

# **CLINICAL RESEARCH**

# Development of a United Kingdom-centric cost-effectiveness model for denture cleaning strategies

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# ABSTRACT

**Statement of problem.** Denture stomatitis is a prevalent condition in denture wearers. Economic evaluations of health care can help stakeholders, including patients, make better decisions about treatments for a given condition. Economic models to assess the costs and benefits of different options for managing denture stomatitis are lacking.

**Purpose.** The purpose of this study was to explore the feasibility of developing a cost-effectiveness model to assess denture cleaning strategies aimed at preventing denture stomatitis from a denture-wearer perspective in the United Kingdom.

Material and methods. A model was developed to identify and estimate the costs and effects associated with 3 denture cleaning strategies. These were low care (LC)—cleaning by brushing and soaking overnight in water; medium care (MC)—brushing with toothpaste and soaking overnight in water; and optimum care (OC)—brushing and soaking overnight in water and antimicrobial denture cleanser. Costs, outcome measures (denture stomatitis–free days), and probabilities (incidence of stomatitis, unscheduled dentist visits, prescription charges, self-medication) associated with each strategy were defined. A sensitivity analysis was used to identify key drivers and test the robustness of the model.

**Results.** The model showed that the total costs for 2015 ranged from £1.07 (LC) to £18.42 (OC). Costs associated with LC were derived from unscheduled dentist visits and use of medication and/or prescription charges. Incremental costs per denture stomatitis–free day were £0.64 (MC) and £1.81 (OC) compared with LC. A sensitivity analysis showed that varying either or both key parameters (baseline incidence of denture stomatitis and relative effectiveness of MC and OC strategies) had a substantial effect. Incremental cost-effectiveness ratios ranged from £4.11 to £7.39 (worst-case scenario) and from £0.21 to £0.61 (best-case scenario).

**Conclusions.** A model was developed to assess the relative cost-effectiveness of different denture cleaning strategies to help improve denture hygiene. An important finding of the study was the lack of evidence on the relative effectiveness of different cleaning strategies, meaning that several assumptions had to be incorporated into the model. The model output would therefore likely be considerably improved and more robust if these evidence gaps were filled. (J Prosthet Dent 2021; $\blacksquare$ : $\blacksquare$ - $\blacksquare$ )

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This work was supported by GSKCH with funding to Lucid Group Communications Ltd, Marlow, Buckinghamshire, UK, for medical writing support (preparation of manuscript drafts for the named authors to edit) for development of the manuscript. No payments were made to the authors for the development of this manuscript. Conflict of interest: M.H. was employed as a contractor to the Office of Health Economics (OHE) at the time of the development of the model; the OHE received a payment from GSKCH for developing the model. C.R.V. was funded by a Clinician Scientist Award from the National Institute for Health Research (NIHR) during the development of the model. S.M. and R.V. are current employees of GSKCH R&D. Newcastle University received a payment from GSKCH for input into developing the model. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care. <sup>a</sup>Head, Health Cutomes, Office of Health Economics, London, UK.

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### **Clinical Implications**

The proposed model offers a patient-centered costeffectiveness framework for dentists when recommending denture cleaning methods. Compared with a low-care approach based on just rinsing dentures, medium-care (brushing with toothpaste) and optimum-care (using denture cleanser) strategies are potential cost-effective alternatives in preventing denture stomatitis. While the current model would benefit from more evidence on the relative effectiveness of different cleaning strategies, such models could help patients make better-informed decisions about their denture care strategies.

