

The INCENTIVE protocol: an evaluation of the organisation and delivery of NHS dental healthcare to patients--innovation in the commissioning of primary dental care service delivery and organisation in the UK

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BMJ Open The INCENTIVE protocol: an evaluation of the organisation and delivery of NHS dental healthcare to patients – *innovation in the commissioning of primary dental care service delivery and organisation in the UK*

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ABSTRACT

Introduction: In England, in 2006, new dental contracts devolved commissioning of dental services locally to Primary Care Trusts to meet the needs of their local population. The new national General Dental Services contracts (nGDS) were based on payment for Units of Dental Activity (UDAs) awarded in three treatment bands based on complexity of care. Recently, contract currency in UK dentistry is evolving from UDAs based on volume and case complexity towards ‘blended contracts’ that include incentives linked with key performance indicators such as quality and improved health outcome. Overall, evidence of the effectiveness of incentive-driven contracting of health providers is still emerging. The INCENTIVE Study aims to evaluate a blended contract model (incentive-driven) compared to traditional nGDS contracts on dental service delivery in practices in West Yorkshire, England.

Methods and analysis: The INCENTIVE model uses a mixed methods approach to comprehensively evaluate a new incentive-driven model of NHS dental service delivery. The study includes 6 dental surgeries located across three newly commissioned dental practices (blended contract) and three existing traditional practices (nGDS contracts). The newly commissioned practices have been matched to traditional practices by deprivation index, age profile, ethnicity, size of practice and taking on new patients. The study consists of three interlinked work packages: a qualitative study to explore stakeholder perspectives of the new service delivery model; an effectiveness study to assess the INCENTIVE model in reducing the risk of and amount of dental disease and enhance oral health-related quality of life in patients; and an economic study to assess cost-effectiveness of the INCENTIVE model in relation to clinical status and oral health-related quality of life.

Ethics and dissemination: The study has been approved by NRES Committee London, Bromley.

Strengths and limitations of this study

- The INCENTIVE model will ensure a robust evaluation of dental practices piloting blended dental contracts that reflect innovative use of skill mix, evidence-based care pathways, funding and quality indicators.
- A rigorous mixed methods scientific approach will add considerable evidence over and above any evaluations of the pilots being undertaken, which are largely limited to survey-based evaluations.
- While this is not a randomised controlled trial, the mixed methods offer insight into not only effectiveness and cost-effectiveness but also into the process of contractual change for the stakeholders, which is important for any subsequent national roll out and implementation of the new dental contracts.

The results of this study will be disseminated at national and international conferences and in international journals.

INTRODUCTION

In England, in 2006, new dental contracts devolved commissioning of dental services locally to Primary Care Trusts (PCTs) to meet the needs of their local population. The new national General Dental Services contracts (nGDS) were based on payment for Units of Dental Activity (UDAs) awarded in three treatment bands based on the

complexity of each patient's care. The contracted number of UDAs was based on historic activity. The nGDS contracts meant that the payment mechanism changed from a one-off fee per item of service to a system whereby providers are paid an annual sum in return for delivering an agreed number of 'courses of treatment' weighted for complexity.

There is an increasing trend to use incentives in UK NHS primary care.¹ Within dentistry this manifests as changes to dental practitioners' contractual arrangements. Local commissioning allowed modifications that may have been influenced by the Steele Review² of NHS dentistry, which recommended that payments explicitly recognise prevention and *reward the contribution of the dental team to improvements to oral health, reflected in patient progression along the pathway, compliance with nationally agreed clinical guidelines and the achievement of expected outcomes* (ref. 2, p.67). In addition, commissioners were asked to *support dentists to make best and most cost effective use of the available dental workforce*.²

