Amalgam phase-out: what next for dentistry?

Costs and benefits of the alternative direct restorations

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Abstract

Introduction

Dental amalgam has been used to restore posterior teeth for centuries. It contains mercury and concerns around its toxicity have mandated a phase-down of its use and an exploration of the feasibility of its phase-out in England by 2030. This thesis explored the current use of amalgam and the relative costs and benefits of the directly placed alternatives in the English NHS primary care setting.

Methods

This thesis comprised three complimentary phases. Phase one quantified the use of materials and techniques to restore posterior teeth by UK primary care clinicians, alongside their opinions of the phase-down using an online questionnaire. Phase two quantified UK public preferences for different aspects of posterior restorations in terms of differences in their willingness to pay using a discrete choice experiment. Phase three was an economic evaluation of amalgam versus the alternative restorations in the English NHS setting. A model of restoration and reintervention was built to compare the lifetime costs and outcomes of amalgam with the alternatives. Data from all phases were then used in a cost-consequence analysis which quantified the differences in various outcomes and costs from the perspective of funders, patients and clinicians.

Results

Amalgam is frequently used in NHS primary care and clinician confidence in the alternatives is limited, with significantly higher reported post-operative complications. The lifetime monetary and time costs to patients, funders and clinicians are significantly higher for composite than amalgam and clinical outcomes are significantly worse. In terms of preferences, the UK public value amalgam more than composite, with the largest relative difference seen in low-income groups.

Discussion

An imminent phase-out of amalgam in England would lead to concerns around survival of restored teeth, funding, patient safety and access to care, which risk exacerbating existing health inequalities.

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Table of contents

List of Figures

List of Tables

List of Abbreviations

2s – Two-surface

3s – Three-surface

AAE – American Association of Endodontists

ADHS – Adult Dental Health Survey

ADJ – Amelo-dentinal junction

AIC – Akaike Information Criterion

AP – Allocation probability

ASC – Alternative specific constant

BADT – British Association of Dental Therapists

BDA – British Dental Association

BIC – Bayesian Information Criterion

BPA – Bisphenol A

BSDHT – British Society of Dental Hygiene and Therapy

CADTH – Canadian Drug and Health Technology Agency

CARS – Caries associated with restorations

CBA – Cost-benefit analysis

CCA – Cost-consequence analysis

CCC – Core curriculum in cariology

CDS – Community dental services

CEA – Cost-effectiveness analysis

CHEERS - Consolidated Health Economic Evaluation Reporting Standards

CI – Confidence interval

CLM – Conditional logit model

CMA – Cost-minimisation analysis

Composite – Resin-based composite

COP – Conference of Parties

CPD – Continuing professional development

CSC – Calcium silicate cement

CUA – Cost-utility analysis

CV – Contingent valuation

DALY – Disability-adjusted life year

DAM – Decision analytic model

DCE – Discrete choice experiment

DHSC – Department of Health and Social Care

DMP – Data management plan

FDI – World Dental Federation

FG – Focus group

GDP – General dental practitioner

GDC – General Dental Council

GIC – Glass ionomer cement

HEE – Health economic evaluation

HR – Hazard ratio

HTA – Health technology assessment

IADR – International Association of Dental Research

ICCC - International Caries Consensus Collaboration

ICCM – Institute of Crematorium and Cremation Management

ICCMS – International caries classification and management system

ICDAS – International caries detection and assessment system

ICER – Incremental cost-effectiveness ratio

ISPOR - The Professional Society for Health Economics and Outcomes Research

LCU – Light-curing unit

LL5 – Lower left second premolar tooth

MB – Mail-based

MI – Minimally invasive

MID – Minimally invasive dentistry

MIOC – Minimally invasive oral healthcare

MLR – Multiple linear regression

MM – Mixed-mode

MO – Mesio-occlusal

MOD – Mesio-occluso-distal

MS – Mutans streptococci

mWTP – Marginal willingness to pay

NCD – Non-communicable disease

NCPA – Norwegian Climate and Pollution Agency

NHS – National Health Service

NMA – Network meta-analysis

OHID – Office for Health Improvement and Disparities

OHRQoL – Oral health-related quality of life

ONS – Office for National Statistics

OR – Odds ratio

p_acm – Probability of all-cause mortality

PDP – Personal development plan

PPI – Patient and public involvement

PSA – Probabilistic sensitivity analysis

QALY – Quality-adjusted life year

QATY – Quality adjusted tooth year

RaCT – Randomised controlled trial

RAI – Relative attribute importance

ResRa – Response rate

RD – Rubber (dental) dam

RMGIC – Resin-modified glass ionomer cement

RoCT – Root canal treatment

RPLM – Random parameters (mixed) logit model

RR – Risk ratio

SCENIHR – Scientific Committee on Emerging and Newly Identified Health Risks

SD – Standard deviation

SDCEP – Scottish Dental Clinical Effectiveness Programme

SDF – Silver diamine fluoride

TP – Transition probability

UK – United Kingdom

UDA – Unit of dental activity

UNEP – United Nations Environment Programme

VIF – Variance inflation factor

VPT – Vital pulp therapy

WB – Web-based

WTP – Willingness to pay

Dissemination

Publications

Work from this thesis has been published in the following articles (Bailey *et al.*, 2022c; Bailey *et al.*, 2022d; Bailey, 2021; Bailey *et al.*, 2022b; Bailey, 2025) which are included in Appendix A.

Bailey O, Vernazza C R, Stone S, Ternent L, Roche A-G and Lynch C. (2022) Amalgam phase-down part 1: UK-based posterior restorative material and technique use. *JDR Clinical and Translational Research*, 7(1), pp. 41-49. (Epub 2020 Dec 10).

Bailey O, Vernazza C R, Stone S, Ternent L, Roche A-G and Lynch C. (2022) Amalgam phase-down part 2: UK-based knowledge, opinions, and confidence in the alternatives. *JDR Clinical and Translational Research*, 7(1), pp. 50-60. (Epub 2020 Dec 10).

Bailey O. (2021) Sectional matrix solutions: the distorted truth. *British Dental Journal*, 231(9), pp. 547-555.

Bailey O, Stone S, Ternent L and Vernazza C. (2022) Public valuation of direct restorations: a discrete choice experiment. *Journal of Dental Research*, 101(13), pp. 1572-1579.

Bailey O. (2024) The long-term oral-health consequences of an amalgam phase-out. *British Dental Journal*, 238(8), pp. 621-629.

Abstract publication (Bailey *et al.*, 2022a)

Bailey O, Stone S, Ternent L, Vernazza CR. (2022) Public valuation of direct posterior restorations: a discrete choice experiment. *Journal of Dental Research,* Vol 101(Spec Iss A) (AADOCR):0352.

Conference paper (Bailey, 2022)

Bailey O. (2022) Sub-gingival posterior composites: How confident are you? *BDJ In Practice,* 35(3): pp. 28-29.

The following published research was developed from the thesis, but is not part of the thesis (Bailey, Shand and Ellis, 2023)

Bailey O, Shand B and Ellis I. (2023) Class II composite technique teaching: A randomised controlled crossover laboratory-based trial involving a novel ringless sectional matrix technique. *European Journal of Dental Education*, 27(4), pp. 963-973.

Chapter 1. Introduction

Tooth decay, or dental caries is the most prevalent global disease (Marcenes *et al.*, 2013). It is conventionally treated by operatively removing the decay and placing a restoration. Globally over 1.1 billion restorations were placed directly in the mouth in 2014 (Jäggi, 2015). In the UK Adult Dental Health Survey (ADHS) 2009, 31% of adults had active decay and 86% had at least one dental filling (restoration). The percentage of adults without teeth, who cannot therefore experience the disease, has fallen to just 6% (NHS Digital, 2011), meaning that more adults are retaining teeth into older adulthood. Though caries is a preventable disease, and management should ultimately look to eradicate it through management of modifiable risk factors, untreated caries in permanent teeth affected 2.4 billion people worldwide in 2010 (Marcenes *et al.*, 2013). Complete prevention is therefore not the current reality, with many affected teeth requiring restoration. Because restorations have a finite lifespan, replacement restorations are also very commonly required to deal with historical disease. Teeth that have been restored therefore enter the 'restorative cycle' (Elderton and Nuttall, 1983). There is therefore an ongoing need for maintenance, replacement and ever increasingly more complex, time consuming and expensive treatment which is commonly less predictable. This cycle may ultimately result in the loss of the tooth and the potential need for replacement with a false tooth (prosthesis) of variable design, functionality, longevity and expense, which may then compromise more of the dentition.

Minimally invasive (MI) treatment philosophies have been heavily promoted. Overarching strategies, such as 'Minimum Intervention Oral healthCare' (MIOC) allied with operative philosophies, such as 'Minimum Intervention Dentistry' (MID) have looked to reduce the restorative footprint on the tooth, through prevention and non-operative intervention, but also with minimally invasive restorative techniques (Frencken *et al.*, 2012; Banerjee, 2020). These restorative techniques have become possible primarily through a greater understanding of the disease process and the development of adhesive technologies, which allow the maintenance of more tooth structure when invasive treatments are required. This has allowed tooth-coloured resin-based composite restorations (composites) to be bonded to teeth, rather than removing further tooth structure to mechanically lock in silvery/grey dental amalgam restorations. This philosophy seems logical with a strong narrative of delaying the restorative cycle, and keeping teeth for longer with so called biomimetic, aesthetic restorations (Frencken *et al.*, 2012; Malterud, 2006; Wilson and Lynch, 2022). Such restorations, even when extensive, can be very successful (Opdam *et al.*, 2010). However, these materials, which are used to underpin the philosophy, are currently more expensive, and technically demanding to place relative to amalgam (Kielbassa *et al.*, 2016) and have not performed as well in randomised controlled clinical trials (RaCTs) (Worthington *et al.*, 2021). Therefore, how they perform clinically in the hands of primary care clinicians in general and in healthcare systems which do not currently incentivise their use may be questioned, with potentially increased adverse patient-centred outcomes (Lynch *et al.*, 2018b; Burke *et al.*, 1999). The UK has a National Health Service (NHS) which provides publicly-funded dental care but with co-payments for most adult patients. A large majority of direct posterior restorations placed under this system were amalgam (Lynch *et al.*, 2018b).

Mercury, which is toxic, is a constituent of amalgam. When set, amalgam contains relatively inert mercury compounds and it has been placed for nearly two centuries to restore teeth affected by tooth decay. There have been no clear, commonly occurring, serious, negative implications on the health of patients or clinicians associated with amalgam (Ajiboye, Mossey and Fox, 2020). Amalgam restorations have been held up as major historical contributors to tooth loss and said to be responsible for creating a legacy of unaesthetic weakened teeth in a 'heavy metal generation' (Lynch and Wilson, 2013; Wahl, 2012). Though this anti-amalgam sentiment may be understandable in those advocating a minimally invasive narrative, it may not reflect the broader clinical reality in a primary care setting operating with multiple constraints.

Amalgam is subject to the Minamata Convention on Mercury, 2013, an international treaty developed by the United Nations Environment Programme (UNEP) which committed to protect human health and the environment from mercury pollution (UNEP, 2013). This was ratified in law by the European Union (EU) (*Regulation (EU) 2017/852*, 2017) which mandated a phase-down of dental amalgam use in 2018, limiting its use in certain groups and requires that the feasibility of a complete phase-out by 2030 is explored. The UK subsequently left the EU, but the regulation has not changed (Walker, 2021; legislation.gov.uk).

Though a recent review of the alternatives based on a World Dental Federation (FDI) policy statement said that there is no single material which can replace amalgam in all applications (Schmalz *et al.*, 2024), posterior composites are almost universally accepted as the most appropriate, currently available, directly placed alternatives to replace amalgam in this time frame (Schmalz *et al.*, 2024; Lynch and Wilson, 2013). Composite is, however, an umbrella term for numerous formulations of tooth-coloured materials which can behave differently with potentially meaningful differences in cost, handling, application and clinical outcomes, and there are fairly well-accepted classifications into which similar materials can be grouped (Rawls and Whang, 2019).

Composite materials are recommended for use as direct restorations of posterior teeth (Lynch *et al.*, 2014) and have been universally adopted in some regions (mainly more affluent countries) where the extra costs are borne by patients (UNEP, 2016; NCPA, 2012)). This has raised concerns that an amalgam phase-out may widen existing oral health inequalities in the UK where amalgam is still frequently being used (Steele *et al.*, 2015; Aggarwal *et al.*, 2019; Lynch *et al.*, 2018b). Despite the suggested advantages to the longevity of teeth, alongside the improved aesthetics, various stakeholders in the UK have concerns if amalgam is phased-out and replaced with composite (Lynch *et al.*, 2018b; Sanderson, 2022). This thesis explores the perspectives of three key stakeholders in three phases: Phase One considers the clinicians who will provide the treatment; Phase Two, the patients who will receive, and often partially pay for the treatment, and Phase Three the policy makers who are responsible for choosing the treatment offered and directing public money to subsidise it in an English setting.

It is not currently clear which materials the clinicians who provide the majority of direct restorations in England are using and if a complete amalgam phase-out is feasible by 2030. A survey of primary care clinicians exploring their material use and opinions was used to inform Phase One. Restorations of different materials differ in longevity, as has been focused on in previous health economic evaluations (HEEs) (Smales and Hawthorne, 1996; Tobi *et al.*, 1999; Schwendicke *et al.*, 2018b; Khangura *et al.*, 2018). They also differ in other ways which are potentially important to patients, including colour, post-operative complications, cost and processes of care, for example the type of clinician providing the treatment, waiting time for treatment and treatment time. Considering patient valuation of differing treatments is important to respect their wishes, but also to favour uptake of healthy choices (Ostermann *et al.*, 2017). Data on this are not currently available. These preferences were explored using a discrete choice experiment (DCE) survey of the UK general public in Phase Two. As previously stated, HEEs of different dental restorations have been quite narrow in their scope and not relevant to the English primary care setting. A cost-consequence analysis in an English setting was therefore used to provide a more holistic and interpretable approach to HEE, allowing decision makers the freedom to consider the costs and benefits of the different restorations relevant to them in Phase Three.

1.1 Aim

This thesis therefore aimed to explore the relative costs and benefits of the directly placed alternatives to posterior amalgam restorations within the UK (primarily NHS) primary care setting. It also aimed to inform policy on direct posterior restoration provision in response to the new regulations on amalgam which mandate the exploration of a phase-out by 2030.

1.2 Objectives

The objectives of Phase One were to:

a. identify and quantify current techniques, material use, and reported incidence of postoperative complications by UK dentists and therapists for placement of different direct posterior restorations;
b. determine primary care clinicians' knowledge of newly imposed restrictions, opinions on the phase-down and potential phase-out (including confidence in placement of the available direct posterior restorative materials in various situations), and educational experience related to posterior composites;
c. identify and quantify differences between subgroups, including those based on clinician type (dentists working primarily in private or NHS practice, or dental therapists for example) and years qualified.

The objectives of Phase Two were to quantify:

a. the preferences of the UK population for differing levels of direct posterior restoration attributes in terms of marginal WTP (mWTP);
b. the relative attribute importance (RAI);
c. any differences in these based on income subgroups.

The objective of Phase Three was to quantify:

a. The relative costs and consequences of amalgam versus composite direct posterior restorations in adult permanent teeth in the English NHS setting over the short and longer term.

Chapter 2. Direct restoration of permanent posterior teeth

2.1 Introduction

This chapter discusses the causes and need for restoration of permanent posterior teeth. Posterior teeth are restored with direct restorations for multiple reasons. These include teeth which have lost structure due to wear (Bailey, McGuirk and O'Connor, 2022) or those suffering from cracked tooth syndrome (Bailey and Whitworth, 2020; Bailey, 2020), as examples, but the vast majority are restored due to dental caries or its sequelae (Pitts and Mayne, 2021). A discussion of caries therefore follows, along with the different restorative materials available to operatively manage it. The impact of legislation and health service provision on their use is explored, before considering how materials vary, and how this may impact on their failure and future reintervention. It then describes the evidence on material use in primary care and clinicians' opinions of the materials, followed by a consideration of the issues around implementing material choice.

2.2 Caries

Caries is a complex disease process, involving the destruction of tooth tissues by acid produced through microbial metabolism of dietary carbohydrate (primarily sugar). The bacteria involved are attached to the tooth in the form of a biofilm, which is a complex protected habitat. The tooth loses mineral in a process known as demineralisation. Remineralisation of the damaged structure can then occur when the sugar has been metabolised or cleared. This can be helped by various protective factors (for example fluoride and saliva). The process may also be influenced by genetic, epigenetic and complex psychosocial determinants (Pitts *et al.*, 2017), but caries is the net loss of tooth structure.

The following sections describe the main causes of caries, and protective factors which can modulate the process. They then go on to describe its pathogenesis, the structure of the lesion and its natural progression, including the potential effects beyond the confines of the tooth. This will set the scene to later explain the importance of the disease at both the individual and societal levels, whilst helping to explain the rationale for the current concepts in managing (and preventing) the disease. This includes tooth restoration, and how factors, including the restoration material and caries risk, for example, influence the need for reintervention, and what that reintervention may be.

2.2.1 Aetiological factors

Caries requires hard tooth structure, an attached microbial biofilm, and dietary carbohydrate. In the absence of either a microbial biofilm, or dietary carbohydrate, the disease cannot occur, so prevention, and management of the early stages of the disease tends to focus on elimination, or more realistically minimisation of these elements, alongside optimising protective elements.

Tooth surfaces are all susceptible to dental caries throughout an individual's life, though sites that are difficult to clean and therefore tend to harbour biofilm, such as occlusal pits and fissures, and interproximal areas tend to be the most affected (Zero, 1999). Biofilm formation on a tooth surface however does not necessarily mean that caries will occur. The nature and constituents of the biofilm, and the presence of dietary carbohydrate, mainly in the form of sugars, are key factors in the initiation and progression of the disease (Touger-Decker and van Loveren, 2003). Evidence suggests that when free-sugar intake is restricted to provide less than 10% of energy, caries experience is reduced (Moynihan and Kelly, 2014).

2.2.2 Protective factors

Saliva has numerous protective factors and mechanisms of action in helping to combat the carious process. Saliva can aid clearance of cariogenic food and drink, and modulate the biofilm, but it is thought to act primarily in caries prevention through its ability to buffer acidic changes in biofilm fluid, reducing demineralisation and favouring remineralisation. Saliva composition is influenced by flow rate and both composition and rate are also influenced by diet and chewing, which can be therapeutically exploited (Rethman *et al.*, 2011).

Fluoride has multiple modes of action in helping to protect against caries. It is available naturally in some water supplies and foods, whilst also being added artificially to water and certain foods as public health measures. It is present in toothpastes and many other vehicles, which can be professionally or personally applied. These modes of delivery have variable levels of efficacy in preventing caries, various levels of evidence for their efficacy, and variable efficacy in different populations (ten Cate, 2004). There is consensus on fluoride's major mode of action, which involves fluoride inhibiting demineralisation and favouring remineralisation by the common ion effect, thus decreasing destruction of tooth tissue. Its incorporation into the surface of the tooth has another protective effect, as the mineral formed is relatively less soluble than when no fluoride is present. It also has been shown to affect bacterial metabolism and growth *in vitro*, though the clinical relevance of this is uncertain (ten Cate, 2004).

Silver diamine fluoride (SDF) can be applied to teeth to halt the carious process primarily through anti-bacterial and remineralising effects. It commonly results in dark staining of the treated teeth however which can be unsightly. The staining may be partially mitigated by application of potassium iodide immediately after SDF placement. It is increasingly commonly used in children, and shows some promise in arresting and preventing root caries in the elderly, but has obvious aesthetic downsides and results in impaired dentine bonding which is required for composite restorations (Mungur *et al.*, 2023).

Fluoride promotes surface remineralisation which can inhibit deeper remineralisation. Amorphous calcium phosphates can slow early surface remineralisation whilst promoting sub-surface remineralisation (Bayne *et al.*, 2019) which can also reverse the appearance of white spot lesions (Güçlü, Alaçam and Coleman, 2016).

2.2.3 Pathogenesis

There are complex interactions between many of the factors involved in caries pathogenesis, making it difficult to understand their relative importance. The following discussion aims to discuss the dynamic inter-relationships to provide a holistic understanding of the process.

Tooth and restoration surfaces adsorb salivary proteins and glycoproteins forming the acquired pellicle. This can act to bind initial microbial colonisers on the one hand, whilst providing protection against diffusion of acids in the biofilm fluid on the other (Hara and Zero, 2010). Variation in the nature of the biofilm formed on different restorative materials could partially explain differences in caries associated with restorations (CARS) also known as secondary or recurrent caries (Svanberg, Mjör and Orstavik, 1990; Pinna *et al.*, 2017; Askar *et al.*, 2020). This is explored later in section 2.17.2, whereas primary disease of unrestored teeth is the focus of the following sections.

Hydroxyapatite is the major mineral component of all dental hard tissues and exists in dynamic equilibrium with its surroundings. In health, there will be periods of demineralisation (due to acidic challenges) followed by periods of remineralisation, but crucially there is no net change in mineral levels.

If the periods of demineralisation exceed remineralisation, the equilibrium is lost, and there tends to be a net loss of mineral. In the area of an acidogenic biofilm, this loss is the process known as caries. The frequency and length of these attacks are important in the initiation and progression of a carious lesion (Touger-Decker and van Loveren, 2003).

This understanding of the pathogenesis of the disease can be exploited to prevent its progression, which is explored in section 2.6.2.

Initially this demineralisation process will tend to progress, after an initial surface softening, more at the sub-surface level of the enamel. The tooth will therefore suffer from surface roughening, but will remain macroscopically intact (Kidd and Fejerskov, 2004). It will however result in a change in appearance forming a white lesion which allows the caries to be detected clinically. It is important to diagnose the disease early, as remineralisation is possible, through implementation of preventive management strategies to favour this process, preventing the need for operative management (Pitts and Zero, 2016).

If the caries process is left unchecked however, the tooth will progressively break down, affecting the full thickness of the enamel, before penetrating the dentine, with attendant microbiological and metabolic changes.

Dentine is a living tissue, which enamel is not, and is therefore able to react to the damaging progression of the carious process. This means that the progression of the disease is dependent on both the carious destruction of the dentine and the defensive response of the pulpo-dentinal complex. Dentine is structurally quite different to enamel, having a much lower mineral content and a large organic component which is composed predominantly of collagen which acts as a scaffold. It also contains much more water than enamel. These differences in structure are important considerations when disease is managed with adhesive materials, as the techniques used to achieve adhesion differ, as do the mechanisms at play and behaviour of the bonding over time (Van Meerbeek *et al.*, 2020) as discussed in section 2.8.

The dentine has tubules running through it which commonly house odontoblastic processes. These allow detection of the insult, resulting in a defensive response in the form of dentinal sclerosis and tertiary dentine formation in the pulp chamber. These responses attempt to slow the rate of progression and limit the damage to the pulp. The specific nature of the dentine can have a large effect on the ability to bond restorative materials to it and how the bond behaves over time (Van Meerbeek *et al.*, 2020).

Caries of the dentine generally develops from the enamel caries overlying it (when present). The lesion tends to spread laterally along the amelo-dentinal junction (ADJ- the interface of the enamel and dentine), which then allows for extensive progression down many dentinal tubules. The disease process proceeds through acid demineralisation followed by both endogenous and exogenous proteolytic breakdown of the collagen matrix as the lesion progresses. Bacteria colonise and extend down the dentinal tubules, forming the zone of bacterial invasion. Acid produced by the bacteria diffuses ahead of this zone resulting in the zone of demineralisation, which is softened, but potentially sterile dentine. Further progression of the lesion results in a zone of destruction, with loss of dentine structure and frank cavitation occurring coronal to and involving the zone of bacterial invasion.

These zones correlate with what are commonly known as, 'the caries infected dentine' and 'the caries affected dentine' (Fusayama, Okuse and Hosoda, 1966), which are thought to have clinical relevance in operative management of the disease (Hosoda and Fusayama, 1984). This will be discussed in section 2.6.4 alongside refutations of these zones.

The change in environment as the lesion progresses deeper, results in a change in the microbiological make-up of the lesion, with the further progression resulting in huge diversity, sometimes with a preponderance of asaccharolytic, proteolytic bacteria and more anaerobic species (Rôças *et al.*, 2015). This suggests that deep carious lesions in dentine may be able to propagate without the requirement of an external source of nutrition, which becomes a potentially important feature to consider when managing the disease at this level of progression (Ricucci *et al.*, 2019; Marending, Attin and Zehnder, 2016).

Understanding the pathogenesis of the carious lesion and its effects on the structure of the dental substrates, alongside the structure of the unaffected enamel and dentine are therefore critically important in terms of the clinical management and prevention of the disease.

Left unchecked, the carious lesion will ultimately reach the pulp despite the defensive responses mounted. The pulpal response to a carious lesion is complex and multifactorial however.

The risk of pulpal pathology increases with increasing carious lesion depth (Reeves and Stanley, 1966). Pulp tissue that is not infected is vital, whereas necrotic areas of pulp tissue favour bacterial accumulation (Langeland, 1987). Animal models have shown that if bacteria are removed and the tooth is appropriately restored, pulp tissue is able to repair (Mjör and Tronstad, 1974). Pulpal preservation allows developmental dentinogenesis and defensive dentinogenesis, alongside an immunoresponsive ability and mechanoreception (Bjorndal *et al.*, 2019).

Involvement of the pulp may cause pain and eventually pulpal necrosis, which has a further impact on management of the disease. This can lead to disease progression beyond the confines of the tooth, potentially resulting in swelling and systemic disease, which can ultimately lead to death if not appropriately managed (Casamassimo *et al.*, 2009).

This description of the initiation, progression and potential for arrest of the disease process has highlighted our current understanding of caries. This has provided a rationale for the staging (and activity) of disease, which has enabled the development of a classification system for caries which is useful for a number of reasons which are described below.

2.3 Classification

Primary disease classification can be helpful in many ways; at an epidemiological level, an individual level and a tooth level. It helps to understand the extent of a problem at each of these levels, guiding management and policy. It is also important in research and education. Numerous caries classification systems have been proposed and are used in different areas, but The International Caries Detection and Assessment System (ICDAS) has found favour (Pitts and Stamm, 2004). Interproximal caries diagnosis is based on a combination of visual inspection and radiographic assessment, but given these areas are difficult to see directly, it tends to rely on the appearance of a bitewing radiograph, especially in the early stages.

Management differs based on the cavitation of the lesion and the radiographic extension into dentine.

The ICDAS has now been merged and essentially subsumed within the International Caries Classification and Management System (ICCMS), which guides education, practice, public health and research (Ismail, Pitts and Tellez, 2015).

Figure 2.1 summarises this diagnostic system (Panyarak *et al.*, 2023). A European Core Curriculum in Cariology (CCC) (Schulte *et al.*, 2011b) was developed following a survey which showed a large variation amongst undergraduate caries educators (Schulte *et al.*, 2011a).

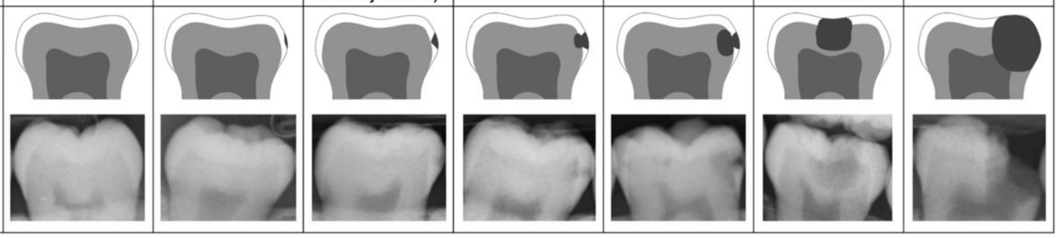
2-class classification	**Non-carious tooth**	**Carious tooth**					
4-class classification	**0**	**RA Initial stages**			**RB Moderate stage**	**RC Extensive stage**	
7-class classification	**0**	**RA1**	**RA2**	**RA3**	**RB4**	**RC5**	**RC6**
Description	No radiolucency	Radiolucency in the outer half of the enamel	Radiolucency in the inner half of the enamel ± EDJ (enamel-dentin junction)	Radiolucency limited to the outer one-third of dentin	Radiolucency reaching the middle one-third of dentin	Radiolucency reaching the inner one-third of dentin, clinically cavitated	Radiolucency into the pulp, clinically cavitated
Schematic and radiographic examples							

Figure 2.1. Schematic and radiographic examples of the ICCMS diagnostic classification system

Reproduced, with permission (Appendix B), from Panyarak et al., 2023.

In caries approaching the pulp, a further classification system is based around a position statement issued by The European Society of Endodontology (ESE), which differentiates 'deep caries' from 'extremely deep caries' (Dummer *et al.*, 2019). These terms are quite similar, but do not exactly correlate in terms of definition with the ICCMS.

2.4 Epidemiology

Epidemiological data on dental caries is key to understanding the disease prevalence, incidence and patterns. This enables policy makers especially to plan and implement appropriate management strategies. The Global Burden of Disease Studies found untreated dental caries in permanent teeth to be the most prevalent disease assessed, with a global prevalence of 35% (Marcenes *et al.*, 2013). There is evidence of a shift in burden from children to adults, and with population growth and aging populations retaining more teeth there will be an increasing burden of untreated caries (Kassebaum *et al.*, 2015). Much evidence also shows that the socio-economically deprived and other disadvantaged groups suffer the majority of the disease both in the UK and globally (Steele *et al.*, 2015; Peres *et al.*, 2019). Therefore, operative caries management and restoration, though seen as a last resort when managing caries, is still a very real necessity in the present and for the foreseeable future.

2.5 Impacts

There are obvious advantages to preventing caries which extend beyond the level of the tooth. The disease also impacts the individual and broader society. Members of the UK public were willing to pay to avoid decay with and without pain, showing that they value having healthy teeth (Lord *et al.*, 2015). The ADHS 2009 showed that around one in four adults with untreated caries and around one in three with extensive caries reported frequent and severe impacts on their quality of life (White *et al.*, 2012). A systematic review showed that caries consistently negatively impacted individuals' oral health-related quality of life (OHRQoL) (Haag *et al.*, 2017). Caries can also result in social embarrassment and have large financial implications, both in direct costs of treatment, and indirect costs from productivity losses, for example due to time off work, for the affected individuals and employers. Untreated caries was responsible for nearly 5 million disability adjusted life years (DALYs) in 2010 (Marcenes *et al.*, 2013). The global economic burden of oral diseases was estimated most recently at $357 billion in direct costs and $188 billion in indirect costs (Righolt *et al.*, 2018) and it has been estimated that dental caries accounts for 45% of those costs (Pitts and Mayne, 2021). Direct restorations are frequently placed following the operative management of dental caries. Worldwide, more than 1.1 billion direct restorations were placed in 2014 (Jäggi, 2015).

2.6 Management strategies

The fusion of ICCMS and CCC endorsed a shift towards MI management philosophies (Pitts *et al.*, 2021). This guides a management cycle based on an individualised risk factor approach, caries staging and disease activity assessment, with a care plan (implementing operative and non-operative treatment at tooth and patient levels), before active surveillance by re-appraisal and ongoing prevention and control. It very much makes the dental care professional both physician and surgeon. This contrasts with the previous, almost ubiquitously used, surgery-oriented classification and management system described by Black (Black and Black, 1924), based on standardised operative cavity designs relating to caries location, irrespective of the stage or size of the lesion (FDI, 2013). Having said this, Black's Classification is still taught and used extensively in both the literature and primary care, so a brief overview of the cavity classification relevant to this thesis is described below and in Figure 2.2.

- Class I – involving only the occlusal surface of a posterior tooth
- Class II – involving a posterior proximal tooth surface
- Class V – involving a cervical (non-proximal) tooth surface

It should be noted that whilst class I and V cavities can vary in their size and depth to a reasonable degree, class II cavities can have huge heterogeneity, ranging from a small single surface, to situations where most of the tooth has been lost (Figure 2.2). This can lead to problems interpreting the 'class II restoration' data (including survival) where multiple other parameters are not recorded. It has been shown that restorations which are deeper, and involve more surfaces have increased failure rates on average (Laske *et al.*, 2016), and that nearly all randomised controlled trials (RaCTs) on class II restorations involve more minimal restorations in low-risk patients with questionable relevance to general practice (Opdam *et al.*, 2018). Section 2.15 further critically evaluates study designs and examines clinical outcome data on direct restorations.

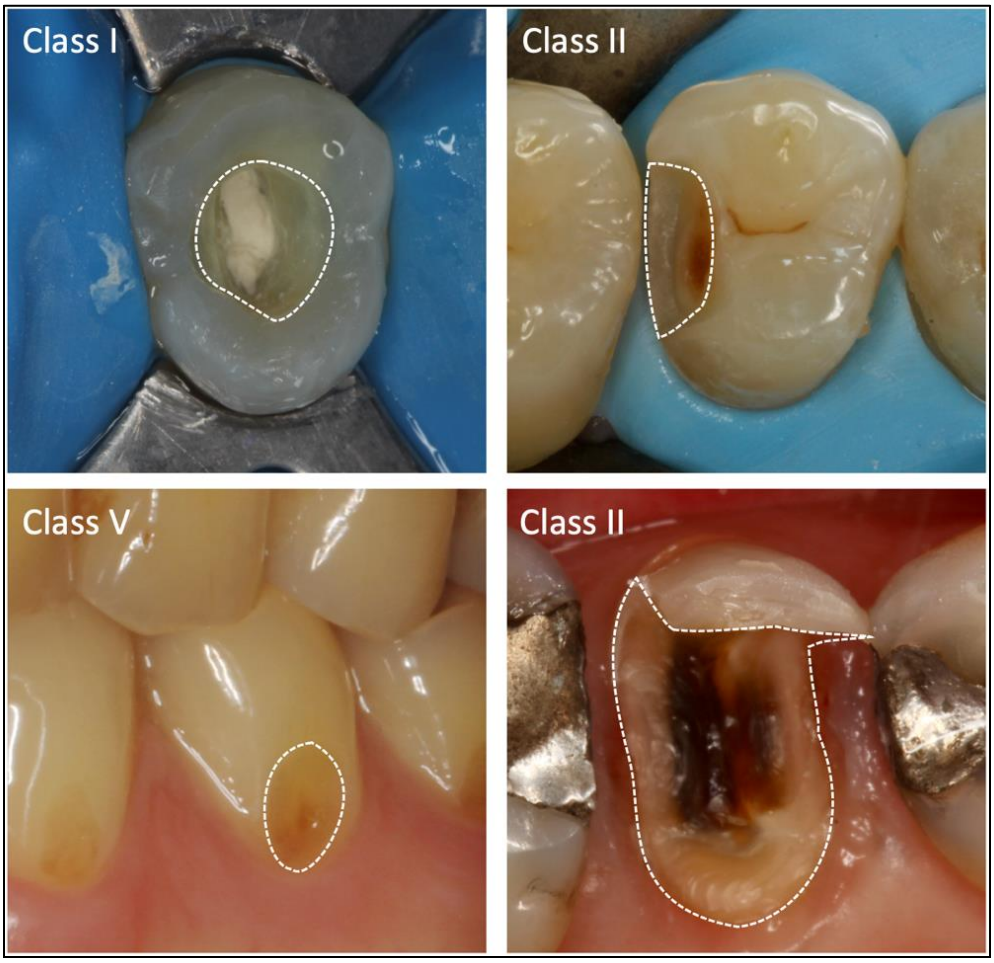


Figure 2.2. Black's cavity classification examples

Though proposed caries management strategies have undergone a shift from a primarily surgical, resective approach predicated on Black's classification system, to a more preventive and conservative approach based on an improved understanding of the disease process over the previous 30-40 years, the change has not been universally adopted amongst general dental practitioners (GDPs) (Chana *et al.*, 2019; Laske *et al.*, 2019b). This would appear to be due to many different and diverse factors, with clinician knowledge and opinion important, but the mode of remuneration for dental care provision, which has tended to incentivise the surgical over the preventive approach in primary care (and still does in the UK as discussed in section 2.12), has been identified as a major barrier (Schwendicke *et al.*, 2018a; Pitts and Zero, 2016).

The preventive approach has now been adopted in undergraduate dental education to varying degrees in many countries, aiming to move the future of the profession towards an evidence-based approach to caries management (Pitts and Zero, 2016).

2.6.1 Rationale for avoiding initiation of surgical intervention

Surgical intervention weakens a tooth and is thought to lead to a 'repeat restorative cycle', whereby what might initially be a small restoration, will inevitably require replacement over time. This operative replacement leads to further removal of tooth tissue, which further weakens the tooth and potentially compromises the health of the pulp, which may ultimately affect the survival of the tooth (Elderton and Nuttall, 1983). It seems logical that operative treatment would also be relatively more expensive, with increased material costs, longer appointments with more time required by clinicians and patients to treat the disease. This usually increases both direct costs, where money is paid for a service, and indirect costs, where the patient loses the opportunity to use their time more productively, by travelling to and from the appointment and receiving treatment. It then also often necessitates ever increasing operative treatment with spiralling costs (Pitts and Mayne, 2021). It also potentially increases the time required to treat a patient by a clinician, which impacts on how many patients they can treat and can therefore create dental service access issues where the workforce is limited. We do not have clear evidence for these contentions however, or any idea of the magnitude of those costs in the English setting. The evidence on reintervention following restoration failure will be discussed in section 2.18.

It has therefore been suggested that surgical intervention should be seen as the last resort, and that when restoration is required, it should be as minimally interventive as possible. This should be achieved by utilising new technologies and materials with adhesive properties, in an attempt to limit the operative footprint and improve the survival of the tooth. It should ideally be performed when modifiable risk factors have been controlled, otherwise it risks rapid failure (Pitts and Zero, 2016).

MI philosophies have been heavily promoted. These tend to be encompassed by the overarching MIOC which combines domains of detection and diagnosis, prevention and disease control, MI operative interventions (MID) and recall. It focuses on team delivery and patient-centred care with the aim of maintaining life-long oral health (Heidari, Newton and Banerjee, 2020). They also include MID, which appears rational suggesting that all operative procedures should be as minimally invasive as possible utilising state-of-the-art operative technologies and bio-interactive materials (Banerjee and Domejean, 2013).

MI philosophies aim to shift the profession away from the primarily surgical, restorative driven approach associated with Black's classification. They are the driving principles behind disease management with the ICCMS.

2.6.2 Prevention: a cavity free future, the ultimate goal

The development of cavities in teeth due to caries is wholly preventable, therefore this should be the ultimate goal of caries management. Prevention should be targeted at both the population and individual level. The Alliance for a Cavity-Free Future published a global consensus document on how this could be achieved (Pitts and Mayne, 2021). It highlighted many of the barriers which need to be overcome, alongside organising a policy lab with key stakeholders including international policymakers, in an attempt to promote the benefits of a cavity free world and provide concrete actions to secure increased resource allocation to prevention (Vernazza *et al.*, 2021). While systems of remuneration incentivise operative care over prevention, making a change to reorient services can be difficult within the confines of a finite budget (Vernazza, Birch and Pitts, 2021). Though the goal of a cavity free future is laudable, it is not the reality currently faced however based on the epidemiology.

Prevention is often less costly than the cure, especially where an operative intervention necessitates a lifetime of treatment with ever increasing complexity and costs (both direct and indirect). The outcomes are not really comparable either, and the multiple benefits to both the individual and society of avoiding treatment beyond the direct costs often aren't accounted for (Listl *et al.*, 2022). A systematic review showed that caries preventive interventions can be cost-effective (Davidson *et al.*, 2021). Reorienting healthcare systems to preventive approaches face challenges around remuneration to providers, and traditional economic approaches using quality-adjusted life years (QALYs) may not be appropriate for oral health as discussed in section 3.4. Techniques which measure broader value, with more patient-centred outcomes, including process of care may be more relevant (Listl *et al.*, 2022; Vernazza, Birch and Pitts, 2021; Boyers *et al.*, 2021).

Given the links between oral and systemic health, public health strategies look to utilise a common risk factor approach to the prevention of non-communicable diseases (NCDs) (Sheiham and Watt, 2000). Good hygiene practices and a healthy diet are fundamental to caries management, alongside many other NCDs which carry significant morbidity, mortality and cost, such as obesity, cardiovascular disease and diabetes. The primary aetiological factors in caries are all modifiable, and patients, dentists, physicians and their wider teams, public health practitioners and policy makers all have a role to play in optimising healthy choices and positive change.

Caries prevention can be separated into three elements, primary, secondary and tertiary prevention. Each will be described in turn.

Primary prevention aims to maintain a disease-free state and requires strategies involving policy makers and public health services, dentists and the general public. Examples include sugar taxes and water fluoridation (Office for Health Improvements and Disparities (OHID, 2022); Department of Health and Social Care (DHSC, 2022)). Increasing resistance to the disease, for example through the use of fluoride, in its many guises, at both the population and individual level, have also been shown to be beneficial (Marinho *et al.*, 2013; Walsh *et al.*, 2019; ten Cate, 2004), as can additional technologies which modify the biofilm through the use of probiotics, reduction of sugar consumption, slowing down of bacterial metabolism and supporting of saliva functions (Twetman, 2018).

Secondary prevention looks to arrest and potentially reverse the progression of early, clinically detectable caries prior to cavitation. This should be specific to the individual and relies on early detection. It acts through prevention of further demineralisation, and promoting remineralisation through non-invasive, or micro-invasive interventions (Schwendicke *et al.*, 2020). Non-invasive interventions include oral hygiene advice, fluoride application and dietary advice. Micro-invasive interventions constitute caries sealing and infiltration techniques without prior excision of tissue. Lesion behaviour should be closely monitored over time and personalised caries risk assessment periodically reappraised to appropriately manage the disease.

Once cavitation has occurred and the lesion is no longer cleansable, operative (invasive) intervention is required. This is sometimes referred to as tertiary prevention. Expert consensus has been published on when and how to intervene in the caries process (Schwendicke *et al.*, 2019; Schwendicke *et al.*, 2020) (which is summarised in Figure 2.3). Evidence suggests that the advised thresholds are often not adhered to, and perhaps not well known, with primary care clinicians commonly indicating that they would intervene earlier than advised (Schwendicke *et al.*, 2018a; Schwendicke *et al.*, 2022; Chana *et al.*, 2019).

2.6.3 Overview of the restorative process

Modern operative dentistry looks to prevent these unwanted sequelae by intervening at an appropriate time. It involves removing some of the diseased tooth tissue, the amount of which is commonly based on a risk assessment of where the caries extends to, a knowledge of the disease process, the lesion structure and reparative capacity of the tooth (alongside the clinical evidence base). A number of operative caries removal approaches have been described for the definitive restoration of teeth including non-selective (complete), where all of the caries is removed, and selective approaches where some of the caries is left. These will be described in more detail in the following sections.

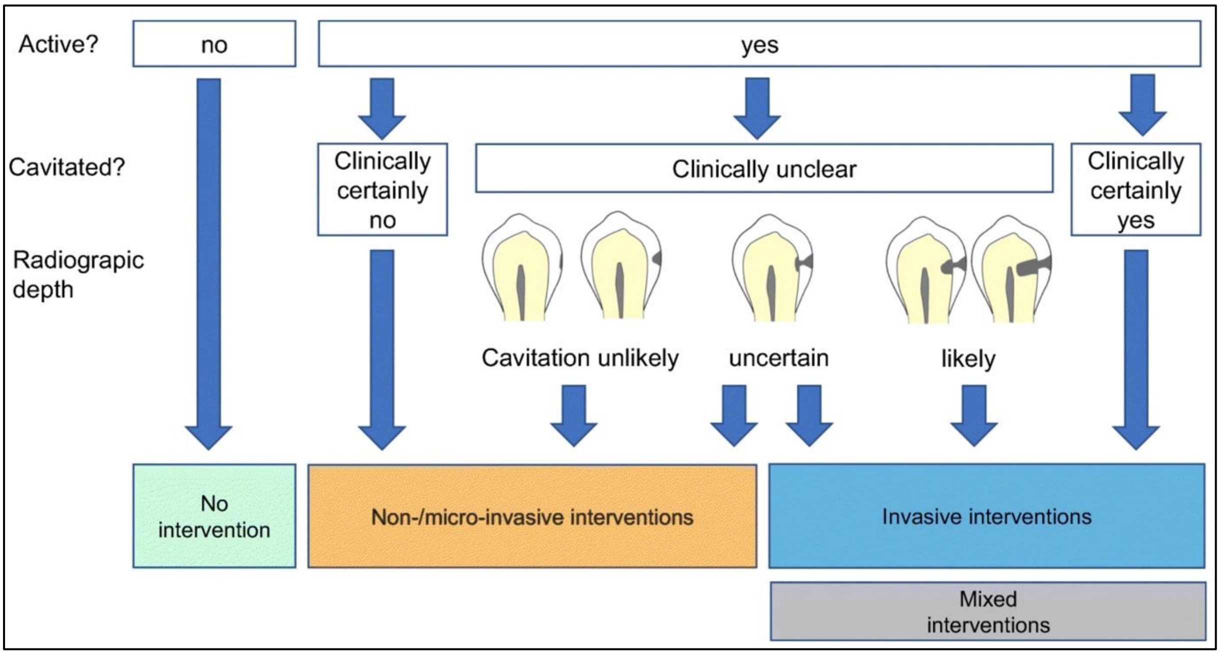


Figure 2.3. When to intervene in the caries process

Reproduced, with permission [Appendix B], from Schwendicke et al., 2020.

Micro-invasive interventions constitute caries sealing and infiltration techniques without prior excision of tissue.

The cavity formed is then restored to the original shape of the tooth, with the aim of allowing ongoing pain free function, facilitating the formation of an environment for the tooth to repair itself, and allowing easy cleaning. The cavity can be restored by using initially soft materials which are placed directly into the tooth by the clinician and then harden (direct approach), or by recording an impression of the cavity (or preparation) allowing a rigid restoration to be fabricated outside of the mouth, usually in a laboratory, which is then cemented or bonded into place by the dentist (indirect approach, including crowns and onlays). The direct method is more commonly used, as it is cheaper and quicker and can be done in one visit (though single visit indirect techniques are becoming increasingly available). However, as a tooth becomes more broken down, there are advantages to using the indirect method. These include restoring the rigidity of the compromised tooth by using stronger materials, which provide protection against fracture of the remaining tooth structure, and an improved ability to build the tooth back to an ideal shape, as it is made outside the confines of the mouth. This can help to prevent food impaction and more accurately recreate the biting surface to aid function, for example.

There are various materials available for the direct restoration of teeth, which include resin-based composites (composites) of various formulations, amalgam, glass ionomer cements (GICs) and resin modified glass ionomer cements (RMGICs). Broadly, composites, GICs and RMGICs are tooth-coloured (commonly referred to as white) in appearance, whereas amalgam is silvery/grey.

The different direct materials have differing costs and consequences, with differences suggested in terms of required sacrifice of tooth tissue, patient acceptance, the process of care, such as time required for treatment, post-operative complications, restoration survival and monetary costs for example. The materials need to be handled by the treating clinician in differing ways, often using different associated equipment and techniques. Composite materials also require the tooth to be dry and uncontaminated by blood or saliva, for example, for them to work optimally during placement, which isn't the case for amalgam (or GICs to a degree). This primarily relates to how the different materials are retained. Composite usually relies on a separate adhesive to bond it to the tooth, whereas amalgam is primarily retained by mechanically engaging undercuts in the cavity. It has been suggested that this makes composites more difficult to use especially where the cavity being restored extends under the gum (sub-gingivally), or in patients with limited cooperation (Kielbassa *et al.*, 2016; Lynch *et al.*, 2018b), because controlling the environment becomes more difficult in these situations. These elements will be expanded upon in the following sections.

Prior to staging of disease (as occurs with ICCMS), and an awareness of the potential for arrest and repair of early carious lesions, what would now be considered an aggressive excisional approach was favoured for even caries confined to enamel. It included a philosophy of extending cavity preparations to supposedly prevent progression of caries, by providing large clear disease-free margins, and also to include other areas of the tooth deemed ‘at risk’ of future caries activity (Black and Black, 1924). Preparations were also designed around mechanical principles, requiring retention and resistance form to prevent displacement and dislodgement of the non-bonded restorations. The mechanical properties of the direct restoratives used was also a consideration in terms of amount of tooth preparation. This was to ensure an adequate thickness of material was used to prevent its fracture. In summary, the retention and resistance to fracture of the restoration were the primary guiding principles in cavity preparation which often involved fairly judicious sacrifice of sound tooth structure. The main directly placed restorative material at this time was amalgam, though alternatives, for example gold leaf, were also used.

These principles were commonly based on the erroneous belief that such restorations would last a lifetime, which was still suggested as a possibility in the 1970s by authors promoting a more conservative approach to amalgam restoration placement (Almquist, Cowan and Lambert, 1973). Given that most operative dentistry is performed to replace failed existing restorations (Mjör *et al.*, 2002), this was misguided.

Cavity preparation for amalgam restorations evolved, but there was quite a lag from Black’s initial suggestions at the beginning of the 20th century, until more minimally invasive approaches were published in the 1970s. Preparations became much more conservative as the biological rationale for caries and its management emerged.

The finding that the carious lesion in dentine could be separated into two distinct layers- the more superficial caries infected zone, and the deeper caries affected zone (Fusayama, Okuse and Hosoda, 1966), as previously discussed, proved to be pivotal in changing operative dentistry. The same group of researchers went on to recognise the potential clinical benefit suggesting that the caries infected dentine (with micro-organisms) should be removed, but the deeper caries affected dentine could be left. This was based on the finding that the collagen scaffold was intact in the affected zone and therefore able to remineralise. This was experimentally supported by animal models (Kato and Fusayama, 1970) and human studies (Miyauchi, Iwaku and Fusayama, 1978).

These findings, allied with emerging technologies which allowed materials to bond to tooth structure, meant that a complete shift in the way cavitated carious lesions could be managed was proposed (Hosoda and Fusayama, 1984). These changes resulted in the ability to conserve tooth structure, which reduced the mechanical weakening of the remaining tooth structure, whilst also reducing the risk of devitalising the dental pulp, and therefore more often avoiding, or at least delaying more invasive or complex treatment (extraction or root canal treatment (RoCT)) (Edwards *et al.*, 2021c).

2.6.4 Caries removal strategies

The main caries removal strategies for vital teeth are non-selective, selective and stepwise (Innes *et al.*, 2016). The difference between selective and non-selective approaches is shown in Figure 2.4 (Edwards *et al.*, 2021c). All start with non-selective caries removal (determined by tactile sensation) at the periphery of the cavity in enamel and dentine which allows the creation of a restorative seal. They differ in their central excavation endpoint.

Figure 2.4. Caries removal endpoints based on strategy
CID, caries infected dentine; CAD caries affected dentine. Adapted from, and first published in, Edwards et al., 2021c.

It is very difficult, if not impossible to determine clinically where the boundary lies between the infected and affected dentine. Many excavation techniques have therefore been suggested and appraised in an attempt to predictably remove the infected dentine, but leave the affected dentine, based on the previous work which showed a difference in the potential of the differing tissues to remineralise. The feel of the dentine, in terms of its resistance to penetration by a dental probe or hand instruments (usually spoon excavators), though obviously fairly subjective, is still deemed the best way of reaching an appropriate endpoint (Innes *et al.*, 2016; Schwendicke *et al.*, 2016).

With the selective technique, the endpoint changes based on how deep the cavity is. If it is thought that there is no risk of exposing the pulp in shallow or moderately deep cavities, soft tissue is removed to optimise the adhesive bond and provide a firm base under the restorative material which favour restoration longevity. Selective excavation to firm dentine is therefore preferred. The need to remove all of the infected dentine over the pulp in deep lesions has subsequently been further challenged. Consensus guidance suggested that in deep lesions, soft caries can be left over the pulp to avoid exposing it (Schwendicke *et al.*, 2016; Dummer *et al.*, 2019). The bond to soft dentine is reduced, but soft dentine is only left in a small area of the cavity. It has been shown that sealing soft caries into the tooth can reduce viable bacteria, arrest and remineralise even disorganised infected dentine and induce tertiary dentine formation protecting the pulp, with favourable clinical outcomes seen (Bjorndal *et al.*, 2019; Bitello-Firmino *et al.*, 2018). This justifies the guidance in taking a risk-based approach to caries removal based on cavity depth, though this concept has been challenged and is currently an area of debate between professional organisations (Ricucci *et al.*, 2019; AAE, 2021; Duncan *et al.*, 2021).

A recent RaCT supported this guidance when treating deep carious lesions with a selective caries removal approach to firm versus soft dentine (Gözetici-Çil *et al.*, 2023). It also showed that teeth with exposed pulps managed with recommended techniques (Edwards *et al.*, 2021d; Dummer *et al.*, 2019) (where bleeding was arrested with hypochlorite and calcium silicate cement (CSC) was placed as a liner) fared less well than those without exposures in terms of maintenance of pulp vitality in the short-term. Research in the UK shows these recommended materials and techniques for manging the exposed pulp are rarely used however, especially in NHS practice (Edwards *et al.*, 2021b). The RaCT described (Gözetici-Çil *et al.*, 2023) also showed that where no pulp exposure was seen, lining with CSCs versus not placing a lining had no effect on success, suggesting that in the absence of an exposure, a lining is not required under a composite restoration. Longer-term results would be useful however as this goes against most previous guidance (Schwendicke *et al.*, 2016; Dummer *et al.*, 2019) where a liner was advised prior to restoring deep caries. Liners were suggested to act as a barrier to prevent penetration of resin monomer through the permeable carious dentine, which was thought to irritate the pulp, and also to prevent resin bonding to the weakened carious dentine which risks its fracture when the composite restorative material shrinks and pulls on the bond when setting (polymerisation contraction stress). Another RaCT supports a no liner approach when excavating to firm dentine in deep lesions (Singh, Mittal and Tewari, 2019). A Cochrane review advises against the use of liners in non-deep cavities under composite restorations (Schenkel and Veitz-Keenan, 2019), alongside expert guidance (Blum and Wilson, 2018), and the previous studies discussed involved restoration with composite. Liners have however been advised under deep amalgam restorations, to prevent thermal damage to the pulp because of their increased conductivity (Schwendicke *et al.*, 2016). However, evidence suggests that whilst liners may reduce the duration of post-operative sensitivity in amalgam restored teeth, after 90 days there was no difference in the liner versus no liner groups (and no residual sensitivity in any of the restored teeth, including deep cavities) (Al-Omari, Al-Omari and Omar, 2006). The relevance of this to patients is uncertain.

Since the publication of the guidance previously mentioned (Schwendicke *et al.*, 2016; Dummer *et al.*, 2019), systematic reviews suggest that selective caries removal may be more appropriate than the stepwise approach in terms of clinical success (Barros *et al.*, 2020; Yao, Luo and Hao, 2023), whilst also having other compelling advantages, such as improved treatment efficiency, with reduced number of treatment visits required for the patient, and therefore direct and indirect costs.

2.6.5 Material-based considerations

When the appropriate amount of caries has been removed, it is necessary to consider if the cavity requires modification prior to restoration. This may be required to provide undercut to help retain the chosen restorative material, which is relevant for mechanically retained restorations such as amalgam. It may also be prudent to smooth restorative margins to optimise bonding (Peumans *et al.*, 2021) and alter their location slightly so they are not at the contact area with the adjacent tooth. This facilitates effective matrix band placement allowing the subsequent restoration to have a cleansable shape, and allows appropriate finishing of the restoration margins and direct observation and maintenance of the restoration over time (Bailey, 2021). Cavities for amalgam are commonly more box-like, closed and upright, whereas for composite they commonly have more flare, are open and saucer, or C-shaped, which relates to how the materials are retained (Banerjee and Domejean, 2013; Bailey and Stone, 2021).

Air-borne particle abrasion is beneficial to clean the cavity, remove any loosely adherent enamel prisms, homogenise the smear layer in preparation for bonding and improve dentine bond strengths prior to placing composite restorations (Lima *et al.*, 2021), but the equipment is costly.

In posterior teeth bevelling of margins prior to placement of composite is a controversial topic. It depends on the location and marginal substrate (dentine or enamel), with evidence for and against in different locations (Opdam *et al.*, 1998; Isenberg and Leinfelder, 1990; Apel *et al.*, 2021). It can be technically difficult to perform without the use of expensive specialised ultrasonic equipment. It is generally not advised however, to avoid unnecessary sacrifice of tooth structure. This occurs when placing bevels, but also when replacing restorations in teeth with bevelled cavities, as the restoration appears larger than it actually is, which risks overcutting of the tooth during removal. Placing thin sections of composite in areas of high occlusal load renders them prone to fracture (Isenberg and Leinfelder, 1990). Moving from an enamel margin to a dentine margin results in an increased chance of bond breakdown over time and therefore restoration failure. Some popular modern restorative systems are now advocating an approach which includes occlusal bevels (Burgess and Hassall, 2023), but are currently unsubstantiated in the literature.

2.7 Direct restorative materials

The main direct restorative materials will be described in turn followed by a discussion of techniques and considerations relating to the different materials. Later sections will then further discuss and summarise the differences between the materials.

2.7.1 Amalgam

Amalgam is a silvery-grey alloy of primarily mercury, silver, copper, tin and zinc. High copper amalgams are almost universally used now eliminating the gamma 2 phase which historically made the material weak and susceptible to fracture and corrosion. It comes encapsulated with the liquid mercury separated from the other solid metal alloys. It is then mixed in a triturator forming a soft malleable mass which can be applied directly to a cavity and firmly packed and condensed. This favours adaptation of the material to the cavity and minimises marginal gaps. It hardens through an amalgamation reaction over time, with an initial set of around 3-8 minutes, but takes 24 hours to develop its maximum strength, which renders it susceptible to early fracture. It is dimensionally stable undergoing a very small expansion on setting, again limiting the likelihood of peripheral gaps at the interface with the tooth, which are a common source of restoration failure (see section 2.17). Amalgam is quick and relatively easy to place. It is technique insensitive, so can be used successfully in difficult situations, such as where it is challenging to keep a cavity dry. This may include clinical situations where cavity margins extend sub-gingivally or patients have limited cooperation. It demonstrates good strength, wear resistance and general clinical performance exhibiting superior longevity to composite in most meta-analyses (see section 2.15). It is however unaesthetic, can (very rarely) exhibit galvanic issues, 'ditch' at the margins, (though this is very rarely a clinical issue (Operative Dentistry, 2005)), and contains mercury, which has been posited as a risk to clinical personnel, patients and the environment. These issues will be further explored in section 2.11.

2.7.2 Composite

Resin-based composite materials are made up of solid glass or ceramic filler particles embedded in and coupled with an initially fluid resin monomer matrix. They contain various initiators which can be activated in different ways, allowing the resin matrix to undergo a polymerisation setting reaction.

All of these constituents are varied by the different manufacturers, producing subtly different variants with differing properties. The term composite is therefore an umbrella term which represents a broad collection of materials that can be classified in many different ways. The most commonly used restorative composite classifications are filler particle size and load, whether a material is light, chemically or dual cured (a combination of both methods), the handling characteristics- whether the material is flowable or paste-like, and whether the composite is a bulk-fill or conventional material. These will be discussed in turn.

Composites can be classified by the size of the filler particles they contain. Hybrid composites have a range of filler particle sizes, whereas microfill composites have only small filler particles. Hybrid composites generally have a higher percentage of filler by volume, which in turn influences the material properties in both set and unset states. Nano-filled composites are essentially hybrid composites, due to clumping of nanoparticles into nanoclusters. The filler particles are often forms of glasses, ceramics or salts.

By widely varying the filler particle sizes, hybrid composites contain an increased concentration of filler particles compared to microfills, which results in superior physico-mechanical properties, other than polishability and retention of polish, and they are therefore recommended for use in posterior teeth. A recent systematic review with meta-analysis on longevity of direct tooth-coloured posterior restoratives classified the different composite materials as hybrids, microhybrids, nanohybrids or bulk-fills (Heintze *et al.*, 2022). Bulk-fills are hybrids of various kinds however and may be flowable or paste-like. Manufacturers sometimes advise that flowable bulk-fills should not be left exposed to the oral environment, or at least not used to restore the occlusal surface due to concerns over wear resistance and strength, which in turn necessitates that they are covered by a hybrid composite again potentially of different compositions. Bulk-fill paste-like composites have no such requirement however, which clearly makes the classification in this paper spurious. Bulk-fill composites are discussed in more detail later in this section. The systematic review concluded that there was no difference between the different formulations in terms of overall longevity, colour stability, surface texture and fracture incidence however. A subsequent broader review focussed on composite concluded that the material is of limited importance for restoration longevity, and the patient and operator are much more significant (Demarco *et al.*, 2023). The importance of prevention and managing patient specific risk factors in controlling caries and secondary caries has previously been discussed, so this comes as no great surprise. The importance of the operator will be explored throughout this chapter.

With restorative composite materials, polymerisation most commonly occurs by light activation, but can occur chemically or by a combination of both modes, referred to as dual curing. Light curing allows a relatively large working time to sculpt the composite to the appropriate shape, before allowing the material to be command set, but it also limits the depth of material which can be placed per increment, as the light must penetrate the full thickness of the material to cure it. Multiple increments commonly have to be placed and individually cured, which is not the case for chemically or dual cured composites, so can be more time consuming. Light curing commonly results in an increased degree of conversion of the resin monomer (which is still incomplete) and no need for mixing which incorporates porosity compared to chemical curing, resulting in better physico-mechanical properties of the set material. This creates an increased and more rapid shrinkage however, which results in increased interfacial polymerisation contraction stress compared with chemically or dual cured composites (Rawls and Whang, 2019). This can result in gaps between the tooth and restoration, and flexure and cracking of the surrounding tooth if not managed by using an appropriate placement technique (Rosatto *et al.*, 2015). The tooth may then suffer from microleakage, sensitivity, fracture or recurrent caries which may result in early failure of the restored tooth. Light-curing composite at the base of deep class II cavities can be difficult for many reasons. The light intensity is attenuated in air proportionally by the square of the distance for example, and as metal matrices are commonly used to recreate the shape of the missing tooth and prevent restorative material from sticking to the adjacent tooth, they completely block the light if care and attention is not taken with the positioning and angulation of the light-curing unit (LCU). This can result in unset material at the base of the cavity which can contribute to restoration failure as discussed later in section 2.17. This can be improved by thoroughly light curing the composite from the lateral aspects of the restoration after removal of the matrices, but there is risk of contamination from oral fluids after removing the matrix.

Conventional flowable composites generally have a reduced filler load compared to conventional paste-like composites. This difference in viscosity aids their adaptation to the cavity, but negatively impacts their physico-mechanical properties and generally increases the interfacial polymerisation contraction stress because of the increased linear shrinkage (Rawls and Whang, 2019). For these reasons they are commonly applied as a thin layer at the base of a cavity. They are also used in the injection moulding or 'snow-plough' technique, where they are applied in a thin layer and not cured, before a paste-like composite is applied into the unset material under pressure, displacing the flowable material to the periphery of the cavity and reducing gap formation (Opdam *et al.*, 2002; Bailey, Shand and Ellis, 2023). Any paste-like composite can however be made more flowable by applying heat whilst a similar effect can be created by application of sonic energy to specific paste-like bulk-fills which again complicates the classification somewhat.

There are now a huge number of bulk-fill composites on the market with varying constituents and handling, and all behave differently (Van Ende *et al.*, 2017). They can be placed in larger increments than conventional composites (commonly 4 or 5mm compared to 2mm) for light-cured composites due to their increased depth of cure and reduced development of interfacial contraction stress (Van Ende *et al.*, 2017). These properties are generally achieved by using more translucent constituents and patented resins which allow the light to penetrate further. The materials do not necessarily shrink less, but do develop reduced interfacial polymerisation shrinkage primarily by utilising novel resins (Van Ende *et al.*, 2017).

Composite materials often become outdated as companies release newer formulations. This means that materials used in trials are often unavailable when medium-term data are available on their performance which can be problematic (Opdam *et al.*, 2018). An important point to note however is that whilst the modern composite materials have been shown to have little influence on clinical survival, there is no clinical data on 'own-brand' or private label materials which are sold by many large distribution companies. These materials have incredibly limited scientific data and are much cheaper than branded materials (Burke, 2013; Burke, 2017). Anecdotally they are increasingly being used by dentists, under increasing economic pressures, to run viable businesses (Burke, 2013). The very limited evidence on these materials is mixed (Johnsen *et al.*, 2017; Shaw *et al.*, 2016) suggesting own-brand composites may be better avoided (Burke, 2017).

Fibre reinforced composites have recently been developed and show some promise in vitro, though their clinical benefits are as yet uncertain (Bompolaki, Lubisich and Fugolin, 2022). Research is underway into antimicrobial and 'self-healing' composites suggesting future directions of development (Bompolaki, Lubisich and Fugolin, 2022; Rawls and Whang, 2019).

2.7.3 Composite application techniques

Most companies supply their paste composites in both compule and syringe form to cater for clinician preference. The syringe is usually slightly cheaper per quantity of composite and may result in less waste, both in terms of packaging and composite. A study showed that application of paste bulk-fill composite from a compule in a composite gun, which injects the material into the cavity, is quicker than from a syringe where the material is applied using an instrument (Tardem *et al.*, 2019).

Factors other than the material can influence polymerisation contraction stress, including the mode of polymerisation, the LCU, and the configuration of the cavity (C-factor- which is the ratio of bound to unbound surfaces of a cavity) for example. Composite placement techniques developed to reduce this damaging stress (Bailey and Stone, 2021).

In the conventional layering technique, individual 2mm increments of composite are placed which do not connect across the cavity. This limits the bound surface area of composite in relation to unbound (effectively reducing the C-factor), allowing stress dissipation when each increment is individually cured. This therefore minimises the development of interfacial contraction stress. The technical execution of this can be difficult however, especially in small cavities. Horizontal layering with bulk-fill materials is technically easier to perform, faster and overcomes the need to dissipate damaging stresses, even in small, high C-factor cavities, though the different materials behave differently (Van Ende *et al.*, 2016). It has also been shown to improve marginal adaptation and reduce inter-layer voids. This is especially so when used with a snow-plough, or injection-moulding technique using composite compules in a gun to allow application of the material under pressure, even with inexperienced operators (Bailey, Shand and Ellis, 2023; Leinonen *et al.*, 2023). Voids are an important factor related to failure of restorations as discussed later. A clinical RaCT with medium-term follow-up showed reduced marginal staining, but no survival difference with a paste bulk-fill composite (Yazici *et al.*, 2022). Equally a flowable bulk-fill composite covered with a conventional paste hybrid composite showed similar medium-term survival to a conventional layered composite (van Dijken and Pallesen, 2017). This technique requires more than one type of composite which could be more costly and has been shown to take longer than the paste bulk-fill approach, though both are quicker than the conventional technique (Leinonen *et al.*, 2023; Bellinaso, Soares and Rocha, 2019; Güler and Karaman, 2014). A paste bulk-fill was quicker to apply from a compule than a syringe, both of which were quicker than conventional composite placement (using a syringe, which was not stated in the paper but was clarified by the author through personal communication) (Tardem *et al.*, 2019). There is likely more waste (of composite and packaging) associated with compules however and they are usually slightly more costly. Bulk-fill materials are often more translucent than conventional materials to allow light penetration, so can appear a little grey and less aesthetic than conventional composites, which are available in a wider range of shades and opacities and potentially can be more aesthetic. Conventional dual-cured composites have been remarketed as bulk-fills, with many of the advantages and limitations of chemical curing that have previously been discussed.

2.7.4 Glass Ionomer (polyalkenoate) Cements

Traditional GICs set by an acid-base reaction between powdered glasses and polymeric acids. The components can be mixed by hand or automatically when encapsulated. These materials form an inherent bond to tooth structure, though this can be improved by prior conditioning of tooth tissues with polyacrylic acid. GICs can release fluoride, though this is limited after the first two weeks and of uncertain clinical benefit. GICs have high solubility, low compressive strength and fairly lengthy setting times. Manufacturers have termed newer GICs with varying glass particle sizes 'glass hybrids' which are claimed to have improved physico-mechanical properties. They are also being combined with resin coats in an attempt to improve their opaque appearance and wear-resistance.

Resin materials have been combined with various elements of GICs resulting in different materials with different properties, which include compomers and RMGICs. Compomers have more of a resin component and set primarily by polymerisation, whereas RMGICs set by both polymerisation and an acid-base reaction. They aim to improve the physico-mechanical properties of GICs, also allowing them to be command set, whilst still retaining their inherent ability to bond to tooth structure, which does not need such stringent moisture control in comparison to composites.

There is a perception that GICs and RMGICs are commonly used for minimal load-bearing class V restorations and provisional direct load-bearing restorations. It is however uncertain if these materials are being used regularly in primary care for definitive posterior load-bearing restorations in permanent teeth.

A recent systematic review with meta-analysis showed that various GICs and compomers had significantly reduced lifespans compared to composites, and demonstrated other shortcomings, including excessive wear and surface roughness (Heintze *et al.*, 2022).

Another recent systematic review and meta-analysis compared high-viscosity GICs with resin coating and composite for restorations in posterior permanent teeth with alternative findings however (Cribari *et al.*, 2023). All studies involved Equia Forte Fil with Equia Forte Coat, or precursors of this from the same manufacturer (Equia Fil, Equia Coat, Fuji IX GP Extra and G-Coat Plus). None of the included studies had a follow-up of more than 3-years. The authors concluded that HV-GIC and composites presented similar clinical performance in conservative class I and II cavities in posterior permanent teeth. There was some evidence of increased wear in the HV-GIC groups.

2.7.5 Newer self-adhesive restorations

Manufacturers have understandably tried to make tooth-coloured materials which do not need a separate application of bonding agent as amalgam alternatives. They have had limited success however. A self-adhesive flowable composite had significantly inferior restorative outcomes in load bearing areas at 2-years' follow up compared to conventionally placed flowable composite (Sabbagh *et al.*, 2017). Research has been published on two novel, patented self-adhesive materials from separate dental manufacturers, 3M and Dentsply Sirona. Both show promise, but clinical follow up is limited (Rathke *et al.*, 2022; Cieplik *et al.*, 2022).

2.8 Material retention

Direct restorations can be retained in a cavity adhesively, mechanically or both. Adhesive retention involves bonding the restoration to the tooth chemically or micro-mechanically. This can either occur naturally, as part of the material's interaction with the tooth substrate during setting, as is the case with GICs, RMGICs and self-adhesive composites, or with the prior placement of a bonding agent. Bonding agents act like a glue, sticking the material, most commonly composite, but also amalgam (Eakle, Staninec and Lacy, 1992), to the tooth. Macro-mechanical retention for direct restorations involves the set material engaging physical undercut in the cavity preparation to prevent its displacement. Mechanical methods alone can be used for the retention of amalgam, but whilst they can help to provide retention for composite, they are not advocated by themselves. This is because amalgam undergoes a very minor expansion whilst setting and is capable of creating a marginal seal, preventing ingress of bacteria, fluids and carbohydrate, for example. Composite shrinks when it sets however, having a tendency to pull away from cavity walls and margins, leaving gaps if not bonded in place (and the contraction appropriately managed). This can then result in post-operative sensitivity and microleakage which may lead to CARS as discussed later in section

2.17.2. Composite should therefore be used with an appropriate bonding agent. The bonding process is very technique sensitive, and requires that the tooth is dry and uncontaminated by blood or fluids from the oral cavity (a naturally wet environment). This can be difficult to achieve, especially in difficult situations as previously discussed. Amalgam is much less technique sensitive, being much more forgiving of cavity contamination (Kielbassa *et al.*, 2016), but extra tooth preparation to provide undercuts may be necessary if they don't already exist, which is (slightly) more destructive of tooth tissue.

Resin bonding agents enable the functional attachment of a restorative material to tooth structure. Enamel, being inanimate and dry, allows the formation of predictable and durable bonds. In contrast, dentine is living, subject to change and moist, making bonding more variable, technique sensitive and susceptible to degradation (Van Meerbeek *et al.*, 2020). Avoiding contamination of a tooth with oral fluids is critical during the process of achieving an effective bond (Chen *et al.*, 2024). This requires isolation of the operative field. The common methods of achieving this are described later in this section.

Enamel bonding is primarily micromechanical, facilitated by its differential acid etching. This creates a pitted surface into which a low viscosity bonding resin can flow and set (usually on command by using a LCU) forming tags which provide micromechanical retention. Subsequently the restorative material is applied and chemically attaches to the bonding agent, adhesively bonding it to the tooth.

Different acids are used depending on bonding technique. Total-etch systems employ phosphoric acid, which is applied and then rinsed away, whereas self-etch systems use weaker acidic primers which are left on the tooth. Clinical data has shown that phosphoric acid etching of enamel results in reduced staining and marginal breakdown of restorations compared to self-etch systems (Heintze and Rousson, 2012). This reduces the tendency for clinicians to reintervene, as staining can easily be mistaken for caries (Operative Dentistry, 2005) as discussed later in section 2.17.2. Whilst it may seem that the use of self-etching systems is therefore inadvisable, they offer certain advantages when it comes to bonding to dentine. The issue of the inferior enamel bond can also be overcome by selective enamel etching with phosphoric acid prior to placing the bonding agent (Van Meerbeek *et al.*, 2020). Confining the placement to enamel can be very difficult however and inadvertent placement onto dentine can reduce the dentine bond strength considerably (Van Meerbeek *et al.*, 2020).

Bonding to dentine is more complex and varies depending on the type of bonding system used, but can result in high bond strengths, even surpassing those obtained with enamel (Van Meerbeek *et al.*, 2020). The bond strengths vary considerably however depending on the condition of the dentine- for example if it is caries affected or not. There is a suggestion that self-etching systems are less technique sensitive and therefore more predictable to use than total-etch systems (Van Meerbeek *et al.*, 2020). There is no risk of over-etching the dentine and no subjective judgement required by the clinician on how damp to leave the dentine prior to applying the bonding agent, which there is with total etch systems and these can markedly impact bond efficacy (Van Meerbeek *et al.*, 2020). The dentine bond resulting from both bonding systems predictably breaks down over time, especially where cavity margins are in dentine and the bond is therefore exposed to the mouth (De Munck *et al.*, 2003; Tjäderhane, 2015). Using systems with separate priming and bonding agents (two bottle products in both bonding systems) can slow, but not stop the degradation process (Perdigao, 2020). However, manufacturers have focussed on developing single bottle systems which are cheaper, quicker and simpler to use, potentially at the expense of ultimate clinical efficacy. Modern universal bonding systems can be used in both total- and self-etch ways and though most are single bottle systems, two bottle systems are recently available. They overcome the issue of inadvertently getting phosphoric acid on dentine when selective enamel etching making the technique more predictable (Van Meerbeek *et al.*, 2020).

Again, bonding agents are very expensive, and cheaper own-brand versions exist, which have no scientific data to support their use (Burke, 2017).

Keeping the tooth dry is critical when adhesively bonding composite restorations to allow the effective formation of a functional attachment. Though a sealed rubber (dental) dam (RD) is seen as the ideal technique used to achieve this, adequate relative isolation using cotton wool rolls and saliva ejectors, for example, may suffice (Miao *et al.*, 2021; Lynch *et al.*, 2014). A RD has the added advantages of improving the enamel bond (Falacho *et al.*, 2023), preventing contamination of an exposed pulp and protecting the airway. It can also prevent equipment, debris and fluids from traumatising the oral cavity and gastro-intestinal tract or being ingested, whilst also reducing bioaerosols during operative procedures (Balanta-Melo *et al.*, 2020). RD is more expensive than the alternatives, may take longer to apply than alternatives, requires further specialised equipment and its effective application is potentially more difficult, especially in patients with poor cooperation. Isolating the most posterior tooth in an arch with RD whilst enabling restorative procedures can be awkward, especially without additional, specialised equipment. Obtaining a seal in cavities with sub-gingival margins can be very difficult without taking steps to manage the soft tissues, or employ additional techniques to raise the restorative margin (Bailey and O'Connor, 2019; Lührs, Jacker-Guhr and Herrmann, 2018). Some patients will not tolerate RD use. Amalgam placement does not require such stringent isolation however, which makes it technically easier to place and provides more predictable outcomes in the difficult situations discussed.

Compromised adhesion may result in a poorly sealed cavity leading to loss of the restoration, post-operative sensitivity, CARS or fracture of the restoration or tooth and need for further treatment. Some of these are discussed in more detail in section 2.17.

2.9 Matrices

As discussed, caries commonly occurs where teeth contact one another and requires operative removal when it progresses beyond a certain point. Matrices are used to help rebuild missing tooth walls, and to avoid sticking teeth together or the creation of marginal ledges. Failure to achieve these goals can make the restored tooth difficult to clean, which potentially increases the risk of future caries and periodontitis (gum disease) (Millar and Blake, 2019; Operative Dentistry, 2005).

Additionally, failure to create a contact area between the restored and adjacent tooth in an appropriate location can lead to food impaction in the area, which can be uncomfortable for patients and is anecdotally a common cause of complaint. It may also potentially increase the risk of caries and periodontitis, though research commonly cited to support this is cross sectional or opinion-based and therefore contentious (Hancock *et al.*, 1980; Jernberg, Bakdash and Keenan, 1983).

Matrices are available in numerous shapes and sizes, made from various metals or plastics and they may be contoured or flat, and circumferential (wrap the whole tooth) or sectional (partial wrap). Sectional matrices are usually contoured, and when used in conjunction with wooden wedges to seal cavity boxes and provide separation of teeth greater than the width of the matrix, are very useful to achieve contact areas posteriorly with composite (Bailey, 2021). Contacts can be difficult to achieve with simple inexpensive flat circumferential matrices due to the relatively passive nature of composite placement, whereas this is not the case for amalgam as it is actively compacted against the band. The formation of tight contact areas can also be facilitated by the use of separating rings and anatomically shaped plastic wedges (Gomes *et al.*, 2015; Saber *et al.*, 2010), though their use can result in negative outcomes (Bailey, 2021; Bailey, Shand and Ellis, 2023). The various materials and equipment also vary significantly in price, with expensive equipment often being advised when using sectional matrices (which are generally much more expensive) for composite restorations.

Using different matrices can affect the proximal shape of direct posterior composite restorations which can impact on their patient-centred outcomes (though minimal evidence currently exists to support this contention), subsequent failure, and need for replacement or repair, as summarised in

Figure 2.5.

As more tooth structure is lost, and margins extend deeper sub-gingivally, placing a well-adapted matrix-wedge (sometimes with an added separating ring) assembly to directly restore a tooth becomes much more challenging. Because the marginal seal is not as critical for amalgam, they are often favoured in these more difficult situations (Aggarwal *et al.*, 2019; Jebur *et al.*, 2023). Composite restorations can however be successful in these difficult situations, though they commonly require additional steps, for example by using multiple different matrix bands per case or managing the soft tissues (Opdam *et al.*, 2010; Loomans and Hilton, 2016; Bailey and O'Connor, 2019) (Opdam, personal communication, 2023).

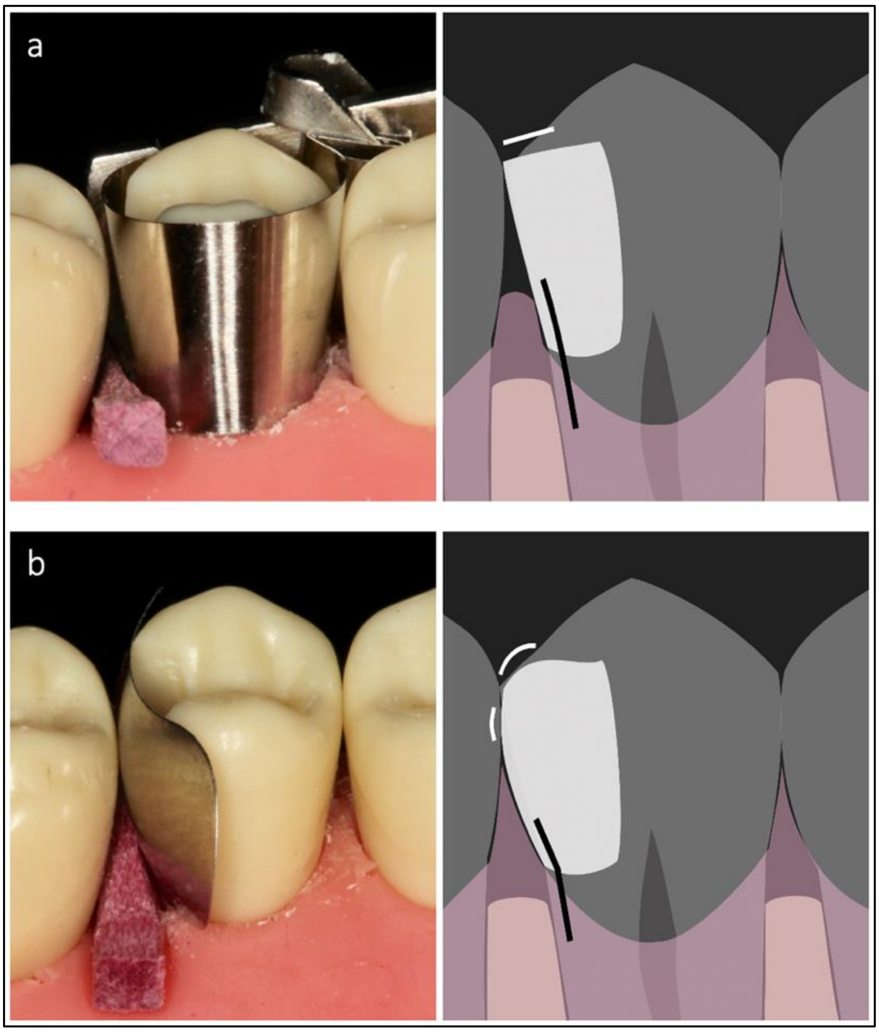


Figure 2.5. Matrix differences

Reproduced from, and first published in, Bailey, 2021

a) Contact point not achieved or positioned high up adjacent tooth. Marginal ridge thin and unsupported and more susceptible to fracture (Loomans *et al.*, 2008). Embrasure flat and therefore susceptible to catching and shredding floss (Bailey, 2021). Non-anatomical 'flat' cervical emergence coupled with high contact results in tendency to inter-proximal dead space allowing food packing which can be uncomfortable for patients.

b) Contact area broader and lower. Marginal ridge more anatomically positioned and supported allowing unimpeded floss access and reducing fracture tendency. Anatomical cervical emergence allows complete interproximal papilla infill.

2.10 Periodontal response to sub-gingival restorative materials

A large cross-sectional study showed that amalgam restorations with intra-crevicular margins had statistically significantly increased probing depths and clinical attachment loss than composite restorations (Collares *et al.*, 2018). Another cross-sectional study, with smaller sample sizes showed the opposite effect however (Al-Fawaz, Alofi and Diab, 2017). These study designs have many obvious limitations including the lack of baseline measures prior to providing restorations and the considerable risk of indication bias (the situation dictating the choice of material, for example) which limits the confidence in the conclusions drawn. Some histological studies support the biocompatibility of composite restorations with the periodontium, as do their sub-gingival use in combination with periodontal plastic surgery without causing gingivitis or periodontitis (Ercoli *et al.*, 2021). Other evidence has shown increased inflammation around sub-gingival composite restorations and increased bleeding on probing when using composite for deep margin elevation procedures (which raise the restorative margin with composite prior to providing indirect restorations) when the distance between alveolar bone and restorative margin was 'approximately less than 2mm' however (Chun *et al.*, 2022). The clinical significance of these findings is uncertain.

2.11 Restorative material safety, policy and regulation

A thorough Canadian Drug and Health Technology Agency (CADTH) health technology assessment (HTA) comparing amalgam and composite restorations included a narrative review titled 'Historical Overview of the Amalgam Debate' (Khangura *et al.*, 2018). It showed that debate over the safety of amalgam has existed for well over a century, with many still asserting the danger of amalgam restorations. It went on to conclude that the evidence showed no clinically important differences in the safety of amalgam compared with composite to both patients and dental personnel which was supported by a Cochrane review on the topic (Worthington *et al.*, 2021). The known risk of a localised lichenoid reaction in the mucosa adjacent to amalgam restorations was shown to be very low (Gupta *et al.*, 2022).

In its 2015 document, 'The safety of dental amalgam and alternative dental restoration materials for patients and users', the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2015) acknowledged that dental amalgam is an effective restorative material but noted a shift away from its use in the EU due to concerns about mercury. It suggested that alternatives like tooth-coloured materials are increasingly preferred. It stated that whilst dental amalgam can cause rare local adverse effects in the oral cavity, its systemic effects, primarily related to mercury, are a subject of debate with weak evidence for significant harm. The report identified fish consumption and dental amalgam as the main sources of mercury exposure to the general population, noting that dental personnel may also be exposed during placement and removal of amalgam fillings, but that studies showed no significant adverse effects.

It noted that alternative dental materials have their limitations and toxicological hazards, with limited clinical data on their adverse effects. The SCENIHR did not rule out the use of either dental amalgam or alternatives but recommended considering patient characteristics, allergies and renal clearance when choosing materials. It called for further research on the neurotoxicity of mercury from dental amalgam, genetic factors influencing mercury toxicity and the toxicity profile of alternative dental materials. Additionally, a need for the development of more biocompatible materials was suggested.

A 2020 policy statement published by The International Association of Dental Research (IADR) (Ajiboye, Mossey and Fox, 2020) said:

> *"On the basis of the best available evidence, the IADR affirms the safety of dental amalgam for the general population without allergies to amalgam components or severe renal diseases. The IADR supports maintaining its availability as the best restorative option when alternatives are less than optimal for clinical, economic, or practical reasons.*
>
> *The IADR supports the phase-down strategy described in the Minamata Convention on Mercury. Consistent with the recommendations of the treaty, the IADR emphasizes the need, first, for increased oral disease prevention efforts to reduce the need for any kind of restorative material and, second, for further research on new biocompatible and environmentally friendly restorative materials and approaches that are proven to have equal or improved clinical longevity and cost-effectiveness when compared with amalgam restorations."*

The World Dental Federation (FDI) echoed this statement in a policy document, and provided limited guidance on alternative material choices (Schmalz *et al.*, 2024).

The safety of the alternatives has not been thoroughly investigated, but there are multiple reports of resin allergy involving patients and dental personnel (Barber and Dhaliwal, 2018; NCPA, 2012). The FDI policy document concluded that providers should protect themselves from this possibility by employing a no-touch technique when handling resin-containing materials (Schmalz *et al.*, 2024). It also suggested protection against the damaging effects of blue light from LCUs and the use of copious water spray when adjusting or removing composites to mitigate the inhalation or ingestion of micro-particles which are released during such processes. There are also health concerns surrounding some of the monomers used in composite, for example bisphenol A (BPA) and the potential environmental impact of waste microplastics which are produced (Mulligan *et al.*, 2018). A recent review stated that the environmental safety of composite is currently uncertain (Mulligan, Hatton and Martin, 2022). Similarly, the Canadian HTA concluded that whilst the environmental impact of the release of mercury from amalgam was small, the impact from composites was unknown (Khangura *et al.*, 2018).

The UNEP promoted the need for international regulation in controlling the use and environmental impact of mercury. It resulted in the 'Minamata Convention on Mercury' global treaty being agreed in 2013 which advised a global phase-down of amalgam (UNEP, 2013). This has been implemented by the European Parliament, who introduced an amalgam phase-down in July 2018 restricting its use in certain groups whilst also stating that the feasibility of a phase-out by 2030 should be investigated (*Regulation (EU) 2017/852*, 2017). The provisions relating to dental amalgam are listed below:

- **Article 10(1)**: from 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form.
- **Article 10(2)**: from 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15-years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.
- **Article 10(3)**: a requirement for a national plan, by 1 July 2019, on measures to phase down the use of amalgam.
- **Article 10(4)**: from 1 January 2019 a requirement for dental facilities to be equipped with an amalgam separator.

The Conference of Parties (COP), a regular follow up to the Minamata Convention, also agreed to the global implementation of these measures at its fourth iteration in 2022 (Minamata Secretariat, 2022). Mercury mining and international trade is also now limited, which will likely have consequences for the manufacture, supply and costs of amalgam in the future (Hurley, 2022). Dental amalgam has a relatively low impact environmentally (as previously discussed), especially when disposed of appropriately, but some is still converted to active methylmercury in the environment by microbes, with the potential for it to get into waterways and have harmful effects.

The CADTH HTA stated costs from amalgam waste management could occur at the practice level, at water plants, and as a result of the consequences of mercury reaching surface water (Khangura *et al.*, 2018). It deemed the performance of amalgam separators sufficient to make other costs negligible. As stated, use of amalgam separators is a legal requirement in the UK, and when combined with sewage purifying plants, it is estimated that 99% of mercury from dental amalgam in wastewater is removed before reaching the natural environment (Mulligan *et al.*, 2018). Modern suction units commonly have inbuilt amalgam separators, with no specific maintenance costs advised beyond standard suction maintenance. Separate amalgam separators can be purchased and retrofitted to existing suction units however.

Cremation is the preferred method for disposal of bodies in the UK, and mercury vapour is released if amalgam restorations are present. Emissions can be reduced by 90-98% through use of various mercury abatement systems. The Institute of Cemetery and Crematorium Management (ICCM) estimated 70% of crematoria in the UK have such systems in place (ICCM 2021). Electric machines have these inbuilt as standard, with many other benefits posited over traditional gas machines from a manufacturer (CDS, 2019). Guidance considered that mercury emissions should be considered a key environmental issue, particularly for unabated plants though it appears that there are no legal requirements around this or statutory air quality standards for mercury (ICCM 2021).

The Department of Health and Social Care (DHSC) published a policy paper 'National plan to phase down use of dental amalgam in England' (with each of the home nations publishing similar plans) in 2019 as required by Regulation (EU) 2017/852 2017 (DHSC, 2019). It focussed on a movement towards caries prevention, promotion of a minimal intervention approach to restoring teeth at all levels of dental education and the need for an NHS dental primary care system which incentivises a focus on prevention by trialling a new approach.

The Scottish Dental Clinical Effectiveness Programme (SDCEP) have released guidance for practitioners based on the new requirements, as have the British Dental Association (BDA), to help communicate the changes to patients, alongside helpful printable explanatory leaflets for patients addressing many of the potential concerns (though the BDA guidance is only available to members) (SDCEP, 2018).

A recent concise review of the alternatives based on a World Dental Federation (FDI) policy statement concluded that there is no single material which can replace amalgam in all applications, but focussed on direct posterior composites (Schmalz *et al.*, 2024). It recognised the difficulties which would be faced following an amalgam phase-out, and the limitations of the current materials and data saying,

> *"Further basic and clinical research is needed to improve overall material properties and to demonstrate their clinical performance (particularly in real-world settings and for special risk groups). Greater understanding of the wider impact of using these materials in terms of implementation and oral health economics is needed".*

Composite has been described as the only reasonable alternative to amalgam in the proposed time frame for the phase-down and -out of amalgam (Lynch and Wilson, 2013). Whilst this appears to discount GICs and their derivatives, there has been some more recent evidence to suggest that they may be valid alternatives for small cavities as previously discussed, though follow-up is limited (Cribari *et al.*, 2023). Their acceptance and use as definitive load-bearing posterior restorations in UK primary care is uncertain however.

