

Engagement exercise

To seek views on possibilities for introducing independent prescribing responsibilities for podiatrists



DH INFORMATION READER BOX

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About this engagement exercise

In July 2009 the Department of Health (DH) Allied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project recommended that further work be undertaken in order to extend independent prescribing to appropriately trained chiropodists/podiatrists (from now on referred to only as podiatrists), in order to improve the safety, effectiveness, patient experience and productivity of healthcare. The DH Non-Medical Prescribing Board accepted the recommendations and agreed that further work should be undertaken to explore independent prescribing by podiatrists.

This engagement exercise provides background information and invites views on possible changes to medicines legislation, which would enable appropriately trained podiatrists to prescribe independently. Depending on the outcome of this exercise, and subject to agreement by Ministers, it may then inform and assist the development of a formal public consultation led by the Medicines and Healthcare products Regulatory Agency (MHRA) proposing specific amendments to the relevant legislation.

This engagement exercise will remain open for 12 weeks, ending Friday 26 November 2010.

What is non-medical prescribing?

Over recent years changes to the law have permitted a number of professions, other than doctors and dentists, to play an increasing role in prescribing and managing medicines for their patients. There are now over 16,000 qualified nurse independent prescribers and around 1000 qualified pharmacist independent prescribers. More recently, Optometrists have been added to the list of professions able to prescribe independently. Evidence from evaluation of nurse prescribing in 2005¹ and a recent evaluation of nurse and pharmacist prescribing by the Universities of Southampton and Keele (due for publication 2010) indicates that such prescribing is valued by patients and gives them quicker access to the medicines that they need.

¹ University of Southampton (2005) Evaluation of extended formulary independent nurse prescribing – Executive Summary, Department of Health, London.

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Podiatrists have been involved in the direct care of patients for many years. Podiatrists have experience in the treatment of conditions with medicines through the use of Exemptions – which enable a limited list of Prescription Only (POM) and Pharmacy (P) plus all General Sales (GSL) medicines to be sold, supplied or administered in the course of their professional practice. These Exemptions sit alongside Patient Specific Directions² and Patient Group Directions³. Since 2005, experienced podiatrists have been able to train as Supplementary Prescribers (Appendix 1 contains further detail about the various non-medical prescribing and medicines supply mechanisms).

This engagement exercise seeks views on possibilities for introducing independent prescribing responsibilities for podiatrists.

Who can respond to this engagement exercise?

Everyone is welcome to respond. We hope to hear from the public, patients/patient representative groups, healthcare providers, commissioners, doctors, pharmacists, regulators, non-medical prescribers, the Royal Colleges and other representative bodies.

How to respond

You can respond in one of two ways:

- By using the electronic response form. Type your answers to the questions into the boxes provided. When you have completed the final question (question 11) and entered your details below it, click on 'Save form'. This creates a pdf file which you should save to your computer desktop. You can then email the pdf file to us at ahprofessionalleadershipteam@dh.gsi.gov.uk using the 'Attach to email' option in the 'File' menu of the pdf.
- Alternatively, you may print the form and send it in hard copy to: Shelagh Morris, Professional Leadership Team, Department of Health, Quarry House, Leeds LS2 7UE

² The term "Patient Specific Direction" is not defined in legislation. It refers to the written instruction of a prescriber which enables a person to sell, supply or administer a medicine to a named patient.

³ The term "Patient Group Direction" and the associated legal requirements are defined in medicines legislation.

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If you have any queries or require further information in relation to this engagement exercise please contact Alex Hill, alexandra.hill@dh.gsi.gov.uk or 0113 254 5846.

Confidentiality of Your Response

We manage the information you provide in response to this engagement exercise in accordance with the Department of Health’s *Information Charter*.

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be passed on to colleagues within the UK Health Departments.

What podiatrists do

Podiatrists are statutorily registered health professionals who focus on the diagnosis, management and treatment of foot and lower limb disorders. Their key role is to help prevent or correct deformity and maintain normal mobility and function. Podiatrists’ manage gait problems and identify associated medical or surgical conditions that may require further referral and management. They

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also help to relieve painful foot conditions, treat foot infections and other disorders of the skin, nail, soft tissue and connective tissues, often working in conjunction with other members of the health care team. Podiatrists can also give expert advice on footwear. Specialist podiatrists see many patients at high risk of amputation, for example those who suffer from impaired blood supply to the lower limb, foot ulcers and wounds, or those requiring surgery, for example to correct bunions. Podiatrists are active in health promotion, preventative healthcare, treatment and rehabilitation using physical treatments, medicines and sometimes surgery.

