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The INCENTIVE protocol – An evaluation of the organisation and delivery of NHS dental health care to patients - innovation in the commissioning of primary dental care service delivery and organisation in the UK



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The INCENTIVE protocol – An evaluation of the organisation and delivery of NHS dental health care to patients - innovation in the commissioning of primary dental care service delivery and organisation in the UK

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Abstract

Background

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 (UDA) awarded in three treatment bands based on complexity of care. More 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-contact model (incentive-driven) compared to traditional nGDS contracts on dental service delivery in practices in West Yorkshire, England.

Methods and Analysis

INCENTIVE uses a mixed methods approach to comprehensively evaluate a new incentive-driven model of NHS dental service delivery. The study includes 20 dental surgeries located across three newly commissioned dental practices (blended contact) 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 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 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.

Keywords

Dentists, contracts, financial incentives, pay for performance, reimbursement, effectiveness, cost effectiveness, quality

Strengths and Limitations

- The INCENTIVE evaluation is of strategic importance to the Department of Health to generate information that will be of immense value for designing and commissioning future NHS dental services
- Whilst a new contract is due to be introduced for NHS dental services in 2016-17 in line with a more blended or incentivised model there is limited evidence of the effectiveness of these types of contract
- INCENTIVE 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 that are largely limited to survey based evaluations
- As a consequence our article is guaranteed to draw attention of the scientific and commissioning communities. The work is ongoing and already attracting considerable interest from key stakeholders
- Whilst this is not an RCT the mixed methods offers 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 current article reports the protocol only

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 (UDA) 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 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 which may have been influenced by the Steele Review ^[2] 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* ^[2; p67]. In addition commissioners were asked to

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3 *support dentists to make best and most cost effective use of the available dental workforce*
4 ^[2].

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

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

33
34 The INCENTIVE Study aims to evaluate a blended-contact model (incentive-driven)
35 compared to traditional nGDS contracts on dental service delivery in practices in West
36 Yorkshire, England to generate information that will be of value for designing and
37 commissioning future NHS dental services.

38 **Methods and Analysis**

39 **Study Objectives**

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

INCENTIVE 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 20 dental surgeries located across three newly commissioned dental practices (blended contract) and three existing traditional practices (nGDS contracts) in West Yorkshire (10 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 (e.g. 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 health and monitoring outcomes within the practices. The outcomes for year one involved focused 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 evidence-based preventive interventions ^[10] are delivered in line with identified needs for a defined population; increased access to dentistry; 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 Table 1). This type of traffic-light system has not been

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3 fully explored, although early work is on-going in the North West of England ^[11]. The patient
4 care pathway includes evidence based prevention and advice, appropriate recall interval
5 and restorative care as appropriate (red risk category treatment being limited to
6 stabilisation and lowering risk status). Patient status is reviewed at their next oral health
7 assessment allowing them to move between risk categories.
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10 Within practice monitoring ensures evidence-based prevention is delivered in line with
11 identified needs and monitors access to dentistry. Oral health improvement is assessed
12 through the delivery of a performance framework. Payment is linked to three elements: a
13 register by age group of those having risk assessment, management of care appropriate to
14 need and evidence-base and the measurement of oral health outcomes.
15

16 17 18 Qualitative Study

19 A qualitative study will explore the meaning of key aspects of the new service delivery
20 model for three discrete stakeholder groups: (a) public and patients (i.e. both non-patients
21 and patients); (b) commissioners and (c) the primary care dental teams. Preliminary
22 observational studies will help develop the topic guides for subsequent semi-structured
23 interviews and focus groups. Recruitment will continue until no new variation in
24 observations can be found (saturation). If necessary additional participants will be identified
25 using theoretical sampling. For planning purposes, we anticipate conducting approximately
26 5 interviews and three focus groups with 4 or more participants within each stakeholder
27 group.
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32 The sampling matrix for the public and patient group will include criteria linked to the
33 objectives of the programme including demographic factors (age, gender, ethnicity, socio-
34 economic status), risk category, treatment need and participation in the user forum. Broad
35 eligibility criteria at the participating practices will recruit patients: aged 16 years and over;
36 willing to be interviewed and give informed consent; if a translator is needed the availability
37 of provision of translation service in the spoken language of the participant via the normal
38 dental practice access routes to such services.
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41 As the new contracting model considers access to care it is important that the sample
42 includes non-patients. These participants will include representatives of community groups
43 with whom the practices should have engaged.
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45 Commissioners will comprise commissioning staff, general dental practice advisors and
46 consultants in Dental Public Health. Staff members will be recruited from the primary care
47 dental teams from the six participating practices as well as those that may have recently left
48 them as it is important to capture the potential impact of working under these different
49 models of service delivery and their professional satisfaction. Staff will comprise the full skill
50 mix within the practices. As with previous work ^[1] we will pay particular attention to the
51 way in which INCENTIVE promotes greater participation for the entire dental team.
52

53 Transcripts of the interviews and focus groups will be analysed with framework analysis. The
54 first stage will involve familiarisation with the data to verify, and if necessary, revise the
55 framework in the light of emerging themes. The revised framework forms an index, allowing
56 the data in the transcripts to be labelled according to each theme. The data will then be
57 sorted by theme to enable constant comparison across themes and cases. The goal of our
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3 analysis will be to establish typologies for participation, health improvement, access,
4 professional involvement and care pathways. These typologies will identify the general
5 nature of each of these aspects and will enable us to analyse the way in which the emerging
6 model can develop new directions for primary care dentistry. The findings will be
7 triangulated with a range of literatures including definitions of health, current policy, access,
8 quality and public involvement.
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11 The study focuses on innovative commissioning models which are commissioned within a
12 real world environment. Should a new national contract, or indeed local commissioning
13 arrangements be introduced during the study period, the study will examine the impact of
14 the change and differences between the innovative and traditional models in adapting to
15 implementing the new contractual model.
16

17 18 19 **Effectiveness Study**

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21 The key characteristics of the traditional and new model incentive-driven practices are
22 summarised in Table 2. A non-randomized- natural experiment will compare three incentive
23 driven dental practices with the three matched traditional practices. The practices are
24 matched by size, number of dentists, location and patient demographics. The primary
25 outcome will be gingivitis measured as the proportion of sites that bleed on probing (BOP).
26 Secondary/exploratory outcomes include oral health related quality of life (OHIP14) and
27 generic health related quality of life (EQ-5D). The dental caries experience will be recorded
28 using the International Caries Detection and Assessment System (ICDAS).
29

30
31 To detect a clinically meaningful reduction in BOP of 10% and assuming a 10% drop out rate,
32 275 patients are required in from the incentive-driven practices and from the nGDS
33 practices to give 80% power with a significance level of 5%. The inclusion criteria for this
34 part of the study are patients aged 16 years and over, willing to be followed up for 24
35 months and give informed consent, a new patient to the dental practice and able to
36 complete the patient completed questionnaires (if a translator is needed, the availability of
37 provision of translation service in the spoken language of the participant will be via the
38 normal dental practice access routes to such services). Whilst edentulous patients will not
39 be excluded, they will be considered supplementary to the core sample of 550 patients and
40 provide additional specific data
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43 Data will be collected at baseline and 24 months. BOP and ICDAS will be completed by the
44 dental practitioner at the dental appointment. Training will be provided to all practices on
45 use of the ICDAS. For the risk assessment, data from the traffic light system (refer to Table
46 1) will be collected outlining variations when the protocol is over-ruled by clinicians and
47 why. Recruitment will take place over a 6 month period beginning in April 2012. The
48 OHIP14 and EQ-5D will be completed by the patients.
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51 Multiple linear regression will be used to model differences in BOP from baseline to 24
52 months. Changes in oral health quality of life (OHQoL) will be explored using structural
53 equation modelling to identify the relationships between changes in clinical status and
54 patient perspective.
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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 base^[14] for the future development of a preference-based dental health related quality of life instrument.

