Title: Independent Prescribing of Certain Controlled Drugs by Therapeutic Radiographers and Paramedics, and Supply by Podiatrists **IA No:** 9619 **RPC Reference No:** Not referred / Out of scope **Lead department or agency:** Dept. of Health & Social Care **Other departments or agencies:** Home Office, NHS England	**Impact Assessment (IA)** **Date:** 8 December 2023 **Stage:** Final stage **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Enquiries:** lauren.teer@homeoffice.gov.uk

Summary: Intervention and Options

RPC Opinion: Out of scope

Cost of Preferred (or more likely) Option (in 2023 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£326m	< £5m	Negligible	Not applicable

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

The Misuse of Drugs Regulations 2001 (the 2001 Regulations) restrict independent prescribing by therapeutic radiographers and paramedics for certain scheduled (controlled) drugs. This puts demand on other prescribers to approve prescriptions, puts pressure on secondary care and can lead to delays in treatment. The Advisory Council on the Misuse of Drugs (ACMD) has recommended that these restrictions be lifted with appropriate safeguards for certain named drugs, thereby delivering efficiency and health gains. This builds on reforms in 2016 and 2018 which extended the relevant clinicians' ability to independently prescribe non-scheduled drugs without the need to consult a doctor. The restrictions are set in legislation and government intervention is required to change them. Restrictions also apply to supply of three codeine products by registered podiatrists, although in this case supply is already permitted through a ministerial written authority. The proposed legislation amendment will not change existing practice for podiatrists, but will update and clarify the regulations, give stronger legal force and ensure greater consistency of care.

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

- Improve NHS efficiency, by reducing pressure on doctors and secondary care.
- Improve health, by enabling faster access to controlled drugs when medically justified.
- Improve equality and fairness, by clarifying the regulations and facilitating consistent application.
- Ensure safety, by maintaining appropriate safeguards.

The aim is to make it easier for existing patients to obtain appropriate medication. It is not expected to change the total number of patients needing or seeking treatment, or to increase demand for the products.

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

- Option 0 (baseline) – maintain the current limitations on prescribing of controlled drugs.
- Option 1 (preferred) – amend the 2001 Regulations to allow:
  - i) therapeutic radiographer independent prescribers to independently prescribe tramadol, lorazepam, diazepam, morphine, oxycodone and codeine.
  - ii) paramedic independent prescribers to independently prescribe lorazepam, diazepam, morphine sulphate, codeine phosphate and midazolam.
  - iii) Registered podiatrists to supply co-codamol, co-drydamol and codeine phosphate (this is already permitted by a ministerial written authority, but formal legislation would simplify and reinforce which activities are lawful).

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** [tbc]

Is this measure likely to impact on international trade and investment?		**No**		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions?		Not applicable		

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: Chris Philp Date: 7th December 2023

Summary: Analysis & Evidence Policy Option 1 – Amend legislation

Description: Amend the Misuse of Drugs Regulations 2001 to allow independent prescribing of controlled drugs by therapeutic radiographers and paramedics in the situations specified.

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 49	**High:** 877	**Best Estimate:** 326

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	2	1	Negligible	2
High	6		Negligible	6
Best Estimate	4		Negligible	4

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

The main cost is training independent prescribers to prescribe certain controlled / scheduled drugs. Existing eligible staff are already able to prescribe independently - it is only the marginal additional cost related to the relevant controlled drugs that is attributable to this reform, and that is expected to be low. The cost is optional and there is no requirement to train unless people need to as part of their scope of practice (although uptake amongst eligible staff is expected to be high). Most of the cost is assumed to be upfront with a 5% churn effect thereafter.

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

There may be a very low cost relating to familiarisation among other staff who may work with the affected clinicians.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0	-	6	54
High	0		96	880
Best Estimate	0		36	330

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

The primary benefit is an efficiency (time) saving resulting from the removal of the need to refer patients to a second clinician to prescribe controlled drugs. Instead, a paramedic or radiographer qualified to prescribe independently can issue the prescription directly, saving both their and their colleagues' time. Such savings are assumed to be recycled within the NHS, generating additional health gains. The second benefit is a direct health gain, primarily from faster pain relief, among those patients prescribed the relevant drugs.

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

The new rules should deliver a more consistent patient experience, reducing the current variation seen when delays in prescribing occur.

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

The number of clinicians likely to be affected is reasonably well identified but could change in future. The number of referrals avoided per clinician and the time saved per referral are significant and uncertain. Marginal training costs are likely to be low. Risks around inappropriate prescribing will be addressed through training, existing local governance and monitoring. Business impacts are relatively insignificant because the vast majority of activity is performed within the NHS. Where business does gain a benefit, its size will depend on the extent to which time savings can be recycled into profit-generating activity. All numbers are rounded to £1m.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m: n/a			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	
Negligible	Negligible	Negligible	Not applicable

Evidence Base

Problem under consideration and rationale for intervention

1. Medicines are strongly regulated to ensure their use is clinically appropriate and safe. The Human Medicines Regulations 2012 (HMRs) set out the circumstances in which different medicines can be prescribed, and by whom. Drugs are controlled under the Misuse of Drugs Act 1971 (the 1971 Act), owing to their potential to cause harm to the individual and society when misused. This means they carry offences of possession, supply, manufacture, import and export except as allowed by regulations or by licence issued by the Secretary of State. The 2001 Regulations provide for certain exemptions from the provisions of the 1971 Act to produce, export, import, possess and supply certain controlled drugs. Controlled drugs are placed into Schedules (1 to 5) to the 2001 Regulations, with each Schedule dictating the degree of lawful access and administrative requirements applicable. The 2001 Regulations also permit specified activities to take place by specified groups, including healthcare professionals. For a controlled drug to be prescribed to address a particular medical need, both the HMRs and the 2001 Regulations must allow its use in that situation.
2. Prescribing of controlled drugs is restricted to certain registered healthcare professionals, meaning that other professionals need to refer patients if controlled drugs are required, rather than being able to issue prescriptions directly. This adds complexity, places additional burdens on GPs and/or secondary care and may delay treatment.
3. The Advisory Council on the Misuse of Drugs (ACMD) has identified several specific situations where the current restrictions are no longer appropriate. This is where the downsides of restrictions are significant and the risks of reducing them can be appropriately managed. Amending the 2001 Regulations would allow more flexible prescribing and deliver efficiency and health gains without introducing unacceptable risk.
4. The ACMD has recommended that the 2001 Regulations should be amended to allow prescribing of controlled drugs in the following situations. The HMRs have already been amended where necessary.

Prescriber	**Medicine**	**Method of delivery**
Therapeutic radiographer independent prescribers	Codeine phosphate	Oral
	Morphine sulfate	Oral + injection
	Oxycodone	Oral
	Tramadol	Oral
	Diazepam	Oral
	Lorazepam	Oral
Paramedic independent prescribers	Codeine phosphate	Oral
	Midazolam	Oromucosal + injection
	Morphine sulfate	Oral + injection
	Diazepam	Oral + injection
	Lorazepam	Injection

5. The ACMD has also recommended that amendments to the 2001 Regulations are made to allow registered podiatrists to supply co-codamol, co-drydamol and codeine phosphate. In practice, this already happens under a Ministerial written authority but making provision in the 2001 Regulations will provide a stronger legal basis.
6. This statutory instrument (SI) will also make some technical amendments in respect of podiatrist independent prescribers, physiotherapist independent prescribers and healthcare professionals acting under patient group directions, which will correct historic anomalies in the 2001 Regulations caused by previous amendments made in line with previous ACMD recommendations.
7. The specific rationale for intervention is:
    - Current prescribing practice is sub-optimal and inefficient, requiring referrals when (in certain specified situations) faster and safe prescribing can be carried out independently by frontline professionals such as paramedic and therapeutic radiographer independent prescribers.
    - Whilst there is already a Ministerial written authority to enable supply of the three codeine products by podiatrists, these changes to legislation are needed to provide legal clarity on existing measures.
    - The ACMD has made recommendations to this effect.
    - The technical amendments are required to correct historic anomalies in the 2001 Regulations caused by previous amendments, providing clarity to the healthcare professionals affected but with no change to existing practice.
    - Adopting those recommendations requires legislative change because the relevant rules are regulatory in nature.

Policy objective

8. The technical objective is to amend the 2001 Regulations to allow independent prescribing of specified controlled drugs by a wider range of professionals. Such prescribing would not be compulsory, but clinicians would have greater flexibility to respond to patient needs.
9. The operational objective is to realise a series of benefits as follows:
    - Reduce pressure on GPs and the NHS, by removing the need to refer prescribing decisions;
    - Reduce costs of treatment, in the same way;
    - Improve health, by reducing delays and speeding up treatment while simultaneously freeing up capacity in the system;
    - Improve equality of access to healthcare; and
    - Improve patient experience.
10. At the same time, any reforms should be introduced in a way which:
    - Maintains safety, through appropriate safeguards and restrictions;
    - Includes appropriate training being made available to clinicians;
    - Minimises any costs associated with the reform; and
    - Will be monitored and reviewed, in line with ACMD advice.

11. The reforms are not intended or expected to lead to an increase in prescribing of the medicines concerned. The aim is simply to adopt a faster and more efficient way of managing existing demand.

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

12. These proposals are an administrative reform recommended by an expert body. The expected effect is that most people will continue to be treated with the same medications as currently, but more quickly and efficiently. It is not intended or expected that the reforms would change demand for medicines, only to simplify existing processes or ensure stronger legal clarity on activities already carried out in practice under Ministerial written authority or group authority.
13. The nature of the costs and benefits is well understood. The main cost, training, is expected to be low and that assessment has high confidence because only a marginal addition to existing training is required. For benefits, uncertainty is greater. The argument that benefits will accrue is very strong, and that they will exceed the costs is also strong. But their absolute size is dependent on uncertain assumptions and influenced by the considerable variation in individual patients.
14. On balance, the analysis has been kept relatively simple. Sensitivity analysis has been included to stress test the cost/benefit numbers, and an optimism bias adjustment has also been included to provide further reassurance that significant positive benefits can be delivered.
15. Impacts on business are dependent on (1) the degree to which clinicians work in non-NHS settings (believed to be less than 10% of the total, and (2) the degree to which time savings can be converted into additional profit-making activity in the private sector. Given that business costs are expected to be both low and voluntary, the business analysis has been kept high-level.
16. The bottom line is that these proposals are expected to be beneficial to all stakeholders, potentially significantly so, and that conclusion is not particularly sensitive to the results of the analysis.

Regulatory Policy Committee (RPC)

17. This IA is out-of-scope for RPC referral. There is a specific exemption for regulatory provisions that implement changes to the classification and scheduling of drugs under the Misuse of Drugs Act 1971 and similar legislation, where these follow the recommendations of the relevant independent advisory body (ACMD). As this reform deals specifically with the restrictions pertaining to prescribing of controlled drugs, and follows an explicit ACMD recommendation, it meets the exemption criteria. The IA nevertheless sets out the rationale and expected impacts as fully as possible, to inform and assist stakeholders.

