

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

Overview

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) Ethnographic study on dental care

This 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.

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 purpose of ethnography is to provide in-depth accounts of people's views and behaviours as well as the significance of the inhabited space of the interaction. It is anticipated that the majority of ethnographic data collected will come from observing dental appointments, which can be considered the 'front-stage' of interaction (Goffman 1959). This recognises that dental staff and patients may behave differently in formal appointments than in other spaces and interactions. For example a dentist may accept a patient's claim to be complying with treatment during an appointment (front-stage), but complain about lack of compliance to colleagues later on (back-stage). Observing either the front-stage or back-stage alone may produce a bias in only examining one part of the interaction. Ethnography provides the means to look at how risk is constructed and negotiated between dentist and patients within dental interactions. Cross-examining accounts with observations of dental professionals' everyday practices allows the discrepancies between what dentists and patients do and what they say to become apparent.

A researcher will observe dental visits in at least four NHS dental practices, investigating the type of information patients currently receive when having dental check-ups and whether they see information from the dentist in radically different ways to practitioners. The researcher will observe the dental visit itself, and take detailed field 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.

Following this, patient interviews will take place away from the surgery itself to examine how patients interpret the information given during dental appointments and discuss the alternative forms of information giving the patient would want, need or prefer to receive. 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. Where possible 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 conducting in-depth one-to-one

interviews with patients, 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).

We plan to continue to observe within the study practices during Phase 2 to investigate how the clinician-patient relationship is influenced by the patients having access to the three different forms of information. In addition to Phase 1 observations within the study practices the researcher will also observe the traffic light system and the QLF technology in other dental settings not taking part in Phase 2. This will ensure there is no contamination with the study practices during Phase 1 but will allow the researcher to observe how the whole dental team react to the technology and traffic light system without the accompanying intervention of experimental study processes.

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). We will collect patients' 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 well as plaque coverage measured from successive QLF photographs, we will also gather information on 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 oral health outcomes; 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. Piloting will involve taking members of the public and patients, including Patient and Public Involvement members of the project team through the WTP exercise and then discussing the process with them, to understand where improvements could be made.

Phase 1 preparation will also involve training dentists and dental team members to take QLF photographs and for clinical staff to interpret these and give information to patients. Dental team members will also receive training in Good Clinical Practice and study procedures such as: gathering consent for the study, undertaking randomisation procedures and completing study records such as recruitment logs etc. A checklist of the main preventive messages given by dentists to patients at the check-up will be produced for use in all three arms of the experimental study.

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. We will include patients with low literacy, but exclude patients who require an interpreter for dental care.

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 (Aleksiejuniene 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 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 and Study Crib sheet*)Visit 1 (V1):

Before their dental check-up, for patients recruited to the study a measure of the patients' literacy (REALM) will be administered by a dental nurse. The following data will then be gathered as self-reports: demographic (age, gender, income, education, employment status); psycho-graphic (previous experience of dental care, self-rated oral health, dental anxiety (MDAS); and oral health behaviours (diet, oral hygiene and smoking).

Information on patients' 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), will be gathered. The systems will be explained hypothetically using written and visual information giving a generalised description of that type of information, but without reference to the patients' personal oral health status/risk. Following an outline of the 3 scenarios, patients will first be asked which of the 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.

WTP will be elicited using a shuffled payment card method, where a range of values are shown to the patient 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. 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 patient will then be 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.

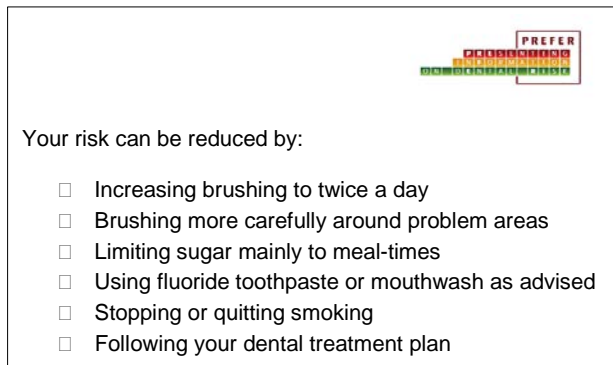
Baseline QLF photographs will then be taken of all patients to measure plaque levels. The patients will then brush their teeth and a second QLF photograph taken to measure tooth mineralisation. At this stage there will be no disclosure of the photograph to patients.