Whilst 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 medicaments 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 (Galloway et al, 2002)^[15]. Skill-mix is advocated in several current proposals for change that continue a trend seen in UK dentistry over the last twenty years^{[2] [16] [17] [18] [19]}. For example, dental therapists may now work in general dental practice^[17] their clinical remit has expanded^[20]

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3 [21] and more recently in March 2013 the GDC permitted direct access to some dental care
4 professionals, hygienists and therapists can now carry out their full scope of practice
5 without prescription and without the patient having to see a dentist first. Whilst there are
6 few hard data to support skill-mix in dentistry [15] some data are beginning to emerge; for
7 example, a recent practice-based study found the success of fissure sealants placed by
8 dentists, hygienists and therapists to be comparable [22]. However, research is needed to
9 assess whether new models of delivery and service design will encourage their use and
10 whether they are acceptable to dentists and patients.
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12
13 Emphasis of the new incentivised contracts lies on quality and outcomes. Whilst quality
14 indicators linked to contracts and payments have been used widely in other branches of
15 healthcare, the results are complex. The indicators can drive organisational change towards
16 best practice, but may also be a disincentive to important but non-rewarded activities [7].
17 Used alongside demographic data, the indicators can measure practice performance,
18 identify areas for development and assist sharing of best practice [23]. The indicators often
19 increase the quantity of service provision, but not always the quality [24]. Whilst offering
20 great potential, quality indicators have not been comprehensively evaluated in dentistry. A
21 recent systematic review was only able to provide a framework for how such indicators
22 might work [25].
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25 In respect of improved health outcomes, the dental community is united that outcomes in
26 terms of clinical effectiveness should focus on major public health challenges including
27 caries and periodontal diseases where health improvement is needed. However the
28 community lacks consensus in how to best to measure change.
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31 There is also little in the literature regarding care pathways in primary dental care, although
32 the concept has been around for a number of years. The concepts and benefits of the care
33 pathway approach in dental primary care were described by Hally and Pitts [26]. As a result of
34 Government recommendations [17] the first widely disseminated care pathway in UK dental
35 primary care was the Oral Health Assessment (OHA) within the National Institute for Health
36 and Clinical Excellence guidance on dental recall intervals [27]. The OHA care pathway was
37 designed to enable more prevention within personalised care plans taking into account their
38 social and dental histories as well as clinical findings. This pathway informs what to
39 commission from the practices involved in this study but has not been fully evaluated in
40 practice.
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43 The emerging service delivery models in the UK should include innovative use of skill mix,
44 evidence based care pathways, funding and quality indicators [18]. A robust evaluation of
45 new dental contracts is called for [1], which is what this study aims to achieve.
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48 Study Status

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51 The first patient for the effectiveness and cost effectiveness studies was recruited in June
52 2012 and the last patient in January 2013. Recruitment for the qualitative study is on-going.
53 The results will be reported in 2015
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Ethics and dissemination

The study has been approved by NRES Committee London-Bromley (Reference No: 12/LO/0205) prior to entering patients into the study. 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 patient information leaflet to consider, if they are willing to join INCENTIVE they will be 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 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 operations across WP1-3. 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 DOB only). Should it be required to send any patient identifiable information (e.g. 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 which contains

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3 the patient's signature, that are transferred to or from the research team at University of
4 Leeds or University of Sheffield will be coded with a unique study number and will include
5 two patient identifiers: initials and date of birth.
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7 **Declaration of interests**

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9 The research team has no identified conflict of interest to conduct this research.
10

11 **Dissemination policy**

12 **A. Data analysis and release of results**

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14 The scientific integrity of the project requires that the data from all BEST [Beta-Blocker
15 Evaluation of Survival Trial] sites be analyzed study-wide and reported as such. Thus, an
16 individual center is not expected to report the data collected from its center alone . . . all
17 presentations and publications are expected to protect the integrity of the major
18 objective(s) of the study; data that break the blind will not be presented prior to the release
19 of mainline results. Recommendations as to the timing of presentation of such endpoint
20 data and the meetings at which they might be presented will be given by the Steering
21 Committee.
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26 **B. Review process**

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28 Each paper or abstract, as described below, must be submitted to the research group for
29 review of its appropriateness and scientific merit prior to submission and to the funding
30 body.
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33 **C. Primary outcome papers**

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35 The primary outcome papers of INCENTIVE are papers that present outcome data from the
36 3 works packages.
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39 **D. Other study papers, abstracts and presentations**

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41 All studies other than those designated as "Primary Outcome" fall within this category. All
42 papers and abstracts will be approved by the research group before they are submitted.
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44 Every attempt will be made to reduce to an absolute minimum the interval between the
45 completion of data collection and the release of the study results. We expect to take about
46 3 to 4 months to compile the final results paper for an appropriate journal.
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49 **B. Reporting of study results**

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51 The study results will be released to the participating practitioners, patients, commissioners
52 and the general dental community.
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Authors' contributions

SP contributed to the design of the study and, leads the Patient and Public Involvement (PPI) aspects of the study. PBa contributed to the study design and has responsibility for the design of the statistical analysis plan. PBr and JG contributed to the study design and liaison with the health commissioner stakeholders. JG also liaises with the dental practices. BG, MH, JP and PR 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. 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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Trial Sponsor: University of Leeds

List of abbreviations

AE	Adverse Event
DH	Department of Health
EQ5D	EuroQOL 5 Domains (Quality of Life Health Questionnaire)
GCP	Good Clinical Practice
ICDAS	International Caries Detection and Assessment System
LDI	Leeds Dental Institute
nGDS	new General Dental Services contracts
NHS	National Health Service
NIHR	National Institute of Health Research
OHA	Oral Health Assessment
OHimp	Oral Health Improvement
OHIP	Oral Health Impact Profile (Questionnaire)

PCT	Primary Care Trusts
PIS/ICD	Patient Information Sheet/Informed Consent Document
QALY	Quality-Adjusted Life Year
QOF	Quality and Outcomes Framework
PPI	Patient Public Involvement
PROM	Patient reported outcome measures
REC	Research Ethics Committee
SOP	Standard Operating Procedure
INCENTIVE MG	INCENTIVE Management Group
INCENTIVE AG	INCNTIVE Advisory Group
UDA	Units of Dental Activity

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Figure/Table legends

Table 1: 'Traffic Light' Risk Assessment

Table 2: Key Characteristics of Traditional and New Model Incentive Practices under evaluation in the INCENTIVE Study

Figure 1: Flow diagram INCENTIVE study

peer review only

Flow diagram –INCENTIVE SDO 09/1004/04:

Improving the organisation and delivery of dental health care to patients.

INCENTIVE: innovation in commissioning and delivery of primary dental care services in dental practice pilots