The United Kingdom (UK) Adult Dental Health Survey in 2009 showed that 1 in 5 adults wore removable dentures of some description (partial or complete), with the greatest proportion observed in the elderly.<sup>1</sup> Denture stomatitis (DS), a condition characterized by mild inflammation and erythema of the oral cavity, affects between 15% and more than 70% of denture wearers.<sup>2,3</sup> DS has been reported to result from inadequate denture cleaning, denture plaque, mucosal damage from poorly fitting dentures, wearing removable dentures overnight, and overgrowth of commensal Candida albicans.4-10 Many patients are asymptomatic, whereas for others, symptoms can include oral pain and mouth ulcers<sup>2,8</sup> which may require individuals to stop using their dentures, thereby impairing diet and quality of life.<sup>2,8,11</sup>

Although considered largely preventable and manageable with effective oral hygiene, DS nevertheless affects healthcare resources in terms of office visits and prescription costs.<sup>12</sup> Antifungal treatment can help relieve symptoms, but stomatitis is likely to recur when therapy is stopped unless denture hygiene is also improved.<sup>13-15</sup> Notably, because daily oral hygiene is important to the management of this condition, care for DS is shared between patients and healthcare providers, with out-of-pocket costs for denture cleansers, oral hygiene, and analgesic products.

Denture wearers clean their dentures with a variety of products, including soap, water, bleach, and antimicrobial products.<sup>16</sup> Although some of these are inexpensive, how they are used and their associated costs vary significantly. As such, understanding how these costs affect patient choices and denture hygiene is important.<sup>11,17,18</sup>

Evidence-based guidelines provided by the American College of Prosthodontists<sup>11</sup> recommend that dentures should be cleaned daily by soaking and brushing with a



Figure 1. Decision tree model structure.

denture cleanser and then thoroughly rinsed. However, a recent comprehensive review of denture maintenance guidance worldwide has shown a lack of consensus and standardization.<sup>19</sup>

Cost-effectiveness models can help maximize health interventions while making efficient use of available resources and allow policy makers, clinicians, and patients to make informed choices. Such models are often developed from a health-service provision perspective<sup>20</sup>; however, consumers or patients also bear out-of-pocket costs for preventing and managing their conditions. The authors are unaware of attempts to develop such a model for DS.<sup>21-24</sup> Therefore, this proof-of-concept approach examined the null hypothesis that developing a cost-effectiveness model to assess the potential benefits of using denture cleansers from a patient perspective in the UK is not feasible.

### **MATERIAL AND METHODS**

A decision tree model was used because such models have been reported to be useful for evaluating interventions within a short time (Fig. 1).<sup>25</sup> The model estimated the costs and effects associated with 3 different strategies for denture cleaning. A low-care (LC) strategy consisted of cleaning the denture by brushing and soaking overnight in water; a medium-care (MC) strategy consisted of brushing with toothpaste and soaking

overnight in water; and an optimum-care (OC) strategy consisted of brushing and soaking overnight in water and denture cleanser. The 3 strategies were selected based on a review of the literature, a multicountry denture cleaner diary study (GlaxoSmithKline Consumer Healthcare [GSKCH] data on file), and recommendations from the General Dental Practitioners' Association.<sup>26</sup> These were agreed by a panel of experts from GSKCH together with an author (I.J.) and broadly represented the most common approaches used by denture wearers. The model time horizon was 1 year (4 cycles of 3 months) to adequately capture costs and outcomes to allow the 3 strategies to be compared.

The model focused on the number of DS-free days as an outcome. The model was constructed by using an approach in health economics in dentistry, examining costs to the denture wearer (the patient). Only direct costs to the patient (toothpaste, denture cleansers, prescription, and dental visit charges) were used when generating model outputs; resource use from a healthcare system perspective was not included. The cost of a toothbrush was common to all strategies and was therefore not included in the model.

As many people who wear dentures in the UK would likely be exempt from healthcare-related costs relevant to the model, such as prescription and dentist visit charges (because of age and/or economic status), an adjustment was made based on prescription payment estimates and assuming only 20% of denture wearers would pay these costs. However, it was assumed that the denture wearer would pay for self-medication. Costs and probabilities used to populate the model were obtained from a literature review and through consultation with clinical experts at 2 workgroups. Table 1 shows the costs (UK pounds sterling 2015) and probabilities associated with each strategy, including their sources. Calculations were based on these parameters. When these factors were multiplied by the associated probabilities for each denture cleaning strategy, the average cost and outcome components were calculated (for example, DS would incur certain treatment costs and negative outcomes, for instance, more days of compromised denture function).

