# The cost and value of different forms of information on oral health status and risk given to patients following a check-up in dental practice

NIHR HSDR Project Number 13/33/45

## Protocol

## Background

Currently there is no information about the most effective way to communicate information to patients following a dental check up. Important information to be communicated at the check-up is 1) the condition of the patients' mouth and 2) the likely risk of future disease and 3) what the patient needs to do in terms of self care. Although research has identified a link between effective clinical-patient communication and the adoption of health behaviours by patients (Wanyonyi et al, 2011), there is less research specifically on what ***form*** of information best facilitates this communication in order to form a 'therapeutic alliance'. We particularly do not know whether patients from different socio-economic backgrounds react differently to different forms of information, and how this influences the clinical-patient relationship and the patients' behaviour. This is something which is relevant not just to dental disease, but to a range of chronic conditions. Waldron et al (2011) for example, in a systematic review of effective strategies to communicate cardiovascular risk information to patients, highlight the lack of quality trials that compare different risk presentation formats.

Currently there is an emphasis on paper-based means of communicating risk and other information to patients. Reforms to the NHS dental contract are being piloted in 90 dental practices, with wider implementation anticipated in the next few years. The dental check-up forms a crucial part of this new model of care with all pilot practices patients with being given paper copies presenting their risk and oral health status as a traffic light (Red=High risk/need etc). This, however, is at odds with the government's ambition of a paperless NHS by 2018. Moreover, the Department of Health (2012) strategy 'The power of information', recognises the potential of technology 'to make the best use of evidence and support innovative approaches to behaviour change; and a relatively new technology currently exists which would allow the patients' oral health status and risk of disease to be presented as a photograph of their mouth with areas of the mouth at risk of disease highlighted using Quantitative light-fluorescence (QLF). QLF allows visualisation of tooth mineral loss at a stage before it is visible with the naked eye. It also highlights mature plaque which fluoresces red. Wireless technology allows transmission of these images to devices such as mobile phones. Literature reviews in the area conclude that visual displays (e.g. graphics) enhance people's understanding of risk, particularly holding attention when they are given in a vivid way (Rotham & Kiviniemi,1999; Houts et al, 2006). Whilst all patients can benefit when pictures are used, people with low literacy skills are found to be especially likely to benefit (Houts et al, 2006). QLF presentation of oral disease risk is certainly vivid, but a Traffic Light presentation may be simpler – both are alternative forms of giving visual information.

What we do not know is whether using a newer technology to present information to patients at the dental check-up is something which is valued by patients, and merits the additional cost. Whilst technological developments in patient information systems are reported to be transformative in the nature of the interaction between patient and provider, there are

concerns about a possible age-based digital divide (Tang & Lansky, 2005), and that the use of e-health may widen ethnic and socio-economic health inequalities (Hsu et al, 2005). Our research then asks the question: 'What is the cost and value of purely verbal information on oral health and risk of disease, compared to information based on a Traffic Light presentation information or QLF images sent to mobile phones?'

## Aims and Objectives

**Aims:** To describe how patients value and respond to information on their oral health status and risk and to compare the value of three different methods for presenting information on patient's oral health and risk (verbal, paper-based traffic light rating, electronic QLF image)

**Objectives:**

1. To describe what type of information patients' want, need and prefer when having a dental check-up and how they use this information.

2. To describe how patients' interact with three different forms of information

3. To investigate whether and how the clinician/patient relationship is influenced by patients having access to different types of information

4. To measure individuals' preferences, by using the economic preference based valuation methodology Willingness to Pay for each of the three different methods of giving information.

5. To identify differences in preference for different types of information by differing demographic, behavioural and psychographic groups.

6. To use variables from derived established models of the behavioural change process to predict the likelihood that different forms of communication will lead to behaviour change; and to measure any actual behaviour change and link these with differences in valuations

7. To conduct a cost-benefit framework analysis of the three different methods and to explore financial implications for NHS dentistry.

## Research Plan

<u>Overview</u>

The work is divided into two phases: Phase 1 (months 1-12) which has three components which will run concurrently: a) a scoping literature review; b) a qualitative study involving interviews with patients and observation of patient care; and c) piloting of behaviour change and economic measures, and study procedures to be used in the second (experimental) phase. Phase 2 (months 13-24) involves an experimental study undertaken in four NHS dental practices involving patients being given different forms of information. In the final six months we will analyse and report Phase 2 quantitative findings and draw data streams together in final reporting.

Consent, confidentiality and anonymity

All participants in the study will receive a written information sheet relating to their aspect of the study, and a written, signed consent obtained, before their involvement in the study. All participants will be free to decline any further involvement in the study at any point. Records identifying participants will use a system of ID numbers, with no names associated with data. Data related to the views of individual patients will not be divulged to members of the dental team caring for patients, and vice versa.

**Phase 1**

a) Scoping literature review

We will undertake a scoping literature review (Levac et al, 2010) to map the existing literature and summarise findings concerned with how patients value and respond to health information given in different forms. This will be limited to a comparison of different forms of giving personalised feedback about health states or health risks (for example, but not limited to verbal, written, diagrammatic, photographic). Outcome variables of interest will include patients' preferences and economic valuations, objectively verified behavioural change, self-reported behavioural change and potential mediators of change including behavioural intentions and risk perceptions; as well as impacts on patient-carer communication and patient satisfaction. An analytic framework or thematic construction will be used to provide an overview of the breadth of the literature but not a synthesis. A numerical analysis of the extent and nature of studies using tables and charts will be presented. We will approach electronic searching iteratively, in the same way as recent approaches reviewing evidence in the public health sphere, where there is a deliberate use of a purposive sampling of the literature (Pawson et al, 2013; Baxter et al, 2010), rather than a focus on rigid inclusion criteria and exhaustive searching of all available articles. We will include in our review qualitative as well as quantitative studies.

b) Qualitative study The qualitative study will help us to explore our first three objectives:

- To describe what type of information patients' want, need and prefer when having a dental check-up and how they use this information.
- To describe how patients' interact with three different forms of information
- To investigate whether and how the clinician/patient relationship is influenced by patients having access to different types of information

We will also seek to identify what patients' see as personally important negative outcomes from poor dental health in order to provide insights that will help us to develop the most appropriate measures of oral health behaviour to be used in the Phase 2 quantitative study.

