

1. Full title of project: Evaluation of the impact of changing provider remuneration on the technical efficiency and quality of care provided by NHS dentists in Northern Ireland

2. Summary of Research

This proposal is for a follow on study from HS&DR Project: 11/1025/04 – ‘Determining the optimal model for role-substitution in NHS dental services in the UK’. Project: 11/1025/04 compares the technical efficiency of different models of skill-mix for delivering dental services in different remuneration systems within the UK. Policy makers in Northern Ireland (NI) want to change the NHS dental service system of remuneration from fee for service (FFS) to a capitation-based payment system. The main reasons behind this policy change are to contain costs, promote prevention rather than treatment of disease and improve the quality of care provided to patients. This policy change provides a golden opportunity to build on the findings of Project: 11/1025/04 by undertaking a broader-based study to investigate the impact of a change in the remuneration system on productivity and the quality of care provided.

Negotiations between the Department of Health, Social Services and Public Safety (DHSSPS) in Northern Ireland and the British Dental Association (BDA), the organisation representing the interests of dentists in Northern Ireland, have fixed the timetable for the evaluation and the number of practices that will be involved. These negotiations ensure that the capitation dentists’ remuneration will be based on the same total remuneration as under the previous year’s FFS contract. This proposed study provides an opportunity to expand and add academic rigour to the simple, internal evaluation that was originally envisaged by the DHSSPS and the Northern Ireland Health and Social Care Board (NIHSCB). It will also inform the English pilots, due to their lack of detailed information at a patient level. The NIHSCB will recruit 5 test practices to an initial pilot. This pilot activity will be undertaken before the start of this proposed project, although activity data will be available retrospectively. The outcomes of the pilot could influence the design of the capitation contract that we will evaluate.

The aim of the proposed research is to evaluate the impact of a change in the system of provider remuneration on the productivity, quality of care and health outcomes of dental services. The study uses a randomised controlled trial design allied to qualitative methods and is divided into three workstreams (WS1-WS3).

WS1: This will collect activity data from 15 test practices and 15 control practices involved in the study, using the existing systems used to collect activity data and pay dentists managed by the Business Service Organisation (BSO – see <http://www.hscbusiness.hscni.net>) of the NIHSCB. The 30 practices in the study will be randomly allocated to test and control groups. All practices will start the study providing dental care under the existing FFS contract, the test practices will convert to a capitation contract for a 12-month period and then will revert back to FFS. The control practices will provide care under the existing FFS contract for the duration of the study. The same activity and payment data will be collected in both test and control practices in each of the 3 phases of the study:

Phase 1 - 12-month base line period prior to introduction of the new capitation contract in the test practices;

Phase 2 - 12-month capitation period for the test practices;

Phase 3 - 12-month period following reversion of the test practices back to FFS.

The following outcome measures will be used:

- Productivity – the quantity of care delivered per provider;
- Change in service mix – changes in the profile of treatments provided (the volume of commonly provided treatments undertaken by the practice);
- Change in co-payment income (NHS dentistry in NI recovers some 20% of its budget from patient charges);
- Change in number or mix of patients.

These measures will be assessed in different patient population sub-groups; gender, age groups and socio-economic status (based on means-tested eligibility/exemption from patient charges).

WS2: This will use the qualitative paradigm to examine the perceptions of both dentists and patients towards the quality of care provided under both systems, and for dentists the influence of the change in the system of remuneration on their behaviour. We will recruit approximately 60 patients and 60 dentists from both test and control practices and use semi-structured telephone interviews to obtain their views in each of the three phases of the study.

WS3: This involves the distribution of a questionnaire to patients through the post on a serial cross-sectional basis, at:

- baseline;
- at the end of the capitation period;
- at the end of the 12 month period following reintroduction of FFS.

The same patients will not be surveyed at each phase. We will use a quota sampling approach and aim to obtain 2,000 responses in each phase; 1,000 in test and 1,000 in control practices. Collecting patient health outcomes from clinical examinations would be unjustifiably expensive. Also, the policy-maker determined start date for the change in contract means that logistically it would be very difficult to organise collection of baseline data within this timescale and the intervention period of 12 months is too short for changes in traditional clinical outcomes to be observed. Caries prevention trials usually require a sample size of >1,000 and a 3-year follow up period. Instead we will use patient rated and patient reported measures of:

- Oral health status;
- Oral health knowledge, attitudes and behaviour;
- Quality of care provided.

These outcomes will be compared between test and control practices and in different population sub-groups, by gender, age and socio-economic status.

3. Background and Rationale

In 2013 our team published a Cochrane Effective Practice and Organisation of Care Group (EPOC) review on the effects of different methods of remuneration on the behaviour of primary care dentists (Brocklehurst *et al.*, 2012). The aim of this review was to evaluate the effects of different methods of remuneration on the level and mix of activities provided by primary care dentists and the impact this has on patient outcomes. We concluded *“Financial incentives within remuneration systems may produce changes to clinical activity undertaken by primary care dentists. However, the number of included studies is limited and the quality of the evidence from the two included studies was low/very low for all outcomes. Further experimental research in this area is highly recommended given the potential impact of financial incentives on clinical activity, and particular attention should be paid to the impact this has on patient outcomes”*. In medicine, a review of reviews found serious methodological limitations have again limited the completeness and generalisability of the evidence about changing remuneration systems (Flodgren *et al.*, 2011). There was also insufficient evidence to determine the effect of financial incentives on the quality of health care provided (Scott *et al.*, 2011).

As the dental pilots in NI will switch from FFS remuneration to capitation and then back to FFS, it will provide a unique opportunity to observe and document the scale of effect, issues around implementation and record any unintended consequences of the two changes in remuneration (FFS to capitation, capitation to FFS). The evidence from the literature would suggest that practitioners respond very quickly to changes in the dental contract, to ensure the viability of their practices (Coventry *et al.*, 1989). Changes to the NHS dental contract in England in 2006, saw an immediate drop in clinical activity that reduced profit margins for the practice and an increase in clinical activity in areas where profit margins could be improved (NIHR SDO, 2007).

Although the dental pilots in England presented an ideal opportunity to address the issues raised by the EPOC review, hypotheses formulated a priori have not been tested and the findings reported have been mainly descriptive in nature (NHS dental contract pilots, 2014). The evaluation of an oral health assessment, which forms the cornerstone of the new approach was limited to professional and social acceptability. The ability of the associated

risk algorithms to correctly classify patients and predict future disease was not tested, only a count of the number of additional appointments being made for those considered to be at most risk (NHS dental contract pilots, 2014 Section 7). During the evaluation, changes were made to the data being collected, amidst concerns about the quality of the information being generated (NHS dental contract pilots, 2014 Section 5). Only a small sample (n=10) of the 70 pilot practices were subsequently chosen to record this data (NHS dental contract pilots, 2014 Section 8). This makes conclusions about the impact of the English pilots difficult to infer and highlights the importance of stating hypotheses *a priori*, collecting data at an individual tooth level and conducting research that is experimental in design.