Model outputs calculated were average yearly cost of each strategy per denture wearer; average effects for each strategy per denture wearer per year in terms of DS-free days and days with DS implying reduced denture function; incremental costs and effects for the MC and OC strategies compared with the LC strategy; and the incremental cost-effectiveness ratio (ICER) of the MC and OC strategies relative to the LC strategy (the ICER is expressed as cost [UK pound sterling] per additional DSfree day compared with the LC strategy).

Two types of sensitivity analysis were performed to identify key drivers and test the model's robustness by repeating the comparison between inputs and consequences while varying key assumptions. A 1-way analysis involved varying the values of 1 parameter at a time and observing the effects on the model's conclusions, and a multiway analysis involved varying more than 1 parameter at a time. The 2 parameters included in the sensitivity analysis were the baseline incidence of DS and relative effectiveness of MC and OC strategies in reducing the incidence of DS compared with the LC strategy. As incidental costs (unscheduled dentist visits, prescription charges, and self-medication costs) only had a minor impact on the model, they were not varied in the sensitivity analysis. As product costs are relatively fixed, they were not varied in the sensitivity analysis either.

The range of values tested in the sensitivity analysis was based on applying a 50% decrease (and a 100% increase) in baseline DS incidence in patients following an LC strategy and on either an increase or decrease in the relative effectiveness of the MC and OC strategies compared with the LC strategy. This approach provided insight into how different magnitudes of variation could affect model outcomes. While prevalence studies on DS presented a range of values given the heterogenous nature of the populations studied, standard assumptions based on common economic evaluation practice were used. The variations in baseline incidence and relative effectiveness were applied in new models, both separately (1-way sensitivity analysis) and in combination (multiway sensitivity analysis). The 6 models used were as follows: model 1 (50% decrease in baseline incidence of DS); model 2 (increase in baseline incidence of DS to 100% probability in LC strategy); model 3 (increase in relative effectiveness of MC and OC strategies compared with the LC strategy); model 4 (decrease in relative effectiveness of MC and OC strategies compared with the LC strategy); model 5 (multiway sensitivity analysis, best-case scenario); and model 6 (multiway sensitivity analysis, worst-case scenario).

#### RESULTS

Key outcomes for the base case are shown in Table 2. Total yearly costs for each strategy ranged from £1.07 (LC strategy) to £18.42 (OC strategy); for context, in United States (US) dollars, these values correspond to annual costs of \$1.64 and \$28.15, respectively (based on a mean 2015 exchange rate of  $\times$ 1.5285; data from https://www.exchangerates.org.uk/). However, given the differences in the US and UK healthcare systems, these data are for illustrative purposes only, and costs from this UK model are not directly applicable to US patients.

The costs associated with the LC strategy were derived from unscheduled dentist visits and medication and/or prescription charges. The incremental cost for the MC and OC strategies was their costs minus the LC strategy costs. Almost all additional costs