Description of options considered

Option 0 – Baseline / No change

18. Maintain the current limitations on prescribing of controlled drugs. This preserves all current processes and requires no action or investment. It implicitly rejects the expert ACMD advice

to reform the 2001 Regulations and misses the opportunity to achieve the desired benefits. This option does set the baseline against which any reform can be judged.

Option 1 – Amend the 2001 Regulations to allow independent prescribing or supply in certain specified situations.

19. Each situation can be considered on its merits and implemented (or not) on a case-by-case basis. In practice, the recommended option would allow:
    - therapeutic radiographer independent prescribers to prescribe tramadol, lorazepam, diazepam, morphine, oxycodone and codeine.
    - paramedic independent prescribers to prescribe lorazepam, diazepam, morphine sulphate, codeine phosphate and midazolam.
    - podiatrists to supply co-codamol, co-drydamol and codeine phosphate (as they do now under a Ministerial written authority, but on a strengthened legal basis).
20. In each case, there will be further criteria and restrictions that must be met, for example with respect to training or experience of the clinician. Full details will be set out in the regulations and accompanying guidance.
21. Option 1 is the preferred option, as it follows all ACMD recommendations.

Rejected options

22. The ACMD also considered amending the regulations for Fentanyl (transdermal) but decided not to recommend any change at this time, pending further monitoring.

Analysis of the Current Situation

Relevant clinicians and situations covered by the reforms

23. Therapeutic radiographer independent prescribers

    - The proposed reform would authorise therapeutic radiographer independent prescribers to prescribe the specified medicines. Such clinicians consolidate and develop their specialist skills and capabilities to an enhanced or advanced level and have a significant portfolio of evidence and expertise, including clinical leadership. Following additional accredited higher education, they develop high-level critical reasoning and skills that enable them, as part of a multidisciplinary team, to independently assess and treat (where appropriate) radiotherapy patients. In line with NHS recommendations, The Society of Radiographers recommends that enhanced and advanced radiographers should be educated to a minimum of MSc level or equivalent. All therapeutic radiographers are required by law to be registered with the Health and Care Professions Council (HCPC).

    - The main purpose of therapeutic radiographer independent prescribers is to support patients undergoing radiotherapy treatments. Those working at an enhanced or advanced level of practice typically work within multi-disciplinary teams alongside radiation oncologists and specialist nurses assessing, diagnosing and treating patients during their radiotherapy treatment. They are specialists within a cancer type, having

significant expertise in preparing, supporting and following up patients having radiotherapy with specific types of cancer such as head and neck, breast or prostate. This ensures patients are seen in a safe and timely manner by a professional with expertise in their disease type allowing them to access the appropriate treatment promptly and without the need for further appointments to see other health professionals. Therapeutic radiographer independent prescribers are currently utilised in a narrow range of settings including (but not limited to):

- Planning and preparation for radiotherapy: inpatients and outpatients
- Scheduled on treatment review
- In-patient/out-patients urgent unscheduled review
- Long term effects clinics.

- The specific medicines and situations covered by the proposals include:

  Analgesia – Codeine Phosphate, Morphine Sulphate, Oxycodone and Tramadol provide prompt relief of pain caused as a side effect of radiotherapy, immediate relief of pain for radiotherapy patients receiving palliative treatment to reduce suffering.

  Diazepam and Lorazepam address the needs of patients experiencing anxiety or an inability to stay still for their treatment where a failure to do so would result in a delayed or cancelled appointment.

- Currently, independent prescriber radiographers are required to interrupt a clinical oncologist in order to obtain a prescription for a controlled drug or, if there is nobody available, to seek a further appointment later. Enabling therapeutic radiographer independent prescribers to prescribe the six controlled drugs specified in this legislation will reduce the risk of error, reduce delays in treatment and use fewer resources. Therapeutic radiographer independent prescribers may also deprescribe a controlled drug where the effect is not as anticipated or is no longer needed.

- In practice the new powers will allow advanced therapeutic radiographer independent prescribers to prescribe and authorise the administration of a greater range of medicines to a significantly larger group of patients without the need to refer patients onto other colleagues to complete an episode of care. This will significantly increase patient flow and allow more episodes of care to be completed in a timely manner. For each drug specifically:

  - **Codeine phosphate and morphine sulphate** will allow prompt relief of pain and also allow advanced therapeutic radiographer independent prescribers to direct others to administer that pain relief, in line with current prescribing guidelines. Currently, these radiographers are required to interrupt a radiation oncologist or cancer nurse prescriber from their own work, to obtain a prescription for codeine or morphine. Enabling therapeutic radiographer independent prescribers to prescribe the six controlled drugs specified in this legislation will reduce the risk of error and use fewer resources.
  - **Tramadol and Oxycodone hydrochloride** will be affected as above for patients who cannot tolerate codeine or morphine.
  - **Lorazepam and Diazepam** reduce anxiety and allow patients to better tolerate the physical and psychological demands of treatment regimens such as

stereotactic radiotherapy. This treatment requires complete immobilisation for up to an hour and employs devices such as a plastic mask which covers the patient's whole face. The therapeutic radiographer could be the most senior clinician within the radiotherapy department as many services have minimal access to specialist oncology doctors and rely heavily on highly skilled therapeutic radiographers working at advanced and consultant levels to provide clinical care. This change would allow safe effective treatment to be initiated by the most appropriate team member. It would remove the need for the therapeutic radiographer to leave the patient and the department to seek a prescription from another healthcare provider, or to rebook the patient once a controlled drug has been prescribed at a separate appointment. This would facilitate timely and comfortable treatment for the patient and supports efficient working for the team.

- In all cases, the new rules will allow independent prescriber radiographers the flexibility to prescribe the most appropriate drug for each patient/situation taking account of allergies, sensitivities, contraindications, and patient preference.

24. Paramedic independent prescribers

- Paramedics can be sub-divided into entry level, specialist and advanced. The proposed reform would authorise only paramedic independent prescribers, a type of advanced paramedic who has successfully completed a prescribing programme, to prescribe the specified medicines. Such clinicians consolidate and develop their specialist skills and capabilities to an advanced level, and have a significant portfolio of evidence and expertise, including clinical leadership. Following additional higher education, they develop high level critical reasoning and diagnostic skills that enable them to independently assess and treat (where appropriate) patients with more complex presentations and care needs, including the acutely ill and those with exacerbations of long-term conditions. The College of Paramedics recommends that advanced paramedics should be educated to a minimum of MSc level or equivalent. All paramedics are required by law to registered with the Health and Care Professions Council (HCPC).

- The main purpose of paramedic independent prescribers is to allow those working at an advanced level of practice to be able to independently assess, diagnose and treat patients in a single episode of care. This ensures patients are seen in a timely and safe manner and allows them to access the appropriate treatment promptly and without the need for further appointments to see other health professionals.

- Paramedic independent prescribers are currently utilised in a wide range of settings including (but not limited to):

    - Emergency departments (ED)
    - Same day emergency care (SDEC)
    - Air ambulances
    - General Practice Surgeries
    - Out Of Hours Services
    - Walk in centres
    - Community palliative care teams
    - Virtual wards and hospital at home services

- Hospices
- On general and specialised wards

- In practice the new powers would allow paramedic independent prescribers to prescribe and authorise the administration of a greater range of medicines to a significantly larger group of patients without the need to either further consult with colleagues or having to refer patients onto other colleagues to complete an episode of care. This will significantly increase patient flow and allow more episodes of care to be completed in a timely manner.

    - **Codeine and morphine** in all settings will allow prompt relief of pain and also allow paramedic independent prescribers to direct others to administer that pain relief, in line with current prescribing guidelines. Currently, these paramedics in primary care are required to interrupt a GP or other healthcare provider from their own work, in order to obtain a prescription for codeine. Enabling paramedic independent prescribers to prescribe the five controlled drugs specified in this legislation will reduce the risk of error and use fewer resources.
    - **Lorazepam** which is the recommended first line treatment for seizures will be able to be administered in emergency departments, intensive care units and in critical care services and allow paramedic independent prescribers to direct others to administer whilst they are managing other aspects of patient care for example a difficult airway. This could ensure rapid termination of a seizure which can be a life-threatening event for a patient. In many of these settings, the advanced paramedic could be the most senior clinician initially by the patient's side, this change would allow safe effective treatment to be initiated by the most appropriate member of the team. It would avoid the paramedic having to leave the patient to seek a prescription from another healthcare provider and allow them to continue leading the team looking after the patient.
    - **Diazepam** as above and also prescribing for anxiety.
    - **Midazolam** for procedural sedation in critical care, emergency departments and on ward as well as palliative care and in hospices. Some patients require administration of sedative medication in order to safely treat, for example, a badly deformed fracture of a limb. This would allow prompt care, delivered by a skilled individual in this environment, reducing delays and worsening of the condition.

- Paramedic independent prescribers are capable of 'seeing and treating' patients with complex needs in range of healthcare settings, including:

    - **Primary care** (including urgent care) - paramedics may work in GP surgeries (undertaking planned and on-day appointments and home visits), in the wider primary care team (attached to community specialist teams focusing on supporting patients with long term conditions, end of life care, and admission avoidance), or in out of hours services alongside GPs and other advanced practitioners. Prescribing focuses mainly on timely access to the correct medicines and would include controlled drugs.
    - **Secondary care** (emergency departments and critical care)- the main setting in secondary care is in the emergency department, usually working as advanced clinical practitioners under the supervision of the medical team. Prescribing would include controlled drugs.

- **Ambulance services** - owing to the current infrastructure, it is challenging and discouraged for paramedics to practise as independent prescribers in ambulance settings. The reform is not expected to change this.

25. Registered podiatrists

- Restrictions also currently apply to the supply of three codeine products by registered podiatrists, specifically to co-codamol, co-drydamol and codeine phosphate. In this case supply is already permitted through a ministerial written authority. The proposed legislation will not change existing practice for podiatrists, but will update and clarify the regulations, giving stronger legal force and ensuring greater consistency of care.

- In such a situation, there is no change to existing practice and therefore any costs or benefits will be negligible. Familiarisation with the change in legal basis is not expected to require any significant time. The main benefit (legal clarity) is not quantifiable but justifies the inclusion of podiatrists in the wider update of the 2001 Regulations.

- On proportionality grounds, this impact assessment does not discuss podiatrists in further detail, and instead concentrates on the expected changes in clinical practice for paramedics and radiographers.

Number of clinicians affected

26. Within each profession, only a subset of clinicians will be eligible to prescribe controlled drugs independently. They will need to have or acquire appropriate levels of training and experience. Clinicians may or may not seek to prescribe all permitted products depending on the patients they see and their scope of practice.

