

Non-medical prescribing, patient group directions and minor ailment schemes in the treatment of drug misusers



The National Treatment Agency for Substance Misuse

The National Treatment Agency for Substance Misuse (NTA) is a special health authority within the NHS, established by Government in 2001, to improve the availability, capacity and effectiveness of treatment for drug misuse in England.

Treatment can reduce the harm caused by drug misuse to individuals' well-being, to public health and to community safety. The Home Office estimates that there are approximately 250,000–300,000 problematic drug misusers in England who require treatment.

The overall purpose of the NTA is to:

- Double the number of people in effective, well-managed treatment between 1998 and 2008
- Increase the percentage of those successfully completing or appropriately continuing treatment year-on-year.

Reader information

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1 Executive summary

Non-medical prescribing (particularly nurse and pharmacist prescribing), patient group directions (PGDs) and minor ailment schemes (MAS) are all part of a range of NHS reforms designed to improve patients' access to medicines, develop workforce capability, utilise skills more effectively and ensure provision of more accessible and effective patient care. Successful implementation requires robust clinical governance mechanisms and teamworking, as well as access to specialist pharmaceutical support. Commissioners, managers and practitioners can now explore the potential of all these different mechanisms as ways of improving access to medicines for drug misusers.

1.1 Non-medical prescribing

Successful implementation of non-medical prescribing can result in significant improvements in access to medicines for drug misusers with reduced waiting times, increased choice of appointment times and increased throughput of clients. Medical time can be released to deal with more complex cases and the improved skill mix within teams can result in successful service redesign with overall improvement of care and treatment of service users. Ensuring only appropriate healthcare professionals go forward for training and ensuring that teams have a clear vision of how non-medical prescribing will improve patient care, be safe and make better use of clinicians' time are the first steps in developing a robust clinical governance framework for non-medical prescribing to be implemented.

Up to 20 per cent of qualified non-medical prescribers in primary care may not actually start prescribing. Many of the reasons for this can be attributed to lack of strategic planning, delayed agreement of clinical governance procedures, lack of audit, and lack of support for the service or non-medical prescriber. This represents a waste of resources.

Drug misuse is a special field because nurse and pharmacist prescribers will almost invariably need to consider prescribing controlled drugs. This brings added responsibility and it is important that commissioners and managers are clear about the drugs that nurse and pharmacist prescribers can prescribe, which prescription forms to use, and when they can or cannot work as supplementary prescribers or independent prescribers. Commissioners, managers and practitioners also need to be aware of changes to controlled drugs legislation likely to occur in 2008.

This is a practical step-by-step guide to implementing non-medical prescribing together with brief descriptions of practice-based examples.

1.2 Patient group directions

Patient group directions (PGDs) for supply and administration of medicines can be utilised by a range of registered healthcare professionals, including nurses and pharmacists. Practitioners must be authorised by their employers for each particular medicine they will be administering or supplying under a PGD. The most common PGDs in use for drug-using clients are for hepatitis vaccination and managing withdrawal symptoms, but they can also be used for supplying a wide range of medicines in a wide range of settings such as prisons and needle exchanges. As with non-medical prescribing, legislation is precise and implementation requires robust clinical governance structures. However, where introduced successfully, PGDs can provide a cost-effective way of providing quicker access to treatment for many patients.

1.3 Minor ailment schemes

Minor ailment schemes are provided through community pharmacies in many parts of the country. They provide a mechanism for patients to access medicines without visiting their GPs. Many of these pharmacies also provide other enhanced services to drug misusers but unfortunately few drug misusers or drug services are aware that minor ailment schemes exist. By working with primary care trusts and community pharmacists, it may be possible to extend such schemes to provide care and treatment of minor ailments to drug misusers.

2 Introduction

2.1 Why produce guidance?

Non-medical prescribing (NMP) – particularly nurse and pharmacist prescribing, patient group directions (PGDs) and minor ailment schemes (MAS) – are all part of a range of NHS reforms designed to improve patient access to medicines, develop workforce capability, utilise skills more effectively and ensure provision of more accessible and effective patient care. These processes all have a role to play in the care and treatment of drug misusers.

There are no centrally held records for the number of nurses and pharmacists who are in training or qualified to prescribe in the field of substance misuse. However, anecdotal reports suggest that, in England, there may be 80–100 who are trained, in training or considering training. In addition, many nurses and pharmacists have been involved in PGDs for administering hepatitis vaccines and other medicines to drug or alcohol clients, and some community pharmacists operating MAS are keen to ensure their services attract and include drug misusers.

What is important to recognise is that despite these mechanisms being available, nurses, pharmacists, managers and commissioners have sometimes found it difficult to get these processes implemented on the ground. Over 10,000 nurses and nearly 1,000 pharmacists in England have now qualified as non-medical prescribers. Statistics from the Prescription Pricing Division of the NHS Business Services Authority (PPD) indicate that around 80 per cent of those qualified in primary care are prescribing.

This guidance is therefore designed to:

- Describe the terms non-medical prescribing (NMP), patient group directions (PGDs) and minor ailment schemes (MAS) and explain when, where and how these mechanisms can be used to the benefit of drug (and alcohol) using clients
- Set out the necessary steps that need to be considered before and during implementation, in order to ensure successful introduction
- Signpost clinicians, managers and commissioners to others in their localities who may already be providing such services for other patient groups
- Highlight the clinical governance mechanisms that need to be in place in order to ensure such services are being provided safely and effectively
- Remind clinicians that prescribing controlled drugs does require special care and attention, in particular ensuring full compliance with the law
- Describe practice examples.

2.2 Who is this guidance for?

This guidance has been produced as a resource for commissioners, provider organisations and practitioners who are considering, developing or already delivering non-medical prescribing and related mechanisms for making medicines available to drug misusers. This guidance refers to nurses and pharmacists throughout, as it is most unlikely that an allied health professional (AHP) supplementary prescriber would be in a position to prescribe for the treatment of drug misusers. However AHPs would be able to prescribe for drug misusers provided they are working within their competences.

2.3 What is it?

This guidance is divided into sections. Section 3 provides an overview of nurse and pharmacist involvement in the treatment of drug misusers and the importance of clinical governance. Sections 4, 5 and 6 describe how non-medical prescribing, patient group directions and minor ailment schemes can be implemented successfully to the benefit of drug misusers and alcohol clients.

3 Drug treatment context

3.1 Overview of nurse and pharmacist involvement

The 1999 edition of Drug Misuse and Dependence – Guidelines on Clinical Management (DH, 1999) emphasised the importance of different professionals working together to benefit the care of drug misusers. Of particular importance were the increased roles and responsibilities of nurses and pharmacists in the management of drug misusers. Nurses were increasingly more involved in the treatment of patients by taking on a keyworker role, for example, and pharmacists were being asked to provide daily supervised consumption of prescribed methadone and later buprenorphine, as well as monitoring compliance with treatment.

In 2001, the RCGP introduced the Certificate in the Management of Drug Misuse in Primary Care, aimed at GPs with a special interest in drug misuse. Significantly, this training was opened up in 2002 to pharmacists, nurses and service users. Later this was renamed the part two certificate. A part one certificate was introduced, also multidisciplinary, aimed at generalist GPs, pharmacists, nurses and user-advocates.

In addition, pharmacists and pharmacy technicians were given access to open learning programmes provided free of charge by the Centre for Pharmacy Postgraduate Education (CPPE). These CPPE packs include Substance Use and Misuse for Pharmacists (CPPE, 2006a) and Substance Use and Misuse: Fundamentals and Practicalities for the Pharmacy Technician (CPPE, 2006b).

Significantly, this increased access to and availability of treatment and training has ensured that there are now cohorts of nurses, pharmacists and technicians with wide-ranging experience of working with drug misusers. As a result, these nurses and pharmacists have developed, or are developing, the necessary experience and competences to move on to provide ever-expanding services for drug misusers. This has coincided with national drivers aimed at improving patient access to medicines, such as the introduction of minor ailment schemes, implementation of patient group directions and non-medical prescribing. The implementation of the pharmacy and GP contracts as well as the promotion of Mental Health: New Ways of Working for Everyone (DH, 2007a) have been aimed at ensuring roles and responsibilities are aligned with competence rather than profession. The 2007 update of the clinical guidelines, Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007b), continues to promote multidisciplinary working and significantly includes a section explaining the benefits of non-medical prescribing and patient group directions.

For managers, commissioners and practitioners, the first principle of treatment must be that patient safety is paramount. Therefore,

implementation of such schemes must be within a robust clinical governance framework.

3.2 Clinical governance

Non medical prescribing (NMP), patient group directions (PGDs) and minor ailment schemes (MAS) represent relatively new means of providing service users with medication to help them achieve their treatment goals. They fit well with NHS priorities to increase patient choice and capacity, but in order to provide an improvement in care they must also be provided within a robust clinical governance framework. The Health Act 1999 places on each health authority, primary care trust and NHS trust a duty to implement and maintain arrangements to monitor and improve the quality of healthcare they provide to individuals. NHS trusts are required to introduce governance frameworks to ensure that nurse and pharmacist prescribers – or nurses and pharmacists administering or supplying medicines under a PGD or by means of a MAS – are competent and supported by a governance structure.

Clinical governance NMP self-assessment tools are available from the Royal Pharmaceutical Society of Great Britain, some NHS trusts and strategic health authority NMP leads. Examples are:

- Clinical Governance Framework for Pharmacist Prescribers and organisations commissioning or participating in pharmacist prescribing (RPSGB, 2005)
- Non-Medical Prescribing in North East London Clinical Governance Self-Assessment and Action Planning Tool. (NELM, 2007)
- Non-medical prescribing. A framework to support clinical governance in trusts across Thames Valley (Thames Valley and South Central SHA, 2004)

The setting where the non-medical prescriber will be working or the PGD used is a vital consideration. There are already examples of specialist substance misuse nurse or pharmacist prescribers working in primary care, specialist prescribing teams, community pharmacies and prisons, and of PGDs being used in all these settings as well as private and voluntary settings. Each setting has a different approach to clinical governance and different approaches to care. In order for the NMP or PGD to be integrated into the setting as safely as possible, the clinical governance arrangements for each setting must be carefully considered. Commissioners must acknowledge and ensure that nurse and pharmacist prescribers are not being placed in situations outside their competences and that there are structures in place for them to question the safety of the practices being commissioned.

3.3 Controlled drugs legislation and the accountable officer

It is important not to forget that prescribing, administering or supplying medicines to drug misusers almost invariably means working with controlled drugs, which does carry special additional responsibilities. The Misuse of Drugs Regulations 2001, as amended, permit the use of CDs in medicine and divide CDs into various schedules, which determine the level of control concerning prescribing, ordering, supplying, possession, storage, record keeping and destruction. Examples are:

- Schedule 2 (CD) drugs include methadone, dexamphetamine, morphine and diamorphine
- Schedule 3 (CD) drugs include buprenorphine and temazepam
- Schedule 4 Part I (CD Benz) drugs include most benzodiazepines such as diazepam and chlordiazepoxide
- Schedule 4 Part II (CD Anab) drugs include a number of anabolic steroids
- Schedule 5 (CD Inv) drugs are preparations that contain drugs listed in Schedules 2 and 3, but in such small quantities that they are harmless and pose minimal risk of misuse.

The Shipman inquiry, which followed the murder of over 200 people by a GP who had injected his patients with lethal doses of diamorphine, has produced its fourth report, *The Regulation of Controlled Drugs in the Community* (Shipman Inquiry, 2004). It has resulted in an overhaul of controlled drugs legislation and many legislative changes, in relation to the provision of prescribing for substance misusers, have been introduced, with more anticipated. Part of this new legislation and DH guidance requires NHS healthcare providers and independent hospitals to appoint an accountable officer to be responsible for the management of controlled drugs and related governance issues in their organisations.

Health professionals who do not comply with current legislation are at risk of criminal prosecution and losing their professional registrations. All practitioners who work with controlled drugs must liaise with their local accountable officers.

4 Non-medical prescribing

4.1 Background

When the government introduced non-medical prescribing, the intention was to improve health services and patient care by making it easier for patients to get the medicines they need through best utilising the skills of health professionals. This has involved a stepwise process starting with the Cumberledge report in 1986, with the first nurse prescribing in a community setting piloted in 1994. Legislation in 2001 and 2002 expanded nurse prescribing, and regulations in 2003 introduced supplementary prescribing for nurses and pharmacists, followed by four other health professions in 2005. From May 2006, nurse and pharmacist independent prescribers have been able to prescribe any medicine for any medical condition within their competences including, for nurse prescribers, some controlled drugs (CDs) for specific medical conditions. Nurse and pharmacist prescribing training later changed so that those attending courses could automatically qualify as independent prescribers.

It is just over 18 months since the Department of Health revised its guidance on prescribing, *Improving Patient Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing in the NHS In England* (DH, 2006). This very useful document details the entry and prescribing training requirements for nurses and pharmacists as well as governance arrangements that need to be in place.

The potential for the use of nurse and pharmacist prescribers in the substance misuse field is being increasingly realised. The field of drug misuse carries a higher level of risk than other areas of community prescribing. Annual death rates of drug misusers in treatment can be as high as one per cent. It is therefore highly probable that nurse or pharmacist prescribers in this field will experience death of one of their clients. In some cases, this may be due to the prescribed drug being used inappropriately. The higher level of risk and responsibility for non-medical prescribers of CDs needs to be recognised.

4.2 Aims of this section

This section gives the definition and a brief description of non-medical prescribing, including the legal and good practice requirements. This is followed by guidance on the implementation and development of non-medical prescribing by nurses and pharmacists, which is supported by a clear set of principles and arrangements:

- To ensure service improvement and increased access to medication for patients
- To ensure the selection of appropriate clinicians to undertake the non-medical prescribing qualification

- To guide managers and clinicians through the process of implementing non-medical prescribing within their services
- To ensure robust clinical governance arrangements support the implementation of non-medical prescribing.

