Drug misuse and dependence

UK guidelines on clinical management

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The working group would also like to thank the many people who responded during the consultation on the draft update to the Clinical Guidelines, and the many others who contributed informally during the development of the 2007 Clinical Guidelines.

FOREWORD

Who are the Clinical Guidelines for?

Drug Misuse and Dependence: UK Guidelines on Clinical Management – hereafter referred to as the 2007 Clinical Guidelines – is intended for all clinicians, especially those providing pharmacological interventions for drug misusers as a component of drug misuse treatment.

What are the 2007 Clinical Guidelines?

This document updates and replaces *Drug Misuse and Dependence – Guidelines on Clinical Management* (UK health departments 1999) – hereafter referred to as the 1999 Clinical Guidelines. It has the same status across the UK as the 1999 Clinical Guidelines.

The 2007 Clinical Guidelines provide guidance on the treatment of drug misuse in the UK. They are based on current evidence and professional consensus on how to provide drug treatment for the majority of patients, in most instances.

The 2007 Clinical Guidelines do not provide rigid protocols on how clinicians must provide drug treatment for all drug misusers. Neither does this guidance override the individual responsibility of clinicians to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient (and guardians and carers if appropriate). In instances where clinicians operate outside the framework of this guidance, they should be able to demonstrate the rationale for their decisions.

Why update the Clinical Guidelines?

UK guidelines for the clinical management of drug misuse were last revised in 1999. Since then there have been substantial developments in the evidence for drug treatment and clinical practice. These include:

- greater recognition of and investment in the importance of drug treatment and a massive expansion in the numbers receiving treatment in the UK
- an expanded evidence-base and resulting policy and practice guidance
- consensus on doctor competencies in substance misuse treatment (RCPsych and RCGP, 2005)
- changes in contractual arrangements for general practitioners who provide drug treatment.

NICE and the 2007 Clinical Guidelines

In 2004, the National Institute for Health and Clinical Excellence (NICE) was charged with developing a suite of guidelines and technology appraisals on various aspects of the treatment and care of drug misusers. The 2007 Clinical Guidelines were developed concurrently with the NICE suite of guidance on drug misuse treatment and NICE had observer status on the working group.

NICE published technology appraisals in January 2007 on:

- methadone and buprenorphine maintenance
- naltrexone for relapse prevention.

NICE published its final clinical guidelines in July 2007 on:

- opioid detoxification
- psychosocial interventions for drug misuse.

NICE also produced public health guidance on community-based interventions to reduce substance misuse among vulnerable and disadvantaged children and young people (NICE, 2007).

The working group considered NICE clinical guidelines and technology appraisals in drafting the 2007 Clinical Guidelines. The working group interpreted and incorporated the NICE suite of guidance as appropriate, but the 2007 Clinical Guidelines cover the management and treatment of drug misusers in a more wide-ranging manner. These Clinical Guidelines and NICE guidance should be taken together with other key documents to provide a comprehensive picture of current clinical guidelines on the treatment of drug misuse.

It is important to note the different status of NICE in England and Wales, Northern Ireland and Scotland.

In England and Wales health professionals (and their organisations) are expected to take NICE guidance on health technologies and on clinical practice fully into account when exercising their clinical judgement. NICE guidance on public health covers England only. In relation to the main types of guidance relating to drug misuse,

Table 1 lists what NHS organisations are expected to do.

NHS Quality Improvement Scotland (NHS QIS) provides advice to NHSScotland on the suitability for Scotland of NICE advice and the status of NICE advice in Scotland varies according to product type. For NHS QIS-validated NICE multiple technology appraisals, NHSScotland will take account of the advice and evidence from NHS QIS and ensure that recommended medicines and treatment are made available to meet clinical need. This status applies to the NICE multiple technology appraisals on methadone and buprenorphine, and naltrexone. NICE single technology appraisals and clinical guidelines currently have no formal status in Scotland and are for information only in NHSScotland.

In Northern Ireland the Department for Health, Social Services and Public Safety reviews NICE guidance for its applicability to Health and Personal Social Services (HPSS) and decides whether it should be endorsed for implementation. NICE health technology appraisals endorsed by the Department will be treated as essential within the Quality Standards for Health and Social Care. The NICE clinical practice guidelines and public health guidance that have been endorsed will be regarded as standards that the HPSS are expected to achieve over time. As in England and Wales, it is expected that endorsed NICE guidance will help health and social care professionals in their work but it does not override clinical responsibility for making decisions in specific circumstances.

