hpc health professions council

Education and Training Committee, 16 September 2010

Changes to prescribing rights for chiropodists/podiatrists and physiotherapists

Executive summary and recommendations

Introduction

Chiropodists/podiatrists, physiotherapists and radiographers can all currently complete post-registration training to become supplementary prescribers. The Department of Health is currently undertaking a project to extend independent prescribing rights to chiropodists/podiatrists and physiotherapists.

This paper explores the issues around changes to prescribing rights. It also proposes a new approach to setting standards for prescribing.

Any change to prescribing rights would also require public consultation by the Medicines and Healthcare products Regulatory Agency and a change in legislation. As a result, the proposals may be subject to amendment. At this stage therefore, the Committee is invited to agree a number of decisions in principle.

Decision

The Committee is invited to discuss the attached paper and agree the following in principle:

- that the Executive should draft standards for independent prescribing depending upon the outcomes of the public consultation by the Department of Health;
- that the standards should sit alongside standards for supplementary prescribing in a separate document; and
- that the Executive should provide the Committee with regular updates on the progress of the AHP medicines project board.

Background information

The Committee has not previously considered a paper on this topic. However, post-registration qualifications have previously been considered by the Committee on a number of occasions. The most recent discussion was on 8 June 2010. The paper can be found here:
http://www.hpc-uk.org/aboutus/committees/educationandtraining_archive/index.asp?id=492

Resource implications

Subject to the Committee's decision, the resource implications include writing standards and a consultation document as well as meetings with relevant stakeholders. These resource implications are accounted for in the Policy and Standards Department workplan for 2010-2011.

Depending upon the outcomes of the public engagement exercise and consultation being run by the Department of Health, there may be further resource implications for 2011-2012. These would be incorporated within the relevant workplans for 2011-2012

Financial implications

Subject to the Committee's decision, the financial implications could include printing and mailing of a consultation document and eventual publication of standards.

Depending upon the outcomes of the public engagement exercise and consultation being run by the Department of Health, there may be further financial implications for 2011-2012. These would be incorporated within the relevant budgets for 2011-2012.

Appendices

- Department of Health engagement exercise to seek views on possibilities for introducing independent prescribing responsibilities for physiotherapists
- Department of Health engagement exercise to seek views on possibilities for introducing independent prescribing responsibilities for podiatrists

Date of paper

12 August 2010

Changes to prescribing rights for chiropodists/podiatrists and physiotherapists

1. Introduction

1.1 The Department of Health is currently undertaking a project to extend independent prescribing rights to chiropodists/podiatrists and physiotherapists.

1.2 This paper explores the issues around changes to prescribing rights. It also proposes a new approach to setting standards for prescribing.

1.3 This paper is divided into four sections:

- Section one provides an introduction to the paper, including information on prescribing, an explanation of the role of the project board and how we regulate post-registration qualifications.
- Section two outlines the standards and guidance that other regulators provide for non-medical professions which have independent prescribing rights.
- Section three identifies points for discussion.
- Section four outlines the resource implications of changes to prescribing rights and how we could approach setting standards for independent prescribing.

Supplementary prescribing and independent prescribing

1.4 At present, chiropodists/podiatrists, physiotherapists and radiographers can become supplementary prescribers, if they complete the appropriate training and have their entry on the Register annotated.

1.5 Supplementary prescribing is a voluntary prescribing partnership between the independent prescriber (doctor or dentist) and supplementary prescriber, to implement an agreed patient-specific clinical management plan (CMP), with the patient's agreement.[1]

1.6 Following agreement of the CMP, the supplementary prescriber may prescribe any medicine for the patient that is referred to in the plan, until the next review by the independent prescriber. There is no formulary for supplementary prescribing, and no restrictions on the medical conditions that can be managed under these arrangements. However, the supplementary prescriber cannot prescribe a medicine which is not referred to in the plan.

1.7 Independent prescribing is prescribing by a practitioner (such as a doctor, dentist, or nurse) responsible and accountable for the assessment of

[1] Department of Health, 'Medicines Matters' July 2006

patients with undiagnosed or diagnosed conditions and for decisions about the clinical management, including prescribing.[2]

1.8 Independent prescribers can prescribe any medicine for any medical condition within their competence, including some controlled drugs for specified medical conditions. They must also comply with any relevant medicines legislation.

1.9 Supplementary prescribers can only prescribe a medicine where it is referred to in the CMP. By contrast, independent prescribers have autonomy and can prescribe any medicine within their competence and knowledge.

Department of Health scoping project

1.10 The allied health professions (AHP) prescribing and medicines supply mechanisms scoping project was established in September 2008. The project was established to consider whether there was evidence of service and patient need to support extending non-medical prescribing and medicines supply mechanisms for AHPs. A member of the Executive was on the scoping project board.

1.11 The scoping project board produced a report which was published in July 2009.[3] The report made the following recommendations of further work, which were divided into phases on the basis of priority.

1.12 Phase one – further work should be undertaken to establish:

- independent prescribing by physiotherapists;
- independent prescribing by chiropodists / podiatrists;
- supplementary prescribing by dietitians (and consideration of a specific list of potential exemptions for dietitians) and
- a specific list of exemptions for orthoptists.

1.13 Phase two – further work should be undertaken, when appropriate, to consider the need for:

- independent prescribing by radiographers;
- supplementary prescribing by speech and language therapists;
- supplementary prescribing by orthoptists; and
- supplementary prescribing by occupational therapists.

AHP medicines project board

1.14 The Department of Health then established a project board to take forward phase one of the recommendations listed above. A member of the Executive is on the project board.