Once a decision has been made to implement non-medical prescribing in a service, it can take approximately 12 months before the nurse or pharmacist will be working as an NMP. The prescribing training course itself is 38 days spread over up to six months. This guidance is aimed at helping clinicians, managers and commissioners understand the processes involved so that non-medical prescribing can be implemented safely, effectively and speedily to the benefit of patients. A number of practice examples are described briefly at the end of the section to demonstrate ways in which non-medical prescribing is already being used in the treatment of drug misusers.

It is important to emphasise one of the key messages in Roles and Responsibilities of Doctors in the Provision of Treatment for Drug and Alcohol Users (RCPsych, 2005) – that treatment systems require a complete spectrum of medical provisions to meet the range of needs and numbers of substance misusers requiring treatment. A competent and suitably trained NMP, provided with appropriate governance arrangements and support, can fulfil some but not all of these roles and responsibilities.

4.3 Definitions and brief description

All NMPs are professionally accountable for their prescribing decisions, including any actions and omissions, and cannot delegate this accountability to another person. They must only ever prescribe within their levels of experience and areas of competence, acting in accordance with their professional code and ethics. If they move to a new role, the requirements of the new role must be considered as NMPs must only ever prescribe within their levels of competence and experience.

It is important to distinguish between the three different types of non-medical prescribing; community practitioner nurse prescribers, supplementary prescribing, and nurse and pharmacist independent prescribing.

4.3.1 A community practitioner nurse prescriber

This is a registered nurse or midwife who is qualified to prescribe appliances, dressings and a smaller number of medicines listed in the Nurse Prescribers' Formulary for Community Practitioners (NPF). The NPF is reproduced in the Drug Tariff, which is published monthly by the Prescription Pricing Division. The range of drugs and appliances they can prescribe is limited but includes, for example, wound management products, laxatives and mild analgesics.

4.3.2 Supplementary prescribing

Supplementary prescribing is defined in legislation as a “voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement.” A supplementary prescriber can be a registered nurse or midwife, pharmacist, chiropodist, podiatrist, physiotherapist, radiographer or optometrist and can prescribe any drug named on the CMP.

It involves diagnosis by the doctor and agreement by the patient to be managed by the supplementary prescriber, and the preparation of a CMP – agreed by both prescribers – that is specific to a named patient and that patient's specific conditions. The patient's prescriptions are then managed by the supplementary prescriber within the terms of the CMP, with regular clinical reviews of the arrangement by the independent prescriber. In addition, the independent prescriber (a doctor) and supplementary prescriber must share access to, consult and use the same common patient record (DH, 2007b). Legislation dictates what the CMP must contain and examples of CMPs used in substance misuse are included on the Department of Health website (DH, 2007c).

Appropriately qualified and trained nurses and pharmacists working as supplementary prescribers can, with a doctor's agreement, prescribe licensed Schedule 2, 3, 4 and 5 controlled drugs within the parameters of a mandatory CMP. This includes the prescribing of methadone, buprenorphine and benzodiazepines for the treatment of substance misuse. The only exceptions in the treatment of drug addiction are diamorphine (heroin), dipipanone and cocaine. These can only be prescribed for addiction by medical practitioners who hold a special licence issued by the Home Secretary (a non-medical prescriber is not classed as a medical practitioner in this context).

Prescribing a prescription only medicine (POM) as a supplementary prescriber but outside a CMP constitutes a criminal offence under medicines regulations. Prescribing a non-POM outside the agreement of a CMP could result in the supplementary prescriber being disciplined by an employer and referral to the NMP's respective professional body should a charge of professional misconduct follow.

There are no legal restrictions on the clinical conditions that supplementary prescribers may treat, although the National Prescribing Centre suggests that, because of the need to draw up a clinical management plan before commencing prescribing, supplementary prescribing is best suited to the management of continuing or long-term medical conditions.

4.3.3 Independent prescribing

This is defined in legislation as “prescribing by a practitioner (such as a doctor, dentist, nurse, pharmacist – and soon an

optometrist) responsible and accountable for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing.”

Therefore, NMPs are accountable and take responsibility for the clinical assessment of patients, for establishing a diagnosis and the clinical management required, as well as for prescribing where necessary and for the appropriateness of any prescription.

All current and future NMP training for nurses and pharmacists will result in them qualifying as independent prescribers. Those pharmacists who have qualified as supplementary prescribers are required to complete an additional short conversion course should they wish to become registered as independent NMPs.

Since May 2006, nurse and pharmacist independent prescribers have been able to prescribe independently any licensed medicine for any medical condition within their competences including, for nurses only, some controlled drugs (CDs) for specific medical conditions listed – including acute alcohol withdrawal.

The substance misuse field has lagged behind other clinical specialties, partly because of the current restrictions on the independent prescribing of CDs. In practice, no NMPs (or doctors) will prescribe for every medical condition and will restrict themselves to areas where they are competent.

Pharmacist independent prescribers (PIPs) are as yet unable to prescribe CDs independently. Nurse independent prescribers (NIPs) are currently (as of December 2007) able to prescribe 12 controlled drugs independently, including diamorphine and morphine, but solely for specified medical conditions. For example, NIPs working within their own competences are able to prescribe:

- Buprenorphine transdermal patches for use in palliative care
- Chlordiazepoxide or diazepam oral for the treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it
- Diamorphine oral or by injection for use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief.

NIPs cannot prescribe any CDs independently for the treatment of drug addiction (except for acute alcohol withdrawal). Therefore, they cannot currently (as of December 2007) independently prescribe methadone, buprenorphine or diazepam for the treatment of drug misusers. However, changes in legislation are likely in early 2008.

From January 2007, pharmacists started to qualify as pharmacist independent prescribers. PIPs are not currently allowed to prescribe independently any scheduled CDs at all (including Schedule 5 CDs such as codeine linctus, kaolin and morphine mixture, and pholcodine linctus, although they are allowed to sell

or supply Schedule 5 controlled drugs). Changes are likely in early 2008.

However, proposed changes to Home Office misuse of drugs regulations mean that these restrictions may be removed in the near future. If approved, nurse and pharmacist independent prescribers will be able to independently prescribe CDs used in the treatment of addiction such as methadone, buprenorphine, diazepam, and any other licensed medicine provided the condition treated falls within their areas of competence.

Nurse and pharmacist independent prescribers must not independently prescribe unlicensed medicines. However, prescribing a licensed medicine for an unlicensed indication is allowable, provided nurse or pharmacist prescribers take full responsibility for their actions.

4.4 Registration of non-medical prescribers

For nurse or pharmacist prescribers to practise as NMPs there must be, against their names in the professional register, an annotation or entry signifying they are qualified as supplementary prescribers or independent prescribers. Chief executives are legally accountable for the quality of care delivered to patients and all NMPs must work within their employers' clinical governance frameworks. NMPs are accountable to their employers and their professional regulatory body.

- Confirmation of a nurse prescriber's registration can be obtained by contacting the NMC confirmation interactive voice response system (Tel: 020 7631 3200 from 06.00–21.00, seven days a week)
- Confirmation of a pharmacist prescriber's registration can be obtained from the Royal Pharmaceutical Society of Great Britain website, www.rpsgb.org.uk.

If an employer decides to appoint an NMP who is already qualified and registered as an NMP, it is important for the manager to ensure the NMP is competent to prescribe in the chosen area of medicine. Line managers and lead clinicians are advised to ensure a newly appointed NMP is processed through the appropriate governance mechanisms in the same way that an NMP training and qualifying while in their employment would be.

4.5 Professional indemnity

NMPs are expected to use professional judgement and work within their professional competences. They are accountable for and must be able to justify their actions.

NMPs are strongly recommended by their professional body to ensure that they have professional indemnity insurance by means of a professional organisation or trade union. However, when an NMP is employed by an NHS (or other) organisation, that organisation also has vicarious liability for the NMP's actions. For the purposes of vicarious liability, it is important that the

prescribing role is reflected in the job description for the post. This does not replace the NMP's own professional accountability.

4.6 Supplementary prescribing of controlled drugs in substance misuse

Section 4.3.2 details the CDs that current legislation (as of December 2007) allows nurse and pharmacist supplementary prescribers to prescribe.

The NTA is aware of approximately 80 nurses and pharmacists working as supplementary prescribers in the substance misuse field who are actively prescribing controlled drugs such as methadone, buprenorphine and diazepam under a clinical management plan, have just qualified, or are in training or planning to train to become NMPs. Practice examples of nurse and pharmacist supplementary prescribing are given at the end of this section.

The dependence on agreement by a doctor before an SP can prescribe can result in a necessary short delay in treatment for some patients. However, when working as an SP, the input and agreement of a doctor at initial assessment and development of the CMP ensure there is a clearly defined and agreed treatment plan and line of accountability.

With increased experience, some SPs prescribing for drug misusers are providing a convincing argument to allow them to prescribe more CDs independently once regulations are changed to allow this. However, some SPs believe supplementary prescribing of CDs to be a safer way of working and would be reluctant to take the next step of prescribing CDs independently in the treatment of substance misuse, should the law change.

4.7 Independent prescribing in substance misuse

Suitably qualified nurse and pharmacist prescribers can independently prescribe any licensed medicines for any medical conditions within their competences, with the exception of controlled drugs. These may include medicines such as antidepressants, lofexidine, naltrexone and medicines for minor ailments, but only if they are working within their competences and they have been suitably authorised by their employers to prescribe such medicines.

Nurse and pharmacist independent prescribers may prescribe as supplementary prescribers (working within a CMP), independent prescribers, or a mixture of both depending on the governance processes of their employers and their own competences, confidence and expertise in different fields of medicine. Legislation is likely to change in 2008 to allow independent non-medical prescribing of CDs. In substance misuse, some NHS trusts may make the decision to only allow nurse and pharmacist prescribers

to practise as supplementary prescribers, but this will be a local decision for individual trusts.

4.8 Benefits of non-medical prescribers

The benefits of using non-medical prescribers, particularly nurse and pharmacist prescribers, have already been identified in many areas of medicine and many of these can be extrapolated to the management and treatment of drug misusers:

- Providing services in areas and at times where doctors are hard to recruit
- Improving patient care through quicker access to medicines
- Increasing patient access by service reconfiguration
- Increasing patient choice about who, when and where services can be accessed
- Allowing doctors time to deal more effectively with complex cases
- Reducing waiting time for treatment or review
- Preventing additional waiting time for patients to see a doctor to get a prescription
- Increasing skill mix in the team by using nurse or pharmacist prescribers
- Financial benefits may include reducing doctors' time input, reducing staff time, cutting out duplicated effort to produce a prescription, preventing admission to hospital, preventing secondary care referrals and managing patients in a community setting
- NMPs can take on education and training roles increasing the competence and knowledge of the whole team and facilitating multidisciplinary prescribing decisions.

4.9 Risks of non-medical prescribing

Despite the potential advantages listed in the previous section, there is a cautious approach to introducing non-medical prescribing for substance misuse, in particular of controlled drugs. The field of substance misuse carries a higher level of risk than other areas of prescribing. The expected legislation to expand prescribing of CDs independently for the treatment of substance misusers must not weaken the requirement for oversight of individual practitioners' work.

By concentrating on prescribing, especially when commissioning services, the treatment the client receives may become more focused on prescribing – with assessment, care planning and care co-ordination not being given the emphasis they warrant. It is vital that the NMP has adequate support and resources to ensure that each client has a care plan and care co-ordination in line with the NTA's Care Planning Practice Guide (NTA, 2006).

Doctors and managers in the team may not understand that nurse and pharmacist prescribers must not prescribe outside their competences. NMPs may be put under pressure to prescribe other medicines for which they have little competence or knowledge. To protect the nurse or pharmacist prescriber, an agreed list of medicines may need to be produced involving the doctor, manager and NMP.

Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007b) states that “clinicians need to work with a range of professionals” and encourages multidisciplinary working. Nurses and pharmacists working as independent and supplementary prescribers must be adequately tied into a multidisciplinary team to ensure they are not working in isolation and have access to adequate supervision.

Capacity may not increase as much as expected, since nurses and pharmacists may be more used to spending longer with service users and may require a little more time set aside for more intensive clinical supervision. On the other hand, some nurse and pharmacist prescribers may begin to spend less time with service users and this could lead to a reduction in quality unless clients are supported by additional keyworker sessions.

Special consideration needs to be given as to how private and voluntary sector agencies employing NMPs, especially if prescribing CDs, will be monitored to ensure their practice is compliant with best practice. The role of the accountable officer is key.

4.10 Commissioning and management issues

Commissioners and budget holders may view the use of nurse and pharmacist prescribers in place of doctors as financially attractive. There are some anecdotal reports suggesting that this may not necessarily be a cheaper option. Nurse and pharmacist prescribers generally spend more time with individual patients and may not be able to manage the same caseload. However, there are other examples where a nurse or pharmacist prescriber is specifically employed to prescribe, with other practitioners taking the keyworker role. In some circumstances, this can result in an increased throughput of clients and an improved access to treatment for clients.

In some services, non-medical prescribing has been implemented by managers as part of service redesign, freeing up medical time to deal with cases that are more complex. It is important that commissioners and managers wishing to introduce non-medical prescribing ensure that the nurse or pharmacist prescriber has adequate clinical supervision, access to ongoing training and CPD, and robust clinical governance support. Having several NMPs within a team or trust can ensure service continuity covering staff absences and also has the advantage of providing NMPs with peer support.

Managers and commissioners must ensure that nurse and pharmacist prescribers have a significant level of experience, expertise and competence before they start the training to become an NMP. They should not be expected to manage patients with complex needs without easy access to adequate support. Commissioners need to be aware that there will be a limited supply of nurses and pharmacists competent to prescribe in the area of substance misuse and will need to ensure there are adequate resources in place to cover sickness, annual leave and study leave. In many cases, this will mean access to a suitably experienced doctor.