Thus contract currency in UK dentistry is evolving from UDAs based on volume and case complexity towards 'blended contracts' that include incentives linked with key performance indicators such as quality and improved health outcome.² Overall, evidence of the effectiveness of incentive-driven contracting of health providers is still emerging. A review by Christianson *et al*³ found mixed results of the effect of payer initiatives that reward providers for quality improvements whereas Clarkson *et al*⁴ found targeted payments to be a cost-effective intervention in changing a clinician's behaviour, with significant improvement in professional practice.⁴ O'Donnell *et al*⁵ found within the new General Medical Services contracts in primary care that the Quality and Outcomes Framework (QOF) incentivised performance, motivating staff towards QOF targets. Similarly, a review by McDonald *et al*¹ of the effect of incentives on the primary care workforce found them to be powerful motivators. A more granular view suggests that their process-based nature may limit their long-term effects on health outcomes.⁶ There is also a danger that important activities that lack a target may be underemphasised.^{6,7}

In order to inform an appropriate model of care to maintain and improve oral health, a number of dental contracts have been locally commissioned focused on oral health improvement and quality, in addition, national pilots are underway in England developed by the Department of Health. All share common features of being capitation based, of having a quality element, of conferring a responsibility for long-term care of the patient on the contract holder and of being based on an oral health assessment (OHA) and pathway.⁸

The INCENTIVE Study aims to evaluate a blended contract model (incentive-driven) compared to traditional nGDS contracts on dental service delivery in practices in West Yorkshire, England to generate information that will be of value for designing and commissioning future NHS dental services.

METHODS AND ANALYSIS

Study objectives

- ▶ To explore stakeholder perspectives of the new blended contract service delivery model. We will also explore whether these practices already operating an incentive-driven service delivery by a multidisciplinary team are able to adapt more readily to the introduction of further new dental contracts as these will be negotiated during the study period.
- ▶ To assess the effectiveness of the new service delivery model in reducing the risk of and amount of dental disease and enhancing oral health-related quality of life in patients.
- ▶ To assess cost-effectiveness of the new service delivery model in relation to oral health-related quality of life.

Design

The INCENTIVE model will use a mixed methods approach combining qualitative and quantitative techniques to comprehensively evaluate a new incentive-driven model of NHS dental service delivery. The study will include 6 dental surgeries located across three newly commissioned dental practices (blended contract) and three existing traditional practices (nGDS contracts) in West Yorkshire (3 in each of the two arms). The newly commissioned practices have been matched to traditional practices by deprivation index, age profile, ethnicity, size of practice and taking on new patients.

The study consists of three interlinked work packages: a qualitative study to explore stakeholder perspectives of the new service delivery model and whether those practices already operating incentive-driven service delivery by a multidisciplinary team are ready to adapt more readily to a new dental contract; an effectiveness study to assess the effectiveness of the INCENTIVE model in reducing the risk of and amount of dental disease and enhance oral health-related quality of life in patients; and a cost-effectiveness study to assess cost-effectiveness of the INCENTIVE model in relation to clinical status and oral health-related quality of life. An overview of the study incorporating the three work packages is contained in figure 1.

Setting

Focus lies on a new blended dental contract introduced in 2007 for three newly commissioned NHS dental practices in West Yorkshire. The specification was innovative and although pre-dating the Steele Review,² it reflected its ethos and recommendations with emphasis on quality of care, achieving health outcomes and patient-reported outcome measures (PROMS).⁹

In brief, 60% of the contract value is apportioned to delivery of a set number of UDAs. The remaining 40% is dependent on the delivery of quality—20% systems, processes, infrastructure (eg, dental standards of quality and safety overseen by The Care Quality Commission) and 20% oral health improvement (OHImp). The framework is an evolving mechanism for improving oral