Patients will then have their dental check-up appointment (which will include a BPE examination). The dentist will open the randomisation envelope and 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 photographs taken earlier.

In the QLF arm the dentist will discuss the images with the patient in an electronic form on a Tablet PC. These patients will be offered an e mailed electronic image and/or a printed copy of the most meaningful image (either plaque or mineral loss) in a credit card size. A record will be made if an electronic image is sent. In the Traffic Light arm patients will be given a

credit-card sized information showing their risk level according to colour on the card. In the Verbal only arm patients will receive a plain card with a checklist where the message given by the dentist is written. The reverse of the credit-card sized information from the QLF arm and the Traffic Light arms will have the same checklist (Figure 1):

Figure 1: Checklist of possible preventive messages given to patients





Your risk can be reduced by:

- ☐ Increasing brushing to twice a day
- ☐ Brushing more carefully around problem areas
- ☐ Limiting sugar mainly to meal-times
- ☐ Using fluoride toothpaste or mouthwash as advised
- ☐ Stopping or quitting smoking
- ☐ Following your dental treatment plan

Following the check-up the dentist or nurse will record as data variables:

- The number of natural teeth present
- Whether the patient is exempt or not from NHS charges
- Any messages given as checked against the Figure 1 list
- The Red, Amber or Green risk rating assigned to patients in the Traffic Light arm

Following the dental appointment, all patients 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, patients 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.

Self-report data will then be collected at this point on:

- Intention to behave according to the behaviours listed in Figure 1 before the next appointment
- Behaviour change variables as outlined by the Extended Parallel Process Model (EPPM) (Severity of Threat, Susceptibility of Threat, Self-Efficacy and Response Efficacy). The 'threat' here will be the threat of poor oral health and its consequences identified from Phase 1 (for detail see Measures: 5b Risk (threat) perception). An additional set of items will be added to reflect affect concerned with negative oral health outcomes i.e. '*How would you feel if...*' (in addition to the cognition set reflected in EPPM domains).
- Patient-Clinician communication (Communication Assessment Tool, CAT).

Visit 2 (V2):

At the second visit (scheduled 2-3 weeks later), but before seeing the dentist or other dental team member, self-reported data will be collected on: self-assessed oral health data and oral health behaviours in the areas listed on the message card (given at the first visit) using an item stem of 'Since my last appointment I have..'. This will be followed by questions oral hygiene, diet and smoking behaviours as repeated measures from Visit 1. A set of EPPM items related to perceived susceptibility to risk of negative oral health outcomes will also be repeated.

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 this appointment dentists or other team members will take another BPE score.

Visit 3 (V3): (scheduled 2-3 weeks after visit 2 (V2)), Self-assessed oral health and self-reported behaviour data collected on V2 will be repeated and a third QLF photograph taken to provide clinical (objectively verified data) on behaviour change.

At this appointment dentists or other team members will take another BPE score.

Telephone follow up (F1, F2):

There will be a telephone follow up interview of all 400 patients 6 months and 12 months after V1 to gather further data on behaviour change outcomes (self-assessed oral health and oral health) in order to give a longer term measure of change in behaviour.

