.

Lilly: You wear glasses and you will be funny.

I: Oh shall we tell him that he is going to be wearing glasses.

Lilly: and it’s going to be really strange, that you are wearing glasses, he might even [15.09]

I: So they should tell him why he is wearing glasses, ok. Sydney what else could we tell Dougie before the dentist comes to school so he is all ready for the day, and he knows what is going to happen. What should we be telling him?

Sydney: It’s funny

I: Right. Before we finish is there any last things we could tell Dougie about when the dentist come? How do you think he will feel on the day? I think I have got something that might help us.

William: I know that, that’s Daisy’s happy faces.

I: What face is that?

? Sad

I: That’s a sad one we all agree that is

? Happy, laughing,

I: What face is that?

? Happy

I: Happy laughing face yes.

? A smile

? Cross

I: Ok,

? Mad

I: Mad or cross

? Happy
I: Shall we agree it's a mad one.

I: Ok, so when the dentist come see Dougie which one of those faces is he going to feel, which is he going to be really, you pick one or any of those. He might have a few of those feelings mightn't he. Which Lilly do you want to choose.

Lilly: Happy

I: A happy laughing one. Any more, happy face. Any more

[interrupt]

I: Right Lilly why did you choose these faces?

Lilly: Because he is going to be happy.

I: He is going to be happy. He is going to be

I: Why will he feel those?

Lilly: Because it's [18.29]

I: And this one, why would he feel this one?

Lilly: Because [18.41]

I: Sydney, same question for you Sydney when the dentist come which of these faces will you feel? Crying one, why will he feel that one?

Sydney: Because some people cry.

I: Is there any other face he will fear as well? That one as well which one was that?

Sydney: The sad one.

I: Why might he feel sad?
Sydney: Because it’s a bit scary.

I: Ok. Any more or just these?

Sydney: Just them

I: These two, right well done. William, which would you choose for Dougie, which face is he going to feel when the dentist come to his school? Which one are you going to choose? He is going to be happy. Why is he going to be happy?

William: Because kind of fun. [20.11]

I: Ok, is there any more feelings he would have? Which one was that one? Cross, why might he feel this one?

William: Because I prefer [20.41]

I: Ok you have all been very, very helpful today, I think Dougie is going to have learnt a lot today, I think he might be ready when the dentist comes to his school I think he will be very prepared now won’t he? Is there any last thing we should tell him.

Lilly: He will be really happy.

I: good. William.

William: He will be really, really excited and he might win a sticker.

I: Ok, Sydney, any last thing from you you would like to tell Dougie?

Sydney: He will feel really funny.

I: Ok, thank you all very much.
Example of Children’s (10-/11-yr olds) Interview Transcripts with Coding for Data Analysis

I: **Ok children if you all think about when the dentist came to your school last Friday, yes. A few nods yes, so please tell me what happened when they came in to school. Zara?**

Zara: I found it really weird because when we walked in you saw like everyone lying across the table, just lying down and it looked a bit weird when you first walked in but then after a while you just got used to it.

? They came to get the [0.41] called from the register and no one was saying anything about it, we just walked in and it looked like the music room was just converted to a dental studio, because of all the tables I couldn’t see all the walls.

I: **How did you feel about that when you came in?**

? Felt quite good that it was on the tables, [1.09] because if it’s more tables I guess that they would have more money on the project. But it ought to have been much better, ok if there is only one table it might not be very important project.

I: **Ok so you thought because there was a lot of tables there it was an important project. Ok, anybody have anything to say about what happened when they came in, Zara?**

Zara: It was good because it wasn’t scary because when you go to the dentist you think they are going to pull all your teeth out, but here you just knew that they were just going to check it and the lady explained it as well.

I: **Ok,?**

? I think it was cool because they give you free toothbrush and toothpaste, at the end.

? At the end of the day.

I: **Ok, right, so what I want you to tell me about now is how you actually felt when you went into the room. Ok,**

? I felt quite [2.15] because they started putting the things in the mouth and it felt quite nice.

I: **What about you Lee?**

Lee: Well I went in to the room and I felt like oh my God what are they doing. Then, they just like put stuff in your mouth and I didn’t really like it.
I: You didn’t like it at all? Ok. Why didn’t you like it?
Lee: Because you had to open your mouth
I: And you didn’t like opening your mouth? No, ok.
Suleiman: I liked it because they kept saying them words like [2.59] 1, 2, 3 and when I heard it makes me laugh.
I: It made you laugh you found it funny,
Suleiman: But I tried not to.
?: I tried to work out what 6 sound, 5 8, meant so I didn’t take that much notice of anything else so it went quite quickly.
?: I liked it when they put the camera in your mouth.
I: Right, what we will do now is shall we talk about, because you had two different things there didn’t you, you had the dentist having a look with the mirror, and then with the camera, so if we talk about the mirror first, so if you Lee you go first yes, if you tell me how it felt when you had the mirror.
Lee: Well when the mirror was in my mouth I didn’t really get it because everyone else were doing that, it was just like why all do it, when someone else has already done it. I didn’t understand it really.
I: How did it feel?
Lee: Normal.
I: Ok, what about you Hussein, how did it feel when you had the mirror?
Hussein: Again it felt normal because like a couple of weeks before I had it done,
I: Oh you had just been to the dentist ok, so you weren’t, it was fine was it?
Hussein: Yes
I: What about you how did it feel when you had the mirror in your mouth?
?: It felt quite strange because normally I just go like 4 times a year and [4.30] take it out of my mouth, I wanted to take it out with my tongue but I couldn’t.
I: Take what out?
?: That mirror thing, it wasn’t comfortable.
I: It was uncomfortable the mirror ok, alright, what about you Ethan?

Comment [GRK8]: 402-1-0080 Experience: mirror: counting teeth; positive
Comment [GRK9]: 402-1-0100 Experience: mirror: understanding counting teeth
Comment [GRK10]: 402-1—0110 Experience: mirror: lack of understanding
Comment [GRK11]: 402-1-0120 Expectation: mirror: expectations met
Comment [GRK12]: 402-1-0130 Experience: mirror: sensitivity; uncomfortable
Ethan: It was alright, it wasn’t meant to actually touch the teeth it was meant to go at an angle so the dentist can look at the teeth not touch them, they were trying their best not to touch the teeth they were trying to look at, they were trying their best not to do that but because they were trying to look, positioned it so they could look at the teeth they could be touching the teeth.

I: so how did you feel about that?

Ethan: It was alright.

I: It was alright?

Ethan: Yes I didn’t mind it.

I: Ok, what about you Zara?

Zara: It felt quite normal, the only thing I don’t like is that sometimes you have to open your mouth a bit too wide and it can hurt the side of your mouth.

I: of your mouth having to open too wide. Zara has actually said what she didn’t like about it, would anybody else, Lee would you like to tell me something you didn’t like about it, what didn’t you like about it tell me about that?

Lee: Well I know it’s the dentist and I know you have to open your mouth, but I just don’t like opening my mouth.

I: At all

Lee: No I don’t like seeing what’s inside.

I: Why don’t you like, because with the mirror you couldn’t really see what was inside your mouth could you?

Lee: No

I: So what didn’t you like about having the mirror?

Lee: I didn’t like seeing what was if my teeth were yellow or something, I know that everyone’s teeth are a bit yellow but I don’t like yellow teeth.

I: anybody else have anything to say about what they didn’t like. Ethan was there anything you didn’t like?

Ethan: Not really, no.

? I didn’t like the bit where you had to bite on that little white thing.

I: We are still talking about the mirror is that, did you, is that what you are talking about the mirror?

? No
I: Ok, 

? Do you know when they [6.45] that mirror thing, that light and had that [6.45] on the end, they touched your teeth with it, I didn't like that. 

I; You didn't like that ok. Right. So, anything else that anybody didn't like that they would like to talk about? 

? No 

I: Ok. So, now what I would like you tell me about do you want to tell me about anything more you would have liked the dentists to say to you before they started having a look, does that make sense? We are still talking about the mirror, what would you have wanted the dentist to say to you before they started having a look?

Lee: What they were actually doing with the mirror. 

I; Did they tell you, can anybody tell me what the dentist said to them before they started having a look? 

? The first dentist I had they said that we are just going to have a little look at your teeth now, and then they just started then after they went thank you for letting us have a look at your teeth. 

I: Tell me what more you would have liked them to tell you? 

? I would like them to tell us what they were going to do because they might have done anything inside the mouth, like if they were going to touch something, I don't know. 

I: So what about you Ethan? What did they tell you, 

Ethan: Well they just said I am going to put this mirror in your mouth, to look at your teeth, 

I: And was there more you would have liked them to tell you, 

Ethan: Not really in fact that, it was important for [8.22] nothing important but, I never ever guessed what 6 , 5, 8 

I: So you would have liked to know a bit more about that, ok. What about you, what did the dentist say to you before, 

? She said open a big wide mouth and I just opened my mouth and she started. 

I: What would you have liked her to say to you? 

? Like we are going to put this in your mouth, we are going to put that in your mouth and stuff like that.
I: And they didn’t say that?

? No

I: Ok, what about you.

? Well what [9.02] they didn’t care, they only told us that really they were going to look at our teeth, but I didn’t know they were going to put like a mirror in or anything else in it.

I: Right, so you would have liked them to tell you about exactly what they were going to do,

? Yes

I: What did they tell you before they started?

Lee: We are just going to have a look at your teeth.

I: What more would you have liked them to tell you?

Lee: About the sound because I didn’t really get what they meant, like sound means voice and stuff doesn’t it, and I didn’t really know what it meant.

I: Ok, now we can talk about the camera. You all had the camera, so starting with you Lee, could you please tell me what it felt like when you had the camera in your mouth.

Lee: Again just like the normal,

I: Normal ok. What about Hussein what did it feel like when you had the mirror, tell me what it felt like.

Hussein: It felt quite nice because it was nice and warm.

I: Right

Hussein: and then just felt a bit cold then. And then [10.20]

I: What about you, what did it feel like when you had the mirror in your mouth?

? Same as Hussein I liked it because it was hot and when it touched your teeth it was nice and warm and it didn’t hurt you or anything and it was like a round thing [10.38]

? I know it wasn’t designed actually to make the teeth feel nice but because it was quite [10.49]

I: The camera
and it wasn’t designed to actually feel nice, but because it’s quite modern, it was rounded so when it touched your tongue or the roof of your mouth it actually felt quite nice.

I: Ok, what about you Zara how did it feel when you had the camera in your mouth?

Zara: It felt normal and it didn’t really feel really different to anything, it just was warm like Lee said before and it was, if it did come near your teeth it didn’t touch them or anything so that was alright.

I: Right, so now, if you tell me what it was like seeing the pictures of your teeth on the screen?

Zara: I found it funny because you were sitting up waiting for the next dentist to come and then you would someone’s teeth what their teeth would look like inside, and it was a bit funny and then when we sat down and saw your teeth you think are they really my teeth inside.

I: And how did that make you feel?

Zara: It made me feel that I ought to brush my teeth a lot properly. Because bits of it were a bit yellow inside.

Of camera

I: Right,

Zara: So then you think I need to put a lot more effort into brushing my teeth.

I: Ok, what about you Ethan?

Ethan: I liked it when I saw my teeth because naturally humans don’t get to actually look inside their mouth, because of the positioning of their eyes, and except looking at them in the mirror when you are brushing your teeth, there is a brush in the way so you can’t actually see right at the back, where ever the photo was took so quite interesting actually, to see what they actually looked like.

I: Ok, right, what about you,

I thought, like what was it now?

I: We just want to know if you tell us how it felt like seeing the pictures of your teeth on the screen?

I: When I [13.05] pictures of the teeth I realised that I had still food behind and yellow bits, and it made me want to rinse my mouth after I eat now.
I: Right, ok. What about you [13.20]? Lets talk about how you felt seeing the pictures of your teeth on the screen.

?: It felt horrible because its like you could see the gums and everything and the teeth had like yellow stuff on.

I: so you wouldn’t have wanted to see your teeth on the screen?

?: No.

I: Ok, what about you Lee how did it feel seeing your teeth on the screen?

Lee: Well I know everyone has yellow but again I really hate yellow so when I grow up I might get my teeth whitened.

I: Ok right. Again what I would like to know is do you remember what the dentist said to you before, so if you tell me what the dentist said to you before she took the pictures.