Type of NICE guidance	Recommendations for NHS organisations
Clinical guideline	Review current management of clinical conditions and consider the resources and time needed to implement the guideline
Technology appraisal	Fund and resource medicines and treatment recommended usually within three months of NICE issuing guideline
Public health guideline (England)	Review current practice and consider the resources and time needed to implement the guideline

Table 1: Expectations of NHS organisations in England and Wales in relation to NICE guidance

The status of the Clinical Guidelines

The 2007 Clinical Guidelines replace the previous 1999 Clinical Guidelines. They have no specific statutory status. However, any clinician not fulfilling the standards and quality of care in the appropriate treatment of drug misusers as set out in these guidelines will have this taken into account if, for any reason, their performance in this clinical area is assessed.

The General Medical Council states (GMC, 2006):

- You should be familiar with relevant guidelines and developments that affect your work.
- You must keep up to date with, and adhere to, the laws and codes of practice relevant to your work.
- You must provide effective treatments based on the best available evidence.

There are separate, defined legal obligations in relation to the prescribing of controlled drugs which clinicians should act in accordance with. In addition, doctors need to ensure that they act within Home Office licensing arrangements for the prescription of diamorphine, dipipanone or cocaine for the management of drug misuse.

Regulation and inspection

In England, the Healthcare Commission (HC) is the inspection body for NHS and independent health care. It uses national guidance in this context: NICE guidance is used in the HC annual health check, its programmes of review, and in audit and assessment work. The joint HC and NTA Improvement Reviews of drug treatment also take into account NICE guidance and the Clinical Guidelines when setting criteria and benchmarking local commissioning partnerships and providers.

Inspection and investigation of Welsh NHS bodies and private and voluntary provision rest with Healthcare Inspectorate Wales.

In Scotland, there are different organisational arrangements for the governance of different NHS and independent services. NHS boards are responsible and accountable for the quality of NHS services provided directly or secured by contract. Services in the independent healthcare sector required to register with the Scottish Commission for the Regulation of Care ('the

Care Commission') are regulated by it and are expected to provide care and treatment that reflects the relevant NHS QIS standards, and reflects good practice based on relevant research-based studies, audit reports, standards, guidelines and evidence-based treatments.

The Regulation and Quality Improvement Authority (RQIA) is the independent health and social care regulatory body responsible for monitoring and inspecting the availability and quality of health and social care services delivered by Health and Personal Social Services (HPSS) bodies and the independent sector in Northern Ireland.

The process for developing the 2007 Clinical Guidelines

In 2006, the Department of Health (England) and the authorities of the devolved administrations tasked the National Treatment Agency for Substance Misuse (NTA) with supporting an independent working group to update *Drug Misuse and Dependence – Guidelines on Clinical Management* (UK health departments, 1999). It was agreed that it would still be sensible to issue a single set of guidelines for the whole of the UK that would provide a skeleton framework of best practice from which the devolved administrations could develop their own guidance on locally appropriate variations in policy and practice. The terms of reference of the working group were to update the 1999 Clinical Guidelines in 2007.

The chair of the 1999 (and 1991) guidelines working group, Professor John Strang, was invited to again chair the group. The NTA convened and provided a secretariat for the independent working group and separate user and carer advisory groups.

The working group included members who brought a wide range of individual expertise, continuity with previous guidelines, and representation of key groups of stakeholders. These included addiction psychiatrists, general practitioners, nurses, pharmacists, service user and carer representatives. The service user and carer representatives were supported by their own advisory groups. Government departments, the NTA and others had observer status.

Development of the updated guidelines began with the commissioning of a series of reviews to advise the working group on the current evidence-base for a range of drug misuse treatment-related issues, including: prison drug treatment; drugs and driving; injectable opioid treatment; methadone and buprenorphine dose induction; drug testing and its use in practice; drug treatment for young people; treatment of substance misuse in pregnancy; cardiac assessment and monitoring for methadone prescribing. Reviewers were asked to provide recommendations to be considered by the working group and to rate both their recommendations and the evidence behind them in line with established systems.

The working group also considered the key messages from NICE guidance and other relevant research and guidance. The working group then, by a process of consensus, came to a view of the best available evidence from whatever source. The working group considered rating its recommendations and the evidence supporting them in line with common current practice for guidelines. However, it decided against this on the basis that the Clinical Guidelines have traditionally – and usefully – provided consensus opinion which draws extensively on clinical experience as well as on published research. By doing this it is able to make recommendations on important subjects beyond those with a substantial research evidence base and in a way that is of practical use to clinicians. The strength of the working group's recommendations and its opinion on the quality of the supporting evidence is indicated by judicious wording of the recommendation and of the accompanying text.