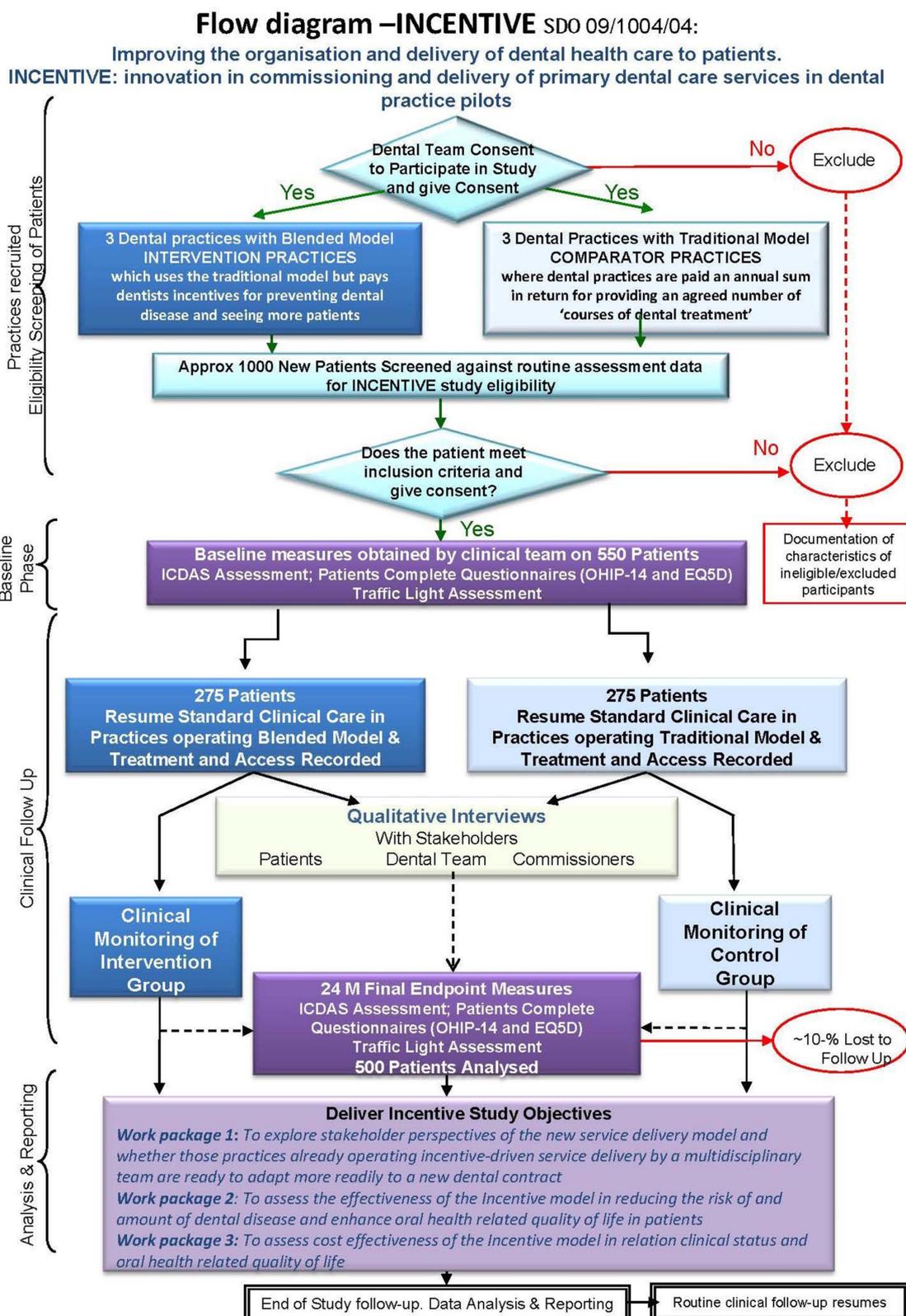


Figure 1 Flow diagram INCENTIVE study.

health and monitoring outcomes within the practices. The outcomes for year 1 involved focusing on ensuring that the foundations were in place for the care pathway approach to evidence-based preventive care, including

appropriate skill mix, staff training, reviewing practice and community profiles.

The new contracts are aimed at: ensuring that evidence-based preventive interventions¹⁰ are delivered

in line with identified needs for a defined population; ensuring increased access to dentistry; and ensuring that care is provided by the most appropriate team member to encourage skill mix. All practices fully utilise skill mix and have hygiene therapists and additional skills dental nurses.