Other considerations, which should be taken into account, concern the professional background of the prescriber. Once qualified as NMPs it must not be assumed that nurses and pharmacists can do exactly the same work to the same level of competence as each other or as a medical prescriber; for example:

- Doctors are trained specifically in diagnostic skills through taking a clinical history, physical examination of clinical signs and using investigations to aid diagnosis and clinical management
- Psychiatrists will have greater skills in assessing the mental state of patients and the diagnosis and treatment of mental health disorders
- Pharmacists and mental health nurses may not be able to manage all physical health checks or psychosocial interventions
- Nurses may have limited pharmacology training and may not be so aware of the potential for drug interactions
- Pharmacists may have little experience of dealing with social services and child protection issues.

From a safety point of view, the separate roles of prescribing, dispensing, keyworking, and administering must still be definable, with each role providing a safety check for other members of the team. Commissioning an NMP may mean that some of these roles can be joined together, but this must be balanced against other factors. Commissioners and managers should ensure that nurse and pharmacist prescribers are adequately supported in their roles by ensuring they have ready access to more experienced specialists.

4.11 Implementing non-medical prescribing

What is important to reiterate is that non-medical prescribing by nurses and pharmacists is well established in many areas of medicine.

4.11.1 Why should services consider implementing non-medical prescribing?

The benefits (and risks) of non medical prescribing have already been highlighted. In many cases the introduction of non-medical prescribing into a service is championed by one person – this may be the lead doctor or the manager of the service. Often there is a nurse or pharmacist who is keen to become trained as an NMP but without the necessary managerial and governance support, the person can become quickly disillusioned. Thinking about how non-medical prescribing will benefit patients (Table 1) is a sensible starting point.

The important emphasis here is that the implementation of non-medical prescribing should be for the benefit of the patient, not just because a nurse or pharmacist thinks it would be a good idea to become qualified. Working through the clinical governance principles detailed in the following sections will help ensure that a high-quality non-medical prescribing service is developed, implemented and maintained safely.

4.11.2 How to get started

To get started, there are a number of clinical governance action points (see Table 2) that will guide managers and clinicians as to where to go for help. The important message here is that “you are not alone”. It is highly probable that there are nurses and pharmacists already practising as NMPs locally and making contact with them is vital at this very early stage.

If it is impossible to find anyone locally, contact the PCT or the NHS trust lead for non-medical prescribing or the SHA strategic lead. The Department of Health provides contact details for the NMP lead in each strategic health authority (DH, 2007e). This person will then be able to provide contact details for local leads as well as providing support, links to local and regional networks of NMPs and links to local and regional NMP clinical governance systems already in place.

Clinical governance principle	Action point
Clear lines of responsibility and accountability for overall quality of clinical care	<p>The service manager and/or lead doctor will need to:</p> <ul style="list-style-type: none"> Identify how non-medical prescribing will improve patient care, make better use of clinician’s time, be safe. Incorporate non-medical prescribing into the organisation’s existing and future clinical governance arrangements.

Table 1: Thinking about how non-medical prescribing will benefit patients

Clinical governance principle	Action point
Organisational structure exists with the NMP lead reporting directly to the professional executive committee and to the board.	<p>The service manager and/or lead doctor will need to:</p> <ul style="list-style-type: none"> Identify how non-medical prescribing will improve patient care, make better use of clinician’s time, be safe. Incorporate non-medical prescribing into the organisation’s existing and future clinical governance arrangements.
There is a service and trust strategy for implementation and governance of NMPs	<p>Develop service strategy for NMPs – link with trust strategy (if private or voluntary agency – link with local NHS trust strategy)</p> <p>Ensure doctors and lead clinicians are included at all stages of planning and development for implementation of non-medical prescribing</p>
Recruitment to NMP course should include an assessment of where prescribing benefits the patient and the candidate has a willingness to prescribe once qualified.	<p>How, when and where will non-medical prescribing be implemented?</p> <p>What are benefits for patients?</p> <p>Who is suitable for training</p>

Table 2: Getting started – clinical governance action points for introducing and implementing non-medical prescribing

Local leads should be able to provide advice, support and information on applying for courses, course entrance requirements and availability of courses. For NHS-employed nurses and pharmacists, the employing NHS trust should already have a trust policy and a trust NMP lead who will be able to advise the potential nurse or pharmacist prescriber and the service manager. If there is no local policy, then the regional lead should be able to provide examples of NMP policies which can then be adapted for the local service. If this will involve the prescribing of controlled drugs, the accountable officer must also be informed.

It is strongly advised that NMPs should always be overseen by an NHS trust whether the service is commissioned by that trust or not. Special consideration needs to be given to private and voluntary sector agencies that are employing NMPs, especially if they may be prescribing controlled drugs. Monitoring needs to ensure their practice is compliant with best practice. This would include ensuring appropriate clinical governance was in place. The role of the accountable officer is important in monitoring this.

4.11.3 Applying to become an NMP – service development requirements

It is a requirement in Department of Health guidance (DH, 2006) that “all individuals selected for non medical prescribing training must have the opportunity to prescribe in the post that they occupy on completion of training”, and “their post is one in which ... there is a local need for them to prescribe”. Therefore, it is vital before nurses and pharmacists are given approval to attend training that managers are able and willing to support the individual once qualified.

Before applying to train as NMPs, most courses will require potential NMPs to provide evidence that they have considered how they will use their qualifications, how this will improve patient care and to clarify they have discussed it with the line manager and budget holder for the service. To help with this process, most NHS trusts have a screening process to ensure only appropriate nurses and pharmacists are accepted onto the course.

The following considerations should be included:

- Patient safety is paramount
- Non-medical prescribing must offer benefit to patients (and the NHS) in terms of quicker and more efficient access to medicines for patients
- Non-medical prescribing must demonstrate better use of the professional's skills
- Decisions to train individuals as NMP's should be linked to personal development plans and candidates should be assessed for competency related to knowledge and skills in their area of potential prescribing practice
- Agreement from a suitable supervisor (a designated medical practitioner – see section 4.11.4) to provide support during training and after successful completion of the course
- The application should explain how cover will be arranged when the NMP is absent. This will be expected to be provided by either a doctor or another NMP. Future plans for additional staff to become NMPs should also be included
- Proposals should demonstrate that all the elements of clinical governance have been considered in detail with confirmation that these will be implemented where appropriate
- Proposals should indicate which prescribing budget will be used for paying the non-medical prescribing costs, including what the current mechanisms are for prescribing medication and how non-medical prescribing will affect patient care
- In the majority of cases, it is anticipated that non-medical prescribing implementation will be through service redesign
- Commissioners and employers may wish to explore the possibility of providing backfill funding to cover the time when the nurse or pharmacist is in training.

4.11.4 Eligibility to access non-medical prescribing preparation and training

It is important to note that non-medical prescribing training courses are generic courses and are not specific to mental health, secondary care, primary care or substance misuse. In some regions a more specific higher education institution (HEI) NMP course is contracted by the strategic health authority and the authority or local NHS trust may fund some places as part of that contract. NHS nurses and pharmacists working in substance misuse should be able to access these courses in the same way as any other NHS nurse or pharmacist in their local NHS trusts.

The NMP course will normally enable nurses and pharmacists to qualify as both supplementary and independent prescribers. Pharmacists who qualified before 2007 will only have qualified as supplementary prescribers and will need to take a short conversion course to become independent prescribers.

All NMP students will need to have designated medical practitioners (DMP) from their own fields of practice who will act as medical supervisors and assessors. DMPs provide supervision, support and assist with shadowing opportunities during the course, ensuring that the student is exposed to a broad range of learning opportunities. Training Non-Medical Prescribers in Practice (NPC, 2005) provides full guidance on the role of the DMP.

There are strict eligibility criteria for nurses and pharmacists wishing to attend the NMP course. The training programme consists of approximately 26 days face-to-face taught time at an HEI, although some elements may be delivered as distance learning. There are also 12 practice placement days, during which time nurses or pharmacists would be expected to demonstrate competences in prescribing in their areas of practice. This programme of training usually takes place over a period of up to six months, with taught days of one or two days a week at the HEI. There are significant elements of self-directed study required as part of the course. The course also requires completion of a personal portfolio, an observed clinical examination and two unseen examination papers. Pharmacists should have a minimum of at least two years post-qualification experience in the area of clinical practice and nurses should have three years.

Nurses and pharmacists applying for the course would be expected to have completed suitable postgraduate study in drug misuse. Local governance processes also need to ensure that the individual NMP is competent to prescribe in a particular setting and service.

It is important that managers and those attending the course recognise that the course needs a significant time commitment from the student and the DMP. Table 3 provides a checklist of clinical governance action points when organising training for NMPs.

Clinical governance principle	Action point
Supervision and mentoring	Find a DMP willing to support the NMP during training (and if possible once qualified)
Continuous professional development to ensure prescribing skills kept up to date	Has the nurse or pharmacist: <ul style="list-style-type: none"> The stamina and competence to complete the course? Proven track record in relation to clinical safety and record keeping? Evidence of post-registration study and application to practice e.g. RCGP part 2 or equivalent? Psychopharmacology training? Ability to perform physical health checks? Demonstrated team working and networking skills (those that can are more likely to seek advice if unsure) Access to education and training provision
Backfill arrangements during training	Determine how backfill arrangements will be organised and paid for. The nurse or pharmacist cannot be expected to continue with all elements of their full-time job during training.

Table 3: Accessing training – clinical governance action points for introducing and implementing non-medical prescribing

4.11.5 Once qualified as a nurse or pharmacist prescriber

There are, however, other steps that need to be completed before a nurse or pharmacist actually starts to prescribe. But much of this work should be begun and undertaken before the prescriber starts his or her course and during it. It requires NMPs, their line managers and independent prescribing leads (for example, the consultant psychiatrist, GPwSI or lead GP) for the service to work together and have a clear vision of where non-medical prescribing will fit into the service. The checklist in Table 4 can be used by nurses and pharmacists and their managers to ensure they have in place all the necessary clinical governance requirements.

4.12 Clinical governance checklist

Table 4 is adapted from Preparing to Prescribe (Berkshire Healthcare NHS Foundation Trust's, 2007 (awaiting publication))

The lead clinician, service manager, line manager and NMP are jointly responsible for guaranteeing prescribing clinics are organised to ensure the NMP prescribes in a manner fully

compliant with high standards of prescribing practice as well as the legal, professional, ethical requirements and local policies

4.13 Clinical management plans

Clinical management plans (CMPs – see section 4.3.2) are a useful tool in gathering knowledge and confidence around prescribing. However, they can be time consuming to produce and there is sometimes resistance and misunderstandings from medical colleagues about the reasons for CMPs. When first introducing non-medical prescribing to a team, full practitioner involvement is necessary to ensure colleagues are educated as to the legislative requirements of CMPs. The following information on CMPs is adapted from the Nursing and Midwifery Council's A-Z Advice Sheet (NMC, 2006) on clinical management plans.

Developing a CMP has often been described as a bureaucratic nightmare, but the plan does not have to be complex. However, the law in respect of CMPs is very clear. The independent medical or dental prescriber must always agree the diagnosis and a CMP for the patient before the supplementary prescriber (SP) can prescribe. The CMP must be developed in partnership between the independent medical prescriber and the SP and with the patient's agreement. It must be individualised and relate to specific medications for specific conditions, and be determined by the needs of the patient following diagnosis.

It is important that CMPs remain individualised. The Medicines and Healthcare Products Regulatory Agency (MHRA) – whose responsibility it is to ensure medicines legislation is complied with – is clear that if an independent prescriber agrees in advance that the SP can prescribe for a patient, by virtue of them being on an agreed practice register and using the same CMP for all patients and then incorporating these into the patient's computer records, this is illegal practice and does not meet the legislative requirements.

Providing the patient has been diagnosed first by the independent prescriber – and the plan is individualised, written and agreed with the independent prescriber, SP and patient – there is no reason why the CMP should not be as simple as possible.

The CMP can refer to national or local evidence-based guidelines to identify the medicines that are to be prescribed, or circumstances where dosage, frequency or formulation should be changed. There is no need to repeat the advice in these guidelines on the CMP. Also, as patient information is contained in the shared patient record there is no need to repeat it on the CMP, unless it is essential for clarity and safety.

Examples of CMPs used in the treatment of drug misusers can be found on the substance misuse management in general practice website (www.smmgp.org.uk).

1. Attend relevant local medicines management training to ensure compliance with local policies on prescribing; pharmaceutical representatives; safe and secure handling of prescription forms; and Drugs and Therapeutics Committee requirements to monitor prescribing. (See also Standards for Medicines Management (Nursing and Midwifery Council, 2007))
2. Give a copy of notification of registration for non-medical prescribing from the NMP's professional body to the trust NMP lead (who is required to keep an up-to-date list)
3. Arrange professional indemnity if necessary (advice from professional body or union)
4. Amend job descriptions to incorporate non-medical prescribing role and the parameters within which the NMP will work. What jobs will be reduced or given to someone else in the team to allow the NMP time to take on the new roles and responsibilities? Consider making this a pharmacist with special interest role (ref 4) or clinical nurse specialist role
5. Develop and agree where relevant CMPs (for supplementary prescribers), treatment plans and care plans (for independent prescribers) for the NMP's area of practice. What medicines is the employer content for the NMP to prescribe?
6. Clarify with the manager, budget holder and trust or lead pharmacist which prescription forms the NMP will be using. Ensure the local NHS accountable officer is aware if the NMP will be prescribing controlled drugs
7. Agree with line or service manager how clinics will be organised; how patients will be referred to the NMP; how annual leave and sickness will be covered; whether any additional administrative support will be needed and how additional administrative support will be accessed
8. Can the NMP access a single patient record?
9. How will dispensing pharmacists and GP practices be informed of intention to prescribe including the scope of medications the NMP will be prescribing? Provide sample signature to local pharmacies?
10. Are doctors and other team members aware of and supportive of the NMP's intention to prescribe?
11. Consider with the manager and lead clinician a probationary period prior to starting prescribing. Who will make the final decision when to start prescribing? How will this be formally authorised? Will this be as a supplementary prescriber? How and when will the NMP be formally authorised to prescribe independently?
12. How will the NMP's prescribing be monitored and who will monitor? Examples include audits, keeping a prescribing log, access to ePACT, patient record system and NDTMS
13. Write a standard operating procedure covering area of work as a non-medical prescriber identifying policies, procedures, roles and responsibilities
14. Attendance at regular clinical supervision. Agree additional clinical supervision appropriate to role as a NMP. Has the lead clinician – for example the consultant or GPwSI – agreed to provide supervision to the same level as provided to a doctor in the same or similar team? Research in other fields of medicine has shown that NMPs who lack support can come across more problems.
15. Access to an experienced prescribing colleague (doctor or NMP) for support and guidance in decisionmaking
16. Identify how ongoing non-medical prescribing continuing professional development (CPD) needs will be met. Attend local academic meetings provided for local prescribers (doctors and NMPs)
17. Keep up to date with evidence-based practice. Access to information about national guidelines (such as NICE, clinical guidelines and best practice documents). Register with the national electronic library for medicines at www.nelms.nhs.uk. This provides a regular bulletin service listing all new developments in medicines including changes in legislation, new products, drug alerts, new guidelines etc.
18. Join an NMP network, whether local, national or specific to substance misuse, for example via the SMMGP; national prescribing centre, RPSGB, RCN (NTA regional managers may be aware of local or national networks.).
19. How will incidents and near-misses be reported? Access to "yellow card scheme" for reporting adverse reactions.
20. Risk management plan to ensure that potential risks associated with extending clinical practice are recognised and minimised. Significant event audits regularly carried out.