Interviews and observations of dental care

A researcher will interview about 30 adult patients (aged 18 years+) and observe dental visits in four NHS dental practices, investigating what type of information patients' want, need and prefer when having dental check-ups and whether they see information from the dentist in radically different ways to practitioners. Patient interviews will take place at the dental practice, away from the surgery itself, whilst the patients attend their dental appointments (interviewing either before, after, or both before and after, the actual care encounter). The researcher will also observe the dental visit itself, and take observation

notes, but will not interfere or contribute to any discussions about care which take place. Field notes will be made during all observations, which will then be annotated immediately after the session to allow an authentic reconstruction of what was witnessed. The researcher may also interview the dentist or another member of the dental team after the clinical visit is finished, to explore some of the observations made. All interviews and some of the surgery conversations between the dental team members and the patients relating to information given at the check-up, will be audio-taped and transcribed for analysis.

We will purposively sample to include different adult groups and explore whether differences exist e.g. by age and socio-economic groups. We will explore barriers to healthy oral self-care, and the gains which are perceived to be possible through improvements in their oral health behaviour; looking to identify 'segments', particularly within the population of people at high/medium risk of oral disease, - groups with similar characteristics in terms of identity, lifestyle, opinions, beliefs and behaviours. We anticipate involving about 30 patients in one-to-one interviews/observations, although the actual number itself will be guided by the qualitative research principle of data saturation – may be a few more or a few less depending on emergent findings (Spencer et al, 2003).

Ethnographic study involving a few patients

Ethnography, as Laura Nader puts it (Nader, 2011), is research *with* rather than *on* people. In that sense, it reverses the polarity of much medical research: the patient is the expert in ethnographic research not the researcher or the health care practitioner. It involves spending time with people in order to find out from them how they do things, and getting a 'patient's eye view' of the matter. Medical anthropologists in particular have looked at all manner of healthcare practices around the world from an ethnographic perspective for well over 100 years. In addition to medical anthropology, there is a great deal of work being done in the field of science and technology studies as with, for example, the studies of Anne-Marie Mol, perhaps most famously her The Body Multiple which looked at multiple sclerosis ethnographically (see http://www.dukeupress.edu/The-Body-Multiple/).

The researcher will therefore aim to recruit about 5-10 patients of those interviewed to gather more in-depth information, going with them on a series (say at least two concurrent) visits. The researcher would go to their home, ask them how they organised/were notified/were reminded of their appointment, how they normally prepare ahead, travel with them to the dentist, sit in on the consultation, finishing with the exit discussion/payment at the desk, travel back with the patient afterwards and ask them what they thought about what they were told and given. This would then be done for a follow up visit to see how things develop in the course of their care. Discussion with these patients will involve their thoughts on paying for NHS care, or being exempt from charges, as well as any thoughts they have on changes in NHS dentistry involving a traffic light system of rating patients' risk and need (one of the messages they may receive from consultations, may be that without taking the appropriate action, they won't receive future treatments). This provides the background against which patients' readings of the information they receive will be set, and is highly relevant to studying how they orient to, interpret and act on that information.

Data analysis

Data sources from interviews, observations and ethnographic work will be integrated into a single analysis. Qualitative data analysis will adopt the principles of grounded theory which include a 'constant comparison' method, where interview texts are analysed line by line, provisional themes noted, and are subsequently compared with other transcripts in order to ensure consistency and to identify negative cases (Walker & Florence, 2006). Literature will be consulted as part of an iterative, inductive and interactional process of data collection, simultaneous analysis and emergent interpretation. Conceptual memos will be written alongside coding to document the development of codes, how codes are related to each other, and to existing theory in the area. Emerging perceptions from both the inductive and aggregate coding will be shared at 'data clinics' where project researchers meet to discuss and test emerging themes. Emerging concepts will be further probed and refined in interviews with the next participants to ensure validity of the data or to reject concepts which do not hold to further scrutiny. We will also involve members of the Research Advisory Group and some of the research participants to check the validity of our perceptions. A diary of thoughts and observations will be kept throughout the study and meetings with people involved in the analysis and interpretation of qualitative data, to provide opportunities to be reflexive about how researchers and the process of conducting research has influenced data collection and analysis. The software package NVIVO Version 10.0 will be used to aid indexing and retrieval, analysis and presentation of coding themes.

c) Preparation for Phase 2

Overview of Phase 2

Phase 2 consists of an experimental design using randomisation at the patient level, of different forms of information (verbal information only, traffic light information QLF information) This will take place in four NHS dental practices (two in Salford, and two in Newcastle). By interviewing patients will we collect their Willingness-To-Pay (WTP) for each of these types of information, as well as data on their perceived risk of dental disease and intended and actual behaviour change. Using clinical data (BPE scores measuring gingival health) and data on tooth mineral loss as plaque coverage measured from successive QLF photographs we will also gather information indicating actual changes in oral health behaviours.