2.12 Healthcare systems

2.12.1 Provision of care

In the UK, the vast majority of restorations are performed in primary care general dental practices by dentists and a smaller, but growing, number of dental therapists (Centre for Workforce Intelligence, 2014). The key differences between dentists and therapists in the UK are that therapists:

- can provide simple fillings, scaling and deep cleaning direct to patients, or under the guidance of a dentist, but not more complicated procedures like crowns, root canal treatments or replacing missing teeth, which are performed by dentists.

- are registered dental professionals required to study at university for 2-4 years to gain a diploma or degree, rather than 5-years as required for a dentist to gain their degree.

Dental professionals in the UK need to be registered with the General Dental Council (GDC). To maintain registration, they must be indemnified, and dentists are required to perform 100 hours of continuing professional development in a five-year cycle, whereas the requirement is 75 hours for therapists. Some are employed and salaried, but the vast majority are self-employed. These requirements are commonly paid for by the individual.

Primary care dental services in the UK are delivered in a mixed market through NHS (publicly funded with co-payments for many) or private systems. Individual clinicians often provide dentistry through both systems to varying degrees.

Private provision of dentistry is increasing in the UK. This can be supplied as fee per-item of care or unit of time, or it can be insurance-based, with general or dental-specific providers, providing varying levels of cover. Some of these systems include any laboratory fees for indirect restorations and prostheses made by technicians, such as crowns, bridges or dentures for example, whereas others do not.

Where treatment complexity is increased due to patient cooperation factors, patients are often referred to community dental services (CDS), which is NHS funded and still subject to NHS related charges (see following section 2.12.2). CDS clinicians are most commonly general dentists who are salaried, so increased time can be spent with patients who are more difficult to treat without remunerative penalties. This is often still seen and referred to as primary care, as it most commonly does not involve a GDC registered specialist.

2.12.2 NHS dental services

NHS dental services were free at the point of delivery when introduced in 1948 and subsidised entirely by public taxation. Primarily due to the high caries prevalence at the time, it soon became apparent that this was not affordable, so the service changed in 1951 to include co-payments for most service users. Patients (when not exempt from charges) paid a set percentage of the overall fee, with the NHS providing the rest. The patient paid 80% when this contract ended in 2006. People exempt from patient charges include children under 16-

years-old, those under 19 who are in full-time education, pregnant women, mothers of children under 1 and various financially disadvantaged adult groups.

Prior to 2006, primary care NHS dental services operated under a universal national contract, without local input, and paid dentists on a fee-per-item basis. This meant that the system incentivised treatment over prevention, and perhaps over-treatment, while having minimal control over where services were delivered and total expenditure. It was shown that exempt patients were treated more intensively by self-employed GDPs than those who were salaried, suggesting financial incentives affect dentists' provision of services (Chalkley and Tilley, 2006). This could reflect overtreatment or a wish to optimise care in disadvantaged patients with high needs (Tickle *et al.*, 2011). The contract fundamentally changed at this point, capping the budget and introducing locally commissioned dental services with the aim of responding to need and improving access to care where it was most required. The patient fee, and remuneration structure also changed considerably, being simplified into three bands based on the highest complexity of work required to render a patient dentally fit in any course of treatment (rather than the number of items within a course of treatment), with the aim of limiting overtreatment and focusing on prevention. These three bands attracted set patient fees, and provided dentists with set numbers of Units of Dental Activity (UDAs) (more for more complex work). Practices working within the system are contracted to perform a set number of UDAs per financial year. The remuneration for a UDA was negotiated at the practice level but was based, to a degree, on historical earnings and activity under the old contract (Tickle *et al.*, 2011), and therefore showed much variation amongst providers. The average price of a UDA has been calculated as £29.32 by the BDA in September 2023 (Diddee, personal communication, 2023). The system remains structurally similar in its current guise, but has changed a little, with two new sub-bands recently introduced (NHSBSA, 2022). These generate more UDAs for clinicians, but the three patient fees still remain (NHS, 2023a). The patient charges did increase significantly by 8.5% April 2023 however. The current bands under which treatment falls are shown in Table 2.1 along with the patient fees and UDAs accrued.

Band		Procedures covered		Patient charge (£)	Units of Dental Activity (UDAs)
1		Examination, diagnosis, advice. Radiographs, scale, preventive treatment as required		25.80	1
2	a	All elements in band 1, plus:	up to two definitive fillings and treatment for periodontal disease	70.70	3
	b		non-molar endodontics or a combined total of three or more teeth requiring definitive fillings or extractions	70.70	5
	c		molar endodontics	70.70	7
3		All elements in Bands 1&2, plus more complex procedures, such as crowns, dentures and bridges which generate a laboratory fee		306.80	12
4		Emergency treatment		25.80	1.2

Table 2.1. National Health Service Dental Service treatment bands, patient fees and Units of Dental Activity
(Correct as of February 2024)

The system has been criticised for basing remuneration simply on activity, which it was trying to move away from (Chestnutt, Davies and Thomas, 2009). Until recently (2022), a patient needing fillings in all their teeth alongside multiple root fillings, for example, would remunerate the dentist the same as if a single filling was required. This contract therefore inevitably has a tendency to move clinicians towards under-treatment, which has been explicitly admitted by dentists working in this system (Mcdonald *et al.*, 2012), with no real incentivisation for prevention. A document on 'phased treatment planning' was published in 2021 aimed at improving this situation for a dentist. It suggested that up to three courses of treatment could be provided (and were chargeable) in a year to deal with patients with extensive disease. This would allow stabilisation and appraisal of a patient's cooperation with preventive advice before deciding whether to definitively manage disease. This situation was expected to be a rarity however and use of this approach was to be monitored (NHS, 2021).

The numbers of treatments for certain common treatments seen before and after implementation of the changed contract were published, which showed fewer restorations (simple and complex), RoCTs and hugely reduced numbers of radiographs alongside increased extractions after implementation (Tickle *et al.*, 2011). It also potentially perversely incentivises certain specific Band 3 treatments such as extracting rather than saving teeth (with time consuming and technically complex Band 2 RoCT) and providing cheap acrylic dentures for example, therefore not promoting high quality dentistry (Tickle *et al.*, 2011; Mcdonald *et al.*, 2012; Steele *et al.*, 2009; Health Select Committee, 2009). Again, the changes could be a result of a level of overtreatment under the previous system, but likely reflects issues with both systems (Tickle, 2012). A similar situation arose in Germany where fee reductions were introduced for RoCT, which led to a marked reduction in provision of RoCT and increase in extractions. This then reversed when the fee reductions were abandoned (Rädel *et al.*, 2015) (Hickel, personal communication, 2024). These data clearly reflect that incentive structures can have huge impacts on provision of dental treatment. Tickle et al., 2011 concluded that, 'the data we report suggest that the desire to maintain and increase income is a powerful one and may override or dilute ethical motivations', which was explicitly demonstrated in a qualitative study (Mcdonald *et al.*, 2012). They also suggested that there was significant goal ambiguity in NHS dentistry which was highly problematic and that policy makers must have a clear understanding of what they want the service to achieve before designing remunerative structures to mitigate against unintended consequences as demonstrated in their findings. Tickle noted in 2012 that there was a rapidly growing divide between resources and demand, with the need for significant cost savings throughout the NHS. He also noted a reduction in dental need, but inequalities in access and utilisation of NHS dental care, with demand-led provision of services of uncertain efficacy. He concluded that basing all elements of the service on a needs-based approach was logical, but was a political decision carrying much political risk (Tickle, 2012).

Although basic data can be obtained from the new system as described above, it is very difficult to get a clear picture of service provision since 2006 because of the banded remunerative structure and the limited clinical information submitted by the treating dentist. This has meant that the available data is of very limited use in understanding and planning dental service provision in England and Wales.

All of these failings were highlighted a long time ago, but very little has been done, despite repeated calls for change. This has resulted in dentists leaving NHS provision in large numbers, with more dentists leaving the service than joining for the first time in 2019/20 and subsequent to that, since the advent of the new contract (NHS England, 2023). Additionally, many more dentists who have remained within the service have also reduced their NHS commitment, resulting in many patients being unable to access NHS care and being forced to take treatment into their own hands (BDA, 2022).

Northern Ireland and Scotland did not adopt the UDA system, maintaining a fee-per-item service which can incentivise over-treatment. Exemptions from payment are broader in

Scotland than in the Northern Irish and UDA system, but paying patients covered 80% of the treatment cost in both countries until recently when Scotland adopted a blended contract based on patient fees and capitation, where general fees are paid to a practice based on the number of registered patients (NHS Scotland, 2023). There is a capped patient contribution of £384, regardless of the total cost of treatment. The Northern Irish system has over 400 separate charges for individual treatment items (similar to the previous Scottish system, now reduced and simplified) and has been criticised for being too complex, favouring over-treatment and incentivising provision of the highest paid option to the detriment of patients (NHS Scotland, 2023; NI Direct, 2023).

£2.9 billion was spent on NHS dentistry in England in 2022/23, falling by over a third in real terms since 2010 (BDA, 2024a). This represents just 1.6% of the total NHS budget. The government have suggested that more money is available, but it is not being spent due to struggling dental practices unable to hit their targets. They introduced the changes to band 2 treatments described in response to record numbers of dentists leaving the service and promised a recovery plan, but the BDA have said that there is currently a recruitment and retention (of clinicians) crisis affecting primary care NHS dentistry (BDA, 2024a). There is currently an issue of accessing NHS dental care, with news coverage again stating that desperate patients are pulling their own teeth out (BDA, 2024a).

2.12.3 Broader dental health services and comparative costs

Health systems vary considerably, even across Europe (Sinclair, Eaton and Widström, 2019). It is very difficult to compare the fee received for a single posterior restoration in England and Wales with other countries because of the UDA system, and therefore it is more appropriate to compare a course of treatment. A study published in 2019 involved a questionnaire being sent to oral-health policy makers in 12 European countries (Eaton *et al.*, 2019). It outlined a simple course of treatment, including two restorations, one a simple disto-occlusal posterior restoration with some preventive advice and scaling. Questions were then asked about the costs. The fee paid to the dentist for the course of treatment in England was €72, as a band 2 treatment and the fee in Scotland was €123.60. The fees in the other countries ranged from €158-603, with an average of €307. Fees contributed by the governments of the countries involved varied from nothing in Spain and Italy, to 100% in Hungary if the practice has a contract with the government. This shows the significant difference in remuneration that exists in the UK compared to other European countries.

As an example, in the Netherlands, dental fees are set by the government, and they cannot be varied. In 2023, the Dutch fees for a two-surface posterior restoration were €73.92 for a composite, or €47.17 for an amalgam, but both would likely also require local anaesthetic (€17.60), and application of RD cost €13.30, for example (Lassuss Tandartsen, 2024). In Scotland the fee for a similar restoration is £22.25, but this includes local anaesthetic. There is a supplement of £10.60 payable if composite is used (for example in patients or situations stipulated in EU Regulation 2017/852 2017), but other than for this stipulation, it cannot be claimed if the restoration involves the occlusal surface (NHS Scotland, 2023). The English NHS purports to provide 'any clinically necessary' dental care (NHS, 2023b). This means different things to different parties, and it is not currently clear what can and cannot be provided under NHS provision, as demonstrated in a recent court case (Veal, 2023). This is often taken to mean that an amalgam restoration is the default option under NHS provision with composite being offered as an aesthetic choice available under private provision (Pandya *et al.*, 2024). Composite can be provided and is provided under NHS provision (though not commonly) (Lynch *et al.*, 2018b), but there is a lack of clarity in the NHS contract with what can and cannot be provided. An extensive review published in 2012 following the phase-out of amalgam in Norway reported that the patient charges were 33-50% higher for composite compared to amalgam, which was an average increase of €51 per filling for all fillings at that time (NCPA, 2012). The increases in fees alone over 10-years ago in Norway are comfortably higher than the current costs of any direct restoration in Scotland, as an example. These increases were generally borne by the adult patients, which is important to bear in mind when considering the next section which looks at the lessons which can be learnt from countries which have already phased-out amalgam, when applying this to the English, primarily publicly-funded, adult dental services. It should also be noted that, as previously described, composite restorations are more expensive than amalgam in all health systems for either funders, patients or both, except for the NHS in England and Wales, where they cost the same. This makes the service unique.

2.12.4 ***Lessons from countries already phasing-out amalgam***

Norway and Sweden banned amalgam use in the late 2000s. Many other, primarily affluent, countries, including the Netherlands and Finland have also hugely reduced their amalgam use and the current EU mandated phase-down drew heavily on the phase-down employed by these countries as discussed in a UNEP document (UNEP, 2016). A review of the ban in Norway reported generally positive experiences with the alternative materials (NCPA, 2012). However, there were increased costs associated with the phase-out which were generally related to increased time required to place restorations and their more frequent replacement (NCPA, 2012; Kopperud *et al.*, 2016). There were also reports of allergy in both patients and dental personnel, as previously discussed and amalgam use was low prior to the ban. As previously stated, the increased costs of treatment were generally borne by adult patients. Understandably, there are concerns of how this would translate to health care systems where amalgam use is still high (Lynch *et al.*, 2018b), with a large publicly-funded element such as the NHS with limited access to care, and that this may lead to a widening of already existing oral health inequalities (Aggarwal *et al.*, 2019).

2.13 Differences between amalgam and composite

To understand the long-term implications of an amalgam phase-out, it is necessary to understand the differences between amalgam and composite restorations. Studies tend to focus narrowly on restoration survival, but the materials vary broadly in other ways which are potentially important to patients, clinicians and funders, as will be discussed. These factors can affect uptake of treatment and access to care which can indirectly affect oral health consequences. These consequences cannot be divorced from a consideration of the differing costs in any healthcare system with limited funding, as this can affect outcomes, and are an important factor in their own right. The following sections will therefore outline the differences in materials, ultimately exploring how these differences can affect long-term health outcomes, relating this to an NHS primary care context.

2.14 Clinical outcomes

The relative clinical outcomes between amalgam and composite are often fiercely contested (Wahl, 2012), with a balanced discussion of the evidence base rarely taken. Relevant clinical outcomes include post-operative issues, such as sensitivity and food packing, restoration survival, failure mode and mode of reintervention, which might ultimately relate to tooth survival. These will each be discussed in the following sections.

2.15 Restoration longevity

Reported restoration longevity outcomes vary in meaningful ways. Data are generated with different experimental designs and in differing settings, over variable periods. It is therefore prudent to first give an overview of these differences in the context of dental restoration or tooth longevity, teasing out the potential reasons for variation in the parameter estimates and suggesting the most appropriate data to use for the subsequent economic evaluation.

Restoration success, survival or failure can be defined in different ways and mean subtly different things. For example, in some studies 'failures' amenable to repair are not deemed failures (Tobi *et al.*, 1999), whereas in others they are (Opdam *et al.*, 2008). In some, repaired restorations, or re-cemented indirect restorations for example, may be classified as 'survived', but not as 'successful' (Opdam *et al.*, 2012; Collares *et al.*, 2016). These definitions are not used consistently however. In large database studies failure is inferred by reintervention. This may underestimate survival, for example if another, separate occlusal restoration is placed on the same tooth. Equally they may overestimate survival, where failed restorations are left untreated, or treatment is carried out under different arrangements (for example private rather than NHS in the UK) and therefore not recorded in the database.

Survival data may be presented in different ways, including annual failure rates (AFRs) (Beck *et al.*, 2015), Kaplan-Meier survival, success or reintervention curves (Heintze *et al.*, 2022) which may be modified (Lucarotti, Holder and Burke, 2005), risk differences (Kunz *et al.*, 2022), risk ratios (RRs, the survival of one restoration in relation to another over a specific time frame) (Schwendicke *et al.*, 2018b), hazard ratios (HRs) (Laske *et al.*, 2019a), failure index (Burke, Singh and Wilson, 2013), survival of failed restorations statistic (discussed in section 2.15.3), median survival time (Antony *et al.*, 2008) or combinations of these. There can be much heterogeneity, often making it difficult to compare or combine data.

There is also a problem of defining when a restoration has failed. In the absence of signs or symptoms obvious to a patient causing them to arrange an appointment outside their usual recall period, age at failure will often relate to the recall period, or when the patient attends.

The time of failure is clearly often not a well-defined point and therefore open to debate which will, in turn, influence parameter estimates, whatever the experimental design. Different clinicians will inevitably suggest intervention at different times (and in different ways as alluded to in section 2.6.1), and this difference is commonly described as indication bias. In studies without randomisation and control groups, this is always present. It could also be argued however, that with randomisation, shared decision making is not truly happening as the choices of the individual and clinician are impacted making the process biased, which will likely select for inclusion of a certain type of person who is unlikely to represent the population.

Materials can affect restoration survival, however many other factors can too which are potentially more important. It is therefore useful to have an overview of the influences on restoration survival and the data sources upon which this is based. Some studies relate a single variable (such as age for example), to restoration outcome data (Lucarotti and Burke, 2018a). This is a very simple model (univariate analysis) of restoration failure and can show a correlation. Many other factors can affect restoration survival however, and if these aren't controlled for, the correlation may be misleading. Multivariate analyses are therefore preferred as they are based on more realistic models of restoration survival (Laske *et al.*, 2019a). Univariate analyses are simple and easy to perform, whereas multivariate analyses can be much more complex, often requiring large amounts of data in terms of both numbers of cases and variables, which therefore require significant computational power.

A recent review (Demarco *et al.*, 2023) investigating longevity of composite restorations, found risk factors for failure included those at the patient-level, tooth-level and operator-level. It concluded that the materials used had minor effects on longevity in general (but it focused on different composite restorations and did not include amalgam). This did however come with the caveat,

> *"assuming that materials and techniques are properly applied by dentists".*

This may be a significant issue in primary care and more important for composite than amalgam restorations, as will be explored. The review did seem to allude to this issue in stating that, *"there is room for cost-effectiveness studies with different composites and adhesives in various clinical scenarios, including large public health systems".*

When attempting to understand the implications of an amalgam phase-out, it is necessary to understand that they will be affected by these variables and many others, including societal norms, health care systems and the prevalence of caries in the population, alongside clinicians appropriately implementing prevention, non-operative and operative intervention and reintervention. There is limited evidence suggesting that UK primary care clinicians are often not managing caries appropriately due to multiple complex factors which need to be addressed (Chana *et al.*, 2019; Edwards *et al.*, 2021a; Pandya *et al.*, 2024).

Restoration survival may be affected by surfaces involved, cavity size (not just surfaces involved), which tooth is being restored- molar or premolar, and also by arch- maxilla or mandible. These differences at the tooth-level, including if a RoCT is present can influence survival (Demarco *et al.*, 2023; Burke and Lucarotti, 2018a).

Patient-level variables can affect restoration survival, including age, ability to cooperate, disabilities (especially intellectual), socio-economic status, the nature of the surrounding teeth or prostheses, the oral environment and caries or parafunctional risk status (Demarco *et al.*, 2023). They can be influenced by lifestyle choices (sugar consumption, stress) and the local environment (for example water fluoridation) as previously discussed in section 2.6.2. Operator-level variables, such as experience, changing clinician (i.e. moving practice), the diagnosing, educating, presenting of treatment options and execution of treatment can have an influence which can be affected by the remuneration for and the system in which this interaction takes place (Lucarotti, Holder and Burke, 2005; Laske *et al.*, 2016). The clinician's education and guidance from scientific institutions (current guidance on caries management differs between the AAE and ESE based on different interpretations of the literature), may be important, or not (Edwards *et al.*, 2021b), alongside governmental policy and insurers' decisions. Socio-cultural norms and values likely influence many of these factors, as do economic constraints and how patients value their teeth or interventions (Antony *et al.*, 2008; Lord *et al.*, 2015; Pandya *et al.*, 2024). The disease and intervention processes are complex and carry uncertainty. This thesis will however now primarily focus on the impact of the direct restorative materials. Broad literature searches were performed as outlined in Appendix C to inform this.

2.15.1 Material-based survival data

Evidence which can be used to obtain estimates for survival and failure of restorations and teeth vary in their experimental design, which can have meaningful impacts on the results. They broadly include RaCTs, prospective cohort studies, cross-sectional studies, retrospective analyses and systematic reviews and meta-analyses with varying inclusion criteria. The following sections will discuss how such studies vary in their estimates of restoration survival, their relative advantages and disadvantages and their relevance to the decision problem.

2.15.2 Randomised controlled trials

RaCTs are commonly used to assess efficacy of restorative materials and techniques without selection bias. Restorations are assessed through the use of accepted extensive clinical trial criteria (United States Public Health Service or FDI (Hickel *et al.*, 2023)) often by calibrated, blinded examiners. Such trials are very expensive in terms of time and cost. They are therefore often performed on small numbers of patients over short follow-up times with materials which are often outdated and replaced by the time they are published. There are also often low patient recall rates over longer time frames. Failure rates are often very low, commonly because treatment is performed by highly skilled clinicians (who know their work will be observed and assessed by others) in academic environments, and high-risk patients are often excluded. Patient samples are therefore often not representative of the populations from which they are taken (Schwendicke and Opdam, 2018; Opdam *et al.*, 2018). Recommended techniques and materials are used in these trials which were not regularly used in UK primary care over a decade ago in a survey (Gilmour *et al.*, 2009), but no recent data exists. A review of direct posterior restoration longevity studies published 2005-2015 showed that 20% of prospective studies had no failures. A large majority of prospective studies had <100 restorations included, <5-years follow-up and either did not include information on patient risk factors such as caries risk and parafunctional habits or excluded them from the study, and therefore did not perform multivariate analyses to understand risk factors for failure (Opdam *et al.*, 2018).

It has been shown that failure rates increase after 5-years of follow up in RaCTs (Beck *et al.*, 2015) which likely skews estimates when including shorter-term studies. This will be discussed further in the following sections when considering failure over time and failure modes.

Whilst having high internal validity, the external validity of such 'gold standard trials' is often low due to exclusion criteria and non-representative recruitment of patients. Such studies also often understandably exclude large restorations, or those with deep sub-gingival margins as potential confounders, but these restorations are commonly faced in primary care and carry higher risk of failure (Laske *et al.*, 2016; Opdam *et al.*, 2018). RaCTs often show the potential survival of restorations under ideal conditions but are not particularly useful for understanding how restorations are surviving at the population level (Opdam *et al.*, 2018).

2.15.3 Non-randomised data

Many cross-sectional analyses have been published, collecting data on age at failure of various restorations, and reporting median age of restoration failure as a metric of restoration performance (Forss and Widstrom, 2001; Sunnegardh-Gronberg *et al.*, 2009; Burke *et al.*, 1999). This has been discounted as a misleading metric often underestimating restoration survival (Opdam *et al.*, 2011). It can however also potentially over-estimate survival, as seen for example in a Swedish study, where amalgam had been banned years before. No new amalgam restorations had therefore been placed in the intervening years, so the failed amalgam restorations were inevitably only those which had survived since the ban years before, clearly skewing the data (Sunnegardh-Gronberg *et al.*, 2009). Any comparative inference drawn is at overwhelming risk of bias.

It is prudent to discuss the role of the clinician and patient in non-randomised studies from the outset. Widely divergent outcomes have been shown between operators or practices, even when many variables are controlled for (Laske *et al.*, 2016). Other long-term studies have shown inter-operator differences to be small however, for example accounting for less than 10% of the variation. This was based on large numbers of restorations (72573) performed by large numbers of dentists (2473) working within the Norwegian public health service (Dobloug, Grytten and Holst, 2014).

Different operator outcomes can obviously be explained to a degree by variation in technique or skill, (which may be controlled in a RaCT by standardisation and calibration), but are also dependant on their patient population (disease progression at presentation or intervention and their risk status for example). They are also potentially highly reliant on differences in treatment planning, which can lead to indication bias. This can be partially explained by patient desires and constraints (e.g. ability to pay), and constraints of the system under which the clinician is working (e.g. differential remuneration for modes of care), but also clinician beliefs and treatment philosophy, all of which are inter-related.

Later sections will look at how direct posterior restorations fail (2.17) and the more limited evidence on how clinicians subsequently re-intervene (2.18).

It has been suggested that survival of class II restorations should be assessed using prospective non-randomised longitudinal studies using practice-based data (Kopperud *et al.*, 2012). This has the advantage that greater numbers of restorations can be included and followed up for longer time periods, but also that advice on choices can be given by a clinician for that specific instance, with a decision then made reflecting the patient's preference. This does not happen in RaCTs as discussed. It has been suggested that non-randomised studies more accurately reflect general practice, and therefore intervention at the population level. Such studies have other problems however (some of which have been discussed and some of which will be explored in the following discussion).

A prospective longitudinal practice-based study involving 27 restoring dentists in Norway found that dentists preferred to place amalgam rather than composite in difficult situations (relating to high caries risk, greater lesion depth and more posterior tooth type, for example) though composite constituted the vast majority of placed restorations (Vidnes-Kopperud *et al.*, 2009). This is a clear example of indication bias, which means comparing the results obtained between the two materials without controlling for relevant clinical factors is inappropriate. This is always potentially an issue in non-randomised studies. It also then makes it inappropriate to combine data from different sources because there is inevitably heterogeneity.

So though prospective longitudinal studies are useful, with potentially more, and longer-term data, which may more accurately reflect the real world, they commonly involve a degree of selection bias in that they often involve a select number of clinicians who wish to participate and know their data is being analysed. It might be expected that they do not therefore accurately represent the population of clinicians, potentially having variable indication biases, so the data has limitations in relation to the current decision problem.

Retrospective studies have frequently been reported, commonly based on practice data, which may come from single (Opdam *et al.*, 2007) or multiple practices (Laske *et al.*, 2016), broadly having similar issues and benefits as non-randomised prospective trials, but with the added issue of incomplete or inconsistent data recording. Again, though comparative AFRs for composite and amalgam are commonly presented, there is often clear indication bias as previously discussed.

Retrospective studies can be very useful in collecting large sets of granular data with the cooperation of motivated clinicians to explore risk factors for restoration failure (Laske *et al.*, 2019a).

So called 'big data', often obtained routinely by insurance companies or payment records without any primary scientific purpose can be mined retrospectively (Raedel *et al.*, 2017; Rädel and Walter, 2019; Lucarotti and Burke, 2018a). They suffer similar issues to non-randomised observational studies, except that sufficient data may be analysed (whole population data in some situations) so that bias associated with self-selecting clinicians and concerns over representativeness of treated patients can be considerably reduced. Indication 'bias' still exists, but worries about sampling being non-representative are minimised. Clinical documentation is often absent, with a record of intervention often totally reliant on fee codes. In cases of reintervention it is therefore often uncertain if a restoration is being replaced, repaired or is separate to the new restoration. This could underestimate survival of the restoration if reintervention is taken as a proxy for failure of the restoration. Equally, failed restorations (for example those lost or fractured) may not be re-restored (especially if not causing symptoms), for many different reasons and would therefore not be captured by a claims database again potentially overestimating survival. Also many clinicians perform treatment under different systems or terms of service (for example privately rather than under NHS regulations in England), so restorations may be replaced privately without being recorded in specific payment records, which could potentially over-estimate survival. With such large numbers of cases, very small differences between groups may be statistically significant. Any differences should therefore be carefully interpreted for clinical relevance (Rädel and Walter, 2019).

Often missing from these data sets is the granularity to run multi-variate analyses, and the computational power required to run such regressions with huge data might be restrictive (Rädel and Walter, 2019). Therefore a truly complete and accurate understanding of the data from a population is often not possible. The quantity of data available can mitigate against some of the issues inherent in other smaller samples and offer an overall general view of clinical reality of a population in a specified health service however. A discussion of the available English NHS data follows in subsequent sections.

2.15.4 Meta-analyses

Many systematic reviews and meta-analyses have been performed reporting the longevity of direct restorations posing subtly different questions. The majority of these studies include only RaCT data (Worthington *et al.*, 2021; Khangura *et al.*, 2018). However, attempts have been made to combine data from non-randomised prospective and retrospective studies to provide AFRs for differing materials (Vetromilla *et al.*, 2020). Given the previous discussion, this is fraught with issues of data heterogeneity and indication bias and is therefore inappropriate. It is the reason why meta-analyses are usually confined to RaCTs.

2.15.5 Differences in outcomes over time based on study design

There is an incongruity between data from longitudinal observational studies and RaCTs relating to how restoration failure rates vary over time, though much heterogeneity exists. RaCTs tend to show low early failure rates, which then increase slightly over time (Beck *et al.*, 2015; Heintze *et al.*, 2022), whereas practice-based longitudinal studies tend to show slightly higher early AFRs, which then reduce over time (Laske *et al.*, 2019a; Lucarotti and Burke, 2018a) or are more linear (Laske *et al.*, 2016). Alongside the previously discussed reasons for these differences (perhaps most notably, high quality care), this may be explained by the exclusion of high-risk patients from RaCTs. In RaCTs composite restorations tend to fail early because of fracture of the tooth or restoration, before caries later becomes the main failure mode (Beck *et al.*, 2015; Astvaldsdóttir *et al.*, 2015). It is often not possible to account for such differences in failure mode in large datasets as data on so many potentially impactful variables are often unavailable, with huge numbers of other variables also not controlled for. Bruxists, or those with parafunctional habits, who are more at risk of fracturing teeth and restorations (Laske *et al.*, 2019a) are often excluded from RaCTs and therefore early failure rates are often low. In longitudinal observational studies, all of these at-risk patients remain which may explain why early failure rates are often higher. Even though high caries risk patients are often excluded from RaCTs, this then becomes the major failure mode over time in these studies, and AFRs rise, whereas the higher early AFRs in longitudinal studies reduce over a longer timeframe, likely because the restorations in high-risk patients, who are often excluded from RaCTs have failed and the lower risk restorations remain. Beck et al., 2015 noted this increase in AFR in prospective studies with less than 5-years of follow up and suggested shorter-term studies underestimate AFRs.

2.15.6 The English perspective

There is minimal data in the UK comparing amalgam and composite posterior restorations. One practice-based cross-sectional study was published in 1999 (Burke *et al.*, 1999) , concluding that amalgam provided significantly greater longevity than composite in posterior restorations, but the study used median age of restoration failure to estimate restoration performance which has been discounted as potentially misleading as previously discussed.

A very large dataset of England and Wales NHS claims first reported retrospective 11-year data on reintervention following restorative procedures at the tooth level from a very large random sample (including over 80,000 patients) in 2005 (Lucarotti, Holder and Burke, 2005). Multiple further analyses were then periodically performed and published which are potentially relevant to the decision problem. 15-year data were presented in a series of articles in 2018. The papers often present subtly different analyses with different time frames. Different analyses were performed into time to both reintervention and survival of the tooth following placement of amalgam restorations with varying surfaces involved and crowns in different tooth types, with and without RoCT (Burke and Lucarotti, 2018a; Burke and Lucarotti, 2018c; Lucarotti and Burke, 2018b; Lumley, Lucarotti and Burke, 2008). The mode of reintervention over time following direct restoration, RoCT and crown placement was also reported in different studies (Burke and Lucarotti, 2009; Lucarotti, Holder and Burke, 2005; Lucarotti *et al.*, 2014; Lumley, Lucarotti and Burke, 2008). Posterior composite restorations were not permitted in non-class V cavities at the time under NHS regulations however (Burke and Lucarotti, 2018b).

In the NHS setting, though reintervention rates for crowned teeth were lower than for directly restored teeth, tooth survival was reduced (Lucarotti and Burke, 2018a). This data is at high risk of indication bias however for multiple, previously discussed, reasons. Most notable here perhaps is that indirect restorations are likely performed on more broken-down teeth. The data is also old. No equivalent data has been available since 2006 due to the change in NHS remuneration as previously outlined.

2.15.7 Amalgam vs conventional composite restoration longevity

The vast majority of studies, including large retrospective studies, big data, RaCTs and meta-analyses show amalgam to have higher survival than composite (Worthington *et al.*, 2021; Heintze and Rousson, 2012; Käkilehto, Salo and Larmas, 2009; Kopperud *et al.*, 2012; Simecek, Diefenderfer and Cohen, 2009; Moraschini *et al.*, 2015; Khangura *et al.*, 2018). Despite explicit indication bias favouring the use of amalgam in difficult situations in a previously described Norwegian study, the mean AFR was lower in amalgam (1.6%) than composite (2.9%) at average 4.6-years of follow-up (Kopperud *et al.*, 2012). Nearly all of the practice-based studies where the survival of composite is the same (Palotie *et al.*, 2017) or (slightly) greater than amalgam (Laske *et al.*, 2016; Casagrande *et al.*, 2017) state the likelihood of indication bias, as amalgam was almost certainly used more frequently in more difficult situations where restorations are deeper and larger and often where moisture control cannot be obtained. Amalgam was only used in a relatively small number of the restorations placed in these studies (7-13%) which could account for these difficult situations, but could include other factors, such as ability of the patient to pay, for example. The difference was no longer significant when controlling for other factors (Casagrande *et al.*, 2017). Amalgam may also be replaced sooner than necessary for health or aesthetic reasons. This means that the AFRs are often not directly comparable.

A single private practice-based retrospective study with a novel design comparing large amalgam and composite restorations (involving ≥3 surfaces) was performed by experienced specialist Niek Opdam (Opdam *et al.*, 2010), often using multiple matrices for each composite restoration (Opdam, personal communication, 2024). The treatments were separated in time in that amalgams were placed exclusively 1983-1993 and composites 1996-2003 with a mix in the years in between (which were excluded from analysis). There was a potential change in indications for replacement/repair throughout this timespan and a possible improvement in technical expertise of the operator. Composite restorations with GIC liners were excluded – which were likely deeper restorations, and therefore makes the direct comparison of the materials questionable. Some amalgam restorations were also replaced for aesthetic reasons and were therefore not classified as survived (a small number).

At 12-years, the AFR was higher for composite (4.05%) than amalgam (3.85%) in high-risk patients, but lower in low-risk patients (0.88% composite compared to 2.05% amalgam). Low-risk patients made up the majority of the sample. The proportion of high-risk patients in this single cohort may also be lower than the English NHS population. An earlier study in the same practice showed no significant difference between composite and amalgam in smaller cavities (Opdam *et al.*, 2007).

Some studies do therefore demonstrate that composite restorations can show acceptable survival, rivalling and even surpassing amalgam in select groups in primary care with the caveats previously described. However, the use of amalgam has been low for a long time in the countries where the studies were performed and remuneration for clinicians is much higher than publicly-funded UK dentistry. It would be hard to suggest that these studies are translatable to NHS primary care dentistry.

In the most recent Cochrane review comparing composite versus amalgam for direct posterior restorations, the main data analysis, which included two large parallel group studies, found the RR for failure of composite compared to amalgam was 1.89 (95% confidence intervals (CIs) 1.52, 2.35, $p<0.001$) (Worthington *et al.*, 2021). The studies included both single surface and class II restorations with variable numbers of surfaces, with only one study presenting the disaggregated data (with 7-years follow up) (Bernardo *et al.*, 2007). It did include restorations in premolars, but the majority were in molars. However there were very minimal non-significant differences in mAFRs with each material between tooth type (mAFR 0.80 and 0.82 for amalgam and 2.18 and 2.21 for composite for premolars and molars respectively). Other studies have shown larger, significant differences however as previously discussed.

The data in the main Cochrane review analysis is made up of two studies in children and adolescents who often have higher caries rates (Vetromilla *et al.*, 2020). One study was set in a university (Bernardo *et al.*, 2007) and the other over mixed sites (Soncini *et al.*, 2007). It could be argued that the studies are more representative of primary care than most RaCTs as higher risk individuals were not excluded. Equally, it could be suggested that this skews the RR in favour of amalgam survival relative to an adult population. Similarly the studies tend to be a little older, as amalgam has barely been used in clinical trials in recent years, likely due to the planned phase-out. The composite materials and techniques have likely improved since then, but the bonding agents have not. Fourth and 5th generation bonding agents have been available for a long time and still have not been superseded by newer materials (Van Meerbeek *et al.*, 2020). Having said that, newer materials are potentially less technique sensitive, which may make them more appropriate for use in primary care (Burke and Mackenzie, 2021). The studies stated that the same technical processes of restoring the cavities were used aside from the different materials, but the details were not provided. RD was used 'where possible' in the Bernardo study. It is very likely that circumferential matrix bands were used, rather than sectional bands which are now recommended for composite restorations, as previously discussed. This is likely similar to the techniques used in UK primary care (Gilmour *et al.*, 2009), but recent data are not currently available. Five split-mouth studies were identified in the Cochrane review, however they were published in 1990 or before with 3-5 years of follow up. There was a big asymmetry in numbers of each restoration (more composite than amalgam restorations in each group in all trials) however. When split-mouth studies were analysed alone RR was 1.42; 95% CIs 0.90, 2.24. Overall RR (including parallel-group and split mouth RaCTs) was 1.78 (95% CIs 1.47, 2.17)

2.15.8 Bulk-fill vs conventional composite

Systematic reviews and meta-analyses show no significant differences between bulk-fill and conventional composites in terms of survival though they tend not to separate paste and flowable bulk-fills and follow-up is generally short-term (Veloso *et al.*, 2019; Arbildo-Vega *et al.*, 2020; Heintze *et al.*, 2022). A network meta-analysis presented in the appendix of a cost-effectiveness study discussed in section 3.8.2 incorporated many trials with very short-term follow up comparing the various bulk-fill composites (and GICs), which have the issues previously described (Schwendicke *et al.*, 2018b).

2.16 Post-operative complications

Common post-operative complications are sensitivity and food packing (Gilmour et al., 2009), as previously described. Though a Cochrane review noted a difference in post-operative sensitivity favouring composite over amalgam at one point in time in the only included study, it did not consider this to be clinically relevant (Worthington *et al.*, 2021).

There are generally accepted differences between the materials, in that amalgam suffers fewer complications, however these opinions are often anecdotal and opinion based (Sabbagh, Fahd and McConnell, 2018; Bailey and Stone, 2021). The perceived differences are likely due to the different technical processes involved in the placement of the different restorations as previously described. Post-operative sensitivity often reduces over time (Al-Omari, Al-Omari and Omar, 2006), but some restorations will need replacing or further intervention to resolve the pain (Sabbagh, Fahd and McConnell, 2018; Kopperud *et al.*, 2016). Studies have shown no difference in post-operative sensitivity between conventional and bulk-fill composites (Kunz *et al.*, 2022). Food-packing is uncomfortable for patients and may predispose to further disease as previously discussed. The patient may need to accept a sub-optimal outcome, or undergo replacement restoration, perhaps with an indirect restoration to overcome the form and contact area issues previously discussed in section 2.9 (Kopperud *et al.*, 2016; Bailey and Stone, 2021). A dated UK survey of dentists reported that 52% respondents encountered issues with food packing and 18% with post treatment sensitivity associated with posterior composite restorations in more than one out of four restorations (Gilmour *et al.*, 2009). Though this seems high, the data was collected over 10-years ago, and there was no data comparing the two materials, so it is hard to understand if there are implications for an amalgam phase-out in the UK. Though patients are affected by these issues sufficiently to seek advice or further treatment, the importance of these issues to patients has not been investigated.

2.17 Restoration failure

As previously stated, most dental restorations are placed to replace failed existing restorations. There are many reasons why restorations fail, and they can fail in many different ways. These have been alluded to previously, but are consolidated and expanded upon in the following sections.

2.17.1 Failure modes

The major ways in which direct posterior restorations fail are caries associated with restorations (CARS) (previously referred to as recurrent or secondary caries) followed by fracture (of the tooth and/or restoration) and then pulpal or endodontic complications (Laske *et al.*, 2019a; Operative Dentistry, 2005). Composite restorations are more at risk of CARS than amalgam, and this may vary by a patient's caries risk status, but evidence for differences between the materials in other failure modes is contradictory and uncertain, and failure mode can vary over time as previously discussed in section 2.15.5 (Worthington *et al.*, 2021; Opdam *et al.*, 2010; Burke *et al.*, 1999; Operative Dentistry, 2005).

A meta-analysis comparing clinical trials of composite restorations reported between 1995-2005, and 2006-2016 showed that direct posterior composite reported failure modes have changed significantly over time (Alvanforoush *et al.*, 2017). There is potentially much heterogeneity in the studies which is unaccounted for however, therefore it is hard to draw firm conclusions. However, this study does show that the proportion of failures caused by fracture of the restoration and tooth significantly increased in the second period, which therefore may question the current relevance of the findings of Beck, which looked at restoration failure from 1996-2015 (Beck *et al.*, 2015). Beck reported that early failure of composite restorations was due to debond or need for endodontic treatment, in the mid-term due to fracture and longer-term due to caries or fracture. Equally, some included studies excluded high risk patients, which then questions the significance of such findings in primary care. How changes in technique, which may account for some of the changes over time (for example reduced failure due to persistent sensitivity more recently), have filtered down to primary care, is a point for exploration and debate. Equally failure between 1995-2005 included wear of the restoration, which hugely reduced in the second period. This could be due to improved physico-mechanical behaviour of newer composites, for example.

These general differences in clinical outcomes between the materials are likely primarily because composite restorations are technically more difficult to perform, especially in difficult situations. In the following sections, the major modes of failure are discussed alongside how the restorative materials may influence them.

2.17.2 Caries Associated with RestorationS

CARS detection methods are poorly validated (in comparison with primary caries) and pose significant diagnostic difficulties. Clinician agreement on diagnosis has been shown to be poor, but visual, radiographic and laser-fluorescence detection appear to be most useful (Askar *et al.*, 2020; Operative Dentistry, 2005). Differentiation of non-carious staining of restorative margins from CARS has been shown to be difficult in clinical studies, especially with tooth-coloured restorations (Heintze and Rousson, 2012; Operative Dentistry, 2005). CARS most commonly occurs (>90%) at the gingival margin of restorations (Askar *et al.*, 2020), which likely then makes the subsequent re-restoration deeper and more difficult to perform and especially so for composite.

It is a consistent finding that CARS occurs more frequently with composites than amalgam, and composite restoration survival is reduced in high caries risk patients. (Worthington *et al.*, 2021; Laske *et al.*, 2019a; Opdam *et al.*, 2010).

CARS can be associated with a defective restoration which allows the sheltered accumulation of biofilm. This can result from ledged restorations, but is likely primarily due to gaps between the restoration and the cavity wall. The size of the gap required to allow this is contentious, due to the apparent disconnect between the models used to study this phenomenon and clinical reality (Hickel *et al.*, 2023; Askar *et al.*, 2020). The likelihood of peripheral gaps between the tooth and restoration is much increased with composite compared to amalgam for several reasons making the placement process much more technique sensitive. This can also preferentially predispose composite to post-operative sensitivity. The potential reasons for these differences are summarised in the following section.

2.17.3 Summary of restorative process differences

As previously discussed, amalgam is compacted under firm pressure during its application into a cavity and undergoes a very small expansion, both of which favour marginal adaptation and avoidance of gaps. In contrast, composite shrinks on setting and is more difficult to adapt during placement due to its softer consistency. It also commonly needs to be placed in multiple increments to respect depth of cure and reduce damaging contraction stress which again increases the chances of gap formation (Bailey, Shand and Ellis, 2023). These issues can also contribute to the increased failure to form contact points with composite when not using specialised equipment, which can potentially contribute to material fracture, food packing and CARS, though the evidence for this is currently limited (Bailey, 2021).

The effective application of a bonding agent to the tooth is required to prevent composite from pulling away from the cavity walls during polymerisation. Achieving an effective bond can be affected by many things including the tooth substrate type (enamel or dentine) and its disease affected state, the bonding agent composition and application, and contamination, which therefore requires the cavity to be meticulously isolated from the oral environment (ideally with a RD) (Pinna *et al.*, 2017; Van Meerbeek *et al.*, 2020; Chen *et al.*, 2024). This can be especially challenging where cavity margins are sub-gingival (Bailey and O'Connor, 2019). Incomplete light-curing of composite at the base of a cavity can occur without attention to detail and can result in washout of uncured components (Askar *et al.*, 2020). Gaps can form following degradation of the composite bond over time which occurs especially with dentine margins (Pinna *et al.*, 2017; Van Meerbeek *et al.*, 2020).

The integrity of an amalgam restoration does not depend on these things to obtain a marginal seal. The technical process is much more complex when providing a composite compared to an amalgam restoration. Many of these issues can however potentially be overcome with appropriate materials and techniques, as demonstrated by high comparative success rates in specific, but limited, studies (Laske *et al.*, 2016; Opdam *et al.*, 2010).

Posterior composite restorations take significantly longer than amalgam to place (Lynch *et al.*, 2018b; Tobi *et al.*, 1999). There is a huge array of materials and equipment which can be used to place composite restorations (Bailey, 2021) which could be causing confusion in primary care, though there is minimal data to show this. Evidence-based guidance on placement of posterior composites recommends the use of relatively expensive equipment such as sectional matrix systems and RD (Lynch *et al.*, 2014; Wilson and Lynch, 2014). They were rarely used in UK primary care when this was assessed many years ago however, though up to date data do not exist. This equipment can offer improved outcomes, minimising post-operative complications which may be valued by patients (though minimal data on this exists), but potentially takes longer (though again no data exists on this, especially in the UK context) and can be technically difficult to place (Bailey, 2021; Bailey and O'Connor, 2019; Heintze and Rousson, 2012). In some health systems a fee is chargeable for placing a RD as discussed, clearly trying to incentivise the use of recommended techniques to optimise outcomes. Whereas class I cavities vary minimally in their presentation, class II cavities can have huge variation which can influence the technical aspects of restoration, especially for composite. As more tooth structure is lost, and margins extend deeper sub-gingivally, placing a well-adapted matrix-wedge (sometimes with an added separating ring) assembly to directly restore a tooth becomes much more challenging (Bailey and O'Connor, 2019; Loomans and Hilton, 2016). Because the marginal seal is not as critical for amalgam, they are often favoured in these more difficult situations (Aggarwal *et al.*, 2019; Jebur *et al.*, 2023).

CARS can also be associated with an intact restoration, for example due to a lower buffering capacity of the restoration compared to the tooth, or due to the restorative material favouring a more cariogenic biofilm accumulation as is seen with composite compared to amalgam (Pinna *et al.*, 2017; Svanberg, Mjör and Orstavik, 1990).

CARS could also occur due to a failure to appropriately treat the primary lesion either (or both) operatively (i.e. not clearing the cavity periphery of caries) or preventively by managing the disease at the level of the individual, which may mean that it is not causally associated with the restoration.

2.17.4 Fractures

In restored teeth, the restoration and/or teeth may fracture. Data suggest that 77% tooth fractures are associated with teeth having three or more surfaces restored. Molars are more susceptible to cusp fracture than premolars, and vital teeth suffer more favourable supra-gingival fractures (91%) than non-vital teeth (61%) (Fennis *et al.*, 2002). Expert guidance recommends indirect cuspal coverage restorations for posterior RoCT teeth generally, and vital teeth with biomechanical compromise, to reduce fracture risk (Mannocci *et al.*, 2021; Cardoso *et al.*, 2023). These restorations are much more costly and time-consuming to perform than direct restorations however, and were often not provided for RoCT teeth in UK primary care, likely due to the higher cost (Lucarotti *et al.*, 2014).

2.17.5 Direct material differences which could affect tooth fracture

Cavity preparations advised for the two materials commonly vary based on how they are retained. Amalgam preparations require mechanical undercuts, whereas composite preparations do not as previously discussed. Composite preparations are therefore purportedly (slightly) more minimally invasive (Chana *et al.*, 2019; Banerjee and Domejean, 2013; Bailey and Stone, 2021). However, one large prospective practice-based study showed that more conventional (amalgam-like) shaped preparations performed better in terms of composite restoration survival than saucer shaped preparations, when controlling for many other potentially relevant factors including the operator (Kopperud *et al.*, 2012).

Countering these data, it might however be expected that the (slightly) more destructive amalgam preparations would result in a higher prevalence of tooth fractures. This may especially be so given that amalgam is generally then not bonded to the remaining tooth, therefore failing to recover lost stiffness of the restored tooth unit in comparison to composite. Some laboratory studies support this whereas others do not, showing more favourable failure of amalgam restored teeth in certain situations (Burke, 1992). One clinical study, with previously highlighted methodological issues (section 2.15.7), showed a small increased likelihood of tooth fracture in amalgam compared to composite restored teeth (Opdam *et al.*, 2010). A Cochrane Review and other, large clinical data do not show increased fracture in amalgam however (Worthington *et al.*, 2021; Wahl, 2012). Though people say that they see more tooth fractures associated with amalgam restorations (higher incidence), and this is likely correct, they commonly come to an unjustifiable conclusion that amalgam restored teeth have a higher rate of fracture (prevalence) (Wahl, 2012). They are not considering the relative number of amalgam to composite restored teeth that they see however, suffering from a 'narrative fallacy' and 'base case neglect' (Wahl, 2012). Many more amalgam restorations were present in a large sample where such data were collected looking at fracture prevalence. There was no significant difference between the materials (with a slightly increased fracture rate associated with composite restorations). The study had limitations in that it was cross-sectional, with no knowledge of the preparations performed, restorations' ages or relative sizes however (Wahl *et al.*, 2004).

A Cochrane review which investigated differences in failure mode between amalgam and composite as a secondary analysis reported no tooth fractures, just restoration fractures, where it found no significant difference between materials (Worthington *et al.*, 2021). Use of more expensive sectional matrix systems may reduce fracture proclivity of composite restorations as previously discussed in section 2.9.

2.18 Reintervention

Following failure, the nature of the subsequent reintervention (i.e. repair, replacement or indirect restoration, for example) is important to understand the long-term impact of the restoration on the tooth. This reintervention may in turn be subject to huge variation however, making it very difficult to study and understand. Existing data on this 'repeat restorative cycle' is sparse. A large, long-term but old NHS dataset (previously described in section 2.15.6) on how differing restorative interventions affect subsequent reintervention and tooth survival at the population level exists (Lucarotti and Burke, 2018a; Lucarotti, Holder and Burke, 2005). More detailed, but very short-term Dutch data are also available (Laske *et al.*, 2019a). Neither can really compare the impact of restoring teeth with amalgam versus composite, as the use of composite was not permitted under NHS provision in posterior non-class V cavities at the time as previously noted, and the proportion of amalgam restorations placed in the Dutch data is very small, so there is high risk of indication bias.

2.19 Managing failed restorations

The mode of failure might indicate a need for preventive measures, and these should be implemented (as previously described in section 2.6.2) prior to managing failed restorations when non-urgent (i.e. not causing pain for example).

2.19.1 Replacement restorations

The management of failed restorations may depend on the failure mode, or the remaining tooth structure and any remaining restoration in place, among many other considerations. Commonly, failed restorations are fully removed prior to replacement in primary care (Gordan *et al.*, 2012).

When removing restorations of composite in comparison to amalgam, operators with varying experience all consistently took more time, removed more sound tooth structure and left more of the existing restoration, likely because it is much more difficult to see (Krejci, Lieber and Lutz, 1995). Another laboratory study showed that when removing direct composite restorations, the original cavity expanded in area and perimeter, and as the preparation got deeper, more tooth structure was lost (Gordan, Mondragon and Shen, 2002). This evidence, allied with previously described studies provides a rationale for the repair, rather than the replacement of failed restorations where possible, which is discussed in the next section.

Replacing restorations therefore results in increasing the size of the restoration, which comes with an increased likelihood of failure as previously discussed.

Deciding when a restoration has failed and intervention is required can be difficult. It has been suggested that there is a tendency to more aggressively intervene, especially in composite restorations, where stained margins may be mistaken for caries as previously discussed (section 2.17.2). Understandably though, the clinician is in a predicament, as they may be uncertain how to proceed. Monitoring a stained margin may be prudent, as replacement will inevitably increase the cavity size, but equally leaving it, when it is caries, may result in further destruction and worse outcomes, including accusations of neglect for the clinician. Dealing with uncertainty can be difficult for both clinician and patient. Exploring margins and resealing them as a form of repair may be appropriate in uncertain situations, but this highlights the importance of informing patients of potential issues and taking a shared-decision making approach described later (section 2.26), as highlighted in a recent FDI policy document (Schmalz *et al.*, 2024). In real world dentistry, the clinicians and patients involved may bring their own individual preferences and values (biases) to treatment decisions. This is another reason why translating the outcomes of 'gold standard' RaCTs to primary care, where clinician and patient may have no input is not straightforward. This, alongside previously mentioned issues discussed in section 2.15 are important when considering the use of data to inform economic evaluations.

2.19.2 Repair

Given that complete replacement inevitably leads to a larger preparation size (especially with composite, as discussed), repairs could prevent this and potentially slow the restorative cycle. Repairs can be performed on different materials, with different materials, and the different combinations requiring different techniques (Loomans and Özcan, 2016). Separate Cochrane reviews investigating repair versus replacement of failed amalgam and composite restorations found no RaCTs (Sharif *et al.*, 2014a; Sharif *et al.*, 2014b). A systematic review on repair vs replacement of restorations was carried out (Martins *et al.*, 2018) but was discredited due to serious methodological issues (Brignardello-Petersen, 2019).

The data on restoration repair are heterogenous, with indications for different options varying between trials, and within trials with multiple operators (Opdam *et al.*, 2012; Fernandez *et al.*, 2015; Gordan *et al.*, 2012; Gordan *et al.*, 2015; Askar *et al.*, 2020; Hickel, Brüshaver and Ilie, 2013). The technical details of performing repairs are often unreported, but vary where stated between studies (Hickel, Brüshaver and Ilie, 2013). In the UK setting, patients receiving repairs were less anxious, and had reduced treatment times and use of local anaesthetic compared to those receiving replacement, and therefore could potentially be less costly, but restoration longevity outcomes were not assessed (Javidi, Tickle and Aggarwal, 2015). Data suggests the survival probability of repaired compared to replaced restorations may be reduced (Askar *et al.*, 2020). Similarly, a prospective cohort US practice-based study at significant risk of indication bias and with 1 year of follow up, but with large numbers, showed that repaired restorations were more likely to require reintervention in the first year (7%), than if replaced (5%), but the reintervention was less severe (fewer pulpal complications) (Gordan *et al.*, 2015). Different outcomes are seen when repairing restorations of different materials, and may depend on the initial failure mode, but are inconsistent (Askar *et al.*, 2020; Hickel, Brüshaver and Ilie, 2013). The studies have multiple sources of heterogeneity and therefore drawing clear conclusions is difficult.

FDI guidance based on expert consensus suggests that repair is generally deemed appropriate where localised, simple defects are present, whereas replacement is indicated where multiple or severe failings exist (Hickel *et al.*, 2023).

2.20 Summary of data sources, and survival and reintervention data

Available RaCTs and meta-analyses from studies on restoration survival likely significantly underestimate AFRs in primary care for many reasons. Clinicians involved in studies providing treatment are often highly trained and know their work will be appraised. The included patients are often not representative of the population with lower risk profiles, the cavities are small and simple to restore and patient numbers and follow up are limited. Composite materials are also much more technique sensitive to use than amalgam though the impact of these issues on outcomes in UK primary care is unknown. Composite materials are perhaps often not used as recommended in UK primary care, which may compound this issue, though the data suggesting this are old and potentially outdated. Performing economic evaluations in primary care settings with RaCT data therefore likely overestimates the efficacy of direct restorations and underestimates the costs, potentially impacting the conclusions drawn. RaCTs and meta-analyses are useful for understanding the relative effects of using different materials however.

Big data obtained from real life primary care environments do not try to control for variables in the same way as RaCTs, and they therefore have issues primarily relating to indication bias, in that it is hard to understand the true difference in material survival if not controlling for multiple other variables (as shown when comparing amalgam with composite).

Taking a large random sample from a big data source is probably the most appropriate way to broadly understand how restorations perform in a health service of interest. This represents the realities of clinical primary care dentistry. It provides a picture of actual provision within a given healthcare system where decisions and treatment are shaped by the system and socio-cultural values in an interactive process between both clinician and patient. Big-data exists which are representative of the English and Welsh population who receive NHS dental care, but are old and have limitations.

Numerous studies, including a Cochrane review, have shown significant and clinically important differences between materials, especially amalgam and composite and there is some evidence showing that these materials fail differently and with different incidences in patients with differing risk profiles. Other evidence challenges these associations however, and defining those at risk and estimating risk within the population is uncertain and will change over time. How these factors might influence the mode of failure and the subsequent reintervention is uncertain. The existing evidence relating different restorative interventions to subsequent tooth loss is very limited.

2.21 Non-clinical, or non-health outcomes

Restorations can also differ in non-clinical ways. The treatment and waiting times may be longer and the appearance may be different for example. These factors may influence people's decisions to choose one restoration over another (Birch and Ismail, 2002). Patient preferences, how they can be measured, their importance, and the limited data on them relating to restorations will be discussed in section 3.4.

2.22 Restoration provision in primary care

Evidence exists on posterior restorative material provision from around the world with many affluent countries using no or very little amalgam, whereas developing countries often use relatively more (Eklund, 2010; Alexander *et al.*, 2016; WHO, 2011; Mumtaz *et al.*, 2010; UNEP, 2016; Callanan *et al.*, 2020b; Sunnegardh-Gronberg *et al.*, 2009).

Two surveys of material use for direct posterior restorations by GDPs have recently been carried out in the UK. One survey looked at material provision for restoration of posterior teeth, suggesting that composite has displaced amalgam as the most used dental restorative material in posterior permanent teeth in the UK (Wilson *et al.*, 2019). The sampling frame was limited however, meaning the results may be less applicable across the UK. These results do not appear to correlate with the other survey results which collected data from NHS GDPs but was limited to Wales (Lynch *et al.*, 2018b). The Welsh survey does provide data on materials and techniques used, but was not specific in assessing use of the different technique and material options currently available. Neither survey gives an indication of percentage use of the different available direct materials, with respondents being asked either which material was used most commonly (Wilson *et al.*, 2019), or to rank their preferred choice of materials in specific situations (Lynch *et al.*, 2018b). An older, well-designed survey suggested amalgam was the most commonly used material in both premolars and molars in UK primary care (Brunton *et al.*, 2012), but there is uncertainty as to current material use in the UK.

Amalgam was the most frequently used material to restore posterior teeth under NHS provision in Scotland in 2017-8 (Information Services Division, 2017), and the expenditure on NHS amalgam fillings in England has been crudely estimated at £200-300 million in 2015-16 (Carr, personal communication, 2018).

The most recent survey of NHS GDPs in Wales showed a large majority felt that direct posterior composite provision was too expensive for NHS funded dentistry and that there was a higher incidence of post-operative complications with posterior composite than amalgam restorations (Lynch *et al.*, 2018b), supporting the notion that composites are much more technique sensitive.

None of the current evidence relates to provision of restorations by dental therapists, or CDS dentists, whose patients commonly have behavioural difficulties and special requirements.

This makes achieving moisture control and higher levels of cooperation, as required for the placement of composite compared to amalgam restorations, very difficult, as evidenced by CDS dentists' responses to the SDCEP consultation document on the phase-down of amalgam (West, personal communication, 2018).

2.23 Clinician perspective

The perspective of clinicians is critical in understanding if the existing primary care workforce could transition away from amalgam, how this would potentially affect them, their practices and their patients in providing composite restorations. This leads to many questions, for example:

- How would this be remunerated?
- Would this impact on their clinical success, their patients' experience of post-operative complications?
- Would they need to spend more time on placing restorations, dealing with complications and removing failed restorations?
- Would they be able to see patients in a timely fashion, affecting their patients' access to care?
- How would it affect their ability to treat more broken-down teeth in difficult clinical situations, or in patients with limited compliance?
- Would more teeth need more expensive, time-consuming indirect restorations, or extraction?
- Would this impact everyone in society the same, or would it preferentially negatively impact the lower socio-economic groups, where health inequalities already exist?
- How confident are the clinicians in using the newer materials?
- Does this vary in different, more challenging situations and is there a difference between materials?
- Is the current education available meeting the needs of clinicians to face the challenges with composite restorations at both undergraduate and postgraduate levels?
- What is their knowledge of and how do they feel about the amalgam phase-down and potential phase-out?

Evidence exists from around the world on dentists' opinions of an amalgam phase-down (Alexander *et al.*, 2014; Callanan *et al.*, 2020a; Alexander *et al.*, 2017b; Alexander *et al.*, 2017a) and phase-out, from countries where amalgam has been banned (Kopperud *et al.*, 2016) as previously discussed in section 2.12.4..

A recent study provided data on the opinions of NHS general dentists (GDPs) on the phase-down and potential phase-out of amalgam limited to Wales (Lynch *et al.*, 2018b). Whilst confidence in placing composite in different situations was assessed, confidence in placing amalgam was not assessed, making the potential impact of a phase-out difficult to quantify. A large majority did not feel confident in placing direct posterior composites in cavities with sub-gingival margins, which is a concern, but it was unclear if this was also an issue when using amalgam. Respondents suggested that it would take them 1.61 times as long on average to place a composite compared to amalgam restoration of comparative size. In another survey, many issues were identified by UK primary care clinicians regarding posterior composites alongside the failure of the majority to use recommended techniques (Gilmour *et al.*, 2009). Difficulty achieving moisture control was the most commonly identified difficulty faced when placing composite restorations, and RD use was low. However again it is difficult to understand the implications of a potential amalgam phase-out as data on amalgam restorations were not sought, and the data are also dated, with the potential for change in opinions and practice in the intervening years. In the previous UK-based surveys, opinions were not sought from CDS dentists or the growing UK therapist workforce, making the potential impact of the phase-down on primary care difficult to assess.

A majority also felt there was an issue of longevity with composite compared to amalgam . This is supported by stringently assessed clinical trial data as previously discussed, which is clearly of concern for both tooth survival and the likely lifetime costs of replacement.

2.24 Education

The role of education at all levels was prominent in the DHSC policy papers on the national plans to phase-down the use of dental amalgam as discussed in section 2.11 (DHSC, 2019). Education is required on the alternative restorative options, but it highlighted a focus on prevention.

As can be seen from the previous discussions, posterior composite restorations are very technique sensitive, and though they can be very successful, they commonly are not, and the operator and patient seem to be the most important variables for success. It therefore seems plausible that varying techniques employed by the clinician could explain much of this variation on restoration survival. The clinical evidence base has been discussed, but there is no good outcome data investigating the effects of different techniques when restoring technically demanding class II cavities. Guidance documents on placement of composites and their teaching tend to make broad statements, but often do not address technical aspects of their use in difficult situations (Lynch *et al.*, 2014; Wilson and Lynch, 2014).

Articles have been published detailing techniques for successful placement of composite restorations in difficult situations (Bailey, 2020; Bailey and O'Connor, 2019; Lührs, Jacker-Guhr and Herrmann, 2018; Loomans and Hilton, 2016), but they are opinion-based. It is also likely that these are not readily accessible for the majority of primary care clinicians and their adoption in undergraduate and postgraduate education is uncertain.

The guidance to repair rather than replace failed restorations where possible has been implemented at undergraduate level in a large majority of dental schools throughout Europe and North America (Blum, Lynch and Wilson, 2012a; Blum, Lynch and Wilson, 2012b; Lynch *et al.*, 2012; Kanzow *et al.*, 2018), but is not so ubiquitous in other regions of the world (Nassar et al., 2021). Though repairs are being carried out in primary care in countries around the world including the UK, the numbers reported suggest that replacement is still heavily favoured and this is especially so in older graduates (Gordan *et al.*, 2012; Javidi, Tickle and Aggarwal, 2015; Kopperud *et al.*, 2016), suggesting a need for improved post-graduate education.

Amalgam use has decreased significantly in UK dental schools recently with many more posterior composites being placed by undergraduates (Lynch *et al.*, 2018a). Adoption of newer techniques can be driven by undergraduate teaching (Bailey, Shand and Ellis, 2023). For example, teaching of sectional matrices for posterior composites is increasing in the UK and other parts of the world (Wilson and Lynch, 2014; Lynch *et al.*, 2018a; Hayashi *et al.*, 2018; Loch *et al.*, 2019; Kanzow *et al.*, 2020; Sidhu *et al.*, 2021; Zabrovsky *et al.*, 2019), and though bulk-fill composite teaching was low in UK and Irish dental schools in 2015, many were considering its implementation (Lynch *et al.*, 2018a). Whether this has translated to their use in UK primary care is uncertain.

Recent evidence, suggesting that confidence was low in Welsh primary care dentists when using alternatives to amalgam in difficult situations, suggests a failure of both undergraduate and perhaps postgraduate education. However, given that only 16% had attended postgraduate education on posterior composites (Lynch *et al.*, 2018b), it perhaps indicates a failure to reflect and a lack of insight on their part to drive improvement. The GDC recently required UK registrants to have a personal development plan (PDP) which would hopefully identify clinicians' weaknesses and therefore guide CPD where required. It is unclear if this lack of confidence and education is present across the UK. A qualitative study has shown that training on unfamiliar dental techniques can allow their implementation whilst improving clinicians' confidence, and that a lack of knowledge of a technique negatively affects confidence in using it which provides a significant barrier to its implementation (Pandya *et al.*, 2024).

Given the extensive use of amalgam in Welsh publicly-funded primary care (Lynch *et al.*, 2018b), it seems there is still a need to teach amalgam, as most newly qualified UK dentists work in this system (DHSC, 2024), though the broader use across the UK is uncertain.

2.25 Changing professional practice

It was discovered that there was significant variation in thresholds for operative intervention amongst clinicians many years ago (Elderton and Nuttall, 1983). This lead to the publication of a guidance document titled, 'Criteria for placement and replacement of dental restorations' (Anusavice, 1988). The guidance talks about prevention, non-operative intervention for early lesions, changing individual risk and limiting operative procedures, it also talks about repair and the need for a change in the way dentistry was funded, so that remuneration was not only provided for technical procedures. Sadly, though this was published 35-years ago, there are still dentists operatively intervening for caries limited to enamel in the most recent English survey (Chana *et al.*, 2019) and we are still struggling to change remuneration for dental care (Vernazza, Birch and Pitts, 2021).

2.26 Shared decision making

There has been a move from a paternalistic style of clinical decision-making, where the clinician made the decisions without really involving the patient, to a shared-decision making approach between clinician and patient which has clear clinical and ethical advantages (Charles, Gafni and Whelan, 1997). It is reliant on the clinician being abreast of the evidence base and communicating options in a way which the patient can understand, whilst considering the patient's values (which may show inter-individual variation) to obtain consent. Understanding how patients value different health and non-health related aspects of restorations and their variation is also potentially important when commissioning services if alternative treatments have different characteristics.

2.27 Implementation of restoration choice

The CADTH HTA explored issues around implementing composite and amalgam restorations (Khangura *et al.*, 2018). A literature review and telephone consultations using semi-structured interviews with targeted experts and stakeholders (without using surveys) were completed by an 'information specialist'. They then provided a narrative 'overview of policy, funding, practice and issues related to using dental amalgams and composite resins in dental care settings in Canada', finding that many factors influence the choice of one material over another. These included funding and reimbursement, setting – public or private, clinician attitudes and perceptions, education and training, patient perceptions, education and preferences, and socio-cultural attitudes towards materials. It stated that clinicians were expected to educate patients on the most appropriate use of material for a specific situation, but that patients may make choices based on a variety of reasons, including availability, cost, appearance, health concerns and recommendations from a clinician. It concluded that ultimately each case and patient is different, so that factors could be both barriers or facilitators to the use of different materials.

2.28 Summary

It is clear from the preceding discussion that the different materials available to directly restore posterior teeth have different costs and consequences to a number of stakeholders, including patients, clinicians, and policy makers. HEE allows the relative differences to be quantified which is helpful in guiding stakeholders to make a material choice for posterior direct restorations. HEE will be discussed in the following chapter.

Chapter 3. Health Economic Evaluation

3.1 Introduction

This chapter will provide an overview of HEE. It introduces the methodologies used in this thesis and discusses relevant work on patient preferences and HEEs. It concludes with a summary of the evidence from Chapters 2 and 3 which justifies the empirical work subsequently presented.

Health systems are under resource pressure worldwide. Resources are finite, so difficult decisions must be made as to what to fund (priority setting) and what not to fund (rationing). Money spent on an intervention which results in benefit, necessarily means that another intervention which would also yield benefit cannot be funded in a system with finite resources. This is the benefit foregone and is referred to as the opportunity cost. In any such system there will be winners and losers. HEEs, which have been defined as, *"the comparative analysis of alternative courses of action in terms of both their costs and consequences"* (Drummond, Stoddart and Torrance, 1987), are used to inform decisions of which health care interventions to fund from a fixed budget. A HEE is therefore an appropriate method to understand the economic implications of a potential shift in material use for direct posterior restorations allowing rational planning of service provision.

When asking economic questions, they are really asking questions of optimising efficiency. HEEs vary and different methods and types of analysis can answer different efficiency questions, which can be described as technical, allocative or both. Technical efficiency relates to the question of which intervention a society should choose, given that it has decided to provide a specific programme. It assesses how output can be optimised in a specific area for a given input. Allocative efficiency relates to the question of whether an intervention should be provided and if it is, how much should be provided in relation to other programmes. The latter is therefore a broader evaluation and has the potential to optimise societal benefit.

3.2 An overview of traditional health economic approaches

In health economics, there are two main approaches to the evaluation of health interventions. These are welfare economics and extra-welfarist economics (Brouwer *et al.*, 2008). Both frameworks aim to inform policy decisions by assessing the costs and consequences of health care interventions (HCIs), but they differ significantly in their philosophical foundations, methods, and practical applications. Understanding these differences is crucial for policymakers, researchers, and healthcare professionals who aim to design and evaluate HCIs effectively.

Welfare economics has strong theoretical underpinnings in classical economics and focuses on maximising societal welfare through the efficient allocation of resources. It assumes that individuals are the best judges of their own welfare and that individual preferences should guide economic decisions (Brouwer *et al.*, 2008). This approach often employs consumer utility theory, where utility represents a measure of individual satisfaction or value. The goal is to achieve Pareto efficiency, where resources are allocated such that no one can be made better off without making someone else worse off (Drummond *et al.*, 2015).

In welfare economics, cost-benefit analysis (CBA) is a common tool. CBA involves comparing the total expected costs of an intervention to its total expected benefits, both of which are typically quantified in monetary terms. This method requires assigning a monetary value to health outcomes, often using willingness-to-pay (WTP) or willingness-to-accept (WTA) measures derived from individual preferences. Another key concept in welfare economics is the social welfare function, which combines individual utilities into a measure of total societal welfare (Drummond *et al.*, 2015).

Despite its comprehensive framework, welfare economics has several limitations, particularly in the context of health. Assigning monetary values to health outcomes can be challenging and controversial. WTA and WTP estimates are often different for the same health changes, with WTA values often higher (Grutters *et al.*, 2008). This is likely primarily due to an endowment effect, where people attach a higher value to something which they own and an income effect whereby people have a ceiling of what they are able to pay due to income constraints, whereas there are no constraints as to what they can accept (Grutters *et al.*, 2008). The endowment effect has been challenged however, with a suggestion that differences may be due to misconceptions around the nature of the hypothetical tasks (Plott and Zeiler, 2005). Hypothetical bias is discussed further later in section 3.4.7. WTP is affected by ability to pay, which may lead to issues of equity and fairness (Tan, Vernazza and Nair, 2017). In healthcare, where equity and access to care are important considerations, these limitations have led to the development of alternative economic frameworks (Brouwer *et al.*, 2008).

Extra-welfarist economics emerged as a response to the limitations of welfare economics, particularly in addressing health outcomes and equity concerns (Brouwer *et al.*, 2008). This approach shifts the focus from individual preferences and utility to broader measures of well-being and health status. It emphasizes the intrinsic value of health and uses non-monetary metrics to assess health outcomes. Extra-welfarist economics commonly aims to capture the multi-dimensional nature of health and its impact on health-related quality of life (Brouwer *et al.*, 2008; Drummond *et al.*, 2015).

Cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) are central tools in extra-welfarist economics. CUA commonly uses quality-adjusted life years (QALYs) for example (or occasionally quality-adjusted tooth years (QATYs) (Listl, Grytten and Birch, 2019) in the dental setting) to measure health outcomes (Drummond *et al.*, 2015). These metrics combine the quantity and quality of life into a single index, allowing for the comparison of different health interventions. CEA compares the costs and health effects of different interventions without converting outcomes into monetary terms, focusing instead on achieving the best health outcomes with limited resources.

One of the perceived strengths of extra-welfarist economics is its consideration and incorporation of equity and fairness by removing monetary valuation of outcomes. This approach can also incorporate distributional concerns by weighting health gains differently for different population groups, thereby addressing disparities in health outcomes (Brouwer *et al.*, 2008). For instance, interventions targeting disadvantaged groups might be valued more highly, reflecting assumed societal preferences for reducing health inequalities. However, extra-welfarist approaches commonly use utility values obtained from populations to value HCIs. Income affects how people value health states within a population, so differences in valuations of health states based on income are almost certainly still present but tend to be hidden in this approach (Donaldson, Birch and Gafni, 2002). It could also be argued that weighting of health gains for different groups is a political decision, not one for economists, and incorporating them into an overall economic metric reduces transparency (Donaldson, Birch and Gafni, 2002). Extra-welfarist approaches have limited theoretical basis (Birch and Donaldson, 2003) and are narrower evaluations, in that they do not consider non-health benefits (as described in section 2.21), which may be important differences between HCIs to patients (Boyers *et al.*, 2021).

Both welfare and extra-welfarist economic approaches offer valuable insights for health policy and HCI evaluation each with various strengths and limitations which will be further explored in subsequent sections.

The following section discusses the common types of HEE in more detail and how they vary, before making a case for an appropriate methodology in this thesis.

3.3 Types of health economic evaluation

In HEEs the costs are always measured in monetary terms. The consequences vary in their unit(s) of measurement however, reflecting the different types of analysis. Commonly employed analyses include cost-effectiveness (CEA), cost-utility (CUA), cost-benefit (CBA) and cost-consequence (CCA). Cost-minimisation analyses (CMA) can only be used where the outcomes of interventions are known to be the same. The analyses are summarised in Table 3.1.

Type of Economic Evaluation	Decision making use	Measurement of health effects	Economic summary measure	Potential scope and efficiency question addressed
Cost-minimisation analysis	Comparison of strategies with the same outcomes	Any	Cost saving	Narrow, Technical, potentially allocative
Cost-effectiveness analysis	Comparison of strategies with common consequences	Natural/clinical units e.g. restoration survival in years	Cost-effectiveness ratio	Narrow. Technical
Cost-utility analysis	Comparison of strategies with morbidity and mortality consequences	Utility/morbidity (patient/population preference for a health state) weighted life (or tooth) years gained e.g. QALY or QATY	Cost per QALY or QATY	Narrow. Technical and allocative within health
Cost-benefit analysis	Comparison of strategies with differing units of consequence (e.g. health and non-health)	Monetary terms	Net benefit	Broad. Technical and allocative beyond health
Cost-consequence analysis	Comparison of strategies with differing units of consequence and/or varied perspectival consequences and costs	Varied, measures not specific to type of analysis	No single summary measure. Multiple disaggregated measures with marginal differences between interventions where appropriate	Broad, beyond easily quantifiable measures. Technical

Table 3.1. Types of economic evaluations

QALY, quality adjusted life year; QATY, quality adjusted tooth year. Based on Hoomans and Severens, 2014 and Vernazza et al., 2012.

3.4 Measuring health outcomes

The consequences of compared interventions must be comparable in a given HEE. Consequences commonly focus on outcome measures for compared interventions and the specific measures used will commonly dictate the type of HEE performed and are shown in Table 3.1.

CEAs use clinical measurements specific to the intervention (such as survival of different dental restorations) and can therefore only answer questions of technical efficiency. They are useful where it is known that a service is required, such as dental restorations, but a provider wishes to know which restorative material is the most economically efficient to use i.e. to maximise benefits from finite resources. CEAs compare the difference in outcome (incremental effects) with the difference in costs (incremental costs) between HCIs. When the incremental effects and costs have different signs (positive and negative), the decision of which HCI to choose is simple, as one costs less and is more effective than the other, and it is therefore said to dominate the alternative option. Commonly however, a new HCI may be more effective and more costly. In these situations an incremental cost effectiveness ratio (ICER) is calculated by dividing the incremental costs by the incremental effects. It therefore provides a cost per unit of effect to help the provider make a decision on which HCI to choose (example, (Homer *et al.*, 2020)).

Incremental costs and incremental effectiveness can also be represented on a cost-effectiveness plane as shown in Figure 5.10 (Briggs, Sculpher and Claxton, 2007; Graziadio *et al.*, 2020). If an intervention sits in the SE quadrant, it is said to dominate the alternative, and an intervention sitting in the NW quadrant is dominated by the alternative, so decision making is easy. Often however, an intervention costs more and is more effective, sitting in the NE quadrant, or is less costly but less effective sitting in the SW quadrant. Here, decisions are not as easy, and the ICER can be gauged in relation to the ICER WTP threshold line as shown in Figure 3.1. If the intervention plot falls below the threshold line it should be adopted, whereas it should be rejected if lying above the line.

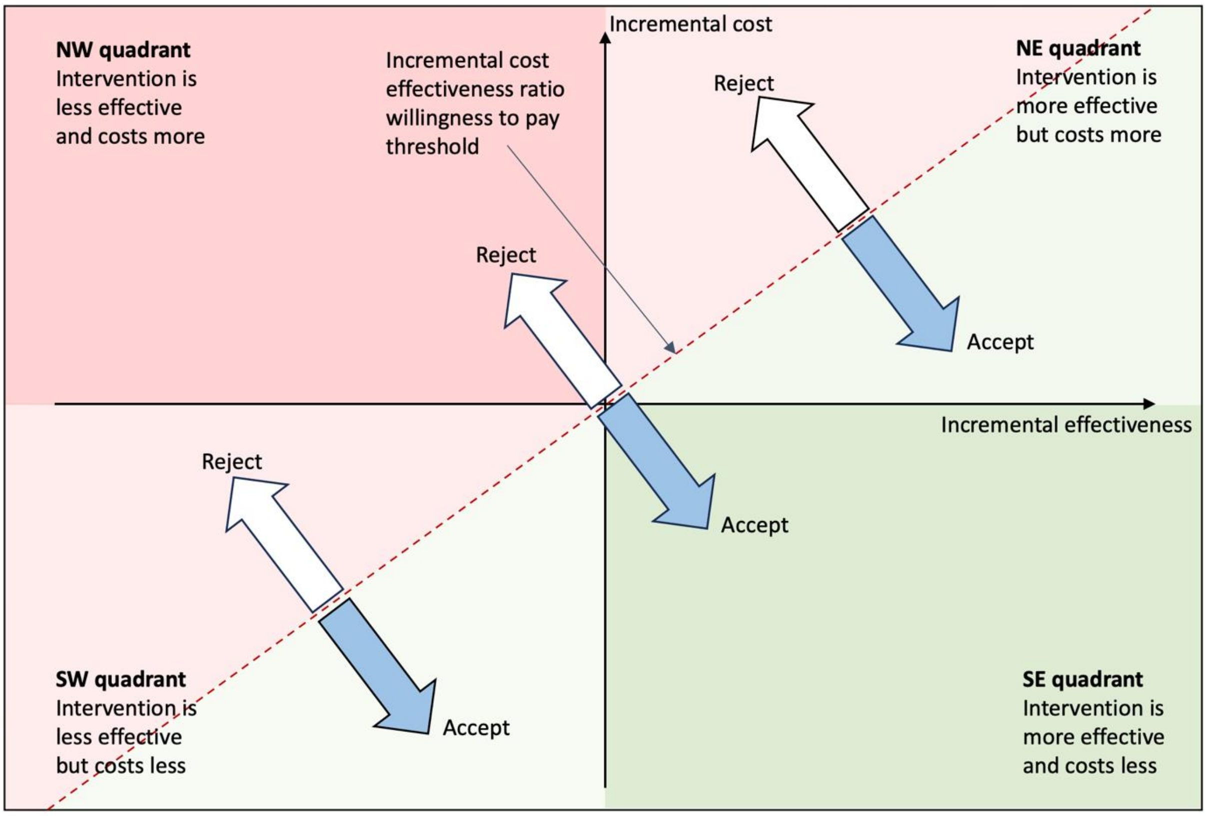


Figure 3.1. Cost-effectiveness plane: Intervention versus control
Adapted from Briggs, Sculpher and Claxton and Graziadio et al., 2020.

CEAs provide quite a narrow evaluation however, as it is uncertain what impact the specific clinical outcome measured will have on the individual. There may be differences in HRQoL, or the process of care between interventions which are not accounted for (Birch and Ismail, 2002). It is also not possible to say how worthwhile an intervention is in comparison to another intervention for a different problem with CEAs. It may be that differences in interventions beyond the clinical measures are insignificant, or the intervention is not easily compared to other interventions, and the CEA is therefore appropriate. Often however, there are differences between interventions beyond the clinical measurements. For some of these reasons, changes in utility values in different health states are commonly ascribed as outcomes in health economics, leading to CUAs.

Utility values represent the strength of individuals' preferences for differing health states. Health utilities are measured on a scale of 0 (death) to 1 (optimal health). They can be measured directly or indirectly. Direct methods involve eliciting preferences directly from individuals, using stated preference (SP) techniques, whereas indirect methods use standardised questionnaires with representative utility value weightings attached (Drummond *et al.*, 2015). Direct methods provide detailed, individualised data, but can be influenced by cognitive biases and are often more complex to perform. Examples include time trade-off, standard gamble and WTP. Indirect methods provide standardised, comparable data that are easier to collect and analyse, though they may miss more subtle health state differences (Drummond *et al.*, 2015).

Indirect methods are more commonly used for these reasons. Questionnaires use various HRQoL measures to determine the effects of a disease on various aspects of an individual's life. The HRQoL measure can be disease specific, or (as is much more common) generic, allowing it to be used to evaluate outcomes across different HCIs, promoting a level of transparency in funder decision making (Drummond *et al.*, 2015). Each health state in the instrument is ascribed a weighting, which is determined by surveying a population (often the general public in different countries or settings, but also patient groups, using SP techniques which are discussed in section 3.4.4 (Drummond *et al.*, 2015). This allows the average impact of a particular health state on a population to be calculated and therefore broadens the evaluation beyond clinical outcomes of uncertain impact. It also allows impacts to be compared across different HCIs, but as previously alluded to, these weightings are prone to vary based on the perspective taken.

Health state preference measures (or utilities), when assessed over time and combined with survival outcomes can be used to calculate the number of QALYs gained through a HCI. CUAs, like CEAs, allow calculation of an ICER. In CUAs this most commonly provides a value for the incremental cost per QALY gained. This is useful when deciding whether to commission a new health technology, as this value is generic and can be compared across other HCIs. This allows HEEs conducted in this way to address questions of allocative efficiency, within a healthcare system that has a finite budget and a known average existing reference level (threshold) for the incremental cost per QALY (at least partially, given there would still be questions if many interventions fell below the threshold). HCIs with a lower incremental cost per QALY than the reference threshold can be invested in, whilst existing interventions with higher values can be disinvested to optimise the health benefits within a society. The National Institute for Health and Care Excellence (NICE) are responsible for commissioning new health technologies in the UK. Their HEE guidelines generally favour the use of CUAs, using QALYs as described with a threshold (actually various thresholds depending on the nature of the condition for the incremental cost per QALY of an intervention which they are willing to fund (NICE, 2024; McCabe, Claxton and Culyer, 2008). The reference threshold level, and how this is determined are subject to debate, and equally, there may still be an allocation problem if all of the interventions below the reference level sum to more than the total budget (McCabe, Claxton and Culyer, 2008; Claxton *et al.*, 2015).

Whilst CUAs are commonly favoured in healthcare for the reasons discussed, they have a number of limitations, many of which are particularly relevant to dentistry and will be discussed in the following section.

Health outcome measures alone, even when expressed as health utilities, are a narrow way of valuing HCIs (Listl, Grytten and Birch, 2019; Listl *et al.*, 2022). Many of the differential benefits of one HCI over another are non-health consequences, such as patient experience factors, aesthetic appearance and process of care for example. These are not recorded with these instruments, even though they are important to people (Mooney, 1994; Mooney, Jan and Seymour, 1994), and especially so in dentistry (Listl, Grytten and Birch, 2019; Listl *et al.*, 2022; Boyers, 2019). In addition, societal productivity benefits from increasing societal health are often not considered and existing generic instruments may be insufficiently sensitive to accurately record the importance of disease processes or HCIs in certain fields (dental interventions, some eye interventions and public health interventions for example) (Vernazza *et al.*, 2012; Burr *et al.*, 2012; Listl, Grytten and Birch, 2019; Kastenbom *et al.*, 2019; NICE, 2024).

These diseases, which are inadequately valued when assessed by change in QALYs, are commonly seen where the initial state of disease has minimal, if any, impact on an individual, or in chronic, generally asymptomatic diseases, which can have a very short but extreme symptomatic exacerbation. Dental caries is an example of both situations. It requires an intervention (for example dental restorations) to prevent more serious effects (and the incurrence of higher costs) for example severe pain requiring time off work and the need for more complex treatment as previously discussed. In some countries, for example The Netherlands, when a disease is deemed to result in a low QALY loss per patient, (as is seen with dental caries (Kastenbom *et al.*, 2019)), it is not funded publicly and requires out of pocket payments. To a degree, this is what happens in the UK with NHS provided dental care, as discussed in section 2.12.2.

3.4.1 Attempted solutions in dentistry

Whilst disease specific utility outcome measures can be used in these situations, for example The Caries Impacts and Experiences Questionnaire for Children - Utility Version (CARIES-QC-U) (Rogers *et al.*, 2022), or more generic oral health utility measures, as have been explored in dentistry (for example the use of Oral Health Impact Profiles [OHIP] (Slade and Spencer, 1994) and QATYs (Listl, Grytten and Birch, 2019)), the benefits of comparing QALYs across interventions is lost. Mapping more specific to generic outcome measures has been explored in an attempt to overcome this issue, but with varying or little success (Brennan and Spencer, 2006; Vernazza *et al.*, 2012). Assessment of allocative efficiency is therefore more difficult.

3.4.2 Incorporating health and non-health consequences

Valuing health consequences in terms of clinical outcomes and health utilities has been discussed. Interventions may however differ more broadly, for example in non-health consequences as previously described. Broader HEEs include CBAs and CCAs which can incorporate non-health benefits and are therefore more appropriate when interventions vary across a broad range of different consequences (NICE, 2024).

However, when allocating finite resources for healthcare which have been generated from taxation of the general public, questions might arise which could include, 'should the process of care be taken into consideration?' or, 'does the process of care differ sufficiently between interventions to be worth taking into consideration?' and 'should utility arising from appearance- such as might occur from the use of different dental filling materials (silvery-grey or white) be factored into the decision making process by a funder?'. If a funder was considering ignoring potential process and appearance utility, it may then be prudent to ask, 'would this affect healthcare uptake and impact negatively on society as a whole?'.

Some of the inherent problems with CUA can be addressed by taking a more global perspective through the use of CBA as previously discussed. Valuing consequences in monetary terms can provide an estimate of holistic utility, rather than the restricted health utility measures used in CUA. Productivity outcomes and process utility can be more effectively accounted for. Given that both costs and consequences are valued in monetary terms in CBAs, they are simpler to interpret. Net benefits are directly estimated (total benefits minus total costs). Incremental net benefits can then be calculated in relation to a reference cost. Most economic analyses performed outside of healthcare are CBAs. This means that it is uncertain whether the whole budget is being allocated efficiently between healthcare (when assessed with CUA) and other governmental departments, which means that it is impossible to assess if societal benefit is being optimised. Healthcare CBAs are therefore comparable beyond the confines of healthcare, facilitating a broader, societal perspective to allocative efficiency (Drummond *et al.*, 2015). NICE has recently stated that CBAs are the appropriate economic evaluations for public HCIs (NICE, 2024).

Reservations are commonly raised relating to the monetary valuation of healthcare generally. This may be due to the unease in putting a price on a life or health, and the general lack of awareness of patients or the general public on the costs of healthcare, as it is often paid for by the state or through insurance (Drummond *et al.*, 2015). Dentistry is quite different however, as caries is most commonly asymptomatic at intervention, is very rarely life threatening, and the majority of people in the UK are used to paying at least a major portion of the cost of dental fillings. Additionally, some or all of the non-health benefits associated with a HCI might be unimportant to a funder. Including these in an economic evaluation which presents a single economic summary measure, such as a CBA, would therefore be inappropriate, making funders doubt the relevance of the outcome to their decision making.

Sometimes interventions have different consequences which are hard to quantify, for example based on environmental impacts or geopolitical concerns as exist for amalgam versus composite restorations. These considerations are therefore hard to incorporate into a traditional HEE.

Presenting the consequences separately in a CCA can therefore overcome the limited scope of the CUA or CEA and allow a funder to rationally weight the different consequences when making a decision, overcoming the limitation of combining all of these into a CBA with a single outcome. The following section will discuss SP techniques which are commonly used for valuing outcomes in monetary terms.

3.4.3 Measuring consequences in monetary terms

Monetary valuation of a good or strategy has been measured using revealed preferences (RPs) or SPs. RPs refer to situations where market prices or uptake data are available and believed to be undistorted. SP techniques are survey-based methods used where undistorted free markets are absent, such as commonly exist in healthcare. Unlike RP methods, which infer preferences from actual behaviour, SP methods rely on individuals' responses to designed questions.

SP techniques are crucial in health economics for several reasons. They allow for the evaluation of hypothetical scenarios that might not yet exist in the market, capture non-market values such as environmental or health benefits, and help policymakers understand the trade-offs individuals are willing to make. This information is vital for designing effective health policies and interventions that reflect public values and preferences.

3.4.4 Stated preference techniques

Monetary valuations or uptake of an intervention are estimated by asking people hypothetical questions, using techniques which elicit their WTP or WTA. The value of an intervention to an individual is revealed through the maximum amount of money that they are willing to pay for it. It is not what someone might feel is a fair price. Likewise, WTA is the minimum amount of money that someone would take to sell a good or service, or to accept a negative consequence. The price of any transaction will be a point lying between a purchaser's WTP and a vendor's WTA. The net difference is referred to as the consumer surplus (Drummond *et al.*, 2015). This approach assumes consumer theory, whereby individuals are rational and wish to maximise their utility and obtain best value for money when making choices, which may be contested (Lancaster, 1966).

WTP can incorporate all elements of value or consequences, encompassing likely health benefits, but importantly also non-health differences between interventions and can therefore provide a more holistic assessment of the consequences of an intervention. WTP has been described as the most appropriate measure of oral health preferences in a review of the topic (Matthews, Gafni and Birch, 1999), whereas another review was less prescriptive (Birch and Ismail, 2002). WTP can be assessed directly using contingent valuation (CV) techniques, or indirectly by using DCEs for example. They will be discussed in the following section.