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[2] Department of Health website http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/TheNon-MedicalPrescribingProgramme/Background/index.htm

[3] Allied health professions prescribing and medicines supply mechanisms scoping project report http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_103948

1.15 At present, the project board is focussing on delivering independent prescribing for chiropodists/podiatrists and physiotherapists. This will require public consultation as well as an amendment in legislation. The board has launched a public engagement exercise which will help to shape the additional work being undertaken.

1.16 Once the outcomes of the public engagement exercise are known, the Medicines and Healthcare products Regulatory Agency (MHRA) would need to consult on changes to legislation, in order to allow independent prescribing for chiropodists/podiatrists and physiotherapists.

1.17 The Department of Health has set up Education and Governance work streams to help the project board to implement the changes in prescribing rights. Two members of the Executive are involved in these work streams. The work streams are designed to allow joint working across the key stakeholders on key issues around ensuring safe and effective prescribing.

1.18 The project board understands that we would set the standards which independent prescribers would have to meet. However, the practice guidance will be produced by the professional bodies representing the relevant professions.

1.19 Any decision to implement a change in prescribing rights would be subject to government agreement and would require an amendment to legislation. An amendment to legislation requires time and resources to implement and as such may be subject to delay or alteration.

Paramedics and prescribing responsibilities

1.20 The Department of Health is currently reviewing paramedic prescribing, in particular whether it would be appropriate to introduce prescribing responsibilities for paramedics.

1.21 The Department of Health has recently closed an informal stakeholder engagement exercise on paramedic prescribing, which we responded to. The engagement exercise outlines a number of different options for changing paramedics' prescribing responsibilities. These include supplementary prescribing; prescribing from a limited formulary or for specific conditions; and independent prescribing.

1.22 The intention is that, subject to the outcomes of the consultation, the MHRA would then consult formally on proposals on paramedic prescribing.

1.23 The project board taking forward the work on independent prescribing for chiropodists/podiatrists and physiotherapists is following a similar model of engagement and consultation.

The Health Professions Order

1.24 We have powers to annotate the Register. These powers are set out in the Health Professions Order 2001 ('the Order') and in the Health Professions Council (Parts and Entries in the Register) Order of Council 2003 ('the Parts Order').

1.25 Article 19 (6) of the Order says:

'In respect of additional qualifications which may be recorded on the Register the Council may establish standards of education and training and articles 15(3) to (8) and articles 16 to 18 shall apply in respect of those standards as if they were standards established under article 15(1)(a)'

1.26 Article 2 (4) of the Parts Order says:

'The Council may also include such entries in the register as it considers appropriate to indicate that a registrant possesses any other qualification (whether or not it is an approved qualification) or competence in a particular field or at a particular level of practice.'

1.27 Those Orders give the Council powers around post-registration qualifications. They are the power to:

- record post-registration qualifications or additional competencies in the Register;
- approve post-registration qualifications for these purposes;
- approve and establish standards of education and training for post-registration entitlements; and
- produce standards of proficiency or their functional equivalent (if included within the standards of education and training).

Existing annotations of the Register

1.28 Currently the Register is annotated to indicate where a registrant has undertaken additional training and has obtained entitlements to supply, administer or prescribe these medicines. The Prescriptions Only Medicines (Human Use) Order 1997, places the requirement to annotate the Register on the HPC.

1.29 The Register is annotated where:

- A chiropodist/podiatrist, physiotherapist or radiographer has completed an approved programme enabling them to become a supplementary prescriber.
- A chiropodist/podiatrist has completed an approved programme allowing them to sell/supply prescription only medicines (POM) and/or administer local anaesthetics (LA).

1.30 There is a clear link between the legislation, the annotation on the Register and a function. For example, an individual cannot act as a supplementary prescriber unless they have both completed a supplementary prescribing programme and had their entry on the Register

annotated. Individuals who act as supplementary prescribers without doing this could be prosecuted.

Standards of proficiency

1.31 The standards of proficiency are the threshold standards necessary for safe and effective practice within a profession. Most standards of proficiency relate to competencies that individuals must gain before they apply to join the Register. Once on the Register, they must continue to meet the relevant standards for their scope of practice.

1.32 In addition to these standards of proficiency, we also currently set a standard of proficiency for chiropodists/podiatrists, physiotherapists and radiographers who undertake supplementary prescribing. The standard is incorporated within the standards of proficiency for the relevant profession and says:

'know and be able to apply the key concepts which are relevant to safe and effective practice as a supplementary prescriber'

1.33 In addition to meeting this standard, supplementary prescribers would also have to meet the other standards of proficiency relevant for their scope of practice, as well as the standards of conduct, performance and ethics and standards for continuing professional development.

1.34 The standard of proficiency related to supplementary prescribing currently sits within the pre-registration standards for the particular profession. This is anomalous as the standard for supplementary prescribers can only be met by individuals who have completed their pre-registration training and are now registered with us. This standard is not therefore a pre-registration standard.

1.35 We do not set practice standards so do not define how professionals should practice as supplementary prescribers. Instead, we look to other organisations, like the National Prescribing Centre (NPC), to produce guidance and practice standards which supplementary prescribers can use to support their practice.

Approval of education programmes

1.36 We approve pre-registration education programmes against the standards of education and training (SETs).[4] We assess programmes against the SETs to make sure that students completing those programmes meet the standards of proficiency for their profession.