?: they said lie down, on the table, and I think it was you who did the camera when we came in, you said like please could I look at your teeth and put the camera on and it wasn’t as scary as putting the mirror in really because it felt different from the mirror. And it was more comfortable with the camera in my mouth than the mirror.

I: Ok what more would you have liked the dentist to tell you?

?: That where these pictures were going to go of our teeth, if they were going to put them in the newspaper or something like that.

I: Right, ok. Ethan?

Ethan: I like the camera much more than the mirror because with the mirror the dentist would just look at my teeth, and they weren’t going to show them, he just said do this, do that and then 6R and 5 8 and things like that, but when you did the camera on me you were showing us a picture of our teeth, you weren’t just saying, things that we didn’t understand.

I: Ok, and how did you feel when you saw the pictures of your teeth on the screen?

Ethan: Felt quite interested because like I said before you can’t see your teeth, and definitely you can’t see them right at the back.

I: Ok, thank you. What about you? What did the dentist say to you before she took the pictures?

?: She just said lie down and I will just take pictures of your teeth.

I: Right, and what more would you have liked her to tell you before she started taking the pictures?
She was going to put a big massive stick in my mouth and to take the pictures.

I: You could see the camera yourself. So what did the camera look like to you then? Did it look really small?

? It looked like, it looked like a machine or that it’s going take all the food out and everything.

I: Ok, what about you Lee?

Lee: I am just going to take pictures of your teeth and that’s it.

I: What more would you have liked to be told?

Lee: Don’t know, no I don’t really need more information.

I: Ok. What did the dentist say to you before she took the pictures?

? She said that I am going to take pictures of your teeth, when she took the pictures and I looked at the laptop it looked a bit weird and I was thinking that’s not my teeth. They were massive.

I: How did that make you feel?

? Like there is a monster inside me or something.

I: And was that scary or?

? Well it was quite nice that I have a monster inside me.

I: Ok, Zara?

Zara: I thought it was pretty cool to see inside your mouth because you never see inside your mouth unless you are in mirror but then you can’t see very detailed what your mouth looks like inside and I thought it would be good because when you saw inside your mouth you can improve on your brushing.

I: Ok,

? I actually thought before, I knew they were going to like take our pictures before we went in the room, before I actually saw that camera I thought they would just be open wide, like that, like a normal camera but when I saw the thing it looked like some sort of modern torch that the children’s counsellor gave me when I was appointed to children’s counselling. Modern torch.

? It was kind of disguised, you didn’t know it was actually a camera it looked like a little thing that was going to feel around in your mouth, [4.27] digital camera, the stick inside it, it looked really different.
I: Ok, thank you. So now I would like you each to tell me of the two the mirror and the camera, which you preferred. It could be that you preferred the mirror better than the camera, or you prefer the camera better than the mirror, that you liked both of them, or that you didn't like any of them. Ok, so Lee you first.

? I liked the camera better than the mirror.

I: Why did you like the camera better than the mirror?

Lee It was quicker than the mirror.

Hussein: I liked the camera because instead of the mirror they were just like pretending it was like a big massive machine like doing things in your teeth, but the camera it was just like nice and gently and

I: Which did you prefer it’s the mirror than the camera, or the camera than the mirror or that you liked both or you didn’t like any of them.

? I preferred the camera because it’s like more better, normally in you just open your mouth and you don’t know what’s in your mouth with the mirror, because you can’t feel it anywhere, but with the camera you could feel it on your teeth.

I: What about you Ethan?

Ethan: I liked them both quite a bit,

I: Why did you like them both?

Ethan: Because I liked the mirror because it was something to think about, I could think about what 5 8, 6 meant, when I was doing it that made it much quicker. And, with the camera I could look at the picture on the screen like [6.23] said it looked a bit like a monster inside you, the grey pictures. When it was grey and black.

I: What about you Zara which did you prefer, or if you didn’t like both of them, or you liked both.

Zara: I liked them both, and I thought they were both really good, but I would prefer the camera because it wasn’t as scary and you could see what was inside it, instead of [6.48] look at the laptop and see what was inside your mouth.

I: Ok, thank you. We are nearly finished now but what I would like to know is if you had to do it again in a different school, would like to know how we can improve things, yes. So, what I want to know is what would you do if you were the dentist, going to look in the children’s mouth with a mirror, what would you do to make the children comfortable and make them happy to have that done, Zara you first.
Zara:  I would describe to them what I am going to do in their mouth and that it is all going to be alright, and just like trying to distract them while you are doing it, so they don’t really think, they don’t really think that it’s scary and get tense.

I:  Ok, and what about the camera what would you do?

Zara:  The camera was fine. But, I don’t think, I didn’t have any fault with the camera I thought the camera was perfect, see inside your teeth.

I:  Right, Ethan what about you?

Ethan:  I would have said show them the thing, put it their mouth, with no pictures or no little thing on 5, 8, 6 and seeing that it felt quite nice.

I:  Is that the mirror you are talking about now the camera?

Ethan:  Both. I would show them what it is from the mouth, and seeing the light.

I:  Ok, do you feel the dentist did that?

?  Yes

I:  Ok, right, what about you?

?  I think the, do you know that white thing that goes in your mouth.

I:  The cotton wool roll?

?  Yes that wasn’t really good because I had a wobbly tooth and she moved it more, and it made it move.

I:  Ok, so remember what we were asking if you were the dentist going into check children’s teeth, what would you do to make it more comfortable for the children to be happy for these dentist to be able to do,

?  Tell more information what you are going to do to their teeth.

I:  Ok, thank you what about you Hussein?

?  Instead of the table I would have got like you know like things that fold up yes, get about like 10 of them yet, and put them on like in spaces, so you can sit down on them and lie down and then that’s it really just tell them that they are going to put everything in and they were just going to tell them that they were going to put the cotton wool roll in.

I:  And how do you feel the dentist did on that, do you think they gave you that information that they were supposed to or not?

?  They only give us like one thing that they were going to do but they did a couple of things, that they did it us, that was putting the mirror down, but they told us about the photo.
Ok what about you Lee what would you do differently if you were the dentist?

I would tell them what sound meant and I, oh I have forgot now, oh,

Think about it and we will come back to you when you remember. Ok.

Ethan:

My mom found this quite funny because that is the they put samples of wee in things that they gave you to put your toothpaste in, because she came contact with them twice, because she had to do my Grandma who has got dementia, she came in contact with exactly the same make twice, and she was thinking it was quite funny that they put my samples and wee

Ok, now we are nearly finished now is there anything more that anybody has to say before we finish?

Zara:

The toothpaste things we got I thought they were good, but I thought they could have give them out at the end of the day because we put all ours on the side and when we went, we came back and everyone was running round getting theirs, and one of my friends all she was left with was a sticker a mirror and them little tubey white things, and then I think someone who didn’t even do the test they took one.

Unfortunately the dentist didn’t really have control over that, remember we are talking about what happened, we are not talking about anything that happened in class after yes. Ok.

It was good that they give us toothpaste because at the shops they are about 3.50 we got them free.

I like the fact that they gave us a mirror because my sister in reception and she got a mirror and she got those sticks and later I made a dentist chair out of the coffee table with blankets for her and she loved playing with the mirror, putting it in her mouth and her teddy’s mouth and

Do you have anything more to say? No. Zara.

I:

I think it was good because it was like the actual dentist and they made it like the actual dentist by putting things in your mouth and saying, A sound, B ok, then but the thing that was a bit different was that you don’t have the camera at the dentist.

Ok,

They have a different kind of camera at the dentist don’t they? There is like you stand up and you put you bite something and it takes a picture of your teeth.

That is not the same, it’s a different camera. Ok.
The dentist were, he goes have you got any sore parts and then you tell him and then he doesn’t like, he doesn’t push on it hard with the mirrors.

I: Ok, so thank you very much everyone. Thank you.
Example of Examiners’ Interview Transcripts with Coding for Data Analysis

U: Ok, thank you all for coming. Now that we have all had opportunity to have a look at the photographs, and also having done the clinical exam I think, it’s time to capture your thoughts round what you thought about the photograph as compared to the clinical exam. I think start off; we will just look at the photographic method. Just want to consider a few of the issues round the conditions under which you viewed your photographs. So we will start with you then Sian; what time of the day did you view them?

S: I started in the morning and finished at night.

U: So both morning and night.

S: Right through the day. I did try doing them on my laptop but I felt that was too, the screen was too small, so I ended up doing it on a full size you know.

U: On a desk top?

S: Yes, desk top.

U: What about lighting?

S: When I was doing it in work it was just natural light through the window, but at home our computer is on the landing, we don’t have a window there, so that was artificial light.

U: Ok was it fluorescent or just a normal bulb

S: One of those long light you know those new bulbs that take forever to warm up. One of those.

U: Alright, what about you Caroline?

C: I did them all in the evening, couldn’t do them at work. I did them all in the evening and with an ordinary long life light bulb on a lap top.

U: Ok and you Angela.

A: I did mine day and night, on a desk top and it was either with natural light or with just a normal light bulb.

U: And you Liz.

L: I did it day time and evening time, any time I did them, and it was either just natural light or both, or just a normal bulb, because sometimes, because I was near a window but I also had a light on, sometimes. So it was any, I did it on an ordinary desk top at home. Erm, yes.
U: That is interesting it sounds as if everybody did it across the day. No specific times! Did you find a difference in your viewing? was there a difference whether you viewed during the day or night time? I mean did the time of day affect you diagnosis?

S: Not if I was coming to it fresh, you know if I was doing it in the morning for a short while that was the same as doing it in the evening for a short while but I definitely thought if you stuck at it, you know for a long, long time you were aware that you were getting tired and looking at them longer or after a while to make a diagnosis

U: Did you think there was a difference in the diagnosis if you viewed in the morning or night time?

S: No, not if you were coming at it fresh.

U: Right, ok. Anybody else have anything different, no? You thought the same?

? [3.08]

U: so you all think it was, there was no difference in viewing what time of the?

? No

U: Talking about the length of time of viewing; approximately how long do you think it took you to view each photograph, Liz do you want to start us off on that?

L: What happened was when I added up how many hours I spent, I divided it by the number of cases, and it came out with the whole thing, including the charting obviously came to 3 minutes approximate you know on average, but some were much quicker than others. But the actual viewing of the photographs was quicker you know so I don’t really know how many of the actual viewing but by the time you had viewed and charted and sort of you know, the whole thing for me, rather than you know glancing looking at the photographs and actually diagnosing it, might have been much quicker really but, then you thought oh right

U: Charting

A: Yes I think I did it a slightly different way in that I did all the paperwork I photocopied everything so everything was in the numbers that I needed for each, you know whether it was 6, 8, 6 or 4, so I had all the paperwork ready to go, I had already photocopied it with the school name on and the number, so all I actually had to do, and I had actually put the numbers on the forms, so when I actually got them I just had, the forms were all ready and I just had to dot the ts, and I would think it probably took about 10 seconds per photo, I had done everything before, but then some you would be thinking hmm but I need to have a look at that a bit more so basically, per you know if there were 8 it would take about a minute, well it still took about a minute by the time you know for each one

U: Yes, what about you Caroline?
C: I wrote down how long I spent and the number of people that I saw and it worked out an average of 26 people per hour so, from that you can work out at, but that only works out about 10 seconds, but it seemed to take me roughly 2 minutes per child, more with the 8 and less with the 5, with the four photos they were a bit easier. But, on average it was roughly less than 30 per an hour.

U: So if we work on 8 photos shall we say, would you say the photos were quicker or slower than doing a clinical exam on average?

C: Quicker, slower, they were slower whether that was because I didn’t have a scribe.

U: Right

C: but it still seemed slower

? Yes I would say

? I would agree, that it’s slower

A: Yes, I suppose I would, yes I think it is very slow, because I mean it literally it did take me a good hour or two in fact I gave up counting, just to do all the paper work

U: Yes

A: So that was split off from my viewing, once I actually got to look at them, I just looked at the photos so I just kept going with them, but everything else was actually done, so if there was a child that was actually, you know dentally fit, then there was nothing to do, the paperwork was already done. But it still took me an awfully long time.

U: So ignoring the paperwork because we have got to do paperwork for the clinical as well, so taking out the paper work, just concentrating on viewing the photographs, if you compare viewing, just viewing the photographs with just doing a clinical exam which one would you say on average takes longer?