The contracts encourage a care pathway approach in which all patients should be assessed formally on joining the practice and at each subsequent recall. Four sets of information (age group, medical history, social history (self-care, habits/diet) and clinical assessment) are used to inform a traffic-light system for patients with high (red), medium (amber) or low (green) risk of oral disease (refer to [figure 2](#)). This type of traffic-light system has not been fully explored, although early work is ongoing in the North West of England.¹¹ The patient care pathway includes evidence-based prevention and advice, appropriate recall interval and restorative care as appropriate (red risk category treatment being limited to stabilisation and lowering risk status). Patients' status is reviewed at their next OHA allowing them to move between risk categories.

Within practice monitoring ensures evidence-based prevention is delivered in line with identified needs and monitors access to dentistry. Oral health improvement is assessed through the delivery of a performance framework. Payment is linked to three elements: a register by age group of those having risk assessment, management of care appropriate to need and evidence base, and the measurement of oral health outcomes.

Qualitative study

A qualitative study will explore the meaning of key aspects of the new service delivery model for three discrete stakeholder groups: (1) public and patients (ie, both non-patients and patients); (2) commissioners and (3) the primary care dental teams. Preliminary observational studies will help develop topic guides for subsequent semistructured interviews and focus groups. Recruitment will continue until no new variation in observations can be found (saturation). If necessary, additional participants will be identified using theoretical sampling. For planning purposes, we anticipate conducting approximately five interviews, with three focus groups having four or more participants within each stakeholder group.

The sampling matrix for the public and patient group will include criteria linked to the objectives of the programme, including demographic factors (age, gender, ethnicity, socioeconomic status), risk category, treatment need and participation in the user forum. Broad eligibility criteria at the participating practices will recruit patients: aged 16 years and over; willing to be interviewed and to give informed consent; if a translator is needed provision of translation services in the spoken language of the participant will be available via the normal dental practice access routes to such services.

As the new contracting model considers access to care it is important that the sample includes non-patients.

A mixture of approaches will be used to recruit people who may not engage with local dental care services, such as the employment of snowball sampling techniques and site-based approaches to recruitment. However, snowball sampling used alone can result in biased samples and it is important that any sample recruited to the study adequately represents the target population. In order to achieve this goal specific attention may be required for adequate recruitment of participants from different groups of the community. Therefore, a site-based approach will be used to control bias and obtain a more representative sample. A representative list of sites (eg, places, organisations or services), which may include churches, community centres, social clubs or housing projects, will be identified, with the researcher contacting the 'gatekeeper' for each of these sites (eg, church pastor) so that the study can be explained; the gatekeeper's help in recruitment can also be enlisted and the researcher can collect information about the number and characteristics of site members.

Commissioners will comprise commissioning staff, general dental practice advisors and consultants in Dental Public Health. Staff members will be recruited from the primary care dental teams from the six participating practices as well as those that may have recently left them as it is important to capture the potential impact of working under these different models of service delivery and their professional satisfaction. Staff will comprise the full skill mix within the practices. As with previous work,¹ we will pay particular attention to the way in which the INCENTIVE model promotes greater participation from the entire dental team.

Transcripts of the interviews and focus groups will be analysed with framework analysis. The first stage will involve familiarisation with the data to verify and, if necessary, revise the framework in the light of emerging themes. The revised framework forms an index, allowing the data in the transcripts to be labelled according to each theme. The data will then be sorted by theme to enable constant comparison across themes and cases. The goal of our analysis will be to establish typologies for participation, health improvement, access, professional involvement and care pathways. These typologies will identify the general nature of each of these aspects and will enable us to analyse the way in which the emerging model can develop new directions for primary care dentistry. The findings will be triangulated with a range of literatures including definitions of health, current policy, access, quality and public involvement.

The study focuses on innovative commissioning models that are commissioned within a real-world environment. Should a new national contract or indeed local commissioning arrangements be introduced during the study period, the study will examine the impact of the change and differences between the innovative and traditional models in adapting to implementing the new contractual model.