3.4.5 Contingent valuation

CV involves asking respondents directly how much they would be willing to pay for a good or service using various approaches, such as dichotomous choice with or without follow up, open ended, (shuffled) payment cards and bidding games for example. It tends to focus on outcomes (though it doesn't have to) as it has traditionally been aligned with welfare economics and therefore consumer utility theory. Utility theory classically held that people only derive utility from outcomes (irrespective of the process).

3.4.6 Discrete choice experiments

DCEs are a SP technique based on assumptions, underpinned by economic theory (Lancaster, 1966) and random utility theory (McFadden, 1973), that healthcare services can be described by their characteristics (attributes) and that individuals value services depending on the levels of these attributes (Ryan, 2004b). DCEs value goods indirectly, by presenting respondents with a series of hypothetical scenarios involving different attributes and levels. Respondents are then asked to choose an option from each choice set. This allows the relative importance of the levels of the attributes to be estimated, alongside marginal willingness to pay (mWTP) values for each attribute level (where a cost attribute is included). DCEs are therefore particularly useful in health economics for valuing complex health interventions where multi-dimensional trade-offs are of interest. They are well established in valuing health interventions (Clark *et al.*, 2014) but have been sparsely used in dentistry (Barber and Dhaliwal, 2018). Though the inclusion of cost attributes in valuing healthcare is perhaps controversial (Bryan and Dolan, 2004), their use in dentistry is less so as the public are often used to paying for dental treatment (Boyers *et al.*, 2021).

Much guidance has been provided on designing and conducting DCEs (Bridges *et al.*, 2011; Johnson *et al.*, 2013; Hauber *et al.*, 2016; Muhlbacher and Johnson, 2016; Staniszewska *et al.*, 2017). A summary of the process follows. The research question and population of interest should be clearly defined. Relevant attributes of the HCI to include should be identified and their levels defined. This can be done using literature reviews, focus groups, interviews, expert opinion or a combination of these. Patient focus groups are deemed especially useful however. The experiment should then be designed. Combinations of attributes and levels are created forming hypothetical scenarios. Each choice set should contain two or more choices which respondents then choose between. Consideration should be given to including an opt-out (for example not proceeding with treatment) and this should be included if it is a realistic option. The number of choice sets should be limited to a reasonable number for a respondent. A full factorial design, which includes all combinations of attributes and attribute levels is usually not possible as the number of attributes and levels increase. Fractional factorial efficient designs are therefore commonly used to reduce the number of choice sets to a feasible number whilst maintaining statistical power. The questionnaire is then designed providing clear instructions on how to complete the survey and the choice sets should be presented in a user-friendly format, considering the use of visual aids. The questionnaire should be piloted to refine it and ensure it is fit for purpose. The survey can then be distributed to an appropriate representative sample of the target population and the respondent data captured. The data should then be analysed using an appropriate model, which can include conditional or mixed logit. Model choice will be dependent on the data obtained and produces outputs of the relative importance of each attribute level included in the DCE. This, alongside further DCE considerations, is expanded in Chapter 5.

3.4.7 Willingness to pay concerns

SP techniques are at risk of hypothetical bias, where respondents might not behave as they would in real-life situations (Rakotonarivo, Schaafsma and Hockley, 2016). There is therefore a tendency to overestimate WTP in SP tasks generally (Clark *et al.*, 2014). However it can also be underestimated and the correlation may not be clear, or variable as noted when comparing SPs (obtained with CV) with RPs in the dental setting (Vernazza *et al.*, 2015; Boyers, 2019). This leads to uncertainty in terms of the generalisability of the results (external validity), and has important implications when valuing healthcare. It should be noted however that all SP methods, including those used to value outcomes for health preferences as used in CUAs, have questionable external validity, but are still commonly used in making healthcare decisions (Boyers, 2019). A meta-analysis of SP studies showed that SP techniques are good predictors of actual behaviour when respondents are familiar with the task being valued and its context (Schläpfer and Fischhoff, 2012). Cognitive burden and complexity of the tasks can result in attribute non-attendance which may affect the quality of the responses. This is more likely to be an issue with DCEs (Danyliv *et al.*, 2012). However, it has been suggested that respondents to DCEs concerning dental care are likely to be familiar with receiving and paying for dental care, and therefore their choices may accurately reflect their true preferences (Boyers, 2019). Additionally Boyers suggested that DCEs may result in low levels of hypothetical bias, especially in the dental setting, which would likely be of limited concern for policy makers.

There is the potential for strategic bias in CV, where respondents might mis-state their preferences to influence outcomes. This is less likely to be a problem with DCEs, though can still occur (Ryan, 2004a).

As previously noted, ability to pay affects WTP (Tan, Vernazza and Nair, 2017), which raises equity concerns. The perspective taken with WTP tends to be that of an individual (either a patient or a member of the general public) in a hypothetical situation of requiring an intervention, i.e. under conditions of certainty. Most people will however be uncertain as to their need to access a HCI in the future. Outcomes obtained in healthcare often also carry uncertainty as has been alluded to. It is important to recognise and address these issues when valuing HCIs, as choices made with certain need and certain outcomes, whilst cognitively simpler, are different from those made without and can affect WTP (Birch and Ismail, 2002).

People are not good at making decisions under conditions of uncertainty. The presentation of the information can have a large impact on decision making, and they often resort to heuristics (decision making shortcuts) (Kahneman, 2011). This may be especially so when it comes to healthcare, where there is often an asymmetry of information between the provider (who has expertise and a deeper understanding of the disease and interventions) and the patient (Listl, Grytten and Birch, 2019).

As discussed, CBA is underpinned by welfarist principles, but health is not a good that can be traded, it is non-transferrable (Donaldson, Birch and Gafni, 2002). Compensating variation is a measure of consumer surplus. It can be defined as the monetary value to get back to the initial utility. However in the dental health setting, a tooth which is restored is never the same again. It has been shown to have reduced utility for both patients and dentists (Alharthi *et al.*, 2022), in that it is now at much greater risk to further negative events and disutility.

3.4.8 Whose preferences, which perspective?

As previously discussed, when eliciting preferences, there are a number of interested parties who could claim to be the appropriate groups to value healthcare consequences. These include the funder, those delivering the healthcare, patients who receive the HCI or the general public.

Patient-centred care has garnered much interest of late, and healthcare systems are more and more interested in taking this perspective into consideration. However, a patient suffering from a disease, may be more likely to overvalue an intervention, as it may be in their interests to do so (Dolan *et al.*, 2003; Drummond *et al.*, 2015). While this could result in the implementation of a costlier intervention than is necessary, it may lead to better patient adherence or uptake. A patient may however have learnt to live with a condition and therefore the impact of the disease and HCI may be undervalued by the patient in relation to a member of the general population (Drummond *et al.*, 2015).

Clearly, difficulties can arise when deciding who should be asked to value interventions. In a strictly welfarist approach, it has been said that 'the 'goodness' of any action should be judged solely on the basis of the utility levels attained by individuals in that situation' i.e. patients (Hurley, 2000). This assertion may be relaxed however, with social welfare commonly understood to be a function of individual utilities (Brouwer *et al.*, 2008). Interventions invested in will necessarily result in an opportunity cost, therefore it would seem that a general population perspective might be more appropriate when HCIs are paid for (at least partially) by taxation of the general population. Individuals from the general population will value an intervention differently, based on their previous experience of the intervention, and their appraisal of their potential future need for the intervention, reflecting the uncertainty of this need (Mott, 2018). Other issues which arise from this approach are that it may be very difficult for someone with no previous experience of a disease to understand the impact it would have on them, meaning the information provided and the design of the study to elicit this information is critical (Schläpfer and Fischhoff, 2012). Such studies tend to appraise the preferences or choices made by an individual to optimise their own utility, and not the utility of society at large. These values may be at odds, as previously discussed, which is of concern because individual utilities are then often used to estimate societal utilities. For example, an individual's ability to pay for an intervention, may be very different from society's ability to pay, and any preferences expressed when framed under those two different perspectives may well differ. WTP studies tend to focus on measuring the personal preferences of an individual in a hypothetical position of needing an intervention (Drummond *et al.*, 2015).

Even health economists find it hard to agree on the level of importance of the patient perspective in decision making (Brazier *et al.*, 2005), and suggested further work to attempt to reach a consensus, though clearly, each situation should be taken on its own merit.

NICE has recently published guidance on the use of patient preference data in health technology assessment decision making (Bouvy *et al.*, 2020), suggesting that,

> *'In the context of the National Institute for Health and Care Excellence's methods and processes, we do not see a role for quantitative patient preference data to be directly incorporated into health economic modelling. Rather, we see a role for patient preference studies to be submitted alongside other types of evidence. Examples where patient preference studies might have added value in health technology assessments include cases where two distinctly different treatment options are being compared, when patients have to decide between multiple treatment options, when technologies have important non-health benefits or when a treatment is indicated for a heterogenous population.'*

When assessing the utility of the different restorations by using DCEs, not including attributes which are important to patients would lead to omission bias, making the results questionable. Quantifying the importance the general public place on these factors would seem relevant, as the decision maker could still reasonably choose to ignore these characteristics, but any decision made would then be based on a more complete picture of the alternatives.

3.5 Existing patient preference data on dental restorations

A previous DCE looked at the importance of restoration longevity, colour and adverse outcomes to young patients and dental professionals (Espelid *et al.*, 2006). Attributes were not selected with public or patient involvement, and this study is likely to suffer from omission bias given many important restoration attributes weren't included in the study. A cost attribute was also not included (justifiably given the frame of the study), therefore the results had limited scope to inform an economic analysis (which was not the intention of the study). The 'adverse outcomes' attribute levels were not based on robust evidence, merely on reports of patient numbers referred to a single unit for adverse reactions. The representativeness of the example photo shown in the survey of an adverse reaction to a filling material, allied with the incidence levels chosen are contentious in that they are likely to give the impression that adverse reactions are more serious and more frequent than is the case. It is also uncertain how different restorations differ in producing adverse reactions. The study was confined to specific groups in Norway and Denmark, therefore was not generalisable to the population.

It was unclear if the survey asked for respondents to indicate their preference between two choices, or which option they would choose, as both were stated in the paper. There is a subtle but important difference. Indicating a preference does not necessarily mean that the preferred option would actually be chosen. This is an issue where an opt-out option, in this case to not proceed with treatment, is a possibility in the real world. This was not included in the study, which reduces the realism of the choice task as it likely overestimates treatment uptake. Such a study design is therefore at risk of hypothetical bias.

The CADTH HTA included a section investigating patient perspectives on composite versus amalgam restorations (Khangura *et al.*, 2018). A literature search resulted in the inclusion of four studies which focussed on patients' symptoms and ill health which they attributed to their amalgam restorations. No studies were found addressing patient experiences with composite. The review found that the patients involved felt that they struggled to be understood and believed, as they sought causes for their health issues.

There is currently no data showing patient preferences for direct restorations in the UK context which could provide marginal monetary valuations to be used to inform a HEE comparing amalgam and the alternatives.

3.6 Measuring costs

As previously discussed in section 2.6.1, costs associated with HCIs can be described as direct, where money changes hands, or indirect, where potentially productive time is lost. Indirect costs commonly occur due to the time required for treatment, but also the time required to travel to and from appointments. There are also commonly direct costs of transport required to travel to and from appointments, for example. These costs most commonly fall on the patient, whereas direct costs of a restoration usually fall on the funder, the patient, or both. There may also be direct costs falling on the treating clinician, or the dental practice for example. It might also be considered that there are indirect costs on a clinician or health service where an intervention requires more time for the clinician to provide it, which therefore reduces the amount of disease which can be treated in the service, which could lead to access issues for patients.

In HEEs, top-down and bottom-up (micro-costing) approaches are two common methods for estimating costs. These approaches differ in how they aggregate or disaggregate data to estimate the total cost of HCIs (Ternent *et al.*, 2022).

The top-down approach starts with aggregate data (e.g. total expenditure or budget for a healthcare system) and then breaks it down to assign costs to individual units or components of service. The total costs associated with healthcare workers (including dentists) working in NHS primary care have been estimated in this way, resulting in a cost-per-hour for practice owners (providing-performer) and associates (performer-only) (Jones *et al.*, 2023), for example. This approach is quick and straightforward, especially when large-scale data is available. It may however lack detail and specificity, as it assumes an average cost across units and can overlook variations in costs due to differences in patient needs, resource use, or efficiency, for example.

The bottom-up approach starts with detailed, individual-level data and builds up the cost by summing the costs of all resources used in providing a HCI. It commonly involves costing each component of a HCI, including consumables and equipment which is reused, alongside staff time, for example. These detailed costs are then aggregated to estimate the total cost of providing the service. It can provide a more accurate and detailed estimate of costs and can capture subtle variations in resource use. It is more time consuming however, as it is data-intensive, requiring detailed tracking of all resource use.

The two approaches are not mutually exclusive however and may be combined (Ternent *et al.*, 2022; Homer *et al.*, 2020)

Previous HEEs of dental restorations commonly only consider costs from a single perspective (Tobi *et al.*, 1999; Mjör, Burke and Wilson, 1997; Chadwick *et al.*, 2001b; Schwendicke *et al.*, 2018b). However, the costs to the clinician of providing an NHS dental restoration are different from the patient, which in turn are different from the funder, for example. The patient might have to pay direct costs in the form of a fee for the restoration, but there are also indirect costs relating to the loss of productive time as previously discussed. Indirect costs have only very occasionally been accounted for in evaluating restorations and often inadequately so (Khangura *et al.*, 2018), as will be discussed in section 3.8. The failure to consider different perspectives potentially leads to negative effects when implementing policy (for example patients not utilising health services, or clinicians leaving a health service and creating patient access issues).

3.7 Cost-consequence analyses

The previous discussions have shown the limitations of traditional HEEs. CEAs, CUAs and CBAs incorporate either select consequences and costs, or all of them into a single economic outcome measure. These values can be complex to understand for policy makers, especially where outcomes are presented as single incremental ratios, and they may be ignored (Mauskopf *et al.*, 1998).

Where broad and varying costs and consequences of HCIs exist from differing perspectives, as is the case for dental restorations, they can be transparently presented in disaggregated form in a CCA as recommended by NICE (NICE, 2024). This makes the HEE more intuitive to understand for policy makers (Mauskopf *et al.*, 1998). A decision can then be made which considers all of the stakeholders and weights them based on the policy maker's preferences. A National Institute for Health and Care Research (NIHR) guidance document has described it as an underused method of HEE (NIHR, 2019). Guidance on the process has also been provided by the UK Government, NICE and journal articles (Mauskopf *et al.*, 1998; NICE, 2017; OHID, 2020). It is also useful for clinical decision-making, allowing clinicians to understand the comprehensive effects of treatments, balancing clinical outcomes with patient preferences and resource use (Khangura *et al.*, 2018). Equally however it can make synthesising the information into usable form difficult, and may not help to inform allocative decisions (Hoomans and Severens, 2014).

3.8 Existing economic evaluations comparing direct restorations

HEEs of restorative dental care have commonly focussed on a single outcome, such as the lifespan of a restoration or tooth falling under the banner of CEAs (Tobi *et al.*, 1999; Chadwick *et al.*, 2001b; Kanzow, Wiegand and Schwendicke, 2016; Schwendicke *et al.*, 2018b; Schwendicke *et al.*, 2021). The different restorative options do not commonly only vary in longevity however, they may vary in multiple ways as discussed in sections 2.14 and 2.21, which may be important to all, or various stakeholders. Such economic evaluations are therefore limited. Patient or public valuation of the importance of these parameters is not commonly sought (Listl *et al.*, 2022) and where the intention has been to include them in an HEE, the existing evidence was limited and insufficient to be used (Khangura *et al.*, 2018). Other important factors have also not been considered including the aesthetic outcome, process of care considerations, for example, how long the treatment would take, or out of pocket monetary costs, which can be critical to optimising not only patient satisfaction, but also uptake of services (Ostermann *et al.*, 2017). This is especially important to understand in patients of low socio-economic status where disparities in oral health already exist (Steele *et al.*, 2015).

No previous HEE of amalgam restorations versus the direct posterior alternatives has been performed in the UK for over 20-years. Prior to this there was a simplistic UK-based HEE

(Mjör, Burke and Wilson, 1997) and a more comprehensive one which found limited useful evidence (Chadwick *et al.*, 2001b; Chadwick *et al.*, 2001a). None of the existing evaluations in different settings have used quantitative methods to value broad patient-centred outcomes. Nearly all use restoration or tooth survival as effectiveness measures alone, though one evaluation did take a broader perspective in the form of a CCA (Khangura *et al.*, 2018). The relevant papers will be discussed.

Tobi et al., 1999 performed a trial-based cost-effectiveness analysis comparing the replacement of failed class II amalgam restorations with composite or amalgam as part of a larger RaCT. Treatment time was measured and alone used to approximate costs. This doesn't consider other potentially important differences in cost between the interventions. There was a significantly increased time required to replace restorations when using composite for two-surface restorations (and also a large difference in 3-surface restorations, but very low numbers), even though both materials were placed under RD. The study was performed in The Netherlands with a time horizon of 5-years (the length of the trial) and all restorations survived, though two composite restorations were repaired (not costed, or counted as failures). The study tentatively concluded that amalgam was to be preferred when re-restoring class II amalgam restorations because they were associated with the consumption of fewer resources.

This study demonstrates that clinical studies have a limited time horizon, primarily due to the costs of running a longer-term trial and logistical issues as previously discussed. This short-term approach inevitably underestimates the true longer-term costs and consequences of interventions. Decision analytic models (DAMs) project outcomes and costs of treatments over a longer-term time horizon (often a lifetime) allowing for a more comprehensive HEE, but inevitably introduce more uncertainty and assumptions. Whilst data from a specific trial may be projected, meta-analyses can be used to potentially improve the accuracy of estimates. The relevance of the data source to the decision problem (for example the geographical location, and setting i.e. primary or secondary care) does need to be borne in mind however (Khangura *et al.*, 2018). A number of model-based economic evaluations assessing amalgam versus the direct alternatives have been performed in the last 10-years (Khangura *et al.*, 2018; Kanzow, Wiegand and Schwendicke, 2016; Schwendicke *et al.*, 2018b). These will be discussed in turn, following a brief overview of decision analytic modelling.

3.8.1 Decision analytic modelling

Good research practice for decision modelling relevant to this decision problem is discussed in a series of articles from The Professional Society for Health Economics and Outcomes Research (ISPOR) (Caro *et al.*, 2012; Eddy *et al.*, 2012; Roberts *et al.*, 2012; Siebert *et al.*, 2012; Briggs *et al.*, 2012) which also reference a useful practical guide (Briggs, Sculpher and Claxton, 2007). Decisions made relating to the model development and analysis are discussed where relevant. The reporting of the study is consistent with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (Husereau *et al.*, 2022).

When developing a model, a tension exists between appropriately modelling the complexity of the disease process, based on data, and the availability of sufficiently appropriate, quality data to populate the model. It is often held and advised that the model should not be simplified because of a lack of data (Roberts *et al.*, 2012).

"Decisions cannot be avoided just because data are unavailable to inform them, and 'expert judgement' will frequently be necessary" (Briggs, Sculpher and Claxton, 2007) to construct and parameterise the model. Whilst this process can be 'transparent', and quantifies opinion which is more acceptable to 'scientific' sensibilities, it does not detract from the fact that one of the original purposes of modelling was to eliminate this overtly subjective element from the process and move away from expert opinion. Estimates can be incredibly influential, and as the number of estimates increases, the influences begin to compound. It may be better to avoid over-reaching and be more explicitly honest about areas of ignorance. Alternatively, broad ranges for such parameters can be used in sensitivity analyses to give an idea of the 'uncertainty', but again, these may simply be opinion-based. Understanding the available data on disease progression (and its limitations) can help to guide the development of an appropriately complex model and future research needs, and any simplifying assumptions must be made explicit (Caro *et al.*, 2012). The progression through disease states, or restorative status of the tooth have to be limited and sequentially progressive to a degree when modelling a process, but still need to capture important variations in costs and effectiveness of interventions (Roberts *et al.*, 2012).

The most common types of model structure are shown in Table 3.2. Commonly, various model types will be suitable to address the decision problem and elements of each can be combined (Caro *et al.*, 2012)). The current decision problem requires a model which follows the impacts of the different restorations over a lifetime, which makes a decision tree alone unsuitable. Patients and groups receiving restorations are generally assumed to be independent of each other, therefore more complex models, including discrete event simulation and dynamic transmission are deemed unnecessary.

Model type	**Description**	**Advantages**	**Disadvantages**
Decision trees	Models decisions and their consequences in a tree-like structure, with branches for different outcomes	-Simple -Easy to understand and communicate -Useful for one-off decisions or short-term decisions	-Struggle with longer time horizons or repeating events, and time or event-dependent probabilities
Markov	State-transition models which follow cohorts who move between various states based on fixed probabilities	-Simple and widely used in health economics -Handles chronic or long-term conditions well -Computationally efficient	-Memoryless (doesn't track individual history) -Pragmatically limited number of states possible -Can oversimplify complex processes
Microsimulation	State-transition models which simulate the movement of individuals through a model, allowing for individual variability and modelling of stochastic uncertainty	-Can model individual variability and time-dependent changes -Provides detailed information -Flexible to model more complex systems	-Computationally demanding. -Requires detailed data inputs. -individual interactions not permitted -Less efficient
Discrete event simulation	Models a process as a sequence of individual events which occur at specific time-points	-Can model complex systems with time and resource dependent events -Can handle variability in patient pathways and resource constraints	-Computationally demanding. Requires detailed event data. -Difficult to conceptualise and validate
Dynamic transmission	Models the transmission of infectious diseases in a population including individual interactions	-Captures how infectious diseases spread. -Can account for herd immunity, behaviour change etc.	-Computationially intensive. -Requires detailed population-level data -Difficult to conceptualise and validate

Table 3.2. Summary of model types

State transition models are commonly made up of states, events, cycles, transition probabilities (TPs) and allocation probabilities (APs). A state represents a specific situation which an individual (or cohort) occupies at a specific time frame. Events occur which cause individuals to move from one state to another. Events (aside from death) commonly incur a cost as they usually relate to a treatment intervention. A cycle is the time-period for which an individual remains in a state before it is possible to transition to another state. TPs represent the chance that an individual will move from one state to another following a cycle. TPs must sum to 1 for each event - non-event occurrence, as an individual must transition to one of the possible future states (which includes the chances of there being a non-event where the patient therefore remains in the same state). APs can refer to how individuals are initially distributed across states at the start of the model, and, more relevant to this model, how individuals are distributed across different interventions following an event (such as failure of the restoration). Again these must sum to 1.

3.8.2 Modelling caries in dentistry

The following sections review existing models relating to caries in dentistry, with a focus on those informing HEEs comparing amalgam restorations with the direct alternatives. It assesses the potential for previous models to be used in the English NHS context to address the aims of this thesis.

A variety of modelling techniques for the economic evaluation of various caries interventions have been used in various settings, over varying time horizons, as shown in a systematic review performed in 2018 (Qu *et al.*, 2019). The perspective taken – that of the policy maker or patient for example, population and disease/health state of individual patients or cohorts at model entry varied, as did the outcome measures, models, assumptions and analyses performed. The majority of DAMs focused on, or included, preventive or non-operative strategies, and the modelling of subsequent operative intervention was generally quite rudimentary and not really applicable to the current decision problem. The methodological quality of the studies was deemed to be unsatisfactory in relation to previously published criteria. These findings were supported by another review of economic evaluations in dentistry (Eow *et al.*, 2019). The search for caries DAMs was updated April 2022 (also including restoration as outlined in Appendix C) to see if any pre-existing models would be more applicable to the current decision problem. This revealed more relevant models including a review of models relevant to the decision problem by the CADTH HTA (Khangura *et al.*, 2018).

The main model-based HEEs comparing amalgam and composite posterior restorations in permanent teeth will be discussed in the following section. This will include the model type, perspective, setting and time horizon, alongside their findings and limitations.

One model, an adaptation of a Markov model initially described by Kanzow et al., 2016 was used in a CEA of amalgam alternatives in a German healthcare setting (Schwendicke *et al.*, 2018b). It took a lifetime perspective and showed that incrementally placed composite dominated BF composites, GIC and indirect composite restorations. It also stated that all alternatives are likely to be inferior to amalgam.

It was limited in terms of progression pathways in some respects, as shown in Figure 3.2, particularly in relation to the decision context, as no teeth were extracted without first receiving RoCT and a crown (which was always assumed to be placed following RoCT). This shows a significant difference to English and Welsh data showing that most RoCT teeth are restored with direct restorations only (Lucarotti *et al.*, 2014) and many restored teeth are extracted prior to receiving a crown (Lucarotti, Holder and Burke, 2005).

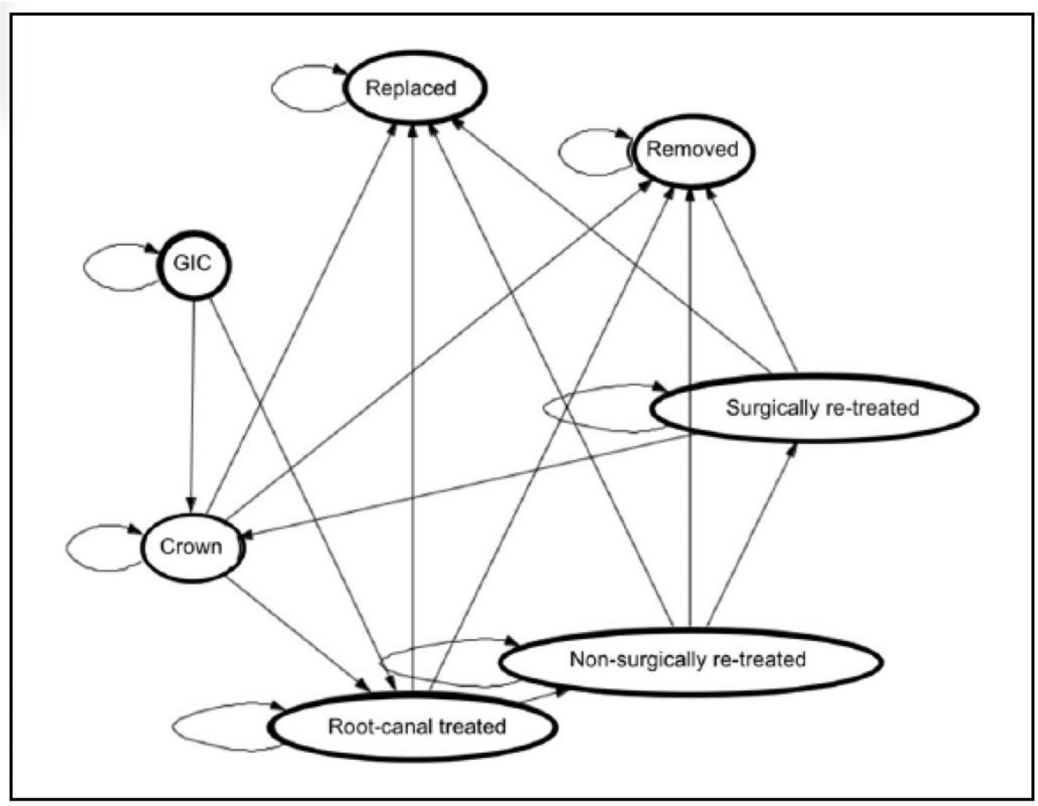


Figure 3.2. State transition diagram for a GIC restored tooth
Reproduced, with permission, from Schwendicke et al., 2018 [Appendix B]

Clearly therefore, these assumptions are at odds with the evidence in England and Wales previously described, making the way restored teeth progress through the model (APs) inappropriate for use in relation to the current decision problem. External validation of the model and its structure was not obviously performed. It also included unrealistic interventions in the context of the current decision problem (surgical re-RoCT and provision of implants in 50% of those having the tooth extracted). RRs for amalgam alternatives were applied to a baseline of amalgam failure which was obtained from a German insurance claims big data source captured over just 4-years (Raedel *et al.*, 2017). This aims to relate the difference in failure rates between the interventions, as determined (ideally) by well-designed RaCTs, to primary care data where it exists for one of the interventions, a method advocated by Briggs et al., 2007. The method importantly recognises the higher failure rates in the primary care setting of the decision problem. However, in the Schwendicke et al., 2018 study, there are some important concerns to raise in relation to the primary data set used and its relevance to the CEA published. The short time frame has issues as previously discussed, though the study did use alternative data sources in sensitivity analyses.

More concerning however is that the authors of the CEA seem to assume (not explicitly stated) that the restorations in the study were amalgam. Saying,

> *"Using data on restoration survival within the statutory insurance in Germany, which currently covers amalgam restorations for posterior teeth (Raedel et al. 2017), a constant annual hazard for amalgam was estimated".*

However, this data source did not separate data on different materials, and also included indirect restorations. The data source stated that,

> *"A rough estimation of the distribution of materials can be derived from the results of a limited explorative survey conducted by the study group independently from this analysis"* (Raedel et al., 2017),

citing Rädel et al., 2015. This citation is a report (written in German, translated by Chat GPT 3.5 (chat.openai.com)) which includes a survey of over 600 insured individuals asking them which type of posterior restorations they had received. 44% reported receiving composite, 20% amalgam, 9% indirect restorations and 5% 'cement' (assumed to be GIC). The remainder did not know (20%) or did not answer the question (1%) (Rädel *et al.*, 2015). Using this data to derive a transition probability for amalgam in any DAM therefore cannot be supported.

An alternative study by Kanzow et al., 2016, upon which the previously described study was based, assessed the cost-effectiveness of repairing versus replacing failed amalgam or composite restorations in a German healthcare setting. There are serious concerns surrounding parameterisation of the model in this study. It used very low transition probabilities (the chance of failure) for re-intervention for replaced restorations derived from data from a single private practice, with limitations as previously discussed in section 2.15.7. It then selectively chose 'non-systematically retrieved literature' to compare and 'reflect the uncertainty' by constructing 'triangular distributions between the minimum and maximum values from these studies relative to those reported by Opdam et al., 2010' as stated in the study appendix. Triangular distributions are not advised to reflect uncertainty (Briggs *et al.*, 2012). Though the decision context was the German healthcare setting, the included studies all had low AFRs and those which compared amalgam and composite did not include any where the AFR of composite was higher than that of amalgam. Both were at significant risk of indication bias as previously discussed. None of the studies used reflected the majority of the evidence, including an available Cochrane review at the time (Rasines Alcaraz *et al.*, 2014), showing that the AFR of composite is higher than amalgam in RaCTs and the majority of primary care data as previously discussed.

Perhaps the main issue with the study however was its over-reliance on one study (Opdam *et al.*, 2012), using uncontrolled outcome data to calculate RRs for failure of repaired amalgam and composite restorations. When controlled for multiple factors, including the restoration size (as presented in the source study), a large opposite effect of the influence of restorative material on repaired restoration failure was seen (favouring amalgam). It should also be noted that this source study only included failed large (≥3-surfaces) restorations and most failures in this specialist practice were repaired, rather than replaced or restored with an indirect restoration, which likely does not reflect clinical practice in the UK (or elsewhere). The results would therefore likely not be representative of primary care dentistry. The results from the other studies used to derive the RRs (which were critical to the decision problem) were different and varied and based on low numbers.

The study by Kanzow et al., 2016 also used studies by Opdam et al., 2010 and Opdam et al., 2012 to create the model structure for re-intervention following repair or replacement with issues as discussed. It assumed that cracked teeth (suffering from cracked tooth syndrome (CTS)) were extracted when modelling reintervention, despite a previous RaCT from the same practice as the studies on which the allocation probabilities were based showing very high survival rates of teeth presenting with CTS over 7-years when directly restored (Opdam et al., 2007). These issues raise significant questions about the outcomes of this economic evaluation.

The CADTH HTA comparing amalgam and composite restorations performed a CCA taking a Canadian societal perspective (Khangura *et al.*, 2018).

Seven consequences were assessed for inclusion, with only four ultimately included. These were useful life of a restoration; lifetime need for restoration replacement; annual mercury waste management and patient productivity losses associated with undergoing direct posterior restoration. The consequences not included or modelled were, mercury/BPA exposure, as no clinical consequences were found from the clinical review, adverse events, as there were no noted patterns of effects between the material groups from the clinical review and patient preferences or utilities for composite or amalgam restoration of posterior teeth, as no relevant data was identified.

A very simple model was constructed as the base case to assess the lifetime need for restoration replacement in Canada which included many simplifying assumptions. These included that restorations failed at the same rate and were replaced by the same size of the same restoration over a lifetime, with no loss of teeth as shown in Figure 3.3. The cited reason for these assumptions was the 'lack of data on the natural history following a failed restoration'. The studies in the English NHS decision context as previously described do however provide this to a degree. Exploratory models involved teeth being crowned after two or three restoration failures, and then extracted when the crown failed, or extracted after three restoration failures.

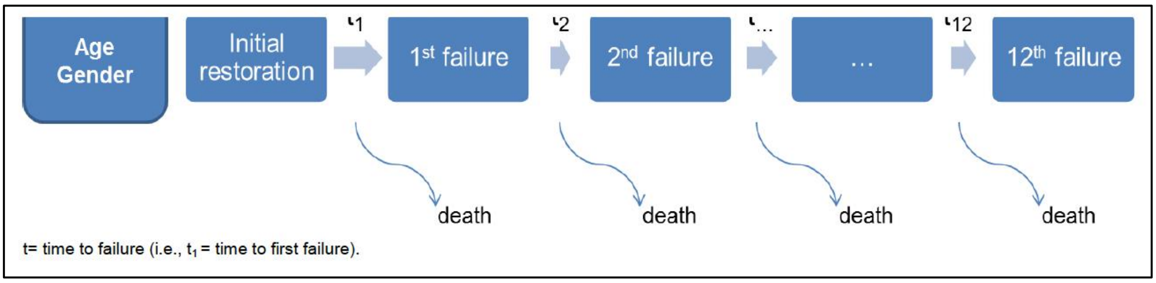


Figure 3.3. State transition diagram for a restoration
Reproduced, with permission [Appendix B], from Khangura et al., 2018.

For the useful life of a restoration (2- or 3-surface), data used to specify this was taken from a study which did not differentiate numbers of surfaces or teeth (Soncini *et al.*, 2007). It was higher for amalgam than composite (133 vs 96 months). Restorations repaired in the study were not counted as failures in the model. Restoration costs were taken from a patient perspective and lower for amalgam than composite restorations (2- and 3-surface restorations in molar and premolar teeth were averaged, and weighted averages across private and public settings calculated).

Lifetime costs were around half for amalgam compared to composite restorations. Different scenario analyses incorporated crowns or extractions with similar lifetime costs between materials, but delayed time to extraction or crown.

The annual cost for amalgam separators in Canada was estimated at around 16 million Canadian dollars. Owing to their use and efficacy, the costs of managing the mercury burden in surface water was deemed to be trivial.

Data on differences in time required for placement of different restorations were ignored in favour of expert opinion which estimated composite restorations take 15% longer than amalgam restorations (significantly reducing differences in relation to the data). This informed (potentially underestimating) the productivity loss for patients which showed an incremental loss of under 2 Canadian dollars per patient for composite. The travel and waiting time was not taken into consideration as it was assumed to be the same for both restorations, however where there is an increased frequency of replacement for one intervention, this results in a difference which was not considered.

The previous discussion shows that existing HEEs comparing amalgam and the alternatives have methodological issues and are generally limited. They are also not relevant to the UK primary care setting and many patient relevant outcomes were not included.

3.9 Summary

If, as previously discussed, the feasibility of an amalgam phase-out in England by 2030 is to be rationally considered, a comparative analysis with the alternative direct posterior restorative materials is required. Though economic evaluation data (including public preferences) are important in guiding this process, they must also consider the ability and capacity of the available clinicians to safely provide an intervention.

The existing data on material and technique use in England is old and though it explores potential issues for clinicians when using direct posterior composite restorations, it does not do so in relation to amalgam. The likely impact of an amalgam phase-out for primary care clinicians is therefore currently unknown. Phase One of this PhD will therefore use a questionnaire to elicit this information and this is described in Chapter 4.

The data on patient and public preferences for restorations is non-existent in England. The restorative options potentially vary in many health- and non-health related ways. Understanding patient preferences in relation to HCIs is important for their satisfaction with services, but also to encourage their use, promoting societal health. Phase Two will use a DCE to quantify how the general public value different aspects of a restoration in monetary terms and this is presented in Chapter 5.

Existing economic evaluations comparing amalgam and composite use simple models and have other failings, including considering only limited perspectives. They also do not relate to the English setting. Phase Three will involve the construction of a decision-analytic model to quantify the costs and consequences of amalgam and the alternatives over a lifetime which is presented in Chapter 6. This, along with data from the earlier phases will be used to perform a CCA, considering the perspectives of all major stakeholders; the funders, the patients and the clinicians, which is presented in Chapter 7.

An overall discussion with conclusions is presented in Chapter 8.

Chapter 4. Direct posterior restorations in UK primary care: the clinician perspective

4.1 Introduction

This chapter will provide an overview of the rationale for using surveys, before discussing relevant methodological issues. The survey process is explored, focussing on potential sources of error and how to minimise them, before presenting a survey of UK primary care clinicians which aimed to explore their provision of direct posterior restorations. The objectives were to: 1) identify and quantify current techniques, material use, and reported incidence of postoperative complications by UK dentists and therapists for placement of different direct posterior restorations; 2) determine primary care clinicians' knowledge of newly imposed restrictions, opinions on the phase-down and potential phase-out (including confidence in placement of the available direct posterior restorative materials in various situations), and educational experience related to posterior composites; 3) identify and quantify differences between subgroups, including those based on clinician type (dentists working primarily in private or NHS practice, or dental therapists for example) and years qualified. This work has been published (Bailey *et al.*, 2022c; Bailey *et al.*, 2022d) (Appendix A).

4.1.1 Survey rationale

The objective of a survey is to accurately and efficiently obtain information from a group of people (Biemer, 2010). Surveys can be distributed rapidly and cheaply to large numbers of people and answered anonymously, favouring honest responses (Dillman, Smyth and Christian, 2014). They are commonly cross-sectional, recording data at a single point in time to provide an understanding of the current situation, but can also be repeated over time to understand trends as demonstrated in the previous chapter. They can therefore be used for diverse purposes, ranging from research (both academic and market for example, and quantitative and qualitative), to evaluative processes, which often guide planning and decision making. Surveys may also be exploratory providing a basis for further investigation (Dillman, Smyth and Christian, 2014).

4.1.2 Survey process

The survey process has been succinctly conceptualised as shown in Figure 4.1. Having a clear idea of the aims and objectives of the survey helps to guide all aspects of the process. Equally, understanding the potential sources of error at each stage allows their minimisation with effective strategies. This optimises accuracy of whichever parameters are being measured. A survey quality framework has been suggested to aid this process as shown in Table 3.1, and is helpful to consider when carrying out surveys. These elements will be explored throughout the chapter.

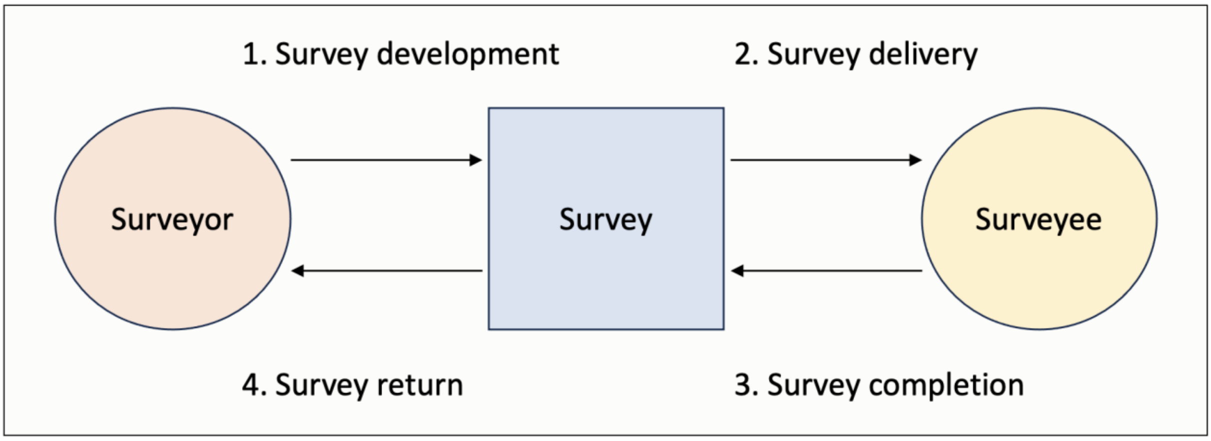


Figure 4.1. The survey process
Adapted from Fan and Yan, 2010.

Dimension	Description
Accuracy	Total survey error minimised
Credibility	Data considered trustworthy
Comparability	Valid demographic, spatial and temporal comparisons
Usability	Clear documentation with well-managed metadata
Relevance	Data satisfy users' needs
Accessibility	Easy access to data
Timeliness	Data deliveries adhere to schedules
Completeness	Data are sufficiently rich to satisfy analysis objectives whilst minimising burden on respondents
Coherence	Estimates from different sources can reliably be combined

Table 4.1 Common dimensions of a survey quality framework
Adapted from Biemer, 2010.

The following sections broadly discuss how survey quality is assessed, and the potential biases and error which can affect this. A comparison of web-based (WB) and mail-based (MB surveys) then follows, before exploring the evidence base on reducing error. Contradictory evidence exists relating to questionnaire design and use, coming, as it does, from diverse disciplines with huge variation in process. Drawing firm conclusions can therefore be difficult and are often context dependent. Surveys can be self-completed, or interviewer assisted. The following discussion will be confined to self-completed studies.

4.2 Measuring survey quality

Measuring survey quality can be difficult, therefore response rates (ResRas) are commonly used as measures of credibility because they are often easily quantifiable. Though important to consider, they reflect just a small part of potential error within a survey. Low ResRas do not necessarily invalidate survey results (Groves, 2004).

Total survey error (TSE), which has been defined as 'the accumulation of all errors that may arise in the design, collection, processing and analysis of survey data' (Biemer, 2010), may provide a more holistic and nuanced approach to characterise potential biases, but is much more difficult to quantify and is therefore rarely used or reported. Attempts to quantify TSE by calculating mean squared error have been suggested (Biemer, 2010), but this requires an error free estimate of the parameter to be measured, which may then question the need for the survey.

Despite the issues with ResRas, and perhaps because of the problems with the alternatives, ResRas are still deemed important (Blumenberg and Barros, 2018) and their ease of quantification and comparability make them useful to guide best practice.

Following a discussion of the potential errors and biases which can occur, the evidence (primarily with reference to ResRas) is explored to understand how data quality can be pragmatically maximised within an appropriate time frame and existing budget.

4.2.1 Potential error or biases

Survey errors or biases reflect the deviation of survey responses of a sample from the underlying true values of the population from which it is drawn. Attention to survey design can mitigate against their occurrence. Limiting survey error to a tolerable level, within the time and budget constraints, is a pragmatic aim. Errors can occur in relation to the respondent sample obtained, the instrument and questions used (specification and measurement of parameters), or the data processing. The following section is an explanatory overview of these biases, which leads into an exploration of the evidence base around best practice and available guidance.

Sampling design can have a large effect on ResRas, but also on error (Blumenberg and Barros, 2018). Sample errors occur where the sample obtained is not representative of the population from which it is drawn. They can be affected by sampling frame and coverage, i.e. how the sample is obtained, non-response (often measured as ResRa) and sample size. Open sampling frames, for example, where a shareable link to a survey is placed on social media, potentially allow repeat responses, or responses from unintended respondents (for example non-UK-based respondents when the survey intends to sample UK-based respondents only). They also do not allow calculation of an accurate response rate and therefore potentially have more risk of bias than closed sampling frames, where the response rate and characteristics of the population may be more accurately known. Closed sampling frames may still be at risk of bias however, if the group surveyed is potentially different from the intended population, which are often termed non-coverage errors and clearly cannot be assessed by ResRa. Collection of respondent demographic data can help to assess potential sampling error. Random or probability sampling often provides better quality data than when using non-probability or opt-in samples (for example when using online panels) however this is not always the case and may be mitigated (to a degree) by using representativeness quotas for some characteristics (Callegaro *et al.*, 2014; Evans and Mathur, 2018). Probability sampling is often much more labour intensive and costly than opt-in samples. Responders may be systematically different to non-responders (non-response bias), and small sample sizes are at more risk of bias, reduce precision and may preclude more sophisticated and interesting methods of data analysis. Sample errors limit data generalisability i.e. can lead to issues of external validity.

Measurement error can arise from respondents unintentionally, for example, as a result of faulty recall, or being more likely to agree to any statement - acquiescence bias. They can also arise intentionally, for example because of social desirability bias, where people wish to be perceived as doing the socially or commonly accepted thing, when in fact they would not or do not. This is often seen when asking sensitive questions. Whilst social desirability bias is more of an issue with face-to-face interviews, it can still have an effect in self-completed surveys, as can an aversion to answering sensitive questions (Grimm, 2010). Assurances of anonymity rather than confidentiality have been shown to minimise such errors in certain situations (Durant, Carey and Schroder, 2002), but not in others (Werch, 1990). Specification error is a form of measurement error which can occur where a survey question is confusing, poorly worded or ambiguous, such that the respondent answers the question in an unintended way and therefore does not meet the objective. This, as well as excessively long surveys or cognitively complex questions, can also lead to non-completion of surveys (attrition) or careless responses, for example when a respondent selects the same answer for all questions. Data collection may be more easily validated in WB rather than MB surveys, for example by assessing completion times. Better quality results, in terms of response bias, due to reduced question non-response, have been achieved with WB over MB surveys, despite reduced ResRas (Shin, Johnson and Rao, 2012). Respondent's prior knowledge of the survey subject and how interesting this is to them (topic salience) is often much more impactful on error than ResRas, alongside the design features of the survey and characteristics of the sample, for example (Groves and Peytcheva, 2008). Survey attrition and careless responses have been shown to result in measurement error, but there was minimal association between these two elements. Careless responses and attrition should therefore be borne in mind when assessing responses and the validity of results (Ward *et al.*, 2017).

Data processing error includes issues with data entry, coding and editing. Pre-specifying a data analysis plan, defining variables in advance and collecting data in an appropriate form minimises the need for subsequent coding and editing, which can minimise error. Measurement and data processing errors can lead to poor internal validity.

The mode of distribution can influence many of the previously described biases as mentioned. As an example, data entry is much less likely to be problematic in WB surveys than MB, given the automated input. Choosing a mode of delivery is an important decision in the survey process and will vary depending on many diverse factors. The following sections will therefore discuss the different modes of distribution and their relative advantages and disadvantages to allow a rational decision to be made in the given context. It should be noted that throughout this section, the continuing development of the internet and its expanding coverage have had large effects on WB questionnaires (Evans and Mathur, 2018), inevitably in unforeseen ways. This potentially challenges the relevance of older evidence in a rapidly evolving field.

4.3 Mode of delivery

The strengths and weaknesses of WB surveys (in relation to MB surveys) were summarised two decades ago as shown in Figure 4.2 (Evans and Mathur, 2005). They are still valid today perhaps with the exception of the worries about lack of respondent online experience (for example if considering a current population of UK dentists and therapists).

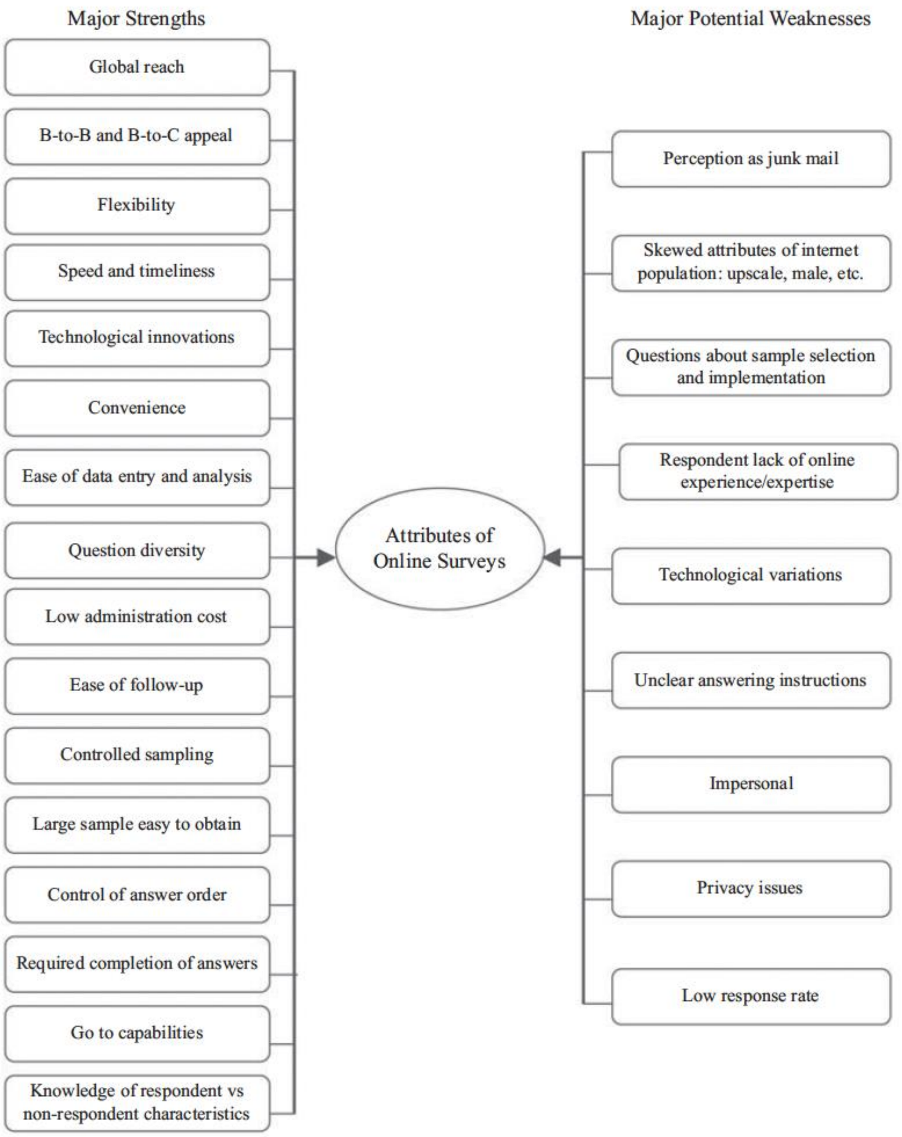


Figure 4.2 Strengths and weaknesses of web-based surveys
Reproduced, with permission [Appendix B], from Evans and Mathur, 2005.

Selecting the appropriate mode of delivery is dependent on multiple factors, including characteristics and accessibility of the intended survey population. General Data Protection Regulation (GDPR) now limits how people can be contacted, and potentially complicates MB surveys. Use of existing mailing lists and online panels held by associations with consent to contact is a benefit of WB surveys. The main advantages of WB surveys however are cost, speed, convenience and ease of obtaining large sample sizes, with the main concern relating to potentially low ResRas. This is not necessarily an indicator of poor survey quality however, as will be explored in the following sections.

As previously shown, Fan and Yan 2010 conceptualised the survey process as four steps: development, delivery, completion and return. The elements show considerable overlap however, so they will be discussed narratively in terms of good practice and how the evidence base supports them.

4.4 Effects of survey design on response rate

A summary of a very large Cochrane review (including the medical literature) on optimising ResRas in WB and MB surveys is presented in Table 4.2 (Edwards *et al.*, 2002). There was no evidence that different ordering of questions had an effect on ResRas in MB surveys, no evidence for an effect when varying the value of non-monetary or monetary incentives in WB surveys and no evidence of any difference in ResRas with university sponsored WB surveys, in contrast to the MB surveys. There was substantial heterogeneity noted for many of the pooled analyses, which suggested the results should be interpreted with caution.

Methods to increase response rates in descending order of effect size	
Mail-based	**Web-based**
Teaser suggesting benefit to open envelope	Picture included in the email
More interesting topic (relevant to respondent)	More interesting topic (relevant to respondent)
Monetary incentive	Shorter vs longer
Sent by recorded delivery	Non-monetary incentives (e.g. gift cards, lottery participation)
Shorter vs longer	Including a statement that others had responded
Unconditional incentive not reliant on response	Lottery incentive with immediate notification vs delayed
Mention of obligation to respond	Offer of survey results
Second copy of questionnaire included in follow up	White background vs black
Pre-notification of survey	Personalised e-questionnaires
Follow-up contact (reminder)	Using a simple header vs complex
Assurance of confidentiality	'Survey' not included in subject line
University sponsorship vs not	No male signatory in email
Handwritten addresses	
Inclusion stamped addressed envelope vs franked	
Non-monetary incentives (e.g. gift cards, lottery participation)	
Personalised questionnaires	
First class outward mailing	
No sensitive questions	

Table 4.2 Mail- and web-based survey features resulting in increased response rates
Adapted from Edwards et al., 2002.

The following section discusses reviews directly comparing WB and MB ResRas, but the conclusions drawn are more limited due to the more limited data.

WB studies have consistently lower ResRas than MB studies and reviews agreed that reminders may not be as effective in improving responses in WB compared to MB studies (Shih and Fan, 2008). Interestingly however, in one study when respondent groups were split, no differences were found (Manfreda *et al.*, 2008), whereas in another study student ResRas were higher with WB than MB (Shih and Fan, 2008). Both studies, and especially 'professionals' showed lower ResRas with WB however. Perhaps surprisingly the year the study was conducted did not affect the results. Both studies reported no differences when incentives were offered or not between the different distribution modes.

In a review of variables affecting ResRas specific to surveying general medical practitioners, which could be deemed translatable to surveying other healthcare professionals, only one study compared WB and MB delivery (Pit, Vo and Pyakurel, 2014). This showed a reduced ResRa with WB, but much quicker responses, and more frequent and longer comments. Survey completion was not affected by delivery mode (Seguin *et al.*, 2004). In the MB surveys, monetary and non-monetary incentives were shown to be more effective than no incentive and larger incentives more effective than small. Upfront incentives were more effective than promised incentives. Mixed-mode (MM) surveys, which use elements of both WB and MB surveys showed increased ResRas over MB surveys. Evidence relating to pre-contacting participants was sparse, but showed some benefit, similar to the findings of a Cochrane review (Edwards *et al.*, 2009).

Though participation has been shown to increase with topic salience (Groves, Presser and Dipko, 2004; Keusch, 2013), it can however be reduced if the topic feels threatening to respondents (Nederhof, 1985). Providing rewards (as is often the case with online panels) can mitigate against this aversion to answering sensitive questions and maintain high data quality alongside providing an option of 'prefer not to say' (Dillman, Smyth and Christian, 2014). Respondent motivation to answer surveys varies however and the effects of external motivations such as incentives can be unpredictable (Roster, Albaum and Smith, 2017). More recent studies than the Cochrane review (Edwards *et al.*, 2009) have shown lottery incentives to improve ResRas over other incentives in WB surveys (one MM with MB pre-contact) (Gajic, Cameron and Hurley, 2012; Pedersen and Nielsen, 2016).

Based on a very large analysis of over 25,000 web surveys on broad topics and with diverse populations, surveys which were longer, and those with difficult or sensitive questions had lower completion rates (Liu and Wronski, 2018), similar to earlier findings (Edwards *et al.*, 2009). It also showed that surveys without progress bars showed higher completion rates than those which did (Liu and Wronski, 2018), despite their inclusion often being deemed best practice (Evans and Mathur, 2018) and perhaps more ethical. Two student surveys showed a significant drop in ResRas when completion time exceeded 13 minutes in a later review (Asiu, Antons and Fultz, 1998; Handwerk, Carson and Blackwell, 2000; Fan and Yan, 2010).

4.5 Questionnaire design: further considerations

There are many texts which provide expert (alongside evidence-based) guidance on questionnaire design, and these are drawn on in the following sections (Dillman, Smyth and Christian, 2014; Fowler, 1995; McColl *et al.*, 2001; Sudman and Bradburn, 1982).

4.5.1 Piloting and questionnaire appraisal

Piloting a questionnaire has been deemed the best way to assess the quality of a survey before its use (Geisen and Bergstrom, 2017), especially when WB (Fan and Yan, 2010). Various methods have been suggested, from the simple use of informal testing on colleagues and friends, to expert review, and use of think aloud techniques, with or without interviewer rating forms (Fowler, 1995). Field testing with usability testing, respondent debriefing, and cognitive interviewing have also been suggested (Campanelli, 1997; Lazar and Preece, 1999; Geisen and Bergstrom, 2017), but there is limited evidence on which is most effective. These techniques could help to reduce measurement, specification, non-response, attrition and careless response errors.

4.5.2 Question formulation guidance

Use of exact, specific wording of questions has been deemed important. Ambiguous concepts and words should be clarified, which may require a definition as part of a question, or a definition prior to a question. Adjuncts to provide definitions, such as using links as underlined words to provide definitions in WB surveys are rarely accessed by respondents and should therefore be avoided (Conrad *et al.*, 2006).

Where possible, questions should be short, simple and clear, which can be a trade off with the use of definitions, detail and explanations. If in doubt, brevity should not be favoured over clarity. It has been recommended to avoid vague quantifiers where possible (often, sometimes etc). Numbers and number ranges are generally preferred (Fowler, 1995). Care is required with ranking, this is best avoided in self-completion surveys, as rating is preferred by respondents, and it provides information as to where items are located on a value continuum, which ranking does not (Fowler, 1995; Alwin and Krosnick, 1985). Recommendations advise the avoidance of 'tick all that apply' lists, as there is a risk of primacy effect whereby respondents select from the top of the list, due to the visual layout. The absence of a response introduces uncertainty as to whether the respondent has considered the statement or not. It is better to have a yes/no response to each question (Thomas and Klein, 2006; Sudman and Bradburn, 1982). A ‘don’t know’ option should only be included if this is a valid possibility, for example when asking for long-term recall due to memory decay effects (Dex, 1995). Including such an option did not affect ResRas to MB surveys (Edwards *et al.*, 2009).

It has been advised to avoid context effects where possible, which can arise through question ordering. This is where answers provided to questions can subsequently affect responses to later questions. Similarly caution is advised with hypothetical questions, especially where respondents have limited experience on which to base their answers (Fowler, 1995).

Likert-type scales can be unipolar, where there is no conceptual mid-point (a middle category), and a zero point at one end; or bipolar, where there is a conceptual mid-point (e.g. ‘neither agree nor disagree’) and two opposing alternatives. Although contentious, some scales can be considered continuous, whereas labelled rating scales are more appropriately considered ordinal in nature (Harpe, 2015).

The labelling of scales depends on the specifics of the scale and the intended analysis. Fully-labelled scales are generally easier for respondents to use than end-labelled scales, however this generally commits data obtained to being analysed ordinally, rather than continuously. While longer scales may be preferred as they are generally more discriminatory, they require more thought and become more cognitively complex for respondents. They are also at risk of measurement error due to false precision (Peeters, 2015).

Despite this concern, four options (+/-1) has been described as ideal based on our ability to process information (Peeters, 2015). Inclusion of a middle category should only be used if a true middle position can be held. It can however still offer an easy way out for the respondent, which may not reflect their true position. Five categories are therefore advised if a middle category is included. Agree/disagree questions using Likert-type scales are cognitively complex, and are prone to acquiescence or yea-sayer bias, as respondents have a tendency to confirm rather than disconfirm statements (Kahneman, 2011). Balance should be created where possible with both positive and negative statements, however this exacerbates the complexity of an already complex cognitive task.

Opinions may be better explored using open questions, but this is much more time consuming and data interpretation is more complex (Fowler, 1995). Likert scales are often collapsed to binary (agree/disagree) variables in analysis, as interpretation of the results is easier. Forced binary choices have been shown to be simpler, less time consuming and equally as reliable as Likert scales when surveying managers (Dolnicar, Grün and Leisch, 2011), which potentially impacts on survey completion and careless responses. There is less granularity however, so the type of data and method of analysis should also be borne in mind when using rating scales. It has also been suggested that forcing answers should be avoided, as this may bias results, irritate the respondents, and should ethically respect the voluntary nature of the process (Dillman, Smyth and Christian, 2014), which may be relevant when surveying different populations. Soft prompts in pop-ups have been shown to be beneficial in reducing omission of answers (Schonlau, Ronald Jr and Elliott, 2002).

Vignettes present a hypothetical situation, commonly using concrete situations which the respondents are familiar with. This can engender participant engagement. They are therefore often more realistic than conventional survey questions, which can be seen as abstract. Variables can easily be modified, for example by changing single variables, to understand their effects. The vignette experiment methodology can therefore achieve a high internal validity, and when combined with a survey methodology can extend the external validity, making the results more generalizable, with the caveat that generalisations are drawn from a specific situation (Schonlau, Ronald Jr and Elliott, 2002).

4.5.3 Sequencing, format and presentation

Much is often made of sequencing of a survey, often advising a funnelling approach that starts with broad questions, before becoming more focussed (Dillman, Smyth and Christian, 2014), but the evidence base didn’t show any significant effects when this was altered (Edwards *et al.*, 2009). Guidance suggests that there should be a meaningful flow to the survey with a consistency of styling and layout. Answer spaces should be placed to the right of the question and be close by, or indicated by differential colours or shading (Dillman, Smyth and Christian, 2014). White backgrounds have been shown to promote increased ResRas compared to black (Edwards *et al.*, 2009).

WB surveys can progress through a scrolling approach or a paging approach. Evidence suggests there is minimal difference between outcomes when using the two approaches (Peytchev *et al.*, 2006). Scrolling is generally beneficial in short surveys, whereas paging is more practical in longer surveys, allowing answers to be saved as the respondent progresses. With paging, a balance should be struck between the number of questions on a page and font size. More questions on a page can improve response time, but pages shouldn't appear crowded. Natural section breaks should be taken advantage of (Conrad *et al.*, 2006).

Breaking the survey into clear sections can be beneficial, as can numbering of questions, especially in paper and scrollable WB surveys as they facilitate respondent navigation. This is less of an issue with paging WB surveys. Generous spacing on the page is beneficial, and in paging web surveys the whole question and answer options should fit on the screen (Dillman, Smyth and Christian, 2014). It is also important that WB surveys are compatible with mobile devices, given that many surveys are accessed and answered on such devices and it seems this is only likely to increase (Evans and Mathur, 2018).

Routing in response to certain answers is beneficial to avoid multiple 'does not apply' answers, which could stop the respondent from completing the survey. Routing should be automatic in WB surveys to reduce respondent burden (Dillman, Smyth and Christian, 2014).

There were no differences in the quality of responses with easily used question formats on small screens, when comparing responses from mobile devices or PCs (Antoun, Couper and Conrad, 2017).

Many elements of good design, as discussed in the previous subsections have been shown to maximise ResRas in WB surveys (Fan and Yan, 2010).

4.6 Guidance documents on performing and reporting surveys

In addition to the texts described, evidence-based guidance on performing online surveys with suggestions of best practice has been thoroughly described in checklists by Evans and Mathur, 2018. There are also many checklists available to understand important survey parameters to report which include, Strengthening The Reporting of Observational Studies in Epidemiology (STROBE) guidance (von Elm *et al.*, 2014; Bennett *et al.*, 2011; Eysenbach, 2012).

4.7 Summary

There are many ways in which ResRas can be optimised which are consistent across delivery modes, whereas other elements appear to be mode specific. An awareness of these similarities and differences can help guide and select appropriate survey processes to achieve the desired objectives and to maximise ResRas. Where money is no object and time is plentiful, MB surveys can offer improved ResRas. Low ResRas constitute a small part of the TSE however. Many other elements are important in producing quality outputs and an overview of the evidence has been presented along with references to good practice guidance and reporting checklists. WB studies have grown as internet coverage has grown, with added benefits of lower costs, more efficient and validated processes of delivery and data capture, often with greater consistency. These can potentially provide better quality results compared to MB surveys despite commonly obtaining reduced ResRas, resulting in timely, accessible and relevant data.

The remainder of the chapter will describe the empirical research.

4.8 Objectives

The objectives of the study were to:

a. Identify and quantify current techniques, material use, and reported incidence of postoperative complications by UK dentists and therapists for placement of different direct posterior restorations;
b. determine primary care clinicians' knowledge of newly imposed restrictions, opinions on the phase-down and potential phase-out (including confidence in placement of the available direct posterior restorative materials in various situations), and educational experience related to posterior composites;
c. identify and quantify differences between subgroups, including those based on clinician type (dentists working primarily in private or NHS practice, or dental therapists for example) and years qualified.

4.9 Methods

4.9.1 Questionnaire development

A cross-sectional WB survey was developed as shown in Appendix D1 (including a link to the online questionnaire), loosely based on the recent Welsh survey (in collaboration with the lead author) (Lynch *et al.*, 2018b), alongside other surveys identified in Chapter 2 (Gilmour *et al.*, 2009; Brunton *et al.*, 2012; Alexander *et al.*, 2016; Alexander *et al.*, 2017a; Alexander *et al.*, 2017b). It was modified, based on best practice questionnaire methodology outlined in the previous section, to reduce survey error and to reflect the objectives of the study. These included obtaining quantitative information on current techniques and materials used, rather than material preferences in particular situations. The study received a favourable ethical opinion from Newcastle University Research Ethics Committee (ref 7262/2018) and a data management plan (DMP) was created. It was reported with reference to STROBE guidelines (Bailey *et al.*, 2022c; Bailey *et al.*, 2022d).

Open and closed questions were used, with utilisation of clinical scenario vignettes and various Likert scales. The survey sought information on respondent demographics, education, current provision of direct posterior restorations (excluding localised cervical [class V]), and perceived issues with the different available materials. It also assessed clinicians' opinions and confidence in amalgam and the alternatives in various situations, and knowledge of the amalgam phase-down and proposed phase-out. Their experience of undergraduate and postgraduate education on direct posterior composites was also obtained. The questionnaire spanned a maximum of 24 screens containing 90 items, with one screen conditional on a previous response.

The questionnaire underwent an initial round of piloting in paper and email form with usability testing using systematic form appraisals and 'think aloud' techniques as described in section 4.5.1. The piloting involved distribution to GDPs, hospital consultants, CDS dentists, dental therapists and academic dentists aiming to engage with all major divisions in the target demographic. Verbal and written feedback was received in a continually evolving process, so that good suggestions for change were incorporated in a newly updated questionnaire prior to further appraisal. It was then formatted electronically by the BDA, who also offered suggestions for improvement, for use with the SmartSurvey online platform (www.smartsurvey.co.uk). It then underwent further piloting including observational usability testing and assessing the ease of navigation with mobile devices. Time taken to complete the survey ranged from a reported 8 minutes to a recorded 9 minutes 43 seconds, which was deemed sufficiently short to not risk lowering completion or ResRas based on the literature review presented in the first part of this chapter. Changes were made based on these processes relating to wording, using a consistent direct questioning style, ordering of questions, layout, omissions, and replications of similar questions. Clarification of options was required, with addition of examples suggested and implemented.

4.9.2 Sample

A sample size calculation was performed, based on the core aspect of analysis, a multiple linear regression (MLR) investigating factors influencing time booked for placement of a mesio-occluso-distal (MOD) direct posterior composite with 21 independent variables. Treatment time was the primary outcome as it would be used in the subsequent model described in Chapter 6. Various 'rule of thumb' calculations exist for MLR minimum sample size, providing various estimates (Roscoe, 1975) with 630 the largest obtained and therefore used (Pedhazur and Schmelkin, 2013).

The questionnaire was then distributed by email to all BDA member GDPs and CDS dentists, and all therapist members of the British Society of Dental Hygiene and Therapy (BSDHT) and the British Association of Dental Therapists (BADT) (11092 invitations). A closed sampling frame was used for BDA members, which allowed tracking of respondents through the use of specific identifiers. This allowed the prevention of duplicate entries, whilst allowing the use of targeted reminders and a monetary incentive of £100 for one respondent selected by random draw. Due to the systems in use, it was not possible to identify individual responders in the BSDHT and BADT groups, therefore targeted reminders and incentivisation were not possible. It was specified that the link should not be shared to limit the sampling frame to only those therapists receiving the invitational email. Two blanket reminders were sent to all three groups, with a link to the questionnaire attached. To encourage responses, the questionnaire was advertised on social media platforms and through the BDA In Practice (March 2019) magazine (the questionnaire was not accessible through these platforms however). The questionnaire was launched 14th February 2019 and the deadline for response was 31st March 2019.

The first screen of the survey detailed its anonymity, the research purpose and team involved, data handling and option and directions for opt-out. Consent was provided through a simple yes/no question after eligibility and understanding were similarly confirmed.

Survey data were received electronically and automatically captured by the BDA. Any identifiers were removed, and the anonymised data were passed securely to Newcastle University for analysis.

4.9.3 Data analysis

Data were cleaned, imported and analysed using Stata software (version 16; StataCorp LP). Sub-groups were defined in relation to prior hypotheses and are presented in the results section. Respondents were asked to indicate how often they used each restorative technique and materials or suffered from post-operative complications. They were given eight options, including 0%, 100% and five ranges in between. A not applicable option (N/A) was also included which was only to be used if the clinician placed no restorations in the specified material. These were analysed and combined into the groupings shown in the relevant tables under percentage use. N/A answers were removed to calculate incidence of post-operative sensitivity. The tables indicate the percentage of respondents who stated that they use the technique or material for each of the percentage use bands. Clinicians were also asked their opinions about various aspects of the phase-down based on a 5-point Likert scale. Responses for ‘strongly agree’ and ‘agree’; and ‘strongly disagree’ and ‘disagree’ were combined and presented. Clinicians were also asked to state how confident they were placing direct posterior restorations in different clinical situations based on a 5-point Likert scale. Responses for ‘complete confidence’ and ‘high confidence’; and ‘no confidence’ and ‘low confidence’ were combined and presented.

Descriptive statistical testing was performed and datasets were assessed for normality of distribution using Shapiro-Wilk tests. Two-way hypothesis testing was performed with Chi^2, Kruskal Wallis and Wilcoxon signed rank sum tests, depending on the data type and distribution. Regression analyses were run with backwards stepwise elimination. Best fit models were selected by the lowest Bayesian Information Criterion (BIC) value. Potential multicollinearity was assessed using variance inflation factors (VIFs) with values under 5 accepted as not problematic (Kim, 2019).

MLR analyses were run to assess the impact of clinician and technique variables on private fee charged, and appointment time booked for the placement of a direct posterior mesio-occlusal (MO) and MOD composite. Logistic regression analyses were carried out to assess the impact of clinician and technique variables on reported low (0-10%) incidences of post-operative food packing and sensitivity with direct posterior composite restorations, and with high or complete confidence in placing direct posterior composite restorations in various situations (MOD cavity, sub-gingival margins, and in patients with limited cooperation).

4.10 Results

1570 responses were received. 54 respondents were not suitable to participate in the study, answering negatively to one of the eligibility questions. This was mainly due to the respondents not currently practicing dentistry or placing direct restorations (or both) (n=51). Three respondents were suitable, but then failed to answer any further questions. 1513 usable responses were received. Dentists' response rate was 14%, and therapists' estimated minimum response rate was 6%. One respondent did not answer the final question but all other remaining respondents did, giving a survey completion rate of 99.8% (of those who indicated their eligibility). A small minority of respondents gave contradictory answers (in the material usage section), which were excluded from analysis to reduce measurement error.

The minimum time taken for respondents to complete the questionnaire was 5 minutes (which was deemed sufficient time to complete the questionnaire), with a median value of 16 minutes.

Percentages are rounded to the nearest integer throughout. Direct posterior restorations exclude localised cervical (class V) restorations.

4.10.1 Demographics

The basic demographics are shown in Table 4.3. Categorisation of a dentist's primary role was determined by the dominant number of sessions performed in general dentistry or CDS.

NHS and mixed GDPs were evenly represented by gender, whereas private GDPs had a greater proportion of males, and CDS dentists and therapists had a much greater proportion of females (Appendix D2.1 Table) and the differences were statistically significantly different (Chi^2 $p<0.001$).

Respondents whose primary dental qualification was EU (non-UK) or Non-EU based, mainly worked in general dentistry, with a lower proportion working in the CDS and none working as therapists (Appendix D2.2 Table). The differences between groups were statistically significant (Chi^2 $p=0.001$).

As dentists' number of years of qualification increased, the proportion working as NHS GDPs reduced and the proportion working as private GDPs increased (Appendix D2.3 Table) and this difference was statistically significant (Chi^2 $p<0.001$).

Variable	**Category**		**Number**	**Percent**
Gender	Female		743	49
Clinician primary role	Dentist	NHS General (75-100% NHS patient base)	617	41
		Mixed General (25-74% NHS patient base)	194	13
		Private General (0-24% NHS patient base)	509	34
		CDS	118	8
	Therapist		75	5
Primary dental qualification location	UK		1294	88
	EU (non-UK)		101	7
	Non-EU		81	5
Years qualified	≤2		57	4
	3-5		82	5
	6-10		159	11
	11-15		157	10
	16-20		195	13
	21-25		176	12
	26-30		195	13
	31-35		252	17
	≥36		239	16

Table 4.3. Respondent demographics

4.10.2 Material use for direct posterior restorations

Table 4.4 shows the percentage of premolars and molars respondents restored with composite, amalgam and other materials. Composite was the most used directly placed material to restore premolar teeth, whereas amalgam was marginally the most used in molar teeth. Only 6.7% respondents used no amalgam and 0.4% respondents used no composite for direct posterior restorations.

Composite use in molar teeth increased as the clinicians' number of years qualified increased from a mean of 32% (standard deviation (SD)=24) in those qualified for 0-5 years, to 52% (SD=33) in those qualified ≥26 years as shown in Figure 4.3. The differences were statistically significant (Kruskal-Wallis p=0.0001). The percentage of molar teeth restored directly with composite was lower in NHS GDPs (26%; SD=22), but higher in private GDPs (73%; SD=26), than therapists (41%; SD=29), mixed GDPs (45%; SD=25) or CDS dentists (38%; SD=28) as shown in Figure 4.4. The differences were statistically significant (Kruskal-Wallis p=0.0001).

Material	**Average use by tooth (%)**					
	Premolar			**Molar**		
	%	Standard deviation	Missing (%)	%	Standard deviation	Missing (%)
Composite	55	32	0.1	46	32	0.01
Amalgam	38	31	0.01	48	32	0.1
Other	6	10	0.1	6	9	0.3

Table 4.4. Average percentage use of amalgam, composite and other direct materials (GIC/RMGIC/Other) by posterior tooth type

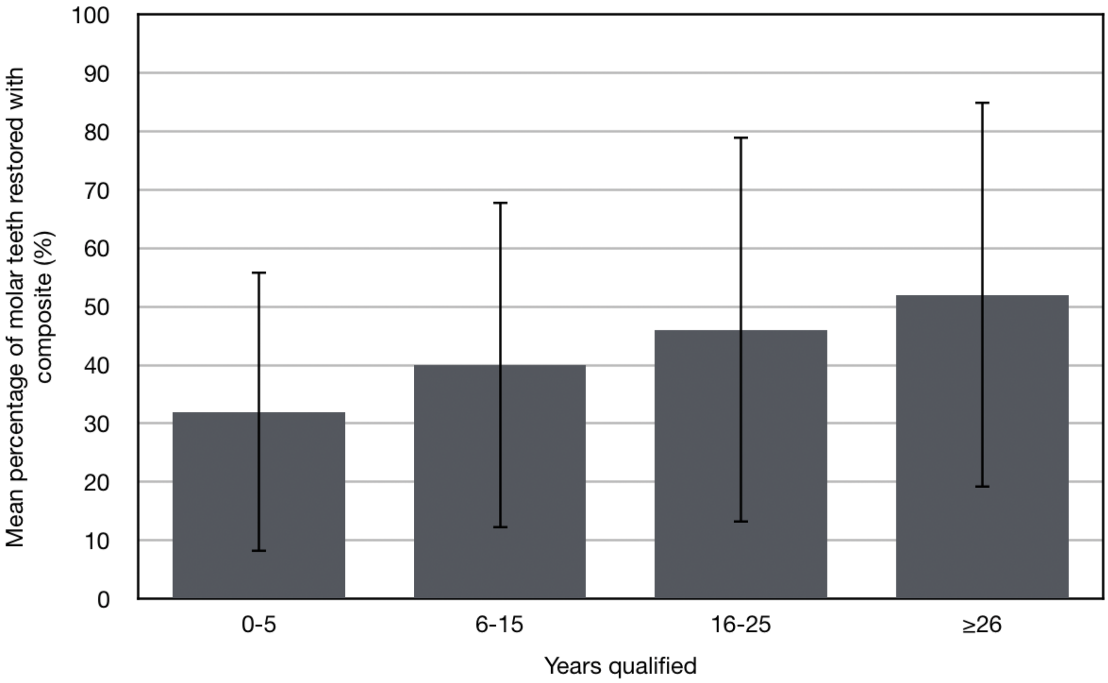


Figure 4.3. Mean percentage of molar teeth restored with composite by clinician experience

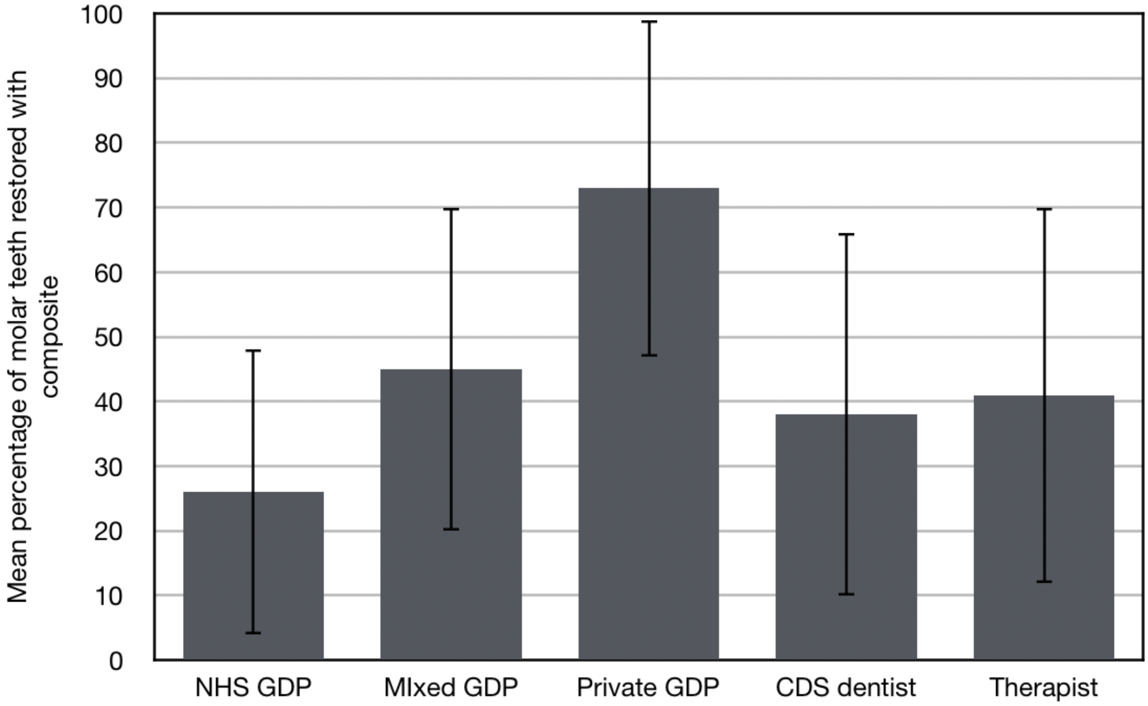


Figure 4.4. Mean percentage of molar teeth restored with composite by clinician type

4.10.3 Appointment time and fees charged

Table 4.5 details the mean appointment time booked and mean private fees charged for different clinical scenarios. Wilcoxon signed rank tests showed appointment time booked and private fee charged for a 3-surface MOD restoration in a molar tooth were statistically significantly higher ($p<0.0001$) when comparing composite with amalgam as the restorative material. Similar statistical differences were shown for the 2-surface MO premolar restorations. Clinicians booked 45% more time, and charged 45% more (as a private fee), to perform a direct MOD composite in a molar tooth, than for the same restoration in amalgam. The ranges of appointment time booked and fees charged were wide.

For MOD composites, NHS GDPs booked shorter appointment times, and private GDPs longer appointment times than therapists, mixed GDPs and CDS dentists. These differences were statistically significant (Kruskal-Wallis p=0.0001). NHS GDPs booked shorter appointment times than other clinician types for 2- and 3-surface amalgam restorations (Appendix D2.4 Table).

Restoration	**Material**	**Appointment time booked (minutes)**					**Cost (£)**			
		Mean	SD	Range	95% CI	Missing (%)	Mean	SD	Range	Missing (%)
2-surface MO premolar	Composite	34	9	15-90	34 - 34	0.4	112	42	30-400	10
	Amalgam	24	7	10-60	24 – 24	4	78	34	13-350	18
3-surface MOD molar	Composite	42	11	15-120	42 – 43	1	138	52	40-460	10
	Amalgam	29	8	5-60	29 - 30	4	96	43	18-450	18

Table 4.5 Appointment time booked, and private fee charged for mesio-occlusal (MO) premolar and mesio-occluso-distal (MOD) molar restorations
SD, standard deviation; CI, confidence interval.

4.10.4 Direct posterior restorative technique and material use

RD use for direct posterior composite restoration was generally low, and barely used for amalgam. Circumferential metal matrices were by far the most used matrix for both materials, but more so for amalgam, with a greater variety of matrices more commonly used for composite. Use of a liner when placing a restoration in a tooth without a pulp exposure was variable for both materials, but was used more commonly for amalgam, and wedges were commonly used when restoring a lost proximal surface for both materials, but slightly more often with composite (Appendix D2.5 Table and Appendix D2.6 Table). When used, GIC/RMGIC liners were the most commonly used for composite (55% of responses), whereas calcium hydroxide-based materials were more commonly used for amalgam (49% of responses) as shown in Appendix D2.7 Table and Appendix D2.8 Table. CSCs were rarely used as liners, accounting for 5% of responses with composite and 1% with amalgam.

Private GDPs were more likely to report high recommended composite technique use (sectional matrix, RD, wedge and no liner use) than any of the other groups, (Appendix D2.9 Table). The differences between clinician groups were statistically significant for all techniques (Chi2 $p<0.0001$). High RD and sectional matrix use was however still uncommon amongst private dentists. Sectional matrix, RD and wedge use was lower in recently qualified graduates, though the difference in RD use did not reach statistical significance (Appendix D2.10 Table).

Incremental conventional composite placement was by far the most commonly used technique to directly restore a posterior tooth with composite compared with various bulk-fill options and non-incremental conventional placements (Appendix D2.11 Table).

Use of a total-etch 2 step bonding technique was by far the most commonly used bonding strategy for posterior composite restoration placement (Appendix D2.12 Table).

4.10.5 Post-operative complications encountered

Table 4.6 shows the clinician reported incidence of post-operative complications. Wilcoxon signed rank tests showed statistically significantly higher clinician reported incidences ($p<0.0001$) of both food packing and sensitivity following direct posterior restoration with composite compared with amalgam. Forty-six percent of respondents (46%) reported that their patients reported sensitivity, and 42% reported that patients reported food packing in more than one in ten composite restorations placed, compared to 18% and 14% respectively with amalgam. Seventeen percent (17%) indicated patient reported sensitivity, and 13% patient reported food packing in more than one in four composite restorations placed, compared to 4% and 3% respectively with amalgam.

Post-op problem	**Material**	**Incidence (%)**			
		0-10%	11-25%	26-50%	50-100%
Sensitivity	Composite	53	29	12	5
	Amalgam	80	15	3	1
Food packing	Composite	59	29	9	4
	Amalgam	85	12	3	0

Table 4.6. Clinician reported incidence of post-operative problems encountered following direct posterior restoration placement with different materials

Private GDPs reported the lowest incidence of sensitivity following direct composite placement compared to other clinicians. 15% of therapists reported post-operative sensitivity in more than one in two direct composite restorations placed (Appendix D2.13 Table). The differences were statistically significant (Chi^2 $p<0.001$). CDS dentists reported the lowest incidence of post-operative sensitivity following amalgam restorations, with therapists again reporting the highest incidence, but much reduced compared to their incidence with composite.

Private GDPs reported the lowest incidence of food packing following direct composite and amalgam placement compared to other clinicians as shown in Appendix D2.14 Table. The incidence of food packing following amalgam placement was highest in therapists. The differences were statistically significant (Chi^2 $p<0.001$).

Appendix D2.15 Table and Appendix D2.16 Table show that reported incidences of both sensitivity and food packing following both composite and amalgam placement generally reduced as years qualified increased (with the exception of sensitivity post composite placement in the 0-5 and 6-15 years qualified groups, where this was reversed, but with a small difference). The differences were all statistically significant (Chi^2 $p<0.001$) except for food packing incidence post composite placement (Chi^2 $p=0.259$).

Appendix D2.17 Table shows that clinicians primarily using sectional metal matrices reported a much lower incidence of food packing following direct posterior composite restoration than those exclusively using circumferential matrices. The difference was statistically significant (Chi2 $p<0.001$). It also shows that clinicians using RD 76-100% of the time resulted in a lower incidence of reported sensitivity following direct posterior composite placement compared with other levels of use. The difference was not statistically significant however (Chi2 $p=0.065$).

4.10.6 Bulk-fill composites

Sixty-eight percent of respondents reported having experience of using bulk-fill composites (n=1513). These clinicians had most experience of using flowable light-cured bulk-fill composites (53%). Smart Dentine Replacement (SDR, Dentsply) was by far the most commonly named material (42%). Non-bulk-fill composites, compomers, GICs and resin-modified GICs accounted for 8% of categorisable responses as shown in Appendix D2.18 Table. Clinicians who had experience of using bulk-fill composites generally found them easier to place, time saving but less aesthetic, with a majority neither agreeing nor disagreeing that they achieved more predictable outcomes, or resulted in reduced post-operative sensitivity as shown in Appendix D2.19 Table).

4.10.7 Regression analyses exploring influences on time, cost and post-operative complications when placing posterior composite restorations

All VIFs were less than 3, indicating low correlation between potential variables and supporting their inclusion in the models, an example of which is shown in Appendix D2.20 Table. In all regression analyses, pseudo or adjusted R^2 values suggested a great deal of the variance was unexplained. However, significant factors in each model are discussed below.

Independent variable (predictor)		Coefficient	SE	t	P>t	95% CI
No undergraduate clinical teaching *(ref had UG teaching)*		0.23	0.93	0.24	0.808	-1.59 - 2.05
No postgraduate training *(ref had PG training)*		-0.31	1.25	-0.25	0.802	-2.77 – 2.14
UK primary dental qualification *(ref non-UK)*		-1.02	1.22	-0.83	0.404	-3.42 – 1.38
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*						
	Private general dentist (0-24% NHS patient base)	5.77	1.15	5.04	**0.000**	3.52 – 8.02
	Mixed general dentist (25-74% NHS patient base)	3.50	1.24	2.83	**0.005**	1.07 – 5.92
	CDS dentist	2.06	1.59	1.29	0.198	-1.07 – 5.18
	Therapist	4.83	2.06	2.35	**0.019**	0.79 – 8.88
Years qualified		-0.07	0.04	-1.73	0.085	-0.16 – 0.01
Female *(ref male)*		-0.32	0.81	-0.39	0.694	-1.91 – 1.27
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*		-0.48	0.95	-0.51	0.613	-2.35 – 1.39
Incremental composite user (76-100% use) *(ref <76% incremental)*		1.92	0.79	2.44	**0.015**	0.37 – 3.45
Bonding system use *(ref self-etch 1 step (76-100% use))*						
	Total-etch 3 step bond (76-100% use)	3.01	1.46	2.06	**0.040**	0.14 – 5.88
	Total-etch 2 step bond (76-100% use)	2.19	1.03	2.12	**0.034**	0.16 – 4.21
	Self-etch 2 step bond (76-100% use)	-3.24	2.85	-1.14	0.255	-8.83 – 2.34
Matrix use *(ref not CM or SM user)*						
	Circumferential metal user (100% use)	0.46	0.87	0.53	0.597	-1.25 – 2.17
	Sectional metal user (51-100% use)	3.54	1.13	3.12	**0.002**	1.32 – 5.77
High wedge use (76-100% use) *(ref <76% use)*		1.55	0.84	1.84	0.066	-0.10 – 3.21
Never liner use *(ref >0% use)*		0.89	0.85	1.05	0.293	-0.77 – 2.55
Rubber dam use *(ref 1-75% use)*						
	Never	-2.38	0.90	-2.65	**0.008**	-4.14 – -0.62
	High (76-100% use)	5.79	1.26	4.61	**0.000**	3.33 – 8.26
High confidence MOD composite placer *(ref not high confidence)*		-2.01	0.89	-2.25	**0.024**	-3.76 – -0.26
Constant		39.02	1.99	19.65	0.000	35.12 – 42.92

Table 4.7. **Factors related to appointment time booked for direct posterior mesio-occluso-distal composite restoration**

SE, standard error; CI, confidence interval; n=769; p<0.001; Adjusted R^2=0.15; AIC=5803; BIC=5905.

A multiple linear regression analysis showed the factors statistically significantly associated with an increase in time booked for placing a direct posterior MOD composite in Table 4.7. They were private GDPs (6 minutes), therapists (5 minutes), and mixed GDPs (4 minutes) compared to NHS GDPs; high RD users (6 minutes) compared to moderate users; primarily sectional metal matrix users (4 minutes); total-etch 3 step bond users (3 minutes), total-etch 2 step bond users (2 minutes) compared to self-etch 1 step bond users; and incremental composite users (2 minutes). Factors statistically significantly associated with a decrease in time booked for placing a direct posterior MOD composite were clinicians who never use RD (2 minutes) compared to moderate users and high confidence MOD composite placers (2 minutes).

A multiple linear regression analysis showed the factors statistically significantly associated with differences in time booked for placing a direct posterior MO composite in a premolar (Appendix D2.21 Table) were similar to the MOD composite with similar magnitudes. Increased time was associated with private GDPs (4 minutes), CDS dentists (4 minutes), and therapists and mixed GDPs (3 minutes) compared to NHS GDPs; high RD users (5 minutes) compared to moderate users; primarily sectional metal matrix users (3 minutes); total-etch 3 step bond users (4 minutes), total-etch 2 step bond users (2 minutes) compared to self-etch 1 step bond users; and high wedge users (2 minutes). The only factor statistically significantly associated with a decrease in time booked for placing a direct posterior MO composite was increasing years qualified (0.07 minutes/year).