Members of the clinical guidelines working group were fully involved in the consultation process, which was conducted by the NTA. All consultation responses were collated and fed back to the group at regular intervals during the consultation period. The group was asked to comment on key issues arising and their advice taken into account when redrafting the document. A meeting of the working group was held to discuss topics that were the focus of most consultation comment, or where more discussion or consensus was required. Issues amended or clarified as a result of the consultation process included child protection and blood-borne infections. Greater emphasis has been put on child protection and clinicians' responsibilities to maximise opportunities to identify and prevent harm to both the children of drug-misusing parents and young drug

misusers themselves. In relation to blood-borne infections, much greater detail on hepatitis C has been included and information has been added on bacterial infections that may be an increasing problem in drug misusers.

The 1999 Clinical Guidelines noted that "there is currently, with some exceptions, a limited amount of rigorous reviews in this area". Although the evidence base for drug misuse treatment has improved, the working group found that, in many areas of drug treatment, evidence was either lacking or was based on research from countries other than the UK.

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CHAPTER 1
INTRODUCTION

Some key principles underlying appropriate care of drug misusers

- Drug misusers have the same entitlement as other patients to the services provided by the National Health Service.
- The General Medical Council has stated: "The investigations or treatment you provide or arrange must be based on the assessment you and the patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options. You must not refuse or delay treatment because you believe that a patient's actions have contributed to their condition. You must treat your patients with respect whatever their life choices and beliefs. You must not unfairly discriminate against them by allowing your personal views [including your views about a patient's lifestyle] to adversely affect your professional relationship with them or the treatment you provide or arrange."
- It is the responsibility of general practitioners to provide general medical services for drug misusers. Health authorities, primary care trusts in England, local health boards in Wales, and health boards in Northern Ireland and Scotland all have a duty to provide treatment for drug misusers, to meet local population needs. This should include interventions to reduce drug-related harm such as hepatitis B vaccinations and needle exchange provision, together with evidence-based drug treatment.
- All doctors must provide medical care to a standard that could reasonably be expected of clinicians in their positions. An increasing number of clinicians are trained and supported to provide drug treatment under the terms of a contract negotiated with their local commissioners.
- The focus for the clinician treating a drug misuser is on patients themselves. However, the impact of their drug misuse on other individuals – especially dependent children – and on communities should be taken into consideration.

1.1 Key points

- A range of drug misuse treatments have been found to be effective in reducing harm to individual drug misusers, their children and families and local communities.
- Current levels of mortality and morbidity among drug misusers remain a concern (particularly due to overdose and blood-borne virus infections).
- Substantial numbers are affected by drug misuse across the UK. Many of these could benefit from drug treatment, which has been increased substantially over the last decade.

1.2 Drug treatment is effective

The effectiveness of well-delivered, evidence-based treatment for drug misuse is well established. UK and international evidence consistently show that drug treatment – covering different types of drug problems, using different treatment interventions, and in different treatment settings – impacts positively on levels of drug use, offending, overdose risk and the spread of blood-borne viruses (Hubbard *et al.,* 1989; 1997; Ward *et al.,* 1998; Simpson *et al.,* 1999; Sorensen and Copeland, 2000; Gossop *et al.,* 2003; Hser *et al.,* 2005). The National Treatment Outcomes Research Study (Gossop, 2001) showed that, for a significant proportion of those entering treatment (between a quarter and a third), drug treatment results in long-term sustained abstinence. The National Institute for Health and Clinical Excellence published two technology appraisals (NICE, 2007a; 2007b) and two guidelines (NICE, 2007c; 2007d) on a range of drug treatment interventions, which endorse much of the mainstream drug treatment provided in the UK as evidence based and cost effective.

It is now more appropriate to stop asking whether treatment for drug misuse is effective, and instead ask how treatment can be improved and how it can be tailored to the needs of different patients.

1.3 Drug misuse and drug treatment

1.3.1 Prevalence and drugs misused

International comparisons of the prevalence of drug misuse are difficult due to differences in data collection and analysis. However, studies consistently show that the UK (Scotland and England in particular) has among the highest rates of recorded illegal drug misuse in the western world. In particular, the UK has comparatively high rates of heroin and crack cocaine misusers. However, over the past ten years there has been a rapid expansion in the provision of drug treatment in the UK and in the number of drug misusers in treatment.

The majority of adult drug misusers in treatment in the UK report opiate drugs as their main problem drugs (primarily heroin). Significant minorities report their main problem drugs to be stimulants or cannabis. However, most adult drug misusers report problems with a range of illegal drugs and alcohol. The majority (two-thirds) of drug or substance misusers in treatment who are under 18 years report cannabis as their main problem drug (often with alcohol). Class A drug misuse is much less common among young problem drug misusers.