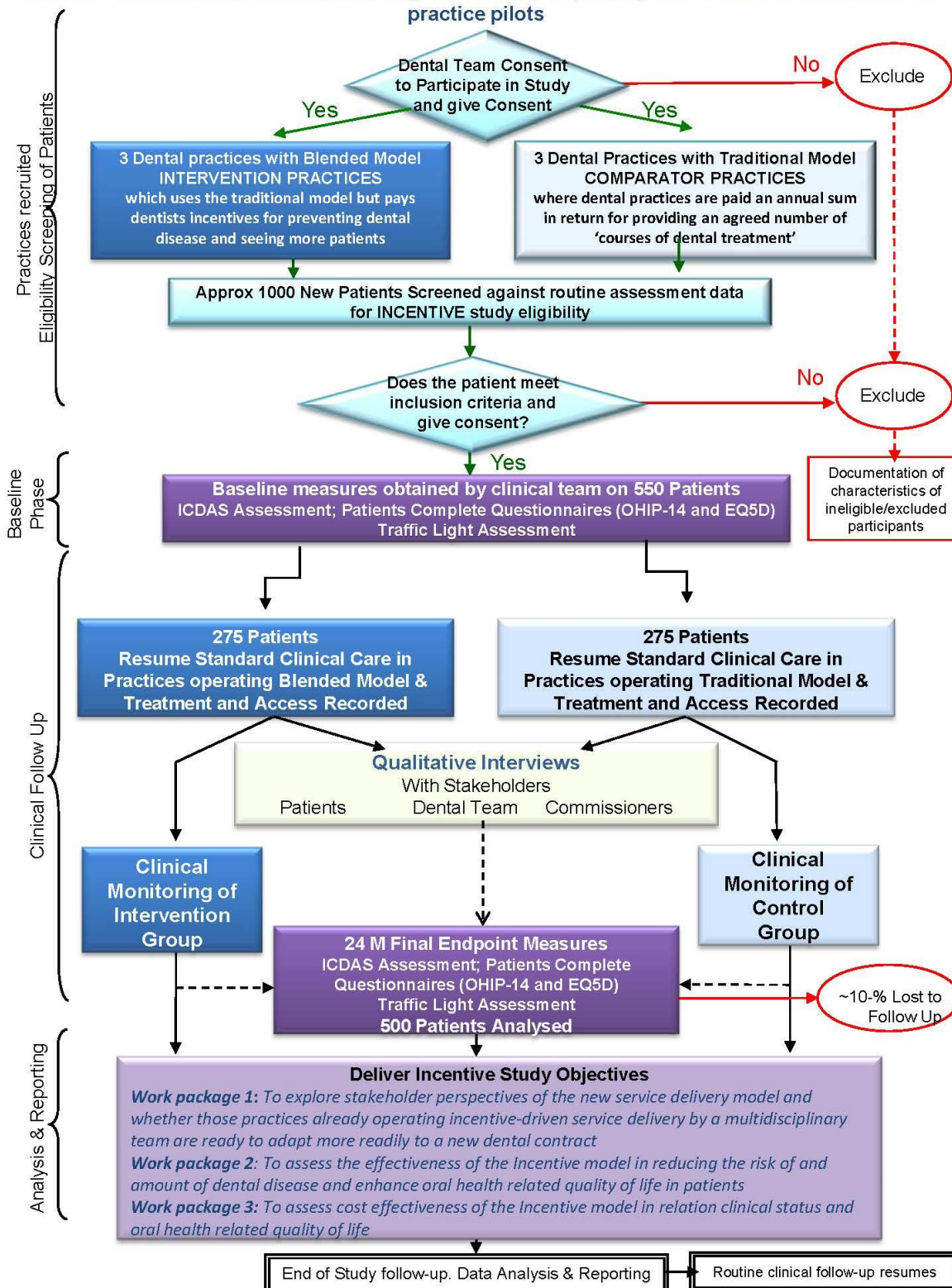





Table 1: 'Traffic Light' Risk Assessment

TRAFFIC LIGHT GUIDELINES

	DESCRIPTOR	EXAMPLE INDICATORS
	❖ High risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in more than one tooth, Basic Periodontal Examination (BPE) score of >2 in 3 or more sextants ❖ Social history: Never brushes teeth
	❖ Medium risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in one tooth, BPE score of >2 in 2 sextants ❖ Social history: brushes once per day
	❖ Low risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: No active decay, BPE score ≤2 confined to 1 sextant ❖ Social history: brushes twice per day

N.B. The overall risk category is triggered by the highest risk level allocated by clinical, social history assessment tools
 A confounding medical history will be excluded from this study as it is usually not amenable to change)

Table 2: 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	Traditional	Incentive-driven
Contract Type	General Dental Services contracts (nGDS)	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- Units of Dental activity (UDAs)	Activity: 60% of contract value-UDA's Incentives: i)Quality systems, processes infrastructure (e.g. cross infection, standards for better health): 20% of contract value, and ii)Oral health improvement: 20% contract value
Incentives and Levers	Driven by delivery of UDAs, with no incentives for preventive 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 preventive focussed care For example, dental therapists can extract baby teeth, place fillings and apply preventive medicaments. Dental nurses may give preventive advice and apply preventive fluoride varnish to teeth
Care Pathway & Recall	Care pathway and recall as prescribed by individual performers.	Risk assessed (traffic light system) evidence based preventive care pathway. Risk assessed recall interval (NICE guidelines on dental recall interval), variations recorded
Stakeholder Feedback on Delivery & Impact of Care	Standard complaints/comments	Patient forum

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The INCENTIVE protocol – An evaluation of the organisation and delivery of NHS dental health care to patients - innovation in the commissioning of primary dental care service delivery and organisation in the UK



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The INCENTIVE protocol – An evaluation of the organisation and delivery of NHS dental health care 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 (UDA) awarded in three treatment bands based on complexity of care. More 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-contact model (incentive-driven) compared to traditional nGDS contracts on dental service delivery in practices in West Yorkshire, England.

Methods and Analysis

INCENTIVE uses a mixed methods approach to comprehensively evaluate a new incentive-driven model of NHS dental service delivery. The study includes 20 dental surgeries located across three newly commissioned dental practices (blended contact) 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. The results of this study will be disseminated at national and international conferences and in international journals.

Strengths and Limitations

- INCENTIVE 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 that are largely limited to survey based evaluations
- Whilst this is not an RCT the mixed methods offers 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

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 (UDA) 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 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 which may have been influenced by the Steele Review^[2] 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*^[2; p67]. 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. Christianson and colleagues'^[3] review 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

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3 significant improvement in professional practice ^[4]. O'Donnell and colleagues ^[5] found
4 within the new General Medical Services contracts in primary care that the Quality and
5 Outcomes Framework (QOF) incentivised performance, motivating staff towards QOF
6 targets. Similarly, McDonald and colleague's ^[1] review of the effect of incentives on the
7 primary care workforce found them to be powerful motivators. A more granular view
8 suggests that their process-based nature may limit their long-term effects on health
9 outcomes ^[6]. There is also a danger that important activities that lack a target may be
10 underemphasised ^[7] ^[6].
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15 In order to inform an appropriate model of care to maintain and improve oral health a
16 number of dental contracts have been locally commissioned focused on oral health
17 improvement and quality, in addition national pilots are underway in England developed by
18 the Department of Health. All share common features of being capitation based, of having a
19 quality element, of conferring a responsibility for long term care of the patient on the
20 contract holder and of being based on an oral health assessment and pathway ^[8].
21

22 The INCENTIVE Study aims to evaluate a blended-contact model (incentive-driven)
23 compared to traditional nGDS contracts on dental service delivery in practices in West
24 Yorkshire, England to generate information that will be of value for designing and
25 commissioning future NHS dental services.
26

27 **Methods and Analysis**

28 **Study Objectives**

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

39 **Design**

40 INCENTIVE will use a mixed methods approach combining qualitative and quantitative
41 techniques to comprehensively evaluate a new incentive-driven model of NHS dental
42 service delivery. The study will include 20 dental surgeries located across three newly
43 commissioned dental practices (blended contact) and three existing traditional practices
44 (nGDS contracts) in West Yorkshire (10 in each of the two arms). The newly commissioned
45 practices have been matched to traditional practices by deprivation index, age profile,
46 ethnicity, size of practice, and taking on new patients.
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3 The study consists of three interlinked work packages: a qualitative study to explore
4 stakeholder perspectives of the new service delivery model and whether those practices
5 already operating incentive-driven service delivery by a multidisciplinary team are ready to
6 adapt more readily to a new dental contract; an effectiveness study to assess the
7 effectiveness of the INCENTIVE model in reducing the risk of and amount of dental disease
8 and enhance oral health related quality of life in patients; and a cost effectiveness study to
9 assess cost effectiveness of the INCENTIVE model in relation to clinical status and oral health
10 related quality of life. An overview of the study incorporating the three work packages is
11 contained in figure 1.
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14 15 16 Setting

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18 Focus lies on a new blended dental contract introduced in 2007 for three newly
19 commissioned NHS dental practices in West Yorkshire. The specification was innovative and
20 although pre-dating the Steele Review ^[2], it reflected its' ethos and recommendations with
21 emphasis on quality of care, achieving health outcomes and patient reported outcome
22 measures (PROMS) ^[9].
23

24 In brief, 60% of the contract value is apportioned to delivery of a set number of UDAs. The
25 remaining 40% is dependent on the delivery of quality – 20% systems, processes,
26 infrastructure (e.g. dental standards of quality and safety overseen by The Care Quality
27 Commission) and 20% oral health improvement (OHImp). The framework is an evolving
28 mechanism for improving oral health and monitoring outcomes within the practices. The
29 outcomes for year one involved focused on ensuring that e foundations were in place for
30 the care pathway approach to evidence based preventive care, including appropriate skill
31 mix, staff training, reviewing practice and community profiles.
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34 The new contracts are aimed at: ensuring evidence-based preventive interventions ^[10] are
35 delivered in line with identified needs for a defined population; increased access to
36 dentistry; that care is provided by the most appropriate team member to encourage skill
37 mix. All practices fully utilise skill mix and have hygiene therapists and additional skills
38 dental nurses.
39