Recruitment of practices

The four dental practices will be selected from a list supplied by NHS Area Teams in Salford and Newcastle where the practice involves more than one practitioner (single handed dental practices are unlikely to be able to offer the patient throughput necessary to achieve the target patient recruitment. Practices will be approached to invite them to be involved in the study on the basis of random selection, working down each list until two practices in each area are happy to participate in the study. We will recruit practices to the study which can confirm that their patient throughput of adult High/Medium risk patients is sufficiently high to ensure timely recruitment.

Piloting of methods

In Phase 1, we will undertake a feasibility and pilot testing of methods of collecting the information which will form part of the Phase 2 dataset. Much of this could be gathered using a questionnaire format, although some may be extracted from patient information held on the clinical database, or by asking the patient directly in an interview. The most effective and efficient means of gathering the information will be piloted in Phase 1: Patient age, gender, Index of Multiple Deprivation (derived from postcode), patients' education level, household income level and socio-economic classification based on occupation, frequency of dental attendance, payment for dental care, dental experience of a variety of procedures, experience of dental pain and number of natural teeth remaining, risk perceptions (patient perceptions of the likelihood and potential severity of negative outcomes such as intensive dental treatment, tooth extractions and dental emergencies) and risk-related worry concern and fear; as well as willingness to pay, and intended, reported and objectively verified (with clinical outcome data) behaviour change.

University of Liverpool researchers (funded by HSDR) will train dental nurses in each of the four dental practices involved in the study to collect this formation as well as gather information on WTP according to a script. Piloting will involve taking patients through the WTP exercise and then discussing the process with them, to understand where improvements could be made. It is envisaged around 30 patients will be sufficient for this piloting.

Phase 1 preparation will also involve researchers training dentists to take QLF photographs, and training dental team members in gathering consent for the study. Researchers will also work with dentists in the four practices to develop a protocol to standardise the content of any delivery of preventive messages given during the intervention phase.

**Phase 2: Experimental study in four dental practices**

The quantitative study will help us to address final four objectives:

- To measure individuals' preferences, by using the economic preference based valuation methodology WTP for the three different methods of giving information.
- To identify differences in preference for different types of information by differing demographic, behavioural and psychographic groups.
- To use variables from derived established models of the behavioural change process to predict the likelihood that different forms of communication will lead to behaviour change; and to measure any actual behaviour change and link these with differences in valuations.
- To conduct a cost-benefit framework analysis of the three different methods and to explore financial implications for NHS dentistry.

Participants

The study will involve 400 adult patients (aged 18 years or older), (100 in each of the four dental practices), who have been identified clinically as having high/medium oral health need/ risk of disease. We will use the nationally developed algorithm categorising patients as Red/Amber to define patients who are eligible for inclusion in the study.

Sample size calculation

As the primary outcome in this study is willingness to pay (WTP), this has been used to calculate the sample size. Differences in mean and median WTP values between the three forms of information are therefore the primary driver of sample size. Lancsar & Louviere (2008) highlight the complexities and problems of performing sample size calculations for stated preference surveys such as discrete choice experiments and contingent valuation studies (Lancsar & Louviere, 2008). In particular, the parameters that will be estimated by the CV survey (willingness to pay) must be known in advance in order to conduct a useful sample size calculation – information we do not have in advance of conducting this work. Previous studies however, using CV in health care settings have included samples ranging from less than 50 to over 1000 respondents. Recent CV work in dentistry has also used similar sizes (between 36 and 200 per group), albeit looking at treatments rather than provision of information (Rosvall et al., 2009). So, we believe that a sample size of 400 i.e. 133 in each group will be adequate in this case.

Whilst WTP is the primary outcome measure, and sample size calculation was done on this basis, we have however calculated the implications of this sample size for the detection of secondary (clinical) outcome effects. Thus we have also carried out a sample size calculation using the secondary outcome of plaque percent index (PPI), (measured using QLF). Published data on a group of 38 college students showed a mean PPI of 14.8, with a standard deviation of 7.7 (Aleksejuniene et al., 2006). As this is likely to be a more homogeneous population than in this study, we can use a more conservative estimate of s.d. of 10, to calculate that a sample size of 133 per group would allow us to detect a mean difference of 3.5 in PPI between groups, with 80% power, at the 0.05 significance level.

Randomisation

After patients are recruited to the study, a trained nurse in each practice will the randomise patients to one of three study arms (Verbal information only (n=133); Traffic Light Information (n=133); QLF information (n=133). This will be done using a randomisation schedule for each practice, drawn up by the statistician (Burnside); allocating patients using sequentially numbered envelopes. The envelope will be opened by the dentist at the check-up and procedure followed according to which study arm the patient has been allocated to.

Procedures (*see Flow diagram*)

Before their dental check-up, for patients recruited to the study, trained dental nurses will collect demographic and psycho-graphic information and then elicit information from patients on their hypothetical incremental Willingness to Pay (WTP) for both the Traffic Light and QLF information systems (using Verbal information only as a base line for comparison). The systems will be explained hypothetically using verbal, written and visual information, using a generalised description of that type of information, but without reference to the patients' personal oral health status/risk (***see example WTP script***).

At the beginning of the patients' first check-up appointment (which will include a BPE examination) all patients will have a QLF photograph of their mouth taken, to be used for baseline measurement of plaque coverage and demineralisation status. Patients will then be given their own personal risk information according to the randomisation schedule: either 1) Verbal only information (Model 1) or 2) Verbal information supported by a printed copy of

the patients' oral health and risk of disease displayed as a traffic light (Red, Amber or Green), (Model 2) or 3) Verbal information supported by the QLF photograph taken earlier either downloaded to the patients' mobile phone or electronic device such as a tablet, or given to the patient in the form of a printed photograph. Only patients in the QLF arm will be shown the baseline QLF photograph.