Parameter		Values(s)	Source	Comments
Cost (UK pound sterling 2015 <sup>a</sup> )				
Cost of cleaning product per strategy	Cleanser	£4.47	Price for 3-min daily cleanser (provided by GSKCH), and compared with costs available online	Cost for over-the-counter 3-min daily cleanser (quantity 30) at £1.49 (£0.049 per tablet). In 3 mo, 3 packages would be needed
	Toothpaste	£1.00	Mean price suggested by authors	Cost based on consumption of 1 tube of toothpaste every 3 mo
Treatment for stomatitis (mean prescription cost per 3-mo cycle)	All strategies	£8.20	NHS Choices website (www.nhs.uk)	-
Self-medication	-	£8.00	Boots website (www.boots.com)	Over-the-counter topical anesthetic gel (£3.00) and oral rinse mouthwash (£5.00), for managing pain relief from aphthous ulceration
Unscheduled dentist visits (cost per visit)	All strategies	£18.80	NHS choices Band 1 course of dental treatment (www.nhs.uk)	Standard national charge
Probabilities (per cycle=3 mo)				
Incidence of stomatitis	LC strategy	0.16	Gendreau and Loewy (2011) <sup>2</sup>	Baseline incidence. Incidence for LC strategy used as starting point to estimate incidence for remaining strategies based on assumptions regarding relative effectiveness
	MC strategy	0.112	Assumption <sup>b</sup>	Assumed 30% reduction for MC strategy compared with LC strategy
	OC strategy	0.08	Assumption <sup>b</sup>	Assumed 50% reduction for OC strategy compared with LC strategy
Unscheduled dentist visits	All strategies	0.02	Assumption plus input from clinical expert $^{\circ}$	Estimated that only 20% of patients with episode of denture stomatitis will make unscheduled dentist visit
Prescription charges	All strategies	0.02	Assumption plus input from clinical expert <sup>c</sup>	All patients making unscheduled dentist visit will receive prescription
Self-medication	All strategies	0.02	Assumption plus input from clinical expert <sup>c</sup>	_

#### Table 1. Cost-effectiveness model input parameters with values for 3-month cycle

LC, low care; MC, medium care; OC, optimum care. <sup>a</sup>Mean exchange rate for UK pound sterling to American dollars in 2015 was 1.5285 (based on data from https://www.exchangerates.org.uk/). <sup>b</sup>Assumptions on incidences of stomatitis with the MC and OC strategies made by authors. <sup>c</sup>Assumptions based on authors plus clinical expert input.

associated with the MC and OC strategies were derived from toothpaste and denture cleansers. An important finding from the model was that costs associated with incidental resource use (dentist visits and medication or prescription costs) only represented a small total cost to patients. For example, for the LC strategy, mean incidental costs amounted to £1.07 per year, with no other associated cost. For the MC and OC strategies, mean incidental costs were lower (£0.75 for MC and £0.54 for OC) owing to the lower (assumed) rates of DS.

The average number of DS-free days per year ranged from 341 days (LC strategy) to 350 days (OC strategy). Using a denture cleanser achieved an extra 9.6 DS-free days per year compared with just brushing and soaking. According to the model, those adopting the LC strategy would have approximately 19 days per year suffering the effects of DS compared with 13.4 days in the MC group and 9.6 days in the OC group.

The main output variable was the incremental cost per DS-free day with the MC and OC strategies compared with the LC strategy. The cost of achieving each additional DS-free day was  $\pounds 0.64$  for the MC strategy and  $\pounds 1.81$  for the OC strategy compared with the

#### Table 2. Base case: cost, effect, and cost-effectiveness

Parameter	Low Care	Medium Care	Optimum Care
Total cost per year (£)	1.07	4.75	18.42
Average days denture stomatitis–free per year (n)	340.8	346.6	350.4
Average days with denture stomatitis per year (n)	19.2	13.4	9.6
Incremental cost <sup>a</sup>	-	3.68	17.34
Incremental effect <sup>b</sup>	-	5.76	9.6
ICER (cost/effect) <sup>c</sup>	-	0.64	1.81

ICER, incremental cost-effectiveness ratio; LC, low care; MC, medium care; OC, optimum care. Low care: cleaning denture by brushing and soaking overnight in water; Medium care: brushing denture with toothpaste and soaking overnight in water; Optimum care: brushing denture and soaking overnight in water and denture cleanser. All costs shown in UK pounds sterling (2015). <sup>a</sup>Incremental cost=cost of OC or MC strategy minus cost of LC strategy. <sup>b</sup>Incremental effect=difference in average number of denture stomatitis-free days per year between LC strategy and OC or MC strategy. <sup>c</sup>Cost of producing additional denture stomatitis-free day compared with reference LC strategy.