The proposed study will also add to the knowledge provided by our current study (NIHR HS&DR Project: 11/1025/04), which addresses different ways of delivering care based on different inputs (skill-mix) by providing complementary information on how care delivery changes according to different provider payment methods. Together these two studies will make a significant contribution to the literature and produce valuable information for UK and EU policy makers at a time when there is the intention in many countries to explore different ways of providing care through the use of different skill-mixes and payment methods (MUNRO, 2014).

4. Evidence explaining why this research is needed now

Over the past 40 years we have witnessed significant improvements in mean levels of oral health in the population (ADHS, 2012). However, there is an enduring problem of persistently high levels of oral disease in marginalised populations (Milsom *et al.*, 2009). Within the last 10 years access to NHS dental services has been a significant political issue and a priority for NHS services across the UK (Tickle, 2012). Recent changes made by the General Dental Council, the UK dental regulator, have opened up the dental workforce market, providing greater opportunities to improve the efficiency of service delivery by changing skill-mix (GDC, 2013). Against all of these changes there are the imperatives to contain the costs of NHS care, improve the quality of care and broaden the population coverage of care to reach marginalised groups (Brocklehurst *et al.*, 2011).

Very little research has examined the impact of changing remuneration systems or co-payments on health inequalities, including access to services. As with general health, oral health follows a social gradient, with the poorest experiencing the majority of the disease (Tickle *et al.*, 2000). However, prevention and treatment of oral diseases is determined by an individuals' ability to pay for services (Leake & Birch, 2008). As a result, access to services tends to be greatest in those groups with fewest needs (Hart, 1971; Tchicaya & Lorentz, 2014). Public funding of health and social care provides a means of overcoming the divergence between the ability to pay for care and need for care and offers the opportunity for improving both efficiency (increasing health gains produced from available healthcare resources) and equity (removing barriers to access to services associated with individuals' income or wealth). In an evaluation of the previous contract reform in England, Birch (co-applicant) & Whittaker found that the dental reforms impacted on access (Whittaker & Birch, 2012).

FFS remunerations systems incentivise treatment volume rather than preventive care (Brocklehurst *et al.*, 2013; Tickle *et al.*, 2011; Grytten, 2005) and are unsuited to the current profile of health care need in the UK population. The current England & Wales dental contracts introduced in 2006 have been widely criticised (HCHSC, 2007). As a result, NI policy-makers are eager to 'pilot' a capitation-based new dental contract. They want to work closely with an independent academic team to rigorously evaluate the impact of the proposed change in policy on the delivery of dental care. The changes in NI provide a unique opportunity to undertake a methodologically rigorous and affordable evaluation of the impact of a change in remuneration system on productivity and quality of care. Exploring the unintended consequences of changes to the remuneration system and co-payments within this programme of research will inform the dental literature and the wider policy context for health and social care. The NI pilots also represent a "pure" fee-for-service system, unlike the English banded system. As such, the research will examine the impact of a change in a system that is widely used in other health care markets. The banded system used by the NHS dental contract in England and Wales has particular idiosyncrasies (NIHR SDO, 2007), which

is unlike other fee-for-service systems and so limits the ability to extrapolate to non-dental health care markets. In addition, it is difficult to determine which element is incentivising what behaviour in a blended contract. This makes the external validity of the proposed study attractive as a case study for medicine and allied health professionals more generally.

The research outputs are also highly relevant for health and social care in England. The King's Fund report (2014) on the future of health and social care has highlighted the fundamental differences in the way in which health services and social care services have been delivered and paid for. It suggests that this has not kept pace with years of social, technological and demographic change, nor changing patterns in the pattern and burden of disease. The report highlights the need for a single health and social care system with a ring-fenced budget. It has also introduced the idea of a broader application of co-payments and supports the underlying principle of a partnership approach in which costs are shared between the individual and the state. However, the potential impact on population behaviour is unknown.

Co-payments have been a fundamental component of the NHS dental contract since the 1950s. An important finding from the concurrent NIHR study into quality, found that "value for money" was an important concept for many patients (NIHR PDG, 2013). Manning *et al.*, (1986) found that dental service use increased as co-payments decreased in a randomised trial of alternative insurance plans, whilst Parkin & Yule (1988) found a negative relationship between price and dental care use in Scotland. Studying the impact of potential changes to the co-payment system is an important part of the proposed programme of research. This will inform both future dental contracts within the NHS and the possibility of introduction of co-payments to other parts of the health and social care system.

5. Aims and objectives

The aim of the proposed research is to evaluate the impact of a change in the system of provider remuneration on the productivity, quality of care and health outcomes of dental services.

Objectives:

1. To measure changes in activity and costs over the different phases of the study in terms of:
 - Productivity as measured by the mean quantity of care delivered per provider;
 - Service mix as measured by the proportions of key indicator treatments, these include: examination plus scale and polish, radiographs, fillings, root canal therapy, crown and bridgework;
 - Dentists' time spent delivering patient care;
 - Co-payment income.
2. To assess dentists' and patients' views about how, why and to what extent the changes in remuneration affect the delivery and quality of care.
3. To measure changes in patient reported oral health knowledge, attitudes and behaviour.
4. To measure changes in patient rated oral health outcomes and quality of care.

We intend to compare measurements across different patient sub-groups by age, gender and socio-economic status.

The proposed research will investigate the effects of changing from a retrospective to a prospective and then back to a retrospective remuneration system on the productivity, the quality of care and patient reported health outcomes within a fixed cost envelope. This approach contrasts with existing studies (Clarkson *et al.*, 2008) which have tended to be based on paying more for prevention, as opposed to paying the same but changing the incentive structure of the total payment budget. It will also identify the impact on revenue derived from co-payments and collect the views and attitudes of dentists to the change in the system, which will inform interpretation of observed changes in activity, service mix and dentist time. A "difference in difference" design will be adopted i.e. recording the change in

outcomes before and after a remuneration change compared to a change in outcomes among control practices (Hutchinson *et al.*, 1996).

The study will also provide information on the impact of the change in remuneration system on self-reported health, knowledge, attitudes and behaviour to assess the effects of preventive care provided. We will also compare patient-rated measures of quality of care provided under both remuneration systems. Working in parallel with another NIHR grant being undertaken by the same research team (NIHR PDG, 2013), changes to the quality of care being provided will be explored and assessed in this research programme. The measures of quality used in the programme will be informed by a data driven approach to ensure all the relevant domains from the literature and from patients are being included (<http://www.dentalqualityresearch.org>). This will determine whether changing incentives for providers and patients in the context of a model of population based 'purchasing' of services subject to hard budget constraints, will impact on the quality of care provided.

6. Research Plan / Methods

6.1 Evidence background

Based on our NIHR SDO work (Tickle *et al.*, 2011; McDonald *et al.*, 2012) and our recently published Cochrane EPOC review (Brocklehurst *et al.*, 2012) on the effects of different methods of remuneration on the behaviour of primary care dentists we know that financial incentives can change dentists' behaviour. Only two studies in the EPOC review were based on experimental methods and met the inclusion criteria of the review; both indicated that financial incentives within remuneration systems could produce changes to clinical activity undertaken by primary care dentists. However, the quality of the evidence from the two studies was rated as low or very low for all outcome measures. We concluded that further high quality studies are required to improve the evidence base for how financial incentives affect the clinical decision making of dentists and the outcomes of the care provided to patients.