A multiple linear regression analysis showed the factors which were statistically significantly associated with an increase in private fee charged for placing a direct posterior MOD composite (Appendix D2.22 Table), were private GDPs (£27.56) and mixed GDPs (£12.91) compared to NHS GDPs; high wedge users (£9.19), high confidence MOD composite placers (£8.47); incremental composite users (£8.04); and appointment time booked for a direct posterior MOD composite (£1.43 per minute increase).

The only factor statistically significantly associated with a decrease in private fee charged for placing a direct posterior MOD composite was clinicians who never use RD (£10.53) compared to moderate use.

A logistic regression analysis showed the factors statistically significantly associated with a low incidence (0-10%) of clinician reported post-operative sensitivity following placement of a direct posterior composite (Appendix D2.23 Table) were primarily composite users (combined premolar and molar composite usage > 100%) (OR=2.3) and clinicians who never use a liner (OR=1.8).

The only factor statistically significantly associated with reduced likelihood of low incidence (11-100%) of clinician reported post-operative sensitivity following placement of a direct posterior composite was being a therapist, compared to NHS GDPs (OR=0.4).

A logistic regression analysis showed the factors statistically significantly associated with a low incidence (0-10%) of clinician reported post-operative food packing following placement of a direct posterior composite (Appendix D2.24 Table) were primarily composite users (OR=2.8); primarily sectional metal matrix users (OR=2.5); and incremental composite users (OR=1.6).

4.10.8 Education in direct posterior composite

As undergraduates, 30% respondents had not received didactic teaching and 36% had not received clinical teaching on direct posterior composites, with 7% unable to remember as shown in Appendix D2.25 Table. A high proportion of respondents had attended a postgraduate course on direct posterior composite placement (88%).

4.10.9 Amalgam phase-down and proposed phase-out

Respondents' knowledge of the amalgam phase-down was ascertained by asking them to state in which patient groups amalgam use should currently be avoided according to regulations (Appendix D2.26 Table) and by which year the phase-out was planned (at the time of the survey).

Forty percent of respondents correctly identified the year (2030) of the proposed phase-out of amalgam (dentists 40%, therapists 38%, no statistically significant difference between groups [Chi^2 p=0.701]) (n=1481). Fifty-one percent (51%) thought it was prior to this. Only 3% of dentists and therapists correctly identified all patient groups in which the use of amalgam should be avoided according to current rules. There was no statistically significant difference between the clinicians (Chi^2 p=0.883).

Opinion relating to the phase-out of amalgam	Agree or strongly agree (%)	Neither agree nor disagree (%)	Disagree or strongly disagree (%)
Will impact on my ability to do my job (n=1506)	65	12	23
Will lead to the need for more indirect restorations (n=1508)	71	14	15
Will lead to more teeth being deemed unrestorable (n=1503)	62	14	25
There is a lack of consensus on best practice when selecting direct alternative materials (n=1506)	69	19	12
There is a lack of consensus on best practice in terms of technique when directly placing alternative materials (n=1503)	61	22	17
My patients won't care (n=1506)	23	27	50
Suitable directly placed alternatives to amalgam are available (n=1497)	45	14	41
I feel up to date with current techniques and practices relating to placement of posterior composites (n=1495)	76	14	10
Having to routinely place posterior composites would cause appointment delays in my practice (n=1493)	62	11	27
Posterior amalgams last longer than directly placed posterior composites (n=1498)	62	24	14
It takes me longer to remove a failed posterior composite restoration than a failed amalgam restoration of equivalent size (n=1498)	70	14	16

Table 4.8. Clinician opinions relating to the potential phase-out of amalgam

Clinician opinions relating to the potential phase-out of amalgam are shown in Table 4.8. A large majority felt that the phasing out of amalgam would impact on their ability to do their job, lead to the need for more indirect restorations, and more teeth being deemed unrestorable, while also thinking that there is a lack of consensus on best practice in both material selection and technique when placing alternatives to amalgam, but that they felt up to date with current techniques and practices relating to placement of direct posterior composite restorations. A majority felt that their patients would care about the phasing out of amalgam, and a large majority felt that posterior amalgams last longer than posterior composite restorations, that having to routinely place posterior composite restorations would lead to appointment delays in their practice, and that it takes longer to remove a failed posterior composite than a failed amalgam restoration of equivalent size.

Clinicians were asked over which time period they felt amalgam should be phased out from UK dental practice. The responses (n=1494) were:

- less than 5 years: 21%
- 5-9 years: 23%
- 10-19 years: 24%
- 20-29 years: 7%
- greater than or equal to 30 years: 26%

4.10.10 Clinician confidence

Clinician confidence levels relating to direct posterior restorations are presented in Table 4.9.

Clinician confidence level	No or low confidence (%)	Moderate confidence (%)	High or complete confidence (%)
In providing 2-surface direct posterior composite restorations involving a proximal surface (n=1507)	2	19	79
In providing 3-surface direct posterior composite restorations involving both proximal surfaces (n=1501)	5	27	67
In providing definitive 2-surface posterior GIC restorations involving a proximal surface (n=1503)	23	31	45
In providing definitive 3-surface posterior GIC restorations involving both proximal surfaces (n=1501)	31	30	39
When placing direct posterior composites with sub-gingival margins (n=1505)	51	31	18
When placing posterior amalgams with sub-gingival margins (n=1476)	4	18	78
When placing direct posterior composites in patients with limited cooperation (n=1505)	69	23	8
When placing posterior amalgams in patients with limited cooperation (n=1483)	7	46	48

Table 4.9. Clinician confidence in providing various restorations in varying clinical situations

Wilcoxon signed rank tests showed statistically significantly lower ($p<0.0001$) clinician confidence when placing direct posterior restorations with sub-gingival margins, and in patients with limited cooperation, when using composite compared to amalgam. The difference was marked, with 51% reporting no or low confidence when placing a direct posterior composite with sub-gingival margins, compared to just 4% when placing amalgam in the same situation, and 69% reporting no or low confidence when placing a direct posterior composite in patients with limited cooperation, compared to just 7% when placing amalgam in the same situation. Clinicians generally had high or complete confidence in placing direct posterior composites involving both proximal surfaces.

4.10.11 Regression analyses exploring influences on confidence when placing posterior composite restorations in different situations

Pseudo R^2 values suggested the models explained only a small portion of the variance for all regression analyses performed. The significant factors in each model are discussed below, however.

Table 4.10 details the logistic regression to explore the influence of various factors on confidence in placing direct posterior MOD composite restorations. Type of practice significantly affected confidence in placing a direct posterior MOD composite, with private GDPs and mixed GDPs more than twice as likely to be confident compared to NHS GDPs, whereas CDS dentists and therapists were less than half as likely to be confident. Primarily composite users and clinicians reporting a low incidence of post-operative food packing after composite placement were twice as likely to be confident, with those using circumferential metal matrices 1.7 times as likely to be confident in placing direct posterior MOD composites. Clinicians who were female (OR=0.6), those who agreed that there was a lack of consensus on composite technique (OR=0.6) and those who disagreed (or strongly disagreed) that suitable alternative to amalgam existed (OR=0.7) were less likely to be confident in placing direct posterior MOD composite restorations.

Appendix D2.27 Table details the regression to explore the influence of various factors on confidence in placing direct posterior composites with sub-gingival margins. Private GDPs were 2.5 times more likely to be confident in placing composites with sub-gingival margins compared to NHS GDPs. Clinicians whose patients reported low post-operative food packing following direct posterior composite placement were 2.6 times more likely to be confident, those with high RD use over twice as likely to be confident, and those primarily using composite 1.8 times more likely to be confident. Those with a UK primary qualification were less than half as confident, and female clinicians and those that disagreed that suitable alternatives to amalgam existed were 0.6 times as confident in placing direct posterior composites with sub-gingival margins.

Independent variable (predictor)	OR	SE	z	P>z	95% CI

No undergraduate clinical teaching *(ref had UG teaching)*	0.57	0.13	-2.48	**0.013**	0.37 – 0.89
No postgraduate training *(ref had PG training)*	0.81	0.22	-0.74	0.457	0.48 – 1.40
UK primary dental qualification *(ref non-UK)*	0.67	0.21	-1.27	0.204	0.37 – 1.24
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*					
Private general dentist (0-24% NHS patient base)	2.20	0.62	2.80	**0.005**	1.27 – 3.81
Mixed general dentist (25-74% NHS patient base)	2.13	0.63	2.58	**0.010**	1.20 – 3.79
CDS dentist	0.37	0.13	-2.80	**0.005**	0.18 – 0.74
Therapist	0.34	0.16	-2.37	**0.018**	0.14 – 0.83
Years qualified	1.00	0.01	0.23	0.816	0.98 – 1.02
Female *(ref male)*	0.64	0.13	-2.27	**0.023**	0.44 – 0.94
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*	2.02	0.46	3.07	**0.002**	1.29 – 3.17
Incremental composite user (76-100% use) *(ref <76% incremental)*	1.09	0.21	0.45	0.653	0.75 – 1.59
Bonding system use *(ref self-etch 1 step (76-100% use))*					
Total-etch 3 step bond (76-100% use)	1.31	0.50	0.70	0.485	0.62 – 2.77
Total-etch 2 step bond (76-100% use)	1.08	0.28	0.28	0.781	0.65 – 1.79
Self-etch 2 step bond (76-100% use)	0.98	0.75	-0.02	0.984	0.22 – 4.39
Matrix use *(ref not CM or SM user)*					
Circumferential metal user (100% use)	1.69	0.34	2.61	**0.009**	1.14 – 2.50
Sectional metal user (51-100% use)	1.73	0.54	1.78	**0.075**	0.95 – 3.18
High wedge use (76-100% use) *(ref <76% use)*	1.10	0.22	0.50	0.616	0.75 – 1.62
Never liner use *(ref >0% use)*	1.30	0.28	1.21	0.225	0.85 – 1.97
Rubber dam use *(ref 1-75% use)*					
Never	0.93	0.19	-0.37	0.712	0.61 – 1.40
High (76-100% use)	1.072	0.35	0.21	0.833	0.56 – 2.05
Agree lack of consensus on material *(ref don't agree)*	0.75	0.21	-1.05	0.292	0.43 – 1.30
Agree lack of consensus on technique *(ref don't agree)*	0.56	0.14	-2.38	**0.017**	0.34 – 0.90
Disagree suitable alternatives to amalgam exist *(ref don't disagree)*	0.69	0.13	-1.97	**0.049**	0.48 – 1.00
Low reported sensitivity (0-10%) *(ref ≥11% sensitivity)*	1.34	0.27	1.43	0.153	0.90 – 2.00
Low reported food packing (0-10%) *(ref ≥11% FP)*	2.13	0.43	3.75	**0.000**	1.44 – 3.17
Constant	2.14	1.11	1.47	0.142	0.77 – 5.93

Table 4.10. Factors related to high or complete confidence in placing direct posterior MOD composite restorations

OR, odds ratio; SE, standard error; CI, confidence interval; n=768; p<0.0001; pseudo R^2=0.22; Log likelihood=-376; AIC=804; BIC=924.

Appendix D2.28 Table details the regression to explore the influence of various factors on confidence in placing direct posterior composites in patients with poor cooperation. Private GDPs were 2.7 times more likely to be confident in placing direct posterior composites in patients with poor cooperation than NHS GDPs. Those with a UK primary qualification were only 0.3 times as confident, those that disagree that suitable alternatives to amalgam exist 0.4 times as confident and those with high wedge use 0.5 times as confident in placing direct posterior composites in patients with poor cooperation.

4.11 Discussion

This research details a UK wide survey of dentists and therapists regarding their practice in placing direct posterior restorations. It also explores different primary care clinicians' opinions and knowledge related to the newly imposed amalgam phase-down and potential phase-out (including confidence in the various materials used for direct restoration of posterior teeth in various situations), and educational experience related to posterior composites. Composite is the most used material for direct restoration of premolars, whereas amalgam is in molar teeth. Comparable data exists in Australia, where private healthcare provision predominates, showing that amalgam use in posterior teeth was 18% (Alexander *et al.*, 2016). While this is different from the general data presented here, it does broadly correlate with data specific to private GDPs. Composite use by private GDPs is much higher than other primary care clinician groups, with the greatest disparity seen in relation to NHS GDPs. This finding is similar to another recent survey of GDPs in the North of England (Aggarwal *et al.*, 2019). Composite use in molar teeth increased as the clinicians' number of years qualified increased, which shows a reverse correlation in relation to data from other countries (Alexander *et al.*, 2016) and directly refutes recent data (at significant risk of bias as described in section 2.22) which suggested that the opposite was the case in the UK (Wilson *et al.*, 2019). This is perhaps surprising given the change in provision of direct restorations in undergraduate training in the UK as discussed in section 2.24. Recent subsequent research has also shown that new graduates are choosing amalgam to restore teeth much more frequently than anticipated, especially in sub-gingival class II restorations (Jebur *et al.*, 2023). It showed that 57% would select amalgam as the optimal restoration for a sub-gingival class II mesio-occlusal restoration in a molar tooth, whereas just 5% selected composite. For a supragingival mesio-occluso-distal class II composite in a premolar however, 48% chose composite and 36% chose amalgam. It is likely that this reflects the variation in composite provision in different types of practicing arrangements, with highest composite use seen by private GDPs, and the proportion of private GDPs increasing with increasing age. It perhaps also reflects the need for a high level of technical skill to successfully restore teeth with composites in difficult situations. Only 6.7% respondents used no amalgam at all, which is different to other countries, such as Australia (30%), where private healthcare provision predominates (Alexander *et al.*, 2016).

Clinicians booked 45% more time, and charged 45% more (as a private fee), to perform a direct MOD composite in a molar tooth than for the same restoration in amalgam. Welsh data suggests that dentists took 61% more time and Irish data 43% more to place an occluso-proximal molar restoration in composite than amalgam (Lynch *et al.*, 2018b; Callanan *et al.*, 2020a). The similarity of factors associated with differences in time booked for placing a direct posterior MO and MOD composite and their magnitudes provides confidence in the findings. Widely recommended posterior composite techniques, as described in Chapter 2 (summarised in section 2.17.3), such as RD use and sectional matrix use were low and have increased modestly in comparison to a UK survey of composite technique use from over 10-years ago (Gilmour *et al.*, 2009). There was a significantly lower use of these techniques and equipment by NHS compared to private GDPs. When used, these techniques were associated with an increased time taken to perform a composite restoration, but a reduction in reported post-operative complications (not RD). When placing posterior composite restorations, the best predictor of reported low post-operative food packing and sensitivity was if the clinician primarily used composite, whilst being a therapist was the best predictor of high reported post-operative sensitivity. Clinicians following current guidance in avoiding liner use under composite restorations as described in section 2.6.4 was associated with reduced reported post-operative sensitivity, further validating such an approach, though liner use was still common. On a positive note, the incidence of reported food packing associated with composite restorations has reduced in UK primary care over the last 10-years, whereas reported sensitivity is fairly similar (Gilmour *et al.*, 2009). However, clinician reported post-operative incidence of sensitivity and food packing was much higher with composite than amalgam. Whilst bulk-fill composites are being adopted, there is still some confusion as to what constitutes a bulk-fill composite, given that when asked to name bulk-fill composites used, 8% of responses were not bulk-fill composites, which has implications for education.

Comprehensive knowledge of the phase-down and phase-out of amalgam is low among primary care clinicians, which is of concern given that phase-down regulations are currently in place, which was similar to another recent survey of GDPs in the North of England (Aggarwal *et al.*, 2019). Members of the associations from which the sample was drawn might be expected to be more informed than non-members, given much information has been repeatedly disseminated by each association on this topic. It seems likely that some respondents looked up the guidelines on the internet, seemingly quoting previous Norwegian guidelines (NCPA, 2012), which are different to UK law (*Regulation (EU) 2017/852*, 2017).

A large majority felt concerned about the potential phasing out of amalgam, feeling that issues existed over the suitability of alternatives and that amalgam restorations last longer than composite restorations (62%). This is in agreement with the opinions of Welsh dentists (57%) (Lynch *et al.*, 2018b), a localised survey of GDPs in the North of England (Aggarwal *et al.*, 2019) and Norwegian dentists after the implementation of the amalgam ban (a clinical vignette showed a class II restoration requiring replacement, with 71% dentists indicating that an amalgam restoration would last longer than a composite) (Kopperud *et al.*, 2016). This is supported by the clinical data discussed in section 2.15.7.

A high proportion of respondents had attended a postgraduate course on direct posterior composite placement (88%) which was much higher than another recent survey sampling dentists in Wales (16%) prior to the implementation of the phase-down (Lynch *et al.*, 2018b). While this is encouraging, it did not translate to higher confidence in placement of posterior composites amongst the respondents in comparison to the Welsh study, with proportionally fewer respondents confident in placing an MOD composite (67% vs 88%). This could be partially explained by the Welsh data being at risk of acquiescence bias. However, when this data is combined with the fact that only a small minority felt confident in placing composites in difficult situations, for example in teeth with sub-gingival margins, the efficacy of current postgraduate education courses must be questioned, given relatively simple techniques, usable by GDPs, have been described to manage such situations as described in Chapter 2 and summarised in section 2.17.3. This data is in marked contrast to the high confidence of a large majority of respondents when placing amalgam in similar, difficult situations, which is therefore a concern considering the amalgam phase-down.

With a large majority feeling a phase-out would impact on their ability to do their job, concerned by the extra time it would take to place and replace alternatives (supported by experimental data described in section 2.19), the consequent appointment delays, the increased need for indirect restorations and that more teeth would be deemed unrestorable, the potential impact on healthcare accessibility, cost, tooth loss, patient safety, dentist wellbeing and the already widening oral health inequalities (Steele *et al.*, 2015) is worrying. These findings are supported by a recent mixed methods study where qualitative data also revealed these issues (Aggarwal *et al.*, 2019). The study concluded that policies moving towards an amalgam phase-out would need to consider the likely impact on widening health inequalities, and both patients' and dentists' incentivisation when designing health policies. Respondents generally also felt that their patients would be concerned about a potential phase-out of amalgam (50%) which is very different from data collected from dentists in Australia where amalgam use is low, with only 16% feeling similarly (Alexander *et al.*, 2016). This is likely primarily due to the difference in fees and public versus private service provision between the countries.

UK graduates were much less confident in placing composites in difficult situations than those qualifying from the rest of the world, which raises questions over UK education and the predominance and impact of NHS practicing arrangements, which favour amalgam placement in the UK as discussed in section 2.12.2. The low relative remuneration also does not favour the use of recommended techniques and equipment as demonstrated, because they are expensive and time consuming and technically more difficult to use as discussed in Chapter 2 and summarised in section 2.17.3.

Primarily being a composite placer is a good predictor for high confidence in placing MOD composites and placing composites with sub-gingival margins. The practicing arrangement in the UK potentially limits clinician skill development as is required for placing posterior composite restorations compared with amalgam and therefore confidence. This likely affects patient outcomes, as supported by data showing that primarily being a composite placer was the best predictor for low reported post-operative incidence of complications when placing direct posterior composites. This would support the notion that repeatedly using a skill engenders competence and confidence, however repetition per se and confidence does not necessarily reflect competence (Davis *et al.*, 2006; Morgan and Cleave-Hogg, 2002). Evidence suggests that repetition of a skill needs to be deliberate and focussed following insightful reflection for improvement to occur (Ericsson and Pool, 2016). The nature of the patient population seen in the different sectors may differ, in terms of disease prevalence and extent, or compliance, for example, with NHS GDPs potentially seeing more challenging patients in this regard than private GDPs. This may also explain some of the differences seen in confidence between the practitioner groups.

CDS dentists tend to face more challenging patients, often with limited cooperation as previously discussed, which makes composite placement more difficult due to the material's technique sensitivity, which could account for their lower likelihood of confidence. The therapist cohort reported very high levels of post-operative sensitivity following the placement of composite restorations, which could explain their relatively reduced likelihood of confidence. It was a concern that therapists had no equivalence of a training year in practice post qualification with an educational supervisor (which dentists do in the UK) until recently. A training programme has been introduced for therapists, but satisfactory completion is still not a requirement for UK graduates to be registered to provide NHS dentistry, as it is for newly qualified dentists. This lack of support at an early stage may be a reason for these concerning responses.

4.12 Limitations

There are various potential sources of error and bias which may have affected the results, with self-selection bias being the primary risk. There are also concerns over social desirability bias in the self-reporting of patient-reported outcomes and self-reporting in general. Recall bias, the possibility of repeat responses and a relatively low response rate, with some small sub-groups could also have affected the results. Clinical vignettes are limited in that they cover specific situations, and do not take other 'real life' factors into account which potentially impact the generalisability of the data obtained. When using Likert instruments, which ask for agreement or disagreement with a statement, there may be a tendency to agree, resulting in acquiescence bias, therefore an attempt was made to balance broadly similar statements positively and negatively to minimise this. Confidence in placing different restorations in different situations may be interpreted as confidence in the material or in the clinician's ability, which could lead to response bias. It was felt that although more questions could be asked to more accurately ascertain this, the facets of confidence were interlinked and repeating similar questions risked overburdening respondents for minimal additional insight and risking potential respondent fatigue bias (Egleston, Miller and Meropol, 2011). There are potential differences in disease prevalence, extent and compliance in the patients seen by different clinician groups which may also have affected the results.

The sampled membership groups may not represent primary care clinicians in the UK as previously stated, potentially being more motivated to stay abreast of developments, and the response rate was low, but comparable with other clinician e-surveys (Rodriguez *et al.*, 2006; Yusuf and Baron, 2006; Golnik, Ireland and Borowsky, 2009). Non-responders and non-members may be less engaged and knowledgeable than responders. There is therefore the potential for sampling and non-response error, but a low response rate is not always synonymous with response bias as discussed in the first part of the chapter. Survey completion was high, suggesting that the survey was usable and respondents were engaged which can limit response bias. Even though responses were anonymised, the self-reporting of material use and post-operative complications may be prone to social-desirability bias, alongside recall bias, which includes the potential for both under and over reporting. An open sampling frame, as used for the therapists, has the potential for repeat responses and inappropriate responses from non-targeted clinicians, though the risk of these is low.

These issues may affect the accuracy and generalisability and accuracy of the data, however, alumni of all relevant UK universities and all clinician groups were well represented.

NHS dentistry in England and Wales is unique in that there is no difference in fee between amalgam and composite restorations and amalgam is the most commonly used posterior material. This limits the generalisability of the findings to other countries where amalgam is rarely or never used, or if the fee charged is lower.

It could however be comparable to other, primarily developing, countries where amalgam use is still high, and important in low- and middle-income countries where there are large disparities in socio-economic status and experience of disease (WHO, 2011; Aggarwal *et al.*, 2019). Such countries may see similar issues for clinicians forced to use alternatives because of the phase-down. However caution is required in translation as health systems, workforce, training and patients are likely different. Data pertaining to private dentists could potentially be generalised to other countries where this is the main mode of healthcare provision and amalgam use is still permitted, bearing the previous caveat in mind.

It is difficult to compare composite and amalgam timings performed by clinicians labelled as private or NHS, as it is likely that most NHS clinicians will provide most of their small number of composites privately rather than under NHS terms, and similarly a 'private' GDP may have a small NHS contract under which they provide most of their amalgam restorations. This limits the value of breaking down treatment times for materials by clinician type.

4.13 Recommendations

The survey indicates a need for improved under- and postgraduate education on composite restorations, especially when faced with difficult situations. The training pathway of new dental therapy graduates should be examined and developed and funding for post-graduate education could be considered, as this is currently primarily funded by clinicians. New and better ways to disseminate information on legal changes and clinical techniques and material developments would be helpful to clinicians and patients, as there is currently a lack of clarity on whose responsibility this is regarding clinicians. The differences noted by clinicians between the materials are important for policy makers to consider as the feasibility of a phase-out by 2030 is considered, as it is for manufacturers developing alternative materials to amalgam.

The survey was administered before the COVID 19 pandemic, which likely had an effect on provision of dentistry in primary care, which may have a lasting impact. Periodic repetition of the survey would be beneficial to academics, educators, policy makers, and clinicians and patients indirectly, to investigate any changes, identifying trends and therefore health service and educational needs over time.

4.14 Future directions in methodology

Future approaches to obtaining some of this information may be based on big data through central accessibility of patient records (which may pose ethical and GDPR issues) rather than self-reported data. This would be limited to improved capture of diagnoses, technique and material use, procedural time and costs. Though algorithms may suggest underlying clinician values based on behaviours, they cannot really understand clinician values, intentions, attitudes or motivations. Surveys will still be required for this. It is likely therefore that mixed methods will be necessary to combine these datasets to more accurately understand clinician behaviour (Evans and Mathur, 2018). Ultimately behaviours could then be more easily tracked observing trends over time through big data mining, and changes could then guide the need to re-survey to understand those changes, which would reduce respondent burden and possibly improve engagement.

4.15 Conclusion

Amalgam use in primary care in the UK is currently high, especially in the publicly-funded sector, which is where the majority of direct posterior restoration provision lies. The alternatives are primarily composites, but there are a wide variety of materials and techniques being used under this banner. There is a much higher reported incidence of post-operative complications with composites, though time consuming techniques, such as sectional matrix use, are associated with reduced reported post-operative food packing. Their use is currently low in the UK however. High posterior composite usage is the best predictor of reduced reported post-operative complications, but posterior composites cost more and take longer to perform.

Primary care dentists and therapists in the UK have some major personal and patient-centred concerns over the phase-down of amalgam. Many lack confidence with the alternative, composite, when restoring posterior teeth in difficult situations, whereas confidence in placing amalgam in similar situations is much higher. They also have limited knowledge of the details of the phase-down.

There is a need for more effective education of clinicians, both technically and in terms of policy, a greater understanding of patients' values, the potential impact on already existing health inequalities and policy changes in terms of health service structure and funding, as the phase-down of amalgam continues.

Chapter 5. UK public valuation of direct posterior restorations: a discrete choice experiment

5.1 Introduction

This chapter presents a discrete choice experiment which aimed to understand the UK general public's preferences for directly placed restorations in posterior permanent teeth. The objectives were to quantify: 1) mWTP values for the differing levels of the attributes; 2) the RAI and 3) any differences in these based on income sub-groups. This work has been published (Bailey *et al.*, 2022b) (Appendix A).

As previously described in section 3.8, economic valuation of restorative dental care commonly focusses on a single outcome, such as the lifespan of a restoration or tooth. Patient or public valuation of the importance of these parameters is not commonly sought (Listl *et al.*, 2022). Other important factors are often not considered including the aesthetic outcome, process of care considerations, e.g. how long the treatment would take, or out of pocket monetary costs, which can be critical to optimising not only patient satisfaction, but also uptake of services (Ostermann *et al.*, 2017).

As previously discussed in section 3.4.4, SP techniques are used to elicit preferences where consumer/patient behaviour in the real world cannot be relied upon to provide an accurate representation of preferences. This lack of reliability is inevitable where imperfect free-market economies exist, as is commonly the case in healthcare. CV and DCEs are common SP techniques used to quantify preferences in monetary terms.

The restorations to be compared have attributes which differ from one another in many respects (i.e. have different attribute levels). There are often incomplete data on how the restoration options to be compared vary in their attribute levels at the beginning of an evaluation. CV must define the parameter estimates for each specific HCI from the outset, and can provide an overall WTP value for a restoration of set characteristics, but this will be fixed and inflexible. Outcome parameters in healthcare carry uncertainty, and CV techniques can therefore be restrictive. They are however simple to use and can be useful to inform the appropriate cost levels to use in the DCE. DCEs, in contrast, can provide mWTP estimates for each attribute level of a restoration. This allows preferences to be understood in more detail and more efficiently. These values can then be added together for each restoration type (based on the most up to date data) to obtain a difference in overall monetary valuation between the restorations. The context in which the restorations are performed (clinical trial versus primary care for example) may also change some of the attribute levels for the restorations (survival, for example, as previously discussed in section 2.15). Given this, understanding the generic value of attribute levels of a restoration allows the health profile of a specific restoration to be varied. This may be important in a subsequent EE, for example when changing the context of a decision model, when performing sensitivity analyses, and following the emergence of new data and even new restoration types.

The DCE approach to obtaining WTP values for restorations, from the general population was therefore deemed the most appropriate to use in this situation.

5.2 Method

The study was carried out and reported in accordance with available guidance as previously described in section 3.4.6. A favourable ethical opinion was obtained from Newcastle University Research Ethics Committee (2320/2020) and a DMP was created.

5.2.1 Attribute and level selection

A scoping literature review revealed one previous DCE valuing aspects of posterior dental restorations (Espelid *et al.*, 2006). It was of limited use in designing this DCE due to the framing and attribute selection as previously discussed in section 3.5. Patient and public involvement (PPI) guided attribute and level selection through an online focus group (FG) (Coast *et al.*, 2012). Participants were recruited through VOICE, which is 'a community of public, patients and carers who are passionate about working with researchers' [www.voice-global.org]). Consent for participation was obtained following issue of a patient information sheet (shown in Appendix E1.1) to all VOICE members showing interest in an overview of the advertised project. A topic guide and explanatory presentation was developed for the FG (shown in Appendix E1.2).

The FG was conducted and recorded on Zoom (11.06.2020) with six participants consisting of five females and one male with an age range 55-78. All had previously had a filling. Three participants received NHS dental care and three private. The FG was led by OB and notes kept by CV. It lasted approximately 90 minutes.

The potential attribute list was generated by the FG participants and is shown in Appendix E1.3. Once the long list of attributes was developed, attendees were then paired to determine their 5 most important attributes using a ranking exercise. Some were generic and wouldn't vary based on the restoration type and were therefore stated as assumptions prior to the choice tasks in the survey (for example, 'Assume the clinician providing the treatment gives a detailed explanation of the procedure and has a caring and friendly manner'). These lists were refined to 7 important attributes to be included following discussion with dental and economic experts. Attributes and level selection can involve tension between those most relevant for any policy question, the clinical outcome and the patient. They must be clinically relevant and/or valued by patients.

Following the FG, a short CV exercise using an online bidding game was undertaken by the participants to inform cost attribute levels. A restoration which had favourable characteristics was presented as shown in Appendix E1.4. The cost levels presented were informed by phase 1 data and expert opinion. WTP ranged from £50-£250 with a mean of £125 and median of £150 as shown in Appendix E1.5.

This was used alongside data obtained from the literature view, phase 1 and research group discussions which included expert opinion from dental specialists to determine relevant attributes and levels for inclusion in the DCE survey. This ensured that the attributes and levels were clinically meaningful and relevant to the general public and policy-makers. Initial attribute levels are presented in Table 5.1, but some were modified following piloting (explained later and shown in Table 5.2).

Attribute	**Levels**
Waiting time for filling	0, 2, 4, 6 weeks
Clinician type	Dentist, dental therapist
Filling colour	White, silvery grey
Length of filling procedure	20, 40, 60, 80 minutes
Likely discomfort after filling	None, mild, moderate, persistent
Average lifespan of filling	5, 8, 11, 14 years
Cost	£25, £50, £75, £100, £150, £200, £250, £300

Table 5.1. Initial direct posterior restoration attributes and levels (later modified)

5.2.2 Experimental design

There were 8192 potential combinations of attribute levels, with none deemed totally implausible, and over 33 million choice sets. A fractional factorial D-optimal design was created using Ngene software (ChoiceMetrics). Based on a main effects full profile approach 64 choice questions were selected and split into four blocks of 16 questions (one block only per respondent, to avoid over-burdening them (Bech, Kjaer and Lauridsen, 2011)). The model selection software was run overnight and the last three designs manually checked for within block level balance and appraised by their Pearson product moments to select the most appropriate design (Ngene design code Appendix E2). Each choice question included two different treatment options and an opt-out (no treatment) to increase task realism.

5.2.3 Questionnaire design

A cross-sectional online survey was developed considering the literature review on surveys presented in the first part of Chapter 4 and is shown in Appendix E3. The survey briefly explained the study and its purpose with a brief consequentiality script explaining that it would influence decision makers (which has been shown to reduce hypothetical bias (Boyers, 2019)) before confirming consent to participate. Demographic information and respondents' experience of restorations were included, alongside the Modified Dental Anxiety Scale (Humphris, Morrison and Lindsay, 1995). The survey also asked about attitudes towards restorative treatment and their perceived future need. It then explained the choice questions before presenting 17 choice tasks, alongside explanatory information.

Attribute levels were modified following initial piloting resulting in the attributes and levels shown in Table 5.2, which were defined in the survey (Appendix E3).

Attributes	Levels
Waiting time for filling	0, 2, 4, 6 weeks
Clinician type	Dentist, dental therapist
Filling colour	White, silvery grey
Length of filling procedure	20, 40, 60, 80 minutes
Likely discomfort after filling	None, mild, moderate, persistent
Average lifespan of filling	5, 8, 11, 14 years
Cost	£15, £25, £35, £45, £60, £90, £150, £250

Table 5.2. Final direct posterior restoration attributes and levels included

Initially the selected cost levels were £25, £50, £75, £100, £150, £200, £250, £300. This seemed to be sufficiently granular at the lower end, but the efficient design led to the following common pairings in the choice tasks: £25 vs £300; £50 vs £250; £75 vs £200; £100 vs £150. This was noted as a problem in the first round of piloting, which went to friends and family with different socio-economic status as a PowerPoint presentation.

Respondents with WTP less than £150 were never able to make a trade-off. They had to select the lower-cost option or no treatment. This ceiling was deemed too high by the people piloting the survey, and based on the phase 1 data and CV bidding game data from the FG participants. The cost attribute levels were revised to those shown in Table 5.2. The Ngene software was used again in the same way as previously described and the most appropriate design was selected as before.

The revised cost attribute level choice task pairings were generally: £15 vs £250; £25 vs £150; £35 vs £90; £45 vs £60. Now respondents could make a trade off in around 50% choice tasks if their WTP was £90. Respondents with a WTP of £60 would be able to make a trade off in approximately 25% of choice tasks. This was deemed more appropriate for the UK general population, allowing more participants to make trade-offs at the lower cost levels.

Further piloting and think-aloud techniques (Coast *et al.*, 2012) were used with dental and economic experts and the general public to assess the survey design, alongside a usability assessment with mobile devices. The layout of the choice tasks was subtly modified to clarify the choice options and a more neutral colour palette was used in an attempt to avoid influencing respondents, alongside minor changes to wording.

An example choice task is shown in Figure 5.1. A repeated choice task was added to assess respondent consistency. A task in each block was selected where one choice appeared dominant (in that the levels were deemed better in all attributes), or close to dominant, to assess respondent rationality. Those failing the tests were not excluded from analysis based on expert guidance (Lancsar and Louviere, 2006; Ryan, Watson and Entwistle, 2009).

5	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Moderate	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£15	£250	£0
Your choice (**tick one box only**)	☐	☐	☐

Figure 5.1. Example choice task

5.2.4 Sample

Sample size calculations for DCEs rely on many factors, including the number of attributes and levels, choice set design and sample heterogeneity for example (Lancsar and Louviere, 2008). They are therefore imprecise (Bridges *et al.*, 2011; Johnson *et al.*, 2013). Calculation methods have been proposed, but rely on estimates of the parameter values (de Bekker-Grob *et al.*, 2015). Rule of thumb guidance suggests a minimum sub-group sample size of 200 (Bridges *et al.*, 2011). Therefore, to achieve sufficiently sized income sub-groups, a sample size of 1000 was deemed appropriate based on population data (ONS, 2021). The DCE was distributed by

Dynata using the FocusVision Decipher platform and their in-house sampling software to create a representative online panel sample of the adult UK population based on population census data to obtain quotas on gender, age and geographical region. Respondents received a small financial incentive for completing the survey. The data was electronically captured by Dynata in May/June 2021.

5.2.5 Data analysis

Data were analysed using Stata software (version 17; StataCorp LP). Collinearity was assessed using VIFs. Categorical variables were effects coded, and potentially continuous variables (waiting time, length of procedure, lifespan and cost) were also explored categorically to assess assumptions of linearity using a conditional logit model. Dummy coding was problematic because of the inclusion of 0 weeks as a level for the waiting time attribute. This led to invalid outcomes as it was confused with the opt-out coding. Dummy coding does not allow the calculation of a mWTP value for the attribute reference level either. The reference level is necessarily set at £0. This limits the use of the results in subsequent economic analyses somewhat. Effects coding is therefore more useful, as it allows the calculation of the reference level WTP, with the WTP values of each attribute level calculated in relation to the mean of all the levels for that attribute. Reference levels and their confidence intervals were calculated using the Delta method (Wooldridge, 2002). Sub-groups were defined as low (≤£20,000) or higher gross household income. Mixed logit models (McFadden and Train, 2000) were explored with parameters modelled as fixed or random to assess intra-sample preference heterogeneity, and potentially continuous variables modelled as continuous or categorical where assumptions of linearity were questionable. Backwards stepwise regressions were then carried out changing the variable modelled as random with the highest SD p-value to non-random. Models were selected by lowest BIC value. The utility function is shown and explained in Appendix E4. RAI and mWTP values were calculated (Muhlbacher and Johnson, 2016).

5.3 Results

5.3.1 Sample

1002 respondents completed the survey. VIFs for included variables were less than 3.5 supporting their inclusion in the model (Appendix E5.1 Table). Appendix E5.2 Table shows respondent consistency and dominance test results. Internal validity was good with 83% passing the consistency test and 91% passing the dominance test. Only 2% of respondents chose the opt-out for every question, and 1% always chose the same treatment option. Appendix E5.3 Table provides characteristics of those opting out of all treatment. Seventeen percent of these were edentulous (compared to 1.6% for the whole sample) and a majority received free NHS dental treatment (exempt from patient charges). Allied with the data showing a large majority had previously had fillings this suggests that the dentate respondents who were not willing to pay for treatment at the levels presented, would accept free restorative treatment.

Demographic, dental experience and attitudinal data are shown in Table 5.3. The sample showed similar proportions to the UK population in terms of gender, age, index of multiple deprivation (describing socio-economic deprivation) and geographical location (ONS, 2016). Comparison of reported gross household income with UK general population data is difficult because of available data presentation (decile means) (ONS, 2021), however there was a broadly similar distribution of income. Based on ADHS 2009 data the sample was representative of those with experience of a filling (85%), but edentulous respondents were slightly under-represented (NHS Digital, 2011).

Characteristic		Sample (%) n=1002	Low income (%) n=221	Higher income (%) n=727
Age years, mean (SD)		48 (16)	49 (18)	47 (16)
Gender	Female	50	57	48
	Male	49	41	52
	Other	<1	1	<1
	PNTS	<1	0	<1
Residence	England	81	80	82
	Wales	5	8	4
	Scotland	8	7	8
	Northern Ireland	6	6	6
Index of multiple deprivation (deciles) (n=986)	1	11	16	9
	2	10	15	9
	3	10	7	11
	4	10	14	9
	5	9	12	8
	6	11	10	11
	7	11	11	11
	8	10	5	11
	9	9	6	10
	10	10	4	11
Annual gross household income	<£10000	7	30	0
	£10k-£19999	15	70	0
	£20k-£29999	18	0	25
	£30k-£39999	16	0	22
	£40k-£49999	11	0	15
	£50k-£59999	7	0	9
	£60k-£69999	6	0	8
	£70k-£79999	4	0	6
	£80k-£89999	2	0	3
	£90k-£99999	3	0	4
	>£100000	5	0	7
	PNTS	5	0	0
Working status	Employed (full-time or part-time)	56	32	65
	Self-employed	7	6	6
	Unemployed	5	12	2
	Retired	22	29	19
	Looking after home/family	4	6	3
	Student	4	7	3
	Other	3	7	1
Educational attainment (highest)	Postgraduate degree	13	7	15
	Undergraduate degree	25	20	28
	A/AS-level/Vocational A/AS-level or equivalent	30	28	31
	GCSE/Vocational GCSE/O-level or equivalent	24	35	21
	Lower than GCSE or equivalent level	7	11	5
Own natural teeth	Yes	98	97	99

Filling in back tooth	Yes	85	82	86
Silver (amalgam filling)	Yes	79	78	79
White filling	Yes	57	49	60
Environmental concern over filling materials (n=911)	Low	46	48	45
	Medium	45	46	45
	High	10	7	11
How at risk of needing a filling in future	Low	29	29	28
	Medium	51	51	52
	High	20	20	20
Keeping my teeth is	Important	87	87	87
	Neither important nor unimportant	11	11	12
	Unimportant	1	2	1
Highly anxious (Modified Dental Anxiety Scale)		26	28	25
Dental care provision	NHS (pay)	52	50	53
	NHS (exempt)	14	26	10
	Insurance based	12	7	14
	Private	16	12	17
	Mixed NHS and private	6	5	6

Table 5.3. Demographic, dental experience and attitudinal data of respondents including income sub-groups

SD, standard deviation; PNTS, prefer not to say; NHS, National Health Service.

5.3.2 Model specification

Assumptions of linearity in the potentially continuous attributes were explored as shown in the Appendix E5.4, Appendix E5.5, Appendix E5.6 and Appendix E5.7 Figures. Model exploration resulted in a best fit mixed logit specification with all parameters random, and potentially continuous variables modelled continuously and linearly except waiting time which was modelled categorically. An explanation of this process follows.

A conditional logit model (CLM) was initially used. The basic model relies on an assumption of linearity for the continuous variables. This assumption was assessed by running the potentially continuous variables (waiting time, treatment time, cost, restoration longevity) as categorical variables, and plotting graphs of the coefficients associated with each level of these attributes used in the choice tasks (Appendix E5.4, Appendix E5.5, Appendix E5.6 and Appendix E5.7 Figures). Based on this, assuming linearity for these variables was questionable. This was confirmed by the lower BIC value for the categorical model. More complex non-linear specifications for these continuous variables could have been investigated, but were deemed beyond the scope of this analysis.

CLMs have two major limitations. They assume that utility is measured equally across individuals and choice tasks (scale homogeneity) and that preferences are fixed and the same between respondents (preference homogeneity). They do not account for differences in choices between choice tasks and individuals (preference and scale heterogeneity). It is generally accepted that differences are often correlated across attribute levels and across respondents, meaning both scale and preference heterogeneity can behave in the same way (Hauber *et al.*, 2016).

A random parameters (mixed) logit model (RPLM) can account for these issues and therefore assess if there are significant differences across respondents in their choices. The mean values obtained indicate the distribution of tastes across a sample, whereas the SD values represent variance at the individual level. If the SD for an attribute level is significantly different from zero, this indicates that there is preference heterogeneity- people vary in their selection of these attribute levels, and therefore the RPLM is more appropriate than the CLM for that variable. Equally, if the SD is not significantly different from zero, this means that there isn't significant preference heterogeneity, there are fixed effects (preference homogeneity) associated with that attribute level (assuming that the sample size is sufficient) and the RPLM collapses to the CLM. Backwards stepwise elimination of the non-significant random effects (SD) attribute level with the highest SD p-value from the original model (making the attribute level fixed) was used to obtain the best model as assessed by the lowest BIC value. Changing the variable with the highest p-value from random to fixed resulted in a higher BIC value however.

Contrary to the CLM, inclusion of linear continuous variables in the RPLM where possible (with the exception of waiting time) yielded better models as judged by BIC values, than when these variables were modelled categorically. Treatment time, restoration longevity and cost were therefore modelled continuously.

The significance of the p-values for the same levels vary based on how the analysis is performed. They depend on the reference point – either the base reference (omitted variable) when dummy coding, or the mean in effects coding, not one level in relation to the next level, making their relevance questionable.

The sample was split into low income (<£20,000) and higher income and the analysis was repeated.

Comparing results across different model specifications can be problematic because of potential scale heterogeneity. This can be negated by calculating and comparing relative attribute importance (RAI) or marginal rates of substitution, such as mWTP.

All variables were assumed to be random and normally distributed.

5.3.3 Model outcomes

The results of the choice analysis are shown in Table 5.4 and Appendix E5.8 Figure. The mean beta values express the strength of respondent preferences relative to the mean which is zero for categorical variables, and the strength of preference per unit change for continuous variables. All attributes exhibited some preference heterogeneity, as shown by significant SD p-values, with the exception of clinician type. Overall, respondents were willing to pay £39.52 to reduce a 6-week wait for treatment to 2-weeks, £13.55 to have treatment by a dentist rather than a therapist, £41.66 to change filling colour from silvery/grey to white, £0.27 per minute of reduced treatment time, £116.52 to move from persistent to no post-operative pain and £5.44 per year of increased restoration longevity.

Sub-group analysis based on income, as shown in Table 5.5, showed that on average, higher-income respondents value restoration longevity more than double (mWTP difference of £3.25/year), and a white restoration almost three times more than those with low-income (mWTP difference of £16.25), and these differences were statistically significant. Higher income respondents were, on average, willing to pay more to have treatment by a dentist rather than a therapist, to avoid post-operative discomfort and to avoid a 6-week wait for a filling, though these differences were not statistically significant.

On average, low-income respondents valued shorter treatment times, willing to pay a third more per minute avoided and also had a higher mean WTP for a 2-week wait for a filling alongside lower mean WTP values for 0- or 4-week waits, than higher income respondents, though these differences were not statistically significant.

The alternative specific constant (ASC) was large and positive indicating that respondents much preferred treatment to no treatment and ASC mWTP was significantly higher for the higher-income than low-income group.

An example of how the mWTP values could be used to comparatively value different restorations with different attribute levels is shown in Table 5.6.

RAI is presented in Figure 5.2, based on Appendix E5.9 Table, which shows the proportionate valuation of each restoration attribute based on the range of valuation of levels within each attribute. This showed that cost is the most important attribute for the general public when selecting a posterior dental restoration, being 2.0 times more important than the next most important attribute which was likely discomfort after the filling. Discomfort in turn was 2.4 times more important than average lifespan, with colour and waiting time next most important, but these three attributes were not statistically significantly different from each other. Treatment time and clinician type, which again were not statistically significantly different from one another were the least important attributes. When analysed by income groups RAI changed, resulting in different ordering in the importance of lifespan, colour, waiting time, treatment time and clinician, but with only colour statistically significantly different between groups.

Attribute	Level	Beta coefficient		mWTP (£)	
		Mean	SD	Mean	95% CI
Waiting time for filling (weeks)	0[a]	-0.020	-	-2.33	-11.90 - 7.24
	2	0.167*	0.004	19.40	8.52 - 30.28
	4	0.026	0.180*	3.05	-7.87 - 13.98
	6	-0.173*	0.004	-20.12	-32.17 - -8.08
Clinician	Dentist[a]	0.058*	-	6.77	4.18 - 9.37
	Therapist	-0.058*	0.036	-6.77	-9.37 - -4.18
Colour	Silvery grey[a]	-0.179*	-	-20.83	-24.69 - -16.97
	White	0.179*	0.336*	20.83	16.97 - 24.69
Treatment time[b]	Per minute	-.002*	0.000	-0.27	-0.40 - -0.15
Likely discomfort	None[a]	0.400*	-	46.46	38.89 - 54.04
	Mild	0.374*	0.030	43.36	36.99 - 49.74
	Moderate	-0.170*	0.0111	-19.78	-25.52 - -14.03
	Persistent	-0.603*	0.735*	-70.05	-79.70 - -60.40
Average lifespan[b]	Per year	0.047*	0.037*	5.44	4.49 - 6.38
Cost[b]	Per pound	-0.009*	0.010*	-	-
ASC	Treatment	4.257*	3.319*	494.26	421.63 - 566.89
	No treatment[a]	-4.257*	-	-494.26	-566.89 - -421.63

Table 5.4. Mixed logit model results showing main effects preferences and willingness to pay for restoration attributes

mWTP, marginal willingness to pay; SD, standard deviation; CI, confidence interval; ASC, alternative specific constant. Respondents = 1002; Observations = 48096; Log likelihood = -9948.44; Akaike information criterion = 19920.89; Bayesian information criterion = 20026.26.

[a]Categorical reference level (in effects coded model); [b]Continuously modelled attribute; *P≤0.001.

mWTP = -(beta attribute[b] or level/beta cost); mWTP estimates are interpreted as the UK general population's mean valuation of attributes and levels. Differences between mWTP values indicate how much the UK general population value moving from one level to another, or for a change of one unit[b]. Therefore, moving from a waiting time of 0-weeks to 2-weeks would be valued = (19.40) - (-2.33) = £21.73; moving from a treatment time of 30-minutes to 20-minutes would be valued (20 x -0.27) – (30 x -0.27) = £2.70.

Attribute	Level	Low income (n = 221) (observations = 10,608)				Higher income (n = 727) (observations = 34,896)			
		Beta		mWTP (£)		Beta		mWTP (£)	
		Mean	SD	Mean	95% CI	Mean	SD	Mean	95% CI
Waiting time for filling (weeks)	0[a]	-0.024	-	-1.98	-16.17 - 12.20	-0.006	-	-0.76	-13.31 - 11.78
	2	0.271**	0.024	22.51	6.10 - 38.92	0.139*	0.019	18.24	4.09 - 32.38
	4	-0.042	0.098	-3.52	-19.94 - 12.91	0.030	0.019	3.95	-10.35 - 18.24
	6	-0.204	0.024	-17.01	-34.97 - -0.95	-0.164**	0.032	-21.42	-37.14 - -5.71
Clinician	Dentist[a]	0.062*	-	5.15	0.89 - 9.42	0.056**	-	7.39	4.03 - 10.74
	Therapist	-0.062*	0.068**	-5.15	-9.42 - -0.89	-0.056**	0.026	-7.39	-10.74 - -4.03
Colour	Silvery grey[a]	-0.107**	-	-8.90	-14.53 - -3.27	-0.192**	-	-25.15	-30.35 - -19.95
	White	0.107**	0.289**	8.90	3.27 - 14.53	0.192**	0.330**	25.15	19.95 - 30.35
Treatment time[b]	Per minute	-0.004**	0.000	-0.32	-0.53 - -0.12	-0.002**	0.001	-0.24	-0.40 - -0.09
Likely discomfort	None[a]	0.418**	-	34.75	21.92 - 47.57	0.373**	-	48.73	39.10 - 58.37
	Mild	0.412**	0.007	34.27	23.94 - 44.60	0.359**	0.014	46.89	38.60 - 55.18
	Moderate	-0.179**	0.022	-14.91	-24.05 - -5.77	-0.164**	0.003	-21.46	-28.93 - -13.99
	Persistent	-0.650**	0.808**	-54.11	-69.55 - -38.67	-0.567**	0.721**	-74.16	-86.51 - -61.82
Average lifespan[b]	Per year	0.037**	0.027	3.10	1.67 - 4.54	0.049**	0.047**	6.35	5.06 - 7.65
Cost[b]	Per pound	-0.012**	0.013**	-	-	-0.008**	0.008**	-	-
Alternative Specific Constant (ASC)	Treatment	3.790**	2.986**	315.33	225.46 - 405.20	3.866**	2.719**	505.51	419.70 - 591.32
	No treatment[a]	-3.790**	-	-315.33	-405.20 - -225.46	-3.866**	-	-505.51	-591.32 - -419.70
Log likelihood		-2076.65				-7385.413			
Akaike Information Criterion (AIC)		4177.30				14794.83			
Bayesian Information Creterion (BIC)		4264.53				14896.35			

Table 5.5. Mixed logit model results showing preferences and willingness to pay for restoration attributes by income sub-groups

mWTP, marginal willingness to pay; SD, standard deviation; CI, confidence interval.

[a]Categorical reference level (in effects coded model); [b]Continuously modelled attribute; *P<0.05; **P≤0.01.

The beta coefficients should not be compared between the two groups because of potential scale heterogeneity. The mWTP values can be compared however as they have been normalised. mWTP = -(beta attribute[b] or level/beta cost).

	Restoration 1 (composite, dentist)				Restoration 2 (amalgam, therapist)			
Attribute	**Level**	**mWTP (£)**			**Level**	**mWTP (£)**		
		Full sample	**Low income**	**Higher income**		**Full sample**	**Low income**	**Higher income**
Wait	4 weeks	3.05	-3.52	3.95	2 weeks	19.40	22.51	18.24
Clinician	Dentist	6.77	5.15	7.39	Therapist	-6.77	-5.15	-7.39
Colour	White	20.83	8.90	25.15	Silvery grey	-20.83	-8.90	-25.15
Treatment time	34 minutes	-9.32	-10.98	-8.30	24 minutes	-6.56	-7.75	-5.86
Discomfort	Moderate	-19.78	-14.91	-21.46	Mild	43.36	34.27	46.89
Lifespan	7.98 years	43.39	24.77	50.71	11.05 years	60.09	34.30	70.21
Total		44.94	9.41	57.44		88.69	69.28	96.94

Table 5.6. Marginal willingness to pay for two hypothetical dental restorations with different attribute levels and between income sub-groups

mWTP, marginal willingness to pay.
The mWTP values for attribute levels of any given restoration can be added to estimate its mean marginal value to the UK population. This allows calculation of WTP differences between restorations with different attribute levels (as shown here) which can then be used in economic evaluations. Treatment opt in values were: Full sample £539.20; Low income £324.74; Higher income £562.95.

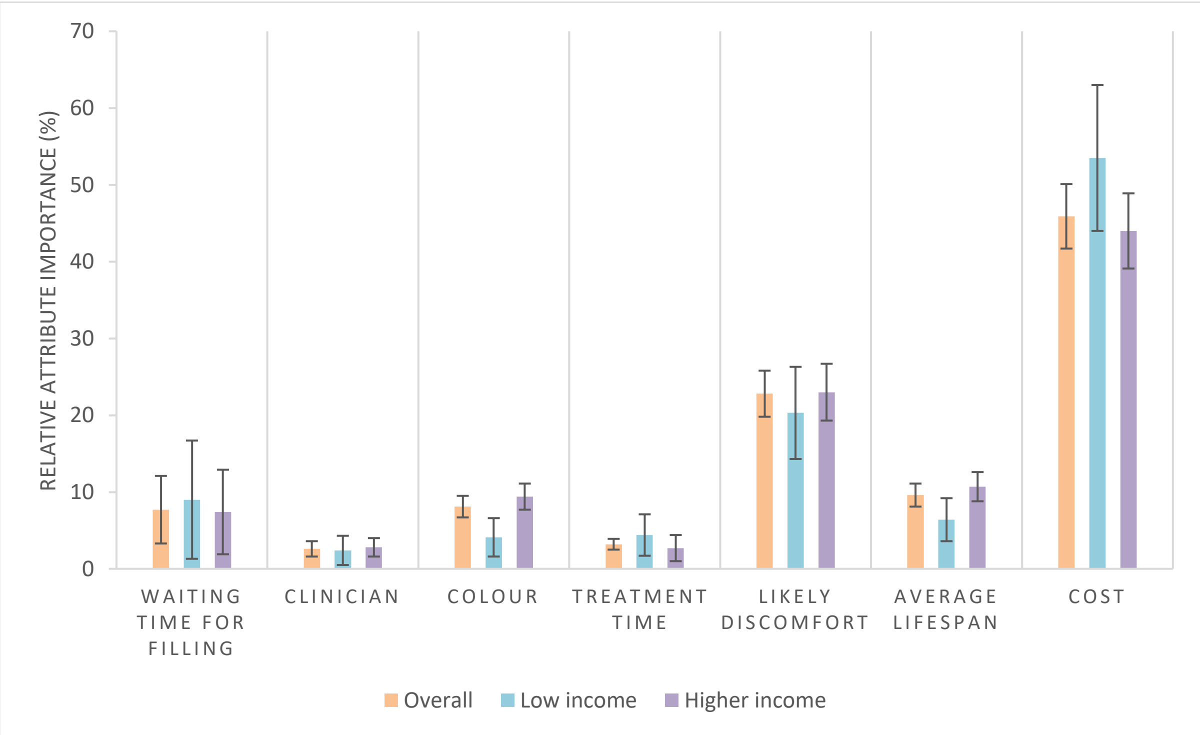


Figure 5.2. Restoration relative attribute importance: overall UK population and by income

5.4 Discussion

This DCE is the first to explore general population preferences for direct posterior dental restorations. Overall, all attributes were valued by the respondents, and the valuation of the levels within each attribute were generally as expected (i.e. increased restoration longevity resulted in higher valuations). This shows that respondents were trading across all included attributes, and were able to discriminate between the levels presented in the choice tasks providing justification for the design and confidence in the results.

The mWTP values obtained can be used to value different direct posterior restorations which have attribute levels included in the DCE as shown in Table 5.6, which in turn can be used to broaden the scope of HEEs, especially when used to value the interventions in CBAs or CCAs. Nearly all previous HEEs of posterior restorations focus on restoration or tooth longevity as the primary outcome measure. This is far from being the most important attribute when judged by the general public, with cost and likely discomfort after filling having much higher RAI. Longevity also has a markedly lower RAI in the low-income group. This suggests that these HEEs are excessively narrow in their scope. Valuing restorations by adding mWTP estimates of their attributes takes a broader, patient-centred approach. It also facilitates an awareness of how preferences differ with income. This information is critical for policy-makers to consider when redesigning restorative dental services, which is pertinent given the recent move towards amalgam phase-down. This research highlights the potential for health economics to move beyond limited cost-effectiveness analyses alone, by combining innovative approaches and considering multiple perspectives to address complex decision problems in oral health and care (Listl, Grytten and Birch, 2019; Listl *et al.*, 2022).

Respondents valued treatment over no treatment, though differences existed in income groups, as they did in attribute levels. Compared to higher-income respondents, restoration longevity was of much lower importance to low-income respondents, though waiting time and treatment time were of higher importance, with increased mWTP values. This could be due to a reduced willingness to wait, or to sacrifice time in the short-term with an increased discounting of future benefits. This in turn could be caused by a wish to minimise time off work and a reduced ability to pay, or simply a preference for short-term versus long-term benefits. Likewise restoration colour was much less important to the low-income group which suggests they value appearance less. Despite these data on sample means, significant variation exists between individuals within the sample and within the sub-groups in all attributes except clinician type.

Respondents favoured shorter waiting times, with an optimal wait of 2-weeks, but did not discriminate hugely between waiting times 4-weeks and under. There was a significant drop in valuation for a 6-week wait however which was more marked in the low-income group, which has implications when planning dental service provision. Given the increased time taken and cost to place composite restorations as demonstrated in Phase 1, and their reduced longevity compared to amalgam as discussed in section 2.15.7, the amalgam phase-down and potential phase-out will likely mean that clinicians will have more restorative work to do. This potentially means increased waiting times to access care with current workforce levels as discussed in Phase 1. These issues potentially impact on those of low-income by limiting the service characteristics which they desire and could reduce their access to and uptake of care. This is further explored in Chapters 7 and 8.

The general public prefer to have their restorations placed by dentists rather than therapists. It is important to consider if the preference (valued as the difference in mWTP) is offset by the increased cost associated with the dentist performing the filling, and the other patient-centred outcomes obtained by differing clinician types (which may not be the same (as shown in Phase 1)). Care responsibilities within the dental team, policy decisions and workforce planning can then be considered rationally, weighing up costs and benefits of alternatives to optimise the use of scarce resources across a diverse population (Listl, Grytten and Birch, 2019).

Preferences for attributes of a posterior direct restoration differ between patients and clinicians (Espelid *et al.*, 2006) and this research shows that inter-individual preferences vary in the UK general population. Clinicians should therefore not make assumptions about what individual patients value. The attributes assessed were all of importance to the general public in aggregate. How they vary between the available direct posterior restorative options should therefore be discussed with individual patients when obtaining consent.

5.5 Limitations

There are a number of limitations, some of which have already been noted. As previously described, some of the variables were modelled as continuous and linear. However these assumptions were questionable based on the plots generated when modelled categorically as described. Some of the levels had non-linear ordering and these are discussed in the following section.

5.5.1 Potential explanations for non-linear ordering of potentially continuous levels

The trend was towards the public showing increased value for a 40-minute appointment over a 20-minute appointment, which is non-intuitive ordering. There was some spread of coefficients around 40-minutes – non-significant small positive coefficient compared with 20-minutes suggesting people may well be fairly indifferent to how long a filling takes up to 40-minutes, which seems reasonable. Additionally, people may feel that 20-minutes may not be enough time to perform a good filling with care, though they were specifically told that the amount of time spent did not relate to quality, as this assumption was considered to be a possibility from the outset ('You should **not** consider that the quality of the filling will increase with increased time or vice-versa'). Then there was non-intuitive ordering of coefficients for 60-minutes and 80-minutes, but with the expected direction of decreased value associated with them (compared to 20-minutes). This non-linear, non-intuitive ordering may also reflect an issue of the design, where 80 and 20, and 60 and 40 were always paired as alternative options in the choice tasks (to aid statistical efficiency), and therefore 80-60, 80-40, 40-20 and 60-20 were never explicitly traded.

This is likely due to an issue with the experimental design in that all potentially continuous attributes were coded continuously. Coding them categorically would have overcome this repetitive pairing and allowed the assumptions of linearity to be checked more robustly whilst still allowing them to be included as continuous variables if appropriate.

People in general did not value a 0-week wait – i.e having the filling performed on the same day as being told they need it, as much as a 2-week wait, which had the highest utility of the waiting times, or a 4-week wait. It might have been assumed that some people would just wish to get the procedure done and out of the way, and not build up the negative aspects of the process in their mind, which would also mean that they did not have to come back to the practice again- potentially requiring more time off work, more organisational issues and increased transport costs etc. However, it seems that people may wish to prepare themselves for an invasive procedure, consider treatment options, require time to deal with bad news, or limit their time at the dental practice into manageable chunks. This sample appears to be more dentally anxious than the general population estimates previously obtained, which could have exacerbated this preponderance. However, as waiting time increases beyond 4-weeks, there was a large reduction in value when facing a 6-week wait, such that respondents would much prefer a 0-week wait. This could be intuitively explained by societal norms of what patients expect and feel is reasonable in terms of waiting time to receive a filling. It could also represent the worry that a now asymptomatic tooth may start to become symptomatic if left for a longer period. They may think that the wait could negatively impact 'success' of the restoration/tooth complex in terms of increased potential for negative sequelae, for example increased chance of post-operative discomfort or need for further treatment (root canal treatment for example). These factors might explain the non-linear distribution of values ascribed to varying waiting times for a filling by the general public. This would suggest that 2-weeks is an optimal waiting time, with 4-weeks acceptable, but that increasing wait time to 6-weeks can have a significant negative impact on a patient's valuing of the restoration.

This variable was coded as continuous, but modelled categorically. This is an issue as previously discussed and is a limitation. Given the high degree of freedom and large sample size, it likely had a limited impact on the results however.

A similar argument could be made at low level costs to that of 20-40 minutes filling time, - that it is insignificant up to a point (£35), shown by small covariate values and lack of significance, and also people mistrust very low costs and might assume poor quality (there was no specific statement in the description of attributes here though). They may not be able to distinguish between cost up to this level. There may also be a similar issue with the experimental design in terms of repetitive pairing of cost levels in each choice task for statistical efficiency as discussed with length of filling procedure. The low-level costs are never paired together and therefore never traded against each other which could have been overcome by coding the variables categorically in the experimental design as discussed.

Ability to pay

Ability to pay often affects WTP (Tan, Vernazza and Nair, 2017) which was again observed in this study. It is therefore important to consider how this might impact choices among those with low-income when making policy decisions. Including a cost attribute biases preferences based on ability to pay. However, removing the cost attribute doesn't necessarily remove this issue- people's choices are influenced by their socio-economic status and environment. Though this sample was generally representative of the UK general population on many levels, there was a higher proportion of highly anxious respondents which could have affected the results. There are also potential confounding factors in splitting the sample, as educational attainment, for example, also varies between sub-groups. Respondents' previous dental experiences and potential varied interpretation of no treatment as delaying care could impact the results, as could the absence of 'unknown' options when asking for descriptive data.

5.5.2 Sample

Based on ADHS 2009 data, which reported that a large majority of the UK population had experience of dental caries and restorations as previously discussed in section 2.5, any representative survey of the general population is likely to have a majority of respondents who have experienced dental caries and its management. There is therefore little to distinguish between the patient perspective and the general population perspective in this project. This is also beneficial in that the majority should have some understanding of dental restorations, and they may therefore be more motivated to engage with the tasks as they would potentially be affected by the research. Given their familiarity with the process, the cognitive burden may also be expected to be lower. This hopefully mitigates against hypothetical bias. Hypothetical bias was also mitigated against by using PPI in the development and design stages and a brief consequentiality script.

Household income was used to split the data, but this potentially would not account for many low-income families, for example those with two adults and multiple children for example. Asking respondents to state how many adults and children there are in each household would allow more accurate ascription of low-income.

5.5.3 Problems with mWTP values from DCEs

Marginal WTP (mWTP) values are not strict WTP values in terms of welfarist economic theory for multiple reasons (Clark, 2014). The values obtained from DCEs must be interpreted within the framing of the experiment, including how the data is coded (dummy versus effects) and in relation to the other attribute levels. Additionally, the cost level can always be traded off against a different cost level and the other attribute levels, therefore the maximum willingness to pay for a treatment is not predictably elicited. The values obtained from DCEs are therefore not technically compatible with traditional welfarist economics and their use in conventional CBAs may be controversial, unlike direct CV methods. WTP values are also potentially affected by ability to pay, and this potentially impacts on how different respondents value different attributes, as seen in this study. mWTP values can however be used to inform economic analyses by calculating the difference between interventions and could be seen as a more pragmatic approach to obtaining valuations of treatments under 'real world' (though still hypothetical) conditions.

All WTP values obtained from a DCE are relative to something else (the reference case in dummy coding and the mean in effects coding), they are not absolute values and this must be recognised when attempting to put an actual monetary value on the benefits of a treatment when using this in a CBA for example, where the costs are represented in actual monetary value.

If there is a choice, with a lower cost alternative, there is likely to be a tendency to select the lower cost alternative if the difference between the two restorations is small (but favouring the higher cost alternative), even though someone would be willing to pay for the high-cost option, should there be no alternative. They would therefore be choosing based on perceived 'value for money', which is a concern anywhere where a choice between two or more alternatives is made (not including an 'opt-out'). This would therefore underestimate a respondent's maximum WTP for a restoration, and therefore undermine the welfarist theory it is based on, as a true reading of consumer surplus is potentially not elicited.

Having said this, DCE studies have commonly estimated mWTP values for health interventions which are higher than the highest cost attribute level (Hernández *et al.*, 2017; Ryan and Watson, 2009). This isn't necessarily unexpected as one of the criticisms of estimating WTP from DCEs is that they can provide higher estimates of WTP in comparison to CV (Ryan and Watson, 2009). Perhaps this could be an issue of modelling cost as a continuous linear variable, and then extrapolating beyond the confines of the data, looking at levels which are totally unrealistic, because the continuous variables are unbounded, and few respondents opted out of treatment.

The difference in mWTP between having treatment, and not having treatment in this study based on the ASC was over £1000 based on £500+ loss of utility for opting-out and £500+ gain for having treatment. Given what has just been said, this value is implausible. It only becomes slightly problematic when comparing income groups, as the ASC values change because the sample was split. The values obtained when omitting the ASC seem more plausible and the marginal values are more relevant when comparing interventions.

In this DCE design, there was always an option to opt into treatment at a maximum value of £45. So someone with maximum WTP of £45 could always opt to have treatment, but could not trade between the choices, they simply had to pick the lowest price alternative or not. If the maximum WTP was £60, the respondents were able to trade attribute levels in a small number, around 25% of the choice tasks, if it was £90 they could trade in around 50% of the choice tasks, if £150 in around 75% and if £250 they could trade in all of them. It is also worth noting that sometimes the high-cost choice is 'dominated' by the low-cost choice, though obviously this makes some assumptions about people's preferences.

An alternative method to get around this issue could be to omit the cost variable (as this may be ignored (Genie, Ryan and Krucien, 2021; Sever, Verbič and Klarić Sever, 2019) and perform a separate contingent valuation study to obtain maximum WTP values. This could then be usable in terms of the classic welfarist approach and CBA, whilst also perhaps obtaining a better understanding of the drivers of choice especially in those of low-income.

5.5.4 Future work

More complex non-linear specifications for the variables modelled continuously and linearly could be investigated, but were deemed beyond the scope of this analysis. Interaction terms were not explored as this was designed as a main effects plan. They could however be explored, being mindful of the power required. Other analyses could include investigating the effect of removing respondents who opted-out of all questions, answered the same for all questions or gave inconsistent or apparently irrational responses from the analysis. Given the low levels of these responders, the impact is likely to be small however. Alternative analyses, by using a latent class model, for example, might better characterise any clustering of responses and therefore heterogeneity in the sample.

5.6 Conclusions

The UK general population value direct posterior restorations highly, placing importance on a variety of restoration attributes beyond longevity. These include process of care, such as waiting time for a filling and treatment time, as well as aesthetics, the care provider, post-operative complications and most importantly, cost. Clinicians should understand potential drivers of restoration choice, so they can be discussed with individual patients to obtain consent. When contemplating the potential phase-out of amalgam restorations policy-makers should consider general population preferences for services and outcomes, with an awareness that income affects these.

Chapter 7 will include these public values in an economic evaluation.

Chapter 6. Health economic evaluation: a decision analytic model of direct posterior restorations

6.1 Introduction

This chapter describes a CEA with secondary outcomes comparing amalgam and the relevant directly placed alternatives for the restoration of posterior teeth using a decision-analytic model. This is used to inform a subsequent CCA which is presented in the following chapter. An overview of decision-analytic modelling was provided in Chapter 3. Further concepts relevant to the model are described and explained throughout the methods where relevant.

Though previous HEEs of restorative interventions have focused on clinical survival data as an outcome measure, this is a narrow approach to valuing restorations as the alternatives do not just vary in longevity. Chapters 2 and 3 broadly discussed how they differ and may potentially differ whilst identifying areas where more data is required. Chapter 4 showed that they vary in other important ways according to the clinicians who would be providing them in the decision context- the English NHS primary care setting. Chapter 5 also showed that though differences in longevity are important to English patients, so are other characteristics, such as colour, cost, post-operative symptoms, which type of clinician is performing the treatment and process of care (waiting and treatment time) and that this varies by income. Many of these attributes are relatively more important than longevity to the general public and most vary by material used, as discussed in Chapter 2 and demonstrated in Chapter 4. Monetary values for these different elements of restorations can be obtained from the general public (as calculated in Chapter 5), which can then be applied to the restorations of different materials under consideration based on their differing attributes. This allows them to be more holistically valued and compared which can be used to support decision making around restoration provision in public systems. Ultimately this favours a public-centred service provision (Listl *et al.*, 2022) which might increase patient satisfaction, uptake of care and promotion of societal health (Ostermann *et al.*, 2017).

While patient-centred values are important in guiding policy decisions, the policy maker must balance them with overall societal values in relation to budget constraints. Direct costs are important to consider (which relate to costs where money changes hands), but so are the indirect costs, which often involve, for example, time lost due to treatment. The patient's time cannot then be used for something more productive – it may necessitate having time off work, or a reduction of leisure time. It should also be noted that they will likely need to travel to the appointment, with the associated direct (fuel and car maintenance, for example) and indirect (time) costs involved. There is also potentially an opportunity cost to the clinician in terms of time spent treating the disease if one intervention takes longer than another, or requires more frequent intervention for example. They cannot therefore manage the same amount of disease in a society, even if they are recompensed similarly for their time. This has the potential to create access issues if there are insufficient clinicians available to cope with the need, or there is insufficient funding to treat all those in need with a costlier treatment, for example. A broader analysis considering these broader costs is said to take a societal perspective, beyond the confines of a purely health perspective.

Though economic evaluation data are important for a policy maker in selecting or eliminating an intervention, they must also consider the ability and capacity of the available clinicians to safely provide treatment and other geopolitical concerns, for example the global directives and legislature relating to material safety which were explored in Chapters 2, 3 and 4. Some of these elements cannot be easily incorporated or captured in classic economic evaluation methodologies. Laying out the differential data on interventions from multiple perspectives helps to ensure that they are all considered and weighted appropriately by the policy maker relative to the decision problem.

The costs and benefits of interventions can be determined in different ways based on the perspective being taken. Most economic evaluations combine costs and consequences into a single outcome measure, as discussed in Chapter 3, but CCAs list all or multiple potential costs and benefits separately. They are therefore more transparent, and are perhaps easier for policy makers to understand as discussed in section 3.7. It also allows them to decide which costs and benefits are more or less relevant to their decision problem. It could therefore potentially be seen as more subjective, however with other forms of HEE these decisions are necessary but are not explicit. By taking a broader perspective and addressing the costs and benefits from multiple perspectives, it also provides an overview of who stands to benefit, or benefit most, and who may stand to lose from implementing an intervention.

Considering these elements in a broad analysis may forestall unintended consequences which can arise from a failure to account for relevant stakeholders' perspectives.

Though this study might broadly be said to take a societal perspective by considering multiple perspectives, it should be noted that modelling HCIs without considering those in the population who do not require a HCI, or do not seek NHS treatment (as was performed here) might preclude its description being societal (Roberts *et al.*, 2012). Not all of the possible costs are accounted for, as will be discussed, which would also support this contention. Though the high prevalence of caries and dental restorations in the population perhaps reduces the impact of the former omission, the perspective may be better described as an extended medical sector perspective with societal considerations.

6.2 Methods

6.2.1 Decision problem, comparators, setting, horizon, population and perspective

The feasibility of an amalgam phase-out by 2030 needs to be explored as described in Chapters 2 and 3. Previous studies have compared amalgam and composite restorations aiming to address this problem, but they have limitations and are limited in their scope as discussed in section 3.8. They also do not consider the question from the unique English dental NHS primary care setting. This study aimed to address some of the limitations in previous HEEs and broaden their scope to inform the amalgam phase-down and potential phase-out in the English NHS primary care setting.

The restorative materials compared in the economic evaluation were amalgam, conventional (hybrid) composite, flowable bulk-fill composite and paste bulk-fill composite, as justified by the evidence base, materials available, expert opinion and their use in UK primary care as described in Chapters 2 and 4. GICs and their derivatives were excluded from the analysis based on the evidence base and expert opinion as discussed in section 2.7.4, and their very low acceptance and use as definitive restorations for load bearing posterior restorations in UK primary care as demonstrated in Chapter 4.

A model of restoration failure and reintervention was constructed in TreeAge Pro 2023-24 (TreeAge Software) to extrapolate costs and outcomes of directly restoring cavitated interproximal carious lesions in permanent lower left second premolar teeth (LL5) with amalgam and composite restorations over a lifetime horizon. This timeframe is more able to estimate the true differences in costs and outcomes of the initial interventions. A closed population of adult 18-year-old English NHS patients all diagnosed with caries as described was modelled. Individual patients were followed over a lifetime or up to 100-years with their deaths modelled using statistics of all-cause mortality (ONS, 2023b). Costs and outcomes which could inform NHS funder, patient and dental practice perspectives were modelled.

6.2.2 Model outputs

Primary outcome measures obtained from the model were:

- Lifetime survival of the restored tooth

Secondary outcomes were:

- Survival of the initial restoration
- Lifetime tooth survival limited to direct restorations
- Total treatment time
- Total number of treatment visits
- Treatment time saved when using bulk-fill flowable and bulk-fill paste composites compared to conventional composite

Costs obtained from the model were:

- Lifetime NHS funder's
- Lifetime NHS patient's
- Lifetime laboratory NHS clinician/practice's

6.2.3 Conceptualising the model

The main decision on choice of a model type for this HEE lay between a Markov cohort simulation and an individual microsimulation. The main advantages and disadvantages of each of these state-transition models are outlined in Table 3.2. Either would be reasonable in this decision context, but where possible a microsimulation offers a richer simulation and overcomes the 'memoryless' limitation of cohort models (Siebert *et al.*, 2012). In a microsimulation model, each individual can experience different paths based on random events or distributions, which is not possible with cohort simulations. Microsimulations capture stochastic uncertainty by running multiple simulated individuals through the model

(Monte Carlo simulations), where each run generates different outcomes based on the randomness of events. Microsimulations therefore produce richer, individual-level datasets for more detailed analysis than cohort simulations.

Systematic search strategies to seek information which inform and build a model may be considered best practice. They are however very time consuming, and relevant systematic reviews and meta-analyses may already exist. Focussed searches on important parameters are therefore more efficient as an initial means of obtaining relevant data. Details of the searches performed are included in Appendix C.

Data sources returned were manually checked for relevance to the decision problem. The methodological rigor, relevance to the decision problem, and risk of bias of the studies obtained were assessed (though without using formal quality assessment tools). A critical discussion of the broad categories of data sources and specific data sources considered in developing and parameterising the most important elements of the model was included in the literature review. The decisions made relating to the model are justified based on summaries of that evidence in the following sections.

Following the review of relevant models in section 3.8, no models were deemed appropriate to use as a basis for the current decision problem.

As previously described in the literature review, data on the type of reintervention following restoration failure is sparse. The model pathway was broadly based on a large, long-term NHS claims dataset described in section 2.15.6, which outlined and quantified the type of reintervention following placement of direct amalgam restorations, the proportion of RoCT teeth which were restored with direct restorations or crowns, and the type of reinterventions following placement of crowns in the setting of interest (Lucarotti, Holder and Burke, 2005; Lumley, Lucarotti and Burke, 2008; Lucarotti *et al.*, 2014; Burke and Lucarotti, 2009).

As discussed in section 2.18, reintervention following failure is also described in a more recent short-term Dutch dataset, where the vast majority of restorations placed were composite (Laske *et al.*, 2019a). It can be seen from the broadly calculated reintervention APs based on the two datasets shown in Table 6.1 that they are quite similar (Lucarotti, Holder and Burke, 2005; Lumley, Lucarotti and Burke, 2008; Lucarotti *et al.*, 2014; Laske *et al.*, 2019a). This is especially so when it is considered that repair is not specifically separated and likely falls under 'new restoration' in the Dutch data, which would make this overall AP very similar to that from the NHS data. The assignation of 'repair' AP from the NHS data is slightly contentious however. Composite or GIC restorations accounted for approximately 11% of reinterventions following amalgam placement (Lucarotti, Holder and Burke, 2005). These restorations could have been repairs (as has been assumed), but may more commonly have been cervical restorations, which may then not reflect failure of the amalgam restorations. Broadly accounting for this in the reintervention rate might seem sensible, but this does not then reflect the increased restorative burden on the tooth and the subsequent likelihood for further, more complex intervention (such as a crown) and ultimately extraction of the tooth. It is difficult to know how exactly to deal with this complexity and the non-adjusted rates are in line with the Dutch data presented.

Reintervention	**Allocation probability**	
	Dutch data	**England and Wales NHS data**
New restoration	0.678	0.56
Repair	-	0.11*
Root canal treatment	0.230	0.12
Crown	0.025	0.08
Extraction	0.067	0.13

Table 6.1. Reintervention following direct restoration failure from Dutch and NHS sources
*This is contentious as discussed.

There are also two further caveats. The short-term Dutch data has a higher proportion of RoCT re-interventions. This should be looked at alongside extraction data however. The AP of extraction and RoCT combined are very similar, and this may simply represent a preference in the Dutch sample for people to retain their teeth, though it may be assumed that failure mode is broadly similar. It may also reflect remuneration for dental care. It is likely that the choice between RoCT and extraction will vary significantly across a population, depending on numerous factors- is the tooth painful, can it be saved or restored by the treating clinician and does the patient wish to save it, alongside other factors such as cost and remuneration for treatment (as evidenced by the change in provision following changes in service structure described in section 2.12.2) for example. Recent changes to the NHS contract to increase remuneration for RoCT as described in the literature review may increase the proportion of teeth receiving this treatment under these services. The NHS data used in the model comes from a time when treatment was remunerated on a fee-per-item basis however, so it is possible that RoCT provision dropped following introduction of the new contract. This justifies the use of scenario analysis to explore changes in the proportion of people receiving RoCT and extractions.

The high early RoCT reintervention seen in the Dutch data might also reflect the increased likelihood of early pulpal complications which tend to reduce over time as previously discussed, and people may wish to save their teeth in the short-term following restoration placement, but this may not be the case in the longer-term. This means longer-term data will likely show a smaller proportion undergoing RoCT. The proportion of teeth requiring RoCT may also be increased in relation to composite restorations (Abbott, 2004; Opdam *et al.*, 2010). Extractions and crowns as interventions are also likely to increase over time. The UK data is a much larger and broader dataset and is likely to be more representative than the self-selected practices involved in the Dutch studies. Still, when taken with the above caveats, the data are quite similar.

It is not currently clear from the limited evidence that there is a meaningful difference in re-intervention following failure of the different initial interventions (composite versus amalgam) as summarised in section 2.20. It would therefore be inappropriate to complexify the model in terms of varying failure mode and reintervention for the different interventions. The available reintervention data following amalgam restoration is therefore also used to structure the model and provide APs for composite, assuming similar patterns of reintervention (Lucarotti, Holder and Burke, 2005; Lumley, Lucarotti and Burke, 2008; Lucarotti *et al.*, 2014; Burke and Lucarotti, 2009).

All possible restoration failure modes and potential treatment options for teeth were listed and discussed with the supervisory team (two specialist clinical dentists and a health economist) alongside the data on reintervention following failure previously discussed. Treatment options for failed restorations that were deemed to be infrequently used under NHS provision were excluded from the model, for example pulpotomies and indirect onlay restorations (Edwards *et al.*, 2021b; Lucarotti and Burke, 2009). The proportion of extracted LL5 teeth which were replaced with the various prosthetic options following extraction was broadly based on ADHS 2009 data (NHS Digital, 2011). Limits to the number of each type of restoration or prosthesis were set, when it was deemed likely that that restoration was no longer possible. These limits are indirectly shown in the possible state-to-state transitions in Table 6.2. and were discussed with the expert supervisory team and modelling experts in creating the final model following iterative modification. The states, and potential options of reintervention following failure of each restoration are represented in the state-transition diagram shown in Figure 6.1. The states and their potential state transitions, including allocation probabilities are shown in Table 6.2 alongside any data sources which were used to justify these.

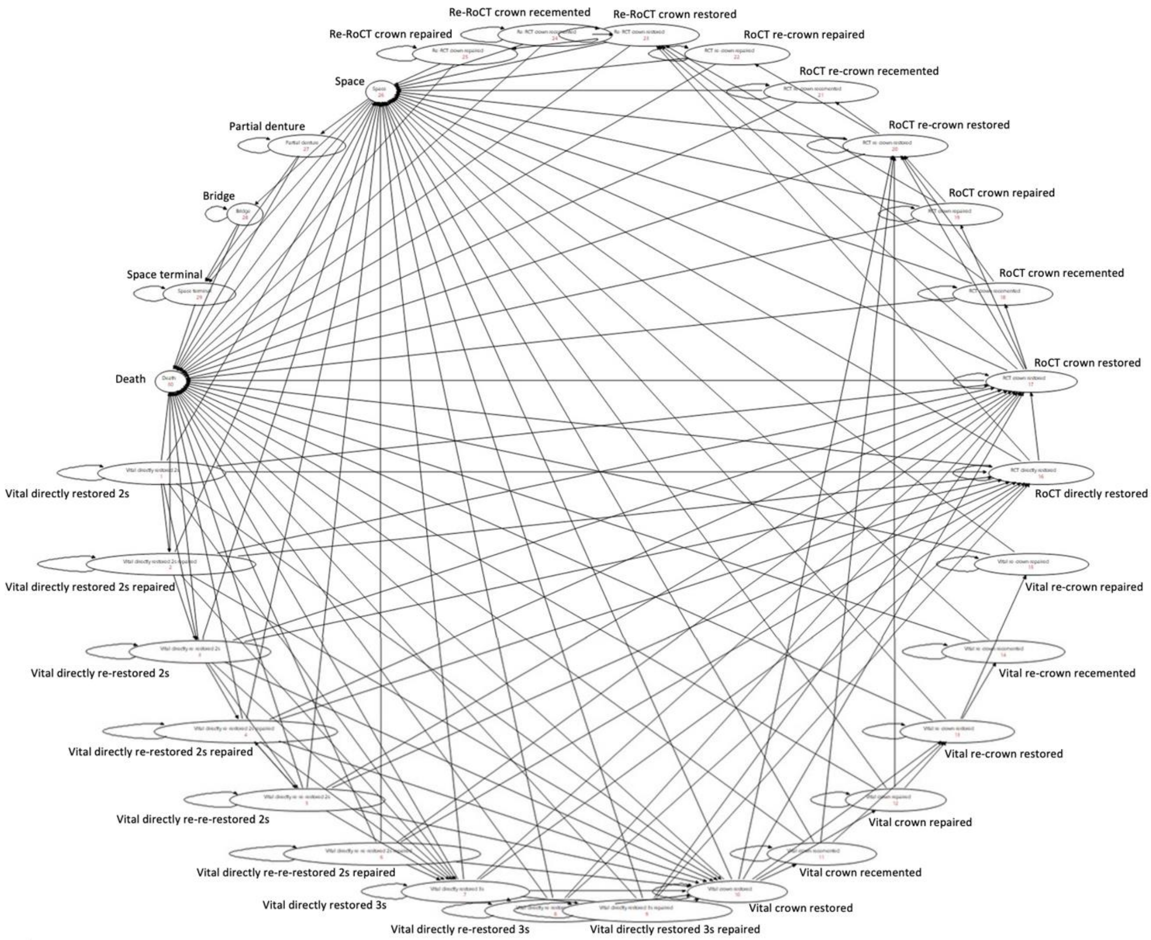


Figure 6.1. State transition diagram of reintervention following direct restoration placement
2s, two-surface; 3s, three-surface; RoCT, root canal treatment.

State	Transition state(s)	Allocation probabilities	Data source
Vital unrestored carious lower left second premolar	2s	1	Phase 2 PhD
Vital directly restored 2 surface (2s)	re2s; 2sR; 3s; C; RoCTD; RoCTC; S	0.28; 0.11; 0.28; 0.08; 0.0888; 0.0312; 0.13	Expert opinion based on Lucarotti et al., 2014; Lucarotti et al., 2005
Vital directly re-restored 2 surface (re2s)	re-re2s; re2sR; 3s; C; RoCTD; RoCTC; S	0.28; 0.11; 0.28; 0.08; 0.0888; 0.0312; 0.13	
Vital directly re-re-restored 2 surface (re-re2s)	re-re2sR; 3s; C; RoCTD; RoCTC; S	0.11; 0.56; 0.08; 0.0888; 0.0312; 0.13	
Vital directly restored 2 surface repaired (2sR)	re2s; 3s; C; RoCTD; RoCTC; S	0.28; 0.39; 0.08; 0.0888; 0.0312; 0.13	Expert opinion
Vital directly re-restored 2 surface repaired (re2sR)	re-re2s; 3s; C; RoCTD; RoCTC; S	0.28; 0.39; 0.08; 0.0888; 0.0312; 0.13	Expert opinion
Vital directly re-re-restored 2 surface repaired (re-re2sR)	3s; C; RoCTD; RoCTC; S	0.67; 0.08; 0.0888; 0.0312; 0.13	Expert opinion
Vital directly restored 3 surface (3s)	3s; 3sR; C; RoCTD; RoCTC; S	0.56; 0.11; 0.08; 0.0888; 0.0312; 0.13	Expert opinion based on; Lucarotti et al., 2014; Lucarotti et al., 2005
Vital directly re-restored 3 surface (re3s)	C; RoCTD; RoCTC; S	0.44; 0.0888; 0.0312; 0.44	
Vital directly restored 3 surface repaired (3sR)	C; RoCTD; RoCTC; S	0.44; 0.0888; 0.0312; 0.44	Expert opinion
Vital crown restored (C)	C; Crec; Crep; RoCTC; RoCTreC; S	0.15; 0.3; 0.15; 0.05; 0.05; 0.3	Expert opinion based on Burke and Lucarotti, 2009
Vital crown recemented (Crec)	C; RoCTC; S	0.45; 0.1; 0.45	Expert opinion
Vital crown repaired (Crep)	C; RoCTC; S	0.45; 0.1; 0.45	
Vital re-crown (reC)	reCrec; reCrep; S	0.3; 0.15; 0.55	
Vital re-crown recemented (reCrec)	S	1	
Vital re-crown repaired (reCrep)	S	1	
RoCT directly restored (RoCTD)	RoCTC; ReRoCTC; S	0.3; 0.18; 0.52	Expert opinion based on Lucarotti et al., 2014; Burke and Lucarotti, 2009; Lumley et al., 2008
RoCT crown restored (RoCTC)	RoCTC; RoCTCrec; RoCTCrep; ReRoCTC; S	0.15; 0.3; 0.15; 0.3; 0.3	
RoCT crown recemented (RoCTCrec)	RoCTC; ReRoCTC; S	0.45; 0.1; 0.45	Expert opinion
RoCT crown repaired (RoCTCrep)	RoCTC; ReRoCTC; S	0.45; 0.1; 0.45	
RoCT re-crown (RoCTreC)	RoCTreCrec; RoRCTreCrep; ReRoCTC; S	0.3; 0.15; 0.55	
RoCT re-crown recemented (RoCTreCrec)	S	1	
RoCT re-crown repaired (RoCTreCrep)	S	1	
Re-RoCT crown restored (ReRoCTC)	ReRoCTCrec; ReRoCTCrec; S	0.3; 0.15; 0.55	
Re-RoCT crown recemented (ReRoCTCrec)	S	1	
Re-RoCT crown repaired (ReRoCTCrep)	S	1	
Space (S)	S; B; PD	0.808; 0.176; 0.016	Expert opinion based on Adult Dental Health Survey 2009
Bridge (B) (2 max)	B	1	
Partial denture (PD) (4 max)	PD	1	

Table 6.2. State-to-state allocation probabilities

The following is a narrative explanation of the model structure with reference to figures to illustrate how it works. A patient presents in the state of having a decayed posterior tooth, 'vital carious LL5 MO' (Figure 6.2). The patient can either have an amalgam or composite restoration, which are events. These events carry a fee. In Figure 6.2 the pathway for a composite restoration is shown. Everyone who moves down each restoration option arm receives that restoration, so the transition probability is 1 and they move from the 'vital carious LL5 MO' state to the 'vital directly restored 2s' (two-surface) state. Now in this new state, the 6-month cycles begin. At the end of each 6-month cycle the patient can either survive or die based on the TP probability of all-cause mortality (p_acm) entered into the model (which changes over a lifetime to reflect age specific mortality probabilities). If they die (an event) they move to the death state and exit the model. Death is therefore said to be an 'absorbing state'. If they survive, the restoration can either be successful (a non-event), in which case it stays in the 'vital directly restored 2s' state, or it can suffer failure (an event). If it fails, it then requires a reintervention, which occurs probabilistically based on the allocation probabilities shown for each possible event for each individual moving through the model. These interventions incur a cost, and the patient then moves to the associated new state. For example, if the restoration fails, the patient may have a 'direct repair' event with a 0.11 probability, which would then move the individual to the 'vital directly restored 2s repaired' state as shown in Figure 6.3. The patient then moves to a new branch with different possible events and states following failure as shown in Figure 6.4.