S: I think I took longer over the photographs because if I was in doubt at all, I was staring at the photographs for a long, long time, whereas if you have got a wriggly child you do just, go in, have a quick look you have got your epidemiology head on so you know it’s a quick look, score low and that is what we are used to doing but when there is a photo on the screen and you think, there might be a shadow there, you can spend a long, long time and you look at it from different angles, you know, so I think the photographs probably took me longer yes.

? And with the 8 photos you are still clicking on the photos on the computer and that takes some time, clicking,

? Yes,

? Whereas with 4 it wasn’t quite so bad, but the 8 photos, and if you want to go back to any of them just to make sure whether there is a 6 (name of a tooth) is there or not, you know, it takes time
U: Am I right in saying that, what you are saying is, if all the photos were on the one screen, that would be easier,

? You would still have to click

U: Bring it up, yes.

? and for 8 that’s, that takes time

[talk together]

U: anybody else have anything to add to the length of viewing?

? I was just thinking, sorry [8.28] when you are doing the clinical exam then you sort of you instantly see the whole tooth don’t you somehow, you are instantly assessing the tooth, aren’t you somehow

? And the whole mouth

L: Yes, the whole, yes the whole mouth and all the surfaces of the teeth, whereas with the photographs you sort of, takes that little bit longer whereas in the mouth you immediately get that sort of view don’t you and [8.52]. I think the photographs were definitely longer.

U: Yes, ok anybody else have anything to add to that? Ok, so the next thing was, I know Sian already said something about how long she was viewing the photographs before taking a break, anyone else has anything to add, to that, how long you went before taking a break.

? I found it varied actually. Sometimes I got, I realised I had been doing it for a lot longer than I thought I would be doing you know without a break somehow, because you got into it somehow you kept, the longest I did I think was about 4 hours, in a stretch or 4.5 once. Yes. Sometimes you got you know something interrupted you anyway, somebody rang the bell or the phone or something, but I did find you could go longer than you realised, sitting there you know,

? definitely

A: I think I tried to limit it actually because I started getting very sharp pains down my side of the neck, truly I think because of going and then, so I limited it to about an hour, and then went off and did something else for 10 minutes and then came back, but I had to do that. I also found my eyes got very dry,

? Yes I did

? With constantly staring at the screen, because we don’t normally stare at the screen.

? Yes I did.
I am quite you know, because you wouldn’t probably look at that many normally would you if you were, because it’s a study we had 100s to go through, but, yes I limited it on the end, I had to, made myself have a break.

C: I tried to just do one school per evening, so that’s 30 / 40, well I never really managed 40 but and so it was basically an hour and then, I had lost concentration really, I could only do it an hour.

S: The way it worked out for me on two occasions I was actually in work and they were short of nurse cover so at very short notice, I couldn’t go out and do what I had planned to do for that day, and I had the photographs with me, so it just happened that I had a whole working day free, and I just made use of that time, you know I hadn’t sat down and thought right, today I am going to do photographs all day, but, it suited, it kept everyone happy just to do that. But it was, its too long to do it for a whole day like that really.

A: Our system actually stopped us putting the memory sticks in, for security so I couldn’t do it at work. It had to be done at home because they wouldn’t allow you know, memory sticks, we are not allowed memory sticks.

C: I had to do it all at home but I tended to do it at weekends and Fridays, I don’t work because I found when I thought about it doing in an evening I found that, I thought I will leave it to the weekend and I tended to do it, during you know, few hours and then go and do something else and then do a few more hours, and do something else.

U: So am I right in summarising that you all sort of thought that you needed constant breaks.

A: I found that eye strain a bit and also quite a bit somehow, and then I had a bit of wrist thing there, I had to devise a sort of pad thing, an elastic band to wear on my wrist because we haven’t got a mouse thing, and also if the writing was much, or anything things like that, so that was going up so I got a bit sore there, so I got this sort of funny thing and put it round my wrist, so

U: So what you are saying is one of the main differences I suppose is that with a clinical exam you have got a scribe with you, whereas you are scribing yourself and viewing. Angela did you try previously having a scribe?

A: Yes, when I done the phase 2, I actually used Cheryl as a scribe, so I have used them and she did as we do in when we are out in the field and that was actually very good. We got through it very quickly then.

? Yes,

A: that was helpful because I couldn’t do them at work this time unfortunately, in that but I found that really, very, very useful.
U: So would you recommend that if somebody has to do this, definitely dentist sitting there viewing with a scribe,

? Yes, yes

A: Absolutely

? Yes definitely and then you could can actually work through them (the photos), you know you can get them done quicker

? Really do them quite fast, a lot faster, get a little scheme going.

? Yes that would be much better yes.

U: That’s interesting. Ok, so any other comments at all that you have got about the viewing conditions? No. I have got a comment here from Sarah Jane, her comment is that, she was wondering whether the type of screen that you use does make a difference. Sian you said you used both laptop and desk top did you think there was any difference in your diagnosis at all?

S: I preferred using the desk top, but that was mainly because my laptop is set up to vista instead of windows so the actual, the way the pictures were presented was, wasn’t right I couldn’t click on them very easily, so I went back to using the desk top. But I used, one in work and one at home so I was using different computers and I didn’t find any difference there.

U: Ok, anybody else with anything to say about using different screens for the viewing? It does it seem to make a difference to some one else?

? It didn’t for me.

? The only thing I would be interested to see, when you get your results, is composites (tooth coloured fillings). I think on a lot of them I scored low, because I wasn’t sure so I did just score them low, whereas I just wondered whether, and also well we will come onto it in a minute but with you know, [15.39] when you just couldn’t see them (tooth coloured fillings) and you know, I did think I bet I have scored a lot lower than I did when I was actually examining them in the schools.

U: So you think it was easier to see the tooth coloured fillings in the mouth, clinically than it was on the photos

? Well yes because you can feel them with a CPITN probe (during a clinical exam),

? Except we didn’t have any probes,

? Oh no we didn’t did we

? We didn’t have any probes when we did it, but normally when you are going out, I would have a probe. And I would use it for that definitely.
And the, I mean the pictures were very, very good but even a small amount of saliva obscured and you know food debris, and I found that quite hard actually and that was by looking at the other you know, slides thinking well yes, there is a lot of debris everywhere so there is probably a [16.33] debris as opposed to, did anybody else have problems with that?

Yes. I think I was like you, I think I thought well if there is bits of debris in other places, its likely to be debris, but it was very difficult I thought yes. I think it was more difficult to tell (on the photo) whether it was a stain or debris than in the mouth you know. I think I have done the opposite I think I have over scored, rather than under scored I think, I don’t know my mind just wasn’t, I don’t know. When you are doing the clinical somehow I don’t know I find it easier to say oh, you know not to score it somehow but for some reason I got into this, thing where I was thinking that every little stain must be a cavity. I had to stop myself somehow you know what I mean, sometimes I don’t think I was very consistent, though sometimes I thought oh well its just stains and other times I put it as a cavity and it was probably a very similar looking thing. I am a bit worried really but,

I agree exactly with what Liz was saying and I think I have probably over scored because as you say you don’t want to think, oh that’s caries and I have missed it because I have scored it low.

Oh that’s interesting because I have done the opposite.

Yes I have, I have definitely done the opposite.

Even when I was saying to myself, score low, score low I still couldn’t do it because I am thinking, normally if in doubt score low, but this time if in doubt, all but its stained, oh I don’t know what to do.

I was like that yes, but I don’t seem to have that trouble so much with the

In a clinical model

No,

So you think making a decision on the photographs on questionable lesions is going to be more difficult.

Yes, definitely.

Yes the obvious lesion is fine,

It was lovely when you got a really obvious one wasn’t it, oh good oh definitely.

Ok. The next thing we want to talk about is how easy you think it was, I think we have touched on that a bit, how easy you think it was to view the photographs.

In what way?
**U:** In what way I suppose in whatever way you want to look at it, was it, easy to make a diagnosis, I think you have already touched on some of the issues you had round things like saliva on the,?

? Yes, and plaque and debris.

**U:** Yes

? Not being able to touch it (*the teeth*) with a probe that was difficult. I think the ones that were obviously healthy or obvious caries that as quite easy and quite quick but it was the doubtful ones, that was where I was having difficulty and spending a lot of time, and still not resolving it at the end you just wanted to poke them really, didn’t you.

? Or else look from another angle?

? Yes, you so wanted to tilt your head and you kept trying on the screen but obviously it didn’t really work.

? Yes I agree

**U:** So am I right in summarising that, not being able to have the your probe in your hand to have a tactile sensation to make that decision or even be able to move your head round, to have a look round the teeth because your picture is fixed.

? Yes

**U:** anything else that made it easy or difficult to view?

? I think otherwise it was quite easy wasn’t it?

? Having a bit of extra time did help to some extent because you could spend longer but that obviously has its downside but you know if the child is not wriggling and all that kind of stuff you could at least sometimes you can’t look so well so, so you could at least go back and look again, so yes that was good in some ways.

? You weren’t fighting a tongue, a cheek and a wriggly child you know, you had captured the tooth there on the screen and you could spend a long time looking at it, so from that point of view that was good.

**U:** Ok, so, shall we move on to again, they seem to flow into each other, erm, move on to what do you think the advantages of using the photographs over going into schools to actually have a look in the children’s mouth.

? Erm,

? Got a couple of things. Well I was thinking that obviously several examiners can look at the child’s teeth and they have only had one examination and one set of photographs taken. But lots of examiners can look at them. And the other thing was that, it might help to eliminate examiner bias if you don’t know where the child has
come from, whether its fluoridated or none fluoridated or not, or what sort of part of town or anything you know, what school or anything that they have come from, so yes.

A: could be used for calibration exercise you know, once you have got your set of photos, quite possible I think that would be quite a good use for it.

? you can view the photos at any time, you are not restricted to when the school can let you in, obviously the person who is taking the photographs is, but the examiners then can look at it, look at them anytime.

C: Yes, just that you did have a bit more time, but you know [22.29]

U: This is what Sarah Jane said, she also thought it was great that you could zoom in, and have a look at the images and also she did say that, as Angela said, it could be used for training purposes and also

A: The only problem with the zooming in though, I mean I did that, it I thought that completely altered the perception of the photograph, if you zoom in you have then magnified it I don’t know how many times, and the chances then of you scoring it higher were far greater, which is why I didn’t, I stopped doing that because I think that was completing altering what I was actually looking at, and in the mouth you are not going to have it, zoomed in in the clinical situation, so aren’t you then therefore altering

U: Increasing your chances of diagnosing decay whether there was one or not

? Yes, so I didn’t think that was the right thing to be doing in that situation. Because you are not having a standard examination, you know you are looking at one patient, with it at one magnification and another patient with something completely different so your results are going to be, quite dramatically different because I did do that on a number of them initially and I thought, well I will zoom in on this one and then so I was like oh yes definitely but then when I went back to it, you think oh no, its not. So I don’t know, I don’t know about that.

U: does anyone have any thoughts about that?

? Maybe because I did it on a laptop but I found the quality was, didn’t particularly help me when I was doing that, I didn’t,

? I stopped doing it as well, I just didn’t think it was very helpful.

U: But I think, it needs to be viewed in a standardised way by the instructions given. Another thing she mentioned which I think Liz has already mentioned, is the fact that you can have, in the clinical situation you have got multiple examiner having a look at a single child and the child can get tired, whereas multiple examiners can just have a look at photographs.

? Yes, sort of that ties in with the training aspect doesn’t it really,

? Yes
U: Any other advantages that you can think of?

? Its got to be cheaper when you look at your cross infection stuff because only the person taking the photographs needs to be gloved up and have instruments, the rest of us are doing it without you know, we are just looking at photographs aren’t we, whereas your normal exercise is everyone is bringing their gloves and you have got disposable mirrors ad everything for each child so it has to work out a bit cheaper, certainly in gloves, in terms of gloves its got to be cheaper.

U: And instruments as well

? Yes

U: Nowadays people are going down the disposable route so that can be quite expensive. Any other advantages that you can think of? Shall we move on to the clinical exam then. So, advantages of a clinical exam over using the photographs?

? I suppose that you can look, you can move the child, you can move your light, you can move your mirror and its what we are used to, that’s more what we are trained in, the photographs are still very new to us, aren’t they so,

U: Caroline do you have anything to add?