Following pre-registration training, most podiatrists gain experience in general practice, mainly in the National Health Service (NHS), or in the private sector. Many podiatrists then go on to specialise, or work exclusively with a specific client group. Perhaps the most well known fields of specialisation include musculoskeletal (such as functional foot and gait problems, also known as biomechanics, and sports injuries), diabetes care (assessing the risk of and managing foot ulcers and wounds) and rheumatology. Other specialisms are in dermatology, footwear, surgery and children’s lower limb problems.

Advanced and consultant podiatry roles have led the development of podiatry to increasing levels of responsibility for diagnosis, onward referral and provision of specialist interventions. The public increasingly use NHS and independent sector podiatrists directly (eg self-referral) for diagnosis and treatment, without contacting a doctor.

Since the Medicines Act (1968) was introduced, some podiatrists have used medicines safely and effectively in their professional practice through Patient Specific Directions issued by a doctor. From 1980, some podiatrists have also had access to certain medicines via statutory exemptions, allowing them to sell, supply and administer from a limited list. For example, since 1980 the use of injectable local anaesthetic agents has become a common part of podiatric practice for those podiatrists qualified to use them. Today, these podiatrists are identified on the Health Professions Council’s register by a special annotation, referred to as ‘local anaesthesia’. Reviews of Exemptions over the years have extended podiatrists access to a wider range of medicines for supply and sale, including some anti-inflammatory medicines, anti-fungal agents and antibiotics for the treatment of

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infections. Access to these additional medicines requires a further qualification, and those podiatrists in possession of this qualification are also annotated on the HPC register, as the ‘POM’ qualification. In 2000, specialist podiatrists were granted rights to supply and administer an even wider range of medicines via Patient Group Directions. All these mechanisms are used in a broad array of community and acute settings, with a range of medicines used, spanning musculoskeletal disorders, diabetes care, skin disorders, foot surgery and in the care of the elderly.

Examples of podiatry roles

Musculoskeletal conditions

Podiatrists have a prime role to play in the assessment and management of musculoskeletal foot and ankle pathology. Advanced practitioners and consultant podiatrists, assess, diagnose and manage complex lower limb musculoskeletal pathology/pain, including the provision of specialist footwear and in-shoe corrective devices. They may use injection therapy and request investigations such as ultrasound, MRI, X-ray and blood tests.

Diabetes Care

Podiatrists are important to the multidisciplinary provision of diabetic foot care in line with local and national requirements. Podiatry management of complex diabetic foot problems includes wound care (including debriding⁴ wounds), the selection of appropriate dressings, physical treatment to remove excessive pressure from vulnerable parts of the foot and the management of infection. Timely prescription of medicines for diabetic foot infections is crucial in order to stop the infection worsening, reduce the risk of amputation and avoid unnecessary hospital admissions. Podiatrists also play an important role in educating other health professionals in the screening of patients for diabetes related foot problems and advising upon treatment to minimise the risk of serious foot problems.

General podiatry care

Podiatrists in general practice work in a range of clinical settings delivering foot care to all ages.

⁴ Debriding – cleansing to prevent infection and promote healing.

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Foot problems can seriously affect quality of life by reducing a person’s mobility, independence and increasing the risk of falls. Podiatrists recognise and diagnose common foot disorders such as skin disease or infection, nail disorders as well as recognising causes of foot pain. This may include a full clinical assessment comprising a history and clinical tests. Effective prompt management of most common foot problems is essential. Foot infections require patient advice and in many cases access to the correct anti-microbial drugs such as antibiotics or anti-fungal agents. Management of acute foot pain often requires analgesia as part of the treatment plan.

Foot surgery

Podiatrists working in this field of practice will have significant experience of working with patients with complex medical conditions. They may be involved in the conservative and surgical management of foot and ankle pathology across a broad patient group. Corrective foot surgery is used to reduce the pain and immobility of problems such as bunions, hammer toes and traumatised nerves. Patients may require medications such as analgesia (for pain management), antibiotics (in managing infection), anticoagulants (following surgery), sedatives for pre-operative anxiety and injectable corticosteroids.