1.37 We follow the same process when we approve post-registration qualifications in supplementary prescribing. We do not set the curriculum framework for supplementary prescribing programmes. Programmes in supplementary prescribing are assessed against all the standards of

[4] Standards of education and training: http://www.hpc-uk.org/aboutregistration/standards/sets/

education and training (apart from SET 1: level of qualification for entry to the Register) and also the standard of proficiency identified above.

1.38 By setting standards which registrants must meet and also quality assuring the education programmes, we can protect the public.

Post-registration qualifications

1.39 As explained above in paragraph 1.28 to 1.30, we only currently annotate the Register to indicate where a registrant has undertaken additional training around medicines and has obtained entitlements to supply, administer or prescribe these medicines.

1.40 The Committee has previously discussed whether we should annotate additional qualifications on the Register. The Committee has proposed some draft criteria which will be used to decide whether additional qualifications are annotated. Those criteria will be consulted on and the outcomes of the consultation will be brought back to the Committee in due course.

1.41 The Committee also agreed that where post-registration qualifications are annotated, we should set standards for those qualifications, in line with our powers under the Order.

2. Approaches to regulating independent prescribing

2.1 Several non-medical professions currently have independent prescribing rights:

- Nurses and midwives
- Optometrists
- Pharmacists

2.2 The approach that each regulator takes to setting standards for independent prescribing is explained below.

Nursing and Midwifery Council

2.3 Nurses and midwives can prescribe as either a community practitioner prescriber, or a supplementary/independent prescriber, depending upon their role and training.

2.4 The NMC has produced the following documents for the different prescribing rights.

Standards of proficiency for nurse and midwife prescribers

2.5 These set the standards and proficiencies for the programmes of preparation for nurses, midwives and specialist community public health nurses to prescribe as either a community practitioner nurse prescriber or a nurse independent/supplementary prescriber.[5] It also sets standards of conduct that nurses, midwives and specialist community public health nurses are required to meet in their practice as a registered nurse prescriber.

2.6 The booklet combines the standards which education providers must meet (for example admission standards) with competency and conduct standards for the registrant (for example standards around prescribing within competency). It also identifies learning outcomes which should be included within detailed curriculum.

2.7 The document is regularly updated through circulars provided by the NMC.

Standards for medicines management

2.8 These standards are set to ensure safe practice in the management and administration of medicines by registered nurses, midwives and specialist community public health nurses.[6]

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[5] Standards of proficiency for nurse and midwife prescribers http://www.nmc-uk.org/Educators/Standards-for-education/Standards-of-proficiency-for-nurse-and-midwife-prescribers/

[6] Standards for medicines management http://www.nmc-uk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf

2.9 The standards cover a variety of topics, including methods of supply/administration, dispensing, storage, standards for practice, delegation and disposal of medicines. They are not designed to cover every situation but to provide standards which professionals can use to support their own decision making.

Maintaining competency in prescribing

2.10 The NPC has previously published a competency framework for nurses acting as supplementary prescribers.[7] However, there is no competency framework for nurses who undertake independent prescribing.

General Optical Council

2.11 The General Optical Council (GOC) registers optometrists, dispensing opticians, student opticians and optical businesses. Optometrists can prescribe as either supplementary or independent prescribers if they meet the necessary training requirements.

Guidance for optometrist prescribers

2.12 The guidance document was produced by the College of Optometry but the General Optical Council would refer to it if a complaint was made about an optometrist who was an independent prescriber.[8] It sets out the conduct expected of an independent prescriber.

2.13 The guidance contains sections which optometrists must meet, alongside guidance which should be followed in normal circumstances. The document provides guidance on prescribing practice, medicines management, clinical governance and other associated topics.

Handbook for optometry specialist registration in therapeutic practice

2.14 The handbook defines the content and standards of education and training necessary to achieve the competencies required for entry to the specialist registers in optometric independent prescribing.[9]

2.15 The handbook brings together useful resources on prescribing from a number of topics. It covers how education providers should establish their programmes, the competency framework, the outline curriculum for prescribing and information on practice based learning.

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[7] Maintaining competency in prescribing – an outline framework to help nurse supplementary prescribers
http://www.npc.co.uk/prescribers/resources/nurse_update_framework.pdf

[8] Guidance for optometrist prescribers
http://www.college-optometrists.org/en/utilities/document-summary.cfm?docid=7C3868AB-6362-4741-87C8C427CA9E870F

[9] Handbook for optometry specialist registration in therapeutic practice
http://www.optical.org/goc/filemanager/root/site_assets/education_handbooks/ip_handbook_july_08.pdf

Competency framework for prescribing optometrists

2.16 This competency framework was jointly produced by the NPC and GOC.[10] The document presents a framework of prescribing competencies which optometrist prescribers can use to check their own expertise and identify any gaps in knowledge and skills which they need to address.

2.17 The framework was used by the GOC in the development of curricula for specialist prescriber training. The competencies contained within the framework are also used for the approval of specialist continuing education and training.

Royal Pharmaceutical Society of Great Britain[11]

2.18 Pharmacists can act as supplementary or independent prescribers. Pharmacist independent prescribers can prescribe for any clinical condition but they must only prescribe within their professional and clinical competence.

Outline curriculum for training programmes to prepare pharmacist prescribers

2.19 The Royal Pharmaceutical Society of Great Britain (RPSGB) has developed a curriculum framework for training programmes providing training in independent prescribing.[12] They have recently published a curriculum framework for supplementary prescribers who want to train to become independent prescribers.

