**CAN DENTAL THERAPISTS MAINTAIN THE ORAL HEALTH OF ROUTINE LOW RISK DENTAL RECALL PATIENTS IN HIGH-STREET DENTAL PRACTICES? A PILOT STUDY**

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**ABSTRACT**

**Background**

Many dental ‘check-ups’ in the National Health Service result in no further treatment. The patient is examined by a dentist and returned to the recall list for a further check-up, commonly in 6 or 12 months’ time. As the oral health of regular dental attenders continues to improve, it is likely that an increasing number of these patients will be low risk and will only require a simple check-up in the future, with no further treatment. This care could be delivered by dental therapists.

In 2013, the body responsible for regulating the dental profession (the General Dental Council) ruled that dental therapists could see patients directly, undertake check-ups and routine dental treatments (e.g. fillings). Using dental therapists to undertake check-ups on low risk patients could help free up resources to meet the future challenges for NHS dentistry.

**Objectives**

To determine the most appropriate design for a definitive study, the most appropriate primary outcome measure, recruitment and retention rates and the non-inferiority margin. We also undertook a realist-informed process evaluation and rehearsed the health economic data collection tool and analysis.

**Design**

A pilot randomised controlled trial over a 15 month period, with a realist-informed process evaluation. In parallel, we rehearsed the health economic evaluation and explored patients’ preferences to inform a preference elicitation exercise for a definitive study.

**Setting**

NHS dental practices in North-West England.

**Participants**

217 low risk patients in eight high-street dental practices.

**Interventions**

The current practice of using dentists to provide NHS dental check-ups formed the control arm (treatment-as-usual) and was compared to the intervention arm, where this care was provided by dental therapists.

**Main outcome measures**

Differences in the proportion of sites with bleeding on probing amongst low risk patients. We also recorded the number of ‘cross-over’ referrals between dentists and dental therapists.

**Results**

No differences were found in the health-status of patients over the 15 months of the pilot, suggesting that non-inferiority is the most appropriate design. However, bleeding on probing suffered from ‘floor-effects’ amongst low-risk patients and recruitment rates were moderately low (39.7%), which suggests that an experimental design might not be the most appropriate. The theory areas that emerged from the realist-informed process evaluation were: contractual, regulatory, institutional logistics, patients’ experience and logistics. The economic evaluation was rehearsed and estimates of cost-effectiveness made; potential attributes and levels that can form the basis of preference elicitation work in a definitive study were determined.

**Limitations**

The pilot was only conducted over a 15 month period and bleeding on probing appeared to have ‘floor-effects’. The number of participating dental practices was a limitation and the recruitment rate was moderate.

**Conclusions**

Non-inferiority, floor-effects and moderate recruitment rates suggest that a randomised controlled trial might not be the best evaluative design for a definitive study in this population. The process evaluation identified multiple barriers to the use of dental therapists in ‘high-street’ practices were highlighted and added real value.

**Future work**

Quasi-experimental designs may offer more promise for a definitive study alongside further realist evaluation.

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**GLOSSARY**

ACORN Assessment of Clinical Oral Risk and Need

ACV Annual Contract Value

ANCOVA Analysis of co-variance

ANOVA Analysis of variance

BOP Bleeding On Probing

BPE Basic Periodontal Examination

CI Confidence Interval

CMO Context, mechanism and outcome

CONSORT Consolidated Standards of Reporting Trials

CRF Case Report Form

CQC Care Quality Commission

DC Dental Commissioners

DCE Discrete Choice Experiment

DCP Dental Care Professional

DH Dental Hygienist

DT Dental Therapist

FFS Fee-for-service

GCP Good Clinical Practice

GDC General Dental Council

GDP General Dental Practitioner

GDS General Dental Services

ID Identification

IPTs Initial Programme Theories

MRT Mid-Range Theories

NICE National Institute of Clinical Excellence

NHS National Health Service

NWORTH North Wales Organisation for Randomised Trials in Health

OHIP Oral Health Impact Profile

PHE Public Health England

POM Primary Outcome Measure

PPI Patient and Public Involvement

RCS Royal College of Surgeons of England

SOPs Standard Operating Principles

SAEs Serious Adverse Events

UDA Unit of Dental Activity

UK United Kingdom

WS Work-Streams

WHO World Health Organisation

**PLAIN ENGLISH SUMMARY**

As the oral health of regular dental attenders improves further, it is likely that an increasing number of these patients will be low risk and will only require a simple check-up in the future, with no further treatment. As a result, the use of the dentist to undertake the routine dental check-up is a potentially costly way of providing care for those patients who are at a low risk of future disease. We undertook a 15 month pilot randomised controlled trial to determine whether dental therapists could manage low risk regular dental attenders in NHS dental practices, instead of dentists. This involved eight practices and 217 patients. We found no difference in the care provided by dental therapists and dentists and no differences in oral health after 15 months.

In parallel, we also undertook interviews with a wide range of stakeholders, including dental commissioners, dentists, dental therapists and patients. We found a number of important barriers to the use of role-substitution in NHS dentistry. These mainly related to contractual and regulatory issues in the NHS, which act as barriers to the greater use of dental therapists.

We collected cost data and analysed this to establish the value to society. We found that the use of dental therapists to manage low risk regular dental attenders appears to be feasible. We also explored how care is currently provided and the outcomes of care that would be most important to patients.

A number of challenges and design issues for a definitive trial were identified. Many relate to the low risk status of the population group and the relative good oral health of many patients attending NHS practices, making the detection of differences difficult. Alternative research designs may be more appropriate.

**SCIENTIFIC SUMMARY**

**Background**

The use of General Dental Practitioners (GDPs) as the ‘front-line’ clinician in NHS ‘high-street’ dental practices is costly. Over half of the 21.7 million check-ups undertaken each year result in no further treatment. Dental Therapists (DTs) have been shown to be equally efficacious at screening for oral diseases. What is not known is whether they are as effective as GDPs at undertaking the check-ups for low risk routine NHS dental patients and whether they could reduce the cost of service provision. This is important as the proportion of low risk routine NHS dental patients is expected to increase further as the oral health of regular dental attenders continues to improve. In contrast, many in the population still do not regularly attend the GDP and this group tend to have the highest need.

Under current NHS regulations, DTs are not allowed to examine NHS patients. However, in 2013/14, regulatory changes made by the General Dental Council allowed DTs to see patients directly, diagnose and form treatment plans, within their competence. DTs can also now undertake all of the direct routine treatments that GDPs can do (e.g. fillings) as part of their Scope of Practice. This opens up the possibility of them being utilised to examine and treat low risk NHS patients in the future, if they can be shown to be as equally effective as GDPs in this regard.

Two earlier NIHR studies investigated both the efficacy and efficiency of DTs in NHS practices (NIHR/CS/010/004 & HS&DR 11/1025/04). The former demonstrated the efficacy (diagnostic test accuracy) and feasibility of using DTs for check-ups and the latter study found that dental practices using DTs in the NHS could be better organised to improve efficiency. The aim of this study was to inform the design for a future definitive trial by undertaking a pilot study to determine whether DTs can maintain the oral health of low risk routine NHS patients, who form the predominant proportion of the regularly attending practice population.

**Objective(s)**

The objectives of the research were to:

1. Determine the most appropriate design of a definitive trial;
2. Determine whether bleeding on probing (BOP) is the most appropriate primary outcome measure (and if not, determine the most appropriate measure);
3. Confirm the appropriateness of the non-inferiority margin of the chosen outcome measure for the definitive trial (i.e. whether the effect estimate lies within an appropriate margin of non-inferiority);
4. Further investigate recruitment, retention and fidelity rates;
5. Confirm willingness to be randomised amongst study participants;
6. Determine the potential for patient cross-overs between arms (e.g. where the patient is considered too complex to be managed by the DT);
7. Undertake a process evaluation underpinned by a realist framework to understand "what works, for whom, why and in what circumstances?"; and
8. Rehearse the health economic analysis and assess the health economic data collection tool to inform the definitive trial design; and explore patients’ preferences in a focus group setting to inform a preference elicitation excise (e.g. discrete choice experiment) in the definitive trial.

**Methods**

The study was undertaken across three workstreams (WSs).

*Workstream 1*

WS1 was an individually randomised pilot study undertaken across the North-West of England over a 15 month period:

* Population: adult asymptomatic low risk routine dentate or partially dentate NHS patients attending ‘high street’ dental practices;
* Intervention: check-up and any subsequent treatment undertaken by a DT;
* Control: check-up and subsequent treatment undertaken by a GDP (treatment-as-usual); and
* Outcome: percentage of sites with bleeding on probing (BOP).

The unit of randomisation was at the patient level and primary end-points were pragmatic. Secondary outcome measures collected were based on simple adaptations of indices that are used commonly in clinical practice:

* Proportion of sites that have visible plaque present (measure of oral cleanliness);
* Proportion of sites with a probing depth that exceeds the Basic Periodontal Examination (BPE) Code 2 using the WHO probe (BPE probe);
* Number of new decayed and filled teeth (see Data Collection for justification);
* Unplanned visits between check-ups;
* Oral health-related quality of life (Oral Health Impact Profile); and
* Patient-centred outcomes to explore behaviour change and dental anxiety through the use of validated questionnaires.

High street NHS dental practices were recruited across the North-West of England (n=8) using the following eligibility criteria:

1. The practice should employ at least one DT, with at least two years clinical experience;
2. The majority of adult service provision should be in the NHS;
3. The patient should be treated under NHS regulations; and
4. The practice should have the support of a practice manager.

217 recruited and consented, low risk, adult NHS dental patients had baseline and outcome measurements (15 months later) undertaken by calibrated and blinded epidemiologists. The following were the eligibility criteria for the individual patients:

1. NHS adult patient (>18 years of age) on the recall list of the participating practice;
2. Presented with no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year;
3. Asymptomatic at time of the check-up;
4. Had no predisposing medical history that elevated their risk status;
5. Were seen for their routine check-up at least six months ago; and
6. Were dentate or partially dentate.

New patients, adult patients presenting in pain, patients requiring root fillings or extractions, who were edentate or were receiving on-going periodontal treatment were excluded. Patients with sites that had a BPE score of 3 or above were excluded.

Randomisation was at the individual level (patient) and performed by NWORTH Clinical Trials Unit. Treatment allocation was on a 1:1 basis using a sequentially randomised dynamic adaptive algorithm. This meant that each participant’s allocation was re-calculated and was based on the overall allocation level, within stratification variables and within stratum level. This enabled the research team to maintain adequate allocation ratios, whilst maintaining the required balance across the two groups.

*Workstream 2*

WS2 was a theoretically-driven process evaluation, which ran in parallel to the pilot to understand what works for whom, why and in what circumstances. Realist evaluation is a recognised methodology used extensively in health services research, because it recognises the complex and contingent nature which underpins the settings for new interventions and service delivery. This approach to process evaluation “supposes that regularities in the patterning of social activities are brought about by the underlying mechanism constituted by people’s reasoning and the resources they are able to summon in a particular context”.

WS2 used purposive and convenience sampling to identify interview participants, which included a Chief Dental Officer, dental commissioners, a Local Dental Network, GDPs and DTs and patients. We sought to recruit across the age-range for adults and ensure a culturally and ethnically diverse sample. We also undertook a ‘systems-wide’ approach to the evaluation, as implementation and change in complex interventions are affected by macro and meso level factors in addition to those identified at micro/individual level.

*Workstream 3*

In WS3, we developed and tested a health economic data collection tool and rehearsed the health economic analysis of the intervention, to inform the definitive trial design. We adopted the viewpoint of both the NHS and the patient, and collected resource-use data which included the costs of dental consultation by GDPs and DTs and the use of primary and secondary NHS dental services, as well as participants’ out-of-pocket expenses relating to any dental problems during the trial’s follow-up period. We also explored patients’ preferences to inform a preference elicitation exercise for the definitive trial.

**Results**

*Workstream 1*

546 NHS patients were invited to participate in the 15 month pilot trial and 217 participants were recruited. This equated to a mean recruitment rate of 43.4 participants per month. The attrition rates for the DT group and the GDP group were comparable (22.4% vs 23.6% respectively). There were 14 protocol deviations in the DT group and none in the GDP group. 13 of the 14 protocol deviations occurred because they were allocated to the DT group but were seen once by the GDP in error. Participants in the pilot trial were predominantly female (72.4%), non-smokers (92.2%), of white ethnicity (93.1%) and were not exempt from patient charges (89.4%). The mean age of the participant was 46 years old with a standard deviation of 15.8 and a range of 18 to 87 years. There was less than 1% missing data for the different primary and secondary outcome measures that were collected across the two time-points (baseline and follow-up).

The difference between the percentage of sites with BOP for the DT group and the GDP group, based on a mixed effect ANCOVA model, was 0%, 95% CI [0%, 0%]. This did not cross the specified non-inferiority boundary of 5%. There were no discernible differences between DTs and GDPs for the other clinical measures. The observed differences for patient-related outcome measures were also negligible. However, there appeared to be ‘floor-effects’ in the measurement of the different primary and secondary measures.

*Workstream 2*

Substantial barriers exist to the practice of role-substitution in NHS dentistry. The two most dominant factors were contractual and regulatory barriers. These appeared to drive the institutional logics at the micro level, with little influence exerted at the meso level by dental commissioners. Where role-substitution was successful, practice owners had found ‘work-arounds’ to the macro factors that dominated any potential implementation.

*Workstream 3*

We demonstrated that we can collect the data required for an economic evaluation using costs based either on UDAs or micro-costing of dental care. The economic evaluation was rehearsed and consistent results produced across the range of analyses conducted. On average, a DT appeared to be less cost-effective in terms of BOP than a GDP. In terms of OHIP scores, it appears that a DT could be more cost-effective, based on society’s willingness to pay for each point reduction on the OHIP. However, the results of the economic evaluation are not a robust basis for decision-making, as they are based on data from the small number of participants included in the pilot trial.

Patients’ preferences proved informative and provided a list of potential attributes and levels for a future discrete choice experiment, alongside a definitive trial. These attributes and levels relate primarily to process and organisational factors about the service.

**Conclusions**

No differences were found in the oral health-status of patients over the 15 months of the pilot, but this may have been influenced by ‘floor-effects’ in the chosen primary outcome measure in this population group (low risk patients). This pattern was seen in the other clinical measures used, which suggests a non-inferiority design would be more appropriate, if a definitive trial was considered. However, although retention and fidelity rates were high, recruitment was more challenging, suggesting that a longer recruitment period would be required in any future empirical study. These two findings may have substantial implications for a definitive trial in this population group, given the higher number of participants that would be required for a non-inferiority design and the length of such a study. Quasi-experimental designs may offer more promise and value of information. Multiple barriers to the use of dental therapists in ‘high-street’ practices were highlighted in the process evaluation, mostly relating to contractual and regulatory issues in the NHS. The economic component showed that a meaningful economic evaluation could be conducted and provided the basis of a preference elicitation tool that could extend the results of the economic evaluation.

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**CHAPTER 1: BACKGROUND TO ROLE-SUBSTITUTION IN DENTISTRY**

**1.1 Role-substitution in NHS dentistry in the United Kingdom**

Workforce planning is an important policy objective in the NHS to ensure that “the right number of people with the right skills are in the right place at the right time to provide the right services to the right people”.1 “Skill-mix” is a term that is used to describe a model of care, in which the whole of the clinical team is utilized in delivering service activity.2 It can be further sub-divided into role-substitution and role-supplementation. In dentistry, the former means that different members of the dental team undertake clinical tasks instead of a General Dental Practitioner (GDP), whilst the latter is where team members augment the activity of a GDP.3 The use of role-substitution in NHS dentistry has been advocated for some time, but its implementation appears to have lagged behind that seen in medical specialties, due to a number of factors including professional regulation, NHS regulations and financial incentives.2 These will be explored in this Chapter, along with the current evidence from the literature.

**1.2 Professional regulation of role-substitution in NHS dentistry**

In 1921, the Dentists Act created the Dental Board of the United Kingdom (UK), which became the professional body for dentistry and oversaw its practice.4 In 1956, following amendments made to the Act, the Dental Board was superseded by the General Dental Council (GDC).5 This reflected the recommendations in the Teviot Report, which argued that the dental profession had become sufficiently mature to self-govern.6 The Act also facilitated the training of ‘dental auxiliaries’ for the first time (referred to as Dental Care Professionals (DCPs) in the remainder of this report). The newly formed GDC subsequently developed the regulated titles of ‘Dental Hygienist’ (DH) and ‘Dental Therapist’ (DT). The duties of the former related to the provision of preventive and periodontal treatment, whilst the latter role was permitted to provide a range of direct restorative procedures and extract deciduous teeth. In 1983, UK dental schools began to offer ‘dual’ integrated training over a period of two years. The new ‘Hygiene-Therapist’ qualification was able to offer the full range of clinical activities that both DHs and DTs could legally undertake, although only the individual titles of DH or DT title were registerable with the GDC.7 In 2002, the Dentists Act was again amended and allowed DTs to practise in NHS dental practices.8 Before this time, the DTs’ role had been limited to the provision of care in NHS Community Dental Service settings only, a role that had been restricted to General Dental Practitioners (GDPs), since 1948.

Despite this change, DCPs were not allowed to practice as ‘front-line’ clinicians in the NHS or in private practice. Instead, patients were required to see a GDP for an examination and treatment plan, before being referred on to DCPs for their NHS care (a condition in both the Dentists Act and NHS regulations). NHS regulations also prevented DCP services from being procured directly, with the ‘knock-on’ effect of DCPs not being able to receive an NHS pension (unlike their GDP counterparts).9 However, after a review of the available literature, a landmark decision by the GDC in 2013 allowed patients to have ‘Direct Access’ to dental care by DCPs without a referral from a GDP.10 This was accompanied by an expansion of the DCPs’ Scope of Practice to incorporate undertaking examinations and developing treatments plans, within their level of competence.7 However, DCPs remained unable to contract directly with the NHS under the NHS regulations.9 Equally, they were also unable to prescribe dental radiographs, the use of fluoride or administer local analgesia (due to restrictions in the Radiography Protection Act and the Medicines Act respectively).11,12

**1.3 Policy recommendations on role-substitution in NHS dentistry in the United Kingdom**

Policy-makers have been interested in the potential of role-substitution in NHS dentistry for some time. In 1993, the Nuffield report inquiry redefined the concept of the dental team through which dental care could be delivered and argued that role of DCPs could be expanded.13 Subsequently, increasing attention has been paid to how role-substitution can deliver the level of care in the NHS that is required to meet population health need. This is now explicitly recognised in a number of policy documents that underpin NHS care. For example, both the NHS Plan in England and the Prudent healthcare policy agenda in Wales call for greater use of role-substitution.14,15

In the UK, population oral health needs are changing. In the most recent epidemiological survey, 90% of young adults are expected to have more than twenty-one teeth in ten years’ time and the levels of dental caries and periodontal disease have fallen dramatically.16 In contrast, levels of dental caries in young children have remained relatively intransigent, despite the fact that dental caries as a non-communicable disease, is totally preventable.17 As highlighted in the Child Dental Health Survey in 2013 “nearly a third (31%) of five-year olds and nearly a half (46%) of eight-year olds had obvious decay experience in their primary teeth. Untreated decay into dentine in primary teeth was found in 28% of five-year olds and 39% of 8 year olds”.17 This pattern of disease also follows a social gradient “a fifth (21 per cent) of the five-year olds who were eligible for free school meals had severe or extensive tooth decay, compared to 11% of five-year olds who were not eligible for free school meals”.17

Equally, the increasing number of partially dentate older people, with varying degrees of independence are giving rise to new healthcare challenges. The oral health of care-home residents is much worse than their community living peers (e.g. caries prevalence is 73% vs 40% respectively) and about half of all care-home residents now retain some of their natural teeth.18,19 Poor oral health may also exacerbate a range of medical conditions including pneumonia and delirium, increasing healthcare costs and leading to poorer outcomes.20 Despite this high level of need, dental service provision in residential care is poor, with little emphasis on prevention.21,22 Access to domiciliary services is difficult and unscheduled care for dental problems (including hospital admissions) is common, complex to deliver and expensive.23,24 The World Health Organisation (WHO) argue that the design of long-term care systems that are fit for ageing populations should take priority and the Royal College of Surgeons of England (RCS), Public Health England (PHE) and the National Institute of Clinical Excellence (NICE NG48) have all called for more high quality research.25,26 The recent Care Quality Commission (CQC) also highlighted the paucity of dental care in care-homes in their report published in June 2019.27

Parallel to these pressing and emerging population health needs, there is also evidence that many who attend dental practices have good oral health. In the Adult Dental Health Survey, 71% of all dentate adults reported that they attended their GDP at least once a year. Six percent said they attended once every two years and a further ten percent less often than every two years. The remaining 13% of dentate adults said that they only attended when they were having trouble with their teeth.28 Data from the Business Services Authority (the organisation responsible for paying GDPs in England and Wales), suggest that many of those that do attend, do not require any further treatment.29 In 2018/19, out of the 39.7 million Courses of Treatment delivered in one year in England, 23.3 million related to patients having check-ups with no further treatment (58.0%). The figures for 2017/18 and 2016/17 were 58.0% and 57% respectively. This is further supported by data from the Assessment of Clinical Oral Risk and Needs (ACORN) in Wales, where GDPs collect ‘risk’ and ‘need’ data as part of the Welsh Dental Contract Reform programme. 60.4% and 47.8% of adults in 2019 were classified as ‘Green’ i.e. no active dental caries or periodontal disease respectively.30 Many of these patients appear to return to their dental practice within a nine-month period.30 This suggests that a substantive level of the resource being invested into primary dental care in the NHS appears to relate to managing low risk dental patients. As a result, there are increasing calls for the development of an NHS dental workforce to meet these emerging population oral health needs and the procurement of relevant NHS service provision, whilst freeing up resources to increase the capacity to care and reduce social inequalities in oral health.3

**1.4 Role-substitution in NHS dentistry**

DCP utilisation by NHS dental practices appears to be heavily influenced by the financial incentives inherent in the NHS contract.31 NHS GDPs run their practices as businesses to offset the cost of the capital risk of the premises and the equipment that they own, whilst ensuring liquidity to cover their overheads.32 In medicine, transaction costs can be offset by economies of scale, which enable a broader range of services to be made available.33 This is more difficult in NHS dentistry, as historically, many practices have not been ‘purpose-built’ and some remain single-handed.34 This limits the extent of role-substitution and supplementation undertaken in the NHS.

Although DHs appear to be well accepted members of the dental team in the UK,31,35 financial considerations appear to play a significant part in the decision to use a DT in the NHS.36,37 In one of the few studies that examined the profitability of using role-substitution, patient charges generated did not cover the cost associated with their use, within the current remuneration system.38 As a result, many DTs have been employed in the NHS as DHs in England rather than being utilized across their full range of skills.36 Equally, some patients expect to pay less for treatment provided by a DCP, when compared to a GDP.39

Dental practices operating within the NHS are acutely sensitive to the incentives within any given remuneration system.40,41 In turn, this can influence the institutional logic of the dental practice (the culture within an organisation that shapes the collective behaviour and actions of those who work there) and whether role-substitution is supported.31,42,43 Retrospective payment systems like Fee-For-Service (where a GDP submits a claim for every single item of completed treatment), have been shown to lead to over-treatment in order to maximise profit.44,45 In these systems, the incentive for practices is to increase the volume of clinical activity delivered, which may not always suit the greater utilisation of role-substitution.31 In contrast, per-capita remuneration systems pay practices a fixed level of funding based on the number of registered patients. This breaks the link between treatment activity and practice income, giving practices greater autonomy on what to focus on.46 This may lead some practices to place greater emphasis on prevention, which would favour role-substitution and supplementation (to reduce staff costs and draw on the strengths of DCPs to deliver prevention).31 However, per capita systems can also lead to under-treatment and patient selection; a preference for low risk patients that require little treatment, given that funding for these practices is capped and unrelated to clinical activity.47,48

Goodwin *et al*., argue that institutional logics at any given NHS practice not only include dentistry as a business, but also professional ethics and contextual factors, based on where the practice is embedded.49 As highlighted by Watt *et al*., the most important factors influencing change in dentistry include: concerns about financial risk, progressive practice environment, supportive organisational structure, supportive professional networks and opportunity for training.50 As such, the drive to maintain (and maximise) the viability of an NHS practice can also be tempered by a practice owner’s view about their sense of duty to their patients and their ideas about how best to deliver care for their patients and community.51 In our earlier study, the views of practice principals on the benefit of role-substitution was found to be one of the most important factors, which could ameliorate concerns about the impact of using DCPs, in relation to the underlying NHS contract.31 Management of change is also a potential problem with role-substitution, as professionals seek to protect their clinical roles and maintain traditional clinical boundaries.52,53 Managing a transition to role-substitution takes time and good human resource skills.54 McDonald *et al*., found that the key factors that determined the acceptability of changes to role boundaries included, the clarity around roles and responsibilities as well as personal relationships with colleagues, which raise issues of mutual trust and respect.55 Nevertheless, the influence of the underlying NHS contract remains substantive and warrants an understanding of the historical development of NHS funding and contractual reform across the UK.

**1.5 The evolution of NHS dental contract in the United Kingdom**

At the turn of the new Millennium, “Modernising NHS Dentistry” set the agenda in England and subsequently gave Primary Care Trusts (the organisations responsible for procuring NHS service provision at the time), powerful new commissioning tools to improve access to NHS dentistry and increase the provision of preventive services across England.56 This was further emphasized in "Options for Change" in 2002.57

Prior to 2006, GDPs were paid on a fee-for-service basis. This meant that GDPs claimed for every item of clinical activity that they undertook. As highlighted above, these payment mechanisms can have a tendency to incentivise over-treatment, as GDPs’ income is directly linked to the level of clinical activity undertaken on each patient.44,46 It also had a negative impact on practices, as many of the individual items of treatment were of a relatively low value and led to GDP complaints about being on a ‘treadmill’ (high level of clinical activity on low value items), in order to maintain the viability of their practices.32 This was particularly relevant after 1990, as the Department of Health had attempted to correct an over-spend on the national dental budget and had placed a downward pressure on the annual review process that controlled how individual items of treatment were costed.58 In 2006, a new General Dental Services (GDS) NHS contract was introduced in England and Wales.59 This contract collated NHS dental activity items into three broad bands in an attempt to lessen the number of individual items of treatment that GDPs would claim for on each patient:

1. Band One: examination, radiographs and a simple scale and polish;
2. Band Two: restorations, extractions and root canal treatments; and
3. Band Three: crowns, bridges and dentures.

These bands of treatment attracted one, three and twelve Units of Dental Activity (UDA), respectively. The value of a UDA varied across NHS dental practices and was based on clinical activity and payments in a ‘reference year’ that were ‘earned’ under the previous fee-for-service NHS dental contract in 2005. As a result, GDPs who had been undertaking significant levels of clinical activity in the ‘reference year’ where rewarded with high UDA values, resulting in considerable heterogeneity and inequity across practices in England. For example, an examination (generating one UDA) in one practice could generate £18, whilst in another, it would be worth £30. Likewise, one or multiple fillings completed within a ‘Course of Treatment’ (generating three UDAs) would attract £54 or £90 respectively, for GDPs on the *same* NHS dental contract.

NHS dental contracts were raised with equity-owning GDPs in England and Wales (known as ‘Providers’). They then subcontracted these contracts to non-equity- owning GDPs at their practices (known as ‘Performers’). DCPs were provided with an income based on the proportion of clinical activity that they undertook, or were paid a salary. The former method of remuneration for DCPs led to a potential conflict of interest between ‘Performers’ (also known as Associate GDPs) and DCPs, as both were funded based on the numbers of UDAs that they delivered.31 Another important element of the 2006 contract was cost-containment, which capped ‘Providers’ annual activity to an agreed number of UDAs per year, known as an Annual Contract Value (ACV).31 NHS GDPs were then paid a “twelfth” of their ACV on a monthly basis. As a result, NHS GDPs’ outputs under the new contract in England were constrained and they were penalized if they under-performed (<96% of their ACV) or over-performed (>102% of their ACV).

The effect of this change to the NHS dental contract led to significant changes in the types of treatments that were offered. For example, as ‘Providers’ and subcontracted ‘Performers’ were paid the same number of UDAs for endodontic treatment and extractions (which are often the two alternative treatment options for many teeth with advanced decay), the number of the former reduced in favour of the latter, given that the latter could be undertaken in a quarter of the time in most cases.40,41 Equally, one or multiple fillings completed within a ‘Course of Treatment’, would generate the same level of revenue for a practice (three UDAs). As a result, there was downward pressure on the number of fillings undertaken in any one ‘Course of Treatment’, leading to multiple ‘Courses of Treatment’ submitted for patients that required more than one restoration.40,41 GDPs were also incentivised to make upper and lower partial or full dentures separately, in order to claim two sets of Band Three payments. Preventive care was not remunerated separately and any preventive activity was expected to be undertaken within an existing ‘Course of Treatment’.40,41

In addition to these unintended consequences at a regional and national level, the 2006 NHS dental contract proved unpopular with GDPs.32 This was largely due to the loss of clinical autonomy and the need for practices to be accountable to local dental commissioners, who closely scrutinised ‘Provider’s’ ability to deliver to their ACV targets. GDPs argued that one form of ‘treadmill’ had simple been replaced by another. As a result of this criticism, an independent review was undertaken in 2008/9 in England, which recommended the greater use of preventive care and a standardised approach to patient assessment leading to patient care pathways.60

This led to the development of a pilot programme in England in 2010, which was predominantly based on capitation.61 It also required GDPs to undertake an oral health assessment, which categorised patients into different risk categories (red, amber, green). However, the pilots in England were beset with a number of informatic problems and based on concerns about the capitation payment system, were relaunched in 2015 as ‘prototypes’.62 ‘Prototype’ practices were paid on the basis of a blended funded system, drawing on features of the 2006 contract (a retrospective payment mechanism based on clinical activity) with capitation. This blended together the financial incentives to ‘care’ and prevent disease (associated with capitation payment mechanisms) with the incentives to undertake clinical activity (associated with fee-for-service mechanisms). In similarity to the earlier pilots in England, the ‘prototypes’ were based on establishing risk and then referring the patient to the appropriate patient care pathway.

An evaluation of the first year of prototyping was published in 2018.63 Attendance marginally increased over the course of the evaluation period (3-6%). 62% of prototype practices reported delivery of preventive care to adults according to evidence-based guidelines compared to 56% in the 2006 contract, with little change to the level of prevention offered to children (60% and 58% respectively). The evaluation concluded: “progress has been made in the first year of prototyping on the key issues of improving oral health, providing appropriate care and quality, and maintaining or increasing access to merit continuation of the programme”.63

The evolution of contractual reform followed a similar pattern in Wales, although the process was different under their devolved Government. In 2011, eight dental practices took part in a pilot.64 This process required these practices to deliver to weighted ‘Key Performance Indicators’ and a capitation target based on the number of unique patients treated in the practice within a defined time period. In 2012, the ‘Quality and Outcome Pilot’ for adults was introduced, with the introduction of a dental care assessment and a risk-based preventative care plan.65 By 2016, all but two practices had reverted back to the 2006 UDA contract. The remaining practices continued as ‘prototype practices’ to test new models of care and formed a ‘learning network’. An early evaluation of the Welsh pilots found a reduction in the numbers of patients attending NHS practices (7% - 10%), compared to baseline.

In 2017, the Welsh Government published ‘Taking Oral Health Improvement and Dental Services Forward in Wales’, which placed greater emphasis on incentivising needs-led care, role-substitution/supplementation and prevention.66 This led to the development of a needs and risk assessment tool. In 2018, the Welsh Government increased the number of ‘contract reform’ practices to 23 and by late-2019, over one hundred NHS practices had entered Phase One of the process. This reduced ACV targets by 10% and raised all ‘Providers’ UDA values to a minimum of £25 to ensure greater parity across the nation. For this 10% reduction in their ACV, practices were required to undertake an Assessment of Clinical Oral Risks and Needs (ACORN) at least once a year under the mantra ‘do it once, do it well’. Phase 2 of the ‘contract reform’ process saw further reductions in ACV targets (reduction to 70%-80% of pre-reform levels), in exchange for greater emphasis on the provision of prevention, increasing the quality of care provided and greater utilisation of role-substitution/supplementation. These policy objectives were further emphasised in ‘The Oral Health and Dental Services Response To A Healthier Wales’, published in 2018 and are being underpinned by a formal evaluation process undertaken by researchers at Bangor University.67 As of Spring 2020, over a quarter of the total NHS practice population were using the ACORN and involved in the Dental Contract Reform programme in Wales.