Table 4: Clinical governance checklist for qualified non-medical prescribers prior to starting to prescribe in a service

Paper type	Colour	Purpose, order code and format
FP10NC and FP10 HNC	Green	Handwritten prescription – including prescriber details and address – printed by manufacturer. For use by GPs and hospitals. Supplied in pads of 50. Hospital-based NMPs can use the FP10HNC prescription forms.
FP10SS	Green	Computer single sheet prescription – prescriber details to be overprinted by computer prescribing system. For use by GPs (and hospital doctors and NMPs using accredited prescription writing software systems). Supplied in boxes of 2,000 forms. Overprinting requirements differ for primary and secondary care prescriptions
FP10MDA (pre-printed)	Blue	Drug misuse installment prescription for prescribing controlled drugs such as methadone, buprenorphine and diazepam. Preprinted with prescriber details by manufacturer – intended for “occasional use” by GPs and doctors using primary care prescriptions (FP10MDA-S, as pads of ten forms), NMPs using primary care prescriptions (FP10MDA-SP, as pads of ten forms)
FP10HMDA (pre-printed). Sometimes referred to as FP10MDA-AD	Blue	Drug misuse installment prescription for hospitals. Preprinted with hospital unit details by manufacturer – intended for “occasional use” by hospital doctors and NMPs using secondary care prescriptions (FP10HMDA-S, as pads of 50 forms).
FP10MDA-SS	Blue	Computer compatible single sheet blank form with prescriber details overprinted by prescriber’s local computer system, for use by GPs, hospitals and non-medical prescribers – supplied in packs of 500 forms. The overprinting requirements for primary care and secondary care prescriptions differ.
FP10SP	Lilac	Handwritten prescription. Prescriber details preprinted by the manufacturer, along with a description of the type of prescriber, for example “nurse independent/supplementary prescriber, NMC No ...” or “pharmacist independent/supplementary prescriber, RPSGB No ...” at the top of the prescribing box. Supplied as pads of 50 forms.
FP10PCDNC	Pink	Private controlled drug prescription, with prescriber details preprinted by manufacturer. For use when prescribing controlled drugs in a private environment only. Available to private prescribers in pads of ten
FP10PCDSS	Pink	Computer compatible private controlled drug single sheet prescription. For use when prescribing controlled drugs in a private environment only. Prescriber details to be overprinted by local prescriber’s computer software system. Available to all private prescribers in boxes of 500

Table 5: Prescription forms that can be used by nurse or pharmacist prescribers

4.14 Prescription forms

Obtaining prescription forms has sometimes been a stumbling block for some NMPs. This section describes the different types of prescription forms, who to contact for advice and medicines management requirements for prescribing.

For each NMP an individual decision will need to be made in conjunction with the lead doctor for the prescribing team, the budget holder for the prescribing costs and the lead medicines management pharmacist, as to which prescriptions the NMP will use. This will depend on what the service is using already and where the NMP intends to work. For NHS prescriptions and private prescriptions for controlled drugs to be dispensed at a community pharmacy, secure FP10 forms will be used. These forms incorporate serial numbers and anti-counterfeit features. They are purchased by PCTs and hospital trusts.

Table 5 describes the different types of forms that can be used by a nurse or pharmacist prescriber. A number of prescription types

have the prescriber details pre-printed by the manufacturer and drug details can be handwritten. However, other forms are blank and are intended to be put through local printers in order to computer generate the prescriber details and the prescribed medication. Where such overprinting is done locally, prescribers should ensure that the details on the prescription comply with the relevant approved overprint specification; a list is available from the Prescription Pricing Division (PPD, 2006).

All prescribers should ensure there is an audit trail in place for recording ordering, receipt and issue of prescriptions. This should include recording serial numbers of prescriptions forms and witnessed destruction of any voided prescriptions.

4.14.1 Prescription writing

As well as complying with legal requirements, nurse and pharmacist prescribers will need to follow local medicines management policies on prescribing. Each prescriber will need to

have ready access to pharmaceutical advice. The Nursing and Midwifery Council has produced standards of proficiency for nurse and midwife prescribers, available from www.nmc-uk.org.uk and in Standards for Medicines Management (NMC, 2007). In particular:

- **The quantity** supplied should be in accordance with legislation and local policies. On installment prescriptions, no more than 14 days supply can be prescribed. On non-installment prescription forms, a maximum of 30 days supply of a controlled drug should only be supplied
- **Controlled drugs.** NMPs prescribing controlled drugs must be fully compliant with current DH controlled drug guidance – in particular keeping abreast of post-Shipman changes to legislation and good practice. These are detailed in Annex 3 of Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007b). NMPs can keep up to date with legislative changes as well as new guidelines and changes in clinical practice by registering with the national electronic library for medicines (www.nelm.nhs.uk) and by regularly checking the controlled drugs section of the Department of Health website. The accountable officer for the local NHS healthcare provider or independent hospital must be informed if an NMP will be prescribing any Schedule 2 (such as methadone) or Schedule 3 (such as buprenorphine) controlled drugs.
- **Medicines should be listed individually by generic name, strength, route of administration, dosage and frequency.** Brand or proprietary names should not be used unless there are clinical implications for a specific brand – for example Subutex® – in which case the brand name must be included in the CMP or patient plan and on the prescription.

4.14.2 Nurse and pharmacist prescribers

Nurse and pharmacist prescribers writing prescriptions:

- Can only issue prescriptions bearing their own names and NMC or RPSGB numbers, or bearing the details of the hospital unit on whose behalf they are prescribing.
- Should understand which budget holder is charged for any drugs they prescribe and ideally should have some formal written authorisation confirming their authority to prescribe against that budget and what drugs they are authorised to prescribe.
- Must never prescribe for themselves, or for relatives, friends, or colleagues.

Supplementary prescribers can only prescribe:

- Medicines referred to in the CMP
- For patients active on their caseload with an agreed CMP.

4.14.3 Primary care prescription forms

NMPs will need to contact the local primary care trust (PCT) medicines management lead pharmacist, who will explain the procedure for obtaining prescriptions. The PCT pharmacist will need to know who holds the budget for the prescribing and will arrange for a prescriber budget code from the Prescription Pricing Division (PPD), which is unique to the individual NMP. Once a code has been allocated, pre-printed prescription forms or blank forms for overprinting can be ordered for use within the practice or hospital as applicable (some hospital substance misuse services may arrange to use primary care prescriptions). The GP practice prescribing software will have to be programmed to print out prescriptions for the new NMP. Some software manufacturers have been slow to include pharmacists. The practice manager or PCT prescribing lead should be able to arrange contact with the software programmers if there are problems configuring the software.

NMPs (or budget holders) will need to ensure agreement has been reached with the prescribing lead of the PCT on:

- Whether they should use a practice-based prescription pad; for example, if they are working only in one GP practice. In such cases, the name of the practice and PPD approved practice budget code will be already printed in the address box on the form.
- Whether they use a PCT-based prescription pad; for example, if they are working across several GP practices. In such cases, the practice code is left blank for the NMP to fill in the relevant GP code.

This ensures the patient's GP practice is charged for the cost of the drugs. Alternatively, the PCT may arrange for the NMP to prescribe using a dummy practice code where all the prescribing costs, irrespective of the GP, are charged to one cost centre.

Whichever system is used, the PCT medicines management lead will be able to monitor all prescribing by the NMP using the web-based Electronic Prescribing Analysis and Cost (ePACT) information service provided by the PPD. This database is password protected and only suitably trained people are allowed access. However, NMPs and their managers and budget holders should contact the PCT prescribing lead regularly to obtain reports of prescribing, which can include the drugs prescribed and their cost, the frequency of prescribing of each particular drug, and whether a drug was prescribed by brand name or by approved name. These reports are produced monthly about six to ten weeks after the prescription is dispensed and can then be used to monitor and audit the NMP's individual prescribing practice. Reports from ePACT do not provide individual patient details.

In the event of concerns about a particular prescription, for example fraud, the original prescription can be recalled from the PPD.

4.14.4 Private prescriptions for controlled drugs

From spring 2006, nurse independent prescribers may issue private prescriptions for any licensed medicines for any medical condition that they are competent to prescribe, except for most controlled drugs. Supplementary prescribers may also issue private prescriptions for any medication covered by the clinical management plan provided the doctor has agreed. Nursing and pharmaceutical professional bodies recommend that NMPs have professional indemnity insurance regardless of whether they prescribe within or outside the NHS. The accountable officer will also need to be informed if the NMP will be prescribing CDs.

A special CD prescription form (FP10PCD/FP10PCDSS – see section 4.14) must be used for any private prescription of Schedule 2 and 3 controlled drugs that will be dispensed in the community. This affects all private prescribers. CD private prescription forms are centrally collated and monitored in the same way as NHS prescriptions.

Any private prescriber of Schedule 2 or 3 controlled drugs, to be dispensed in the community, needs to apply for a private prescriber identification number. It is a legal requirement for this number to be specified, whichever type of prescription form is used. Private prescribers requiring a private prescriber identification number need to contact their local primary care trust (PCT). After carrying out a number of checks, the PCT informs the PPD about the prescriber's details. The PPD then writes to the PCT to provide the prescriber number and the PCT informs the prescriber. Prescribers then order their prescription forms via the PCT.

When private prescriptions for Schedule 2 and 3 CDs have been dispensed, the prescription form is sent to the PPD for processing and inclusion in the ePACT information service. PCTs can then access ePACT via the PPD's website using passwords to monitor their local private prescribers of CDs, in the same way as they monitor NHS activity. The responsibility for this lies with the PCT, usually the PCT prescribing adviser and the accountable officer for CDs.

4.14.5 Secondary care prescription forms

NMPs will need to contact the chief pharmacist or designated lead responsible for medicines management in the trust for advice on which prescription forms the NMP will use. Hospital inpatient and outpatient prescription forms are usually designed and produced locally and the pharmacist will be able to provide information about when and where the forms should be used, how to obtain them, the security arrangements for the forms, how costs of drugs prescribed will be charged to individual budgets

and how medication errors will be monitored and prescribing audited.

Where a secondary care NMP's NHS prescriptions are to be dispensed by a community pharmacist, NMPs should prescribe using the same prescription cost centre as other members of the prescribing team. The disadvantage of this system is that the non-medical prescribing cannot be separately identified via the Electronic Prescribing Analysis and Cost (ePACT) information service or costs separated from prescribing by other members of the team for audit purposes.

Hospital-based NMPs should prescribe using FP10HNC (green pre-printed) forms, FP10SS (green blank) forms or FP10HMDA (blue) forms. It is strongly recommended, although not a legal requirement for secondary care prescriptions, that the prescription forms are overprinted with "nurse independent/supplementary prescriber, NMC No ..." or "pharmacist independent/supplementary prescriber, RPSGB No ..." at the top of the prescribing area on these forms. A rubber stamp can be used (Arial 7–10pt, adjusted so the text fits on one line with "NMC No ..." or "RPSGB No ..." on a second line underneath). This will assist community pharmacists who will need to be able to confirm the prescriber's identity and eligibility to prescribe.

The PPD provides detailed specifications of what should be printed on the prescription form when NMPs work in a hospital environment (PPD, 2006).

In some cases, secondary care-based community drug teams may use practice prescriptions provided by the PCT in particular for prescribing CDs. This has the advantage that each individual prescriber, including each NMP, in the community drug team can be allocated a separate prescribing code enabling monitoring and auditing of prescribing at individual practitioner level rather than service level. As this will require close working with PCT pharmacists, this should be organised as a formal agreement between the secondary care NHS trust and the PCT. This agreement will need to include clinical governance arrangements and agreement as to how drug costs will be paid. The accountable officers for the organisations concerned should also be informed. NMPs must ensure they clearly understand which prescription forms they are authorised to prescribe on and which cost centre their prescribing will be charged to.

Many specialist substance misuse workers may provide prescribing advice to GPs. Again it is important that the GP is kept informed when advice is coming from a non-medical prescriber.

4.14.6 Electronic prescribing

Electronic transfer of prescriptions is currently being introduced across the country. This allows the prescriber to send a prescription electronically to a pharmacy chosen by the patient. Currently, legislation does not allow the electronic transfer of

prescriptions for controlled drugs. A Home Office consultation document has proposed looking at introducing electronic transfer of controlled drug prescriptions. Again nurse and pharmacist prescribers will need to ensure locally that as prescribing software is updated, it includes prescribing by NMPs.

4.15 The dispensing pharmacist

As with medical prescribers, NMPs, when prescribing for drug misusers, should be part of a multidisciplinary team and have a shared care agreement in place that includes the dispensing pharmacist. This will ensure the patient has given permission for the pharmacist to share relevant information about the patient with the NMP.