40 The contracts encourage a care pathway approach in which all patients should be assessed
41 formally on joining the practice and at each subsequent recall. Four sets of information (age
42 group, medical history, social history (self-care, habits/diet) and clinical assessment) are
43 used to inform a traffic-light system for patients with high (red), medium (amber) or low
44 (green) risk of oral disease (refer to Figure 2). This type of traffic-light system has not been
45 fully explored, although early work is on-going in the North West of England ^[11]. The patient
46 care pathway includes evidence based prevention and advice, appropriate recall interval
47 and restorative care as appropriate (red risk category treatment being limited to
48 stabilisation and lowering risk status). Patient status is reviewed at their next oral health
49 assessment allowing them to move between risk categories.
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52 Within practice monitoring ensures evidence-based prevention is delivered in line with
53 identified needs and monitors access to dentistry. Oral health improvement is assessed
54 through the delivery of a performance framework. Payment is linked to three elements: a
55 register by age group of those having risk assessment, management of care appropriate to
56 need and evidence-base and the measurement of oral health outcomes.
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Qualitative Study

A qualitative study will explore the meaning of key aspects of the new service delivery model for three discrete stakeholder groups: (a) public and patients (i.e. both non-patients and patients); (b) commissioners and (c) the primary care dental teams. Preliminary observational studies will help develop the topic guides for subsequent semi-structured 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 5 interviews and three focus groups with 4 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, socio-economic 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 give informed consent; if a translator is needed the availability of provision of translation service in the spoken language of the participant 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 (e.g. 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 (e.g. church pastor) so that the study can be explained, their help in recruitment can 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 INCENTIVE promotes greater participation for 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

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3 sorted by theme to enable constant comparison across themes and cases. The goal of our
4 analysis will be to establish typologies for participation, health improvement, access,
5 professional involvement and care pathways. These typologies will identify the general
6 nature of each of these aspects and will enable us to analyse the way in which the emerging
7 model can develop new directions for primary care dentistry. The findings will be
8 triangulated with a range of literatures including definitions of health, current policy, access,
9 quality and public involvement.
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12 The study focuses on innovative commissioning models which are commissioned within a
13 real world environment. Should a new national contract, or indeed local commissioning
14 arrangements be introduced during the study period, the study will examine the impact of
15 the change and differences between the innovative and traditional models in adapting to
16 implementing the new contractual model.
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20 **Effectiveness Study**

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22 The key characteristics of the traditional and new model incentive-driven practices are
23 summarised in Table 1. A non-randomized- natural experiment will compare three incentive
24 driven dental practices with the three matched traditional practices. The practices are
25 matched by size, number of dentists, location and patient demographics. The primary
26 outcome will be gingivitis measured as the proportion of sites that bleed on probing (BOP).
27 Secondary/exploratory outcomes include oral health related quality of life (OHIP14) and
28 generic health related quality of life (EQ-5D). The dental caries experience will be recorded
29 using the International Caries Detection and Assessment System (ICDAS).
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3 To achieve a recruitment of 550 new patients in the INCENTIVE project, recruitment will
4 take place over the 6 practices for a period of six months. We anticipate 10% lost to follow
5 up so this leaves us with an adequate sample of ~500 for analysis. Recruitment is based on:
6 i) six dental practices included in the study that comprise 20 surgeries; ii) an average list size
7 of 1000 adult patients per dentist; iii) 10% of which per year will be new patients to the
8 practice (estimated from the Dental Public Health audit figures of practices in Bradford and
9 Airedale); iv) of these we estimate a minimum of 50% will agree to participate in the study
10 over the six months recruitment period. Thus at a practice level the three newly
11 commissioned dental practices will be matched with three existing traditional practices of
12 similar size (10 surgeries in each of the two arms), deprivation index, age profile, ethnicity
13 and that the practice is taking on new patients. At a patient level inclusion criteria are that
14 patients must be above 16 years of age and a new patient to the practice during the
15 recruitment period (anticipated being 6 months) willing to be followed up for 24 months
16 and give informed consent and able to complete the patient completed questionnaires (if a
17 translator is needed, the availability of provision of translation service in the spoken
18 language of the participant will be via the normal dental practice access routes to such
19 services). With regard to exclusion criteria and the specific handling of those who are
20 edentulous, they will not be excluded from the sample however they will be considered
21 supplementary to the core sample of 550 patients and provide additional specific data.
22 Postcode, age and ethnicity of all patients included within the sample will be recorded and
23 profiled during the analysis.
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28 To detect a clinically meaningful reduction in BOP of 10% and assuming a 10% drop out rate,
29 275 patients are required in from the incentive-driven practices and from the nGDS
30 practices to give 80% power with a significance level of 5%. The inclusion criteria for this
31 part of the study are patients aged 16 years and over, willing to be followed up for 24
32 months and give informed consent, a new patient to the dental practice and able to
33 complete the patient completed questionnaires (if a translator is needed, the availability of
34 provision of translation service in the spoken language of the participant will be via the
35 normal dental practice access routes to such services). Whilst edentulous patients will not
36 be excluded, they will be considered supplementary to the core sample of 550 patients and
37 provide additional specific data
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40 Data will be collected at baseline and 24 months. BOP and ICDAS will be completed by the
41 dental practitioner at the dental appointment. Training will be provided to all practices on
42 use of the ICDAS. For the risk assessment, data from the traffic light system (refer to Figure
43 2) will be collected outlining variations when the protocol is over-ruled by clinicians and
44 why. Recruitment will take place over a 6 month period beginning in April 2012. The
45 OHIP14 and EQ-5D will be completed by the patients.
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48 Multiple linear regression will be used to model differences in BOP from baseline to 24
49 months. Changes in oral health quality of life (OHQoL) will be explored using structural
50 equation modelling to identify the relationships between changes in clinical status and
51 patient perspective.
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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 base^[14] for the future development of a preference-based dental health related quality of life instrument.

Whilst 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 medicaments 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 (Galloway et al, 2002)^[15]. Skill-mix is advocated in several current proposals for change that continue a trend seen in UK dentistry over the last twenty years^{[2] [16] [17] [18] [19]}. For example, dental therapists may now work in general dental practice^[17] their clinical remit has expanded^[20]

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3 [21] and more recently in March 2013 the GDC permitted direct access to some dental care
4 professionals, hygienists and therapists can now carry out their full scope of practice
5 without prescription and without the patient having to see a dentist first. Whilst there are
6 few hard data to support skill-mix in dentistry [15] some data are beginning to emerge; for
7 example, a recent practice-based study found the success of fissure sealants placed by
8 dentists, hygienists and therapists to be comparable [22]. However, research is needed to
9 assess whether new models of delivery and service design will encourage their use and
10 whether they are acceptable to dentists and patients.
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12
13 Emphasis of the new incentivised contracts lies on quality and outcomes. Whilst quality
14 indicators linked to contracts and payments have been used widely in other branches of
15 healthcare, the results are complex. The indicators can drive organisational change towards
16 best practice, but may also be a disincentive to important but non-rewarded activities [7].
17 Used alongside demographic data, the indicators can measure practice performance,
18 identify areas for development and assist sharing of best practice [23]. The indicators often
19 increase the quantity of service provision, but not always the quality [24]. Whilst offering
20 great potential, quality indicators have not been comprehensively evaluated in dentistry. A
21 recent systematic review was only able to provide a framework for how such indicators
22 might work [25].
23

24
25 In respect of improved health outcomes, the dental community is united that outcomes in
26 terms of clinical effectiveness should focus on major public health challenges including
27 caries and periodontal diseases where health improvement is needed. However the
28 community lacks consensus in how to best to measure change.
29

30
31 There is also little in the literature regarding care pathways in primary dental care, although
32 the concept has been around for a number of years. The concepts and benefits of the care
33 pathway approach in dental primary care were described by Hally and Pitts [26]. As a result of
34 Government recommendations [17] the first widely disseminated care pathway in UK dental
35 primary care was the Oral Health Assessment (OHA) within the National Institute for Health
36 and Clinical Excellence guidance on dental recall intervals [27]. The OHA care pathway was
37 designed to enable more prevention within personalised care plans taking into account their
38 social and dental histories as well as clinical findings. This pathway informs what to
39 commission from the practices involved in this study but has not been fully evaluated in
40 practice.
41

42
43 The emerging service delivery models in the UK should include innovative use of skill mix,
44 evidence based care pathways, funding and quality indicators [18]. A robust evaluation of
45 new dental contracts is called for [1], which is what this study aims to achieve.
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48 Study Status