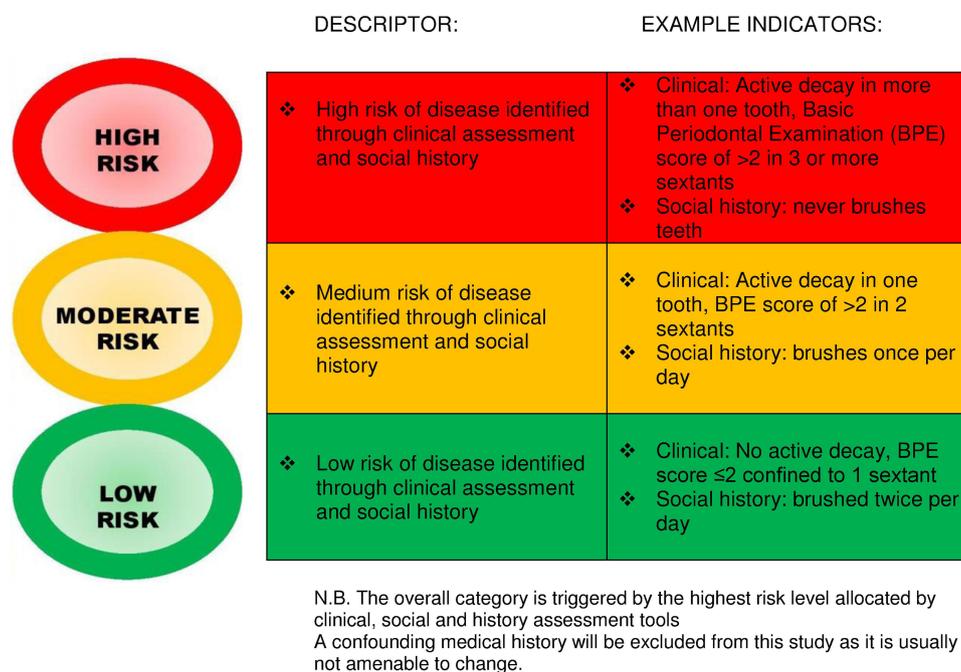


Figure 2 'Traffic Light' risk assessment.

Effectiveness study

The key characteristics of the traditional and new model incentive-driven practices are summarised in [table 1](#). A non-randomised natural experiment will compare three incentive-driven dental practices with the three matched traditional practices. The practices are matched by size, number of dentists, location and patient demographics. The primary outcome will be gingivitis measured as the proportion of sites that bleed on probing (BOP). Secondary/exploratory outcomes include oral health-related quality of life (OHIP-14) and generic health-related quality of life (EQ-5D). The dental caries experience will be recorded using the International Caries Detection and Assessment System (ICDAS).

To achieve a recruitment of 550 new patients in the INCENTIVE project, recruitment will take place over the six practices for a period of 6 months. We anticipate 10% lost to follow-up so this leaves us with an adequate sample of ~500 for analysis. Recruitment is based on: (1) six dental practices included in the study that comprise 20 surgeries; (2) an average list size of 1000 adult patients per dentist; (3) 10% of whom per year will be new patients to the practice (estimated from the Dental Public Health audit figures of practices in Bradford and Airedale) and (4) of these 1000 patients we estimate a minimum of 50% will agree to participate in the study over the 6-month recruitment period. Thus at a practice level the three newly commissioned dental practices will be matched with three existing traditional practices of similar size, deprivation index, age profile and ethnicity, which are taking on new patients. At a patient level, inclusion criteria are that a patient must be above 16 years of age, must be a new patient to the practice during the recruitment period (anticipated being

6 months) willing to be followed up for 24 months, and must give informed consent and be able to complete the patient-completed questionnaires (if a translator is needed, the availability of provision of translation service in the spoken language of the participant will be via the normal dental practice access routes to such services). With regard to exclusion criteria and the specific handling of those who are edentulous, they will not be excluded from the sample, however, they will be considered supplementary to the core sample of 550 patients and provide additional specific data. Postcode, age and ethnicity of all patients included within the sample will be recorded and profiled during the analysis.