1.3.2 Drug-related morbidity and mortality

Drug misusers may have a range of health and social care problems, which may or may not be associated with drug misuse. Although drug misuse exists in most areas in the UK, it is more prevalent in areas characterised by social deprivation, which in turn is associated with poorer health. The majority of drug misusers also smoke cigarettes and many have lifestyles that are not conducive to good health.

Drug misusers, and injecting drug users especially, are particularly vulnerable to contracting and spreading blood-borne viruses and other infections. A long-term follow-up of heroin addicts showed they had a mortality risk nearly 12 times greater than the general population (Oppenheimer *et al.,* 1994). Another study of injecting drug users showed they were 22 times more likely to die than their non-injecting peers (Frischer *et al.,* 1997). Drug-related mortality following release from prison is a particular concern. The high morbidity and mortality rates make it especially important that drug misusers are in contact with treatment services.

1.3.2.1 Blood-borne viruses

Hepatitis B

Over one-third (34%) of all cases of hepatitis B in England are associated with injecting drugs. A prevalence rate of 21% is thought to exist among injecting drug users in the UK, with wide variation between countries and regions. The (self-reported) rate of hepatitis B vaccination doubled since 1998 from 25% to 59% in 2005 (HPA, 2006).

Hepatitis C

In England over 90% of hepatitis C diagnoses are associated with injecting drug use. The HPA (2006) reported that the current prevalence of hepatitis C among injecting drug users (IDUs) in England is 44% and across the UK almost 50% of IDUs are infected. There are wide geographic variations in prevalence, ranging from 58% in London to 20% in the north east. Almost half of IDUs in contact with drug treatment services are unaware of their status. Recent research indicates that those injecting crack cocaine have a much higher prevalence of hepatitis C infection (67%) and cohort studies indicate the incidence has recently increased.

HIV

Injecting drugs accounted for 5.6% of HIV diagnoses reported in in the UK (HPA, 2006). The overall prevalence of HIV among injecting drug users in England, Wales and Northern Ireland remains relatively low at 1.3% (42 of 3,240) infected but the prevalence in London is much higher at 4% (24 of 593) infected.* Of great concern is the recent increase in HIV among IDUs outside London, which has seen an increase in three years from 0.25% of IDUs in 2003 to 0.66% (11 of 1,660) in 2006 (HPA, 2007).* New studies looking at HIV incidence (new cases per year) found evidence of a recent increase in transmission to as much as 3.4% per annum in London and 6% in those injecting crack cocaine.

From 2002 to 2004, the prevalence of newly diagnosed HIV infection among IDUs tested in Scotland remained steady at between 0.47%

* The percentages for HIV prevalence were miscalculated in the September 2007 print and PDF versions of the guidelines. This edition contains the corrected figures, along with more recent data.

and 0.62% (about one in 200 IDUs tested). In 2005 this figure rose to 0.93%. However, 43% (nine out of 21) of the cases who received an HIV antibody test are presumed to have become infected outside Scotland (Health Protection Scotland, 2005).

Trends in sharing injecting equipment and risk behaviour

Injecting is a key factor in the transmission of blood-borne viruses (BBV) in drug misusers and in many overdose deaths. Tackling risky injecting behaviour lies at the heart of combating BBV and overdose deaths in drug misusers. The rate of reports of sharing injecting equipment rose in the late 1990s and remains high. In 2005, 28% of IDUs reported directly sharing needles and syringes and 48% reported sharing other injecting paraphernalia. Other trends in injecting identified by research during 2006 included an increase in injecting heroin with crack cocaine, very risky injecting behaviour among the homeless, and a trend to earlier high-risk groin injecting and poor injecting hygiene (HPA, 2006).

1.3.2.2 Drug-related overdose

Recorded rates of drug-related death due to overdose in the UK are among the highest in Europe. In the UK, acute drug-related deaths accounted for more than 7% of all deaths among those aged 15-39 years in 2004 (EMCDDA, 2006). Following steep increases in the rate of drug-related overdose deaths in the 1990s, just over 1,500 drug-related overdose deaths were recorded in England alone in 2005. The vast majority of these deaths were associated with injecting heroin misuse in combination with alcohol, benzodiazepines or other depressants. A significant proportion of drug-related overdose deaths also occur among drug misusers who have just left prison, with heroin involved in nearly all drug-related deaths in the two weeks after release (Farrell and Marsden, 2003).

Deaths associated with methadone have significantly reduced over the past five years, probably partly reflecting implementation of supervised consumption of methadone prescriptions in the initial stages of drug treatment.

