Title: Consultation Stage Impact Assessment on the proposal for the supply and administration of medicines under exemptions within the Human Medicines Regulations 2012 by dental hygienists and dental therapists across the United Kingdom **IA No:** **RPC Reference No:** **Lead department or agency: Department of Health & Social Care** **Other departments or agencies: Devolved administrations, professional bodies**	Impact Assessment (IA) **Date:** **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** medicines.mechanisms@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not applicable

Cost of Preferred (or more likely) Option (in 2022 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£519.7m	N/A	N/A	Not a regulatory provision

What is the problem under consideration? Why is government action or intervention necessary?

Dental hygienists and dental therapists are currently able to supply and administer medicines using patient specific directions and patient group directions. However, due to the administrative challenges associated with creating patient group directions their use is not widespread. When a patient specific direction has not been produced, dental hygienists and dental therapists are unable to supply and administer required medicines, even though they may be the first to identify the need for a medicine within a clear and established treatment pathway. This leads to unnecessary consultations with other healthcare professionals which represents an inefficient use of public money and may delay access for patients who require their skills.

What are the policy objectives of the action or intervention and the intended effects?

The objectives are to reduce delays in the provision of patient care, and thereby: a) reduce inefficient use of health professional time; b) improve patient experience; c) improve patient health.

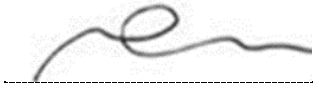
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- Option 1 – Business as usual/no change
- Option 2 – Enable dental hygienists and dental therapists to supply and administer a specified list of medicines using exemptions under the Human Medicines Regulations 2012

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Post-implementation

Is this measure likely to impact on international trade and investment?		N/A		
Are any of these organisations in scope?	**Micro** No	**Small** No	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 14 August 2023

Summary: Analysis & Evidence Policy Option 1 – Business as usual

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2022	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	High: 0	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate				0

Description and scale of key monetised costs by 'main affected groups'

None, this option represents business as usual and would therefore have no monetised costs.
Dental hygienists and dental therapists would retain the ability to administer and supply medicines under PSDs and PGDs.

Other key non-monetised costs by 'main affected groups'

None (no change)

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate				0

Description and scale of key monetised benefits by 'main affected groups'

None, this option represents business as usual and would therefore have no monetised benefits.

Other key non-monetised benefits by 'main affected groups'

None (no change)

Key assumptions/sensitivities/risks	Discount rate (%)	1.5/3.5

None (no change)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: N/A
Costs: N/A	Benefits: N/A	Net: N/A	

Summary: Analysis & Evidence Policy Option 2 – Proposed changes

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2022	PV Base Year 2022	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 414.9m	High: 624.5m	Best Estimate: 519.7m

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate				104.2

Description and scale of key monetised costs by 'main affected groups'

Training costs, which are likely to be borne by the professionals who undergo training. The cost of exemption training has been estimated to be £570 per professional and involves approximately 150 hours of learning (based in training for orthoptists to use exemptions).
There is also an estimated cost for back-filling, based on the hourly cost (including non-wage related costs) of the professionals.

Other key non-monetised costs by 'main affected groups'

None

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				519.1
High				728.8
Best Estimate				623.9

Description and scale of key monetised benefits by 'main affected groups'

Reduction in inefficient search time by dental hygienist/dental therapist.
Reduction in number of consultations with other health professionals (i.e., dentists).
Improved patient experience by reducing 'inconvenience cost' due to delay or having to make additional appointments.

Other key non-monetised benefits by 'main affected groups'

Health benefits associated with more timely access to medicines. Dental hygienists and dental therapists work predominantly with patients suffering from gum disease, where a delay in treatment could cause ongoing suffering/anxiety with the risk of a worsening in condition.

Key assumptions/sensitivities/risks	Discount rate (%)	1.5/3.5

We have assumed that there is no change in risks of inappropriate administration of medicines.
There is uncertainty around our estimates of efficiency savings, particularly in the number of affected appointments used to estimate benefits. Therefore, adjustments have been made in a sensitivity analysis.
We have discounted benefits to patient health and the NHS at 1.5% per annum and all other benefits at 3.5% per annum.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: N/A
Costs: N/A	Benefits: N/A	Net: N/A	

Evidence Base

Problem under consideration and rationale for intervention

1. Over the years, medicines responsibilities have been extended to certain regulated health professional groups where it has been assessed as safe, appropriate, and beneficial for to patients to do so. This supports patients to receive the medicines they require from the professional who is best qualified to help them and means they do not need to see additional professionals simply to access these medicines.