In Northern Ireland, the predominant financial mechanism used to pay GDPs still resembles the pre-2006 contract in England and Wales i.e. the majority of funding draws on fee-for-service and items of service as part of a retrospective payment system. An Oral Health Strategy for Northern Ireland was published in 2007 and reiterated the main themes identified by the Northern Ireland Primary Dental Care Strategy in 2006, namely a shift away from treatment in favour of prevention of disease, whilst maintaining access to services.68 In 2014, the Northern Ireland Health and Social Care Board initiated a pilot NHS dental contract across the Province, which involved over 30 GDPs. In similarity to the English pilots, the chosen remuneration mechanism was prospective in nature, so reduced the incentive for GDPs to engage in unnecessary treatment. The underpinning policy intention was that practitioners would receive the equivalent gross income during the pilot period that they would have received under the GDS, had they maintained their activity and list as per the baseline period. As highlighted in our evaluation of the pilot NHS contract led by Bangor University, we found “rapid changes in the patterns of care provided by GDPs to patients (compared with the control practices) when they moved from a fee-for-service system to a capitation-based remuneration system” and “there were statistically significant reductions in the volume of all treatments in the intervention practices during the capitation period”.58 This highlighted the sensitivity that GDPs have to underlying incentives in the NHS dental contract.

In Scotland, the prevailing dental contact funding mechanism was similar to Northern Ireland’s model. After a consultation exercise in 2016, they published their Oral Health Improvement Plan in 2018 with a forty-one-point plan, focusing on prevention, an oral health risk assessment and a personalised care plan.69 As highlighted by Brocklehurst *et al*., “in contrast to the other three home nations, there were no plans for scrapping the item-of-service system of remuneration; instead there was an intention to ‘streamline’ items of service payments, which would be progressively introduced”.58 The proposed remuneration mechanism was based on a “mixed economy of item of service, capitation and continuing care payments”.58

**1.6 Evidence-base for the use of role-substitution in dentistry**

Proponents of role-substitution argue that it has the potential to free resources, increase the capacity to care for high‐need populations, improve access, and reduce oral health inequalities.70-72 In an international review, Nash *et al*. concluded that “access to basic dental care will not be available without the utilization of dental therapists in the workforce”,73 whilst Johnson argued for a paradigm shift “from treatment to prevention, wellness and self‐care”.74

Role-substitution by DCPs has been established for some time in a number of European countries.71,72 Sweden and The Netherlands legalised the independent use of DCPs in 1964 and 1978.75 Finland, Denmark and Norway have allowed independent practise since 1994, 1996 and 2001, respectively. Similar practices are found in Switzerland, which started in 1997 and in Italy, where DHs have been able to work as independent practitioners since 1999.75 In the United States and Canada, DHs are a growing profession and can practice with varying degrees of independence in a number of US states e.g. California, Colorado, Montana, Nebraska, New Mexico, Oregon, Washington and Canadian provinces British Columbia, Alberta, Saskatchewan and Manitoba, although some restrictions remain in terms of settings.76 Tasmania has a liberal regulatory model in which DHs and DTs practise independently and can own their own practices.75 DTs are also considered to be independent in New Zealand, although they are not able to treat adults.75 In Samoa and Singapore, DTs must work under the supervision of a GDP. Fiji has allowed DTs to assume independent responsibility for managing clinics since 1985 and DTs have been allowed to practise independently in South Africa since 1994.75

The research evidence for the greater use of DCPs is emerging. Despite suggestions from some elements of the dental professional that role-substitution is unsafe, this is not borne out by the limited literature that is available. Two studies by Calache & Hopcraft, undertaken in Australia, found no detrimental evidence to question patient safety, when adult patients were managed by DTs.77,78 No differences were found between DTs and graduating GDPs in infection control, local analgesia, cavity preparation, placement of restoration, occlusion, and patient communication.78 Knowledge and clinical skills were rated as good to high, and 80% of DTs were considered safe to treat adult patients. The potential of DCPs not to identify oral cancer is another frequently cited concern in terms of patient safety. However, in an in vitro study, Brocklehurst *et al*., found that the diagnostic test accuracies of GDPs and DTs were similar, when they were presented with a judgement task that required them to distinguish between malignant and benign diseases of the oral mucosa. Values of sensitivity and specificity were 81% and 73% for GDPs, compared with 77% and 69% for DTs, respectively. DTs also missed fewer frank carcinomas in the judgement task.79

Although the social acceptability of DTs appears to be positive, public awareness of DTs as a professional group is not widespread.39,80,81 In the UK, our earlier study found that the attitudes of practice owners were critical in the process of patients accepting treatment from DTs.31 Despite this, it does appear that adults are willing to receive treatment from DCPs under the NHS and there is evidence of increased patient satisfaction.81 In one of the Calache & Hopcraft studies highlighted above, patients were very satisfied with the dental treatment that was provided.78 In another study conducted by the same team, 356 direct coronal restorations were placed with high patient satisfaction.82 In Canada, 65.8% of respondents stated that they would visit an independent DH to maintain their oral health. In the United States, 98.0% of respondents strongly agreed or agreed that their care by DCPs was satisfactory (based on RAND criteria).83 98.0% patient satisfaction was also reported by Perry *et al*.84 For DTs, the majority of adults and children's caregivers receiving care in Alaska had a positive patient experience.85 In the Netherlands, a quarter of those surveyed (total n=1,500) agreed that ‘simple dental treatments’ could be performed by a DH rather than a GDP and 15% agreed that a DH could undertake a check-up.86,87 In another study, 85.0% of patients who received a simple restoration for the treatment of dental caries provided by a DCP claimed to be satisfied with the treatment provided.88

In terms of efficacy, Wang & Riordan evaluated a population oral health programme undertaken in Norway that allowed DHs to undertake a check-up over a three-year period. The quality of care provided was judged not to deteriorate over this timeframe.89,90 This concurs with Kwan *et al*., who compared the performance of DCPs with GDPs in an epidemiological programme.91 Sensitivity values for GDPs ranged from 0.54 to 1.00, and those for the DCPs from 0.80 to 0.94. The direction of effect in these studies have also been replicated by Patel *et al*., Kwan & Prendergast and Hopcraft *et al*.92-94 In terms of restorative management by DCPs, Bader *et al*. found that 74 of the 84 direct amalgam restorations placed by DTs were considered to be completed to an adequate standard, compared to 32 out of 41 restorations provided by GDPs.95 This was not dissimilar to Wetterhall *et al*.’s study, which found that 88.0% and 78.0% of amalgam restorations were rated as ‘satisfactory’ for DTs and GDPs, respectively.85 Calache *et al*. evaluated 356 restorations placed by DTs in 115 patients. After six months, 95.0% were judged to be successful by blinded evaluators.82 This concurs with studies by Battrell *et al*. and Freed *et al*.83,96 Dyer *et al*.’s Cochrane review identified four randomised controlled trials and one non-randomised controlled trial. Three found no evidence of a difference in retention rates of fissure sealants placed by DCPs compared to GDPs and the one study comparing the comparative effectiveness of ‘Atraumatic Restorative Technique’ restorations again found no difference in survival rates after 12 months.97

These results concur with findings of a number of studies led by our team, undertaken with NHS clinicians. In 2012, we showed that both DTs and GDPs had comparable sensitivity and specificity in the recognition of occlusal caries *in vitro*.98 In 2015, we tested the diagnostic test accuracy of DTs *in vivo*.99 1,899 adult NHS patients were screened by both a DT ('index test') and a GDP ('reference standard') prior to their routine NHS check-ups in ten busy NHS practices. Both sets of clinicians made an assessment on the presence of dental caries and periodontal disease. The sensitivity and specificity values of DTs were 0.81 (95% CI, 0.74 to 0.87) and 0.87 (95% CI, 0.78 to 0.92) for dental caries and 0.89 (95% CI, 0.86 to 0.92) and 0.75 (95% CI, 0.66 to 0.82) for periodontal disease, respectively. This suggests that DTs could recognise the two most common oral diseases. As highlighted above, we also tested whether they could recognise oral cancer. Again, comparable results were found between DTs and GDPs.79

Although diagnostic test accuracy is important as a measure of efficacy, a more important consideration is an assessment of the effect on health of using DTs in 'front-line' roles. Given that precise estimates of effect, recruitment, retention and fidelity were unknown, we undertook a study to test whether a definitive trial could be feasible within the NHS.100 Over a fifteen-month period, adult NHS patients were randomised into one of three arms in two NHS dental practices: patients who only saw a DT (arm 1), those who saw both a DT and a GDP (arm 2) and finally, a third arm who only saw a GDP. The initial recruitment rate for the study was 33.7%. This figure increased to over 82.1% when telephone calls or face-to-face recruitment were utilised. The retention rates were 60% for the DT and DT/GDP arms and 70% for the GDP arm. The proportion of sites with bleeding on probing (BOP, a measure of gum inflammation) at the end of the fifteen-month period was 46.7%, 14.5% and 32.1% in arms 1, 2 and 3, respectively (44.6%, 17.2% and 26.5% at baseline). Similarly, plaque levels were found in 68.2%, 43.7% and 60.9% of patients respectively (60.5%, 44.9% and 56.3% at baseline). As these values did not differ significantly from baseline values, it suggested that oral health could be maintained by role-substitution.

The majority of the studies examining the efficiency of DCP utilisation are from the UK.101,102 Harris & Sun concluded that role-substitution in the UK ”may be limited to particular situations where conditions are conducive”.103 Patients with high levels of disease (many restorations) were thought less suitable for referral because GDPs would undertake care in fewer visits and there was a risk of complications necessitating referral back to a GDP.100 In our earlier study, we found that the extent of role-substitution in NHS dental practices appears to be relatively low and mainly limited to the use of DHs for routine periodontal treatment.31 As highlighted above, this appears to be directly related to the incentives and disincentives within the NHS dental contract. This meant that “NHS dental practices that utilised fewer non-dentist team members were associated with higher levels of technical efficiency, that is as role-substitution in NHS practices increased, their relative efficiency dropped”.31 As highlighted in the report “when UDAs were used as the output measure in England, NHS dental practices operated at a mean level of efficiency of 64.0%. This changed very little when the outputs were measured in terms of number of patients seen, or the number of treatment plans generated. NHS dental practices that did not use any form of role substitution had a higher mean level of efficiency (68.0%; n = 39)”.31 Any use of DCPs was found to be associated with statistically significant lower efficiency scores (14.0% lower for UDAs, 11.0% lower for treatment plans or patients seen) than practices that used no role-substitution.

**1.7 Discussion**

As highlighted in the previous sections, the potential use of role-substitution in NHS dentistry is becoming increasingly recognised by policy-makers. Changes made by the General Dental Council now make this more possible, but there remain regulatory barriers at this point in time: NHS General Dental Services regulations, the Medicines Act and the Radiation Protection Regulations. Financial incentives within NHS dental contracts also play a key role, but can be mitigated by the institutional logics within a dental practice.

All the dental contract reform programmes undertaken across the UK have placed an emphasis on increasing patient access and prevention, whilst maintaining and improving the quality of service being delivered. In many cases, this is facilitated by the development of care pathways based on the risk status of the patient. In Wales, the use of role-substitution is an explicit objective in the second stage of the contract reform process, but is also implicit in many of the other national programmes.

This means that it is timely to draw on the existing evidence-base for the greater use of DCPs. However, the quality of the literature is relatively poor and as Dyer et al.'s Cochrane review highlighted, the number of trials empirically testing role-substitution is limited.97 Although there have been a number of diagnostic test accuracy studies to demonstrate efficacy, no trials have examined the effectiveness of using DTs to undertake the check-up, instead of the GDP. As highlighted by our feasibility study, there was some reservation about recruitment and retention rates in busy NHS dental practices.100 There were also specific design questions which remained unanswered. For example, what is the estimated size of effect of such an intervention and should the design be based on superiority or on the basis of non-inferiority i.e. are DTs better than or no worse than a GDP in undertaking the check-up and any subsequent treatment that is required? The latter is a fundamental question and significantly influences the design of a definitive trial.

As a result, we proposed undertaking an individually randomised pilot study in the North-West of England over a 15 month period, based on the following PICO format:

* Population (P): adult asymptomatic "low risk” routine dentate or partially dentate NHS patients;
* Intervention (I): check-up and any subsequent treatment undertaken by a DT;
* Control (C): check-up and subsequent treatment by a GDP (“current practice”); and
* Outcome (O): proportion of sites that bleed on probing (measured at six sites per tooth).

To facilitate the design of the definitive study, a realist-informed process evaluation was undertaken alongside the pilot study to explore the acceptability of using DTs as 'front-line' clinicians, patient cross-overs (from one arm to the other) and treatment fidelity. We also captured the contextual factors that shaped the intervention in NHS practices, mechanisms that sustained or potentiated effects, unexpected pathways and consequences and the contextual factors that shaped implementation.104 This was framed from a realist perspective to understand “what is it about a programme that works for whom, in what circumstances, in what respects, over which duration”.105 Realist methodology is becoming increasingly used in health services research, because it recognises the complex and contingent nature which underpins the settings for new interventions and service delivery. This approach to process evaluation “supposes that regularities in the patterning of social activities are brought about by the underlying mechanism constituted by people’s reasoning and the resources they are able to summon in a particular context”.106

Finally, we undertook a third work-stream to develop and test the health economic data collection tool and rehearse the health economic analysis of the intervention compared to the current practice. We adopted the view point of both the NHS and the patient, and collected resource use data which included the costs of dental consultation by GDPs and DTs, the use of primary and secondary NHS dental services, as well as participants’ out-of-pocket expenses relating to any dental problems during the pilot’s follow-up period.

* 1. **Aims and Objectives**

The aim of this study was to inform the design for a definitive trial by undertaking a pilot study to determine whether DTs can maintain the oral health of low risk routine NHS patients, who form the predominant proportion of the regularly attending practice population. The objectives of the research were to:

1. Determine the most appropriate design of a definitive trial;
2. Determine whether BOP is the most appropriate primary outcome measure (and if not, determine the most appropriate measure);
3. Confirm the appropriateness of the non-inferiority margin of the chosen outcome measure for the definitive trial (i.e. whether the effect estimate lies within an appropriate margin of non-inferiority);
4. Further investigate recruitment, retention and fidelity rates;
5. Confirm willingness to be randomised amongst study participants;
6. Determine the potential for patient cross-overs between arms (e.g. where the patient is considered too complex to be managed by the DT);
7. Undertake a process evaluation underpinned by a realist framework to understand "what works, for whom, why and in what circumstances?"; and
8. Rehearse the health economic analysis and assess the health economic data collection tool to inform the definitive trial design; and explore patients’ preferences in a focus group setting to inform a preference elicitation excise (e.g. discrete choice experiment) in the definitive trial.

**1.9 Structure of the report**

This report is arranged in Chapters as follows. As highlighted above, Chapter 1 provides a review of the literature and describes the historical context of role-substitution in dentistry. Chapter 2 describes the methods and results of the pilot study. Chapter 3 describes the realist-informed process evaluation and Chapter 4 details the health economic element of the study. Chapters 5 and Chapter 6 present the ‘Discussions’ and ‘Conclusions’ of the study.

**CHAPTER 2: PILOT RANDOMISED CONTROLLED TRIAL**

**2.1 Introduction**

In 2013, the General Dental Council expanded the Scope of Practice for both Dental Hygienists (DHs) and Dental Therapists (DTs), following a review of the scientific evidence.10 This allowed both DHs and DTs to see patients for the first time as the ‘front-line’ health-care worker. This meant that they could now see patients directly without a referral from a General Dental Practitioner (GDP), undertake an examination, formulate a treatment plan and provide clinical treatment, within their competence. For DHs, this amounted to the provision of preventive and periodontal care, whilst for DTs, this also included the provision of temporary and permanent restorations.

These changes formed the basis of this study and an opportunity to test an alternative care pathway for using DTs to undertake the check-up on low risk routine patients within the NHS. Two earlier NIHR grants had investigated the efficacy and efficiency of using DTs in NHS practices (NIHR/CS/010/004 & HS&DR 11/1025/04). The former demonstrated the diagnostic test accuracy and feasibility of using these groups to undertake check-ups and the latter found that dental practices using DTs in the NHS could be better organised. Pilot studies determine “whether something can be done, should we proceed with it, and if so, how”.107 In Work-Stream 1 (WS1), we undertook such an approach to inform the design of a definitive trial.

**2.2 Aims and objectives**

The aim of this WS was to inform the design for a definitive trial by undertaking a pilot study over 15 months to determine whether DTs could maintain the oral health of low risk routine NHS patients, who form a significant proportion of those who regularly attend NHS practices. The objectives of the research were to:

1. Determine the most appropriate design of a definitive trial;
2. Determine whether BOP is the most appropriate primary outcome measure (and if not, determine the most appropriate measure);
3. Confirm the appropriateness of the non-inferiority margin of the chosen outcome measure for the definitive trial (i.e. whether the effect estimate lies within an appropriate margin of non-inferiority);
4. Further investigate recruitment, retention and fidelity rates;
5. Confirm willingness to be randomised amongst study participants;
6. Determine the potential for patient cross-overs between arms (e.g. where the patient is considered too complex to be managed by the DT);

**2.3 Methods**

WS1 was an individually randomised pilot study undertaken across the North-West of England over a fifteen-month period:

* **Population:** adult asymptomatic low risk routine dentate or partially dentate NHS patients attending ‘high street’ dental practices;
* **Intervention:** check-up and any subsequent treatment undertaken by a DT;
* **Control:** check-up and subsequent treatment undertaken by a GDP (treatment-as-usual); and
* **Outcome:** proportion of sites that had BOP.

***2.3.1 Changes to design after pilot study commencement***

The East Midlands (Nottingham 1) Research Ethics Committee provided a favourable ethical opinion on the 9th of November 2017 (Research Ethics Committee reference number 17/EM/0365). Subsequent to this approval, two substantial changes were made to the original protocol and these were again, approved by the East Midlands (Nottingham 1) Research Ethics Committee.

*Amendment 1 02/03/18:* In the original protocol we stated in the participant inclusion criteria that the patient should not have “presented with any active dental decay or required any dental fillings due to caries within the previous two years”. However, during the pre-trial training, consultation with the lead clinicians at participating practices suggested these criteria was too strict. Therefore, the criteria were amended to read that the patient should present with “no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year”.

*Amendment 2 16/03/18:* In the original protocol we stated that we would “recruit participants from up to six practices”. However, it became apparent early in the trial, that it would be difficult to fully recruit the number of participants that we required within the limited recruitment window. The decision was made to extend the number of practices in order for the study team to meet the recruitment target.

Amendment 1 and 2 mitigated any recruitment risks within the specified 5 month recruitment window and were also approved by the National Institute for Health Research.

***2.3.2 Eligibility criteria***

High-street NHS dental practices were recruited across the North-West of England. Initially, contact was made with the NHS practices through the NHS Local Area Teams in Greater Manchester and Cheshire and Merseyside (the latter including the Local Dental Network). PRB ran a workshop to present the study to interested practices on the 30th of May in 2017 and sent follow-up e-mails in June 2017 to confirm their interest. NHS practices were provided with an overview of the pilot and the associated remuneration that was available to them to undertake the pilot trial:

1. £530 payment to each recruited practice for attending the pre-trial training event to cover loss of earnings;
2. £50 payment to each recruited NHS practice per participant recruited into the trial, split into £25 at the beginning and £25 at the end of the pilot trial;
3. £25 and £7 payment per patient in the intervention arm for Band One Courses of Treatment and £75 and £26 for Band Two Courses of Treatment (for exempt and non-exempt patients respectively). This was to cover the loss of NHS payments to the practice caused by the participant being treated by the DT rather than their GDP.

The eligibility criteria for the practices were as follows:

1. The practice should employ at least one DT, with at least two years clinical experience;
2. The majority (>50%) of adult service provision should be in the NHS;
3. The patient should be treated under the NHS; and
4. The practice should have the support of a practice manager.

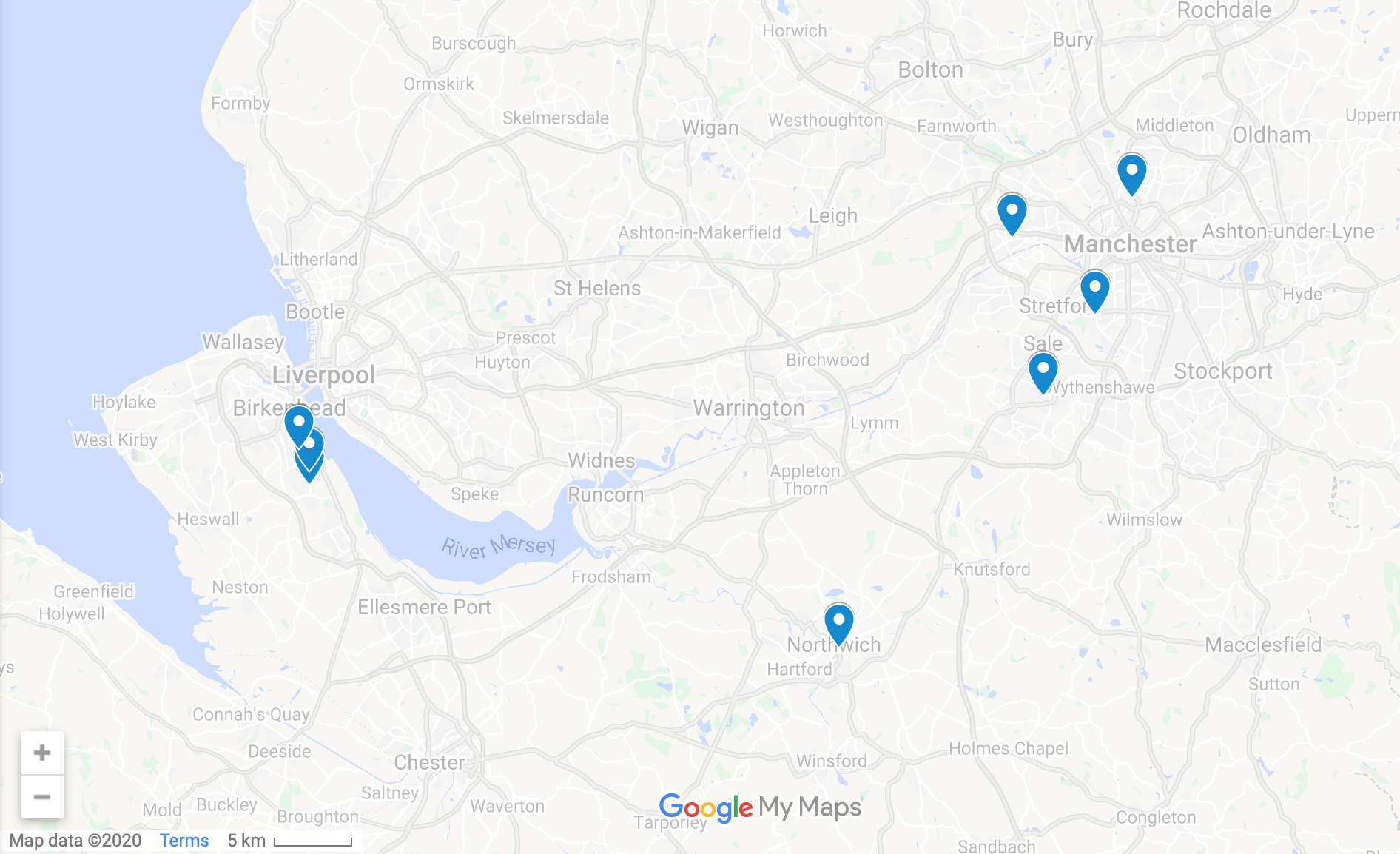
The following were the eligibility criteria for the individual participants:

1. NHS adult patient (>18 years of age) on the recall list of the participating NHS practice;
2. Patient had no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year;
3. Basic Periodontal Examination (BPE) highest score ≤ 2;
4. Asymptomatic at time of the NHS check-up;
5. No predisposing medical history that elevated their oral health risk status;
6. Seen for their routine NHS check-up at least six months ago; and
7. Dentate or partially dentate.

New patients, adult patients presenting in pain, patients requiring root fillings or extractions, who were edentate or were receiving on-going periodontal treatment were excluded. Patients with sites that had a BPE code of 3 or above were excluded (on the recommendation of the Local Dental Network).

***2.3.3 Pilot study setting***

Eight high-street NHS dental practices were recruited across the North-West of England. The geographic distribution of the practices is highlighted in Figure 1.



Map data ©2020 Google

**Figure 1: Geographic distribution of participating practices**

***2.3.4 Patient pathway***

The patient pathway for the pilot study is provided in Figure 2.



**Figure 2: Participant pathway through the NHS practice**

On arrival for their check-up, identified patients were asked by a member of the research team whether they had any questions about the study and if they wished to participate. If they agreed, the participant was then asked to sign the Consent Form and a unique patient identifier was provided to ensure anonymity. A unique patient identifier reference sheet was kept throughout the study, which enabled the participants to be tracked, when necessary. The participants were then examined by a trained epidemiologist who first checked whether the patient was eligible for the study and then undertook the baseline measurements for the Case Report Form (CRF) (Appendix 1). The baseline CRF recorded details that included:

1. Age and gender;
2. Exemption status and employment type;
3. Ethnicity;
4. Number of teeth remaining and number of sites (six per tooth);
5. Number of sites with BOP (to enable proportion to be calculated);
6. Number of sites with visible plaque present (as above);
7. Oral Health Impact Profile (OHIP-14);108 and
8. Reported levels of dental anxiety.

The participant was then randomised, using North Wales Organisation for Randomised Trials in Health (NWORTH) Clinical Trials Unit’s sequential dynamic adaptive randomisation algorithm, to see a DT (intervention arm) or their GDP (‘treatment-as-usual’ arm) (see below).109 After randomisation, each participant received a check-up according to the arm that they were allocated to (see below).

***2.3.5 Intervention group***

Under the National Health Service (GDS) Regulations 2006, the current care pathway for regular attenders is for NHS patients to see their GDP for their check-up. This reflects the regulatory environment at the time, where DTs could not see patients directly or undertake an examination or treatment plan i.e. GDPs were the only clinician type entitled to see patients directly under the NHS regulations.

In the latest epidemiological survey (conducted every decade) (n=11,380), half of all dentate adults reported that they attended their GDP at least once every six months and a further 21 per cent indicated that they attended at least once a year.28 This meant that approximately three-quarters of all the participants in the pilot study were likely to be seen twice within the fifteen-month period. This concurred with our experience in the feasibility study, where patients were seen for three check-ups during the study period.100

The patient pathway in the pilot was based on the procedure detailed in the published feasibility study.100 Given that half of the adult population do not require any further treatment after a check-up (based on national Business Services Authority data), the pilot study focused on low risk patients.28 High risk, complex or symptomatic patients were excluded (as stated above).

In the intervention arm, participants underwent a check-up by a DT and any subsequent treatment within the DTs’ Scope of Practice; the General Dental Council allows DTs to undertake all of the routine direct restorative treatment that GDPs can do, except for root fillings. Subsequent visits and treatment were recorded in a separate CRF, which recorded the following details:

1. Clinical activity/advice provided;
2. Need for any additional input from the GDP;
3. Agreement on the subsequent treatment (DT’s plan took precedence);
4. Need for the patient to be seen by the GDP (i.e. treatment required was beyond the DT’s Scope of Practice); and
5. Detail of the treatment undertaken by GDP (if required).

At the end of the study, the same measures that were undertaken at baseline were collected by the trained and blinded epidemiologist, in additional to the following information:

1. Dental pain/problems over the study period (including detail);
2. Number of new decayed and filled teeth; and
3. Proportion of sites where the Basic Periodontal Examination exceeded a score of ‘2’.

If participants in the intervention group experienced pain or presented with problems *during* the study, they were initially seen by the DT and then offered appropriate treatment, depending on the presenting problem. All treatment information was entered onto the CRF (Appendix 1), which recorded the type of treatment undertaken and the clinician type involved. After the check-up and/or the completion of any opened treatment plans, the patient was placed back on the recall list according to the recommendations of the DT.

In the feasibility study, no patient cross-overs were seen among the 60 patients recruited.100 Patients were willing to be randomised and recruitment and retention rates were 82% and 78% respectively. To assess patient cross-over, records were kept of those participants who started off in the DT arm, but crossed over to the control arm because they were considered to be too complex for DT to manage their care (this was not seen in the feasibility study).100

***2.3.6 Control group***

When participants were allocated to the control group, they saw their usual GDP and had their check-up and any subsequent treatment. As above, after the check-up and/or the completion of any treatment, the patient was placed back on the recall list according to the recommendations of the GDP. In similarity with the intervention arm, baseline and outcome assessments were recorded onto the CRF by a trained and blinded epidemiologist. The GDPs also entered all check-ups and treatment data on the appropriate CRF.

***2.3.7 Randomisation***

Randomisation was at the individual level (patient) and performed by NWORTH Clinical Trials Unit. Treatment allocation was on a 1:1 basis using a sequential dynamic randomised adaptive algorithm.109 This meant that each participants allocation was re-calculated and was based on the overall allocation level, within stratification variables and within stratum level. This enabled the research team to maintain adequate allocation ratios, whilst maintaining the required balance across the two groups.

A number of potential prognostic factors were considered as stratification factors:

• Deprivation;

• Previous history of disease; and

• Number of teeth remaining.

It was decided by the study team that the most appropriate strata to choose was a proxy measure for material deprivation (exemption status). This was recorded on the CRF.

***2.3.8 Primary outcome measures for the pilot***

In alignment with the aims of a pilot study the following were assessed:

1. Willingness to be randomised amongst study participants;
2. Appropriateness of BOP as the POM;
3. Appropriateness of the non-inferiority margin i.e. whether the effect estimate lay within an appropriate margin of non-inferiority;
4. Recruitment, retention and fidelity rates; and
5. Numbers of participant cross-overs between arms (e.g. where the patient is considered too complex to be managed by the DT).

***2.3.9 Proposed primary outcome for the definitive trial***

The proposed clinical POM for a future definitive trial was the proportion of sites with BOP. BOP is both relevant to clinicians and to patients. It was considered by the research team as stable, measurable and had potential to change over the timescale of the project. This view was reinforced by the fact that BOP was used as the primary outcome in a number of recent NIHR Health Technology Assessment trials, conducted in a primary dental care setting.110,111 Other measures of periodontal health (e.g. pocket depths) were considered to be more sensitive to measurement bias, would take a long time to express and were likely to exhibit a smaller effect.112

BOP is routinely assessed in clinical practice to measure the degree of gingival and periodontal inflammation. Whereas the presence of BOP at isolated sites is not a particularly good indicator of risk for future disease progression, absence, or minimal levels of BOP are a very good indicator of periodontal health and tissue stability.113-115 It is also highly relevant to patients, who often complain of bleeding gums as a first sign of gingival and periodontal problems. This pragmatic end-point was relevant to both patients and clinicians, and has high generalizability to every-day clinical practice. Furthermore, within the context of the pilot, BOP was considered to be the most sensitive measure for detecting signs of developing gingival inflammation.

Secondary outcome measures collected were based on simple adaptations of indices that are used commonly in clinical practice:

* Proportion of sites that have visible plaque present (measure of oral cleanliness);
* Number of new decayed and filled teeth (see below);
* Unplanned visits between check-ups;
* Oral health related quality of life (Oral Health Impact Profile); and
* Patient centred outcomes to explore dental anxiety.

Dental caries was chosen as a secondary rather than a potential primary outcome measure because it has a relatively low prevalence and longer ‘time-to-expression’ in routine low risk NHS adult patients. This view was further supported by our 15m feasibility study.100

***2.3.10 Sample Size***

A key issue for a definitive trial to evaluate role-substitution, is whether the design of the definitive study should be a non-inferiority or a superiority design i.e. whether DTs are equally as good at maintaining the oral health of low risk routine NHS dental patients (but are cheaper) or whether DTs would provide superior/inferior care to GDPs. High quality evidence from the literature is limited in terms of the direction of effect for detecting oral disease and undertaking direct restorations (see Chapter 1). Some studies showed equivalence, whilst others showed superiority.