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Where podiatrists work

There are at present 12,581 podiatrists registered in UK (2010 figures) and their work spans a significant cross-section of the healthcare system. Most work in the NHS. They work in hospitals and in a wide variety of community settings, including both GP practices and independent practices. Some podiatrists provide care for patients in their own homes, in nursing homes or day centres, in schools and in health centres. The Society of Chiropodists & Podiatrists estimates that around 55% of practising members undertake an element of their work in the private sector, and podiatrists also work in a variety of occupational health settings, in prisons, schools, industry, sports clubs and for the Armed Forces.

How podiatrists are trained and regulated

Pre-registration training of podiatrists consists of an approved three or four-year university course leading to a BSc (Honours) degree in podiatry. Students who already hold a BSc in a related science subject can also follow a pre-registration MSc in podiatry. Graduates of both the BSc and MSc pre-registration courses are eligible for statutory registration with the regulator – the Health Professions Council (HPC). Registrants are entitled to use the protected titles ‘podiatrist’ and ‘chiropodist’. The HPC sets standards for podiatrists’ education, training, competence, conduct, behaviour and health. Any person who wishes to practise as a podiatrist in the UK must, by law, have their name registered with the HPC. The HPC also regulates the fitness to practice and re-registration of those already on the register and has the powers to remove individuals from the relevant register if they fall below the standards required to ensure public safety.

The scope of podiatry is very wide and covers a variety of physical, pharmaceutical and related interventions aimed at improving foot health and mobility. A podiatrist’s scope of practice will change over time because of experience, specialisation in a certain clinical area or with a particular client group, or a movement into roles in management, education or research. A podiatrist must undertake the necessary ongoing training and experience to demonstrate that they are capable of

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working lawfully, safely and effectively within their given scope of practice and must not practise in areas where they are not proficient. The HPC approves the training, sets the standards required of podiatrist supplementary prescribers and annotates their names on the register.

This regulatory process would also apply to podiatrist independent prescribers.

How would podiatrist independent prescribers be trained?

The present multiprofessional training is provided as an integrated programme for independent and supplementary prescribers. It is the legislative framework which defines the mechanism(s) available to each profession and the assessment of course participants. For example nurses and pharmacists, who successfully complete the programme are able to practice as both independent and supplementary prescribers. However, podiatrists who successfully complete the programme are only able to practice as supplementary prescribers. Appendix 1 provides further details about independent and supplementary prescribing.

The HPC has already approved a number of courses to provide training for podiatrists as supplementary prescribers. An outline curriculum framework for podiatrist independent prescribing would need to be developed and the HPC will have the authority to approve courses for the provision of podiatrist independent prescribing training. Podiatrists already qualified as supplementary prescribers may be required to undertake additional training in order to practice as independent prescribers.

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Eligibility for training as a podiatrist independent prescriber

Not all podiatrists would need to train to become independent prescribers. It is suggested that all entrants to the training programme would need to meet the following requirements:

- Be registered with the Health Professions Council
- Be practising in an environment where there is an identified need for the individual to prescribe independently
- Have at least three years relevant post qualification experience
- Have support from their employer
- Have an approved medical practitioner to supervise and assess their clinical training as a prescriber.

Podiatrist independent prescribers would have an annotation on the HPC register. This would also require them to undertake appropriate steps to maintain their skills and competence in keeping with the HPC regulatory standards. The HPC would need to amend their standards for podiatrists, to reflect podiatrist independent prescribing and they have indicated their willingness to do this in due course if proposals move forward.

QUESTION

1. Do you have any comments on these eligibility criteria?

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What benefits would podiatrist independent prescribing bring?

Independent prescribing would improve outcomes for patients, whilst also providing greater cost-effectiveness and choice for patients and commissioners. Podiatrists would use independent prescribing where autonomy in medicines use would facilitate effective care for the patient, where the timely instigation of appropriate medicines management would prevent a deterioration in a patient's health status and where the appropriate use of medicines would enhance the aims of the programme that has already been established for the patient. For example:

- Timely management of musculoskeletal and rheumatological disorders would reduce unnecessary or inappropriate waiting times for treatment, hasten recovery, and improve patient outcomes. Presently care can be delayed when patients have to make additional visits to doctors for prescriptions, or doctors are not available to support supplementary prescribing. Via independent prescribing, podiatrists would be able to immediately and safely prescribe the medicines needed, adapting and tailoring a patient's medicines alongside their physical treatment.
- Timely prescription of medicines for diabetic foot infections is crucial in order to halt the rapid progression of infection, reduce the risk of amputation and avoid unnecessary hospital admissions. Independent prescribing would allow the podiatrist to play a central role in alleviating delays in timely access to medicines in the community. Service commissioners would also have a greater range of options in meeting the needs of patients in these circumstances.
- In general podiatry clinics, effective management of common foot problems often requires speedy access to antibiotics, effective use of anti-fungal agents, or analgesia to manage foot pain. Where it is safe to do so, independent prescribing would allow podiatrists to promptly supply the necessary medicines to their patients. Prompt treatment would help to alleviate patients' symptoms, encourage a more rapid recovery and avoid the need for patients to make additional appointments with other prescribers.