C: I got very worried whether the 6s(name of teeth) had been extracted and it was so nice clinically to be able to see the whole mouth and you then know whether the 4 or 5 (more names of teeth), [26.38] its so nice to see, yes I really found that very difficult. And cleaning and the drying the teeth, and the probe, all those things but especially that not knowing whether the 6s are through.

? I think about the same really I think it is a lot easier when you have got the child there and you can ask them if they have had any teeth taken out for accuracy, and also it’s the [27.11] [26.38] I did think composite (tooth coloured fillings) in 6s, that I think probably, I scored low on because I wasn’t sure, and I think that is where, you probably were likely to miss out a lot more, and it was very easy if you have got an amalgam in a 6 there is no debate there, but if you have got a composite, there are a lot more people using those now, but it is, you know that’s where the accuracy may fall down.

U: So we probably need to find a way of making tooth coloured fillings more obvious on photographs.

? Yes, I don’t know how you would do that though really, I don’t know how you would do that.

U: anything you want to add Liz?

Lz: No I don’t think so, I think I have got a few things down but I think we have mentioned them really already. Sometimes they can be out of focus occasionally, if the child moves when you are taking the picture, there is one or two that were a
little bit out of focus but not many, really actually I mean, they were very good on the whole weren’t they?

Lz:  Saliva definitely yes.

It only needs a tiny amount of saliva and

Lz:  And the light shines off it doesn’t it, and you can’t tell if there is a cavity,

U:  Any other comments at all about the differences between the clinical exam and the photographs?

No

U:  I think we have already said this but this is what Sarah Jane said. “Because of my greatest uncertainty when assessing [29.20] lesions and tooth coloured” we have all said already, “tooth coloured fillings I found it easier assess the 5 year old photographs than the Year 6 children’s”.

Yes

U:  so you all agree that you found it much easier assessing the 5 year olds, than the older children?

Yes,

U:  That’s interesting.

Because I started with the 5 year olds and I thought when I had finished the 5 year olds, that I had done, that the Y6s would be a bit quicker, and they weren’t. They were worse.

They were worse.

Yes

I did the younger children first like [30.01] and I am thinking oh I am doing alright here and then, oh, took a lot longer with the Y6 children.

U:  And it’s not just because they have got more teeth?

No because you had to look at the photographs longer and trying to decide,

U:  Ok.

I found much more doubt with the Y6s, than the 5 year olds
I agree.

Yes. The five year olds were much easier.

Yes, much less.

Anything else, to capture the differences between the two methods?

Can’t think of anything.

No.

I think we have mentioned discomfort with eye strain and neck pain from looking at the photographs, but to remember sometimes we can get terrible back ache sitting on those little chairs in the school, so there are discomfort for us doing the clinical exam.

With that as well.

From the clinical exam as well.

Yes that’s true.

Ok, anything else? We will move on. Ok, so the next thing we want to talk about is back to the photographs again. What sort of uses, how do you envisage using the photographic method in the future?

I thought the most useful use of them would be if you were doing a cohort study looking at you know, following children through from 5 years or 6 years or you know 5, 8 and 10 and that would be a really good way of looking at how the disease is developed as part of a research project. You know rather than just having something on paper you could actually look at each patient and follow them through, I think that would be a really good way of using them.

so you have actually got an archive of the true representation of pictures rather than a charting.

Yes, yes.

Ok. Any other uses that, Caroline?

I am sure with the 5 year olds that you could quite easily get a lot of people to calibrate on them and then you could use them for anything. I thought with Y6 it was, it would be a bit more difficult but the 5 year old, I did feel that that would be, that people could be trained to do that and would be just as good as clinically, that it would be ok to use them, with no problems.

Sian do you have anything to add to that?
S: I don’t.

U: [32.59]

S: No, can’t think of anything at that moment.

U: Ok

?: I think it was a bit of cheating then because I think this is what the study started off being partly about wasn’t it to do with comparing fluoridated and non-fluoridated areas, you know so that you didn’t know where the children had come from, so

U: so it will be good for blinding.

?: Yes, don’t know whether that would be anything or not. I don’t know how much its true that the examiners might over chart or under chart depending on what area they thought they came from and I don’t know if that happens or not really. I think, did you think that if somebody knew that the child had had fluoridated water, and they saw a lesion they might think oh its not a cavity rather than if they weren’t they might think it was.

U: well

?: I don’t know how much the examiners would you know be biased by, but I don’t know how much you would be biased or not really, you know.

?: It would certainly eliminate any bias wouldn’t it,

?: Yes, it would eliminate any if there was any.

S: If you were doing the study somebody couldn’t criticise it for having bias there, whether or not it really happened, you could say well actually no there is no bias because the examiner didn’t know so you could sort of refute that straight away couldn’t you, if somebody was criticising a study because of that, rather than just saying well actually I don’t think the dentist would be the biased, you say well they definitely aren’t in this study because they have no idea.

?: they might think that if the dentist was in flavour of fluoridation that they might be deliberately under scoring or something you know, that would eliminate that wouldn’t it.

S: It would stop your anti-fluoridation people using bias as a reason for saying that your study was rubbish.

?: It would yes, yes

?: Yes

A: But did any of you find that if you looked at the first 6, and there was a questionable lesion and then you looked at the lower 6s which were code 3s, and you probably
wouldn’t have scored the upper 6, and then you looked at the lower and then actually now I have gone back yes its definitely,

? Yes, yes I did,

**U:** Do you not do that with the clinical as well though?

? Yes you do,

? Yes, you do it with both. Yes. You know, so should you score it again, maybe you are then bias aren’t you, in the when you are first looking at the 1 tooth, you are looking at the whole patient;

? Maybe you should just look at completely random pictures. What’s in front of you yes, and then you could put them back to which patient they belong to.

**U:** We have actually done that. I gave you individual photograph to have a look at at the dental health unit, so we have got that information, we can actually put it together and see.

? but you are right you do look at the rest of the mouth and then you go back and change your mind on it, on a dodgy one.

? There was also a couple of patients where I spent ages humming and aahing, is that, isn’t it and then you know 2 nights later, oh, I remember that one. [36.24], my memory is not good enough to remember what [36.26]

? Because I do find clinically if you are going to better areas rather than deprived areas you do expect to see less decay obviously, and I do feel that, I probably am a little bit biased in that way, I feel that when you go to deprived areas, you see a staining and you think oh that’s more likely to be, whereas you might give them the benefit of the doubt in a better area. So I am sure, you, well I certainly am definitely slightly biased.

**U:** Looking at what Sarah Jane said, she said, and again you have already touched on some of these: that it could be used for training and calibration of examiners, yes. And also to avoid multiple examinations of young children. All agree with her comments?

? Yes

? Yes

**U:** Ok and I was wondering whether you think it would be a good idea to actually, I know you are all very well trained and very experienced in the clinical examinations, and what we have done is we have used your training and experience in the clinical examination as a proxy, for training for the photographs, but do you think it would be useful to have a separate training event for viewing photographs?
Yes. Because it is, it is different you are right we are trained to look at the teeth and score them in a clinical situation, but I think, to have a training exercise looking at the photograph and as we do to be able to discuss with other people because it is slightly different and to get your head round this scoring low I think on photographs I think you do need a bit of training about that, it seems to be easier to do it in the clinical situation than when the photograph is up there in front of you and you are staring at it for minutes on end.

U: What do you think about that suggestion Caroline?

C: I definitely think you could train on it and that you could calibrate on it, and it is a different technique to clinical examination, yes definitely yes.

A: Yes, [38.47] yes I think its good but I still think that there always be the problem of the questionable lesion, that’s not going to go away and that is always the difficult one and I think you know, well just because we have been trained to score low, you know you automatically do if you are in doubt you score low, but yes I think it would be very useful, and I think it would actually be quite useful as a you know to do a calibration, on photographs and see how various different people do compare. And how different the top and the bottom scores would be.

U: We have got, we will have your scores and that’s what we did, compare

A: Compare us all

U: Yes, [39.34] benchmark and yes, but I suppose the only thing is that you haven’t had specific training on the photographs so, it will be interesting to see, yes.

? Because I also found it easier towards the end, when I got the 5 year olds, the first ones were, I mean there was only 4 [39.55] so maybe that had something to do with it, but I did find the later ones easier I felt I got better at it.

? Yes, definitely. Yes.

? The first one took me forever, and then I thought, you know I am going to be here till Christmas, No it definitely got better, I got faster.

U: Liz any thoughts about having specific training on photographs rather than using the training you have had on the clinical method?

Lz: I think a bit of training would be good, useful yes, yes. Yes. Not sure really I think it would, it would help, it would help a bit yes, yes. Because you don’t know whether you should be zooming in or not zooming in and you know.

U: I think it we did mention, we did tell you not to zoom in,

? Yes, yes

U: we did say not to zoom in, we did say we did talk about the views to use so that we were all looking at the photographs in a similar way.
You quickly look at the thumbnail ones and then go in on each individual one in the normal way, I mostly did that.

I did occasionally zoom in I am afraid but it didn’t help I must admit so I don’t think it made any difference really.

Sometimes it was just nice to, you know you think oh, I know I wasn’t supposed to do it,

I didn’t realise I wasn’t supposed to do it.

I haven’t got time for, you did tell me [41.33] I didn’t but occasionally I thought would it make any difference and it would. That was my own little research project.

Just caused more confusion didn’t it I found, if you did it yes.

We are nearly at the end now. Any final thoughts about well how you think we could improve the photographic method.

I feel if I knew, I probably should have known, if I knew that you had taken the photo from the same place each time then that would have eliminated all this worry about what tooth I was actually looking at, whether it was a 7 or a 6 and whether the, if I had known you had taken it in exactly the same place, I don’t know if that’s possible, but obviously it would be incredibly difficult but, to me, if that had been standard I would have found that very helpful.

Yes

Ok. Any other way

The drying of the teeth is so important I think to get a really, really good view and I think that is so hard to do, clinically on a 5 year old. And, but that if you are training people to take photographs, that is one of the big issues, drying the teeth

Would you say that probably, because what we tried to do was to follow a procedure, and just dry with cotton wool rolls and you tend to find the teeth dried with the cotton wool will still have little bit of bubbles of saliva on it. So, what about possibly ignoring BASCD protocol and drying with air stream, how would people feel about that?

I think if you are going to use photographs you are going to have to do something like that, although it will because you cannot assess the photograph with any amount of saliva on it properly I don’t think but I suppose when you have got a patient lying in front of you, you know you immediately have got the overall view of the mouth, so you don’t have to dry every tooth, if everything looks, oh that looks a nice healthy mouth you don’t bother drying each 6 in turn do you? But whereas if you have got a photograph I think you have to do that.

What do you feel about that Sian?
S: Even with the clinical exam we still have that convention that if you can’t see a surface properly, you score it as 0 don’t you, so that is almost the same as not being able to see a surface on the photograph. I don’t know if it makes a huge difference that there are some surfaces that are obscured by bubbles or debris, because that happens clinically as well.

U: Ok, interesting point. What are your views on that Caroline?

C: Erm,

U: Stick to BASCD protocol and try with cotton wool rolls or dry with air?

C: Yes, dry with air, if you were just doing photographic then you could get more people there couldn’t you somebody could dry while you take photos and things so, you might be able to get a better but of course you can’t compare with previous results so, maybe not but if you were just doing photographs then definitely yes, dry with air that kind of thing.

U: Ok so you would like to dry but the drawback is that you won’t be able to compare the information you get with previous [45.15] data.

C: Yes, the whole photograph thing is whether you could compare with previous data I don’t know, I mean maybe the results of this will show, but the photos is a different thing.

U: Any other views on that?

? No I don’t think so.

U: Ok so still talking about how we can improve it, any other views on how we can improve it? These are Sarah Jane’s comments, which we did actually think about anyway. She said instead of using still images or photos, maybe in the future, using moving images, videoing.

A: My husband came up with that last night, we were talking about it and he said why don’t you video do you know,

U: So you can actually have a virtual tour of the mouth yes?

? Oh yes,

? Because then you can just capture each picture can’t you if you need to have a closer look.

? and you can get your over all view of the mouth and [46.37] 

? I imagine it would be hard, I mean I don’t know, I don’t do video but focussing would probably be quite a, technically it would probably be more difficult to do that wouldn’t it?

? [46.50]
U: That would be interesting to find out, because it is definitely something we considered, but I think there were a few issues around that. Even the size of images that you would have to store! Ok, so, any other improvements or ways of [47.29]

? I wonder whether you could take a picture of the whole mouth, upper and lower so you see all the teeth just as a, the upper teeth and then individually but that would be obviously more photos, whether you, you know you have a different kind of lens to do that. I don't know about that one.