2. Medicines legislation restricts who can supply, administer and prescribe medicines. The Human Medicines Regulations 2012 (HMRs) sets out the professions that can operate under specific medicines mechanisms, which are the legal routes for supply, administration and prescribing of medicines. Clinical cases for extending a mechanism to a regulated health professional group are developed between NHS England, DHSC the healthcare professional bodies and other key stakeholders. Changes are reviewed by the Commission on Human Medicines, who consider whether proposals are safe and appropriate, and provide their advice to Ministers. Only regulated health professions are considered for medicines responsibilities; this ensures professions have appropriate governance and meet professional standards set by the regulator. This structure for medicines responsibilities and process for considering change is in place to protect patients.

3. Dental hygienists and dental therapists are separately registered dental professionals who help maintain patients' oral health by treating and preventing dental disease. Dental hygienists treat periodontal disease, deliver dental caries (decay) prevention and promote good oral health practice. Dental therapists also treat periodontal disease and dental caries, deliver dental caries prevention and promote good oral health practice and in addition, dental therapists may also carry out direct restorations (fillings) on primary and secondary teeth, pulpotomies (nerve treatments) on primary teeth and extract primary teeth.

4. Dental hygienists and dental therapists are currently able to supply and administer medicines using patient specific directions (PSDs), and since 2010 they have been able to supply and administer medicines using patient group directions (PGDs). A PSD is a written instruction from a prescriber to administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine. PGDs provide a framework for allowing named, authorised and registered health professions to supply and/or administer specific medicines to a defined group of patients requiring treatment for a condition detailed in the PGD, without the need for prescription or an instruction from a prescriber. Due to the administrative challenges associated with creating PGDs in dental practices that are generally small, their use is not widespread. This means dental hygienists and dental therapists often do not have access to the required mechanism to provide patients with the medicines they need where a PSD is not available.

5. Evidence suggests there are potential efficiency gains and improvements to patient experience and health outcomes if certain healthcare professions are able to supply, administer and/or prescribe a wider range of medicines[1,2]. Currently, dental hygienists

[1] Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs*. Available at: *final-report.pdf (surrey.ac.uk)*
[2] I5 Health (2015). *Non-Medical Prescribing (NMP) – An Economic Evaluation*

and dental therapists are commonly unable to supply or administer medicines, even if they are the first to identify the need for a medicine within a clear and established treatment pathway, and they can identify from patient records if the medicine would not be suitable for the patient. This leads to unnecessary consultations with other healthcare professionals such as dentists, which represents an inefficient use of public money and may delay access for patients who require their skills. It also inconveniences patients.

6. The delay in accessing medicines may worsen health (e.g. by causing pain) for patients if it prevents them having timely access to treatment. In some interventions, both professions are placed in a position of advising a dentist, who may be less familiar with the patient's case or the medicines required to effectively carry out the care required. This practice was highlighted as a matter of concern within the Crown report (1999)[3], and most recently by the General Medical Council (GMC)[4].

Policy objective

7. The objectives of the proposed change are to reduce interruptions and delays in the provision of patient care, and thereby: a) reduce inefficient use of health professionals' time; b) improve patient experience; c) improve patient health outcomes.

Policy change – introducing supply/administration of medicines under exemptions by dental hygienists and dental therapists

8. In 2020, NHS England (NHSE) held public consultations on proposals to extend medicines responsibilities to additional regulated health professions. This included enabling dental hygienists and dental therapists to supply and administer a number of specific medicines under exemptions. This consultation ran from 15 October to 10 December 2020 and is available to view online. Since these consultations took place, the Medicines and Medical Devices Act 2021 (MMD Act) brought in new requirements for consulting on proposed changed to the Human Medicines Regulations 2012 (HMRs), which is why the Department of Health and Social Care is consulting again.

   In 2021, the Commission on Human Medicines (CHM) considered the proposals presented by NHSE and provided advice to Ministers that the HMRs be amended to allow dental hygienists and dental therapists to supply and administer medicines under exemptions.

