## Consultation Stage Impact Assessment:

# Proposal for the supply and administration of medicines using patient group directions by clinical scientists across the United Kingdom

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|---|---|
| **Title:** Consultation Stage Impact Assessment on the proposal for the supply and administration of medicines using patient group directions by clinical scientists across the United Kingdom | **Impact Assessment (IA)** |
| **IA No:** 9552 | **Date:** 10/07/2019 |
| **Publishing Approval Reference:** PAR145 | **Stage:** Consultation |
| **Lead department or agency:** NHS England | **Source of intervention:** Domestic |
| **Other departments or agencies:** Devolved administrations, professional bodies | **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** |
| £126.0m | N/A | N/A | Not in Scope | Not a regulatory provision |

**What is the problem under consideration? Why is government intervention necessary?**

Currently, clinical scientists can only administer and supply medicines using patient specific directions. When a patient specific direction has not been produced, clinical scientists 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 clinical scientists to supply and administer medicines using patient group directions 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:** Optional | **High:** Optional | **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:** 69.4 | **High:** 188.3 | **Best Estimate:** 128.8 |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | | | | 56.6 |
| **High** | | | | 153.5 |
| **Best Estimate** | | | | **105.1** |

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

Administration cost of developing and reviewing patient group directions, borne largely by NHS organisations.
Training costs, borne largely by NHS organisations.

**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** | | | | 125.9 |
| **High** | | | | 341.8 |
| **Best Estimate** | | | | **233.9** |

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

Reduction in inefficient search time by clinical scientists.
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. Clinical scientists are currently able to administer and supply medicines under patient specific directions (PSDs). This is a written instruction to administer or supply a medicine to a named patient who has been assessed by an authorised prescriber.

2. The work of clinical scientists increasingly involves them working in multidisciplinary teams, providing near patient diagnostic and clinical support to doctors. This means they are sometimes in the position of being able to identify appropriate medicines that are required for diagnosis and treatment of patients. Currently they are unable to directly administer and supply medicines that are needed in these situations without acquiring a PSD from a prescriber, typically a doctor. Given the difficulty of anticipating the need for medicines for a particular patient, clinical scientists often do not have the required PSDs, and so are not able to supply and administer the required medicines at the required time.

**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, clinical scientists are commonly unable to supply or administer medicines, even when they are the first to identify the need for a medicine within a clear and established diagnostic or treatment pathway and can identify from patient records if the medicine would not be suitable for the patient. 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. It also inconveniences patients.

4. The delay in accessing medicines may increase health risks for patients if it prevents them having timely access to treatment. In some diagnostic interventions, clinical scientists are placed in a position of advising an independent prescriber, who may be less familiar with the patient's case or the medicines required to effectively carry out the procedures 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**

5. 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 professional time; b) improve patient experience; c) improve patient health outcomes.

**Policy Change – enabling clinical scientists to supply and administer medicines using patient group directions**

6. 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 were aligned with the Five Year Forward View[5]. The resultant report recommended that clinical scientists be able to administer and supply medicines using

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

PGDs to provide timely, evidence-based interventions and avoid unnecessary pressure on other services and professionals.

## Description of options considered

*Option 1 – Business as usual/no change*

7. Clinical scientists continue being only able to administer and supply medicines under PSDs. They will only be able to administer specific medicines for named patients if there is a written instruction to do so from an authorised prescriber.

*Option 2 - Allow clinical scientists to administer and supply medicines using PGDs*

8. Currently clinical scientists are unable to administer a required medicine when a PSD is not in place, and must rely on another professional, typically a doctor, which is likely to cause a delay. The proposed change would allow clinical scientists to use PGDs, which would give them the ability to administer and supply specific medicines to pre-defined groups of patients without the need for a PSD. This would improve the timeliness of diagnostic and treatment procedures, which has the following intended benefits:

    a. **Efficient use of health professional time –** Currently, when a medicine is required there is a burden on the clinical scientist who has to seek out and organise a PSD, and a doctor who has to see the patient and provide this. Removing this burden by allowing the clinical scientist to supply/administer the medicine using a PGD releases time that could be used for patient care.

    b. **Better patient experience** – Reducing delays in accessing the medicines required improves patient convenience and satisfaction. Patients would no longer have to wait for treatment, or arrange, travel to and attend additional appointments.

    c. **Improved patient health** – More timely access to treatment may reduce the risk of patients' conditions deteriorating. It may also reduce the risk that clinical scientists are put in a position of advising an independent prescriber on what medicines are required.