In addition to the literature demonstrating positive effects of changes in incentive structures (financial and otherwise) there is a substantial literature derived from a wide range of sectors on the potential for such performance management systems to generate unintended and dysfunctional consequences. Our NIHR SDO study (Tickle *et al.*, 2011; McDonald *et al.*, 2012) clearly demonstrated this problem with regard to dentistry in particular. But more high quality studies with experimental designs and concurrent qualitative investigations are required to understand how unintended consequences can be minimised. This proposed study is important because it adds to our knowledge base about incentives and provides knowledge of broader policy appeal outside of dentistry.

6.2 Design and theoretical/conceptual framework

The overarching philosophy underpinning the approach we have taken is one of Realistic Evaluation. (Pawson & Tilley, 1997). This views policies as 'theories incarnate'. In other words, whenever a policy is implemented, it is testing a theory about change. RCTs describe 'what' happens. Realistic evaluation also looks at 'how' and 'why' things happen. It starts by making explicit the theories about how the policy might work, identifying the mechanisms through which specific outcomes are hypothesised to occur. Whilst the RCT is testing whether a different remuneration system results in change. However, there is a need to understand how and why such change occurs and if change does not occur, why this is the case. In other words there is a need to go beyond a 'black box' understanding of impact to examine the process that occurs once the change in remuneration has been introduced. In addition, realistic evaluation recognises that the same policy can result in different outcomes in different places. It is important, therefore that we collect and analyse data on implementation in a number of contexts, in order to identify the contextual factors which have an impact on policy outcomes. Realistic evaluation complements the RCT approach and will enable us to provide a relatively detailed understanding of the causal origins of changes we observe. It will also allow us to provide insight to others about how changes in remuneration might work, providing generalisable findings (Byng *et al.* 2005).

We will draw on the conceptual framework developed as part of our NIHR SDO-funded study examining incentives in primary care (Tickle *et al.*, 2011; McDonald *et al.*, 2012). This combines relevant insights from a range of disciplines (i.e. economics, psychology and sociology) in relation to financial incentives. It also encompasses proximal and distal influences in relation to attitudes and behaviour change.

Under the current NHS dental contract in Northern Ireland dentists are paid for providing care for children (<18 years old) under a capitation system of remuneration. For this reason all investigations will be confined to adult patients, 18 years and over.

The study will take a mixed methods approach and can be divided into three workstreams (WS1-WS3). The workstreams will all have three distinctive phases of data collection:

- **Phase 1** Baseline – the 12-month period prior to introduction of the new contract when all dentists are on a FFS contract;
- **Phase 2** Capitation – a 12-month period when the test practices are remunerated according to a capitation-based system on a new contract. The new contract implemented in the initial pilot practices will be a simple wholly capitation based service level agreement. According to this agreement dentists will be paid their annual contract value in 12 monthly instalments. The contract value will be based on historical earnings for the calendar year 2013 and contains the dentists personal remuneration plus all staff, estates, materials and consumables costs. For these costs dentists will be required to maintain the dental health of their registered population. The registered population will be defined by the number of patients registered with each dentist during the 2013 calendar year with a plus or minus tolerance of 5%. The contract to be tested in the proposed study may change slightly from these arrangement based on the findings of the pilot, for example some form of weighted payments could be added to the capitation calculations;
- **Phase 3** Reversion – the 12-month period after the test practices revert to a FFS contract.

WS1 will use a randomised controlled trial methodology to compare activity data from test and control practices. Exactly the same data will be collected and provided by the BSO in the form of a monthly downloaded file for all patients seen by each contract holder (dentist) in all test and control practices for each of the 3 phases of the study. The files will enable the team to compare changes in the:

- Productivity as measured by the mean quantity of care delivered per provider;
- Service mix as measured by the proportions of key indicator treatments, these include: examination plus scale and polish, radiographs, fillings, root canal therapy, crown and bridgework these key or index treatments were used to assess change in service mix in our NIHR SDO study (Tickle *et al.*, 2011; McDonald *et al.*, 2012);
- Dentists' time spent delivering patient care;
- Co-payment income.

WS2 will use semi-structured telephone interviews to explore the views of dentists and patients about the care provided and received. In addition to exploring responses to the changes in remuneration more generally, to build a detailed understanding of 'how' and 'why' things are happening we will explore the extent to which differences in local contexts are important for understanding 'what' happens. This will involve:

- Approximately 60 telephone interviews with dentists (40 working in test practices and 20 working in control practices) at each of the three distinct phases (baseline – capitation – reversion) of the study (180 in total). A number of the same dentists will be interviewed at each phase of the study to provide an understanding of how their views change over the duration of the study.
- Approximately 60 telephone interviews with patients (~40 recruited from test practices and ~20 from control practices) at each of the three distinct phases (baseline – capitation – reversion) of the study (180 in total). Again a number of the same patients will be interviewed at each phase of the study to provide an understanding of how their views change as the remuneration system changes. In addition patients leaving and joining practices will also be interviewed during each phase.

A set of open-ended questions will be developed for the semi-structured interviews informed by the PPI group and the outcomes of parallel NIHR Programme Development Grant (NIHR PDG, 2013) examining quality in dental practice for which Tickle is PI.

WS3 will use serial cross-sectional surveys of patients in test and control groups N=1,000 in each group to collect data at each of the three distinct phases (baseline – capitation – reversion) of the study (6,000 in total) on patient rated and patient reported measures of:

- Oral health status;
- Oral health knowledge, attitudes and behaviour;
- Quality of care provided.

Sub-group comparisons will be undertaken to compare responses by gender, age categories, fee paying/non-fee paying patients. The outputs will be triangulated with outputs from WS1 and WS2.

6.3 Sampling

WS1: A number of key parameters in the study have been predetermined by negotiations between the DHSSPS and the BDA, these include:

- selection of the number of practices and therefore the number of patients involved in the evaluation
- implementing the 'capitation contract' in two pilot practices to inform the design of the contract to be implemented in a further 15 test practices
- duration of the intervention including fixed start and finish dates

These decisions have been taken in order to secure engagement of dentists by guaranteeing their income and also to minimise any clinical and financial risks involved in a change in the remuneration system for the DHSSPS and NIHSCB. So, although a randomised control trial design is possible, the sample size in terms of practices and the duration of follow up have been fixed by these external restrictions. The research team will work with the DHSSPS and NIHSCB to develop a letter, which will be sent to all practices in Northern Ireland by the NIHSCB asking for expressions of interest to participate in the capitation evaluation either as an intervention or control practice. The practices involved in the evaluation will be selected from the practices that provide a positive response to the expression of interest letter. The generalisability of the findings of the proposed study will be limited if the practices expressing an interest in participating in the capitation evaluation differ systematically from those that don't express interest. We will use the BSO datasets to compare the mean characteristics (number of registered patients, number of dentists, socio-demographic profile of patient populations, profile of treatments provided) of responding and non-responding practices. Randomisation will be stratified to ensure there is balance between test and control groups on the following variables:

- size of the practice determined by the number of dentists in each practice
- socio-economic status – determined by the proportion of adult patients who are exempt from patient charges

As all activity delivered by test and control practices in baseline – capitation – reversion periods will be available for analysis a sample size calculation is not required.