LC strategy. However, a greater number of DS-free days were achieved with the OC strategy.

A 1-way sensitivity analysis was performed for models 1 to 4. In model 1, reducing baseline DS incidence by 50% negatively impacted the MC and OC strategies, as their benefits were reduced while their costs

1.e4

1.e5

Table 3. Sensitivity analysis: best-case scenario (increased incidence of denture stomatitis plus increased effectiveness of MC and OC compared with LC)

Parameter	Case	Low Care	Medium Care	Optimum Care
Total cost per year (£)	Base	1.07	4.75	18.42
	Best	1.68	4.84	18.1
Average days with denture stomatitis per year (n)	Base	19.2	13.4	9.6
	Best	30	15	3
Incremental cost <sup>a</sup>	Base	-	3.68	17.34
	Best	-	3.16	16.37
Incremental effect <sup>b</sup>	Base	-	5.76	9.6
	Best	-	15	27
ICER (cost/effect) <sup>c</sup>	Base	-	0.64	1.81
	Best	-	0.21	0.61

ICER, incremental cost-effectiveness ratio; LC, low care; MC, medium care; OC, optimum care. Low care: cleaning denture by brushing and soaking overnight in water; Medium care: brushing denture with toothpaste and soaking overnight in water; Optimum care: brushing denture and soaking overnight in water and denture cleanser. All costs shown in UK pounds sterling (2015). <sup>a</sup>Incremental cost=cost of OC or MC strategy minus cost of LC strategy. <sup>b</sup>Incremental effect=difference in average number of denture stomatitis–free days per year between OC or MC strategy and LC strategy. <sup>c</sup>Cost of producing additional denture stomatitis–free day compared with reference LC strategy.

remained fixed. The MC and OC strategy ICERs approximately doubled (MC £1.33; OC £3.67) compared with the base-case scenario (MC £0.64; OC £1.81). In model 2, an increase in the incidence of DS to a 100% probability of developing at least 1 episode of DS during the year had a positive impact on the MC and OC strategies, as their benefits were increased while the costs remain largely fixed. The ICERs for both MC and OC strategies were considerably reduced (MC £0.40; OC £1.14) compared with the base-case scenario.

In model 3, an increase in the relative effectiveness of the MC and OC strategies was assumed (DS case reduction from 30% to 50% [MC] and 50% to 90% [OC], respectively) compared with the LC strategy in the basecase scenario. Varying the effectiveness parameter in this way led to substantial ICER reductions for the MC and OC strategies (MC £0.36; OC £0.98) compared with the LC strategy. In model 4, a decrease in the relative effectiveness of the MC and OC strategies was assumed (DS case reduction from 30% to 10% [MC] and 50% to 25% [OC], respectively) compared with the LC strategy. Varying the effectiveness parameter in this way led to substantially higher ICERs for the MC and OC strategies (MC £2.03; OC £3.67) compared with the LC strategy. A multiway sensitivity analysis (combining the least and most favorable parameter values) was performed for models 5 and 6. Model 5 results for the best-case scenario are shown in Table 3. Increased incidence of DS and increased effectiveness of the MC and OC strategies compared with LC represents the best possible scenario for the MC and OC strategies in this sensitivity analysis. Under this scenario, the incremental effects are substantial for the MC and OC strategies, with 27 DS-free days gained with the OC strategy compared with LC.