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- Patients receiving foot surgery from a podiatrist may require medicines such as analgesia (for pain management), antibiotics (in managing infection), anticoagulants (following surgery), sedatives for pre-operative anxiety and injectable corticosteroids. Prescribing of these medicines by podiatrist independent prescribers would enable rapid patient care, with a reduction in delays in receiving necessary medicines, and would be consistent with the implementation of national and local guidelines.

Independent prescribing would enable innovative service redesign to make greater use of podiatrists' skills in areas such as diabetes care, to ensure patients receive the medicines they need at the time they need them. For example, in areas as diverse as diabetic foot wound care, foot surgery, fungal skin infections, independent prescribing would enable patients to receive immediate appropriate pharmacological management alongside other physical treatments, whilst avoiding delays associated with additional appointments with other prescribers. Independent prescribing could also provide greater choice for patients and offers wider options for services and commissioners, reducing delays in accessing treatment and improving outcomes.

Independent prescribing would also enhance the flexibility and expertise of the workforce and thereby improve care for patients now and in the future.

Protecting the public

Podiatrist independent prescribing has the potential to improve patient safety by improving medicines management, reducing the delays in receiving care and potentially reducing avoidable hospital admissions.

Safeguards are of utmost importance because independent prescribing by any profession carries inherent risks. The two main risks which must be considered are:

- the potential risk to patient safety of inappropriate prescribing of medicines; and
- the risk to patient safety of failure to share information e.g. if the GP record was not updated in a timely manner.

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The following principles would underpin prescribing responsibilities for podiatrists:

- Patient safety is paramount. Prescribing responsibilities should only be enabled if they will deliver safe, effective and more convenient care for patients
- Prescribers should only prescribe and practice within the limits of their clinical competence and scope of practice
- Prescribing must be underpinned by robust governance structures
- Independent prescribers must take full clinical and professional responsibility for their decisions. Prescribers need to be able to recognise when they need to ask for support in relation to a patient's care
- Training should be determined locally, within a nationally agreed outline curriculum for prescribing training
- Dispensing pharmacists and those charged with reimbursing prescriptions need to be able to identify prescribers easily through an annotation on the professional register
- As is the case for existing prescribers who independently prescribe, the same standards of training, practice, governance and regulation will apply regardless of whether the podiatrist is working in the NHS, independent or other settings.

Governance and safeguards

The Health Professions Council (HPC) was created by the Health Professions Order 2001 and is the statutory regulator of 15 health professions, including podiatry. As part of their duty to protect the public, the HPC has a statutory responsibility to set standards of proficiency for podiatrists. This would include setting standards for independent prescribing. The HPC would also have a duty to assess and accredit educational institutions as recognised providers of training for podiatrist independent prescribing.

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The Society of Chiropractors & Podiatrists (SCP) and the Institute of Chiropractors and Podiatrists (ICP) are the principal professional bodies representing the UK’s registered podiatrists. Together they will produce detailed guidance for practitioners relating to good practice for independent prescribing, if this is introduced. As has been the case for nurses, pharmacists and optometrists, the National Prescribing Centre offered to produce a competence framework for podiatrist independent prescribers. However, the development of a single generic competency framework for all prescribers is currently being considered.

Employers will retain responsibility for ensuring adequate skills, safety and appropriate environments for podiatrist independent prescribing. Employers would also be responsible for ensuring that there is a need for a podiatrist to undertake prescribing responsibilities before they embark on training – as well as ensuring that there is an opportunity to prescribe post-training. The same standards would apply regardless of whether the podiatrist is working in the NHS, independent or other settings.

Continuing Professional Development (CPD):

All podiatrists are required to keep up-to-date in their practice and are required to renew their registration every two years. The HPC sets standards for CPD which all registrants must meet. The HPC undertakes a random sample audit every two years as part of the re-registration process, to ensure that its registrants are meeting its standards for CPD – thus keeping up-to-date and maintaining their fitness to practise. If introduced, podiatrist independent prescribers would have a similar responsibility to keep up-to-date with clinical and professional developments in medicines use to maintain their registration.