9. The medicines proposed for supply and administration are outlined below:

   a. Medicines for administration only:
      - lidocaine with adrenaline
      - articaine hydrochloride with adrenaline
      - mepivacaine hydrochloride
      - prilocaine with felypressin
      - minocycline periodontal gel
      - sodium fluoride (varnish)
      - lidocaine and prilocaine (periodontal gel)

[3] Department of Health (1999). *Review of Prescribing, supply and administration of medicines (the Crown Report).*
[4] Avery, T., Barber, N., Ghaleb, M. et al (2012). *Investigating the prevalence and causes of prescribing errors in general practice.*

b. Medicines for supply:
    - sodium fluoride (dental paste)
    - nystatin oral suspension

In addition, the supply of all general sales list and pharmacy medicines licensed in the UK, within the dental hygienists and dental therapists' scope of practice.

Description of options considered

Option 1 – Business as usual/no change

10. Dental hygienists and dental therapists retain the ability to administer and supply medicines under PSDs and PGDs.

Option 2 - Enable dental hygienists and dental therapists to supply and administer a specified list of medicines using exemptions within the Human Medicines Regulations

11. Currently dental hygienists and dental therapists are unable to administer a required medicine when a PSD or PGD is not in place, and must rely on a dentist, which is likely to cause a delay. The proposed change would allow dental hygienists and dental therapists to use exemptions, which would give them the ability to administer and supply specific medicines without the need for a PSD or PGD. This would improve the timeliness of treatment procedures, which has the following intended benefits:

    a. **Efficient use of health professional time –** Currently where a PGD is not in place and a medicine is required there is often a burden on the dental hygienist/dental therapist who has to seek out and organise a PSD, and a dentist who has to see the patient and provide this. Removing this burden by allowing the dental hygienists/dental therapists to supply/administer the medicine using exemptions releases time that could be better used for more complex patient care.

    b. **Better patient experience** – Reducing delays in accessing the medicines required could improve patient convenience and satisfaction. Patients would no longer have to wait for health professionals during this time, or arrange, travel to and attend another appointment.

    c. **Improved patient health** – More timely access to treatment may reduce the risk of patients' conditions deteriorating. It may also reduce the risk that the dental hygienist or dental therapist is put in a position of advising an independent prescriber on what medicines are required to undertake specific treatments.

Costs

12. Dental hygienists and dental therapists would be required to train to use exemptions. It is anticipated that there could be significant benefits associated with the use of exemptions which will generate strong demand for training to be able to use exemptions. This is informed by the expert opinion of representatives of the professional bodies, who estimate that within 5 years 75% of the profession will be trained and this is considered as 'steady state' for this model. It is possible that this

could be an under- or over-estimate of how many hygienists/therapists would undergo training, however the effects on the costs and benefits would increase or decrease relative to each other, for example a higher proportion of professionals undergoing training would incur a higher cost however this would also increase the benefit. The cost of exemptions training is estimated to be £570 per professional and involves approximately 150 hours of learning. This costing is based on the training for orthoptists to use exemptions.

13. A draft Outline Curriculum Framework to prepare dental hygienists and dental therapists to use exemptions has been developed by the professional bodies in conjunction with key stakeholders, including the General Dental Council. The draft framework is aimed at education providers intending to develop education programmes for dental hygienists and dental therapists interested in education programmes to fulfil the requirements to be qualified to use exemptions. This framework will support education programmes to be developed at pace following legislation changes.

14. We also estimate the back-filling cost, which we have based on the unit cost (including on-costs) of the professional estimated at £37.27 per hour[5]. The hourly cost of staff covering colleagues' absence is assumed to be the same as there are no (or marginal) capital or management costs associated with the additional cost of staff backfill. Multiplying the unit cost by the duration of the training (150 hours) gives a backfilling cost of £5,590 per professional being trained.

15. We estimate that there are currently 8,950 dental hygienists and dental therapists (combined) in the UK, according to the General Dental Council[6]. We also assume that the number of people employed will increase by 2% per year. Given this the total undiscounted training cost over 5 years to reach the 'steady state' is estimated to be £45.7m. The total undiscounted training cost over 10 years is estimated to be £50.4m.

16. Using survey data on the proportion of professionals that work in public vs. private practices (See Annex A) we estimate that 40% of dental hygienists and therapists work mostly in the NHS, while 60% work mostly in private practice. Those working in the NHS will mostly work as subcontractors, and so will likely bear the costs of training themselves (both the financial costs and the time required to train). However, in order to avoid risks of under-stating the costs to the NHS, we assume that these costs are passed on to NHS providers (for example through increased wages). We therefore anticipate that 40% (£20.2m) of these costs accrue to the NHS.