The research team decided to base our design on non-inferiority, as this aligned with our policy question about whether DTs were as good as GDPs. We also thought that it would provide a more robust estimate of the expected confidence intervals, should the results show that a superiority design is warranted. Had the research team undertaken a pilot study based on a superiority design, this would have led to broader estimates of the confidence intervals for the definitive trial, *if* no effect was found (given the lower number of participants required for a superiority design).

As a result, we estimated that 216 (108:108 arm balance) low risk routine dental patients should be recruited across eight NHS dental practices in the North-West of England. This accounted for an attrition rate of 30% over the 15 month period, which was similar to the attrition rate seen in our feasibility study and other dental practice-based trials.100,116 This was based on the confidence interval approach described by Cocks & Torgerson, which considers the likelihood of the main study finding a relevant effect size (using the logic that if the observed difference between the groups in the pilot trial was zero, then the upper confidence interval would exclude the estimate that is considered clinically significant in a future trial).117 Based on an 80% confidence interval, this equated to 9% of the sample determined for the definitive trial. Assuming that bleeding on BOP would be the POM in the definitive trial, taking a non-inferiority margin of 5% would require a sample of approximately 1,618. 9% of 1,619 is approximately 150 (which becomes 216 when attrition is accounted for).

***2.3.11 Exploratory data analysis of clinical outcomes***

From the perspective of potential effectiveness, the analysis was focused on the difference in means in relation to the width of the non-inferiority margin for the proposed primary outcome measure, BOP, and differences in means and proportions for the potential secondary outcome measures. The effect estimate was based on the difference in means between the two arms and was evaluated with respect to clinical significance over the 15 month period. The remaining clinical and patient reported outcomes were analysed similarly and interpreted. Three different analysis models were employed. For outcome measures with a baseline measurement, mixed-effects ANCOVA models were employed with the dental practice as a random effect and the following factors as fixed effects: exemption from dental charges (yes/no), number of teeth and the baseline measurement. For outcome measures without a baseline measurement, mixed-effects ANOVA models were employed with the dental practice as a random effect and exemption from dental charges, number of teeth as fixed effects. For the behavioural change outcome measures using a dichotomous response scale (yes/no), mixed-effects logistic regression models were employed treating the dental practice as a random exempt from dental charge, number of teeth as fixed effects. Analyses were made on an intention-to-treat basis and a per-protocol basis, as per-protocol assessment is considered more conservative for non-inferiority designs. All statistical analyses were fully detailed in a statistical analysis plan that was developed and agreed before completion of data collection.

***2.3.12 Ethical issues***

Patient safety was paramount during the pilot study. Previous research undertaken by Brocklehurst *et al*. had shown that DTs were safe as front-line healthcare workers (in terms of detecting oral cancer and its precursors).79 Two large National Institute of Health Research grants (NIHR) (led again by the Chief Investigator) had also shown that DTs were as good as GDPs in the detection of dental caries and periodontal disease.98,99

Patient acceptability was another potential concern, but results from earlier studies suggested this was positive (including a published feasibility study and a separate large NIHR project).100 The purpose of the study was fully explained in the Participant Information Sheet and patients had the opportunity of asking any questions to the dental team at the practice, prior to being consented.

Patient confidentiality was also a key priority and CRFs from the study were anonymised. All forms and files were kept securely on a password protected personal computer and any paper records kept in a locked drawer.

The protocol specified that all Serious Adverse Events (SAEs) would be described and that we would compare SAEs between the intervention and control groups. This was recorded on the SAE CRF and included the following detail:

1. Patient identification (ID);
2. Details of the SAE;
3. Severity of the SAE (mild/moderate/severe);
4. Date of the SAE;
5. Location of the SAE; and
6. Consideration as to whether the SAE was linked to trial participation.

Information on SAEs throughout the study was a standing item on the Trial Management Group, the Trial Steering Committee and the Data Monitoring Committee.

***2.3.13 Study management***

The study was managed in accordance with Good Clinical Practice (GCP) and overseen by NWORTH Clinical Trials Unit, using a dedicated Trial Manager. The Chief Investigator is the Director of the Unit, which is registered with the UKCRC (#23) and has detailed Standard Operating Procedures (SOPs). As a result, the pilot study adhered to NWORTH’s SOPs, for all trial and data management, statistical and regulatory matters. GCP was employed throughout to ensure the project was managed to the highest possible standard. Appropriate supervision and training of project-specific staff and training in GCP was ensured. Trial-specific training was provided to all the practices at the start of the pilot, reviewed and reinforced throughout the study period. NWORTH’s Quality Assurance Officer co-ordinated the oversight of monitoring, documentation and all aspects of quality management and regulatory issues. NWORTH’s Senior Trials Manager provided advice to the management team on all aspects of the study.

The research was sponsored by Bangor University. The Trial Steering Committee consisted of an independent chair, independent members and PPI representatives. The group oversaw the running of the trial on behalf of the Sponsor (Bangor) and funder (NIHR HS&DR) and had overall responsibility for the continuation or termination of the trial. It ensured that the trial was conducted in accordance with the principles of GCP and the relevant regulations, and provided advice on all aspects of the study.

**2.4 Results**

The outcome of the pilot trial and suitability of a definitive trial design were assessed using the following:

1. Willingness to be randomised: quantified by considering the numbers approached and who subsequently consented (or refused based on not wanting to be randomised) (Section 2.4.1);
2. Recruitment, retention and fidelity rates: quantified throughout the CONSORT flowchart process (Section 2.4.1);
3. Numbers of participant cross-overs between arms (e.g. where the patient is considered too complex to be managed by the DT): quantified from the logs kept by each dental practice (Section 2.4.2);
4. Appropriateness of BOP as the POM: quantified by considering the potential effect size indicated by preliminary exploratory analysis (Section 2.4.3 and 2.4.5); and
5. Appropriateness of the non-inferiority margin i.e. whether the effect estimate lay within an appropriate margin of non-inferiority: quantified by considering the outcome of the preliminary exploratory analysis (Section 2.4.5).

***2.4.1 Recruitment and retention***

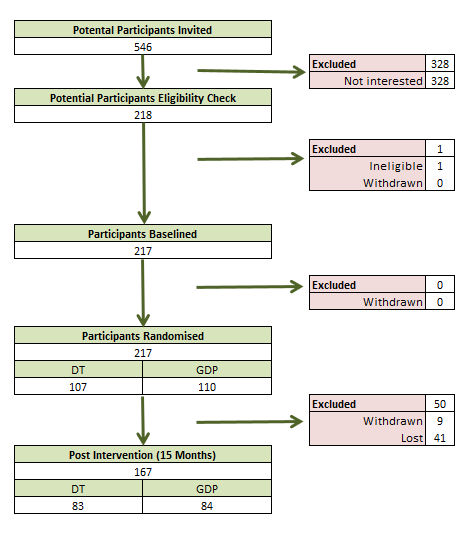
546 NHS patients were invited to participate in the pilot trial. 217 participants agreed to participate over a five-month period (March 2018 to July 2018) and 328 stated that they were not interested in participating. This equated to a recruitment rate of 39.7% and a mean recruitment rate of 43.4 participants per month. The mean number of participants recruited per site was 27.1, across 8 NHS dental practices (Table 1) over the five-month recruitment period. Of the 217 randomised 107 were randomised to the DT group and 110 were randomised to the GDP group. The groups appeared well balanced on stratification variables (Table 1).

**Table 1: Summary of recruitment by the dental practices**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Date of first participant recruited** | **Date of last participant recruited** | **DT group** | **GDP group** | **Overall** |
| **Dental Practice 1** | 05/04/2018 | 03/05/2018 | 16 | 21 | 37 (17.1%) |
| **Dental Practice 2** | 17/07/2018 | 24/07/2018 | 9 | 9 | 18 (8.3%) |
| **Dental Practice 3** | 24/04/2018 | 29/05/2018 | 16 | 17 | 33 (15.2%) |
| **Dental Practice 4** | 02/05/2018 | 05/06/2018 | 18 | 18 | 36 (16.6%) |
| **Dental Practice 5** | 13/04/2018 | 09/07/2018 | 12 | 9 | 21 (9.7%) |
| **Dental Practice 6** | 15/03/2018 | 26/04/2018 | 6 | 4 | 10 (4.6%) |
| **Dental Practice 7** | 11/05/2018 | 22/06/2018 | 14 | 13 | 27 (12.4%) |
| **Dental Practice 8** | 12/03/2018 | 11/07/2018 | 16 | 9 | 35 (16.1%) |
| **Exempt** |  |  | 10 | 13 | 23 |
| **Non-exempt** |  |  | 97 | 97 | 194 |

50 participants did not complete the follow-up assessment at 15 months. Of these 50 (23.0% of the total sample), nine participants withdrew from the trial and 41 were lost to follow-up. These 41 participants were lost due to the logistical difficulties of organising a follow-up appointment with an epidemiologist at the practice that the participant was attending. In some cases, participants could not be contacted (through mail, e-mail, telephone, texts), others were unable to attend the practice on designated days due to work or other commitments. The attrition rate was lower than the attrition rates obtained in previous dental-practice based trials.100,115 This is represented below in the CONSORT diagram (Figure 3).

The attrition rates for the DT group and the GDP group were comparable (22.4% n=24 vs 23.6% n=26) over the 15 month period. There was no statistically significant difference in attrition across the randomisation stratification variables (i.e., Group, p = 0.873; Dental practice, p = 0.676; Number of teeth, p = 0.421; Exempt from patient’s charge, p = 0.432).



**Figure 3: CONSORT diagram for the pilot trial**

***2.4.2 Protocol deviations***

There were 14 protocol deviations, all of which occurred in the DT group. 13 of the 14 protocol deviations occurred because they were allocated to the DT group but were seen once by the GDP in error, initially. The remaining protocol deviation occurred because a participant was allocated to a group before being randomised. These participants continued in the group they were allocated to but were excluded from the per protocol analyses.

No participants permanently crossed over from the DT group to the GDP group or vice-versa. Hence, there were no participants who were considered too complex to be managed by the DT. However, 20 participants from the DT group were seen/treated by the GDP at interim visits, though two of these participants were seen by the GDP because the DT was unavailable. The treatment carried out by the GDPs during these visits included root canal treatment, extraction, crown fitting and restorations.

No adverse events were reported during the study.

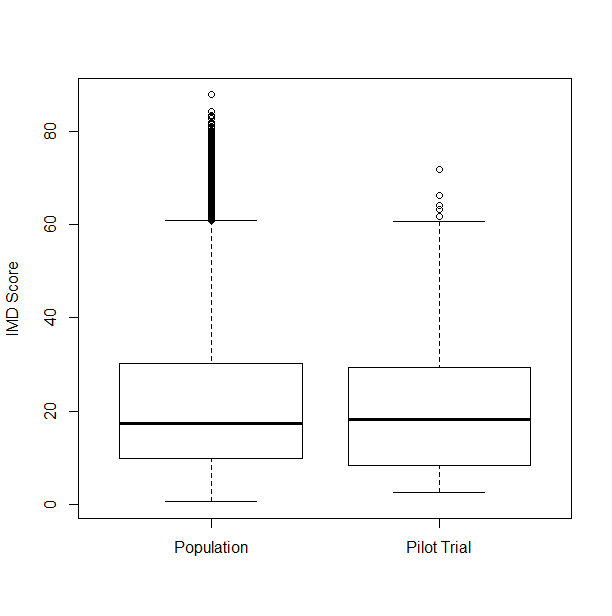
***2.4.3 Baseline measurements***

Participants in the pilot trial were predominantly female (72.4%), non-smokers (92.2%), of white ethnicity (93.1%) and were not exempt from patient charges (89.4%). The mean age of the participant was 46 years old with a standard deviation of 15.8 and a range of 18 to 87 years. The participants’ occupations are summarised in Table 2 below.

**Table 2: Occupation of the participants**

|  |  |
| --- | --- |
| **Occupation Type** | **Percentage** |
| Clerical and sales (e.g. Administration, Salesperson) | 12% |
| Professional and managerial (e.g. Teacher, Doctor, Manager) | 35.5% |
| Semi-skilled and unskilled (e.g. Factory worker, Labourer) | 2.8% |
| Skilled blue-collar (e.g. Electrician, Plumber, Craftsman/woman) | 7.8% |
| Other | 40.6% |
| Prefer not to say | 1.4% |

The mean of the participant’s Index of Multiple Deprivation (IMD) was 22.49 with a standard deviation of 17.02 and were comparable with IMD scores from the population (Figure 4).



**Figure 4: Distribution of the Index of Material Deprivation scores for the pilot trial**

Descriptive statistics of the dental related measures at baseline are provided in Tables 3, 4 and 5.

**Table 3: Dental related measures at baseline (total sample)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **N** | **Mean** | **SD** | **95% CI** | **Median** | **IQR** | **Range** |
| **Number of teeth** | 217 | 25.51 | 2.89 | 25.12 to 25.9 | 26 | 24 - 28 | 11 - 28 |
| **Number of sites** | 217 | 153.04 | 17.32 | 150.72 - 155.36 | 156 | 144 - 168 | 66 -168 |
| **Number sites with BOP** | 217 | 5.08 | 5.97 | 4.28 - 5.88 | 3 | 1 - 8 | 0 - 36 |
| **Number sites with dental plaque** | 217 | 3.30 | 4.95 | 2.64 - 3.96 | 2 | 0 - 5 | 0 - 30 |
| **Number of dental caries lesions** | 217 | 0.01 | 0.1 | 0 - 0.02 | 0 | 0 - 0 | 0 - 1 |
| **Percentage of sites with BOP (%)** | 217 | 3.39 | 3.98 | 2.86 - 3.92 | 2 | 0.60 - 5.13 | 0 - 23 |
| **Percentage of sites with dental plaque (%)** | 217 | 2.25 | 3.32 | 1.81 - 2.69 | 1.19 | 0 - 3.03 | 0 - 19 |
| **OHIP-14 Score (0-56)** | 216 | 0.85 | 2.03 | 0.58 - 1.12 | 0 | 0 - 1 | 0 - 19 |
| **Anxiety of GDP (1-10)** | 217 | 2.10 | 1.77 | 1.86 - 2.34 | 1 | 1 - 3 | 1 - 10 |
| **Anxiety of using DT (1-10)** | 217 | 2.12 | 1.72 | 1.89 - 2.35 | 1 | 1 - 3 | 1 - 10 |

**Table 4: Dental related measures at baseline (DT)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **N** | **Mean** | **SD** | **95% CI** | **Median** | **IQR** | **Range** |
| **Number of teeth** | 107 | 25.48 | 3.02 | 24.9 to 26.06 | 26 | 24 - 28 | 11 - 28 |
| **Number of sites** | 107 | 152.86 | 18.12 | 149.39 - 156.33 | 156 | 144 - 168 | 66 - 168 |
| **Number sites with BOP** | 107 | 5.6 | 6.2 | 4.41 - 6.79 | 3 | 1 - 9 | 0 - 28 |
| **Number sites with dental plaque** | 107 | 3.43 | 5.28 | 2.42 - 4.44 | 2 | 0 - 4 | 0 - 30 |
| **Number of dental caries lesions** | 107 | 0.02 | 0.14 | 0.01 - 0.05 | 0 | 0 - 0 | 0 - 1 |
| **Percentage of sites with BOP (%)** | 107 | 3.79 | 4.24 | 2.98 - 4.60 | 2.08 | 0.60 - 5.95 | 0 - 17.95 |
| **Percentage of sites with dental plaque (%)** | 107 | 2.36 | 3.61 | 1.67 - 3.05 | 1.19 | 0 - 2.88 | 0 - 19.33 |
| **OHIP-14 Score (0-56)** | 107 | 1.07 | 2.43 | 0.6 - 1.54 | 0 | 0 - 2 | 0 - 19 |
| **Anxiety of GDP (1-10)** | 107 | 1.95 | 1.73 | 1.62 - 2.28 | 1 | 1 - 2 | 1 - 10 |
| **Anxiety of using DT (1-10)** | 107 | 1.98 | 1.7 | 1.65 - 2.31 | 1 | 1 - 2 | 1 - 10 |

**Table 5: Dental related measures at baseline (GDP)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **N** | **Mean** | **SD** | **95% CI** | **Median** | **IQR** | **Range** |
| **Number of teeth** | 110 | 25.54 | 2.77 | 25.02 to 26.06 | 26 | 24 - 28 | 14 - 28 |
| **Number of sites** | 110 | 153.22 | 16.59 | 150.08 - 156.36 | 156 | 144 - 168 | 84 - 168 |
| **Number sites with BOP** | 110 | 4.58 | 5.73 | 3.5 - 5.66 | 2.5 | 1 - 6 | 0 - 36 |
| **Number sites with dental plaque** | 110 | 3.17 | 4.63 | 2.3 - 4.04 | 1.5 | 0 - 5 | 0 - 25 |
| **Number of dental caries lesions** | 110 | 0 | 0 | 0 - 0 | 0 | 0 – 0 | 0 - 0 |
| **Percentage of sites with BOP (%)** | 110 | 3.00 | 3.70 | 2.30 - 3.70 | 1.76 | 0.60 - 4.28 | 0 - 23 |
| **Percentage of sites with dental plaque (%)** | 110 | 2.13 | 3.02 | 1.56 - 2.70 | 0.94 | 0 – 3.07 | 0 - 19 |
| **OHIP-14 Score (0-56)** | 109 | 0.64 | 1.52 | 0.35 - 0.93 | 0 | 0 - 1 | 0 - 11 |
| **Anxiety of GDP (1-10)** | 110 | 2.24 | 1.8 | 1.9 - 2.58 | 1 | 1 - 3 | 1 - 8 |
| **Anxiety of using DT (1-10)** | 110 | 2.26 | 1.74 | 1.93 - 2.59 | 1.5 | 1 - 3 | 1 - 8 |

***2.4.4 Missing data***

There was an exceedingly low level of missing data in the pilot trial in participants attending baseline and follow-up appointments. There was less than 1% missing data for the different primary and secondary outcome measures that were collected across the two time-points (baseline and follow-up). The majority of the data points were able to be analysed (76.9%). The summary of the missing data is recorded in Table 6.

**Table 6: Summary of missing data at baseline and follow-up**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Baseline** | | **Follow-up** | |
| **N Missing** | **% Missing** | **N Missing** | **% Missing** |
| **Number of sites with BOP** | 0 | 0 | 0 | 0 |
| **Number of sites with dental plaque** | 0 | 0 | 0 | 0 |
| **Number of teeth with dental caries** | 0 | 0 | 0 | 0 |
| **OHIP-14 Score (0-56)** | 1 | 0.5 | 1 | 0.6 |
| **Anxiety of GDP rating (1-10)** | 0 | 0 | n/a | n/a |
| **Anxiety of DT rating (1-10)** | 0 | 0 | n/a | n/a |
| **Anxiety during pilot trial rating (1-10)** | n/a | n/a | 0 | 0 |
| **Total number of unplanned visits** | n/a | n/a | 0 | 0 |
| **Total time with GDP or DT (minutes)** | n/a | n/a | 1 | 0.6 |

***2.4.5 Exploratory analysis of the Primary Outcome Measure***

The difference between the percentage of sites with BOP for the DT group and the GDP group, based on a mixed effect ANCOVA model, was 0.07%, 95% CI [-0.49%, 0.63%] over the 15 month period. This estimate is based on a mixed-effects ANCOVA model with the dental practice as a random effect and the following factors as fixed effects: exemption from dental charges (i.e., yes, no), number of teeth (less than or equal to 26 teeth, more than 26 teeth) and the proportion of sites with BOP measured at baseline.

This estimate did not cross the specified non-inferiority boundary of 5%. Hence, the proportion of sites with BOP for the DT group could be considered non-inferior to the proportion of sites with BOP for the GDP group when 5% inferiority margin is assumed (Table 7). The adjusted mean difference and the 95% confidence interval was replicated in the per protocol analysis, adjusted mean difference = 0.17%, 95% CI [-0.41%, 0.75%].

**Table 7: Summary of the Primary Outcome Measure Intention-to-Treat analysis**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Adjusted mean DT** | **Adjusted**  **mean GDP** | **Adjusted mean difference (DT-GDP)** | **95% CI for mean difference** |
| **Percentage of sites with BOP (%)** | 1.87 | 1.79 | 0.07 | -0.49 - 0.63 |

***2.4.6 Exploratory analysis of the Secondary Outcome Measures***

For the secondary clinical outcome measures, analysis of the proportion of sites with dental plaque and the proportion of teeth with dental caries were based on a mixed-effects ANCOVA and the analysis of proportion of sites where the Basic Periodontal Examination exceeded a score of ‘2’ (collected at follow-up) were based on mixed effect ANOVA. For the patient reported outcome measures, analysis of the OHIP-14 score was based on a mixed-effects ANCOVA and the analysis of the anxiety rating for trial check-ups was computed using a mixed-effects ANOVA. The analyses results are summarised in Table 8. The adjusted mean differences and associated 95% confidence intervals from the per protocol analyses for the proportion of sites with plaque (adjusted mean difference = -0.26%, 95% CI [-0.77%, 0.26%]), the proportion of teeth with caries (adjusted mean difference = -0.05%, 95% CI [-0.15%, 0.07%]) and the proportion of sites that BPE exceeds 2 (adjusted mean difference = 0.06%, 95% CI [-0.09%, 0.22%]) were not substantially different to the estimates obtained from the intention to treat analyses.

**Table 8: Summary of clinical and patient related Intention-to-Treat analyses**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Adjusted mean DT** | **Adjusted**  **mean GDP** | **Adjusted mean difference (DT-GDP)** | **95% CI for mean difference** |
| **Percentage of sites with dental plaque (%)** | 1.36 | 1.65 | -0.29 | -0.77 - 0.19 |
| **Percentage of teeth with dental caries** | 0.12 | 0.18 | -0.05 | -0.16 - 0.05 |
| **Percentage of sites where BPE>2** | 0.06 | 0.01 | 0.05 | -0.09 - 0.19 |
| **OHIP-14 score (0-56)** | 0.63 | 1.16 | -0.53 | -1.39 to 0.32 |
| **Anxiety rating (1-10)** | 1.42 | 1.77 | -0.36 | -0.84 to 0.13 |

Again, there were no discernible differences between DTs and GDPs for the clinical measures. The observed differences for patient related outcome measures were also negligible. For the OHIP-14 score, a 0.5 difference on a 0 to 56 points scale and for the anxiety rating, a 0.4 difference on a 1 to 10-point scale. Similar differences were also obtained in the per protocol analysis: -0.45 for the OHIP-14 score and -0.30 for the anxiety ratings for trial check-ups.

The behaviour change outcome measures, which were based on a dichotomous response scale (yes/no), were modelled using a mixed-effects logistic regression (Table 9).

**Table 9: Summary of behaviour change Intention-to-Treat analyses**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Proportion DT** | **Proportion GDP** | **Proportion difference (DT-GDP)** | **95% CI difference** | **Odds Ratio** | **95% CI for Odds Ratio** |
| **Reported change in diet** | 0.13 | 0.05 | 0.08 | 0.00 - 0.17 | 0.34 | 0.09 - 1.04 |
| **Reported change in tooth-brushing** | 0.29 | 0.09 | 0.20 | 0.08 - 0.31 | 0.24 | 0.09 - 0.56 |
| **Reported change in toothpaste use** | 0.10 | 0.08 | 0.01 | -0.07 - 0.10 | 0.84 | 0.28 - 2.46 |
| **Reported change in flossing** | 0.20 | 0.18 | 0.02 | -0.10 - 0.14 | 0.88 | 0.40 - 1.92 |
| **Reported change (other)** | 0.19 | 0.09 | 0.10 | -0.01 - 0.20 | 0.44 | 0.17 - 1.07 |

The difference between the proportions for the DT and GDP group in the per protocol analyses were not markedly different from those obtained in the intention to treat analyses: reported change in diet (0.08, 95% CI [-0.01,0.17]), reported change in tooth-brushing (0.23, 95% CI [0.10, 0.35]), reported change in toothpaste use (0.02, 95% CI [-0.07, 0.11]), reported change in flossing (0.01, 95% CI [-0.11, 0.14]) and reported other changes (0.09, 95% CI [-0.02,0.20]). The most substantial difference to note is that 20% more participants in the DT group changed their brushing behaviour. In order to understand the nature of the brushing behaviour change, a descriptive analysis of the open-ended responses associated with brushing behaviour change was conducted. It revealed that 60% (19/32) involved changing to an electric toothbrush, 16% (5/32) entailed use of interdental brushing and 25% (8/32) involved miscellaneous behavioural including time spent brushing, thoroughness, technique and frequency of toothbrushing.

The visit-based outcome measures analyses were based on mixed effect ANOVA models the results are summarised in Table 10. The results from the per protocol analyses were highly comparable with the results obtained from the intention to treat analyses: number of unplanned visits (adjusted mean difference = 0.15, 95% CI [-0.46, 0.76]) and clinical time with clinician (adjusted mean difference = 13.65, 95% CI [-6.49, 33.78]). In both cases there were no substantial differences between the DT and GDP groups.

**Table 10: Summary of process changes Intention-to-Treat analyses**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Measure** | **Adjusted**  **mean**  **DT** | **Adjusted mean GDP** | **Adjusted mean difference** | **95% CI for mean**  **difference** |
| **Number of Unplanned Visits** | 1.21 | 1.03 | 0.19 | -0.39 - 0.77 |
| **Total time with clinician (minutes)\*** | 68.48 | 53.20 | 15.28 | -3.72 - 34.29 |

\*across all appointments

***2.4.7 Post-hoc analysis of intra-class correlation coefficient and power***

The interpretation of the statistical findings and the appropriateness of undertaking a post-hoc analysis is discussed below in Section 2.5. Intra-cluster correlation for the proportion of sites with BOP, where the cluster is defined as a dental practice was 0.00, 95% CI [-0.02, 0.10]. Therefore, a future trial employing the proportion of sites with BOP as the primary outcome could justify using a smaller estimate of cluster effect.

If we were to take the estimates directly generated from this pilot study to power a definitive study, then to achieve 90% statistical power for a non-inferiority test for a full trial and assuming a non-inferiority margin of 0.05 and using the standard deviation of 0.04 for the proportion of sites with BOP we obtain a sample size of 30. If we allow for 23% attrition as observed in the pilot, we obtain a total sample size of 40. If we adopted a more liberal estimate of a 30% attrition rate, we obtain a sample size of 44. Note, that the large discrepancy between the original pre-attrition sample size of 1,618 is due to the standard deviation estimate for the proportion of sites that BOP being vastly higher (0.31).

**2.5 Discussion**

The findings in this pilot trial appear to show that DTs were non-inferior to GDPs (within the non-inferiority boundary set *a priori*) over the 15 month time period. The point estimates were similar between the two groups in terms of the POM (BOP) and for the remaining clinical measures used: proportion of sites with dental plaque and the number of new dental caries lesions. There were also no differences (within the non-inferiority boundary) between the two groups in terms of oral health related quality of life (measured by the OHIP-14) or prospective anxiety about receiving treatment from a GDP or a DT. The process outcomes also showed no differences between groups in any of the clinical measures. This would suggest that DTs are non-inferior in their clinical management of low risk NHS patients when compared to GDPs, over the chosen timescale and using the selected POM. However, finding a ‘significant’ result in a pilot study should not be over-interpreted.118,119 The estimates that we used may have still lacked precision, particularly the variability on our proposed primary outcome and this may have influenced our ability to determine non-inferiority (due to the reliance on the confidence interval estimates for the parameters). In the results section, we provided both Intention-To-Treat and Per Protocol analyses, as the latter in this context, is more conservative. However, it is also possible that the measures used for this study were exhibiting floor effects due to the low risk patient population that we drew from (under-representing the variability).

The interpretation of these findings poses some interesting design questions. The purpose of this pilot trial was to determine the most appropriate design for a definitive trial, determine the appropriateness of the POM and the non-inferiority margin and test recruitment, retention and fidelity rates. It would appear that any future definitive trial to determine the clinical effectiveness of role-substitution in NHS dentistry should be based on non-inferiority. No differences were found in the oral health-status of patients over the 15 months of the pilot. In addition, despite high retention and fidelity rates, recruitment rates were moderately low (39.7%) when based on the number of patients approached (mean recruitment rate of 43.4 participants per month). These two findings may have substantial implications for a definitive trial in this low risk population group, given the higher number of participants that would be required for a non-inferiority design. This could extend the length of the definitive study to the point where the value of information generated becomes questionable in this population group. Equally, there are challenges from a policy perspective, where the recommendations are to see low risk patients every two years.120

A further challenge is the type of POM that should be used. In this study, we considered BOP, which is routinely assessed in clinical practice to measure the degree of gingival and periodontal inflammation. Earlier studies would suggest that the levels of BOP are a very good indicator of periodontal health and tissue stability.112,113,114 As a pragmatic primary end-point that is relevant to both patients and clinicians, BOP would also appear to be sensible and it was amongst the outcome measures used in our earlier feasibility study.100 However, based on evidence from this 15 month pilot study, it could be argued that there are ‘floor’ effects i.e. where the signal/event rate is so limited amongst low risk patients that it makes differentiation between two groups difficult. When compared to the Adult Dental Health Survey (cross-sectional sample of the general population), the levels of both periodontal inflammation and plaque were much lower in this sample.16 Given that we used experienced epidemiologists in this pilot trial, it would suggest that NHS patients exhibit particularly low levels of need, when only low risk participants are included and this only increases the potential for floor effects.

This is even more relevant for clinical measures like dental caries. Dental caries was chosen as a secondary rather than a potential POM in this study because it has a low prevalence and longer time-to-expression in routine low risk NHS adult patients.16 This was supported by the data from this fifteen-month pilot, where no new lesions developed and by our feasibility study, where the proportion of sites with active caries were between 1.19% and 2.60%.100 Systems developed for the detection of small incremental changes in dental caries status such as the International Caries Detection and Assessment System (ICDAS) have been advocated, but some argue that these suffer from measurement bias.121,122 According to Frencken *et al.*, “caries prevalence should not be based on the dmf/DMF index but on cavitated dentine carious lesions (d/D-component) as the M- and F- component do not refer to a disease stage”.120 Whilst it is acknowledged that these tools are used more in epidemiological surveys, signal/event definition, low event rate and slow progression of dental caries in low risk patients remain problematic, when marginal differences are being assessed in a clinical trial.

These issues are pertinent to the design of definitive trial. In the recent NHS contract reform process undertaken in Wales, where need and risk where measured (using the ACORN), over two-thirds of NHS patients were judged to be low risk.30 As a result, even if we were to include higher risk patient population within the study sample for a definitive study, it is likely that any signal of effect would be drowned out by the proportion of low risk NHS patients. It may be possible to consider analysing a ‘complete’ sample (including high and low risk patients) using an appropriate zero-inflated model, but this may not facilitate a full interpretation of effect or non-inferiority. The literature indicates that there are a number of ways of considering the development of various thresholds for a pilot study, but these should all be considered *a priori*.118,119,123

It would appear that the types of clinical outcomes that would be used for a definitive trial on role-substitution in dentistry may not be appropriate to test for non-inferiority. So, what would be an appropriate outcome measure? Patient Related Outcome Measures and Patient Related Experience Measures, may be two options, but their sensitivity and signal-to-noise ratios, may again, be problematic and appear to be further down the causal pathway to assess effectiveness and/or non-inferiority. These issues are explored further in ‘Recommendations for Further Research (Section 6.3).

**2.6 Summary**

The policy-relevant question that underpinned this pilot trial was whether role-substitution is clinically effective in NHS dentistry. By virtue of the nature of the policy context for role-substitution, it did appear that low risk populations were the most relevant population to test, *a priori*. The results from this study would suggest that relaxing the eligibility criteria to include NHS patients with more risk and more clinical need, may be more appropriate from a design perspective. However, the ratio of low to high-risk remains problematic in a practice context, given the potential of the former diluting any effect seen in the latter. This does not mean that the results of this pilot lack any significance from a policy perspective. The results suggest that DTs could provide care for low risk regular attenders in their own right or between longer recall frequencies with GDPs, although caution needs to be exercised in over-interpreting the findings from a statistical perspective. Given that the oral health of regular attenders is improving (Chapter 1), the results of this study will help inform on-going and future NHS dental reform programmes across the UK.