? It would give you a better view but again as you say its going to lengthen the time of examining it depends really what you are using the data for, doesn't it how much you actually need.

U: So am I right in summarising that whatever improvement you think about would depend on how, you want to use the photograph?

? Hmm

U: Ok. Right, so final, final thought, any final thoughts, anything at all that you want to say that we haven't discussed yet?

? No

? I just think it's a very good way of storing information, you know that you can go back to and I think from a research point of view that would be very useful indeed, you know if you have actually got it there, whereas when you have just got it on paper, it is just another way of looking at things isn't it.

U: Hmm. Ok. Is that it then? No more views no? Thank you very, very much ladies. Thank you.
APPENDIX 3: Published Papers and Papers in Press

Paper 1
Paper 3
Paper 4
Comparison of photographic and visual assessment of occlusal caries with histology as the reference standard

Uriana Boye¹++, Tanya Walsh²++, Iain A Pretty³++ and Martin Tickle¹++

Abstract

Background: The purpose of this study was to compare diagnostic performance for the detection of caries using photographs with an established visual examination method and histological sections as the reference standard.

Methods: 50 extracted permanent teeth were assessed for the presence of occlusal caries by 9 examiners using two methods; traditional visual examination developed by BASCD and photographs produced by an intra-oral camera. For both methods, diagnoses were made at “caries into dentine” level. The teeth were histologically sectioned and the diagnostic decisions using visual and photographic assessment were compared to the histological reference standard. Inter- and intra-examiner reliability for the methods was assessed and weighted kappa values were calculated.

Results: The visual examination method had a median sensitivity value of 65.6% and a median specificity value of 82.4%. The photographic assessments method had a median sensitivity of 81.3% and a median specificity of 82.4%.

Conclusions: The photographic assessments method had a higher sensitivity for caries detection than the visual examination. The two methods had comparable specificities and good intra- and inter-examiner reliability.

Background

Dental caries is still the principal challenge that occupies the efforts of clinical and public health dentists alike. Whether in the field of caries research, dental education and dental epidemiology or in the clinical decision making in dental practices, the appropriate means of caries detection and measurement is required. This has led to proliferation of literature about how best to detect and diagnose dental caries in various settings [1]. The most common and traditional method is by a visual inspection of the tooth surfaces. Great progress has been made in the development of novel techniques and technologies that aid the detection of dental caries. These caries detection aids aspire to increase the sensitivity of visual caries detection as well as maintaining a good level of specificity [2]. The majority of these systems were validated using visual caries determination methods [3-5]. The need for clinically reliable caries detection methods has however led to the development and refinement of visual systems such as the ICDAS (International Caries Detection and Assessment System) and the Universal Visual Scoring System (UniViSS) [6,7].

Dental surveillance surveys and large epidemiological studies have traditionally depended on the use of visual dental examination techniques as the caries detection method. This is because for dental public health purposes, visual determination is simple, requires low technology and is easy to administer. This method of caries detection is however not appropriate in comparative studies where examiners collecting caries information need to be “blind” to various attributes of the different populations; for example the residential status of participants in the evaluation of water fluoridation schemes or the allocation of participants in randomized control trials. Other caries detection methods such as radiographs, or more innovative techniques/technologies such as Quantitative Light-induced Fluorescence (QLF), fibre-optic trans-illumination (FOTI)
and electronic caries monitoring (ECM) [8] will not be suitable to use in such studies for a variety of reasons.

The use of radiographs to ensure examiner “blinding” is an unviable proposition as it is fraught with ethical dilemmas in terms of justifiable risks from exposure to ionizing radiation and problems with validity in detecting occlusal caries [9]. Although dental caries and enamel fluorosis present as different lesions, it may be difficult to use the QLF techniques that are commercially available to make a distinction [10]. QLF is more suited to laboratory based research and clinical work involving precise measurement of changes in mineralization of tooth-tissue. ECM is a very sensitive caries detection method which can be affected by factors such as the presence of water, ambient light, and tooth temperature [11].

As digital imaging fibre-optic trans-illumination (DiFOTI) produces images that can be stored, it could be considered for ensuring examiner “blinding”. It is however very cumbersome to handle and time consuming to use. It also requires considerable amount of training to achieve the level of competence needed for it to be used as a caries detection method [8]. As such, none of the so called “novel” methods for caries detection appear appropriate for use in epidemiological studies where blinding is required.

However, a simple and economical method of “blinding” may be for examiners to inspect photographs of participants’ teeth rather than examine the subjects visually.

Photographic images have been used in dentistry in a variety of ways [12-14] and intra- and extra-oral cameras have evolved rapidly over recent years with a commensurate decrease in cost and complexity of use. With the advancement in technology, there are various intra-oral cameras now in use in clinical dental practice. There are however very few studies in the literature that have investigated the use of intra-oral images and caries diagnosis. In a study by Elfrink et al [15], intra-oral photographs were used to score caries and hypo-mineralization on primary molars in a clinical setting and the results suggest that intra-oral photographs may be used in clinical practice and large epidemiological studies with some degree of confidence. The main method of caries determination in the UK National Health Service epidemiological surveys is via a visual examination method developed and described by the British Association for the study of Community Dentistry (BASCD) [16-18]. Before intra-oral photographs can be recommended for use in epidemiological studies their performance must be assessed against the established BASCD visual examination method and the reference standard for caries diagnosis of histological section.

**Aims**

The purpose of this study was to compare diagnostic performance for the detection of caries into dentine of photographs with an established visual examination method and histological section as the reference standard. The following hypotheses will be tested to determine if:

1. There is significant difference in visual examination scores for the extracted teeth recorded by a group of examiners (to test inter-examiner reliability for the visual examination)
2. There is significant difference in visual examination scores for the extracted teeth recorded by the same examiner on two different occasions (to test intra-examiner reliability for the visual examination method)
3. There is a significant difference in photographic assessments of the extracted teeth viewed by a group of assessors (to test inter-examiner reliability for the photographic assessments)
4. There is a significant difference in assessments scores of photographs of the extracted teeth viewed by the same assessor on two different occasions (to test intra-examiner reliability for the photographic assessments)
5. There is a significant difference in recorded dental caries between the visual, photographic and histological methods of detecting caries at “the caries into dentine” level.

**Methods**

Prior to undertaking the study, ethical approval was granted by the University of Manchester Committee on Ethics of Research on Human Beings (Reference Number 06306). Permanent extracted teeth, supplied by the University Of Indianapolis School Of Dentistry were used for the study. Patients from who the teeth were obtained gave their consent for the teeth to be used in any non-DNA dental research. Teeth with lesions other than caries and teeth with restorations and/or fissure sealants were excluded from the study. The teeth were subsequently anonymised. The study was conducted to the Helsinki Declaration and local legislation as determined by the ethics committee whose approval was gained.

Fifty permanent extracted teeth, 32 molars and 18 premolars, varying from sound to grossly carious teeth were used for this study. The teeth were examined visually for caries (without probing) using the method developed and described by BASCD [16]. The BASCD codes used for scoring, classified teeth as being sound (caries-free), having arrested caries, having caries into dentine or having caries extending into the pulp (Figure 1). The teeth were also photographed using an intra-oral camera and the obtained images assessed for caries using the same BASCD codes as were used for the visual examination. The teeth were then sectioned for a histological assessment to detect the presence of dental caries.
Visual examination

Nine examiners trained and calibrated to the BASCD caries examination protocol as members of the team who undertake the UK National Epidemiological Surveys convened to examine the extracted teeth visually for caries. They examined the teeth using the criteria and protocol developed by BASCD. Each examiner assessed the teeth on two separate occasions to test intra-examiner reliability.

The teeth were stored in thymol to prevent microbial contamination. Prior to the examination, two sets of randomly generated identity numbers (ID) were assigned to each tooth, one set for the first exam and the other set for the second examination. For the visual examination each tooth was placed in water within a dappen pot labelled with its assigned ID. The teeth were examined using Daray X100 Lamp with Pivot D desk mount (Daray Healthcare Products Swadlincote, Derbyshire) as the source of light. Each tooth was dried with cotton wool rolls prior to the examination. Caries was diagnosed visually at the ‘caries into dentine’ level (enamel only caries was not recorded). Only the occlusal surfaces of the teeth were assessed and the assigned BASCD score recorded onto a paper pro-forma. The second examination was conducted 1 hour after the first.

Photographic procedure and assessment

Each tooth was photographed using an intra-oral camera, the Sopro 717 (The Acteon Group Eaton Socon, Cambridgeshire), which has an integral LED light source. The teeth were dried using cotton wool rolls prior to being photographed. Each tooth was held in place on an adjustable mount, the level of which was raised or lowered relative to the camera to obtain the best occlusal view photograph. The camera was held by a clamp in a fixed position pointing downwards onto the tooth surface. The digital image of each tooth generated was saved under a file name which was the same as the identity number allocated to that tooth. The photographs were presented as a Microsoft PowerPoint (2003 version) slide show for assessment.

The same 9 examiners who had examined the extracted teeth visually assessed the PowerPoint presentation of the photographs on two separate occasions. On the first occasion, the examiners convened to view the slide show of the teeth. This was to ensure that each examiner assessed the photographs under the same physical conditions. The examiners were seated behind tables and each had a view of one common screen that was 2.5 metres away in a room lit by ambient daylight. The PowerPoint slide show of the teeth was projected onto the screen. Each photograph remained on the screen for 15 seconds. Just as for the visual examination, only the occlusal surfaces of the teeth were assessed for caries using BASCD criteria. Caries was diagnosed as “caries into dentine” level. Each examiner recorded the scores for each tooth onto a paper pro-forma, identical to the one used for the visual examination. The examiners were supervised and did not concur with each other during the process.

For viewing on the second occasion, each examiner was provided with a non-time limited version of the same PowerPoint presentation on a CD ROM. Each examiner viewed the photographs a minimum of 14 days after the first viewing. Each examiner viewed the slide show on either laptops or desktop computer screens at a time of day and room conditions of their choice. The purpose of the second viewing was to compare the caries detection performance when the photographs were viewed under standardized and varying physical conditions. Only the occlusal surfaces of the teeth were scored for caries using BASCD criteria. Caries was again diagnosed at the “caries into dentine” level. The examiners recorded the scores for each tooth onto a paper pro-forma, identical to the one used for the visual examination.

Histological assessment

The extracted teeth were then sectioned for histological assessments. To obtain the histological sections, each tooth was immersed in resin and allowed to set into blocks, with approximately 1.5cm to each side. Each block with an encased tooth was then pressed up against a model grinder, removing thin layers of resin at a time until initial exposure of tooth. The newly exposed tooth surface was polished, dried, and photographed with an extra-oral camera with a ring illuminator. The extra-oral camera with the ring illuminator was pointed upwards, with a small mount on top of it, to house the tooth. This ensured that
the tooth was always in focus at the same zoom. The tooth was then returned to the grinder for a while to remove more resin and tooth. The process of alternative grinding and photographing was repeated about 50 times per tooth. The average distance between one photographed cross-section and the next was 0.16mm (Figure 2).

The histological section with the worst level of caries for each tooth was assessed by a trained and standardized examiner. The sections were scored from photographs that were at 10x magnification. The histological assessment was conducted on two separate occasions, one week apart, by the same examiner to test intra-examiner reliability. Sections were scored as sound (caries-free), caries into outer dentine, caries into inner dentine and caries into pulp. These scores were used in the comparative analysis as the reference standard [19].

**Data processing and analysis**

Data from the visual examinations, photographic and histological assessments of the extracted teeth were collated for analysis. SPSS® version 15.0 (IBM Company, Chicago) was used to compute weighted kappa scores as a measure of agreement to test intra-examiner reliability for the visual examination and the photographic assessments using the Landis and Koch measurement of observer agreement for categorical data [20]. Inter-examiner reliability was also assessed to test the measure of agreement within the group for both the visual examinations and the photographic assessments using Stata® statistical software version 10 (Stata Corporation Texas).