To detect a clinically meaningful reduction in BOP of 10% and assuming a 10% drop out rate, 275 patients are required in from the incentive-driven practices and from the nGDS practices to give 80% power with a significance level of 5%.

Data will be collected at baseline and 24 months. BOP and ICDAS will be completed by the dental practitioner at the dental appointment. Training will be provided to all practices on use of the ICDAS. For the risk assessment, data from the traffic light system (refer to [figure 2](#)) will be collected outlining variations when the protocol is overruled by clinicians and why. Recruitment will take place over a 6-month period beginning in April 2012. The OHIP-14 and EQ-5D will be completed by the patients.

Multiple linear regression will be used to model differences in BOP from baseline to 24 months. Changes in oral health quality of life will be explored using structural equation modelling to identify the relationships between changes in clinical status and patient perspective.

Table 1 Key characteristics of the traditional and new model incentive practices under evaluation in the INCENTIVE study

Characteristics	Traditional (comparator) practices (3 practices; 10 dental surgeries)	Incentive practices (3 practices; 10 dental surgeries)
Model of operation Contract type	Traditional nGDS0	Incentive driven An incentive-driven contract (a blended contract combining nGDS <i>and</i> incentives)
Mode of reimbursement	Activity-based, weighted bands of dental activity Contract currency—UDA	Activity: 60% of contract value UDAs Incentives: (1) Quality systems, processes infrastructure (eg, cross infection, standards for better health 0: 20% of contract value, and (2) Oral health improvement: 20% contract value
Incentives and levers	Driven by delivery of UDAs, with no incentives for prevention approach	Allocation of payment allows commissioners to incentivise key structures, processes and outcomes for quality and oral health improvement
Health professional responsible for delivery of care	Dentist (with no incentives for therapist and hygienist support)	Blended contract incentivises use of skill mix to deliver preventative focused care For example, dental therapists can extract baby teeth, place fillings and apply preventative medicaments. Dental nurses may give preventative fluoride varnish to teeth
Care pathway and recall	Care pathway and recall as prescribed by individual performers	Risk assessed (traffic light system) evidence based preventative care pathway Risk assessed recall interval (NICE guidelines on dental recall interval), variations recorded
Stakeholder feedback on delivery and impact of care	Standard complaints/comments	Patient forum

nGDS, national General Dental Services; NICE, National Institute for Health and Care Excellence; UDA, Units of Dental Activity.

Cost-effectiveness study

Of key importance is that the new model of service delivery shows value for money. Economic evaluation will identify within-study incremental cost-effectiveness ratios for the incentive-driven service as compared to standard practice. Use of these ratios will enable comparison of any additional financial costs and benefits associated with the new model over standard care.

The primary analyses will take the perspective of the commissioners of the service, taking account of differences in contractual payments and including only the costs of dental care. There is no preference-based dental outcome measure and thus the within-study analysis will estimate the expected incremental cost per point increase in OHIP-14 score. In addition, a second analysis will use quality-adjusted life years (QALYs) estimated using utility weights for each health state observed in the trial population. We will use the EuroQol-5D (EQ-5D) instrument for this purpose.^{12 13} Within the study the OHIP-14 scores will also be mapped to the EQ-5D scores in order to add to the evidence base¹⁴ for the future development of a preference-based dental health-related quality of life instrument.

While the primary analyses will adopt the commissioner perspective, secondary analysis will adopt the perspective of the service provider. Integral to this analysis is the exploration of variation of cost-effectiveness results across locations given differences in case and skill mix. Thus the economic analysis will explore the differences

in resource use given the skill mix and care providers by comparing cost and output across the new incentive-driven model of service delivery and traditional practices.

The economic study will use the same sample and time frame as the clinical study. Health resource use associated with each treatment modality will be collected for each dental visit from dental practice records. The EQ-5D and OHIP-14 will be collected at the same time as the other outcome data. Patients will be asked to complete these measures at baseline and 24 months.