**CHAPTER 3: REALIST-INFORMED PROCESS EVALUATION**

**3.1 Introduction**

Work-Stream 2 (WS2) was a theoretically-driven process evaluation that focused on the micro, meso and macro factors that influence implementation of role-substitution in general dental practice. WS2 ran in parallel to the pilot trial using a realist-informed approach to understand “what is it about a programme that works for whom, in what circumstances, in what respects, over which duration”.105 This built on the qualitative work undertaken alongside WS1, which explored operational factors that influenced the delivery of the pilot trial. Realist methodology is used extensively in health services research; the approach recognises the complex and contingent nature which underpins the settings for new interventions and service delivery. This approach alongside process evaluations “supposes that regularities in the patterning of social activities are brought about by the underlying mechanism constituted by people’s reasoning and the resources they are able to summon in a particular context”.124

**3.2 Aims and objectives**

The aims and objectives of this WS was to undertake a process evaluation informed by realist methodology to understand "what works, for whom, why and in what circumstances?".

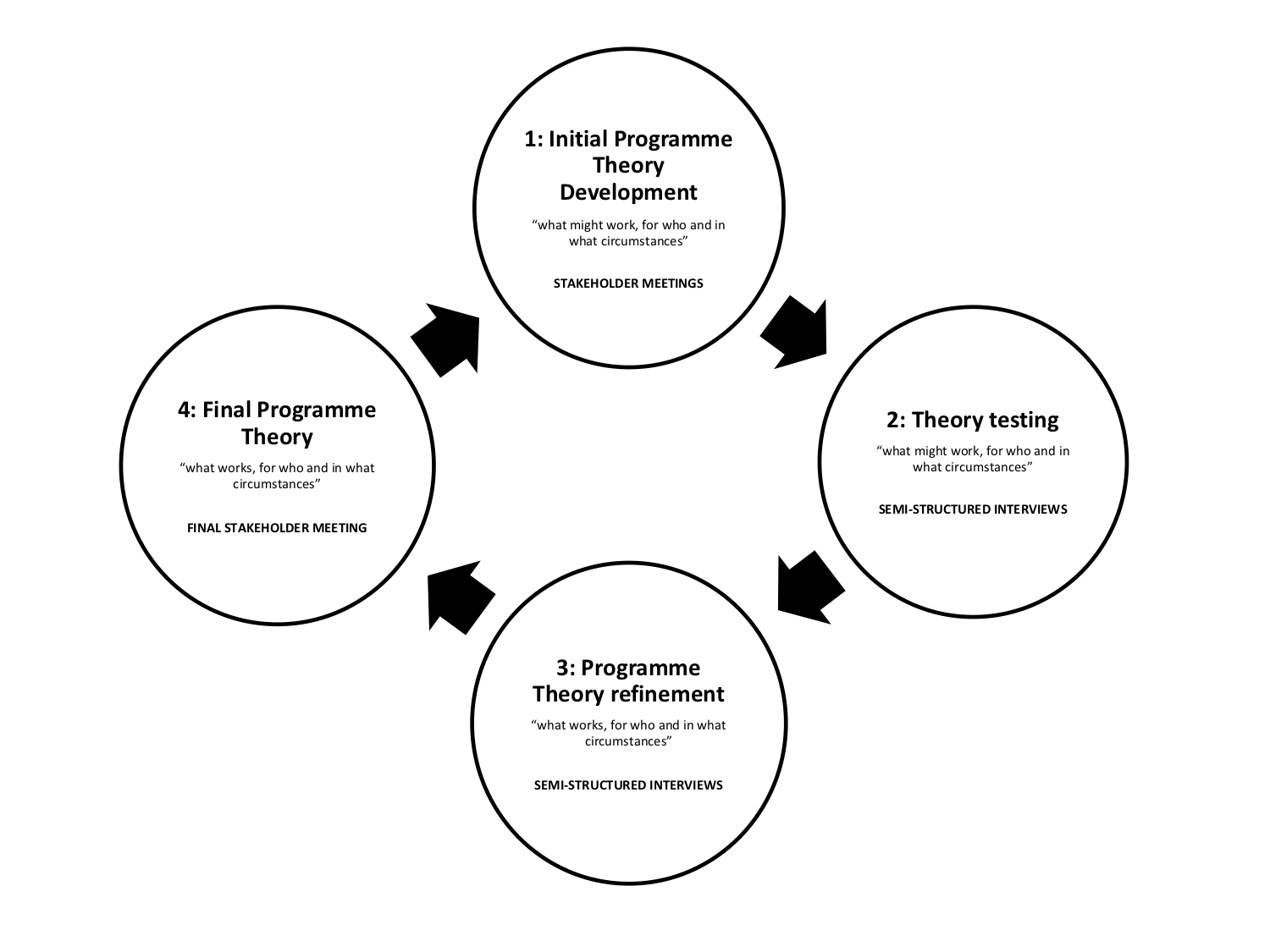
**3.3 Methods**

Moore *et al*. argue that process evaluations should capture the contextual factors that shape the intervention, mechanisms that sustain or potentiate effects, unexpected pathways and consequences and the contextual factors that shape implementation.104 To aid the process, realist principles were used to develop an understanding of “what works about the intervention, why, how and under which circumstances”.106,125 As Rycroft-Malone *et al*. articulate, theories can capture how complex interventions and systems can interact, so a realist approach tends to combine both the elements of substantive theory and stakeholders’ own theories about how an intervention might work; “rather than identifying linear cause and effect relationships through successionist logic (x causes y: often illustrated through logic models), realist enquiry is concerned with identifying the underlying generative mechanisms about how interventions work [or not]”.126

Whilst logic models are helpful for specifying intervention components as inputs and outputs, they can be less useful for developing contingent explanations between them.126 As highlighted by Brand *et al*., "to build implementation and delivery knowledge it is helpful to understand how context (individual, social, cultural, organisational) interacts with intervention components and underpinning mechanisms to bring about desired outcomes".127 In this sense, a mechanism is both the resource that an intervention provides and recipients’ reasoning and response to it.128 Dalkin *et al*., also argue that these mechanisms are not dichotomous in their action (on-off), but rather, operate across a continuum, interacting within a context to produce a specific outcome.128 Realist methodology define mechanisms as a reaction to “a resource that the intervention provides and the recipients’ reasoning about and response to that resource, and the context in which that mechanism will be activated”.125 As we highlighted in Chapter 1, this form of approach adds real value to our over-arching research question about the use of role-substitution, given the range of factors that can influence its utilization in NHS dental practices.

In this Chapter, we also use the idea of theories to refer to key stakeholders’ ideas about how an intervention works, which is derived from their experience.129 Kislov *et al*. argue for a “shift of focus from ‘theory’ as a relatively isolated, static, reified source guiding implementation, towards embracing ‘theorising’ as a set of processes that aim to use empirical data actively in developing, validating, modifying, and advancing conceptual knowledge in the field”.130 Theories in this sense are defined as “an ordered set of assertions about a generic behaviour or structure assumed to hold throughout a significantly broad range of specific instances”.131 Kislov *et al*. argue that *mid-range theories* (MRT) are particularly helpful in understanding the factors that influence the implementation of new working practices.130 Here, the evaluation is focused on a narrow range of factors that could potentially influence adoption, as opposed to *grand theories*, which aim to “construct all-encompassing meta-narratives that span space and time”.131 Realist methodologies commonly present these theories as a function of Contexts (C) and Mechanisms (M) that lead to a particular outcome or set of outcomes (O) [f (C, M, O)]. This can necessitate the apportioning of a specific factor to either a Context or Mechanism, which can sometimes appear to stakeholders as a contorted process, particularly at the outset where Initial Programme Theories (IPTs) are being developed. As a result, a number of realist researchers are now simplifying this process and using IF-THEN propositions capture a combination of f(C, M) that lead to any given outcome.132,133

The process for this study is outlined in Figure 5. Initially, this involved working with a stakeholder group to develop Initial Programme Theories (IPT), framed as IF-THEN statements. This was then followed by a process of testing and refining the IPTs using semi-structured interviews in order to develop ‘mid-level’ Programme Theories, in order to provide an explanatory framework for role-substitution in NHS dentistry.106 It then culminated in a final stakeholder group to ‘sense-check’ these theories and place them in order of priority. Ethics approval for the study was granted by the East Midlands NHS Research Ethics Committee (#17/EM/0365), as part of the larger study.



**Figure 5: Overview of a realist-informed process**

***3.3.1 Initial Programme Theory Development***

Phase 1 of the realist-informed process evaluation aimed to develop an initial set of candidate IPTs. As highlighted by Randell *et al*., “theory elicitation can be carried out in a number of ways, such as interviewing stakeholders, reviewing the extant literature on the topic, identifying relevant theories from the literature, or some combination of these approaches”.125 In this study, we decided not to undertake a review of the literature or undertake a more formal realist synthesis, due to the expertise of the group and the number of studies already known to the team (Chapter 1) and/or undertaken by the Chief Investigator. This report builds on the work undertaken for a five-year Clinician Scientist Award (NIHR/CS/010/004) and two previous NIHR HS&DR grants (11/1025/04 and 14/19/12). As a result, we used this and other evidence gleaned from the literature with key stakeholders as a starting point in order to elicit candidate IPTs, based on their experience of role-substitution in general dental practice (Table 11).

**Table 11: Factors that can influence role-substitution**

|  |  |
| --- | --- |
| **Factor** | **Detail** |
| **Financial** | Dental practices have to maintain their profitability in order to survive as small to medium enterprises. Because of this, supplier-induced demand *can* prevail over healthcare need. Remuneration structures should align with population need. The unit cost for DTs are higher than other DCPs because of their higher level of skills. Coupled with the inability of DCPs to contract directly with the NHS, makes it difficult for dental practices to financially capitalise on the promise of role-substitution. Role substitution in medicine can reduce costs, but this only occurs where nurses release doctors’ time to undertake activities only they can perform. |
| **Estate** | DTs and DHs require sufficient surgery space and clinical support and many practices only have one surgery in operation. |
| **Regulatory** | Regulatory structures governing DCP practice limits the autonomy of DTs and DHs. GDPs are also liable for the acts of DCPs in an NHS contract. Changes to the GDC’s Scope of Practice have facilitated Direct Access to DTs and DHs, but the NHS General Dental Service regulations still requires a GDP to open a course of Treatment. Transactional costs attributed to the time lost during a referral from GDPs to DTs and DHs can affect their use. DTs and DHs cannot prescribe medicines or radiographs, which further increases transactional costs. |
| **Institutional logics** | Role-substitution can challenge professional boundaries and lead to some resistance. Where GDPs support the use of role-substitution, it is more effectively implemented. GDPs’ confidence in their DCPs also influences positive referral relationships |
| **Patients** | Social acceptability of DCPs is generally positive. However, public awareness of the scope of practice of DTs is low, compared to DHs and this may be a barrier to effective implementation. |
| **Training** | Higher Education Institutes (HEIs) receive a lower tariff from the Government for DT and DH training and DCPs do not attract Service Increment For Training (SIFT) payments (unlike doctors and dentists). As such, the incentive for HEIs to train a GDP is greater than for DTs and DHs. Updating workforce planning models and also ensuring demand and supply-side factors are accounted for is necessary to promote the training of DCPs. |

Realist methodology proposes the use of ‘teacher–learner cycles’ in stakeholder interviews, where the researcher teaches back the theories to the interviewees. They then invite them to comment, based on their particular experience and perspective, in order to teach the researcher.105 In similarity to the use of IF-THEN propositions, this type of approach allows greater circumspection in the theory generating stage, ahead of refining into specific [f (C, M, O)] configurations.134 As Nanninga and Glebbeek argue, “explication of what was rejected, modified and contextualized can help in the process of theoretical understanding”, facilitating the “insight that is needed to accumulate knowledge in the sense of families of CMO configurations (middle-range theories) that are more or less stable and (re)cognizable”.134 This was the approach that we adopted in the IPT development and refinement to generate the MRTs, using the information contained in Table 11 as a starting point and working with the stakeholders that we engaged with (Table 12).

**Table 12: Stakeholders invited to develop the Initial Programme Theories**

|  |  |
| --- | --- |
| **Stakeholder type** | **Reasoning** |
| **Chief Dental Officer for Wales** | Senior policy-maker |
| **Local Dental Network (Cheshire and Merseyside)** | Active group of dental commissioners and general dental practitioners, with responsibility for regional commissioning (also included DCPs) |
| **British Association of Dental Therapy**  **(**[**https://www.badt.org.uk/**](https://www.badt.org.uk/)**)** | One of the two professional groups for Dental Care Professionals |
| **Dental Care Professional Lead (Health Education and Improvement Wales)** | Responsible for dental commissioning in Wales in relation to education and training for Dental Care Professionals |

Given the range, geographic distribution and limited availability of the different stakeholders, the research team could not arrange a single focus group and so undertook semi-structured interviews with representatives from each stakeholder type. In each interview, we focused on the current use of role-substitution in general dental practice (informed by Table A) and identified mechanisms that acted to facilitate or potentiate its use. We also sought to understand the unexpected pathways and consequences of using DTs to undertake the check-up and any subsequent treatment. Given the different types of stakeholders that we interviewed, we also focused on the contextual factors that shape implementation at a micro, meso and macro level. The emerging themes were then ‘sense-checked’ by the Chief Dental Officer and the Dental Care Professional Lead.

Semi-structured interviews with the stakeholders were undertaken face-to-face and by telephone, audio recorded and transcribed verbatim. A semi-structured interview schedule ensured the interviews were focused on the views of the participants. In each interview, we presented the stakeholders with the evidence from the literature and asked them for comments, based on their own experience of role-substitution. Open-ended questions were also included to surface new areas for investigation. An iterative approach was taken to the data and a working document was used to record the emergent themes. These were reviewed after each interview. Interviews lasted no longer than 60 minutes.

Data analysis for Phase 1 followed an inductive approach, guided by the literature, but also one that sought stakeholders’ experiences of role-substitution in NHS dentistry. The researchers immersed themselves in the data by initially reading and re-reading the transcripts. Initial codes were then generated from the transcripts by each of the researchers independently (PRB & CW). As part of this process, highlighted phrases were compared and a coding frame was developed to aid in the development of IF-THEN propositions. These statements captured the experience and thoughts of the stakeholders on role-substitution, exploring the different conditional factors that were raised by the different groups (both barriers and enablers) and how this varied with the situational contexts at the micro, meso and macro level.126 The results of the stakeholder analysis are provided below in Section 3.4.1.

***3.3.2 Theory testing***

Phase 2 of the realist-informed process evaluation tested the IPTs developed from Phase 1 (presented as IF-THEN propositions). This was undertaken using semi-structured interviews with a broad range of stakeholders who had active and on-going experience of role-substitution (Table 13). To ensure we could capture ‘mid-range’ theories, Phase 2 focused initially on practice owners (n=3) and DTs (n=5). This enabled the research team to capture the perspective and experience at the micro-level, in order to test the emergent IPTs.105

Each participant was presented with a set of opening IF-THEN propositions (Table 15 in Section 3.4.1) that had been developed from the literature and the research team in Phase 1. They were divided into four main themes: contractual, institutional logics, regulatory and training. These were presented as initial thoughts in order to stimulate discussion, in accordance with the ‘teacher–learner’ approach. As highlighted by Randell *et al*., “there is an infinite number of potential influences on the interactions between a complex intervention and its intended recipients, and an infinite number of potential impacts resulting from those interactions”.125

**Table 13: Stakeholders invited to test the Initial Programme Theories**

|  |  |
| --- | --- |
| **Stakeholder type** | **Reasoning** |
| **Dental Commissioner** | To understand the contextual factors that shape implementation in the supply of service provision at the *meso and macro level* |
| **Dental Practice Owners** | To understand the mechanisms that sustain or potentiate effects, unexpected pathways and consequences in the *supply of service provision* at the *micro level* from the perspective of the *employer* |
| **Dental Therapists** | To understand the mechanisms that sustain or potentiate effects, unexpected pathways and consequences in the *supply of service provision* at the *micro level* from the perspective of the *employee* |
| **Public** | To understand the *acceptability of role-substitution* at the micro level and the factors that may *shape the demand of services* |

Interviews were undertaken face-to-face and by telephone, audio recorded and transcribed verbatim. After the participants were presented with the emergent IPTs (represented as IF-THEN statements), there were asked to reflect whether or not, and in what ways, they fitted with their own experiences. Open-ended questions were also included (Table 14) to elicit new areas for investigation. The ‘teacher-learner’ approach enabled the research team to focus on the key issues that facilitate (or not) the use of ‘role-substitution’ in practice; testing out the stakeholders’ responses to the different IPTs. Thus, the interviews were designed to support both ‘theory gleaning’ and ‘theory refinement’.135

**Table 14: Ancillary interview questions for Phase 2**

|  |  |
| --- | --- |
| **#** | **Question** |
| **1** | a. From stakeholder feedback, we believe that if Dental Therapists could open a Course of Treatment, then it may improve the patient journey through the practice? Do we have that right?  b. Why does this improve the patient journey? How does that work?  c. What does that mean for how patients are managed (work-flow)? Would it be more efficient? Profitable? |
| **2** | a. Do you think that if Dental Therapists could prescribe (fluoride and local analgesia and radiographs), then they could undertake certain treatments autonomously?  b. Would this then improve the patient journey through the practice? Why is this the case? What is stopping this from happening? Would it be more efficient? Profitable? |
| **3** | a. Do Dental Therapists working to their full Scope of Practice pose a professional threat/challenge?  b. What causes this threat/challenge? Competing for the same business? Challenging professional identity.  c. Is this conflict articulated/discussed? Why/why not? |
| **4** | a. It has been suggested that if Dental Therapists are seen to be endorsed by their GDP, then patients are more likely to trust being treated and managed by them? Is this correct? Why is this?  b. What is it that makes a patient trust a clinician? Title? Skills? Context? |
| **5** | a. Is there any difference between practice owners and associate dentists in their opinions about using role-substitution? Why to their opinions differ/not differ?  b. Are all members of the practice team motivated by improving efficiency in a practice? Are there other factors at play? Why is this? |
| **5** | a. It appears from the literature that the use of Dental Hygienists can be favoured over Dental Therapists. Is this your experience? Why is this? Concerns over professional boundaries? Cheaper? More efficient? More profitable? |
| **6** | a. Research suggests that Dental Therapists can perform tasks within their Scope of Practice as effectively as dentists. Is this correct in your experience? |
| **7** | a. Does the training of Dental Therapists prepare them suitably for undertaking clinical tasks in a practice environment? Is it a matter of experience rather than qualification? |
| **8** | a. Some stakeholders have suggested that if Dental Therapists and GDP under-graduate training was more integrated, then dentists would become more aware of their Scope of Practice and clinical skills?  b. What would be the benefit of this? More professional integration? Greater acknowledgment? Workforce cohesion? Practice efficiencies? |

After each interview, the interview topic guide was reviewed and, where necessary, revisions were made to incorporate either new theory areas or refinements to the supplied IF-THEN propositions, in accordance with the ‘teacher-learner’ approach. This enabled the research team to sense-check with participants and explore emergent findings in subsequent interviews. An iterative approach was taken to the emerging data and a working document was maintained that recorded the emergent themes. These were reviewed after each interview by PRB, CW and LW. Any discrepancies were discussed between PRB, CW and LW and were resolved through discussion and reference to the surrounding literature and the emerging data. The latter approach governed the analysis across the project, given the range of backgrounds of the different researchers. CW and LW had no dental experience, whilst PRB had previously undertaken research in this area. Given LW’s experience in realist research, it was possible to ensure that multiple viewpoints were accommodated in a democratic manner.

A deductive approach was taken to the analysis of the interviews, where the IF-THEN propositions required refining. In parallel, an inductive thematic approach was taken to the emergent data, where this provided fresh insight and new candidate IPTs. For the latter approach, the research team (PRB, CW and LW) immersed themselves in the data by initially reading and re-reading the transcripts. New IPTs were then generated from the transcripts, again expressed as IF-THEN statements, which were formed by collating together common emergent themes and looking for patterns in these themes across different contexts, mechanisms and outcomes.

Observation can often be used alongside realist evaluation, to enable IPTs to be “guided and informed by incidents arising from the[se] observations”.135 As a result, our realist-informed process evaluation drew from observations that were made whilst running the pilot study. These took the form of field notes made before and after the semi-structured interviews, to allow for further theory testing.136 We followed the approach adopted by Randell *et al.* and “summarised the anticipated contextual factors from the theories (whether or not they were present), other contextual factors that appeared to exert influence, anticipated mechanisms from the theories (whether or not they appeared to be at play), other mechanisms that appeared to be at play, and anticipated and unanticipated outcomes”.126

To develop new candidate IPT from the emergent data, coded extracts were first elicited from the transcripts and accompanying field notes. This was undertaken iteratively, indexing the earlier transcripts to test the applicability of the codes that were generated and to assess agreement across the research team undertaking the analysis. Where there was variation in the indexing, the codes were refined and definitions were clarified. Overarching themes were then developed from these codes by organising them into clusters, based on the similarity of their meaning. These were then checked against the coded extracts and the raw data (by PRB and CW) to ensure coherence and that they were representative of what the stakeholders were trying to convey.

As data collection continued, new interview transcripts were analysed and this enabled the research team to make across-stakeholder comparisons and develop a richer understanding and new perspectives on both the context and the mechanisms that led to specific outcomes. By presenting the stakeholder with the initial IF-THEN propositions, this allowed the team to explore the broad range of contexts and mechanisms (represented within the ‘IF’ element of the statement) to outcomes (represented within the ‘THEN’ element of the statement). The results of the stakeholder analysis are provided below in Section 3.4.2.

***3.3.3 Refinement of the Initial Programme Theories***

Phase 3 of the realist-informed approach involved refining the IPTs in order to prioritise and consolidate our understanding of pertinent and explanatory ‘mid-range’ theories. Phase 3 of our realist-informed approach to the process evaluation involved interviews with dentists (n=5), DTs (n=8), dental commissioners (n=3) and patients (n=6). Patient interviews were undertaken with a user-researcher, who had been trained in qualitative interviewing for this study. This strengthened the patients’ voice in the interviews and ensured the prioritisation and refinement process were grounded in the patients’ experience. The six interviews equated to thirty-two hours of user-researcher involvement and training.

Again, the interviews were undertaken face-to-face or by telephone according to the geographic location and availability of the different stakeholders. Interviews were analysed deductively in order for the research team to prioritise and refine the IPTs. The results of the refinement of the IPTs are provided below in Section 3.4.3.

***3.3.4 Feedback on the Final Programme Theory***

The final programme theories were presented to a key stakeholder meeting. The results of the refinement of the IPTs are provided below in Section 3.4.4.

**3.4 Results**

The results of the different stages of the realist-informed process evaluation are provided in Sections 3.4.1, 3.4.2, 3.4.3 and 3.4.4.

***3.4.1 Initial Programme Theory Development***

The IF-THEN propositions developed from the stakeholder group are given in Table 15. At this stage of the process, the focus of the discussions were on contractual, institutional logics, cultural, regulatory and training issues (informed by the literature presented in Chapter 1).

**Table 15: Provisional IF-THEN propositions**

|  |  |  |
| --- | --- | --- |
| **Theme** | **#** | **IF-THEN statement** |
| **Contractual** | 1 | **IF** the NHS contract allowed DTs to open a NHS treatment plan **THEN** patients would have direct access to DTs without the need of seeing the DENTIST first, increasing the efficiency of the patient’s journey through the practice |
| 2 | **IF** the NHS contract allowed DTs to be put on the National Performers List **THEN** DTs could earn Units of Dental Activity, thereby increasing the profitability of using DCPs in the practice |
| **Institutional logics** | 3 | **IF** DTs are seen to be endorsed by the DENTISTs in the NHS practice **THEN** patients are more likely to trust being treated and managed by DTs. |
| 4 | **IF** DTs are used to their full Scope of Practice **THEN** they can pose a threat to professional boundaries due to the overlap with GDP’s, leading to a reluctance to delegate clinical tasks. |
| 5 | **IF** DHs are used in NHS practices **THEN** they can be used to upsell NHS courses of treatment, supplementing rather than substituting a GDP’s clinical activity. |
| 6 | **IF** DTs are used in NHS practices **THEN** they are commonly under-utilised as DHs (multiple reasons here: DTs are a challenge to professional boundaries, DH skills are understood better and can be used to upsell NHS courses of treatment). |
| **Regulatory** | 7 | **IF** DTs could prescribe medicines and radiographs **THEN** they could undertake NHS treatment without the need for the GDP to see the patient, which would improve the efficiency and profitability of the practice. |
| **Training** | 8 | **IF** DTs have experience working to their full Scope of Practice **THEN** they can perform tasks as effectively as GDP’s. |
| 9 | **IF** GDPs were trained alongside DTs **THEN** they would become more aware of their Scope of Practice and clinical skills, leading to greater utilization after they qualify. |
| 10 | **IF** there were incentives in the NHS contract to use DTs **THEN** more could be trained by Dental Schools. |

***3.4.2 Theory testing***

In the theory testing phase of the realist-informed process evaluation, we explored the IPTs that had been generated from the theory development phase. The results of this phase are detailed below, with representative quotes. The remainder of the data are presented in the Supplementary Material File 1.

***3.4.2.1 Theory testing: contractual***

As highlighted in Chapter 1, NHS dental contracts can heavily influence the utilization of role-substitution. These were the first two IPTs that we sought to test. We gave some consideration to incorporating these into one ‘contractual’ theory area, but initially there appeared to be two separate issues that arose from the stakeholder workshops: one that related to access and efficiency and a separate (but related) issue on UDA generation.

***IPT1: IF*** *the NHS contract allowed DTs to open a NHS treatment plan* ***THEN*** *patients would have direct access to DTs without the need of seeing the GDP first, increasing the efficiency of the patient’s journey through the practice*

***IPT2: IF*** *the NHS contract allowed DTs to be put on the National Performers List* ***THEN*** *DTs could earn Units of Dental Activity, thereby increasing the profitability of using DCPs in the practice*

For many of the stakeholders, these two theory areas were the most important. For DTs, there was frustration at the current NHS regulations, meaning that only an NHS GDP could open a Course of Treatment.

*At the moment everything’s just...you have to have a dentist to open a course of treatment and for some of the simple examinations, especially that we’ve been doing on this [pilot] trial, there’s no reason why there needs to be a dentist to open a course of treatment [DT 1.13]*

*We should be able to open a course of treatment definitely. And, it would be easier for the patient because they have the periodontal treatment with you, and then they say, and I’m going to see you next time, because you say, I’d like to see you again in three months [DT 3.138]*

*I think that’s a good idea [therapists opening a Course of Treatment], because it just makes it easier, because obviously if they’re going to come in and see a therapist it’s better if they can manage things themselves rather than us having to do it for them [GDP 5.62]*

This was also evidenced by the majority of GDPs’ responses, bar one.

*Especially the therapists that I have for the last few years, I trust them, I trust their judgement; so yes, I will feel confident for them to treat or check the patient from Day One [GDP 2.54]*

*Assuming the therapist model goes ahead, I just feel that there is a role definitely and it’s just the system will need to adjust to it, to adapt to that role where if the patient comes in they can just see the therapist directly and they can open the form, manage and treat them, send the form off and do all the work that they need to do [GDP 5.69]*

*You always need a dentist on site. And it should be the dentist that is the main person, I would say, of the treatment, and the therapist supporting that [GDP 2.378]*

One interesting element that was raised by the stakeholders was how the patient’s health status could mediate this. Opening a Course of Treatment for new or complex patients was seen to be more problematic for a DT, when compared to low risk patients who regularly visited the practice.

*It would be difficult, I suppose, if it is a new patient, which is fair enough, that’s why they can’t always do that as well. But especially with the low risk patients, easily they can open a course of treatment [GDP 2.32]*

*Maybe the initial appointment, I would say just probably the dentist. And then if it’s a long-established patient with really low risk, easily it can be treated and monitored by the therapist, and as soon as they’ve noticed something that is worrying, someone has changed medication, or habits, diet, all these things, obviously they just need to be evolved [GDP 2.43]*

Stakeholders also raised the issue of the management of emergency patients and here, unlike the management of new patients, the response was more nuanced.

*From the patient’s point of view, to have better access to the practice for routine examination as well, instead of waiting for long appointments, or even for emergency appointments, if it’s a small fracture and something that the therapist can deal with, it’s definitely working much better to be able for the therapist to open the course of treatment [GDP 2.105]*

*It’s just the NHS have this rule where we can’t open our courses, as you probably know. So I sometimes think if you have a child in who’s in pain and there was no dentist that could open a course you could probably help that kid, you could take the tooth out or do a filling, but you can’t because you can’t open a course [DT 7.48]*

Stakeholders also highlighted how inefficient the current NHS contract was, in relation to the use of role-substitution (re opening a Course of Treatment).

*They could see us in one appointment rather than having maybe several appointments, especially if the dentist is busy doing stuff that’s obviously outside my scope of practice [DT 1.39]*

*It’s not cost effective either I don’t think for the practice. It would be much more effective if the patient just came once, especially if I’m free then I can see the patient and complete the treatment. The patient doesn’t have to come back [DT 1.49]*

*There are courses of treatment that, for example, periodontal treatments, where the therapist is more than capable of seeing the patient after three months for follow-up appointments without the dentists’ intervention. And, that would be easier for the patient then because they have to, at the moment they have an appointment with the dentist and then an appointment with the therapist and it’s not always possible to have that on the same day. So, it’s two journeys [DT 3.59]*

*The thing that the trial has sort of reinforced me is that the NHS restrictions and regulations are just so outdated and are restricting us to working as efficiently as we could [GDP 6.832]*

The opinions of associate dentists were also referenced in relation to the transactional nature of internal referrals within the practice.

*Sometimes they’re just like oh it’s more hassle to do it and some of the associates don’t necessarily want to refer some of the stuff to us because they’re like well we’re going to lose some of that [DT 1.532]*

*I know why they haven’t sent it through to me as well because they don’t want to pay for it. Because otherwise they’re not making any money on it, UDAs obviously just work out cost efficient for them [DT 4.98]*

*Financially they think they can do it quicker or better. I think restorative, a lot of dentists do their treatment on the spot [DT 4.123]*

In addition to the inability to open a Course of Treatment, the UDA system was constantly referred to by all of the stakeholders.

*The number of UDAs and the holder of the contract, normally the practice owner or owners, have ultimate responsibility for that. And then there’s subcontracting, the self-employed [Associate] dentists in a number of UDAs, and so if you did bring in a therapist, you can’t say, oh, I’ve got another member of the team now, we’ll just attract more UDAs. The NHS has stopped giving out more UDAs [GDP 6.406]*

*You’d have to work out a fair system. I don’t think the UDA system quite does it [DT 3.542]*

*Most of the work then that we’re going to do...say for example you’ve got your three UDAs, the dentist is still going to want that one UDA from you [DT 1.420]*

*In my practice what I’m trying to is that I’m mainly the only person that can refer the patient to the therapist, I don’t really involve my associates; so I don’t have this kind of argument whether to deduct UDAs or deduct…. [GDP 2.423]*

*I can’t just go down to them and be like, can you open it, because they won’t, because then it’s their UDAs, isn’t it, instead of the ones that it should be.... [DT 4.69]*

*If we could open a course of treatment then all the UDAs would then be allocated to the therapists....whereas at the moment the associate would get probably, one UDA and two UDAs would be allocated towards the therapist for doing umpteen fillings whatever.... [DT 3.515]*

***3.4.2.2 Theory testing: institutional logics***

The discussions around the NHS dental contract also related to four other IPTs that were tested within the domain of institutional logics.

***IPT3: IF*** *DTs are seen to be endorsed by the GDPs in the practice* ***THEN*** *patients are more likely to trust being treated and managed by DTs.*

***IPT4: IF*** *DTs are used to their full Scope of Practice* ***THEN*** *they can pose a threat to professional boundaries due to the overlap with GDP’s, leading to a reluctance to delegate clinical tasks.*

***IPT5: IF*** *DHs are used in practice* ***THEN*** *they can be used to upsell NHS courses of treatment, supplementing rather than substituting a GDP’s clinical activity.*

***IPT6: IF*** *DTs are used in practice* ***THEN*** *they are commonly under-utilised as DHs*

Endorsement by key members of NHS dental practices was seen as a key area that strengthened the use of role-substitution.