Access to the medical record:

If independent prescribing is implemented it is essential that prescribing podiatrists have up-to-date relevant and proportionate information about a patient’s medical history and medicines. This is achieved by patient consent, to gain either by direct access to the patients file in secondary care, GP record in primary care or the community and via referral letters in outpatient settings. Individual prescribers must assure themselves that they have all relevant information and if there is any doubt, further information should be sought before prescribing takes place.

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Updating the medical record:

It is essential that any prescribing activity by podiatrists is known to other healthcare professionals caring for the same patient, such as the patient's GP and patients informed of this. Nurse prescribers and existing podiatrist supplementary prescribers are currently expected to update a patient's notes contemporaneously if possible and in any event within 48 hours of the episode of care. This may be done electronically where possible, via an email or electronic update to the GP's office where the patient's notes are held, or by fax to the GP's surgery, ensuring good information governance procedures are taken to ensure its safe transfer. There will be a requirement on prescribing podiatrists to update the patient's relevant medical records in a timely manner.

Options for introducing podiatrist independent prescribing

Independent prescribing by podiatrists could take various forms, such as those outlined in the options below. Appendix 2 outlines the main conditions and medicines pertaining to podiatry practice.

Option 1. No change

Highly skilled and experienced podiatrists would continue to be eligible to train as supplementary prescribers. Depending upon local employment arrangements, appropriately trained podiatrists would continue to supply and/or administer medicines under Patient Group Directions (PGD), patient specific directions (PSD), or existing statutory exemptions.

Benefits

The existing arrangements have proved safe and in some settings, they enable podiatrists to supply patients with the medicines that they need.

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Limitations

Recent scoping work⁵ has indicated that the existing arrangements do not best support the needs of patients, particularly when a podiatrist is providing self referral, first contact, diagnostic, or community care. Where patients require medicines management, outside that specified in a Patient Group Direction or existing statutory exemption, they would continue to have to visit another professional. The existing arrangements are difficult and costly to administer.

Under this option, the creation of innovative new care pathways will continue to be limited. creating less choice and ongoing unnecessary costs for commissioners. Consequently, an opportunity to improve outcomes for patients would be missed.

Option 2. Independent prescribing for specified conditions from a specified formulary

Appropriately trained podiatrists would be permitted to prescribe independently from a list of specified medicines for a specified list of conditions.

Benefits

This option could benefit patients provided that their condition, and the drugs they need, are listed.

Limitations

Patient’s whose condition or medicines needs do not appear on the lists of prescribable medicines and conditions would not be able to benefit. As the podiatry profession spans a large range of patient groups, either the lists of conditions and medicines would need to be extensive, or certain groups of patients would be excluded. In addition, a limited formulary and list of conditions would need updating regularly, to support ongoing current best practice. This would require lengthy administrative and legislative processes and may not be responsive to the needs of patients or developments in clinical care.

⁵ Department of Health (2009). Allied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project Report. www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103949.pdf

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Option 3. Independent prescribing for any condition from a specified formulary

Appropriately trained podiatrists would be permitted to prescribe independently for any condition within their competence but only from a list of specified medicines.

Benefits

A wider range of patients could benefit from this option, than could under option 2.

Limitations

Patients whose medicines needs do not appear on the list of prescribable medicines would not be able to benefit fully. As with option 2, the lists would be difficult to administer and this option would be potentially unresponsive to the needs of patients and current best clinical practice.

Option 4. Independent prescribing for specified conditions from a full formulary

Appropriately trained podiatrists would be permitted to prescribe independently any medicine within their competence, but only for specified conditions.

Benefits

A wider range of patients would benefit from this option, than could benefit under option 2.

Limitations

Patients with a condition that does not appear on the list, would not be able to benefit fully.

As with option 2, the lists would be difficult to administer and keep up-to-date, and potentially unresponsive to the needs of patients and current best clinical practice.

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Option 5. Independent prescribing for any condition from a full formulary

Appropriately trained podiatrists would be permitted to independently prescribe any medicine for any condition, within their competence.

Benefits

Patients would be able to make direct contact with appropriately trained podiatrists and receive the care and medicines they need, without having to make additional appointments with other prescribers. A greater number of patients could benefit from improved care, faster care and greater convenience.

Limitations

This option has no obvious limitations. It is the most flexible option and stands to benefit the most patients.