McNemar test (p<0.05) was performed to compare the performance of the visual and photographic methods using SPSS® version 15.0 (IBM Company, Chicago). SPSS® version 15.0 (IBM Company, Chicago) was also used to compute sensitivity and specificity of the visual examinations using the first histological assessments as the reference standard and sensitivity and specificity of the photographic examinations using histological assessments as the reference standard. For these analyses, the teeth were grouped as sound or carious. All the teeth scored as having arrested caries, caries into inner/outer dentine or caries into pulp by the all the examination types were grouped as carious.

**Results**

The frequency distribution of the codes/scores allocation to the teeth according to the examination type is presented in Table 1. Table 2 summarizes the intra-examiner agreement for both the visual examination and photographic assessments. The level of agreement between the first and second visual examination for the individual examiners ranged from substantial agreement to almost perfect agreement (weighted kappa from 0.67 to 0.92 with a median = 0.85) Landis and Koch [20].

The level of agreement between the first and second photographic assessment for the individual examiners (to compare standardized with varying physical conditions for viewing photographs) ranged from moderate agreement to almost perfect agreement with weighted kappa from 0.59 to 0.92 with a median = 0.74. [20]

The measure of inter-examiner reliability for the visual examinations was a multi-rater kappa of 0.66. This showed there was substantial agreement within the group for the visual scores. The measure of inter-examiner reliability within the group for the photographic assessment was a multi-rater kappa of 0.60. Again this showed a substantial agreement within the group.

McNemar test (p<0.05) calculated to compare the performance of the visual and photographic methods showed no significant difference between the methods.

Sensitivity and specificity as a measure of the diagnostic performance of the visual examination and the photographic assessment methods as compared to the reference standard of histological section assessments are presented in Table 3.

**Discussion**

The main findings of this study showed substantial intra- and inter-examiner reliability for both the visual and photographic assessments. The median sensitivity and specificity values of the visual examinations and photographic assessments as compared to the gold standard of histology were 65.5% & 82.4% and 81.3.8% & 82.4% respectively. These showed that the photographic assessment method in this study has a caries detection capability that is comparable to that of the BASCD visual examination method.

![Figure 2 Examples of tooth sectioning procedure.](http://www.biomedcentral.com/1472-6831/12/10)
The difficulty of convening examiners from wide geographical area made a longer washout period for the visual examinations problematic in this study period. It had to be expected that a decision (one of 50) could not be recalled by the examiners after the washout time allowed in this study. In this study caries was only diagnosed when it was determined by the examiners to have reached dentine. This is because the established visual examination method developed by BASCD that was used for the comparisons determines caries at the caries into dentine level as part of its protocol. Although early caries is not accounted for, this method has provided the main epidemiological data on the state of the dental health of the child population in the UK for almost 30 years [21-23]. Any other caries detection method to be used in dental public health studies in the UK should at least be comparable to the BASCD examination in ease of application, reliability and validity.

The detection of caries was restricted to only the occlusal surfaces of the teeth. The purpose of this approach was to minimize the number of photographs per tooth that had to be assessed by the examiners. This may be seen as limiting the external validity of the findings of this study. However majority of carious lesions occur in pits and fissures on occlusal surfaces [24] and moreover as lesions on occlusal surfaces are the most difficult to reliably diagnose [25] the findings of this study will contribute to the available literature. Future research could include caries detection on other tooth surfaces in vivo.

Table 1 Frequency distribution of tooth scores according to examination method

<table>
<thead>
<tr>
<th>Tooth Condition</th>
<th>Histology Freq</th>
<th>Histology Percent</th>
<th>Mean Visual Scores</th>
<th>Mean Visual Percent</th>
<th>Mean Photo Scores</th>
<th>Mean Photo Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sound</td>
<td>36.7%</td>
<td>Sound 18</td>
<td>52.0%</td>
<td>Sound 26</td>
<td>44.0%</td>
<td></td>
</tr>
<tr>
<td>Caries into Dentine</td>
<td>49.0%</td>
<td>Caries into Dentine 24</td>
<td>44.0%</td>
<td>Caries into Dentine 22</td>
<td>52.0%</td>
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<tr>
<td>Caries into pulp</td>
<td>14.3%</td>
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<td>4.0%</td>
<td>Caries into pulp 2</td>
<td>4.0%</td>
<td></td>
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<td>Missing data 1*</td>
<td></td>
<td>Missing data</td>
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<td></td>
</tr>
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<td>100%</td>
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<td>100%</td>
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<td></td>
</tr>
</tbody>
</table>

* For histology: inner and outer dentine caries was combined into caries into dentine.
* 1 tooth exploded during histological sectioning.

Table 2 Intra-examiner reliability for the Visual and Photographic assessment

<table>
<thead>
<tr>
<th>Wt kappa to show level of agreement between</th>
<th>1st and 2nd visual exams</th>
<th>1st and 2nd Photos assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examiner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>0.87</td>
<td>0.74</td>
</tr>
<tr>
<td>B</td>
<td>0.85</td>
<td>0.59</td>
</tr>
<tr>
<td>C</td>
<td>0.87</td>
<td>0.69</td>
</tr>
<tr>
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<td>E</td>
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<td>0.59</td>
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<tr>
<td>F</td>
<td>0.88</td>
<td>0.78</td>
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<tr>
<td>G</td>
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<td>H</td>
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<tr>
<td>I</td>
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<td>Median</td>
<td>0.85</td>
<td>0.74</td>
</tr>
</tbody>
</table>

*Photographic assessments projected on screen.
** Photographic assessments on personal computers.
Table 3 Sensitivity and Specificity

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Visual Examination</th>
<th>Photographic assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference Standard: Histology</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>1</td>
<td>62.5%</td>
<td>100.0%</td>
</tr>
<tr>
<td>2</td>
<td>62.5%</td>
<td>82.4%</td>
</tr>
<tr>
<td>3</td>
<td>68.8%</td>
<td>76.5%</td>
</tr>
<tr>
<td>4</td>
<td>71.9%</td>
<td>76.5%</td>
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<tr>
<td>5</td>
<td>68.8%</td>
<td>70.6%</td>
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<td>71.9%</td>
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<tr>
<td>9</td>
<td>65.6%</td>
<td>82.4%</td>
</tr>
<tr>
<td>Median</td>
<td>65.5%</td>
<td>82.4%</td>
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</table>

The findings of this study relate to teeth in in-vitro condition. The next stage in the development of the use of intra oral photographs in dental public health epidemiological studies is to explore their performance in an in-vivo study comparing the two methods.

Conclusions

In summary, the comparisons in this study showed that the assessments of the photographs as a method of caries detection had a higher sensitivity than visual examination compared to the reference standard of histology. The two methods however had comparable specificities. There was also good intra examiner and inter examiner reliability for the examiners assessing the photographic images.

Competing interests

None of the authors are aware of any competing interests in the production of this manuscript.

Authors’ contributions

UB contributed to the protocol, undertook the management of the study, took the photographs and wrote part of the manuscript. TW gave statistical advice, assisted with data analysis and contributed to the manuscript. IAP contributed to the protocol, undertook study monitoring and wrote part of the manuscript. MT contributed to the protocol, undertook study monitoring and wrote part of the manuscript. All authors read and approved the final manuscript.

Disclaimer

The views and opinions expressed are those of the authors and do not necessarily reflect those of the NHS.

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References


Children’s views on the experience of a visual examination and intra-oral photographs to detect dental caries in epidemiological studies

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Aim: To elicit children’s views on the established visual examination method used for the epidemiological surveillance of dental caries and an experimental intra-oral photographic examination method. Method: Focus group interviews were conducted with 5-year-olds (with the aid of a puppet) and 10/11-year-olds (without puppet) after experiencing both methods. 10 focus groups were interviewed in each cohort. Results: The children’s views on the methods related to the acceptability of their experience. The key factors affecting acceptability and preferences related to the combined effects of contextual factors prior to the examination and experiences during the examination. These included communication and children’s expectations. These factors influenced the examination experience along with their feelings about the environment and the tactile sensation from instruments in the mouth. Most children preferred the experimental photographic method as a means of caries detection over the traditional visual examination. They also wanted feedback on their oral health and more communication on what was happening during the examination. Conclusion Appropriate communication, attention to the examination environment and handling of instruments can enhance the dental examination experience for children in the school setting. The children’s preferences indicated that generally, the intra-oral camera was well received as a means of caries detection for epidemiological studies within the school setting. These results may have implications for seeking ethical approval and conducting epidemiological studies on children in the future.

Key words: children’s views, caries detection, dental epidemiology, qualitative, intra-oral photographs, visual dental examination

Introduction

Children are examined in dental caries research and surveillance programmes and yet we know little about their views on participation in these studies. Children are not miniature adults therefore undertaking research involving children using adults’ perceptions of what they suppose are children’s views is at best inadequate.

In the UK dental caries remains the disease most commonly affecting children and National Health Service (NHS) epidemiological dental health surveys of children provide data for monitoring caries trends and commissioning dental services. These nationally coordinated surveys use dentists, trained and calibrated in the use of a visual examination method developed by the British Association for the Study of Community Dentistry (Pitts et al., 1997) as the means of detecting dental caries. The dentists visit schools to examine participating children.

To produce top level evidence, studies evaluating the effectiveness of caries interventions require that examiners collecting research data are “blind” to certain attributes of participants e.g. area of residence. Using traditional visual examination methods, the usual way to “blind” examiners to participants’ place of residence is by transporting participants to examination sites outside the test and control areas (Milsom and Mitropoulos, 1990). Ethically and logistically this is impractical in studies involving thousands of children. Although the use of radiographs in epidemiological surveys has been advocated (Gowda et al., 2009), their use may be more appropriate in longitudinal studies to monitor inter-proximal caries progression in permanent teeth (Arrow, 2007). Other novel caries detection methods may not be suitable for epidemiological studies because they are cumbersome to use in the field on children or are dependent on user expertise or the physical environment (Pretty, 2006). An alternative method of “blinding” examiners would be for examiners to inspect intra-oral photographs of participants’ teeth.

Before this alternative method can be recommended for use in research and surveillance programmes, it ought to be tested for acceptability, validity and reliability as a caries detection method. There is little information available on children’s views on the NHS epidemiological surveys. Although the literature records how challenging it can be to obtain accurate reflections of children’s views on issues that affect them, evaluation of therapies and/or services for children would be incomplete without inclusion of their views. Attempts should be made to understand what children truly think of the dental health surveys they participate in. These surveys regularly involve 5-, 10-, 11- and 12-year-olds to allow regional, national and international comparisons. Therefore the development of...
new caries detection methods for use in these surveys should involve the same or similar age groups.

Methods used to appraise children’s views and experiences originated from research assessing pain experienced by children. These included simple visual analogue scales like the Oucher scale and the Children’s Hospital of Eastern Ontario Pain Scale (Beyer et al., 1992; Lyon and Dawson, 2003). Their core feature is the use of facial expressions as a response scale to indirectly measure subjective attitudes. Applying these scales to elicit children’s views can be simplistic. Other techniques have been used to elicit the views of young children across a wide range of themes. These include the use of focus groups and semi-structured interviews, storytelling, art/drawing, writing, role play and the use of puppets (Chapparo and Hooper, 2005; Fredman et al., 2007; Heany and Hennessy, 2002).

To obtain children’s views on both the intra-oral photographic and the visual examination methods, age-appropriate techniques should be employed. Very young children find it easier to communicate with and through puppets in role plays (Hay et al., 1992; Lewis et al., 1992). If this is carried out in small groups, children feel more at ease than having their views sought in isolation. The aim of the study was therefore to elicit children’s views on the visual examination and an intra-oral photographic assessment examination method for detecting caries in epidemiological studies.

Method

Ethical approval was obtained for the study from the National Research Ethics Service, UK (Reference Number: North West 10 09/H1011/57).

The study population comprised 2 groups of children: 5 year olds and 10/11 year olds attending 5 primary schools in Rochdale, a town in north-west England. These age groups were chosen to match those of national and international caries surveys.

Study information sheets, letters and consent forms were sent to parents of eligible children via the schools. The 10/11-year-olds were also given study information sheets. Only children who had experienced both the visual and photographic examination methods in the last week, whose parents gave explicit consent, and themselves agreed, were included in the study.

In each school, the research team liaised closely with teachers to determine a purposive sample comprising 2 focus groups of 5 5-year-olds and 2 groups of 5 10/11-year-olds, a total of 20 groups. Interviews were conducted separately with each focus group in their school and digital audio recorded.