*Because it’s been explained by the dentist who they’ve always seen...it does have to sometimes be then explained by me just to say what we do. But once they’ve seen you once they’re like okay, well yeah you do...you’re the person [DT 1.207]*

*You then find that a part of your career success or your capacity to earn money is your relationship with the dentist, because you’re relying on him so much [DT 1.458]*

*As soon as I mention to the patients, yes, it’s a restoration and a filling or something, that a treatment or scaling, that the therapist can do with a really good success rate, or they are qualified, the patient they are happy to go in to the therapist [GDP 2.266]*

*The [dentist] will say, and I’ll leave you in the capable hands of our therapist and that’s just adding those few little words in there [DT 3.331]*

*A lot of my experience where we send patients to the therapist we have to endorse them, we have to show that we’ve got faith in what they’re doing, just so the patient has the same faith as well [GDP 5.200]*

It was apparent in this phase of the realist-informed process evaluation that the threat to professional boundaries was a consideration when using role-substitution.

*Some of the dentists are actually working as therapists anyway, so they find that that might be a little bit of a threat to their model [DT 1.114]*

*Historically dentists have always been at the top of the tree in the practice and they feel that the gap is closing. There is also that if the therapists are doing all the general dentistry then it’s only complicated stuff that’s left to them [DT 3.467]*

*I think the dentist needs to get over that. Their job is still secure, we are still going to be needing dentists, they have a broader scope of practice than therapists and they are going to be needed. I don’t think therapists are here to take over the dentist role [DT 3.472]*

*I think it’s only natural for anyone to feel threatened by someone else and to doubt their work, I think maybe dentists are this kind of breed of like humanity where it’s very professional, very conscientious of what they’re doing. And they go through university for five years where it’s very competitive as well to get into dental schools as well, I think maybe it’s just one of those traits that’s kind of within that profession [DT 4.379]*

The IPT on professional boundaries was modified by the type of GDP, with equity-owning ‘Providers’ being more positive about the use of role-substitution, compared to non-equity owning ‘Performers’.

*I personally think practice owners will be all for it. Everyone who I know who is a practice owner are all using the skill-mix where possible, are all using the therapists where possible [GDP 5.338]*

*Associate[s] feel a bit more threat because they have to pay for the therapist as well, so they can see their income less; and of course, they feel that it can replace their jobs [GDP 2.400]*

*The only slight conflict probably has been with the associates, and that’s probably just a financial way of how it works and how they’re rewarded and what the therapist costs. It’s a little bit different with me being practice-owner, because I....I think that’s the thought process the dentists will have to get their head round [GDP 5.286]*

*That they’ll panic about we’re possibly taking away the easier work from them, which is probably their bread and butter. I do get that, but for the NHS to survive in dentistry, we’re going to have to make it cheaper to do what we’re doing [DT 8.327]*

IPT5 and IPT6 from Phase 1 captured the idea that the role of DHs is more accepted by GDPs, compared to DTs. This appeared to relate to DH’s non-threatening supplementary role (e.g. prevention and periodontal management) and the ability to upsell DH activity (e.g. scale and polishes) to increase the profitability of the practice.

*They don’t want to see the dentist for the cleaning, I don’t know why, they just want to see the hygienist, so then they’ll come in expecting to see a hygienist. The person that they go through, that’s the hygienist, they’re going to do the cleaning, they’re going to pay for the cleaning, it’s going to be a private clean [DT 1.555]*

*But I think it might just be easier to employ a hygienist and do the restorative work yourself as a dentist. It’s more clearly defined, straightforward and the pay is straightforward [DT 3.791]*

*Mr X only works three days a week and an empty room, so that room will be doing nothing, if you then put a hygienist in, and all the patients who would have had a clean with the dentist will go next door and have the clean with the hygienist. Because it had an additional fee allocated to it, it was a viable model [GDP 6.608]*

*You can charge a lot for a hygienist visit, especially in London, half an hour you could charge 60 quid or something like that. So I think, at the end, it’s a good income stream for dentist practices [DT 7.388]*

*Hygienist will probably be paid more than the work of a therapist because most of the hygienist’s work, they’re done privately and they’re on a percentage [DT 1.413]*

*It’s just it’s new as well, like I said they’ve not seen a therapist before, they’re not sure what a therapist means. Everyone knows what a hygienist means. So it’s just a new situation for them [GDP 5.270]*

*I think it’s easier for a lot of therapists to get jobs as just hygiene, hygienist because it’s so difficult to face the rest of the barriers on the therapy side. And at least they know when they take a job under hygiene [DT 4.619]*

*I think they get bogged down with the NHS and they’ve got a tunnel vision and forget we’re here half the time. I think they push – oh, they don’t push – private hygiene probably pays more than a NHS therapist. I think that’s probably it. I think it’s cost [DT 8.419]*

Nursing support was another issue that was raised.

*Nurse support, so having a nurse and a therapist work without...they’re sometimes asked to work without a nurse [DT 1.598]*

*Totally think we should definitely have a nurse, it’s ridiculous to not have a nurse....to have someone in the room in case of medical emergencies or charting [DT 4.784]*

*They say [GDC] it’s not right for us to work without a nurse and I personally would never work without a nurse because it’s not good for a patient, in my opinion, but some jobs out there, I had a look, they said without nurse support [DT 7.450]*

*It’s one rule for the dentists and a different rule for us, and it is totally wrong and I feel really strongly about that… It’s just wrong, dangerous, insulting [DT 8.502]*

***3.4.2.3 Theory testing: regulatory***

Regulation is another important factor that can affect the use of role-substitution in NHS dentistry. The most important of these factors stem from the Radiation Protection Act, the Ionising Radiation (Medical Exposures) Regulations (in relation to prescribing radiographs) and the Medicines Act (relating to the professional use of fluoride and local analgesia).

***IPT7: IF*** *DTs could prescribe medicines and radiographs* ***THEN*** *they could undertake treatment without the need for the GDP to see the patient, which would improve the efficiency and profitability of the practice.*

This IPT was discussed at length in the theory testing phase. For many, this reinforced some of the issues that were discussed above in relation to improving efficiency in NHS practices.

*How is it in the best interests of the patient that I then have to say to them, actually I’m sorry but I can’t do anything to you, I can’t prescribe you anything, I can’t do anything to your tooth in order to get you out of pain [DT 1.380]*

*Then the only thing that I wouldn’t be able to do then is apply the Duraphat varnish because that’s under a prescription of the dentist. So that could then obviously free up the dentist to be doing other things that are outside of my scope of practice and more complicated things that they need to do [DT 1.139]*

*Obviously they’re [GDP] writing the prescription for it, because it’s a prescription medicine. But if we had an exemption or we were able to do an additional course to then enable us to prescribe these medicines it would just make much more sense [DT 1.87]*

*If I was to see a patient [under direct access] and they need a local anaesthetic I would then have to then leave the surgery or message the dentist to then add the prescription on, to wait for the prescription to come on to then administer the local anaesthetic [DT 1.150]*

*[IF] they are able to provide fluoride, varnish, and even x-rays, and local anaesthetic, without our referral, I would say; and that will definitely work better again from the patient’s point of view, because sometimes the patient will need to come back just only for the referral or just for a review with a dentist [GDP 2.131]*

*It’s going to be five minutes before the messenger gets through to the right person, they look at the notes, or see the patient, and write that prescription, that referral form, to give the local anaesthetic [DT 3.255]*

*You’ll take longer in the appointment because you can’t always get a dentist [to prescribe] because they’ve got patients to see as well, like you’ve got to then sit around and wait for them to say yes or no. It just makes your day really difficult, you can’t just crack on and do your job [DT 4.177]*

*Unless everything is set up [re prescribing] and every dentist is on board and happy to just drop what they’re doing and come in. But even then, you still feel like a burden on the dentist as well when you’ve got to keep going into there and stopping their treatment, you feel like you’re being a pain and you’re incompetent almost [DT 4.215]*

*I think definitely like fluoride varnish, fissure sealants on the prevention side, perio and things like that, I think they’re perfectly capable of prescribing it and managing it [GDP 5.171]*

*These are registered professionals who have a high level of responsibility and training to carry out the treatments that they’re carrying out. The thought that they can’t do the other things you just described [prescribing] is again just ridiculous [GDP 6.166]*

*I think that’s [prescriptions] another massive barrier, as you’re aware, you can administer these things but you just can’t...it just doesn’t make sense [DT 7.113]*

***3.4.2.4 Theory testing: training***

We had proposed a number of IPTs in the domain of ‘training’.

***IPT8: IF*** *DTs have experience working to their full Scope of Practice* ***THEN*** *they can perform tasks as effectively as GDP’s.*

***IPT9: IF*** *GDPs were trained alongside DTs* ***THEN*** *they would become more aware of their Scope of Practice and clinical skills, leading to greater utilization after they qualify.*

***IPT10: IF*** *there were incentives in the NHS contract to use**DTs* ***THEN*** *more could be trained by Dental Schools.*

These theory areas were not given as much credence in the theory testing phase. Whilst a few of the stakeholders did comment on the importance of integrated training to increase the awareness about what clinical duties DTs can undertake, others didn’t see this as the critical issue.

*A lot of dentists don’t really know what we are or who we are, what we do [DT 4.708]*

*I trained at Manchester and I would say that we did work very closely with the dentists and they were fully aware of what we did. We did clinical skills together on the first year. We were very close...we worked very closely with them. So we had a great relationship with them and I’d hope that everyone who we graduated with fully understood what we did, because we were on clinical skills and we were also in the clinics with them [DT 1.633]*

*They should be trained together. It’s the same job, same cavity preparation, same bacteria, so they should train together in the parts, in the elements that cross over [DT 3.889]*

There was also some unhappiness expressed about the inability of DTs to subsequently train as GDPs. There appeared to be no concessions to DTs, despite the level of training that they had and this appeared to further highlight the disparity between the two roles.

*If I wanted to go and do dentistry I’d have to go and either do a postgraduate for four years or another five years course. So there’s no kind of...if anyone ever wanted to up skill to something outside their Scope of Practice they can’t do it [DT 1.656]*

*If I want to be a dentist as well I have to go to uni again for the four, five years which seems daft to me [DT 7.664]*

***3.4.2.5 Theory testing: patients’ experience***

A series of new theories were developed as a result of the theory testing, which related to the patients’ experience. Many of the stakeholders felt that role-substitution was better for the patient.

*From the patient’s point of view, to have better access to the practice for routine examination as well, instead of waiting for long appointments, or even for emergency appointments, if it’s a small fracture and something that the therapist can deal with, it’s definitely working much better to be able for the therapist to open the course of treatment [GDP 2.105]*

*But then some of them, who have been referred to see the therapist they see a different side of dentistry as well and they are quite open, they want to be seen by me for certain treatments and they ask to be referred [DT 3.391]*

*I think it’s what works for the patient. I think it’s just nice for them to come in, see the same person who’s going to look after them, manage and take care of them. It’s just a better way of doing it [GDP 5.154]*

*There’s a nice thing to that model, which is the patient gets a feeling of two people thinking about their care, and sometimes, potentially, a better outcome because two people have considered what each other think for that patient’s care [GDP 6.63]*

Some stakeholders also argued that patients don’t make the differentiation between a GDP and a DT.

*Most of the time the patients don’t necessarily care who they get treated by, they just see you as the person [DT 1.172]*

In similarity to the research highlighted in Chapter 1, many argued that patients don’t understand what a DT is*.*

*I mean people understand what a hygienist does and people understand what a dentist does, but not many people understand what a therapist does [DT 1.189]*

*Often they don’t even know what a therapist is. We haven’t got on the wall, dental therapist, this is the scope of a dental therapist, this is the scope of a nurse, this is what the dentist can do [GDP 2.350]*

*We don’t say therapist….but yeah, I’m going to refer you to the hygienist, but when it’s the therapist we try to avoid that as much as possible, so that they understand who they are actually going to see [DT 3.425]*

*And also it’s quite new to them. A lot of patients haven’t seen a therapist before, so they’re probably worried they’re going to get inferior treatment or not get the treatment by the right person [GDP 5.222]*

*So lots of patients are shocked when I tell them that I’m a therapist and what it is. So what we try and watch is we try and education patients what my role is, whether it’ll be on websites or there’s a TV screen upstairs that’s got rolling adverts on and stuff, and we’re just trying to ingrain it and tell you what I can do or what we can do as a workforce for patients [DT 7.191]*

***3.4.2.6 Theory testing: logistics***

Another new area that emerged from the theory testing phase was the importance of having enough surgeries and ‘real estate’ within the practice to make the most of role-substitution. A number of the dental commissioners (DC) had views on this theory area.

*Skill mix can be difficult if you’re limited with your surgery space and surgery chair time [DC 9.173]*

*If you trained your nurse to apply fluoride and you haven’t got another chair for them to do that in is that really that efficient? [DC 9.173]*

*I can think of examples of practices where there is going to be a problem because they have only one or two surgeries, and the only way you can really move around without having building work undertaken is to expand the hours and for the performers within the practice to change their working practices… So even though they’re not actually doing more hours, the surgery is utilised for more hours [DC 10.432]*

*So yeah, you are quite restrained really, if you have a small practice, on how you’re able to change things going forward, unless you physically change the building [DC 10.464]*

***3.4.3 Refinement of the Initial Programme Theories***

As a result of our theory testing phase, we prioritized and modified our IPTs (Table 16). These were then taken out for further testing with a different set of stakeholders, as outlined in Section 2.4.3.

**Table 16: Modified IF-THEN statements**

|  |  |  |
| --- | --- | --- |
| **Theme** | **#** | **IF-THEN statement** |
| **Contractual** | 1 | **IF** the NHS contract allowedDTs to be on the National Performers List **THEN** they could open and complete an NHS Course of Treatment, increasing the relative efficiency of role-substitution (through UDA generation) and the patient’s journey through the practice |
| **Institutional logics** | 2 | **IF** DTs are seen to be endorsed by the GDPs in the NHS practice **THEN** patients are more likely to trust being treated and managed by DTs |
| 3 | **IF** DTs are used to their full Scope of Practice **THEN** they can pose a threat to some GDPs (e.g. associate dentists), leading to a reluctance to delegate clinical tasks. |
| 4 | **IF** DTs are used in NHS practices **THEN** they are commonly under-utilised as DHs |
| **Regulatory** | 5 | **IF** DTs could prescribe medicines and radiographs **THEN** they could undertake NHS treatment without the need for the GDP to see the patient, which would improve the relative efficiency of role-substitution and the patient’s journey through the practice |
| **Patients’ experience** | 6 | **IF** patients were better educated about the DT role **THEN** they would accept treatment by DTs more readily |
| 7 | **IF** patients trust the DT **THEN** they are just as happy to be treated by a DT, as they are a GDP |
| **Logistics** | 8 | **IF** NHS dental practices had sufficient surgery space and/or time **THEN** role-substitution is more likely to be utilised |

During this phase, attention was paid by the research team to the specific contexts and mechanisms that influenced the use of role-substitution in NHS practices. In the following sections, we present the main findings in the different theory areas (transcripts are presented in Supplementary Material File 2).

***3.4.3.1 Theory refinement: contractual***

GDP, DT and dental commissioner groups all agreed that under the current NHS contractual model, the use of role-substitution can be difficult to implement. DTs work for NHS dental practice-owners (‘Providers’) that are run as small businesses that seek to maximise profit whilst discharging their professional responsibility to their patients (context). NHS General Dental Service Regulations do not allow DTs to open a Course of Treatment (mechanism). This means that DTs can’t act as the front-line clinician, reducing practice efficiency (outcome) and causing disruption to the patient’s journey (outcome). All the stakeholders agreed that this creates difficulties managing their ‘books’ if the GDP or DT haven’t synchronized their diaries, as any referrals from GDPs to DTs then require a separate appointment. As such, GDPs argued that the NHS dental contract does not support the use of a team-based approach (outcome). NHS General Dental Service Regulations require the claims for the number of UDAs undertaken to be split between those that opened a Course of Treatment and those that undertook the treatment. This creates an ‘internal market’ (mechanism) leading to competition in the practice between associate dentists and DTs and a disincentive for associate dentists to refer to DTs (outcome). Additionally, GDPs argued that the target-driven nature of the current NHS contract to deliver to their ACVs (mechanism) did not allow the freedom or flexibility for GDPs to experiment with different models of care. Instead, GDPs argued that they had to be innovative, in spite of the current contract, in order to utilize role-substitution.

One model suggested by the DTs was based on ‘upward referral’ (akin to medicine), whereby a DT could triage patients and only refer, should patients be seen to require treatment that was beyond their Scope of Practice. Whilst many DTs felt confident in recognising situations where they were likely to encounter tasks that were beyond their Scope of Practice, some felt that additional training would be beneficial. As a professional group, DTs were highly frustrated by the time taken to refer a patient back to a GDP. At worst, the patient would need to be recalled to see the GDP for a check-up and then referred back to the DT, often taking months. This only served to confuse the patient and led to inefficient processes within the NHS practice.

The dental commissioner group argued that there could be an option of using an intermediate performer level that would allow DTs to open preventative courses of treatment within the NHS, within a broader recall structure. This broader recall structure may include extended recall periods, DT fluoride application and GDP oversight for clinical safeguarding. The dental commissioner group also felt that the current NHS contract, based on UDAs, is not fit for purpose in contemporary dentistry. NHS GDS dental contract reform, and other innovative initiatives, were cited as an opportunity to re-align the remuneration system for DTs away from the reliance on UDAs. More broadly, it was suggested that the current contract did not sufficiently incentivise the level of access and the quality of care required by local populations.



**Figure 6: CMO configurations (contractual)**

***3.4.3.2 Theory refinement: institutional logics***

All the stakeholders were in agreement that the use of DTs was strongly influenced by the prevailing culture in NHS practices and the equity-owner’s view/s about role-substitution and how best to deliver care for their patients and their community (context). Endorsement of ‘team dentistry’ and the provision of support and clinical leadership by the equity-owner (‘Providers’) in an NHS practice (mechanisms), was seen as critical to help overcome some of the difficulties associated with role-substitution within the current NHS contract. Examples provided by the stakeholders included their influence on securing additional surgery space (see logistics below), exploring different care-pathways or internal payment systems for staff (‘Performers’) that ‘work-around’ current NHS service regulations. At its simplest, endorsement also related to the very practical task of providing reassurance for patients that are being referred from GDPs for treatment with DTs. There was unanimous agreement that a supportive team approach was required for effective use of role-substitution. Endorsement of DTs through outward displays of trust, positive feedback and support were recognised as essential for effective implementation. There was also recognition that some GDPs require some experience of working with DTs. Overall, equity-owner’s were seen to be supportive of role-substitution in practice as ultimately it represented a mechanism for increasing profitability: meeting the needs of the local population using a less expensive workforce (outcome).

The GDP, DT and dental commissioner groups also recognized that DTs working to their full Scope of Practice can also be seen as a professional challenge (mechanism) to associate dentists and that this could influence the institutional logics within an NHS practice. This was for three reasons. The first mechanism was referred in the previous section (immediate conflicts in the ‘internal’ market). The second related mechanism was the associate dentists’ perception that this only added complexity to intra-practice referrals. The third mechanism related to more medium-term concerns about DTs ‘taking over’ their future role.

Where role-substitution wasn’t working, a number of the stakeholders mentioned that DTs would often be undertaking DH roles (outcome). This was highlighted particularly by the DT stakeholder group, where they stated that they’d often be asked to perform as DHs (outcome). Many DTs reported that there was a feeling of resignation amongst many in the profession; that they would be fortunate to work to their full Scope of Practice (outcome) in a typical NHS practice. Ultimately, this results in de-skilling of the DTs workforce leading to a loss of clinical confidence (outcome), and many DTs not returning to their full Scope of Practice (outcome).



**Figure 7: CMO configurations (institutional logics)**

***3.4.3.3 Theory refinement: regulatory***

NHS dental practices and DTs are required to work to Ionising Radiation Regulations Act, Ionising Radiation (Medical Exposure) Regulations and Medicines Act and the GDC’s Scope of Practice (context). The DTs inability to prescribe radiographs, fluoride varnish and local analgesia were all cited by the stakeholder groups as creating substantive inefficiencies (outcome) and practice disruption (outcome), when managing NHS patients. The DT group argued that this could manifest itself as the need to re-book the patient’s appointment, which had significant financial implications under the current NHS contract. Some DTs identified mechanisms for working around the inefficiencies of obtaining a prescription, these typically involved leaving some ambiguity in the treatment plan, or GDPs issuing prescriptions *post-hoc*, based on a trusting clinical relationship with the DT. The inability to prescribe for even basic treatments reduced the DTs’ sense of professional autonomy and an addition burden for the referring GDP (outcomes).

All the stakeholder groups agreed that the current Scope of Practice for DTs could present challenges within an NHS practice environment. Examples were given of how certain clinical presentations would initially appear to be within the DTs’ scope, but which later required a GDP to intervene (outcome). In these instances, the inefficiencies (outcome) caused by the need for a GDP intervention outweighed the efficiencies gained by referring to a DT. If DTs had a wider Scope of Practice (mechanism), it was thought that these instances would be less common. There was unanimous opinion that, when operating within their Scope of Practice, DTs could perform clinical tasks as well as GDPs.



**Figure 8: CMO configurations (regulatory)**

***3.4.3.4 Theory refinement: patients’ experience***

Patient acceptability was considered to be important at the theory testing phase, but most patients that were interviewed in this phase argued that they’d accept new ways of working. Given the importance of capturing the patient voice, key themes are supported by quotes from the patient group.

*I probably wouldn’t be bothered who I saw in the first place, as long as you knew there was a structured approach [22.33]*

*But if I went somewhere else, I would accept the way they worked straightaway, almost certainly, and probably without question [22.636]*

*I would have faith in the profession, that they would do that. It’s not as if you just drag somebody off the street and say, fill this bloke’s teeth. They have been trained [25.132]*

*I would go there in expectation that I was going to be seen by the most appropriate person for my condition… I wouldn’t want to know, I’d just expect, it’s like if the car mechanic said, which of our mechanics would you like to do your car [25.227]*

*I would make the assumption that once you’d asked the question, they were qualified to deal with what was wrong, and off you go, give it a try [27.459]*

*Put our faith in the system. So, I would, unless the person that was treating me was very indecisive or didn’t look the part, or looked a bit rough or something, which gave me doubt as to their proficiency, then otherwise I’d accept that the dental practice knew what they were doing [25.172]*

*I’ve absolutely no preference who I see. I know some people are really adamant that they only want to see the person that’s the most specialised, but I think that’s just ignorance as to what that person can do really [26.355]*

*I don’t think it’s the job title or…it’s just the situation. You know, it’s fine, I don’t think it matters who’s doing it, as long as they can meet the needs, and that’s what’s happening…you know, they want to know they’ve seen the right person for it to be resolved [27.268]*

*Yes, so, yes I think in that situation. And also, if you’ve got a persistent problem, you really would want it fixed… So, I think that, you know, if it was really bothering you, you’d see whoever could solve it, you wouldn’t mind [27.449]*

Some of the patient stakeholders also raised the issue of complexity as a factor.

*You’re in a more complex situation, maybe having bridges…which, touch wood, you know, we’re not in, then I can understand why somebody might feel that they needed a particular person. But people like us, we wouldn’t mind at all, we wouldn’t be bothered. We’d be quite happy [27.131]*

Others argued about the importance of consistency, in terms of the clinicians that they see in practice.

*That’s probably one thing that will probably affect the changes more than anything else is that somebody my age probably for simplicity expects the same person because it’s stability, it’s a sense of comfort [22.289].*

*Perhaps older people who are more used to seeing, the dentist, you know, the authority figure, man, usually, traditionally, might be a bit wary, perhaps the other people, not so much [25.423]*

They also emphasized the role of the whole of the dental team.

*It’s the receptionist which is the first face that you meet, which is probably the person that can make the difference [22.25]*

A key element was the need for the practice to communicate any process of change.

*But as long as I was explained the benefits I would receive, and I think they’ve got to be, if that was projected that way, then I would probably see that [22.785]*

Our user-researcher provided her thoughts on the key context, mechanisms and outcomes that govern patients’ response to role-substitution in NHS dentistry. Given that the public have no understanding of the current NHS system (context), a number of key mechanisms were identified:

1. Low patient awareness of what DTs can do (mechanism) means that patients are only receptive to DT utilisation (outcome) if they are explained the benefits (mechanism);
2. Patients want minimum disruption to their daily lives (mechanism);
3. Continuity and consistency are important (mechanism) in order to build trust; and
4. Trust in the ‘system’ of NHS dentistry (mechanism) also reduces patient anxiety (outcomes).



**Figure 9: CMO configurations (patients’ experience)**

***3.4.3.5 Theory refinement: logistics***

Both the GDP and the dental commissioner groups argued that there were significant logistical barriers to the successful implementation of role-substitution. Role-substitution in NHS dentistry requires additional surgery space and/or surgery time to enable DTs to undertake patient management (context). They argued that NHS dental practices that only had one/two chair practices would find it difficult to make role-substitution work under the current NHS contract. Role-substitution is predicated on NHS practices having sufficient clinical space to employ a DT. This was often difficult, as most ‘high-street’ practices were not purpose built for ‘team dentistry’. Instead, their design had been strongly influenced by the incentives in previous NHS contracts that rewarded high levels of clinical activity undertaken by GDPs to maximise profitability (mechanisms). This ‘small business’ economic model was exacerbated further by the fact that NHS practices were essentially independent contractors with no structural investment from the NHS (mechanism). This meant that practice expansion was difficult (outcome) and that members of the dental team that could maximise profit (DHs) were preferred over DTs (outcome).

Some suggestions were made by the dental commissioners as to how best to counter this, including: extended opening hours, building extensions and forming hubs for local health services in primary care, where capital resources would be pooled between providers to enable patients to access NHS dentistry, ophthalmology and pharmacy.



**Figure 10: CMO configurations (logistics)**

A common theme to all these five areas of programme theory related to the NHS dental contract. As a result, these have been collated into one model to highlight the different influences on role-substitution in NHS dentistry (Figure 11). It highlights how contractual issues affects the business model in NHS dentistry and the institutional logic of the individual NHS dental practice. In turn, these can impact on the logistics within the practice, in terms of decisions around the numbers of surgeries needed and how much of the available clinical time is given to role-substitution. It also highlights how regulatory issues impact on the business model of the NHS dental practice, whilst concomitantly impacting directly on utilisation (given that DTs have a duty in their own right to discharge their Scope of Practice in accordance with the GDC regulations). Regulatory and contractual issues are seen to operate at a macro level and influence the business model and institutional logic at the micro level. These factors operate independently to the meso level, where there is little that dental commissioners can do to facilitate role-substitution (given the contractual and regulatory underpinning of the NHS system at the macro level), bar structural investment, which is difficult given the independent contractor status of NHS Providers.



**Figure 11: Over-arching model**

***3.4.4 Feedback on the Final Programme Theory***

The final programme theories were presented to a key stakeholder meeting at the Cheshire and Merseyside Local Dental Network, with representation from the Local Dental Committee, Consultants in Dental Public Health, Dental Commissioners and the Post-graduate Dental Dean. The theory areas were presented sequentially, with stakeholders given the opportunity to feedback, before moving on to subsequent theory areas.

*Contractual:* Stakeholders agreed that the NHS contract influences the utilisation of role-substitution. As evidenced in the first *f*[C,M,O] configuration (Figure 6), significant attention was paid to the professional strain that is placed on DT’s and associates, as a result of the UDA system. It was suggested that this conflict for resources is minimised when DT’s are salaried, as is seen in the Community Dental Services and some dental practices. However, the majority of stakeholders argued that there was no ideal model for practice owners, should they try to implement role-substitution within the current NHS dental contract. Many felt that it was difficult for established (compared with new) practices to adapt their business model to accommodate DT’s without causing friction amongst their associates. It was suggested that clinical activity (UDAs) should only form part of an NHS dental contract model, if role-substitution was to be encouraged.

*Institutional Logics:* Stakeholders agreed that the prevailing institutional logics within an NHS practice heavily influences the adoption of role-substitution. They all agreed that strong leadership was required in order to ‘sell’ the benefits of DT’s to their dental teams. The stakeholders supported the second *f*[C,M,O] configuration (Figure 7) and argued that the ‘internal market’ was an important factor that mediated the referral process within the practice and how this links back to the contractual issues highlighted in the first *f*[C,M,O] configuration (Figure 6). This was thought to drive the under-utilisation (and de-skilling) of DT’s, in favour of DH use. The increasing feminisation of the dental workforce and the changing expectations of new dental graduates were also recognised as emerging drivers that could increase DT utilisation.

*Regulatory:* There was unanimous agreement on the disconnect between DT’s training, scope of practice and the current regulatory framework in NHS dentistry (Figure 8). The group expressed their frustration over the inability of DTs to prescribe fluoride, radiographs and local analgesia. They highlighted how DT’s could prescribe in certain clinical settings (in Community Dental Services with Patient Group Directives), but that this was difficult in a GDS environment. The stakeholders agreed that regulatory barriers impacted upon the efficiency of dental practices, given the need for GDP oversight. Additionally, the group argued that there was a need for a review of current NHS contracts, alongside regulatory changes, to promote different referral models within the practice.

*Patients’ Experiences’:* The stakeholders agreed that most patients would be happy being treated by a DT providing certain criteria were met (Figure 9). These criteria included, appropriated patient education, trust and endorsement from the dental team. As highlighted by the fourth *f*[C,M,O] configuration, “communication of the role and benefits of being managed by DT’s” was critical. It was also felt that this could be further facilitated by the education of the whole dental team. Moreover, the stakeholders suggested that members of the team such as receptionists and dental nurses were best positioned to deliver this education/information to patients.

*Logistics:* Stakeholders emphasised the importance of the final theory area (Figure 10), arguing that many NHS dental practices are bound by their size/scope of their building and associated clinical space. Stakeholders agreed that, for most NHS dental practices in the current contractual framework, role-substitution typically requires additional surgical space. The stakeholders also highlighted how practices often find it difficult to source capital investment from the NHS, due to their status as independent contractors. The group did think that most ‘NHS practices are working to maximum efficiency’ within the current contractual and regulatory frameworks, but could become more efficient if the issues highlighted above were addressed.

Overall, no new theory areas were suggested by the stakeholder group and no amendments were thought necessary to the mechanisms and outcomes that were presented.

**3.5 Discussion**

The realist informed process evaluation added value to the study and captured many of the themes that were discussed in Chapter 1. Following a detailed and iterative process, it elicited five principle areas of programme theory: contractual, institutional logics, regulatory, patients’ experience and logistics. This enabled the research team to understand and capture the contextual factors that shaped the intervention, the mechanisms that sustained or potentiated effects, unintended consequences and the contextual factors that shape the use of role-substitution in NHS dentistry.104 As highlighted by Rycroft-Malone *et al*., these theory areas were complex and to a large extent interdependent.126 The underlying generative mechanisms were largely at the macro and the micro level, with the latter being driven by the former and related to individual, social, cultural and organisational factors.127 They were also seen to operate across a continuum and provided the research team with a rich explanatory narrative of the factors that potentially influence adoption.128,130

The two most important elements that appear to shape the practice of NHS dentistry in the UK are contractual and regulatory factors. Despite the relaxation of the Scope of Practice from the regulator’s perspective, the requirements under the GDS contract for dentists to open a course of treatment, appears to significantly limit the practice of role-substitution in NHS dentistry.9,10 This is further potentiated by the fact that DTs cannot contract directly with dental commissioners and this appears to undermine strategic objectives at the level of the policy-maker, to promote the use of the whole dental team.9,14,15 The results from this workstream also highlight how this appears to fundamentally impact on the institutional logics of NHS practices. As highlighted by Goodwin *et al*. and Watt *et al*., the institutional logics at any given NHS practice not only include dentistry as a business, but also professional ethics and contextual factors, based on where the practice is embedded.49,50 The drive to maintain (and maximise) the viability of an NHS practice does appear to be tempered by a practice owner’s view about their sense of duty to their patients and their ideas about how best to deliver care for their patients and community.51 However, contractual incentives remains a fundamental driver. As such, the results in this study concur with our earlier work, where the views of practice principals were found to highly influential.31 This is important, as promoting role- substitution and any potentially disruptive transition, caused by changes to local working practices, takes time and good human resource skills.54 In this study, most examples of successful implementation of role-substitution in NHS dentistry appeared to be where the practice owner/s had found ‘work-arounds’ to the contractual and regulatory barriers.