A record of the length of time taken during the check-up appointment to give the information will be made, as will the type of provider of the information (dentist/nurse/hygienist) and individual provider ID. Dental staff giving verbal information will work to a simple protocol to ensure some similarity in the topics covered in giving verbal advice: e.g. oral health status/risk, areas where self-care could be improved in relation to their oral health/risk 1. Tooth-brushing (frequency, technique, length of time); 2. Diet (sugary drinks, sugary foods, acidic drinks/foods).

Following the patients receiving their information, a trained dental nurse will then elicit the patients' Intention to change behaviour, risk perception and other variables related to behaviour change, based on the information received at their check-up and also give patients an opportunity to revise their WTP for the information system they have received.

At the second visit (scheduled 2-3 weeks later), dentists will take another BPE score. A nurse will record any Reported Behaviour Change following the first visit, and a second QLF will be taken for all patients (none of these will be given to patients – they will be used to measure clinical outcomes). At Visit 3 (scheduled 2-3 weeks after visit 2), Reported Behaviour Change data will be collected and a third QLF photograph taken to provide clinical (objectively verified data) on behaviour change.

A researcher will also extract patient data from the clinical database on: frequency of attendance for appointments, failed appointments, as well as clinical data on number of decayed, missing and filled teeth and BPE.

There will be a telephone follow up interview of all 400 patients 6 months and 12 months after Visit 1 to gather further data on behaviour change outcomes (oral health behaviours, stage membership and intention strength risk perception) in order to give a longer term measure of change in behaviour.

Detail on collection of valuation data

i) Collection of WTP information: For initial hypothetical WTP elicitation, the nurse will describe the relevant systems (Traffic Light and QLF) using visual aids and verbal description. Where participants ask for clarification a standard glossary giving more detailed explanation will be used where possible or reasonable explanations will be given by the interviewer (a dental nurse). Following this outline of the scenarios, participants will first be asked which of forms of information is preferred including the current practice of Verbal information only (ranking) and then incremental WTP will be elicited for traffic light and QLF both compared to verbal only (i.e. what extra would some be willing to pay (if at all) to receive either traffic light or QLF over verbal information only) in this face to face setting.

In order to minimise order bias (Carson et al., 2001), participants will be randomised as to the order they value the two forms of information. Each form is valued in turn. The WTP exercise will be prefaced with an explanation of the shuffled payment card method along

with a script (***see example WTP script***) to ensure that patients understood that the exercise is hypothetical but to encourage realistic and budget constrained responses. WTP will be elicited using a shuffled payment card method, in which a range of values are printed on individual cards and presented to the participant one at a time in a random order (Smith, 2006). The participant then decides for each value whether they are willing to pay the amount, unwilling to pay it or unsure, placing the card on a sheet with corresponding areas marked on it. This then leaves a range between the lowest value that the participant is unwilling to pay and the highest value that they are willing to pay. The participant is then asked to name the value between (and including) these values that would be the maximum they would be willing to pay. The decision for each card therefore is similar to a dichotomous choice (as recommended by Arrow and Solow, 1993)), but the whole process finishes with an open ended question. This approach minimises some of the problems associated with using either one of these methods on their own, such as starting point and range bias and making the cognitive task too difficult.

Where participants give a zero value, they will be asked to identify the reason for the zero valuation from a range of options presented verbally and on a card. This will allow zeros to be later classified as true zeros or protest responses.

Once the participant has received their own personal information in the form determined by their arm of the study, participants will be given the opportunity to revise their WTP for the information form experienced (therefore this will not be relevant to those in Model 1 who receive only verbal information and they will not undertake this part of the study). For this re-valuation, participants will be reminded of their initial valuation and then asked in a single open-ended question format if they wish to change the value and what amount they would change to.

ii) Cost data: Cost data will be gathered both prospectively during Phase 2 and using existing routine data sources. Costs will be measured from an NHS perspective and will be calculated, where necessary, using a micro-costing approach. One off costs such as training and non-consumable equipment will be priced directly. For the remaining costs, for a subsample of 10 participants in each practice (40 participants in total) all costs incurred will be recorded. This will include recording of all consumables used and the time spent recording and delivering the oral health risk status. Interviews with relevant staff at the practice (principal dentist or practice manager) will be used to identify overhead and staff costs. As any behaviour change resulting from the risk information systems to be studied may influence future oral health interventions required, it will be necessary to cost these likely interventions too. These will be costed using existing data including published estimates of costs from other research and national fees and tariffs (e.g. NHS (Dental Charges) Amendment Regulations 2008).

Outcome measures

1. Willingness-to-Pay (WTP)

The primary outcome in Phase 2 is the patient valuation of different forms of oral health/risk information. Contingent valuation (in the form of WTP) has been chosen as our measure of value. The principal alternative to this valuation method would be a utility based measure, however no existing oral health related quality of life tools have been successfully mapped to

utility scores (Brennan and Spencer, 2006) and direct utility measures (such as standard gamble or time trade off) are unlikely to be sensitive enough to detect the small changes in utility likely to be observed in oral health (Vernazza et al., 2012).

Another alternative to WTP would be discrete choice experiments (DCE), from which WTP can be derived. However, one of the strengths of a DCE is the ability to incorporate and study a number of attributes defining the studied "good" and in this case only 2 attributes are of interest; the presentation of the information and the value (WTP). A DCE would therefore be over-complicated both from a research design and management point of view, and from a participant point of view. The remaining technique, WTP, has been recommended as the most appropriate valuation tool for oral health (Birch and Ismail, 2002; Vernazza et al., 2012).

2. Risk perception and Behaviour Change

i) The approach

Whilst the focus of the study is valuation of information, a secondary aim is to investigate whether patients' information valuation is linked to their intention to change behaviour and any actual behaviour change.