17. The Department of Health and Social Care (DHSC) estimates that even though the value of a Quality Adjusted Life Year (QALY) is £70,000, NHS funds can be used to generate QALYs at £15,000 per QALY at the margin, due to budget constraints on providers. As a result, diverting £1 of resources towards training costs has an opportunity cost of around £4 of lost health benefits. Taking account of this relationship, this suggests that the opportunity cost of the training that accrues to the NHS is £80.7m. In accordance with the discounting rates recommended in the Green Book[7], discounting NHS costs at 1.5% per annum and non-NHS costs at 3.5% per annum, we estimate a present value cost of £104.2m.

[5] Based on the mid-point of the annual salary range according to the National Careers Service for dental hygienists and dental therapists, with additional on-costs estimated using dentist (provider-only) unit costs from the PSSRU (excluding direct staff employee expenses which may include the cost of employing dental hygienist/therapists).
[6] General Dental Council (2022) Registration Report – September 2022
[7] The Green Book (2022) - GOV.UK (www.gov.uk)

Risk of inappropriate administration of medicines

18. If dental hygienists and dental therapists are able to supply and administer medicines to a patient under exemptions, there is the potential that they will mistakenly supply or administer a medicine that is unsuitable for the patient. If this becomes more likely than in current practice, there will be an associated net health cost. There is little published information testing differences in inappropriate medicines usage or medicines error resulting from expansions in medicines responsibilities. The most extensive relevant study finds no difference between nurse prescribers and consultant doctors, and that nurses outperform junior doctors[8]. Previous evaluations do not find any evidence of increased risk of medicines errors[9]. The Commission on Human Medicines determined that while there was a lack of evidence of the benefits and risks involved in the use of the medicines, commissioners agreed the risks were low. Hygienists and therapists would be working in the context of a dental practice led by a dentist and the proposed list was modest. On balance, we conclude that there is unlikely to be an increase in the risk of inappropriate administration and supply of medicines. We discuss this further in paragraphs 38-40.

Benefits

Method

19. We estimate the benefits per average affected appointment, and scale this up to the total number of appointments per year for the whole workforce in order to estimate the total benefits. In our calculations of averages, we only include the appointments where the process would be affected by the change. The BSDHT conducted a member survey in 2015[10] (unpublished) and the data has been used here (n=721), which is presented in Annex A, with questions asked in the survey available in Annex B.

20. The survey data required a significant amount of interpretation. In this process we were purposefully conservative in our interpretation of the frequency of affected appointments (e.g. if someone reported that most of their appointments were affected, and that they had 30-39 appointments a week, then we assumed that 15 were affected, or if someone said “rarely”, we assumed that in an average week none were affected). We also model an additional, more conservative sensitivity analysis, which is described in paragraphs 32-34.

21. The survey data collected suggests that in 9 of the 50 appointments that dental hygienists and dental therapists have per week they come up against the issue of being unable to supply and administer the medicines that their patients need. We assume that all of these could be resolved by the ability to administer/supply under exemptions, based on the expert opinion of representatives from the professional body.

Efficiency

22. There are two sources of efficiency benefits. The first area of inefficiency in current practice is the time wasted by the dental hygienists/dental therapists in trying to locate a dentist to prescribe the required medicines, which results in delayed treatment. In the survey used, dental hygienists and dental therapists were asked about the delays

[8] Ashcroft, D., Lewis, P., Tully, M. (2015). Prevalence, Nature, Severity and Risk Factors for Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals. Drug Safety, 38:833-843
[9] Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs. Available at:* final-report.pdf (surrey.ac.uk)
[10] BSDHT (2015) *Member survey: Prescription only medicines in use* – Not published

resulting from this barrier to supply and administration, and the frequency of these delays. There were responses where the reported delays were inconsistent with the reported number of incidences that the barrier was faced (for example, if the barrier was reported to be faced 10 times, and more than 10 delays were reported). For the main analysis, we took the delays reported at face value, assuming that any errors would be balanced out and negligible over the whole sample. In sensitivity analysis in paragraphs 32-34, we adjust for over-counting by reducing the number of delays.