27. The numbers expected to benefit from the new flexibilities initially are:

Paramedic Independent Prescribers	1,500 clinicians affected	There are currently around 1,700 paramedic independent prescribers, based on Health and Care Professions Council Register data (March 2023). Nearly all of these are expected to seek to prescribe the relevant controlled drugs when necessary. The analysis takes a 90% uptake rate as indicative, giving around 1,500 clinicians affected in the short term. The analysis assumes that these clinicians would start prescribing immediately, with an additional annual churn rate of 5% in subsequent years.
Therapeutic Radiographer Independent Prescribers	200 clinicians affected	An estimated 219 therapeutic radiographer independent prescribers would be eligible to take advantage of the new flexibilities to independently prescribe controlled drugs (again based on Health and Care Professions Register data). Of those, the “large majority” are expected to take up the opportunity. The analysis takes a 90% uptake rate as indicative, giving around 200 clinicians affected.

		The analysis assumes that these clinicians would start prescribing immediately, with an additional annual churn rate of 5% in subsequent years.

28. Although a normal level of churn is assumed, the analysis does not explicitly allow for any larger shift in future in the number of clinicians expected to prescribe controlled drugs independently. Any such shift would raise or lower the expected costs and benefits proportionately. The proposed reforms are not in themselves expected to change the number of qualifying clinicians, but any change resulting from wider circumstances would affect the expected level of impact. In particular, the numbers of paramedics and therapeutic radiographers may be affected by changes resulting from the recommendations of the NHS Long Term Workforce Plan, although by definition that has an extended timeframe. The change in legislation supports some of the developments in that plan, with benefits to both the patient and the wider healthcare system.

Numbers of referrals affected

29. The need to independently prescribe controlled drugs is likely to arise fairly frequently for those clinicians affected. The analysis makes the following assumptions:

Paramedic independent prescribers	~580,000 referrals affected	The number of referrals per clinician per week is very uncertain and likely to vary considerably. Indicative evidence from the College of Paramedics suggests a clinician working in palliative care might deal with 10 potential referrals per week, an emergency department clinician might handle between 15 and 25, an ICU clinician maybe 5. Larger estimates of 20-40 potential referrals per week are also available. The analysis takes a cautious estimate of 10 referrals per week as being reasonable, but with subsequent sensitivity analysis exploring the effect of different numbers. The central estimate assumes 10 potential referrals per clinician per week, aggregated across all the relevant drugs. Each clinician is assumed to work for 43 weeks per year, giving a total number of referrals as 1,500 x 10 x 43 = 645,000. This is then further reduced by 10% to around 580,000 to allow for some cases currently being handled without referral (e.g. prescribing an alternative drug). The figures assume that all instances where one of the controlled drugs is required would require a referral under the current rules. This may not be true in all situations.
Therapeutic Radiographers	~77,000 referrals affected	The number of potential referrals will again vary with circumstances. A small survey of clinicians by the Society of Radiographers (n=21) found a range of

		between 1 and 30 per week, with both a mean and median of 10. The analysis assumes 10 potential referrals per clinician per week, aggregated across all the relevant drugs. Each clinician is assumed to work for 43 weeks per year, giving a total number of referrals as 200 x 10 x 43 = 86,000. This is then further reduced as above by 10% to allow for situations where a referral may not be needed, giving around 77,000. The figures assume that all instances where one of the controlled drugs is either required or needs to be de-prescribed would require a referral under the current rules. This may not be true in all situations.

Numbers of patients affected

30. It is the number of referrals avoided that will drive the overall size of benefits of reform, both for clinicians and for their patients. The number of individual patients is not known precisely because some patients require repeat treatment and, depending on the specifics of the case, may experience multiple referrals. Therefore, we cannot assume that one referral = one patient. However, for modelling purposes we ignore this limitation and focus just on the number of potential referrals.

31. Similarly, the number of hospitals, clinics or other organisations benefiting is not known, but given the high rates of uptake assumed, the expectation is that all locations employing eligible staff will be affected by the reforms.

Quantity of drugs involved

32. The total quantity of controlled drugs likely to be prescribed under these proposals is unknown (current data on medicine use are not broken down to the required level of detail with respect to the different clinicians and referrals involved). However, because the reform is not expected to change the medication prescribed in any significant way (affecting only the speed with which it is prescribed) this data limitation is not judged to be significant.

Costs of reform

Familiarisation and training

33. The reforms will create training costs for those clinicians wishing to independently prescribe the relevant controlled drugs. Only the incremental costs associated with independently prescribing the relevant controlled drugs are relevant to this impact assessment. Any costs associated with independent prescribing or medical diagnosis skills generally are likely to have already been incurred, or be due to be incurred, under the status quo. They are thus a sunk cost that is not affected by, or relevant to, decisions around the current policy proposal.

34. The costs that are pertinent are expected to be relatively low on a per clinician basis. Evidence collated suggests:

    - Additional training for paramedics is expected to be minimal with most paramedic independent prescribers already possessing the relevant clinical knowledge. The College

of Paramedics intends to introduce a training package for controlled drugs which would be free to members. The cost of producing this package is estimated to be low.

- For radiographers, all current prescribers will already be educated about controlled drugs under existing frameworks. Independent prescribing may already be permitted in some situations as supplementary prescribers. That means that any additional training requirement is likely to be low and may be handled primarily through professional mentoring and continuing professional development activity (both of which would be low volume and managed in-house). Training for new recruits is already incorporated into education programmes because most programmes are multi-disciplinary. The marginal additional cost is expected to be very low.
- Registered podiatrists are not expected to require any training or to incur any cost of significance, given that their skills and practices are not changing.
- There may be some (very minor) familiarisation costs for any other staff or stakeholders who need to understand the new regulations. This has not been monetised. It is unlikely that any formal training would be needed or provided.
- For both paramedics and radiographers there may be some administrative updates required to confirm that clinicians are qualified to independently prescribe controlled drugs, but that is not expected to be time-consuming.

35. For quantification purposes, the amount of time spent training on top of existing requirements is likely to be low, and by implication any backfill or other implications arising from the additional training are also likely to be low. The analysis assumes an overall training impact equivalent to 8 hours per clinician. This is expected to be an overestimate in practice, based on what the professions have said, but is reasonable on conservative appraisal principles. It is intended to cover both the training time and any cost associated with backfill. Training costs are included as a parameter of interest in later sensitivity analysis.

36. The salary rate used for the clinicians being trained is taken to be the average of NHS bands 7 and 8a, which is £37.76 per hour including oncost adjustments like national insurance.[1] Clinicians working solely in the private sector on non-NHS business may have different wage rates. Such people are expected to be a small minority (5%-10%) and the analysis ignores that possibility as a proportional approach.

37. The total training cost on these assumptions is around £520,000 as a one-off impact, plus a further £37,000 per year. The one-off impact is assumed to occur immediately (which maximises the discounted training cost but also the speed with which benefits will arise).

38. Other costs are expected to be minimal if they arise at all. There may be some short-term inefficiencies as people query or are unfamiliar with the new regulations, but this is not expected to be significant or permanent.

Risks

39. Any relaxation of prescribing restrictions may conflict with the rationale for introducing those restrictions in the first place and lose any associated benefits. However, in this case, such risk is minimal.

40. For most of history doctors were the only profession who could prescribe medicines. However, other healthcare professions (paramedics and radiographers in this case) have excellent knowledge of medicines in their areas of practice. Medicines knowledge is now well embedded in preregistration education and training programmes to achieve the

[1] https://www.pssru.ac.uk/pub/uc/uc2022/Unit_Costs_of_Health_and_Social_Care_2022.pdf See table on page 59.

standards of proficiency needed for HCPC registration. Over the last 30 years, the skills and knowledge of medicines that non-medical healthcare professionals have has been more widely understood and the realisation has dawned that this can be put to safe and effective use to benefit patients and the NHS. The formal process started with the Crown Report in 1999 which recommended that some nurses could train to prescribe some medicines and has developed significantly since then. Legislation has tended to follow the expanding skills and knowledge in our healthcare professional workforce – and remains behind the curve in some respects.

41. As such, the proposed reform now is more about ensuring that practice matches the current skills and capabilities of the clinical workforce, delivering benefits to patients in the process, and less about removing a safeguarding measure that addressed some hypothetical identified risk. The result is that amending the current restrictions in the way proposed (including safeguards around qualifying staff and training) does not create any significant risk to patient care. Instead, it removes risks resulting from sub-optimal deployment of scarce clinical resources.

42. DHSC will routinely seek independent clinical advice on proposals to change the Human Medicines Regulations 2012 and/or the Misuse of Drugs Regulations 2001. The Commission on Human Medicines (CHM) advises on the former and the Advisory Council on the Misuse of Drugs (ACMD) advise on the latter. Both bodies are made up of doctors and other clinical professionals with relevant expertise and their role is to scrutinise the clinical appropriateness and safety of the proposals. CHM also considers the skills, and training of the professional groups concerned as well as the professional regulation measures that apply to them. The ACMD also looks at proposals from the perspective of the risk of addiction, misuse and diversion. Only proposals with positive recommendations from CHM and, where controlled drugs are concerned, from ACMD, are taken forward to the legislative stage. This further ensures that any clinical risks are identified and mitigated.

43. There is a potential for training to not be effective, leading to inappropriate or inefficient prescribing, which could lead to costs in some form. This is not considered to be a significant factor given the considerable body of relevant training already provided, coupled with the expectation that recognised professional bodies and/or experienced clinicians will provide or oversee any new training. Professional body guidance recommends that all prescribing activity is audited and reviewed regularly as part of professional development and organisational governance processes. We have not seen any evidence of current referral requests being overruled.

44. It is standard practice for DHSC to consider whether a reform will have any impact on medical supplies (medicines, equipment etc). In this case the expectation is that any impact would be minimal. It is conceivable that faster treatment may lead to a longer duration of treatment, implying a higher quantity of medicines consumed. But it is equally plausible to assume faster treatment may lead to a faster resolution, with the opposite effect. The analysis assumes a broadly neutral impact on medicine supply overall.

45. Most controlled drug prescribing referrals are made solely to deliver that prescription. However, there is a potential risk that if the need for referral is removed then any wider benefits associated with that referral might be lost. This might be the case if the referral were made for more than just prescribing reasons and/or it provided an opportunity to address other issues.

46. It is true that patients may require other aspects of care management alongside the prescription of controlled drugs. For example, therapeutic radiographers may refer patients for further oncology assessment or to a different healthcare professional (such as a dietician or physiotherapist) for wider issues. Advanced paramedic independent prescribers are also trained to make any referral for other services outside their scope of practice.

47. None of this will change because of these reforms. If a controlled drug prescribing referral is made partly for other reasons, then those other aspects will continue. The analysis focuses on the time saving resulting from the removal of the prescribing element, not of all possible referrals. Based on discussion with experienced clinicians, the risk of any wider issues not being addressed is very low.

48. Finally, there is an implementation risk that the reforms may not take effect as quickly as intended. This would be the case if training were not made available, or if clinicians were unable to take advantage of it, once the rules had changed. The former is judged to be unlikely, but it is possible that work pressures may mean that uptake is more spread out, rather than occurring immediately. Such a situation would not affect the balance of costs and benefits but could mean that both occur a little later than planned.