Option 6. A combination of the above options

Appropriately trained podiatrists would be able to prescribe independently by some combination of the above options. This could be achieved in a number of ways. For example, prescribing any medicine within the prescriber’s competence in a hospital setting, but only from a list of specific medicines in a community setting.

Benefits (based on the example above)

This approach could benefit patients, provided that their condition or the medicine they need was on the list, for the setting in which their care was being delivered.

Limitations (based on the example above)

This approach could be difficult to administer and regulate, particularly for individual podiatrists who work in a combination of different settings. Patients whose conditions or medicines needs vary from the defined list would not be able to benefit fully. This option would also create a risk that patients moving between settings would be unable to receive consistent care.

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QUESTION

2. Which of the above options do you believe would safely add the most value to patient care? (if option 6, please provide details)

Empty response area for question 2.

3. Have you any comments on the arrangements outlined above for the governance of independent prescribing by podiatrists if the proposals are taken forward? Are there other factors which should be taken into account?

Empty response area for question 3.

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Controlled drugs

Controlled drugs are prescription medicines containing drugs controlled under the Misuse of Drugs legislation. Examples include benzodiazepine, morphine, and pethidine, but also more commonly used drugs such as diazepam or codeine preparations, which podiatrists may need to use to help control a patient's pain. They are classified by law based on their benefit when used in medical treatment and their harm if misused. If podiatrists are to be able to prescribe controlled drugs independently as part of any of the above options, separate amendments would need to be made to legislation governing controlled drugs within the UK by the Home Office and the Department of Health and Personal Social Services in Northern Ireland (Misuse of Drugs Regulations).

Podiatrists are currently able to prescribe controlled drugs via supplementary prescribing arrangements. At present, nurse independent prescribers can prescribe from a list of 13 controlled drugs, but only for specified conditions. Pharmacist independent prescribers cannot as yet prescribe any controlled drug independently. Optometrist independent prescribers cannot prescribe controlled drugs. However, changes to UK misuse of drugs regulations are anticipated to enable nurse and pharmacist independent prescribing of controlled drugs, thus removing the present restrictions for nurse and pharmacist independent prescribers.

QUESTION

4. In what circumstances would it benefit patients if appropriately trained podiatrists, were able to prescribe controlled drugs independently?

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Mixing of medicines prior to administration

Clinical practice sometimes requires the mixing of two licensed medicines, for example corticosteroid and local anaesthetic agents, in the management of certain musculoskeletal disorders, thus creating an unlicensed medicine. In May 2010, new guidance on mixing was issued⁶ which clarified that:

- Doctors and dentists can mix medicines themselves and direct others to mix
- Nurse and pharmacist independent prescribers can mix medicines themselves and direct others to mix
- Supplementary prescribers can mix medicines themselves and direct others to mix, but only where that forms part of the written Clinical Management Plan for an individual patient.

QUESTION

5. In what circumstances would it benefit patient care if appropriately trained podiatrist independent prescribers were able to mix medicines themselves prior to administration or direct others to do so?

⁶ National Prescribing Centre (2010). Mixing of medicines prior to administration in clinical practice: medical and non-medical prescribing. Gateway ref: 14330

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Prescribing of unlicensed medicines

Unlicensed medicines are those which do not have a Marketing Authorisation (or product licence) which is valid in the UK. The prescribing of unlicensed medicines is permitted under legislation subject to certain conditions which are that the relevant medicinal products are supplied in response to bona fide unsolicited orders, formulated in accordance with the specifications of certain prescribers for use by individual patients on the prescriber's direct personal responsibility, and in order to fulfil "special needs". The product must be made by a person holding a manufacturer's licence for this purpose.

QUESTION

6. In what circumstances would it benefit patient care if appropriately trained podiatrist independent prescribers were able to prescribe unlicensed medicines for their patients?

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“Off-label” prescribing or supply of medicines

These are medicines which have a product licence and a UK marketing authorisation, but are prescribed or supplied for a different use to those detailed in the summary of product characteristics. An example is the use of low dose amitriptyline (an antidepressant) which is also used “off-label” at a low dose for the treatment of neuropathic pain. Presently doctors, dentists, nurse and pharmacist independent prescribers, and allied health profession supplementary prescribers are able to prescribe medicines in this way.

QUESTION

7. In what circumstances would it benefit patient care if appropriately trained podiatrists, acting within their level of competence, were able to prescribe medicines ‘off label’ independently?