The DHSSPS and NIHSCB have structured the introduction of the capitation contract in two parts, a pilot group of practices and a full evaluation:

- The pilot starts 13/11/2014 and will involve two practices and follow up will be for 6 months ends 14/05/15. The introduction of the intervention in these practices will be treated as a pilot. The findings from the pilot will inform any changes to the intervention to be introduced in the full evaluation. We will examine simple descriptive data on productivity, service mix and patient charge revenue before and after the introduction of capitation in the pilot practices. We will conduct 2 focus groups with dentists involved in the pilot practices to discuss any observed changes in activity and identify areas that dentists feel the simple capitation contract can be improved.

The outcomes of the pilot will inform any changes made to the contract in the full evaluation.

- Full evaluation intervention (new capitation contract) starts 14/05/2015 and involves 15 test and 15 control practices and follow up will be for 12 months, ending 30/04/16. All patients who attend these 30 practices during all three phases of the study make up the study population.

WS2: This workstream will only apply to the 15 test and 15 control practices in the full evaluation. We will conduct semi-structured telephone interviews with dentists and patients. Sampling of both groups will be undertaken by the BSO from their datasets and they will contact both dentists and patients to invite them to participate in the interviews. We will oversample dentists and patients in the test group of practices:

- **Dentists:** telephone interviews with ~60 dentists (~40 test and ~20 control) will take place during the three different phases of the study. Dentists will be purposively sampled based on the following variables: allocation of the practice they attend (test/control), practice principal/associate, practice size (number of dentists/number of patients registered), NHS commitment based on NHS earnings in the last financial year.
- **Patients:** telephone interviews with ~60 patients (~40 test and ~20 control) at each of the three distinct phases (baseline – capitation – reversion) of the study. Patients will be purposively sampled based on the following variables: allocation of the practice they attend (test/control), patients attending at each phase as well as leavers and joiners, fee paying status, gender and age.

WS3: This workstream will only apply to the 15 test and 15 control practices in the full evaluation. The sample will be drawn from patients in test and control practices who receive care in the three phases (baseline – capitation – reversion) of the study; some will be regularly attending patients attending at each phase as well as leavers and joiners. We will draw separate samples at each phase and therefore we will measure change in mean values in the surveyed samples. We will use a quota sampling methodology to reduce bias as a result of non-response. The population in the test and control practices will be categorised into 12 groups based on:

- Age – 3 categories – 18-39, 40-59, 60+ to reflect differing dental needs in each age cohort.
- Gender – 2 categories – male and female
- Socio-economic status – 2 categories – exempt from patient charges, pay patient charges

We aim to obtain a response from 1,000 patients in test and 1,000 patients in control practices at each of the three phases of the study baseline – capitation – reversion, $3 \times 100 \times 2 = 6000$ questionnaires in total for analysis. Based on previous experiences of postal questionnaire surveys undertaken by the NIHSB a 30-35% response rate can be expected. We therefore intend to send out 6000 (3,000 test and 3,000 control) questionnaires in a single mail shot at each phase of the study (18,000 in total) in the expectation we will reach the target of 2,000 (1,000 test and 1,000 control) in each phase. The proportions of patients in the 12 categories (based on age, gender and socio-economic status) sampled will reflect the proportions in the total population. We will use pre-paid business reply envelopes to collect responses.

The figure of 1,000 questionnaires per arm is based on the premise that the variables included in the questionnaire will be calculated as proportions accurate to plus or minus 5% (95% confidence interval). To calculate the standard error, we have divided the confidence interval by 1.96 (approximate value of the 97.5 percentile point of the normal distribution). In this case the standard error is $5/1.96 = 2.55$. Assuming a 50% split in responses to each question (this would provide a worse case scenario in terms of minimum sample size required) a sample of 385 would be required. To enable sub group comparisons (maximum of 3 groups) we have pragmatically determined the sample size of 1,000 per arm.

6.4 Setting/context

The research will take place in a primary care setting, with independent, multiple providers (practices). Dental practices are independent, small businesses that have mixed income streams from NHS contracts and from privately provided care. The mix of NHS and private income varies between individual dentists, individual practices and the mix is sensitive to changes in the economy. Currently NHS contracts (and therefore remuneration payments) are made between the NIHSCB and individual dentists, not practices. Dentists are split between:

- Practice principals, who own the business of the practice and pay estates, staff and consumables costs and usually take a greater proportion of income from private fees
- Associates, who are self employed and in effect rent facilities and staff time from the practice principal according to a private agreement between the practice principal and the associate.

The NHS payments made to dentists (principals and associates) covers their personal income and all overhead costs. Under the current FFS contract dentists complete a course of treatment on a patient and submit a claim to the BSO, who check and pay each individual claim. The BSO have a dental reference service, this service comprises of two dentists who undertake clinical examinations on a small number of patients each year. These examinations are targeted according to patterns in claims activity to check the validity of claims and the quality of treatment provided. This is a very small resource and it would be unrealistic to use this service or upscale it to undertake clinical examinations as part of an evaluation.

The study will take place against a backdrop of negotiations between the DHSSPS and the BDA. Because the outcomes of the study are likely to have a direct bearing on dentists' livelihood the study will come under intense scrutiny and it is important that safeguards are put in place to maintain academic independence and for both sides in the negotiations to support the study and recognise that the findings have been produced by an impartial, high quality evaluation. These safeguards are outlined in the research governance section below.

6.5 Data collection

Our selection of outcome measures is being actively shaped through discussions with patients and the public facilitated by the Patient Client Council. Other outcome measures are being developed with PPI groups from our other NIHR projects, most notably the NIHR Programme Development Grant (NIHR PDG, 2013) which investigates definition and measurement of quality in general dental practice.

WS1: We will use the existing claims system overseen by NIHSCB in which dentists submit a paper or electronic record all of the items of treatment they have provided for each patient. Each item of treatment has an agreed price, which is paid to the dentist. The price is calculated to cover the dentist's personal remuneration and all overhead costs including staff costs, materials, consumables and estates costs. The claims are processed by the BSO and entered onto its database. The BSO checks the personal details of each claim for each patient against existing patients on their database, so treatments for individual patients can be tracked over time. The BSO also cross-references claims against benefits system databases to verify if patients who claim to be exempt from patient charges are eligible for exemption.

Measures of the inputs and outputs of health care provision in each practice will be required for the Longitudinal Data Envelopment Analysis (DEA) modelling and Longitudinal Stochastic Frontier Analysis (SFA) modelling work. These data will be provided by the practices when they choose to be enrolled into the capitation remuneration trial using a questionnaire we have developed in our NIHR HS&DR Project: 11/1025/04 – 'Determining the optimal model for role-substitution in NHS dental services in the UK'.

The most important input we will measure is the amount of paid hours each staff group at the practice works, but we also collect information on all other healthcare inputs such as the size

of the practice (measured by number of dental surgeries, expertise of staff (qualifications) and stock and material usage routinely recorded in administrative records. The main practice output measures will be (1) number of discrete patients seen (2) number of procedures performed in each of the ten most common (index) dental procedures (examination, scale & polish, restorations, crowns, bridges, endodontics, extractions, periodontal treatment etc. In addition we will also include (3) the estimated number of patient visits (see below) (4) A measure which combines the total number of the ten most common dental procedures weighted by estimated average treatment time for each procedure (see below) to produce a measure of total time treating patients. Output measures 3 and 4 will be secondary outcome measures due to the methodological limitations of collecting high quality data on number of visits per course of treatment and also the time taken to provide the index treatments.