Benefits of reform

49. The expected savings are likely to be dependent on individual patient circumstances and thus variable. The common factor is that the need to refer prescribing of the proposed medicines to a second clinician is removed. This could save anything from a few minutes to avoiding a delay of hours or even days. Alternatively, it might not save any significant time at all, but instead lead to a (beneficial) change in the treatment provided.

50. Health gains will vary similarly. In most cases the impact is likely to be faster or more effective pain relief. In a minority of cases, where there is a potential threat to life, the health gains may be larger.

51. The analysis draws on a series of illustrative case studies provided by the College of Paramedics and the Society of Radiographers. These both illustrate the types of impact that reform is expected to deliver, and also help to quantify those effects. The scenarios are not intended to be comprehensive, but instead to give a plausible picture of the types and size of impacts that might occur.

52. Full descriptions of these scenarios are provided in Annex A. They cover all the main drugs affected by the proposals, a variety of settings, and a range of time and health-related outcomes.

Time (efficiency) savings

53. Based on an analysis of these scenarios, and further evidence provided with them, the expected time savings resulting from independent prescribing of controlled drugs are as follows:

Time savings per referral (Estimated average)	First Clinician	Referral clinician	Patient
Paramedics	3-4 mins	10 mins	5 mins
Radiographers	35 mins	10 mins	5 mins

54. The figures for paramedics are based solely on the scenarios and assume that each scenario is equally likely to occur. Some scenarios imply a time saving for all actors, others do not. But the average indicative saving is shown, net of any new activity required (for example the first clinician would have to issue a prescription when previously they sought out a referral, although their familiarity with the patient might shorten that extra time).

55. The figures for radiographers are taken from a small (n=21) survey of experienced clinicians performed by the Society of Radiographers. That found that the average time spent sorting out a referral was 41.5 minutes (could be up to 2 hours) for the first clinician, and a further 8-13 minutes (could be up to 20) for the referral clinician to issue the prescription. This is very variable. Assuming that the first clinician would in future need to issue the prescription, but would already be familiar with the patient, we assume a net time saving of 35 minutes.

56. While the referral clinician and patient time impacts are similar, the first clinician saving is very different between paramedic and radiographer. We believe this is the result of radiographers performing primarily in hospital settings where, for example, it might be plausible to spend more time looking for a referral clinician. Paramedics in contrast may be working in a wider variety of settings where potential time savings are lower (albeit more numerous). The ease or otherwise of finding colleagues will of course depend on their number and availability which will vary by profession among other factors. In practice, the higher number of paramedics affected by the reforms means that the weighted average saving is closer to the lower figure.

57. Given the uncertainty around time savings, and their significance in quantifying overall benefits, later sensitivity analysis considers the effect of varying the assumptions.

58. These time savings are valued at the following rates:[2]

- £37.76 per hour for the first clinician (average of NHS bands 7 and 8a, incl. oncosts);
- £53.18 per hour for the referral clinician (average of band 8a and consultant rates);
- £15.00 per hour for patient time (DHSC assumption). It is very case dependent whether a patient saves time: faster treatment may or may not reduce the duration of overall indisposition. Patients themselves may come from any walk or stage of life.

59. The total value of the expected time savings is calculated by multiplying the time savings by the respective salary rates, giving a total figure of £9.3m per year for clinicians (£6.7 paramedics and £2.6m radiographers), and £0.8m per year for patients (£0.7m paramedics and £0.1m radiographers).

	Paramedic	Referral prescriber	Patient	
Overall time saved per year (minutes) per year	2,368,440	5,921,100	2,960,550	hours
Hourly rate	37.76	53.18	15.00	£ per hour
Total valuation of time saved per year	1,490,488	5,247,788	740,138	£ per year
Total (advanced paramedics)	6,738,275		740,138	

[2] See para 31 and https://www.pssru.ac.uk/pub/uc/uc2022/Unit_Costs_of_Health_and_Social_Care_2022.pdf See tables on page 59 (bands 7 and 8a) and on page 95 (for medical consultants).

	Radiographer	Referral prescriber	Patient	
Overall time saved per year (minutes) per year	3,051,108	762,777	381,389	hours
Hourly rate	37.76	53.18	15.00	£ per hour
Total valuation of time saved per year	1,920,099	676,039	95,347	£ per year
Total (therapeutic radiographers)	2,596,137		95,347	

60. The clinician savings are a benefit to the NHS, but the value is enhanced by the likelihood that the time saving will be reinvested in additional healthcare activities by the clinicians involved. The NHS marginal rate of delivery is assumed to be 1 QALY per £15,000 of cost, hence the efficiency savings can be converted to QALYs to the amount of £9.3m / 15,000 = around 622 QALYs (using unrounded cost numbers).
61. The societal value of these QALYs is then monetised at £70,000 per QALY, giving an overall annual benefit of £44 million, plus the patient benefit of £0.8m.
62. In theory it is possible that the efficiency savings could be used to cut NHS costs, and thus the societal value of delivering additional health would not be realised. However, the expectation and policy intention is that the efficiencies would be used to allow more value to be delivered within the NHS for little or no extra cost, rather than any other aim.

Health benefits

63. The main health benefit will come from the potential redeployment of time saved by avoiding referrals to prescribers. The reforms should also deliver a small but significant additional gain for the patients benefiting directly from faster prescribing.
64. The most common scenario is faster treatment for pain relief. Typically, this may save a few minutes, but could speed up treatment by hours or days in some cases. The analysis places weight on the former (short-term pain relief) and applies average estimates of 20 minutes saved (paramedic scenarios) and 40 minutes saved (radiographer scenarios). This is likely to be conservative, and it does not consider the potential for more extreme benefits (which will occur in some cases, particularly when cases are delayed overnight or longer).
65. According to the EQ5D Index Value Calculator (produced by EuroQol in 2018)[3] differing levels of pain can be expressed in terms of QALY multipliers. A value of 1.00 represents no pain, 0.59 moderate pain and 0.38 severe pain. It would follow that a reduction in pain might deliver a QALY improvement of 0.21 (severe to moderate) and 0.41 (moderate to zero). Given the nature of the prescribing concerned, the analysis assumes the former, with a 0.2 QALY gain per case, multiplied by the length of any existing delay in treatment.
66. The calculation is essentially either 20 or 40 minutes x 0.2 QALYs per year x the number of referrals per year. This comes to around 5 or 6 QALYs, which is small (and as stated probably conservative) but notable. These can be valued at the societal value of £70,000 each, giving a benefit of around £0.4 million per year.

Other benefits

67. There may be additional benefits in terms of clearer and more consistent processes being followed, leading to a more uniform level of treatment being provided to patients with similar conditions. This has not been monetised.

[3] https://euroqol.org/support/analysis-tools/index-value-set-calculators/

Time profile of costs and benefits

68. In broad terms, the costs of this policy will be incurred upfront, assuming that clinicians wishing to prescribe independently are able to access any training or other advice required, and are able to take time away from front-line duties to complete such training. There will then be a churn effect (assumed to be about 5% of staff) each year.

69. The benefits will occur annually, and for the most part assumed to occur at or very shortly after the time at which referrals are avoided. It is possible that some health impacts may have a longer-lasting effect, but the analysis assumes impacts are immediate for simplicity. This will be true in the vast majority of cases where pain relief is the main objective of intervention.

70. Any impacts in later years must be discounted in line with HMT Green Book principles, reflecting societal preferences for benefits to occur sooner rather than later. The established methodology requires health impacts to be discounted at 1.5% per year, and non-health impacts to be discounted at 3.5% per year. The difference arises because of the so-called wealth effect, which assumes that people may value wealth less in future as wealth increases, but that health would continue to be highly valued (hence merits a lower discount rate). In practice, time savings for patients are discounted at 3.5%, but all impacts on clinicians are effectively monetised as QALYs so are discounted at 1.5%.

71. Applying these discount rates to the relevant costs and benefits over the standard IA appraisal period of ten years (perfectly reasonable for this appraisal) gives an estimate of around £408 million NPV.

Undiscounted impacts

Description	Units	One-off impact	Annual impact
Training time (backfill) - monetised as QALYs lost	£	-521,705	-26,085
	QALYs	35	2
	Social value	-2,434,622	-121,731
Efficiency savings (clinician) - monetised as QALYs gained	£	-	9,334,412
	QALYs	-	622
	Social value	-	43,560,591
Efficiency savings (patient) - monetised at value	Social value	-	835,485
Health gain from faster treatment - monetised as QALYs gained	QALYs	-	6
	Social value	-	396,430

Total discounted impacts

		Discounted £
Training time (backfill)	1.50%	-3,521,268
Efficiency savings (clinician)	1.50%	401,723,811
Efficiency savings (patient)	3.50%	6,948,396
Health gain from faster treatment	1.50%	3,655,950
Total		408,806,889

Optimism Bias

72. Optimism bias reflects the observed human tendency to take an overly optimistic view of costs and benefits in project planning or reform appraisal. In this case, it is possible that costs, risks or practical difficulties may be underestimated, or the benefits overestimated.

73. The Treasury Green Book recognises the desirability of adjusting to mitigate the risk of optimism bias, but it does not specify an empirical level for such an adjustment. In practice, risks must be assessed on an individual case basis. The main risks are likely to be:

    - Scenarios with higher or exceptional benefits may have experienced a selection bias when exploring the effects of reform, and vice versa for those with lower benefits.
    - Training costs may have been underestimated.
    - Implementation times may be optimistic – in practice it may take time for all eligible staff to be trained and apply the new flexibilities.
    - Other risks or downsides may exist but not have been deemed significant at this stage.

74. The analysis addresses these risks in four ways:

    - It relies on the work done by the Advisory Committee to fully and expertly appraise the situation before making its recommendations for reform.
    - At a number of points in the analysis, assumptions are designed to err on the side of being conservative (while accepting that that judgement may in itself be optimistic).
    - Sensitivity analysis is applied to the most significant modelling parameters (next section).
    - A further optimism bias adjustment of 20% is made to the monetised cost and benefit figures (essentially assuming that benefits will be 20% lower and costs 20% higher than predicted).[4]

75. The 20% adjustment is arbitrary, but intended to provide further confidence that the reforms will deliver a significant net benefit, even under more pessimistic assumptions.

76. The optimism bias adjustment reduces the expected NPV from £433m over 10 years to £326m on a net basis.

Estimated net impact after optimism bias adjustment

	Discounted £
Training time (backfill)	-4,225,522
Efficiency savings (clinician)	321,379,049
Efficiency savings (patient)	5,558,717
Health gain from faster treatment	2,924,760
Total	325,637,004

[4] In some cases, where a parameter affects both costs and benefits (such as the number of clinicians incurring a cost while being trained and then delivering a benefit) the adjustment takes the form of a 20% reduction in net impact.

Sensitivity analysis

77. The size of costs and benefits is uncertain, and heavily dependent on assumptions made about parameters of influence. Exploring the effect of different assumptions is helpful in identifying the potential range around any projections.