23. Of the 9 delayed appointments per week, the survey data suggested that 5 resulted in a minor (0-10 minute) delay, 3 resulted in a major (10+ minute) delay, and 1 resulted in a rearranged appointment. We assume that these delays represent inefficient search time by the dental hygienist/dental therapist. Assuming a minor delay wastes an average of 5 minutes of dental hygienist/dental therapist time, and both a major delay and rearranged appointment waste an average of 15 minutes of dental hygienist/dental therapist time, we estimate that when the required mechanism is not in place, the average wasted dental hygienist/dental therapist time is 9.4 minutes per affected appointment. Using the unit costs of the dental hygienist/dental therapist (£37.27, including on-costs), this gives an average estimated cost of £5.83 per appointment, which would be removed by the proposed option.

24. The second source of efficiency benefit represents the savings to other professional's time. Once a dentist has been located, there is another source of inefficiency in that the dentist has to prescribe the required medicines that could have been competently supplied and/or administered by the dental hygienist/dental therapist, thus wasting the dentist's time. Generally, when the patient's dentist is in the same practice, a reassessment is not necessary. The survey data suggests this happens 6.5 of the 9 times, and it uses 3.6 minutes of dentist time. When a reassessment is needed, this requires more of the dentist's time; the survey data suggests that this happens in 2.5 of the 9 appointments and takes 5.6 minutes of dentist time. We therefore estimate that the average wasted dentist time when the required mechanism is not available is 4.2 minutes. Using the unit cost of a dentist estimated at £105 (based on the hourly cost including on-costs for performer only dentists[11]), this is a cost of £7.28 per appointment that would be removed by the proposed option.

Patient Experience

25. We consider the impact on patients to be an 'inconvenience cost' due to delay or having to make additional appointments. Firstly, as described in paragraph 23, there is an average delay of 9.4 minutes per affected appointment. Secondly, approximately 1 in 9 affected appointments are estimated to result in a rearranged appointment. We assume that this requires an additional 45 minutes of patient time, which takes into account the hassle of rearranging the new appointment, attending including travel. This suggests an average 16.1 minutes wasted patient time per appointment that is affected by current restrictions.

26. The Department of Transport published research in 2015 on the value of 'delayed travel time'. They estimate that for all modes/distances that travellers would be willing to pay (workers and non-workers) on average £11.21 in order to save one hour of

[11] PSSRU, Unit Costs Database of Health and Social Care Professionals, 2020/21, available at: *Unit Costs of Health and Social Care | PSSRU*

travel time[12]. We consider this as the cost of wasted patient time, and an indication of patient dissatisfaction resulting from delays, although this is likely to underestimate the anxiety and inconvenience for patients.

27. Using the average wasted time of 16.1 minutes per affected appointment; we estimate that a current cost of £3.01 per affected appointment could be avoided as a result of the proposed changes.

Health benefits

28. Dental hygienists and dental therapists work predominantly with patients suffering from gum disease. A delay in treatment may cause ongoing suffering/anxiety, and there is a risk of escalation of conditions. Neither of these effects is quantified, as we have insufficient data to attempt to scale it.

Total benefits

29. This gives a total benefit of £16.12 per appointment affected, or £6,510 per professional per year. These assumptions and resulting benefits are expressed in Table 1.

Table 1. Lost Time and Unit Cost for two professions and patients.

	Dental hygienists/ Dental therapists (£37.27 per hour)		**Dentist (£105.00 per hour)**		**Patient (£11.21 per hour)**		**Total**
	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Cost (£)
Average per affected appointment	9.4	£5.83	4.2	£7.28	16.1	£3.01	£16.12
Total per professional per year	3,800	£2,356	1,700	£2,940	6,500	£1,214	£6,510

30. Based on the modelling of the number of professionals, this approximates to an undiscounted benefit over 10 years of £422.2m. Using survey data on the proportion of professionals that work in public vs. private practices and excluding the patient wellbeing benefits, we estimate benefits to the NHS of £2,118 per professional per year, or £137.4m (undiscounted) over 10 years.

31. DHSC estimates that even though the value of a QALY is close to £70,000, NHS funds can be used to generate QALYs at £15,000 per QALY at the margin, due to budget constraints on providers. As a result, releasing £1 of resources by making efficiency savings is estimated to produce around £4 of health benefits. Taking account of this relationship, we estimate an undiscounted £549.5m of benefits from NHS savings. This relationship does not hold true for individuals and private practices, as they do not face the same budget constraints, and so there is assumed to be no difference between the cost of producing a QALY and the value of a QALY. Adding the

[12] Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*

adjusted NHS benefits (£549.5m) and the non-adjusted other benefits (£284.8m) gives the total undiscounted benefits of £834.3m. Discounting NHS benefits at 1.5% per annum and non-NHS (private practice and patient) benefits at 3.5% per annum, we estimate a present value benefit of £728.8m.