1.4 The impact of drug misuse on families and communities

Protecting children from the potential impact of drug misuse is an important issue across the UK and a policy priority in Scotland. For example, Scotland has recognised and promoted the need to provide better outcomes for children, especially for those in need of care and protection and the importance of joined-up working for those agencies involved with children. In England, the *Common Assessment Framework* (DfES, 2006) has been introduced to assist practitioners. There is additional information at annex A9.

Drug misuse can place an enormous strain on the families of drug misusers including the children of drug-using parents, and can have a serious negative impact on the long-term health and wellbeing of family members.

The *Hidden Harm* report by the Advisory Council on the Misuse of Drugs (ACMD, 2003) estimated there were between 250,000 and 350,000 children of problem drug misusers in the UK. The report stated that parental problem drug use can and does cause serious harm to children at every age, and that reducing harm to children from parental problem drug misuse should become a main objective of policy and practice. It concluded that effective treatment of the parent can have major benefits for the child, and services and clinicians need to work together to protect and improve the health and wellbeing of affected children. Drug treatment can also have a positive impact in improving the quality of life for families and carers.

Drug-related crime has been estimated to inflict a major cost on local communities and the national economy. The evidence that drug treatment significantly reduces drug-related crime has been one of the main drivers behind the 1998–2008 UK Drugs Strategy and the subsequent priority accorded to expanding drug treatment.

1.5 Models of drug treatment

There are major changes likely in the delivery of healthcare over the coming years. The trend to devolve responsibility to regional and local levels will present risks and opportunities for drug treatment. A single 'shared care' model – described in the 1999 Clinical Guidelines as partnerships between primary, secondary and

specialist providers – has, in practice, developed into a range of different models, often driven by local circumstances and including a wider range of providers. Primary care has moved on since the Clinical Guidelines were last published in 1999. There are new organisational arrangements and the new GP contract, introduced in 2003. General practitioners can now opt out of many 'non-core' aspects of work, which are then commissioned directly.

General practitioners, nurses and pharmacists have been encouraged through NHS plans in Britain to develop areas of special clinical interest and many clinicians have done so, leading services within primary, secondary and custodial care settings. There are also new opportunities for non-medical prescribers, and increasing numbers of pharmacists and nurses have acquired the training necessary to prescribe for their patients.

Whatever the local treatment system model, the following principles are still key:

1.5.1 Local drug treatment systems based on local need

Local partnerships (and clinicians) need to work together to ensure local drug treatment systems are commissioned and provided to meet the changing needs of local drug-misusing populations within defined resources. In England, *Models of Care for Treatment of Adult Drug Misusers: Update 2006* (NTA, 2006) provides a basic commissioning framework for the range of drug treatment recommended within each local area, depending on local need. In Scotland, *Integrated Care for Drug Users* (Scottish Executive Effective Interventions Unit, 2002) provides the principles and practice underlying the design and delivery of effective treatment. Wales has the *Substance Misuse Treatment Framework for Wales* (Welsh Assembly Government). Drug misuse trends and potential treatment populations can change rapidly, and local partnerships and providers need to work together to ensure local systems keep abreast of locally changing needs.

1.5.2 Partnership

Many drug misusers have a myriad of health and social problems, which require interventions from a range of providers. Joint working across health and social care is therefore a key feature of effective treatment. It is seldom the case that one clinician will be able to meet these needs in isolation. One of the special features and strengths of drug treatment in the UK is the valuable partnership between statutory NHS drug treatment services and non-statutory or voluntary sector drug treatment providers, which comprise up to half of service provision in some local areas.

1.5.3 Doctors with a range of competencies

Each local system will need to have a cohort of doctors providing treatment for drug misusers, ranging from those able to provide general medical services to those with specialist competencies in treating drug dependence.

1.5.4 Clinical governance

Ensuring good clinical governance systems within and between different providers will enable the provision of good-quality drug treatment.

1.5.5 Involving patients

Involving patients as active partners in their drug treatment is essential and is associated with good outcomes. Patients should be fully involved in the development of their care or treatment plans, in setting appropriate treatment goals and reviewing their progress in treatment. It is also good practice to involve patients in the design, planning, development and evaluation of services, and in advocacy and support groups linked to local drug treatment systems. Patients may also be involved in peer education schemes to reduce the risk of overdose and blood-borne viruses.

1.5.6 Involving carers

The families and other carers of drug-misusing patients are a valuable resource in drug treatment and can be involved wherever possible and agreed by the patient. However, they are often in need of information and support for themselves, and their needs should not be overlooked.