2.20 The RPSGB also produces an accreditation manual for pharmacist independent prescribing courses. This manual explains the accreditation process and outlines the criteria that programmes will be assessed against.[13]

Professional standards and guidance for pharmacist prescribers

2.21 This document expands upon the code of ethics which all pharmacists must meet, to explain a pharmacist prescriber's additional responsibilities within the principles identified in the code.[14] The document is divided into mandatory standards (indicated by a 'must') and good practice (indicated by a 'should').

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[10] Competency framework for prescribing optometrists http://www.npc.co.uk/prescribers/resources/competency_framework_optometrist.pdf

[11] The RPSGB will finish transferring its regulatory functions for pharmacists to the General Pharmaceutical Council in September 2010. At the time of writing however, these functions remain with the RPSGB.

[12] Outline curriculum for training programmes to prepare pharmacist prescribers http://www.rpsgb.org/pdfs/indprescoutlcurric.pdf

[13] The accreditation of pharmacist independent prescribing courses http://www.rpsgb.org/pdfs/indpresman09.pdf

[14] Professional standards and guidance for pharmacists prescribers http://www.rpsgb.org.uk/pdfs/coepsgpharmpresc.pdf

Maintaining competency in prescribing

2.22 The NPC has worked with other relevant stakeholders to produce a competency framework for pharmacists in prescribing. The framework is similar to that for the optometrists.[15]

Clinical Governance Framework for Pharmacist Prescribers and organisations

2.23 The RPSGB has produced a clinical governance framework for pharmacists to follow.[16] It is designed to be used in conjunction with the competency framework and the standards for pharmacist prescribers. The framework sets out good practice for employers and individual independent prescribers around clinical governance.

Summary of information provided by different regulators

2.24 As can be seen above, each of the regulators have either standards or guidance for independent prescribers. In some cases, these are supported by competency frameworks developed by the NPC. In addition, some of the regulators also set the curriculum framework for independent prescribing.

2.25 The project board looks to us to produce standards for independent prescribing. The competency framework and practice guidance will be developed by other organisations

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[15] Maintaining competency in prescribing – an outline framework to pharmacist prescribing http://www.npc.co.uk/prescribers/resources/competency_framework_oct_2006.pdf

[16] Clinical governance framework for pharmacist prescribers and organisations commissioning or participating in pharmacist prescribing
http://www.rpsgb.org/pdfs/clincgovframeworkpharm.pdf

3. Discussion

3.1 Any change to prescribing rights would require an amendment to the necessary legislation. It is likely that a change to The Prescriptions Only Medicines (Human Use) Order 1997 would mean we would have to annotate independent prescribers.

3.2 As outlined in paragraphs 1.4 to 1.9, when a professional prescribes independently, they have autonomy and can prescribe on the basis of their knowledge and competence. This is different to supplementary prescribing, where the supplementary prescriber must still have the appropriate knowledge and skills but they prescribe in line with an agreed clinical management plan, rather than having complete autonomy.

3.3 The project board has previously discussed the differences between supplementary and independent prescribing and how these can be reflected in the standards and practice guidance produced to ensure public protection.

3.4 If the prescribing rights for chiropodists/podiatrists and physiotherapists changed to include independent prescribing we would need to set standards to ensure safe and effective practice

3.5 The Committee has previously agreed that post-registration qualifications should be annotated on the Register where it is necessary for public protection. Where qualifications are annotated, standards should be set to ensure safe and effective practice.

3.6 The Executive proposes that a new approach should be taken to the standards set for post-registration qualifications. It proposes that a new set of standards should be produced specifically for prescribing, whether for supplementary or independent prescribers. It is proposed that there should be one set of standards for prescribing, with additional standards for either supplementary or independent prescribers where appropriate.

3.7 Under the Order, we have powers to set standards of education and training for post-registration qualifications, but no express powers to set standards of proficiency for post-registration qualifications (see paragraphs 1.24 to 1.27).

3.8 However, the standards of education and training are described in the Order as the standards necessary to achieve the standards of proficiency which the Council has set. Therefore, although the legislation does not give express powers to produce standards of proficiency for post-registration qualifications, the definition of standards of education and training means that standards of proficiency can be produced.

3.9 The Executive suggests that a practical solution would be to produce standards of education and training and standards of proficiency for post-registration qualifications which can sit within a single document.

3.10 The Executive recommends that such a document should be created as a stand alone document rather than sitting within the published standards of proficiency which are set for entry to the Register.

3.11 At the moment, the timescales for the implementation of independent prescribing are still being finalised. In addition, the outcomes of the public engagement exercise and consultation by the MHRA are not yet known. At this stage therefore, the Committee is asked to make decisions in principle.

3.12 By making these decisions at this stage, we can communicate our approach to the project board and also respond quickly once the outcomes of the engagement exercise and subsequent consultation are known.

3.13 The Committee is therefore invited to discuss and agree the following in principle:

- that the Executive should draft standards for independent prescribing depending upon the outcomes of the public consultation by the Department of Health;
- that the standards should sit alongside standards for supplementary prescribing in a separate document; and
- that the Executive should provide the Committee with regular updates on the progress of the AHP medicines project board.

4. Resource implications and timetable

4.1 Any decision to change prescribing rights for the professions we regulate would have resource implications for us and it is likely that the proposed change in prescribing rights would constitute a major project.

4.2 If chiropodists/podiatrists and physiotherapists gained the entitlement to practice as independent prescribers, we would need to set standards for that practice. This would involve liaison work with stakeholders and public consultation on the standards.

4.3 We would also need to approve the education programmes which offered training in independent prescribing. We would need to recruit partners to help us with this process.

4.4 We would approve them against the standards that we set. We require at least six months notice to set up an approval visit, to ensure that the appropriate resources are available.