The social-acceptability of role-substitution appeared high and patients appeared to trust the ‘system’ of NHS dentistry. Most suggested that they’d accept new ways of working, but would want NHS practices to articulate the benefits of being managed by DTs. Equally, many highlighted the importance of continuity and consistency in their care and the need to keep disruption at a minimum. This appears key to the success of role-substitution in NHS dentistry, as this issue was also raised by many dentists and DTs, who were frustrated at the difficulty of ensuring a smooth transition for patients, given the restrictions within the GDS contract.

From a dental public health perspective, these factors are critically important, given the trend in future population health needs.16,29,30 Oral health is improving overall and where there remains existing intransigent problems or new oral health challenges, there will become a pressing need to better target the available resources in NHS dentistry.17,18,19 All the dental contract reform programmes undertaken across the UK place an emphasis on increasing patient access and prevention, whilst maintaining and improving the quality of service being delivered.60-69 It would appear that a key element in any reform programme would be to change the underlying contractual and regulatory incentives.

**3.6 Summary**

Substantial barriers exist to the practice of role-substitution in NHS dentistry. The two most dominant factors were contractual and regulatory barriers. These appeared to drive the institutional logics at the micro level, with little influence exerted at the meso level by dental commissioners. Where role-substitution was successful, practice owners had found ‘work-arounds’ to the macro factors that dominated any potential implementation.

**CHAPTER 4: HEALTH ECONOMIC ANALYSIS**

**4.1 Introduction**

The first part of this Chapter (Workstream 3) reports the methods and results for the within trial economic evaluation. This analysis developed and tested the health economic data collection tool. It also rehearsed the economic evaluation of the intervention compared to the current practice that would be conducted in the definitive trial. Both pieces of work were designed to inform the definitive trial design. With regard to effects, we used the clinical measure, bleeding on probing, and the oral health related quality of life as measured by Oral Health Impact Profile when estimating cost-effectiveness. The economic evaluation was conducted following best practice guidelines conforming to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).137

Neither the clinical measure, BOP, nor the OHIP are ideal for use in an economic evaluation as it is unclear how important a unit change in either measure is valued by decision-makers. This means that any incremental cost-effectiveness ratio (ICER) calculated is difficult to interpret except in the sense that higher values for an ICER are less likely to be considered worthwhile compared to lower values. For this reason, preparatory work undertaking an investigation of patients’ preferences over being seen by DTs compared to being seen by GDPs is undertaken. Participant views were explored in the setting of focus groups and one-to-one interviews. The results of the qualitative work informed the development of a preference elicitation exercise (e.g. a discrete choice experiment) that would be administered as part of the future definitive trial. The preference elicitation exercise in a definitive trial would then be able to provide a metric to value the benefits of the intervention in monetary terms. This would extend the cost-effectiveness analysis into a cost-benefit analysis (where both costs and benefits are measured in commensurate, normally monetary, units). The methods and results of this work are presented in the second half of this Chapter.

The Chapter finishes with a brief summary of the principal findings of the two elements of the health economics work.

**4.2 Aims and objectives**

The aims of this workstream were to:

1. Pilot the health economic data collection tool and rehearse the health economic analysis to inform the definitive trial design; and
2. Explore patients’ preferences through focus groups to inform a discrete choice experiment in a definitive trial.

For clarity these will be presented as two separate sections within this Chapter, each with its own methods and results section.

**4.3 Methods**

***4.3.1 Methods for the within trial economic evaluation***

***4.3.1.1 Data collection***

The following information was collected for Workstream 3:

*Clinical and Quality of Life data:* the number of sites with BOP and OHIP-14 data was collected at baseline and at the end of study follow-up period at the epidemiologist visit as described in Chapter 2.

*Dental treatment received:* Case Report Forms (CRFs) were completed by healthcare professionals at first and interim visits to dental practices which captured the nature of the appointment (e.g. check-up, emergency), any treatment provided and the staff present.

*Participant Cost Questionnaire (PCQ):* A self-completed questionnaire posted to patients at 12 months aimed to capture additional health service that was not recorded in the CRF as well as out of pocket costs. It also asked patients to provide time and travel information to dental appointments, as well as details of usual activity if they were not attending the dental appointments and any lost earnings during to their dental appointments. As the PCQ referred to a six-month time period all costs were scaled to the 15 month study duration.

***4.3.1.2 Costing methods (NHS costs and the use of health-care services)***

In the main analysis, NHS costs were considered to primarily consist of Unit of Dental Activity (UDA) payments made to practices as part of their contract and incorporated prescription charges (in a sensitivity analysis as described below these NHS costs were also estimated using a microcosting approach).

*NHS UDA payments:* Details on attendance and treatment provided at dental appointments were recorded by clinicians in the CRF. Treatment described was examined with reference to the NHS treatment band inclusion criteria and each treatment allocated a band.138 NHS (and patient) costs were based on ‘courses of treatment’. Where appointments were classified as ‘emergency’ they were assumed to occur outside an existing course of treatment and were costed separately.139 Each course of treatment was then assigned a corresponding number of UDAs (described in Appendix 2); where allocation to the appropriate band was unclear a decision was made following discussion with clinical members of the research team.138 As UDA values can vary between geographic locations and practices and are dependent on the contract in place, earlier work was used to estimate a value of £25 per UDA for the primary analysis.140 This was varied between £20 and £30 in a sensitivity analysis to reflect this potential variation. All treatment described in the CRF was considered to be received on the NHS unless explicitly stated otherwise or when that treatment was generally unavailable in NHS primary dental care (e.g. implants or botox treatment). Where exclusively private treatment was described in the CRF, these were considered to occur outside of NHS treatment costs. Where the CRF and the PCQ overlapped (e.g. attendance at secondary care dental visits and dental visits between check-ups), CRF data was used in preference to PCQ to avoid costs being double-counted and to avoid recall bias with the PCQ data.

*Secondary care costs:* In cases where a referral to secondary care was described in the CRF, a cost was applied based on the value of an outpatient attendance using the most up-to-date value available from the National schedule of reference costs.139 This was considered more appropriate than costing the price of the treatment referred for because: (i) it was not known if the treatment took place; and (ii); the treatment may have taken place outside the duration of the trial. Additional secondary care appointments reported in the PCQ were also included in this cost.

*Prescription medication*: The cost of any prescription medicine referred to in the CRF was taken into account. In the small number of prescriptions described, details were limited and assumptions of medication, dosages and durations were estimated based on details provided in the British National Formulary in order to estimate cost.141

***4.3.1.3 Costing methods (patient costs)***

Patient costs comprised of five categories:

1. NHS treatment charges: NHS treatment band charges were applied to courses of treatment as described for NHS costs above, using NHS patient charges rather than UDA payments. No cost was applied to NHS treatment where a patient was exempt from charges.
2. Prescription costs: Based on CRF data describing medications prescribed at the dental practice. These were costed at the standard NHS prescription charge rate.
3. Over the counter medication costs: These costs were reported in the PCQ. If patients did not complete this questionnaire it was assumed that they did not have associated out of pocket costs.
4. Private treatment: Where private treatment was referred to in the CRF this was estimated using NHS information, practice price-lists and a national survey of private dental charges.
5. Time and travel: Based on time and travel data reported in the PCQ, a mean unit cost per appointment was calculated from patient’s providing complete time and travel information. This unit cost consisted of the following:
   1. Travel costs: calculated as public transport cost to appointments or costs of mileage if a private car was used. Parking costs were included where reported;
   2. Time costs: A time value per appointment was based on the combined travel and appointment time reported by patients. Time was costed based on the Department of Transport value for leisure time, where individuals reported not missing work to attend appointments.142 Where individuals reported unpaid absence from work, an average hourly pay rate was used to calculate this (Appendix 2); and
   3. The same cost calculations were undertaken for any additional accompanying person to the patient, where participants reported that they were accompanied by a companion.

A mean cost was taken which provided a time and travel unit cost. This was then applied to every appointment reported in the CRF data.

*Inflation:* Unit cost calculations were based on 2019 data, where available; and where these were unavailable, costs were inflated using the Consumer Price Index.143

*Discounting:* As the duration of the study extended beyond 12 months, all costs beyond one year from study entry were discounted at the recommended National Institute for Health and Care Excellence (NICE) rate.

***4.3.1.4 Analysis of costs and ‘benefits’***

Clinical outcomes used in this analysis were those used in the primary trial analysis:

1. Bleeding on probing (BOP); and
2. Oral Health Impact Scale (OHIP).

The economic analysis used both of these clinical outcomes to rehearse the effectiveness measure that would be used in the definitive trial and was performed on the basis of intention-to-treat (ITT). Mean cost and effectiveness in each of the trial arms were used to estimate the adjusted incremental cost, incremental effectiveness and incremental cost per unit change in the effectiveness measure (i.e. ICER: the incremental cost-effectiveness ratio) as point estimates. Seemingly unrelated regression (sureg) analysis, a recommended method when costs and effects are likely to be correlated, was used to generate the estimates of incremental costs and incremental effectiveness.144 Both the incremental costs and incremental effects were adjusted for age, sex, baseline proportion of sites with BOP, baseline OHIP point, charge exemption status and number of teeth at baseline and dental practice. The point estimates for the incremental cost effectiveness ratio do not reflect the statistical imprecision surrounding estimates of costs, effects and cost-effectiveness. As such the deterministic results alone are not sufficient to support decision-making. In order to assess the level of uncertainty around point estimates a stochastic analysis was conducted with the application of the bootstrapping technique. The results of this stochastic analysis (1,000 simulations) were presented as cost effectiveness plane and as cost-effectiveness acceptability curves. Deterministic sensitivity analysis was used to explore the changes in the results with the variation in the value of UDA payments of (i) £20 and (ii) £30 and when the analysis was based on patient costs alone. All the analyses were performed in Stata (Version 15.1).

***4.3.1.5 Treatment of missing data***

Although CRF entries varied in the level of detail that they recorded, and therefore the level of interpretation required, no data were missing which were required to calculate costs and therefore no imputation methods were required.

For the PCQ, patients who did not return a questionnaire or who provided no data for a particular question were assumed to have no costs associated with that category.

With regard to outcome measures and as described in Chapter 2, baseline and follow-up BOP data were present for all participants and only two participants were missing OHIP data at baseline and follow-up respectively. Given the extremely low level of missing data, no imputation was performed. The implication of this is that participants missing outcome data were excluded from the analysis.

***4.3.1.6 Sensitivity analysis***

As an alternative approach to basing NHS dental costs on UDA values a microcosting approach was taken separately. This was undertaken to estimate actual staff time and materials associated with check-ups and treatments carried out in each arm. Capital costs were not considered as these were considered fixed and unaffected by the level of activity. The treatments costed in this way were those described in the CRF data collected at each appointment. These costs were not included in the cost effectiveness analysis reported in the results below.

*Materials:* Methods for calculating material costs for each treatment were based on previous dental micro-costing work [alongside personal communication with the corresponding author and personal communication, Tara Homer, Newcastle University, July 2019] with all costs updated to current values through reference to up-to-date costs of materials using a dental supplies website.145 Where treatments not featured in this trial were described in the CRF, clinical input was provided in order to assemble and cost a list of likely consumable and reusable equipment. Laboratory costs were estimated through discussions with clinicians on the study team and reference to available published price lists. Resources were inflated by 20% to account for value-added tax. It was assumed that reusable items had a three-year lifespan and were used six times per week for their duration. The total cost per item was converted into the equivalent annual cost, using a 3.5% discount rate, and combined with an autoclave cost where appropriate to estimate a per-use cost (Appendix 2).146

*Staff costs:* Staff costs included in the microcosting were based on estimates published by the Personal Social Sciences Research Unit (PSSRU) in 2019.147 It was assumed that a dental nurse was present for appointments in addition to either a DT or GDP (dependent on trial arm). It was assumed that participants saw the type of staff consistent with the arm they were randomised to, unless it was indicated on the CRF that the participant saw another practitioner (e.g. in error, for an emergency appointment, through patient preference, or for additional clinical input). In the DT arm, where GDP time was described as additional, this was costed in addition to the DT time. When clinical notes indicated that a treatment had been provided by the GDP, it was assumed that the DT was not present at this appointment.

The staff salaries provided by the PSSRU were adjusted to account for employer pension and national insurance contributions not included in the taxable income provided and a per-minute salary calculated.

***4.3.2 Preparatory work for a discrete choice experiment***

While there is potential for overlap with Chapter 3, the objectives were different for the preparatory work for a discrete choice experiment (DCE). In this workstream, we aimed to understand the acceptability of receiving check-ups from DTs (from the perspective of a health service-user) to inform future preference elicitation work in the form of a DCE.

***4.3.2.1 Methods for the preparatory work***

Two rounds of qualitative data collection were conducted. The first comprised of focus group discussions held at practices participating in the pilot study. The second comprised of one-to-one interviews with members of the public who were not connected to the pilot study or participating practices. This latter sample provided a more heterogeneous sample and a broader range of perspectives.

***4.3.2.2 Preparatory work recruitment***

*Round 1:* Focus group participants were approached by a member of staff at their practice and asked if they would be interested in taking part in a focus group discussion about the use of DTs in the management of low-risk patients. If interested, participants liaised with the practice and three focus groups were arranged on the practice premises. Written consent was taken by the group facilitator (MB) ahead of the focus group.

*Round 2:* This part of the study was advertised locally in a newspaper, a number of community centres and on a patient and public involvement forum. Participants contacted the researcher (MB) directly or through a volunteer coordinator (in the case of the public involvement forum) if interested.

For those participants who contacted the volunteer coordinator, the researcher then made initial contact by phone or email and sent out an information sheet. For these interviews, we aimed to achieve a more heterogeneous sample so were flexible with regard to the format and setting of interviews; offering participants the choice of location and face-to-face or telephone interviews.

Prior to the interview a consent form was signed (or in the case of telephone interviews a signed form was returned in a freepost envelope). As there were no clinical data re: risk as there was in round one, three brief questions were asked at the start of the interview; 1) whether the participant was currently experiencing pain from their teeth, 2) whether the participant had received more than one filling in the past year and 3), whether the participant’s gums bleed during brushing. Answering any of these questions positively, classified patients as non-low risk for the purpose of this qualitative work. Participants in both rounds were given a £10 shopping voucher as a gratuity for taking part.

***4.3.2.3 Data collection for the interviews***

A flexible topic guide was used which contained questions on the following topics:

* Understanding of different dental professionals’ roles and the importance of level of training;
* Relationship with existing dentist and views on seeing a different practitioner;
* Confidence in DTs to carry out routine check-ups;
* Factors influencing choice of dentist;
* Attitudes towards cost; and
* Perception of individual risk.

Data were transcribed verbatim by an external transcription company. While efforts were made in focus groups to identify participants (participants were asked to introduce themselves in addition to stating their name before speaking), this was later anonymised.

***4.3.2.4 Data analysis of the interviews***

Data analysis followed the principles of thematic analysis (used in Chapter 3) and NVivo 12 was used to manage the analysis process:

1. Familiarisation was achieved through reading transcripts multiple times in conjunction with listening to the interview recording. This also served as an opportunity to correct any transcription errors observed. Notes were made on initial thoughts using NVivo;
2. Data were initially coded using a mixture of inductive and deductive codes, referring back to the study objectives as well as emerging themes from the process evaluation;
3. Coded data were then examined in order to identify common themes; and
4. Data were discussed regularly within the health economics and the wider study team to inform subsequent versions of the topic guide.

**4.4 Results**

***4.4.1 Completeness of data***

A total of 167 participants were eligible for inclusion in the primary intention to treat (ITT) sample and were included in the analysis of costs. At six months, 133 respondents returned the PCQ, however, due to missing identification numbers this could not be matched to individuals and is not included in this analysis. One-hundred and twenty-three respondents (95 included in the ITT sample comprising 47 and 48 in the DT and GDP arms respectively, i.e. 28 were subsequently lost to follow-up) returned the PCQ at 12 months describing healthcare appointments and out of pocket costs in the past six months. Of these respondents, 44 provided complete time and travel details of a healthcare appointment in the past six months, which was used to generate a time and travel unit cost.

***4.4.2 Estimates of resource use and cost***

Table 17 describes resource use; no formal testing was conducted to explore difference between groups. Similar mean numbers of visits to dental practices were observed with the average appointment length being longer in the DT group (Table 10). The number of Band One, Two and Three treatments appeared similar in both arms as did the number of emergency appointments. The mean time spent with a GDP in the DT group appeared high, although this is understandable, as the GDP would be undertaking more complex and time-consuming procedures, given the nature of the study (where these were likely to be treatments that could not be undertaken by the DT). Notably no participants reported use of other primary care services and this suggests that data collection might be simplified for the definitive trial. The number of people reporting additional hygienist visits in the PCQ was low (n=2), as were the number of people referred to secondary care (n= 4) and those reporting a visit to an emergency or out-of-hours dental service (n=1).

**Table 17: Resource use per patient over the trial in the ITT analysis**

|  |  |  |  |
| --- | --- | --- | --- |
| **Resource use** | **Data source** | **DT arm**  **(n= 83)**  **(Mean; SD)** | **GDP arm**  **(n= 84)**  **(Mean; SD)** |
| **Number of visits to dental practice (minutes)** | CRF | 3.3 (2.3) | 3.0 (2.2) |
| **Average recall appointment length in minutes (minutes)** | CRF | 18.4 (5.9) | 14.0 (6.2) |
| **GDP time in DT arm (minutes)** | CRF | 14.5 (39.0) | n/a |
| **DT in GDP arm (minutes)** | CRF | n/a | 0.2 (2.2) |
| **Number of visits to other primary care (Mean; SD)** | PCQ | 0 (0) | 0 (0) |
| **Number of Band One courses treatments** | CRF | 1.9 (0.9) | 1.8 (0.9) |
| **Number of Band Two courses of treatments** | CRF | 0.3 (0.7) | 0.2 (0.5) |
| **Number of Band Three courses of treatments\*** | CRF | 0.1 (0.3) | 0.1 (0.4) |
| **Number of emergency band treatments** | CRF | 0.3(0.8) | 0.2 (0.5) |
| **Number of dental specialist visits** | PCQ & CRF | 0.02 (0.15) | 0.02 (0.15) |
| **Number of emergency visits (e.g. A&E or Dental Emergency Clinics)** | PCQ | 0.1 (0.5) | 0 (0) |
| **Number of additional hygienist appointments** | PCQ | 0.09 (0.47) | 0 (0) |

\*in the DT arm some participants received Band 3 treatments,

which were provided by a GDP and costed accordingly.

Table 18 describes the average (mean) cost per patient for each cost category in each arm. As would be expected, the similar UDA payments reflect the similar number of Bands described in Table 17. Prescription costs were low for both groups due to a small number of prescriptions being reported in the CRF (n=5 in the DT arm and n=4 in the GDP arm) and the relatively low unit cost of these medications. Given the minimum impact on cost estimates, this also suggests that data collection might be simplified for the definitive trial.

While the cost of private care appears higher in the DT arm, it is worth noting that private treatment was recorded for a small number of patients (n=6) and the private costs for one of these patients in the DT arm was nearly £1400. Thus, whilst infrequent, the use of private care would be important to capture in a definitive trial given its potentially high costs.

**Table 18: Average cost per patient for each cost category in each arm**

|  |  |  |
| --- | --- | --- |
| **Cost type** | **DT arm (n=83)** | **GDP arm (n=84)** |
|  | Mean (SD) | Mean (SD) |
| **NHS Cost** |  |  |
| **UDA payments** | 126.50 (127.74) | 114.93 (130.10) |
| **Prescription medicines cost** | 0.15 (0.65) | 0.13 (0.63) |
| **Secondary care costs** | 4.66 24.22 | 2.95 19.03 |
| **Total NHS costs** | 131.31 (132.57) | 118.01 (131.26) |
| **NHS Costs minus patient contributions (prescription and dental charges)** | **44.30 (70.29)** | **36.75 (64.03)** |
| **Time/materials** |  |  |
| **Reusable & consumables costs** | 22.08 (30.41) | 24.53 (53.18) |
| **Staff costs** | 39.78 (42.80) | 44.70 (60.52) |
| **Total** | **61.86 (71.07)** | **69.22 (111.67)** |
| **Patient cost** |  |  |
| **NHS dental charges** | 86.57 (93.40) | 80.73 (104.68) |
| **Prescription charges** | 0.43 (1.94) | 0.54 (2.14) |
| **Over the counter medication charges** | 0.16 (1.37) | 0.21 (1.45) |
| **Private treatment** | 21.00 (153.48) | 5.02 (40.38) |
| **Time and travel costs** | 12.06 (8.05) | 10.37 (7.48) |
| **Total** | **120.23 (176.62)** | **96.86 (122.82)** |

\*all costs in 2019 pound Sterling

Figure 12 illustrates the distribution of costs within each of the two randomised groups. This shows the data is highly skewed (as expected), with a small number of participants incurring substantially higher costs and over 60% of participants in both randomised groups having total NHS costs of less than £50.

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**Figure 12: Total NHS cost by intervention group**

***4.4.3 Effectiveness data***

The evidence on the impact of the intervention on both BOP and OHIP scores are described in detail in Chapter 2. Figures 13 and 14 describe the distributions in scores within the study population. As Figure 13 illustrates, more participants in the GDP arm had close to zero sites (where there was BOP) compared to the DT arm. However, in both arms a small number of participants had a 10% of sites BOP. The low proportion of sites BOP is to be expected given the selection criteria for the study but it is possible that the distributions would change should a larger sample (from a definitive trial become available).

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**Figure 13: Proportion of sites with BOP by intervention group**

With respect to OHIP scores, the majority of participants had a very low score (where low scores indicate better oral health) (Figure 14). However, a small number of participants in both arms had higher scores. As with the other outcomes it is possible that the distribution of scores would change if data from more a sufficiently large sample was available (re a definitive randomised controlled trial).

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**Figure 14: OHIP14 score by intervention group**

***4.4.4 Incremental cost-effectiveness analysis***

The adjusted CEA investigating BOP shows that the strategy of DT was on average less effective [Incremental site with BOP: 0.0006 (95% CI: -0.005 to 0.006)] and more costly [Incremental cost: £14.85(95% CI: -8.5 to 38.20)] than the strategy of GDP. Therefore, in terms of BOP, DT is dominated by the strategy of GDP and thus no ICER is calculated (Table 19).

When benefits were considered in terms of the OHIP score the strategy of DT was on average more effective [Incremental OHIP point: -0.64(95% CI: -1.51 to 0.23)] but more costly [Incremental cost: £14.85(95% CI: -8.5 to 38.20)] than the strategy of GDP (Table 19). The incremental cost per unit reduction in OHIP score was £23.20.

The cost-effectiveness plane (Figure 15) illustrates that, for the majority of the bootstrap iterations, DT is more likely to have more site with BOP than GDP. Contrary to this, in terms of OHIP the majority of the bootstrap estimates show that DT provides better OHIP scores compared with GDP. DT is also likely to be more costly than GDP (Figure 16 and Figure 18).

With respect to BOP, Figure 16 shows that there is a 91% chance that the current practice with GDPs would be a more cost-effective strategy than a strategy of DT, should society be willing to pay £100 per proportion of site with BOP avoided. With respect to OHIP there is an 84.4% chance that the DT strategy would be a more cost-effective strategy than the current practice with GDPs, should society be willing to pay £100 for a one point improvement in OHIP score (Figure 17).

The evidence on costs and cost-effectiveness should be treated cautiously as the results reported above are not conclusive given that the results were derived from pilot data. Figures 12, 13 and 14 illustrate there was marked variability in both cost and effectiveness parameters and it is likely that these results may change substantially, should data from more participants become available in a definitive trial.

**4.4.5 Sensitivity analysis**

The results of the sensitivity analyses where high NHS Costs are used (Table 20) or low NHS costs are used (Table 21) are very similar to the base case analysis, indicating that the results are not sensitive to the differing methods that costs have been considered in this workstream. Furthermore, the cost-effectiveness results that take into account the patient and carer perspective (derived from the PCQ), do not change the main findings either (see Table 22).

**Table 19: Summary of the cost-effectiveness analysis**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean proportion of sites with BOP**(95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental proportion of sites with BOP**  (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP per proportion of site with BOP avoided** | | | |
| ***£0*** | | ***£100*** | ***£500*** |
| **Incremental cost per additional site with BOP avoided** | | | | | | | | | |
| **DT (N=82)\*** | 55.66  (34.15 to 77.17) | 0.018  (0.013 to 0.023) | 14.85  (-8.5 to 38.20) | 0.0006  (-0.005 to 0.006) | Dominated | 9.3% | | 9.0% | 9.2% |
| **GDP (N=84)** | 36.75  (22.86 to 50.65) | 0.013  (0.009 to 0.017) |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean OHIP point**  (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental OHIP point**  (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP for each point of OHIP reduced** | | | |
| ***£0*** | ***£100*** | | ***£500*** |
| **Incremental cost per OHIP point reduced** | | | | | | | | | |
| **DT (N=82)\*** | 55.66  (34.15 to 77.17) | 0.54  (0.09 to 0.97) | 14.85  (-8.5 to 38.20) | -0.64  (-1.51 to 0.23) | £23.20 per OHIP point | 9.3% | | 84.4% | 92.3% |
| **GDP (N=84)** | 36.75  (22.86 to 50.65) | 1.01  (0.26 to 1.76) |

\* There was missing clinical outcome data for one participant who is not included in this analysis

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\*positive Incremental proportion of site with BOP means DT is more effective than GDP

**Figure 15: Cost-effectiveness Plane showing Incremental proportion of sites with BOP and Incremental cost (DT versus GDP)\***

\*as the expected difference in BOP between arms is very small, over the threshold ranges of WTP considered the decision is that the GDP arm is more likely to be cost-effective, primarily due to lower cost

**Figure 16: Cost-effectiveness acceptability curve showing probability cost-effectiveness for a given WTP per proportion of site with BOP avoided\***

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\*positive Incremental OHIP point means that DT has higher quality of life than GDP

**Figure 17: Cost-effectiveness Plane showing Incremental OHIP point and Incremental cost (DT Vs GDP)**

\*as with BOP GDP is expected to be less costly, but for OHIP is also expected to be less effective

(although the confidence intervals for a difference include ‘no difference’)

**Figure 18: Cost-effectiveness acceptability curve showing probability cost-effectiveness for a given WTP per OHIP point reduced\***

**Table 20: Sensitivity analysis using high NHS costs**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean proportion of sites with BOP** (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental proportion of sites with BOP** (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP per proportion of site with BOP avoided** | | | |
| ***£0*** | | ***£100*** | ***£500*** |
| **Incremental cost per proportion of sites with BOP reduced** | | | | | | | | | |
| **DT (N=82)\*** | 81.15  (55.77 to 106.53) | 0.018  (0.013 to 0.023) | 15.41  (-13.13 to 43.95) | 0.0006  (-0.005 to 0.006) | Dominated | 15.7% | | 15.7% | 15.6% |
| **GDP (N=84)** | 59.73  (41.94 to 77.53) | 0.013  (0.009 to 0.017) |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean OHIP point**  (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental OHIP point**  (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP for each point of OHIP reduced** | | | |
| ***£0*** | ***£100*** | | ***£500*** |
| **Incremental cost per OHIP point reduced** | | | | | | | | | |
| **DT (N=82)\*** | 81.15  (55.77 to 106.53) | 0.54  (0.1 to 0.97) | 15.41  (-13.13 to 43.95) | -0.64  (-1.51 to 0.23) | £24.08 per OHIP point reduced | 15.7% | | 84% | 92.3% |
| **GDP (N=84)** | 59.73  (41.94 to 77.53) | 1.01  (0.26 to 1.76) |

Note: Incremental costs, Incremental proportion of sites with BOP and Incremental OHIP point estimates derived using sureg in stata adjusted on covariates: age, sex, baseline proportion of sites with BOP, baseline OHIP point, charge exemption, number of teeth, practice. \*There was missing clinical outcome data for one participant who is not included in this analysis.

**Table 21: Sensitivity analysis using low NHS costs**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean proportion of sites with BOP** (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental proportion of sites with BOP** (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP per proportion of site with BOP avoided** | | | |
| ***£0*** | | ***£100*** | ***£500*** |
| **Incremental cost per proportion of sites with BOP avoided** | | | | | | | | | |
| **DT (N=82)\*** | 30.18  (11.60 to 48.75) | 0.018  (0.013 to 0.023) | 14.30  (-5.42 to 34.02) | 0.0006  (-0.005 to 0.006) | Dominated | 5.1% | | 5.0% | 4.6% |
| **GDP (N=84)** | 13.76  (2.22 to 25.31) | 0.013  (0.009 to 0.017) |
| **Intervention strategy** | **Mean NHS Cost (£)**  (95% CI) | **Mean OHIP point**  (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental OHIP point**  (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP for each OHIP reduced** | | | |
| ***£0*** | ***£100*** | | ***£500*** |
| **Incremental cost per OHIP point reduced** | | | | | | | | | |
| **DT (N=82)\*** | 30.18  (11.60 to 48.75) | 0.54  (0.1 to 0.97) | 14.30  (-5.42 to 34.02) | -0.64  (-1.51 to 0.23) | £22.34 per OHIP point reduced | 5.1% | | 85.3% | 92.5% |
| **GDP (N=84)** | 13.76  (2.22 to 25.31) | 1.01  (0.26 to 1.76) |

Note: Incremental costs, Incremental proportion of sites with BOP proportion and Incremental OHIP point estimates derived using sureg in stata adjusted on covariates: age, sex, baseline proportion of sites with BOP, baseline OHIP point, charge exemption, number of teeth, practice. \*There was missing clinical outcome data for one participant who is not included in this analysis.

**Table 22: Sensitivity analysis using patient costs**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Intervention strategy** | **Mean Patient Cost (£)**  (95% CI) | **Mean proportion of sites with BOP** (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental proportion of sites with BOP** (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP per proportion of site with BOP avoided** | | | |
| ***£0*** | | ***£100*** | ***£500*** |
| **Incremental cost per proportion of sites with BOP avoided** | | | | | | | | | |
| **DT (N=82)\*** | 121.06  (82.05 to 160.1) | 0.018  (0.013 to 0.023) | 17.0  (-29.15 to 63.14) | 0.0006  (-0.005 to 0.006) | Dominated | 28.9% | | 29.1% | 28.3% |
| **GDP (N=84)** | 96.86  (70.21 to 123.52) | 0.013  (0.009 to 0.017) |
|  | **Mean Patient Cost (£)**  (95% CI) | **Mean OHIP point**  (95% CI) | **Incremental cost (£)**  (95%CI) | **Incremental OHIP point**  (95% CI) | **ICER (£)** | **Probability of DT intervention being considered cost-effective at different threshold values for society’s WTP for each OHIP reduced** | | | |
| ***£0*** | ***£100*** | | ***£500*** |
| **Incremental cost per OHIP point reduced** | | | | | | | | | |
| **DT (N=82)\*** | 121.06  (82.05 to 160.1) | 0.54 (0.1 to 0.97) | 17.0  (-29.15 to 63.14) | -0.64  (-1.51 to 0.23) | £25.6 per OHIP point reduced | 28.9% | | 79.6% | 91.6% |
| **GDP (N=84)** | 96.86  (70.21 to 123.52) | 1.01(0.26 to 1.76) |

Note: Incremental costs, Incremental proportion of sites with BOP proportion and Incremental OHIP point estimates derived using sureg in stata adjusted on covariates: age, sex, baseline proportion of sites with BOP, baseline OHIP point, charge exemption, number of teeth, practice. \*There was missing clinical outcome data for one participant who is not included in this analysis.

***4.4.6 Results of the preparatory work for the discrete choice experiment***

In total 32 people took part in the qualitative study. One focus group was held with non-low risk patients who were not taking part in the study (n=6) and two focus groups were held with low-risk patients taking part in the study (n=7 and n=6). Thirteen patients took part in face-to-face interviews. Overall, the sample consisted of eight males and 24 females and the mean age of the sample was 61 (range: 23-84). Seven participants were employed, four were not working, nineteen were retired, one was a student and one participant did not answer this question. Thirty participants described themselves as ‘white British’ with the remaining two not answering this question. Seventeen participants were classed as low risk and two reported being exempt from charges (one did not answer this question).

Interview participants were asked to describe factors which were important in choosing which dental practice or dentist they attended. This raised a number of considerations, from simple practical factors to descriptions around relationships with health professionals.