Feedback on health status can serve two functions; if individuals do not already intend to change unhealthy behaviours it can motivate consideration of change and, once they have decided to change, it provides them with information that allows them to develop and implement specific behaviour change plans. We will therefore use the health action process approach model (HAPA), (Schwarzer, et al 2011) as a basis for collection of behaviour change data. This model is a staged model of health behaviour change that provides descriptions of both pre-intentional and post-intentional self-regulation processes. The HAPA has been successfully applied to a range of health-related behaviours including dental self-care (Schuz, Sniehotta & Schwarzer, 2007). The HAPA categorises individuals into three stages characterised by differing goals and psychological processes; pre-intentional, planning and action stages.

Motivation to change behaviour is stimulated by awareness that current behaviours involve a risk of negative health or social outcomes, that the risk may be avoided or attenuated by behavioural change (Weinstein and Sandman, 1993) and that the individual possesses the capacity to make those changes. Risk perception has two components, the perceived likelihood and severity of negative outcomes. Outcome expectancies refer to the potential for specific behavioural changes to reduce risk. Outcome expectancies also refer to desirable or undesirable non-risk outcomes, such as the anticipated expenditure of time and effort required to make behavioural changes. Self-efficacy refers to individuals' subjective beliefs that they can complete behavioural changes (Bandura, 2000). If low, self-efficacy reduces the likelihood that individuals will decide to change behaviour. According to the HAPA, feedback from dentists to patients should emphasise the risk of negative outcomes contingent on current behaviours, describe specific behaviours that will reduce this risk, and provide specific and achievable plans to implement new behaviours.

ii) Measures of likelihood of behavioural change and mediators

Oral health behaviours: There is no generally recognised measure of oral health behaviour, with individual studies using measures suited to their research questions and population characteristics. Buunk-Werkhoven et al. (2011) provide a comprehensive index of oral health behaviours derived from a Delphi method survey of oral health professionals. From this item set, we will select items based on the outcomes of the qualitative study.

Stage algorithm:The measurement of stage membership will be that used in HAPA-based research on dental health (Schuz, et al 2013 based on Weinstein et al 1993). Patients will be asked to indicate a single item of a set of seven characteristics that describe pre-intentional (e.g., 'I am thinking about engaging in (target behaviour)'), planning (e.g., 'I am planning to (target behaviour)') or post-intentional (motivational (e.g., 'I am currently engaged in (target behaviour)') states.

Intention strength: We will assess intentions to change target behaviours using a categorical yes/no measure (which forms part of the algorithm). Strength of intention is a continuous measure that has been shown to subsume motivational variables such as risk perception and self-efficacy (Gollwitzer & Moskowitz, 1996). We will ask patients to indicate the strength of their intentions to change each of the target behaviours using a seven point Likert scale anchored at the endpoints by the phrases 'none at all' (1) and 'extremely strong' (7).

Risk perception: From the qualitative study, we shall obtain a list of 4-6 perceived negative outcomes of poor oral health (e.g., teeth loss or intensive dental treatment) that are likely to be important to participants. To eliminate the confounding effects of intentions to improve behaviour in future, participants will be asked to make conditional estimates of likelihood, "If you continue to __ the way that you do, what is the likelihood of __ occurring" (van der Velde, van der Pligt & Hooykaas, 1996). Estimates are rated on a seven-point Likert scale anchored by the statements 'completely certain' and 'no chance'. Potential outcome severity is assessed using the question 'How bad would it be if __ were to occur, on a seven-point Likert scale anchored by the statements 'the worst event possible' and 'not at all'. Recent work suggests that risk is experienced in emotional terms (Lowenstein, et al. 2001; Weinstein et al 2007), and that measures that access these emotions often provide better prediction of behaviour than likelihood and severity ratings (Weinstein, et al., 2007). To capture this we will ask participants how worried/concerned/anxious they feel regarding their dental health (Brown, et al., 2013) and how vulnerable they feel to each negative outcome (Weinstein, et al., 2007). Again, seven-point scales anchored by the terms 'not at all' and 'extremely' will be used.

Outcome expectancies: Key outcome expectancies for each behavioural change will be elicited during qualitative work. As advised by Schwarzer, et al (2011), these will be elicited using the question format 'If I engage in __, I expect __ to occur'.

Self-Efficacy: As advised by Schwarzer et al. (2011); task self-efficacy will be assessed using the item format 'I am certain that I can __', coping self-efficacy 'I am certain that I can __, even if it is initially difficult' and 'I am certain that I can __, even it it takes some tries before I can be successful', and recovery self-efficacy 'I am certain that I can resume __ if I start to slide back into my previous behaviour'.

Planning: Action plans that are specific to context and time improve the prediction of behaviour compared to non-specific intentions (Rutter, Steadman & Quine, 2006). Based on

Schwarzer et al. (2011), items will examine whether participants agree that they possess plans that are specific to when, where and how behavioural change will be implemented (e.g., 'I have decided exactly when I will clean my teeth', 'I have decided exactly where I will clean my teeth' and 'I have decided how to brush my teeth').

Action Control: Action control behaviours, self-monitoring, awareness of standards and self-regulatory effort are assessed through self-reported use of these strategies. Schuz et al. (2007) developed an action control measure to assess tooth flossing, which we shall use as a model for our questionnaire. Example items are 'I have consciously monitored myself to make sure that I __' and 'If necessary, I pull myself together so that I __'.

The four sets of variables above will all be measured on a seven point Likert scale anchored by the statements 'Not at all' and 'Absolutely'.