4.5 In addition, we would also need to make amendments to our Register to enable us to record where an individual has successfully completed the training and is annotated as an independent prescriber.

4.6 If we changed the standards for supplementary prescribers (which currently sit within the standards of proficiency), we would need to give education providers time to make amendments where necessary to their programme.

Development of the standards

4.7 Setting standards for independent prescribers would need a standards development process. This process could be undertaken through a combination of work by the Executive, the project board and scrutiny by the Committee. We would need to consult on any standards that we would produce, separate to the consultations being undertaken by the Department of Health and MHRA.

4.8 Timescales for the development of the standards would be subject to external decisions and the progress of the public consultations. The Committee will be kept updated on the project board’s progress.

Department of Health

Engagement exercise

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

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Gathering INFORMATION
Gateway Reference	14685
Title	Engagement exercise to seek views on possibilities for introducing independent prescribing responsiblilites for physiotherapists
Author	Department of Health
Publication Date	03 Sep 2010
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Directors of Adult SSs, PCT Chairs, NHS Trust Board Chairs, Directors of HR, Directors of Finance, Allied Health Professionals, GPs, Directors of Children's SSs
Circulation List	
Description	This engagement exercise provides background and invites views on possible changes to medicines legislation, which would enable physiotherapists to prescribe independently. It may then inform and assist the development of a formal public consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) proposing amendments to the relevant legislation.
Cross Ref	N/A
Superseded Docs	N/A
Action Required	Respond to the questions provided to the mailbox or in writng
Timing	**Responses required by 26 Nov 2010**
Contact Details	Shelagh Morris AHP PLT Room 5E58 Quarry House, Quarry Hill, Leeds LS2 7UE 0113 2546061
For Recipient's Use	

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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 to extend independent prescribing to appropriately trained physiotherapists, 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 physiotherapists.

This engagement exercise provides background information and invites views on the possible changes to medicines legislation, which would enable appropriately trained physiotherapists 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 2005[1] 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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Physiotherapists have been involved in the direct care of patients for many years. Physiotherapists have experience in the treatment of conditions with medicines through Patient Specific Directions[2] and Patient Group Directions[3]. Since 2005, experienced physiotherapists 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 physiotherapists.

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 a number of ways:

By using the online response form. Type your answers to the questions into the boxes provided, and then click on 'submit' after the final question (Question 11).

By email to **ahpprofessionalleadershipteam@dh.gsi.gov.uk**

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.

www.dh.gov.uk/en/FreedomOfInformation/DH_088010

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What physiotherapists do

Physiotherapists are statutorily registered health professionals who diagnose and treat disorders of movement, function, physical performance and / or pain caused by activity, disease, disability or ageing, particularly those that affect the muscles, bones, nervous system, heart, circulation and lungs. They identify and maximise movement and function through health promotion, preventative healthcare, treatment and rehabilitation using a variety of physical, electro-physical, cognitive and pharmaceutical modalities.

Following pre-registration training, many physiotherapists gain experience within a number of disciplines in their early career. Most physiotherapists then go on to specialise, or work exclusively with a specific client group. Perhaps the most well known fields of specialism include musculoskeletal (such as back pain), sports injuries, neurological rehabilitation (such as stroke, brain injury and neurological disease) and trauma rehabilitation (such as broken bones). Respiratory and cardiovascular disease are other areas in which large numbers of physiotherapists specialise. Less well-known areas in which physiotherapists specialise include women's health, acute trauma, vascular, mental health, learning disabilities, spinal injuries, occupational health and military rehabilitation.

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

Since the advent of modern medicines legislation in 1968, some physiotherapists have been using medicines safely in their professional practice via a Patient Specific Direction from a doctor. The role of medicines in physiotherapy practice has developed in recent years. The use of injection-therapy in physiotherapy became accepted practice during the 1980's and 1990's, whereby local anaesthetics and corticosteroids are administered by specialist physiotherapists trained in injection therapy for

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the management of some musculoskeletal disorders. There are now estimated to be around 3000 trained injection-therapy physiotherapists. More physiotherapists have administered medicines in practice since the introduction of Patient Group Directions in 2000 and the first physiotherapist Supplementary Prescribers qualified in 2005. Currently, Patient Specific Directions and Patient Group Directions for supply and administration, and supplementary prescribing are used in a broad range of primary care and acute settings. Physiotherapists use these mechanisms with a range of relevant medicines in clinical areas spanning musculoskeletal, pain management, neurological, respiratory, emergency care, women's health, paediatric and elderly care.

Examples of physiotherapy roles

Musculoskeletal conditions

An NHS Consultant Physiotherapist for example, will often lead a multidisciplinary team of health professionals in the management of non-surgical musculoskeletal problems, such as back pain and osteoarthritic conditions. They request and interpret investigations such as XRay, MRI scans and blood tests, make diagnoses and deliver treatment including exercises, postural advice, manipulation and medicines. Presently care can be delayed when patients have to make additional visits to other prescribers.

Respiratory physiotherapy

Respiratory physiotherapists work across a range of settings managing disorders of the heart and lungs which in turn will affect a person's ability to move and function to their best ability. Respiratory physiotherapists use a range of medicines to support optimum lung function including oxygen, bronchodilators, antibiotics and pain relief.

Respiratory physiotherapists manage and deliver hospital and domiciliary services for the management of long term conditions such as asthma, chronic obstructive pulmonary disease and cystic fibrosis. They also provide acute management for exacerbations of respiratory disease, manage ventilated patients who may have suffered trauma to the lungs and provide palliative care to those receiving end-of-life care for chronic respiratory disease.