The number of visits per course of treatment is not routinely collected in the BSO datasets. Although we will be able to identify all treatments completed in one visit, usually simple courses of treatment such as examination plus scale and polish, or examination plus a single filling, as the commencement and completion dates for the treatment would be the same. However, for other more complex courses of treatment, such as crown and bridgework, endodontics, dentures, multiple fillings, we would need to empirically identify the average numbers of visits to complete these more complex courses of treatment. Likewise information on the time taken (and therefore costs) to complete routine treatments is not recorded in the BSO datasets and we will again need to empirically measure the average time taken to complete routine procedures under FFS and capitation remuneration systems.

It would not be sensible to do this by observation in the trial practices, as observation is likely to change dentist's behaviour. Also asking dentists to record these outputs would be extremely costly and would be a major risk to successful recruitment. Instead, we propose to identify the average time taken to complete the various index treatments by research assistants observing clinical practice in dental practices not involved in the trial and logging the time taken to complete various treatments. We will also identify the average number of visits per course of treatment again by review of clinical records in dental practices not involved in the trial. We will undertake this work in a representative group of practices in Northern Ireland who are not involved in the trial who are working on the current FFS contract. We will also measure time to complete treatments and the number of visits per course of treatment in practices working under a capitation contract. Approximately five years ago in response to widespread concerns about access the NIHSCB went through a procurement exercise to set up some new practices to expand access to dental care across the Province. These practices work according to a capitation contract and provide routine care to the general population. There are limitations to this approach as the capitation contract may not exactly mirror the capitation contract to be tested in the trial. Also time to complete treatments and the number of visits per course of treatment may subtly change as the test practices move through the three phases of the study and using a static proxy measure will not capture these changes. However, we feel that it is important to include these measures as secondary outputs recognising the limitations in the methodology used. We will explore the nuances of how these two outputs change in each phase of the study qualitatively via the interviews with dentists and patients.

WS2: We will record all telephone interviews and focus groups with dentists and patients as MP3 files. They will be transcribed verbatim to Word documents.

WS3: The BSO will send out questionnaire to the sampled participants. Responses will be sent back in business reply envelopes to the BSO who will arrange for electronic capture of the data in the questionnaires. Data entry will be commissioned from an external commercial provider and double entered to validate accuracy. The data from the questionnaire will be able to be linked to each patient's activity data by reference to the BSO datasets, which were used to sample the data.

The measures in the questionnaire will include:

- patient reported oral health status - validated measures of Oral Health Quality of Life [e.g. OHIP 14 – (Slade, 1997)], measures of gingival health including self reported measures of gingival bleeding on tooth brushing. These measures will be discussed

with our PPI group to ensure the measures we use are appropriate for the aims of the study.

- measures of patient reported oral health knowledge, attitudes and behaviour. There are no validated measures of oral health knowledge, attitudes and behaviour. We will undertake a systematic search of the literature to identify potential measures and work with our PPI group to agree and finalise the most appropriate measures to use for WS3.
- patient-rated measures of quality of care. There are no validated measures of patient-rated quality of care in dentistry, such these measures are being developed as part of the NIHR Programme Development Grant (NIHR PDG, 2013) examining quality in dental practice for which **Tickle** is PI. This programme involves a systematic review of quality indicators and tools, a national survey and a significant PPI piece to identify what factors patients feel are important in terms of the care they receive from dentists. The outcomes of academic work and the PPI work will be shared with our PPI group in Northern Ireland to identify the most important aspects of quality to measure for people using the dental services in Northern Ireland.

6.6 Data analysis

Analysis will broadly follow two phases; a simple observational comparison of changes in activity (outputs) in test and control groups, followed by more complex health economic modelling to determine how outputs change for given inputs.

WS1: We will be using a difference in difference approach to analyse activity, service mix and charge revenue. We will measure how the difference in activity/ service mix/charge revenue observed in the intervention group of practices between baseline (phase 1) and the intervention period (phase 2) differs from the corresponding difference in activity/service mix/charge revenue in the control group of practices between phase 1 and 2. We will repeat this difference in difference approach for phase 3 (the return to FFS period) compared to the pre intervention (baseline, phase 1) and intervention (phase 2) periods. It is important to investigate the reversion to FFS, as it may be that changing practice as a result of the payment change is found to be a preferred practice by dentists and they may maintain the change in practice even after FFS is reintroduced.

As all data on all patients attending the practices during the study period will be available for analysis probabilistic theory and statistical inference will not be used. The difference observed between practices will be the actual difference. Longitudinal changes in activity by practice and by individual dentists for key outcome measures will be plotted using monthly aggregates. Comparisons will be made between test and control groups and by population sub-groups, according to age, gender and socio-economic status using co-payment exemption status as a dichotomous measure of socio-economic status at the individual level. (Sub-group analysis by socio-economic status will not apply to co-payments)

Longitudinal DEA modelling and Longitudinal SFA will be used to estimate the level of technical efficiency of practices and the change in technical efficiency associated with the change in provider remuneration method (Hollingsworth, 2008; Jacobs, 2001). The Frontier Production Function (FPF) is the maximum potential output that could be produced by practices given available resources of labour, capital and consumables. This will be estimated in the Test practices in each period (Baseline, Capitation and Reversion). Practices on the FPF serve as anchors of maximum output to score practices that deviate from this highest level of efficiency, with lower scores indicating a lower level of technical efficiency.

DEA will estimate the FPF and calculate practice-specific indices of technical efficiency relative to it. However, this finding would be based on the assumptions of DEA that assumes no statistical noise. In other words, there is no measurement error or random fluctuations whatsoever in output between practices or in the same practices between the three phases of the study. In order to relax this assumption we will conduct SFA that will also identify practice-specific indices of technical efficiency but allows for measurement error. However, it does so only by introducing a non-testable assumption about the distribution of measurement error (between study phases and between practices). In addition, the SFA approach requires that a

functional form of the FPF be specified beforehand in a regression equation while the DEA is a linear-programming approach that does not require the functional form of the FPF to be specified. Hence, the SFA model will perform better in the presence of measurement and data errors, while the DEA will perform better where there is specification error such as specifying an incorrect relationship between inputs and the way they combine to produce outputs.

DEA and SFA models are both measures of technical efficiency and can be compared directly to each other. As is usual in the empirical research literature on dental practice efficiency, the final set of results will be based on the DEA estimates. We will then examine the sensitivity of these results to assumptions inherent in the DEA modelling approach (of no measurement error) by examining the degree of convergence between DEA efficiency scores and those obtained from SFA. Large differences indicate possible specification, measurement and data errors. In which case, we will assess the validity of each model based on the sensitivity of results to changes in specification and error term assumptions, findings from the research literature of the likelihood of each type of error in this service setting (where the unit type is general dental practices), and the relative merits of each model in overcoming each type of error.