This process re-occurs every 6-months which is based on the cycle length chosen to reflect the common period of patient re-attendance at the dentist, which therefore reflects when diagnoses of failure are most commonly made. The tooth accrues 6-months survival for every cycle it moves through until it is extracted or the patient dies. Following extraction, the tooth no longer survives, so it no longer accrues an outcome. It may still accrue a cost however, if the now missing tooth is replaced as shown in Figure 6.5.

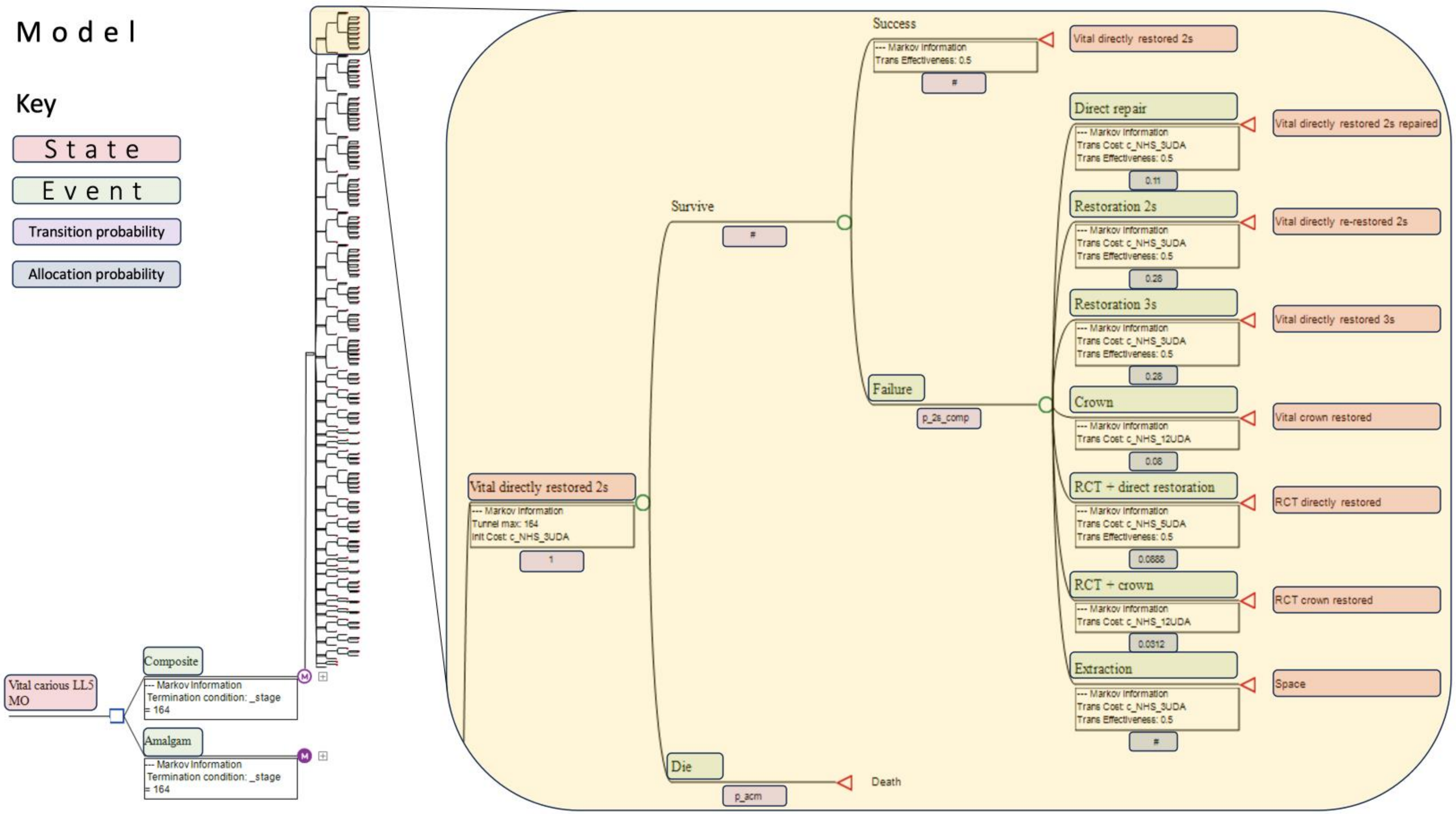


Figure 6.2. Model structure showing interventions, states, events, transition and allocation probabilities

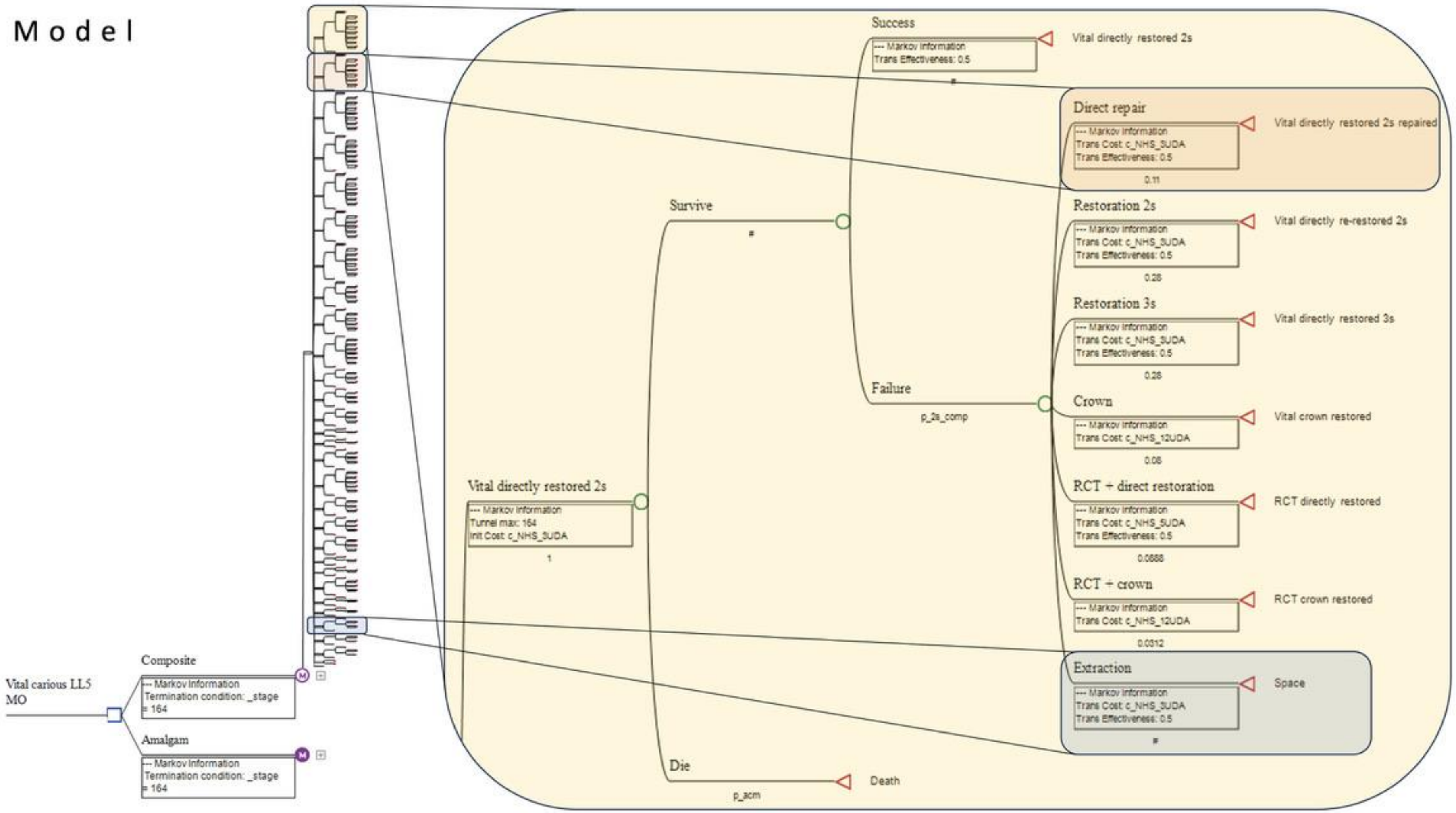


Figure 6.3. Model structure 2

Movement to a new state results in new potential events and allocation probabilities (see examples in Figure 6.4 [orange box] and Figure 6.5 [blue box]).

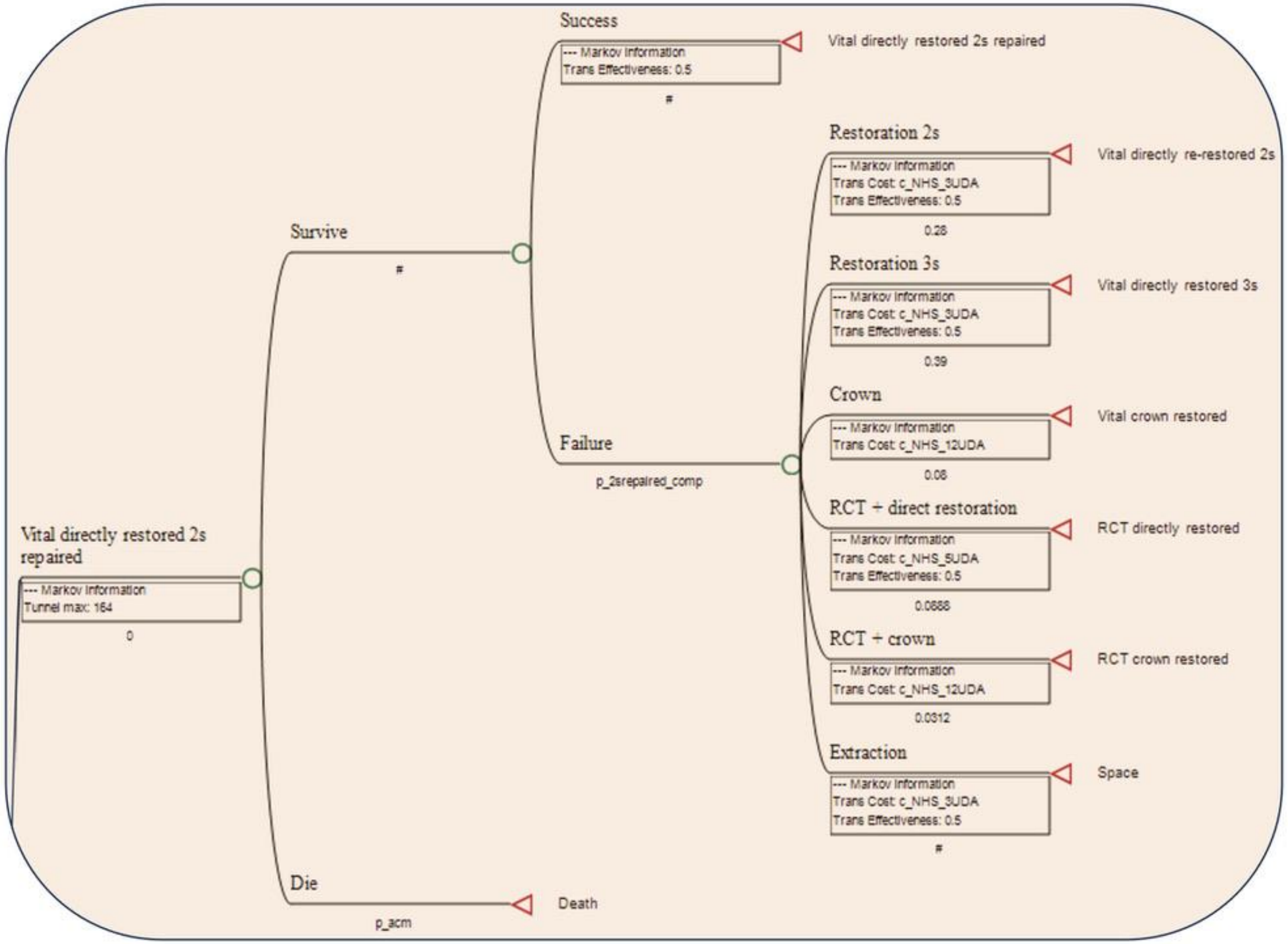


Figure 6.4. Model structure 3

New transition probabilities and potential events and allocation probabilities associated with the new state. (An assumption is made here that a repaired restoration cannot be re-repaired).

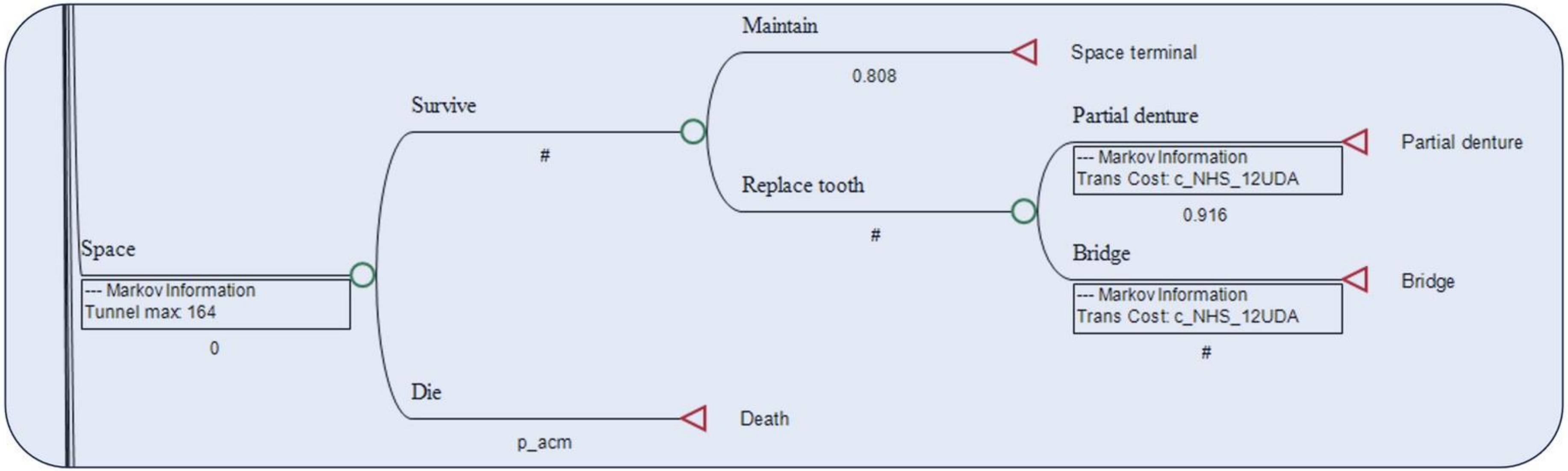


Figure 6.5. Model structure 4
Management of the space by providing a prosthesis attracts a cost, but no effectiveness measure as the tooth has been extracted.

6.3 Model inputs

6.3.1 Transformation of the data

It is important to consider the potential effect of time when identifying and selecting model parameters. TPs are commonly assumed to be fixed and unvarying over time when modelling dental restoration failure (Kanzow, Wiegand and Schwendicke, 2016; Schwendicke *et al.*, 2018b). This assumption may not always reflect reality however, and a decision needs to be made if it is appropriate, or could provide misleading results. TPs could vary throughout the model, or change within a specific state. With the example of dental restorations, their failure rate may vary over time, or they may not, the data are heterogenous as described in section 2.15.5. Quantifying this difference can be very difficult as the granular data required are often not available (Briggs, Sculpher and Claxton, 2007).

This leads to another issue in that event rates are often presented in the literature rather than TPs (Briggs, Sculpher and Claxton, 2007). A rate is presented as failure over time. Probability refers to the chance that an event will occur within a specific time-period. The time frame expressed in a rate may not match the cycle length. Rates can be converted to probabilities using the following equation:

$$probability = 1 - e^{-rate\ x\ time}$$

Where e is the base of the natural logarithm

Time dependent probabilities may be more appropriate for some decision problems where detailed patient-level time-to-event data exists (Briggs, Sculpher and Claxton, 2007). Their use, and the process for assessing their need is described in NICE guidance (Latimer, 2013; NICE, 2024).

Where comparative data of the interventions does not exist in the setting of interest, but data does exist for one of the interventions in that setting, an approach can be taken to use that data to provide baseline TPs. Comparative data can then be used from other sources (ideally from RaCTs if available) to create a RR (or HR) which is then applied to the baseline TP to parameterise the model for the alternative intervention. This approach is advocated and was used in a previous CEA of amalgam alternatives (Schwendicke *et al.*, 2018b; Briggs, Sculpher and Claxton, 2007). It can also be useful to model subsequent interventions, especially where the data source used reports outcomes over different time frames, which could create incongruities. Using RRs can overcome this issue to a degree.

Where RRs are not already reported, they can be estimated using a standard two-by-two table (Table 6.3) with the associated equation shown (Briggs, Sculpher and Claxton, 2007). RRs calculated over a fixed time-period assume a constant hazard over time. Hazard ratios can be used where more detailed time-to-event data exist and may be more appropriate in certain situations (Latimer, 2013).

	Treatment group	**Control group**	**Total**
Event present	a	b	a+b
Event absent	c	d	c+d
Total	a+c	b+d	n

Table 6.3. Standard two-by-two table for estimating relative risk
(adapted from Briggs et al., 2006)

$$RR = \frac{a}{a+c} \Big/ \frac{b}{b+d}$$

6.3.2 Restoration survival inputs

Data which is not significantly flawed does not exist in the English setting comparing the survival of composite and amalgam restorations as discussed in Chapter 2. Also discussed was the limited value of existing clinical trial data in relation to the decision problem setting, and the availability of large, long-term datasets on the survival of amalgam restorations in the setting of interest. An approach of parameterising the model with a baseline for amalgam under NHS provision and the application of RRs for alternatives was therefore chosen. Following critical appraisal of the extensive NHS claims data publications previously described in section 2.15.6, bearing in mind the decision problem, the most relevant analyses were used to obtain estimates for TPs relating to 2-surface amalgam restorations in premolar teeth, and also subsequent reinterventions where available. These are shown in Table 6.4 (Lucarotti and Burke, 2018b; Gordan *et al.*, 2015; Lucarotti *et al.*, 2014; Burke and Lucarotti, 2012; Kwak *et al.*, 2019; Vermeulen *et al.*, 1996). A function in TreeAge Pro was used to convert time-to-event - non-event data into rates and then back to probabilities to parameterise each cycle with transition probabilities which are shown in Table 6.4. The transition probabilities were assumed to be fixed over time, with an approach taken to assess the external validity of this assumption against available data to assess its suitability.

State	Transition probability / 6-month cycle	Distribution	Data source
Vital unrestored carious lower left second premolar	1	-	Phase 2 PhD
Vital directly restored 2 surface*	0.028	Beta	Lucarotti and Burke, 2018b
Vital directly restored 2 surface repaired*	0.044	Beta	Lucarotti and Burke, 2018b and Gordan et al., 2015
Vital directly restored 3 surface*	0.034	Beta	Lucarotti and Burke, 2018b
Vital directly restored 3 surface repaired	0.054	Beta	Lucarotti and Burke, 2018b and Gordan et al., 2015
Vital crown restored*	0.020	Beta	Lucarotti and Burke, 2018b
Vital crown recemented*	0.020	Beta	Lucarotti and Burke, 2018b
Any vital crown repaired*	0.020	Beta	Lucarotti and Burke, 2018b
RoCT directly restored	0.044	Beta	Lucarotti and Burke, 2018b and Lucarotti et al., 2014
RoCT crown restored*	0.026	Beta	Lucarotti and Burke, 2018b and Lucarotti et al., 2014
RoCT crown recemented*	0.026	Beta	Lucarotti and Burke, 2018b and Lucarotti et al., 2014
RoCT crown repaired*	0.026	Beta	Lucarotti and Burke, 2018b and Lucarotti et al., 2014
Re-RoCT crown restored	0.033	Beta	Lucarotti and Burke, 2018b; Lucarotti et al., 2014 and Kwak et al., 2019
Re-RoCT crown recemented	0.033	Beta	Lucarotti and Burke, 2018b; Lucarotti et al., 2014 and Kwak et al., 2019
Re-RoCT crown repaired	0.033	Beta	Lucarotti and Burke, 2018b; Lucarotti et al., 2014 and Kwak et al., 2019
Bridge*	0.015	-	Burke and Lucarotti, 2012
Partial denture*	0.032	Beta	Vermeulen et al., 1996

Table 6.4. State transition probabilities
*includes replacement interventions of that restoration.

Though the data source chosen to inform the model and baseline amalgam TPs is quite old (data collection stopping in 2006 with the introduction of the UDA), materials and techniques used for amalgam restorations, RoCTs (under NHS regulations), PFM crowns and bridges are likely not dissimilar today from when the treatment was performed at data collection. Whilst rotary files are more accessible, and RD possibly more universally advocated for endodontic procedures, they are still not commonly used under NHS regulations (Gemmell, Stone and

Edwards, 2020). The nature of the current NHS dental services (since the introduction of the UDA) and the limited data collection are of minor use in assessing current service provision and planning future services as previously discussed in section 2.12.2 however.

6.3.3 Parameterising the alternatives using risk ratios

The following sections describe the data used to obtain RRs to apply to the baseline described. The values used are presented in Table 6.5.

6.3.4 Amalgam vs conventional composite restoration longevity

Following the discussion in section 2.15.7, the data from Bernardo et al., 2007 were used because they come from a RaCT and specify differential failure rates for two and three surface restorations, allowing individual RRs to be estimated as shown in Table 6.5. Techniques used to place both restorations (except material application) were also the same which is likely reflective of their use by the vast majority of NHS dental practitioners as evidenced in Chapter 4.

6.3.5 Conventional composite vs bulk-fill composite

There are issues with current data comparing conventional and bulk-fill composites due to limited follow-up as described in section 2.15.8. The search was therefore updated in 2023 for this thesis to seek individual RaCTs comparing bulk-fill and conventional composites that had at least 5-years follow-up and more than 20 restorations in each group available for assessment, given the issues previously discussed in section 2.15 (search details shown in Appendix C).

Just three studies comparing a conventional composite with a bulk-fill composite with the stated inclusion criteria were found. One used a flowable bulk-fill composite covered with a conventional paste composite (van Dijken and Pallesen, 2017) and two used paste bulk-fill composites (Yazici *et al.*, 2022; Schoilew *et al.*, 2023). None of the studies reported significant differences in survival outcomes. Two studies reported the same number of failures in each group tested (Schoilew *et al.*, 2023; van Dijken and Pallesen, 2017) with low AFRs of 1.4% and 1.6% respectively, whereas the other reported no failures. The two categories of bulk-fill composites were therefore assumed to have the same longevity as conventional composites. There was a statistically significant difference noted in one study for marginal stain, favouring the paste bulk-fill material as previously discussed (Yazici *et al.*, 2022), but the clinical significance of this is uncertain. The bulk-fill composites were therefore not included in the model as separate options, given the survival outcomes were the same as conventional composite (and restoration costs to funders and patients under the English NHS setting are the same irrespective of material).

6.3.6 Other risk ratio estimates

RRs were also estimated for other relative interventions modelled as shown in Table 6.5 and applied to various baseline transition probabilities as shown in Table 6.4. The alternative study used to estimate the combined RR for composite versus amalgam has been thoroughly described in section 2.15.7 (Worthington *et al.*, 2021). The RR for repair versus replacement data comes from a prospective cohort US practice-based study with limitations as previously described in section 2.19.2 (Gordan *et al.*, 2015). The RR for re-RoCT versus RoCT comes from a very large National Health Insurance Korean database (of nearly 3 million interventions) (Kwak *et al.*, 2019). It is assumed that these outcomes are similar to those obtained in NHS English primary care. The RRs for the survival of restorations with and without RoCT is taken from the NHS big dataset (Lucarotti *et al.*, 2014).

Relative intervention	Risk Ratio	ln(RR) (se)	Distribution*	Data source
Composite vs amalgam (2-surface restoration)	2.05	0.72 (0.20)	Normal	Bernardo et al., 2007
Composite vs amalgam (3-surface restoration)	3.29	1.19 (0.35)	Normal	Bernardo et al., 2007
Composite vs amalgam (combined restorations)	1.90	0.64 (0.11)	Normal	Worthington et al., 2021
Repair vs replacement direct restoration	1.60	0.47 (0.14)	Normal	Gordan et al., 2015
Re-RoCT vs RoCT	1.30	0.26 (0.01)	Normal	Kwak et al., 2019
Direct restoration vital vs RoCT	1.30	0.26 (0.01)	Normal	Lucarotti et al., 2014
Crown vital vs RoCT	1.30	0.26 (0.03)	Normal	Lucarotti et al., 2014

Table 6.5. Risk ratios to apply to baseline transition probabilities

ln, natural logarithm; se, standard error; RoCT, root canal treatment; *distribution sampled on log scale (Briggs et al., 2006).

6.3.7 Treatment time, visit and laboratory cost differences

Data from Chapter 4 was used to estimate treatment time for the differing direct restorations as shown in Table 4.5.

Expert opinion was obtained from three NHS practice owners to provide inputs on the average number of visits required, treatment time and laboratory fee for each intervention modelled (not including 2- and 3-surface restorations) as shown in Table 6.6.

Procedure (lower second premolar)	Average number of visits (range)	Average treatment time (minutes) (range)	Average lab bill (£) (range)
Crown	2	50 (45-60)	32.33 (30-35)
RoCT	1	38.33 (30-45)	N/A
RoCT + direct restoration	1	46.67 (40-60)	N/A
RoCT + crown	2 (2-3)	83.33 (75-100)	32.33 (30-35)
Re-RoCT	1 (1-2)	51.57 (45-60)	N/A
Re-RoCT + crown	3 (2-4)	96.67 (90-110)	32.33 (30-35)
Extraction	1	23.33 (20-30)	N/A
Partial denture	4 (3-4)	50 (30-60)	90 (70-120)
Resin bonded bridge	2	50 (45-60)	53.33 (45-65)
Conventional bridge	2	50 (45-60)	68.33 (65-70)
Bridge: average*	2	50 (45-60)	66.23 (45-70)
Recement crown	1	16.67 (15-20)	N/A
Repair crown	1	16.67 (15-20)	N/A
Direct restoration repair	1	16.67 (15-20)	N/A

Table 6.6. Intervention events (other than 2 and 3 surface restorations) average number of visits, treatment time and lab bill for English NHS provision.

Based on expert opinion (n=3). RoCT, root canal treatment; N/A, not applicable; *Based on 86% conventional bridge and 14% resin bonded bridge provision under NHS regulations (Burke and Lucarotti, 2012).

6.3.8 Marginal treatment time differences

Though survival outcomes showed no differences based on the data described, treatment time differs between conventional composite and bulk-fill materials as described in Chapter 2. The most appropriate study to use for estimates of the differences was a controlled in vitro study which provided estimates of the time required to restore a 3-surface cavity with conventional, bulk-fill paste and bulk-fill flowable composites (Güler and Karaman, 2014), and the marginal differences with 95% CIs from this study were presented in a systematic review (Bellinaso, Soares and Rocha, 2019). As no estimates compared all three materials for 2-surface restorations, a ratio of treatment time for 2-surface : 3-surface composite restoration from Phase 1 data was calculated: 34.0/42.4 = 0.802. This was applied to 3 surface bulk-fill in vitro data (Güler and Karaman, 2014) to obtain estimates for 2 surface bulk-fill flowable and paste timings which are shown in Table 6.7. Marginal differences in time between the different composite restorations over a lifetime were modelled with these inputs.

Composite material	Restoration surfaces involved	Extra time (minutes)	Distribution	Data source
Conventional vs bulk-fill flowable	2	1.74	None*	Extrapolation Phase 1 data and Güler and Karaman, 2014
	3	2.17	Gamma	Güler and Karaman, 2014
Conventional vs bulk-fill paste	2	2.33	None*	Extrapolation Phase 1 data and Güler and Karaman, 2014
	3	2.91	Gamma	Güler and Karaman, 2014

Table 6.7. Marginal time differences for varying composite restorations
*No genuine distribution exists due to the estimate derivation from data extrapolation.

6.3.9 Costs

The costs used in the model are shown in Table 6.8. NHS dental patient charges were used to estimate intervention costs from a patient perspective. Currently in the English NHS context, the fees for composite and amalgam are the same, as described in Chapter 2. The patient charge for a band 1 treatment was subtracted from the fees for all non-urgent treatment (band 2 and 3 treatments) to more accurately reflect the costs of treatment alone. The band 1 charge relates to the fee for an exam, diagnostics and prevention which is usually carried out at the initial examination appointment, and it is assumed that the patient is reappointed for any treatment required. Equally it is assumed that the only treatment required relates to the LL5 and the sequelae of the initial modelled restoration. Other treatment may be required and carried out under the same band for the same patient charge and UDA fee however, as described in Chapter 2. This costing therefore represents the highest estimate under NHS provision, as other treatment would reduce the relative cost to the patient and the NHS. Similarly, the estimated cost to the NHS is reduced by one UDA for each non-urgent treatment to reflect the fee paid to the dentist for the treatment alone. An assumption is made that none of the treatment is carried out as emergency, other than recementing a crown. The band 4 patient charge and UDA fee is therefore not altered, as this would be carried out without a comprehensive exam and dealt with on the day of attendance with the problem. Crown repair likely relates more often not to an actual repair of the crown, but to a restoration involving a crowned tooth, which may be restoration of a non-carious cervical (class V) lesion or secondary caries at the crown margin for example. This uncertainty is due to the limited granularity of information collected as part of the claims process in NHS dental care. It is therefore assumed to be managed under a non-urgent course of treatment.

The average UDA value of £29.32 is used (BDA data, Diddee, personal communication, 2023). The average patient charge and NHS cost is based on the proportion of exempt patients accessing NHS dental care being 23.6% and paying patients 76.4% (NHS England, 2023). It is assumed that treatment provision between these groups is the same.

Treatment	**NHS band**	**UDAs ^**	**UDA fee (£)**	**Patient charge§ (payer) (£)**	**Patient charge (exempt) (£)**	**Average patient charge±§ (£)**	**Total NHS cost# (payer) (£)**	**Total NHS cost# (exempt) (£)**	**Average NHS cost± (£)**
Direct restoration (including repair crown) or extraction	2a	2	58.64	44.90	0	34.30	13.74	58.64	24.34
Root canal treatment +/- direct restoration	2b	4	117.28	44.90	0	34.30	72.38	117.28	82.97
Any treatment involving an indirect restoration*	3	11	322.52	281.00	0	214.68	41.52	322.52	107.84
Recement crown (emergency)	4	1.2	35.18	25.80	0	19.71	9.38	35.18	15.47

Table 6.8. English NHS dental costs

NHS, National Health Service; UDA, unit of dental activity; *includes tooth-borne fixed and removable prosthodontics (not implant-borne); ±Based on exempt 23.6% : payer 76.4% adult courses of treatment (NHS England, 2023) (example calculation for average NHS cost band 2a = [13.74 x 0.764] + [58.64 x 0.236] = £24.34); #Average UDA value £29.32 (BDA data, Diddee, personal communication, 2023); ^with 1 UDA subtracted for non-emergency treatments; §with band 1 charge subtracted for non-emergency treatments.

6.4 Additional assumptions

Some important assumptions have already been described. There are however many others which are considered in the following sections.

6.4.1 All patients received treatment

It was assumed that all patients diagnosed with caries went on to receive treatment. It is likely that not everyone diagnosed with caries requiring restorative intervention would go on to access treatment or NHS care. Whilst those opting-out could be modelled, they were not for simplicity with the following justification. The DCE sample (Chapter 5) was broadly representative of the UK population but with a higher proportion of highly dentally anxious responders, which might have been expected to increase treatment avoidance. However just

2% of respondents opted out of all treatment. Of these, there were over ten times the number of edentulous responders compared to the whole sample. It is possible, perhaps likely, that these edentulous respondents may not have followed the instructions to answer as if they had teeth. Also importantly, a majority of those opting out received free NHS dental treatment (exempt from patient charges). Allied with the data showing a large majority had previously received fillings, this suggests that the dentate respondents who were not willing to pay for treatment at the levels presented, would accept free restorative treatment. This justifies excluding 'no treatment' from the model, as those refusing treatment likely represents a trivial proportion of the general population.

6.4.2 Parameterisation

The restorative status of the teeth receiving 2-surface amalgam restoration is unknown from the claims data, so the restoration could be a reintervention or the original intervention (and this holds for subsequent interventions) (Lucarotti and Burke, 2018b). The first intervention, and subsequent reinterventions of the same number of surfaces (or repairs or crowns) are assumed to have the same reintervention rate (which vary by the presence or absence of a root filling) which is a simplification, but will reflect the generic nature of the data. AFRs were assumed to be linear for all restorations and interventions, with constant proportional hazards, which is a simplification of the data. The fit of the model data with the NHS data was examined to assess the validity of these assumptions.

The pre-existing presence of a root filling in a restored tooth is also unknown. Only new RoCTs, which are provided on the same course of treatment as a restorative intervention, are recorded showing the influence of RoCT on restoration survival (Lucarotti *et al.*, 2014). These data have been used with the assumption that teeth not receiving a RoCT on that course of treatment are not root filled, when it is likely that some have been previously. This will therefore likely underestimate the difference in failure rate. The premolar data on direct restorations, which are broken down by surfaces involved, do not state the RoCT status of the teeth. It is assumed that they haven't been RoCT, as the 10-year survival data of 2-surface restorations in premolar teeth (48%) (Lucarotti and Burke, 2018b) is very similar to the premolar teeth with direct restorations (of any size) not receiving RoCT on that course of treatment (49%) (Lucarotti *et al.*, 2014).

Amalgam restorations are easier to see than composite restorations which makes their removal quicker and reduces overcutting in comparison to composite as discussed in section 2.19. This potential difference was not modelled, with both restorations assumed to take the same time to replace at reintervention as initial intervention, and to impact the retention of tooth tissue in the same way between interventions. This is likely to underestimate any differences in survival following reintervention and time taken to replace the restorations favouring composite, leading to a smaller difference than might be expected.

Once a tooth received a crown, it was assumed that the direct restoration material did not affect subsequent TPs.

The data source for the TP of partial dentures relates to metal-based dentures provided in the Dutch healthcare setting for 748 patients (Vermeulen *et al.*, 1996), whereas it is likely that the majority of dentures provided on the NHS are acrylic. The model assumes that metal-based and acrylic dentures have similar longevity.

Patients going through the model have the potential to die from all-cause mortality in each cycle. The data used to provide transition probabilities likely excludes dead patients and therefore this is not accounted for, which is a limitation.

6.4.3 Reintervention

Certain reinterventions, such as pulpotomies, post-retained direct or indirect restorations, and partial coverage restorations (e.g. onlays) have not been modelled. The impact of posts is hard to fully elucidate and will be encompassed to a degree in the RoCT survival data. The other reinterventions mentioned are not often performed in NHS dentistry (Edwards *et al.*, 2021b; Lucarotti and Burke, 2009). Implants to replace missing teeth are not provided in NHS primary care, and therefore are not modelled given the perspective taken.

Teeth are extracted for many reasons at the tooth level, commonly due to sequelae of caries including pulpitic or endodontic pain and inability to restore them, but also due to periodontitis. As a person gets older their risk of tooth loss due to periodontitis increases and the claims data will include such tooth loss and not distinguish between the different reasons for extraction. Therefore using the claims data will likely overestimate the levels of tooth loss due to restorative intervention in the caries process, but does however reflect the reality of multiple disease processes progressing often simultaneously. Multiple factors may then influence a decision to extract a tooth and therefore the data accurately reflects all cause tooth loss, as does the reintervention data which informs the allocation probabilities. The reintervention data takes account of these often simultaneously ongoing disease processes on average (though assuming a linear influence over time, which is a simplification). The tooth loss inevitably then impacts future interventions and costs, and some replacement options may not be possible for certain individuals based on multiple factors. The simplifying assumption is therefore made that all (NHS) replacement options are equally applicable to all individuals having the teeth extracted, and the proportions of patients having teeth replaced and then choosing a replacement option are broadly based on ADHS data.

The reinterventive pathway of the restored tooth was assumed to be the same irrespective of material. The data from Phase 1 suggest however that if amalgam was unavailable, heavily restored teeth would be more likely to be deemed unrestorable or require earlier intervention with more expensive indirect restorations. It also suggested that many people may not be able to afford these and would lead to earlier extraction of the teeth.

It is assumed that exempt and non-exempt patients would have the same reinterventive pathway, however data suggests that exempt patients receive a higher proportion of higher band treatment (NHS England, 2023). Varying the proportion of exempt and non-exempt patients was performed as deterministic sensitivity analyses to assess the impact of this assumption.

It was assumed that 2-surface restorations could be replaced a maximum of four times, with a maximum of two repairs. The longevity of 2-surface restoration reinterventions was assumed to be the same, which is unlikely to reflect clinical reality as the restorations will almost certainly get bigger after each replacement. The different restorative options of all complexities, RoCT and extractions were available as reinterventions immediately following the initial intervention and were throughout (though obviously restorations were unable to reduce in complexity), except where further assumptions were made as detailed later. Repairs of direct restorations could not be re-repaired as the next reintervention. It was assumed that 3-surface restorations could be replaced twice and repaired once, and following a repair it was assumed that the next reintervention had to be a crown or root canal treatment with either a direct restoration or crown, or an extraction. A maximum of three crowns could be placed prior to extraction. A maximum of one repair or recement of a crown was allowed prior to its replacement, RoCT or extraction. Repairing or recementing a crown was assumed not to affect the subsequent survival of the repaired or recemented crown which likely underestimates the transition probabilities from these states. A failed RoCT could be redone a maximum of once and this necessitated the placement of a new crown. Further treatment at this stage was limited to crown repair or recement, or extraction. When a tooth was extracted, the space could be left, where this was assumed to be never replaced, or replaced with either a bridge or a denture. It was assumed that a maximum of two bridges or four dentures could be placed after which a space was left. All assumptions were made based on expert opinion from within the research group.

The primary data source used to define APs for reintervention following an amalgam restoration did not include RoCT as a mode of reintervention (Lucarotti, Holder and Burke, 2005). Other data sources describing the proportion and survival of premolar teeth with and without RoCT and the proportions of those teeth with RoCT which had direct versus indirect restorations were therefore used (Lucarotti and Burke, 2018b; Lucarotti *et al.*, 2014). The proportion of each type of reintervention following failure of amalgam restorations reported, included all sizes and configurations of restorations, not just two-surface restorations which was modelled. The proportion of replacement direct restorations which involved the same number of surfaces as the original failed restoration versus more was not available. The multiple data analyses do not perfectly align. Expert opinion from the supervisory team, informed by the data, was therefore required to specify the APs and subsequent allocation probabilities for other tooth states. Given the large size of the data sets used, the variation is likely to be small, and because imperfect data sets are combined and other assumptions are made as subsequent direct reinterventions occur (as discussed), no attempt was made to obtain a distribution which would characterise the uncertainty in each of these AP estimates for each individual tooth state. Given the relative uncertainty around the proportion of teeth receiving RoCT at reintervention, a scenario analysis was performed to increase the proportion of teeth receiving RoCT whilst decreasing the proportion extracted. This was deemed to be a plausible scenario under new (2023) NHS arrangements given the increased remuneration now provided for RoCT in a premolar, without the patient paying an increased fee for this as described in section 2.12.2.

The reinterventions following crowns is broadly based on data (Burke and Lucarotti, 2009). The endodontic status of the crowns from the data is uncertain however, so it was assumed that none had RoCT (but it is likely that some did) and the data was not premolar specific. Survival of premolar crowns (upper and lower) was slightly higher than all crowns at 15-years (80% vs 77%) (Lucarotti and Burke, 2018b; Burke and Lucarotti, 2018c). Expert opinion from the supervisory team was therefore used to apply allocation probabilities to the differing crown restorations, bearing the data and its limitations in mind alongside clinical experience.

Reinterventions based on RoCT teeth in terms of performing re-RoCTs were broadly based on data (Lumley, Lucarotti and Burke, 2008). However the data relates to the proportion of all teeth receiving re-RoCT, not just premolars. re-RoCT is likely to be performed more often in upper anterior teeth than premolar teeth, as people are generally keener to save these teeth for aesthetic reasons. Therefore these data likely overestimate re-RoCT allocation. There is some suggestion of this from available data comparing re-RoCT prevalence for anterior and posterior teeth in the UK, however premolar teeth were analysed as anterior teeth and compared against molar teeth (Essam *et al.*, 2022). The data collection did not allow further breakdown (Essam, personal communication, 2023), so it is not possible to say with any certainty.

6.4.4 Individual risk

There are potential risk factors for restoration failure which could have been modelled at the individual-level. Clinician ascribed patient risk of restoration failure may be very variable however, and risk inevitably varies throughout an individual's life as discussed in Chapter 2 and summarised in section 2.20. The proportion of patients deemed to be at risk of restoration failure in the English population is complex and unknown. It is therefore currently justifiable, when modelling reintervention following restoration failure, that TPs and APs are assumed to be the same regardless of patient risk characteristics, which are therefore not differentially modelled.

6.5 Analysis

Six-monthly cycle Monte Carlo microsimulations were performed for the analysis with a closed population of 10,000 independent 18-year-old patients run through the model. Individual patients were followed over a lifetime or up to 100-years. Their probability of death changed with age at each subsequent cycle based on UK statistics of all-cause mortality (ONS, 2023b). Evaluations were performed for a single premolar tooth to simplify interpretation and avoid potential clustering effects (Schwendicke *et al.*, 2018b). The previously defined outcomes were reported alongside costs. The base-case scenario considered costs from an NHS funder's perspective. Deterministic analyses considered costs from the alternative perspectives previously defined.

6.5.1 Half-cycle correction

Transitions between states with discrete cycle lengths are assumed to occur at the beginning or end of each cycle. In reality they could occur at any point in the cycle. Half-cycle correction is a technique used to account for this, making estimates more accurate. This was applied to the first and last cycle in TreeAge Pro (Caro *et al.*, 2012).

6.5.2 Discounting

Discounting is the process of attempting to adjust future costs and outcomes to their present value. Discount rates of 3.5% were applied to all costs and outcomes after the first year as recommended by NICE (NICE, 2024). Multiple non-discounted analyses were also run to assess the effects of discounting.

6.5.3 Validity

There are different forms of uncertainty in decision modelling as shown in Table 6.9. Characterising uncertainty is important to reflect how it potentially affects conclusions of the analysis and allows funders to make more informed decisions under uncertainty (Briggs *et al.*, 2012).

Uncertainty type	Concept	Alternative terms used
Stochastic	Random variability in outcomes between identical patients	Variability, Monte Carlo error, first order uncertainty
Parameter	The uncertainty in estimation of the output of interest	Second order uncertainty
Heterogeneity	Patient variability attributable to their characteristics	Variability, observed or explained heterogeneity
Structural	Assumptions inherent in the decision model	Model uncertainty

Table 6.9. Uncertainty in decision modelling

Adapted from Briggs et al., 2012.

Microsimulations assess the impact of stochastic uncertainty as discussed. Structural uncertainty can be assessed by comparing model outputs with data, for example by comparing restoration survival over time and tooth survival over time in the current model with available NHS data as previously discussed. This analysis could appraise the external and predictive validity of the model and the impact of stated assumptions. Stating assumptions made is also helpful in providing transparency. Explicit heterogeneity was not modelled as justified previously.

Where a parameter does not have a distribution, for example as seen when applying discounting, or data distributions are not available, changing a parameter to assess its impact can be useful. To assess parameter uncertainty deterministically however, the parameter change must be based on data, as may be performed when using expert opinion to obtain plausible extreme values. Changing parameters to reflect different scenarios (which are not necessarily based on data) and therefore assess their impact is known as scenario analysis, but does not characterise uncertainty if not based on data (Briggs *et al.*, 2012). Deterministic analyses are also useful to assess the internal validity of the model, by assessing if changes to the input parameters result in expected changes in the direction of outputs, for example.

Probabilistic sensitivity analyses (PSA) more accurately account for holistic parameter uncertainty. Instead of using fixed, point estimates for parameters, PSA assigns probability distributions to each uncertain parameter. The model is then run multiple times using randomly sampled values from these distributions. This results in a range of possible outcomes, providing a more robust understanding of the uncertainty surrounding the model's results. PSA helps decision-makers understand how variability in input parameters might affect the conclusions of the analysis where multiple parameters are uncertain and changing at the same time, allowing for more informed decision-making under uncertainty.

6.5.4 Scenario and sensitivity analyses performed

The following deterministic sensitivity or scenario analyses were performed with 10,000 patients run through each model as previously described:

- Base-case without discounting
- NHS costs where all patients pay
- NHS costs where no patients pay
- Patient costs (average NHS direct costs paid accounting for the proportion of paying and exempt patients)
- Patient costs where all pay
- Patient costs where none pay
- Composite RR unvarying and highest 95% CI value (Worthington *et al.*, 2021)
- Composite RR unvarying and lowest 95% CI value (Worthington *et al.*, 2021)
- Composite RR unvarying and average value (Worthington *et al.*, 2021)
- 50% patients replace missing teeth (with and without discounting)
- Extraction AP halved for vital direct restorations and equally applied to RoCT direct or RoCT crown restored (with and without discounting)
- Effectiveness outcome limited to direct restoration survival (with and without discounting)

A PSA was run with 1000 iterations of 10,000 patients, sampling parameter values randomly from the available distributions shown in Table 6.4, Table 6.5 and Table 6.7.

6.5.5 Data distributions

Beta distributions were used for the TPs which were based on event - non-event data at a time point, as there are two TPs (success and failure) which must sum to 1 (Briggs, Sculpher and Claxton, 2007), as shown in Table 6.3.

RR distributions are obtained by sampling normal distributions on the log scale of RRs and their CIs which are then exponentiated to recover the estimate (Briggs, Sculpher and Claxton, 2007). Where RRs are reported with 95% CIs, natural logs (ln) of the point and interval estimates should be taken. The range is then divided by 2 x 1.96 to estimate the log scale standard error (se) (Briggs, Sculpher and Claxton, 2007). This method was used to estimate the RR distributions for repair versus replacement of direct restorations and re-RoCT versus RoCT shown in Table 6.5. Where these values are not reported, the ln(RR) and se[ln(RR)] can be calculated using the following equations (following on from the previous RR equation in section 6.3.1) (Briggs, Sculpher and Claxton, 2007), which were used to calculate the remaining values presented in Table 6.5:

$$\ln(RR) = \ln(a) - \ln(a+c) + \ln(b+d) - \ln(b)$$

$$se[\ln(RR)] = \sqrt{\frac{1}{a} - \frac{1}{a+c} + \frac{1}{b} - \frac{1}{b+d}}$$

Gamma distributions were used for time-based parameters as they have to take positive values and are generally right skewed (Briggs, Sculpher and Claxton, 2007). Though normal distributions can be justified for large datasets due to the central limit theorem, they resulted in negative values which are inappropriate. Minimum outcome time values were checked for plausibility as a means of internal validation.

True (data-based) distributions for the APs do not exist, therefore distributions were not modelled. Similarly, data based on expert opinion or extrapolation were not modelled as distributions. Key parameters without available distributions were assessed deterministically in scenario analyses as described.

The uncertainty where marginal time distributions were not available for 2-surface restorations was assessed by using plausible upper and lower bounds in deterministic sensitivity analyses obtained through expert opinion (n=3). These were 1 - 2.5 minute savings for the bulk-fill flowable and 1.5 - 3 minute savings for the bulk-fill paste composites compared to conventional composites.

6.6 Results

6.6.1 Model validation

External and internal validity checks were carried out with the undiscounted model to compare against actual NHS survival data (Lucarotti and Burke, 2018b). The survival percentage over time of an initial premolar 2 surface amalgam restoration is shown in Figure 6.6 comparing actual NHS data with model data.

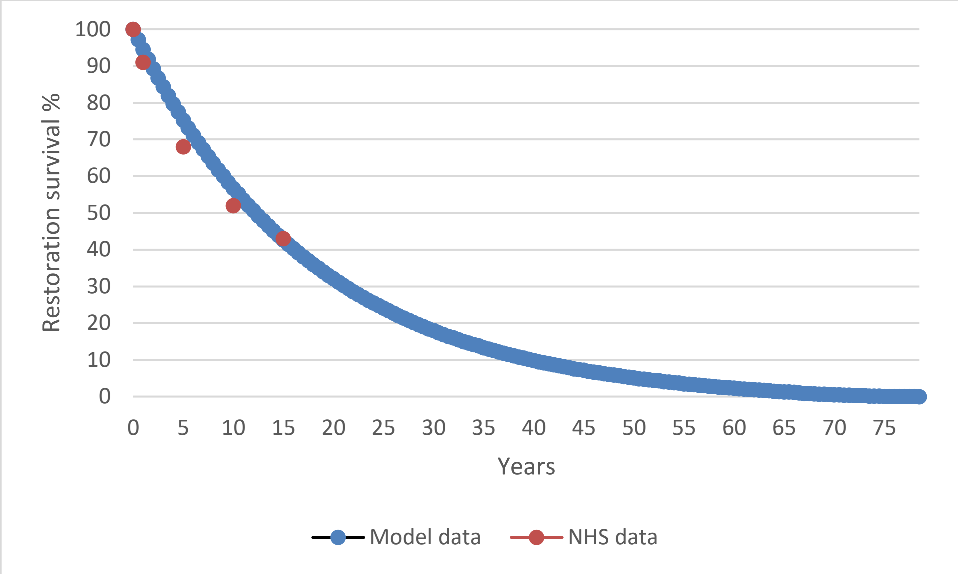


Figure 6.6. Premolar 2-surface amalgam restoration survival
NHS data from Lucarotti and Burke, 2018b.

Restoration survival at 15-years was the same in the model and the NHS data. This was used to parameterise the model providing evidence for the internal validity of the model. The model slightly overestimates restoration survival initially, then potentially underestimates survival later.

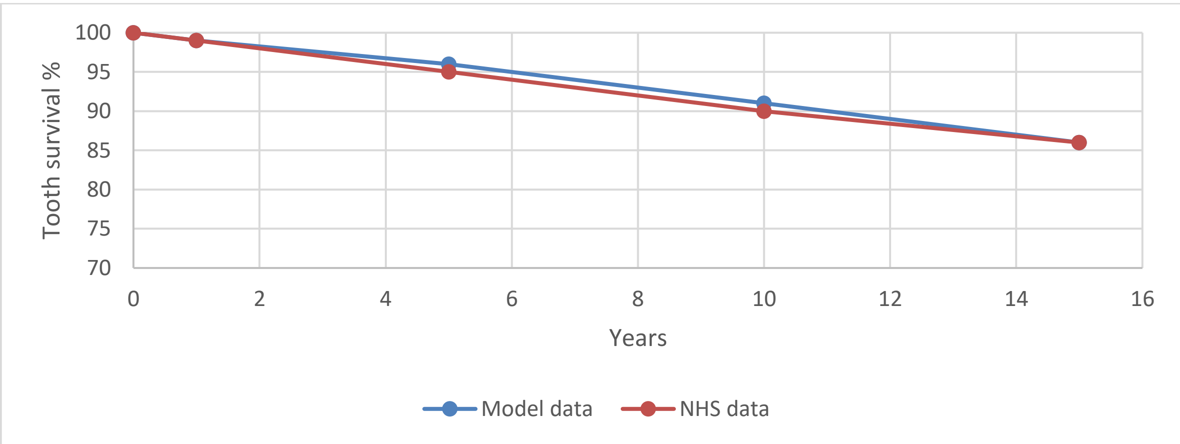


Figure 6.7. Premolar tooth survival following a 2-surface amalgam restoration
NHS data from Lucarotti and Burke, 2018b.

The undiscounted model obviously projects beyond the data presented, but the influence of people dying gets bigger as more people die year-on-year, making projections less sound (though over the 15-year period this percentage is very small- well below 1%). Tooth survival from the model is very similar to NHS data over 15-years however as shown in Figure 6.7.

Extrapolating beyond the NHS data (Lucarotti and Burke, 2018b) with a crude (assumed) linear graphical projection resulted in an estimate of median premolar tooth survival of approximately 51-years following a two-surface amalgam restoration as shown in Figure 6.8. The undiscounted model provides a median estimate of 44-years. The model does however include people dying at increased rates year-on-year. These results are not dissimilar, however the model seems to underestimate tooth survival slightly.

Restorations do however get larger and more complex (for example, three surface amalgams and crowns) over an extended time-period as people move through the model and get older, both of which reduce tooth survival following restoration (Lucarotti and Burke, 2018b). Therefore, when considering premolar survival after all restorations, again with crude (assumed) linear graphical projection of the NHS data, the median survival is the same as the model data (44-years) as shown in Figure 6.9, again with the caveat that the model includes people dying. This evidence provides a level of external and face validity for the model.

The base case statistics shown in Table 6.10 show that people move through the model with a wide range of costs and outcomes, providing a level of internal validity. Minimum values for time values show that distributions are reasonable and provide plausible data (additionally shown in marginal time difference outcomes in Table 6.11. Equally, minimum values for restoration survival of 0-years (to nearest integer) show that the half-cycle correction was operational. The direction of effects of deterministic analyses on costs and outcomes were as expected as shown in Table 6.12, providing additional evidence for the internal validity of the model. When the AP of extraction for direct restorations was reduced by 50% and equally redistributed to RoCT with direct restorations and crowns (justified based on the Dutch data), the non-discounted average survival of amalgam restored teeth moved from 44 to 49-years, closer to the previously described 51-years from crudely projected NHS data.

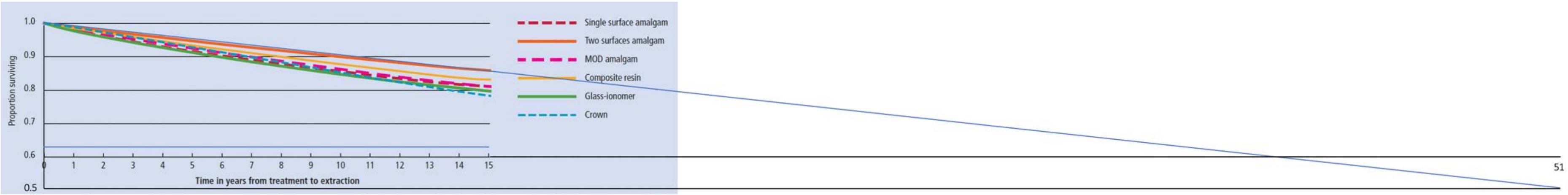


Figure 6.8. Time to extraction of restored premolar teeth, following various restorations. Two surface amalgam crudely linearly projected
Modified and reproduced, with permission (Appendix B), from Lucarotti and Burke, 2018b.

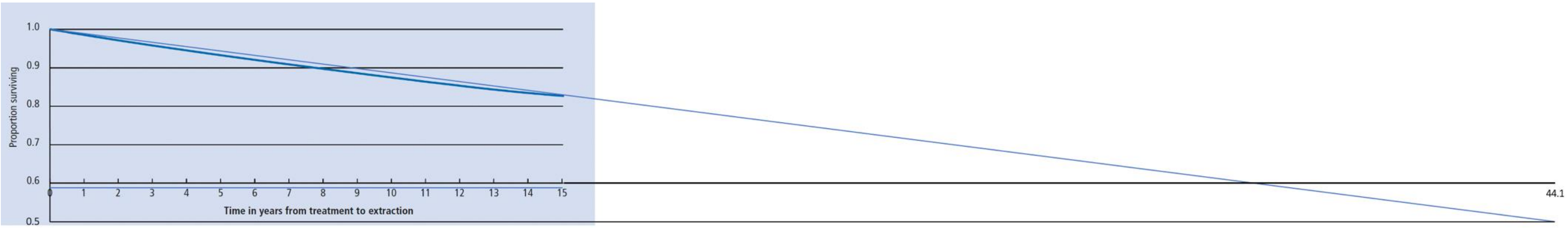


Figure 6.9. Time to extraction, of all restored premolar teeth crudely linearly projected
Modified and reproduced, with permission (Appendix B), from Lucarotti and Burke, 2018b.

Statistic		Cost (£)		Tooth survival (years)		Treatment time (minutes)		Treatment visits		Laboratory costs (£)	
		Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
Mean		81	115	21	17	64	107	3	4	11	18
Standard deviation		46	55	7	8	30	42	1	1	18	23
Quantiles	Minimum	24	24	0	0	8	18	1	1	0	0
	Median	68	110	23	18	59	103	2	3	5	14
	Maximum	402	413	28	28	252	351	13	13	227	227
Prediction interval	95% lower bound	80	114	21	17	64	106	3	3	10	18
	95% upper bound	81	116	21	17	65	108	3	4	11	19

Table 6.10. Base-case scenario 3.5% discounting

Values rounded to nearest integer or one significant figure when <1.

Statistic		Time saving for bulk-fill compared to conventional layered composite (minutes)					
		Bulk-fill flowable			Bulk-fill paste		
		3.5% discounted	No discounting	Probabilistic sensitivity analysis	3.5% discounted	No discounting	Probabilistic sensitivity analysis
Mean		3	4	3	4	5	4
Standard deviation		2	2	0.02	2	3	0.02
Quantiles	Minimum	2	2	3	2	2	4
	Median	3	4	3	4	5	4
	Maximum	9	12	3	12	15	4
Prediction interval	95% lower bound	3	4	3	4	5	4
	95% upper bound	3	4	3	4	5	4

Table 6.11. Marginal time differences for composite material variations. Base-case with and without 3.5% discounting and probabilistic sensitivity analysis

Values rounded to nearest integer or one significant figure when <1.

Scenario	Mean cost (£) (SD)		Mean tooth survival (years) (SD)		Mean treatment time (minutes) (SD)		Mean treatment visits (SD)		Mean laboratory costs (£) (SD)	
	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
Base-case (NHS costs)	81 (46)	115 (55)	21 (7)	17 (8)	64 (30)	107 (42)	3 (1)	4 (1)	11 (18)	18 (23)
Probabilistic base-case	80 (0.5)	114 (0.6)	21 (0.1)	17 (0.1)	64 (0.3)	106 (0.4)	3 (0.01)	3 (0.01)	11 (0.2)	18 (0.2)
No discounting	147 (91)	181 (97)	44 (22)	32 (22)	110 (56)	156 (68)	4 (2)	5 (3)	25 (36)	35 (41)
NHS costs - all pay	43 (24)	60 (29)	21 (7)	17 (8)	64 (30)	107 (41)	3 (1)	4 (1)	11 (18)	19 (23)
NHS costs - none pay	201 (126)	290 (153)	21 (7)	17 (8)	64 (30)	106 (42)	3 (1)	4 (1)	11 (18)	18 (23)
Patient costs	120 (80)	175 (99)	21 (7)	17 (8)	64 (30)	107 (43)	3 (1)	3 (1)	11 (18)	18 (23)
Patient costs – all pay	158 (106)	228 (128)	21 (7)	17 (8)	64 (30)	106 (42)	3 (1)	3 (1)	11 (18)	18 (23)
Patient costs – none pay*	0 (0)	0 (0)	21 (7)	17 (8)	64 (30)	106 (41)	3 (1)	3 (1)	11 (18)	18 (23)
Composite RR upper bound unvarying (3.57)	80 (46)	130 (58)	21 (7)	15 (8)	64 (30)	119 (43)	3 (1)	4 (1)	11 (18)	22 (25)
Composite RR lower bound unvarying (0.9)	80 (46)	77 (45)	21 (7)	21 (7)	64 (30)	77 (34)	3 (1)	2 (1)	11 (18)	10 (17)
Composite RR unvaried by surfaces involved (1.89)	80 (46)	107 (53)	21 (7)	18 (8)	64 (30)	101 (39)	3 (1)	3 (1)	11 (18)	16 (22)
50% replace missing tooth	88 (50)	127 (58)	21 (7)	18 (8)	68 (32)	113 (42)	3 (1)	4 (2)	17 (24)	29 (30)
50% replace missing tooth[ND]	169 (101)	209 (103)	44 (22)	32 (22)	120 (61)	169 (71)	5 (3)	6 (3)	42 (50)	57 (51)
Extraction AP halved for vital direct restorations and equally applied to RoCT direct or RoCT crown restored	87 (49)	125 (55)	22 (6)	18 (7)	69 (32)	114 (42)	3 (1)	4 (1)	12 (17)	20 (22)
Extraction AP halved[ND]	164 (91)	201 (94)	47 (21)	35 (22)	120 (58)	170 (68)	5 (2)	6 (2)	28 (36)	38 (41)
Effectiveness outcome limited to direct restorations survival	80 (46)	114 (56)	18 (8)	12 (7)	64 (30)	107 (42)	3 (1)	4 (1)	11 (18)	18 (23)
Effectiveness outcome limited to direct restorations survival[ND]	147 (91)	180 (97)	35 (21)	18 (14)	109 (56)	156 (68)	4 (2)	5 (2)	25 (36)	34 (41)

Table 6.12. Scenario and sensitivity analyses

RR, risk ratio; SD, standard deviation; AP, allocation probability; RoCT, root canal treatment; [#] Amalgam – composite; [ND] No discounting. Values rounded to nearest integer or one significant figure when <1. All incremental cost effectiveness ratios (ICERs) negative other than * ICER = 0.

6.6.2 Model outputs

As discussed, ICERs are usually presented in CEAs to show the cost differences per effectiveness differences of the interventions as described in Chapter 3. However, amalgam was more effective (in terms of tooth survival, initial restoration survival and lifetime tooth survival limited to direct restorations) and less costly than composite (from all perspectives). This makes the presentation of ICERs inappropriate. The direction of outcomes was also the same in all the sensitivity analyses performed except for two, as shown in table 5.13. One was an extreme deterministic sensitivity analysis where the lowest 95% CI estimate of composite RR was used (from a secondary analysis (Worthington *et al.*, 2021)). In this situation composite was both more effective and less costly than amalgam. In all these situations the cheaper and more effective option is said to dominate the alternative, and calculation of ICERs is inappropriate. The other deterministic scenario analysis where amalgam did not dominate composite was where costs were used from the exempt patient perspective, so no-one paid for any treatment. The ICER was therefore 0. This analysis was primarily performed as a test of internal validity for the model. A cost-effectiveness plane would therefore offer little help in interpretation of these results.

Secondary outcomes (mean treatment time, mean treatment visits and mean laboratory costs) were all higher for composite in comparison to amalgam in the base-case scenario. This was also the same for all sensitivity or scenario analyses except for the extreme deterministic sensitivity analysis where the lowest 95% CI estimate of composite RR was used as previously described. It should also be noted however that treatment time was still higher for composite in this analysis, whereas the other outcomes were lower compared to amalgam. The initial two surface restoration mean survivals were 17-years (SD 16) for amalgam and 9-years (SD 9) for composite without discounting, and 11 (SD 7) and 7-years (SD 5) with 3.5% discounting respectively.

Bulk-fill paste composite use resulted in a higher treatment time saving than bulk-fill paste composites in relation to conventional composites in the base-case scenario and the PSA. As no data distribution existed for the reduction in time for two surface bulk-fill composite compared to conventional composite restoration placement, upper and lower plausible expert values were used deterministically as described, resulting in 3.5% discounted lower and upper bounds of time reductions over a lifetime of 2 - 4 minutes for bulk-fill flowable and 3 - 5 minutes for bulk-fill paste composites.

The main results of the PSA are shown in Table 6.12 and in Figure 6.10, which shows the point estimates of each iteration of 1000 instances of following 10,000 patients through the model for base-case NHS funder costs and tooth survival. The clear separation of the estimates for each intervention shows that amalgam was more effective and less costly than composite with negligible chance of uncertainty. The PSA results for marginal time differences between composite types are shown in Table 6.11.

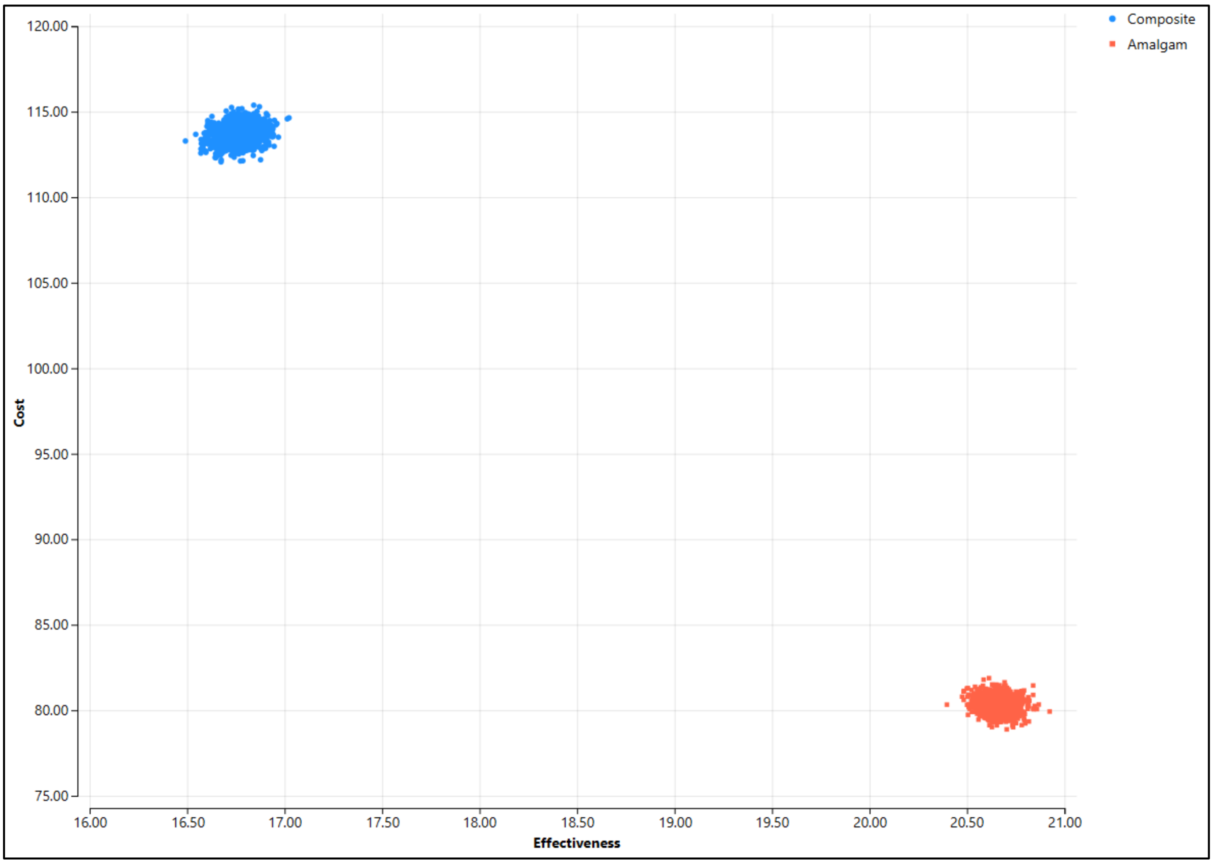


Figure 6.10. Probabilistic sensitivity analysis cost-effectiveness scatterplot

6.7 Discussion

Based on the outcomes and costs modelled, amalgam was superior to conventional composite in that it was less costly from all perspectives, with the restoration, tooth limited to direct restorations only, and tooth all surviving longer, whilst incurring reduced numbers of visits, treatment time and laboratory costs. It was also therefore superior to both bulk-fill composites, given that there were no differences in survival and NHS costs found between bulk-fill composites and conventional composite. There was a treatment time saving noted between bulk-fill composites and conventional composites, with the highest saving noted for bulk-fill paste composite, though this was still small (4 minutes over a lifetime with 3.5% discounting).

Whether the PSA represents the true uncertainty is questionable to a degree, as no representative data in the English NHS setting on composite survival exists (section 2.15.6). The dataset used to parameterise the base model of amalgam is very large, and therefore estimates are precise. The RRs for composite applied in relation to the base amalgam model have 95% CIs which are all much greater than 1 and therefore the separation seen is perhaps unsurprising. As discussed in Chapter 4, it is likely that in English NHS practice, the techniques employed for placement of composite restorations are very similar to those used in the RaCT which was used to generate the RRs (Bernardo et al., 2007). It could be argued that the data comes from children who are often at higher risk of caries as discussed in section 2.15.7, questioning the validity of the results, but the RRs generated from meta-analyses of RaCT data comparing all composite and amalgam restorations and outcomes in the deterministic sensitivity analyses when using this data are not dissimilar to the base case. It may be expected however, in a different setting where recommended techniques are employed, that the uncertainty could increase.

The differences in outcomes and costs and the implications of these results will be discussed more thoroughly in the CCA in the following chapter.

Comparing outputs with other models used to economically evaluate amalgam versus composite restorations show broadly similar relative outcomes where comparable, despite the limitations and differing assumptions made with the previous and current models as previously discussed in section 3.8. This provides a level of external validity. One model did however report a difference in survival between conventional and bulk-fill composites suggesting conventional composite was more cost-effective (Schwendicke *et al.*, 2018b). Data with much shorter follow-up and very few failures were used in that analysis however and this can be misleading as previously discussed in section 2.15. The current analysis is based on longer-term clinical data. Only restoration survival, tooth survival and limited costs have been modelled previously, so this analysis is broader in its scope. It also modelled a more realistic treatment pathway broadly based on data, which the previous models did not. The available NHS data (and Dutch data) was able to provide a level of external validity for the model, which the previous models did not.

6.8 Limitations

A number of assumptions were made in constructing and parameterising the model as previously described throughout this chapter and in section 6.4. In summary however, old data were used from the setting of interest, alongside data from other settings with questionable relevance. Several parameters were estimated based on expert opinion.

6.9 Potential future related work

The assumptions of constant hazards for the TPs and the impact of using RRs in the model rather than HRs could be investigated as advised by NICE guidance (NICE, 2024; Latimer, 2013).

Modifying the base reintervention transition probability to assess its impact could be further explored beyond the PhD. Up to date data on restoration survival and reintervention in English NHS primary care would be useful to inform policy. A system which collected more detailed data would be very helpful in providing this, including who provided the restoration (dentist versus therapist).

Some parameters were not varied in the PSA. APs were not varied based on distributions. This is unlikely to have much of an effect as many were broadly based on studies with large datasets, but the uncertainty could be (broadly) estimated with Dirichlet distributions in the future based on numbers of teeth involved in the various studies. Costs were not varied in the PSA as the distribution of UDA values was not characterised. This could be explored in the future, though again is unlikely to have much impact as the average value used was robust.

Any subsequent iterations of the Dutch study (Laske *et al.*, 2019a) would be useful to assess the parameterisation of the APs. This may be useful in the future to inform parameterisation of the NHS-based model, if composite is more universally adopted in English primary care, but the current differences in healthcare systems and restoration provision limits the justification of using TPs derived from this data. As previously shown in Chapter 4, primary care clinicians primarily working in the NHS are not regularly using direct composite for restoring posterior teeth, are not using them as recommended when doing so, and clinician reported negative post-operative outcomes were significantly related to low use of composite in UK GDP. The model might, fairly easily, be adapted to the Dutch setting however.

An expected value of information analysis could be performed, which determines the value of obtaining additional information before making a decision. The economic evaluation is clear cut here, and the outcome is unlikely to change with more data. However, the lack of data and therefore uncertainty around the magnitude of the relative longevity of restorations in English primary care may be important to decision makers, given the additional geo-political context which favours an amalgam phase-out.

A molar tooth, or an occlusal restoration could also be modelled. Collection of up to date, representative data from the English NHS setting, including from therapists and the CDS would be beneficial to inform this process.

6.10 Conclusion

When modelling costs and outcomes of different direct posterior restorations over a lifetime in English NHS primary care, amalgam was less costly to all stakeholders with better outcomes than composites for all outcomes modelled with very little uncertainty.

Chapter 7. Health economic evaluation: a cost-consequence analysis of direct posterior restorations

7.1 Introduction

CCAs were introduced in Chapter 3 alongside justifying their use for the current decision problem in Chapter 6. This chapter will describe a CCA comparing amalgam and composite restorations in an English NHS primary care setting.

The economic evaluation aimed to evaluate the comparative costs and consequences of using directly placed amalgam, conventional (hybrid) composite, bulk-fill paste composite and bulk-fill flowable composite to restore posterior permanent teeth in adults. The study was set in the English NHS taking an extended medical sector perspective with societal considerations as described in Chapter 6. The CEA presented in Chapter 6 is only part of the picture however, and this chapter presents a CCA which broadens the analysis.

7.2 Methods

The consequences of interest were developed from the literature review (Chapters 2 and 3), and the DCE described in Chapter 5. They were, clinical outcomes of initial restoration survival, time until direct restorations were no longer possible, tooth survival and post-operative complications; treatment time for each restoration and over a lifetime, number of treatment visits over a lifetime, and the public/patient valuation of each initial direct restoration including itemisation of the relevant characteristics. The data used to value each outcome were drawn from the previous four chapters, alongside further information presented here on valuing patient preference outcomes. These outcomes for amalgam and composite restorations will be presented in a single table which shows the differences.

7.2.1 Valuing patient preference outcomes

Quantifying patient preferences for amalgam and composite restorations using mWTP values obtained from the DCE described in Chapter 5 was performed by ascribing levels for each attribute from the DCE to each restoration type. There was deemed to be insufficient data on the levels of attributes for restorations placed by therapists, so it was performed only for dentists. Estimates on restoration treatment times were obtained from Chapter 4 data, longevity from the model in Chapter 6, and the restoration colour was ascribed as white for composite and silvery-grey for amalgam. No data was available to value post-operative complications or waiting time for the differing restorations. Expert opinion was therefore sought from the research team and NHS practice owners by email, the content of which is shown in Appendix F1. This data on post-operative complications is presented in Appendix F2.1 Table. Averages alongside mWTP valuations based on Chapter 5 data for the population, and those of low and higher income (with 95% CIs) are presented in Table 7.1. Similar data on waiting times are presented in Table 7.2. The mWTP data is presented in the CCA later.

7.2.2 Extended costing approach

As the data is presented in a disaggregated form in a CCA, a variety of costing approaches can be used beyond the direct costs to the patient and funder obtained from the model in the previous chapter. These include indirect patient costs, NHS dental practice costs, the cost to the practice of using recommended techniques for composite restorations over the most common approach and consumable costs. These costs for amalgam and composite restorations will be presented in a single table which shows the differences.

7.2.3 Indirect patient costs

The model provided estimates for treatment time for the different restorations (and a marginal difference of the different bulk-fill materials compared to conventional composites) over a lifetime. This data was used to estimate the indirect costs and marginal indirect costs of the differing restorations to patients associated with treatment time. This was performed by multiplying the UK mean pay per minute by the overall or marginal treatment time (Ternent *et al.*, 2022). The UK mean hourly pay for full time workers in 2023 was £20.83 (ONS, 2023a) which is equivalent to £0.35 (to nearest pence) per minute.

7.2.4 NHS dental practice costs

The treatment time can also be used to calculate the costs to an NHS dental practice per dentist by using a top-down costing approach. The unit cost data for dentists (which takes into account all costs to a practice) is multiplied by the treatment time as previously described. The relevant cost document provides different cost estimates for practice owners and associates (£150/hour and £108/hour respectively) (Jones *et al.*, 2023). The numbers of each worker in the 2022/23 NHS dental workforce was 4604 and 19512 respectively which equates to 19.1% and 80.9% (NHS England, 2023). Weighting the costs based on this proportion provides an average cost/minute of delivering a dental service of £1.93 ([(0.191 x 150) + (0.809 x 108)]/60).

7.2.5 Using recommended techniques costs

Recommended techniques for placing composite as described in Chapter 2, which were not commonly performed by UK clinicians (especially NHS practitioners) as shown in Chapter 3, included the use of RD, sectional matrices, wedges and no liner. Commonly using these recommended techniques was shown to take more time in Chapter 4. Adding these differences for each technique provides the total extra time required to use the recommended techniques for 2- and 3-surface restorations as shown in Table 7.3. It is inappropriate to extrapolate the differences for extra time and costs when using recommended composite techniques, as they would likely result in superior clinical outcomes, and the model does not change to reflect this. The clinical data required to re-parameterise the model to reflect this difference is not available.

Post-operative complications	Amalgam				Composite			
	Proportional incidence§	mWTP * proportion (£) (95% CIs)			Proportional incidence§	mWTP * proportion (£) (95% CIs)		
		General population	Low-income	Higher-income		General population	Low-income	Higher-income
None	0.76	35 (30 - 41)	26 (17 - 36)	37 (30 - 44)	0.58	27 (23 - 31)	20 (13 - 28)	28 (23 - 34)
Mild	0.16	7 (6 - 8)	5 (4 - 7)	8 (6 - 9)	0.25	11 (9 - 13)	9 (6 - 11)	12 (10 - 14)
Moderate	0.06	-1 (-2 - -1)	-1 (-1 - 0)	-1 (-2 - -1)	0.12	-2 (-3 - -2)	-2 (-3 - -1)	-3 (-3 - -2)
Persistent	0.03	-2 (-2 - -2)	-2 (-2 - -1)	-2 (-3 - -2)	0.06	-4 (-5 - -4)	-3 (-4 - -2)	-4 (-5 - -4)
Average	N/A	39 (32 - 46)	29 (17 - 42)	41 (32 - 51)	N/A	31 (24 - 38)	24 (12 - 36)	33 (24 - 42)

Table 7.1. Post-operative complication marginal willingness to pay for different restoration materials in NHS primary care relating to discrete choice experiment levels based on expert opinion

mWTP * proportion, marginal willingness to pay of value for each complication level multiplied by the proportional incidence for each restoration; §unrounded values used to calculate mWTP; 95% CIs, 95% confidence intervals; mWTP values given to nearest integer.

Expert	Waiting time (weeks)							
	Amalgam				Composite			
	Weeks	mWTP (£) (95% CIs)			Weeks	mWTP (£) (95% CIs)		
		General population	Low-income	Higher-income		General population	Low-income	Higher-income
1	4	3 (-8 - 14)	-4 (-20 - 13)	4 (-10 - 18)	4	3 (-8 - 14)	-4 (-20 - 13)	4 (-10 - 18)
2	2	19 (9 - 30)	23 (6 - 39)	18 (4 - 32)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
3	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
4	4	3 (-8 - 14)	-4 (-20 - 13)	4 (-10 - 18)	4	3 (-8 - 14)	-4 (-20 - 13)	4 (-10 - 18)
5	4	3 (-8 - 14)	-4 (-20 - 13)	4 (-10 - 18)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
6	2	19 (9 - 30)	23 (6 - 39)	18 (4 - 32)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
7	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
8	2	19 (9 - 30)	23 (6 - 39)	18 (4 - 32)	6	-20 (-32 - -8)	-17 (-35 - -1)	-21 (-37 - -6)
Average	4	3 (-8 - 15)	3 (-14 - 19)	3 (-12 - 18)	6	-14 (-26 - -3)	-14 (-31 - 3)	-15 (-30 - 0)

Table 7.2. Expert opinion on waiting times converted to marginal willingness to pay values for different restoration materials in NHS primary care relating to discrete choice experiment levels

95% CIs, 95% confidence intervals; mWTP, marginal willingness to pay; unrounded mWTP values used; results given to nearest integer.

Recommended technique (High use)	Extra time taken (minutes) (95% confidence interval)	
	2-surface composite	3-surface composite
Rubber dam	5 (2 - 9)	8 (4 - 12)
Sectional matrix	3 (0 - 6)	4 (0 - 8)
Wedge	2 (0 - 3)	2 (0 - 3)
No liner	1 (-1 - 2)	1 (-1 - 3)
All (total)	10 (1 - 20)	15 (3 - 26)

Table 7.3. Extra time taken for composite restorations using recommended techniques frequently versus not

Results presented to nearest minute.

7.2.6 Consumable costs

The costs of consumables used per restoration type to the clinician or practice were taken from the Henry Schein (a supplier and distributor of dental materials and equipment) website (www.henryschein.co.uk) accessed August 2023. For each consumable product used in each restoration at least three alternatives were recorded (where available) with their prices. Mean average costs were calculated (except when costing own brand/cheapest alternatives). Minimum and maximum costs of each consumable product were also recorded (aside from own brand/cheapest alternative restorations). The mean, minimum and maximum disposable material costs were then calculated for each restoration type and VAT added (itemised costs/restoration are shown in Appendix F2.2-F2.8 Tables, which include disposal costs for amalgam). Costs for recommended composite restorations included the use of RD, sectional matrices and no liner, and did not include unbranded restorative materials, whereas an average conventional composite involved the use of a setting calcium hydroxide liner, cotton wool rolls, a saliva ejector and a Tofflemire matrix band (which was determined by the most common use of equipment and materials when providing composite restorations by UK primary care clinicians in Chapter 4) and branded and unbranded restorative materials. A summary of these costs per restoration is shown in Table 7.4.

Material	Cost/restoration (with 20% VAT) (£)		
	Mean	Minimum	Maximum
Amalgam	5	3	6
Basic (own brand) conventional composite	7*	-	-
Average conventional composite	12	7	17
Recommended conventional composite	21	17	27
Basic (own brand) bulk-fill flowable composite	11*	-	-
Recommended bulk-fill flowable composite	22	18	27
Recommended bulk-fill paste composite	16	12	21

Table 7.4. Consumable costs for each restoration type

VAT, value added tax; *lowest cost.

7.2.7 Non-consumable costs

It was assumed that non-consumable costs of providing each restoration are similar for each material. This relates to amalgam triturators, amalgam separators, Tofflemire matrix retainers, amalgam carriers and wells for amalgam; and light curing units, air-borne particle abrasion units, composite heaters, ultrasonic cavity preparation tips, composite finishing burs and discs, composite application gun, RD and Tofflemire matrix retainers or sectional matrix kits as appropriate for composite. It is likely that the non-consumable costs are slightly higher for composite. Composite restorations also require more regular replacement so the equipment is therefore used relatively more regularly, including handpieces and equipment for maintenance of these for example. Given the long lifespan of these items in general, it is likely that the differences are negligible however. Extended patient/provider safety costs and cremation and environmental costs were not newly estimated in this thesis, but discussions and estimates from the work of others were described in sections 2.11 and 3.8 and these were used to inform the CCA.

7.3 Results

Table 7.5 and Table 7.6 summarise the consequences and costs of amalgam and the alternatives. Table 7.7 summarises the differences between composite restoration techniques and materials.

Outcomes			Amalgam	Composite	Difference[#]
Clinical	Restoration survival[D] (years)		11	7	-4
Clinical	Restoration survival[ND] (years)		17	9	-9
Clinical	Tooth survival[D] (years)		21	17	-4
Clinical	Tooth survival[ND] (years)		44	32	-12
Clinical	Time until direct restorations were no longer possible[D] (years)		18	12	-6
Clinical	Time until direct restorations were no longer possible[ND] (years)		35	18	-17
Clinical	Post-operative complications (%)[§]	None	76	58	Greater risk with composite. Higher for NHS dentists and therapists
Clinical	Post-operative complications (%)[§]	Mild	16	25	
Clinical	Post-operative complications (%)[§]	Moderate	6	12	
Clinical	Post-operative complications (%)[§]	Persistent	3	6	
Treatment time (minutes)	2 surface restoration		24	34	10
Treatment time (minutes)	Lifetime[D]		64	107	43
Treatment time (minutes)	Lifetime[ND]		110	156	46
Treatment visits	2 surface restoration		1	1	0
Treatment visits	Lifetime[D]		3	4	1
Treatment visits	Lifetime[ND]		4	5	1
Patient / public valuation (mWTP) (£) (95% CIs)	General population	Waiting time[§]	3 (-8 - 15)	-14 (-26 - -3)	-18 (-18 - -17)
	General population	Clinician type	7 (4 – 9)	7 (4 – 9)	0 (0 – 0)
	General population	Colour	-21 (-25 - -17)	21 (17 – 25)	42 (42 – 42)
	General population	Treatment time	-7 (-10 - -4)	-9 (-14 - -5)	-3 (-4 - -1.5)
	General population	Post-operative complications[§]	39 (32 - 46)	31 (24 - 38)	-8 (-8 - -8)
	General population	Lifespan	93 (77 – 109)	47 (39 – 55)	-47 (-38 - -55)
	General population	**Total**	115 (71 – 159)	82 (44 – 120)	-33 (-27 - -40)
	Low income	Waiting time[§]	3 (-14 - 19)	-14 (-31 - 3)	-17 (-17 - -17)
	Low income	Clinician type	5 (1 – 9)	5 (1 – 9)	0 (0 – 0)
	Low income	Colour	-9 (-15 - -3)	9 (3 – 15)	18 (18 – 18)
	Low income	Treatment time	-8 (-13 - -2)	-11 (-18 - -4)	-3 (-5 - -1)
	Low income	Post-operative complications[§]	29 (17 - 42)	24 (12 – 36)	-6 (-5 - -6)
	Low income	Lifespan	53 (29 – 78)	27 (14 – 39)	-27 (-14 - -39)
	Low income	**Total**	74 (5 – 142)	40 (-19 – 97)	-34 (-24 - -45)
	Higher income	Waiting time[§]	3 (-12 - 18)	-15 (-30 – 0)	-18 (-19 - -17)
	Higher income	Clinician type	7 (4 – 11)	7 (4 – 11)	0 (0 – 0)
	Higher income	Colour	-25 (-30 - -20)	25 (20 – 30)	50 (50 – 50)
	Higher income	Treatment time	-6 (-10 - -2)	-8 (-14 - -3)	-2 (-4 - -1)
	Higher income	Post-operative complications[§]	41 (32 – 51)	33 (24 – 42)	-8 (-8 - -8)
	Higher income	Lifespan	109 (87 – 131)	54 (43 – 66)	-54 (-43 - -65)
	Higher income	**Total**	129 (71 – 188)	97 (47 – 146)	-33 (-24 - -42)

Table 7.5. Outcome differences between amalgam and composite direct posterior restorations

mWTP, marginal willingness to pay; [#]composite – amalgam using unrounded values; *vs conventional composite; [D]3.5% discounted; [ND]no discounting; [§]Estimates derived from experts; CIs, confidence intervals. All values rounded to nearest integer (unrounded values used in calculations). Unless specifically stated, 95% CIs and prediction intervals show very little variation for all parameters modelled and they are therefore not presented in this table.

Costs (£)			Amalgam	Composite	Difference
2-surface restoration	Funder (NHS)	Average patient⁺	24	24	0
		Paying patient	14	14	0
		Exempt patient	59	59	0
	Patient	Direct*	45	45	0
		Indirect	8	12	4
	Dental practice	Overall practice§	46	66	20
		Consumables	5^	12±	7
Over lifetime (3.5% discounting)	Funder (NHS)	Average patient⁺	81	115	34
		Paying patient	43	60	17
		Exempt patient	201	290	89
	Patient	Direct*	158	228	70
		Indirect	22	37	15
	Dental practice	Overall§	124	207	83
		Laboratory	11	18	8
Environmental impact#			Low	Uncertain	Uncertain
Patient / provider safety#			Low	Low, uncertain	Minor, uncertain

Table 7.6. Cost differences between amalgam and composite direct posterior restorations
NHS, National Health Service; *Paying patients only; #Not investigated in this PhD; §Based on Unit Costs of Health and Social care (Jones et al., 2022) with proportion of owners (providing-performers) 19.1% and associates (performer-only) 80.9% (NHS England, 2023); ±Minimum composite cost = £7, large increase in costs when using branded composite materials; ^Minimum amalgam cost = £3, includes waste disposal fees; ⁺Based on exempt 23.6% : payer 76.4% adult courses of treatment (NHS England, 2023) (example calculation for average NHS cost band 2a = [17.26 x 0.764] + [87.96 x 0.236] = £20.76). All values rounded to nearest pound (unrounded values used in calculations). 95% confidence intervals and prediction intervals show very little variation for all parameters modelled and they are therefore not presented in this table.

Composite technique / material	Extra time (minutes) (95% CIs)		Extra cost (£) (95% CIs)				
			Patient indirect		Dentist consumables	Dental practice overall§	
	Per 2s restoration	Lifetime D	Per 2s restoration	Lifetime D	Per 2s restoration	Per 2s restoration	Lifetime D
Recommended techniques vs not	10 (1 – 20)	*	3	*	10	20 (2 – 39)	*
Conventional vs bulk-fill flowable	2	3	1	1	0# -4±	3	6
Conventional vs bulk-fill paste	2	4	1	1	6# ^	5	8

Table 7.7. Composite restoration time and cost differences with recommended techniques or bulk-fill materials
2s, 2 surface. D3.5% discounted *Inappropriate to extrapolate additional time and costs over a lifetime when using recommended techniques with the current model given the likely improved outcomes; §Based on Unit Costs of Health and Social care (Jones et al., 2022) with proportion of owners (providing-performers) 19.1% and associates (performer-only) 80.9% (NHS England, 2023); #Recommended technique and branded material restorations; ±Basic (own brand) materials; ^No basic bulk-fill paste composite available; All values rounded to nearest integer (unrounded values used in calculations). CIs, confidence intervals. Unless specifically stated, 95% CIs and prediction intervals show very little variation for all parameters modelled and they are therefore not presented in this table.

The UK public valued amalgam more highly than composite restorations based on the public valuation of different aspects of restorations obtained in Chapter 5 and the levels attributed to the different restorations when parameterised based on the data presented (including expert opinion). The additional monetary valuation of amalgam over composite restorations by low- and higher-income groups and the general population were within a pound (£33-34). However, in terms of relative valuation, the low-income group valued amalgam 1.9 times more than composite restorations, which was higher than the higher-income group (1.3) and the general population (1.4).

There was a small difference between public valuation of conventional and bulk-fill composites in relation to the small treatment time differences. They were all less than a pound (for both bulk-fill composite types and income groups), so further details were not displayed.

7.4 Discussion

7.4.1 Outcomes and costs

This CCA comparing direct restorations of composite and amalgam draws on the previous chapters to summarise the differences. It can be seen that, except for the appearance of the restorations, where composite is valued more than amalgam by the public, all other outcomes and costs measured favour the use of amalgam for patients, funders and clinicians. The average cost differences over a lifetime were much higher for composite compared to amalgam for all stakeholders, but were higher for the patient compared to the funder, which were higher still for the dental practice or clinician.

Given that the remuneration for all direct restorations is the same in the English NHS, but composite incurs higher consumable, time, clinician and practice costs, the system essentially disincentivises their use. The data on material use by clinician type from Chapter 4 bears this out. It also disincentivises the use of recommended techniques for composite restorations which incur much higher consumable and time costs. For example, it takes 10 minutes longer to place a composite restoration using recommended techniques, which equates to extra overall dental practice running costs of £20 based on generic average time costs. This likely underestimates the true difference in costs as the extra consumable costs are £10. This does not include the higher non-consumable costs, or the use of expensive equipment for other recommended techniques such as air-borne particle abrasion, for example. There is then the issue of how to quantify and value how the increased time taken to treat the same disease impacts on the broader provision of dental care and patients' access to care, but this is potentially also impacted by other considerations such as the workforce and budget for example.