Any staged theory of behavioural change requires different outcome indicators for individuals in different stages. For example, increases in risk perception will be relevant in pre-intenders, but not action control strategies. Stage transitions (e.g. from pre-intention to planning) are also important. We do not make assumptions about the stages that patients are likely to be in, but will use the algorithm to measure stage membership immediately before and after each intervention and at follow-up.

3. Clinical Outcomes

i) Basic Periodontal Examination (BPE) scores

BPE scores are undertaken by dentists as routine in each dental check-up. Dentists will therefore, as routine, collect this data at Visit 1. They will in addition collect BPE scores at Visits 2 and 3. We will use this clinical data as a secondary outcome variable as an objectively measured indicator of behaviour change, concentrating on conversions between codes 1 (bleeding) and 0 (health).

ii) Measurement of early caries lesions using QLF

Formation of a 'normal' carious lesion takes at least six months (Ekanayake & Sheiham, 1987), with measurement of caries incidence using visual examination of teeth therefore only possible as a clinical outcome if follow up is extended over a significant time period. With the naked eye it is difficult to detect mineral loss in a short follow up period time because decay has to be fairly well advanced (at least 15% of mineral lost) before it can be seen by eye, usually as a white spot on the tooth. QLF extends detection of tooth mineral loss from 15% down to 0%. Thus demineralisation and remineralisation is detected in a matter of weeks. Brochner et al (2011) show significant regression of white spot lesions in four-weeks in patients where post orthodontic white spots were treated with preventive agents. Many other studies report similar findings. QLF thus provides an alternative, timely and more sensitive method for detection and measurement of early caries lesions than visual methods (De Josselin de Jong, 1995). As teeth demineralise there is a loss of fluorescence due to the increase in tooth porosity which in turn leads to a decrease in the refractive index of the carious lesion. Software allows changes in fluorescence of dental enamel to be quantified into mineral content. Detecting early caries is important because this gives an early indication of the likelihood of developing larger lesions, but at a stage where preventive

behaviour can still lead to tooth remineralisation. Because QLF allows both mineral loss and gain to be quantified it is particularly useful for measuring early impacts of preventive interventions. Presence or absence of lesions will be scored on a per-surface base in each patient, using 3 photographs of buccal/labial tooth surfaces (one anterior image and right/left posterior images), producing data on percentage of surfaces affected for each patient. Data will also be recorded on severity where lesions are present, with $\Delta Q$ denoting the product of the fluorescence loss and area over the demineralised lesion.

iii) Measurement of plaque using QLF

In addition to being able to quantify mineral loss and gain, QLF technology has been used to quantify regions of mature dental plaque accumulation on teeth, due to fluorescent porphyrins within bacteria which fluoresce red, with different intensities depending on the amount and maturity of plaque present related to porpyhrin concentration. Presence of red fluorescent indicates that plaque has been present for 48 hours or more, and is therefore a useful indicator of longer term tooth-brushing behaviour than that related just to the day of the oral examination. Computer based plaque analysis have been shown to be more reliable, precise, objective and sensitive (Pretty et al, 2005). Plaque Percent Index (PPI) data gathered from QLF photographs permit plaque assessment on an interval scale and shows excellent reliability when repeated measurements of the same image are analysed (Pretty et al, 2005). The tooth surface area of red auto-fluorescence of dental plaque will also be measured.

Phase 2 Analysis

WTP

We will compare hypothetical Willingness to Pay for each of the information systems across the whole sample (primary outcome) across the 3 arms. We will also compare hypothetical WTP with WTP for a good that has been “consumed” by comparing WTP before and after receiving the information. WTP data will be analysed both descriptively, comparatively and econometrically. Descriptive data analysis will consist of WTP value means with standard deviations along with medians and quartiles for each information system. The WTP values for each system will be compared using appropriate comparative tests (e.g. most likely to be Mann Whitney U tests given the likely distribution).

In order to understand fully how the dental and demographic factors influenced values (WTP), econometric regression analyses will be carried out. A regression model of individual co-variates on WTP will be specified. The regression method will be dependent on the data but is likely to be either OLS or Tobit regression analyses. Tobit models have been recommended for analysis of WTP data because of the censoring of the data at zero (Halstead et al., 1991). The Ramsey RESET test will be used to test for model specification. Individual Tobit models will be constructed for each information system.

Finally, hypothetical WTP data for each information form will be compared to WTP following experience again using the most appropriate comparative tests.

Probable hypothesis tests to be used to compare WTP for different arms and also at different time points and econometric analysis plans to analyse factors that influence WTP. The Ramsey RESET test (Ramsey, 1969) will be used to test for model misspecification.

The RESET test tests for omitted variables, incorrect functional form and correlation between independent variables and the error term. Sensitivity analysis using alternative regression analysis (e.g. tobit, OLS Interval regression analysis) will be performed to test whether the results are sensitive to model specification.

Behaviour change and mediating variables

Plaque coverage provides an objective measure of tooth cleaning behaviour in the 48 hours preceding the measurement (because QLF images capture the maturity of the plaque), although it is not known whether consistent toothbrushing can be inferred. Plaque scores derived from the QLF analysis will be compared to the self-reported toothcleaning behaviour to assess the correlation between the two methods.

Differential reported behaviour change between the conditions will be assessed by creating a change score from one observation to the next by subtracting baseline scores from follow-up scores and conducting an analysis of mean differences using the baseline score as a covariate (Weinstein, 2007). Unless abnormally distributed, tooth cleaning behaviour will be treated as a continuum. Changes in stage membership between time-points (e.g., progression from pre-intention to planning stages) will be computed and represented numerically; 0 for no change, positive numbers for stage progression (1 for progression of a single stage and 2 for progression two multiple stages) and negative numbers for stage regression. Within stage measures (e.g., risk perceptions or planning scales) will be used as mediating variables, used in a three-stage cross-lagged analysis to predict both stage progress and changes in tooth-cleaning (Weinstein, 2007).