Measures

1. Explanatory variables

- a) Patients' characteristics: the following data will be collected at V1

Demographic characteristics

- Socio-economic status measured by area classification: Postcode allocated to IMD quintile
- Whether the patient is exempt from dental charges or not.
- Gender: Male, Female
- Age: in years
- Education: The highest level of education given in 5 categories 1= GCSE or NVQ level 1 or similar, to 5= postgraduate degree.
- Employment status: 1=employed or self-employed full-time, 2=employed or self-employed part-time, 3=unemployed at the moment, 4= full-time education
- Household Income (before deductions e.g. income tax): according to 9 categories given as weekly or yearly amounts, ranging from 1= £0 to 9= over £52,000 per year

Measures of education and income will be according to the Office for National Statistics (2015) standard ways of categorising households according to demographics.

Literacy (V1)

- Patients' literacy (Using the Rapid Estimate of Adult Literacy in Medicine - REALM-R), Bass (2003): collected by a dental nurse using a laminated sheet of the 8 REALM medical words (including 3 practice words, with the American spelling of anemia substituted for the English spelling anaemia).

Dental visiting and previous dental experiences (V1). Four items were taken from the Adult Dental Health Survey, 2009 (Health and Social Care Information Centre, 2011).

- *In general do you go to the dentist for: a regular check-up/an occasional checkup/only when having trouble with my teeth/dentures?*
- *How many times have you been to the dentist in the last five years purely for a checkup?*
- *We would like to know about the types of dental care/treatment that you have received from dentists over the course of your whole life. This includes any care or treatment you may have had as a child (Have you ever had fillings/teeth extracted (taken out)/a dental bridge or a tooth crowned/a root canal treatment/a scale and polish?)*
- We included an additional question on pain experience: *Have you ever experienced dental pain bad enough to make you go to the dentist (tick all that apply): 1=currently in pain, 2=In the last 6 months, 3=6 months to 2 years ago, 4=more than 2 years ago, 5=never).*
- Number of failed appointments in the course of the study (from recruitment log records)

Dental Anxiety (MDAS): (V1). The Modified Dental Anxiety Scale (Humphris, et al, 1995) consists of 5 questions relating to how the patient would feel about various aspects of dental treatment if it were to happen tomorrow. For each item there is a 5 category rating scale, ranging from 'not anxious' to 'extremely anxious'.

Self-assessed oral health: (V1, V2, V3, F1, F2) using one item and a 5 point Likert scale: *Would you say your dental health (mouth, teeth and/or dentures) is:* 1=very good, 2=good, 3=fair, 4=poor, 5=very poor was derived from the Adult Dental Health Survey, 2009 (Health and Social Care Information Centre, 2011).

b) Dentists' characteristics collected at V1

Patient-Clinician communication (Communication Assessment Tool, CAT). This 15 item tool is designed to test the interpersonal and communication skills of clinicians (Makoul, Krupat and Chang, 2007). It has been applied in a range of settings including dentistry (Waylen, Makoul and Albeyatti, 2015), where 'doctor' is replaced by 'dentist'. A five point Likert scale is used (1=poor, 2=fair, 3=good, 4=very good, 5=excellent).

Individual clinician code for the appointment (V1, V2, V3)

2. Valuation data

a) Willingness-to-Pay (WTP) – collected at V1

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).

b) 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).

3. Oral health behaviours – collected at V1, V2, V3, F1, F2

There is no generally recognised measure of oral health behaviour, with individual studies using measures suited to their research questions and population characteristics. We therefore derived our set of measures for a number of sources.

- a) Questions on diet: were adapted from the National Diet and Nutrition Survey (Walker et al, 2000): ‘How often, on average do you eat or drink these things?’ (with response in a seven point scale from more than once a day to never); and the Adult Dental Health Survey, 2009 (Health and Social Care Information Centre, 2011): ‘Do you usually have sugar (not artificial sweetener) in hot drinks like tea and coffee?’.
- b) One question on oral hygiene behaviour was taken from the Adult Dental Health Survey, 2009 (Health and Social Care Information Centre, 2011): ‘How often do you brush your teeth nowadays?’, with responses 1=More than twice a day, 2=Twice a

day, 3=Once a day, 4=Less than once a day, 5=Never. This was supplemented with two items adapted from the Index of Oral Hygiene Behaviour (Buunk-Werkhoven et al, 2011): '*How long do you clean your teeth for nowadays?*' (with responses 1=longer than 3 minutes, 2= 3 minutes, 3= 2 minutes, 4= 1minute, 5= shorter than 1 minute), and '*How often do you do interdental cleaning? (e.g. with floss, interdental brushes, tooth sticks etc).*' with responses 1=At least once a day, 2=At least twice a week, 3=Weekly, 4=Monthly, 5=Never.