We will produce summary information on the average (mean) level of technical efficiency in each of the three period phases for the Test and Control practices, and the organisational composition (in terms of level and mix of inputs) of the most efficient practices in each period phase. We will also show how the same practices experienced increases or reductions in technical efficiency associated with the move from one remuneration system to another. A change in the ratio of observed level of output to potential level of output, holding the input mix in practices the same, in the Test group will be interpreted as an efficiency change that is associated with and could be accountable to the change in remuneration method. We will be able to check this assumption (that outside the organisational restructuring that practices conduct in response to the change in remuneration method there would be no change in efficiency) by examining whether a change in mean level efficiency takes place in the Control practices.

The estimate of the change in technical efficiency in moving to the capitation remuneration method will involve comparing the efficiency scores of practices in the same study group (Test or Control) in the intervention phase to their scores in the baseline phase. A second estimate will examine the impact on efficiency in movement from capitation and involves a comparison of efficiency scores of practices in each study group in the intervention phase to their performance in the reversion phase. Together these two estimates will determine if the technical efficiency of the same practices varies when they move to different retrospective and prospective remuneration methods for adults in the UK and whether that variation is linked to the form of remuneration or is robust to reverting back to FFS.

These findings will provide decision-makers with important information that informs commissioning decisions about provider remuneration. Specifically, the study results could be used to set performance targets for the capitation system, for example if we find that without any reduction in quality of care or patient outcomes practices that move to a capitation system typically see 15% more patients (with the same staffing level and inputs) or reduce staffing levels and other costs by an average of 25% and see the same amount of patients. In addition, identifying the operating practices associated with the highest levels of technical efficiency in each remuneration method and those that see the greatest improvement in technical efficiency from the change in FFS to capitation remuneration could be used to establish a guide to “best practice” for others to emulate.

WS2: Our analysis will be guided in part by our theoretical framework to develop sensitising concepts to provide a general sense of reference and guidance in approaching the empirical data. However, we will ensure that this does not constrain our ability to identify new themes, outside of our framework, where these are present in the data. Thematic analysis of individual transcripts will be undertaken. Analysis will initially involve coding transcripts using NVivo software and identifying themes. A constant comparative method will be used to

interpret the data. Key concepts will be identified using an open coding method. Once coding is complete, the codes that have common elements will be merged to form categories.

The analysis will commence shortly after the data collection begins. As part of our realistic evaluation approach we will develop a preliminary understanding of relevant 'Context Mechanism Outcome (CMO) configurations i.e. this mechanism, in this context appears to lead to this outcome. Mechanisms can be positive, absent or negative. Analysis will move from within-case (i.e. a single practice) to cross-case analysis to identify both site specific and more general issues. As analysis progresses we will refine our understanding of CMO configurations. Finally we will move from single case, through cross case CMOs to develop 'middle range theory' (Pawson and Tilley 1997) allowing us to produce generalisable knowledge of what, how and why happened in response to change.

WS3: In initial analyses the outcome measures will be presented as proportions with 95% confidence intervals. We will compare changes in test and control groups across the 3 phases of the study. We will compare outcome measures in different socio-demographic groupings, age categories (18-40, 40-60, 60+), gender and co-payment exemption status. Statistically significant differences at the 0.05 level will be identified if there is no overlap in confidence intervals of the outcome measures.

We will then use the same policy impact evaluation method of analysis as in WS1. We will construct a triple differences model in which the impact of the capitation contract will be measured as the mean difference of the health, quality of care and processes of care outcome parameters for practices allocated to the capitation intervention as compared to a counterfactual outcome. As in WS1, the counterfactual comparison for the estimate of the impact of Test practices moving from FFS to capitation remuneration will be formed from a combination of average parameter scores in the Test group in the Baseline phase and a comparison of average parameter scores in the Control Group in the Baseline and Capitation phases. The counterfactual comparison for the estimate of the impact of Test practices reverting from capitation back to FFS remuneration will be formed from a combination of average parameter scores in the Test group in the Reversion phase and scores in the Control group in the Reversion and Capitation phases.

7. Dissemination and projected outputs

We will disseminate our academic outputs in the usual way through high impact academic journals and presentations to national and international academic conferences. We will also update the EPOC review (Brocklehurst *et al.*, 2012), as the study will meet the inclusion criteria. We will produce lay summaries of the outputs of the project for presentation on the University web site and issue press releases in agreement with NIHR and NIHSCB. We will also present the outcomes of the research at professional meetings in NI and across the UK. We have strong links with policy makers in Europe and we aim to present our findings at a meeting of EU Chief Dental Officers. In addition we want to develop new and novel methods to support dissemination in a more accessible way for a lay audience. One approach is to record a 'virtual abstract' video to post on University and NHS websites.

The main avenue for knowledge mobilisation is to share and discuss the findings with UK policy makers. The results will naturally be of great interest to policy makers in NI, but the other home countries are developing their ideas concerning redesign of dental health care systems. The knowledge we generate about how behaviour changes according to financial and contractual incentives and the impact of this change in behaviour on productivity, costs and health outcomes will be of great interest to policy makers. As policy makers are the key audience we will host a closed-doors invited seminar to present the results and discuss their implications with Department of Health, representatives from the home countries.

The knowledge from this follow on study will be complementary to NIHR HS&DR Project: 11/1025/04 – 'Determining the optimal model for role-substitution in NHS dental services in the UK' and the NIHR Programme Development Grant (NIHR PDG, 2013) (and future Programme Grant) which investigates quality in dental practice; definition, measurement and

improvement. Together, these programmes will provide a significant expansion of the knowledge base in dentistry, which will support policy decision-making.

8. Plan of investigation and timetable

The timetable of the project is dictated by the outcomes of the negotiations of policy makers and the BDA. The start date and duration of the intervention have been fixed. Indeed baseline data for the full evaluation is already being collected via the BSO datasets as a result of claims made by dentists from 01/03/2014. As the same activity data will be collected continuously during each of the 3 phases in both test and control groups, the baseline data files can be assembled retrospectively. We have therefore designed the study around these restrictions. We assume we will learn the outcomes of the application by mid-November 2014. The NIHR HS&DR project will formally start 01/01/2015 and run for 35 months ending 30/11/2017. A table setting out key milestones is provided below and a Gantt chart for the project has been uploaded as a separate file.