Predicting oral health behaviours will involve the use of Health Action Process Approach variables assessed during visits 1, 2 and 3 to predict later behavioural change. The key task is to eliminate the possibility of reverse causation (that oral health behaviours predict HAPA variables) by using HAPA variables to predict later changes in oral health behaviours. Change is defined by the subtraction of the initial oral health behaviour score, measured at the same time as the HAPA variables, from the later oral health behaviour score. The initial oral health behaviour score is used as a covariate in this analysis. Based on Brown (2010), we will also compute HAPA change scores, using them to predict later changes in oral health behaviour scores. This allows us to understand how changes in HAPA variables caused by the intervention predict later changes in oral health behaviour.

The intervention is performed at the first visit. Thus, the change in HAPA variable scores from visit 1 (V1) to visit 2 (V2) will be used as the primary predictor variable. This will be used to predict changes in oral health behaviour from V2 to V3. We shall also use V1-V2 change scores to predict oral health behaviour changes from V2 to 6-month and 12-month (telephone) follow-ups. Structural equation models will be developed to represent these predictions, testing the predicted model as the model of best fit. Full information maximum likelihood methods (FIML) will be used to account for missing data (Muthén & Muthén, 1998–2010). With sample sizes greater than 250 participants, TLI, RMSEA, and SRMR are recommended. A TLI of .95, RMSEA of .06, and SRMR of .09 are recommended as cutoff values to accept the model as a good fit (Hu & Bentler, 1999).

Comparing clinical outcomes between the three intervention arms

Comparison of QLF outcomes between the three groups will use a repeated measures mixed model approach. These models allow for analysis of multiple measurements within each participant. In this case each QLF outcome will be measured at three time-points. The first time-point is the baseline measurement, and the measurement taken here will be used as a covariate in the final model. The repeated measures approach allows us to analyse both follow-up measures (visits 2 and 3) together, while adjusting for the correlation of repeated measurements within participants. Using a mixed model approach, rather than a repeated measures ANOVA, allows for flexibility in the event of missing data, and can adjust for multiple covariates in the model. If there is a high level of missing data, a multiple imputation approach will be used to assess the robustness of the results. Using all the data which is available, 5 complete case data sets will be imputed, and each analysed in the same way. The results can then be combined, and compared with the analysis excluding missing data, to assess whether this would be likely to change the overall conclusions.

The cost-benefit framework analysis

The valuation data will be most meaningful if compared to costs. Although a cost-benefit analysis would be the ideal way of combining costs and benefits in a meaningful way, a robust cost benefit analysis of oral health risk information would entail modelling changes in disease levels resulting from behaviour change linked to the information given. In turn, it would be important to understand the lifetime (or certainly long term) consequences in terms of costs and benefits of changing disease levels. This would result in a hugely complex model, for which we have very little (and in many areas, no) evidence or data. Such a robust full scale cost-benefit analysis is therefore impossible not possible. We therefore propose to undertake a more limited outline cost-benefit framework analysis.

Thus WTP data will be combined with a cost-benefit framework analysis. The principal outcome of any such analysis would be net benefit or cost in monetary terms (i.e. £). Given that cost-benefit analysis expresses both costs and benefits in commensurate units the decision rule for cost-benefit analysis is therefore relatively simple. If the benefits (measured in £ via WTP) exceed the costs (also measured in £) this represents a gain in welfare and the strategy deemed worthwhile (Drummond et al., 1997). The level of complexity of this analysis will depend on the data available in the literature concerning longer term effects of risk information and oral health behaviour change on oral health. The cost-benefit framework analysis will also give an indication of the likely effect of any sustained behaviour change. Data from the endpoint of the study (12 months) will be used to illustrate the effect of the behaviour change resulting for the different interventions at this time point. Results will be presented as incremental net benefits (net benefits = mean WTP – mean cost of intervention).

## References

Aleksejuniene J, Scheie AA, Holst D (2006). Inter-individual variation in the plaque formation rate of young individuals. *Int J Dent Hygiene* 4; 35–40.

Arrow K, Solow R, Leamer E, Portney P, Radner R, Schuman H (1993). Report of the NOAA Panel on Contingent Valuation. *Federal Register* 58:4601-4614.

Bandura A. (2000). Self-efficacy. In A. E. Kazdin (Ed.), Encyclopedia of psychology. New York: Oxford University Press.

Baxter S, Killoran A, Kelly MP, Goyder E (2010). Synthesizing diverse evidence: the use of primary qualitative data analysis methods and logic models in public health reviews. *Public Health* 124; 99-106.

Birch S, Ismail AI (2002). Patient preferences and the measurement of utilities in the evaluation of dental technologies. Journal of Dental Research 81: 446-450.

Brennan DS, Spencer AJ (2006). Mapping oral health related quality of life to generic health state values. BMC Health Services Research 6.

Brochner A, Chrisensen C, Kristensen B, Tranaeus S, Karlsson L, Sonnesen L, Twetman S. Treatment of post-orthodontic white spot lesions with casein phosphopeptide-stabilised amorphous calcium phosphate. Clin Oral Investig. 2011 Jun;15(3):369-73.

Brown, S.L. (2010). Changes in risk perceptions prospectively predict changes in self-reported speeding. Risk Analysis. 30, 1092-1098.

Brown SL, Nowlan L, Taylor PJ. & Morley AM (2013). Fuzzy Risk Perception: Correlates of 'Fuzzy' and Specific Measures of Outcome Likelihood in Young Drinkers. *Journal of Experimental Psychology: Applied, 19,* 120-129.