For the 5-year-olds’, the children and the interviewer (with the puppet) sat in a circle in a quiet room familiar to the children. Before starting each interview, the children were familiarised with the recording equipment, the puppet and the rules of engagement for the interview. The visual prompts were used to help the children recall their examinations. Told that the puppet was going to have both examinations the children discussed what the puppet could expect and how it might feel. Interviews lasted on average about 30 minutes.

The 10/11-year-olds’ interviews were conducted in a similar fashion without the use of the puppet. They were asked directly their individual views on the two examination methods.

The audio recordings of the interviews were transcribed and analysed using a grounded theory approach, the constant comparative method (Green and Thorogood, 2004; Strauss and Corbin, 1998). After each 4 interviews, transcripts were analysed using line-by-line open coding. The words and short phrases generated summarised the substance of the text. Data collection and analysis proceeded concurrently allowing the emerging findings to be developed (Pope et al., 2000) and refine the interview guide for subsequent interviews and so clarify the data being captured. Data were scrutinized for deviant cases and confirming views across the range of children. Data collection halted once there were little new data emerging from the analysis. To validate the analysis transcripts were scrutinized by an independent reader not otherwise involved in the study. Quotes indicative of the children’s views are reported to show that the analysis is grounded in their accounts.

Results

From 5 primary schools, 100 children participated in the study: 50 5-year-olds and 50 10/11-year-olds. The male to female ratio was 1:1. There were no drop-outs as the sample was purposefully obtained.

Six categories emerged from the analysis: Communication – recall of information given pre-examination and desired explanation or reassurance; Expectation – perceptions of what examinations would entail; Initial Impressions – feelings on entering the examination room; Experiences – relates to the examination itself; Preferences – choice of examination method; and, Improvements – suggested enhancements. The Experiences category was sub categorised as: dental examinations in general (further divided into environmental and feelings properties); examination with mirror (sensations in the mouth and feelings properties); the camera (also sensations in the mouth and feelings properties); and, seeing camera images of one’s teeth. Each property had positive and negative dimensions.

Overarching these categories was the perception of the acceptability of the dental examination. The main and sub-categories were constructed to present a preliminary model of the dental examination in a school setting and how these contribute to children’s acceptance of the intra-oral camera and mirror (Figure 1).

Most children preferred the photographic method and the visual examination. A third were equally happy with both methods while a minority expressed negative views on both methods.

Discussion

The main finding of this study was that the children’s experiences affected their views on the examination methods’ acceptability. Factors affecting acceptability and the preference related to the combined effects of contextual factors before examination and experiences during the examination including communication and
children’s expectations. These factors influenced the examination experience along with their feelings about the environment and the tactile sensation in their mouths from instruments. They also wanted more communication during the examination and feedback on their oral health.

The responses about communication indicated that in general the examiners gave directive instructions and brief information to the children about what was happening and in some cases this was child focused. The level of fear, nervousness and lack of understanding, in some cases however, suggests that those children had not been fully informed about the dental examination or had misunderstood the information given. The responses about the communication they would have liked revealed a discontinuity with the communication actually received.

“They could have given us more information on what they were actually like doing and how the teeth were. Not just say they are OK, like tell us” Child 15-1

The children in this study considered communication between the dental epidemiology team and themselves to be a factor which contributed to their level of acceptability of the examination methods. This was emphasised in the improvements suggested by children for the examinations.

Past dental experiences and preconceived ideas shaped the children’s expectations of dental examination which in turn seemed to affect their initial impressions of the examination room in both examination methods. This is not surprising as generally dentistry produces anxiety and fear in a number of children (Tickle et al., 2009). Although some children were not daunted by the dental examination and had resilience to what was a new experience, the responses showed that for others, their expectations were negative, dominated by fear, uncertainty and nervousness.

“At first before I walked in to the room, I felt really happy and excited”. Child 4-4

Figure 1. A grounded theory of children’s acceptability of the dental examination in the school setting
“When we first walked in we were all scared and nervous because I didn’t know what we were going to do…” Child 4-2

It was apparent from the children’s responses that the environment in which the examinations were performed played a part in determining the acceptability of both methods as did sensations in the mouth from instruments and items such as cotton wool used for the examinations.

“when they put the light on and I put my sunglasses on, you know that mirror thing, it looks like a knife but, then I took my glasses off and it was, it didn’t look like a knife so I just put them back on while they counted my teeth” Child 8-3

This is consistent with findings in the literature that the environment in which dental care is provided and the manner in which care is received influences how patients perceive the experience. A supportive dental environment with strategies to make patients feel relaxed and in control, increases the patient’s acceptability of the dental care provided (Law and Blain, 2003). An important part of these strategies is communication between the dental team and the patients.

Fewer participants preferred the visual examination method over the photographic method. Of those children who preferred the visual examination method, familiarity with the process and the fact that they could keep the disposable examination mirrors used contributed considerably to its acceptability. Others complained of a dry mouth and disliked the taste of the examination gloves used. Although gloves were also worn for the intra-oral camera examination method, the children did not comment on their taste. This could be explained by the children being distracted by their interest in the intra-oral camera’s images of their teeth.

Children generally liked the intra-oral camera. Some liked the technology, others liked seeing images of their teeth.

“I liked it when I saw my teeth because naturally humans don’t get to actually look inside their mouth, because of the positioning of their eyes, and except looking at them in the mirror when you are brushing your teeth, there is a brush in the way so you can’t actually see right at the back, wherever the photo was took so quite interesting actually, to see what they actually looked like”. Child 7-5

Some children would have preferred to see these images throughout the examination though others found the magnified view and yellow teeth shocking.

“It felt horrible because … the teeth had like yellow stuff on… I really hate yellow so when I grow up I might get my teeth whitened” Child 8-2

Another characteristic of the camera commented on was its temperature after repeated use. The warmth was liked by some but painful or uncomfortable for others. Switching periodically to a new camera might overcome this difficulty.

Very few children were happy with both examination methods and even fewer expressed negative views on both. The latter group were generally those who had negative experiences and expectations of dental examinations.

Although children may consent by their conduct to partake in epidemiological studies, dental epidemiological teams could enhance the experience for child participants by conducting the dental examinations in conducive environments with more explanatory and effective communication.

Other improvements suggested by the older children related to privacy and confidentiality issues. Peer victimisation, teasing and bullying among school children are still major issues (Lunde et al., 2007) even though most schools have policies to control these problems. Physical appearance such as malocclusion has been listed as one of the characteristics for which children are bullied (DiBiase and Sandler, 2001). A few of the children in the study were worried by other children seeing or hearing what the examiners had to say about their teeth. For dental examinations taking place in the school setting, the environment that dental epidemiology teams have to work in is often dictated by the space schools can spare. This can result in children being examined in a non-confidential manner. Other children especially those with negative experiences and preconceived ideas about dentistry however requested reassurance from the presence of a friend or teacher if required.

As far as we can discover, this is the first study to use a grounded theory to explore children’s views and experiences of the established visual examination method and obtaining intra-oral photographs for dental examinations in schools. The findings demonstrate that children should not be considered passive participants in the dental examination but rather as a group able to express their views on their experiences and exercise discernment in their attitude regarding what happens to them. Dental epidemiology teams need to be sensitive to children’s needs and improve the acceptability of the dental examination experience by managing the contextual factors including communication, the examination environment and handling instruments in the mouth.

Intra-oral photographs enable archiving of images which can be revisited for a number of purposes, for example longitudinal studies; enable examiner blinding in research studies; offer the possibility of remote dental examination and screening; and support the use of a single examiner to assess all participants in epidemiological studies thus eliminating concerns about inter-examiner reliability.

In order to progress the development of the use of intra-oral photographs as a means of detecting caries in dental public health epidemiological studies, as well as the children’s views, the views of other stake-holders especially those of the dental epidemiology team should be sought on how user-friendly and cost effective the experimental method is compared to the established method.

**Conclusion**

Children’s views on the examination methods related to the level of acceptability of their experience. The key factors affecting acceptability and children’s preferences related to the combined effects of contextual factors prior to the examination and experiences during the examination. Appropriate communication, attention to the examination environment and sensitivity in handling instruments could enhance the dental examination experience for children in the school setting. The children’s preferences indicated that generally the intra-oral camera
was well received as a means of caries detection for epidemiological studies within the school setting.

These results may have implications for seeking ethical approval and conducting epidemiological studies on children in the future.

References


The views of examiners on the use of intra-oral photographs to detect dental caries in epidemiological studies

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Introduction

Despite a decline in the prevalence of dental caries in many countries, it still remains the most significant disease in children (Marthaler, 2004). The prevention and treatment of dental caries consumes most of the dental resource allocation of state-funded health budgets. Data collated through dental epidemiological studies to inform the allocation of these resources should provide dental public health planners with appropriate information to complete this task efficiently. Different caries detection methods of varying sensitivity and specificity depend on the degree of progression of lesions have been described in the literature (Bader et al., 2001). The choice of caries detection method for such studies is dependent on a numbers of factors. Validated caries detection methods with high sensitivity for identifying early carious lesions are useful in longitudinal caries progression studies and in the clinical management of the disease (Ismail, 1997). Epidemiological assessment of caries traditionally relies on visual assessments. Many countries including the UK use traditional visual examination methods for their national epidemiological studies and record caries at the dentinal level. The visual examination method used in the UK National Health Service (NHS) epidemiological surveys was developed by the British Association for the Study of Community Dentistry (BASCd) (Pine et al., 1997). This method is however unsuitable for comparative studies where examiner “blinding” to some attributes of participants is required to reduce the risk of bias. An alternative inexpensive and simple method of “blinding” suggested by Boye and colleagues (2012b) is for examiners to assess intra-oral photographs of participants’ teeth instead of direct visual examination. An additional benefit of this method is the ability to archive the obtained photographs, undertake repeated and remote analysis and the possibility of using a differently skilled workforce such as hygienists to acquire the images which may reduce the costs of such surveys.

This method has been shown to be a valid and reliable means of assessing caries (Boye et al., 2012b). It has also been shown to be acceptable to children the main participants of the caries epidemiological surveys (Boye et al., 2012a). The experiences and views of examiners on diagnosing caries from the intra-oral photographs in epidemiological surveys has however not been reported in the literature. This is an important aspect of the implementation of such systems. While they may be scientifically and philosophically ideal, unexplored barriers to their effective and efficient use in the field could hinder their uptake. By understanding the views of the users such barriers can be explored, and often reduced or eliminated.

The aim of this study was to obtain the views of examiners on their experience of using the established visual examination developed by BASCd and the assessment of intra-oral photographs as means of detecting caries in epidemiological studies and explore how these experiences were influenced by some of the practical issues encountered during the examinations.

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Method

Ethical approval was obtained for this study from the National Research Ethics Service (Reference Number: North West 10 09/H1011/57).

The examiners used in the study had been trained and calibrated to the BASCD caries examination protocol as members of the UK National Epidemiological Surveys team (outside the current study). Completion of this national training and calibration in the BASCD caries examination protocol was used as the main selection criterion for recruitment of the examiners into this study. Five examiners, all dentists trained, calibrated and experienced in the use of the visual examination method developed by BASCD for use in the UK NHS dental epidemiology programme, took part in the study. These examiners had each participated in the visual examination of more than 200 5-year-olds and 200 10/11-year-olds in schools. The same dentists (after appropriate training) had also assessed intra-oral photographs of the same children as a means of detecting caries. The intra-oral photographs were obtained by a single examiner (not one of the 5) at the time when the visual examinations were carried out. For the photographic assessments, each of the five examiners was provided with a Universal Serial Bus (USB) flash drive loaded with labelled folders containing a set of intra-oral photographs of each participant’s teeth at least two months after the visual examinations. Each examiner viewed the photographs on either laptop or desktop computer screens at a time of day and room conditions of their choice. Caries was diagnosed at the “caries into dentine” level. Examiners recorded their diagnosis on score sheets.

The examiners convened three weeks after they had carried out both the visual examination and photographic assessments for a focus group discussion to explore their views on their experiences of using the two methods and also to clarify any issues that needed further explanation.

All five examiners were invited to attend the focus group and they were given the topic areas that would be covered in the discussion. A member of the research team facilitated the discussion. Another individual was present solely to take additional notes about the group interactions. Before the start of the focus group discussion the facilitator informed the participants of the ground rules and established the guiding principles of the discussion. Confidentiality was also assured.