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51 The first patient for the effectiveness and cost effectiveness studies was recruited in June
52 2012 and the last patient in January 2013. Recruitment for the qualitative study is on-going.
53 The results will be reported in 2015
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Ethics

The study has been approved by NRES Committee London-Bromley (Reference No: 12/LO/0205) prior to entering patients into the study. 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 patient information leaflet to consider, if they are willing to join INCENTIVE they will be 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 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 operations across WP1-3. 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 DOB only). Should it be required to send any patient identifiable information (e.g. 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 which contains

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3 the patient's signature, that are transferred to or from the research team at University of
4 Leeds or University of Sheffield will be coded with a unique study number and will include
5 two patient identifiers: initials and date of birth.
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7 **Dissemination policy**

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9 An end of project national dissemination meeting will be undertaken with dental
10 commissioners and a lay summary of project findings for circulation to study participants. It
11 is anticipated that there will be two publications in international peer reviewed, high impact
12 journals and conference dissemination at the National meeting of the British Dental
13 Association or equivalent and the International American Dental Research or equivalent.
14

15 The Chief Investigator, Co-Applicants and senior management staff will be named as authors
16 in any publication, and an appropriate first author agreed through discussion amongst the
17 Study Management Group (SMG) members. In addition, all collaborators will be listed as
18 contributors for the main study publication, giving details of their roles in planning,
19 conducting and reporting the study. The INCENTIVE team will be acknowledged in all
20 publications, as will the funder. Other key individuals will be included as authors or
21 contributors as appropriate and at the discretion of the SMG. Any disputes relating to
22 authorship will be resolved by the SAB.
23
24

25 The Chairs and Independent members of the TSC will be acknowledged, but will not qualify
26 for full authorship, in order to maintain their independence.
27

28 To maintain the scientific integrity of the study, data will not be released prior to the first
29 publication of the results of the primary endpoint analysis, either for study publication or
30 oral presentation purposes, without the permission of the SMG.
31

32 The SMG will agree a publication plan and must be consulted prior to release or publication
33 of any study data.
34

35 Individual collaborators must not publish data concerning their participants which is directly
36 relevant to the questions posed in the study until the main results of the study have been
37 published. Local collaborators may not have access to study data until after publication of
38 the main study results unless with agreement of the SMG.
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FOOTNOTES

Contributorship statement

SP contributed to the design of the study and, leads the Patient and Public Involvement (PPI) aspects of the study. PBa contributed to the study design and has responsibility for the design of the statistical analysis plan. PBr and JG contributed to the study design and liaison with the health commissioner stakeholders. JG also liaises with the dental practices. BG, MH, JP and PR 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. 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.

Competing interests

The research team has no identified conflict of interest to conduct this research.

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Trial Sponsor: University of Leeds

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List of abbreviations

AE	Adverse Event
DH	Department of Health
EQ5D	EuroQOL 5 Domains (Quality of Life Health Questionnaire)
GCP	Good Clinical Practice
ICDAS	International Caries Detection and Assessment System
LDI	Leeds Dental Institute
nGDS	new General Dental Services contracts
NHS	National Health Service
NIHR	National Institute of Health Research
OHA	Oral Health Assessment
OHimp	Oral Health Improvement
OHIP	Oral Health Impact Profile (Questionnaire)
PCT	Primary Care Trusts
PIS/ICD	Patient Information Sheet/Informed Consent Document
QALY	Quality-Adjusted Life Year
QOF	Quality and Outcomes Framework
PPI	Patient Public Involvement
PROM	Patient reported outcome measures
REC	Research Ethics Committee
SOP	Standard Operating Procedure
INCENTIVE MG	INCENTIVE Management Group
INCENTIVE AG	INCNTIVE Advisory Group
UDA	Units of Dental Activity

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	Traditional	Incentive-driven
Contract Type	General Dental Services contracts (nGDS0)	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 – Units of dental activity (UDAs)	Activity: 60% of contract value UDAs Incentives: i) Quality systems, processes infrastructure (e.g. cross infection, standards for better health): 20% of contract value, and ii) 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 focussed 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 & Impact of Care	Standard complaints/comments	Patient forum

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Figure/Table legends

Figure 1: Flow diagram INCENTIVE study

Figure 2: ‘Traffic Light’ Risk Assessment

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7 **The INCENTIVE protocol** – An evaluation of the organisation and delivery of NHS dental
8 health care to patients - innovation in the commissioning of primary dental care service
9 delivery and organisation in the UK

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Abstract

Background 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 (UDA) awarded in three treatment bands based on complexity of care. More 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-contact model (incentive-driven) compared to traditional nGDS contracts on dental service delivery in practices in West Yorkshire, England.

Methods and Analysis

INCENTIVE uses a mixed methods approach to comprehensively evaluate a new incentive-driven model of NHS dental service delivery. The study includes 20 dental surgeries located across three newly commissioned dental practices (blended contact) 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 ~~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 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.

Dissemination and Ethics and dissemination

The study has been approved by NRES Committee London-Bromley. The results of this study will be disseminated at national and international conferences and in international journals.

Keywords

Dentists, contracts, financial incentives, pay for performance, reimbursement, effectiveness, cost effectiveness, quality

Strengths and Limitations

- ~~• The INCENTIVE evaluation is of strategic importance to the Department of Health to generate information that will be of immense value for designing and commissioning future NHS dental services~~
- ~~• Whilst a new contract is due to be introduced for NHS dental services in 2016-17 in line with a more blended or incentivised model there is limited evidence of the effectiveness of these types of contract~~
- INCENTIVE 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 that are largely limited to survey based evaluations
- ~~• As a consequence our article is guaranteed to draw attention of the scientific and commissioning communities. The work is ongoing and already attracting considerable interest from key stakeholders~~
- Whilst this is not an RCT the mixed methods offers 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 current article reports the protocol only~~

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 (UDA) 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 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 which may have been influenced by the Steele Review^[2] of NHS dentistry which recommended that payments explicitly recognise prevention and

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7 *reward the contribution of the dental team to improvements to oral health, reflected in*
8 *patient progression along the pathway, compliance with nationally agreed clinical guidelines*
9 *and the achievement of expected outcomes* [2; p67]. In addition commissioners were asked to
10 *support dentists to make best and most cost effective use of the available dental workforce*
11 [2].

12
13 Thus contract currency in UK dentistry is evolving from UDAs based on volume and case
14 complexity towards “blended contracts” that include incentives linked with key
15 performance indicators such as quality and improved health outcome [2]. Overall, evidence
16 of the effectiveness of incentive-driven contracting of health providers is still emerging.
17 Christianson and colleagues’ [3] review found mixed results of the effect of payer initiatives
18 that reward providers for quality improvements whereas Clarkson et al [4] found targeted
19 payments to be a cost-effective intervention in changing a clinician’s behaviour, with
20 significant improvement in professional practice [4]. O’Donnell and colleagues [5] found
21 within the new General Medical Services contracts in primary care that the Quality and
22 Outcomes Framework (QOF) incentivised performance, motivating staff towards QOF
23 targets. Similarly, McDonald and colleague’s [1] review of the effect of incentives on the
24 primary care workforce found them to be powerful motivators. A more granular view
25 suggests that their process-based nature may limit their long-term effects on health
26 outcomes [6]. There is also a danger that important activities that lack a target may be
27 underemphasised [7] [6].
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30 In order to inform an appropriate model of care to maintain and improve oral health a
31 number of dental contracts have been locally commissioned focused on oral health
32 improvement and quality, in addition national pilots are underway in England developed by
33 the Department of Health. All share common features of being capitation based, of having a
34 quality element, of conferring a responsibility for long term care of the patient on the
35 contract holder and of being based on an oral health assessment and pathway [8].
36

37 The INCENTIVE Study aims to evaluate a blended-contact model (incentive-driven)
38 compared to traditional nGDS contracts on dental service delivery in practices in West
39 Yorkshire, England to generate information that will be of value for designing and
40 commissioning future NHS dental services.
41

42 **Methods and Analysis**

43 **Study Objectives**

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

Design

INCENTIVE 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 20 dental surgeries located across three newly commissioned dental practices (blended contact) and three existing traditional practices (nGDS contracts) in West Yorkshire (10 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 (e.g. 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 health and monitoring outcomes within the practices. The outcomes for year one involved focused 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 evidence-based preventive interventions^[10] are delivered in line with identified needs for a defined population; increased access to dentistry; 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.