***4.4.6.1 Practical considerations***

*Location and convenience:* Many described initially registering with a dental practice purely on the basis that they were local to them. In the absence of any other factors, this seemed to be the most likely primary reason to register with a particular GDP:

*I saw the dentist at [previous employer] and then when I left in the '70s, then looking for another dentist and this was the nearest [FG1 Participant]*

Others agreed that distance was important but cited practical factors such as parking, public transport and proximity to other services or shops.

*Personal recommendation:* Similarly, people were likely to be guided by personal recommendations when choosing a dentist, whether this came from friends, their family, or other health professionals:

*So, the last time I was at a dentist, it was on a personal recommendation. [Interview 7]*

Participants also talked about other factors which impacted on how satisfied they were with their dental practice. These commonly focused on the ongoing relationship they had with both the practice and the health professionals therein.

*Availability:* The availability of services was cited as an important factor by many participants. Whilst there may not have been as much importance placed on routine appointments (typically made months in advance), many stated that it was important that practices were able to deal promptly with emergency appointments. Some suggested that larger practices were more likely to have capacity and flexibility to meet these urgent needs:

*And the appointments, you seem to be able to get one quite regular even in an emergency, but they seem to have quite a few staff. [Interview 7]*

Many argued that they would want to be seen quickly, should they or their family have urgent medical needs. This appeared to effect the type of relationship that they had with a practice, as it highlighted the extent to which they were cared for:

*If they can't fit you in fair enough but they do seem to try and say, "Come along. You may have a half an hour wait or so but we'll fit you in, even if it's just a quick look and then we do another appointment," but they are willing to do for you. [FG1 Participant]*

*Trust and continuity of care:* Continuity of care was a dominant topic at many interviews and occupied much of the discussions within the focus groups. This was more than simply seeing the same GDP, it also appeared to impact on their perceived level of care that they received and indicated that they were valued as a patient. This discussion drew parallels with access to care from named General Medical Practitioners:

*I see the same dentist every time. And that is pleasing as opposed to doctors, for example, where if you want to see the same doctor the next appointment is about five years away, but you can see someone else tomorrow. [Interview 11]*

Some talked about continuity of care in an almost nostalgic manner, but acknowledged that role-substitution may improve efficiency in larger practices, for example, being able to get an appointment on the same day for an urgent issue:

*Before it was more like a family house, you know, had goldfish in the waiting room, you know what I mean? And it has all been much enlarged and modernised and they take NHS and private patients. And I think a lot more people go, mind, if it’s an emergency and you are in pain they will see you the same day. But of course you might not always get the dentist you always have, you might just have to take whoever is available. [Interview 4]*

Participants also spoke about the importance of continuity of care for people with complex medical histories or care needs:

*She knows because I've had different things going on with my teeth. I prefer to see her because she knows my history without me going through everything again. [FG1 Participant]*

*My son is autistic and they are really calm with him and explain everything to him because he doesn’t like sudden noses or the environment, and they are lovely with him – they understand. [Interview 13]*

Another important element within this theme was the establishment of trust with health professionals. Participants commonly described a relationship with a GDP built-up over time, which could help ameliorate dental anxiety and deliver more tailored treatment according to their needs:

*I don’t like to be flat when the treatment is done. And I said could he raise me up a bit and he didn’t mind doing that, so I was comfortable in the chair which was important. And he said if I was nervous or worried to put my hand up and he would stop – I found him very reassuring actually. [Interview 4]*

Although the importance of trust was often inferred at the level of an individual practitioner, some participants also described being attached to a dental practice:

*They are very nice. I haven't met anyone who hasn't inspired me, they've [practice] actually got my interests at heart. [FG3 Participant]*

***4.4.6.2 National Health Service status***

Although a minority of patients described using non-NHS services, the NHS status of a practice was of great importance to many participants. Some people described their choice of practice as being based on it being an NHS practice which was accepting new patients:

*Obviously, I was aware that there are pressures on NHS lists, but in the town I like there were some available appointments and asking around they seemed like an okay type of dentist and I enrolled with them. [Interview 2]*

A change from NHS status was enough motivation for some patients to seek treatment elsewhere; several people reported changing practices when their existing NHS practice went private and some described how they did this despite being happy with their existing GDP. These participants spoke about an ‘NHS principle’ as well as financial motivation for not wishing to attend on a private basis:

*I was with my dental practice for approximately 40 something years, and they were an NHS provider and they turned them totally private. So, my finances and principles said that I wanted to go to a NHS dentist. [Interview 2]*

This wasn’t always the case and one participant described how they preferred to stay with their GDP after they became private, to ensure their continuity of care. In this particular case, the participant described a previous negative experience with a GDP, which meant that they did not want to change GDP despite them having gone private:

*About 10 or 15 years ago my dentist gave up the practice and I transferred to another one, and I didn’t have a very pleasant experience. And the guy I go to now I have a good relationship with – it’s about relationships for me, I really need to have trust in somebody who is doing anything inside my mouth. [Interview 6]*

Whilst NHS dentistry was highly valued, a minority of participants expressed the view that paying for NHS treatment was not in line with NHS principles:

*I said to the receptionist the last time she gave me a bill, I said, “Nye Bevan would be turning in his grave.” [Interview 8]*

Although this is an extreme example there were other criticisms of how NHS dentistry is funded, highlighting the strong attachment to the NHS held by many.

***4.4.6.3 Acceptability of Dental Therapists***

For the purpose of these study, we were interested in whether the introduction of a DT and the use of role-substitution might be socially acceptable.

*Understanding of Dental Therapist role:* For most participants, the DT was a role they had not heard of and this was frequently confused with the role of the dental hygienist. Exceptions to this were a number of low risk participants who were in the DT arm of the study and a small number of people whose practice employed a DT. Confusion was perhaps exacerbated by the name ‘Dental Hygiene Therapist’ which was similar to the more familiar term of dental hygienist:

*What we're getting slightly confused about is we're still thinking hygienist because we don't know what a hygiene therapist... you've told us now what their role is but we've not been used to that. We're thinking hygienist who just cleans your teeth. [FG1 Participant]*

This term was subsequently avoided during interviews, but highlighted both the unfamiliarity of the role, as well as the importance of an understanding the role for people to consider its acceptability:

*If somebody had offered me to see a dental hygiene therapist, I would have been reluctant. Obviously, I'm unsure. I was thinking they were a hygienist. [FG2 Participant]*

This perhaps highlighted the need for patient to be well informed about roles and their scope of practice in order for them to make treatment decisions.

*Efficiency:* Some participants described seeing how the role of the DT could improve efficiency in dental practices, particularly for low risk patients. Conversely, others felt that this could have the opposite effect, requiring more professional and patient time, if the DT identified an issue but was unable to carry out the necessary treatment. The following focus group exchange illustrated both sides of this debate:

*I can understand why they don't, because out of every hundred people that come in, I've no idea how many of them need something doing but let's say half of them. That means half the routine appointments are taken off the shoulders of the dentists, which to me is fine. If there's anything wrong then you see a dentist. You may have to come back to see a dentist. [FG3 Participant]*

*But that's got implications, hasn't it, because that's extra time not only for you as the patient, it is extra time that they thought they'd save for the dentist. Where do the cost implications start to come in then? [FG3 Participant]*

*Cost:* From the perspective of patient and provider, some questioned whether a DT would cost less to see than a GDP, although some suggested that patients should pay less to see a DT than a GDP:

*I think even if it was a couple of pounds, you know, people count their pennies these days. [Interview 12]*

In general, there was agreement that within the patient payment bands, the cost of a check-up represented fairly good value for money and that it was the check-up itself that the value was attached to, rather than the type of healthcare professional undertaking it:

*I: Do you think you should pay the same amount to see somebody who has a different qualification?*

*R: If they done the same work, then probably, yeah. [Interview 6]*

Motivation for the introduction of DTs into practice was questioned, in some cases angrily, by some participants who questioned the rationale for introducing a less-qualified and lower paid individual:

*Well it smacks of cheapness, doesn't it? That's what it's about, cost cutting, isn't it? [FG1 Participant]*

*What are they freeing the dentist up to be doing? Are they going more towards cosmetic dentistry? Is that giving them more time to be doing that and the hygiene therapist is taking over a big role of what the dentist was doing in the first place? [FG1 Participant]*

In this respect, some saw the introduction of a less-qualified professional as a reduction in the quality of a service they were receiving:

*At the time I didn’t realise when he said, and when I went I thought hmm, no. I go to see my dentist and I felt like I was being fobbed off. [Interview 3]*

This quote came from a participant whose practice employed a DT and they had unknowingly been referred for an appointment with them. One participant also described leaving a former practice when he was referred to a DT for a filling as they felt that this should be done by a GDP.

A small group of participants believed that any change motivated by cost cutting would reduce the quality of the service they received, although this was countered by a number of participants who described a service that is publicly funded, as having a responsibility to provide a cost-effective service. However, a counter-argument was that as a publicly funded service, there was a responsibility for NHS dentistry to operate in an efficient manner:

*And then obviously reserve the dentists for the more highly intense jobs because they have had longer training, etc, etc. So, it’s like in the realm of making use of your resources to full efficiency. [Interview 10]*

*Competence and risk:* Interestingly, amongst those who saw advantages to seeing a DT, there appeared to be differences in how people saw this role. These were particularly apparent between low and non-low risk focus groups. Some low risk participants described being happy with a DT performing a check-up but reported that if they identified any problems then they would prefer treatment to be carried out by a GDP:

*I'm quite happy to see the therapist, whatever. If she then says, "Right, well I think you actually now need a tooth out," I would then prefer to go to the dentist. But for routine things, I am quite happy and I would prefer to see her than I would the dentist. [FG3 Participant]*

Conversely, the opposite was sometimes expressed within the non-low risk group, with debate about continuity of care being important at dental check-ups:

*I'd rather see the same dentist. I mean as you say, for a filling or something in between, I wouldn't mind seeing somebody else but the actual check-up, I'd rather see the same dentist. [FG1 Participant]*

The question of scope of practice prompted a large amount of discussion of individual circumstances, with participants citing their medical and dental history as rationale for their beliefs on the appropriateness of a DT to conduct their check-ups. People suggested that people with complex medical or dental histories were more likely to require a GDP because of the necessary additional precautions or considerations:

*I wouldn’t expect my wife to be seen by one because she is on blood thinners and I wouldn’t expect someone to be poking in her mouth and making her bleed. I would expect them to be more trained, yeah. [Interview 11]*

These views appeared to be based on peoples’ perceptions of risk; not only with regard to their oral health but other existing or past medical conditions. Participants seemed to agree that if someone was at low risk of dental problems then it would be appropriate for them to be seen by a DT. Equally, they felt that a stratified approach was a good one and that it would be reassuring for a patient to understand that they were being seen by a DT because of their low risk status:

*Yeah, I think that is a good way of doing it, because obviously if you are high-risk you would feel that it’s better to see someone who has trained for a bit more because they should have knowledge on those kind of things, so I think that is fair. And if you are low-risk why should you take up a dentist’s time instead of someone who is high-risk, when you can just get the same service off a therapist. [Interview 5]*

Although some questioned the appropriateness of a label of ‘risk’ and wondered whether their risk status could change. They argued that basing risk on the level of recent dental activity did not account for the dental treatment they may require in the near future:

*But my worry is am I always going to be a simple, straight forward patient with no issues? [FG3 Participant]*

Part of the acceptance of the DT role may be derived from their level of faith in their training. Some emphasised that seeing someone who was ‘less’ qualified than a GDP was concerning:

*I think it's just being told that that person's the therapist, it puts you off a little bit, doesn't it? You would think then that they're not qualified [FG1 Participant]*

Although others felt that a DT was appropriately qualified to carry out check-ups:

*Absolutely yeah, obviously they have gone through the right training and qualifications to be qualified to do that. [Interview 13]*

This view to be highly personal and some suggested that this may be related to the existing relationship with the dental practice:

*I just think if them, as a practice has decided that is the service that is suitable for me, then I would take that as a given that it’s fine and it doesn’t necessarily mean it’s a lesser service. [Interview 1]*

Some participants felt that there were advantages to seeing a DT over a GDP for routine care, particularly with regards to their expertise in oral hygiene and appointments feeling less time-pressured:

*Well for me, she actually got a mirror and showed me all the back of my gums and showed me where I wasn't brushing it right and how to brush there. [FG3 Participant]*

Others felt that a DT would be an acceptable part of a dental team but were concerned about not seeing a GDP again, suggesting that a compromise would be to maintain some form of periodic review with a GDP:

*Perhaps they should have a system which says you must see a dentist once every two years. [FG3 Participant]*

*Change:* Ultimately, given the pros and cons of DTs raised at the interviews, the idea of seeing a different practitioner occupied much of the discussion, particularly among the focus groups. The idea of changing practitioner seemed almost unthinkable to some:

*If I am going to see a dentist I want to see a dentist. [Interview 3]*

However, in many cases this didn’t appear to be a rejection of role-substitution *per se*, rather a concern at seeing someone other than their existing GDP who knew them (continuity of care) and who they had built a relationship with (trust):

*As I say, he knows my mouth inside out as it were and he knows me and what have you so I really wouldn't go to anybody else. [FG2 Participant]*

Other participants argued that it was possible to establish a relationship and build trust with a different practitioner:

*I: Okay. So, it would be a personality thing?*

*R: Yeah. And because obviously she [current dentist] seems to know what I needed, but no, I would be fine, I think I would just make up a relationship with the next person. [Interview 13]*

And by one participant’s own admission, people’s positions were influenced by emotion:

*I mean, I know logically – I think it’s emotionally that I find difficulty with that having had 50 years of going to the dentist – because I have gone regularly since I was a child – it’s hard to actually accept that change, as much as my logical brain tells me it would be okay. \*Laughter\*. [Interview 2]*

Those who expressed more resistance to the idea of DTs often had complex medical histories or high levels of anxiety, sometimes attributed to a past dental experience:

*I mean I was anaesthetised too much and blinded in my eye by one dentist for twelve hours. That's the reason I went to \*current dentist\*. He put faith back into me because it was a really bad experience and I had to pay for the job as well, mentioning no names. But that was terrifying in itself so to gain confidence again, he was really, really good [FG2 Participant]*

On the other hand, many participants described being happy with the idea of attending a DT for check-up appointments:

*I would be fine with a dental therapist because they still know what they are doing – they have still gone through multiple years of training – so they can still provide adequate care and give advice. [Interview 10]*

While these views expressed opposite ends of the spectrum, it was not the case that everyone was emphatically for or against the idea of being seen by a DT, there was also a group of people who might be a little disappointed at seeing someone other than their dentist, but ultimately felt that they would be accepting of a change of system:

*So, yes, I suppose if I knew that my dentist was in charge – there was a team as it were – then I suppose I would be content, but I wouldn’t be happy with it, but I would be content with that, yes. [Interview 8]*

***4.4.6.4 Discrete Choice Experiment design***

These data have provided us with both an understanding of factors that people value, and how these might feature in a DCE. They have been useful in highlighting not only important potential attributes for a subsequent study, but demonstrated important dimensions within these attributes which could inform levels within a DCE. The work also highlights the importance of including more subjective factors as attributes and levels.148,149 These would help capture issues such as patient-practitioner relationships, continuity of care and trust, which were discussed at length within the qualitative interviews. From the results of the interviews, a long list of suggested attributes and levels describing each attribute can be identified:

1. Distance/travel time (walking distance/short drive/long drive)
2. Location (public transport/parking/town centre)
3. Waiting time for routine appointment (days/weeks/months)
4. Waiting time for urgent appointment (same day/same week)
5. Cost (current payment bands/ cheaper for DT/ more expensive for GDP)
6. Practice status (NHS/Corporate/Private/Dental Plan)
7. Qualifications of healthcare professional (GDP/H-T)
8. Length of time in practice (newly qualified/experienced)
9. Continuity of care (same practitioner/ different practitioners in same practice)

In line with good practice for the development of DCEs this stage focused on the identification of potential attributes.150,151 It would be followed by further design work would be needed to narrow down and clarify the precise attributes and levels for a definitive study. Part of this consideration would be the statistical design of the DCE, so that the chosen DCE design results in data that are analysable in order to inform an economic evaluation. Further work is also needed to consider who would complete the DCE. Having participants from the trial complete the DCE is likely to be more consistent with economic welfare theory but consideration would need to be given about when the DCE is completed (for example, at baseline or at the end of trial follow-up) as this will influence responses. There may also be concerns about response burden on participants as DCE questionnaires can be quite lengthy and cognitively demanding to complete. Administering a DCE at baseline in a definitive trial may reduce retention rates, if it is seen as indicative of the burden of data collection to come. The alternative would be to administer the DCE in a sample of the general population and used the resultant analysis to score data for each trial participant on the level of each attribute being assessed.

***4.5 Discussion***

This workstream has demonstrated that we can collect the data required for an economic evaluation using costs based either on UDAs or micro-costing of dental care. The economic evaluation has been rehearsed and consistent results produced across the range of analyses conducted. On average DT, was more costly and less effective in terms of BOP. Over the range of WTP values for society’s willingness to pay to get one less site of BOP, it is debatable whether DTs are cost-effective (although this may have been influenced by the floor effects of the BOP measure). In contrast, in terms of OHIP scores, the DT would be increasingly likely to be considered cost-effective as society’s willingness to pay for a point on the OHIP reduced. GDP care is estimated to be less costly, but also less effective (although the confidence intervals for a difference include ‘no difference’). Given that the measure of cost-effectiveness is incremental cost per one-point improvement in OHIP score and the mean difference in OHIP is likely to be approximately 0.5 points, the ICER is likely to be less than the WTP thresholds considered, especially when the WTP threshold increases.

Critical here is “what is society’s WTP for a unit change in each outcome measure?”, which is uncertain. It is for this reason that we undertook the preparatory work for a DCE to be developed. An alternative to a DCE would be a contingent valuation study. However, valuing a unit reduction in BOP or OHIP would exclude people’s preferences over the way care is provided. It is important to note however, that although we have been able to use the data to estimate cost-effectiveness results, these may be unreliable, because we do not have an accurate representation of costs and possible outcomes. For example, private costs are uncommon but very high. As the incidence of incurring private costs is quite low, we may not have an accurate estimate of the impact on total mean of private costs.

The interviews demonstrated that there are many issues that patients consider in relation to the use of DTs to conduct check-ups. Whilst the rationale for including a wider sample was to elicit a broad range of perspectives, this also meant that we gathered data from a broader range of participants with disparate views. These data suggest that the social acceptability of using DTs is mixed. It also highlights the need for patient education: about how a new system might work; alleviate concerns about training and competence; and the referral process. This suggests that understanding patients’ information needs ahead of service change is vital, particularly as concerns about the continuity of care and loss of long-held personal relationships with GDPs was raised a number of times.

The potential attributes and levels collected in the study primarily relate to process and organisational factors about the service. One of the proposed purposes of the DCE is to develop a tool that could be useful to gather information for NHS decision-makers to be conducted. A potentially important element of this is the inclusion of a cost attribute, which appears appropriate, given the responses provided in the interviews.

Whilst we have demonstrated that we can collect data on the use of services, within the pilot study sample only low levels of service use was reported. Some of these data, such as referrals to secondary care were duplicated in the CRF. This raises questions about the value of a detailed PCQ. An alternative solution might be to ask use of services at appointment at the same time OHIP data were collected. For the majority of participants only a simple yes/no question would be needed.

The estimation of the use of private treatment was also unclear. Some data were collected in the CRF but in the PCQ the question focused on ‘problems with face and mouth’. This blurred the line between dental services in relation to maintaining or improving oral health and dental services for cosmetic services. Furthermore, while there were no significant differences in any cost category (NHS, Patient and Time/Materials) observed between those who had not returned PCQs and those who had (p > 0.05), the assumptions of missing data in the PCQ meant that where patients did not return questionnaires describing additional costs these costs were potentially underestimated.

The data collection via the CRF facilitated a micro-costing exercise. For the definitive trial consideration needs to be given as to the value of this exercise. The microcosting arguably identifies the ‘economic’ cost of care as opposed to the charges for care. Differences between the two illustrate potential inefficiencies caused by charges that do not reflect the economic costs. However, such data might not be considered of sufficient importance to NHS decision makers given the costs of collecting such data.

With respect to the UDA costing, further information about treatment bands and patient charges could have been included. The precision of current estimates of cost may be improved by revisions to the CRF, which might be completed at the time of each appointment. This would however be balanced against the increase time of busy staff in completing the CRF.

With respect to measures of cost-effectiveness, it is unclear what the value is of a unit change in either of the two measures used in the pilot. This limitation could be overcome by seeking to formally estimate the value of a unit change. However, the finding of the qualitative work reported in the second half of this Chapter suggest that a broader range of impacts is worth consideration.

***4.6 Summary***

This workstream has demonstrated that a meaningful economic evaluation could be conducted and has provided valuable information to inform a definitive trial. The qualitative component of this work stream has elicited views from patients regarding the acceptability of management of low risk patients by DTs and allowed us to compile a list of potential attributes and levels for inclusion in a preference elicitation exercise in a definitive trial.

**CHAPTER 5: DISCUSSION**

**5.1 Summary of main findings**

The aim of this study was to inform the design for a definitive trial by undertaking a pilot study to determine whether Dental Therapists (DTs) can maintain the oral health of low risk routine NHS patients. Workstream 1 (WS1) was an individually randomised pilot study run over a 15 month period. Eight NHS practices from the North-West of England recruited 217 NHS patients, who were randomised into one of two groups. One involved DTs undertaking the routine check-up and any treatment the intervention period, whilst the other was ‘treatment as usual’ (using General Dental Practitioners (GDPs) to undertake the check-up and treatment). WS2 was a theoretically-driven process evaluation, which ran in parallel to the pilot to understand “what worked, for whom and under what circumstances”.105 In WS3, we developed and tested a health economic data collection tool and rehearsed the health economic analysis of the proposed intervention. We also explored patients’ preferences to inform a preference elicitation exercise to inform the design of the definitive trial.

In WS1, we approached 546 patients and 217 were recruited over the fifteen-month period, equating to a mean recruitment rate of 43.4 participants per month. The attrition rates were comparable with our feasibility study.100 These were 22.4% and 23.6% for the DT group and the GDP group respectively and there were no statistically significant differences in attrition across the randomisation stratification variables.

13 of the 14 protocol deviations occurred because they were allocated to the DT group but were seen once by the GDP in error. The other remaining protocol deviation occurred because a participant was allocated to a group before being randomised. The recruited participants in WS1 were predominantly female (72.4%), non-smokers (92.2%), of white ethnicity (93.1%) and were not exempt from patient charges (89.4%). Deprivation scores across the two groups did not show any statistically significant differences.

We found no difference between the two groups in BOP over the 15 month period in the Intention-To-Treat analyses. As such, the performance of the DT group in this pilot study was non-inferior to the GDP group. This lack of difference between the two groups was also found across all of the secondary clinical, patient-related and process outcomes. The only substantial difference to note was that 20% more participants in the DT group changed their brushing behaviour. These results were also supported by the Per Protocol analyses. As a result, the findings appear to suggest that DTs were non-inferior to GDPs in the context of a pilot trial run over a 15 month period. However, it is important to be cautious and not over-interpret these findings.118,119 As we highlighted in Chapter 2, it is possible that the estimates that we used may have still lacked precision, particularly the variability on our proposed primary outcome and this may have influenced our ability to determine non-inferiority (due to the reliance on the confidence interval estimates for the parameters). We explore these issues further in Chapter 6.

Despite high retention and fidelity rates, recruitment rates were moderately low (39.7%), which was lower than our earlier feasibility study.100 This may have been caused by the broader range of practices recruited in the pilot study, compared to the two practices recruited in our earlier study. To reduce self-selection bias, we deliberately targeted a wide range of NHS practices across the North-West of England, which would need to be expanded further for a definitive study. The mean recruitment rate of 43.4 participants per month, along with the non-inferiority design, may have substantial implications for a definitive trial in a low risk population group. The length of the recruitment period could become extensive and this could be compounded by the time needed in the intervention period to detect enough of a signal, to make comparison between the two groups meaningful.

In WS2, we elicited five areas of programme theory: contractual, institutional logics, regulatory, patients’ experience and logistics. These theory areas were largely interdependent and operated at both a macro and micro level. It appears that the two most important elements that shape the use of role-substitution in NHS dentistry are contractual and regulatory factors, which in turn, drives institutional logics at a micro level. All of the stakeholders were in agreement that the current NHS contractual model makes it difficult to implement role-substitution. Despite the relaxation of the Scope of Practice from the regulator’s perspective, the requirements under the GDS contract for GDPs to open a course of treatment, appeared to limit the extent of role-substitution in NHS dentistry.9,10 DTs work for NHS dental practice-owners (‘Providers’) that are largely run as small businesses. The inability of DTs to open courses of treatment, means that DTs can’t easily act as the front-line clinician. This has ‘knock-on’ effects in terms of reducing the efficiency of the practice and in many cases, causes disruptions to the patient’s journey. The ‘Provider’ and ‘Performer’ split also tends to create an ‘internal market’ within NHS practices, leading to competition for work between associate GDPs and DTs. We also found that it acted as a disincentive for associate GDPs to refer to DTs.

Given the need for NHS dental practices to work to Ionising Radiation Regulations Act, Ionising Radiation (Medical Exposure) Regulations and the Medicines Act, DTs weren’t allowed to prescribe radiographs or fluoride. These restrictions added to practice inefficiency and patient disruption.

In similarity to our earlier research, there was also agreement that the views of the equity-owner were highly influential.31 They were seen as critical in setting the tone in the institutional logics of the NHS practice and over-coming the barriers associated with role-substitution at the macro level (contractual and regulatory factors). As highlighted in Chapter 3, a positive attitude towards role-substitution saw the equity-owners actively seeking ‘work-arounds’ to facilitate different care-pathways or internal payment systems for staff (‘Performers’). It could also influence the extent by which their estate was partitioned to promote role-substitution (e.g. securing additional surgery space). This was often difficult in NHS dentistry as most practices were not purpose built for ‘team dentistry’.

Endorsement of DTs through outward displays of trust, positive feedback and support were recognised as essential for effective implementation. Whilst the social acceptability of role-substitution was positive, patients did express the need for better communication, in order for them to understand what a DT could do clinically. Most of the patients that were interviewed argued that they would accept new ways of working, but they were concerned about the potential disruption to their care and the need to potentially re-book their appointments.

As NHS practices were essentially independent contractors, structural investment from the NHS was more difficult. This highlighted the limited number of mechanisms that were available at a meso level in order for dental commissioners to facilitate the implementation of role-substitution.

In WS3 we demonstrated that the data required for an economic evaluation can be reliably collected in terms of costs based on UDAs and/or micro-costing of dental care. The pilot study has identified areas where data collection can be refined and simplified for a definitive trial (e.g. simplifying the data collection of use additional health services as these were rarely reported). The economic evaluation was rehearsed and estimates of cost-effectiveness made.

The findings of the qualitative work, in preparation for discrete choice experiment, identified a long list of potential attributes and levels that can form the basis of a future preference elicitation exercise. This could be used to combine the different clinical and process outcomes into a single metric, so that the results of the study would be more useful to decision-makers. The attributes and levels identified relate primarily to process and organisational factors about the service (e.g. practice premises).

Qualitative data also highlighted how social acceptability of role-substitution can be complex, with strongly held views on either side and these views were impacted by factors including previous oral health and experience of dental care. This suggests that there may be a role for patient information and/or education ahead of any proposed service changes.

**5.2 What have we added to the evidence base?**

As highlighted by Barnes *et al*., "there is considerable scope to delegate routine examinations and restorations to DTs".152 It is estimated that approaching one-third of restorative interventions could be undertaken by DTs, which would produce a 'knock-on' reduction in the number of dentists required to undertake these routine tasks.153,154 By conducting a pilot trial and rehearsing a health economic evaluation, we have thoroughly tested the feasibility of a future definitive trial to evaluate role-substitution in NHS dentistry in a highly policy-relevant area of research.

The Cochrane Effective Practice and Organisation of Care review found a lack of experimental or quasi-experimental evidence for the expanded role of DTs, which concurred with the earlier study by Brocklehurst *et al*.97,155 In this study, we have confirmed recruitment and retention rates and found high levels of clinical fidelity to the intervention in NHS practices. We have also confirmed that a non-inferiority design is the most appropriate, but highlighted further challenges to empirically testing role-substitution using experimental studies. Of particular note, is the challenge of determining the most appropriate primary and secondary outcome measures. As detailed in Chapter 2, even if the eligibility criteria were relaxed to include high risk patients, there is still a high probability that the strength of any effect may remain undetected, given the large numbers of low risk patients in NHS practices. To detect clinically meaningful changes, it is also possible that we’d need to extend the length of the trial (at least doubling the length of the pilot study) and even then, Type II errors may still be possible as any potential signal may remain undetected.

Despite this, the direction of effect in this study i.e. non-inferiority, is not dissimilar to the non-experimental studies we highlighted in Chapter 1. A number of studies have shown that GDPs and DTs perform to similar standards in terms of their efficacy and effectiveness. The results presented in Chapter 2 concur with Wang & Riordan, Kwan *et al*. Kwan and Prendergast, Patel *et al*. and Hopcraft.89,90,91,92,93,94 DTs appeared able to diagnose and manage low risk patients within their competency. They were also able to perform routine restorative tasks over the study period, which supports earlier studies by Bader *et al*., Wetherhall *et al*., Calache *et al*., Battrell *et al*. and Freed *et al*.82,83,85,96,97

The realist-informed process evaluation has reinforced findings from our earlier research and also concurs with a recent realist synthesis and case-study analysis.31,146

Barnes *et al.* identified the following key mechanisms, which map well onto the results of Chapter 3:

1. A payment system that supports appropriate employment of DTs;
2. Appropriate referral systems to promote DTs utilisation;
3. Workplace values and culture;\*
4. Good communication within the practice;\*
5. Experience of working with DTs;\* and
6. Team training;\*

\*described in this study as institutional logics

In similarity to our study, Barnes *et al*. also contrast the position of the GDC (who allow direct access) with the contractual legislation in the GDS,9 which only allows a dentist to open a course of treatment. The dominance of the contractual theory area in our study is supported by our earlier Cochrane review on the effects of financial incentives and also the work of Robinson *et al*., who argue that contractual incentives appear to "determine dentists’ and patients’ perceptions of need, their behaviours, health outcomes and patient satisfaction".58,156 It is also supported by the work of Harris & Sun, who explored the efficiency of NHS practices that employ DTs.102,103 Barnes *et al*. contrasts this with other countries, where direct access has been facilitated by favourable regulatory frameworks.157,158

As highlighted in our study, Barnes *et al*. also found institutional logics to be critical, which are described as intra and interpersonal factors, alongside a lack of knowledge of DTs' role and their scope of practice. Again, this concurs with earlier studies.150,159 Attitudes towards DTs were also a key factor in influencing the amount and type of work referred to them in practice.160-162 Barnes *et al*., also identified the conflict in the 'internal market' between DTs and associate GDPs (because of the competition for UDAs).146

Our findings also concur with Goodwin *et al*. and the work of Harris *et al.* in two large NIHR HS&DR projects undertaken in NHS practices.49,163 Goodwin *et al.* found that “general dental practitioners are affected by a number of competing interests and incentives and that this can influence their behaviour in a variety of ways”. As Harris *et al.* argue, there appears to be differences in institutional logic in NHS dental practices, when compared to NHS medical practices. They describe the differences between these two groups of NHS practitioners in terms of 'population health managerialism' and ‘public health good’. These relate to the extent, by which, clinicians feel responsible and accountable to their immediate community and the extent that practices operate to improve the health of their local community. Amongst General Medical Practitioners, this appears to be prominent and explicitly stated. This contrasts with the prevailing institutional logic in dental practices, which relates to "ownership responsibility, professional clinical values and entrepreneurialism".157 This may have implications for role-substitution in NHS practices, where the decision to support DTs and/or increase surgery space appears to be driven by a 'business model' (linking to contractual incentives), rather than a logic driven by 'population health managerialism' or 'public health good'. This appears to be exacerbated in NHS dentistry by the relative lack of levers that dental commissioners can apply at a meso level to promote role-substitution.