## Method

9. The clinical scientist profession is comprised of 13 professional modalities which encounter very different issues in their healthcare practice, and so would be affected differently by the ability to use PGDs. As a result, we consider the following four professional modalities which are most likely to use PGDs – audiology, cardiology, respiratory and biochemistry. We assess what the typical effects might be (costs and benefits) for each and then aggregate these to derive estimates for all clinical scientists as a group. Given the diversity of the clinical scientist professions, the evidence varies between them as expressed in table 1.

**Table 1: Sources of evidence**

| Profession | Sources of evidence |
|---|---|
| Cardiology | Existing training packages, survey data, professional judgement |
| Biochemistry | Existing training packages, professional judgement |
| Respiratory | Existing training packages, survey data, recorded individual experience, professional judgement |
| Audiology | Existing training packages, professional judgement |

## Costs

*Patient Group Direction costs*

10. There will be an additional cost of developing and approving PGDs for clinical scientists. Based on an estimate of forty hours' input by different professional and administrative staff, including pharmacists, doctors and clinical scientists, we estimate the average cost of producing a routine PGD is £1,700. The cost of reviewing them is estimated to be £1,200.

11. The number of PGDs that we estimate will be produced varies by modality, and is expressed in table 2. The extent to which clinical scientists' work is patient-facing will vary across the country and there are a relatively small number of professionals in some modalities (for example we estimate that only 50 respiratory and biochemistry clinical scientists will be trained over 5 years). This makes it difficult to estimate the number of health organisations that will produce PGDs for clinical scientists. For all of the four modalities considered, we anticipate that fewer clinical scientists will be trained after 5 years than there are health organisations in the UK[6], and so we assume that a set of PGDs (one for each medicine, with the number of medicines varying by modality) will be produced for each clinical scientist who is trained. This gives an estimated average number of PGDs of 6.7 per clinical scientist. Multiplying this by the numbers trained results in total undiscounted cost over 10 years for producing and reviewing PGDs of £15.2m.

**Table 2: Number of Patient Group Directions for each modality**

| | Audiology | Cardiology | Respiratory | Biochemistry | Average |
|---|---|---|---|---|---|
| Number of PGDs per site | 5 | 10 | 7 | 2 | 6.7 |

12. We also assume that there is an administrative cost associated with reading and signing the PGDs once they are created. Based on the advice of professions that currently use PGDs, we estimate that this will require an average of 2 hours per trained clinical scientist per year, to cover all their PGDs, and we estimate the costs of backfill of this time (to capture either the financial cost of backfilling staff or the economic cost of reduced appointments) based on a unit cost of £22.61 per hour (top of band 7, bottom of 8A in Agenda for Change pay scales[7,8] – note that in general entry-level clinical scientist posts will be band 7). The total undiscounted cost over 10 years for reading and signing PGDs is estimated to be £0.2m. This is likely to be an underestimate, as clinical scientists will need to re-sign all the required PGDs if they move between NHS trusts as PGDs are not transferable across organisations.

13. This results in a total undiscounted administrative cost over 10 years of £15.4m.

*Training costs*

14. In line with NICE Guidance[9], additional on-line training (most likely using the programme available from the Centre for Postgraduate Pharmacy Education[10]) will be required in the use of PGDs for clinical scientists. This will take 90 minutes, and we estimate the costs of backfill for those being trained based on a unit cost of £22.61 per hour. 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. We have made estimates of the numbers that will be trained to use PGDs within five years. For audiology, cardiology and respiratory, we assume this is 50% based on a rough estimate of the proportion who will be suitably experienced practitioners to use PGDs based on NHS Workforce Statistics[11]. The estimate for biochemistry is lower, as the majority will not be working in patient-facing roles. We assume that these proportions remain constant after year 5 as the profession grows at 2% per annum. These estimates are expressed in table 3. These suggest that 500-600 clinical scientists from these modalities will be trained to use PGDs over 10 years, resulting in a total undiscounted training cost over 10 years of less than £0.1m.