78. The most influential assumptions are the number of referrals likely to be seen each year under the current system, and the average time savings that might be achieved by removing the need for those referrals. Both of these may be influenced by other assumptions (such as the number of clinicians affected) but in simple terms, they are the two main drivers of impact.

79. The following is not intended to define absolute limits on the impacts that might be delivered, but instead to present a plausible assessment of uncertainty. The numbers here include QALY conversion, the overall optimism bias adjustment discussed above, and all other adjustments mentioned to date.

Parameter	Central	Worst case	Best case
Training (NPV)	-4,225,522	-5,504,849	-2,446,600
Training (annual)	-147,816	-192,569	-85,586
Number of clinicians expected to take up the new flexibilities	1,727	1,500	2,000
Referrals per clinician per week	9	5	15
Time/efficiency savings (minutes per referral)	14	5	20
Overall efficiency impacts (per year)	321,379,049	53,320,312	853,124,998
Patient time impact	5,558,717	922,252	14,756,034
Health impacts	2,924,760	242,625	11,645,996
Overall impact	325,637,004	48,980,340	877,080,428

80. In simple terms, the sensitivity explores the effect of varying three main parameters up or down to more extreme, but still hopefully plausible, values. The number of clinicians is varied by around +/- 15%, the number of referrals per clinician per week is varied by +/- 50%, and the average time saving per referral by around +/- 33%. These tolerances vary according to the level of variation in the evidence for each one – it doesn't follow that uncertainty margins would be the same for each.

81. It is unlikely that all parameters would fall at the extreme upper or lower end of their ranges, such that the combined effect of these uncertainties is likely to be lower than a simple sum of their upper or lower bounds. Nevertheless, that simple summation gives a range of net benefit from £49 million to £877 million over 10 years. The central estimate remains £326 million.

82. One conclusion is that even under very pessimistic assumptions, the proposals are expected to deliver a significant net benefit to health and to the NHS. A second conclusion is that while the existence of benefits is associated with high confidence, the actual size of those benefits is uncertain.

Business impacts

83. The proposed regulations will apply to all relevant clinicians in Great Britain, although in practice we expect that similar arrangements would be made in Northern Ireland. The rules will apply regardless of whether they are working in an NHS setting or the private sector. In practice, the professional bodies estimate that less than 5%-10% are likely to be working exclusively in a private setting. It is true that a significant proportion of clinicians may be employed on an NHS contract with a private firm, but in this case efficiency savings are likely to accrue to the NHS rather than the private firm (but see below).

84. The main impacts on business are expected to be:

    - Up to 5%-10% of the main time saving impact, based on the private sector's market share of clinician activity. However, this depends on the ability of a business to monetise efficiency savings as a gain for that business, such as by deploying time saved on new income-generating work. It is not known to what extent business would be able to do this. If they did then in principle, there would be a wealth transfer effect from patients or their insurers to their private healthcare provider.
    - These time-related benefits would not be valued as a QALY impact, but instead at their raw financial value (approximately 20% of the former) and then further adjusted by the net profit margin. In other words, a saving of time worth £100 in staffing costs might be used to generate £150 income. The value of that time is thus only £50 (ignoring any wider opportunity costs).
    - There is a possible benefit from efficiency savings achieved by private firms working on NHS contracts – but again only if those savings can be monetised for additional profit. This is judged unlikely – it is more likely that such savings would be recycled into additional NHS care with no change to the actual NHS contract being worked.
    - A possible indirect benefit from patients being treated more quickly, leading to reduced sickness absence amongst employees. This is not expected to be significant.

85. In summary, the vast majority of costs and benefits will fall on the NHS, with only 5%-10% affecting the private sector. Any impacts on business are (1) expected to be positive and beneficial, and (2) voluntarily incurred – although in practice the uptake rate is expected to be high. The net benefit to business is dependent on the private sector's ability to convert time savings into income-generating activity.

86. The value of net business benefits is very uncertain but is expected to be modest. Indicatively, the main NPV of £326m over 10 years would become about £25m for the private sector by market share. Valuing at cost rather than in terms of QALYs reduces this to around £5m, with a further adjustment dependent on the degree to which such benefits can be used to generate a net income for the business. Costs would be negligible on an annual basis (around £3k).

87. The reforms are not expected to affect barriers to entry, competition or small businesses in any significant way. Although beneficial, the reforms only affect a small number of clinicians and products as a proportion of total business activity.

88. The assumption and expectation that there will be no significant change in treatment (instead just a reduction in delays) means that the impact on the supply chain, manufacturers and so on is likely to be negligible.

Equality / Distributional Impacts

89. Impacts are expected to be slight but beneficial. A reduction in delays, which by their nature are variable, may make treatment more consistent between patients in similar situations. That will improve equality of treatment and potentially lead to less variation in clinical outcomes. There is no reason, however, to suppose that any particular sub-population would be disproportionately affected.

Proposed implementation plan of preferred option

90. The expected timetable is for the amended legislation to be laid before Parliament on 6 December 2023, with the new regulations taking effect from 31 December 2023.

Evaluation and Monitoring

91. ACMD stressed the importance of evaluation when making their recommendations. Evaluation and monitoring plans are expected to be led within NHS England. The curriculum and the personal formulary will be subject to regular review. There will be a process for NHS England's Innovation and Research Unit to evaluate the outcomes of independent prescribing of controlled drugs by all permitted Allied Health Professions. The curriculum would also be revalidated yearly in the light of the new recommendations.

92. It is not clear to what extent information on "avoided referrals" will be recorded. It is likely that the number of prescriptions made by paramedics or radiographers will be identifiable or could be estimated, but not the amount of time that would have been incurred had such prescriptions continued to need a referral. The IA analysis sets a baseline that will help, and this would need to be reviewed in the light of any changes in patterns of clinical need.

93. ACMD also stated that they wished to monitor these reforms for a period before deciding whether or not to further modify the regulations to include other scheduled drugs (such as fentanyl). The timing of such decisions is to be decided.

Acknowledgments

94. DHSC would like to acknowledge the considerable advice received from the Society of Radiographers and the College of Paramedics, in building an understanding of the current situation and the likely effect of change. In particular, the case studies in the attached annex have been supplied by those two organisations. Notwithstanding that input, this impact assessment remains the responsibility of the Department of Health and Social Care, working alongside the Home Office. All opinions, drafting and use of data are the responsibility of the authors.

ANNEX A CASE STUDIES

This annex presents a series of illustrative case studies, kindly provided by the College of Paramedics and the Society of Radiographers as evidence to support this impact assessment. We are very grateful in acknowledging their input.

They are not intended to be comprehensive, either by covering all possible situations or by covering all possible outcomes from any one situation. But they are intended to present a realistic and experience-based view of many of the current situations that arise and the expected effect of the proposed reforms on those situations. The studies help describe the current situation in the NHS, identify how and where reform would make a difference, and help gauge the nature and size of that impact.

The studies are:

1	Paramedic Independent Prescribers	Analgesia (morphine)
2	..	Codeine
3	..	Midazolam
4	..	Diazepam
5	Therapeutic Radiographer Independent Prescribers	Codeine
6	..	Diazepam
7	..	Lorazepam
8	..	Morphine
9	..	Oxycodone
10	..	Tramadol

Setting:	Advanced Paramedic Practitioner
Drug/Group of Drugs:	Analgesia

Context:

Advanced Paramedic practitioners (APP) are now working alongside general practitioners and nurse and advanced nurse practitioners in general practice seeing patients with acute and long-term conditions. APP can offer a variety of patient's appointments at surgeries as well as home visits.

Description of case:

A patient has recently been diagnosed with cancer and is under the care of secondary care cancer clinic. The patient has started on chemotherapy and has been issued a prescription for regular paracetamol and oral morphine solution by secondary care to take on a when required basis. The clinic has advised the patient to obtain further prescriptions from the GP.

The patient is now running low on oral morphine and has asked for an appointment at the practice. The APP is able to access the GP computer system and reviews the hospital letter from the cancer clinic including the diagnosis, prognosis and recommended treatment for the patient which includes the appropriate use of opioid analgesia.

The patient is seen by the APP for a review of their analgesia. The APP takes an appropriate history from the patient along with an appropriate examination to ensure the patient is not suffering from any acute conditions. The APP identifies that the patient is adherent with their current regime but is suffering from break through pain on a regular basis thought out the day due to their cancer and is taking their oral morphine 4 times a day.

In line with NICE guidance (KTT21 medicines optimisation in long term pain) , BMA guidance (analgesic use) and BNF guidance (prescribing in palliative care) the APP identified the patient should be taking regular paracetamol, regular modified release morphine for back ground pain along with when required oral morphine for break through pain.

Current practice & drawbacks associated with existing mechanisms:

Paramedics are only able to administer morphine under exemption.
Paramedics are not able to supply or administer schedule 2 controlled drugs under PGD.
Drawback

- Would be unable to supply patient with ongoing medication needed to treat condition.
- Would need to involve another prescribing health care professional to treat patient therefore delaying treatment or forcing patient to pay a second visit to GP surgery.
- Would tie up a second appointment with another health care professional.

• Would be unable to issue a prescription for dispensing by a pharmacist. (Separation of the prescribing / supply / administration process).
With independent prescribing:
The APP issues a prescription taking into account the total daily dose of morphine the patient takes, for paracetamol 1g four times a day, morphine sulphate 10mg modified release tablets twice a day and oral morphine solution 10mg/5mls when required along with a laxative to overcome any side effects. The APP notes the patients next appointment with the cancer clinic is in 2 weeks time so issues a prescription for a 14 day supply. The APP is able, using the GP computer system to fully document the interaction with the patient as well as recording the script issued and the clinical reasoning for this. The APP is also able to write to the cancer clinic requesting a review of the patient at their next appointment. A script is issued and the patient is able to take this to their local pharmacy for dispensing. Benefits • No delay to patients treatment • APP is able to document interaction with patient and correspond with cancer clinic. • Separation of prescribing, dispensing (supply) and administration of controlled drugs medication. • Another health care appointment is avoided to the benefit of the patient and the wider patient community (another appointment is available with another health care professional).

https://www.nice.org.uk/advice/ktt21/chapter/Evidence-context
https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/analgesics-use
https://bnf.nice.org.uk/guidance/prescribing-in-palliative-care.html

Setting:	General Practice: Out-of-hours home visit
Drug/Group of Drugs:	Codeine Phosphate Tablets

Context:

Paramedic independent prescribers are now working alongside several agencies to provide support for General Practitioner (GP) cover both in-hours and out-of-hours. Good practice dictates that the patients suitable for visit by the paramedic independent prescriber should have been triaged by telephone prior to the visit and deemed appropriate for assessment by the paramedic

Description of case:

Mrs C is 65 years old and has had recent surgery on her knee 4 days ago. She is largely self-caring but has had help from her family since discharge from hospital 2 days ago. She copes well with daily living tasks and is an active member of several clubs/schemes in her warden controlled flat including being captain of her local bowling team. She has been supplied with analgesia (paracetamol 500mg tablets) two to be taken four times day and non-steroidal anti-inflammatory (NSAIDS) ibuprofen 400mg tablets one to be taken three times a day for pain control following the procedure on discharge.