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CHAPTER 2
CLINICAL GOVERNANCE

2.1 Key points

- Clinicians working with drug misusers must be appropriately competent, trained and supervised.
- Effective, safe and responsive services for drug misusers will usually involve clinicians working together and with others in teams in primary care, in secondary care or across both.
- The setting in which health professionals work in treating drug misusers will affect the clinical governance mechanisms that need to be in place. Those working in relative isolation must ensure they have an opportunity to discuss and review their work with colleagues in the field, to maintain good and up-to-date practice.
- Services should be provided consistent with national guidance and principles, and in line with the evidence base.
- Policy and statutory frameworks for providing substance misuse treatment to those under 18 years of age are often different from adults and different approaches are required from clinicians.
- The expansion of non-medical prescribing has implications for drug misuse treatment and care and clinical governance.
- A timely and regular audit and review cycle should be in place.
- Information governance policies and practice are critical, including confidentiality and information sharing. They should specifically include guidance for clinicians working with drug-misusing parents.
- Patients must be involved in their own treatment and should be involved in planning, developing, designing and delivering local drug treatment services, as far as their competence and interests allow.
- Families and carers of drug misusers are both an important resource in treating drug misusers and often in need of support for themselves. Carers of adults can be involved in patients' treatment, usually with the patients' consent, although there may be an obligation to involve the carers of young people in their treatment.

2.2 Principles of clinical governance

2.2.1 Introduction

Clinical governance is a term used to describe a systematic approach to monitoring and continuously improving the quality of clinical interventions (DH, 1998). Drug misuse treatment provider organisations and individual clinicians working in them have to take account of both formal and informal clinical governance structures.

Underpinning clinical governance implementation is a series of components. These are a mixture of responsibilities for organisations and individual health or social care professionals, and ensure that systems necessary to meet standards are in place. The following components of clinical governance only include some of those relevant to the provision of clinical services to drug misusers.

2.2.1.1 Clinical effectiveness

Clinicians should use evidence-based interventions and monitor their implementation and effectiveness using clinical audit. Protocols may be useful to ensure consistent provision and share good practice. For some clinicians, carrying out research to establish the evidence base is a priority.

2.2.1.2 Competence and continuous professional development

Clinicians need to have appropriate competencies for their clinical roles and receive training to achieve those competencies. They need to have appropriate certification, such as specialist registration, and take account of professional revalidation. Non-clinical skills such as leadership and management development are also important. Clinicians may benefit from individual or peer supervision, mentoring or other forms of professional support. Clinicians have an obligation to update their knowledge and skills base according to emerging evidence and developments in professional practice. Appraisal is mandatory for all clinicians working in the NHS and is good practice in other settings, and needs to be carried out according to current regulations.

2.2.1.3 Working in a team

Clinicians need to work with a range of other professionals and may work as part of a wider

organisation or in a multidisciplinary team. Clinical governance of a team may have different best practice requirements depending on the setting and nature of the organisation, for example a community drug treatment service within a mental health trust, a primary care led drug treatment service, or a voluntary sector drug treatment service working in partnership with primary care clinicians. Whatever the team arrangements, clinicians should be aware of which clinical governance arrangements are mandatory and which are best practice, and work in accordance with both. General practitioners providing drug misuse treatment for patients may need to liaise with other GPs in their practices to ensure fully effective care.

2.2.1.4 Information management

Clinicians need to:

- keep patient records
- ensure appropriate information sharing, confidentiality and data protection
- collect and analyse data
- make effective use of information and data.

Information sharing can be of great value to the direct care of individual patients and may also contribute indirectly to the delivery and effectiveness of the drug treatment system. Information sharing protocols should be consistent with guidance from the local Caldicott Guardian (Caldicott Guardians are senior staff in the NHS and social services appointed to protect patient information – see the Department of Health website for more information) and any national guidance, and acknowledge that patient consent to disclosure is key in most situations where identifiable information is shared. Clinicians must be satisfied that local information sharing is consistent with guidance from their professional and regulatory bodies.

2.2.1.5 Patient, public and carer involvement

Clinicians must take account of the needs and views of patients (and, if appropriate, their carers) in planning the delivery of care. They may also have to take into account the views of the local community.

2.2.1.6 Risk management

Incident reporting, investigation and review, risk assessment, risk prevention and control and infection control normally constitute a duty of both an individual clinician and the organisation in which they work. Staff at risk of infection from patients should be appropriately immunised.

2.2.1.7 Public health

Clinicians should take account of disease prevention, health promotion and addressing health inequalities. This is particularly pertinent when working with drug misusers who are at high risk of blood-borne viruses and other infections, smoking-related disease and drug-related death due to overdose.