Incremental cost-effectiveness ratios will be calculated as the difference between the mean costs and difference in OHIP score/QALYs in each arm. Non-parametric bootstrapping will be used to produce a within-trial probabilistic sensitivity analysis of the incremental cost-effectiveness ratios. The expected incremental cost-effectiveness ratio, a scatterplot on the cost-effectiveness plane and the cost-effectiveness acceptability frontier will be presented. Discounting will use the recommended rate at the time.

DISCUSSION

The move to blended or incentivised contracts is gathering pace within the UK, yet there is mixed evidence on its usefulness. There are potential advantages; not least more efficient use of the dental team through greater use of skill mix. For example, dental therapists can extract

milk teeth, place fillings and apply preventive medications, and dental nurses may give preventive advice and apply preventive fluoride varnishes to teeth. Intuitively, the delegation of treatment to staff specialised in only a specific range of treatments could reduce costs and increase access to care but this hypothesis needs testing.¹⁵ Skill mix is advocated in several current proposals for change that continue a trend seen in UK dentistry over the past 20 years.^{2 16–19} For example, dental therapists may now work in general dental practice,¹⁷ their clinical remit has expanded^{20 21} and recently, in March 2013, the GDC (General Dental Council) permitted direct access to some dental care professionals; hygienists and therapists can now carry out their full scope of practice without prescription and without the patient having to see a dentist first. While there are few hard data to support skill mix in dentistry,¹⁵ some data are beginning to emerge; for example, a recent practice-based study found the success of fissure sealants placed by dentists, hygienists and therapists to be comparable.²² However, research is needed to assess whether new models of delivery and service design will encourage their use and whether they are acceptable to dentists and patients.

Emphasis of the new incentivised contracts lies on quality and outcomes. While quality indicators linked to contracts and payments have been used widely in other branches of healthcare, the results are complex. The indicators can drive organisational change towards best practice, but may also be a disincentive to important but non-rewarded activities.⁷ Used alongside demographic data, the indicators can measure practice performance, identify areas for development and assist sharing of best practice.²³ The indicators often increase the quantity of service provision, but not always the quality.²⁴ While offering great potential, quality indicators have not been comprehensively evaluated in dentistry. A recent systematic review was only able to provide a framework for how such indicators might work.²⁵

In respect of improved health outcomes, the dental community is united that outcomes in terms of clinical effectiveness should focus on major public health challenges including caries and periodontal diseases where health improvement is needed. However, the community lacks consensus in how best to measure change.

There is also little in the literature regarding care pathways in primary dental care, although the concept has been around for a number of years. The concepts and benefits of the care pathway approach in dental primary care were described by Hally and Pitts.²⁶ As a result of government recommendations¹⁷ the first widely disseminated care pathway in UK dental primary care was the OHA within the National Institute for Health and Care Excellence guidance on dental recall intervals.²⁷ The OHA care pathway was designed to enable more prevention within personalised care plans taking into account their social and dental histories as well as clinical findings. This pathway informs what to

commission from the practices involved in this study but has not been fully evaluated in practice.

The emerging service delivery models in the UK should include innovative use of skill mix, evidence-based care pathways, funding and quality indicators.¹⁸ A robust evaluation of new dental contracts is called for,¹ which is what this study aims to achieve.

Study status

The first patient for the effectiveness and cost-effectiveness studies was recruited in June 2012 and the last patient in January 2013. Recruitment for the qualitative study is on-going. The results will be reported in 2015. The research team provided the NRES Committee London-Bromley with a copy of the final protocol, patient information sheets, consent forms and all other relevant study documentation.

Consent

The direct NHS Dental team will perform an eligibility screen of all new patients to the practice based on the information the practice routinely captures when a patient joins the practice. Eligible patients will be given a patient information leaflet to consider, if they are willing to join INCENTIVE they will be consented and registered. This will result in them being assigned a unique patient-specific study number that will then be used on all subsequent case report forms for data capture. For lay participants who are not currently seeing an NHS dentist but whom we would like to interview to understand access to dental care in the community, we will recruit using a mixture of approaches, such as the employment of snowball sampling techniques and site-based approaches to recruitment. Snowball sampling is a convenience sampling technique which involves an existing participant providing the researcher with the name of an individual who may also be interested in taking part in the research. This individual may be asked, in turn, to provide the researcher with a name of another potential participant. One of the main advantages of this method of recruitment is that it enables researchers to make contact with hard to reach populations.