We do not have data comparing the survival outcome of composite restorations performed with or without recommended techniques however. Other comparative outcome data relating to the use or not of recommended techniques, other than self-reported post-operative complications from Chapter 4, with their many potential described biases, do not exist. It is therefore hard to justify using the current model based on NHS data to explore long-term outcomes when using recommended techniques for important reasons. These include that the TPs and APs may be different. Patients seeking private treatment also likely differ considerably from those accessing NHS care in important ways, and clinicians providing dental treatment likely differ considerably from those providing primarily NHS services. The economic implications of the varying approaches are therefore currently unknown.

7.4.2 Comparison with previous Canadian cost-consequence analysis

The direction of findings in this study are the same as the CADTH CCA (Khangura *et al.*, 2018). This study includes broader consequences and a more sophisticated model to estimate lifetime outcomes for more consequences. The magnitude of some of the differences vary however.

In the CADTH base-case scenario, teeth were not extracted, restorations were simply replaced with the same sized restoration with the same risk of failure for each restoration of each material as previously discussed. This seems an excessive simplification, making the data obtained questionable. The outcome measured was the lifetime number of replacements, and the high numbers stated over a lifetime therefore lack face validity.

Costs are therefore based on this problematic model with different outcomes, and composite restorations are more expensive from the patient perspective taken in the CADTH study, which is not the case in the present study.

The CADTH also uses a lower discount rate (1.5%) than that recommended by NICE (3.5%). This also obviously impacts the comparability of the results. Undiscounted values are available which can be compared to a degree, but the model and outcomes were very different making comparisons difficult.

The present study also estimates public valuation differences between the restorations (in monetary terms based on Chapter 4 data), which the CADTH study could not, as it failed to find any suitable studies and did not undertake any primary data collection.

Additionally, the present study calculates costs from more perspectives, not just that of the patient, whilst also showing the limitations of CADTH's approach in only calculating marginal patient indirect costs per restoration, assuming that travel and waiting time was the same for each restoration. Whilst this assumption is reasonable, it does not account for the increased number of visits required for composite over a lifetime as shown in the present study and therefore underestimates the difference. It also does not account for potentially increased direct transport costs (similar to the present study). CADTH also estimated treatment time differences based on expert opinion, ignoring data. The data from Chapter 4 and other presented data suggests that the expert opinion underestimated the treatment time differences quite considerably compared to multiple data sources and therefore also the marginal indirect costs. The treatment time differences were not modelled over a lifetime in the CADTH study, which again underestimates the indirect costs to patients when composite is used, as was demonstrated in this study.

The CADTH study did however estimate the mercury waste management costs which this study did not. It did not attempt to estimate the environmental costs of composite restorations however.

7.4.3 Extended differences not accounted for in the cost-consequence analysis

There are a number of differences between the materials not accounted for in this CCA, the vast majority of which tend to underestimate the difference between amalgam and composite in terms of both costs and outcomes.

Broad, overall costs to a dental practice were calculated, but the consumable costs over a lifetime were not calculated, which would be higher for composite given the increased unit cost and need for replacement, alongside the increased amount of relatively more complex, more expensive treatment required. Further work could quantify these costs.

The use of untested own brand bonding agents and composite materials in NHS primary care is unknown, but likely significant given the cost savings that can be made. The extent of their use and efficacy is an area to investigate in the future.

Indirect and direct costs to patients of travelling to and from appointments to receive restorations were not calculated. Composite restorations resulted in increased numbers of visits compared to amalgam, which would incur higher indirect costs, and also direct travel and potential parking costs for example. This suggests that costs are underestimated for composite compared to amalgam.

Time to remove a failed composite restoration is generally greater than that required to remove a failed amalgam. This was not accounted for in the timings for reintervention restorations, so again, the time taken to restore and therefore the indirect costs to patients and clinician costs, including opportunity cost of time are likely to be higher than recorded for composite.

There will be inevitable upfront costs for phasing-in alternatives relating to implementation and administration, alongside costs for dental education which have not been considered (Schwendicke *et al.*, 2018b), but will inevitably increase the differential costs for composite compared to amalgam.

Emergency costs were not generally considered, but they are likely to be higher for composite given the increased number of visits, interventions and self-medication (for example analgesics for post-operative pain).

The CCA does not capture the likely increased need for extraction of teeth restored with composite. Where isolation cannot be achieved, some teeth will be deemed unrestorable without amalgam which is much more tolerant of contamination during the procedure. This may also lead to the need for more expensive indirect restorations and earlier intervention with them. All of this will likely disproportionately affect those with higher need in society.

Increasing the use of clinician time to treat the same disease in society can potentially reduce access to treatment. The impact of this also depends on budget constraints, disease prevalence and the available workforce however. Quantifying these elements is difficult.

7.5 Limitations

The public valuation of restorations relies on expert opinion to parameterise the levels of two attributes of the different restorations. Micro-costing approaches might provide more detailed costings. The consumable costs are only provided for the initial restoration, and could be extended to all interventions in the model to gain a better understanding of the total consumable costs over a lifetime. Estimates for specific non-consumable costs are not estimated. The datasets used to provide the estimates in the CCA have limitations as discussed in each of the three preceding chapters.

As has been discussed, discounting is arbitrarily applied, usually at the same rate year-on-year, with different bodies asking for different discount rates with little justification (NICE, 2024; Canada's Drug Agency, 2017). It has non-intuitive effects on costs and outcomes, when compared to non-discounted outcomes, which can be hard to interpret, as shown in the results tables. It can also make the face validity of a model questionable to experts or decision makers with limited knowledge of HEE processes. Presenting the non-discounted results can help with this.

A common limitation of economic evaluations, including this one, is that they cannot answer the questions of whether the suppliers will provide the intervention, if there are sufficient providers to supply it, or if there are sufficient resources to implement it. Discrete event simulation can help to answer these questions, but requires additional data on population need, the available workforce, proposed remuneration and budget, all of which are difficult to know as they are constantly in flux.

7.6 Conclusion

This CCA, which took an extended English NHS medical sector perspective with societal considerations, showed that, except for appearance, all other outcomes and costs favoured the use of amalgam over composites for the direct restoration of posterior teeth for all stakeholders.

Chapter 8. General discussion

8.1 Introduction

This thesis aimed to explore the relative costs and benefits of the directly placed alternatives to posterior amalgam restorations within the UK (primarily NHS) primary care setting. It also aimed to inform policy on direct posterior restoration provision in response to the new regulations on amalgam which mandate the exploration of a phase-out by 2030. This final chapter will summarise and bring together the findings of the previous chapters before providing a broad overall summary.

The objectives are re-stated below and key findings relating to each presented.

8.2 Objectives and key findings

8.2.1 Phase One

a) Identify and quantify current techniques, material use, and reported incidence of postoperative complications by UK dentists and therapists for placement of different direct posterior restorations.

Amalgam was the most used material for restoration of molar teeth, whereas composite was for premolars. Appointment times booked were consistently higher to place composite compared with amalgam restorations. Post-operative complications were much more frequently reported when using composite compared to amalgam. Use of recommended techniques for the placement of composite was low.

b) Determine primary care clinicians' knowledge of newly imposed restrictions, opinions on the phase-down and potential phase-out (including confidence in placement of the available direct posterior restorative materials in various situations), and educational experience related to posterior composites.

Knowledge of amalgam restrictions was limited, and a majority of practitioners had broad concerns regarding the phase-out of amalgam. A majority had attended postgraduate courses on the placement of composite, but this did not translate to confidence when using composite in difficult situations, which was in marked contrast to amalgam.

c) Identify and quantify differences between subgroups, including those based on clinician type (dentists working primarily in private or NHS practice, or dental therapists for example) and years qualified. (this has been discussed in the relevant sections).

Amalgam was the most used material for restoration of all posterior teeth provided under NHS services, whereas composite was under private provision. Composite use increased as clinicians' number of years qualified increased. Use of recommended techniques for the placement of composite restorations were especially low in primarily NHS practitioners, and still low but significantly higher in private practitioners. Dental therapists reported higher levels of post-operative sensitivity for both amalgam and composite than other groups, with private practitioners reporting the lowest levels.

8.2.2 Phase Two

a) Quantify the preferences of the UK population for differing levels of direct posterior restoration attributes in terms of mWTP.

A representative sample of the UK population were willing to pay, on average, £42 more for a white compared to a silvery-grey restoration, £117 more to experience no post-operative pain compared with persistent pain, £49 more for their restoration to survive 14-years compared to 5-years, £40 more to reduce a 6-week wait to 2-weeks, £16 more to reduce an 80-minute appointment to 20-minutes and £14 more to have treatment by a dentist rather than a therapist.

b) Quantify the relative attribute importance.

Cost was the most important attribute for the general public when selecting a posterior dental restoration, being twice as important as the next most important attribute which was likely discomfort after the filling. Discomfort in turn was more than twice as important as average lifespan, with colour and waiting time next most important, but these three attributes were not statistically significantly different from each other. Treatment time and clinician type, which again were not statistically significantly different from one another, were the least important attributes.

c) Quantify any differences based on income subgroups.

On average, higher-income respondents value restoration longevity more than double and a white restoration almost three times more than those with low-income. Higher income respondents were, on average, willing to pay more to have treatment by a dentist rather than a therapist, to avoid post-operative discomfort and to avoid a 6-week wait for a filling, though these differences were not statistically significant.

On average, low-income respondents valued shorter treatment times, were willing to pay a third more per minute of treatment avoided, had a higher mean WTP for a 2-week wait for a filling alongside lower mean WTP values for 0- or 4-week waits than higher income respondents, though these differences were not statistically significant.

When analysed by income groups RAI changed, resulting in different ordering in the importance of lifespan, colour, waiting time, treatment time and clinician, but with only colour statistically significantly different between groups.

8.2.3 Phase Three

a) Quantify the relative costs and consequences of amalgam versus composite direct posterior restorations in adult permanent teeth in the English NHS primary dental care setting over the short and longer term.

Direct costs for composite and amalgam restorations were the same to patients and funders for the restorations, but composite direct costs were markedly higher for clinicians (including practice running costs and consumables). Time costs to clinicians, in terms of impacting on how much disease could be treated over a lifetime, were higher in the short- and long-term for composite compared to amalgam. In the long-term, composite costs (including laboratory costs to clinicians) were higher for all stakeholders, but relatively higher for clinicians and patients than funders. Indirect patient costs were greater for composite in the short- and longer-term. Consumable costs and time-based practice running costs for composite restorations were higher when using recommended techniques compared with the most commonly used techniques (as identified in Chapter 4). There were minor marginal time savings when using bulk-fill composites compared to conventional composites, resulting in reduced practice and indirect patient costs.

Initial restoration survival, time until direct restorations were no longer possible, tooth survival, post-operative complications and the public/patient valuation of each initial direct restoration were all superior for amalgam compared to composite. Though the public/patient marginal valuation of composite and amalgam restorations were very similar between income groups, the relative valuation of amalgam was much higher in low-income groups.

8.3 Application of findings to the NHS Dental Services

The NHS primary dental care service is structured similarly in Wales to England, and the model was based on English and Welsh data, so the findings can likely be applied to the Welsh NHS Dental Service. The Welsh service will however increasingly diverge from next year (BDA, 2024b). Chapters 4 and 5 took a UK perspective, which gave them broader scope as individual pieces of research, but made the project as a whole slightly less coherent, as the final phase had to take a narrower perspective due to the differences in provision of NHS Dental Services between the devolved nations.

In England 2022-23 there were 4.3 million band 2 courses of treatment with 'permanent' fillings recorded in adults, out of a total of 5.1 million courses of treatment with 'permanent' fillings recorded (NHS England, 2023). This obviously does not specify whether the restorations were anterior, posterior or both, or the number of restorations placed, which is very limiting when trying to apply the findings of the research to existing English NHS Dental Services.

Recent NHS dental service changes have resulted in increased remuneration for premolar (and molar) RoCT, without the patient paying an increased fee. This might therefore be expected to result in a reduction in the proportion of teeth extracted in the shorter term, with an increased provision of RoCT. However, the data used to build the model may not reflect current practicing arrangements, given that large changes in prescription occurred following the implementation of the 2006 contract (Tickle *et al.*, 2011), and the model is built on pre-2006 data. The deterministic analysis increasing the proportion of teeth receiving RoCT more closely reflects the allocation probabilities estimated from the short-term Dutch data as previously described. Similarly, composite can now be used for posterior load-bearing cavities (though it likely commonly is not, as shown in Chapter 4), whereas it could not pre-2006, which may impact outcome data.

8.4 The clinician perspective

The vast majority of new UK graduates move from a university environment where they predominantly use composite, into a foundational training year under NHS provision where they commonly favour and place more amalgams based on this research and other work (Aggarwal *et al.*, 2019; Jebur *et al.*, 2023). Most UK dentists were primarily NHS practitioners in the first 5-years following qualification and composite use increased as clinicians' number of years qualified increased, which is an opposite trend to that seen in Australia, for example, where private practice predominates (Alexander *et al.*, 2016).

Amongst UK primary care clinicians, the best predictor for low reported post-operative issues when placing composite restorations, was when the majority of their total posterior restorations placed were composites. Other predictors were not using liners and using sectional matrices (recommended techniques which were not commonly used, especially by NHS dentists). Primarily using composite was also predictive of confidence when placing sub-gingival composites alongside those commonly using RD and being a predominantly private dentist, for example. The current NHS system, with its lack of incentivisation for using composite, which takes longer and costs more for the clinician, essentially incentivises the use of amalgam. It is therefore not conducive to producing dentists who can confidently and predictably use composite posteriorly. This is likely because they are not using it regularly and are therefore not improving technically, whilst also having limited incentives to improve.

Though a large majority of clinicians had attended post-graduate education on posterior composites, a large majority also lacked confidence in placing it in difficult situations. There was also a perceived lack of consensus on material choices and techniques used to place them. This suggests that the educational courses are not meeting the needs of clinicians. The vast majority of primary care clinicians have to pay for CPD. Though the NHS often provide subsidised courses on direct posterior composite restorations in different regions, they still usually carry a fee to attend. Many private CPD courses are available, which are often expensive thus favouring or aimed at the majority private practitioner or those wishing to increase private provision. This expense could be a further barrier to effective education and upskilling of predominantly NHS practitioners.

Failure to consider or value clinician perspectives in HEEs risks patient access issues. This can result from clinicians leaving the health service, or due to the increased time demands from the implementation of an alternative treatment with a limited workforce.

Incentives matter, so dentists are likely leaving the NHS in record numbers due to remuneration issues, but also a loss of trust in the NHS after the implementation of the 2006 contract in England and Wales (Mcdonald *et al.*, 2012). This has already created an access problem for patients as previously described. Composite takes longer to place, longer to replace, and requires more frequent replacement than amalgam, resulting in large increases in treatment time over a lifetime. The restorative process required to predictably place a composite restoration is much more complex than that of an amalgam, with many more opportunities for problems to arise which can result in early failure or an increased frequency of post-operative complications. Composite material costs (and equipment costs when using recommended techniques) are also currently much higher for clinicians, with no increase in remuneration in the English NHS. Relative amalgam costs may change following the EU amalgam phase-out which has recently been brought forward to 2025 however (*Regulation (EU) 2024/1849*, 2024). A large majority of UK primary care clinicians reported that an amalgam phase-out would impact on their ability to do their job, create appointment delays and lead to the need for more indirect restorations and extractions. An amalgam phase-out would therefore exacerbate the current access issues.

Dental therapists are an increasing part of the NHS workforce. Practice costs for a therapist have not been published. They are likely lower than for associate dentists. The proportion of primary care treatment provided by therapists is unknown as they commonly work under a course of treatment ascribed to a dentist who claims the UDAs. The therapist will then be remunerated at the practice level based on personally agreed terms, none of which the funder will be privy to. Direct access of patients to therapists, rather than requiring referral from dentists, was introduced in 2013 based on the findings of a review (Turner, Tripathee and MacGillivray, 2012), with further amendments proposed in 2024 to permit the supply of a limited number of prescription only medicines under exemption (UK Draft Statutory Instruments, 2024). This was an attempt to reduce costs and improve access to dental services. The use of direct access in primary care is uncertain however. Though therapist numbers are increasing, anecdotally many therapists do not perform restorations and provide services akin to those which are within the scope of a dental hygienist. This, alongside the issues around education could account for the high levels of post-operative sensitivity following both composite and amalgam restorations reported by therapists. There is however no clinical data on restoration outcomes specific to therapists in the UK.

Service provision is complex and uncertain, due to a varying skill mix, and immigration and emigration of the workforce both geographically and in relation to the NHS. A better understanding of these issues would be beneficial in planning education and service provision.

8.5 The patient perspective

Though there are aesthetic benefits to composite over amalgam restorations which the public highly value, the other restoration features, on average, outweigh this value, favouring the use of amalgam. This holds across different income groups. Though patients predictably valued treatment by a dentist more than they did a therapist, the amount was relatively small. Cost was by far the most important attribute to people when selecting a restoration, therefore raising the out-of-pocket costs to patients to offset costs to funders and clinicians may have negative consequences. Considering these values when designing or changing a dental healthcare system can be critical to optimising not only patient satisfaction, but also uptake of services (Ostermann *et al.*, 2017). Intervening at an appropriate time can prevent more advanced disease. This can avoid pain, morbidity, and higher treatment costs. The costs can be direct, out of pocket costs to the patient and funder, but can also be indirect, where affected individuals miss work which also affect employers and general societal productivity.

Traditional HEEs commonly only consider costs from a single perspective. For example, the costs to the patient of providing an NHS dental restoration are different from the clinician's or funder. The indirect costs for the patient of losing productive time due to having treatment performed and travelling to and from appointments, for example have only very occasionally been accounted for in evaluating restorations and partially so as previously discussed. This thesis has shown that direct and indirect costs are higher for composite than amalgam and different between stakeholders, with clinicians and patients standing to lose more than the funder if amalgam is phased out.

8.5.1 Which patients will the phase-down and -out preferentially affect?

Phasing out amalgam risks preferentially impacting those with the most need in society, as shown in this thesis, but also other research (Aggarwal *et al.*, 2019). This includes low socio-economic status groups and those with disabilities, who are all at higher risk of caries (Schmalz *et al.*, 2024). Adequate control of the operative field to place composite may not be possible in the latter group. There is evidence of a shift in caries burden from children to adults, and with population growth and aging populations retaining more teeth there will be an increasing burden of caries to manage in older patients, many of whom have contributory comorbidities with or without cooperation issues (Kassebaum *et al.*, 2015). Amalgam performs better in high caries risk groups and is more forgiving where cooperation is limited as discussed.

In general, low-income groups value the appearance of restorations much less than higher income groups (the difference in their average willingness to pay for a white compared to a silvery/grey filling was nearly three times lower), whereas they were willing to pay more to limit the waiting and treatment time, and cost was relatively more important. All groups valued amalgam restorations more than composite, but the highest relative valuation was amongst low-income groups. Phasing out amalgam risks access issues from both the increased clinician time required to place composite and reintervene, and the potential loss of the workforce to private practice, alongside a likely increase in patient costs. This would not provide what low socio-economic groups value in direct restorations in the UK. It risks reducing treatment uptake, leading to more significant dental disease with increased morbidity and productivity loss, whilst widening already existing health inequalities (Steele *et al.*, 2015). There was a large increase in time until a direct restoration was no longer possible when amalgam was placed compared to composite, which is potentially important for tooth survival in people who cannot afford more expensive indirect restorations.

The current amalgam phase-down restricting the use of amalgam in certain groups is caveated to say, 'except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient' (*Regulation (EU) 2017/852*, 2017). Although this is a potential solution for difficult situations, anecdotally, primary care clinicians feel placing an amalgam in child or pregnant patients carries risk for them, to which many do not wish to be exposed. The strict wording of the caveat leads to uncertainty in the consent process, justification required and support provided by an indemnifier should a complaint arise, alongside fear of the regulator and legal repercussions, which make it much simpler and safer for clinicians to disregard the caveat and treat the regulation as an unmitigated ban. This undermines a shared decision-making process, which should be at the heart of clinical dentistry as promoted by the FDI (Schmalz *et al.*, 2024). It clearly affects patients, especially high caries risk children, in whom cooperation can be limited and there is clear evidence of clinical benefit for amalgam over composite.

8.6 Broader perspectives

Many of the broader costs associated with each material are not commonly considered when performing EEs, whilst others have been estimated. A Canadian HTA concluded that whilst the environmental impact of the release of mercury from amalgam was small, and amalgam separation, disposal and crematorium costs have been explored, the impact from composites was unknown (NCPA, 2012; Khangura *et al.*, 2018). Other reviews have reported that mercury pollution from amalgam is a concern however, including the Minamata Treaty (UNEP, 2013; Mulligan *et al.*, 2018). There are a number of potential environmental issues and therefore costs associated with composite restorations which should be characterised (Mulligan, Hatton and Martin, 2022).

8.7 The funder perspective

Posterior amalgam restored teeth cost less and survive longer than composite restored teeth over a lifetime. They also have demonstrated net benefits from the patient and clinician perspectives. The environmental risks associated with mercury from amalgam restorations are likely small. The environmental risks associated with composite have not been characterised. There is however geopolitical pressure to phase out amalgam. The funder must weight the various perspectives in coming to a decision.

The NHS purports to provide ‘any clinically necessary’ dental care (NHS, 2023b). This means different things to different parties, and it is not currently clear what can and cannot be provided under NHS provision, as demonstrated in a recent court case (Veal, 2023). The NHS is hugely underfunded relative to other European countries as described in section 2.12.3. Tickle noted in 2012 that there was a rapidly growing divide between resources and demand, with the need for substantial cost savings across the NHS (Tickle, 2012). Alternative solutions could include raising patient fees, as current and historical prices are also relatively very low, or limiting coverage by services provided or population groups. The low fees likely result in an anchoring effect however, whereby any increase in price is judged in relation to previous fees (Kahneman, 2011). Significant price increases would therefore likely be poorly received by the public, and risk uptake issues which brings negative potential sequelae as previously discussed.

8.8 Future goals

The minimal intervention (MI) philosophy is rational, and a cavity free future of perfect prevention rendering restoration unnecessary should be the ultimate goal. This would hugely reduce the impact of any restorative material phase-out. Prevention under the MI banner is the focus of the Department of Health and Social Care’s policy paper ‘National plan to phase down use of dental amalgam in England’ (DHSC, 2019). The MI philosophy is then expanded in a seemingly rational way, to favour the use of composite through focusing on its ability to adhere to tooth structure which allows more minimal tooth preparations. It is also tooth-coloured which is one element of a restoration that patients prefer. However, when these rational abstractions are made to face the empirical reality of current untreated caries prevalence, quality clinical data, HEEs, patient preference data, UK clinician reported data, and healthcare system constraints, all of which generally favour the use of amalgam, it does seem to fall apart somewhat. Wahl captured this well in his article titled, ‘The ugly facts on dental amalgam’ with a quote subtitle, ‘The great tragedy of science: the slaying of a beautiful hypothesis by an ugly fact’ (Wahl, 2012; Huxley, 1873).

Amalgam alternatives need to improve, and their environmental impact needs to be characterised. Under- and postgraduate composite education is not generally making clinicians confident when faced with difficult situations and needs to improve. Expert consensus on the use of techniques for restoring different cavity presentations with composite would be beneficial in guiding this due to an absence of relevant clinical data. Understanding how educational content can improve confidence would help, whilst also considering how it can be more effectively disseminated. This could include providing better access to high quality, affordable education. Quantifying the active workforce is very difficult due to funding arrangements, especially with respect to therapists. The current UDA system provides very limited data on restorations performed to plan future healthcare provision. It is also therefore difficult to interrogate these data in terms of identifying and tracking mean restoration longevity across the NHS primary dental care services. This includes potential differences in outcomes between clinician groups (dentists versus therapists, for example). The NHS dental service ideally needs to clearly define its goals. Following a consideration of its budgetary constraints, it could then design a service which allows effective monitoring of restoration provision and survival, and incentivises the achievement of these goals whilst minimising unintended consequences. Explicitly limiting the service, giving clinicians clear guidance on what can and cannot be provided under NHS dental services, whilst implementing modest price increases seems the obvious solution, but making changes is a political decision and carries political risk (Tickle, 2012).

There are benefits to eliminating amalgam from clinical dentistry, but there are also considerable costs, and being explicit as to what those currently are, is important in focussing our collective attention on ways to address the problems, and sustainably plan future healthcare provision.

8.9 Conclusions

The long-term oral health implications of an amalgam phase-out are complex to understand. However, amalgam is a simpler and quicker material to place and replace than composite, which is currently the main alternative. It is also highly cost-effective for all stakeholders, with clinicians and patients likely most impacted by a phase-out. It also has fewer post-operative complications in UK primary care, which is highly valued by the UK population. Composite restorations can be effective in difficult situations with extensive cavities, but they require high levels of technical skill and the use of expensive and time-consuming specialised equipment. These are not commonly being used in UK primary care, especially by NHS dentists, and confidence in using composite in difficult situations is generally low. NHS remuneration for clinicians is significantly lower than in the rest of Europe. The NHS system, by doing nothing to incentivise the use of composite, therefore essentially incentivises the use of amalgam borne out by the data presented. It also disincentivises the use of recommended expensive and time-consuming equipment for composite, potentially resulting in suboptimal restorations and is therefore likely contributing to a failure of dentists to upskill and be confident in providing posterior composite restorations safely. These factors, alongside a loss of trust, have led to dentists leaving the NHS, which has created access issues for patients. The most at need in society are disproportionately affected by this. An amalgam phase-out would very likely compound this issue, resulting in increased treatment time to manage the same disease over a lifetime. This would likely widen existing health inequalities whilst not providing restoration characteristics which the most affected patients value most. These issues must be urgently addressed to avert an oral health crisis in the UK if amalgam is imminently phased-out.

Appendices

Appendix A. Papers published from thesis

Vol. 7 • Issue 1 Amalgam Phase-Down Part 1

ORIGINAL REPORT: HEALTH SERVICES RESEARCH

Amalgam Phase-Down Part 1: UK-Based Posterior Restorative Material and Technique Use

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Abstract: ***Introduction:*** *A European Union amalgam phase-down has recently been implemented. Publicly funded health care predominates in the United Kingdom with the system favoring amalgam use. The current use of amalgam and its alternatives has not been fully investigated in the United Kingdom.*

Objectives: *The study aimed to identify direct posterior restorative techniques, material use, and reported postoperative complication incidence experienced by primary care clinicians and differences between clinician groups.*

Methods: *A cross-sectional survey was distributed to primary care clinicians through British dentist and therapist associations (11,092 invitations). The questionnaire sought information on current provision of direct posterior restorations and perceived issues with the different materials. Descriptive statistical and hypothesis testing was performed.*

Results: *Dentists' response rate was 14% and therapists' estimated minimum response rate was 6% (total N = 1,513). The most commonly used restorative material was amalgam in molar teeth and composite in premolars. When placing a direct posterior mesio-occluso-distal restoration, clinicians booked on average 45% more time and charged 45% more when placing composite compared to amalgam ($P < 0.0001$). The reported incidences of food packing and sensitivity following the placement of direct restorations were much higher with composite than amalgam ($P < 0.0001$). Widely recommended techniques, such as sectional metal matrix use for posterior composites, were associated with reduced food packing ($P < 0.0001$) but increased time booked ($P = 0.002$).*

Conclusion: *Amalgam use is currently high in the publicly funded sector of UK primary care. Composite is the most used alternative, but it takes longer to place and is more costly. Composite also has a higher reported incidence of postoperative complications than amalgam, but time-consuming techniques, such as sectional matrix use, can mitigate against food packing, but their use is low. Therefore, major changes in health service structure and funding and posterior composite education are required in the United Kingdom and other countries where amalgam use is prevalent, as the amalgam phase-down continues.*

Knowledge Transfer Statement: *This study presents data on the current provision of amalgam for posterior tooth restoration and its directly placed alternatives by primary care clinicians in the United Kingdom, where publicly funded health care with copayment provision predominates. The information is important to manage and plan the UK phase-down and proposed phase-out of amalgam and will be of interest to other, primarily developing countries where amalgam provision predominates in understanding some of the challenges faced.*

Keywords: caries treatment, health services research, restorative dentistry, restorative materials, composite materials, clinical outcomes

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A supplemental appendix to this article is available online.

Introduction

This is the first of 2 articles reporting a UK survey of primary care dentists and therapists investigating opinions, materials, and techniques used for direct posterior restoration provision. This article focuses on clinicians' use of restorative techniques and materials, as well as experience of postoperative complications.

A global treaty prescribed the phase-down of amalgam on environmental grounds (Minamata Convention on Mercury 2013). The European Parliament agreed to the Regulation on Mercury (Regulation [EU] 2017/852 2017), which stipulated a phase-down beginning in July 2018. The regulation also specifies that the feasibility of a phase-out of amalgam, preferably by 2030, should be investigated.

Lynch and Wilson (2013) suggested the only viable directly placed alternative to amalgam, in the time frame specified for the amalgam phase-down, is composite resin (Lynch and Wilson 2013), although other options exist (Kielbassa et al. 2016), which include glass ionomer cements (GICs), or resin-modified GICs. There are a wide variety of composite materials with differing properties, and they can be placed with a variety of different techniques (Rosatto et al. 2015).

Evidence exists on posterior restorative material provision from around the world (Sunnegardh-Gronberg et al. 2009; Eklund 2010; Alexander et al. 2016), but health care provision generally differs from the primarily publicly funded health care with copayments for many (National Health Service [NHS]) provided in the United Kingdom.

Two surveys of material use for direct posterior restorations by general dentists (GDs) have recently been carried out in the United Kingdom. One survey looked at material provision for restoration of posterior teeth (Wilson et al. 2019), suggesting that composite has displaced amalgam as the most used dental restorative material in posterior permanent teeth in the United Kingdom. The sampling frame was limited, however, meaning the results may be less applicable across the United Kingdom. These results do not appear to correlate with the other survey results, which collected data from NHS GDs but was limited to Wales (Lynch et al. 2018). The Welsh survey does provide data on materials and techniques used but was not specific in assessing use of the different technique and material options currently available. Neither survey gives an indication of percentage use of the different available direct materials, with respondents being asked either which material was used most commonly (Wilson et al. 2019) or to rank their preferred choice of materials in specific situations (Lynch et al. 2018).

Amalgam was the most frequently used material to restore posterior teeth under NHS provision in Scotland in 2017–208 (Information Services Division 2017), and the expenditure on NHS amalgam fillings in England has been crudely estimated at £200 to £300 million from 2015 to 2016 (C.R. Vernazza and K. Carr, personal communication, 2018).

The most recent survey of NHS GDs in Wales showed a large majority felt that direct posterior composite provision was too expensive for NHS-funded dentistry and that there was a higher incidence of postoperative complications with posterior composite than amalgam restorations (Lynch et al. 2018), supporting the notion that composites are much more technique sensitive (Kielbassa et al. 2016), with differing techniques, materials, operators, and patient characteristics associated with differing outcomes (Demarco et al. 2012; Heintze and Rousson 2012; Schwendicke et al. 2018).

None of the current evidence relates to provision of restorations by dental therapists, who are a growing workforce in the United Kingdom (Centre for Workforce Intelligence 2014), or from dentists working in community dental services (CDS), who work with more challenging patients. Their patients commonly have behavioral difficulties and special requirements, which make achieving moisture control and higher levels of cooperation, as required for the placement of composite compared to amalgam restorations, very difficult, as evidenced by CDS dentists' responses to the Scottish Dental Clinical Effectiveness Programme (SDCEP) consultation document on the phase-down of amalgam (M. West, personal communication, 2018).

Understanding current provision of direct posterior restorations in UK primary care is therefore critical to strategic planning for the potential phase-out of amalgam, and existing work does not provide sufficient detail. The objectives of this study were therefore (a) to identify and quantify current techniques, material use, and reported incidence of postoperative complications by UK dentists and therapists for placement of direct posterior restorations and (b) to determine any differences between subgroups.

Methods

A cross-sectional e-survey was developed (accessible in the Appendix, with a link to the online questionnaire) consistent with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines, based on the recent Welsh survey (Lynch et al. 2018), alongside others identified in a literature review (Gilmour et al. 2009; Brunton et al. 2012; Alexander et al. 2016, 2017a, 2017b). It was modified, based on best practice questionnaire methodology (Dillman et al. 2014), to reduce survey error and to reflect the objectives of the study to obtain quantitative information on current techniques and materials used, rather than material preferences in particular situations. The study received a favorable ethical opinion from Newcastle University Research Ethics Committee (ref 7262/2018).

Open and closed questions were used, with utilization of clinical scenario vignettes and various Likert scales. The survey sought information on respondent demographics, education, current provision of direct posterior restorations (excluding localized cervical [class V]), and perceived issues with the different available materials. The questionnaire spanned a maximum of 24 screens containing 90 items, with 1 screen conditional on a previous response.

The questionnaire underwent initial usability testing through piloting, administered in paper form to internal and external academic dentist experts, as well as members of target respondent groups, using systematic form appraisals and "think-aloud" techniques (Geisen and Bergstrom 2017). It was then formatted electronically for use with the SmartSurvey online platform (www.smartsurvey.co.uk) before undergoing further piloting as previously described, alongside observational usability testing (Geisen and Bergstrom 2017), including ease of navigation with mobile devices. Modifications were made based on these processes to minimize survey error.

Sample

A sample size calculation was performed, based on the core aspect of analysis, a multiple linear regression (MLR) investigating factors influencing time booked for placement of a mesio-occluso-distal (MOD) direct posterior composite with 21 independent variables. Various "rule-of-thumb" calculations exist for MLR minimum sample size, providing various estimates (Roscoe 1975), with 630 the largest obtained and therefore used (Pedhazur and Schmelkin 2013).

The questionnaire was then distributed by email to all British Dental Association (BDA) member GDs and CDS dentists, as well as all therapist members of the British Society of Dental Hygiene and Therapy (BSDHT) and the British Association of Dental Therapists (BADT) (11,092 invitations). A closed sampling frame was used for BDA members, which allowed tracking of respondents through the use of specific identifiers. This allowed the prevention of duplicate entries while allowing the use of targeted reminders and a monetary incentive of £100 for 1 respondent selected by random draw. Due to the systems in use, it was not possible to identify individual responders in the BSDHT and BADT groups; therefore, the sampling frame had to be open, and targeted reminders and incentivization were not possible. It was specified that the link should not be shared to limit the sampling frame to only those therapists receiving the invitational email. Two blanket reminders were sent to all 3 groups, with a link to the questionnaire attached. The questionnaire was launched February 14, 2019, and the deadline for response was March 31, 2019.

The first screen of the survey detailed its anonymity, the research purpose and team involved, data handling, and option and directions for opt-out. Consent was provided through a simple yes/no question after eligibility and understanding were similarly confirmed.

Survey data were received electronically and automatically captured by the BDA. Any identifiers were removed, and the anonymized data were passed securely to Newcastle University for analysis.

Data Analysis

Data were cleaned, imported, and analyzed using Stata software (version 16; StataCorp LP). Subgroups (see Appendix data) were defined in relation to prior hypotheses. Data sets were assessed for normality of distribution graphically and using Shapiro-Wilk tests. Descriptive statistical testing was performed alongside 2-way hypothesis testing with χ^2, Kruskal-Wallis, and Wilcoxon signed rank-sum tests, depending on the data.

Regression analyses were run with backward stepwise elimination. Best-fit models were selected by the lowest Bayesian information criterion value. Potential multicollinearity was assessed using variance inflation factors, with all obtained values less than 2.5. Multiple linear regressions were run to assess the impact of clinician and technique variables on private fee charged and appointment time booked for the placement of a direct posterior MOD composite. Logistic regressions were carried out to assess the impact of clinician and technique variables on reported low (0%–10%) incidences of postoperative food packing and sensitivity with direct posterior composite restorations. Data, samples, or models will be provided on request to the corresponding author.

Results

In total, 1,570 responses were received. Fifty-four respondents were not suitable to participate in the study, answering negatively to one of the eligibility questions. This was mainly due to the respondents not currently practicing dentistry and placing direct restorations ($n = 51$). Three respondents were suitable but then failed to answer any further questions. A total of 1,513 usable responses were received. Dentists' response rate was 14%, and therapists' estimated minimum response rate was 6%. One respondent did not answer the final question, but all other remaining respondents did, giving a survey completion rate of 99.8% (of those who indicated their eligibility). A small minority of respondents gave contradictory answers (in the material usage section), which were excluded from analysis to reduce measurement error.

The minimum time taken for respondents to complete the questionnaire was 5 min (which was deemed sufficient time to complete the questionnaire), with a median value of 16 min.

Percentages are rounded to the nearest integer throughout. Direct posterior restorations throughout this article exclude localized cervical (class V) restorations.

Demographics

The basic demographics are shown in Table 1.

Categorization of a dentist's primary role was determined by the dominant number of sessions performed in general dentistry or CDS.

NHS and mixed GDs were evenly represented by gender, whereas private

Table 1.
Summary Demographics.

Variable	Category		Frequency	Percent
Gender	Female		743	49
Clinician primary role	Dentist	NHS general (75%–100% NHS patient base)	617	41
		Mixed general (25%–74% NHS patient base)	194	13
		Private general (0%–24% NHS patient base)	509	34
		CDS	118	8
	Therapist		75	5
Primary dental qualification location	United Kingdom		1294	88
	EU (non–United Kingdom)		101	7
	Non-EU		81	5
Years qualified	≤2		57	4
	3–5		82	5
	6–10		159	11
	11–15		157	10
	16–20		195	13
	21–25		176	12
	26–30		195	13
	31–35		252	17
	≥36		239	16

CDS, community dental services; NHS, National Health Service.

GDs had a greater proportion of males, and CDS dentists and therapists had a much greater proportion of females (Appendix Table 1), and the differences were statistically significantly different (χ^2 $P < 0.001$).

Respondents whose primary dental qualification was European Union (EU; non–United Kingdom) or non-EU based mainly worked in general dentistry, with a lower proportion working in the CDS and none working as therapists (Appendix Table 2). The differences between groups were statistically significant (χ^2 $P = 0.001$).

As dentists' number of years of qualification increased, the proportion working as NHS GDs reduced and the proportion working as private GDs increased (Appendix Table 3), and this difference was statistically significant (χ^2 $P < 0.001$).

Material Use for Direct Posterior Restorations

Respondents were asked to state the percentage of premolars and molars that they restored with composite, amalgam, and other materials (Table 2). Composite was the most used directly placed material to restore premolar teeth, whereas amalgam was marginally the most used in molar teeth.

Only 6.7% of respondents used no amalgam and 0.4% of respondents used no composite for direct posterior restorations.

Composite use in molar teeth increased as the clinicians' number of years qualified increased from 32% (SD = 24) in those qualified for 0 to 5 y to 52% (SD = 33) in those qualified ≥26 y (Appendix Table 4). The differences were statistically significant (Kruskal-Wallis $P = 0.0001$).

The percentage of molar teeth restored directly with composite was lower in NHS GDs (26%; SD = 22) but higher in private GDs (73%; SD = 26) than therapists (41%; SD = 29), mixed GDs (45%; SD = 25), or CDS dentists (38%; SD = 28) (Appendix Table 5). The differences were statistically significant (Kruskal-Wallis $P = 0.0001$).

Appointment Time and Fees Charged

Table 3 details the mean appointment time booked and mean private fees charged for different clinical scenarios.

Table 2.
Average Percentage Use of Amalgam, Composite, and Other Direct Materials (Glass Ionomer Cements/Resin-Modified Glass Ionomer Cements/Other) by Posterior Tooth.

Material	Average Use by Tooth (%)					
	Premolar			Molar		
	%	SD	Missing (%)	%	SD	Missing (%)
Composite	55	32	0.1	46	32	0.01
Amalgam	38	31	0.01	48	32	0.1
Other	6	10	0.1	6	9	0.3

Table 3.
Appointment Time Booked and Private Fee Charged for Mesio-Occlusal (MO) Premolar and Mesio-Occluso-Distal (MOD) Molar Restorations.

Restoration	Material	Appointment Time Booked (min)				Cost (£)			
		Mean	SD	Range	Missing (%)	Mean	SD	Range	Missing (%)
Two-surface MO premolar	Composite	34	9	15–90	0.4	111.70	42	30–400	10
	Amalgam	24	7	10–60	4	77.60	34	13–350	18
Three-surface MOD molar	Composite	42	11	15–120	1	138.43	52	40–460	10
	Amalgam	29	8	5–60	4	95.50	43	18–450	18

Wilcoxon signed rank tests showed that appointment time booked and private fee charged for a 3-surface MOD restoration in a molar tooth were statistically significantly higher ($P < 0.0001$) when comparing composite with amalgam as the restorative material. Similar statistical differences were shown for the 2-surface mesio-occlusal (MO) premolar restorations. Clinicians booked 45% more time and charged 45% more (as a private fee) to perform a direct MOD composite in a molar tooth than for the same restoration in amalgam. The ranges of appointment time booked and fees charged were wide.

NHS GDs booked shorter appointment times and private GDs longer appointment times than therapists, mixed GDs, and CDS dentists for direct MOD composite restorations. These differences were statistically significant (Kruskal-Wallis $P = 0.0001$) (Appendix Table 6).

Direct Posterior Composite Technique and Material Use

Respondents were asked to indicate how often they used each composite technique, composite material, and bonding technique. They were given 8 options, including 0%, 100%, and 5 ranges in between. A not applicable option (N/A) was also included, which was only to be used if the clinician placed no composite restorations. These were analyzed and combined into the groupings shown in Appendix Tables 7, 8, and 9 under percentage use. The tables indicate the percentage of respondents who stated that they use the technique or material for each of the percentage use bands.

Rubber dam use for direct posterior composite restoration was generally low. Circumferential metal matrices were by far the most commonly used matrix. Use of a liner when placing a restoration in a tooth without a pulp exposure was variable, and wedges were commonly used when restoring a lost proximal surface (Appendix Table 7).

Incremental conventional composite placement was by far the most commonly used technique to directly restore a posterior tooth with composite compared with various bulk-fill options and nonincremental conventional placements (Appendix Table 8).

Use of a total-etch 2-step bonding technique was by far the most commonly used bonding strategy for posterior composite restoration placement (Appendix Table 9).

Incidence of Postoperative Complications Encountered with Direct Posterior Restorations

Respondents were asked to indicate how often their patients experienced postoperative complications of sensitivity and food packing following placement of direct posterior composite and amalgam

Table 4.
Clinician-Reported Incidence of Postoperative Problems Encountered following Direct Posterior Restoration Placement with Different Materials.

Postoperative Problem	Material	Incidence (%) 0–10	11–25	26–50	51–100	N/A
Sensitivity	Composite (n = 1,506)	52	29	12	5	1
	Amalgam (n = 1,507)	73	14	3	1	9
Food packing	Composite (n = 1,498)	58	29	9	4	1
	Amalgam (n = 1,508)	77	11	3	0	9

N/A, not applicable (i.e., the clinician does not use the material).

restorations. They were given 8 options, including 0%, 100%, and 5 ranges in between. A not applicable option (N/A) was also included, which was only to be used if the clinician placed no restorations of the indicated material. These were analyzed and combined into the groupings shown in Table 4 under the incidence (%) heading and its more specific variants. The percentage of respondents stating each frequency of complication groupings is shown.

Wilcoxon signed rank tests showed statistically significantly higher clinician-reported incidences ($P < 0.0001$) of both food packing and sensitivity following direct posterior restoration with composite compared with amalgam. Forty-six percent reported sensitivity, and 42% reported food packing in more than 1 in 10 composite restorations placed, compared to 18% and 14%, respectively, with amalgam. Seventeen percent reported sensitivity, and 13% reported food packing in more than 1 in 4 composite restorations placed, compared to 4% and 3%, respectively, with amalgam (Table 4).

The N/A answers were removed and cross-tabulations performed, providing the following results.

Private GDs reported the lowest incidence of sensitivity following direct composite placement compared to other clinicians. Fifteen percent of therapists reported postoperative sensitivity in more than 1 in 2 direct composite restorations placed (Appendix Table 10). The differences were statistically significant (χ^2 $P < 0.001$).

Private GDs reported the lowest incidence of food packing following direct composite placement compared to other clinicians (Appendix Table 11). The differences were statistically significant (χ^2 $P < 0.001$).

Clinicians primarily using sectional metal matrices reported a much lower incidence of food packing following direct posterior composite restoration than those exclusively using circumferential matrices (Table 5). The difference was statistically significant (χ^2 $P < 0.001$).

Clinicians using rubber dam 76% to 100% of the time resulted in a lower incidence of reported sensitivity following direct posterior composite placement compared with other levels of use (Table 5). The difference was not statistically significant, however (χ^2 $P = 0.065$).

As the clinicians' number of years qualified increased, the incidence of postoperative food packing and sensitivity following amalgam and composite restorations reduced (Appendix Tables 12–15). The differences were all statistically significant (χ^2 $P < 0.001$) except for food packing incidence after composite placement (χ^2 $P = 0.259$).

Bulk-Fill Composites

Sixty-eight percent of respondents reported having experience of using bulk-fill composites (n = 1,513). These clinicians had most experience of using flowable light-cured bulk-fill composites (53%). Smart Dentine Replacement (SDR; Dentsply) was by far the most commonly named material (42%). Interestingly, non-bulk-fill composites, compomers, GICs, and resin-modified GICs accounted for 8% of categorizable responses (Appendix Table 16).

Clinicians who had experience with using bulk-fill composites generally found them easier to place and were time saving but less aesthetic, with a majority neither agreeing nor disagreeing that they were more predictable or resulted in reduced postoperative sensitivity (Appendix Table 17).

Regression Analyses

Full details of the regression analyses are shown in the Appendix information (Appendix Tables 18–21). In all cases, pseudo- or adjusted R^2 values suggested a great deal of the variance was unexplained. However, significant factors in each model are discussed below.

A multiple linear regression analysis ($n = 769$; $P < 0.001$; adjusted R^2 = 0.15) showed the factors statistically significantly associated with an increase in time booked for placing a direct posterior MOD composite (Appendix Table 18) were private GDs (6 min), therapists (5 min), and mixed GDs (4 min) compared to NHS GDs; high rubber dam users (6 min) compared to moderate users; primarily sectional metal matrix users (4 min); total-etch 3-step bond users (3 min); total-etch 2-step bond users (2 min) compared to self-etch 1-step bond users; and incremental composite users (2 min).

Table 5.
Clinician-Reported Incidence of Food Packing and Sensitivity following Direct Posterior Composite Restoration with Various Matrix and Rubber Dam Use.

Problem after Composite Placement	Technique Use	Incidence after Composite Placement (%)			
		0–10	11–25	26–50	51–100
Food packing	100% circumferential metal matrix ($n = 534$)	50	32	12	6
	51%–100% sectional metal matrix ($n = 266$)	79	15	5	1
Sensitivity	0% rubber dam ($n = 472$)	49	32	13	6
	1%–10% rubber dam ($n = 399$)	55	28	13	4
	11%–75% rubber dam ($n = 395$)	52	32	12	5
	76%–100% rubber dam ($n = 180$)	64	22	9	5

Factors statistically significantly associated with a decrease in time booked for placing a direct posterior MOD composite were clinicians who never use rubber dam (2 min) compared to moderate users and high-confidence MOD composite placers (2 min).

A multiple linear regression analysis ($n = 711$; $P < 0.0001$; adjusted $R^2 = 0.28$) showed the factors statistically significantly associated with an increase in private fee charged for placing a direct posterior MOD composite (Appendix Table 19) were private GDs (£27.56) and mixed GDs (£12.91) compared to NHS GDs, high wedge users (£9.19), high-confidence MOD composite placers (£8.47), incremental composite users (£8.04), and appointment time booked for a direct posterior MOD composite (£1.43 per minute increase).

The factor statistically significantly associated with a decrease in private fee charged for placing a direct posterior MOD composite was clinicians who never use rubber dam (£10.53) compared to moderate use.

A logistic regression analysis ($n = 770$; $P < 0.0001$; pseudo-$R^2 = 0.11$) showed the factors statistically significantly associated with a low incidence (0%–10%) of clinician-reported postoperative sensitivity following placement of a direct posterior composite (Appendix Table 20) were primarily composite users (combined premolar and molar composite usage >100%) (odds ratio [OR] = 2.3) and clinicians who never use a liner (OR = 1.8).

The factor statistically significantly associated with reduced likelihood of low incidence (11%–100%) of clinician-reported postoperative sensitivity following placement of a direct posterior composite was being a therapist compared to an NHS GD (OR = 0.4).

A logistic regression analysis ($n = 768$; $P < 0.0001$; pseudo-$R^2 = 0.09$) showed the factors statistically significantly associated with a low incidence (0%–10%) of clinician-reported postoperative food packing following placement of a direct posterior composite (Appendix Table 21) were primarily composite users (OR = 2.8), primarily sectional metal matrix users (OR = 2.5), and incremental composite users (OR = 1.6).

Discussion

This article details a UK-wide survey of dentists and therapists regarding their practice in placing direct posterior restorations. Composite is the most used material for direct restoration of premolars, whereas amalgam is in molar teeth. Amalgam use in posterior teeth in Australia, where private health care provision predominates, was 18% (Alexander et al. 2016). While this is different from the general data presented here, it does broadly correlate with data specific to private GDs. Composite use by private GDs is much higher than other primary care clinician groups, with the greatest disparity seen in relation to NHS GDs. Composite use in molar teeth increased as the clinicians' number of years qualified increased, which shows a reverse correlation from data from other countries (Alexander et al. 2016) and directly refutes recent suggestions that the opposite was the case in the United Kingdom (Wilson et al. 2019). It is likely that this reflects the variation in composite provision in different types of practicing arrangements, with highest composite use seen by private GDs and the proportion of private GDs increasing with increasing age. Only 6.7% respondents used no amalgam at all, which is different from other countries, such as Australia (30%), where private health care provision predominates (Alexander et al. 2016).

Clinicians booked 45% more time and charged 45% more (as a private fee) to perform a direct MOD composite in a molar tooth than for the same restoration in amalgam. Dentists took 61% more time to place an occluso-proximal molar restoration in composite than amalgam from Welsh data (Lynch et al. 2018) and 43% from Irish data (Callanan et al. 2020a). Widely recommended posterior composite techniques, such as rubber dam use and sectional matrix use (Lynch et al. 2014), were low and have increased modestly in comparison to a UK survey of composite technique use from over 10 y ago (Gilmour et al. 2009). When used, these techniques were associated with an increased time taken to perform a composite restoration but a reduction in reported postoperative complications (not rubber dam). When placing posterior composite restorations, the best predictor of reported low postoperative food packing and sensitivity was if the clinician primarily used composite, while being a therapist was the best predictor of high reported postoperative sensitivity. Clinicians following current guidance in avoiding liner use under composite restorations (Blum and Wilson 2018) was associated with reduced reported postoperative sensitivity, further validating such an approach, although liner use was still common. On a positive note, the incidence of reported food packing associated with composite restorations has been hugely reduced in UK primary care over the past 10 y, whereas reported sensitivity is fairly similar (Gilmour et al. 2009).

However, clinician-reported postoperative incidence of sensitivity and food packing was much higher with composite than amalgam.

While bulk-fill composites are being adopted, there is still some confusion as to what constitutes a bulk-fill composite, which has implications for education.

Various potential sources of error and bias may have affected the results, with self-selection bias being the primary risk. In addition, there are concerns over recall bias, self-reporting, the possibility of repeat responses, a relatively low response rate, some small subgroup sizes, and potential differences in patients seen by different clinician groups in terms of disease prevalence, extent, and compliance, which may also have affected the results. Periodic repetition of the survey would be beneficial to support the findings, identifying trends and therefore health service and educational needs over time.

Clinical vignettes are limited in that they cover specific situations and do not take other "real-life" factors into account that potentially affect the generalizability of the data obtained.

The unique nature of publicly funded provision of dental services makes extrapolation of much of the data beyond the UK setting unsound, as evidenced by differences in material provision in other countries (Sunnegardh-Gronberg et al. 2009; Eklund 2010; Alexander et al. 2016; Callanan et al. 2020b), although primarily developing countries, which rely on amalgam to restore posterior teeth, may see similar postoperative issues for clinicians forced to use alternatives because of the phase-down. The data obtained from private dentists, however, may be generalized to many other countries where this mode of provision predominates and use of amalgam is permitted.

Conclusion

Amalgam use in primary care is currently high, especially in the publicly funded sector, which is where the majority of direct posterior restoration provision lies. The alternatives are primarily composites, but there are a wide variety of materials and techniques being used under this banner. There is a much higher reported incidence of postoperative complications with composites, although time-consuming techniques, such as sectional matrix use, are associated with reduced reported postoperative food packing, although their use is currently low in the United Kingdom. High posterior composite usage is the best predictor of reduced reported postoperative complications, but posterior composites cost more and take longer to perform. This suggests that major changes in health service structure and funding and education on posterior composite technique are required in the United Kingdom and other countries where amalgam use is still prevalent, as the amalgam phase-down continues.

Author Contributions

O. Bailey, contributed to conception, design, and data analysis, drafted the manuscript; C.R. Vernazza, contributed to conception, design, data analysis, and interpretation, drafted and critically revised the manuscript; S. Stone, L. Ternent, A.-G. Roche, contributed to conception, design, data analysis, and interpretation, critically revised the manuscript; C. Lynch, contributed to design, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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Original Report: Health Services Research

Amalgam Phase-Down Part 2: UK-Based Knowledge, Opinions, and Confidence in the Alternatives

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Abstract: ***Introduction:*** *Amalgam use has recently been phased down, and the potential for a phase-out is being investigated.*

Objectives: *The study aimed to identify knowledge of the phase-down and opinions of a potential phase-out of amalgam by UK primary care clinicians and assess their confidence in using different materials in different situations.*

Methods: *An anonymized, prepiloted cross-sectional e-survey was used to assess primary care clinicians' knowledge and opinions of the amalgam phase-down and potential phase-out and their confidence in using amalgam and the alternatives in different situations. In total, 11,902 invitations were distributed through British dentist and therapist associations. Prior hypotheses were tested alongside descriptive statistics.*

Results: *Response rate was 13% (n = 1,513). Knowledge of the amalgam phase-down was low, with just 3% clinicians correctly identifying all patient groups in whom amalgam use should be avoided in the United Kingdom. Postgraduate education on posterior composite placement was high (88%), but a large majority had personal and patient-centered concerns over the suitability of the alternatives and lacked confidence when placing composite in comparison to amalgam in difficult situations ($P < 0.0001$). Logistic regressions revealed that the best predictors of high confidence in placing mesio-occluso-distal composites and composites in difficult situations were being a private general dentist or being primarily a composite user.*

Conclusion: *Primary care clinicians have major personal and patient-centered concerns regarding the amalgam phase-down (of which they have limited knowledge) and potential phase-out. Many lack confidence in using the alternative, composite, to restore posterior teeth in difficult situations, whereas confidence in using amalgam in similar situations is high. Effective education of clinicians and understanding patients' needs, alongside policy changes, are required to enable a successful amalgam phase-down and potential phase-out.*

Knowledge Transfer Statement: *This study shows that UK primary care clinicians are worried about the phase-down of amalgam for themselves and their patients. Many lack confidence in the alternative, composite, when used in difficult situations, which is in stark contrast to amalgam. Knowledge of the phase-down is limited. There is a need for more effective education of clinicians, an understanding of patients' values, and policy changes to ensure the success of the phase-down and potential phase-out of amalgam.*

Keywords: caries treatment, health services research, restorative dentistry, restorative materials, composite materials, clinical outcomes

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A supplemental appendix to this article is available online.

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Introduction

This is the second of 2 articles detailing a UK survey of primary care dentists and therapists exploring opinions, techniques, and materials used for the provision of direct posterior restorations. This article focuses on clinicians' opinions and knowledge of the phase-down and potential phase-out of amalgam while assessing their confidence in using different materials in different situations.

The Minamata Convention on Mercury was agreed on in 2013, prescribing an amalgam phase-down to protect the environment (Minamata Convention on Mercury 2013). This has been implemented by the European Parliament, which introduced a phase-down in July 2018 while also stating that the feasibility of a phase-out by 2030 should be investigated (Regulation (EU) 2017/852 2017).

Evidence exists from around the world on dentists' opinions of an amalgam phase-down (Alexander et al. 2014; Callanan et al. 2020) and phase-out from countries where amalgam has been banned (Kopperud et al. 2016). The cost of the amalgam phase-out in Norway, for example, has mostly been borne by patients and providers, and the use of amalgam prior to the phase-out was low (Norwegian Climate and Pollution Agency 2012). The context of health care provision is very different from that of the United Kingdom, however, where publicly funded National Health Service (NHS) with some copayment provision predominates, with amalgam still being commonly used (Lynch et al. 2018).

A recent study provided data on the opinions of NHS general dentists (GDs) on the phase-down and potential phase-out of amalgam limited to Wales (Lynch et al. 2018). While confidence in placing composite in different situations was assessed, confidence in placing amalgam was not assessed, making the potential impact of a phase-out difficult to quantify. A large majority did not feel confident in placing direct posterior composites in cavities with subgingival margins, which is a concern, but it was unclear if this was also an issue when using amalgam. However attendance on postgraduate courses on posterior composites was also low (16% of respondents) (Lynch et al. 2018). Opinions were not sought from community dental service (CDS) dentists, who work with more challenging patients (e.g., those with special requirements or behavioral issues) and worry that the amalgam phase-out could widen already existing health inequalities (Steele et al. 2015; M. West, personal communication, 2018), or the growing UK therapist workforce (Centre for Workforce Intelligence 2014), making the potential impact of the phase-down on primary care difficult to assess.

A majority also felt there was an issue of longevity with composite compared to amalgam (Lynch et al. 2018). This is supported by stringently assessed clinical trial data (Rasines Alcaraz et al. 2014; Khangura et al. 2018), but the discrepancy is not as great as seen in the practice environment, both in the United Kingdom and Scandinavia, where cross-sectional data suggest a greater disparity (Burke et al. 1999; Forss and Widström 2001; Sunnegardh-Gronberg et al. 2009), which is clearly of concern for both tooth survival and the likely lifetime costs of replacement.

Given that an amalgam phase-down has recently been implemented in the United Kingdom, which is still an area of high amalgam use, the objectives of this study were to determine different primary care clinicians' knowledge of newly imposed restrictions, opinions on the phase-down and potential phase-out (including confidence in placement of the available direct posterior restorative materials in various situations), and educational experience related to posterior composites while determining differences between subgroups.

Methods

An anonymized cross-sectional e-survey (available on request from the authors) was developed to assess clinicians' opinions and confidence in amalgam and the alternatives in various situations, as well as knowledge of the amalgam phase-down and proposed phase-out. Clinicians' experience of undergraduate and postgraduate education on direct posterior composites was also assessed. The questionnaire used Likert instruments and open and closed questions based on previous studies (Alexander et al. 2016; Lynch et al. 2018), which were modified in relation to best practice methodology (Dillman et al. 2014) and prepiloting to minimize survey error. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed and a favorable ethical opinion was obtained from the Newcastle University Research Ethics Committee (ref. 7262/2018).

Further details of the methods used have been described elsewhere (Bailey et al. 2022).

Sample

A sample size calculation based on core analysis has previously been described, obtaining an estimate of 630 (Bailey et al. 2022). The questionnaire underwent email distribution on February 14, 2019, to all therapist members of the British Association of Dental Therapists (BADT) and the British Society of Dental Hygiene and Therapy (BSDHT), as well as all GD and CDS members of the British Dental Association (BDA) (11,902 invitations), with a deadline for response March 31, 2019. The therapist sampling frame was open with no incentivization, whereas the dentist sampling frame was closed with a random draw £100 incentive provided for 1 respondent. Two reminders were sent. Eligibility, understanding, and consent for participation were confirmed with yes/no questions. Data were automatically electronically captured by the BDA and passed securely to Newcastle University for analysis.

Data Analysis

Stata software (version 16; StataCorp LP) was used to import, clean, and analyze the data. Basic statistical testing

Table 1.
Opinions Relating to the Potential Phase-out of Amalgam.

Opinion Relating to the Phase-out of Amalgam	Agree or Strongly Agree (%)	Neither Agree nor Disagree (%)	Disagree or Strongly Disagree (%)
Will impact on my ability to do my job (*n* = 1,506)	65	12	23
Will lead to the need for more indirect restorations (*n* = 1,508)	71	14	15
Will lead to more teeth being deemed unrestorable (*n* = 1503)	62	14	25
There is a lack of consensus on best practice when selecting direct alternative materials (*n* = 1,506)	69	19	12
There is a lack of consensus on best practice in terms of technique when directly placing alternative materials (*n* = 1,503)	61	22	17
My patients won't care (*n* = 1,506)	23	27	50
Suitable directly placed alternatives to amalgam are available (*n* = 1,497)	45	14	41
I feel up to date with current techniques and practices relating to placement of posterior composites (*n* = 1,495)	76	14	10
Having to routinely place posterior composites would cause appointment delays in my practice (*n* = 1,493)	62	11	27
Posterior amalgams last longer than directly placed posterior composites (*n* = 1,498)	62	24	14
It takes me longer to remove a failed posterior composite restoration than a failed amalgam restoration of equivalent size (*n* = 1,498)	70	14	16

was performed. Wilcoxon signed rank tests were used to analyze differences in confidence in placing direct posterior restorations, of composite or amalgam, with subgingival margins, and in patients with limited cooperation. Differences in response between clinicians relating to knowledge of the amalgam phase-down were analyzed using χ^2 tests. Clinician and technique-based factors associated with high or complete confidence in placing direct posterior composite restorations in various situations (mesio-occluso-distal [MOD] cavity, subgingival margins, and in patients with limited cooperation) were analyzed using logistic regressions (using backward stepwise elimination). Lowest Bayesian information criterion values were used to select the models of best fit. Variance inflation factors were calculated to assess multicollinearity, with all values lower than 2.5. Data, samples, or models will be provided on request to the corresponding author.

Results

Of the 1,570 responses received, 1,513 were usable. Fifty-four respondents were not suitable to participate, and 3 respondents were but failed to answer any questions. The response rate was 14% for dentists and an estimated minimum of 6% for therapists. Survey completion rate was 99.8% for eligible responders.

Direct posterior restorations throughout this report exclude localized cervical (class V) restorations, and percentages are rounded to the nearest integer. Demographic data have already been presented (Bailey et al. 2022), but there was good representation of groups by sex, years qualified, and practicing arrangement. Given that dental workforce demographics are not published, it is not possible to judge how representative the sample is.

Education in Direct Posterior Composite

As undergraduates, 30% respondents had not received didactic teaching and 36% had not received clinical

Table 2.
Clinician Confidence in Providing Various Restorations in Varying Clinical Situations.

Clinician Confidence Level	No or Low Confidence (%)	Moderate Confidence (%)	High or Complete Confidence (%)
In providing 2 surface direct posterior composite restorations involving a proximal surface (*n* = 1,507)	2	19	79
In providing 3 surface direct posterior composite restorations involving both proximal surfaces (*n* = 1,501)	5	27	67
In providing definitive 2 surface posterior GIC restorations involving a proximal surface (*n* = 1,503)	23	31	45
In providing definitive 3-surface posterior GIC restorations involving both proximal surfaces (*n* = 1,501)	31	30	39
When placing direct posterior composites with subgingival margins (*n* = 1,505)	51	31	18
When placing posterior amalgams with subgingival margins (*n* = 1,476)	4	18	78
When placing direct posterior composites in patients with limited cooperation (*n* = 1,505)	69	23	8
When placing posterior amalgams in patients with limited cooperation (*n* = 1,483)	7	46	48

GIC, glass ionomer cement.

teaching on direct posterior composites, with 7% unable to remember. A high proportion of respondents had attended a postgraduate course on direct posterior composite placement (88%) (Appendix Table 1).

Amalgam Phase-Down and Proposed Phase-Out

Respondents' knowledge of the amalgam phase-down was ascertained by asking them to state in which patient groups amalgam use should currently be avoided (Appendix Table 2) and by which year the phase-out was planned.

Forty percent (40%) respondents correctly identified the year (2030) of the proposed phase-out of amalgam (dentists 40%, therapists 38%; no statistically significant difference between groups, χ^2 $P = 0.701$) (n = 1,481). Fifty-one percent thought it was prior to this. Only 3% of dentists and therapists correctly identified all patient groups in which the use of amalgam should be avoided according to current rules (Regulation (EU) 2017/852 2017). There was no statistically significant difference between the clinicians (χ^2 $P = 0.883$).

Clinicians were also asked their opinions about various aspects of the phase-down based on a 5-point Likert scale. Responses for *strongly agree* and *agree*, as well as *strongly disagree* and *disagree*, were combined and are presented in Table 1. A large majority felt that the phasing out of amalgam would affect their ability to do their job and lead to the need for more indirect restorations and more teeth being deemed unrestorable, and they also believed that there is a lack of consensus on best practice in both material selection and technique when placing alternatives to amalgam but felt up to date with current techniques and practices relating to placement of direct posterior composite restorations. A majority felt that their patients would care about the phasing out of amalgam, and a large majority felt that posterior amalgams last longer than posterior composite restorations, that having to routinely place posterior composite restorations would lead to appointment delays in their practice, and that it takes longer to remove a failed posterior composite than a failed amalgam restoration of equivalent size.

Clinicians were asked over which period of time they felt amalgam should be phased out from UK dental practice. The responses (n = 1494) were as follows: less than 5 y, 21%; 5 to 9 y, 23%; 10 to 19 y, 24%; 20 to 29 y, 7%; and ≥30 y, 26%.

Clinician Confidence

Clinicians were asked to state how confident they were placing direct posterior restorations in different clinical situations based on a 5-point Likert scale. Responses for "complete confidence" and "high confidence," as well as "no confidence" and "low confidence," were combined and are presented in Table 2.

Wilcoxon signed rank tests showed statistically significantly lower ($P <$ 0.0001) clinician confidence when placing direct posterior restorations with subgingival margins, as well as in patients with limited cooperation, when using composite compared to amalgam. The difference was marked, with 51% reporting no or low confidence when placing a direct posterior composite with subgingival margins, compared to just 4% when placing amalgam in the same situation, and 69% reporting no or low confidence when placing a direct posterior composite in patients with limited cooperation, compared to just 7% when placing amalgam in the same situation. Clinicians generally had high or complete confidence in placing direct posterior composites involving both proximal surfaces.

Regression analyses

Pseudo-R^2 values suggested the models explained only a small portion of the variance for all of the regression analyses performed. The significant factors in each model are discussed below, however.

Table 3 details the logistic regression to explore the influence of various factors on confidence in placing direct posterior MOD composite restorations.

Type of practice significantly affected confidence in placing a direct posterior MOD composite, with private GDs and mixed GDs more than twice as likely to be confident compared to NHS GDs, whereas CDS dentists and therapists were less than half as likely to be confident. Primarily composite users and clinicians reporting a low incidence of postoperative food packing after composite placement were twice as likely to be confident, with those using circumferential metal matrices 1.7 times as likely to be confident in placing direct posterior MOD composites. Clinicians who were female (odds ratio [OR] = 0.6), those who agreed that there was a lack of consensus on composite technique (OR = 0.6), and those who disagreed (or strongly disagreed) that suitable alternative to amalgam existed (OR = 0.7) were less likely to be confident in placing direct posterior MOD composite restorations.

Table 4 details the regression to explore the influence of various factors on confidence in placing direct posterior composites with subgingival margins.

Private GDs were 2.5 times as likely to be confident in placing composites with subgingival margins compared to NHS GDs. Clinicians whose patients reported low postoperative food packing following direct posterior composite placement were 2.6 times as likely to be confident, those with high rubber dam use over twice as likely to be confident, and those primarily using composite 1.8 times as likely to be confident. Those with a UK primary qualification were less than half as confident, and female clinicians and those who disagreed that suitable alternatives to amalgam existed were 0.6 times as confident in placing direct posterior composites with subgingival margins.

Table 5 details the regression to explore the influence of various factors on confidence in placing direct posterior composites in patients with poor cooperation.

Private GDs were 2.7 times more likely to be confident in placing direct posterior composites in patients with poor cooperation than NHS GDs. Those with a UK primary qualification were only 0.3 times as confident, those who disagree that suitable alternatives to amalgam exist 0.4 times as confident, and those with high wedge use 0.5 times as confident in placing direct posterior composites in patients with poor cooperation.

Discussion

This study aimed to explore different primary care clinicians' opinions and knowledge related to the newly imposed amalgam phase-down and potential phase-out (including confidence in the various materials used for direct restoration of posterior teeth in various situations) and educational experience related to posterior composites.

Comprehensive knowledge of the phase-down and phase-out of amalgam is low among primary care clinicians, which is of concern given that phase-down regulations are currently in place. Members of the associations from which the sample was drawn might be expected to be more informed than nonmembers, given much information has been repeatedly disseminated by each association on this topic. It seems likely that some respondents looked up the guidelines on the Internet, seemingly quoting previous Norwegian guidelines (Norwegian Climate and Pollution Agency 2012), which are different from UK guidelines (Regulation (EU) 2017/852 2017). Alternative modes of dissemination should be explored.

A large majority felt concerned about the potential phasing out of amalgam, feeling that issues existed over the suitability of alternatives and that amalgam restorations last longer than composite restorations (62%). This is in agreement with the opinions of Welsh dentists (57%) (Lynch et al. 2018) and Norwegian dentists after the implementation of the amalgam ban (a clinical vignette showed a class 2 restoration requiring replacement, with 71% dentists indicating that an amalgam restoration would last longer than a composite) (Kopperud et al. 2016). Clinical data also support this perception, both trial based and, importantly for consideration of primary care, cross-sectional based, which show marked differences in survival between composite and amalgam (Burke et al. 1999; Forss and Widström 2001; Sunnegardh-Gronberg et al. 2009; Rasines Alcaraz et al. 2014; Khangura et al. 2018). Not all data reviews agree with this, but these are primarily based on short-term clinical trial data (Heintze and Rousson 2012), with included individual studies often excluding patients at higher risk of restoration failure, for example, those with high caries risk, poor oral hygiene, and bruxism (Gallo et al. 2005), or include extensive retrospective data specific to a single dental practice (Opdam et al. 2014), all of which make translation of the data to primary care difficult.

A high proportion of respondents had attended a postgraduate course on direct posterior composite placement (88%),

Table 3.
Factors Related to High or Complete Confidence in Placing Direct Posterior Mesio-Occluso-Distal Composite Restorations: A Logistic Regression Analysis.

Independent Variable (Predictor)	Odds Ratio	Standard Error	*z*	*P* > *z*	95% Confidence Interval
No undergraduate clinical teaching (reference had UG teaching)	0.57	0.13	−2.48	**0.013**	0.37–0.89
No postgraduate training (reference had PG training)	0.81	0.22	−0.74	0.457	0.48–1.40
UK primary dental qualification (reference non-UK)	0.67	0.21	−1.27	0.204	0.37–1.24
Type of practice (reference NHS general dentist 75%–100% NHS patient base)					
Private general dentist (0%–24% NHS patient base)	2.20	0.62	2.80	**0.005**	1.27–3.81
Mixed general dentist (25%–74% NHS patient base)	2.13	0.63	2.58	**0.010**	1.20–3.79
CDS dentist	0.37	0.13	−2.80	**0.005**	0.18–0.74
Therapist	0.34	0.16	−2.37	**0.018**	0.14–0.83
Years qualified	1.00	0.01	0.23	0.816	0.98–1.02
Female (reference male)	0.64	0.13	−2.27	**0.023**	0.44–0.94
Composite user (combined premolar and molar composite usage >100%) (reference combined use <100%)	2.02	0.46	3.07	**0.002**	1.29–3.17
Incremental composite user (76%–100% use) (reference <76% incremental)	1.09	0.21	0.45	0.653	0.75–1.59
Bonding system use (reference self-etch 1 step [76%–100% use])					
Total-etch 3-step bond (76%–100% use)	1.31	0.50	0.70	0.485	0.62–2.77
Total-etch 2-step bond (76%–100% use)	1.08	0.28	0.28	0.781	0.65–1.79
Self-etch 2-step bond (76%–100% use)	0.98	0.75	−0.02	0.984	0.22–4.39
Matrix use (reference not CM or SM user)					
Circumferential metal user (100% use)	1.69	0.34	2.61	**0.009**	1.14–2.50
Sectional metal user (51%–100% use)	1.73	0.54	1.78	0.075	0.95–3.18
High wedge use (76%–100% use) (reference <76% use)	1.10	0.22	0.50	0.616	0.75–1.62
Never liner use (reference >0% use)	1.30	0.28	1.21	0.225	0.85–1.97
Rubber dam use (reference 1%–75% use)					
Never	0.93	0.19	−0.37	0.712	0.61–1.40
High (76%–100% use)	1.072	0.35	0.21	0.833	0.56–2.05
Agree lack of consensus on material (reference don't agree)	0.75	0.21	−1.05	0.292	0.43–1.30
Agree lack of consensus on technique (reference don't agree)	0.56	0.14	−2.38	**0.017**	0.34–0.90
Disagree suitable alternatives to amalgam exist (reference don't disagree)	0.69	0.13	−1.97	**0.049**	0.48–1.00
Low reported sensitivity (0%–10%) (reference ≥11% sensitivity)	1.34	0.27	1.43	0.153	0.90–2.00
Low reported food packing (0%–10%) (reference ≥11% FP)	2.13	0.43	3.75	**0.000**	1.44–3.17
Constant	2.14	1.11	1.47	0.142	0.77

$n = 768$; $P < 0.0001$; pseudo-$R^2 = 0.22$.
CDS, community dental service; CM, circumferential matrix; FP, food packing; NHS, National Health Service; PG, postgraduate; SM, sectional matrix; UG, undergraduate.

Table 4.
Factors Related to High or Complete Confidence When Placing Direct Posterior Composites with Subgingival Margins: A Logistic Regression Analysis.

Independent Variable (Predictor)	Odds Ratio	Standard Error	*z*	*P* > *z*	95% Confidence Interval
No undergraduate clinical teaching (reference had UG teaching)	0.67	0.18	−1.52	0.129	0.40–1.12
No postgraduate training (reference had PG training)	1.07	0.43	0.16	0.876	0.48–2.35
UK primary dental qualification (reference non-UK)	0.47	0.14	−2.45	**0.014**	0.26–0.86
Type of practice (reference NHS general dentist [75%–100% NHS patient base])					
Private general dentist (0%–24% NHS patient base)	2.47	0.80	2.81	**0.005**	1.31–4.65
Mixed general dentist (25%–74% NHS patient base)	1.66	0.60	1.41	0.158	0.82–3.36
CDS dentist	0.61	0.41	−0.73	0.466	0.17–2.28
Therapist	1.04	0.70	0.06	0.953	0.28–3.91
Years qualified	0.99	0.01	−0.64	0.520	0.97–1.02
Female (reference male)	0.58	0.13	−2.34	**0.019**	0.37–0.92
Composite user (combined premolar and molar composite usage >100%) (reference combined use <100%)	1.83	0.51	2.17	**0.030**	1.06–3.15
Incremental composite user (76%–100% use) (reference <76% incremental)	1.18	0.26	0.76	0.446	0.77–1.82
Bonding system use (reference self-etch 1 step [76%–100% use])					
Total-etch 3-step bond (76%–100% use)	0.65	0.25	−1.13	0.257	0.31–1.37
Total-etch 2-step bond (76%–100% use)	0.64	0.17	−1.70	0.089	0.38–1.07
Self-etch 2-step bond (76%–100% use)	0.83	0.57	−0.27	0.789	0.22–3.18
Matrix use (reference not CM or SM user)					
Circumferential metal user (100% use)	1.05	0.27	0.18	0.856	0.64–1.73
Sectional metal user (51%–100% use)	0.96	0.28	−0.13	0.900	0.55–1.70
High wedge use (76%–100% use) (reference <76% use)	0.62	0.15	−1.92	0.055	0.38–1.01
Never liner use (reference >0% use)	1.36	0.30	1.37	0.171	0.88–2.11
Rubber dam use (reference 1%–75% use)					
Never	0.98	0.26	−0.07	0.941	0.58–1.65
High (76%–100% use)	2.17	0.65	2.56	**0.010**	1.20–3.92
Agree lack of consensus on material (reference don't agree)	0.80	0.22	−0.80	0.425	0.46–1.39
Agree lack of consensus on technique (reference don't agree)	0.75	0.20	−1.05	0.293	0.44–1.28
Disagree suitable alternatives to amalgam exist (reference don't disagree)	0.59	0.14	−2.19	**0.029**	0.36–0.95
Low reported sensitivity (0%–10%) (reference ≥11% sensitivity)	0.77	0.20	−1.00	0.316	0.47–1.28
Low reported food packing (0%–10%) (reference ≥11% FP)	2.59	0.70	3.51	**0.000**	1.52–4.41
Constant	0.42	0.24	−1.55	0.122	0.14–1.26

$n = 768$; $P < 0.0001$; pseudo-$R^2 = 0.17$.
CDS, community dental service; CM, circumferential matrix; FP, food packing; NHS, National Health Service; PG, postgraduate; SM, sectional matrix; UG, undergraduate.

Table 5.
Factors Related to High or Complete Confidence in Placing Composites in Patients with Poor Cooperation: A Logistic Regression Analysis.

Independent Variable (Predictor)	Odds Ratio	Standard Error	z	P > z	95% Confidence Interval
No undergraduate clinical teaching (reference had UG teaching)	1.22	0.44	0.57	0.570	0.61–2.46
No postgraduate training (reference had PG training)	1.53	0.82	0.80	0.426	0.54–4.35
UK primary dental qualification (reference non-UK)	0.34	0.13	−2.80	**0.005**	0.16–0.73
Type of practice (reference NHS general dentist [75%–100% NHS patient base])					
Private general dentist (0%–24% NHS patient base)	2.69	1.26	2.11	**0.035**	1.07–6.74
Mixed general dentist (25%–74% NHS patient base)	2.63	1.34	1.90	0.057	0.97–7.14
CDS dentist	1.50	1.11	0.55	0.580	0.35–6.39
Therapist	3.05	2.29	1.49	0.137	0.70–13.27
Years qualified	0.98	0.02	−0.93	0.351	0.95–1.02
Female (reference male)	0.96	0.31	−0.12	0.905	0.52–1.79
Composite user (combined premolar and molar composite usage >100%) (reference combined use <100%)	2.00	0.79	1.77	0.077	0.93–4.32
Incremental composite user (76%–100% use) (reference <76% incremental)	1.27	0.39	0.79	0.431	0.70–2.32
Bonding system use (reference self-etch 1 step [76%–100% use])					
Total-etch 3-step bond (76%–100% use)	1.51	0.75	0.82	0.413	0.57–4.01
Total-etch 2-step bond (76%–100% use)	1.32	0.52	0.70	0.485	0.61–2.85
Self-etch 2-step bond (76%–100% use)	1	(omitted)			
Matrix use (reference not CM or SM user)					
Circumferential metal user (100% use)	1.56	0.54	1.27	0.203	0.79–3.08
Sectional metal user (51%–100% use)	1.12	0.45	0.27	0.786	0.50–2.48
High wedge use (76%–100% use) (reference <76% use)	0.49	0.17	−2.07	**0.038**	0.25–0.96
Never liner use (reference >0% use)	1.05	0.33	0.15	0.884	0.57–1.93
Rubber dam use (reference 1%–75% use)					
Never	0.65	0.25	−1.10	0.270	0.31–1.39
High (76%–100% use)	1.83	0.74	1.49	0.137	0.80–4.04
Agree lack of consensus on material (reference don't agree)	0.52	0.20	−1.73	0.083	0.24–1.09
Agree lack of consensus on technique (reference don't agree)	1.05	0.39	0.12	0.904	0.50–2.18
Disagree suitable alternatives to amalgam exist (reference don't disagree)	0.38	0.14	−2.57	**0.010**	0.18–0.79
Low reported sensitivity (0%–10%) (reference ≥11% sensitivity)	1.55	0.58	1.19	0.236	0.75–3.21
Low reported food packing (0%–10%) (reference ≥11% FP)	1.49	0.57	1.05	0.292	0.71–3.15
Constant	0.09	0.07	−3.12	0.002	0.02–0.40

$n = 768$; $P < 0.0001$; pseudo-$R^2 = 0.17$.
CDS, community dental service; CM, circumferential matrix; FP, food packing; NHS, National Health Service; PG, postgraduate; SM, sectional matrix; UG, undergraduate.

which was much higher than another recent survey sampling dentists in Wales (16%) prior to the implementation of the phase-down (Lynch et al. 2018). While this is encouraging, it did not translate to higher confidence in placement of posterior composites among the respondents in comparison to the Welsh study, with proportionally fewer respondents confident in placing an MOD composite (67% vs. 88%). This could be partially explained by the Welsh data being at risk of acquiescence bias. However, when these data are combined with the fact that only a small minority felt confident in placing composites in difficult situations, for example, in teeth with subgingival margins, the efficacy of current postgraduate education courses must be questioned, given relatively simple techniques, usable by GDs, have been described to manage such situations (Bailey and O'Connor 2019). These data are in marked contrast to the high confidence of a large majority of respondents when placing amalgam in similar, difficult situations, which is therefore a concern in light of the amalgam phase-down.

With a large majority feeling a phase-out would affect their ability to do their job, concerned by the extra time it would take to place and replace alternatives (supported by experimental data; Krejci et al. 1995), the consequent appointment delays, the increased need for indirect restorations and that more teeth would be deemed unrestorable, the potential impact on health care accessibility, cost, tooth loss, patient safety, dentist well-being, and the already widening oral health inequalities (Steele et al. 2015) is worrying. Respondents generally also felt that their patients would be concerned about a potential phase-out of amalgam (50%), which is very different from data collected from dentists in Australia, where amalgam use is low, with only 16% feeling similarly (Alexander et al. 2016). This is likely primarily due to the difference in public versus private service provision between the countries.

UK graduates were much less confident in placing composites in difficult situations than those qualifying from the rest of the world, which raises questions over UK education and the predominance and impact of publicly funded practicing arrangements, which favor amalgam placement in the United Kingdom (Lynch et al. 2018).

Primarily being a composite placer is a good predictor for high confidence in placing MOD composites and placing composites with subgingival margins. The practicing arrangement in the UK potentially limits clinician skill development, as is required for placing posterior composite restorations compared with amalgam (Kielbassa et al. 2016) and therefore confidence. This affects patient outcomes, as supported by data showing that primarily being a composite placer was the best predictor for low reported postoperative incidence of complications when placing direct posterior composites (Bailey et al. 2022). This would support the notion that repeatedly using a skill engenders competence and confidence, but repetition per se and confidence do not necessarily reflect competence (Morgan and Cleave-Hogg 2002; Davis et al. 2006). Evidence suggests that repetition of a skill needs to be deliberate and focused following insightful reflection for improvement to occur (Ericsson and Pool 2016). The nature of the patient population seen in the different sectors may differ, in terms of disease prevalence and extent, or compliance, for example, with NHS GDs potentially seeing more challenging patients in this regard than private GDs. This may also explain some of the differences seen in confidence between the practitioner groups.

CDS dentists tend to face more challenging patients, often with limited cooperation (M. West, personal communication, 2018), which makes composite placement more difficult due to the material's technique sensitivity, which could account for their lower likelihood of confidence. The therapist cohort reported very high levels of postoperative sensitivity following the placement of composite restorations (Bailey et al. 2022), which could explain their relatively reduced likelihood of confidence. It was a concern that therapists had no equivalence of a training year in practice postqualification with an educational supervisor (which the dentists do in the United Kingdom) until recently. A training program has been introduced, but satisfactory completion is still not a requirement for UK graduates to be registered to provide NHS dentistry, as it is for newly qualified dentists. This lack of support at an early stage may be a reason for these concerning responses.

When using Likert instruments, which ask for agreement or disagreement with a statement, there may be a tendency to agree, resulting in acquiescence bias; therefore, an attempt was made to balance broadly similar statements positively and negatively to minimize this. Confidence in placing different restorations in different situations may be interpreted as confidence in the material or in the clinician's ability, which could lead to response bias. It was felt that although more questions could be asked to more accurately ascertain this, the facets of confidence were interlinked and repeating similar questions risked overburdening respondents for minimal additional insight and risking potential respondent fatigue bias (Egleston et al. 2011).

Limitations around sampling, survey design, and response rates have been further discussed elsewhere (REF paper 1).

Publicly funded restoration provision predominates in the United Kingdom, with amalgam the most commonly used posterior material. This limits the generalizability of the findings, although it could be comparable to other, primarily developing, countries where amalgam use is still high (Mumtaz et al. 2010; World Health Organization 2011). Data pertaining to private dentists could potentially be generalized to other countries where this is the main mode of health care provision and amalgam use is still permitted.

Conclusion

This survey has shown that primary care dentists and therapists in the United

Kingdom have some major personal and patient-centered concerns over the phase-down of amalgam. Many lack confidence with the alternative, composite, when restoring posterior teeth in difficult situations, whereas confidence in placing amalgam in similar situations is much higher. They also have limited knowledge of the details of the phase-down. There is a need for more effective education of clinicians, a greater understanding of patients' values, and policy changes to ensure the success of any phase-down and potential phase-out of amalgam.

Author Contributions

O. Bailey, contributed to conception, design, data analysis, and interpretation, drafted and critically revised the manuscript; C.R. Vernazza, S. Stone, L. Ternent, contributed to conception, design, data analysis, and interpretation, critically revised the manuscript; A.-G. Roche, contributed to design and data acquisition, critically revised the manuscript; C. Lynch, contributed to design, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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Sectional matrix solutions: the distorted truth

Oliver Bailey[1]

Key points

- Considers the advantages and disadvantages of using sectional matrix techniques.
- Explores the key elements in selecting, placing and stabilising sectional matrices, whilst separating teeth sufficiently to achieve a contact with the adjacent tooth.
- Describes the mechanisms of sectional matrix distortion and suggests techniques to minimise these, resulting in predictable patient-centred outcomes.

Abstract

Sectional matrix techniques offer more predictable solutions to achieving contact areas when placing direct interproximal posterior composites than circumferential matrix techniques, resulting in reduced reported complaints of food packing from patients. Despite this, a large majority of UK dentists and therapists don't currently use them. Sectional matrix systems are technique-sensitive to use, which can be a barrier to implementation for inexperienced users. The matrices can easily distort during their placement and stabilisation and when placing the restorative material. This can result in unwanted, clinically relevant problems in the resulting restorations, some of which may not be discernible once they have occurred. This paper explores the advantages and disadvantages of sectional matrices and the processes and techniques involved in their use, before discussing the potential for distortion at each step. It offers solutions to some of the commonly seen problems which will provide more predictable outcomes for those already using these techniques and encourage non-users to add them to their armamentarium.

Introduction

Posterior composite restorations generally perform less well than amalgam restorations,[1,2] especially in primary care.[3] Clinicians are much less confident in placing posterior composite restorations, especially in difficult situations due to their increased technique sensitivity.[4] Techniques classically taught at undergraduate level to rebuild the lost interproximal portion of a tooth involve the use of a circumferential matrix band with a matrix holder (for example, Toffelmire and Siqveland) and a wooden wedge.[5] This is by far the most commonly used technique in UK primary care for the placement of both amalgam and composite restorations.[6] Amalgam is actively placed, in that it must be firmly packed and compacted into the cavity to form the restoration. This packing, alongside the firm placement of a wooden wedge,[7] puts pressure on a pre-burnished matrix, which favours the formation of a contact point (or more accurately, contact area). Creating a contact area between the restored tooth and adjacent tooth is important to prevent food impaction in the area, often being uncomfortable for patients and a common cause for complaint.[6,8] It can also potentially increase the risk of further caries and periodontal disease, though evidence commonly cited to support this contention is cross-sectional and therefore not robust.[9,10]

Composite on the other hand is passively placed, in that there is limited force imparted and maintained during placement before curing (most commonly) with a light. It also shrinks when undergoing polymerisation.[11] This explains the tendency of composites to perform less well than amalgam in terms of contact point creation and prevention of food impaction,[6,7] even with so-called 'packable composites'.[11] The consistency of the composite material can have an effect on contact point formation, however, with paste-like formulations performing better than flowable formulations.[12] When restoring proximal cavities where only one surface is lost, the circumferential matrix band also has to pass through the intact contact point at the other side of the tooth, which will result in tooth displacement, further reducing the chances of achieving a contact area between the resulting restoration and adjacent tooth.[13]

Sectional, pre-contoured (more anatomically shaped) matrices were developed to overcome these problems. They are classically used in combination with a separating ring, which provides separation of the teeth and stabilises the matrix coronally, favouring the formation of a contact area.[13,14,15] Circumferential matrices are tightened around the tooth and are therefore described as being placed actively. This active placement does potentially confer an advantage over sectional matrices, which are passively placed (not tightened), in that it stabilises the matrix, both cervically and coronally, resulting in reduced formation of overhangs, especially bucco-palatally.[16] This is also very useful for teeth which are heavily broken down.[11] Circumferential matrices have many relative disadvantages however, in that it is very difficult to recreate an anatomical emergence[12,15] which makes achieving a contact area difficult.[14,17] They also result in an inferior

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morphological contact with reduced contact tightness.[15,17] Even if a contact is achieved, it is more akin to a single point of contact rather than a broad area and is positioned in a non-anatomical, more coronal position.[18] This then often results in a laterally positioned, unsupported marginal ridge form which is more susceptible to fracture[19] and a flatter emergence form from the embrasure with the potential to catch and shred floss, resulting in a patient complaint. The combination of a higher or non-existent contact point and a flatter, non-anatomical cervical emergence lead to an increased chance of incomplete papilla infill.[20] This leads to dead space (seen as black triangles) below the contact point which can predispose to food impaction, as evidenced by the increased reported food packing when using circumferential compared with sectional matrices for posterior composites in primary care (Fig. 1).[6] The matrix holder also often limits access for wedge placement, which can have an impact on their efficacy (see later).

Recent research suggests that the use of sectional matrices for placing posterior composites where an interproximal surface has been lost is low in the UK,[6] despite the advantages previously described and their use being referred to as a gold standard of care.[5] There is a fairly steep learning curve involved in using sectional matrices however, and they are quite technique-sensitive to place, such that inexperienced operators preferred to use circumferential matrices even when obtaining better clinical outcomes.[14] Sectional matrices are available in different material constructions, opacities, heights, widths, rigidities and emergence profiles (Fig. 2), with a bewildering array of associated equipment, which can make selection difficult for any dentist with limited experience in this area.

While sectional matrix techniques using separating rings can result in the predictable establishment of contact areas,[13,14,15] they have been shown to result in surface concavity in the restoration at the contact area, which is much less of a problem with circumferential matrices.[21] A concavity in the restored surface at the contact area will be inaccessible to cleaning and tend to harbour biofilm and is often not identifiable clinically[21] (Fig. 3). Given that composite materials favour growth of a cariogenic biofilm on their surface,[22] this could potentially result in the initiation and progression of caries in the proximal surface of an unrestored adjacent tooth.