It is a legal requirement for pharmacists to confirm the legality of prescriptions before they can dispense them. This includes the authority of the person signing the prescription as well as confirmation that signatures are genuine. To further prevent fraud, the pharmacist cannot confirm a prescription is genuine by telephoning the telephone number printed on the prescription form in case that too is a forgery. Therefore pharmacists are required to identify unknown names and signatures by alternative means.

There are a number of examples of community pharmacists failing to dispense prescriptions written by NMPs because they do not recognise the signature. NMPs are advised to contact the community pharmacist who will be dispensing the prescription.

In all cases, NMPs should ensure their names are printed next to the signature to ensure dispensing pharmacists are able to verify the authenticity of prescriptions and to contact prescribers should there be any query on them.

It is not the responsibility of the dispensing pharmacist to determine whether a drug prescribed is included in the CMP or whether the NMP is competent to prescribe a particular drug. However, pharmacists may wish to confirm that an NMP is working as a supplementary prescriber within a CMP when prescribing CDs. In addition, the dispensing pharmacist will check not only the legality and authority of the prescription, but also any concerns about the prescription.

Where nurses and pharmacists are writing prescriptions dispensed by the hospital pharmacist, they should ensure the hospital pharmacy is aware when the non-medical prescriber is authorised to prescribe and provide the pharmacy with a sample signature. This should be organised as part of the medicines management training.

4.16 Authorisation to prescribe

It is advisable for NMPs, employers and managers to have a formal governance process in place to authorise an NMP to start prescribing. This could be confirmation from the NMP and the

manager that they have complied with an agreed checklist (such as the one given in Table 4) that can be used to confirm that the NMP, manager, lead clinician and employer are confident that appropriate systems are in place. NMPs should ensure there is clear documentation that agreement has been given by the employer for them to prescribe to ensure the employer will accept vicarious liability for an NMP.

Again, it is likely that all NHS trusts will already have such a system in place.

4.17 Supplementary prescribing or independent prescribing?

No NMP is expected to, and should not, prescribe from the full range of drugs listed in the BNF. NMPs should only prescribe within their competence, usually from a list of drugs previously agreed by their employers. Depending on their expertise and competence, NMPs working with drug misusers may be able to treat common infections, for example, skin, chest, urine, mouth or genital area infections; as well as managing conditions and medicines such as wound care, withdrawal symptoms, constipation, alcohol-related anti-craving medicines, vitamins, anxiety, depression and emergency contraception. Local decisions will need to be made and processes agreed as to when NMPs should start to independently prescribe medicines outside the field of substance misuse.

It would appear sensible for most NMPs working in the field of substance misuse to work as supplementary prescribers initially while they demonstrate their competence in working with each drug. The CMP will ensure the nurse or pharmacist is only prescribing drugs in specific circumstances for named patients which both the supplementary and the independent prescriber have agreed are within the supplementary prescriber's competence. NMPs will need to spend time developing confidence, starting slowly and gradually increasing their prescribing profile. This system will also ensure the NMP is supported through the process of setting up what will, in effect, be a new service.

Different skills are needed in order to be able to prescribe independently, including critical appraisal skills as well as diagnostic and assessment skills. Getting the diagnosis right requires good history-taking skills, expertise in making (working) diagnoses and importantly, awareness of differential diagnoses and the ability to act appropriately on alarm signs and symptoms.

Individual employers and NHS trusts are likely to have in place local clinical governance processes which may restrict NMPs; for example, some NHS trusts will only allow NMPs to prescribe as SPs or may require all NMPs to work as SPs for a probationary period.

4.17.1 Moving from supplementary prescribing to independent prescribing

A systematic approach is recommended for employers authorising nurse and pharmacist prescribers in substance misuse to prescribe independently, which should be automatically linked to the annual appraisal framework and personal development plans. The doctor providing clinical supervision of the NMP should also be closely involved in any appraisal process and should be specifically asked their opinion as to the suitability of an NMP to move from supplementary to independent status.

Further changes to enable and expand prescribing of CDs by nurse prescribers, and the introduction of pharmacist independent prescribing of CDs are likely in early 2008. Robust governance arrangements should be in place to ensure that NMPs appointed to work as IPs in drug misuse have sufficient competence, experience and training to manage the specific risks associated with working with CDs and working with this special client group.

Lead doctors – for example the lead consultant psychiatrist, clinical director or GP practice lead – should be closely involved in the organisation's clinical governance committee's decision as to whether independent prescribing of CDs by NMPs should be introduced into their services. If approved, a probationary period is recommended whereby the NMP works for a period as a supplementary prescriber within agreed CMPs. This will identify the areas of expertise required of the NMP in a particular setting and ensures training and continuing professional development requirements are fulfilled before the NMP takes on independent prescribing of these drugs. This system will also provide maximum flexibility for an employer so that an agreed formulary of drugs appropriate to the individual NMP and the individual setting are agreed in a systematic and considered way.

4.17.2 Prescribing within one's competence

Nurse and pharmacist prescribers will need to be aware that as they move to independent prescribing, they may be asked by patients and other practitioners to prescribe drugs outside their areas of expertise and competence. This can be a particular problem for prescribers, both medical and non-medical, working in substance misuse services when patients may not have a GP or may present with an acute physical health problem needing urgent attention. Prescribers can be put under considerable pressure to prescribe and newly authorised independent prescribers may find it difficult to refuse. All prescribers – both medical and non-medical – are professionally accountable for all their prescribing decisions, which cannot be delegated. Therefore, clinical governance systems will need to be in place to support prescribers through such decision processes, supporting them to make sure they do not prescribe outside their areas of competence. This may take the forms of agreed formularies of drugs and conditions that prescribers are specifically authorised

to prescribe. Colleagues should also be informed to ensure they do not expect nurses or pharmacists to prescribe in situations outside their competence. All prescribing should be monitored by a pharmacist to ensure compliance with local formularies, including antibiotic policies and the budget holder will want to ensure that all prescribers, including nurse and pharmacist prescribers, do not prescribe for situations outside the remit of the commissioned service.

If nurses or pharmacists move to another area of practice, they must consider the requirements of the new role and ensure they only continue to prescribe within their area of competence.

4.18 Maintaining excellence in non-medical prescribing

Nurses and pharmacists should use clinical supervision arrangements as an opportunity for reflection on prescribing, as well as other aspects of practice. The model of clinical supervision should be agreed at a local level, taking account of other staff support mechanisms and resources.

Nurse and pharmacist prescribers who work outside NHS settings, where clinical governance systems may be different or may not be applied in the same way, must ensure they comply with requirements to demonstrate their competence to practice. For example, they must be able to show how they audit their practice, keep up-to-date with current guidance, and how they safeguard the patients in their care.

NMPs, like any other prescriber, should be supported to develop their prescribing so that, in time, they can take on the management of more complex cases. The key here is to ensure that individual NMPs have regular appraisal, clinical supervision, access to peer support and are supported to maintain best practice, which includes not working in isolation.

4.18.1 Maintaining good practice

"The current schemes for training nurse and pharmacist prescribers are too short to fully equip a professional for independent prescribing practice. It is essential that additional training support and mentorship are available after such training programmes." (Avery and Pringle, 2005).

For NMPs, maintaining competency is about being able to do what an NMP says they can do. Nurse and pharmacist prescribers will be expected to keep up-to-date with best practice in the management of conditions for which they may prescribe. Nurses may use the learning from this activity as part of their post registration education and practice (PREP) activity. For pharmacists it will contribute to the RPSGB's CPD requirements. Documents (NPC, 2001; 2006) are available from the NPC's website (www.npc.ppa.nhs.uk) and are useful tools.

However, some NMPs can find it difficult to access CPD specifically relevant to their own needs and NMPs should be supported and encouraged:

- To attend medical supervision and academic training events
- To audit their practice regularly
- To peer-review their prescribing
- To join local and national NMP networks
- To be included in training to prevent and review medication and prescribing errors.

Possibly one of the most important skills of any prescriber is the ability to say “I don’t know” and systems should be in place for the NMP to be able to refer a patient, or a specific problem, to a more experienced colleague.

There are a number of local and national networks for NMPs, for example, organised through the RPSGB, the RCN and the National Prescribing Centre. In some cases these are specifically for nurses and pharmacists, working in the field of substance misuses, for example, the SMMGP (Substance Misuse Management in General Practice) runs an online forum for nurse and pharmacist prescribers. A national substance misuse non-medical prescribing group has been formed by a group of NMPs which aims to run two or three meetings a year across the country. (Contact mike.flanagan@surreypct.nhs.uk or caroline.frayne@nhs.net for more information.) In addition, some NTA regional teams have helped to facilitate local NMP networks, for example, in Leeds.

Nurse and pharmacist prescribers must be able to demonstrate relevant competence to be able to manage, treat and prescribe for patients. Ideally, this should be in the form of a competence-based assessment to reflect the NMP’s current work. Competences for NHS-employed staff may be assessed through the Knowledge and Skills Framework (KSF) and it may be possible for an appraisal template to be devised specifically for line managers to use when appraising NMPs. As part of their training, NMPs will have been required to produce a portfolio as evidence of their competence and NMPs should be encouraged, and are well advised, to continue to maintain such a portfolio.

The doctor providing clinical supervision to the NMP should ideally be involved in developing the NMP’s learning objectives, particularly if the nurse or pharmacist’s line manager is not themselves an NMP.

4.18.2 Good practice for non-medical prescribers

As part of good practice, non-medical prescribers should:

- Only ever order a medicine for patients they have assessed for care
- Communicate with service users and carers in a way that allows the prescriber to understand service users’ needs,

concerns and expectations about their medicines and enables service users to make informed choices about their treatment, including the risks and benefits

- Ensure that patients are aware that they are being treated by an NMP and of the scope and limits of their prescribing
- Be able to audit patient views of non-medical prescribing
- Prescribe within their own competence and within their own scope of practice
- Prescribe safely, appropriately, and cost-effectively
- Ensure patients receive appropriate information about their prescribed medication; should participate in audits of the communication pathways they use, to ensure the correct patient information (relating to prescribing) is included in a timely manner in patients’ medical notes, or when care is transferred to another prescriber
- Monitor responses to therapy and modify treatment or refer appropriately
- Not prescribe for themselves or anyone else with whom they have a close personal relationship (such as family and friends), other than in an emergency, and where there are no other reasonable options without compromising patient care
- Develop effective relationships with the service users’ keyworkers, the multidisciplinary team and the wider healthcare team involved in service user care
- Write prescriptions clearly and legibly, and ensure that they are identifiable as prescribers and only write prescriptions on a prescription pad bearing their own unique NMC/RPSGB registration number
- Only prescribe when they have access to individual patients’ main service records at the time of prescribing
- Make a contemporaneous, comprehensive, clear record of their consultations and prescriptions for individual patients in the main clinical records. If this is not possible, it should be added within 48 hours of the consultation
- Store prescription pads safely and take appropriate action if they are lost or stolen (contact the local medicines management pharmacist or trust chief pharmacist)
- Not ask for any inducement, gift or hospitality that may affect or be seen to affect their judgement when making a prescribing decision
- Attend regular managerial and clinical supervision, making diary notes of discussions at prescribing supervision meetings of what was discussed and who attended
- Regularly participate in CPD relating to prescribing and maintain a record of their CPD activity within their CPD portfolio

- Where acting as pharmacist prescribers, separate prescribing and dispensing whenever possible. Where NMPs are both prescribing and dispensing or administering for individual patients, a suitably competent second person should be involved in accuracy checking of the dispensed or administered medicine
- Carry out any relevant physical examination of service users competently and with regard to patients' dignity and privacy
- Be able to demonstrate improved service to patients through audit and patient satisfaction surveys.

If nurses or pharmacists have not prescribed for over one year (this may be due to a changing role or the need for support) or failed to maintain their relevant CPD requirements, their employers may decide to withdraw support for the NMP to prescribe.

4.18.3 Good practice for service managers

As part of good practice, managers should:

- Understand that the NMP training is rigorous and of a high standard but that it is a "generic" qualification. The same training is provided to nurses who are training to prescribe in diabetes and pharmacists training to prescribe cancer chemotherapy
- Ensure NMPs have regular managerial supervision as well as appropriate and adequate clinical supervision. It is important to recognise that nurse and pharmacist prescribers may require more intense and more frequent clinical supervision
- Ensure NMPs have formal approval from their employers to prescribe drugs
- Be responsible for ensuring the competency of any NMPs who are employed to work as NMPs (including any NMP who is already qualified when first employed). This includes ensuring NMPs complete any required additional training relevant to their jobs
- Ensure NMPs have access to adequate and appropriate CPD
- Ensure that relevant CPD requirements are included in NMPs' annual personal development plans and appraisals
- Ensure NMPs are supported in their role; for example, assessing the need for additional administrative support
- Ensure the workloads of NMPs are regularly reviewed and that if additional duties are taken on, some duties can be handed over to other members of staff.

4.19 What can go wrong?

Many of the reasons for failure to implement non-medical prescribing in a service or practice can be attributed to lack of strategic planning, inadequate clinical governance procedures and

lack of support for the service or the NMP (Jones *et al.*, 2007). Following this NTA guidance will help to prevent these problems.