Mrs C is now undertaking community physiotherapy as part of her rehabilitation programme and is now complaining of increasing pain around the knee, which is adversely affecting her rehabilitation.

The paramedic independent prescriber reviews the medication on the GP records system and considers that a home visit is deemed appropriate given the issues affecting her mobility.

Following a detailed history take and neuro-muscular examination, confirming that no new trauma has occurred and there are no signs of infection, nor visible discharge from the wound site. Mrs C can weight bear and mobilise. Mrs C scores her pain as 5/10. The paramedic independent prescriber concludes that the patient is suffering from post-operative pain, exacerbated by movement and classified as moderate to severe.

Mrs C has been concordant with paracetamol and ibuprofen.

The paramedic independent prescriber decides that in line with local formulary guidelines that a prescription for codeine phosphate 30mg tablets one or two to be taken up to four times a day when required for breakthrough pain is appropriate. The paramedic independent prescriber discussed the benefits and drawback of the medication with the patient (pain relief and ability to carry on with physiotherapy versus side effects of medication). Mrs C agrees that this is appropriate in this case.

Current practice & drawbacks associated with existing mechanisms:

The paramedic independent prescriber must make another appointment for Mrs C's GP or another prescribing colleague. This would inevitably lead to delay in achieving optimal analgesia, prolong suffering, delay the physiotherapy, adversely affect patient satisfaction and inconvenience the patient further.

Current evidence suggests that post-operative pain can lead to morbidity and complicate the healing process; up to 75% of the patients who have post-operative pain state that it is severe and non-controlled (Chou, et al., 2016[5]). Mrs C is complaining that the pain is moderate to severe at times, worse on movement and toileting etc. NICE (2013) [6]guidelines state that a combination of opioids and non-opioids are recommended in such cases. This approach is also recommended by the World Health Organisation (WHO) pain ladder which endorses that patients experiencing severe pain should be treated with strong opioids +/- combinations of other medicines. In accordance with NICE (2013) a strong opioid such as Morphine Sulphate tablets were discussed and subsequently declined by the patient following a number of concerns that she held. The patient has made a fully informed decision regarding the choice of medicines following a discussion of potential risks and adverse side-effects, and decided upon a weak opioid, namely Codeine Phosphate. Arrangements were then made for the patient to be seen and assessed by a prescribing colleague and commenced on Codeine Phosphate 30-60mg up to four times a day when required for breakthrough pain to a maximum 240 mg daily for two weeks in addition to paracetamol 1g four times a day and ibuprofen 400mg three times a day.

Drawbacks

1. 2. Patient would either have to make their own way to hospital, out-of-hours surgery or walk-in centre.
3.Mrs C has unnecessary delay in achieving pain relief and experiences additional suffering.
4. Unnecessary visit to additional healthcare professional, adversely impacting on the health system
5. Patient left feeling unsatisfied

With independent prescribing (IP):

The paramedic independent prescriber would be able to prescribe Codeine Phosphate on a prescription. for the patient at the conclusion to the visit. They could also contact the patient's pharmacist and arrange for collect of the prescription and delivery of the medication.

Benefits

- Prompt access to medicines to optimise patient care and reduce suffering.

[5] Chou, R., Gordon, D., De Leon-Casasola, et al. (2015) Management of Postoperative Pain: A Clinical Practice Guideline from the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council.

[6] National Institute of Clinical Excellence (2015) Analgesia – mild-to-moderate pain.

- Safe Care closer to Home – NHS 5 year forward view
- Equality of access to the correct medicines in a timely manner regardless of which advanced practitioner healthcare professional sees the patient.
- Enhanced patient experience by minimising the number of healthcare providers seen.
- Improved efficiency of the primary care system
- Clear lines of accountability for prescribing decisions made.
- To Comply with World Health Organisation (WHO) Guidelines on treating pain the introduction of Codeine into paramedic practice should form part of an overall pain management strategy (Parkinson, 2016). Currently APP cannot employ Codeine Phosphate as an option. This restricts the APP ability to effectively manage mild to moderate pain which is a relatively common pre-hospital condition

References:

NHS Improvement (2015) Moving healthcare closer to home. [Accessed 30/12/2018]

Parkinson, M. (2016) Working towards Improving Pain Management. *Paramedic Insight June 2016: Vol 2, No.2*

National Institute of Clinical Excellence (2015) Analgesia – mild-to-moderate pain. [Accessed 30/12/2018]

Setting:	Emergency Department
Drug/Group of Drugs:	Intravenous Midazolam - Benzodiazepines

Context:

Paramedic independent prescribers commonly work alongside other allied health professionals, nursing and medical colleagues within the Emergency Department (ED) managing a diverse range of patients either autonomously or as part of a multi-disciplinary team.

Description of case:

Mr S, a thirty-eight year old male presents to ED by ambulance with a fracture dislocation to his right ankle which requires urgent manipulation to prevent ongoing damage to ischaemic tissue overlying bony prominences. The paramedic independent prescriber establishes a detailed history, performs a thorough clinical examination of Mr S to exclude other injuries, Mr S had already received intravenous (IV) Paracetamol, IV Morphine and Entonox® from the paramedic ambulance crew who had attended the scene and conveyed him to hospital.

Mr S was placed on full monitoring which included: pulse oximetry (SpO2), non-invasive blood pressure, ECG monitoring, and end-tidal carbon dioxide (ETCO2) monitoring by nursing colleagues at the request of the advanced paramedic.

Other pharmacological options were considered, many of which include the use of controlled drugs. During the management of this case, Mr S would require IV Midazolam, initial dose of 2-2.5mg approximately 5-10 minutes prior to the intended procedure (ankle reduction and plaster application) at a rate of approximately 2mg/minute. Further 1mg aliquots of IV Midazolam were considered to achieve the desired level of sedation up to a maximum of 5mg, and were titrated to effect as stipulated in the British National Formulary[7]. IV Morphine was also be titrated to effect in line with the Royal College of Anaesthetists and College of Emergency Medicine 2016 Guidelines[8], remaining cognisant to previous doses administered by the ambulance crew. Once adequate sedation and analgesia had been achieved, Mr S's dislocated ankle was manipulated back into place, restoring circulation to the ischaemic tissue without delay. A post-manipulation x-ray was undertaken to confirm successful reduction.

Current practice & drawbacks associated with existing mechanisms:

Many paramedic independent prescribers working within the ED have received recognised sedation training and are familiar with the use of IV benzodiazepines, IV opiates and Entonox as these have been used by Ambulance Trusts under either PGD or exemptions for many years. Paramedics possess advanced airway skills and are advanced life support providers in case any issues are encountered during the sedation. Royal College of Anaesthetists and College of Emergency Medicine 2016 Guidelines advocate the use of IV benzodiazepine (Midazolam) and IV opioid

[7] Joint Formulary Committee (2019) British National Formulary – Midazolam

[8] Royal College of Anaesthetists & College of Emergency Medicine (2016) Safe Sedation of Adults in the Emergency Department. London, UK (Pg.9)

(Morphine) combinations for conscious (procedural) sedation, with intervals between doses and recommend reversal agents (such as Flumazenil) be present when undertaking the procedure. 'Conscious sedation for procedures' is a licensed indication for IV Midazolam in the British National Formulary. There is currently no exemption in place that covers the use of IV Midazolam.

An advanced paramedic could administer Midazolam under a Patient Group Direction (PGD) if this existed within their place of work. If a PGD was in place, the advanced paramedic would be required to administer the medication themselves, rather than delegating administration to another member of the team, potentially delaying the time taken to reduce the time critical ankle reduction. Alternatively, another clinician who was able to prescribe Midazolam would need to be called in to see the patient and prescribe accordingly, which can often duplicate physical examinations, delay patient care, and unnecessarily involve a third party to prescribe on behalf of the treating clinician.

Summary of drawbacks:

- Prolonged patient suffering, cause ongoing joint issues from prolonged dislocation, and risk further damage to ischaemic tissue overlying bony prominences.
- Would require the involvement of an additional prescribing clinician to complete the care episode often blurring the lines of professional accountability.
- May impose a requirement for third-party prescribing without formal examination in person by prescriber, a process which is not advocated by many professional bodies[9] [10] [11] [12] [13]
- The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, and further delay patient care.
- Patient's expectation that the paramedic independent prescriber treating them would be able to complete the episode of care is not realised.

With independent prescribing (IP):

[9] College of Paramedics (2018) Practice Guidance for Paramedic Supplementary and Independent Prescribers V2.0. College of Paramedics, Bridgwater, UK (Pg.25)

[10] General Medical Council (2013) Good practice in prescribing and managing medicines and devices. GMC, London, UK (Pg.6)

[11] Health and Care Professions Council (2012) (Updated in 2016) Standards for Prescribing (Pg.10)

[12] Nursing and Midwifery Council (2006) Standards of proficiency for nurse and midwife prescribers. NMC, London (Pg.27)

[13] Royal Pharmaceutical Society (RPS, 2016) A Competency Framework for all Prescribers. RPS, London, UK (Pg.13)

The paramedic independent prescriber would be able to promptly prescribe intravenous Midazolam on a prescription chart in ED and would be able to delegate the administration to a suitably trained clinician, and enable the paramedic independent prescriber to undertake the time-critical procedure with appropriate nursing assistance in a seamless and timely manner thereby improving patient care/experience.

(continued)

Summary of benefits

- Prompt access to medicines to optimise patient care and reduce suffering.
- Optimal utilisation of the skills, knowledge and competence of the advanced paramedic independent prescribers in ED.
- Equality of access to the correct medicines in a timely manner regardless of which healthcare professional sees the patient.
- Enhanced patient experience by minimising the number of healthcare providers involved.
- Improved departmental efficiency.

Clear lines of accountability for prescribing decisions made.

Setting:	Advanced Paramedic – Minor Injuries
Controlled Drug	Diazepam

Context:

Paramedic independent prescribers commonly see patients with acute non-traumatic musculo-skeletal back pain as part of their role within a minor injuries unit (MIU).
Patients are encouraged to attend local MIU with this condition rather than present to emergency departments, call 999 for an ambulance or use a GP appointment.

Technology now in place permits appropriate access to GP healthcare records via Summary Care Records, and other similar remote versions of practice computer systems (such as EMIS-web) which informs treatment decisions, enables two-way communication and safe prescribing.

The ability to treat patients outside of emergency departments adds an important context to the need for the introduction of independent prescribing of controlled drugs by paramedics practising in urgent care and minor injuries settings.

Description of case:

Mr A presents to MIU experiencing non-traumatic back pain (pain with no obvious sign of trauma such as a fracture) following a minor road traffic collision 48 hours previously. He attended the emergency department following the collision and fracture was excluded. He was advised to purchase over-the-counter co-codamol and ibuprofen, however, he reports the combination is not giving him sufficient pain relief. He states this problem is causing him distress and he is off work at the moment.