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7 The contracts encourage a care pathway approach in which all patients should be assessed
8 formally on joining the practice and at each subsequent recall. Four sets of information (age
9 group, medical history, social history (self-care, habits/diet) and clinical assessment) are
10 used to inform a traffic-light system for patients with high (red), medium (amber) or low
11 (green) risk of oral disease (refer to [Figure 2Table 1](#)). This type of traffic-light system has not
12 been fully explored, although early work is on-going in the North West of England ^[11]. The
13 patient care pathway includes evidence based prevention and advice, appropriate recall
14 interval and restorative care as appropriate (red risk category treatment being limited to
15 stabilisation and lowering risk status). Patient status is reviewed at their next oral health
16 assessment allowing them to move between risk categories.

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

22 23 24 **Qualitative Study**

25
26 A qualitative study will explore the meaning of key aspects of the new service delivery
27 model for three discrete stakeholder groups: (a) public and patients (i.e. both non-patients
28 and patients); (b) commissioners and (c) the primary care dental teams. Preliminary
29 observational studies will help develop the topic guides for subsequent semi-structured
30 interviews and focus groups. Recruitment will continue until no new variation in
31 observations can be found (saturation). If necessary additional participants will be identified
32 using theoretical sampling. For planning purposes, we anticipate conducting approximately
33 5 interviews and three focus groups with 4 or more participants within each stakeholder
34 group.

35
36 The sampling matrix for the public and patient group will include criteria linked to the
37 objectives of the programme including demographic factors (age, gender, ethnicity, socio-
38 economic status), risk category, treatment need and participation in the user forum. Broad
39 eligibility criteria at the participating practices will recruit patients: aged 16 years and over;
40 willing to be interviewed and give informed consent; if a translator is needed the availability
41 of provision of translation service in the spoken language of the participant via the normal
42 dental practice access routes to such services.

43
44 As the new contracting model considers access to care it is important that the sample
45 includes non-patients.

46 [A mixture of approaches will be used to recruit people who may not engage with local
47 dental care services, such as the employment of snowball sampling techniques and site-
48 based approaches to recruitment. However, snowball sampling used alone can result in
49 biased samples and it is important that any sample recruited to the study adequately
50 represents the target population. In order to achieve this goal specific attention may be
51 required for adequate recruitment of participants from different groups of the community.
52 Therefore, a site-based approach will be used to control bias and obtain a more
53 representative sample. A representative list of sites \(e.g. places, organisations or services\),
54 which may include churches, community centres, social clubs or housing projects will be](#)

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7 [identified with the researcher contacting the 'gatekeeper' for each of these sites \(e.g. church pastor\) so that the study can be explained, their help in recruitment can be enlisted and the researcher can collect information about the number and characteristics of site members.](#)

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11 ~~These participants will include representatives of community groups with whom the practices should have engaged.~~

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14 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 INCENTIVE promotes greater participation for the entire dental team.

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21 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.

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33 The study focuses on innovative commissioning models which 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.

34 35 36 37 38 39 40 **Effectiveness Study**

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The key characteristics of the traditional and new model incentive-driven practices are summarised in Table 21. A non-randomized- 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 (OHIP14) 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).

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7 To achieve a recruitment of 550 new patients in the INCENTIVE project, recruitment will
8 take place over the 6 practices for a period of six months. We anticipate 10% lost to follow
9 up so this leaves us with an adequate sample of ~500 for analysis. Recruitment is based on:
10 i) six dental practices included in the study that comprise 20 surgeries; ii) an average list size
11 of 1000 adult patients per dentist; iii) 10% of which per year will be new patients to the
12 practice (estimated from the Dental Public Health audit figures of practices in Bradford and
13 Airedale); iv) of these we estimate a minimum of 50% will agree to participate in the study
14 over the six months recruitment period. Thus at a practice level the three newly
15 commissioned dental practices will be matched with three existing traditional practices of
16 similar size (10 surgeries in each of the two arms), deprivation index, age profile, ethnicity
17 and that the practice is taking on new patients. At a patient level inclusion criteria are that
18 patients must be above 16 years of age and a new patient to the practice during the
19 recruitment period (anticipated being 6 months) willing to be followed up for 24 months
20 and give informed consent and able to complete the patient completed questionnaires (if a
21 translator is needed, the availability of provision of translation service in the spoken
22 language of the participant will be via the normal dental practice access routes to such
23 services). With regard to exclusion criteria and the specific handling of those who are
24 edentulous, they will not be excluded from the sample however they will be considered
25 supplementary to the core sample of 550 patients and provide additional specific data.
26 Postcode, age and ethnicity of all patients included within the sample will be recorded and
27 profiled during the analysis.

28
29 To detect a clinically meaningful reduction in BOP of 10% and assuming a 10% drop out rate,
30 275 patients are required in from the incentive-driven practices and from the nGDS
31 practices to give 80% power with a significance level of 5%. The inclusion criteria for this
32 part of the study are patients aged 16 years and over, willing to be followed up for 24
33 months and give informed consent, a new patient to the dental practice and able to
34 complete the patient completed questionnaires (if a translator is needed, the availability of
35 provision of translation service in the spoken language of the participant will be via the
36 normal dental practice access routes to such services). Whilst edentulous patients will not
37 be excluded, they will be considered supplementary to the core sample of 550 patients and
38 provide additional specific data

39 Data will be collected at baseline and 24 months. BOP and ICDAS will be completed by the
40 dental practitioner at the dental appointment. Training will be provided to all practices on
41 use of the ICDAS. For the risk assessment, data from the traffic light system (refer to
42 [TableFigure 24](#)) will be collected outlining variations when the protocol is over-ruled by
43 clinicians and why. Recruitment will take place over a 6 month period beginning in April
44 2012. The OHIP14 and EQ-5D will be completed by the patients.

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

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 base^[14] for the future development of a preference-based dental health related quality of life instrument.

Whilst 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 medicaments 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 (Galloway et al, 2002)^[15]. Skill-mix is advocated in several current proposals for change that continue a trend seen in UK dentistry over the last twenty years^{[2] [16] [17] [18] [19]}. For example, dental therapists may now work in general dental practice^[17] their clinical remit has expanded^[20]

^[21] and more recently in March 2013 the GDC 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. Whilst 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. Whilst 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]. Whilst 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 to 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 recommendations ^[17] the first widely disseminated care pathway in UK dental primary care was the Oral Health Assessment (OHA) within the National Institute for Health and Clinical 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

Ethics

The study has been approved by NRES Committee London-Bromley (Reference No: 12/LO/0205) prior to entering patients into the study. 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 patient information leaflet to consider, if they are willing to join INCENTIVE they will be 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 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 operations across WP1-3. 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 DOB only). Should it be required to send any patient identifiable information (e.g. 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 which contains

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7 [the patient's signature, that are transferred to or from the research team at University of](#)
8 [Leeds or University of Sheffield will be coded with a unique study number and will include](#)
9 [two patient identifiers: initials and date of birth.](#)

10 **Dissemination policy**

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

16 [The Chief Investigator, Co-Applicants and senior management staff will be named as authors](#)
17 [in any publication, and an appropriate first author agreed through discussion amongst the](#)
18 [Study Management Group \(SMG\) members. In addition, all collaborators will be listed as](#)
19 [contributors for the main study publication, giving details of their roles in planning,](#)
20 [conducting and reporting the study. The INCENTIVE team will be acknowledged in all](#)
21 [publications, as will the funder. Other key individuals will be included as authors or](#)
22 [contributors as appropriate and at the discretion of the SMG. Any disputes relating to](#)
23 [authorship will be resolved by the SAB.](#)

24 [The Chairs and Independent members of the TSC will be acknowledged, but will not qualify](#)
25 [for full authorship, in order to maintain their independence.](#)

26 [To maintain the scientific integrity of the study, data will not be released prior to the first](#)
27 [publication of the results of the primary endpoint analysis, either for study publication or](#)
28 [oral presentation purposes, without the permission of the SMG.](#)

29 [The SMG will agree a publication plan and must be consulted prior to release or publication](#)
30 [of any study data.](#)

31 [Individual collaborators must not publish data concerning their participants which is directly](#)
32 [relevant to the questions posed in the study until the main results of the study have been](#)
33 [published. Local collaborators may not have access to study data until after publication of](#)
34 [the main study results unless with agreement of the SMG.](#)