The areas discussed by the group included the participants’ views on the following topics:

• The conditions for conducting the examinations
• Their experience of the two examination methods
• The differences between the use of intra-oral photographs and visual examination as means of detecting of caries
• Their perceived advantages of assessing intra-oral photographs to detect caries instead of performing a visual examination using BASCD criteria
• Their perceived advantages of performing a visual examination using BASCD criteria instead of assessing intra-oral photographs to detect caries
• How the intra-oral photographic method could be used for future epidemiology work
• Their views on how the intra-oral photograph method could be improved.

The focus group discussion was audio recorded digitally and lasted for 50 minutes.

An audio typist transcribed the focus group discussion recording verbatim. Thematic analysis identified the common themes from the transcripts by first assigning codes to the emergent themes then, using an inductive process for constructing interpretations, the codes were used to develop an overall classification of themes. Transcripts were then closely examined for sections that did not fit the emergent framework. The overall classification of themes was assured by an independent researcher’s analysis of the transcripts and the notes taken during the focus group discussion (Barbour, 2001). To add to the credibility and trustworthiness of the research process, a protocol for the method and data analysis used in the study was produced to create an audit trail for reproducibility (Jootun et al., 2009). In the presentation of the study findings, selected quotes from the focus group discussions are used to illustrate how analysis of the data reflects the views of the examiners (Gill et al., 2008).

Results

All the five examiners contributed to the focus group discussion. As they were experienced in the use of the visual examination method, in their discussions, the characteristics of the intra-oral photographic assessments method were compared to the former. The main themes that emerged from discussions were: viewing/examination conditions; the viewing/assessment process; utility; and, improvements.

Viewing/Examination conditions - This theme relates to the participants’ responses about the environments in which the photographs were assessed including lighting, time of day and type of viewing screen used (examples have the examiner’s identification number appended):

“when I was doing it in work it was just natural light through the window, but at home our computer is on the landing, we don’t have a window there, so that was artificial light”³⁸

“I did mine day and night, on a desk top and it was either with natural light or with just a normal light bulb.”³⁹

“... I used one (desktop) in work and one (laptop) at home so I was using different computers and I didn’t find any difference there”.⁵⁵

and “I did try doing them on my laptop but I felt that... the screen was too small, so I ended up doing it on one with a full size you know”⁶²

Viewing/Assessment process - This theme comprised the participants’ views on their experiences of assessing the intra-oral photographs and the associated demands on the examiners as compared to the visual examination method. The following sub-categories were identified: duration of viewing which consists of time taken to view an intra-oral photograph, time taken to view all the intra-oral photographs of a patient and the total length of time participants spent “sitting” carrying out all the assessments. Some spent whole days on this activity or described it as taking “an awfully long time”⁶¹ but acknowledged that it “got easier towards the end”⁶².

“I think I took longer over the photographs because if I was in doubt at all, I was staring at the photographs
for a long, long time, whereas if you have got a wriggly child you do just, go in, have a quick look you have got your epidemiology head on so you know it’s a quick look, score low and that is what we are used to doing, but when there is a photo on the screen and you think, there might be a shadow there, you can spend a long, long time and you look at it from different angles, you know, so I think the photographs probably took me longer.”

Regarding the mental and physical demands of the viewing process;

“I tried to just do one school per evening, so that’s 30/40 children, well I never really managed 40 and so it was basically an hour and then, I had lost concentration really.”

“I think I tried to limit it actually because I started getting very sharp pains down my side of the neck, so I limited it to about an hour, and then went off and did something else for 10 minutes and then came back at it fresh”.

Then any additional support required such as a scribe;

“I actually used (dental nurse) as a scribe, so I have them (paperwork) and she did as we do in when we are out in the field and that was actually very good. We got through it very quickly then.”

Utility - This category relates to the participants’ views on the utility of the two examination methods. They described advantages and problems of each method. They found it difficult to make decisions about the presence of tooth-coloured restorations and the extent of carious lesions especially when assessing the intra-oral photographs of the permanent dentition.

“Because of my greatest uncertainty when assessing early lesions and tooth colour filled fillings I found it easier to assess the 5-year-olds’ photographs than the older children’s”.

The use of a zoom facility to enlarge the view of the photograph was suggested by one participant as a way to aid caries detection decisions when there is doubt.

“it would be great if you could zoom in, and have a look at the images”.

The rest of the participants however voiced concerns about altered perceptions of the magnified tooth and questioned whether that would be helpful as in their opinions photographs needed to be viewed in a standard way in studies involving multiple examiners.

“I didn’t think that is the right thing to be doing in that situation. Because you are not having a standard examination, you know you are looking at one patient, with it at one magnification and another patient with something completely different so your results are going to be, quite dramatically different…”

The examiners said that the tactile sense derived from touching the teeth with a probe was a valuable aid in detecting caries, restorations, fissure sealants and malformations of enamel or dentine; hypoplastic teeth could be mistaken for caries on a photograph.

“I suppose that you can look, you can move the child, you can move your light, you can move your mirror and it’s what we are used to, that’s more what we are trained in, the photographs are still very new to us, aren’t they so?”

“Not being able to touch it (the tooth) with a probe; that was difficult. I think the ones that were obviously healthy or obviously carious that was quite easy and quite quick but it was the doubtful ones, that was where I was having difficulty and spending a lot of time, and still not resolving it at the end you just wanted to poke them really, didn’t you?”

The examiners reported that saliva and debris on teeth were problematic when assessing the photographs.

“I think they were very good photographs but saliva is still a problem. Saliva definitely yes, It only needs a tiny amount of saliva and the light shines off it doesn’t, and you can’t tell if there is a cavity.”

Despite the drawback of extended viewing experienced by some examiners, being able to look at an intra-oral photograph of a tooth on a screen at any time “examining the subjects from the comfort of your arm chair” without “fighting a tongue, cheek and a wriggly child” was considered advantageous.

This theme also includes the participants’ expressions of further applications for the photographic method in dental epidemiology studies. These were the use of intra-oral photographs for remote training and calibration of examiners in epidemiological skills and in longitudinal caries progression studies.

Improvements - This theme sums up the participants’ views on how the intra-oral photographs examination method could be improved to enhance its usefulness. The main improvement they suggested for the photographic method was the use of more efficient means of moisture and debris removal such as compressed air instead of cotton wool prior to taking the intra-oral photographs.

“... yes, dry with air, if you were just doing photographs then you might be able to get a better views ... definitely yes, dry with air”.

Also more training on assessing intra-oral photographs for caries was requested by the group

“we are trained to look at the teeth and score them in a clinical situation, but I think, to have a training exercise looking at the photograph and as we do to be able to discuss with other people because it is slightly different and to get your head round this scoring ... on photographs I think you do need a bit more training about that”.

Discussion

The study explored the views of a number of experienced examiners trained and calibrated in the visual examination method developed by BASCD for use in the UK NHS dental epidemiology program on their experiences of assessing intra-oral photographs as a means of detecting caries as compared to the BASCD developed visual method. The main findings of the study are that the time taken by examiners to assess intra-oral photographs becomes extended when compared to performing a visual examination. The ability to assess intra-oral photographs on a screen at a convenient time and place was considered advantageous. The examiners found it easier to make caries detection decisions on intra-oral photographs of primary teeth than permanent teeth.

In common with other qualitative research, a limitation of this study is that in its pursuance of an in-depth understanding of the subject under investigation, a small number of participants who may not be representative
of all examiners were engaged in the study. This makes it less easy to generalise the findings from the study to the population (Allen et al., 2010). However the purpose of this method of enquiry is to uncover all the issues pertinent to the subject matter not their prevalence or frequency distribution (Green and Thorogood, 2009).

As experienced examiners in the visual examination method, the participants acknowledged and expressed the need for and requested further training in the assessment of intra-oral photographs as a means of detecting caries. This is similar to the finding by Assaf et al., (2006) that although the use of new methodology may be possible in epidemiological surveys, strategies to improve training in diagnosis and calibration of examiners are necessary. The use of photographs enables such calibrations to be undertaken with ease. A standard portfolio of photographs can be prepared and presented to examiners for such purposes. It is also possible for this calibration to be undertaken online, with real time responses to decisions and immediate feedback. Such calibration can be undertaken at the examiners’ convenience and does not require access to schools or children. The use of a standardised validated and calibration set of photographs that can be used across multiple examiners, in multiple sites over multiple years is advantageous.

The examiners’ familiarity with the visual examination method could explain why most of them reported spending less time making a diagnosis during the visual examination method while the photographic method took time to get used to. This is because in the examiners’ experiences the whole mouth is in sight and can be viewed as part of the person during the visual examination. Also the child being examined as well as any equipment and the instruments e.g. light source and hand mirror can be repositioned to aid the examiner. All these options were not available to the examiners in the photographic method. The ability of those collecting data to be able to view the teeth and mouth as an extension of the person and their environment as part of the diagnosis decision making process however could be a potential source of bias in epidemiology studies evaluating oral health interventions (Milsom and Mitropoulos, 1990).

The participants reported that sitting for an extended time in front of a computer screen, interpreting photographs, made physical and mental demands on them. The participants expressed that they experienced tiredness, physical strains and loss of concentration. Physical symptoms included sharp pains down the side of the neck, dry eyes, eye strain and wrist strain. As in studies of those working with visual display units (Korhonen et al., 2003) has shown, these factors made it more difficult to make a diagnosis. The examiners however had ways of overcoming these difficulties that included working for shorter periods, taking breaks away from the computer and “coming at it fresh”. A way around this is to standardise the process by ensuring time limited viewing of images and the standardisation of the size and resolution of images. There is however no consensus in the literature currently, whether the photographs of teeth should be viewed as life sized or magnified.

The examiners described how they spent time deliberating over the interpretation and scoring of questionable carious lesions. While some examiners saw the ability to view the intra-oral photographs again at a later time as an opportunity to affirm their diagnosis (an opportunity not available with the visual examination method) others felt it extended the time for indecision. This could be mitigated by time limited access to photographs (Langer et al., 2006).

The accompanying paperwork for recording diagnostic decisions was seen by the examiners as exacerbating the duration for viewing photographs and they felt this could be reduced by preparing the paperwork prior to the photographic assessments and the use of a scribe as occurs when undertaking the visual examination method. This may reduce the potential cost savings of using the photographic method. Alternatively an electronic on screen recording system synchronised to the images could be developed.

The examiners reported experiencing more difficulty interpreting and scoring photographs of the permanent teeth than those of the primary teeth, similar to the findings in other studies. Costa et al. (2007) found that diagnostic methods for occlusal caries were more efficient in primary teeth than permanent teeth.

The examiners also expressed experiencing problems associated with identifying the presence of tooth coloured restorations, clear fissure sealants and non-carious lesions and attributed this to the lack of tactile sensation. Bader et al. (2001) found no evidence to suggest the superiority of tactile methods. Factors which obscured the tooth surface such as saliva, food debris, plaque and stains were problematic. Some of these factors can be more easily eradicated in the visual examination method; however any moisture or debris that remains on the tooth when the intra-oral photograph is captured is in effect a permanent obstruction which will always impair caries detection from that image. Moisture control in children can however be challenging (Tran and Messer, 2003) and even more so when obtaining intra-oral photographs. In the view of the examiners, using more efficient means of moisture control such as compressed air when obtaining intra-oral photographs rather than using cotton wool rolls as stipulated for use in the visual examination method developed by BASCD will improve their utility. The use of a camera with an inbuilt drying nozzle could also assist.

The use of the photographic method could support epidemiological surveys as part of the training, calibration and data collection processes. It allows multiple examiners to inspect a tooth without the difficulties often encountered when a child experiences multiple examinations. Participants identified that this feature will lend itself to e-learning training and calibrating examiners in caries epidemiology skills remotely or by convening.

Examination of archived intra-oral photographs in a longitudinal study of caries progression was identified as more likely to allow accurate and reliable comparisons than the comparisons of visual and written records.

As the debate continues about the level at which caries should be recorded in dental epidemiology surveys there is increasing support for the use of intra-oral photographs in this field (Ellfrink et al., 2009). The examiners in this study were optimistic about the possible use of the photographic method for remote training and calibration of examiners in epidemiological skills with improved utility.
Conclusion

The views of examiners in this study suggest that to improve the utility of photographic method, further research is needed to determine adequate drying methods for use in the field. Consideration should be given to a time-limited, standardised presentation of the photographs including the size and resolution. Specific training on caries detection from photographs is also required.

References