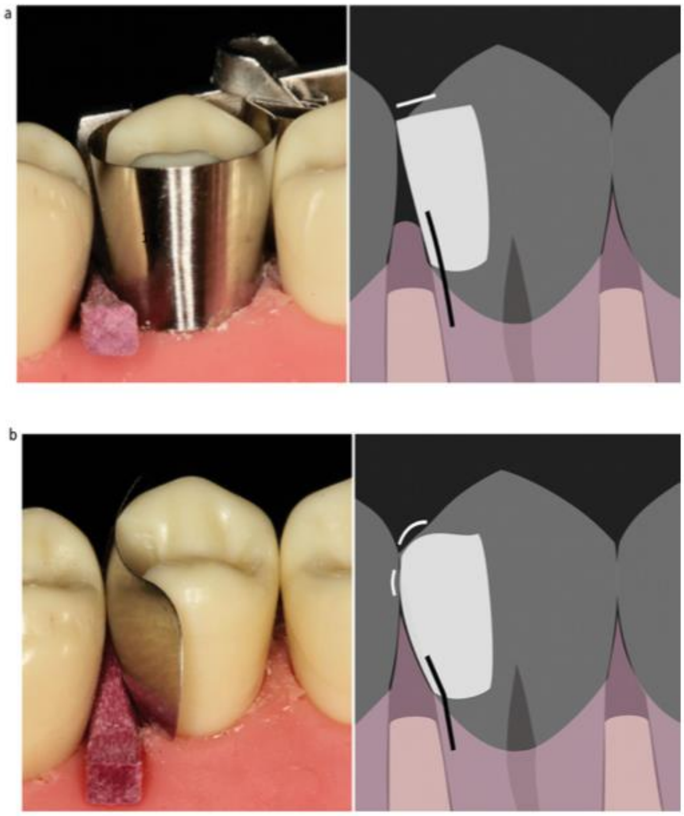

Fig. 1 a) Contact 'point' placed above point of maximum convexity of adjacent tooth if achieved (often not). Marginal ridge laterally positioned (to maintain contact) and therefore thin, unsupported and susceptible to fracture. Embrasure flat resulting in a tendency for floss to catch and shred. Non-anatomical 'flat' cervical emergence coupled with high contact point. Tendency to interproximal dead space allowing food impaction. (Wedge position limited by matrix holder). b) Contact area broader. Marginal ridge anatomically positioned and well supported. Embrasure convex resulting in supported anatomical marginal ridge and allowing easy, unimpeded floss access. Anatomical cervical emergence. Papilla fills interproximal area

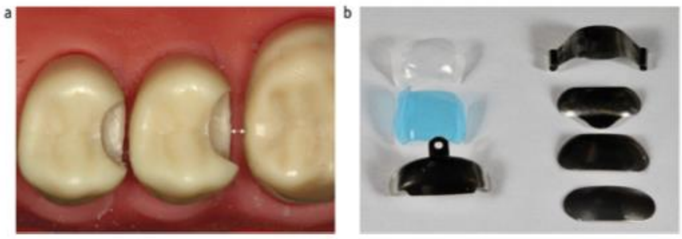

Fig. 2 a) Distance from cavity to adjacent tooth important in matrix selection. b) Flexible matrices on left, more rigid matrices on right, available in a variety of shapes and sizes allowing appropriate selection in each individual situation (see Figure 3)

This paper will explore why this, along with the increased propensity for overhangs occurs and potential solutions to these problems.

Sectional matrix technique

Aim

The aim of a sectional matrix is to produce a cleansable, anatomical restoration with a smooth convex surface, which is continuous with the remaining tooth structure and has a contact area at the level of the maximum convexity of the intact adjacent tooth.

This is achieved by fulfilling the objectives related to sectional matrices summarised in Table 1. These will be explained in turn, before discussing matrix distortion, its possible sequelae and how available materials and techniques can influence this.

Well-adapted matrix in contact with the adjacent tooth

There are a wide variety of sectional matrices available (Fig. 2) and selection of the most appropriate one can influence the resulting marginal overhang, with flexible types performing better than malleable, soft types.[16] Matrix choice will primarily be governed by the shape of the tooth, the shape and depth of the cavity and its proximity to the adjacent tooth (Fig. 2). A matrix should be selected such that it extends beyond the extent of the cavity and can be engaged and stabilised. The maximum convexity of the matrix should be positioned against and in contact with the maximum convexity of the intact adjacent tooth to create an appropriate contact area (Fig. 4). The matrix should be able to be placed passively, unimpeded by contact with the adjacent tooth.

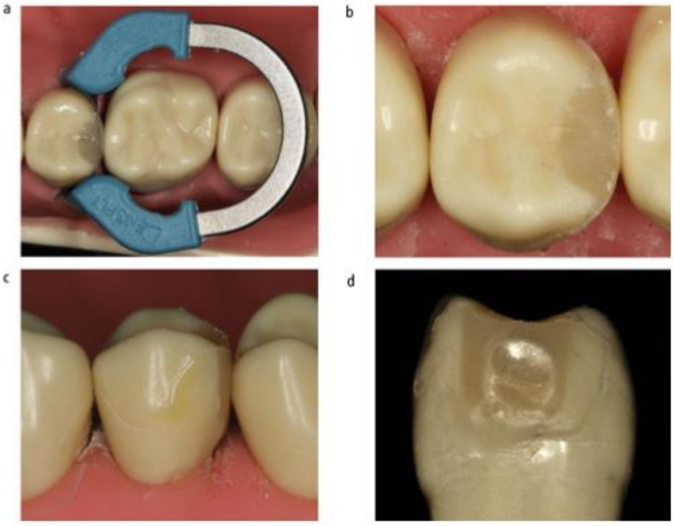

Fig. 3 a, b, c, d) Tooth restored using sectional matrix and separating ring. Very tight contact, with peripheral ledging and concavity at contact area and beyond. Concavity only evident when tooth removed

Table 1 A summary of objectives, methods used to achieve them and how they can be affected, when selecting and placing a sectional matrix

Objective	Methods used/how objective can be affected
A well-adapted matrix in contact with the adjacent tooth at the point of maximum convexity	Affected by cavity design, dimensions and configuration, matrix selection and placement, stabilisation techniques, restorative material placement
Cervical seal and stability	Methods: wooden and plastic wedges, mechanical separators (eg Elliott), adjunctive use of PTFE teflon tape, 'Teflon floss' technique
Separation of the teeth greater than or equal to the width of the matrix used	Methods: wedges, separating ring, Elliott separators
Coronal stability	Methods: separating ring (active), unbonded flowable resin (passive). (Also affected by matrix material, rigidity and shape)
An undistorted matrix	Potentially affected by all of the above

Fig. 4 a) Matrix with insufficient occluso-cervical curvature not contacting adjacent tooth following appropriate wedging. b, c) Matrix with increased occluso-cervical curvature resulting in acceptable positioning of contact (potentially slightly coronal). However, adaptation occlusal to the contact area is sub-optimal, potentially requiring increased finishing. Repositioning the matrix more apically may address these issues. This may require adjustment of the matrix cervically. d, e) Matrix with increased occluso-cervical curvature resulting in good positioning of contact and improved adaptation occlusal to the contact. This is the most appropriate matrix selection from these three matrices in this specific situation. Note however that the increased curvature may lead to increased potential for placement distortion

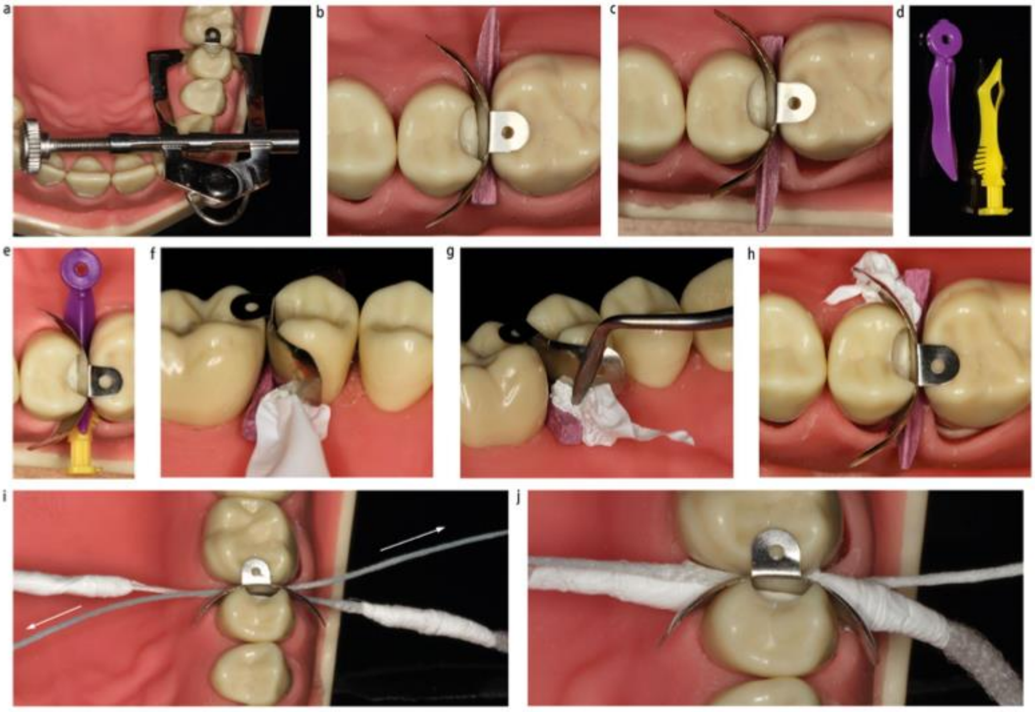

Fig. 5 a) Elliott Separator. b, c) Wedge placement direction affecting cervical seal. d, e) Plastic contoured wedges allowing engagement around cervical curvature and synchronous placement from both sides providing improved cervical adaptation. f, g, h) Packing of PTFE tape to provide cervical seal and stabilization of matrix. i, j) Teflon-floss technique. Teflon-floss pulled simultaneously in directions of arrows creating seal

The mesio-distal matrix curvature and curvature occlusal to the contact area will also affect the marginal adaptation and therefore potential ledge formation in the resulting restoration, which will impact on the need for finishing of the restoration (Fig. 4). Matrices may need to be modified; for example, by trimming them cervically, to optimise adaptation.

Matrix stabilisation and seal – cervical

The matrix has to be stabilised and sealed at the base of the cavity. These elements optimise the adhesive bonding process and prevent ledge formation in the resultant restoration. Once formed, ledges in this area can be difficult to remove. If left, ledges can be difficult to clean, resulting in biofilm accumulation, potentially resulting in secondary caries and periodontal disease.[23] Composite resin and resin adhesives have been shown to support and favour the development of a cariogenic biofilm on their surfaces,[22,24] which could exacerbate the potential for secondary caries in ledged composite restorations.

Wedges are most commonly used for cervical stabilisation of a matrix, though mechanical separators (for example, Elliott) or the 'Teflon-floss' technique may be used as alternatives (Fig. 5).[17,25] Insertion of the wedge from the buccal or palatal can have varying effects on the cervical stability and seal achieved (Fig. 5). Plastic wedges are available in multiple designs, though the majority are contoured and flexible with the aim of engaging around the interproximal curvature (Fig. 5) in an attempt to seal the whole base of the cavity. They also generally have concavities on their undersides, which allow them to sit over the papilla with a low profile[26] and facilitates their insertion from each side of a cavity to further obtain a better cervical seal (Fig. 5). Polytetrafluoroethylene (PTFE) tape can also be applied in conjunction with a wedge to stabilise and seal any open area at the base of a cavity (Fig. 5). The Teflon-floss technique involves winding PTFE tape around two pieces of knotted floss and simultaneously drawing them in from both sides of the matrix, adapting the matrix to the base of the cavity[25] (Fig. 5). This is purported to result in a reduced tendency to break the dental dam seal than when using wedges, which can pick up and drag the dam, opening up gaps. The Elliott Separator is suggested to have a similar advantage, but can be difficult to position and stabilise. Likewise, there is reduced control over the positioning of the Teflon-floss due to its lack of rigidity, which could potentially move the matrix and it may therefore be better used after a separating ring has been placed,[25] which can result in its own issues (discussed later).

Following this process, the matrix should be in contact with the adjacent tooth. If it isn't, a different matrix should be selected with more cervico-occlusal curvature (Fig. 4).

Fig. 6 a, b, c, d, e) Resultant placement distortion of matrix shown

Tooth separation

When placing an interproximal composite with the aim of creating an interproximal contact between the restored and adjacent teeth, the thickness of the matrix is critical to consider. The matrix is removed after placement of the restoration and would therefore result in a gap between the restored tooth and the adjacent tooth, if these teeth aren't separated before placement of the restoration. The teeth can be transitorily moved apart by virtue of the compressibility of their periodontal ligaments before placement, thus allowing the formation of a contact when the matrix is removed.[7] This can be achieved by using wooden wedges, separating rings, or Elliott Separators,[7,13,17] though whether this is the case for the different designs of plastic wedges or the Teflon-floss technique is currently uncertain. Wooden wedges can predictably provide lasting separation of 50 microns,[7] which is sufficient to accommodate most metal matrices available, but some clear matrices are 75 microns thick, therefore separation with a wooden wedge alone would not be recommended.

Matrix stabilisation – coronal

The matrix has to be stabilised coronally. Lack of coronal stabilisation can lead to distortion of the matrix during composite placement.[21] Coronal stabilisation is also important to minimise ledge formation, though this is also affected by the adaptation of the matrix. Coronally located overhangs are much more accessible for finishing than those at the base of the cavity when the cavity is appropriately designed (see later), so they aren't as critical to avoid. Coronal stabilisation can be active, where a force is applied to the matrix using a separating ring, or passive, where the stabilisation is provided without an applied force, through the use of unbonded flowable composite. More rigid matrices have a tendency to self-stabilise to a degree, whereas more flexible ones do not.

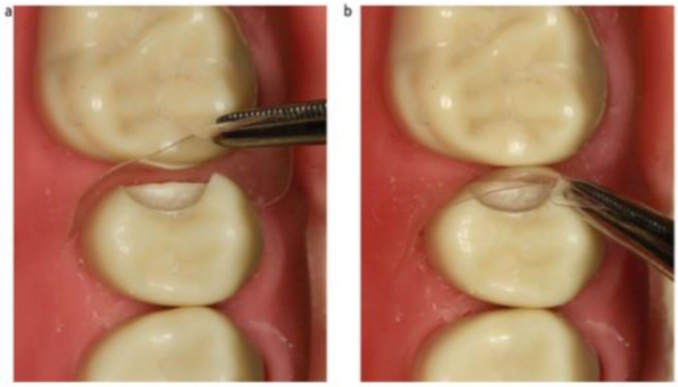

Fig. 7 a) Clear matrix distorted on insertion. b) No permanent deformation when seated

Matrix distortions

When a force is applied to a sectional matrix, distortions can occur. They can arise during placement, separation and (cervical and coronal) stabilisation of the matrix and when placing the restorative material.

Sectional matrix distortions can occur peripherally and/or centrally, with different potential sequelae. Peripheral gaps or distortions commonly result in ledged restorations, or failure to seal the base of the cavity, whereas central distortions often lead to concavities at the contact area (Fig. 3). Distortions can also result in the loss of a contact.

Placement distortion

A cavity design where the proximal contacts are cleared both cervically and bucco-palatally is critical to facilitate passive matrix placement (Fig. 3). This helps to avoid distortion of the matrix during placement (Fig. 6). It also has the added benefits of placing the tooth-restoration interface away from a contact area, allowing access to the margin for optimal finishing of the restoration and subsequent cleaning of the restored tooth, thereby potentially reducing the risk of future caries development. Distortion can also occur around the critical contact area during placement of the matrix, as this is the most bulbous part of the pre-contoured matrix and therefore the part most likely to be distorted by contact with the adjacent tooth during placement (Fig. 7). Distortion of metal matrices during placement is more likely to be permanent than with clear matrices. More curved matrices are also more susceptible to this distortion. This results in an altered matrix shape. Clear matrix distortions are more able to be resolved once positioned, due to their increased elasticity (Fig. 7).

Stabilisation distortion

As the sectional matrix is passively placed and often not stabilised before placing the wedge, it can have a tendency to move. This potentially results in distortion of the matrix

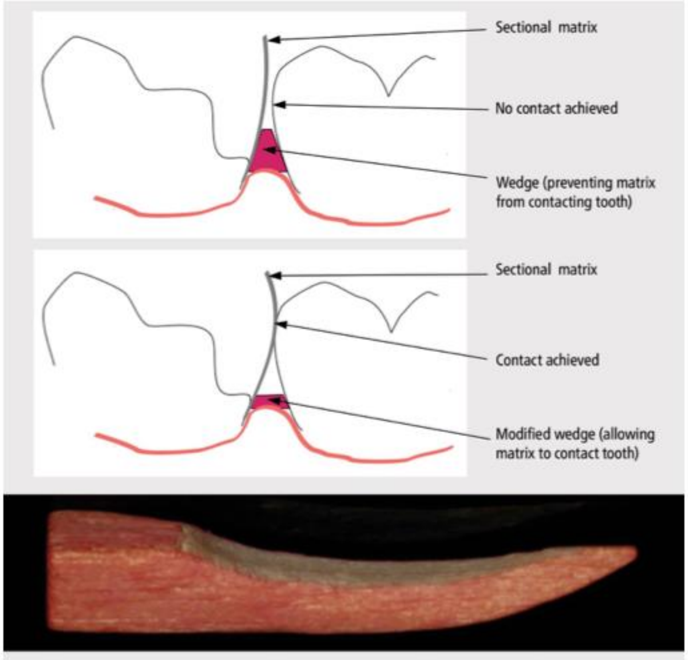

Fig. 8 Importance of wedge modification in facilitating contact area establishment

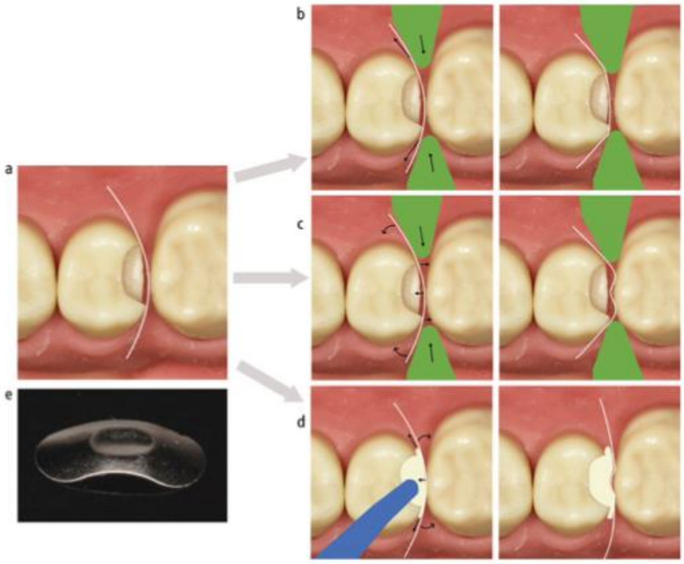

Fig. 9 Mechanisms of distortion. a) Undistorted matrix. b) Coronal stabilisation distortion. Separating ring. Loss of contact. c) Coronal stabilisation distortion. Separating ring. Tenting. Peripheral and central distortion. d) Extrusion distortion. Composite dispensed. Peripheral and central distortion. e) Central matrix distortion

peripherally and/or centrally, or moving the matrix to an incorrect position. Stabilising the matrix from the occlusal with a finger or thumb while placing the wedge can generally overcome this tendency.

It is important to ensure that the wedge is inserted below and subsequently lies below the base of the cavity.[26] Fulfilling these objectives help to obtain a seal and prevent both peripheral and central matrix distortion. Appropriate management of the papillae to achieve this is important where the cavity margin lies sub-gingivally.[26] Wooden wedges may require modification to prevent their protrusion coronally above the base of the cavity (Fig. 8). This process can be performed with a bur and has previously been pictorially demonstrated.[26] When inadequately performed, the wedge can impinge on the matrix, which in turn can prevent the recreation of an anatomical emergence and subsequent formation of a contact area in the resulting restoration (Fig. 8). The Teflon-floss technique is also prone to this distortion because of its own propensity to distort, which offers an advantage in adapting the matrix to the base of the cavity, but a lack of control over positioning (Fig. 5e). Ideally, the wedge would engage the tooth at the level of the cavity margin, preventing the potential for gaps to open up when subsequently applying forces to the matrix, but this is unrealistic and other solutions should be sought to minimise peripheral stabilisation distortion (see later). Wedges are therefore ideally tried in to check their adherence to the achievable goals before insertion of the matrix.

Active coronal stabilisation and separation with a separating ring can result in loss of a contact (Fig. 9) and/or peripheral and/or central distortion, which depends on the type of ring and placement technique, though the rings assessed in these studies are mostly outdated (Fig. 9).[16,21,27] This potential exists with all designs of ring, in the author's experience (Fig. 10). The rings often create persistently tighter contacts than those occurring naturally, quite likely due to this distortion, suggesting the separation obtained is more than required.[13,28] The peripheral and central distortion often results from a tendency of rings to tent the matrix, opening up gaps peripherally and forcing the contacting area against the adjacent tooth causing it to dimple in (Figures 9 and 10). Ultimately, different rings affect different

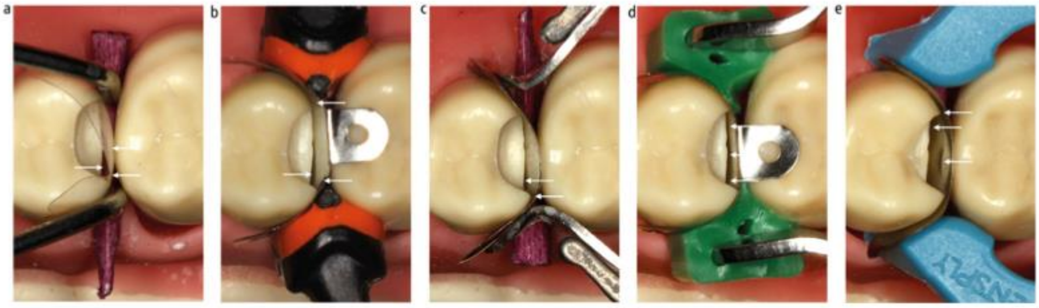

Fig. 10 a, b, c, d, e) Different matrix/wedge/separating ring combinations resulting in various distortions (arrows) at the base of the box, bucco-palatally and in the contact area

matrices in different situations in different ways (Fig. 10), but then even the same ring, with the same matrix in the same situation, will result in different distortions even when placed by the same operator (Fig. 11). Therefore the technique, though it can be effective, has a level of unpredictability. These issues have led to the exploration of other methods to coronally stabilise sectional matrices in a more passive way, such as the use of unbonded flowable composite resin (Fig. 12), which reduces coronal stabilisation distortion.

Extrusion distortion

Distortion can also occur when a matrix is insufficiently stabilised (coronally or cervically), during placement of uncured composite resin which is then able to extrude beyond the confines of a cavity. Pressure is therefore exerted on the moveable periphery of the matrix, potentially changing its shape, leading to peripheral and central distortion (Fig. 9).[21] Anecdotally, flexible matrices are more susceptible to this distortion than rigid designs.

Discussion

Concavities in the restoration at the contact area are often not visible clinically,[21] so they will often not be identifiable after they have occurred. It is therefore critical to assess the matrix in terms of its adherence to the previously discussed objectives before placement of the restorative material.

Though distorted matrices can be burnished in an attempt to re-establish the shape at the contact area, this will always result in an uneven external topography to the resultant restoration if the matrix is made of metal. This may be less of an issue for clear matrices; however, the reason for the distortion (placement versus stabilisation) will impact on the ability for it to be easily resolved. Active stabilisation which results in central distortion cannot be simply resolved by burnishing because of the tenting mechanism of distortion.

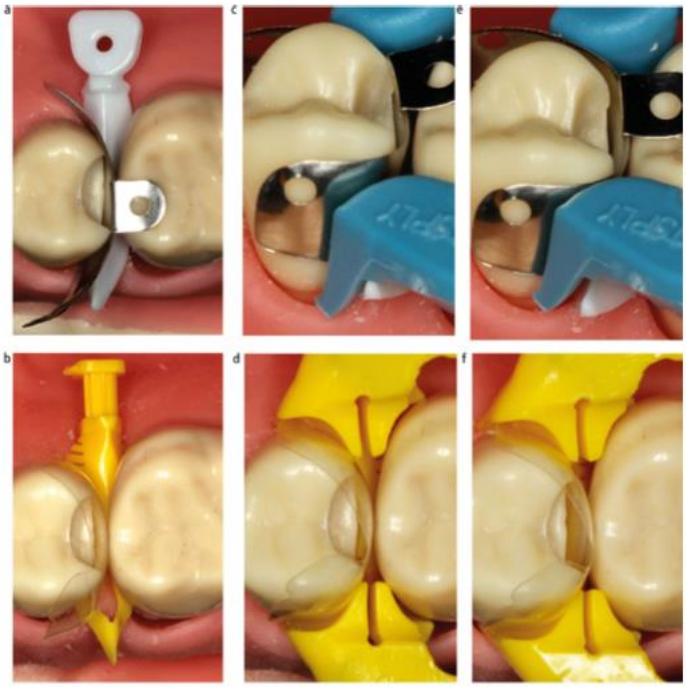

Fig. 11 Stabilisation distortion. a, b) Undistorted, well-positioned matrices. c, d) Separating ring resulting in potential loss of contact. e, f) Same separating ring/matrix/wedge combination resulting in central and/or peripheral distortion

Anecdotally, rigid metal matrices lend themselves to a degree of self-stabilisation coronally, which facilitates their use without a separating ring in many situations. When a ring is not used, separation with a firmly placed wooden wedge or mechanical separator is required. While plastic wedges and the

Fig. 12 a, b, c, d, e, f) Rigid metal matrix separation and cervical stabilisation wooden wedge. Passive coronal stabilisation unbonded flowable composite. Good contact location and smooth convex surface to restoration at contact area. Minimal bucco-palatal excess accessible for finishing. g) Appropriate cavity design with all contact areas cleared. h) Wooden wedge providing apical stabilisation and separation. Rigid metal matrix and flowable resin providing passive coronal stabilisation. i, j) Good contact area, cervical and occlusal emergence achieved. Panels g, h, i and j courtesy of Christopher O'Connor

Teflon-floss technique could potentially provide improved cervical adaptation in comparison with wooden wedges, their ability to separate teeth is currently uncertain. Although stiff matrices can have an element of coronal self-stabilisation, it is prudent to further stabilise the matrix with unbonded flowable composite (Fig. 12). This passive coronal stabilisation, allied with the minimised potential for extrusion distortion, likely increases the chances of obtaining an undistorted matrix. When an appropriately shaped matrix is chosen, this potentially results in an optimal cervical emergence and occlusal emergence out of the contact. There is also a smooth convex contact area in the resulting restoration with minimal ledging, accessible to finishing (Fig. 12). Flexible sectional matrices (≤50 microns thick) can also be stabilised coronally with this technique and can be used in larger cavities where walls are missing. It can however be technically more challenging to stabilise these matrices in the desired position. They often benefit from cervical stabilisation and sealing with PTFE tape following application of the wooden wedge, before coronal stabilisation with flowable composite. Further research to formally assess these issues would be beneficial.

Conclusion

Sectional matrices are superior to circumferential matrices in terms of their ability to recreate lost interproximal walls in a seemingly more anatomical way. This has many potential patient-centred benefits, including the more predictable formation of contact areas which result in reduced reported food packing. It is apparent, however, that the achievement of a contact area could well be a Pyrrhic victory, if a clinically undetectable, inaccessible concavity in the restoration results in caries in the adjacent tooth.

Armed with an understanding of appropriate cavity design, where all contact areas are cleared, and the intricacies, advantages and limitations which exist for all of the various sectional matrices, methods of placement, stabilisation and separation are available, the practitioner can adopt a flexible approach. This will help to avoid many of the pitfalls associated with sectional matrix systems. Sectional matrices are susceptible to distortion at various stages in the restorative process. The practitioner should be aware of these issues to minimise their occurrence and to identify and address them before restoration placement, should they occur.

This will engender confidence in obtaining predictable, anatomical contact areas resulting in improved patient-centred outcomes when restoring posterior interproximal cavities with direct composite.

Ethics declaration

The author declares no conflicts of interest.

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Correction to: Honours, awards, appointments

The original article can be found online at https://doi.org/10.1038/s41415-021-3538-2.

Journal's correction note:

News article *Br Dent J* 2021; **231:** 373.

When this article was originally published, the affiliation for Nabeel Ilyas was incorrectly listed as 'ST1 Paediatric Dentistry, King's College NHS Trust' and should have read 'ST3 Paediatric Dentistry, King's College NHS Trust'.

The journal apologises for any inconvenience caused.

Research Reports: Clinical

Public Valuation of Direct Restorations: A Discrete Choice Experiment

Journal of Dental Research
1–8

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Abstract

Direct posterior dental restorations are commonly provided following management of dental caries. Amalgam use has been phased down and the feasibility of a phase-out by 2030 is being explored. Alternative direct restorative materials differ in their outcomes and provision. This research aimed to elicit the UK population's preferences for different attributes of restorations and their willingness to pay (WTP) for restorative services and outcomes. A discrete choice experiment (DCE) was designed with patient and public involvement and distributed to a representative sample of the UK general population using an online survey. Respondents answered 17 choice tasks between pairs of scenarios that varied in levels of 7 attributes (wait for filling, clinician type, filling color, length of procedure, likely discomfort after filling, average life span of filling, and cost). An opt-out (no treatment) was included. Mixed logit models were used for data analysis. Marginal WTP for attribute levels and relative attribute importance were calculated. In total, 1,002 respondents completed the DCE. Overall, respondents were willing to pay £39.52 to reduce a 6-wk wait for treatment to 2 wk, £13.55 to have treatment by a dentist rather than a therapist, £41.66 to change filling color from silvery/gray to white, £0.27 per minute of reduced treatment time, £116.52 to move from persistent to no postoperative pain, and £5.44 per year of increased restoration longevity. Ability to pay affected willingness to pay, with low-income respondents more likely to opt out of treatment and value restoration color (white) and increased longevity significantly lower than those with higher income. Clinicians should understand potential drivers of restoration choice, so they can be discussed with individual patients to obtain consent. It is important that policy makers consider general population preferences for restorative outcomes and services, with an awareness of how income affects these, when considering the potential phase-out of amalgam restorations.

Keywords: dental caries, operative dentistry, dental economics, patient preference, healthcare policy, health services research

Introduction

Direct restorations are frequently placed following the operative management of dental caries. Worldwide, more than 1.1billion direct restorations were placed in 2015 (S. Heintze, personal communication, 2022) and amalgam has long been an effective, low-cost material (Norwegian Climate and Pollution Agency 2012). An amalgam phase-down has been implemented (Regulation (EU) 2017/852 2017) following a global convention (Minamata Convention on Mercury 2013), and the feasibility of a complete phase-out by 2030 is currently being assessed. The World Health Organization has stated that "systematic studies on the economic and social costs and benefits of quality mercury-free materials have not yet been published" (Fisher et al. 2018). Understanding these social costs and benefits in relation to existing materials is critical when planning patient-centered service provision (Listl et al. 2022).

English National Health Service primary care expenditure on amalgam in permanent teeth was crudely estimated at £200 to £300 million in 2015–2016 (C. Vernazza and K. Carr, personal communication, 2018). A 2019 survey of UK clinicians indicated that amalgam remains the most used material in permanent molars, with only 6.7% respondents using no amalgam. Clinicians took longer to place composite compared to amalgam, charged more, reported an increased incidence of postoperative complications, and were much less confident placing composite in difficult situations (Bailey et al. 2022a, 2022b). Systematic reviews indicate the superior longevity of amalgam restorations in permanent posterior teeth compared to composite (Khangura et al. 2018; Worthington et al. 2021).

Economic valuation of restorative dental care commonly focuses on a single outcome, such as the life span of a restoration or tooth (Smales and Hawthorne 1996; Tobi et al. 1999; Khangura et al. 2018; Schwendicke et al. 2018). Patient or public valuation of the importance of these parameters is not commonly sought (Listl et al. 2022), and other important factors are often not considered, including the aesthetic outcome,

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A supplemental appendix to this article is available online.

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process of care considerations (e.g., how long the treatment would take), or out-of-pocket monetary costs.

Stated preference techniques are used to elicit preferences where consumer/patient behavior in the real world cannot be relied upon to provide an accurate representation of preferences. This lack of reliability is inevitable where imperfect free-market economies exist, as is commonly the case in health care. Discrete choice experiments (DCEs) are a stated preference technique based on assumptions, underpinned by economic theory (Lancaster 1966) and random utility theory (McFadden 1973), that health care services can be described by their characteristics (attributes) and that individuals value services depending on the levels of these attributes (Ryan 2004). DCEs are well established in valuing health interventions (Clark et al. 2014) but have been sparsely used in dentistry (Barber et al. 2018). Although the inclusion of cost attributes in valuing health care is perhaps controversial (Bryan and Dolan 2004), their use in dentistry is less so as the public is often used to paying for dental treatment (Boyers et al. 2021). After relevant attributes are determined, a hypothetical survey is carried out where respondents make choices between a series of pairs of alternatives with different levels of the relevant attributes. This allows the relative importance of the levels of the attributes to be estimated, alongside marginal willingness to pay (mWTP) values for each attribute level (where a cost attribute is included).

A previous DCE looked at the importance of restoration longevity, color, and adverse outcomes to young patients and dental professionals (Espelid et al. 2006). However, the results had limited scope to inform policy given the framing and sampling of the survey, which was confined to specific groups in Norway and Denmark. In addition, no cost attribute was included, meaning mWTP values could not be calculated.

The aim of this study was therefore to understand the UK general public's preferences for directly placed restorations in posterior permanent teeth. The objectives were to quantify 1) mWTP values for the differing levels of the attributes, 2) the relative attribute importance (RAI), and 3) any differences in these based on income subgroups.

Method

The study was carried out and reported in accordance with available guidance (Bridges et al. 2011; Johnson et al. 2013; Hauber et al. 2016; Staniszewska et al. 2017). A favorable ethical opinion was obtained from Newcastle University Research Ethics Committee (2320/2020).

Attribute and Level Selection

A scoping literature review revealed 1 previous DCE valuing aspects of posterior dental restorations (Espelid et al. 2006). It was of limited use in designing this DCE due to the framing and attribute selection. Patient and public involvement (PPI) guided attribute and level selection through an online focus group (Coast et al. 2012) (participants recruited through VOICE [www.voice-global.org]). A short contingent valuation exercise using an online bidding game was undertaken with the focus group participants to inform cost attribute levels. This was used alongside recent cross-sectional data from UK dentists and therapists (Bailey et al. 2022a), the clinical evidence base (Khangura et al. 2018), and research group discussions, which included expert opinion from dental specialists to determine relevant attributes and levels for inclusion in the survey. This ensured that the attributes and levels were clinically meaningful and relevant to the general public and policymakers. Initial attribute levels were modified following piloting, resulting in the following attributes and levels:

Waiting time for filling: 0, 2, 4, 6 wk
Clinician type: dentist, dental therapist
Filling color: white, silvery-gray
Length of filling procedure: 20, 40, 60, 80 min
Likely discomfort after filling: none, mild, moderate, persistent
Average life span of filling: 5, 8, 11, 14 y
Cost: £15, £25, £35, £45, £60, £90, £150, £250
The attributes and their levels were defined in the survey (Appendix Questionnaire).

Experimental Design

There were 8,192 potential combinations of attribute levels, with none deemed totally implausible, and over 33 million choice sets. A fractional factorial D-optimal design was created using Ngene software (ChoiceMetrics). Based on a main effects full-profile approach, 64 choice questions were selected and split into 4 blocks of 16 questions (1 block only per respondent) (Bech et al. 2011). The model selection software was run overnight and the last 3 designs checked for within-block-level balance and appraised by their Pearson product moments to select the most appropriate design (Ngene design code, Appendix Fig. 1). Each choice question included 2 different treatment options and an opt-out (no treatment) to increase task realism. An example choice task is shown (Fig. 1). A repeated choice task was added to assess respondent consistency. A task in each block was selected where 1 choice appeared dominant (in that the levels were deemed better in all attributes), or close to dominant, to assess respondent rationality. Those failing the tests were not excluded from analysis based on expert guidance (Lancsar and Louviere 2006).

Questionnaire Design

A cross-sectional online survey was developed (Appendix Questionnaire). The survey briefly explained the study and its purpose before confirming consent to participate. Demographic information and respondents' experience of restorations were included, alongside the Modified Dental Anxiety Scale (Humphris et al. 1995). The survey also asked about attitudes toward restorative treatment and their perceived future need. It then explained the choice questions before presenting 17 choice tasks, alongside explanatory information. Piloting and think-aloud techniques (Coast et al. 2012) were used with dental and economic experts and the general public to assess the survey design, alongside a usability assessment with mobile devices.

Sample

Sample size calculations for DCEs are imprecise (Bridges et al. 2011; Johnson et al. 2013). Guidance suggests a minimum subgroup sample size of 200 (Bridges et al. 2011). Therefore, to achieve sufficiently sized income subgroups, a sample size of 1,000 was deemed appropriate (Office for National Statistics [ONS] 2021). The DCE was distributed by Dynata using the FocusVision Decipher platform and their in-house sampling software to a representative online panel sample of the adult UK population based on population census data to obtain quotas on gender, age, and geographical region. Respondents received a small financial incentive for completing the survey. The data were electronically captured by Dynata in May/June 2021.

5	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Moderate	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£15	£250	£0
Your choice **(tick one box only)**	☐	☐	☐

Figure 1. Example choice task.

Data Analysis

Data were analyzed using Stata software (version 17; StataCorp LP). Collinearity was assessed using variance inflation factors. Categorical variables were effects coded, and potentially continuous variables (waiting time, length of procedure, life span, and cost) were also explored categorically to assess assumptions of linearity using a conditional logit model. The utility function is shown and explained in Appendix Figure 2. Reference levels and their confidence intervals were calculated using the Delta method (Wooldridge 2002). Subgroups were defined as low (≤£20,000) or higher gross household income. Mixed logit models (McFadden and Train 2000) were explored with parameters modeled as fixed or random to assess intrasample preference heterogeneity and potentially continuous variables modeled as continuous or categorical where assumptions of linearity were questionable. Backward stepwise regressions were then carried out, changing the variable modeled as random with the highest standard deviation (SD) *P* value to nonrandom. Models were selected by highest log-likelihood. RAI and mWTP values were calculated (Mühlbacher and Johnson 2016).

Results

In total, 1,002 respondents completed the survey. Internal validity was good, with 83% passing the consistency test and 91% passing the dominance test. Only 2% of respondents chose the opt-out for every question, and 1% always chose the same treatment option.

Demographic, dental experience, and attitudinal data are shown in Table 1. The sample shows similar proportions to the UK population in terms of gender, age, index of multiple deprivation (describing socioeconomic deprivation), and geographical location (ONS 2016). Comparison of reported gross household income with UK general population data is difficult because of available data presentation (decile means) (ONS 2021), but there is a broadly similar distribution of income. Based on 2009 Adult Dental Health Survey (ADHS 2009) data, the sample is representative of those with experience of a filling (85%), but edentulous respondents are slightly underrepresented.

Assumptions of linearity in the potentially continuous attributes were explored (Appendix Figs. 3–6). Model exploration resulted in a best-fit mixed logit specification with all parameters random and potentially continuous variables modeled continuously and linearly except waiting time, which was modeled categorically.

The results of the choice analysis are shown in Table 2 and Appendix Figure 7. The mean β values express the strength of respondent preferences relative to the mean, which is zero for categorical variables, and the strength of preference per unit change for continuous variables. All attributes exhibited some preference heterogeneity, as shown by significant SD *P* values, with the exception of clinician type. Overall, respondents were willing to pay £39.52 to reduce a 6-wk wait for treatment to 2 wk, £13.55 to have treatment by a dentist rather than a therapist, £41.66 to change filling color from silvery/gray to white, £0.27 per minute of reduced treatment time, £116.52 to move from persistent to no postoperative pain, and £5.44 per year of increased restoration longevity. An example of how the mWTP

Table 1. Demographic, Dental Experience, and Attitudinal Data of Respondents Including Income Subgroups.

Characteristic	Sample (*n* = 1,002)	Low Income (*n* = 221)	Higher Income (*n* = 727)
Age, mean (SD), y	48 (16)	49 (18)	47 (16)
Gender			
Female	50	57	48
Male	49	41	52
Other	<1	1	<1
PNTS	<1	0	<1
Residence			
England	81	80	82
Wales	5	8	4
Scotland	8	7	8
Northern Ireland	6	6	6
Index of multiple deprivation (deciles) (n = 986)			
1	11	16	9
2	10	15	9
3	10	7	11
4	10	14	9
5	9	12	8
6	11	10	11
7	11	11	11
8	10	5	11
9	9	6	10
10	10	4	11
Annual gross household income			
<£10,000	7	30	0
£10,000–£19,999	15	70	0
£20,000–£29,999	18	0	25
£30,000–£39,999	16	0	22
£40,000–£49,999	11	0	15
£50,000–£59,999	7	0	9
£60,000–£69,999	6	0	8
£70,000–£79,999	4	0	6
£80,000–£89,999	2	0	3
£90,000–£99,999	3	0	4
>£100,000	5	0	7
PNTS	5	0	0
Working status			
Employed (full-time or part-time)	56	32	65
Self-employed	7	6	6
Unemployed	5	12	2
Retired	22	29	19
Looking after home/family	4	6	3
Student	4	7	3
Other	3	7	1
Educational attainment (highest)			
Postgraduate degree	13	7	15
Undergraduate degree	25	20	28
A/AS level/Vocational A/AS level or equivalent	30	28	31
GCSE/Vocational GCSE/O level or equivalent	24	35	21
Lower than GCSE or equivalent level	7	11	5
Own natural teeth			
Yes	98	97	99
Filling in back tooth			
Yes	85	82	86
Silver (amalgam filling)			
Yes	79	78	79
White filling			
Yes	57	49	60
Environmental concern over filling materials (*n* = 911)			
Low	46	48	45
Medium	45	46	45
High	10	7	11

(continued)

Table 1. (continued)

Characteristic	Sample (*n* = 1,002)	Low Income (*n* = 221)	Higher Income (*n* = 727)
How at risk of needing a filling in future			
Low	29	29	28
Medium	51	51	52
High	20	20	20
Keeping my teeth is			
Important	87	87	87
Neither important nor unimportant	11	11	12
Unimportant	1	2	1
Highly anxious (Modified Dental Anxiety Scale)	26	28	25
Dental care provision			
NHS (pay)	52	50	53
NHS (exempt)	14	26	10
Insurance based	12	7	14
Private	16	12	17
Mixed NHS and private	6	5	6

Values are presented as percentages unless otherwise indicated.
GCSE, General Certificate of Secondary Education; NHS, National Health Service; PNTS, prefer not to say; SD, standard deviation.

Table 2. Mixed Logit Model Results Showing Main Effects Preferences and Willingness to Pay for Restoration Attributes.

		β Coefficient		mWTP (£)	
Attribute	Level	Mean	SD	Mean	95% CI
Waiting time for filling (wk)	0[a]	−0.020	—	−2.33	−11.90 to 7.24
	2	0.167*	0.004	19.40	8.52 to 30.28
	4	0.026	0.180*	3.05	−7.87 to 13.98
	6	−0.173*	0.004	−20.12	−32.17 to −8.08
Clinician	Dentist[a]	0.058*	—	6.77	−9.37 to −4.18
	Therapist	−0.058*	0.036	−6.77	4.18 to 9.37
Color	Silvery gray[a]	−0.179*	—	−20.83	−24.69 to 16.97
	White	0.179*	0.336*	20.83	16.97 to 24.69
Treatment time[b]	Per minute	−0.002*	0.000	−0.27	−0.40 to −0.15
Likely discomfort	None[a]	0.400*	—	46.46	38.89 to 54.04
	Mild	0.374*	0.030	43.36	36.99 to 49.74
	Moderate	−0.170*	0.0111	−19.78	−25.52 to −14.03
	Persistent	−0.603*	0.735*	−70.05	−79.70 to −60.40
Average life span[b]	Per year	0.047*	0.037*	5.44	4.49 to 6.38
Cost[b]	Per pound	−0.009*	0.010*	—	—
ASC	Treatment	4.257*	3.319*	494.26	421.63 to 566.89
	No treatment[a]	−4.257*	—	−494.26	−566.89 to −421.63

mWTP = −(β attribute[b] or level/β cost); mWTP estimates are interpreted as the UK general population's mean valuation of attributes and levels. Differences between mWTP values indicate how much the UK general population values moving from one level to another, or for a change of 1 unit.[b] Therefore, moving from a waiting time of 0 wk to 2 wk would be valued = (19.40) − (−2.33) = £21.73; moving from a treatment time of 30 min to 20 min would be valued (20 × −0.27) − (30 × −0.27) = £2.70. Respondents = 1,002; observations = 48,096; log-likelihood = −9,948.44; Akaike information criterion = 19,920.89; Bayesian information criterion = 20,026.26.
ASC, alternative specific constant; CI, confidence interval; mWTP, marginal willingness to pay; SD, standard deviation.
[a]Categorical reference level (in effects coded model).
[b]Continuously modeled attribute.
*$P \leq 0.001$.

values could be used to comparatively value different restorations with different attribute levels is shown in Table 3.

Subgroup analysis based on income (Appendix Table 1) showed that on average, higher-income respondents value restoration longevity more than double (mWTP difference of £3.25/y) and a white restoration almost 3 times more than those with low income (mWTP difference of £16.25), and these differences were statistically significant. Higher-income respondents were, on average, willing to pay more to have treatment by a dentist rather than a therapist, to avoid postoperative discomfort and to avoid a 6-wk wait for a filling, although these differences were not statistically significant.

Table 3. Marginal Willingness to Pay for 2 Hypothetical Dental Restorations with Different Attribute Levels and Between Income Subgroups.

	Restoration 1 (composite, dentist)				Restoration 2 (amalgam, therapist)			
		mWTP (£)				mWTP (£)		
Attribute	Level	Full Sample	Low Income	Higher Income	Level	Full Sample	Low Income	Higher Income
Wait	4 wk	3.05	−3.52	3.95	2 wk	19.40	22.51	18.24
Clinician	Dentist	6.77	5.15	7.39	Therapist	−6.77	−5.15	−7.39
Color	White	20.83	8.90	25.15	Silvery gray	−20.83	−8.90	−25.15
Treatment time	34 min	−9.32	−10.98	−8.30	24 min	−6.56	−7.75	−5.86
Discomfort	Moderate	−19.78	−14.91	−21.46	Mild	43.36	34.27	46.89
Life span	7.98 y	43.39	24.77	50.71	11.05 y	60.09	34.30	70.21
Total		44.94	9.41	57.44		88.69	69.28	96.94

The mWTP values for attribute levels of any given restoration can be added to estimate its mean marginal value to the UK population. This allows calculation of WTP differences between restorations with different attribute levels (as shown here), which can then be used in economic evaluations. Treatment opt-in values were as follows: full sample, £539.20; low income, £324.74; higher income, £562.95.
mWTP, marginal willingness to pay.

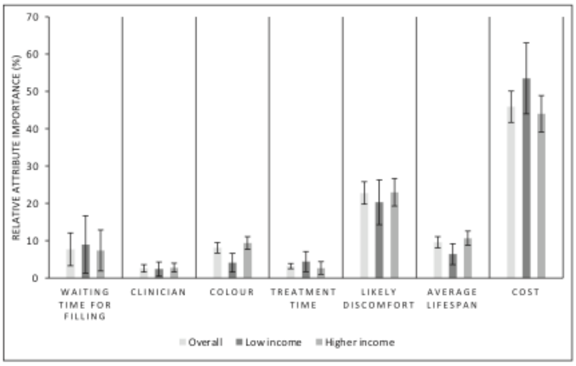

Figure 2. Restoration relative attribute importance: overall UK population and by income.

On average, low-income respondents valued shorter treatment times, willing to pay a third more per minute avoided, and also had a higher mean WTP for a 2-wk wait for a filling alongside lower mean WTP values for 0- or 4-wk waits than higher-income respondents, although these differences were not statistically significant.

The alternative specific constant (ASC) was large and positive, indicating that respondents much preferred treatment to no treatment, and ASC mWTP was significantly higher for the higher-income than the low-income group.

RAI is presented in Figure 2, based on Appendix Table 2, which shows the proportionate valuation of each restoration attribute based on the range of valuation of levels within each attribute. This showed that cost is the most important attribute for the general public when selecting a posterior dental restoration, being 2.0 times more important than the next most important attribute, which was likely discomfort after the filling. Discomfort, in turn, was 2.4 times more important than average life span, with color and waiting time next most important, but these 3 attributes were not statistically significantly different from each other. Treatment time and clinician type, which again were not statistically significantly different from one another, were the least important attributes. When analyzed by income groups, RAI changed, resulting in different ordering in the importance of life span, color, waiting time, treatment time, and clinician, but with only color statistically significantly different between groups.

Discussion

This DCE is the first to explore general population preferences for direct posterior dental restorations. Overall, all attributes were valued by the respondents, and the valuation of the levels within each attribute was generally as expected (i.e., increased restoration longevity resulted in higher valuations). This shows that respondents were trading across all included attributes and were able to discriminate between the levels presented in the choice tasks, providing justification for the design and confidence in the results.

The mWTP values obtained can be used to value different direct posterior restorations, which have attribute levels included in the DCE, as shown in Table 3, which in turn can be used to broaden the scope of economic evaluations, especially when used to value the interventions in cost-benefit analyses. Nearly all previous economic evaluations of posterior restorations focus on restoration or tooth longevity as the primary outcome measure. This is far from being the most important attribute when judged by the general public, with cost and likely discomfort after filling having much higher RAI. Longevity also has a markedly lower RAI in the low-income group. This suggests that these previous economic analyses are excessively narrow in their scope. Valuing restorations by adding mWTP estimates of their attributes takes a broader, patient-centered approach. It also shows how preferences differ with income. This information is critical for policy-makers to consider when redesigning restorative dental services, which is pertinent given the recent move toward amalgam phase-down. This article highlights the potential for health economics to move beyond limited cost-effectiveness analyses, by combining innovative approaches and considering multiple perspectives to address complex decision problems in oral health and care (Listl et al. 2019; Listl et al. 2022).

Respondents valued treatment over no treatment, although differences existed in income groups, as they did in attribute levels. Compared to higher-income respondents, restoration longevity was of much lower importance to low-income respondents, although waiting time and treatment time were of higher importance, with increased mWTP values. This could be due to a reduced willingness to wait, or to sacrifice time in the short term with an increased discounting of future benefits. This in turn could be caused by a wish to minimize time off work and a reduced ability to pay, or simply a preference for short-term versus long-term benefits. Likewise, restoration color was much less important to the low-income group, which suggests they value appearance less. Despite these data on sample means, significant variation exists between individuals within the sample and within the subgroups in all attributes except clinician type.

Respondents favored shorter waiting times, with an optimal wait of 2 wk, but did not discriminate hugely between waiting times of 4 wk and under. There was a significant drop in valuation for a 6-wk wait, however, which was more marked in the low-income group, which has implications when planning dental service provision. Given the increased time taken and cost to place composite restorations and their reduced longevity compared to amalgam (Bailey et al. 2022a; Khangura et al. 2018), the amalgam phase-down and potential phase-out will likely mean that clinicians will have more restorative work to do. This potentially means increased waiting times to access care with current workforce levels (Bailey et al. 2022b). These issues potentially affect those of low income by limiting the service characteristics that they desire and could reduce their access to and uptake of care. This is countered by the higher value placed on having a white compared to a silvery-gray filling. This value was significantly reduced, however, in the low-income group. An amalgam phase-out therefore potentially risks exacerbating already existing socioeconomic disparities in oral health (Steele et al. 2015), but an economic evaluation is required to better understand the potential impacts.

The general public prefers to have their restorations placed by dentists rather than therapists. It is important to consider if the preference (valued as the difference in mWTP) is offset by the increased cost associated with the dentist performing the filling and the other patient-centered outcomes obtained by differing clinician types (which may not be the same; Bailey et al. 2022a). Care responsibilities within the dental team, policy decisions, and workforce planning can then be considered rationally, weighing up costs and benefits of alternatives to optimize the use of scarce resources across a diverse population (Listl et al. 2019).

Preferences for attributes of a posterior direct restoration differ between patients and clinicians (Espelid et al. 2006), and this research shows that interindividual preferences vary in the UK general population. Clinicians should therefore not make assumptions about what individual patients value. The attributes assessed were all of importance to the general public in aggregate. How they vary between the available direct posterior restorative options should therefore be discussed with individual patients when obtaining consent.

Ability to pay often affects willingness to pay (Tan et al. 2017), which was again replicated in this study. It is therefore important to consider how this might affect choices among those with low income when making policy decisions. Although this sample was generally representative of the UK general population on many levels, there was a higher proportion of highly anxious respondents, which could have affected the results. There are also potential confounding factors in splitting the sample, as educational attainment, for example, also varies between subgroups. Respondents' previous dental experiences and potential varied interpretation of no treatment as delaying care could affect the results, as could the absence of "unknown" options when asking for descriptive data.

Hypothetical bias was mitigated against by using PPI in the development and design stages. Where respondents have experience of the treatments being valued, as the vast majority did in this study, it is also likely to be minimized. There are, however, limited numbers of studies investigating the ability of stated preference techniques to predict revealed preferences in dentistry, with equivocal results (Vernazza et al. 2015).

Conclusions

The UK general population values direct posterior restorations highly, placing importance on a variety of restoration attributes beyond longevity. These include process of care, such as waiting time for a filling and treatment time, as well as aesthetics, the care provider, postoperative complications, and, most important, cost. Clinicians should understand potential drivers of restoration choice, so they can be discussed with individual patients to obtain consent. When contemplating the potential phase-out of amalgam restorations, policy-makers should consider general population preferences for services and outcomes, with an awareness that income affects these.

Author Contributions

O. Bailey, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; S. Stone, contributed to conception, design, and data interpretation, critically revised the manuscript; L. Ternent, contributed to conception, design, data analysis, and interpretation, critically revised the manuscript; C.R. Vernazza, contributed to conception, design, data acquisition, and interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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Expert review

The long-term oral health consequences of an amalgam phase-out

Oliver Bailey[1]

Key points

Phasing out amalgam presents complex challenges due to its cost-effectiveness and quicker and simpler placement compared to composite, which requires more technical skill and time-consuming expensive equipment to place predictably and effectively.

The NHS remuneration system, which favours amalgam use by providing significantly lower fees compared to the rest of Europe, is likely contributing to a failure of dentists to upskill or use recommended time-consuming and expensive equipment, which would allow them to place composite restorations safely.

Dentists are leaving the NHS, creating access issues, which disproportionately affects those most at need in society while widening existing oral health inequalities and this would likely be exacerbated by an amalgam phase-out.

Abstract

Understanding the long-term oral health implications of an amalgam phase-out is complex. However, amalgam is a simpler, cheaper, quicker, more predictable and effective material to place and replace than composite, which is the main alternative. It also has fewer postoperative complications in United Kingdom (UK) primary care and has been shown to be more cost-effective over a lifetime. Existing economic evaluations are limited, however, with rudimentary models which fail to consider clinicians and patients, and likely significantly underestimate the broader costs of placing composite compared to amalgam. Amalgam alternatives require improvement and their environmental impacts require characterisation. Composite restorations can be successful in extensive cavities, but they require much technical skill and expensive and time-consuming specialised equipment, which are not being commonly used in UK primary care, especially by National Health Service (NHS) dentists. Postgraduate composite education is not generally making UK clinicians confident when faced with difficult cavities and requires improvement. Expert consensus on the use of techniques to restore varying cavity presentations with composite would help to guide this, while also considering how its dissemination could be improved. NHS clinician fees are significantly lower than in Europe. The NHS system therefore essentially incentives the use of amalgam and disincentivises the use of expensive and time-consuming recommended equipment for composite restorations. This has likely contributed to a failure of clinicians to upskill and be confident in providing posterior composite restorations safely. These issues, alongside a loss of trust, have led to dentists leaving the NHS, which has created access issues for patients, disproportionately affecting the most at need in society. An amalgam phase-out would almost certainly exacerbate this issue, widening existing health inequalities while not providing restoration characteristics which the most affected patients most value. Failure to urgently address these issues risks an oral health crisis in the UK if amalgam is imminently phased out.

Introduction

Amalgam use has been phased-down and will be phased-out in the European Union (EU) in 2025.[1] The United Kingdom (UK) is assessing the feasibility of a complete phase-out by 2030 following the 2017 phase-down.[2] This is based on the Minamata Convention on Mercury, which is a global treaty designed to protect the environment and human health by limiting the use of mercury.[3] Most countries in the EU either already have an amalgam ban, or use relatively small numbers of amalgam restorations.[4] The UK is different in that, especially under National Health Service (NHS) provision, posterior teeth are much more commonly restored with amalgam.[5,6,7] NHS dental care is publicly funded but with co-payments for many.

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Alternatives

Composite resin was described as the only reasonable alternative to amalgam in the proposed timeframe for the phase-down and phase-out of amalgam.[8] A more recent World Dental Federation (FDI)-approved review reported recent evidence to suggest that glass ionomer cements (GICs) and their derivatives may be valid alternatives for small cavities, though follow-up is limited.[9] The review focused on direct composite, however, and concluded that there is no single material which can replace amalgam in all applications. It also noted that amalgam is favoured in health systems with limited resources due to the higher costs of the alternatives. The review's discussion centred on difficult situations. These included restoring teeth where cavity margins are deep sub-gingival, caries risk is high (for example, in the older person and those of low socioeconomic status) and cooperation is limited, as seen in patients with disabilities. The review also noted the need to improve the alternative materials' properties and demonstrate their clinical performance, especially in 'real-world settings and for special risk groups'. Indirect restorations will be briefly discussed later.

Direct restoration survival

Restoration survival is hugely complex and multifactorial, and the material used, though often important, is just one of many relevant factors. In a recent review investigating the survival of composite restorations (ie not including amalgam), the operator, compromise of the tooth (number of surfaces involved in a cavity and presence of a root filling, for example) and the patient and their risk factors (caries, parafunction and socioeconomic status, for example) were much more important than the material.[10] This did, however, come with the caveat 'assuming that materials and techniques are properly applied by dentists'.[10] This may be a significant issue in primary care and more important for composite than amalgam restorations, as will be explored. When attempting to understand the implications of an amalgam phase-out, it is necessary to understand that they will be affected by these variables and many others, including societal norms, healthcare systems and the prevalence of caries in the population, alongside clinicians appropriately implementing prevention, non-operative and operative intervention, and reintervention. There is limited evidence suggesting that UK primary care clinicians are often not managing caries appropriately due to multiple complex factors, which need to be addressed.[7,11,12,13] This paper will, however, now primarily focus on the impact of the direct restorative materials.

Differences between amalgam and composite

This paper aims to review and synthesise the existing evidence base relating to the long-term oral health consequences of an amalgam phase-out. To understand these consequences, it is necessary to understand the differences between amalgam and composite restorations. Studies tend to focus narrowly on restoration survival, but the materials vary broadly in other ways, which are important to patients, clinicians and funders. These factors can affect uptake of treatment and access to care, which can indirectly affect oral health consequences. These consequences cannot be divorced from a consideration of the differing costs in any healthcare system with limited funding, as this can affect outcomes and are an important factor in their own right. The following narrative review will therefore outline the differences in materials, discussing their clinical outcomes and how the differences in restorative processes involved can affect these. It will explore how these, in turn, can be affected by the setting in which they are provided and the costs involved. The review will critically evaluate the economic evaluation data comparing the materials and consider funder, patient and clinician perspectives before addressing who a phase-out will likely most affect in society. It will explore how all of these elements can affect long-term health outcomes, relating this to an NHS primary care context. Previously proposed future goals will be critically appraised and suggestions made.

Clinical outcomes

The relative clinical outcomes between amalgam and composite are often fiercely contested,[14] with a balanced discussion of the evidence base rarely taken. Relevant clinical outcomes include postoperative issues, such as sensitivity and food packing, restoration survival, failure mode and mode of reintervention, which might ultimately relate to tooth survival. As an example, those supporting the use of composite will nearly always cite one study which shows superior survival of composite over amalgam.[15] Amalgam survival was higher in high caries-risk patients, however, and while all of these differences were statistically significant, there was minimal clinical difference in outcomes. The mean annual failure rates (AFRs) were very low for extensive (three surfaces or more) restorations with long-term follow-up. Not commonly mentioned is that this retrospective data comes from treatment by a single expert specialist Dutch dentist, who frequently used multiple matrices per tooth (as per a personal communication with N. Opdam in 2024), and that composite restorations with GIC liners were excluded, which were likely deeper restorations. This, therefore, makes the direct comparison of the materials questionable and translation of this data to NHS primary care inappropriate.

Restoration survival

A Cochrane review which included only randomised controlled trials in two meta-analyses suggests that posterior amalgam restorations survive longer than composite with large differences.[16] Again, there are issues which can be levelled at this data, the main one being that data in the primary analysis mostly involved children who are often at high caries risk. The data in the secondary analysis did not, however, but came from split-mouth studies with smaller numbers of restorations. It showed similar results, but with slightly reduced effect sizes. The studies are not particularly recent and resin-based materials and techniques have likely improved since then. There have been many non-controlled studies published, but they are generally at significant risk of bias against amalgam. This was explicitly shown in a large Norwegian prospective study where clinicians favoured the use of amalgam over composite in difficult situations (relating to high caries risk, lesion depth and tooth type).[17] Despite this, the AFR was significantly lower in amalgam than composite, but both AFRs were low.[18] This phenomenon, of choosing one intervention over another based on circumstances, is termed 'indication bias' and is an issue with nearly all non-controlled data. This makes the drawing of comparisons in these studies problematic. There is minimal data in the UK comparing amalgam and composite posterior restorations. One practice-based cross-sectional study was published in 1999, concluding that amalgam provided significantly greater longevity than composite in posterior restorations, but the study used a potentially misleading metric to estimate restoration performance, which has been discounted.[19,20]

Postoperative complications

Though a Cochrane review noted a difference in postoperative sensitivity favouring composite over amalgam at one point in time in the only included study, it did not consider this to be clinically relevant.[16] These data are in stark contrast to UK primary care clinician-reported data, which showed significantly increased chances of postoperative complications, such as sensitivity and food packing with composite compared to amalgam.[7] Here, 42% reported food packing and 46% sensitivity when placing composites in more than 10% of restorations, compared to 14% and 18% with amalgam, respectively. Additionally, 13% reported food packing and 17% sensitivity in more than 25% of composite restorations compared to 3% and 4% with amalgam, respectively. Private dentists reported the lowest incidence of sensitivity and food packing following direct composite placement compared to other clinicians, whereas 15% of dental therapists reported sensitivity in more than 50% of composite restorations placed. This could well have influenced their relatively reduced likelihood of confidence compared to other primary care practitioners when placing composite restorations and highlights potential issues of therapist education in the UK as they become an expanding part of the workforce.[7,21]

Failure modes

The major ways in which direct posterior restorations fail are caries associated with restorations (CARS) (previously referred to as recurrent or secondary caries), followed by fracture (of the tooth and/or restoration) and then pulpal or endodontic complications.[19,22,23] Composite restorations are more at risk of CARS than amalgam but evidence for differences between the materials in other failure modes is contradictory and uncertain, and failure mode can vary over time.[15,16,19,22,23,24,25]

These general differences in clinical outcomes between the materials are likely primarily because composite restorations are technically more difficult to perform, especially in difficult situations, though some other issues are relevant.[21,26,27]

Caries associated with restorations

CARS detection methods are poorly validated and pose significant diagnostic difficulties.[28] Differentiation of non-carious staining of restorative margins from CARS is difficult in clinical studies, especially with composite compared to amalgam, potentially resulting in premature re-intervention.[22,29] CARS most commonly occurs (>90%) at the gingival margin of restorations,[28] which likely then makes the subsequent re-restoration more difficult to perform, and especially so with composite.

CARS can be associated with a defective restoration which allows the sheltered accumulation of biofilm. This can result from ledged restorations but is likely primarily due to gaps between the restoration and the cavity wall.[28] The likelihood of peripheral gaps between the tooth and restoration is much increased with composite compared to amalgam for several reasons, making the placement process much more technique-sensitive. This can also preferentially predispose composite to postoperative sensitivity. Composite materials may also favour a more cariogenic biofilm accumulation compared to amalgam, potentially predisposing them to CARS.[30,31]

Fractures

In restored teeth, the restoration and/or teeth may fracture. Data suggests that 77% of tooth fractures are associated with teeth having three or more surfaces restored, and vital teeth suffer more favourable supra-gingival fractures (91%) than non-vital teeth (61%).[32] Expert guidance recommends indirect cuspal coverage restorations for posterior root canal-treated (RCT) teeth generally, and vital teeth with biomechanical compromise, to reduce fracture risk.[33,34] These restorations are much more costly and time-consuming to perform than direct restorations, however, and were often not provided for RCT teeth in UK primary care, likely due to the higher cost.[35] In the NHS setting, though reintervention rates for crowned teeth were lower than for directly restored teeth, tooth survival was reduced.[36] These data are at high risk of indication bias, however, as indirect restorations are likely performed on more broken-down teeth. It is also old. No equivalent data has been available since 2006 due to the change in NHS remuneration.

Direct material differences which could affect tooth fracture

Cavity preparations advised for the two materials commonly vary based on how they are retained. Amalgam preparations are commonly more box-like, closed and upright, with preparation of sound tooth structure to provide mechanical undercuts, whereas composite preparations commonly have more flare and are open and saucer-shaped, not requiring mechanical retention form due to the adhesion obtained. Composite preparations are therefore purportedly more minimally invasive.[11,27,37] However, one large prospective practice-based study showed that more conventional (amalgam-like)-shaped preparations performed better in terms of composite restoration survival than saucer-shaped preparations when controlling for many other potentially relevant factors, including the operator.[18]

Countering this data, it might, however, be expected that the (slightly) more destructive amalgam preparations would result in a higher prevalence of tooth fractures. This may especially be so given that amalgam is generally then not bonded to the remaining tooth, therefore failing to recover lost stiffness of the restored tooth unit in comparison to composite. Some laboratory studies support this whereas others do not, showing more favourable failure of amalgam-restored teeth in certain situations.[38] One study, with previously highlighted methodological issues, showed a small increased likelihood of tooth fracture in amalgam compared to composite restored teeth.[15] A Cochrane review and other, large clinical data do not, however.[14,16,39] Though people commonly say that they see more tooth fractures associated with amalgam restorations (higher incidence), and this is likely correct, they commonly come to an unjustifiable conclusion that amalgam-restored teeth have a higher rate of fracture (prevalence). They are not considering the relative number of amalgam-to-composite-restored teeth that they see, suffering from a 'narrative fallacy' and 'base case neglect'.[39] Many more amalgam restorations were present in a large sample where such data were collected looking at fracture prevalence. There was no significant difference between the materials (with a slightly increased fracture rate associated with composite restorations). The study had limitations in that it was cross-sectional, with no knowledge of the preparations performed, restorations' ages or relative sizes.[39]

Restorative process differences

Amalgam is compacted under firm pressure during its application into a cavity and undergoes a very small expansion, both of which favour marginal adaptation and avoidance of gaps. In contrast, composite shrinks on setting and is more difficult to adapt during placement due to its softer consistency. It also commonly needs to be placed in multiple increments to respect depth of cure and reduce damaging contraction stress, which again increases the chance of gap formation.[40] These issues can also contribute to the increased failure to form contact points with composite when not using specialised equipment, which can potentially contribute to material fracture, food packing and CARS.[7,26]

The effective application of a bonding agent to the tooth is required to prevent composite from pulling away from the cavity walls during polymerisation. Achieving an effective bond can be affected by many things, including the tooth substrate type (enamel or dentine) and its disease-affected state, the bonding agent composition and application, and contamination, which therefore requires the cavity to be meticulously isolated from the oral environment (ideally with a rubber dam [RD]).[31,41,42] This can be especially challenging where cavity margins are sub-gingival.[43] Incomplete light-curing of composite at the base of a cavity can occur without attention to detail and can result in washout of uncured components.[28] Gaps can form following degradation of the composite bond over time, which occurs especially with dentine margins.[31,41]

The integrity of an amalgam restoration does not depend on these things to obtain a marginal seal. The technical process is much more complex when providing a composite compared to an amalgam restoration. Many of these issues can, however, potentially be overcome with appropriate materials and techniques, which will be discussed, and as demonstrated by high comparative success rates in specific but limited studies.[15,44]

Posterior composite restorations take significantly longer than amalgam to place.[5,7,45] There is a huge array of materials and equipment which can be used to place composite restorations, with a large majority of UK primary care clinicians feeling there was a lack of consensus on which materials and techniques to use.[21] Evidence-based guidance on placement of posterior composites advises the use of relatively expensive equipment, such as sectional matrix systems and RD.[46] They are rarely used in UK primary care, however,[7] especially by primarily NHS compared to private practitioners (Appendix 1). This equipment offers improved outcomes, minimising postoperative complications which are highly valued by patients, but takes longer and can be technically difficult to place.[7,26,29,43,47] In some health systems, a fee is chargeable for placing a RD, clearly trying to incentivise the use of recommended techniques to optimise outcomes.[48] Whereas Class I cavities vary minimally in their presentation, Class II cavities can have huge variation, which can influence the technical aspects of restoration, especially for composite. As more tooth structure is lost and margins extend deeper sub-gingivally, placing a well-adapted matrix-wedge (sometimes with an added separating ring) assembly to directly restore a tooth becomes much more challenging.[43] Because the marginal seal is not as critical for amalgam, they are often favoured in these more difficult situations.[6,49]

The cavity variables are often not considered in most randomised controlled trials involving composite, which tend to focus on comparing materials. Studies generally include the treatment of simple cavities with low-risk patients by experts, who commonly use specialised equipment without time constraints.[25] Follow-up is commonly limited and AFRs are therefore often very low. These studies are not translatable to primary care where all patients, whatever their risk, and all cavities have to be treated.[25] Some expert-led opinion papers offer technical guidance on placing composite restorations in varying and difficult situations,[26,43,50,51,52,53] but there is no real clinical evidence base or expert consensus to draw on in terms of how varying techniques influence outcomes when restoring varying cavity presentations. Modern techniques, such as injection moulding with bulk-fill composites and simplified sectional matrix techniques without the use of a separating ring, can offer simpler, more predictable and efficient solutions.[26,40,54,55,56]

Differences in confidence

Though a large majority of UK primary care clinicians were confident placing posterior composites in standard situations, 67% from a sample of over 1,500 reported no or low confidence placing composite in patients with limited cooperation, compared to just 7% with amalgam.[21] Similarly, 51% reported low or no confidence when restoring sub-gingival cavities with composite, compared to just 4% with amalgam. This was despite a large majority having attended postgraduate composite courses.[21] This suggests a failure of education given the publication of articles offering guidance on using composite in sub-gingival cavities.[43,50,51] These journal articles are often not easily accessible to primary care clinicians however. Expert consensus guidance on restoration technique may help but disseminating guidance to primary care is a challenge with multiple barriers.[13]

Undergraduate to primary care transition

The vast majority of new UK graduates move from a university environment where they predominantly use composite, into a foundational training year under NHS provision where they commonly favour and place more amalgams.[7,49,57] Most UK dentists are primarily NHS practitioners in the first five years following qualification and composite use increases as a clinician's number of years qualified increases,[7] which is an opposite trend to that seen in Australia, for example, where private practice predominates.[58]

Composite skill development

Among UK primary care clinicians, the best predictor for low-reported postoperative issues when placing composite restorations was when the majority of their total posterior restorations placed were composites.[7] Other predictors were not using liners and using sectional matrices (recommended techniques which were not commonly used, especially by NHS dentists) (Appendix 1).[7,21] Primarily using composite was also predictive of confidence when placing sub-gingival composites alongside those commonly using RD, and being a predominantly private dentist, for example.[21] The current NHS system, with its large relative discrepancies in remuneration, essentially incentivises the use of amalgam. It is therefore not conducive to producing dentists who can confidently and predictably use composite posteriorly. This is likely because they are not using it regularly and are therefore not improving technically, while also having limited incentives to improve.

Reintervention

Following failure, the nature of the subsequent reintervention (ie repair, replacement, or indirect restoration, for example) is important to understand the long-term impact of the restoration on the tooth. This reintervention may in turn be subject to huge variation, making it very difficult to study and understand. Existing data on this 'repeat restorative cycle' is sparse. A large, long-term but old and limited NHS dataset on how differing restorative interventions affect subsequent reintervention and tooth survival at the population level exists.[36,59] More detailed, but very short-term Dutch data are also available.[23] Neither can really compare the impact of restoring teeth with amalgam versus composite, as the use of composite was not permitted under NHS provision in posterior non-Class V cavities at the time, and the proportion of amalgam restorations placed in the Dutch data is very small, so there is high risk of indication bias.

When removing restorations of composite in comparison to amalgam, operators with varying experience all consistently took more time, removed more sound tooth structure and left more of the existing restoration, likely because it is much more difficult to see.[60] This is one argument for repairing rather than replacing restorations where possible in an attempt to slow the restorative cycle,[61,62] but how often this is carried out in UK primary care is uncertain. The current evidence on repair versus replacement of both materials is limited, with two Cochrane reviews yielding no eligible studies.[63,64] The relevant studies have different indications for repair and vary in their reported outcome measures, making drawing meaningful conclusions difficult.[28,61]

Safety

Both a thorough Canadian health technology assessment (HTA) and Cochrane review comparing amalgam and composite restorations concluded that the evidence showed no clinically important differences in the safety of amalgam compared with composite to both patients and dental personnel.[16,65] The known risk of a localised lichenoid reaction in the mucosa adjacent to amalgam restorations is very low.[66] The safety of the alternatives has not been thoroughly investigated, but there are multiple reports of resin allergy involving patients and dental personnel.[9,67] There are also health concerns surrounding some of the monomers used in composite, for example bisphenol A, and inhalation and ingestion of microplastics.[9]

Lessons from other countries phasing-out amalgam

A United Nations Environment Programme (UNEP) document on *Lessons from countries phasing down dental amalgam use*[4] drew heavily on a 2012 review following the phase-out of amalgam in Norway.[67] It, alongside follow up-research, reported that the phase-out was generally well-accepted, as amalgam use was low before the ban, but there were increased costs associated with the phase-out, which were generally related to increased time required to place restorations and their more frequent replacement.[67,68] These increases were generally borne by adult patients and were 33–50% higher for composite compared to amalgam, which was an average increase of €51 per filling for all fillings at that time.[67] These increases in fees alone over ten years ago are comfortably higher than the current cost of any NHS direct restoration in Scotland, for example.[69]

Costs

Posterior composite restorations take longer and are more expensive than amalgam in nearly all health systems for funders and patients.[7,48,65,67,69,70] An exception is the NHS in England and Wales, where they cost the same.[71] They are therefore only more expensive for the clinician in time and material costs. This essentially disincentivises their use.

Remuneration for NHS dental provision is considerably lower than in the rest of Europe. It is very difficult to compare the fee received for a single posterior restoration in England and Wales with other countries because of the unit of dental activity (UDA) system introduced in 2006; therefore, comparing a course of treatment is more appropriate. A study published in 2019 involved a questionnaire being sent to oral health policymakers in 12 European countries.[72] It outlined a course of treatment, including two restorations, one a simple posterior restoration, with some preventive advice and scaling. Questions were then asked about the costs. The fee paid to the dentist for the course of treatment in England was €72, and in Scotland was €123.60. The fees in the other countries ranged from €158-603, with an average of €307, which equates to over four times the English fee. Though new bands to the UDA system and a minimum UDA value have recently been introduced, aiming to improve remuneration and retention of dentists within the service, the treatment plan described would still fall under the same UDA banding and therefore the fee received would not be significantly different.[73]

The differences in composite use before the ban, health service structure and costs make it very difficult to translate lessons described in the UNEP document to the current NHS system.

Economic evaluations on amalgam versus composite restorations

Clinical outcome data and costs have been used to economically evaluate different restorative interventions. Economic evaluations (EEs) can be based solely on data gathered from a clinical trial for the period of the trial,[45] or look to extrapolate findings over a lifetime using modelling techniques.[65,70] Extrapolation attempts to reflect the differences between restorations over a lifetime but inevitably carries more uncertainty. All EEs and HTAs comparing amalgam with composite posterior restorations have shown amalgam to be more effective in terms of restoration and tooth survival (where assessed) and less costly.[45,65,67,70,74,75,76] Models used have inevitably simplified the restorative cycle as the reintervention data are very limited.[65] They have also used data sources to form the model and inform how restorations fail throughout the model, which are not relevant to the UK primary care perspective. For example, two very basic models assume restorations are replaced by the same restoration each time they fail with the same longevity.[65,74] A slightly more sophisticated model assumes that all teeth receive replacement restorations before receiving root canal treatment and crowns, only after which they can be extracted.[70] While this may broadly reflect the situation in Germany, which is the setting for the analysis, this does not reflect the reality of UK primary care dentistry pre-2006, with many restored teeth extracted before receiving root canal treatment and many teeth with root canal treatment not receiving crowns.[35,59] Up-to-date information on restorations placed under NHS provision in England and Wales is very limited because of the limited data recording associated with the UDA system. This makes modelling and therefore planning future dental services in the UK difficult.

What existing economic evaluations fail to address

Previous EEs focus on survival of restorations and teeth, and while these are clearly important to all stakeholders, composite and amalgam restorations vary in other ways which are important to UK patients, clinicians and therefore, potentially, funders.

Patient perspectives

There are clear aesthetic benefits to composite, and data from a discrete choice experiment showed a representative sample of the UK population were willing to pay, on average, £42 more for a white compared to a silvery-grey restoration.[47] However, they were also willing to pay £117 to experience no postoperative pain compared with persistent pain, £49 for their restoration to survive 14 years compared to five years, £40 to reduce a six-week wait to two weeks, £16 to reduce an 80-minute appointment to 20 minutes, and £14 to have treatment by a dentist rather than a therapist, as examples. Cost was by far the most important factor when selecting a restoration, however. Most of these findings favour the use of amalgam.[47] Considering these values when designing or changing a dental healthcare system can be critical to optimising not only patient satisfaction but also uptake of services.[77] Intervening at an appropriate time can prevent more advanced disease. This can avoid pain, morbidity and higher treatment costs. The costs can be direct, out-of-pocket costs to the patient and funder, but can also be indirect, where affected individuals miss work, which also affect employers and general societal productivity.

Traditional EEs commonly only consider costs from a single perspective. For example, the costs to the patient of providing an NHS dental restoration are different from the clinician or funder. The indirect costs for the patient of losing productive time due to having treatment performed and travelling to and from appointments, for example, have only very occasionally been accounted for in evaluating restorations, and partially so.[65,78]

Clinician perspectives

Failure to consider or value clinician perspectives in EEs risks patient access issues. This can result from clinicians leaving the health service, or due to the increased time demands from the implementation of an alternative treatment with a limited workforce.

Incentives matter, so dentists are likely leaving the NHS in record numbers due to remuneration issues, but also a loss of trust in the NHS after the implementation of the new contract.[79,80] This has already created an access problem for patients.[81,82] Composite takes longer to place, longer to replace, and likely requires more frequent replacement than amalgam. Composite material costs are also currently higher for clinicians, though this may change following the EU amalgam ban. A large majority of UK primary care clinicians reported that an amalgam phase-out would impact on their ability to do their job, create appointment delays and lead to the need for more indirect restorations and extractions.[21] An amalgam phase-out would therefore exacerbate the current access issues.

Broader perspectives

Many of these broader costs associated with each material are not commonly considered when performing EEs, while others have been estimated. A Canadian HTA concluded that while the environmental impact of the release of mercury from amalgam was small, and amalgam separation, disposal and crematorium costs have been explored,[65,67] the impact from composites was unknown.[65] Other reviews have reported that mercury pollution from amalgam is a concern, however, including the Minamata Treaty.[3,83] There are a number of potential environmental issues and therefore costs associated with composite restorations, which should be characterised.[84]

Which patients will the phase-down and phase-out preferentially affect?

Phasing out amalgam risks preferentially impacting those with the most need in society.[6,21] This includes low socioeconomic status groups and those with disabilities, who are all at higher risk of caries.[9] Adequate control of the operative field to place composite may not be possible in the latter group. There is evidence of a shift in caries burden from children to adults, and with population growth and ageing populations retaining more teeth, there will be an increasing burden of caries to manage in older patients, many of whom have contributory comorbidities.[85] Amalgam performs better in high caries-risk groups, as discussed.

In general, low-income groups value the appearance of restorations much less than higher-income groups (the difference in their average willingness to pay for a white compared to a silvery/grey filling was nearly three times lower), whereas they were willing to pay more to limit the waiting and treatment time, and cost was relatively more important.[47] Phasing out amalgam risks access issues from both the increased clinician time required to place composite and reintervene, and the potential loss of the workforce to private practice, alongside a likely increase in patient costs. This would not provide what low socioeconomic groups value in direct restorations in the UK. It risks reducing treatment uptake, leading to more significant dental disease with increased morbidity and productivity loss, while widening already existing health inequalities.[6,21,86]

The current amalgam phase-down restricting the use of amalgam in certain groups is caveated to say 'except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient'.[2] Although this is a potential solution for difficult situations, anecdotally, primary care clinicians feel placing an amalgam in children or pregnant patients carries risk for them, to which many do not wish to be exposed. The strict wording of the caveat leads to uncertainty in the consent process, the justification required and the support provided by an indemnifier should a complaint arise, alongside fear of the regulator and legal repercussions, which make it much simpler and safer for clinicians to disregard the caveat and treat the regulation as an unmitigated ban. This undermines a shared decision-making process, which should be at the heart of clinical dentistry as promoted by the FDI.[9] It clearly affects patients, especially high caries-risk children, in whom cooperation can be limited and there is clear evidence of clinical benefit for amalgam over composite.

Future goals

The minimal intervention (MI) philosophy is rational, and a cavity-free future of perfect prevention rendering restoration unnecessary should be the ultimate goal. This would hugely reduce the impact of any restorative material phase-out. Prevention under the MI banner is the focus of the Department of Health and Social Care's policy paper *National plan to phase down use of dental amalgam in England*.[87] The MI philosophy is then expanded in a seemingly rational way to favour the use of composite through focusing on its ability to adhere to tooth structure which allows more minimal tooth preparations.[11,37] It is also tooth-coloured, which is one element of a restoration that patients prefer. However, when these rational abstractions are made to face the empirical reality of current untreated caries prevalence,[88] quality clinical data, EEs, patient preference data, UK clinician-reported data, and healthcare system constraints, all of which generally favour the use of amalgam, it does seem to fall apart somewhat. Wahl captured this well in his article titled 'The ugly facts on dental amalgam' with a quote subtitle: 'the great tragedy of science: the slaying of a beautiful hypothesis by an ugly fact'.[14,89]

Amalgam alternatives need to improve and their environmental impact needs to be characterised. Postgraduate composite education is not generally making clinicians confident when faced with difficult situations and needs to improve. Expert consensus on the use of techniques for restoring different cavity presentations with composite would be beneficial in guiding this, while also considering how it can be more effectively disseminated. Existing economic evaluations use rudimentary models and fail to consider clinicians and patients. They are therefore likely to significantly underestimate the broader costs of placing composite compared to amalgam over a lifetime. The current UDA system provides very limited data on restorations performed to plan future healthcare provision. The NHS dental service ideally needs to clearly define its goals. Following a consideration of its budgetary constraints, it could then design a service which incentivises the achievement of these goals while minimising unintended consequences.[90]

There are benefits to eliminating amalgam from clinical dentistry, but there are also considerable costs, and being explicit as to what those currently are is important in focusing our collective attention on ways to address the problems and sustainably plan future healthcare provision.

Appendix 1 Further analysis of dataset presented in previous paper

Further analysis of dataset presented in:

Bailey O, Vernazza C, Stone S, Ternent L, Roche A-G, Lynch C. Amalgam phase-down part 1: UK-based posterior restorative material and technique use. *JDR Clin Trans Res* 2022; **7:** 41–49.

The study received a favourable ethical opinion from Newcastle University Research Ethics Committee (ref 7262/2018) as part of an ongoing PhD. All participants consented to participate in the study as detailed in the paper. Data will be shared upon reasonable request to the corresponding author.

High advocated composite technique use by UK primary care clinician type

Clinician type	High* advocated composite technique use (%)			
	Sectional matrix**	Rubber dam**	No liner**	Wedge**
NHS general dentist	13	7	23	48
Mixed general dentist	20	14	30	66
Private general dentist	31	19	37	72
CDS dentist	2	9	14	44
Therapist	10	17	26	42

Key:
* = ≥76% use rubber dam, no liner, wedge, ≥51% use sectional metal matrices
** = $p<0.0001$ (Chi^2)
NHS = National Health Service
CDS = Community Dental Services

Conclusions

The long-term oral health implications of an amalgam phase-out are complex to understand. However, amalgam is a simpler, quicker and more cost-effective material to place and replace than composite, which is currently the main alternative. It also has fewer postoperative complications in UK primary care, which is highly valued by the UK population. Composite restorations can be effective in difficult situations with extensive cavities, but they require high levels of technical skill and the use of expensive and time-consuming specialised equipment. These are not commonly being used in UK primary care, especially by NHS dentists. NHS remuneration for clinicians is significantly lower than in the rest of Europe. The NHS system, by therefore essentially incentivising the use of amalgam, and also disincentivising the use of recommended expensive and time-consuming equipment for composite, is likely contributing to a failure of dentists to upskill and therefore be confident in providing posterior composite restorations safely. These factors, alongside a loss of trust, have led to dentists leaving the NHS, which has created access issues for patients. The most at need in society are disproportionately affected by this. An amalgam phase-out would very likely compound this issue, widening existing health inequalities while not providing restoration characteristics which the most affected patients value most. These issues must be urgently addressed to avert an oral health crisis in the UK if amalgam is phased out in the near future.

Ethics declaration

The author declares no conflicts of interest.

Data availability

Data sharing is not applicable for this article as no new data were generated for it. The data presented in the appendix is based on a dataset from another project that will be made available on reasonable request to the author.

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8th/9th March 2022

(dent* OR teeth) AND (restor* OR filling*) AND amalgam* AND (longevity OR surviv*)

401 total

Since 2000. 254

(dent* OR teeth) AND (restor* OR filling*) AND (repair* OR refurb*) AND (longevity OR surviv*)

497 total

Since 2000 470

(dent* OR teeth) AND (restor* OR filling*) AND (composite* OR resin* OR bulk*) AND (longevity OR surviv*)

2347 total

Since 2000 2101

(restor* OR filling*) AND (composite* OR resin* OR bulk* OR low)

Last 5yrs clinical trial / RCT

631 total

Re-run prior to data parameterisation due to lack of paste B-F data

8th March 2023

Last year

148 total

1 paper yielded to be used

Excluded:

Less than 5yrs follow up

Less than 20 restorations per group

ART (atraumatic restorative technique)

Sandwich technique

Dental student involvement

NCCLs/cervical/class V

Silorane

In vitro trials

Studies related to tooth wear

Non-English

5th April 2022

(economic evaluation OR cost effectiveness OR cost utility OR cost consequence OR cost benefit) AND dent* AND (caries OR restoration)

Last 5 years

496 total

Appendix D1. Phase 1 questionnaire

Online questionnaire available at:

https://www.smartsurvey.co.uk/s/preview/82YU5/A693DA6425DF4DAB4A113A34AEF0E2

A Newcastle University, BDA and BSDHT study on alternatives to dental amalgam

Newcastle University   BDA British Dental Association   BSDHT

The phase-down of amalgam is currently a much-debated topic in dentistry in the UK. We would hugely value your input on this topic.

This questionnaire is a collaboration between Newcastle University, the British Dental Association (BDA) and the British Society of Dental Hygiene and Therapy (BSDHT). The data will be used in a PhD project that is being undertaken at Newcastle University. This will investigate the cost effectiveness of directly placed restorative materials, compared to dental amalgam. The results will be used by the BDA to campaign on this issue and to advise governments on the issues for dentists in relation to amalgam phase-down. The BSDHT will use them to inform policy.

This survey will assess current material use, and techniques employed in the direct (non-laboratory) restoration of posterior teeth. It will also assess the opinions of dentists and therapists surrounding this topic, so your participation would be greatly appreciated and is important for the validity of this study. We would like you to be as honest as possible about your individual practice and opinions.

The questionnaire should take around 10 minutes to complete. Only complete this questionnaire if you place direct posterior restorations and please do not forward the web link on to avoid sampling errors.

Identifiable information will be separated from responses prior to transfer and analysis at Newcastle University, therefore all information will be anonymous. This study has ethical approval from Newcastle University.

The results of the survey and the cost effectiveness analysis will be submitted for publication in due course.

If you wish to opt-out of this survey at any point, please email Research@bda.org with "AM OPT-OUT" in the subject line

GDPR statement

How the information will be used

The information is collected by the British Dental Association (BDA) to support the policy activity it undertakes on behalf of the profession, to provide evidence in a PhD project undertaken at Newcastle University and to inform BSDHT policy. All data will be used for research purposes only and any information you provide will be treated confidentially.

What happens to the data collected?

Data from all participants will be coded, combined and analysed independently. Parts of the study may also be submitted for publication. Direct quotes from the survey may be used in reports and publications but quotes will be anonymised to ensure that participants cannot be identified.

Storage of your personal data

All information you provide to us is stored on secure servers. The data that we collect from you will not be transferred to, or stored at, a destination outside the European Economic Area ("EEA"). Your personal data collected through this survey will be stored for up to seven years. Data will be stored on our servers and our survey platform which is SmartSurvey.

Access to information

You have the right to request a copy of the information we hold about you.

What do I need to do?

You are not required to take part in this study but your participation will help us to improve the working lives of dentists and therapists. Your information will be aggregated with the other respondents' information.

The data controller

For the purpose of the General Data Protection Regulation 2018 (the Act), the data controller is The British Dental Association of 64 Wimpole Street, London W1G 8YS.

The data processor

For the purpose of the Act, the data processors are both The British Dental Association and SmartSurvey Ltd of Unit 23, Basepoint Business Center, Tewkesbury, GL20 8SD. For more information, consult their Privacy Policy and Notice at https://www.smartsurvey.co.uk/privacy-policy, Part 2 covers Privacy of Survey Respondents.

If you are not happy

If you feel that we have mistreated the handling of your data please contact us in the first instance. If you are not satisfied with our response you are entitled to lodge a complaint with the Information Commissioner, Wycliffe House, Water Lane, Wilmslow SK9 5AF.

Thank you for taking the time to read this information

2. HOW TO NAVIGATE ...

To navigate the questionnaire, please use the Previous Page and Next Page buttons located at the bottom of each page.