[6] We estimate this to be 215 organisations, based on 152 acute trusts and 35 community trusts in England, 16 regional health boards in Scotland, 5 NHS trusts in Northern Ireland and 7 Local Health Boards in Wales.
[7] NHS Employers (2019). *Agenda for Change pay scales - Hourly 2019/20*
[8] 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.
[9] National Institute for Clinical Excellence (2017) *patient group directions: medicines practice guideline*
[10] Centre for Postgraduate Pharmacy Education *PGD e-learning package*
[11] NHS Digital (2017), *NHS Workforce Statistics, September 2017).*

**Table 3: Training requirements for each modality**

| | Audiology | Cardiology | Respiratory | Biochemistry | Total / Average |
|---|---|---|---|---|---|
| Number of professionals | 400 | 350 | 100 | 550 | 1400 |
| Proportion trained (5 years) | 50% | 50% | 50% | 10% | 34% |
| Patient Group Direction training (hours) | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |

15. Clinical scientists who will be using PGDs will have experience of administering medicines using PSDs, and therefore will not be expected to need additional training on pharmacology, drug interactions and methods of administration. Whilst it is possible that the scope of practice of clinical scientists may expand as a result of these changes, which may require additional training, neither the costs or benefits of broader changes in the role of the profession are considered here, as these effects are highly uncertain.

*Total costs*

16. Adding the administrative costs of PGDs with the training costs suggests a total undiscounted cost over 10 years of £15.4m.

17. 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 PGD production and training has an opportunity cost of £4 lost health benefits. Taking account of this relationship, and assuming that all costs are borne by NHS providers, we estimate that the opportunity cost of training and PGD production undiscounted over 10 years is £61.7m. Discounting costs to the NHS at 1.5% per annum results in a present value cost of £56.6m.

18. While these modalities are likely to be among the most affected by the proposed changes profession, they only account for 23% of clinical scientists. We therefore consider the £56.6m as a lower bound estimate of the costs. For our central estimate, we scale up the costs, assuming that the average costs for the remaining 77% of clinical scientists would be a quarter of the average cost for the four modalities considered, giving a present value cost of £105.1m. For our upper bound estimate, we do the same but assume the average costs for the remaining 77% of clinical scientists would be half of the average cost for the four modalities considered, giving a present value cost of £153.5m.

*Risks of inappropriate administration of medicines*

1. If clinical scientists are able to supply and administer medicines to a patient through PGDs, 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[12]. 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 355-377, 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.

[12] 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

## Benefits

*Method*

19. For each of the four clinical scientist professions considered, there is a "typical case" where a PGD would be beneficial within the current scope of practice. These clinical scenarios are taken from the NHS England full consultation guide. We have used these clinical scenarios to estimate the benefits. We have estimated the weighted average of these effects (based on the reported frequency of the cases and the numbers in the profession who will be trained), to derive an average effect among cases that would be affected by having a PGD. We acknowledge that these clinical scenarios will not capture all of the possible effects, but believe that they are relatively representative of the nature of the cases that are affected.

20. These estimates are expressed in Table 4. The relative frequencies of each scenario are also expressed.

**Table 4: Parameter estimates of benefits from clinical scientist profession**

| | Audiology | Cardiology | Respiratory | Biochemistry | Weighted Average |
|---|---|---|---|---|---|
| Relative Frequency | 33% | 38% | 21% | 7% | |
| Typical delays to clinical scientist (mins) | 10 | 20 | 25 | 10 | 15 |
| Delays to other professional (mins) | 15 | 15 | 6 | 5 | 13 |
| *Unit cost of other professional* | *62* | *54* | *54* | *54* | *58* |
| Wasted time for patient (mins) | 60 | 60 | 28 | 25 | 53 |
| Affected cases per professional per week | 7 | 9 | 18 | 5 | 9 |

*Efficiency*

21. The time savings to the clinical scientist and other professionals result in efficiency benefits. The value of this time is assumed to be the unit cost of the professional – £22.60 per hour for the clinical scientist, £62.50 per hour for a GP (hourly equivalent of midpoint of GP salary according to PSSRU[13]) in the audiology case and £54.10 per hour for a consultant doctor (the hourly equivalent of the midpoint of consultant salaries according to NHS Health Careers[14]) in the three other cases. Unit costs for GPs and consultant doctors have been adjusted using an inflation rate of 2% per year to bring them in line with 2019/20 prices. Multiplying these unit costs by the time saved, and finding the weighted average gives an estimated efficiency benefit of £18.10 per affected case.

22. 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. Assuming that all efficiency benefits are realised by NHS providers, we estimate efficiency benefits of £72.50 per affected case.

*Patient Experience*

23. We consider the impact on patients to be an 'inconvenience cost' due to delay or having to make additional appointments. We consider a rearranged appointment to take up an hour of patient time and find that on average patient time that is taken up by delays per affected case is estimated to be 53 minutes.