Table 4. Sensitivity analysis: worst-case scenario (decreased incidence of denture stomatitis plus decreased effectiveness of MC and OC compared with LC)

Parameter	Case	Low Care	Medium Care	Optimum Care
Total cost per year (£)	Base	1.07	4.75	18.42
	Worst	0.54	4.48	18.28
Average days with denture stomatitis per year (n)	Base	19.2	13.4	9.6
	Worst	9.6	8.6	7.2
Incremental cost <sup>a</sup>	Base	-	3.68	17.34
	Worst	-	3.95	17.75
Incremental effect <sup>b</sup>	Base	-	5.76	9.6
	Worst	-	0.96	2.4
ICER (cost/effect) <sup>c</sup>	Base	-	0.64	1.81
	Worst	-	4.11	7.39

ICER, incremental cost-effectiveness ratio; LC, low care; MC, medium care; OC, optimum care. Low care: cleaning denture by brushing and soaking overnight in water; Medium care: brushing denture with toothpaste and soaking overnight in water; Optimum care: brushing denture and soaking overnight in water and denture cleanser. All costs shown in UK pounds sterling (2015). <sup>a</sup>Incremental cost=cost of OC or MC strategy minus cost of LC strategy. <sup>b</sup>Incremental effect=difference in average number of denture stomatitis-free days per year between OC or MC strategy and LC strategy. <sup>c</sup>Cost of producing additional denture stomatitis-free day compared with reference LC strategy.

This increase in benefits under the best-case scenario translated to an ICER of £0.61 per additional DS-free day using the OC strategy.

Model 6 results for the worst-case scenario are shown in Table 4. Decreased incidence of DS and decreased effectiveness of the MC and OC strategies relative to the base case represented the worst scenario for MC and OC strategies in this sensitivity analysis. In this scenario, the incremental effects were substantially reduced for the MC and OC strategies compared with the base case, with only 2.4 additional DS-free days gained with the OC strategy compared with LC. This reduction in benefits in the worst-case scenario translated to an ICER of £7.39 per additional DS-free day using the OC strategy.

### DISCUSSION

This proof-of-concept approach demonstrated that it is possible to develop a conceptual model to explore the relative cost-effectiveness of different denture cleaning strategies to help prevent DS from a patient or consumer perspective. The null hypothesis—that developing a UKbased denture cleaning cost-effectiveness model to assess the potential benefits of using denture cleansers from a patient perspective in the UK is not feasible—was rejected.

A review of the literature showed that no economic models or standardized recommendations were previously available in this area. The presented approach provided the first cost-effectiveness model of this type for DS. Important decisions taken during model development included defining the primary outcome (DS-free days) by using 3 different denture care strategies, restricting to only patient-borne costs, and defining the

parameters to be varied in sensitivity analysis. The number of DS-free days was chosen as the model outcome given it is a relatively objective measure meaningful to both denture wearers and policy makers. However, as the model emphasis was on the cost-benefit to the patient for each strategy, as opposed to highlighting the least expensive care option, investigating other patient-relevant outcomes such as days where patients are free from pain or days where patients are unable to use their dentures may also be of interest. This would also provide information that both denture wearers and dental care professionals can understand as tangible benefits.

Three different denture care strategies were used, as they broadly reflect the different options available to denture wearers. Notably however, the available strategies might vary by country, and individuals might vary their approach over time. The lack of data on the relative efficacy of different cleaning strategies in preventing DS should also be noted. This emphasizes another benefit of patient-centric economic models, namely that they can highlight evidence gaps. To rigorously compare the 3 strategies used, more evidence on their comparative effectiveness is required. With the cost and effectiveness data currently available, the MC and OC strategies were found to increase the number of DS-free days (by up to 10) compared with an LC strategy, with associated ICER values ranging from £0.64 to £1.81.