2.2.2 Other relevant clinical governance frameworks

The General Medical Council's guidance, *Good Medical Practice* (GMC, 2006), sets out the principles and values on which good medical practice is founded. Together with a range of supplementary guidance – including booklets on consent, confidentiality and doctors' responsibilities towards children and young people, and shorter statements on a number of issues including prescribing – GMC guidance provides another framework for ethical decision making in clinical practice.

Other standards may be relevant to doctors such as guidance from the Royal College of Psychiatrists and the Royal College of General Practitioners, the Department of Health and the National Treatment Agency in England, and NHS QIS in Scotland (NHS QIS, 2005).

Other clinicians have guidance from their professional bodies, including the Nursing and Midwifery Council, The Royal Pharmaceutical Society of Great Britain and the British Psychological Society.

Prescribing governance and an adequate understanding of the law relating to prescribing for drug misusers is important. Prescribers have a responsibility to keep up-to-date on changes in the law and guidance on prescribing controlled drugs. An example of this is changes following the Shipman enquiry.

2.2.3 Policies and protocols

It is usually good practice to ensure that practice is standardised through local area or agency policies and protocols. It is important to note that the individual clinician may need to vary and deviate from protocols in some clinical

situations. This should only be done within the limits of a clinician's competence and recorded as a matter of course.

2.2.4 Competencies

Individual clinicians will have different fields of expertise and their professional background and training will predict, to a large extent, their competence to work in a particular type of service. Individual clinicians and employing organisations have a duty to ensure they have the right competencies, and continuing professional development and appraisal, to allow them to practice in their positions.

Competencies of clinicians may be viewed across the following domains: advice; identification and assessment; patient management; training, supervision and teaching; research and audit; and management and service development. Appropriate training assists clinicians to acquire and maintain the required competencies. The document *Roles and Responsibilities of Doctors in the Provision of Treatment for Drug and Alcohol Misusers* (RCPsych and RCGP, 2005) sets out the competencies for doctors in detail. Some of the terms used to describe doctors working with drug misusers are also summarised in this document and at annex A1.

2.3 Doctors' training

Clinicians need to ensure that they have been trained to gain the appropriate competencies to treat drug misusers.

Medical students receive a very limited amount of training in drug misuse issues in their medical training.

Addiction psychiatrists have a formal training route now reformed by MMC (modernising medical careers) which provides a six year run-through training leading to a certificate of completion of training and entry to the specialist register. During this training period individuals can elect to spend time in addiction services and gain an endorsement in addiction psychiatry. The curriculum and examination of the training are delivered by the Royal College of Psychiatrists and results in gaining the MRCPsych. Following training they need to be registered for CPD with the appropriate Royal College. CPD can be monitored through the appraisal process.

General practitioners have formal training in drug misuse as part of the Royal College of General Practitioners curriculum. Increasing numbers take the Certificate in the Management of Drug Misuse Parts 1 and 2, which may be taken by nurses, pharmacists and other professionals. Part 1 combines e-learning and some local training. Part 2 combines large and small group teaching and is designed to teach the competencies needed to provide tier 3 interventions at a special interest level. After completing part 2 the clinician undertakes CPD and appraisal specific to their work with drug misusers. This can be monitored formally through the GP appraisal process.

The White Paper, *Trust, Assurance and Safety – the Regulation of Health Professionals* (DH, 2007) sets out plans for revalidation for doctors and other health professionals.

2.4 Non-medical prescribing

2.4.1 Introduction

The term 'non-medical prescribing' refers to the prescribing of medication by health professionals other than doctors and dentists. It is 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. There are two main categories of non-medical prescribing: supplementary prescribing and independent non-medical prescribing. These are described in more detail in section 2.4.2.

Drug Misuse and Dependence: UK Guidelines on Clinical Management is equally applicable to non-medical prescribers and to doctors. In practice in drug misuse, non-medical prescribing is undertaken by nurses and pharmacists, although there are a number of other professional groups eligible to train as supplementary prescribers. However, it is important to understand that non-medical prescribers are only able to prescribe within their area of competence.

To become a non-medical prescriber, the nurse or pharmacist must have completed the recognised non-medical prescribing training. For a nurse or pharmacist to practise as a non-medical prescriber, there must be, against their name in the relevant professional register, an annotation or entry signifying that they are qualified as a supplementary and/or independent non-medical prescriber.

2.4.2 Definitions of non-medical prescribing

2.4.2.1 Supplementary prescribing

Supplementary prescribing is a voluntary partnership between an independent (doctor) prescriber and a supplementary prescriber (a non-medical health professional) to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement. It involves diagnosis by the doctor, agreement by the patient to be managed by the prescribing partnership, and preparation of a CMP signed by both prescribers. 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.