24. 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

[13] Curtis, L. Burns, A. (2018). *Unit Costs of Health and Social Care 2018*. Personal Social Services Research Unit
[14] NHS Health Careers (2018). *Pay for doctors*.

non-workers) on average £11.21 in order to save one hour of travel time[15]. 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.

25. Reduced wasted time resulting from the proposed changes has a benefit of £9.80 per affected case.

*Health Benefits*

26. There are likely to be health benefits associated with more timely access to medicines. In particular, the cardiology clinical scenario gives an indication of the health costs associated with delayed diagnostic procedures. The current arrangements may result in a delayed appointment by 6 weeks, during which time there is a risk of deterioration or a preventable catastrophic event. Because these events are uncertain, and there is little data to estimate the consequences of delaying diagnosis, we have not attempted to quantify the health benefits. However, they are expressed qualitatively in table 5.

**Table 5: Health benefits**

| Case | Health benefit |
|---|---|
| Cardiology | Potential catastrophic event/death due to patient suffering from stroke while waiting for the delayed re-investigation. |
| Biochemistry | Delayed or incorrect administration and sampling can invalidate the procedure |
| Audiology | Delay in treatment; exacerbation of condition with additional co-morbidities/complications |
| Respiratory | Consequences may be significant (e.g. failure to obtain correct diagnosis at time of investigation; surgical or other invasive procedures such as bronchoscopy delayed) |

*Total benefits*

27. Weighting based on the relative numbers trained in each modality gives an estimated 9 affected cases per professional per week. Using this estimate, and assuming there are 46 working weeks per year, we scale up the impacts on the average affected case (£82.30).

28. The undiscounted 10 year benefit is estimated to be £140.9m. Discounting benefits to the NHS at 1.5% per annum and all other benefits at 3.5% per annum results in a present value benefit of £125.9m.

29. While these modalities are likely to be among the most affected by the proposed changes, they only account for 23% of clinical scientists. We therefore consider the £125.9m as a lower bound estimate of the costs. For our central estimate, we scale up the benefits, assuming that the average benefits for the remaining 77% of clinical scientists would be a quarter of the average benefit for the four modalities considered, giving a benefit of £233.9m. For our upper bound estimate, we do the same but assume the average benefits for the remaining 77% of clinical scientists would be half of the average benefit for the four modalities considered, giving a benefit of £341.8m.

## Net Benefits

30. Net benefits are the difference between the total benefits and the total costs. Based on the four professions that we have considered, the net present value is £69.4m.

31. While these modalities are likely to be among the most affected by the proposed changes in the profession, they only account for 23% of clinical scientists. We calculate a central estimate of £128.8m by subtracting the central net present cost from the central net present benefit, and an upper bound estimate of £188.3m by subtracting the upper bound net present cost from the upper bound net present benefit. Table 6 below provides a summary over 10 years for the central estimate, with this table provided for lower and upper estimates in Annex A.

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

**Table 6 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 | 2.1 | 2.0 | -0.1 |
| Year 2 | 2.2 | 4.1 | 1.9 |
| Year 3 | 2.3 | 6.2 | 4.0 |
| Year 4 | 3.8 | 8.5 | 4.6 |
| Year 5 | 4.0 | 10.8 | 6.8 |
| Year 6 | 1.8 | 11.0 | 9.2 |
| Year 7 | 3.4 | 11.2 | 7.9 |
| Year 8 | 3.5 | 11.5 | 8.0 |
| Year 9 | 2.0 | 11.7 | 9.7 |
| Year 10 | 3.6 | 11.9 | 8.4 |
| *Total (undiscounted)* | *28.6* | *88.9* | *60.2* |
| *Total (discounted)* | *26.3* | *80.6* | *54.3* |
| **Total with opportunity costs (undiscounted)** | **114.5** | **261.7** | **147.1** |
| **Total with opportunity costs (discounted)** | **105.1** | **233.9** | **128.8** |

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

32. The clinical scenarios used to illustrate the potential benefits are based upon typical real life situations where clinical scientists could use PGDs to improve patient care. There is not a significant amount of data available on the possible impacts of these changes, and so using estimates from the professional body, reality checked by the Chief Professions Officers' Medicines Mechanism (CPOMM) programme: PGD project working group (which includes professional bodies 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 and that some of the non-monetised benefits could make this an under-estimate. The area of greatest uncertainty is how representative the four modalities are of the rest of the profession. We have tried to account for these uncertainties by including a wide sensitivity analysis around the way we scaled up costs and benefits**.**

34. This impact assessment does not consider the costs and benefits of broader changes in the role of clinical scientists. This would require significant additional training during post-graduate qualifications, but would also offer the opportunity for development of new care pathways that use NHS funds more efficiently, increase patient satisfaction and improve patient health.

