Consultation Stage Impact Assessment:

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

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:** 9546 **Publishing Approval Reference:** PAR145 **Lead department or agency:** NHS England **Other departments or agencies:** Devolved administrations, professional bodies	**Impact Assessment (IA)** **Date:** 10/07/2019 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** england.cpomedicinesmech@nhs.net

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£221.8m	N/A	N/A	Not in Scope	Not a regulatory provision

What is the problem under consideration? Why is government 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 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

Does implementation go beyond minimum EU requirements?		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 SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Option 1 – Business as usual

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019/20	NPV base Year 2019/20	Time Period: 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**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

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				
High				
Best Estimate				**0**

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

None

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

None

Key assumptions/sensitivities/risks

None

Discount rate 1.5/3.5

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	**Costs:** N/A	

Summary: Analysis & Evidence

Option 2 – Proposed changes

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019/20	NPV base Year 2019/20	Time Period: 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 176.8	**High:** 266.8	**Best Estimate**: 221.8

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate				**46.3**

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

Training costs likely to be borne by the professionals who undergo training

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				223.0
High				313.1
Best Estimate				**268.1**

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.
Improved patient experience.

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

Health benefits associated with more timely access to medicines.

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.
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 (for summary sheets)

Narrative summary
Problem under consideration

1. 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). Both professions 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..

2. 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.

Rationale for intervention

3. There are restrictions within UK-wide medicines legislation as to who can supply, administer and prescribe medicines. 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 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.

   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

4. 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.

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

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

5. In 2015 NHS England commissioned a scoping project to look at the evidence for extending the responsibilities for prescribing, and supply and administration of medicines to a number of health professions. Prioritisation was given to professions which demonstrated benefits to a wide patient population and where changes aligned with the Five Year Forward View[5]. The resultant report recommended that dental hygienists and dental therapists be able to supply and administer medicines under exemptions to provide timely, evidence-based interventions and avoid unnecessary pressure on other services and professionals.

6. The British Society of Dental Hygiene & Therapy (BSDHT) and the British Association of Dental Therapy (BADT) have proposed that 9 medicines are listed in legislation for dental hygienists and dental therapists to be able to supply or administer in the course of their professional practice.

    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)

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

Description of options considered

Option 1 – Business as usual/no change

7. 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

8. 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

[5] NHS England (2014). *Five year forward view.*

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

9. 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 'steady state'. 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.

10. We also estimate the back-filling cost, which we have based on the unit cost of the professional estimated at £17.80 per hour (based on the mid-point of the annual salary range according to the National Careers Service[6,7] - this falls within the hourly wages of band 6 staff according to NHS Agenda for Change[8,9] pay scales). 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 £2,700 per professional being trained.

11. We estimate that there are currently 7,550 dental hygienists and dental therapists (combined) in the UK, according to the General Dental Council[10]. We also assume that the number of people employed will increase by 2% per year. Given this the total undiscounted training cost over 10 years is estimated to be £22.4m.

12. 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% (£9.0m) of these costs accrue to the NHS.

[6] National Careers Service (2019) *Job profiles – dental hygienist*
[7] National Careers Service (2019) *Job profiles – dental therapist*
[8] NHS Employers (2019). *Agenda for Change pay scales - Hourly 2019/20*
[9] Throughout the Impact Assessment the 2019/20 Agenda for Change (AfC) pay scales for England and Wales have been used. Pay rates in Scotland and in Northern Ireland are not identical to those in England and Wales, but differences are assumed to make a negligible difference to the overall net benefit. Furthermore, we expect similar differences in pay between the home nations for professions outside of the AfC, again we believe there will be no difference to overall net benefits.
[10] General Dental Council (2019). Registrant Report – April 2019

13. The Department of Health and Social Care (DHSC) estimates that even though the value of a Quality Adjusted Life Year (QALY) is close to £60,000, 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 £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 £35.8m. Discounting NHS costs at 1.5% per annum and non-NHS costs at 3.5% per annum, we estimate a present value cost of £46.3m.

Risk of inappropriate administration of medicines

14. 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[11]. Previous evaluations do not find any evidence of increased risk of medicines errors[1,2]. 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 34-36, and a table of potential risks and governance measures already in place to manage them can be found in section 4.5 of the full consultation guide.

Benefits

Method

15. 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 collected the survey data used here (n=721), which is presented in Annex A.

16. 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 28-30.

17. 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

[11] 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

18. 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 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 28-30, we adjust for over-counting by reducing the number of delays.

19. 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, this gives an average estimated cost of £2.80 per appointment, which would be removed by the proposed option.

20. 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 re-assessment 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 £47.30 (based on the mid-point of the annual salary range for dentists in mixed practices according to Graduate Prospects[12], and adjusted using an inflation rate of 2% to bring in line with 2019/20 prices) this is a cost of £3.30 per appointment that would be removed by the proposed option.

Patient Experience

21. 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 19, 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.

[12] Prospects (2018), *Job Profile - dentist*

22. 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 travel time[13]. 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.

23. Using the average wasted time of 16.1 minutes per affected appointment; we estimate that a current cost of £3.00 per affected appointment could be avoided as a result of the proposed changes.