Sensitivity analysis

32. We made an adjustment to our assumptions in a sensitivity analysis, based on limitations of the survey data. As discussed in paragraph 22, there were issues where responses on the number and nature of delays were inconsistent with the number of incidences that the barrier was faced (for example, where the barrier was reported to be faced 10 times, but more than 10 delays were reported). For those who reported a higher number of delayed appointments than the total number of appointments affected, there was a total excess of 1900 appointments (across the 721 respondents). This indicated an average of 2.6 excess delays per professional, and we adjusted down the number of delays to account for this (from 9 to 6).

33. We assumed that distribution of the nature of these excess delays (i.e. split of minor, major and rearranged appointment) was the same as the distribution of total reported delays. For example, 60% of reported delays across the sample were minor, and so 60% of the excess was assumed to be over-reporting of minor delays. The result is that the sensitivity analysis does not change the average benefit per affected appointment but does change the annual benefit per professional. Table 2 expresses the assumptions and resulting benefits used in the sensitivity analysis.

Table 2. Lost Time and Unit Cost for two professions and patents, sensitivity analysis

	Dental hygienists/ Dental therapists (£37.27 per hour)		**Dentist (£105.00 per hour)**		**Patient (£11.21 per hour)**		**Total**
	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Cost (£)
Average per affected appointment	9.4	£5.83	4.2	£7.28	16.1	£3.01	£16.12
Total per professional per year	2,700	£1,678	1,200	£2,094	4,600	£865	£4,637

34. Making these adjustments resulted in a present value benefit of £594.3m, with a discounted benefit of £519.1m. If we consider the central estimate as the mid-point of the sensitivity analysis and our main analysis estimate of £728.8m, this gives a total discounted benefit £623.9m.

Net Benefits

35. Net benefits are the difference between the total benefits and the total costs. The discounted net present value is estimated to be £519.7m for the main analysis. Using the sensitivity analysis, we estimate a net present value of £414.9m. Considering the best estimate as the mid-point of the main analysis and the sensitivity analysis gives a

total net present value of £519.7m. Table 3 below provides a summary over 10 years, with this table provided for lower and upper estimates in Annex C.

Table 3. Summary of 10 year costs and benefits, central estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	11.3	10.2	-1.1
Year 2	11.7	20.8	9.1
Year 3	12.2	31.8	19.6
Year 4	6.7	37.8	31.1
Year 5	3.9	41.3	37.4
Year 6	1.2	42.4	41.2
Year 7	0.6	43.0	42.4
Year 8	1.0	43.8	42.9
Year 9	1.0	44.7	43.8
Year 10	1.0	45.6	44.6
Total (undiscounted)	*50.4*	*361.4*	*311.0*
Total (discounted)	*48.2*	*329.0*	*280.8*
Total with opportunity costs (undiscounted)	**110.9**	**714.3**	**603.4**
Total with opportunity costs (discounted)	**104.2**	**623.9**	**519.7**

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

36. Research by the University of Surrey is looking into the impact of supplementary prescribing by dietitians and independent prescribing by radiographers. This research may provide learnings more broadly for the introduction of medicines mechanisms by regulated health professionals[13]. There is not a significant amount of data available on the possible impacts of these changes, and so using survey responses from the BSDHT, reality checked by the Chief Professions Officers' Medicines Mechanism (CPOMM) programme: exemptions working group (which includes professional bodies, regulators and staff from NHS England) and interpreted cautiously by analysts is appropriate.

Risks and assumptions:

37. We believe our estimates of the monetised value of the benefits of this change are reasonable. The areas of greatest uncertainty are the frequency of affected appointments. We have tried to account for these uncertainties by including a sensitivity analysis around the frequency of affected appointments.