*Risks of inappropriate administration of medicines*

35. 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 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[16], 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. The medicines considered were chosen based on their known clinical effect, and so assume that this QALY cost represents the 0.4% of serious errors, and the remaining errors have no substantial health effect. 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 was 3-4 times higher than the current error rate. This suggests that the conclusion that these changes would lead to net benefits may be 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 clinical scientist's practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

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

a. PGDs offer well-defined, specific instructions on how to administer medicines, which have been created with safety in mind and rely on significant input from senior pharmacists. This reduces risks of selecting the wrong medicines.

b. The clinical scientist 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. The clinical scientist may have a better understanding of the patient's history and situation than an independent prescriber who has not previously met the patient and may therefore be in a better position to understand the patient's suitability for the medication;

d. In line with NICE guidance[9] clinical scientists would have local competency assessment on PGD administration every two years.

37. 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. All clinical scientists are registered with the Health and Care Professions Council (HCPC). The HCPC sets the standards that all registrants have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the minimum standards that the HCPC considers necessary to protect members of the public. Registrants must meet all these standards when they first register and complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet the standards relevant to their scope of practice to stay registered. Registrants must also ensure that they have appropriate indemnity in place to cover all of their work. This indemnity may be provided by an employer, a professional body or by private arrangement.

[16] 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. Once registered, clinical scientists must undertake continuing professional development (CPD) and demonstrate that they continue to practise both safely and effectively within their changing scope of practice, in order to retain their registration.

c. When the members of a profession renew their registration, the HCPC randomly audits the CPD of 2.5% of professionals. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. A failure to submit or complete successfully an audit may lead to removal from the register[17].

d. The HCPC regulatory processes for clinical scientists, as outlined above, will support the profession in mitigating the risk of supply or administration errors.

**Proposed implementation plan**

38. A change in legislation is required to allow clinical scientists to administer and supply medicines under PGD.

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

40. 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**

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.

[17] HCPC (2017) *Continuing professional development and your registration*

## Annex A

**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 | 1.1 | 1.1 | 0.0 |
| Year 2 | 1.2 | 2.2 | 1.0 |
| Year 3 | 1.2 | 3.4 | 2.1 |
| Year 4 | 2.1 | 4.6 | 2.5 |
| Year 5 | 2.1 | 5.8 | 3.7 |
| Year 6 | 1.0 | 5.9 | 4.9 |
| Year 7 | 1.8 | 6.0 | 4.2 |
| Year 8 | 1.9 | 6.2 | 4.3 |
| Year 9 | 1.1 | 6.3 | 5.2 |
| Year 10 | 1.9 | 6.4 | 4.5 |
| *Total (undiscounted)* | *15.4* | *47.8* | *32.4* |
| *Total (discounted)* | *14.1* | *43.4* | *29.3* |
| **Total with opportunity costs (undiscounted)** | **61.7** | **140.9** | **79.2** |
| **Total with opportunity costs (discounted)** | **56.6** | **125.9** | **69.4** |

**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 | 3.0 | 2.9 | -0.1 |
| Year 2 | 3.2 | 5.9 | 2.8 |
| Year 3 | 3.3 | 9.1 | 5.8 |
| Year 4 | 5.6 | 12.4 | 6.8 |
| Year 5 | 5.8 | 15.8 | 10.0 |
| Year 6 | 2.7 | 16.1 | 13.4 |
| Year 7 | 4.9 | 16.4 | 11.5 |
| Year 8 | 5.1 | 16.7 | 11.6 |
| Year 9 | 3.0 | 17.1 | 14.1 |
| Year 10 | 5.2 | 17.4 | 12.2 |
| *Total (undiscounted)* | *41.8* | *129.9* | *88.0* |
| *Total (discounted)* | *38.4* | *117.8* | *79.4* |
| **Total with opportunity costs (undiscounted)** | **167.4** | **382.4** | **215.1** |
| **Total with opportunity costs (discounted)** | **153.5** | **341.8** | **188.3** |