Key tasks and milestones	Start date	Finish date
Phase 1 pilot (5 practices) (Start date predetermined by policy makers)	13/11/2014	14/05/15
Practice selection and randomisation (Phase 2)	01/02/2015	31/03/2015
Draw samples for baseline surveys and the patient and dentists to be interviewed from BSO databases	01/03/2015	30/04/2015
Pre contract preparations – ethical approvals, NHS research governance approval, Information governance approvals, establish study governance infrastructure and procedures. Draw up sub-contracts.	01/01/2015	14/05/2015
Baseline activity (Phase 1) data collection for full evaluation starts – this will be provided retrospectively by the BSO	15/05/2015	30/09/2015
NIHR HS&DR Follow-up study formal start and end dates (35 months in total)	01/01/2015	30/11/2017
2 Focus Groups made up of dentists involved in the pilot	15/05/2015	31/07/2015
Descriptive assessment of 6 month baseline and 6 month activity data from the pilot	15/05/2015	31/07/2015
Send out Baseline (Phase 2) questionnaires for full evaluation	01/04/2015	30/04/2015
Conduct Baseline (Phase 2) telephone interviews with dentists and patients for full evaluation	01/04/2015	31/07/2015
Full evaluation implementation of new contract Intervention (Phase 2) starts (runs for 12 months)	14/05/2015	17/05/2016
Draw sample for questionnaires to be disseminated during intervention	01/02/2016	29/02/2016
Send out questionnaires during Intervention (Phase 2)	01/12/2015	31/12/2016
Conduct Intervention (Phase 2) telephone interviews with dentists and patients	01/12/2015	31/03/2016
Revert back to fee for service – Reversion – (Phase 3) starts (runs for 12 months)	14/05/2016	13/04/2017
Draw sample for questionnaires to be disseminated during FFS Reversion (Phase 3) period	01/12/2016	31/12/2017
Send out questionnaires during FFS Reversion (Phase 3) period	01/12/2016	31/12/2017
Conduct Intervention (Phase 3) telephone interviews with dentists and patients	01/12/2016	31/03/2017
Undertake quantitative analyses of activity and questionnaire data	15/05/2017	31/07/2017
Complete qualitative analyses of dentists and patient interviews	15/05/2017	31/07/2017

Write report for NIHR HS&DR	01/08/2017	30/11/2017
Write academic outputs for publication in peer reviewed journals	01/08/2017	30/11/2017
Prepare presentations for various audiences	01/10/2017	30/11/2017
Organise seminar for policy makers	01/10/2017	30/11/2017

9. Project management and governance

The team has experience of working effectively together on different sites during the HS&DR Project: 11/1025/04. **Tickle** and **McDonald** worked successfully together on the NIHR SDO project HS&DR - 08/1618/158: The impact of incentives on the behaviour and performance of primary care professionals (<http://www.nets.nihr.ac.uk/projects/hsdr/081618158>). **Tickle**, **Birch** and **Donaldson** have worked successfully on the NIHR HTA project - 08/14/19: A randomised control trial to measure the effects and costs of a dental caries prevention regime for young children attending primary care dental services (Northern Ireland Caries Prevention In Practice Trial - NIC-PIP trial) (<http://www.nets.nihr.ac.uk/projects/hta/081419>) located in Northern Ireland. These projects have been managed effectively through regular teleconference/Skype meetings interspersed with face-to-face meetings at key points in the project dictated by the milestones. The team have long-standing, close relationships, which have been successful in delivering large, complex NIHR projects. We have very strong support and involvement from DHSSPS, NIHSCB and the BSO. We also have strong PPI from the NI Patient Client Council through **Schofield**.

Brocklehurst will be the PI supported by **Tickle**, **McDonald** will lead on the qualitative elements of the study, **Walsh** will be study statistician, **Birch** will oversee the health economic elements with **Hill** as the project manager. **Donaldson** and **O'Carolan** will provide support from the NIHSCB and **Fitzpatrick** will be the main contact with the BSO. We will establish an operational management group to oversee the management of the project. This group will meet monthly via teleconference with quarterly (in the early and late stages of the study) and 6-monthly face-to-face meetings in Northern Ireland.

The study will be high profile within the dental profession and politically because of concerns about access to dental services. We will set up an Independent Project Steering Group to ensure independent oversight and that academic freedom is maintained. This will be chaired by an independent senior academic, with strong lay membership and professional representation. The make up of this group will be agreed with the NIHR.

10 Approval by ethics committees

We will seek NHS ethical approval to undertake the interviews with patients and dentists and for the questionnaire surveys. We will also seek ethical approval from the University of Manchester's ethical committee, which when granted will provide indemnity cover for the PI. We will also seek NHS research governance approval. **Fitzpatrick** will ensure that access to BSO datasets is covered by the necessary information Governance approvals. We plan to obtain the approvals before the formal start of the project on 01/01/2015 (see timetable above).

11. Patient and Public Involvement

This is a high profile project the outcomes of policy decisions informed by this research will have a direct bearing on services provided to patients. It is therefore vital to have strong public and private involvement in every stage of the project. The NIHSCB has had an on-going dialogue with the NI Patient Client Council about the design and conduct of the evaluation of a new dental contract. **Schofield** from the Patient Client Council is a co-applicant on the study and will act in a facilitative capacity to help us develop our PPI programme for the study.

The research team need to develop its own PPI input. We have therefore recruited **Slee**, who has been actively involved in the design and conduct of the NIC PIP trial (NIHR HTA project - 08/14/19) as part of the PPI reference group. **Slee** is keen to develop her interest in research, which has been fostered by her involvement in the NIC PIP trial and wants to be an active co-applicant on this proposal.

Schofield and **Slee** will work with the Patient Client Council to set up a specific Patient Reference Group for the study. **Slee** and member of the Patient Reference Group will be involved in the study in the following roles–

- **Slee** will be a full member of the research team and sit on the operational management group and will be actively involved in the detailed design, the management of the project and dissemination;
- Members of the Patient Reference Group will provide advice on development of interview proformas for the WS2 qualitative study and the questionnaires to be used in WS3;
- Members of the Patient Reference Group will be actively involved in the interpretation and dissemination activities of the project.

We will also link the PPI activities of this group with PPI activity in our other parallel NIHR projects: NIHR HTA project - 08/14/19; NIHR HS&DR Project: 11/1025/04 and NIHR Programme Development Grant (NIHR PDG, 2013). In the latter two projects the research team has worked closely with the Citizen Scientist programme at Salford Royal Foundation Trust (<http://www.citizenscientist.org.uk/research-opportunities/dental-research/>). A series of web-pages have been posted to allow interested parties to become involved and “tweeted” to the wider PPI network across Greater Manchester. Our Programme Development Grant (RP-DG-1211-1007) seeks to understand patients’ attitudes towards quality and their experience of primary dental care, a series of one-minute interviews with patients on this subject have been posted to a dedicated website (<http://www.dentalqualityresearch.org>). These results have influenced the design of the research programme, in particular, work-streams two and three.

We will build on traditional and these novel means of patient and public engagement and involvement during the project to interact with patients and the public to provide information about the project and to elicit views from members of the public about the provision of dental services. In addition the training programme for user researchers being developed by the Citizen Scientist programme at Salford Royal Foundation Trust will be offered at sites within Northern Ireland to **Slee**, members of the Patient Reference Group and to wider user groups in the Province.