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Women's health

Physiotherapists provide management for conditions such as stress urinary incontinence, overactive bladder symptoms, constipation, other urinary tract and bowel disorders, and specialist post–natal care for women experiencing pelvic pain and dysfunction. Many standardised care pathways advocate primary management with medicines alongside conservative interventions. Women's health physiotherapists work in hospital and community settings, some within self-referral and direct access pathways.

Sports physiotherapy

For many athletics, rugby and football clubs, a physiotherapist will be the main health professional in regular and prolonged contact with athletes and players. The majority of sports physiotherapists will either be employed by sporting federations, or will work in a self-employed capacity providing self-referral and direct access routes to care for athletes. The physiotherapist will provide immediate pitch side care such as wound management and suturing, immediate injury care and ongoing rehabilitation for a variety of conditions, in collaboration with a player's GP and or sporting federation doctors as needed. The physiotherapist is often the only health professional travelling with the sports team in the UK and overseas.

Where physiotherapists work

There are at present over 42,000 physiotherapists registered in UK and their work spans a wide cross-section of the healthcare system. Most work in the NHS. They work in hospitals and in a wide variety of community teams, GP practices and independent settings. Many physiotherapists provide care for patients and carers in their own homes, in nursing homes or day centres, in schools and in health centres. The Chartered Society of Physiotherapy estimates that around 35% of physiotherapists undertake an element of their work in the private sector. In addition physiotherapists work in other settings such as schools, occupational health, the Armed Forces and with sports teams.

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How physiotherapists are trained and regulated

Pre-registration training of physiotherapists consists of an approved three or four-year university course leading to a BSc in physiotherapy. Students who already hold a BSc in a related science subject can also follow a pre-registration MSc in physiotherapy. 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 title 'physiotherapist'. The HPC sets standards for a physiotherapist's education, training, competence, conduct, behaviour and health. Any person who wishes to practise as a physiotherapist in the UK must, by law, have their name registered with the HPC. Physiotherapists must undertake continuing professional development in order to remain 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 their register if the person falls below the standards required to ensure public safety.

The scope of physiotherapy is very wide and covers a variety of physical, cognitive and kindred interventions, including pharmaceutical interventions aimed at improving physical movement and function. A physiotherapist'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 physiotherapist must undertake the necessary ongoing training and experience to demonstrate that they are capable of 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 physiotherapist supplementary prescribers and annotates their names on the register.

This regulatory process would also apply to physiotherapist independent prescribers.

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How would physiotherapist 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, physiotherapists 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 physiotherapists as supplementary prescribers. An outline curriculum framework for physiotherapist independent prescribing would need to be developed and the HPC will have the authority to approve courses for the provision of physiotherapist independent prescribing training. Physiotherapists already qualified as supplementary prescribers may be required to undertake additional training in order to practice as independent prescribers.

Eligibility for training as a physiotherapist independent prescriber

Not all physiotherapists 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

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Physiotherapist 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 physiotherapists, to reflect physiotherapist 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?

What benefits would physiotherapist independent prescribing bring?

Independent prescribing would improve outcomes for patients, whilst also providing greater cost-effectiveness and choice for patients and commissioners. Physiotherapists 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 physiotherapy programme that has already been established for the patient. For example:

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- Many musculoskeletal services are delivered by physiotherapists and often the total patient pathway may not need the involvement of a doctor. This scenario is increasing with the adoption of self-referral to physiotherapy in the NHS. The care pathways for many musculoskeletal and orthopaedic conditions indicate the use of certain medicines, yet patients may experience a delay in effective pain management if they need to see more than one professional at different times. Independent prescribing would mean that the patient is able to receive all their care from one professional where it is appropriate to do so.
- Many chronic long-term respiratory conditions are effectively managed in the patient's own home by a physiotherapist. From time to time, a physiotherapist may assess that a patient's respiratory function is quickly declining requiring immediate additional medication to prevent an acute exacerbation of a chronic condition. Where the physiotherapist is immediately able to prescribe appropriate nebulisers and oxygen, the patient's condition may be quickly managed, which reduces the anxiety experienced by the patient and may prevent an unscheduled admission to hospital.
- For patients in many clinical settings, adequate pain control is essential to facilitate compliance and progression with exercise and conditioning based rehabilitation programmes. In addition, as rehabilitation programmes progress many patients are able to reduce their need for pain control. Physiotherapists with autonomy in medicines use would be able to ensure that the patient's medication needs are tailored to their symptoms and suitable for the stage of physiotherapy-led rehabilitation.

Independent prescribing would enable innovative service redesign to be planned to make best use of physiotherapists skills in physical movement and rehabilitation, to ensure patients receive the medicines they need at the time they need them. For example, in areas as diverse as women's health and sports physiotherapy, enabling patients immediate appropriate pharmacological management alongside physical treatment, whilst avoiding delays associated with additional appointments with other pescribers. Independent prescribing could also provide greater choice for patients, GPs and

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commissioners. By reducing unnecessary appointments with different professionals, the costs of care may reduce. As specialist physiotherapists draw upon a variety of non-pharmaceutical treatments, it is possible that fewer prescriptions overall would be needed.

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

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

The following principles would underpin prescribing responsibilities for physiotherapists:

- 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

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- 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 physiotherapist 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 physiotherapy. As part of their duty to protect the public, the HPC has a statutory responsibility to set standards of proficiency for physiotherapists. 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 physiotherapist independent prescribing.

The Chartered Society of Physiotherapy (CSP) is the professional body for the UK's chartered physiotherapists. The CSP 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 physiotherapist independent prescribers. However, the development of a single generic competency framework for all prescribers is currently being considered.