This model was unusual (within a healthcare context) in that it focused on costs to the denture wearer and their denture cleaning strategies and associated cost burden rather than a health service, which would have been a more typical approach.<sup>20</sup> In general, the current approach should be viewed as an exploratory attempt to develop a model to analyze the cost-effectiveness of denture cleaning strategies. The aim was therefore to produce a model for discussion and debate rather than trying to provide wholly conclusive results about the relative cost-effectiveness of the different strategies.<sup>27</sup>

Limitations of the described approach included key gaps in the evidence from the literature, which made it challenging to populate the model. The main gaps were the incidence of DS and the comparative effectiveness of the different care strategies. Values for the different care models were therefore largely based on assumptions and expert opinion. Nevertheless, this can be taken into account to some extent by the use of sensitivity analysis. In this case, varying either or both of these parameters (baseline incidence of DS and relative effectiveness of the MC and OC strategies) was shown to influence model outputs, with ICERs in the best-case scenario ranging from £0.21 to £0.61 and from £4.11 to £7.39 in the worstcase scenario. While systemic factors, prevalent in this age group, are likely to influence outcomes, the range of values used in the sensitivity analysis would likely encompass any changes in outcomes. Discounting was not used in this model<sup>23</sup> because of the relatively short time horizon. A further limitation was the assumption that only 20% of patients would bear health-service charges. Another approach could be to calculate outputs for individual patients depending on whether they would need to pay dentist consultation costs and prescription charges. However, as the impact of those 2 parameters was relatively minor in the model, it is unlikely that this would lead to significant changes. Also, although the key parameters determining the relative cost-effectiveness of the cleaning strategies were the baseline incidence of DS and relative effectiveness of the strategies, neither of these parameters could be easily adapted for the individual denture wearer and so the current model is the most relevant.

The model highlighted potential opportunities for future research in this topic. It would be useful to consider further definitions of different care strategies assessed, baseline figures for DS incidence, assumptions on the relative effectiveness of different care strategies, outcome parameters used (for example, DSfree days), and cost and resource-use data included. It may also be possible to include the health-service perspective or a different country perspective in future versions of the model. This would require detailed information on the proportion of denture wearers with DS visiting the dentist and/or using prescription medication for DS and determining how many were exempt from payment (for example, via a survey). This could provide greater insights into the cost burden for the health service. The model could also be presented to a group of denture wearers (via patient focus groups) to assess the robustness of the results in terms of whether the cost of a DS-free day with denture cleansers is considered reasonable, how easily the model can be understood, and whether it could be improved. Additional aspects that could be incorporated into the model include patient satisfaction with the care strategies (denture cleanliness) by using tools such as the quantitative denture cleanliness index<sup>21</sup> and patient preference for the different cleaning strategies by using an economic instrument of willingness to pay.<sup>22</sup> Finally, how the cost-effectiveness of the different strategies might vary according to whether the patient wears partial or complete dentures could also be explored in new versions of the model.

### **CONCLUSIONS**

Based on the findings of this patient-centered costeffectiveness model, the following conclusions were drawn:

1. This approach demonstrated the feasibility of developing a health-economic model to assess the

relative cost-effectiveness of different denture cleaning strategies for preventing DS from a UK patient perspective.

- 2. The model could be used to show denture wearers (either directly or through dental-health professional support) that they could increase the number of DS-free days they experience by improving their denture cleaning routine and that the cost of achieving those additional DS-free days is not excessive.
- 3. Access to such information would enable denture wearers to make better-informed decisions about their denture hygiene and potentially improve their overall quality of life.

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#### Acknowledgments

The authors thank Juan Carlos Rejón-Parrilla for his contributions in the early stages of the project and Karla Hernandez-Villafuerte for help with the analysis.

#### Author contributions

All authors have made substantial contributions to (1) the conception of this study, acquisition of data, or analysis and interpretation of data; (2) drafting of the manuscript or revising it critically for important intellectual content; and (3) providing the final approval of the submitted manuscript. GSKCH senior management reviewed and approved the manuscript, but final content decisions were made by the authors.

Mike Herdman - Methodology; Formal analysis Ilona Johnson - Conceptualization; Validation Stephen Mason – Conceptualization; Supervision Christopher R Vernazza – Validation; Writing - Review & Editing Roshan Varghese - Conceptualization; Project administration

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