Mr A is seen by the paramedic independent prescriber on duty. They take a comprehensive history of the accident and treatment so far including accessing summary care records to view Mr A's past medical history, drug history and allergies.
Careful scrutiny of the records indicates that Mr A has not had benzodiazepines prescribed in the past and therefore it is unlikely that is seeking a supply for abuse.

The paramedic independent prescriber undertakes an examination including neurological and muscular skeletal examination and reviews the x-rays. Red-flags symptoms such as limb numbness or altered sensation, saddle anaesthesia and bowel and bladder symptoms are excluded. The presence of any of these symptoms could indicate a potential serious back injury, and in these cases Mr A would require emergency referral back to the emergency department.

By asking the patient and scrutinising the medical record, the paramedic independent prescriber establishes that the patient is adherent with their current medicines and not already taking diazepam, and has not been prescribed diazepam or any other benzodiazepine previously, therefore reducing the risk of dependency or abuse (drug seeking behaviour) being a factor.

The paramedic independent prescriber diagnoses that the pain is due to muscular spasm as a result of the collision. In line with Clinical Knowledge Summary[14] guidelines on acute lower back pain, as an adjunct treatment to the oral analgesics, a short course of 5 days of oral diazepam is recommended to relieve the muscle spasm.

Current practice & drawbacks associated with existing mechanisms:

The paramedic independent prescriber would recommend that Mr A continues with over the counter ibuprofen on a regular basis and would supply a 5-day supply of diazepam 2mg tablets using a patient group direction (PGD) in line with NICE[15].

The paramedic independent prescriber would advise Mr A on the potential side effects of the diazepam including potential to cause drowsiness and not to drive if affected, and would also warn of the potential for addiction in long term use (over 2 weeks). They would also update the walk-in centre records, summary care records and inform the patient's own GP of the episode of care including medication issued on PGD.

Drawbacks

- PGDs do not allow for prescribing decision making therefore should Mr A have any factors which may be considered as cautions to the use of diazepam, such as respiratory disease, the PGD may not permit the supply. A prescriber can take the decision that a short course may be an acceptable risk.
- There is an increased cost to the service of the supply of prepacked and labelled packs for supply using PGDs.

With independent prescribing:

Mr A would be advised not to drink alcohol whilst taking the medicine, and counselled on side effects such as drowsiness, and advised not to drive if affected. He would also be warned of dependence issues if the medication is taken long term. Mr A would be advised to see his own GP if symptoms persist or return after 7 days.

[14] https://cks.nice.org.uk/back-pain-low-without-radiculopathy#!prescribinginfosub

[15] https://www.nice.org.uk/guidance/MPG2

The paramedic independent prescriber would also update the walk-in centre records, summary care records and Mr A's medical record on the GP system indicating the presenting complaint, the findings of the clinical examination and the details of the prescription issued, medicines, strength, dose and frequency also adding that the prescription is intended for short term use only.

Benefits

- As prescribing is individually tailored to the needs of a single patient, it should be used in preference to a PGD wherever appropriate.
- Mr A has been discharged with a prescription for dispensing which encourages self-care, and also brings the pharmacist into the encounter, further promoting safe patient care.
- Paramedic independent prescriber would be able to make a prescribing decision based on clinical judgement rather than the content of the PGD.

https://www.nice.org.uk/guidance/mpg2/chapter/Recommendationshttps://www.nice.org.uk/guidance/mpg2/chapter/Recommendations
https://www.medicines.org.uk/emc/medicine/24402/SPC/Diazepam+Tablets+BP+2mg

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Radiotherapy Department: Outpatient
Drug/Group of Drugs:	Codeine phosphate

Context:

Therapeutic Radiographer Independent Prescribers specialising in on-treatment review provide supportive medication to alleviate radiotherapy treatment-related side effects. Up to 44% of patients receiving radiotherapy for painful bone metastases will experience pain flare as a side effect of their treatment[1]. In many cases, this will become moderate to severe and require opioid analgesia for a short time as pain flares usually subside approximately two to three days after completion of treatment.

Description of case:

A patient, Mr A, receives palliative radiotherapy for metastatic prostate cancer. He is currently on treatment 3 of 5 to his thoracic spine for pain relief. He attends for treatment and complains of increasing pain in the treatment area, which is affecting his sleep and mobility.

A therapeutic radiographer independent prescriber is asked to see the patient to review their current analgesia and to optimise their pain relief. The Radiographer undertakes a full assessment, including past medical history, current medication, allergies, and current symptoms. Mr A is taking 1g Paracetamol four times daily and Ibuprofen 400mg three times daily. He describes his pain as stabbing and present at all times. It is exacerbated on movement, and his analgesia only provides a low level of relief.

Following the World Health Organisation Pain Ladder[2] the next step is to add in 60g oral Codeine phosphate 4 times daily. The review radiographer can prescribe both the Paracetamol and Ibuprofen as an Independent Prescriber but not the Codeine as it is classified as a Controlled Drug.

Current practice & drawbacks associated with existing mechanisms:

The Codeine needs to be prescribed by a doctor who may be unavailable due to other clinical commitments.

Summary of drawbacks:

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to delayed treatment and prolonged patient suffering.
- Reduced safety: May require third-party prescribing without formal examination in person by the prescriber. Many professional bodies do not advocate this process because of the risk of potential error. [3 4 5]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may adversely impact on departmental efficiency at peak times and further delay patient care.

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

With independent prescribing from the proposed list of controlled drugs:
The review radiographer would be able to promptly prescribe all three analgesics to provide pain relief and improve patient care/experience. Summary of benefits • Prompt access to appropriate analgesia to optimise patient care and reduce suffering. • Enhanced patient experience by minimising the number of healthcare providers involved. • Equality of access to the correct medicines in a timely manner from the HCP with the right skills, in the best place for the patient. • Seamless diagnosis to intervention process • Optimal utilisation of the skills, knowledge, and competence of the advanced therapeutic radiographers. • Improved departmental efficiency. • Clear lines of accountability for prescribing decisions made.

References:

1 McDonald R, Chow E, Rowbottom L, DeAngelis C, Soliman H. Incidence of pain flare in radiation treatment of bone metastases: A literature review. J Bone Oncol. 2014 Oct 30:3(3-4):84-9. DOI: https://doi.org/10.1016/j.jbo.2014.10.001

2 World Health Organisation (2018) WHO Guidelines for the pharmacological and radiotherapeutic management of cancer pain in adults and adolescents. WHO, Geneva

3 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

4 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

5 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Radiotherapy Department: Outpatient
Drug/Group of Drugs:	Diazepam

Context:

Therapeutic Radiographer Independent Prescribers specialising in site-specialist roles provide supportive medication for the alleviation of radiotherapy treatment-related side effects. They may also sometimes identify the need for benzodiazepines to be prescribed in small doses to allow a patient to be relaxed enough to stay still for a procedure or treatment. These are usually administered at each visit as required, and the patient is monitored carefully for any adverse effects.

Description of case:

A 53-year-old man with a squamous cell right upper lobe lung cancer attended his radiotherapy planning appointment, which involved making a thermoplastic mask and having a CT scan. The patient struggled to keep still due to muscle spasms of unknown aetiology. As the treatment he was to receive was Stereotactic Ablative Body Radiotherapy (SABR), which is very focused and exact and takes longer to deliver than standard radiotherapy, his inability to keep still was a concern. After taking a complete drug and medical history, the therapeutic radiographer independent prescriber, felt that 1.0mg of diazepam, before the planning procedure, might be helpful to manage his symptoms so that he could remain still for the the planning and the CT could be completed swiftly and accurately.

The therapeutic radiographer independent prescriber could not prescribe diazepam, so the patient's appointment was delayed while they found an oncologist to prescribe it. This caused anxiety for the patient and delays for the rest of the patient list for that day.

Once the patient received the diazepam, the mask and CT scan were completed without problems.

Current practice & drawbacks associated with existing mechanisms:

The Therapeutic Radiographer Independent Prescriber must contact the patient's consultant oncologist or another medical prescriber who can prescribe controlled drugs. Medical prescribers are frequently unavailable due to other clinical commitments at that time.

<u>Summary of drawbacks:</u>

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to delayed treatment and prolonged patient suffering.
- Reduced safety: May require third-party prescribing without formal examination in person by prescriber, a process which is not advocated by many professional bodies because of the risk of potential error. [1 2 3]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, and further delay patient care.

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

With independent prescribing from the proposed list of controlled drugs:
The Therapeutic Radiographer Independent Prescribers would be able to promptly prescribe diazepam to improve patient care/experience, checked and administered by an additional competent regulated HCP from the department and the CT scan undertaken. <u>Summary of benefits</u> • Prompt access to medicines to optimise patient care and reduce delays and further anxiety. • Enhanced patient experience by minimising the number of healthcare providers involved. • Equality of access to the correct medicines in a timely manner regardless of which healthcare professional sees the patient. • Optimal utilisation of the skills, knowledge, and competence of the advanced therapeutic radiographers. • Improved departmental efficiency. • Clear lines of accountability for prescribing decisions made.

References:

1 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

2 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

3 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Stereotactic Radiotherapy Department, Satellite Centre: Outpatient
Drug/Group of Drugs:	Lorazepam
Context:	
The Stereotactic Radiotherapy Service (SRS) is a highly precise form of radiotherapy used to treat certain types of tumours within the skull, inoperable lesions and as an adjuvant post-operative treatment or to obliterate abnormal blood vessels. It is an important alternative to invasive surgery, especially for tumours and blood vessel abnormalities located deep within or close to vital areas of the brain. It can be delivered as an outpatient service without the need and associated cost of prolonged hospitalisation, surgical time, and rehabilitation. Due to the high radiation doses involved, it is vital that the patient is adequately immobilised to ensure the accuracy of treatment. To achieve this a rigid plastic mask which covers the patient's whole face is used. The patient wears this for the duration of the treatment, which takes approximately one hour. The number of satellite centres in England is increasing to improve local access to radiotherapy. These centres often have minimal access to specialist oncology doctors and rely heavily on highly skilled therapeutic radiographers working at advanced and consultant level to provide clinical care. Advanced and Consultant Therapeutic Radiographer Independent Prescribers provide supportive medication for the alleviation of radiotherapy treatment-related side effects. They may also sometimes identify the need for benzodiazepines as anxiolytics to be prescribed in small doses to manage anxiety, allowing a patient to stay still for a procedure or treatment. These are usually administered at each visit as required, and the patient is monitored carefully for any adverse effects.	
Description of case:	
Mrs B, a 48-year-old patient, attends for her SRS treatment. Although the advanced therapeutic radiographer tried to reassure and calm Mrs B, as the mask went on she panicked and became so distraught that she could not tolerate the mask for any length of time. As this is a radiographer-led service and no doctor was available there was no one available to prescribe an anxiolytic. The advanced therapeutic radiographer was an experienced independent prescriber but was not able to prescribe controlled drugs. The patient was, therefore, unable to have treatment on that day, a further appointment had to be identified and the original appointment wasted.	
Current practice & drawbacks associated with existing mechanisms:	
The advanced therapeutic radiographer independent prescriber must contact the patient's consultant oncologist or another colleague who can prescribe controlled drugs. In this scenario no-one was available, and the patient could not have treatment. <u>Summary of drawbacks:</u>	

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to the inconvenience of an additional visit, increased anxiety, and prolonged patient suffering.
- Reduced safety: May impose a requirement for third-party prescribing without formal examination in person by prescriber, a process which is not advocated by many professional bodies because of the risk of potential error. [1 2 3]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, wasted treatment appointments and further delay patient care.