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

Continuing Professional Development (CPD):

All physiotherapists 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, physiotherapist 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 physiotherapists 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 physiotherapists 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 physiotherapist 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 physiotherapists to update the patient's relevant medical records in a timely manner.

Options for introducing physiotherapist independent prescribing

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

Option 1. No change

Highly skilled and experienced physiotherapists would continue to be eligible to train as supplementary prescribers. Depending upon local employment arrangements, appropriately trained physiotherapists would continue to supply and/or administer medicines under Patient Group Directions (PGD) and Patient Specific Directions (PSD).

Benefits

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

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Limitations

Recent scoping work[4] has indicated that the existing arrangements do not best support the needs of patients, particularly when a physiotherapist is providing self referral, first contact, diagnostic, or community care. Where patients require medicines management, outside that specified in a Patient Group Direction, 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 physiotherapists 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 physiotherapy profession spans a vast 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.

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4 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 physiotherapists 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 physiotherapists 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. This option would potentially be 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 physiotherapists would be permitted to prescribe independently any medicine for any condition, within their competence.

Benefits

Patients would be able to make direct contact with appropriately trained physiotherapists 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 physiotherapists 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 physiotherapists 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)

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

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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 some codeine preparations, which physiotherapists 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 physiotherapists 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's Misuse of Drugs Regulations.

Physiotherapists 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 physiotherapists, 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 issued[5] 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 physiotherapist independent prescribers were able to mix medicines themselves prior to administration or direct others to do so?

5 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 physiotherapist 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 or 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) in 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 physiotherapists, 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. Physiotherapists are already able to supply a limited range of medicines direct to their patients 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 physiotherapist 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 Patient Group Directions would remain unchanged.

QUESTION

8. How would it benefit patients and in what settings, if appropriately trained physiotherapists 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 physiotherapist prescribing for the impact assessment, eg. Benefits in terms of time savings to GPs, costs relating to the numbers of physiotherapists 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, age, 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 physiotherapists?

Name

Patient/Public ☐ AHP ☐ Doctor ☐ Nurse ☐ Pharmacist ☐

Organisation (if applicable)

Are you responding on behalf of the organisation ☐

Email:

Tel No:

Submit

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APPENDIX 1

Non-medical prescribing and medicines supply mechanisms[6]

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.

6 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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Main conditions and medicines – physiotherapy

System	Medicine category	Indicative conditions	Evidence/guidance
Gastro-Intestinal System	Mucosal protectants	Chronic bowel conditions Stroke care and rehabilitation Chronic pain conditions requiring opioid analgesia use MSK conditions requiring NSAID Respiratory conditions where reflux is a contributing factor e.g. asthma	NICE CG017 (dyspepsia)
	Oral rehydration therapy	Conditions causing acute uncomplicated diarrhoea e.g. overseas travel	
	Anti-motility Laxatives	Urinary/faecal incontinence where constipation is a factor	NHS Clinical Knowledge Summaries (CKS) for Constipation

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System	Medicine category	Indicative conditions	Evidence/guidance
Cardiovascular System	CPR adrenaline Anticoagulants	Cardiac collapse Stroke Post-operative conditions with prolonged reduced mobility	NICE CG8 (MS); NICE CG68 (Stroke); NICE CG35 (PD) NICE CG92 – VTE prevention NICE CG5, chronic heart failure NHS Clinical Knowledge Summaries (CKS) for Stroke and TI
Respiratory System	Short and long term b2 agonists Antimuscarinics Theophyline Combination preparations Corticosteroids Cromoglycants Anaphylaxis Respiratory stimulants	Asthma COPD Bronchiectasis Management of ventilated patients in acute settings. Cystic fibrosis Palliative Care	NICE CG101 (COPD); CG69 (RTI Antibx usage) British Thoracic Society guidelines NHS Clinical Knowledge Summaries (CKS) for Asthma COPD BTS/SIGN guidelines chronic asthma

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Respiratory System (continued)	Oxygen	As required for short-term, long-term, ambulatory, and ventilated use in patients with traumatic, short-term, long-term, and terminal respiratory conditions	
	Mucolytics		
	Expectorants		
	Humidification		
	Decongestants		
	Oral hygiene		
	Oral candida		
	Oral inflammation		
	Other – tracheotomy maintenance	Oral Preparations for ventilated patients	

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Central Nervous System	Neuropathic pain medicines e.g: Tricyclic antidepressants	Chronic pain management Pelvic pain – Women's health End of life or chronic conditions Respiratory distress Chronic pain services Neurological dystonias Chronic pelvic pain/ vulvydynia	NICE CG96 (neuropathic pain) British Pain Society Guidelines for opioid use in pain management
	Non-opioid analgesics	Simple pain Chronic pain Chronic pelvic pain	WHO analgesic ladder
	Opioid analgesia	Post-operative care Oncology services End of life care Chronic pain services Continence services	

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Central Nervous System (continued)	Anti-migraine drugs	MSK pain services e.g. headache	
	Anti-epileptics	Neurological physiotherapy – tonic-clonic seizures	
	SSRIs	Stress urinary incontinence	
	Anti-emetics	Nausea and vomiting from – surgery/from opioid analgesia use/ stomach upsets	
	Torsion dystonia	Adult and paediatric neurological physiotherapy – spasticity	Royal College of Physicians – Spasticity in Adults – Management Using Botulinum Toxin
		Torticollis, dynamic equinus foot, hemi facial spasm, hyperhidrosis	