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Simultaneous prescribing and administration

For safety reasons, it is a long standing principle that prescribers prescribe medicines and a pharmacist then supplies the medicines in accordance with that prescription. However, in certain circumstances it may be in a patient’s best interests for a prescriber to be able to supply or administer a medicine to that patient immediately, without waiting for a pharmacist to dispense it. For example, a patient may benefit from the delivery of a corticosteroid injection for arthritis pain, during the course of an outpatient appointment, rather than having to wait for another appointment to have the injection delivered. Podiatrists are already able to supply a limited range of medicines direct to their patients under Exemptions and similar arrangements exist under Patient Group Directions. In such settings, the supplies of medicines must be stored safely and in accordance with any special conditions relating to specific medicines.

It is not however the intention that podiatrist independent prescribers should, as a normal routine, supply medicines direct to their patients. The dispensing of prescriptions properly lies with pharmacists. The sale, supply and administration arrangements existing under Exemptions and Patient Group Directions would remain unchanged.

QUESTION

8. How would it benefit patients and in what settings, if appropriately trained podiatrists were able to supply and/or administer medicines that they had prescribed independently?

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Additional questions:

9. Can you offer any information about potential costs and benefits of podiatrist independent prescribing for the impact assessment, eg. Benefits in terms of time savings to GPs, costs relating to the numbers of podiatrists likely to go forward for training, or any other factors?

10. Can you offer any information on how these proposals would impact on equality in your area, particularly concerning disability, ethnicity, gender, sexual orientation, ages, religion or belief, and human rights? Could any group be excluded, or better included because of the proposal, and will there be any problems or barriers for any minority group?

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11. Are there any other implications for implementing independent prescribing for podiatrists?

Name

Patient/Public

AHP

Doctor

Nurse

Pharmacist

Organisation (if applicable)

Are you responding on behalf of the organisation

Email:

Tel No:

Now click on 'Save form' to create a pdf which you can email to us at ahpprofessionalleadership@dh.gsi.gov.uk (please refer to page 5 if you need more detailed instructions on how to do this).

Save form

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Non-medical prescribing and medicines supply mechanisms⁷

Mechanism summary

Patient Specific Direction is a prescriber's (normally written) instruction, which enables a person to supply or administer a medicine to a named patient.

Patient Group Direction within the NHS is a written instruction for the supply and/or administration of a licensed medicine to a patient or group of patients, where the patient may not be individually identified before presenting for treatment. The Direction must be agreed/signed by a doctor and a senior pharmacist, and approved by the employer – typically a PCT or NHS Trust. It authorises certain named registered health professional(s) to supply/administer a licensed medicine.

Patient Group Directions outside the NHS are restricted to independent hospitals, clinics and agencies registered with the Care Quality Commission in England and equivalents in the devolved administrations. They can also be implemented, subject to conditions, by the Defence Medical Services, the UK Police Forces and the UK Prison Services. The Direction enables the sale, supply and/or administration of a licensed medicine to a patient or group of patients, where the patient may not be individually identified before presenting for treatment. The Direction must be agreed/signed by a doctor and a senior pharmacist, and approved by the body or representative specified in medicines legislation. It authorises certain named registered health professional(s) to supply/administer a licensed medicine.

Exemptions (to medicines legislation) allow sale, supply and administration of specific drugs in specific circumstances.

⁷ Further details can be found in DH and National Prescribing Centre guidance, and an overview with definitions in Medicines Matters (DH, 2006).

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Mechanism summary

Supplementary Prescribing is a voluntary prescribing partnership between individual members of certain registered healthcare professionals and an independent prescriber (doctor) to provide treatment for an individual patient, with that patient's agreement, through a written clinical management plan. The Supplementary Prescriber can alter dose, remove or write prescriptions according to that plan.

Independent Prescribing involves taking full responsibility for prescribing decisions and autonomously writing prescriptions.