12. Expertise and justification of support required

The academic team (**Brocklehurst, Tickle, Birch, McDonald, Hill**) are delivering HS&DR Project: 11/1025/04 – ‘Determining the optimal model for role-substitution in NHS dental services in the UK’. **Brocklehurst** is PI on NIHR HS&DR 11/1025/04 and a NIHR Clinician Scientist with an interest in health policy research and workforce. **Tickle** was a NIHR Career Scientist and is now Director of the Institute of Population Health in Manchester. He is PI on the HTA NIC PIP trial and has very strong links with colleagues in Northern Ireland. He was dental lead for Greater Manchester and the North West Strategic Health Authorities and has long experience of commissioning dental services. **Birch** is a part-time Chair in Health Economics at the University of Manchester and Professor in the Department of Clinical Epidemiology and Biostatistics and Centre for Health Economics and Policy Analysis at McMaster University. He has over 200 publications in peer-reviewed journals including many in the economics of dental care. In the recent World Bank report on quantity and impact of health economics research he was ranked 35th in the world and 1st in Canada. **McDonald** is a social scientist and former Harkness fellow whose research is largely concerned with changing roles, incentive structures and professional boundaries in healthcare. She has explored these issues in a range of settings including general dental practice, general medical practice, community pharmacy and secondary and tertiary care providers. **Hill** is an early career researcher with a strong background in economics who has been recruited to work with Birch to deliver HS&DR Project: 11/1025/04. During this project he has received training in qualitative research methods and fieldwork. **Walsh** is a biostatistician and trialist. She is a Cochrane Oral Health editor and has been added to the team to provide advice and support on quota sampling of the questionnaire survey and data handling, analysis and reporting of trials data. The team has a very strong NIHR track record with active leadership and involvement on NIHR, HS&DR, HTA, PHR RfPB and Programme Development Grants.

The academic team is complemented by a team of senior managers, clinical consultants in the NIHSCB and senior NHS information officers in the BSO, plus our PPI co-applicants. **Donaldson** is Consultant in Dental Public Health for the NIHSCB and works closely with Tickle as local principal investigator on the HTA NIC PIP trial (HTA project - 08/14/19). **O'Carolan** is Regional Lead for Hospital Dental Services, Community Dental Services and Dental Public Health for NIHSCB and a former Chief Dental Officer of NI and has been a strong supporter of the NIC PIP trial as CDO. **Fitzpatrick** is the Head of Information and Registration Unit, for the Family Practitioner Services in the BSO. He has a detailed understanding of and direct access to the dental activity and payment datasets. He also will provide clear direction to the team on information governance issues. Together, the NIHSCB and BSO members of the team have the necessary senior managerial influence and access to technical knowledge, skills and support to deliver the evaluation. There are strong links between Manchester and NI as a result of **Tickle, Birch, Donaldson, and O'Carolan's** close collaboration on the very successful NIHR HTA NIC PIP trial (HTA project - 08/14/19). Indeed this proposal came out of discussions generated by that relationship. **Slee** has chaired the PPI group on the NIC-PIP trial for several years and has experience in working with academics and senior NHS managers. She has developed an interest in prevention of dental disease and her involvement in this proposal stems from her concerns that the current FFS-based system of remuneration used for dental services in Northern Ireland does not support provision of preventive care. She has also developed an interest in research and wants to develop her knowledge of research methods and management. **Schofield** has long experience working at the interface between user groups and the NHS. Over the last 6 months he has been working with the Patient Client Council on dental matters, and the planned pilots for a new dental contract.

Staff costs

Time for each of the academics has been calculated to ensure that sufficient time is devoted to each of the workstreams so can be effectively managed and ensure that the study is delivered to a high quality. This will be a politically sensitive and high profile study and it is important that operational management, oversight and governance procedures are adequately resourced. **Hill** has been costed to the project on Band 6.8 at 100% WTE for 29 months to account for potential overlap with the extension of the existing HS&DR award (11/1025/04). An RA (50% WTE at Band 6.3) is required to undertake qualitative interviews and support coding and analysis of qualitative data with **Hill** overseen by **McDonald**. The academic team in Manchester will also require 20% WTE (Band 3) secretarial support to organise meetings, take minutes of meetings, keep records of the study, organise teleconferences and travel arrangements.

Time for senior clinical and managerial staff from NIHSCB (**Donaldson, O'Carolan,**) and BSO (**Fitzpatrick**) will not be charged to research costs, as participation in the capitation study is a part of their core role. However, the evaluation proposed in this application is much more rigorous and extensive than initially envisaged by the HSCB and will require more intensive input particularly within the BSO. To support **Fitzpatrick** we require an Assistant Statistician to work within the BSO. This individual would work under supervision from **Fitzpatrick** supported by **Walsh**. In total we require 6 months Assistant Statistician time over the life of the project to extract and prepare monthly activity files from BSO databases for the research team, draw the samples of dentists and patients from BSO databases for the qualitative interviews and draw samples of patients for the questionnaire survey. In addition 2 months of administrative support is also required within the BSO to package invitation letters to dentists and patients to participate in WS2 interviews and to package the WS3 questionnaires to be sent out to patients in each phase of the study and collect and collate responses.

We do not require support from a Clinical Trials Unit, **Walsh** will plan and undertake the randomisation of the practices as part of her role as study statistician.

£3,000 has been allocated to pay for the costs of the printing and distribution of the survey. This has been based on the expected expenditure on printing, envelopes, address labels and postage on 6,000 returns. £8,700 has then been allocated to pay for the cost of data entry at £1.45 each.

Given the importance of incentivising dentists and dental patients for the interviews, £50 per dentist and £20 per patient has been allocated for the three sets of sixty interviews for each group (£12,600 in total). To transcribe these interviews, £13,500 has been budgeted and represents a cost of £37.50 for each interview.

A total of £2,464 has been allocated to ensure that **Slee** and the Patient Reference Group's PPI input plays a major role in shaping the planning of the questionnaire and telephone interviews (40 hours at the £150 per day Involve rate) and the analysis, write up and dissemination of the study (75 hours).

PPI input to the operational management group is important. A payment of £900 will be allocated to support face-to-face attendance at two of the quarterly operational management group meetings (one day twice a year at the £150 Involve rate) and a payment of £450 will support attendance via teleconference (half a day twice per year at the Involve rate). A contribution to the telephone charge will also be made (£50 for the duration of the study). Operational management group travel (total of £1,413) has been allocated on the following basis: a flight twice a year for three years (£900) for the PPI representative along with a taxi to/from the airport (twice a year for three years at £48) and payment for an attending dentist (12 meetings at 50m at a cost of 45ppm). Venue costs of £100 for each of the twelve operational management group meetings have also been allocated.

Given the politically sensitive and high profile nature of the study, costs have been allocated for four of the research team from the University of Manchester to attend quarterly meetings in Belfast to debrief the Health Minister and Chief Dental Officer on the progress of the study (£7,200 for flights, £576 for taxi fares and £10,800 for accommodation and subsistence).

A total of £5,400 has been allocated for dissemination costs. This covers the cost of one of the research team attending the International Association for Dental Research (IADR) (£1,500 for the flights, £900 for accommodation and subsistence for four nights and £450 for the conference fees). It also includes the cost of attendance at the European meeting of the IADR for two of the research team (£300 flights, £900 for accommodation and subsistence for four nights and £450 for the conference fees). Attendance at the British Association for the Study of Community Dentistry has also been budgeted for two of the research team (£225 travel, £225 for accommodation and subsistence for one night and £450 for the conference fees).

£2,400 has been allocated for open access publishing and £200 for ISCTRN registration (a new condition of Research Ethics Committees).

NHS support and NHS Treatment costs

Northern Ireland does not have the equivalent of a CLRN/LCRN to pay NHS support costs. As the DHSSPS and NIHSCB are committed to introducing a new dental contract in NI all NHS support costs and excess treatment costs will be met by the NIHSCB. Specifically these costs include recruitment of practices and financial risks associated with a potential fall in revenue from patient charges.

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