35 **Contributorship statement**

36 [SP contributed to the design of the study and, leads the Patient and Public Involvement \(PPI\)](#)
37 [aspects of the study. PBa contributed to the study design and has responsibility for the](#)
38 [design of the statistical analysis plan. PBr and JG contributed to the study design and liaison](#)
39 [with the health commissioner stakeholders. JG also liaises with the dental practices. BG,](#)
40 [MH, JP and PR contributed to the design of the study, with particular responsibility for the](#)
41 [Qualitative research. GD contributed to the study design and is primarily responsible for the](#)
42 [acquisition of ICDAS clinical. KV was responsible for the study coordination, design of the](#)
43 [case report forms and coordination and the acquisition of clinical data. CH participated in](#)
44 [the design of the study, with particular responsibility for the health economics. All authors](#)
45 [meet regularly to ensure the smooth running of the study, were involved in the protocol](#)
46 [drafting and contributed to and approved the final manuscript.](#)

47 **Competing interests**

48 [The research team has no identified conflict of interest to conduct this research.](#)

Funding

This study is funded by the Health Science and Delivery Programme (previously the Service Delivery & Organisation Programme) as part of the National Institute for Health Research (NIHR) (09/1004/04 INCENTIVE Improving the organisation and delivery of dental health care to patients – innovation in commissioning and delivery of primary dental care service delivery and organisation).

This report is independent research commissioned by National Institute for Health Research. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute of Health Research or the Department of Health.

Acknowledgements

We would like to formally thank the members of the INCENTIVE Advisory Group (James Steele (Chair) Head of School and Professor of Oral Health Services Research, Newcastle University; Sue Gregory: Deputy Chief Dental Officer, Kate Jones: Director of Dental Public Health Sheffield; Susan Neal Patient Representative, Alex Pavitt Patient Representative, Lynn Windle GDP & Clinical Dental Advisor NHS Bradford & Airedale, Ian Kirkpatrick Professor of Work and Organisation, John Hodgson: Senior Manager PCRN, Rebecca Harper: Research & Innovation Facilitator, NHS Airedale, Bradford & Leeds) Trial Sponsor: University of Leeds

Ethics and dissemination

~~**The study has been approved by NRES Committee London Bromley (Reference No: 12/LO/0205) prior to entering patients into the study. 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 patient information leaflet to consider, if they are willing to join INCENTIVE they will be 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

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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 which contains the patient's signature, that 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.

Declaration of interests

The research team has no identified conflict of interest to conduct this research.

Dissemination policy

A. Data analysis and release of results

The scientific integrity of the project requires that the data from all BEST [Beta Blocker Evaluation of Survival Trial] sites be analyzed study wide and reported as such. Thus, an individual center is not expected to report the data collected from its center alone . . . all presentations and publications are expected to protect the integrity of the major objective(s) of the study; data that break the blind will not be presented prior to the release of mainline results. Recommendations as to the timing of presentation of such endpoint data and the meetings at which they might be presented will be given by the Steering Committee.

B. Review process

Each paper or abstract, as described below, must be submitted to the research group for review of its appropriateness and scientific merit prior to submission and to the funding body.

C. Primary outcome papers

The primary outcome papers of INCENTIVE are papers that present outcome data from the 3 works packages.

D. Other study papers, abstracts and presentations

All studies other than those designated as “Primary Outcome” fall within this category. All papers and abstracts will be approved by the research group before they are submitted.

Every attempt will be made to reduce to an absolute minimum the interval between the completion of data collection and the release of the study results. We expect to take about 3 to 4 months to compile the final results paper for an appropriate journal.

B. Reporting of study results

The study results will be released to the participating practitioners, patients, commissioners and the general dental community.

Authors' contributions

SP contributed to the design of the study and, leads the Patient and Public Involvement (PPI) aspects of the study. PBa contributed to the study design and has responsibility for the design of the statistical analysis plan. PBr and JG contributed to the study design and liaison with the health commissioner stakeholders. JG also liaises with the dental practices. BG, MH, JP and PR 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. 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.

Acknowledgements and Funding

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Health Sheffield; Susan Neal Patient Representative, Alex Pavitt Patient Representative, Lynn Windle GDP & Clinical Dental Advisor NHS Bradford & Airedale, Ian Kirkpatrick Professor of Work and Organisation, John Hodgson: Senior Manager PCRN, Rebecca Harper: Research & Innovation Facilitator, NHS Airedale, Bradford & Leeds)
 Trial Sponsor: University of Leeds

List of abbreviations

AE	Adverse Event
DH	Department of Health
EQ5D	EuroQOL 5 Domains (Quality of Life Health Questionnaire)
GCP	Good Clinical Practice
ICDAS	International Caries Detection and Assessment System
LDI	Leeds Dental Institute
nGDS	new General Dental Services contracts
NHS	National Health Service
NHHR	National Institute of Health Research
OHA	Oral Health Assessment
OHimp	Oral Health Improvement
OHIP	Oral Health Impact Profile (Questionnaire)
PCT	Primary Care Trusts
PIS/ICD	Patient Information Sheet/Informed Consent Document
QALY	Quality Adjusted Life Year
QOF	Quality and Outcomes Framework
PPI	Patient Public Involvement
PROM	Patient reported outcome measures
REC	Research Ethics Committee
SOP	Standard Operating Procedure
INCENTIVE MG	INCENTIVE Management Group
INCENTIVE AG	INCENTIVE Advisory Group
UDA	Units of Dental Activity

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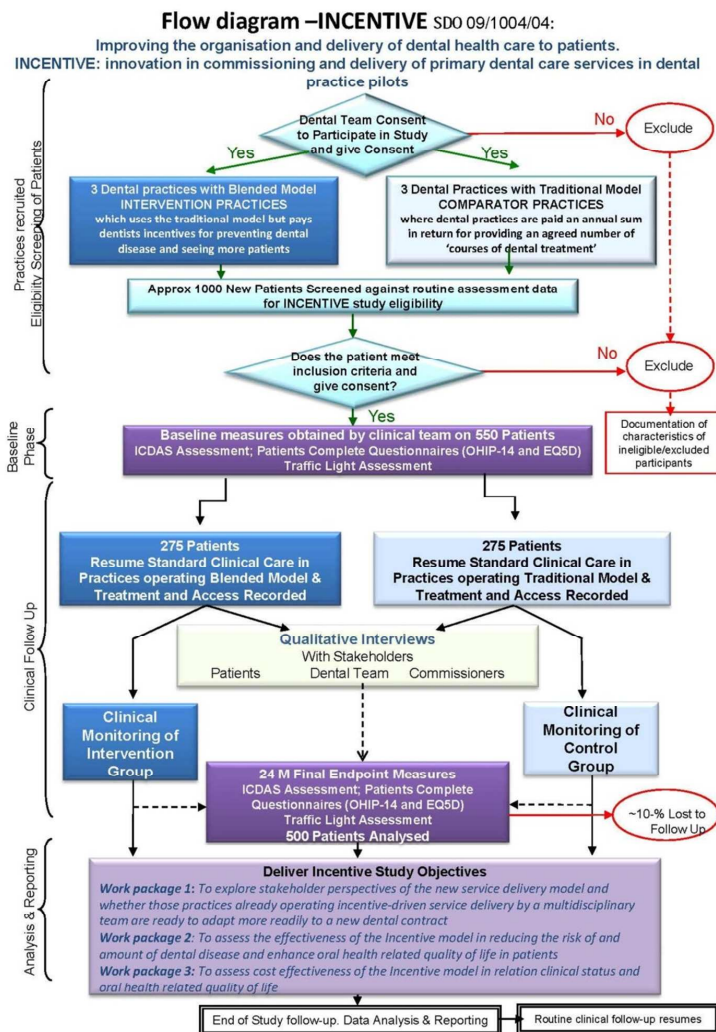
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List of abbreviations