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System	Medicine category	Indicative conditions	Evidence/guidance
Urinary tract Disorders	Anti-muscarinic agents Topical oestrogens/ Non-hormonal moisturisers Vaginal/vulval candidiasis	Detrusor instability Urinary frequency Urinary incontinence Vaginal atrophy Fungal infections Interstitial cystitis	NICE CG49 (Faecal Incont); NICE CG97 (Lwr Urinary tract infect in men); NICE CG40 (Stress Urinary Incont) NHS Clinical Knowledge Summaries (CKS) for UTI

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System	Medicine category	Indicative conditions	Evidence/guidance
Musculoskeletal and Joint Disease	Local corticosteroid injections	Local inflammatory disorders of joints and/or soft tissues e.g. OA	NHS Clinical Knowledge Summaries (CKS) for: Acute LBP chronic LBP Sprains and Strains Neck Pain OA Headache NSAIDS
	NSAIDs	Rheumatic diseases	
	Rubefacients Nutirceuticals Systemic corticosteroids	Local inflammatory disorders and injuries of joints and/or soft tissues e.g. strains, sprains, muscle and ligament tears, swelling, bruising	
	DMARDS	Degenerative joint disorder/soft tissue injuries	British Society for Rheumatology DMARD guidelines
	Skeletal muscle relaxants	Systemic inflammatory disorders/connective tissue disorders	
		Neurological dystonias e.g. stroke/head injury	
	Bisphosphonates	Osteoporosis	NICE TA160/TA161 – Osteoporosis

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System	Medicine category	Indicative conditions	Evidence/guidance
Anaesthesia	Sedatives – Benzodiazepines	Pre-operative anxiety Chronic muscle spasm Vulvydynia Respiratory distress, e.g. end of life care	
	Local Anaesthesia	Local inflammatory disorders of joints and/or soft tissues Conditions requiring ventilatory support via ET tubes	
	Entonox	Acute severe pain	
Other injectable medicines	Sodium chloride 0.9% for injection	Associated with injection therapy	
	Water for injection	Associated with respiratory care	

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System	Medicine category	Indicative conditions	Evidence/guidance
Antimicrobials	Antibiotics inhaled, oral, nebulised, topical	Post-operative infection	NICE GC74: Surgical site infection
		UTI URTI/LRTI Skin infections Throat infections Gastroenteritis Cellulitis Post-injection infection (rare)	HPA Primary Care Guidance – Management of infection guidance for Primary Care consultation and local adaptation
Others	Smoking cessation Obesity management		NICE TA39 & 123

Department of Health

Engagement exercise

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

DH INFORMATION READER BOX

Policy	Estates
HR/Workforce	Commissioning
Management	IM&T
Planning/	Finance
Clinical	Social Care/Partnership Working

Document purpose	Gathering INFORMATION
Gateway reference	**14691**
Title	ENGAGEMENT EXERCISE TO SEEK VIEWS ON POSSIBILITIES FOR INTRODUCING INDEPENDENT PRESCRIBING RESPONSIBILITIES FOR PODIATRISTS
Author	Department of Health
Publication date	3 Sept 2010
Target audience	PPCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Directors of Adult SSs, PCT Chairs, NHS Trust Board Chairs, Directors of HR, Directors of Finance, Allied Health Professionals, GPs, Directors of Children's SSs
Circulation list	
Description	This engagement exercise provides background and invites views on possible changes to medicines legislation, which would enable podiatrist to prescribe independently. It may then inform and assist the development of a formal public consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) proposing amendments to the relevant legislation.
Cross reference	N/A
Superseded docs	N/A
Action required	Respond to the questions provided to the mailbox or in writing
Timing	**Responses required by 26 Nov 2010**
Contact details	Shelagh Morris AHP PLT Room 5E58 Quarry House, Quarry Hill, Leeds LS2 7UE 0113 2546061
For recipient's use	

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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 podiatirsts), 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 2005[1] 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 Directions[2] and Patient Group Directions[3]. 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 a number of ways:

By using the online response form. Type your answers to the questions into the boxes provided, and then click on 'submit' after the final question (Question 11).

By email to **ahpprofessionalleadershipteam@dh.gsi.gov.uk**

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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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

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.

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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 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,

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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 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 debriding[4] 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

4 Debriding – cleansing to prevent infection and promote healing.

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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. 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 physiotherapist 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 Chiropodists & Podiatrists (SCP) and the Institute of Chiropodists 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 work[5] has indicated that the existing arrangements do not best support the needs of patients, particularly when a physiotherapist 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.

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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)

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?

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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 's 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 issued[6] 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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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:

Submit

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Non-medical prescribing and medicines supply mechanisms[7]

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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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 were 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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Cardiovascular system (continued)	Calcium channel blockers Peripheral vasodilators	Raynaud's phenomenon Intermittent claudication	BNF BNF TASC SIGN 2006
Respiratory System	Oxygen Stimulants	Use in day-case theatre settings Life-saving situations	Anaphylaxis (adrenaline/ chlorphenamine/atropine) 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 Rubefacients Nutirceuticals	Local inflammatory disorders and injuries of joints and/or soft tissues e.g. strains, sprains, muscle and ligament tears, swelling, bruising	

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Musculoskeletal and Joint Disease (continued)	Systemic corticosteroids Skeletal muscle relaxants Bisphosphonates	Degenerative joint disorder/soft tissue injuries Systemic inflammatory disorders/connective tissue disorders Osteoporosis	NICE TA160/TA161 – Osteoporosis http://www.nice.org.uk/nicemedia/live/12131/43326/43326.pdf
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