- c) Questions on tobacco use were derived from the World Health Organisation (2011) Global Tobacco Surveillance system.

4. Intention to Change Behaviour - collected at V1

We will assess intentions to change target behaviours using a stem question: '*Before my next appointment I intend to..*' using a five point Likert scale 1= Absolutely disagree to 5 = Absolutely agree.

5. Risk perception and behaviour change mediators –collected at V1, V2 (perceived susceptibility to risk)

- a) The approach: the Extended Parallel Process Model (EPPM)

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.

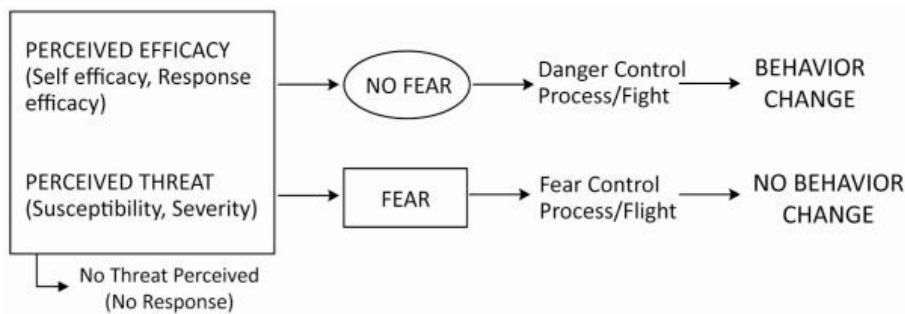
Motivation to change behaviour is stimulated by: awareness that current behaviours involve a risk of negative health or social outcomes and that the risk may be avoided or attenuated by behavioural change (Weinstein and Sandman, 1993), together with an awareness that an individual possesses the capacity to make those changes. 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 of risk (Weinstein, et al., 2007). We will therefore use the Extended Parallel Process Model (EPPM) as a basis for collection of behaviour change data (Figure 2) since it incorporates both cognitive and emotional variables related to behaviour change (Witte, 1992; 1994; 1996). The EPPM takes a dual process approach to explain how individuals respond to fear-inducing messages. The EPPM has been used extensively in health promotion campaigns which aim to encourage people to adopt healthy behaviours, including dental preventive care (e.g. Askelson, et al, 2014).

The EPPM model is based on the concept of "fight or flight." A person is likely to "flee" if the threat is great and there is little hope for the person to overcome the obstacle. The "flight" response is in reply to the fear a person feels. A person will more likely "fight" if the person believes the challenge is important enough and the person has the ability to win. EPPM purports that when someone is faced with a health problem, such as tooth decay, he or she may: a) sense no threat and do nothing; b) become fearful and ignore the health problem; or c) begin a danger control process that allows them to accept the challenge and take action.

According to the EPPM, perceived threat has two components: perceived threat susceptibility and perceived threat severity. The EPPM also incorporates both response

efficacy and self-efficacy. Self-efficacy refers to individuals' subjective beliefs that they can complete behavioural changes (Bandura, 2000). Response efficacy relates to the person's belief about how effective the recommended behavioural change will be to reduce the threat. If low, self-efficacy and/or response-efficacy reduce the likelihood that individuals will decide to change behaviour.