Buunk-Werkhoven YAB, Dijkstra A, van der Schans CP. (2011). Determinants of oral hygiene behavior: a study based on the theory of planned behavior. Community Dentistry and Oral Epidemiology, 39, 250–259.

Carson RT, Flores NE, Meade NF (2001). Contingent valuation: Controversies and evidence. Environmental & Resource Economics 19:173-210.

De Josselin de Jong E, Sundström F, Westerling H, Tranaeus S, Ten Bosch JJ, Angmar-Månsson B. (1995). New Method for in vivo Quantification of Changes in Initial Enamel Caries with Laser Fluorescence. Caries Res 1995; 29: 2–7

Department of Health (2012). The power of information. http://informationstrategy.dh.gov.uk/

Drummond MF, O'Brien BJ, Stoddart GL, Torrance GW (1997). Methods for the economic evaluation of health care programmes. 2nd ed. Oxford: Oxford University Press.

Ekanayake LS, Sheiham A (1987). Reducing rates of progression of dental caries in British schoolchildren: a study using bitewing radiographs. Br Dent J 163: 265-269.

Gollwitzer, P.M. & Moskowitz, G.B. (1996). Goal effects on action and cognition. In E.T. Higgins and A.W. Kruglanski, (Eds.), Social psychology: Handbook of basic principles, (pp.361-399), New York: Guilford.

Halstead JM, Lindsay BE, Brown CM (1991). Use of the Tobit-Model in Contingent Valuation : Experimental-Evidence from the Pemigewasset Wilderness Area. Journal of Environmental Management 33:79-89.

Houts PS, Doak CC, Doak LG, Loscalzo MJ (2006). The role of pictures in improving health information: a review of research on attention, comprehension, recall and adherence. *Patient Education and Counselling* 6: 173-190.

Hsu J, Huang J, Kinsman J, Fireman B, Miller R, Selby J, Ortiz E. (2005). Use of e-Health Services between 1999 and 2002: *A Growing Digital Divide Journal of the American Medical Informatics Association* 12; 164-171.

Hu, L., & Bentler, P. M. (1999). Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Structural Equation Modeling, 6, 1–55.

Lancsar E, Louviere J (2008). Conducting discrete choice experiments to inform healthcare decision making: a user's guide. PharmacoEconomics 26:661-677.

Levac D, Colquhoun H, O'Brien KK (2010). Scoping studies: advancing the methodology. *Implementation Science* 5; 69

Loewenstein GF, Weber EU, Hsee CK, Welch N (2001). Risk as feelings. *Psychological Bulletin, 127*, 267-286.

Muthén, L. K., & Muthén, B. O. (1998 –2010). Mplus user's guide (6th ed.). Los Angeles, CA: Muthén & Muthén.

Nader, L. (2011). Ethnography as theory. Journal of Ethnographic Theory 1, 211-219.

Pawson R, Greenhalgh T, Harvey G, Walshe K (2013). Realist review – a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 10; 21-34.

Pretty IA, Edgar WM, Smith PW, Higham SM (2005). Quantification of dental plaque in the research environment. Journal of Dentistry 33, 193-207.

Ramsey, J. (1969). Tests for specification errors in classical linear least squares regression analysis. *Journal of Applied Econometrics*, 4, 29-59.

Rosvall MD, Fields HW, Ziuchkovski J, Rosenstiel SF, Johnston WM (2009). Attractiveness, acceptability, and value of orthodontic appliances. American Journal of Orthodontics and Dentofacial Orthopedics 135.

Rothman AJ & Kiviniemi MT (1999). Treating people with information: an analysis and review of approaches to communicating health risk information. *Journal of National Cancer Monographs* 25; 44-51

Rutter DR, Steadman L. & Quine L (2006). An implementation intentions intervention to increase uptake of mammography. Annals of Behavioral Medicine*, 32*, 127-134.

Schuz B, Sniehotta FF, Schwarzer R (2007). Stage-specific effects of an action control intervention on dental flossing Health Education Research, 22, 332-341.

Schwarzer R, Lippke S, Luszczynska A (2011) Mechanisms of Health Behavior Change in Persons With Chronic Illness or Disability: The Health Action Process Approach (HAPA) Rehabilitation Psychology, 56, 161-170.

Spencer L, Ritchie J, O'Connor W (2003). Analysis: practices, principles and processes. In: *Qualitative research practice*, Ritchie J, Lewis J, editors. London: Sage Publications Ltd.

Tang PC, Lansky D. (2005). The missing link: bridging the patient-provider health information gap. *Health Affairs* 24; 1290-1295.

van der Velde FW, Hooykaas C, van der Pligt J (1996). Conditional versus unconditional risk estimates in models of AIDS-related risk behaviour. Psychology and Health, 12, 87-100

Vernazza C, Heasman P, Gaunt F, Pennington M (2012). How to measure the cost-effectiveness of periodontal treatments. *Periodontology* 60:138-146.

Waldron C, Van der Weijden T, Ludt S, Gallacher J, Elwyn G. (2011). What are effective strategies to communicate cardiovascular risk information to patients? A systematic review. *Patient Education and Counselling* 82; 169-181.

Walker D, Florence M (2006). Grounded theory: an exploration of process and procedure. Qualitative Health Research 16: 547-559.

Wanyonyi KL, Themessl-Hubber M, Humphris G, Freeman R (2011). A systematic review and meta-analysis of face-toface communication of tailored health messages: implications for practice. *Patient Education and Counselling* doi10.1016

Weinstein ND (2007). Misleading tests of health behavior theories. Annals of Behavioral Medicine, 33, 1-10.

Weinstein ND & Sandman PM (1993). Some criteria for evaluating risk messages. Risk Anal 13; 103-114.