In addition there are other problems that can occur:

- **Patient dissatisfaction** – this can be prevented or minimised by providing a service user leaflet explaining what non-medical prescribing is. Again, most NHS organisations should have a generic leaflet that can be made available to substance misuse service clients
- **Pay** – nurses and pharmacists working for NHS organisations will be employed under the Agenda for Change pay structure (AfC). This pay structure does not specifically recognise non-medical prescribing. This can result in dissatisfaction for nurses and pharmacists who may believe they are entitled to a review of their salary because of increased responsibility. Managers and commissioners are advised to discuss this at the outset with potential NMPs to clarify their expectations. Managers are also alerted to the possibility that it may take time before an NMP will actually start prescribing. Job descriptions will need to be carefully worded to reflect any increase in responsibilities. NIPs may find the "nurse advanced" profile for "lead specialist, clinical nurse specialist, senior specialist nurse" (Band 7) useful to refer to when writing job descriptions to be assessed under AfC. Assessors are unlikely to be aware of any of the practicalities, responsibilities, accountabilities, training or governance requirements, which will all need to be detailed in the job description
- **Promotion** – it is not uncommon for any practitioner who undertakes additional training to be attracted to apply for managerial posts. Often such posts do not involve a need for non-medical prescribing. Implementation of service redesign to introduce non-medical prescribing should also include possibilities for developing a clinical stream of staff development, such as pharmacists with special interest (DH, 2007f; g; h; i), advanced practitioner roles, nurse consultants, and consultant pharmacist roles
- **Prescriber concerns** – as non-medical prescribing is introduced, some medical prescribers working in services may feel threatened either in their jobs or their status as lead clinicians. Usually non-medical prescribing is introduced in order to reduce the workload for doctors, especially where there is a shortage of doctor time available. Doctors already prescribing and who may be directly affected by the introduction of non-medical prescribing should be included in discussions at the outset. They will be needed to provide clinical supervision of NMPs and will need to be reassured about the role of NMPs and be told that they are not accountable for their prescribing. Generally, the NMP will be expected to manage routine prescribing leaving the doctor more time to manage more complicated cases.

There are also lessons that NMPs should learn from the history of medical practitioners prescribing controlled drugs for drug misusers.

4.20 Learning lessons from medical practitioners prescribing controlled drugs

Controlled drug prescribing standards in the treatment of drug misusers have historically been poor in some areas and this needs to be acknowledged and recognised. The recent joint NTA and Healthcare Commission Improvement Review report, *Improving Services for Substance Misusers* (HCC & NTA, 2006), focused on community prescribing services that provide specialised drug treatment. The results of the review showed that improvements can be made across all areas of community (substance misuse) prescribing services. The report highlighted that some treatment systems are much better developed than others and that:

- More emphasis on clinical governance is needed
- Improvements could be made in relation to the consistent use of care plans
- The level of risk assessment was low, with 70 per cent of partnerships scoring weak when assessing and managing risks for service users.

The Royal College of General Practitioners' Guide to the Management of Substance Misuse in Primary Care (Gerada, 2005) highlights three of the themes emerging from doctors appearing before the GMC. These are:

- **Naive doctors**, who feel they have a mission to treat drug misusers. They tend to work in an isolated manner. Unsupported and often not working in a multidisciplinary team, these doctors may become overwhelmed leading them to take short cuts in treatment. Such doctors can become burnt out or may end up before the GMC, accused of irresponsible prescribing
- **Maverick doctors** who believe that they know best. They tend to have some training in drug misuse and have worked in the addictions field. They usually ignore the advice from others practising in the area and believe that clinical guidelines are for others. These doctors are likely to come to the attention of the GMC when a serious incident such as overdose or patient death occurs
- **Criminal doctors**, although rare, do occur – Harold Shipman being the most notorious example. There are other examples of doctors who have supplied drugs for monetary gain.

It is important that the lessons learned from the practice of doctors prescribing CDs inform decisions about implementation of non-medical prescribing. In addition, NMPs need to be alert to the possibility that they may be accused of being naive, maverick or criminal in their prescribing behaviour.

Commissioners and managers must ensure that NMPs are not placed in situations outside their competences and that there are structures in place for NMPs to question the safety of the practices being commissioned and managed.

4.21 National Treatment Agency recommendations

Robust clinical governance systems are essential. There are few aspects of what may be considered a robust clinical governance framework that are binding – those that relate to the syllabus for training and the responsibilities of individual practitioners. There are few requirements placed upon employers and, where suggestions regarding clinical governance remain optional, there is a risk that safe standards will not be maintained. In any case, smaller organisations may experience difficulties providing the same level of support as larger ones because they do not have the infrastructure required. The NTA recommends:

- An appropriate and robust clinical governance framework should be put in place at the organisational planning stage, before NMPs commence their training
- Due to the additional risks associated with the prescribing of CDs for drug misusers, employers should ensure they have robust systems in place, approved by the accountable officer, for specifically authorising nurses and pharmacists to independently prescribe individual CDs for specific approved indications (should legislation be changed to allow this)
- A gradual transition whereby the NMP works initially for a period as a supplementary prescriber within agreed CMPs before moving to independent prescribing. This will identify the areas of expertise required of the nurse or pharmacist in a particular setting and ensures training and CPD requirements are fulfilled before the NMP takes on independent prescribing of these drugs
- This system will also provide maximum flexibility for an employer so that an agreed list of CDs appropriate to the individual NMP and the individual setting is agreed in a systematic and considered way
- Governance issues for the independent prescribing of controlled drugs should be especially highlighted to ensure employers assess the increased responsibility of employing an IP who is prescribing CDs (should legislation change to allow this)
- Whether self-employed or employed by a NHS trust, NMPs must take full responsibility for their own prescribing. NMPs should follow the recommendations of their professional bodies with regard to professional indemnity and employers should accept vicarious liability
- NMPs should refuse to prescribe in the absence of adequate clinical governance arrangements and treatment services

should demonstrate an appropriate level of competence before implementing non-medical prescribing.

4.22 Practice examples of non-medical prescribing for drug misusers

The following examples briefly describe practice examples where nurse and pharmacist non-medical prescribing has been implemented in primary care, and in community and residential drug treatment settings.

4.22.1 Nurse supplementary prescribing in an enhanced primary care setting.

The lead GP in the practice felt there were sufficient patients registered with his own practice to warrant employing a substance misuse nurse, for which he gained funding from the PCT. Initially, the doctor would prescribe for those patients registered with the practice who needed prescribing help for their drug problems and the nurse provided keyworker input. Since qualifying as an NMP in April 2006, the nurse prescriber has been able to take over the care of opiate and benzodiazepine-dependent patients as a supplementary prescriber, in conjunction with the lead GP as the independent prescriber. The nurse currently provides care for 105 patients and the practice will refer on to the specialist community drug team, for example, when patients have chronic and severe mental health problems, are pregnant, are chronic polydrug users or need inpatient detoxification.

Patients may also be referred to the practice by the local DIP or other community drug services providing Tier 2 or Tier 3 interventions. Once registered and known to seek help for a drug dependency problem, they are seen by the substance misuse nurse prescriber for a comprehensive assessment. They are then seen by the lead GP for a healthcare and prescribing assessment. When the assessment demonstrates a need for prescribing substitute opiate treatment, a patient is offered the chance to work with the substance misuse nurse supplementary prescriber. When a patient agrees to the prescribing partnership, a CMP is produced which reflects the patient's needs and, where possible, preference for methadone or buprenorphine.

The nurse is also responsible for delivering or co-ordinating all other aspects of the care plan such as help addressing housing problems, education and employment. Dose induction is set up in the CMP in accordance with Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007). The patient is seen frequently by the nurse during induction onto methadone or buprenorphine in the first two weeks. During this period, the patient is supported and observed for symptoms of sedation or opiate withdrawal and the dose adjusted according to need within the CMP. Once established on the optimal dose, the patient sees the nurse prescriber at least monthly for prescription review and

keyworking appointments, and sees the doctor at least annually. There is no separate keyworker input. In addition to completing the non-medical prescribing training, the nurse prescriber has 12 years experience in substance misuse and has completed the RCGP part two certificate in substance misuse. The nurse receives weekly clinical supervision from the lead GP and peer support from another substance misuse nurse prescriber. There are communication links with the dispensing pharmacies and other partner agencies. This arrangement allows service users to be seen close to their own homes and remain within primary care services.

4.22.2 Pharmacist supplementary prescribing in a community drugs team led by a GP with a special interest

The team, part of a larger community service providing Tier 3 interventions, has two GPs with a special interest (GPwSIs) and a pharmacist prescriber along with two full-time substance misuse practitioners, who work specifically with shared care service users. The substance misuse practitioners run an assessment clinic on Mondays and the doctors run a new patient clinic on Tuesdays, with new dose inductions starting the same afternoon. There is also a weekly whole team clinical review meeting and other review clinics led by the prescribers, as well as keyworker appointments to monitor other aspects of the care plan. Keyworking is provided by the substance misuse practitioners in tandem with the prescribing team, which includes the pharmacist prescriber.

Where service users' needs include substitute prescribing for opiate dependency, an appointment is arranged for clients to be assessed by one of the GPwSIs together with a keyworker. If substitute opiate prescribing is considered appropriate, clients may be offered the choice of seeing the pharmacist supplementary prescriber. The choice will be offered when the service user's needs are for a maintenance prescription, it is within the pharmacist's sphere of competence and the pharmacist has capacity to take the client on. If the patient agrees to seeing the pharmacist prescriber, the pharmacist prepares an agreed CMP that specifies the amount of substitute opiate (methadone or buprenorphine) to be given during dose induction, and with flexibility to increase or decrease the dose according to need, in line with Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007b). The CMP may include other medicines such as senna, paracetamol and lofexidine. The induction normally commences the same day as the medical assessment. Service users begin with supervised consumption of the medication in their local pharmacies and are then seen by a team member, usually their keyworkers, to observe for signs of overdose or any other adverse reactions. Service users are seen two more times during the first week of their prescriptions to monitor the effectiveness of the dose, which will be adjusted

where necessary by the pharmacist prescriber in line with CMPs. After this first week, service users will see prescribers fortnightly and their keyworkers at similar intervals to help address other aspects identified in their care plans. The pharmacist prescriber may also provide support for clients' physical, housing, relationship, criminal justice and child protection needs. Those who are prescribed for by the pharmacist see one of the doctors to review the CMP at least annually.

The pharmacist in the team, working as a supplementary prescriber, receives regular clinical supervision from the two GPwSIs and adds another dimension to the team's multidisciplinary working practices.

4.22.3 Pharmacist supplementary prescribing in community pharmacies

An enhanced service has been developed in conjunction with the PCT where pharmacist prescribers in the area prescribe and dispense from their pharmacies for patients who are stable and whose doctors are unable to prescribe for them. The GP takes care of general medical care and the pharmacy manages the opiate prescribing. The pharmacies are visited fortnightly by the patient's keyworker to establish their stability. Should the keyworker or pharmacist have any concerns the patient is returned to the GPwSI immediately. The PCT monitors the controlled drugs prescribed. Pharmacists have completed the RCGP part two certificate (Schofield, 2007).

4.22.4 Nurse supplementary prescribing in an integrated Tier 3 community drug service

One single building houses the services providing Tier 2 and Tier 3 interventions, as well as a criminal justice substance misuse team. The community Tier 3 team consists of two senior practitioners, one nurse prescriber, two GP liaison nurses, one social worker, nine addiction workers and specialist doctors. The person specification for the nurse prescriber role calls for three years post qualification experience in mental health, five years post-qualification experience in substance misuse, three years experience of supervising less-experienced staff and a diploma or higher in substance misuse. The nurse supplementary prescriber manages around 90 service users at any one time and works alongside the specialist doctors who the nurse sees at least weekly for support. Formal clinical supervision takes place monthly with the specialist doctor. Each service user also has a keyworker from the Tier 3 team, to help address the other needs identified in the care plan. Prescribed treatments for criminal justice team clients are also provided by the Tier 3 prescribing team.

If, following a comprehensive assessment, the assessment team is satisfied that opiate substitute prescribing is indicated, the client is given an appointment with the prescribing team. The patient is usually seen by one of the team doctors and the nurse prescriber,

and usually takes place within a week of the initial assessment. At this appointment clients will discuss appropriate medication, treatment goals (detoxification or maintenance) and dose with the prescribers. If service users' needs can be met by maintenance prescriptions of an opiate substitute and they are within nurse prescribers' spheres of competence, clients are invited to consider working with a nurse prescriber. Service users are given leaflets explaining supplementary prescribing. If the service user chooses to accept the offer of working with the nurse prescriber, a CMP is devised, usually all within the same appointment. Communication between the keyworker and the prescribing team is made easier by the use of shared premises and access to each other's care records.

The CMPs for clients prescribed methadone or buprenorphine make provision for incremental increases decided upon by the nurse prescriber according to need and in line with Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH *et al.*, 2007b). Service users see their nurse supplementary prescribers up to twice weekly and at least fortnightly during their inductions, until a state of maintenance is achieved. Clients also see the independent prescriber (a doctor) with the supplementary prescriber at least every three months initially.

Dispensing arrangements are described in the CMP and begin with supervised consumption from a community pharmacy. The community pharmacy will let the prescriber know if doses are missed or if a patient has been observed as intoxicated. Once established on the appropriate dose, the CMP changes to a maintenance treatment plan and within it there is flexibility so that the supplementary prescriber can adjust the dose up or down to a maximum agreed with the doctor.

Service users are always referred back to their doctors if changes in dose schedule or dispensing arrangements beyond those described are required, if more than three days' doses have been missed, if patients have been noted to be intoxicated, if the patient becomes pregnant, if a change of treatment modality is required or if the supplementary prescriber has concerns or feels the situation exceeds his or her clinical experience.

Otherwise the service user will continue to see the supplementary prescriber fortnightly, monthly or at an agreed and specified less-frequent interval and will see the doctor at least annually. When a service user wishes to detoxify, he or she will be referred back to the doctor.

4.22.5 Nurse supplementary prescribing in a Tier 4 inpatient detoxification unit

A twelve-bedded inpatient unit provides 24-hour care and the medical team consists of an addictions specialist consultant (who carries responsibility for all substance misuse services in the trust), an associate specialist and a senior house officer in psychiatry. There is also a ward manager (who is also the sole nurse

prescriber), a deputy ward manager, two charge nurses, eight staff nurses with four healthcare support workers, two drug workers and two occupational therapists. Most of the aforementioned are whole time equivalent staff. Service users usually stay for two to three weeks to complete their detoxifications and are strongly encouraged to take part in the rehabilitation programme for a further six weeks, for which they either travel in each day from home or remain resident if travel time is too long.