Please do not use the back arrow of your web browser as this will exit the study.

In the eventuality that this happens, please go back to your email invitation and click once more on your SmartSurvey link.

I confirm that I have read and understand the purpose of this research and have had the opportunity to consider the information and my involvement. *

☐ Yes

☐ No

I understand that my involvement is voluntary and I consent to participating in this study. *

- [ ] Yes

- [ ] No

I currently practice dentistry and I place direct posterior restorations. *

- [ ] Yes

- [ ] No

4. FREQUENCY OF PLACEMENT OF DIRECT POSTERIOR RESTORATIONS

When definitively restoring premolar teeth (NOT class V or localised cervical) with directly placed materials, what percentage would you estimate you restore with? Sum total should equal 100%

Composite	
Amalgam	
GIC/RMGIC/Other	

When definitively restoring molar teeth (NOT class V or localised cervical) with directly placed materials, what percentage would you estimate you restore with? Sum total should equal 100%

Composite	
Amalgam	
GIC/RMGIC/Other	

5. TECHNIQUE

How often do you use the following techniques when placing direct posterior restorations (NOT class V or localised cervical) of the indicated materials? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material.

Rubber dam

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Liner (in cavities with no obvious pulp exposure)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐

Please specify materials used under amalgam

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Please specify materials used under composite

6. TECHNIQUE

How often do you use the following techniques when placing direct posterior restorations (NOT class V or localised cervical) of the indicated materials? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material. Matrix bands (when restoring a lost proximal surface) Circumferential metal (e.g. Siqveland, Toffelmire, Disposable types)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Circumferential clear (e.g. Disposable types)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Sectional metal (e.g. Palodent, Garrison)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Sectional clear (e.g. Bioclear)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

7. TECHNIQUE

How often do you use the following techniques when placing direct posterior restorations (NOT class V or localised cervical) of the indicated materials? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material.

Wedge/s (when restoring a lost posterior proximal surface)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

8. TECHNIQUE

How often do you use the following materials when placing direct posterior composite restorations (NOT class V or localised cervical)? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material.

Composite specific: Bonding agents

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Separate etch (and rinse) + bond (in 1 bottle, 2-step) eg. Optibond Solo Plus	☐	☐	☐	☐	☐	☐	☐	☐
Separate etch (and rinse) + prime + bond (in 2 bottles, 3-step) eg. Optibond FL	☐	☐	☐	☐	☐	☐	☐	☐
Self-etch (1 bottle) eg. Prompt-L-Pop, iBond	☐	☐	☐	☐	☐	☐	☐	☐
Self-etching primer + bond (2 bottles) eg. Clearfil SE II bond	☐	☐	☐	☐	☐	☐	☐	☐
Selective enamel etch technique (phosphoric acid on enamel only) with self-etching systems	☐	☐	☐	☐	☐	☐	☐	☐

9. TECHNIQUE

How often do you use the following materials when placing direct posterior composite restorations (NOT class V or localised cervical)? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material.

Composite specific: Composite material/s

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Flowable bulk-fill composite alone	☐	☐	☐	☐	☐	☐	☐	☐
Paste-like bulk-fill composite alone	☐	☐	☐	☐	☐	☐	☐	☐
Flowable bulk-fill composite capped with a conventional composite	☐	☐	☐	☐	☐	☐	☐	☐
Flowable bulk-fill composite capped with a paste-like bulk-fill composite	☐	☐	☐	☐	☐	☐	☐	☐
Incrementally placed conventional (paste-like) composite	☐	☐	☐	☐	☐	☐	☐	☐
Non-incrementally placed conventional (paste-like) composite	☐	☐	☐	☐	☐	☐	☐	☐

10. TECHNIQUE

Do you have experience in using bulk-fill composites?

☐ Yes

☐ No

Name of bulk-fill composite/s used

I have found them ...

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
... easier to place than conventional composites	☐	☐	☐	☐	☐
... time saving compared to conventional composites	☐	☐	☐	☐	☐
... to have reduced post-operative sensitivity compared to conventional composites	☐	☐	☐	☐	☐

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
... to have more predictable outcomes than conventional composites	☐	☐	☐	☐	☐
... more aesthetic than conventional composites	☐	☐	☐	☐	☐

12. CLINICAL SCENARIOS

If you had to restore a moderately deep 2-surface mesio-occlusal cavity in an upper premolar with amalgam, how long an appointment would you book? In minutes

If you had to restore the same cavity with composite, how long an appointment would you book? In minutes

If you restored the tooth with composite privately, what fee would you charge? In £

If you restored the tooth with amalgam privately, what fee would you charge? In £

13. CLINICAL SCENARIOS

If you had to restore a deep 3-surface mesio-occlusal-distal cavity in a lower first molar with amalgam, how long an appointment would you book? In minutes

If you had to restore the same cavity with composite, how long an appointment would you book? In minutes

If you restored the tooth with composite privately, what fee would you charge? In £

If you restored the tooth with amalgam privately, what fee would you charge? In £

14. FEES

What would the percentage change in profitability be, in providing a posterior composite, rather than a posterior amalgam restoration under NHS provision? Only complete one of these two boxes please.

Percentage change

Increase

Decrease

15. POST-TREATMENT PROBLEMS

How often do you see the following complications within one year when using the following materials to directly restore posterior teeth (NOT class V or localised cervical)? Only select 'not applicable' if you do not place any direct posterior restorations using the indicated material.

Sensitivity

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

Food packing (when restoring a proximal contact)

	0%	1-10%	11-25%	26-50%	51-75%	76-99%	100%	not applicable
Amalgam	☐	☐	☐	☐	☐	☐	☐	☐
Composite	☐	☐	☐	☐	☐	☐	☐	☐

16. KNOWLEDGE BASE

The Mercury Regulation that is now in force has as one of its aims a phase-down of the use of dental amalgam. Considerations for a potential 'phase-out' of the material are currently being considered at EU level.

We wish to understand the dentists' and therapists' knowledge and opinions of the 'phase-out' with the following three questions.

In which year is it intended that the possible 'phase-out' of amalgam ought to be complete by?

- ☐ 2020
- ☐ 2025
- ☐ 2030
- ☐ 2035
- ☐ 2040
- ☐ 2045
- ☐ 2050

In which patient groups should the use of amalgam be avoided according to current rules?

Over which period of time do you believe dental amalgam should be 'phased-out' in UK dental practice?

- ☐ Less than 5 years
- ☐ 5 – 9 years
- ☐ 10 – 19 years
- ☐ 20 – 29 years
- ☐ More than 30 years

17. YOUR OPINIONS

Please indicate to which level you agree or disagree with the following statements:

The 'phasing-out' of amalgam ...

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
... will impact on my ability to do my job	☐	☐	☐	☐	☐
... will lead to the need for more indirect restorations	☐	☐	☐	☐	☐

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
... will lead to more teeth being deemed unrestorable	☐	☐	☐	☐	☐
There is a lack of consensus on best practice when selecting direct alternative materials	☐	☐	☐	☐	☐
There is a lack of consensus on best practice in terms of technique when directly placing alternative materials	☐	☐	☐	☐	☐
My patients won't care	☐	☐	☐	☐	☐

18. YOUR OPINIONS

Please indicate to which level you agree or disagree with the following statements:

Alternative direct materials

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Suitable directly placed alternatives to amalgam are available	☐	☐	☐	☐	☐
I feel up to date with current techniques and practices relating to placement of posterior composites	☐	☐	☐	☐	☐
Having to routinely place posterior composites would cause appointment delays in my practice	☐	☐	☐	☐	☐
Posterior amalgams last longer than directly placed posterior composites	☐	☐	☐	☐	☐
It takes me longer to remove a failed posterior composite restoration than a failed amalgam restoration of equivalent size	☐	☐	☐	☐	☐

19. YOUR OPINIONS

Please indicate to which level you agree or disagree with the following statements:

Alternative direct materials

Please indicate your confidence level ...

	No confidence	Low confidence	Moderate confidence	High confidence	Complete confidence
... in providing 2 surface direct posterior composite restorations involving a proximal surface	☐	☐	☐	☐	☐
... in providing 3 surface direct posterior composite restorations involving both proximal surfaces	☐	☐	☐	☐	☐
... in providing definitive 2 surface posterior GICs involving a proximal surface	☐	☐	☐	☐	☐
... in providing definitive 3 surface posterior GICs	☐	☐	☐	☐	☐

	No confidence	Low confidence	Moderate confidence	High confidence	Complete confidence
involving both proximal surfaces					
... when placing direct posterior composites with sub-gingival margins	☐	☐	☐	☐	☐
... when placing posterior amalgams with sub-gingival margins	☐	☐	☐	☐	☐
... when placing direct posterior composites in patients with limited cooperation	☐	☐	☐	☐	☐
... when placing posterior amalgams in patients with limited cooperation	☐	☐	☐	☐	☐

20. DEMOGRAPHICS

At which institution did you obtain your primary dental qualification?

In which year did you obtain your primary dental qualification?

Please indicate your professional role

- ☐ Dentist
- ☐ Therapist

21. DEMOGRAPHICS

Please indicate your gender

- ☐ Male
- ☐ Female

☐ Prefer not to say

Please indicate the number of sessions per week worked in (considering a morning a session, an afternoon a session and an evening a session)

	Number of sessions per week worked in the following settings
Hospital	
Community	
Specialist practice	
General practice	

Approximately, what proportion of your patients do you personally provide NHS care for?

- ☐ 100% (exclusively NHS patients)
- ☐ 75-99% NHS
- ☐ 50-74% NHS
- ☐ 25-49% NHS
- ☐ 1-24% NHS
- ☐ 0% (exclusively private patients)

22. TRAINING

Please select the appropriate box

	Yes	No	Unsure
Did you receive didactic instruction (e.g. lectures, seminars) in posterior composite placement as part of your dental school training?	☐	☐	☐
Did you receive clinical training in posterior composite placement as	☐	☐	☐

	Yes	No	Unsure
part of your dental school training?			
Since graduation have you attended CPD courses relating to the placement of posterior composites?	☐	☐	☐

Any further comments?

Appendix D2. Phase 1 questionnaire supplementary results

Clinician		Female (%)	Male (%)	PNTS (%)
Dentist	NHS GDP (n=615)	49	48	3
	Mixed GDP (n=193)	49	48	3
	Private GDP (n=505)	36	62	2
	CDS (n=118)	78	19	3
Therapist (n=75)		89	7	4

Appendix D2.1 Table. Workforce by gender

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service; PNTS, prefer not to say

Clinician		Primary dental qualification location (%)		
		UK	EU (non-UK)	Non-EU
Dentist	NHS GDP (n=591)	84	9	7
	Mixed GDP (n=190)	84	8	7
	Private GDP (n=503)	89	6	5
	CDS (n=116)	95	3	3
Therapist (n=75)		100	0	0

Appendix D2.2. Table. Workforce by primary dental qualification location

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service; UK, United Kingdom; EU, European Union.

Years qualified	Clinician (%)				
	Dentist				Therapist
	NHS GDP	Mixed GDP	Private GDP	CDS	
0-5 (n=139)	63	10	7	6	13
6-15 (n=316)	53	12	15	7	13
16-25 (n=371)	42	15	32	9	2
≥26 (n=686)	30	13	49	8	1

Appendix D2.3. Table. Workforce by years qualified

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service

Clinician	Appointment time booked (minutes) (standard deviation)			
	Amalgam 2-s	Composite 2-s	Amalgam 3-s	Composite 3-s
NHS GDP	22 (6)	31 (8)	26 (7)	39 (10)
Mixed GDP	23 (7)	35 (10)	28 (8)	43 (11)
Private GDP	26 (7)	36 (9)	33 (9)	46 (11)
CDS Dentist	27 (6)	35 (8)	33 (7)	43 (9)
Therapist	27 (8)	36 (10)	33 (8)	44 (15)

Appendix D2.4. Table. Appointment time booked to place various direct restorations by clinician type

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service; 2-s, 2-surface; 3-s, 3-surface.

Composite technique	% use				
	0%	1-25%	26-75%	76-100%	N/A
Rubber dam (n=1501)	32	37	16	12	3
Circumferential metal matrix* (n=1501)	5	14	19	61	1
Sectional metal matrix* (n=1477)	49	16	12	15	7
Circumferential clear matrix* (n=1476)	59	18	9	7	6
Sectional clear matrix* (n=1494)	75	8	3	2	11
Liner (n=1488)	28	45	19	17	1
Wedge* (n=1505)	4	16	21	57	1

Appendix D2.5. Table. Composite technique use

N/A, not applicable; *Technique use when restoring a lost proximal surface.

Amalgam technique	% use				
	0%	1-25%	26-75%	76-100%	N/A
Rubber dam (n=1497)	72	13	2	1	12
Circumferential metal matrix* (n=1506)	1	1	4	85	9
Sectional metal matrix* (n=1457)	72	7	2	1	17
Circumferential clear matrix* (n=1474)	79	3	1	2	16
Sectional clear matrix* (n=1467)	80	1	0	0	19
Liner (n=1510)	16	28	17	30	9
Wedge* (n=1504)	5	20	21	45	9

Appendix D2.6. Table. Amalgam technique use

N/A, not applicable; *Technique use when restoring a lost proximal surface.

Composite liner material		Number	Percentage use (%)
Glass ionomer based		627	54.7
Calcium hydroxide	Conventional setting	211	18.4
	Resin-based	57	5.0
	Non-setting	4	0.3
	Non-specified	171	14.9
Calcium silicate	Conventional setting	34	3.0
	Resin-based	19	1.7
Others		23	2.0

Appendix D2.7. Table. Composite liner material use among those using liners

Amalgam liner material		Number	Percentage use (%)
Glass ionomer based		485	30.3
Calcium hydroxide	Conventional setting	420	26.2
	Resin-based	51	3.2
	Non-setting	20	1.2
	Non-specified	288	18.0
Zinc oxide eugenol based		165	10.3
Resin-based (without bioactive agents)		76	4.7
Calcium silicate based	Conventional setting	13	0.8
	Resin-based	9	0.6
Ledermix		19	1.2
Zinc polycarboxylate		18	1.1
Varnish		16	1.0
Others		22	1.4

Appendix D2.8. Table. Amalgam liner material use among those using liners

Clinician type	High advocated composite technique use (%)			
	Sectional matrix*	Rubber dam*	No liner *	Wedge*
NHS GDP (%)	13	7	23	48
Mixed GDP (%)	20	14	30	66
Private GDP (%)	31	19	37	72
CDS dentist (%)	2	9	14	44
Therapist (%)	10	17	26	42

Appendix D2.9. Table. High advocated composite technique use by clinician type

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service; *p<0.0001 (Chi^2)

Years qualified	High advocated composite technique use (%)			
	Sectional matrix*	Rubber dam	No liner *	Wedge**
0-5	9	10	32	46
6-15	20	14	26	54
16-25	21	14	34	57
≥26	20	11	25	62

Appendix D2.10. Table. High advocated composite technique use by years qualified

*p≤0.05; **p≤0.01 (Chi^2)

Composite material	% use				
	0%	**1-25%**	**26-75%**	**76-100%**	**N/A**
Bulk-fill flowable only (n=1374)	55	26	5	4	9
Bulk-fill paste only (n=1304)	59	14	8	7	12
Bulk-fill flow & conventional paste (n=1364)	35	24	18	15	8
Bulk-fill flow & bulk-fill paste (n=1264)	68	9	5	3	14
Incremental conventional composite (n=1443)	6	14	20	57	3
Non-incremental conventional composite (n=1254)	63	17	4	2	13

Appendix D2.11. Table. Composite material use (N/A= not applicable, i.e. the clinician does not use composite)

Bonding technique use	% use				
	0%	**1-25%**	**26-75%**	**76-100%**	**N/A**
Total-etch 2 step (n=1413)	14	6	7	71	3
Total-etch 3 step (n=1271)	65	6	3	14	12
Selective-etch 1 step (n=1265)	63	11	6	9	11
Selective-etch 2 step (n=1238)	77	5	2	4	14
Selective enamel etch (with selective etch system) (n=1286)	63	10	4	11	12

Appendix D2.12. Table. Bonding technique use (N/A= not applicable, i.e. the clinician does not use composite)

Clinician	Sensitivity incidence post restoration placement (%)							
	0-10%		**11-25%**		**26-50%**		**51-100%**	
	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
NHS GDP (%)	78	41	17	36	4	17	1	6
Mixed GDP (%)	78	46	18	34	2	15	3	6
Private GDP (%)	87	74	11	18	2	5	0	2
CDS dentist (%)	90	48	10	33	0	14	1	5
Therapist (%)	62	36	29	32	4	17	4	15

Appendix D2.13. Table. Incidence of reported post-operative sensitivity by material and clinician type

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service

Clinician	Food-packing incidence post restoration placement (%)							
	0-10%		**11-25%**		**26-50%**		**51-100%**	
	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
NHS GDP (%)	82	49	14	33	3	12	1	6
Mixed GDP (%)	81	52	14	32	4	11	1	5
Private GDP (%)	91	70	7	24	2	5	1	2
CDS dentist (%)	89	60	7	30	2	8	2	2
Therapist (%)	68	60	23	21	4	13	4	6

Appendix D2.14. Table. Incidence of reported post-operative food packing by material and clinician type

NHS, National Health Service; GDP, general dental practitioner; CDS, Community Dental Service

Years qualified	Sensitivity incidence post restoration placement (%)							
	0-10%		**11-25%**		**26-50%**		**51-100%**	
	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
0-5	64	43	28	30	5	20	2	7
6-15	71	40	23	36	4	17	2	7
16-25	81	54	15	29	3	12	0	5
≥26	89	61	9	26	1	9	1	4

Appendix D2.15. Table. Incidence of reported post-operative sensitivity by material and years qualified

Years qualified	Food packing incidence post restoration placement (%)							
	0-10%		**11-25%**		**26-50%**		**51-100%**	
	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite	Amalgam	Composite
0-5	69	53	19	30	9	12	2	5
6-15	75	53	20	32	4	11	1	4
16-25	85	58	12	28	2	10	1	4
≥26	92	61	6	28	1	7	1	4

Appendix D2.16. Table. Incidence of reported post-operative food-packing by material and years qualified

Problem post composite placement	Technique use	Incidence post composite placement (%)			
		0-10%	**11-25%**	**26-50%**	**51-100%**
Food packing	100% circumferential metal matrix (n=534)	50	32	12	6
	51-100% sectional metal matrix (n=266)	79	15	5	1
Sensitivity	0% rubber dam (n=472)	49	32	13	6
	1-10% rubber dam (n=399)	55	28	13	4
	11-75% rubber dam (n=395)	52	32	12	5
	76-100% rubber dam (n=180)	64	22	9	5

Appendix D2.17. Table. Clinician reported incidence of food packing and sensitivity following direct posterior composite restoration with various matrix and rubber dam use

Category of bulk-fill composite	Experience of use (%)
Flowable light-cured (n=278)	53
Paste light-cured (n=170)	32
Dual cured (n=32)	6
Non-bulk-fill composite/non-composite (n=40)	8

Appendix D2.18. Table. Experience of use of categories of bulk-fill composites

Bulk-fill composites in relation to standard composites	Agree/Strongly agree (%)	Neither agree nor disagree (%)	Disagree/Strongly disagree (%)
Easier to place (n-1033)	68	26	6
Time-saving (n=1029)	81	16	3
Reduced post-op sensitivity (n=1025)	28	63	9
More predictable (n=1024)	27	60	14
More aesthetic (n=1027)	7	38	55

Appendix D2.19. Table. Opinions on bulk-fill composites in relation to standard composites

Variable	Variance inflation factor
No undergraduate clinical teaching	1.41
No postgraduate training	1.13
UK primary dental qualification	1.09
Private general dentist	2.25
Mixed general dentist	1.28
CDS dentist	1.06
Therapist	1.10
Years qualified	1.82
Female	1.14
Composite user	1.77
Incremental composite user	1.09
Total-etch 3 step bond (76-100% use)	1.47
Total-etch 2 step bond (76-100% use)	1.63
Self-etch 2 step bond (76-100% use)	1.11
Circumferential metal user (100% use)	1.26
Sectional metal user (51-100% use)	1.43
High wedge use	1.27
Never liner use	1.08
Rubber dam use - never	1.28
Rubber dam use - high	1.21
High confidence MO composite placer	1.23

Appendix D2.20. Table. Variance inflation factors for variables included in regression analysis investigating composite time booked

Independent variable (predictor)		Coefficient	SE	t	P>t	95% CI
No undergraduate clinical teaching *(ref had UG teaching)*		0.24	0.72	0.33	0.739	-1.18 – 1.66
No postgraduate training *(ref had PG training)*		-0.34	0.98	-0.35	0.730	-2.26 – 1.58
UK primary dental qualification *(ref non-UK)*		0.52	0.95	0.54	0.586	-1.35 – 2.39
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*						
	Private general dentist (0-24% NHS patient base)	4.05	0.89	4.55	**0.000**	2.30 – 5.80
	Mixed general dentist (25-74% NHS patient base)	2.71	0.96	2.83	**0.005**	0.83 – 4.60
	CDS dentist	3.77	1.24	3.03	**0.003**	1.33 – 6.21
	Therapist	3.48	1.61	2.16	**0.031**	0.31 – 6.65
Years qualified		-0.07	0.03	-2.19	**0.029**	-0.14 – -0.01
Female *(ref male)*		-0.19	0.63	-0.30	0.761	-1.43 – 1.05
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*		-0.97	0.73	-1.32	0.187	-2.41 – 0.47
Incremental composite user (76-100% use) *(ref <76% incremental)*		1.03	0.61	1.67	0.095	-0.18 – 2.23
Bonding system use *(ref self-etch 1 step (76-100% use))*						
	Total-etch 3 step bond (76-100% use)	3.84	1.14	3.37	**0.001**	1.60 – 6.08
	Total-etch 2 step bond (76-100% use)	2.00	0.80	2.49	**0.013**	0.42 – 3.58
	Self-etch 2 step bond (76-100% use)	-2.48	2.23	-1.11	0.266	-6.87 – 1.90
Matrix use *(ref not CM or SM user)*						
	Circumferential metal user (100% use)	-0.10	0.68	-0.15	0.883	-1.43 – 1.23
	Sectional metal user (51-100% use)	2.89	0.88	3.27	**0.001**	1.15 – 4.62
High wedge use (76-100% use) *(ref <76% use)*		1.54	0.66	2.33	**0.020**	0.24 – 2.83
Never liner use *(ref >0% use)*		0.52	0.66	0.80	0.427	-0.77 – 1.82
Rubber dam use *(ref 1-75% use)*						
	Never	-0.89	0.70	-1.27	0.205	-2.27 – 0.49
	High (76-100% use)	4.54	0.97	4.67	**0.000**	2.63 – 6.45
High confidence MO composite placer *(ref not high confidence)*		-0.23	0.78	-0.29	0.770	-1.76 – 1.31
Constant		29.63	1.61	18.36	0.000	26.47 – 32.80

Appendix D2.21. Table. Factors related to appointment time booked for direct posterior mesio-occlusal (MO) composite restoration

SE, standard error; CI, confidence interval; n=777; p<0.0001; adjusted R^2=0.15; AIC=5487; BIC=5590.

Independent variable (predictor)		Coefficient	SE	t	P>t	95% CI
Appointment time booked MOD composite		1.43	0.16	9.07	**0.000**	1.12 – 1.75
No undergraduate clinical teaching *(ref had UG teaching)*		-0.30	4.08	-0.07	0.941	-8.30 – 7.70
No postgraduate training *(ref had PG training)*		-2.33	5.63	-0.41	0.679	-13.39 – 8.72
UK primary dental qualification *(ref non-UK)*		-7.88	5.28	-1.49	0.136	-18.24 – 2.48
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*						
	Private general dentist (0-24% NHS patient base)	27.56	5.11	5.39	**0.000**	17.51 – 37.60
	Mixed general dentist (25-74% NHS patient base)	12.91	5.31	2.43	**0.015**	2.49 – 23.33
	CDS dentist	19.58	10.77	1.82	0.070	-1.57 – 40.73
	Therapist	11.86	9.95	1.19	0.234	-7.69 – 31.40
Years qualified		-0.01	0.19	-0.06	0.950	-0.38 – 0.36
Female *(ref male)*		-3.64	3.50	-1.04	0.299	-10.52 – 3.24
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*		1.25	4.39	0.28	0.777	-7.38 – 9.87
Incremental composite user (76-100% use) *(ref <76% incremental)*		8.04	3.47	2.32	**0.021**	1.23 – 14.86
Bonding system use *(ref self-etch 1 step (76-100% use))*						
	Total-etch 3 step bond (76-100% use)	8.81	6.40	1.38	0.169	-3.76 – 21.38
	Total-etch 2 step bond (76-100% use)	-4.33	4.53	-0.96	0.340	-13.21 – 4.56
	Self-etch 2 step bond (76-100% use)	-3.03	12.43	-0.24	0.808	-27.44 – 21.39
Matrix use *(ref not CM or SM user)*						
	Circumferential metal user (100% use)	.571	3.87	0.15	0.883	-7.03 – 8.17
	Sectional metal user (51-100% use)	-7.34	4.89	-1.50	0.134	-16.94 – 2.26
High wedge use (76-100% use) *(ref <76% use)*		9.19	3.73	2.46	**0.014**	1.85 – 16.52
Never liner use *(ref >0% use)*		1.82	3.65	0.50	0.618	-5.34 – 8.98
Rubber dam use *(ref 1-75% use)*						
	Never	-10.53	3.98	-2.65	**0.008**	-18.35 – 2.72
	High (76-100% use)	7.98	5.49	1.45	0.146	-2.79 – 18.76
High confidence MOD composite placer *(ref not high confidence)*		8.47	4.01	2.11	**0.035**	0.60 – 16.34
Constant		62.36	10.63	5.86	0.000	41.49- 83.24

Appendix D2.22. Table. Factors related to private fee charged for a direct posterior mesio-occluso-distal (MOD) composite restoration

SE, standard error; CI, confidence interval; n=711; p<0.0001; adjusted R^2=0.28; AIC=7413; BIC=7518.

Independent variable (predictor)	OR	SE	z	P>z	95% CI
Appointment time booked MOD composite	1.01	0.01	0.75	0.456	0.99 – 1.02
No undergraduate clinical teaching *(ref had UG teaching)*	0.99	0.19	-0.05	0.962	0.68 – 1.45
No postgraduate training *(ref had PG training)*	1.21	0.31	0.74	0.457	0.73 – 2.00
UK primary dental qualification *(ref non-UK)*	1.00	0.25	0.00	0.997	0.61 – 1.63
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*					
Private general dentist (0-24% NHS patient base)	1.50	0.36	1.72	0.085	0.95 – 2.40
Mixed general dentist (25-74% NHS patient base)	0.66	0.17	-1.63	0.103	0.40 – 1.09
CDS dentist	1.14	0.36	0.43	0.670	0.62 – 2.12
Therapist	0.39	0.18	-2.05	**0.040**	0.16 – 0.96
Years qualified	1.01	0.01	1.32	0.186	0.99 – 1.03
Female *(ref male)*	1.15	0.19	0.81	0.416	0.82 – 1.60
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*	2.33	0.44	4.48	**0.000**	1.61 – 3.38
Incremental composite user (76-100% use) *(ref <76% incremental)*	1.15	0.19	0.82	0.410	0.83 – 1.58
Bonding system use *(ref self-etch 1 step (76-100% use))*					
Total-etch 3 step bond (76-100% use)	0.88	0.27	-0.42	0.677	0.48 – 1.62
Total-etch 2 step bond (76-100% use)	0.68	0.15	-1.77	0.076	0.44 – 1.04
Self-etch 2 step bond (76-100% use)	3.15	2.57	1.40	0.160	0.64 – 15.62
Matrix use *(ref not CM or SM user)*					
Circumferential metal user (100% use)	1.12	0.20	0.66	0.512	0.79 – 1.59
Sectional metal user (51-100% use)	1.56	0.38	1.81	0.070	0.96 – 2.52
High wedge use (76-100% use) *(ref <76% use)*	1.18	0.21	0.96	0.335	0.84 – 1.67
Never liner use *(ref >0% use)*	1.75	0.31	3.14	**0.002**	1.23 – 2.49
Rubber dam use *(ref 1-75% use)*					
Never	0.88	0.17	-0.66	0.511	0.61 – 1.28
High (76-100% use)	1.05	0.28	0.17	0.868	0.62 – 1.78
Constant	0.37	0.18	-2.02	0.043	0.14 – 0.97

Appendix D2.23. Table. Factors related to low reported incidence of post-operative sensitivity following direct posterior composite placement

OR, odds ratio; SE, standard error; CI, confidence interval; n=770; p<0.0001; pseudo R^2=0.11; Log likelihood =-471; AIC=986; BIC=1088.

Independent variable (predictor)	OR	SE	z	P>z	95% CI
Appointment time booked MOD composite	0.99	0.01	-1.25	0.212	0.98 – 1.01
No undergraduate clinical teaching *(ref had UG teaching)*	0.81	0.16	-1.10	0.273	0.55 – 1.18
No postgraduate training *(ref had PG training)*	0.94	0.24	-0.25	0.805	0.58 – 1.54
UK primary dental qualification *(ref non-UK)*	1.04	0.26	0.15	0.884	0.63 – 1.70
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*					
Private general dentist (0-24% NHS patient base)	0.78	0.19	-1.02	0.310	0.48 – 1.26
Mixed general dentist (25-74% NHS patient base)	0.66	0.17	-1.65	0.098	0.40 – 1.08
CDS dentist	0.95	0.31	-0.17	0.867	0.50 – 1.79
Therapist	1.25	0.54	0.51	0.608	0.53 – 2.92
Years qualified	1.01	0.01	1.05	0.292	0.99 – 1.03
Female *(ref male)*	0.87	0.15	-0.83	0.406	0.63 – 1.21
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*	2.81	0.56	5.22	**0.000**	1.91 – 4.15
Incremental composite user (76-100% use) *(ref <76% incremental)*	1.60	0.27	2.84	**0.005**	1.16 – 2.22
Bonding system use *(ref self-etch 1 step (76-100% use))*					
Total-etch 3 step bond (76-100% use)	1.09	0.35	0.27	0.784	0.59 – 2.03
Total-etch 2 step bond (76-100% use)	0.90	0.20	-0.50	0.619	0.58 – 1.38
Self-etch 2 step bond (76-100% use)	2.25	1.56	1.18	0.239	0.58 – 8.72
Matrix use *(ref not CM or SM user)*					
Circumferential metal user (100% use)	0.89	0.16	-0.67	0.504	0.63 – 1.25
Sectional metal user (51-100% use)	2.48	0.64	3.51	**0.000**	1.49 – 4.12
High wedge use (76-100% use) *(ref <76% use)*	1.17	0.20	0.91	0.361	0.83 – 1.64
Never liner use *(ref >0% use)*	1.07	0.19	0.38	0.705	0.76 – 1.51
Rubber dam use *(ref 1-75% use)*					
Never	0.81	0.15	-1.17	0.240	0.56 – 1.16
High (76-100% use)	1.42	0.40	1.23	0.219	0.81 – 2.48
Constant	0.98	0.48	-0.04	0.972	0.37 – 2.58

Appendix D2.24. Table. Factors related to low reported incidence of reported post-operative food packing following direct posterior composite placement

OR, odds ratio; SE, standard error; CI, confidence interval; n=768; $p<0.0001$; pseudo R^2= 0.09; Log likelihood=-473; AIC=989; BIC=1091.

Training in posterior composites	Yes (%)	No (%)	Unsure (%)
Postgraduate course (n=1512)	88	10	2
Undergraduate didactic (n=1511)	63	30	7
Undergraduate clinical (n=1507)	58	36	7

Appendix D2.25. Table. Training received in direct posterior composite placement

Knowledge of amalgam phase-down: Patient groups to avoid amalgam placement	% correct	
	Dentist (n=1416)	Therapist (n=73)
Children (either "children mentioned or age implying children")	95	96
Correct age (i.e. 15 and under)	58	56
Deciduous/Primary teeth	5	4
Pregnancy	87	81
Breastfeeding	47	41
All correct apart from deciduous teeth	27	25
All correct	3	3

Appendix D2.26. Table. Knowledge of the phase-down and proposed phase-out of amalgam

Independent variable (predictor)	OR	SE	z	P>z	95% CI
No undergraduate clinical teaching *(ref had UG teaching)*	0.67	0.18	-1.52	0.129	0.40 – 1.12
No postgraduate training *(ref had PG training)*	1.07	0.43	0.16	0.876	0.48 – 2.35
UK primary dental qualification *(ref non-UK)*	0.47	0.14	-2.45	**0.014**	0.26 – 0.86
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*					
Private general dentist (0-24% NHS patient base)	2.47	0.80	2.81	**0.005**	1.31 – 4.65
Mixed general dentist (25-74% NHS patient base)	1.66	0.60	1.41	0.158	0.82 – 3.36
CDS dentist	0.61	0.41	-0.73	0.466	0.17 – 2.28
Therapist	1.04	0.70	0.06	0.953	0.28 – 3.91
Years qualified	0.99	0.01	-0.64	0.520	0.97 – 1.02
Female *(ref male)*	0.58	0.13	-2.34	**0.019**	0.37 – 0.92
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*	1.83	0.51	2.17	**0.030**	1.06 – 3.15
Incremental composite user (76-100% use) *(ref <76% incremental)*	1.18	0.26	0.76	0.446	0.77 – 1.82
Bonding system use *(ref self-etch 1 step (76-100% use))*					
Total-etch 3 step bond (76-100% use)	0.65	0.25	-1.13	0.257	0.31 – 1.37
Total-etch 2 step bond (76-100% use)	0.64	0.17	-1.70	0.089	0.38 – 1.07
Self-etch 2 step bond (76-100% use)	0.83	0.57	-0.27	0.789	0.22 – 3.18
Matrix use *(ref not CM or SM user)*					
Circumferential metal user (100% use)	1.05	0.27	0.18	0.856	0.64 – 1.73
Sectional metal user (51-100% use)	0.96	0.28	-0.13	0.900	0.55 – 1.70
High wedge use (76-100% use) *(ref <76% use)*	0.62	0.15	-1.92	0.055	0.38 – 1.01
Never liner use *(ref >0% use)*	1.36	0.30	1.37	0.171	0.88 – 2.11
Rubber dam use *(ref 1-75% use)*					
Never	0.98	0.26	-0.07	0.941	0.58 – 1.65
High (76-100% use)	2.17	0.65	2.56	**0.010**	1.20 – 3.92
Agree lack of consensus on material *(ref don't agree)*	0.80	0.22	-0.80	0.425	0.46 – 1.39
Agree lack of consensus on technique *(ref don't agree)*	0.75	0.20	-1.05	0.293	0.44 – 1.28
Disagree suitable alternatives to amalgam exist *(ref don't disagree)*	0.59	0.14	-2.19	**0.029**	0.36 – 0.95
Low reported sensitivity (0-10%) *(ref ≥11% sensitivity)*	0.77	0.20	-1.00	0.316	0.47 – 1.28
Low reported food packing (0-10%) *(ref ≥11% FP)*	2.59	0.70	3.51	**0.000**	1.52 – 4.41
Constant	0.42	0.24	-1.55	0.122	0.14 – 1.26

Appendix D2.27. Table. Factors related to high or complete confidence when placing direct posterior composites with sub-gingival margins

OR, odds ratio; SE, standard error; CI, confidence interval; n=768; p<0.0001; pseudo R^2=0.17; Log likelihood=295; AIC=643; BIC=764.

Independent variable (predictor)	OR	SE	z	P>z	95% CI
No undergraduate clinical teaching *(ref had UG teaching)*	1.22	0.44	0.57	0.570	0.61 – 2.46
No postgraduate training *(ref had PG training)*	1.53	0.82	0.80	0.426	0.54 – 4.35
UK primary dental qualification *(ref non-UK)*	0.34	0.13	-2.80	**0.005**	0.16 – 0.73
Type of practice *(ref NHS general dentist 75-100% NHS patient base)*					
Private general dentist (0-24% NHS patient base)	2.69	1.26	2.11	**0.035**	1.07 – 6.74
Mixed general dentist (25-74% NHS patient base)	2.63	1.34	1.90	0.057	0.97 – 7.14
CDS dentist	1.50	1.11	0.55	0.580	0.35 – 6.39
Therapist	3.05	2.29	1.49	0.137	0.70 – 13.27
Years qualified	0.98	0.02	-0.93	0.351	0.95 – 1.02
Female *(ref male)*	0.96	0.31	-0.12	0.905	0.52 – 1.79
Composite user (combined premolar and molar composite usage > 100%) *(ref combined use <100%)*	2.00	0.79	1.77	0.077	0.93 – 4.32
Incremental composite user (76-100% use) *(ref <76% incremental)*	1.27	0.39	0.79	0.431	0.70 – 2.32
Bonding system use *(ref self-etch 1 step (76-100% use))*					
Total-etch 3 step bond (76-100% use)	1.51	0.75	0.82	0.413	0.57 – 4.01
Total-etch 2 step bond (76-100% use)	1.32	0.52	0.70	0.485	0.61 – 2.85
Self-etch 2 step bond (76-100% use)	1	(omitted)			
Matrix use *(ref not CM or SM user)*					
Circumferential metal user (100% use)	1.56	0.54	1.27	0.203	0.79 – 3.08
Sectional metal user (51-100% use)	1.12	0.45	0.27	0.786	0.50 – 2.48
High wedge use (76-100% use) *(ref <76% use)*	0.49	0.17	-2.07	**0.038**	0.25 – 0.96
Never liner use *(ref >0% use)*	1.05	0.33	0.15	0.884	0.57 – 1.93
Rubber dam use *(ref 1-75% use)*					
Never	0.65	0.25	-1.10	0.270	0.31 – 1.39
High (76-100% use)	1.83	0.74	1.49	0.137	0.80 – 4.04
Agree lack of consensus on material *(ref don't agree)*	0.52	0.20	-1.73	0.083	0.24 – 1.09
Agree lack of consensus on technique *(ref don't agree)*	1.05	0.39	0.12	0.904	0.50 – 2.18
Disagree suitable alternatives to amalgam exist *(ref don't disagree)*	0.38	0.14	-2.57	**0.010**	0.18 – 0.79
Low reported sensitivity (0-10%) *(ref ≥11% sensitivity)*	1.55	0.58	1.19	0.236	0.75 – 3.21
Low reported food packing (0-10%) *(ref ≥11% FP)*	1.49	0.57	1.05	0.292	0.71 – 3.15
Constant	0.09	0.07	-3.12	0.002	0.02 – 0.40

Appendix D2.28. Table. Factors related to high or complete confidence in placing composites in patients with poor cooperation

OR, odds ratio; SE, standard error; CI, confidence interval; n=755; p<0.0001; pseudo R^2=0.17; Log likelihood=174;

AIC=399; BIC=515

Appendix E. Supplementary materials for Chapter 5

Appendix E1. Focus group materials

Appendix E1.1. Participant Information Sheet

Participant Information Sheet

Amalgam phase out: What next for posterior teeth? Patient-centred costs and benefits of the alternative direct restorative materials

We would like to invite you to take part in an online group discussion. There will also be a short online survey at the end. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.
Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The use of silver amalgam for dental fillings has already been phased down in the UK on environmental grounds. The potential to completely phase its use out by 2030 is currently being investigated. I am looking at the costs and benefits of the alternative fillings in relation to amalgam, to better inform health policy moving forward.

To get a fuller picture of the situation, we would like to understand this from a patient perspective. The initial part of my research has shown that a majority of dentists think that patients will care about this potential amalgam phase out. We therefore want to understand how patients value different attributes of a filling. The way we are planning to do this is a with an online survey of the general public using a specific technique called Discrete Choice Experiments.

In order to develop the survey, the standard protocol involves undertaking focus group work first, to establish what aspects of a dental filling are important to the public in order for these to be incorporated into the survey.

Voice participants will therefore explore and help determine these aspects.

Why have I been invited?

You indicated your willingness to participate.

Do I have to take part?

No, it is up to you to decide. This information sheet will describe the study and the group discussion so you can decide whether you would like to participate. If you wish to withdraw from the study after the focus group has been completed, you must let us know within 24 hours of the focus group, otherwise the data collected will be included in the analysis of the research project.

What will happen to me if I take part?

We are hosting a group discussion online using Zoom, which will be recorded. This discussion will explore what aspects of a dental filling you value or would value, and how much you value them. The information collected will be anonymous, but you will be asked to provide basic demographic information such as your age, gender and working status among others, and some information on your experience of dentistry.

Unfortunately we cannot provide you with any compensation for your time.

What do I need to do if I would like to take part?

The discussion will take place online using Zoom at the following time:

11th June 2020 10.00am

An invitation to the discussion will be sent to you

What if there is a problem?

Any complaint about the way the discussion has been conducted will be addressed. If you have a concern about any aspect of this study, you should direct your complaint to the researchers who will do their best to answer your questions (Oliver Bailey via email Oliver.bailey1@ncl.ac.uk).

If you remain unhappy and wish to complain formally you could contact the School of Dental Sciences, Newcastle University (0191 208 8347).

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you or the views you have expressed will be handled in confidence. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the University will have your name and identifiable details removed so that you cannot be recognised. The information will be stored securely at Newcastle University. Anonymised data will be kept indefinitely in line with the Data Management Plan (available on request). Only the researchers and the authorities who regulate research will have access.

What will happen if I agreed to come to the discussion but can no longer come?

You can change your mind at any point, but we have limited spaces. If you no longer want to attend or can no longer attend, due to changing your mind, illness or other commitments please let the research team know as soon as possible as we may be able to offer your space to someone else.

What will happen to the results of the research study?

The results of the study may be presented at academic conferences. In addition, the results will be published in scientific journals. You will not be identified in any results. A summary of the results will be available to you after the study on request.

Who is organising and funding the research?

The research is being organised and funded by the School of Dental Sciences at Newcastle University. It is part of Oliver Bailey's PhD.

Who has reviewed the study?

The Newcastle University Ethics Committee, which has responsibility for scrutinizing proposals for research undertaken by the university, has examined the proposal and has raised no objection from the point of view of ethics.

GDPR statement

Newcastle University will be using information from you in order to undertake this research study and will act as the data controller for this study. This means that Newcastle University is responsible for looking after your information and using it properly. When we use personally-identifiable information from people who have agreed to take part in research, we ensure that it is in the public interest. Your rights to access, change or move your information are limited, as Newcastle University needs to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, the minimum personally-identifiable information will be used. You can find out more about how Newcastle University uses your information at **https://www.ncl.ac.uk/data.protection/dataprotectionpolicy/privacynotice/** ***and/or by contacting Newcastle University's Data Protection Officer (Maureen Wilkinson,*** **rec-man@ncl.ac.uk*****).***

Further information and contact details

If you want any more information you can contact the research team via:

Oliver Bailey, School of Dental Sciences, Newcastle University, Framlington Place, Newcastle upon Tyne. NE2 4BW
Email: oliver.bailey1@ncl.ac.uk

Appendix E1.2. Topic guide for online focus group to determine attributes of dental restorations to inform discrete choice experiment study

For researcher use only

11th June 2020, 10.00 on Zoom video call

Allow everyone to join Zoom discussion

Introduction of the researchers and project with PowerPoint presentation

(10 mins)

Ideally we'll go through the process in the way that it'd happen, from getting access to care, finding out you need a filling, the waiting time for an appointment to have it done, the day or the time of the appointment, the choice of materials and healthcare options- whether it be NHS or private, through to the aspects of the procedure itself, the clinician involved and then the outcomes, what the complications may be and how long the fillings will last. Then we'll try and summarise the things that are most important to you all and then get you to discuss them in small groups, before we come back together as a complete group and come to an agreement on how important they are to all of you by ranking them. We've also got a very, very short questionnaire for you to fill in when the focus group finishes and that will be emailed to you during the focus group by Voice, and it's got really important information in it, but we'll talk to you more about that at the end.

It's quite difficult to hear when people talk over each other, especially online, so we really do want people to give everyone the chance to speak and get their points across. Although it's a bit like being back at school, so I apologise for that, I think raising your hand when you wish to speak may be the best way of allowing everyone a say, so perhaps we can try to stick to that. It'd be great to get to know you a little bit by hearing a little introduction from each of you before we get stuck into the discussion, and perhaps we can just trial the hand raising to start us off with this!

Just before we start, what I will say is that we've got quite a bit to get through, and if we start to get off topic, and it is quite easy to wander off topic, I'll probably interrupt just to try and get us back on track, so please don't be offended by that, it's just that we've got limited time.

Initial access to dental care:
(10 mins)
I want to start by thinking about the last time that you attended your dental practice. Don't worry if you haven't been for a while or if you've never been at all. Think about why you chose the specific dental practice, or what would be important in you choosing a practice to go to.

Prompts:

- Location
- Travel time
- Ease of getting appointment
- Trust dentist/therapist/team
- Reputation
    - Other practice aspects of importance, facilities etc.

- NHS service/not
- Willing to be placed on a waiting list to access care
- Parking
- Appointment times offered

Access to dental treatment and pre-treatment options:

(20 mins)

Imagine you've been told you need a filling at your routine examination. I want you to think about the things that are important to you in terms of arranging an appointment to have the filling done

Prompts:

- Waiting time to receive filling
    - How long have you had to wait for an appointment for a filling? Importance? Thoughts?
    - Wait in waiting room

- Appointment time
    - Have to take time off work?
    - Get someone to take you?
    - Clinic location
    - Cost of travel
    - Evening appts?
    - Weekend appts?

What about the healthcare system choices?

- Healthcare system
    - Private / NHS, anyone both? Differences? Insurance based (monthly fee)
    - Perceptions of quality

What about who provides the care?

- Clinician choices
    - Dentist, therapist, time difference for access? rapport, trust

    - Familiar, continuity of staff

    - Caring and friendly
    - Neutral and professional
    - Treats with dignity
    - Recognises pain/stress
    - Reassures
    - Listens to you
    - Gives information
    - Accepts your decisions

- Materials/Teeth aspects of care
    - Colour

    - Position of tooth – premolar/molar; upper/lower
    - Materials and constituents
    - Environmental concerns (mercury / BPA / plastics)

Process of dental treatment:

(10 mins)

Assuming you're numb, what are the important aspects to you during the treatment?

Prompts:

- Time in the chair
- Rubber sheet placed over teeth?
- Dark glasses, TV, music etc
- Reassurance
- Feeling of control
- Drilling, noise, rattling
- Suction
- Water down throat

Outcomes of dental care (20 mins)

What are important outcomes to you from the treatment?

Prompts:

- Longevity
    - How long the filling lasts
    - How long tooth lasts – slight difference in preparation
- Side effects
    - Problems after having had a filling
    - Severity
    - Longevity of problem
    - In terms of experienced specific outcomes
    - Sensitivity,- what is understood by this term?
    - Food packing
    - Floss snagging
    - Filling falls out
    - Replacement required
    - Feel – rough/smooth
- OR
    - In terms of function vs functional limitation
    - No effects vs affected when eating hot/cold/chewing, after eating with food getting stuck
    - How long this lasts for important?
    - Time periods 1wk, 2, 4, 8, 12, lifetime of restoration
- OR
    - Chances of occurrence
    - Importance of knowing the difference between different options before choosing

- COMBINED functional limitation or not?

Summary of attributes and ranking discussion (20mins)

Summarise what seemed to be of high importance to people, see if any important attributes are missing. Discuss in smaller groups an order of importance of the attributes from high to low. Bring groups back together and discuss again to come up with a final ranking

Willingness to pay, wrap up and "Thank You" (10 mins)

Give participants final contingent valuation willingness to pay question online link. Explain why this information is important.

We want to know what the maximum price is that you'd be willing to pay for a filling. This isn't what you think's a fair price. I'll give you an example, you might pay 80p for a can of coke, but often that's not the maximum you'd be willing to pay for it. You may well have paid much more for it in a specific situation- like a sporting event, or a concert. A couple of years ago, I was on holiday in France, and I refused to pay 8 euros for a can. So I handed it back, and I now know my WTP is less than that. For us to understand how much people value a filling, and critically how they value it in relation to other health treatments or interventions, we need to know the absolute maximum value they'd be willing to pay for it, so we can understand how the money for health services is divided up and given to different aspects of healthcare. This is the method used for valuation across different healthcare treatments and interventions to make the results comparable. So when we do the survey of the population, and people have to decide between choices, it's important that we can set reasonable scenarios for the respondents to choose between, with relevant amounts of money.

If you don't pay for dental care, I'd ask you to try and imagine a situation where there's no subsidisation of dentistry, or, for example if you were in another country where dental treatment isn't covered

So hopefully now you've received an email from Voice, with the website link to the survey. It's all done anonymously and what you're going to see is that in the survey, we'll give you a fee for a filling, and if you'd be willing to pay that, you tick yes, and then we'll give you another fee, and we'll keep on going until you're no longer willing to pay the fee shown. It'll take just a couple of minutes and it'll be really really useful for us.

Thank you so much for your time, it's been really helpful, I'm very grateful. Thank you very much.

Appendix E1.3. All suggested attributes

Amalgam phase-down Newcastle University

Important factors for a filling

NHS/Private
Confidence in dentist (+ skill)
Continuity of dental team
Communication skills of dentist/Treating pt holistically
Attitude of dental team
Time spent with patient
Practice environment
Dentist/therapist
Travel distance to dentist
Choice of appointment times
Wait for appointment
Information about process in advance
Choice of options

Colour
Safety of filling material
Environmental impact
Treatment duration (time in chair)
Water going down throat
Amount of items in mouth
Gentle
Description of ongoing process
How long filling/tooth lasts
Damage to tooth of filling preparation
Smoothness of filling after filling
Quality of filling
Getting food stuck between teeth after filling
Pain/discomfort after filling
Sensitivity after filling
Bite correct/comfortable
Cost

From Newcastle. For the world.

Appendix E1.4. Willingness to pay bidding game initial screen

You need a filling in the tooth circled, and the filling will have the outline shown in black on the close up view of the tooth. You won't have to wait to get your appointment, the filling will be done by a dentist, will take 30 minutes and it will be white. There will be a low risk of discomfort after the filling is placed, the average lifespan is 15 years and there will be a low environmental impact.

p.4 Maximum willingness to pay for a filling in a lower back (molar) tooth

Add item

2 Would you be willing to pay an out-of-pocket fee of £25 for the filling described? *

Yes

No

Appendix E1.5. Bidding game responses

Jisc Online surveys

WTP focus group

Showing 6 of 6 responses

Showing **all** responses

Showing **all** questions

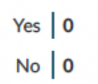
Response rate: 6%

1 Please enter the unique participant identifier given to you below (it begins with 'P')

Showing first 5 of 6 responses	
P6	602895-602886-61321542
P4	602895-602886-61323781
P1	602895-602886-61321191
P3	602895-602886-61340955
P2	602895-602886-61345721

2 Would you be willing to pay an out-of-pocket fee of £25 for the filling described?

3 Would you be willing to pay anything (i.e. more than £0) for the filling described?



4 Would you be willing to pay an out-of-pocket fee of £50 for the filling described?

1 / 3

5 Would you be willing to pay an out-of-pocket fee of £100 for the filling described?

6 Would you be willing to pay an out-of-pocket fee of £150 for the filling described?

7 Would you be willing to pay an out-of-pocket fee of £200 for the filling described?

8 Would you be willing to pay an out-of-pocket fee of £250 for the filling described?

9 Would you be willing to pay an out-of-pocket fee of £350 for the filling described?

10 Would you be willing to pay an out-of-pocket fee of £500 for the filling described?

Yes	0
No	0

11 Would you be willing to pay an out-of-pocket fee of £750 for the filling described?

Yes	0
No	0

12 Would you be willing to pay an out-of-pocket fee of £1000 for the filling described?

Yes	0
No	0

Appendix E2. Ngene software design code

This code generated a d-efficient design to estimate a mixed logit preference model

```
;alts = alt1, alt2, alt3

;block = 4

;rows = 64

;eff = (mnl, d)

;model:

U(alt1) = asc1 + b1 * WAIT[0,2,4,6] + b2.dummy[0] *
CLINICIAN[1,2] + b3.dummy[0] * COLOUR [1,2] + b4 *
TIME[20,40,60,80] + b5.dummy[0|0|0] * DISCOMFORT[1,2,3,4] +
b6[(u,0,0.001)] * LIFESPAN[5,8,11,14] + b7[(u,-0.001,0)] *
COST[25,50,75,100,150,200,250,300] /



U(alt2) = asc2 + b1 * WAIT + b2.dummy * CLINICIAN + b3.dummy *
COLOUR + b4 * TIME + b5.dummy * DISCOMFORT + b6 * LIFESPAN + b7
* COST

$
```

Appendix E3. Discrete choice experiment questionnaire

Survey presented as a word document. It was reformatted onto the Decipher platform before being sent electronically by the distribution company (Dynata) using their in-house sampling tool. This is Block 1. There were four blocks. The blocks differ only in the choice questions.

Introduction

This survey is about dental fillings and how you value different aspects of them.

You will be presented with two different imaginary situations of having a filling in a tooth, with the likely outcomes, and you will be asked to choose between them.

This will be explained in more detail if you wish to take part.

The results of the survey will help decision makers to take patients' opinions into account and therefore make better decisions, when deciding how to provide dental fillings in the UK.

The questionnaire should take around 10 minutes to complete.

Information (and GDPR statement)

Information which could identify you will be separated from responses before they are transferred and analysed at Newcastle University, therefore all information will be pseudonymous.

This study has ethical approval from Newcastle University.

Newcastle University will be using information from you in order to undertake this research study. Dynata will act as the data controller for this study. This means that Dynata and Newcastle University are responsible for looking after your information and using it properly. When we use personally-identifiable information from people who have agreed to take part in research, we ensure that it is in the public interest.

Dynata will use your name and email address to contact you about the research study. They will receive your responses should you choose to take part in the study. This information will be pseudonymised before being transferred to Newcastle University and will not be combined with other information in a way that could identify you. The information will only be used for the purpose research, and cannot be used to contact you. It will not be used to make decisions about future services available to you. Your rights to access, change or move your information are limited, as Newcastle University needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, Newcastle University will keep the information about you that has already been obtained. To safeguard your rights, the minimum personally-identifiable information will be used. You can find out more about how Newcastle University uses your information at ***https://www.ncl.ac.uk/data.protection/dataprotectionpolicy/privacynotice/*** *and/or by contacting Newcastle University's Data Protection Officer (Maureen Wilkinson,* ***rec-man@ncl.ac.uk****).*

Newcastle University will not have access to your name or email address, but we will use your post code and other personal information provided by you in order to ascertain how representative the sample is of the general population, and to assess how or if this information affects the results of the research. Individuals at Newcastle University may look at your research data to check the accuracy of the research study. The only individuals at Newcastle University who will have access to information that identifies you will be individuals who are performing the research, or auditing the data collection process.

If you agree to take part in the research study, information provided by you may be shared with researchers running other research studies at Newcastle University. Your information will only be used by Newcastle University and researchers to conduct research.

Consent

1. I confirm that I have read and understood the purpose of this research and have had the opportunity to consider the information and my involvement.

- Yes
- No

2. I understand that my involvement is voluntary and I consent to participate in this study.

- Yes
- No

Respondent information

The following questions ask about your characteristics so that we can demonstrate that we have collected information from a representative sample of people living in the UK.

It will also allow us to explore how people's varying characteristics affect their choices for dental fillings and therefore potentially provide solutions that will be acceptable to people with different characteristics.

Age

S1. What is your age in years?

Gender

S2. What gender are you?

- Female
- Male

- Other
- Prefer not to say

S3. Which region do you live in?

North East

North West

Yorkshire and the Humber

East Midlands

West Midlands

East of England

London

South East

South West

Wales

Scotland

Northern Ireland

Postcode

S4. Please enter your home postcode

Education

S5. Move down the list and tick your highest level of educational qualification

• Postgraduate degree
• Undergraduate degree
• Higher qualification below degree level
• A-level/Vocational A-level or equivalent
• AS-level/Vocational AS-level or equivalent
• International baccalaureate
• O-levels or equivalent
• GCSE/Vocational GCSE or equivalent
• Other work related or professional qualification • School Leavers Certificate
• None

Working status

S6. Which of the following best describes your current working status?

- Working
    - Employed (full-time or part-time)
    - Self-employed
- Unemployed
- Retired
- Student
- Apprentice
- Furloughed
- Maternity leave
- Short-term sick leave
- Long-term sick leave
- Looking after home/family

Annual household income

S7. Please provide an estimate of your combined annual gross household income last year, before taxes and deductions Single code

Up to £10,000

£10,000 - £19,999

£20,000 - £29,999

£30,000 - £39,999

£40,000 - £49,999

£50,000 - £59,999

£60,000 - £69,999

£70,000 - £79,999

£80,000 - £89,999

£90,000 - £99,999

£100,000 or more

Teeth

First, we'd like to know a little about your teeth, and how your dental care is provided

Please answer the following questions:

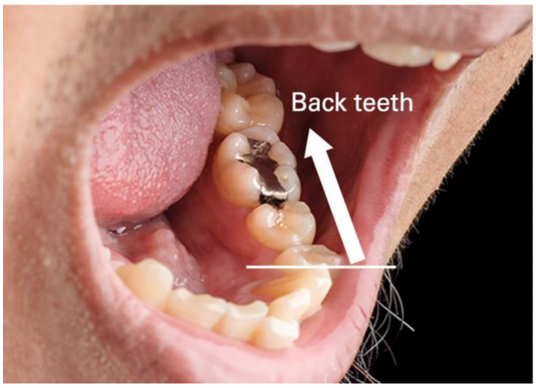
Teeth

3. Do you have any of your own natural teeth in your mouth?

- Yes
- No

4. Have you ever had a filling in a back tooth? Teeth behind line on picture classed as back teeth (same for upper teeth). This does not include a crown or onlay ('cap') that was made outside of your mouth and needed an impression or a scan of your teeth.

- Yes
- No



Teeth continued (dependent on previous question)

5. Have you ever had a silver (amalgam) filling in a back tooth?

- Yes
- No

6. Have you ever had a white filling in a back tooth?

- Yes
- No

7. What is your level of concern about the environmental impact of dental filling materials?

    - Low
    - Medium
    - High

Risk

8. How at risk would you say you are of needing a filling in one of your back teeth in the future?

    - Low
    - Medium
    - High

Importance of your teeth

9. I feel that keeping my natural teeth is:

- Important
- Neither important nor unimportant
- Unimportant

Dental anxiety

Can you tell us how anxious, if at all, you get when visiting the dentist?

10. If you went to your dentist for TREATMENT TOMORROW, how would you feel?

Not anxious

Slightly anxious

Fairly anxious

Very anxious

Extremely anxious

11. If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?

Not anxious

Slightly anxious

Fairly anxious

Very anxious

Extremely anxious

12. If you were about to have a TOOTH DRILLED, how would you feel?

Not anxious

Slightly anxious

Fairly anxious

Very anxious

Extremely anxious

13. If you were about to have your TEETH SCALED AND POLISHED, how would you feel?

Not anxious

Slightly anxious

Fairly anxious

Very anxious

Extremely anxious

14. If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back molar tooth, how would you feel?

Not anxious

Slightly anxious

Fairly anxious

Very anxious

Extremely anxious

15. Please indicate how your dental care is provided

- NHS (you pay the NHS ‘band’ charges)
- NHS (you do not pay and are exempt from NHS charges)
- Insurance based, you pay a monthly fee – this includes all treatment except laboratory bills
- Insurance based, you pay a monthly fee with discounts on any private treatment provided
- Privately (you pay full costs of private treatment)
- Mixed of some NHS banded and some private treatments

The choice questions

In the questions which appear on the following pages, you will be presented with two imaginary treatments.

Each treatment describes a different imaginary situation of having a filling in a tooth, with the likely outcomes.

Please think about each option, as if you were making a decision between the two options in real life circumstances, and tell us which treatment you would choose.

If you do not have any teeth, obviously you will never require a filling, but try to imagine yourself with teeth and make the choice as you would if you had teeth, because we are really interested to hear your opinions too.

A filling is placed when a tooth is decayed.

Imagine the tooth circled is decayed, but not causing you pain, and needs a filling with the outline shown on the close-up view of the tooth.

Assume that the clinician providing the treatment gives a detailed explanation of the procedure and has a caring and friendly manner.

There is also another choice available to you- you can choose not to have any treatment done. If you choose the option ‘no treatment’, this means that the decay will get worse, which will likely result in the tooth:

breaking
going dark in colour
becoming painful and/or infected which may cause a swelling or an abscess

Ultimately the tooth will likely need to be extracted, or need longer and more difficult root canal treatment. This more difficult treatment will likely be more expensive and with more uncertain results.

Also imagine that you cannot shop around and get a different price for the required treatment somewhere else. For each choice question, imagine that the treatments would be exactly the same at any dental practice you went to (including the prices).

Each treatment you will be presented with relates to the above situation, and includes seven different aspects of having the filling, covering the following areas:

Waiting time for filling

The amount of time you have to wait to have the filling done in weeks- 0, 2, 4 or 6 weeks

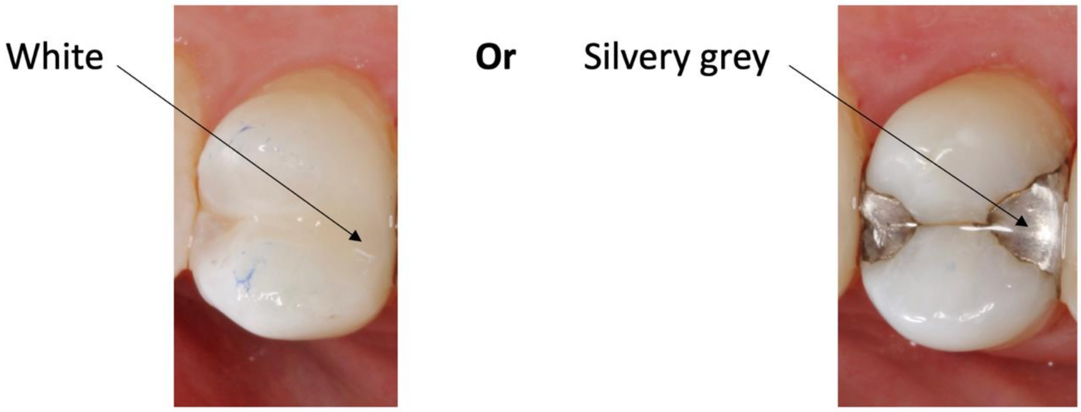
Clinician type

Dentist or dental therapist.
The key differences between a dentist and dental therapist are:

Therapists:

- can do simple fillings, scaling and deep cleaning, but not more complicated procedures like
  crowns, root canal treatments or replacing missing teeth, which are performed by dentists.
- can provide simple fillings direct to patients, or under the guidance of a dentist
- Are registered dental professionals required to study at university for two to four years to gain a diploma or degree, rather than five years for a dentist to gain their degree.

Filling colour
White **Or** Silvery grey



Length of filling procedure

This is how long you will need to be in the dental chair to have the filling placed in minutes- 20, 40, 60 or 80 minutes. (You should **not** consider that the quality of the filling will increase with increased time or vice- versa.)

Likely discomfort after filling

This relates to the likely level of discomfort when eating and drinking after having a filling placed.
This could be:

None
Mild (short-lived low-level sensitivity for 2-4 weeks not causing problems with function)
Moderate (requiring painkillers and may mean that you would avoid eating, chewing or drinking certain foods or drinks for 2-4 weeks)
Persistent (requiring reattendance at the dental practice for the management of a problem after 2-4 weeks)

Filling will last on average

The likely average time in years that the filling lasts until it needs another procedure- for example, until it needs a replacement filling- 5, 8, 11, 14 years

Cost

The out-of-pocket fee in UK pounds sterling which you would have to pay for the filling in each scenario- £15, £25, £35, £45, £60, £90, £150, £250

Going to an appointment for treatment may also mean that you have transport costs and will miss work, or other activities that you do, which could affect your disposable income, wage and leisure time.

It is likely that once a filling has been placed, it will need to be replaced and each time it is replaced there will be associated costs involved with this. Each time a filling is replaced, the filling is also likely to get bigger, which could impact on the need for more complicated future treatments, which may be more expensive, and ultimately could reduce the amount of time the tooth will last in your mouth before needing extraction. Replacing the missing tooth, would also have costs.

Please factor these things in when choosing.

We are interested in your choices of filling procedures and outcomes.

You may think the choice between different scenarios seems repetitive and irrelevant, but your answers, in combination with responses from other people, will help decision makers to make more informed, patient-centred decisions when deciding how to provide dental fillings in the UK.

It is important that you consider your choices carefully. There are no right or wrong answers; it is your personal choice that is important.

Choice questions

5	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Moderate	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£15	£250	£0
Your choice **(tick one box only)**	☐	☐	☐

12	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	40 minutes	60 minutes	N/A
Likely discomfort after filling	None	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	5 years	14 years	N/A
Cost	£250	£15	£0
Your choice (tick one box only)	☐	☐	☐

16	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	6 weeks	0 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	40 minutes	60 minutes	N/A
Likely discomfort after filling	Moderate	Mild	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	8 years	11 years	N/A
Cost	£60	£45	£0
Your choice **(tick one box only)**	☐	☐	☐

23	Treatment 1	Treatment 2	No treatment
Waiting time for filling	6 weeks	0 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	80 minutes	20 minutes	N/A
Likely discomfort after filling	Persistent	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	11 years	8 years	N/A
Cost	£35	£90	£0
Your choice **(tick one box only)**	☐	☐	☐

26	Treatment 1	Treatment 2	No treatment
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	Persistent	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	5 years	14 years	N/A
Cost	£150	£25	£0
Your choice **(tick one box only)**	☐	☐	☐

27	Treatment 1	Treatment 2	No treatment
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Moderate	Mild	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	8 years	11 years	N/A
Cost	£60	£45	£0
Your choice **(tick one box only)**	☐	☐	☐

31	Treatment 1	Treatment 2	No treatment
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	80 minutes	20 minutes	N/A
Likely discomfort after filling	Mild	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	8 years	11 years	N/A
Cost	£45	£60	£0
Your choice **(tick one box only)**	☐	☐	☐

33	Treatment 1	Treatment 2	No treatment
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	40 minutes	60 minutes	N/A
Likely discomfort after filling	Moderate	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	11 years	8 years	N/A
Cost	£35	£90	£0
Your choice **(tick one box only)**	☐	☐	☐

23	Treatment 1	Treatment 2	No treatment
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	None	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	8 years	11 years	N/A
Cost	£90	£35	£0
Your choice **(tick one box only)**	☐	☐	☐

40	Treatment 1	Treatment 2	No treatment
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	None	Mild	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£35	£90	£0
Your choice **(tick one box only)**	☐	☐	☐

43	Treatment 1	Treatment 2	No treatment
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	Persistent	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	5 years	14 years	N/A
Cost	£90	£35	£0
Your choice **(tick one box only)**	☐	☐	☐

49	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	2 weeks	4 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	80 minutes	20 minutes	N/A
Likely discomfort after filling	Moderate	None	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	8 years	11 years	N/A
Cost	£25	£150	£0
Your choice **(tick one box only)**	☐	☐	☐

50	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	0 weeks	6 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	None	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£25	£150	£0
Your choice **(tick one box only)**	☐	☐	☐

52	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	6 weeks	0 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	40 minutes	60 minutes	N/A
Likely discomfort after filling	Mild	Moderate	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	11 years	8 years	N/A
Cost	£150	£25	£0
Your choice **(tick one box only)**	☐	☐	☐

56	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	20 minutes	80 minutes	N/A
Likely discomfort after filling	Mild	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£150	£25	£0
Your choice **(tick one box only)**	☐	☐	☐

58	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	2 weeks	4 weeks	N/A
Clinician type	Therapist	Dentist	N/A
Filling colour	Silvery grey	White	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Persistent	Mild	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	14 years	5 years	N/A
Cost	£90	£35	£0
Your choice **(tick one box only)**	☐	☐	☐

62	**Treatment 1**	**Treatment 2**	**No treatment**
Waiting time for filling	4 weeks	2 weeks	N/A
Clinician type	Dentist	Therapist	N/A
Filling colour	White	Silvery grey	N/A
Length of filling procedure	60 minutes	40 minutes	N/A
Likely discomfort after filling	Mild	Persistent	N/A however, the decay will get worse, which will likely result in the tooth breaking, going dark in colour, being painful and/or causing swelling, and ultimately the tooth will likely need to be extracted, or need longer and more difficult treatment, which will likely be more expensive and with more uncertain results.
Average lifespan of filling	11 years	8 years	N/A
Cost	£250	£15	£0
Your choice (tick one box only)	☐	☐	☐

Thank you for completing the survey!

Appendix E4. Utility function

$$V_j = \alpha ASC + \beta_1 Wait_0 + \beta_2 Wait_2 + \beta_3 Wait_4 + \beta_4 Wait_6 + \beta_5 Clinician_{Dentist} + \beta_6 Clinician_{Therapist} + \beta_7 Colour_{Silvery\ grey} + \beta_8 Colour_{White} + \beta_9 Length + \beta_{10} Discomfort_{None} + \beta_{11} Discomfort_{Mild} + \beta_{12} Discomfort_{Moderate} + \beta_{13} Discomfort_{Persistent} + \beta_{14} Lifespan + \beta_{15} Cost$$

Where:

V_j = observable component of utility of dental restoration

αASC = alternative specific constant, a random normally distributed parameter which reflects the observable utility of choosing a treatment option versus choosing no treatment.

$\beta_{1\text{-}8,10\text{-}13}$ = categorical variables

$\beta_{9,14\text{-}15}$ = continuous variables

β = coefficient (value) of each attribute level for categorical variables, and the coefficient of changing a continuous variable by one unit in the units of measurement for each categorical variable. For example with lifespan, the beta represents the value of increasing the longevity of a restoration by one year.

Appendix E5. Discrete choice experiment supplementary results

Variable	**Variance inflation factor**
Choice	1.27
Wait 2	3.31
Wait 4	3.41
Wait 6	3.31
Clinician (T)	1.27
Colour (W)	1.29
Time	2.14
Discomfort 1	1.56
Discomfort 2	1.54
Discomfort 3	1.53
Lifespan	2.48
Cost	1.43

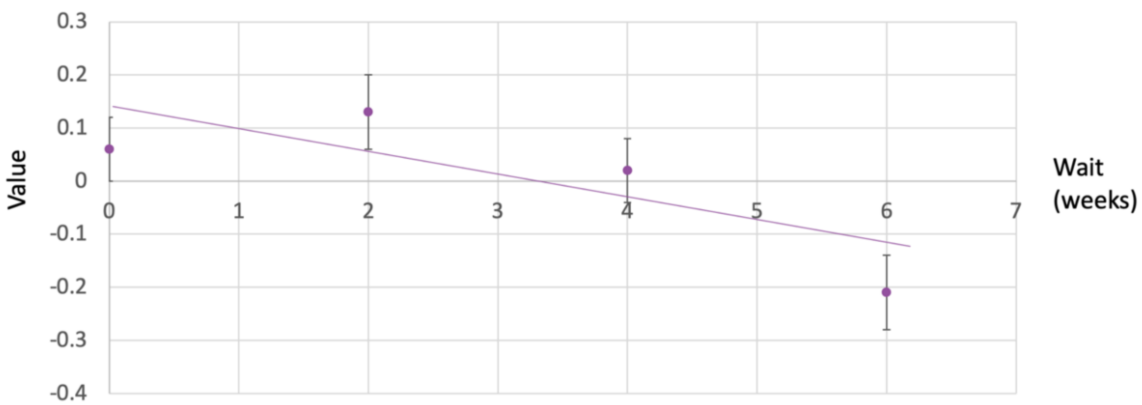
Appendix E5.1 Table. Discrete choice experiment variable variance inflation factors

	Block 1 (%) (n=250)	Block 2 (%) (n=251)	Block 3 (%) (n=251)	Block 4 (%) (n=250)	Total (%) (n=1002)
Passed dominance test	90.4	91.6	90.8	92.4	91.3
Passed consistency test	78.0	84.9	85.3	85.6	83.4
Passed both tests	73.6	79.7	79.7	81.2	78.5
Failed both tests	5.2	3.2	3.6	3.2	3.8
Chose same treatment option (all 1 or all 2)	1.2	0.8	0.8	0	0.7
Chose all treatment 1	0	0.4	0.4	0	0.2
Chose all treatment 2	1.2	0.4	0.4	0	0.5
Chose all 'No treatment'	2.4	1.6	2.4	2.8	2.3

Appendix E5.2 Table. Respondent consistency and dominance test results

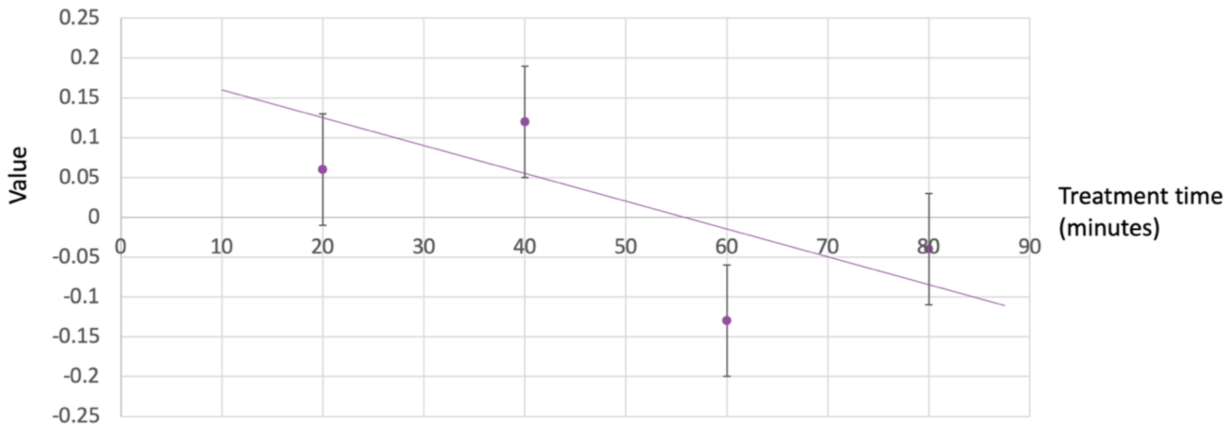
Respondent id	Income (£)	Working status	IMD	High dental anxiety	Own teeth	Dentistry provision	Previous filling
1752	<10000	Long-term sick	1	Yes	Yes	NHS (pay)	No
924	<10000	Long-term sick	3	No	No	NHS (exempt)	No
30	<10000	Long-term sick	9	Yes	Yes	Private	Yes
443	<10000	Retired	1	No	No	NHS (exempt)	Yes
3104	20k-29999	Employed	5	No	Yes	NHS (exempt)	No
285	20k-29999	Unemployed	1	Yes	Yes	NHS (exempt)	No
217	20k-29999	Employed	2	No	Yes	NHS (exempt)	Yes
1574	PNTS	Employed	8	Yes	Yes	NHS (exempt)	No
487	10k-19999	Retired	3	Yes	Yes	NHS (pay)	Yes
2466	PNTS	Retired	6	No	Yes	NHS (pay)	No
444	100000+	Employed	9	No	Yes	NHS (pay)	Yes
1703	PNTS	Home care	2	Yes	Yes	NHS (exempt)	Yes
608	<10000	Unemployed	3	Yes	Yes	NHS (exempt)	Yes
1830	<10000	Student	9	No	Yes	NHS (pay)	Yes
304	30k-39999	Retired	6	Yes	No	NHS (pay)	No
295	60k-69999	Retired	5	No	Yes	NHS (pay)	Yes
470	30k-39999	Self-employed	8	No	Yes	NHS (exempt)	Yes
1565	PNTS	Home care	3	Yes	Yes	NHS (pay)	Yes
375	10k-19999	Retired	9	No	Yes	NHS (exempt)	Yes
579	10k-19999	Retired	9	No	Yes	NHS (exempt)	Yes
1587	20k-29999	Retired	8	No	Yes	NHS (pay)	Yes
2042	60k-69999	Employed	4	Yes	Yes	NHS (pay)	Yes
1728	10k-19999	Retired	5	No	No	NHS (exempt)	Yes

Appendix E5.3. Table. Characteristics of those opting out of all treatment

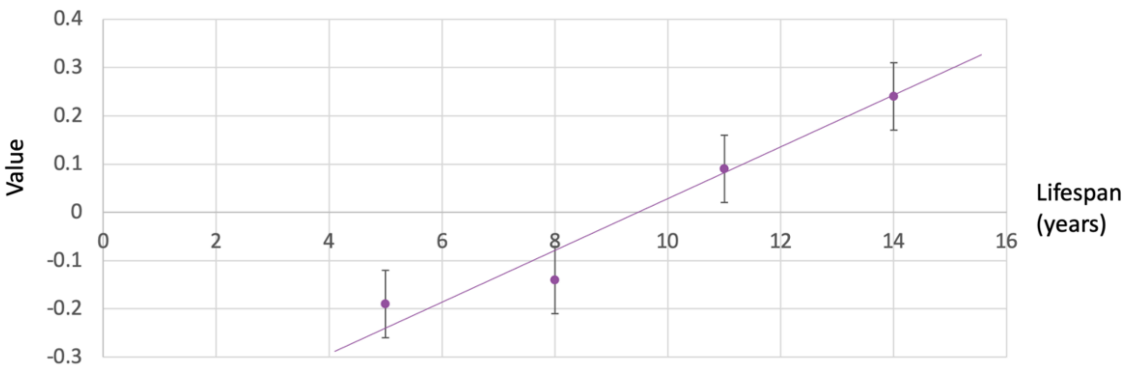


Appendix E5.4. Figure. General public valuation of varying waiting time for filling

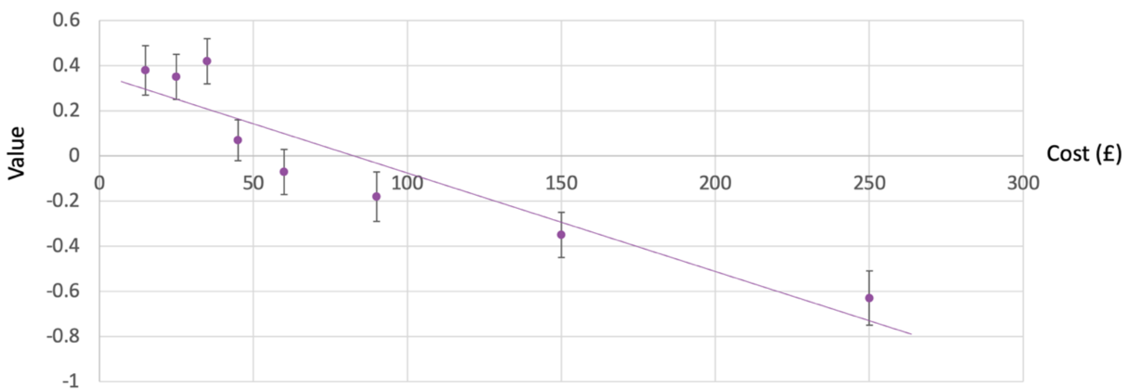
Exploratory conditional logit categorical model



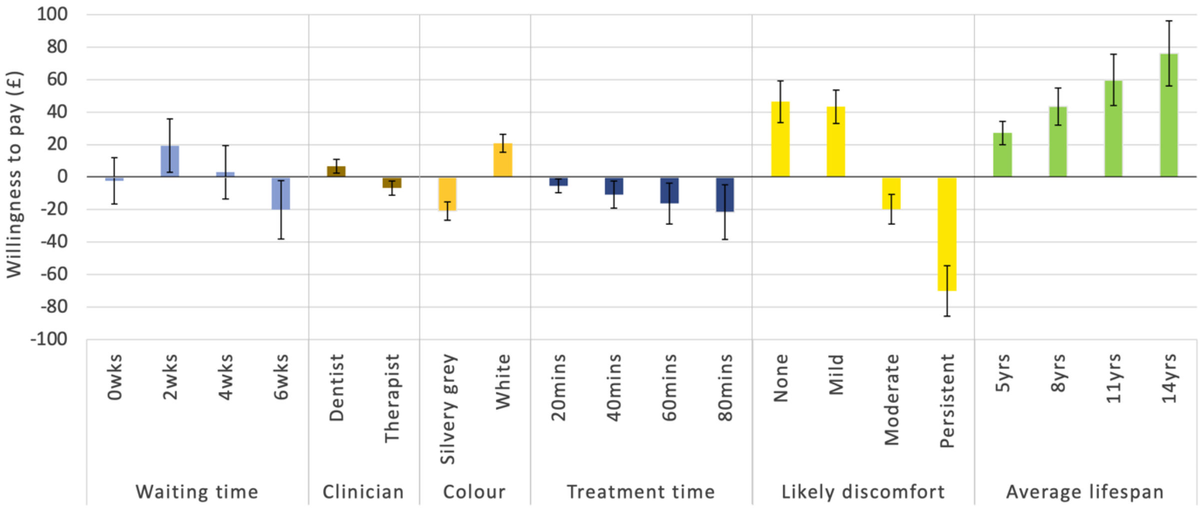
Appendix E5.5. Figure. General public valuation of varying treatment time for filling
Exploratory conditional logit categorical model



Appendix E5.6. Figure. General public valuation of varying lifespan of filling
Exploratory conditional logit categorical model



Appendix E5.7. Figure. General public valuation of varying cost of filling
Exploratory conditional logit categorical model



Appendix E5.7. Figure. Overall UK population marginal willingness to pay for direct posterior restoration attribute levels

Attribute	Overall (n=1002)		Low income (n=221)		Higher income (n=727)	
	Range beta (+/- 95% CI)	RAI (%) (+/- 95% CI)	Range beta (+/- 95% CI)	RAI (%) (+/- 95% CI)	Range beta (+/- 95% CI)	RAI (%) (+/- 95% CI)
Waiting time for filling	0.340 (0.196)	7.7 (4.4)	0.475 (0.404)	9.0 (7.7)	0.303 (0.227)	7.4 (5.5)
Clinician	0.116 (0.043)	2.6 (1.0)	0.124 (0.099)	2.4 (1.9)	0.113 (0.049)	2.8 (1.2)
Colour	0.358 (0.060)	8.1 (1.4)	0.214 (0.129)	4.1 (2.5)	0.385 (0.069)	9.4 (1.7)
Treatment time	0.142 (0.032)	3.2 (0.7)	0.233 (0.142)	4.4 (2.7)	0.112 (0.070)	2.7 (1.7)
Likely discomfort	1.003 (0.134)	22.8 (3.0)	1.068 (0.317)	20.3 (6.0)	0.940 (0.150)	23.0 (3.7)
Average lifespan	0.422 (0.065)	9.6 (1.5)	0.336 (0.147)	6.4 (2.8)	0.437 (0.078)	10.7 (1.9)
Cost	2.024 (0.183)	45.9 (4.2)	2.824 (0.502)	53.5 (9.5)	1.797 (0.202)	44.0 (4.9)

Appendix E5.9. Table. Relative attribute importance: overall and by income

RAI, relative attribute importance; CI, confidence interval.

Appendix F. Supplementary Materials for Chapter 7

Appendix F1. Expert opinion request

Request for expert opinion on restoration parameter information

Dear all,

I'd appreciate it if you could take a couple of minutes and fill in the following information (highlighted) which would be really helpful for my PhD. I'm trying to get a rough idea of expert opinion. The values are not specific to you, but what you feel the values would generally be for NHS primary care dentists restoring posterior teeth in adult patients. I'll also be pooling the answers and not recording your name so they'll be anonymised. Could you reply just to me please, so you don't influence others. I'd be grateful if you could respond by 6th September.

Likely waiting time for a restoration (within an NHS practice setting) (0,2,4 or 6 weeks)

Composite =
Amalgam =

And

Post operative complications (in NHS primary dental care)

The levels were: none, mild, moderate, persistent.

This relates to the likely level of discomfort when eating and drinking after having a filling placed.
None - self-explanatory
Mild (short-lived low-level sensitivity for 2-4 weeks not causing problems with function)
Moderate (requiring painkillers and may mean that you would avoid eating, chewing or drinking certain foods or drinks for 2-4 weeks)Persistent (requiring reattendance at the dental practice for the management of a problem after 2-4 weeks)

Could you record a percentage of each option for each restoration type adding up to 100% for each material please

Composite
None =
Mild =
Moderate =
Persistent =

Amalgam
None =
Mild =
Moderate =
Persistent =

Appendix F2. Cost consequence analysis supplementary results

Expert	Post-operative complications (%)							
	Amalgam				Composite			
	None	Mild	Moderate	Persistent	None	Mild	Moderate	Persistent
1	70	20	5	5	50	25	15	10
2	80	10	7	3	50	30	20	10
3	95	2	1	1	90	6	2	2
4	95	3	2	1	80	10	8	2
5	90	7	2	1	70	15	10	5
6	75	15	7	3	60	25	10	5
7	40	40	15	5	25	50	20	5
8	60	30	5	5	40	40	10	10
Average	76	16	6	3	58	25	12	6

Appendix F2.1 Table. Expert opinion on post-operative complication incidence for restoration materials in NHS primary care relating to discrete choice experiment levels.

Averages given to nearest integer.

Material (generic)	Cost/restoration (with 20% VAT) (£)		
	Mean	Minimum	Maximum
Local anaesthetic solution	0.60	0.56	0.62
Local anaesthetic disposable barrel	0.36	0.36	0.36
Bib	0.12	0.06	0.19
Disposable cup	0.04	0.02	0.05
Tray cover	0.08	0.04	0.15
3-in-1 tip	0.29	0.08	0.48
Suction tip	0.06	0.05	0.09
Mask IIR (operator and assistant)	0.14	0.12	0.19
Gloves nitrile (operator and assistant	0.23	0.16	0.29
Articulating paper	0.07	0.04	0.11
Total (unrounded values)	1.99	1.49	2.54

Appendix F2.2 Table. Generic restoration consumable costs (same for all restorations)

Material	Cost/restoration (with 20% VAT) (£)		
	Mean	**Minimum**	**Maximum**
Amalgam (2 spill)	1.76	1.37	1.99
Calcium hydroxide lining	0.05	0.04	0.07
Tofflemire matrix band	0.48	0.18	0.91
Wooden wedge	0.21	0.14	0.25
Cotton wool rolls	0.06	0.03	0.09
Liner	0.05	0.03	0.07
Amalgam capsule waste storage*	0.15	0.13	0.17
Generic disposables	1.99	1.49	2.54
Total (unrounded values)	4.74	3.40	6.08

Appendix F2.3 Table. Amalgam consumable costs

*Based on 4-5 restorations performed/day NHS practice, 5 working days and 47 working weeks per year (N. Diddee (Clinical director Riverdale corporate group), private communication, August 2024) = 1057.5 (range 940-1175) amalgam restorations/year.
Amalgam waste pots cost: £131.04 per surgery per year (2 of each 500ml and Bulk pot per surgery per year (includes disposal cost) (N Diddee, personal communication, May 2024). With 20% VAT = £157.25.
Therefore disposal cost/amalgam restoration = £157.25/1057.5 = £0.15
Minimum: £157.25/1175 = £0.13
Maximum: £157.25/940 = £0.17

Material	Minimum cost/restoration (with 20% VAT) (£)		
	Mean	**Minimum**	**Maximum**
Conventional paste composite	5.11	2.19	6.78
Calcium hydroxide lining	0.05	0.04	0.07
Phosphoric acid etch gel + tips	0.62	0.62	0.62
Bonding agent	2.50	0.98	3.58
Microbrushes	0.54	0.22	0.82
Finishing discs	0.65	0.49	0.8
Light curing shield	0.08	0.08	0.08
Tofflemire matrix	0.48	0.18	0.91
Wooden wedge	0.21	0.14	0.25
Cotton wool rolls	0.06	0.03	0.09
Saliva ejector	0.05	0.05	0.05
Generic disposables	1.99	1.49	2.54
Total	12.34	6.50	16.59

Appendix F2.4 Table. Average conventional composite consumable costs

Material (conventional composite 'recommended' with branded material)	Cost/restoration (with 20% VAT) (£)		
	Mean	Minimum	Maximum
Conventional paste composite	6.09	5.22	6.78
Conventional flowable composite	4.94	3.81	6.26
Phosphoric acid etch gel + tips	0.62	0.62	0.62
Bonding agent	2.89	2.47	3.58
Microbrushes	0.54	0.22	0.82
Finishing discs	0.65	0.49	0.80
Light curing shield	0.08	0.08	0.08
Sectional matrix	1.80	1.04	3.46
Plastic wedge	0.56	0.50	0.62
Rubber/dental dam (latex free)	1.29	1.08	1.74
Generic disposables	1.99	1.49	2.54
Total	21.43	17.02	27.30

Appendix F2.5 Table. Recommended conventional composite consumable costs

Material	Cost/restoration (with 20% VAT) (£)		
	Mean	Minimum	Maximum
Bulk-fill paste composite	5.51	3.78	6.40
Phosphoric acid etch gel + tips	0.62	0.62	0.62
Bonding agent	2.89	2.47	3.58
Microbrushes	0.54	0.22	0.82
Finishing discs	0.65	0.49	0.80
Light curing shield	0.08	0.08	0.08
Sectional matrix	1.80	1.04	3.46
Plastic wedge	0.56	0.50	0.62
Rubber/dental dam (latex free)	1.29	1.08	1.74
Generic disposables	1.99	1.49	2.54
Total	15.92	11.77	20.66

Appendix F2.6 Table. Recommended bulk-fill paste composite consumable costs

Material	Cost/restoration (with 20% VAT) (£)		
	Mean	Minimum	Maximum
Bulk-fill flowable composite	5.35	4.89	6.00
Conventional paste composite	6.09	5.22	6.78
Phosphoric acid etch gel + tips	0.62	0.62	0.62
Bonding agent	2.89	2.47	3.58
Microbrushes	0.54	0.22	0.82
Finishing discs	0.65	0.49	0.80
Light curing shield	0.08	0.08	0.08
Sectional matrix	1.80	1.04	3.46
Plastic wedge	0.56	0.50	0.62
Rubber/dental dam (latex free)	1.29	1.08	1.74
Generic disposables	1.99	1.49	2.54
Total	21.84	18.10	27.04

Appendix F2.7 Table. Recommended bulk-fill flowable composite consumable costs

Material (bulk-fill flowable composite basic)	**Minimum cost/restoration (with 20% VAT) (£)**
Bulk-fill flowable composite	4.16
Conventional paste composite	2.19
Phosphoric acid etch gel + tips	0.62
Bonding agent	0.98
Microbrushes	0.22
Finishing discs	0.49
Light curing shield	0.08
Tofflemire matrix	0.18
Wooden wedge	0.14
Cotton wool rolls	0.03
Saliva ejector	0.05
Generic disposables	1.49
Total	10.62

Appendix F2.8 Table. Basic (own brand) bulk-fill flowable composite consumable costs

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