Figure 2: Extended Parallel Process Model



If the perceived threat is low, the message will be ignored, efficacy will not be considered and no further action will be taken. However if the perceived threat is high the individual will follow one of two pathways, 'danger control processes or fear control processes' (Witte et al., 2001). If perceived threat and efficacy are both high the individual will follow the danger control pathway and focus on dealing with and solving the problems posed by the threat (Gore, 2005). If perceived threat is high but efficacy is low the individual will follow the fear control pathway. This involved maladaptive coping strategies such as denial, reactance or avoidance (Witte, 1992; 1994; Gore, 2005)

b) Risk (threat) perception:

From the qualitative study, we identified 5 perceived possible negative outcomes of poor oral health likely to be important to participants.

1=*If your teeth were to make you feel uncomfortable when smiling, talking and laughing in front of people*

2=*If people thought you had failed to look after your own teeth*

3=*If your teeth were to become more painful and sensitive*

4=*If you were to need treatment which meant spending more time at the dentist*

5=*If you were to need treatment which you could not afford*

Threat susceptibility: To eliminate the confounding effects of intentions to improve behaviour in future, participants will be asked to make conditional estimates of likelihood, "If you do not

follow the dentist's advice, how likely is it that.. [negative outcome..] Estimates are rated on a five-point Likert scale ranging from 1=absolutely unlikely to 5 absolutely likely.

Threat severity: Potential outcome severity is assessed using the question '*How serious would it be to you if [negative outcome] were to occur*', on a five-point Likert scale ranging from 1=not at all serious to 5=absolutely serious.

Self efficacy: will be assessed using a stem question of '*Please consider how confident you are that you can perform the behaviour properly, regularly and on a long term basis*' for each of the 6 target behaviours, using a 5 point Likert response scale from 1=not at all confident to 5=absolutely confident.

Response efficacy: will be assessed using the item format '{target behaviour] *means I am less likely to have dental problems*, using a 5 point Likert response scale from 1=Absolutely disagree to 5=Absolutely agree.

Affect regarding threat: To capture this we will ask participants how they would feel if they experienced each negative outcome (Brown, et al., 2013). and how vulnerable they feel to each negative outcome (Weinstein, et al., 2007). Again, five-point scales ranging from 1='not bad' at all to 5='absolutely bad' will be used.

Message Fear: Message fear will be assessed using the item format, '*how much did the advice you received make you feel... frightened/tense/nervous/anxious/uncomfortable*' using a five point Likert scale anchored with the statements 'not at all' and 'very much'

Fear control responses:

Defensive Avoidance: Defensive avoidance will be assessed using the item format: e.g. '*I prefer not to think about the advice given to me by the dentist*' using a five point Likert scale anchored with the statements 'strongly disagree=1' and 'strongly agree=5'

Perceived Manipulation: Perceived manipulation will be assessed using the item format, '*The advice given to me by the dentist is untrue or manipulated*' using a five point Likert scale anchored with the statements 'strongly disagree=1' and 'strongly agree=5'

Message Derogation: Message derogation will be assessed using the item format: '*The advice given to me by the dentist is exaggerated*' and '*I do not personally believe the advice given to me by the dentist*' using a five point Likert scale anchored with the statements 'strongly disagree=1' and 'strongly agree=5'

Danger control response: This will be assessed using three items, with a stem '*How likely it will be before your next appointment that you will: 'follow the advice given by the dentist completely', follow some of the advice given by the dentist and; talk to someone about the advice the dentist gave you*'. Responses will be in a 5 point Likert scale from 1=absolutely unlikely to 5=absolutely likely

6. Clinical Outcomes

i) Basic Periodontal Examination (BPE) scores (V1, V2, V3)

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 (V1, V2, V3)

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 ΔQ denoting the product of the fluorescence loss and area over the demineralised lesion.

iii) Measurement of plaque using QLF (V1,V2,V3)

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-variables 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..

Predicting oral health behaviours will involve the use of EPPM variables assessed during V1, and partly at V2 to predict later behavioural change.

The intervention is performed at the first visit. Thus, the change in EPPM scores (susceptibility to risk) from V1 to 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 (V2 and V3) 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).

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