Risks of inappropriate administration of medicines

38. In our main analysis, we have not attempted to quantify any risks of the potential harm to patients (health loss) that might occur if inappropriate supply or administration of

[13] Evaluation of supplementary prescribing by dietitians and independent prescribing by radiographers | University of Surrey

medicines is more likely as a result of the proposed changes. Although the evidence suggests this is unlikely, we have attempted to conduct a break-even analysis to understand the scale of this risk. We try to estimate how much the rate of medicines errors would need to increase to offset the benefits.

a. A medicine error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. The frequencies of medication errors are not known with any precision either in general or in specific settings, but limited data below reveals they are quite common but that they do not always result in noticeable harm. A UK hospital study of 36,200 medication orders found that a prescribing error was identified in 1.5% of cases and 0.4% of errors were serious[14], and we take this 1.5% as the baseline medicines error rate[15].

b. We estimate the cost of a medicines error based on a study on the costs and benefits of reducing prescription errors[16]. They identify six medicines[17] where errors are clinically important and estimate the QALY difference between prescriptions with and without errors using parameters from the literature. Using these estimates, and the relative frequency of these, we estimate that prescription errors cost an average of 0.08 QALYs. Given that the medicines considered were chosen based on the known clinical effect, we assume that this represents the 0.4% of serious errors and assume that the rest of the errors have no effect. This results in a QALY cost per error of 0.02. Valuing a QALY at £70,000[18], this suggests an economic cost per medicine error of £1,500.

c. Given this cost per medicines error, we estimate that the net benefits would be offset if the error rate were 2-3 times higher than the current error rate. This suggests that the conclusion that these changes would lead to net benefits may be somewhat sensitive to the theoretical risk of increased inappropriate supply or administration of medicines.

d. Note that this analysis is highly uncertain; we have taken a conservative approach to estimating the value of risk in QALYs using a study on six medicines that are a higher risk than the medicines considered in the proposed option. We believe the error rate is likely to be an overestimate. It is also not clear that the rate of prescription error would be the same rate of administration or supply error, the estimated costs are not likely to be representative of a dental hygienist's / dental therapist's practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

39. The likelihood of any increased risk in inappropriate administration of medicines is considered to be low. This is for three main reasons:

e. The use of exemptions requires significant training and will be limited to medicines that dental hygienists/dental therapists are already competent in administering. This reduces risks of selecting the wrong medicines.

[14] Dean B, Schachter M, Vincent C, Barber N. (2002) Prescribing errors in hospital inpatients: their incidence and clinical significance, Qual Saf Health Care, vol. 11 (pg. 340-4)]

[15] This error rate is based on a higher number of medications compared to the list in the proposed option and is therefore indicative and the true rate is likely to be lower.

[16] Elliott, R.A., Putman, K.D., Franklin, M. *et al.* Cost Effectiveness of a Pharmacist-Led Information Technology Intervention for Reducing Rates of Clinically Important Errors in Medicines Management in General Practices (PINCER). (2014) *PharmacoEconomics* **32**, 573–590

[17] NSAIDs, Beta blockers, ACEIs, Methotrexate, Lithium, Amiodarone

[18] Green Book (2022) The Green Book (2022) - GOV.UK (www.gov.uk)

f. The dental hygienist/dental therapist will have access to the patient's notes, and so would be in a position to understand if they have any contraindication, allergies or previous adverse reactions to the medicine required.

g. Due to their proximity to the patient, the dental hygienist/dental therapist may have a better understanding of their history and situation than a dentist who has not previously met them. They may therefore be in a better position to understand the patient's suitability for the medication.

40. Although we think any increased risk in inappropriate administration of medicines is unlikely, there are a number of processes in place that mitigate any risks:

h. Practice guidance published by the professional bodies and professional standards from the General Dental Council (GDC) will advise regarding ongoing training and supervision, adherence to local formularies and working within scope of practice and competence.

i. If an error in supply or administration occurs whilst using exemptions, dental hygienists and dental therapists must take immediate action to manage the effects on the patient, prevent potential side effects to the patient and must report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way, in order that anything learned from the incident is shared as appropriate.

j. If a patient experiences an adverse reaction to a medication: once the required treatment has been undertaken, this should be recorded in the patient's notes and, if indicated, the Medicines and Healthcare products Regulatory Agency should be notified via the Yellow Card Scheme. Dental hygienists and dental therapists are expected to be able to recognise common side effects and adverse reactions to the medicines they administer, and to know when there is a potential risk of an interaction.

k. Lack of compliance with standards would lead to action from the GDC which could include removal from the professional register.

Private sector impact

41. It is not anticipated that this change in legislation will have an impact upon the private sector. There is no obligation for private sector providers or individuals not working for the NHS to take up the option to train to do this.