Service users are normally referred by their community drugs team keyworker and will have developed an agreed care plan that includes inpatient detoxification prior to admission. The unit provides detoxification for opiate, benzodiazepine and alcohol dependence. As well as prescribed medication, there is a comprehensive programme of rehabilitation in the form of group work and individual support that builds in intensity as the service user becomes drug free.

Admission normally takes place within two weeks of referral and begins with an assessment of current levels of dependence and any other healthcare needs. This is carried out by the senior house officer with the nurse prescriber. Service users are given the option of nurse supplementary prescribing and, if agreeable, a CMP to meet their needs is produced by the nurse prescriber and is then signed off by the associate specialist. A range of detoxification options are available, including methadone, buprenorphine and lofexidine. Where sleep is a problem, zopiclone may be given and is specified in the CMP. The nurse supplementary prescriber is able to provide a daily review of prescribing treatments without the need for the daily involvement of a specialist doctor. The NMP is also available at other times of the day to review care and can help maintain a consistent approach to care for individual service users and the unit as a whole.

The current policy of the NHS trust on non-medical prescribing requires NMPs to act only as supplementary prescribers until they have met various requirements – even for drugs that could legally be prescribed independently – so all medication that may be given is specified in the CMP. The prescribing part of the care plan is reviewed daily by the nurse prescriber and adjusted according to reported need from the service user and observations of levels of sedation or withdrawal by the ward team. Out-of-hours medical cover is provided by the trust's on-call psychiatry rota and at least one member of the medical team visits the ward each day to take part in team clinical reviews. NMPs employed by the trust are required to complete ten days relevant continuing professional development each year.

In order to practise independently, NMPs must have completed the trust's preceptorship pathway, which includes providing evidence of continuing practice as a prescriber for at least twelve months in their specialist area since qualifying. They will have

attended the trust's in-house training programme for NMPs and fulfilled all other CPD requirements. In addition, the nurse (or pharmacist) prescriber's service area must advise the trust's medicines management committee as to how nurse or pharmacist independent prescribing would enhance patient care, and produce a formulary appropriate to the service area, to which the prescriber would be restricted. NMPs are then interviewed by a panel of senior clinicians in the trust in order to demonstrate their competency and suitability to prescribe independently.

5 Patient group directions

In most cases, the most appropriate clinical care will be provided on an individual basis by a specific prescriber to a specific individual patient. PGDs for supply and administration of medicines should only be considered where it would offer a benefit to patient care without compromising safety in any way and where it is consistent with appropriate professional relationships and accountability.

As with non-medical prescribing, most NHS organisations will already have implemented patient group directions (PGDs) to allow nurses, pharmacists and other professionals to administer or supply prescription-only medicines without a prescription. PGD legislation is very specific.

5.1 Aims of this section

This section explains the definition and gives a brief description of PGDs, including the legal and good practice requirements. This is followed by brief guidance on their application in the treatment of drug misusers and includes use for controlled drugs (CDs) as well as clinical governance requirements for the implementation and development of PGDs and considerations for commissioners and managers. Practice examples are given throughout this section.

5.2 Definition and brief description

The legislative framework to allow patient group directions (PGDs) was put in place in August 2000. (Note: patient group directions are sometimes incorrectly referred to as patient group directives.)

PGDs are written instructions for the supply or administration of particular medicines to patients with a defined diagnosis, condition or need, who may or may not be individually identified before presentation for treatment. A PGD must be signed by a senior doctor and a pharmacist, both of whom should have been involved in developing the PGD together with a member from the professional groups who will be using the PGD. For example, if it is going to be used by nurses, a senior nurse with the relevant competence and experience needs to be involved in its development. It must also be authorised by the organisation in which it will be used, normally an NHS trust or PCT. Clinical governance leads are best placed to do this on behalf of these organisations. Someone within the organisation must take responsibility for ensuring that the relevant staff are competent to work under the PGD and the individual practitioner must sign the specific PGD in order to be able to administer or supply medicines under it.

PGDs can be utilised by a range of registered healthcare professionals, including nurses and pharmacists and several other allied health professionals (RPSGB, 2007). The list does not include psychologists or social workers. It is important to note that authorised professionals may only supply or administer

medicines under a PGD to a named individual who exactly meets the criteria determined by the PGD. If a patient falls slightly outside the criteria for inclusion in the PGD, then the patient must be referred in line with the guidelines in the PGD. When a nurse or pharmacist or other health professional is authorised to administer or supply a medication via a PGD, this authority cannot then be delegated to another person.

PGDs allow authorised healthcare professionals:

- To supply medicines on behalf of an NHS trust
- To assist a doctor or dentist providing primary care NHS services
- To supply prescription only medicines (POMs) from a community pharmacy
- In addition, supply of POMs under a PGD can be made on behalf of an independent clinic, hospital or medical agency, which is registered under the Care Standards Act, a prison service or a police force.

Unlike non-medical prescribing, health professionals do not need to be separately registered with their professional regulatory bodies in order to administer or supply a medicine under a PGD. However, they do need to be authorised by their employing organisation or NHS trust and this authorisation process will involve ensuring that the person is competent to follow the PGD.

NHS staff, provided they are named and assessed as competent to use PGDs by their employers, are indemnified by their employers. Bank staff may also be indemnified but should check their positions as should those working outside the NHS or working as agency staff.

Non-medical prescribers may supply or administer drugs under a PGD that they would not normally prescribe, provided they have been trained and authorised as competent by their employers to use a particular PGD. A healthcare professional does not have to be trained as a prescriber in order to administer medicines under a PGD but does require authorisation of competence by their employer to use a PGD.

5.3 Patient group directions for controlled drugs

Controlled drugs (CDs) can only be administered or supplied in certain situations under a PGD (note that the legislation concerning PGDs and controlled drugs is likely to change in 2008):

- A registered nurse may supply or administer diamorphine (a Schedule 2 CD) under a PGD for the treatment of cardiac pain in a patient admitted to a coronary care unit or A&E department of a hospital (this is likely to be extended to include morphine and the restrictions on the place where the drug can be administered and the conditions treated lifted)

- Midazolam injection (which is likely to be changed to a Schedule 3 controlled drug from January 2008) can now and will continue to be allowed to be supplied or administered under a PGD. (If allowed, this will be an exceptional situation as Schedule 3 controlled drugs are not otherwise allowed to be supplied or administered under PGDs.)
- An authorised health professional may supply or administer under a PGD:
 - Any Schedule 5 drug (low-strength opiates such as codeine)
 - Schedule 4 controlled drugs (mostly benzodiazepines) provided it is not a drug in parenteral (injectable) form for the treatment of addiction or an anabolic steroid.

Under no other circumstances can a CD be considered for inclusion in a PGD. Therefore methadone (Schedule 2 CD) and buprenorphine (Schedule 3 CD) cannot be supplied or administered using a PGD but chlordiazepoxide (Schedule 4 CD) for treatment of alcohol withdrawal can.

5.4 Patient group directions in the treatment of substance misusers

The NTA's Models of Care for Treatment of Adult Drug Misusers: Update 2006 (NTA, 2006) advocates a much greater emphasis on the need to reduce drug-related harm, including risks of blood-borne viral infections, overdose and other infections. PGDs have a part to play in addressing all three of these risks and can help to meet wider health service targets to improve access to medicines and utilise skills more effectively.

Generally, a PGD is not meant to be a long-term means of managing a service user's clinical condition: this is best achieved by a healthcare professional prescribing on a one-to-one basis. However, PGDs can be of particular benefit to drug misusers when they come into contact with services and are in need of a specific short-term or one-off intervention at times or in places where a prescriber is not immediately available.

5.4.1 Examples of patient group directions relevant to substance misusers

These include administration or supply of:

- Hepatitis B vaccination
- Hepatitis A vaccination
- Combined hepatitis A and B vaccination
- Adrenaline injection (for anaphylaxis)
- Antibiotics
- Emergency hormonal contraception
- Naloxone injection

- loperamide
- Lofexidine
- Non-opioid analgesics such as ibuprofen
- Symptomatic relief of opiate withdrawal
- Nicotine replacement therapy
- Chlordiazepoxide for alcohol withdrawal
- Diazepam for alcohol withdrawal
- Emergency hormonal contraception.

5.4.2 Settings where patient group directions can be used

These settings allow the use of PGDs provided the settings come under the control of one of the organisations listed in section 5.2

- Needle exchanges
- GP practices
- Substance misuse services
- Walk-in clinics
- Community pharmacies
- Minor ailment schemes
- Prisons
- Police custody suites.

5.4.3 Blood-borne virus and bacterial infection

With a PGD in place, nurses and pharmacists can administer hepatitis vaccine to service users without the need for a prescription or a prescriber being involved. This means that drug misusers can be immunised in an increased range of settings including needle exchanges, prisons, community pharmacies, nurse or pharmacist-led clinics. This improves availability and access to treatment for drug misusers and improves the success rate of completion of vaccination.

PGDs for antibiotics may also be used by non-medical practitioners, for example to treat injecting-related infections in patients they are prescribing methadone or buprenorphine to, if antibiotics are outside their agreed range of competence for prescribing. Thus PGDs can be used as one way for NMPs to gain and demonstrate the necessary competence to prescribe.

5.4.2 Naloxone

Another possible application of PGDs in harm reduction is for naloxone injection (used in the treatment of opiate overdose) to be made available for drug misusers to take home. Articles have been published on the possible benefits of take-home naloxone for service users (Strang *et al.*, 2006) and it has been available to heroin injectors in Italy for over ten years. In the UK, there are a

small number of pharmacies and drug services supplying naloxone to opiate misusers by means of a PGD.

As a prescription-only medicine, it can only be prescribed or supplied to named individuals for use on themselves. However, legislation allows anyone to administer naloxone “for the purposes of saving life” and so a client who had been supplied the naloxone for their own use could administer it to another person in an emergency. In all cases where naloxone is being issued, the supply must be accompanied by specific training on managing overdoses.

On healthcare premises where there is the potential risk of overdose from opiates, substance misuse teams should have naloxone available to use for emergency administration while awaiting the arrival of the ambulance (DH *et al.*, 2007b). Although legally anyone can administer naloxone injection “for the purposes of saving life”, it is considered good practice for health practitioners to be specifically trained and authorised to administer naloxone and a PGD provides a useful clinical governance framework for this.

5.4.3 Prisons and custody suites

PGDs can also be useful in prisons, custody suites and court holding cells (provided the settings come under the control of one of the organisations listed in section 5.2 where no prescriber is immediately available but where there is, for example, nursing cover. PGDs can be used to treat the symptoms of withdrawal, for example, loperamide for diarrhoea; metoclopramide or prochlorperazine for nausea and stomach cramps; or diazepam (or other benzodiazepines or “Z-drugs” as appropriate) for anxiety, agitation and sleeplessness. These medicines could be given for short-term symptomatic relief until such time as a prescriber is available to review the client’s needs.

5.5 Benefits and advantages of patient group directions

Many of the benefits of using PGDs are similar to those for non-medical prescribing, such as:

- Providing medicines in situations and at times where doctors are unavailable
- Improving patient care through quicker access to medicines
- Increasing patient access to medicines
- Increasing patient choice about who, when and where services can be accessed
- Reducing waiting time for treatment
- Preventing additional waiting time for patients to see a doctor to get a prescription

- Increasing skill mix in the team by using nurse, pharmacist and other healthcare practitioners to administer or supply medicines
- Financial benefits may include reducing doctors’ time input, reducing staff time and duplicated effort to produce a prescription, managing patients in a community setting.

Even with non-medical prescribing becoming more widely available, the demand for PGDs has continued to increase and, in the same way that both supplementary and independent non-medical prescribing are finding their place in improving access to treatment, so are PGDs.

Whereas non-medical prescribing requires completion of a 38-day specific training course, training for PGD implementation can be shorter and can be delivered within a service or NHS trust. Although PGDs cannot be used for CDs such as methadone or buprenorphine, they do provide a useful mechanism for administering and supplying other medicines to service users without the need for intervention from a prescriber. Services need to take a view on the balance of patient safety, service access, quality and cost-effectiveness in looking at how they use PGDs and prescribing. Two very useful tools are available on the PGD website to help services assess their need to use PGDs. These are called To PGD or Not to PGD and So You Think You Need a PGD and can be accessed through the national electronic library for medicines www.portal.nelm.nhs.uk/PGD/default.aspx.

In practice, implementation of PGDs is seen as a stepping-stone for many services and practitioners towards introduction of non-medical prescribing.

5.6 Clinical governance to support the safe use of patient group directions

Because PGDs are instructions to supply medicines to patients who are not individually identified at the time the instruction is written, there is potentially greater risk than with individual prescriptions that the medicine could be given inappropriately. However, provided appropriate governance procedures are in place these risks can be overcome.

Time and professional engagement is needed to prepare and implement a PGD so a clear vision of how they fit within the service’s overall plan for making care accessible to service users is vital. Clear governance processes and good documentation systems are required to make sure that PGDs and the staff using them comply with legal requirements.

Services need to ensure that robust training and assessment is in place to ensure that their staff who are using PGDs:

- Can correctly assess whether a patient belongs to the group for whom the direction is intended

- Have adequate understanding of drug interactions, contraindications and side-effects to make a realistic risk assessment
- Have sufficient training or experience to administer the medicine safely, particularly when it is given by injection
- Can correctly calculate dosage
- Know when follow up arrangements are required and put them in place appropriately.

Use of PGDs should be audited to ensure that these requirements are being met and arrangements must be made to ensure that staff can keep their skills up to date. PGDs once in use require regular review to ensure they do not become out of date and they continue to reflect current best practice.

5.7 Implementing patient group directions in practice

As with non-medical prescribing, most NHS trusts will already have PGDs in place and a governance process to ensure safe and effective implementation. When considering implementing PGDs in a service, initial discussions should be with the service manager and the lead pharmacist for the service or organisation, such as the trust chief pharmacist, the PCT medicines management lead or the specialist substance misuse pharmacist.