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APPENDIX 2

Main conditions and medicines – podiatry

System	Medicine category	Indicative conditions	Evidence/guidance
Gastro-Intestinal System	Mucosal protectants	Chronic pain conditions requiring opioid analgesia use MSK conditions requiring NSAID/anti-platelet use	NICE CG017 (dyspepsia)
	Anti-motility	Conditions causing acute uncomplicated diarrhoea – during medical management of infection (in post-operative situations or severe diabetic infection)	Antimicrobials are reported to be responsible for 25% of acute diarrhoea. Early management can reduce the chance of longer term complications Drug Saf. 2000 Jan;22(1):53-72. Drug-induced diarrhoea. Chassany O, Michaux A, Bergmann JF

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System	Medicine category	Indicative conditions	Evidence/guidance
Gastro-Intestinal System (continued)	Oral rehydration therapy	During acute diarrhoea (early management)	Progression of such clinical presentation would indicate referral on for medical management in secondary care
	Laxatives	NSAID use has a well reported incidence of dyspepsia – Upper Bowel. (The NSAIDs include aspirin (33%), ibuprofen (17%), naproxen (11%), piroxicam (9%), indomethacin (8%), and diclofenac (7%)) Additionally lower bowel problems such as constipation is seen. Therefore management of this is required	NHS Clinical Knowledge Summaries(CKS) for Constipation Br J Clin Pract. 1995 Mar-Apr;49(2):67-70. Gastrointestinal side-effects of NSAIDs in the community. Jones RH, Tait CL

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System	Medicine category	Indicative conditions	Evidence/guidance
Cardiovascular System	CPR adrenaline	Cardiac collapse Stroke	NICE CG8 (MS); NICE CG68 (Stroke); NICE CG 35 (PD) NICE CG92 – VTE prevention NICE CG5, chronic heart failure
	Anticoagulants	Post-operative conditions with prolonged reduced mobility Thromboprophylaxis (surgery or in any clinical situation where a patient is immobilised) Assessment using the VTE proforma is required – to identify risk factors	NHS Clinical Knowledge Summaries (CKS) for Stroke and TI NICE: CG92 Venous thromboembolism – reducing the risk: full guideline (Low-Molecular weight Heparin/Enoxaparin)
	Skeletal muscle relaxants	Nocturnal cramp	BNF Drug Safety Update June 2010 (cautious use)

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System	Medicine category	Indicative conditions	Evidence/guidance
Cardiovascular system (continued)	Calcium channel blockers	Raynaud’s phenomenon	BNF
	Peripheral vasodilators	Intermittent claudication	BNF TASC SIGN 2006
Respiratory System	Oxygen	Use in day-case theatre settings	Anaphylaxis (adrenaline/ chlorphenamine/atropine)
	Stimulants	Life-saving situations	Asthma (Acute) – in clinical setting/during response to procedure (Salbutamol) Generally in community clinical (surgery) setting ability to stock and administer in life saving events. The IP status would afford access

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Central Nervous System	Neuropathic pain medicines e.g. Tricyclic antidepressants	Chronic pain management Diabetic neuropathy MSK/rheumatoid pain Post-operative care	NICE CG96 (neuropathic pain) British Pain Society Guidelines for opioid use in pain management WHO analgesic ladder
	Opioid analgesia	CRPS Chronic pain services	NHS Clinical Knowledge Summaries (CKS) for NSAID prescribing
	Torsion dystonia	Adult and paediatric spasticity equinus foot	Royal College of Physicians – Spasticity in Adults – Management Using Botulinum Toxin
Musculoskeletal and Joint Disease	Local corticosteroid injections	Local Inflammatory disorders of joints and/or soft tissues e.g. OA Rheumatic diseases	NHS Clinical Knowledge Summaries (CKS) for Sprains and Strains RA/OA
	NSAIDs	Local inflammatory disorders and injuries of joints and/or soft tissues e.g. strains, sprains, muscle and ligament tears, swelling, bruising	
	Rubefacients		
	Nutriceuticals		

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System	Medicine category	Indicative conditions	Evidence/guidance
Musculoskeletal and Joint Disease (continued)	Systemic corticosteroids	Degenerative joint disorder/soft tissue injuries	NICE TA160/TA161 – Osteoporosis http://www.nice.org.uk/nicemedia/live/12131/43326/43326.pdf
	Skeletal muscle relaxants	Systemic inflammatory disorders/connective tissue disorders	
	Bisphosphonates	Osteoporosis	
Anaesthesia	Sedatives	Pre-operative anxiety Chronic muscle spasm	
	Local anaesthesia Inhalational anaesthesia	Procedure & operative management Acute severe pain	
Other injectable medicines	Sodium chloride 0.9% for injection Water for injection	Associated with injection therapy	
Antimicrobial	Antibiotics – topical, oral and IV	Wound infection Post-injection infection (rare) Post-operative infection Skin infections Cellulitis	http://www.nice.org.uk/nicemedia/live/10934/29243/29243.pdf