With independent prescribing from the proposed list of controlled drugs:

The advanced therapeutic radiographer independent prescriber would be able to promptly prescribe diazepam improve patient care/experience and reduce delays.

Summary of benefits

- Prompt access to medicines to optimise patient care and reduce delays and further anxiety.
- Enhanced patient experience by minimising the number of healthcare providers involved.
- Equality of access to the correct medicines in a timely manner from the HCP with the right skills, in the best place for the patient.
- Optimal utilisation of the skills, knowledge, and competence of the advanced therapeutic radiographers.
- Improved departmental efficiency.
- Clear lines of accountability for prescribing decisions made.

References:

1 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

2 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

3 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Radiotherapy Department: Outpatient
Drug/Group of Drugs:	Morphine sulphate (Oral administration)

Context:

Consultant Therapeutic Radiographers (CTR) specialising in palliative radiotherapy streamline the patient pathway from consent for treatment to follow-up by minimising delays and providing rapid access. Worldwide 40–50% of radiotherapy treatments are delivered with palliative intent[1] and the aim to improve quality of life. Most CTRs will have completed training to prescribe independently so that they can prescribe supportive medicines for their patients whilst undergoing radiotherapy.

Description of case:

A patient, Mr S, has been transferred from another Trust for emergency treatment of metastatic spinal cord compression. A nurse escort accompanied the patient and brought the medical notes and prescription chart.

The CTR goes to assess and consent Mr S for treatment and finds that he is in considerable pain due to the metastatic disease and cord compression. A review of the medical notes and prescription chart shows the regular analgesia being given:

- 1g Paracetamol four times daily.
- 10mg Modified Release Morphine Sulphate twice daily.
- 10mg morphine sulphate oral solution 10mg/5mL every hour as required.

He had had 10mg morphine sulphate on leaving one hour ago and 1g Paracetamol at 8am that morning. Mr S was given 10mg Oramorph and 1g Paracetamol for pain relief; his last dose had been 5 hours previously.

Current practice & drawbacks associated with existing mechanisms:

The CTR can prescribe the Paracetamol as an Independent Prescriber however, a doctor is needed to prescribe the Oramorph as it is classed as a Controlled Drug.

<u>Summary of drawbacks:</u>

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to delayed treatment and prolonged patient suffering.
- Reduced safety: May impose a requirement for third-party prescribing without formal examination in person by prescriber, a process which is not advocated by many professional bodies. [2 3 4]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, and further delay patient care.

(continued)

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

With independent prescribing from the proposed list of controlled drugs:
The CTR would be able to promptly prescribe both the paracetamol and morphine oral sulphate solution to provide pain relief and improve patient care/experience. Summary of benefits • Prompt access to medicines to optimise patient care and reduce suffering. • Enhanced patient experience by minimising the number of healthcare providers involved. • Equality of access to the correct medicines in a timely manner from the HCP with the right skills, in the best place for the patient. • Seamless diagnosis to intervention process. • Optimal utilisation of the skills, knowledge, and competence of the CTR. • Improved departmental efficiency. • Clear lines of accountability for prescribing decisions made.

References:

1 Murphy JD (2013) Patterns of care in palliative radiotherapy: a population-based study. J Oncol Pract 9(5):e220–e227 DOI: https://doi.org/10.1200/jop.2012.000835

2 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

3 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

4 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Radiotherapy Department: Outpatient
Drug/Group of Drugs:	Oxycodone hydrochloride

Context:

Therapeutic Radiographer Independent Prescribers specialising in on-treatment review provide supportive medication to alleviate radiotherapy treatment-related side effects. Many cancer patients will experience pain as a side effect of their treatment, and this will increase as their radiotherapy progresses. This will often become moderate to severe and require opioid analgesia for a few weeks until acute effects subside. A treatment summary is sent to the patient's GP on completion of treatment, offering advice on the appropriate reduction and cessation of opioids and other supportive medications once symptoms have subsided.

Description of case:

Mr C is a 31-year-old man receiving chemoradiotherapy to his oropharynx and bilateral neck nodes. The therapeutic radiographer independent prescriber, specialising in head and neck review, had been seeing the patient weekly and undertaking a full assessment of the patient's history and symptoms as well as an oral care assessment and physical examination. For the first few weeks of treatment, Mr C's symptoms had been controlled by regular paracetamol, ibuprofen, and benzydamine hydrochloride mouthwash. By week four, Mr C was experiencing an oral candida infection and needed fluconazole to treat the infection, which the radiographer prescribed, and uncontrolled pain due to mucositis for which he required an opioid, following the World Health Organisation Guidelines[1]. The oncologist prescribed morphine sulphate oral solution, with instructions to take it four times a day as required, in addition to the paracetamol and ibuprofen. After five further days of treatment, the patient was still complaining of uncontrolled pain. The therapeutic radiographer was asked to see the patient again. After questioning him, it became apparent that he had only been taking the morphine at night as it made him feel very drowsy. Oxycodone would usually be the second line option for patients unable to tolerate the adverse effects of morphine, and the patient was happy to try a different drug, but the radiographer could not prescribe this. The oncologist was unavailable, and the patient was unwilling to wait to see the on-call doctor, so the patient went home without adequate analgesia to manage his pain.

Current practice & drawbacks associated with existing mechanisms:

The therapeutic radiographer independent prescriber must contact the patient's consultant oncologist or another colleague who is able to prescribe controlled drugs. They may be unavailable at that time due to their other clinical commitments.

Summary of drawbacks:

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to delayed treatment and prolonged patient suffering.

- Reduced safety: May impose a requirement for third-party prescribing without formal examination in person by prescriber, a process which is not advocated by many professional bodies because of the risk of potential error. [2 3 4]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, and further delay patient care.

With independent prescribing from the proposed list of controlled drugs:

The therapeutic radiographer would be able to promptly prescribe an alternative to morphine to provide pain relief and improve patient care/experience.

Summary of benefits

- Prompt access to medicines to optimise patient care and reduce suffering.
- Enhanced patient experience by minimising the number of healthcare providers involved.
- Equality of access to the correct medicines promptly regardless of which healthcare professional sees the patient.
- Optimal utilisation of the advanced therapeutic radiographers' skills, knowledge, and competence.
- Improved departmental efficiency.
- Clear lines of accountability for prescribing decisions made.

References:

1 World Health Organisation (2018) WHO Guidelines for the pharmacological and radiotherapeutic management of cancer pain in adults and adolescents. WHO, Geneva

2 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

3 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

4 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK

CASE STUDIES (THERAPEUTIC RADIOGRAPHERS)

Setting:	Radiotherapy Department: Outpatient
Drug/Group of Drugs:	Tramadol

Context:

Therapeutic Radiographer Independent Prescribers specialising in on-treatment review provide supportive medication to alleviate radiotherapy treatment-related side effects. Many cancer patients experience pain as a side effect of their treatment, and this increases as their radiotherapy progresses. The pain becomes moderate to severe and requires opioid analgesia for a few weeks until acute effects subside. A treatment summary is sent to the patient's GP upon treatment completion, offering advice on the appropriate reduction and cessation of opioids and other supportive medications once symptoms have subsided.

Description of case:

Miss Z is 34 years old and receiving daily outpatient radiotherapy treatment for a squamous cell carcinoma of the base of the tongue. She is in her final week of treatment and is experiencing side effects commonly associated with this stage of radiotherapy: inflammation of mucous membranes, dry mouth, and pain on swallowing.

The review radiographer has been seeing the patient weekly for on-treatment review, which involves undertaking a full assessment including past medical history, current medication, allergies, physical examination, and current symptoms, and has managed her pain by following the World Health Organisation (WHO) pain ladder[1], prescribing paracetamol 1g four times a day and ibuprofen 400mg three times a day. It was apparent at this review that her pain was no longer controlled and that an opioid analgesic was required, as expected at this treatment stage. The patient agreed that stronger analgesia would enable her to eat and maintain her nutritional requirements. At this point, the paracetamol could be substituted for co-codamol 30/500, 2 tablets four times daily; however, Miss Z had experienced side effects with morphine previously and wasn't keen to take codeine. She had taken tramadol previously, and this had been well tolerated.

The review radiographer felt that tramadol would be appropriate to manage the patient's pain but could not prescribe a controlled drug. The oncologist wasn't available to prescribe the tramadol before the patient left the department, resulting in a delay of 24 hours before adequate analgesia was provided.

Current practice & drawbacks associated with existing mechanisms:

The therapeutic radiographer must contact the patient's consultant oncologist or another colleague who can prescribe controlled drugs. They may be happy to prescribe tramadol based on the radiographer's consultation decision, or they may feel that it is more appropriate to assess the patient again before prescribing. Either scenario will result in a delay in providing optimal analgesia for the patient.

<u>Summary of drawbacks:</u>

- Disjointed care: Would require the involvement of an additional prescribing clinician to complete the care episode often leading to delayed treatment and prolonged patient suffering.
- Reduced safety: May require third-party prescribing without formal examination in person by the prescriber. Many professional bodies do not advocate this process because of the risk of potential error. [2 3 4]
- Duplication: The further examination undertaken by the responsible prescriber as per professional body recommendation duplicates the examination already undertaken and may impact adversely on departmental efficiency at peak times, and further delay patient care.

With independent prescribing from the proposed list of controlled drugs:

The review radiographer would be able to promptly prescribe an alternative to codeine to provide pain relief from moderate to severe pain and improve patient care/experience.

Summary of benefits

- Prompt access to medicines to optimise patient care and reduce suffering.
- Enhanced patient experience by minimising the number of healthcare providers involved.
- Equality of access to the correct medicines in a timely manner from the HCP with the right skills, in the best place for the patient.
- Optimal utilisation of the skills, knowledge, and competence of the advanced therapeutic radiographers.
- Improved departmental efficiency.
- Clear lines of accountability for prescribing decisions made.

References:

1 World Health Organisation (2018) WHO Guidelines for the pharmacological and radiotherapeutic management of cancer pain in adults and adolescents. WHO, Geneva

2 General Medical Council (2021) Good practice in prescribing and managing medicines and devices. GMC, London, UK

3 Royal Pharmaceutical Society (RPS, 2022) A Competency Framework for all Prescribers. RPS, London, UK

4 Society and College of Radiographers (2016) Practice Guidance for Radiographer Independent and/or Supplementary Prescribers. ScoR, London, UK