<u>AE</u>	<u>Adverse Event</u>
<u>DH</u>	<u>Department of Health</u>
<u>EQ5D</u>	<u>EuroQOL 5 Domains (Quality of Life Health Questionnaire)</u>
<u>GCP</u>	<u>Good Clinical Practice</u>
<u>ICDAS</u>	<u>International Caries Detection and Assessment System</u>
<u>LDI</u>	<u>Leeds Dental Institute</u>
<u>nGDS</u>	<u>new General Dental Services contracts</u>
<u>NHS</u>	<u>National Health Service</u>
<u>NIHR</u>	<u>National Institute of Health Research</u>
<u>OHA</u>	<u>Oral Health Assessment</u>
<u>OHimp</u>	<u>Oral Health Improvement</u>
<u>OHIP</u>	<u>Oral Health Impact Profile (Questionnaire)</u>
<u>PCT</u>	<u>Primary Care Trusts</u>
<u>PIS/ICD</u>	<u>Patient Information Sheet/Informed Consent Document</u>
<u>QALY</u>	<u>Quality-Adjusted Life Year</u>
<u>QOF</u>	<u>Quality and Outcomes Framework</u>
<u>PPI</u>	<u>Patient Public Involvement</u>
<u>PROM</u>	<u>Patient reported outcome measures</u>
<u>REC</u>	<u>Research Ethics Committee</u>
<u>SOP</u>	<u>Standard Operating Procedure</u>
<u>INCENTIVE MG</u>	<u>INCENTIVE Management Group</u>
<u>INCENTIVE AG</u>	<u>INCENTIVE Advisory Group</u>
<u>UDA</u>	<u>Units of Dental Activity</u>

Figure/Table legends

Figure 1: Flow diagram INCENTIVE study



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Figure 2 Table 1: 'Traffic Light' Risk Assessment

TRAFFIC LIGHT GUIDELINES

	DESCRIPTOR	EXAMPLE INDICATORS
HIGH RISK	❖ High risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in more than one tooth, Basic Periodontal Examination (BPE) score of >2 in 3 or more sextants ❖ Social history: Never brushes teeth
MODERATE RISK	❖ Medium risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in one tooth, BPE score of >2 in 2 sextants ❖ Social history: brushes once per day
LOW RISK	❖ Low risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: No active decay, BPE score ≤2 confined to 1 sextant ❖ Social history: brushes twice per day

N.B. The overall risk category is triggered by the highest risk level allocated by clinical, social history assessment tools
A confounding medical history will be excluded from this study as it is usually not amenable to change)

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Table 21: Key Characteristics of Traditional and New Model Incentive Practices under evaluation in the INCENTIVE Study

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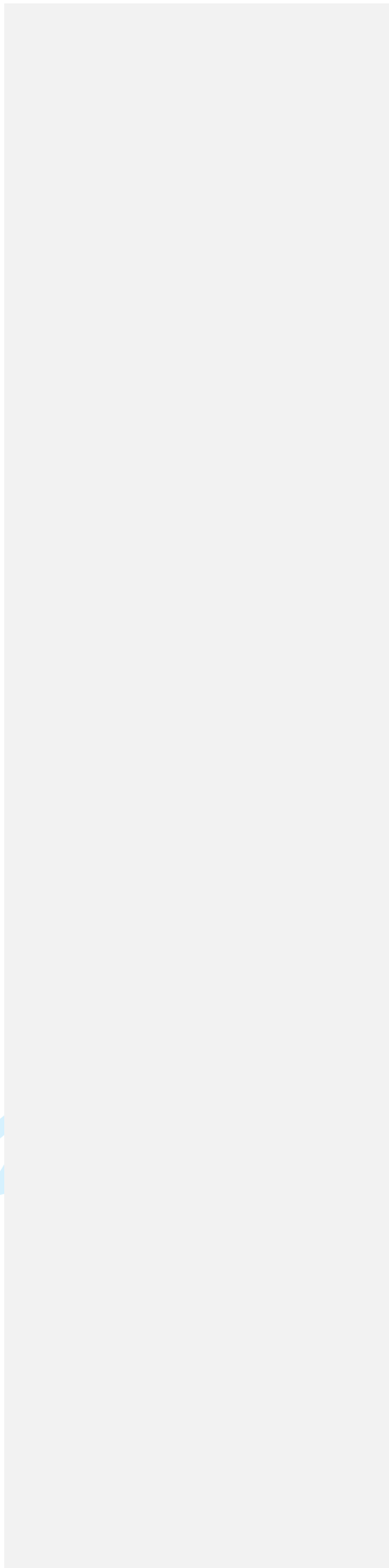
Table 2: Key Characteristics of the Traditional and New Model Incentive Practices under evaluation in the INCENTIVE Study

Characteristics	Traditional (Comparator) Practices (3 practices; 10 dental surgeries)	Incentive Practices (3 practices; 10 dental surgeries)
Model of Operation	Traditional	Incentive-driven
Contract Type	General Dental Services contracts (nGDS)	An incentive-driven contract (a blended contract combining nGDS and incentives)
Mode of Reimbursement	Activity based, weighted bands of dental activity Contract currency- Units of Dental activity (UDAs)	Activity: 60% of contract value-UDA's Incentives: i)Quality systems, processes infrastructure (e.g. cross infection, standards for better health): 20% of contract value, and ii)Oral health improvement: 20% contract value
Incentives and Levers	Driven by delivery of UDAs, with no incentives for preventive 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 preventive focussed care For example, dental therapists can extract baby teeth, place fillings and apply preventive medicaments. Dental nurses may give preventive advice and apply preventive fluoride varnish to teeth
Care Pathway & Recall	Care pathway and recall as prescribed by individual performers.	Risk assessed (traffic light system) evidence based preventive care pathway. Risk assessed recall interval (NICE guidelines on dental recall interval), variations recorded
Stakeholder Feedback on Delivery & Impact of Care	Standard complaints/comments	Patient forum

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| ~~Figure 1- Flow diagram INCENTIVE study~~

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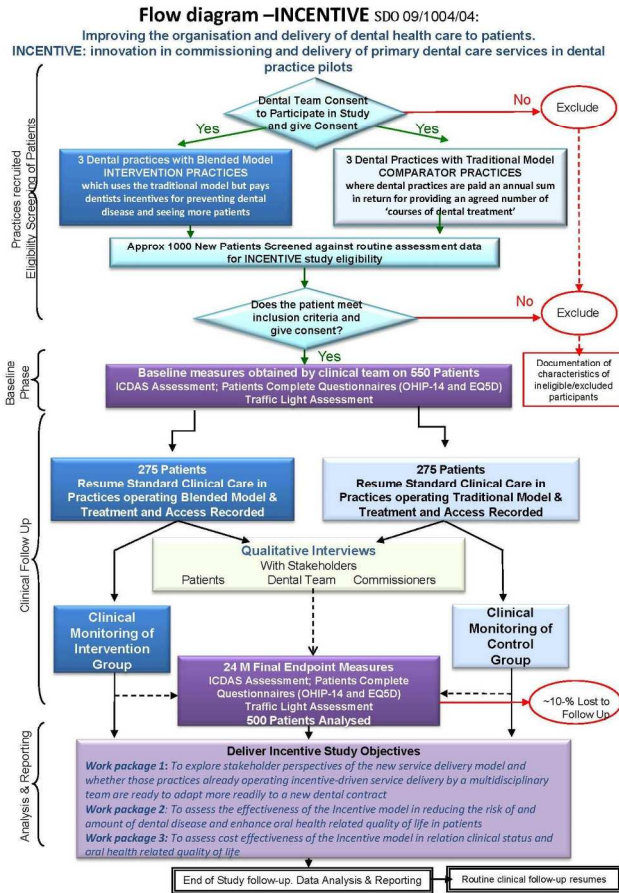





Figure 1: Flow diagram INCENTIVE study 210x297mm (300 x 300 DPI)

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Figure 2: 'Traffic Light' Risk Assessment

	DESCRIPTOR:	EXAMPLE INDICATORS:
	❖ High risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in more than one tooth. Basic Periodontal Examination (BPE) score of >2 in 3 or more sextants ❖ Social history: never brushes teeth
	❖ Medium risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: Active decay in one tooth, BPE score of >2 in 2 sextants ❖ Social history: brushes once per day
	❖ Low risk of disease identified through clinical assessment and social history	<ul style="list-style-type: none"> ❖ Clinical: No active decay, BPE score ≤2 confined to 1 sextant ❖ Social history: brushed twice per day

N.B. The overall category is triggered by the highest risk level allocated by clinical, social and history assessment tools
A confounding medical history will be excluded from this study as it is usually not amenable to change.

'Traffic Light' Risk Assessment
297x420mm (300 x 300 DPI)