Health benefits

24. 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

25. This gives a total benefit of £9.10 per appointment affected, or approximately £3,670 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 (£17.80 per hour)		**Dentist (£47.30 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	£2.80	4.2	£3.30	16.1	£3.00	£9.00
Total per professional per year	3800	£1,130	1700	£1,320	6500	£1,210	£3,670

26. Based on the modelling of the number of professionals, this approximates to an undiscounted benefit over 10 years of £200.5m. Using survey data on the proportion of professionals that work in public vs. private practices and excluding the patient well-being benefits, we estimate benefits to the NHS of £980 per professional per year, or £53.6m (undiscounted) over 10 years.

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

27. DHSC estimates that even though the value of a QALY is close to £60,000, 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 £4 of health benefits. Taking account of this relationship, we estimate an undiscounted £214.5m 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 adjusted NHS benefits (£214.5m) and the non-adjusted other benefits (£146.8m) gives the total undiscounted benefits of £361.3m. 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 £313.1m.

Sensitivity analysis

28. We made an adjustment to our assumptions in a sensitivity analysis, based on limitations of the survey data. As discussed in paragraph 18, 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).

29. 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 patients, sensitivity analysis

	Dental hygienists /Dental therapists (£17.80 per hour)		**Dentist (£47.30 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	£2.80	4.2	£3.30	16.1	£3.00	£9.00

Total per professional per year	2700	£800	1200	£945	4600	£865	£2,610

30. Making these adjustments resulted in a present value benefit of £257.4m, with a discounted benefit of £223.0m. If we consider the central estimate as the mid-point of the sensitivity analysis and our main analysis estimate of £313.1m, this gives a total discounted benefit £268.1m.

Net Benefits

31. Net benefits are the difference between the total benefits and the total costs. The discounted net present value is estimated to be £266.8m for the main analysis. Using the sensitivity analysis, we estimate a net present value of £176.8m. Considering the best estimate as the mid-point of the main analysis and the sensitivity analysis gives a total net present value of £221.8m. Table 3 below provides a summary over 10 years, with this table provided for lower and upper estimates in Annex B.

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	5.0	4.8	-0.2
Year 2	5.2	9.9	4.7
Year 3	5.4	15.1	9.7
Year 4	3.0	18.0	15.0
Year 5	1.7	19.6	17.9
Year 6	0.5	20.1	19.6
Year 7	0.3	20.4	20.1
Year 8	0.4	20.8	20.4
Year 9	0.4	21.2	20.8
Year 10	0.4	21.7	21.2
Total (undiscounted)	*22.4*	*171.6*	*149.2*
Total (discounted)	*21.4*	*156.2*	*134.8*
Total with opportunity costs (undiscounted)	**49.3**	**309.4**	**260.1**
Total with opportunity costs (discounted)	**46.3**	**268.1**	**221.8**

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

32. 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:

33. 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

34. 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 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.

    b. We estimate the cost of a medicines error based on a study on the costs and benefits of reducing prescription errors. They identify six medicines 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 £60,000, this suggests an economic cost per medicine error of £1,280.

    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; it is 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.

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

    a. 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)]

b. 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.

c. 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.

36. 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:

    a. 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.

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

Proposed implementation plan

37. A change in legislation is required to enable dental hygienists/dental therapists to administer and supply medicines under exemptions.

38. NHS England are consulting on the proposed changes until 10th December 2020.

39. Following the consultation, the proposed changes to medicines legislation and the findings of the consultation will be presented to the Commission on Human Medicines who make recommendations to Ministers regarding changes to the Human Medicines Regulations. Subject to the agreement of the proposed changes by Ministers; the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments.

Private sector impact

40. 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.

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

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	5.0	4.0	-1.0
Year 2	5.2	8.2	3.0
Year 3	5.4	12.6	7.2
Year 4	3.0	14.9	12.0
Year 5	1.7	16.3	14.6
Year 6	0.5	16.8	16.2
Year 7	0.3	17.0	16.7
Year 8	0.4	17.3	16.9
Year 9	0.4	17.7	17.2
Year 10	0.4	18.0	17.6
Total (undiscounted)	*22.4*	*142.8*	*120.4*
Total (discounted)	*21.4*	*130.0*	*108.6*
Total with opportunity costs (undiscounted)	**49.3**	**257.4**	**208.1**
Total with opportunity costs (discounted)	**46.3**	**223.0**	**176.8**

Summary of 10 year costs and benefits, upper estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	5.0	5.6	0.6
Year 2	5.2	11.5	6.3
Year 3	5.4	17.6	12.2
Year 4	3.0	21.0	18.0
Year 5	1.7	22.9	21.2
Year 6	0.5	23.5	23.0
Year 7	0.3	23.8	23.6
Year 8	0.4	24.3	23.9
Year 9	0.4	24.8	24.4
Year 10	0.4	25.3	24.9
Total (undiscounted)	*22.4*	*200.5*	*178.1*
Total (discounted)	*21.4*	*182.5*	*161.1*
Total with opportunity costs (undiscounted)	**49.3**	**361.3**	**312.1**
Total with opportunity costs (discounted)	**46.3**	**313.1**	**266.8**