Confidentiality

Access to medical records: Monitoring of patient notes may be undertaken by the authorised individuals from the study team, regulatory bodies, funder or Sponsor (University of Leeds) in order to check that the study is being carried out correctly. The Clinical Research coordinator will be University of Leeds employed and have oversight of day-to-day operations across work package (WP) 1–3. There will be a similar research assistant coordinating the qualitative Workpackage 1 based in the University of Sheffield. Electronic transfer: data will be sent to and from participating research sites, however, no patient-identifiable information will be sent via electronic means (use of coded study number, patient initials and date of birth (DOB) only). Should it be required to send

any patient identifiable information (eg, for long-term follow-up data), then data will be sent password protected (with a complex password to be sent separately) to the appropriate person. We follow local guidance and Standard Operating Procedures, which ensure the Data Protection Act 1998 will be adhered to at all times.

Use of personal postcode: Patient 4 digit postcode will be collected on the Consent Form for the trial, and will be kept separately to any other clinical data. The postcode and full name are being collected to allow for collection of deprivation index from standard local registries.

The research team and participating sites will comply with all aspects of the Data Protection Act 1998. All information collected during the course of the study will be kept strictly confidential. Participant name will be collected when the patient consents to the trial for long-term follow-up. All other data collection forms, except the consent form that contains the patient's signature, which are transferred to or from the research team at University of Leeds or University of Sheffield will be coded with a unique study number and will include two patient identifiers: initials and date of birth.

Dissemination policy

An end of project national dissemination meeting will be undertaken with dental commissioners and a lay summary of project findings for circulation to study participants. It is anticipated that there will be two publications in international peer reviewed, high-impact journals and conference dissemination at the National meeting of the British Dental Association or equivalent and the International American Dental Research or equivalent.

The chief investigator, co-applicants and senior management staff will be named as authors in any publication, and an appropriate first author agreed through discussion among the Study Management Group (SMG) members. In addition, all collaborators will be listed as contributors for the main study publication, giving details of their roles in planning, conducting and reporting the study. The INCENTIVE team will be acknowledged in all publications, as will the funder. Other key individuals will be included as authors or contributors as appropriate and at the discretion of the SMG. Any disputes relating to authorship will be resolved by the Senior Advisory Board/Steering Committee (SAB).

The Chairs and Independent members of the SAB will be acknowledged, but will not qualify for full authorship, in order to maintain their independence.

To maintain the scientific integrity of the study, data will not be released prior to the first publication of the results of the primary endpoint analysis, either for study publication or oral presentation purposes, without the permission of the SMG.

The SMG will agree a publication plan and must be consulted prior to release or publication of any study data.

Individual collaborators must not publish data concerning their participants which are directly relevant to the questions posed in the study until the main results of the

study have been published. Local collaborators may not have access to study data until after publication of the main study results unless with agreement of the SMG.

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Contributors SHP contributed to the design of the study and led the Patient and Public Involvement (PPI) aspects of the study. PDB contributed to the study design and was responsible for the design of the statistical analysis plan. PAB and JG contributed to the study design and liaised with the health commissioner stakeholders. JG also liaised with the dental practices. BJG, MH, JP and PGR contributed to the design of the study, with particular responsibility for the Qualitative research. GD contributed to the study design and is primarily responsible for the acquisition of ICDAS clinical data. KV was responsible for the study coordination, design of the case report forms and coordination and the acquisition of clinical data. CH participated in the design of the study, with particular responsibility for the health economics. All authors meet regularly to ensure the smooth running of the study, were involved in the protocol drafting and contributed to and approved the final manuscript.

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Competing interests None.

Ethics approval The study has been approved by NRES Committee London-Bromley (Reference No: 12/LO/0205) prior to entering patients into the study.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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