As highlighted in Chapter 3, the institutional logic at NHS dental practices also impacts on our final theory area of logistics. Logistics was also found to be a substantive barrier to role-substitution in the NHS by Barnes *et al* i.e. the need for NHS practice owners to invest in additional surgery space to promote role-substitution*.*146 International evidence also supports these findings. Where NHS dentists are working in larger multi-surgery practices, they are more likely to support role-substitution, because of their capacity to optimise surgery space.164,165

The social acceptability of role-substitution found in this study concurs with earlier work, referred to in Chapter 1.31 It also supports the findings from a survey undertaken in 2018 by Barnes *et al*., who found that both patient satisfaction and their confidence in dentists’ or DTs’ ability was uniformly high (97% and 99% respectively).166 This concurs with the studies cited in Chapter 1, where social acceptability was positive once patients had been educated about the role of the DT.78,81,82,83,84,85,86,87,98 No questions around patient safety were raised in this study, in similarity to other studies cited in Chapter 1.77-79

The study directly builds on a five-year Clinician Scientist Award (NIHR/CS/010/004) and a HS&DR grant (11/1025/04).31 As highlighted in Chapter 1, to date, the research team have demonstrated that DTs can identify occlusal caries in-vitro, can screen for dental caries and periodontal disease in-vivo and are safe as front-line health care workers.79,98,99 In addition, the feasibility of undertaking a full trial has been tested as part of NIHR/CS/010/004 over a fifteen-month period.100

**5.3 Strengths and limitations of the research**

This study has provided a wealth of information to design a definitive randomised controlled trial. Workstream 1 was conducted in NHS dental practices and recruited a relatively large number of NHS patients. This means the findings are grounded in the experience of NHS dentists and conducted in a manner that helps research teams understand the challenges of working in an NHS environment. The pilot study has confirmed that the recruitment and retention rates of NHS patients are sufficient to test role-substitution in a definitive trial. Fidelity rates were also shown to be high. It also provided estimates of effect for a future definitive study and highlighted the challenges of determining the most appropriate primary and secondary outcome measures. In addition, it revealed the impact that study eligibility might have on the strength of the signal and the impact that including low risk patients has on a study of this nature.

Four limitations of Workstream 1 related to the exclusion of high risk patients, the number of practices included in the study, the length of the pilot and the number of patients lost to follow-up. The eligibility criteria of the study were amended to low risk patients on the advice of the funding board. Budgetary constraints also required the research team to limit the number of practices and length of the pilot, but we felt that the design provided enough data to test recruitment, retention and fidelity rates across the practices. The data also showed relatively limited variance, suggestive of a broadly representative sample of practices and patients. Additionally, while we tried to be as flexible as possible with regards to the availability of epidemiologist, the fact that we could not schedule appointments with some participants due to their prior commitments contributed to a number of participants being lost to follow-up. The information we have about the 41 participants who were lost to follow-up suggests that participants were lost primarily due to logistical difficulties, it is important to acknowledge the limitations of this assumption i.e. that this data is missing at random and these participants did not represent a group with different clinical outcomes to those included in the ITT analysis.

Workstream 2 has provided a novel approach to conducting the process evaluation by using the principles of the realist approach to evaluation of complex social programmes to build on the qualitative component of the study. Realist approaches can help build an explanatory account of what works in any given situation, and places emphasis on the stakeholders’ experiences and perspectives to identify and refine the underlying (unseen) mechanism of action. In this study, using the principles of realist methodology were important to articulate and explain the factors that underpin intervention success or failure.

As expected, there are limitations to using realist approaches in this way. Due to the timeframe, pragmatic decisions were made not to conduct a full systematic realist synthesis of evidence. In this instance, the team chose to rely on data derived from experts. As such, it could be argued that other information is lost in this way. Purposive and convenience sampling used could have missed other opportunities to gain insight into theories driven by wider catchment of different stakeholders. Finally, the theories articulated are at particular level of abstraction. However, further additional cycles of testing and refining could have developed the theories towards more practice level specification.

Workstream 3 has demonstrated the feasibility of collecting data required for an economic evaluation from multiple perspectives (health service and patient). We have successfully rehearsed the economic analysis which produced consistent results across the range of analyses conducted in terms of cost-effectiveness. Additionally, the qualitative component of this work has provided rich data regarding the acceptability of the use of DTs in the management of low-risk patients and provided us with a number of attributes and levels to take forward in a future preference elicitation exercise. We were able to recruit both low-risk and non-low-risk participants for qualitative work which has provided us with a wide spectrum of views on DTs and role-substitution.

As discussed within Chapter 4, there are some limitations to the health economics work. With regard to the data collection processes, the collection of service-use data from both clinicians and patients meant there was potential overlap or conflict between the two data sources. The importance of accurately capturing data such as secondary care use and patient costs such as private treatment should be taken into account in a definitive trial as these costs have the potential to be high and skew the data and alternative methods to capturing this data should be investigated, for example capturing this data during clinic visits or through follow-up telephone calls would be a quick way of collecting data with the potential to reduce the level of missing data. The 6M PCQ questionnaire data was missing by design and this meant that additional assumptions were made regarding participants having consistent costs over both of the 6M periods covered by the questionnaires. Additionally, our assumption that patients with missing Patient Costs Questionnaire data had no additional costs, had the potential to underestimate cost categories covered in this questionnaire in both arms. While our micro-costing work was based on a previous study, the accuracy of our unit costs could be potentially improved by further exploring materials and methods used by participating practices in a future study.

In the qualitative work, while the inclusion of non-low risk patients provided us with a range of perspectives, it could also be argued that prominent views were included by those who would be unlikely to be impacted by changes in service provision.

**CHAPTER 6: Conclusions**

**6.1 Possible considerations for future policy**

The results of this study are important for policy, given the predicted trends in future population health needs.16,29,30 There remain challenges in improving the oral health of young children and providing adequate care for older people is an emerging public health challenge. As a result, there will be a pressing need to better target the available resources in NHS dentistry, which appear to be increasingly spent on low risk NHS patients.17,18,19

As highlighted in earlier Chapters, all the dental contract reform programmes undertaken across the UK place an emphasis on increasing patient access and prevention, whilst maintaining and improving the quality of service being delivered.60-69 Increasing the use of role-substitution is an important consideration for policy-makers and explicitly stated as a strategic objective in Wales.14,67

Whilst our pilot study confirmed the potential of using role-substitution in NHS dentistry, our realist-informed process evaluation highlighted the barriers to its use. Contractual and regulatory factors were dominant and concurred with our earlier work and the international literature.31,146 Given that the supply of NHS dentistry is provided by NHS practices operating to a ‘business model’, there is a need to align the financial incentives within NHS GDS contracts, with the policy objective of greater use of role-substitution. This is concomitant with recommendations from WHO, who argue that there “is an opportunity to not only change the way that we think about educating future health workers [and] an opportunity to step back and reconsider the traditional means of health-care delivery”.167 Whilst amending the regulations to the use of medicines (local analgesia and fluoride) and radiographs may be more problematic, changing the GDS contract is within the scope of many dental policy-makers.

**6.2 Implications for Practice**

As this study was a pilot study, care needs to be exercised in the interpretation of the findings. As highlighted in Chapter 5, the direction of effect concurs with earlier non-experimental research and the same barriers and enablers were identified to the use of role-substitution in NHS practices. Institutional logics at a micro level were found to be important, but were largely secondary and dependent on the contractual and regulatory factors at a macro level. It appears that the social acceptability of role-substitution is high, if the DT’s role and benefits are clearly articulated to NHS patients. As such, the implications for practice would appear secondary to the dominant factors that could be influenced at a policy-level. As NHS practices largely operate as small businesses, financial incentives that promote role-substitution appear key in shaping the response at the level of the practice.

From a patient perspective, the qualitative data collected as part of this study have highlighted that the acceptability of role-substitution may vary greatly between patients, influenced by a number of factors including perceived risk, history of oral health, prior dental treatment and dental anxiety. A further understanding of these factors is of vital importance to understand how any changes to services may impact patients.

**6.3 Recommendations for further research**

As highlighted in Chapter 2, the interpretation of the findings of the pilot study poses some interesting design questions. The purpose of the pilot was to determine the most appropriate design for a definitive trial, determine the appropriateness of the primary and secondary outcome measures and the non-inferiority margin. It also tested recruitment, retention and fidelity rates.

It would appear that a future definitive trial should be based on non-inferiority, should one be warranted. This would align to the findings in this study and the international literature, but would require a large number of participants, depending on the size of the non-inferiority margin. The relatively low recruitment rates also have practical implications for a future trial and may prolong the recruitment period in order to reach the desired number of participants in each arm. As highlighted earlier, this could be compounded further by the length of time needed in the intervention period to detect enough of a signal (on the chosen POM), to make comparison between the two arms meaningful.

The nature of the POM is also problematic. It would appear that the inclusion of low risk NHS patients in a future study would pose a number of design challenges in relation to the POM, yet this is the group of patients where role-substitution would be the most relevant, from a policy perspective. In this study, we used BOP as the POM. Earlier studies would suggest that BOP is a good indicator of periodontal health, tissue stability and is well-known to NHS practitioners.112,113,114 However, it would appear that there are ‘floor’ effects with this measure in low risk patients. We anticipate the same kind of effects in clinical measures like dental caries, due to its low prevalence and longer time-to-expression.16 As highlighted in Chapter 2, there are systems that measure incremental changes in dental caries status, but marginal changes in low risk patients may create issues with measurement error.121,122 As we argue, it may be possible to consider analysing a ‘complete’ sample (including high and low risk patients) using an appropriate zero-inflated model, but this may not facilitate a full interpretation of effect or non-inferiority. As a result, it would appear that the types of clinical outcomes that would be used for a definitive trial on role-substitution in dentistry may not be appropriate to test for non-inferiority. Patient Related Outcome Measures and Patient Related Experience Measures, may be two options, but their signal-to-noise ratio may be problematic. They are also further down the causal pathway to assess effectiveness and/or non-inferiority.

These issues highlight the challenge of designing a definitive randomised controlled trial to test role-substitution in NHS dentistry. It would appear that both measuring changes to health and/or care pose substantial design problems. This is further exacerbated by the length of time that may be needed to capture the effect of the intervention and the knock-on effect on the cost of the trial. This raises genuine queries about the role of definitive studies to answer these types of important policy questions, when they are undertaken on largely healthy participants.

Alternative methods to experimental designs may be advocated here. There is a developing argument about the need to embrace a broader range of research methods for policy related and population health issues, rather than restricting the approach to randomised controlled trials. As argued by Brocklehurst *et al*. “we need to consider a broader range of conceptual and methodological approaches to increase the value of information generated. This should be undertaken either in parallel with empirical and experimental designs, or in some cases, instead of. This is important if we are going to understand the complexity and contextual knowledge of the ‘system’, within which interventions are implemented”.168 What is evident from Chapter 3, is that this ‘system’ is complex with multiple interdependent elements, that operate at different Macro, Meso and Micro levels. As Braithwaite et al. argue, accounting for this complexity is key; there is “no simple solutions, no single ingredient”.169,170

There are alternatives to experimental designs and these may be warranted here to determine whether role-substitution is both effective and cost-effective. As highlighted by Brocklehurst *et al.* and Listl *et al*., “ex-post techniques typically evaluate the impact of an already implemented health policy programme and include a range of quasi-experimental methods including Instrumental Variables, Difference-in-Difference, panel data analyses using fixed or random effects, and Regression-Discontinuity-Designs” and “ex-ante methods include structural modelling, agent-based modelling and micro-simulation” to help model the short, mid and long-term health effects of an intervention.171,172 For example, Difference-in-Difference designs have been used in other dental public health studies before.58,173 In Northern Ireland, Difference-in-Difference was used to assess the implementation of a NHS pilot based on capitation.58 This enabled the research team to measure changes in activity levels during three time periods and the coefficients were triangulated by an Interrupted Time Series approach, undertaken in parallel. Such methodologies can “provide very helpful information on the evaluation of policies and interventions that would otherwise not be rigorously evaluated as the standard RCT related methodologies are neither feasible nor suitable”.171 They might also prove eminently more affordable, when compared to a lengthy definitive trial based on non-inferiority. They would also allow multiple outcome measures to be followed over time, rather than selecting one single POM.

In addition to the empirical aspect of any future study, it would be important to undertake a parallel process evaluation to further explore the factors that influence the pathway to impact for role-substitution. In this study, Workstream 2 provided helpful insight to the barriers and enablers to role-substitution in NHS dentistry. This element of the study captured how complex interventions and systems can interact and identified the underlying generative mechanisms about how role-substitution works.126 This gave us a good understanding of “how context (individual, social, cultural, organisational) interacts with intervention components and underpinning mechanisms to bring about desired outcomes".127 This allowed the research team to develop a set of focused mid-range theories that enabled us to determine the range of factors that could potentially influence adoption.130 As such, we remained focused on the barriers and enablers that could make a difference at both a policy and practice level, as opposed to constructing “all-encompassing meta-narratives that span space and time”.131 As a result, we commend the use of these types of approaches alongside future experimental and quasi-experimental study designs. Future teams could make use of the different CMO configurations that were generated in this study as a starting point for undertaking a further realist cycles.

Following this pilot study, there is an important role for economic evaluation work in any future study to establish cost-effectiveness of role substitution in the management of low-risk dental patients (Workstream 3). As discussed in Chapter 4, recommendations from this workstream include potentially revising data collection methods with regard to patient reported data, possibly integrating these into the collection of clinical data at dental appointments; given that the routine nature of appointments, this has the potential to achieve higher levels of accuracy and completion. Telephone interviews have been used successfully in past studies to collect details of health service use and this may also offer a method of supplementing data collection. Additionally, completion of clinical data has the potential to be simplified therefore reducing burden on participating healthcare professionals and standardising the data collected. In a future study there is potential to improve the accuracy of a resource-based micro-costing through further investigation into materials and methods. These methods could be incorporated into either an experimental or quasi-experimental design.

The preparation work undertaken in this pilot demonstrated the importance of including a discrete choice experiment, to help further understand the relative importance of different attributes. These could provide valuable data for future service design. Additionally, given the need to understand the impact of service changes to people using these services, there is an important role for future qualitative work to explore some of the questions to arise out of the qualitative component of the health economics work, such as, patient information needs or exploring the experience of receiving care from different health professionals.

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**Authors Contributions**

Brocklehurst (Professor of Health Services Research), along with Hoare, Preshaw, Williams, Burton, Shen, Gough and Ashley wrote the application to secure the research funds from the NIHR. Brocklehurst led the project, provided Dental Public Health input and oversaw the writing of the report. Hoare and Brand provided statistical input all through the study and made a substantive contribution to the design of the pilot study and the writing-up of Chapter 2, along with Brocklehurst. Woods and Jenkins managed the pilot trial. Woods also conducted the interviews for the realist-informed process evaluation and undertook the analysis, alongside Williams and Brocklehurst. Brocklehurst, Woods and Williams wrote Chapter 3, with input from Burton. Shen and Breckons planned and conducted the discrete choice experiment development work and along with Bhattarai, planned and conducted the pilot health economic evaluation. They also wrote-up Chapter 4. Ashley and Gough provided input to the study design from the perspective of an NHS GDP and Consultant in Dental Public Health (respectively). Preshaw provided valuable input at the design stage and also proof-read the iterations of the final report. Shepherd acted as our user-researcher in WS2, co-wrote the Plain Language Summary and contributed to our dissemination strategy.

**Data sharing**

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

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**APPENDIX 1: Case Report Forms (baseline and outcome)**

**Case Report Form (Baseline)**

|  |  |
| --- | --- |
| **Dental practice** |  |
| **Patient ID**  Completed by PM |  |
| **IMD**  Completed by PM |  |
| **Eligibility criteria**  Completed by PM | **Date: ………………………**  **NHS adult patient (> 18 yoa) on the recall list ☐**  **Dentate (or partially dentate) ☐**  **Asymptomatic at ‘check-up’ ☐**  **No active dental decay in last two years ☐**  **No restorations due to dental caries in last two years ☐**  **BPE ≤ 2 ☐**  **No Past Medical History that increases risk to dental caries ☐**  **Seen ≥ 6 months ago ☐**  **HAVE YOU TICKED ALL THE BOXES?** |
| **Demographic data** Completed by PM | **Gender: Male ☐ Female ☐**  **Age: ………………………**  **Exempt from dental charges: Non-exempt ☐ Exempt ☐**  **Which of the following occupations best describes the nature of employment?**  **☐ Professional and managerial (e.g., Teacher, Doctor, Manager,**  **Solicitor)**  **☐ Clerical and sales (e.g., Administration, Salesperson)**  **☐ Skilled blue-collar (e.g., Electrician, Plumber, Craftsman/woman)**  **☐ Semi-skilled and unskilled (e.g., Factory worker, Labourer)**  **☐ Prefer not to say**  **Choose ONE option that best describes your ethnic group or background**  **White**  **☐ English / Welsh / Scottish / Northern Irish / British 2. Irish**  **☐ Gypsy or Irish Traveller**  **☐ Any other White background, please describe…………………………………………………**  **Mixed / Multiple ethnic groups**  **☐ White and Black Caribbean**  **☐ White and Black African**  **☐ White and Asian**  **☐ Any other Mixed / Multiple ethnic background, please**  **describe…………………………………………………**  **Asian / Asian British**  **☐ Indian**  **☐ Pakistani**  **☐ Bangladeshi**  **☐ Chinese**  **☐ Any other Asian background, please describe…………………………………………………**  **Black / African / Caribbean / Black British**  **☐ African**  **☐ Caribbean**  **☐ Any other Black / African / Caribbean background, please**  **describe…………………………………………………**  **Other ethnic group**  **☐ Arab**  **☐ Any other ethnic group, please describe…………………………………………………** |
| **Baseline data**  Completed by epidemiologist | **DENTAL MEASURES**  **CONFIRM**  **No active dental decay in last two years ☐**  **BPE ≤ 2 ☐**  **Date: ………………………**  **Number of teeth remaining (excluding implants): ………………………**  **Number of sites\*: ………………………**  **Number of sites\* with BoP: ………………………**  **Number of sites\* with plaque: ………………………**  **\*Six sites per tooth**  **ORAL HEALTH IMPACT PROFILE (as a separate form)**  **1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **3. Have you had painful aching in your mouth? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **5. Have you been self conscious because of your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **6. Have you felt tense because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **14. Have you been totally unable to function because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **OHIP ADDITIONAL QUESTIONS**  **15. Have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaw? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **16. Have you felt uncomfortable about the appearance of your teeth, mouth, dentures or jaws? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **17. Have you felt that there has been less flavour in your food because of problems with your teeth, mouth, dentures or jaws?**  **Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **DENTAL ANXIETY**  **On a scale of 1 to 10 (10 is very anxious), how anxious are you about your check-up if you are seen by your dentist? ………………………**  **On a scale of 1 to 10 (10 is very anxious), how anxious are you about your check-up if you are seen by the H-T? ………………………** |

|  |  |
| --- | --- |
| **First check-up visit** after epidemiologist | **DATE: ………………………**  **TIME IN: ………………………**  **AT THIS VISIT: Check-up ☐**  **Please detail any other clinical activity/advice provided:**  **TIME OUT: ………………………**  **FOR THOSE ALLOCATED TO THE H-T ARM**  **Did you need any additional input from your dentist? Yes ☐ No ☐ If yes, please detail why:**    **If yes, please detail the length of time this took: ………………………**  **If treatment plan not agreed (H-T takes precedence), detail here:**  **Does the patient need to be seen by a dentist (treatment required beyond Scope of Practice for the H-T)?**  **Yes ☐ No ☐**  **If yes, please detail the treatment undertaken by the dentist:** |
| **Investigator's signature** |  |

**Case Report Form (Outcome Assessment)**

|  |  |
| --- | --- |
| **Dental practice** |  |
| **Patient ID** |  |
| **Outcome assessment** | **DENTAL MEASURES**  **Date: ………………………**  **Dental pain/problems over the study period: Yes ☐ No ☐ If yes, please give details:**  **Number of teeth remaining (excluding implants): ………………………**  **Number of new decayed and filled teeth: ………………………**  **Number of sites\*: ………………………**  **Number of sites\* with BoP: ………………………**  **Number of sites\* with plaque: ………………………**  **Number of sites with a probing depth that now exceed Code 2 of the Basic Periodontal Examination periodontal probe:**  **Number of sites\* exceed BPE Code 2: ………………………**  **\*Six sites per tooth**  **ORAL HEALTH IMPACT PROFILE (as a separate form)**  **1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **3. Have you had painful aching in your mouth? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **5. Have you been self conscious because of your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **6. Have you felt tense because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **14. Have you been totally unable to function because of problems with your teeth, mouth or dentures? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **OHIP ADDITIONAL QUESTIONS**  **15. Have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaw? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **16. Have you felt uncomfortable about the appearance of your teeth, mouth, dentures or jaws? Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **17. Have you felt that there has been less flavour in your food because of problems with your teeth, mouth, dentures or jaws?**  **Yes ☐ No ☐**  **If yes, HOW OFTEN have you had the problem during the last three months?**  Very often ☐  Fairly often ☐  Occasionally ☐  Hardly ever ☐  Never ☐  Don’t know ☐  **BEHAVIOUR CHANGE AT THE END OF THE STUDY**  **Since entering the study, have you been doing anything differently?**  **Diet Yes ☐ No ☐ If yes, please give details:**    **Brushing Yes ☐ No ☐ If yes, please give details:**  **Toothpaste Yes ☐ No ☐ If yes, please give details:**  **Flossing Yes ☐ No ☐ If yes, please give details:**  **Other Yes ☐ No ☐ If yes, please give details:**  **DENTAL ANXIETY**  **On a scale of 1 to 10 (10 is very anxious), how anxious have you been about your check-ups in the study period? ………………………** |
| **Investigator's signature** |  |

**APPENDIX 2: Unit costs**

Table 23 highlights the costs used in Chapter 4.

**Table 25: Unit costs for the health economic analysis**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Resource** | **Unit** | **Cost in pounds sterling** | **Source** |
| **UDA payments** | **Band 1** | 1 UDA | 25 (varied between 20-30 in sensitivity analysis | Brocklehurst P, Birch S, McDonald R, Hill H, O’Malley L, Macey R, et al. Determining the optimal model for role substitution in NHS dental services in the UK: a mixed-methods study. 2016. |
| **Band 1 Urgent** | 1.2 UDAs | 30 (varied between 24 – 36 in sensitivity analysis) |
| **Band 2** | 3 UDAs | 75 (varied between 60 – 90 in sensitivity analysis) |
| **Band 3** | 12 UDAs | 300 (varied between 240 – 360 in sensitivity analysis) |
| **Treatment provider** | **GDP** | Cost per minute | 0.68 | Personal Social Services Research Unit. Unit Costs of Health and Social Care 2019 2019 [Available from: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2019/. |
| **Dental therapist** | Cost per minute | 0.29 |
| **Dental hygienist** | Cost per minute | 0.23 |
| **Treatment costs - materials** | **Check-up cost** | 1 (applied to all appointments) | 2.21 | Materials informed by previous dental microcosting work: Homer T, Maguire A, Douglas GV, Innes NP, Clarkson JE, Wilson N, et al. Cost-effectiveness of child caries management: a randomised controlled trial (FiCTION trial). BMC Oral Health. 2020;20(1):45.  Updated based on 2019 prices) from dental supplies website: Dental Sky 2019 [Available from: https://www.dentalsky.com/.  Laboratory: MediMatch Dental Laboratory. MediMatch Catalogue 2019 2019 [Available from: https://www.medimatch.co.uk/. |
| **Composite Filling** | One  Subsequent fillings | 18.66  12.01 |
| **Glass Ionomer filling** | One  Subsequent fillings | 11.21  4.56 |
| **Amalgam filling** | One  Subsequent fillings | 11.15  4.70 |
| **Ultrasonic scaling cost** | Per treatment | 0.64 |
| **Hand scale cost** | Per treatment | 0.48 |
| **Periodontal treatment** | Per treatment | 1.98 |
| **Crown preparation** | Per tooth | 20.48 |
| **Crown fit** | Per tooth | 48.65 |
| **Crown & post fit** | Per tooth | 61.37 |
| **Temporary crown** | Per tooth | 20.48 |
| **Fluoride varnish** | 1 tooth  Subsequent teeth | 2.71  2.53 |
| **Pulp extirpation** | 1 tooth | 12.78 |
| **Access & drainage/Root canal appointment 1** | Per tooth | 10.75 |
| **Chlorohexidine irrigation** | Per treatment | 0.57 |
| **Dental impression** | Set of impressions | 1.93 |
| **Bite raising appliance** | Per | 48.93 |
| **Extraction** | 1 extraction | 2.78 |
| **Dry socket treatment** | 1 site | 1.28 |
| **Root canal treatment appointment 1** | Per single tooth | 10.75 |
| **Root canal treatment appointment 2** | Per single tooth | 12.78 |
| **x-ray unit cost** | 2 x-rays | 1.57 |
| **Charting (BPE/6PPC)** | Charting performed | 0.48 |
| **Local anaesthetic** | Per appointment | 1.23 |
| **Filling adjust** | Per appointment | 5.42 |
| **Denture adjust** | Per appointment | £3.21 |
| **Private treatments** | **Scale and polish** | 1 treatment | 55 | Which? Private and NHS dental charges 2019 [Available from: https://www.which.co.uk/reviews/dentists/article/private-and-nhs-dental-charges. |
| **Crown** | 1 crown | 715 |
| **Botox** | 1 treatment | 225 | National Health Service. Botox injections 2020 [Available from: https://www.nhs.uk/conditions/cosmetic-procedures/botox-injections/. |
| **Implant consultation** | 1 appointment | 125 | Dental Care Plus Implant Centres. 2019 [Available from: https://www.dentalcareplus.org.uk/implant-costs. |
| **Prescription medicine** | **Penicillin** | Course of treatment | 3.26 | National institute for health and Care Excellence. British National Formulary 2019 [Available from: https://bnf.nice.org.uk/. |
| **Aciclovir** | Course of treatment | 1.69 |
| **Duraphat** | Course of treatment | 3.26 |
| **Prescription charges** | Per prescription | 9.00 | NHS Business Services Authority. NHS Help with Health Costs 2019 [Available from: https://www.nhsbsa.nhs.uk/help-nhs-prescription-costs. |
| **Patient dental charges** | **Band 1** | Course of treatment | 22.70 | National Health Service. How much will I pay for NHS dental treatment? 2019 [Available from: https://www.nhs.uk/common-health-questions/dental-health/how-much-will-i-pay-for-nhs-dental-treatment/ |
| **Band 2** | Course of treatment | 61.10 |
| **Band 3** | Course of treatment | 269.30 |
| **Emergency appointment** | Course of treatment | 22.70 |
| **Time and travel costs** | **Leisure time** | Per hour | 4.23 per hour | Department for Transport. TAG Data Book. In: Transport Appraisal and Strategic Modelling (TASM) Division, editor. London; 2019. |
| **Average salary** | Per hour | 11.77\* | Gov.uk. Average hourly pay 2018 [Available from: https://www.ethnicity-facts-figures.service.gov.uk/work-pay-and-benefits/pay-and-income/average-hourly-pay/latest. |
| **Mileage rate** | Per mile | 0.45 | HM Revenue & Customs. Travel - mileage and fuel rates and allowances 2019 [Available from: https://www.gov.uk/government/publications/rates-and-allowances-travel-mileage-and-fuel-allowances/travel-mileage-and-fuel-rates-and-allowances. |
| **Secondary Care cost** | **Accident and emergency outpatient attendance** | 1 attendance | 138.31\* | NHS Improvement. National Schedule of reference costs 2017/18. 2018. |
| **Dental Medicine Specialties outpatient attendance** | 1 attendance | 124.07\* |

\*2019 values unavailable – adjusted for analysis using CPIH rates (Office for National Statistics. CPIH ANNUAL RATE 00: ALL ITEMS 2015=100. Source dataset: Consumer Price Inflation time series dataset (MM23) 2020 [Accessed February 2020]; Available from: https://www.ons.gov.uk/economy/inflationandpriceindices/timeseries/l55o/mm23.

**APPENDIX 3: Patient and public involvement**

Two Patient and Public Involvement (PPI) representatives supported the research team throughout the study and where active members of the Trial Steering Committee. A dedicated PPI user-researcher (KS) also supported the research team in the patient-facing research elements of WS2. The user-researcher had considerable experience as a PPI representative and was recruited from the PARC-Bangor network (see note below). However, this was their first experience in a user-researcher role. As a result, the user-researcher was provided with training by the research team to familiarise themselves with the context of the intervention i.e. role-substitution in NHS dentistry and the corresponding roles of the dental team. The training consisted of two three-hour sessions over two weeks. Following this, the user researcher received further one-day specific training on semi-structured interviews. This training was provided by an independent contractor (Social Research Association, London, UK).

The user-researcher was employed to support the PPI element in the following ways:

1. To strengthen the patient voice in semi-structured interviews. By using a user-researcher the interviews naturally assumed a peer-to-peer dynamic, with topics and inputs supplied by the core research team and explored in detail between the user-researcher and interviewee.
2. To guide the research team on appropriateness of language and communication. This included reviewing developing research documents ahead of patient involvement to ensure the appropriateness of topics and language.
3. Provide a patient voice in the realist research cycle. Specifically, to ‘sense check’ in the analysis of research data and the development and understanding of theory areas to ensure that the interpretation was correct.

A PPI group was also established to determine the impact of the intervention on the patient experience. This group consisted of six individuals from the PARC-Bangor network, all of which we currently, or had been, registered with an NHS dental practice.

As highlighted in Chapter 3, clinical stakeholder groups had been used to understand the context for role-substitution in NHS dentistry. From these discussions, it became apparent that the patient experience was influenced by the prevailing clinical model adopted at the level of the practice. Clinicians had indicated that issues such as institutional trust, dental team endorsement and stability were important factors in maintaining the patient experience and embedding role-substitutive practices. The research team, in conjunction with the user-researcher, used this data to develop an emerging theoretical framework for the ‘patient experience’ theory area as part of the broader programme theory development.

Individual semi-structured interviews were held with members of the PPI group, the user-researcher and a member of the research team. These interviews explored, amongst other things, the patents experiences of NHS dentistry and their thoughts on role-substitution. Additionally, patients were guided towards specific topics determined from the emerging theoretical framework and associated coding document. Patients were encouraged to explore areas of personal interest and concern.

Where possible, the transcribed data from the PPI interviews was reviewed by the research team and the user-researcher before the subsequent interviews. In this way, the research team where able to reflect and update the programme theory in conjunction with the user-researcher as the interviews progressed.

The emergent findings were compiled in a coding framework document (Table 24). The document was co-populated with themes, codes and quotes from PPI focus groups held as part of the health economic analysis (Chapter 4). Three focus groups were conducted with a total of nineteen PPI participants for WS3, this was later supplemented with a further 13 semi-structured interviews. This data, coupled with the existing PPI findings, was reviewed in detail by two members of the research team (CW, PRB) and the user-researcher (KS). This review formalised the *f*[C,M,O] contingency on patients experiences’ (Figure 9).

In total, the project accrued over 70 hours of PPI activity during the realist informed process evaluation (Chapter 3), including over 32 hours of individual user-researcher activity for WS3 (Chapter 4).

KS also read through the Plain Language Summary and will be a key member of the team during the dissemination phase of the project.

*Note: PARC-Bangor*

PARC-Bangor is the Public Involvement and Engagement Group at the North Wales Trials Unit (NWORTH), Bangor University (<https://nworth-ctu.bangor.ac.uk/parc-bangor.php.en>). Members of the public across North Wales can sign up to the PARC-Bangor database if they are interested in taking part in research or taking part in developing research ideas at NWORTH Trials Unit.

Members of the PARC-Bangor network meet four times per year to discuss new and ongoing studies. Some members of PARC-Bangor sit on Trial Steering Committees and others engage with projects as and when their input is required. The functions of PARC-Bangor are to:

1. Provide insight and a public perspective to the development of research questions
2. Ensure documents and information associated with a study are easy to understand for patients and the public taking part in the research
3. Discuss and comment on the research process described in funding applications to ensure patient perspectives are accounted for
4. Provide a ‘patient voice’ to NWORTH’s Executive

Being a member of PARC-Bangor means that members of the Public can:

1. Learn about and influence health research in their area;
2. Use their experience as patients, service users, carers or family members to help others;
3. Influence study designs to make funding applications more successful;
4. Discuss the work with research teams via email, in person, or over the telephone; and
5. Access free training about health and social care research.