There is no requirement to develop every PGD from scratch and those used by other services or in other areas can be used as the basis for local PGDs. Any ready-drafted PGD requires thorough review to ensure it is locally appropriate and, of course, the necessary signatures and support mechanisms to be in place before it can be used.

A number of agencies and organisations have produced sample PGDs designed for use in substance misuse services. Useful contacts include the Avon and Wiltshire Mental Health Partnership, which has produced a PGD resource pack to support their development in this field. (This can be requested by writing to Bristol Specialist Drug Service, Cedar House, Blackberry Hill Hospital, Manor Road, Fishponds, Bristol, BS16 2EW.) Hampshire PCT has also arranged with the national electronic library for medicines for several PGDs to be made available to other NHS trusts (www.nelm.nhs.uk – patient group directions section). These PGDs are also available to prisons, police and non-NHS organisations for a nominal fee.

5.7.1 Preparing a patient group direction

A designated team must be identified to write a new local PGD or review one from elsewhere for local use. The team must include a doctor, a pharmacist and a representative of any professional group which may be expected to supply the medicines under the PGD. It is also good practice to involve local clinical governance

leads, medicines management committees and similar advisory bodies.

Using the local template, the necessary sections of the PGD will need to be written. In practice, PGDs can be 10–20 pages long. The PGD must include:

- The name of the body to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicines to which it applies
- The clinical conditions covered by the direction
- A description of those patients excluded from treatment under the direction
- A description of the circumstances under which further advice should be sought from a doctor and arrangements for referral made
- Appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- Relevant warnings, including potential adverse reactions
- Details of any follow-up action and the circumstances
- A statement of the records to be kept for audit purposes.

Once completed, the PGD will need to be signed by each member of the multidisciplinary group including the clinical governance lead if it is being used in an NHS organisation, who will ensure ratification. The PGD will also have to be reviewed regularly – this is usually every two years. That review should include clinical governance arrangements and an assessment of whether the PGD remains the most effective way of providing the relevant services.

If the PGD is being used in the provision of healthcare by or on behalf of the police or the prison service it must also be authorised as follows:

- For a police force in England or Wales the PGD must be signed by or on behalf of the chief officer of police for that police force (within the meaning of the Police Act 1996)
- For the prison service in England and Wales the PGD must be signed by or on behalf of the governor of the prison in relation to which the healthcare in question is being provided.

Some other considerations:

- There must be comprehensive arrangements for the security, storage and labelling of all medicines. Medicines that will be supplied to patients should be available pre-packed, prepared by a pharmacist
- There must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and outgoings on a patient-by-patient basis

- Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded. The document Controls Assurance Standard: Medicines Management (Safe and Secure Handling) (DH, 2003c) provides guidance on related legislative requirements and best practice
- The EC Labelling and Leaflet Directive 92/97 applies to all supplies of medicines, including those supplied under PGDs and means that a patient information leaflet should be made available to patients treated under PGDs
- It is important that the use of any medicine is consistent with the summary of product characteristics (www.emc.medicines.org.uk) for the relevant product and any relevant authoritative good practice guidance
- Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up the PGD
- The local drugs and therapeutics committee or area prescribing committee, where they exist, should ensure that any directions are consistent with local policies and subject to regular external audit
- Ensure a standard operating procedure is in place to allow amendment of PGD to take account of staff changes.

5.7.2 Requirements for training and continuing professional development

Organisations using PGDs should designate an appropriate person within the organisation (for example a clinical supervisor, clinical governance lead, line manager or general practitioner) to ensure that only fully competent, qualified and trained healthcare professionals use PGDs. Introductory training should also include pharmacy-led medicines management training relevant to the use of PGDs – this will often include a resource pack and a local policy.

Healthcare professionals using PGDs do not have to become specifically qualified to do so but they must be registered members of their profession and act within the appropriate code of professional conduct. In addition, they must be assessed as fully competent and trained to operate within the particular PGD by their organisations. This includes understanding their responsibilities in relation to using PGDs as well as ensuring they have the necessary knowledge of medicines and their side-effects, and the potential for interacting with other drugs.

The National Prescribing Centre has developed a list of nine competences which, if acquired and maintained, should help individuals work safely and effectively with PGDs.

Practitioners also have a responsibility to ensure they are proficient and competent to work within each individual PGD. They must understand the criteria for use including safe storage and handling of the medicines, an understanding of anatomy and, if the PGD involves administration of the medicine, positioning the patient correctly. They must also be able to provide advice and information to patients before and after administration and must be up to date on current advice.

Each qualified person, once assessed as competent to use each specific PGD, must sign the PGD and their competence must be confirmed by a supervisor assessing who should also sign the PGD. The clinical governance lead for the employer would be expected to keep a central record of all those who have been deemed competent to use a PGD and a list of which PGDs each person has been authorised to use.

5.7.3 Considerations for managers and commissioners

PGDs offer greater flexibility in making specific medicines available to drug misusers with specific needs. In order to make their use safe and effective, resources should be made available to ensure they are drawn up following the steps in section 5.7.1 and to ensure those staff giving the medication are trained appropriately, have time to maintain their CPD and for audit to be carried out. In the field of substance misuse, PGDs may be of particular help regarding harm minimisation and reducing drug related deaths in settings such as needle exchange where a prescriber is unlikely to be available. Their safe and effective use can also increase overall service capacity by freeing up prescriber time.

A key consideration in utilising PGDs is the need to develop mechanisms for ordering, maintaining, labelling, storing and supplying appropriate medication on site as well as ensuring compliance with all legal requirements. There must also be arrangements in place to ensure that supply or administration of medicines under PGD is recorded on the patient record.

Managers' responsibilities also include ensuring that staff using PGDs:

- Have a copy of the up to date PGD (signed) in their personal file
- Have access to the employing organisation's resource pack or policy
- Have access to up to date British National Formulary information and summary of product characteristics for the medicines in the PGDs
- Can demonstrate they meet the relevant professional responsibilities and competences stated on the PGDs

- Managers should also ensure they have audit mechanisms in place; for example, confirming that all records are being kept, that stock usage can be reconciled with patient records, that training, CPD and PGDs are kept up to date
- A standard operating procedure in place to allow amendment of PGD to take account of staff changes.

6 Minor ailment schemes

People with substance misuse problems tend to have poorer general health and to be more vulnerable to minor ailments than the rest of the population. Drug misusers may be less willing to consult their GPs or dentists for such problems.

Pharmacists who provide services for drug misusers – such as needle exchange, dispensing prescribed medicines and supervising consumption – may be ideally placed to help this vulnerable group with treating their minor ailments and further contribute to harm reduction measures.

6.1 Description

A community pharmacy minor ailment scheme is a locally tailored scheme whereby patients are encouraged to consult a participating pharmacy, rather than their GP, for a defined list of minor ailments. The pharmacist will supply medication from an agreed formulary, give advice or refer the patient to the GP if necessary. If service users are exempt from NHS prescription charges, then medicines are supplied free of charge. Therefore the payment barrier, which can prevent patients choosing to see a pharmacist instead of their GP, is removed. If the scheme is also open to people who normally pay prescription charges, they will pay a prescription charge for each medicine supplied. Community pharmacists may supply or administer prescription-only medicines including some CDs under a patient group direction (PGD).

Many PCTs have set up minor ailment schemes (NPC, 2004) through community pharmacies. These are aimed at people who would have otherwise gone to their GP for a prescription for treatment of a minor ailment. The costs of the medicines supplied by the pharmacists are charged back to the individual's GP practice and are therefore paid out of the GP or PCT prescribing budget. It may be possible to work with PCTs if a case can be made that a particular group of people is identified; for example, drug misusers who are not accessing treatment for minor ailments because of cost or because of limited access to a GP. The success of minor ailment schemes has led to the Government pledging support for such schemes (DH, 2003a).

6.2 Pharmacists providing “support for self care”

Community pharmacists are required to provide, under the terms of the pharmacy contract, “support for self care” This is described as “the provision of advice and support by pharmacy staff to enable people to derive maximum benefit from caring for themselves or their families.”

Commissioners should be able to work with PCTs and community pharmacists to enable patients on substitute prescriptions, needle exchange clients or drug misusers in general to access advice and treatment for self-limiting conditions and minor ailments.

Pharmacists, PCTs and commissioners, by working together, should ensure that pharmacists and their staff are trained to be proactive in providing support for self-care for drug misusers. Indeed, most pharmacists will be doing this as part of their everyday work when they dispense prescriptions or provide needle exchange. Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Misusers (NTA, 2006) includes a section on understanding the pharmacy contract and explains how commissioners and providers can make best use of the community pharmacist.

6.3 Enhanced service

Many PCTs may have a minor ailment scheme (MAS) in place as an enhanced service provided through community pharmacies. Commissioners of drug misuse services will be familiar with the supervised consumption and pharmacy needle exchange enhanced services that can be commissioned from community pharmacies. The main difference is that the MAS will not be drug misuser specific.

The key difference between the support for self care service and the minor ailment service is that the medicines are provided free of charge if the patient is exempt from NHS prescription charges. Individuals who are eligible are usually required to be registered with a specific GP and a specific pharmacy as the cost of the service and any medicines supplied are charged back to the patient's GP practice or the PCT. However, commissioners, PCTs and community pharmacists should be able to work together to ensure that the service is tailored to suit the needs of drug misusers – including those who have no GP.

MAS services require no specific legislation since they only relate to the use of drugs which, under the provisions of The Medicines Act 1968 and the Misuse of Drugs Regulations 2001 (as amended), are already available from community pharmacies without a prescription. Prescription only medicines can also be supplied under PGDs as part of an MAS.

What is important to emphasise is that an MAS may already be up and running in a particular locality. Commissioners and pharmacists should work with the PCT lead commissioning the MAS to ensure that drug misusers who are eligible for this service are able to take full advantage of the service and that they are not unintentionally discriminated against.

6.4 Practice examples of minor ailment schemes

6.4.1 Minor ailment schemes in prison

MAS can also be provided in the prison setting. A Department of Health report (DH, 2003b) recommended that pharmacists provide services for prisoners with minor ailments. This allows medical staff to concentrate on more serious problems.

A pharmacist describing the service he was able to provide in a prison with 1,000 prisoners (Tucker, 2007) explains that he was able to provide treatment for a range of minor ailments including various skin conditions such as eczema, fungal infections, acne, psoriasis, dry skin and urticaria, as well as, toothache, analgesics, insomnia, dyspepsia and constipation. Some medicines were supplied under PGDs and he also then went on to become qualified as a non-medical prescriber specialising in dermatology.

6.4.2 Minor ailment service scheme in a PCT

Out of 33 GP practices in one PCT, 26 practices participate in a minor ailment scheme along with 48 pharmacies. The scheme enables drug misusers and others to gain access to a limited formulary of prescription drugs without the need for a GP consultation.

Anybody who is registered at one of the participating GP practices can join the scheme by getting a registration form from a surgery. Registration can be initiated either by GP receptionists or participating community pharmacists. If people present in need of treatment out of normal surgery hours they can register on the spot, at the pharmacist's discretion. Once they have a card they can go to any of the participating pharmacies for treatment for a specified list of 16 minor ailments, including constipation, diarrhoea, earache, headache, sore throat and thrush.

Pharmacists who join the scheme are required to undergo training and complete documentation that gives a record of each consultation. Once they have joined the scheme they receive payment for each consultation, whether or not they supply medication. For each ailment there is a specific list of questions to ask the service user in order to help decide if medication should be given. It is also clear when to refer users on to their GP or to A&E, where there are complications or contra-indications. Pharmacists on the scheme can also provide emergency contraception and nicotine replacement therapy under PGDs to those who meet the criteria specified. A record is made of each consultation and any medication given.

Although not specifically set up with drug misusers in mind, the MAS clearly has potential to be of benefit to this group. Of the 48 participating pharmacies, 41 dispense methadone to patients with opiate dependency and 11 also offer needle exchange. These pharmacists are therefore both in regular contact with drug misusers and in a position to treat them.

A survey of 29 drug misusers attending one of the pharmacies, found that all had experienced minor ailments but few had consulted their GP about them. For example, almost half had experienced constipation and more than half had suffered from colds, flu and coughs, toothache and infection of injection sites. However, none of those questioned were aware of the minor ailment scheme before the survey. Following the survey,

arrangements were made for the local specialist drug service to give out the MAS information pack at assessment.

7 Summary

Non-medical prescribing, patient group directions and minor ailment schemes are well-established systems in the NHS for improving access to medicines. However, the substance misuse field has not always been able to implement these new mechanisms as quickly as other fields of medicine. As legislation is changing, in particular relating to controlled drugs, these mechanisms are increasingly more relevant to the substance misuse field.

Multidisciplinary working and training in drug misuse mean that many nurses and pharmacists have developed expertise and competence in working with drug misusers. However, to ensure safety for patients and clinicians, effective implementation of NMP, PGDs and MAS must be within robust clinical governance frameworks. Many practitioners working with drug misusers have found it difficult to work through these clinical governance processes promptly with the result that they have experienced difficulties introducing such systems locally. It is hoped that this guidance will help improve access to medicines for drug misusers.

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8.1 Further information

Department of Health, www.dh.gov.uk (non-medical prescribing)

National Prescribing Centre, www.npc.nhs.uk, www.npc.co.uk (non-medical prescribing)

Medicines and Healthcare Products Regulatory Agency, www.mhra.gov.uk

National Patient Safety Agency, www.npsa.nhs.uk

Nursing and Midwifery Council, www.nmc-uk.org (nurse prescribing)

Royal Pharmaceutical Society of Great Britain, www.rpsgb.org.uk (non-medical prescribing, pharmacist prescribing)

National Electronic Library for Medicines, www.nelm.nhs.uk (non-medical prescribing in “support materials”)

National Treatment Agency for Substance Misuse

8th floor, Hercules House, Hercules Road, London SE1 7DU

Tel 020 7261 8801. Fax 020 7261 8883

Email: nta.enquiries@nta-nhs.org.uk Website: www.nta.nhs.uk

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