Effects of inflation

42. CPI inflation rates rose by 10.1% in the year to September 2022 compared to 0.5% in the year to September 2020, however a further sensitivity analysis taking the increase in inflation into account has not been carried out for this impact assessment. The proposed policy would enable dental hygienists/therapists to undergo training to supply and administer a wider range of medicines under exemptions to free up dentists' time. Training to use exemptions is optional and it would be for practices to determine whether it would be beneficial for their area. The costs of training are likely to be borne by the professionals who undergo the training and therefore the proposed

policy does not commit to spending.

43. By freeing up dentists' time, this creates a cost saving when comparing hourly pay rates for dentists and dental hygienists/therapists and therefore elements of the IA modelling are based on unit costs of dental professionals' time. This element has not been modelled as dental professionals pay is negotiated individually on an annual basis, so there is a large amount of uncertainty in terms of future wage levels.

Annex A

Survey Data
(Survey conducted by the British Society of Dental Hygiene and Therapy)

In the last week…	Main analysis	Sensitivity analysis
Number of appointments	50	50
Number where prescription barrier faced	8.8	6.3
5 minute delay	4.9	3.5
15 minute delay	2.5	1.8
Rearranged appointment	1.3	0.9
Time wasted for patient	16.1	16.1
Time wasted for professional	9.4	9.4

Supporting data	Frequency	Time to prescribe
No reassessment	6.4	3.6
Other dentist	2.4	5.6
Average		4.2

Practice	
NHS	40%
Private	60%

Annex B

Questions asked in the BSDHT survey

How many patients do you see in a week?

- 0-9
- 10-19
- 20-29
- 30-39
- 40-49
- 50-59
- 60+

What length is your average appointment time?

- 15 mins
- 20 mins
- 30 mins
- 1 hour
- Other

How many times this week did you have to deal with a patient where there wasn't an appropriate PSD/PGD in place?

Of these, how many resulted in a minor delay to treatment? (0-10 minutes)

Of these, how many resulted in a significant delay to treatment? (10+ minutes, not including rearrangement)

Of these, how many resulted in rearranging an appointment?

When there wasn't an appropriate PSD/PGD in place (in a typical week), and you had to get a prescription from another professional which professional usually provides the prescription? (drop down list of possible professionals)

- The patient's dentist
- Any dentist on the premises
- Principle dentist
- Patient's doctor
- Other (please specify)

How many times did it require a reassessment of the patient?

When it did not require a reassessment of the patient, how much of another professional's time does it typically take? (minutes)

- 1-2 mins
- 3-5 mins
- 5+ mins

How long would a reassessment take?

- 0-2 mins
- 3-5 mins
- 6-10 mins
- 10+ mins

How would you describe your practice?

- Private
- Mixed but mainly private
- Mixed but mainly NHS
- NHS

To have an accurate picture of money lost it would be helpful to understand how much the running costs for your surgery per hour are. Could you please provide the following information? (This information will be anonymised and typical surgery running costs will be factored into this) What is your daily rate, assuming normal practice hours, to the dental practice?

What is the daily total of patient's payment (NHS/Private) to the practice for your services?

Do you have nursing support?

Annex C

Summary of 10 year costs and benefits, lower estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	11.3	8.5	-2.8
Year 2	11.7	17.3	5.6
Year 3	12.2	26.4	14.3
Year 4	6.7	31.5	24.8
Year 5	3.9	34.4	30.5
Year 6	1.2	35.3	34.1
Year 7	0.6	35.8	35.1
Year 8	1.0	36.5	35.5
Year 9	1.0	37.2	36.2
Year 10	1.0	38.0	37.0
Total (undiscounted)	*50.4*	*300.7*	*250.3*
Total (discounted)	*48.2*	*273.7*	*225.5*
Total with opportunity costs (undiscounted)	**110.9**	**594.3**	**483.4**
Total with opportunity costs (discounted)	**104.2**	**519.1**	**414.9**

Summary of 10 year costs, upper estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	11.3	11.9	0.6
Year 2	11.7	24.3	12.6
Year 3	12.2	37.1	24.9
Year 4	6.7	44.2	37.5
Year 5	3.9	48.3	44.4
Year 6	1.2	49.5	48.3
Year 7	0.6	50.2	49.6
Year 8	1.0	51.2	50.3
Year 9	1.0	52.2	51.3
Year 10	1.0	53.3	52.3
Total (undiscounted)	*50.4*	*422.2*	*371.7*
Total (discounted)	*48.2*	*384.2*	*336.1*
Total with opportunity costs (undiscounted)	**110.9**	**834.3**	**723.4**
Total with opportunity costs (discounted)	**104.2**	**728.8**	**624.5**