A supplementary prescriber can prescribe any medicine that has been agreed in the CMP including all controlled drugs.

2.4.2.2 Independent non-medical prescribing

Independent non-medical prescribing means that the prescriber takes responsibility for the clinical assessment of the patient, for establishing a diagnosis and the clinical management required, for prescribing where necessary and for the appropriateness of any prescription.

Nurse independent prescribers can prescribe a limited range of controlled drugs for specific medical conditions but this does not yet extend to the independent prescribing of controlled drugs for the treatment of opiate dependency. Proposals for changes in this legislation at the time of publication suggest that these restrictions may be removed shortly, in which case nurses and pharmacists with the appropriate competencies would be able to prescribe controlled drugs independently (with the exception of those requiring a special licence for their use in the treatment of drug dependence).

2.4.3 Clinical governance requirements for non-medical prescribing

These clinical governance requirements are in addition to those required for medical prescribers.

- Accountability for decisions – each qualified non-medical prescriber is individually and professionally accountable for their prescribing decisions, including actions and admissions, and cannot delegate this accountability to any other person. Non-medical prescribers are also expected to work within the standards and code of professional conduct set out by their own regulatory body as well as the policies and guidelines ratified by their employing organisation.
- Clear lines of responsibility and accountability for overall quality of clinical care – non-medical prescribers agree in advance with the independent prescribers and services how to maintain continuity of patient care when they are not available.
- Clinical audit – non-medical prescribing is included in audit programmes and monitored as part of overall prescribing monitoring.
- Clinical supervision – non-medical prescribers meet regularly with the independent prescriber and are provided with regular and frequent clinical supervision.
- Insurance and liability – non-medical prescribers must have in place comprehensive professional indemnity insurance. Employing bodies accept vicarious liability for non-medical prescribers who adhere to their non-medical prescribing policy.
- Evidence based practice – systems should be in place to ensure that national guidelines, local guidelines, local agreements and formularies are disseminated to all non-medical prescribers.
- Management of poor performance – all organisations employing non-medical prescribers should have systems in place for identifying poor professional performance, in line with other prescribers. Prescribing responsibilities need to be considered as part of this process.

In addition, for supplementary prescribers:

- Supplementary prescribers must refer all patient circumstances that fall outside the clinical management plan, or outside their competency, to the independent prescriber.
- For supplementary non-medical prescribing the clinical management plans must be patient specific, up to date and reviewed regularly (at least annually).
- Supplementary prescribing should be monitored as part of clinical audit to ensure it stays within clinical management plans.

Clinical governance for non-medical prescribing is covered in:

- *Standards of Proficiency for Nurse and Midwife Prescribers* (NMC, 2006), which provides standards of conduct that nurses, midwives and specialist community public health nurses are required to meet in their practice as a registered nurse prescriber.
- *Clinical Governance Framework for Pharmacist Prescribers and Organisations Commissioning or Participating in Pharmacist Prescribing* (GB wide) (RPSGB, 2005), which suggests indicators of good practice for pharmacist prescribing and examples of good clinical governance practice relating to prescribing.

2.4.4 Patient group directions

Patient group directions (PGD) are a mechanism for supply and administration only. They are not a form of non-medical prescribing. PGDs are written instructions for the supply or administration of particular medicines to patients with a defined diagnosis, condition or need, who are not individually identified before presentation for treatment. The directions should be drawn up by multidisciplinary groups and must be authorised by the appropriate local NHS body and signed by a senior doctor and a pharmacist. PGDs can be utilised by a range of healthcare professionals, including nurses, pharmacists and occupational therapists. There are no specific training programmes for PGDs but individual organisations must ensure that people using them are competent to do so.

PGDs can be of particular benefit to drug misusers when they come into contact with services and are in need of specific short term or one-off intervention at times or in places where a prescriber is not immediately available.

Examples of PGDs relevant to drug misuse include: hepatitis vaccination, antibiotics for infections, emergency hormonal contraception and take-home emergency naloxone.

2.5 Confidentiality, information sharing and child protection

2.5.1 Confidentiality and information sharing

Clinicians must be satisfied that local decisions concerning information sharing are consistent with GMC and other professional guidance, and with guidance from the local Caldicott Guardian. Patient consent to disclosure is required in most situations where identifiable information is shared and information will be shared on a 'need to know' basis only. Whenever a confidential relationship is entered into, the boundaries of this confidentiality must be discussed with the patient so that they understand what it means and how and when information is likely to be shared.

Information sharing can be of great value to the direct care of individual patients and may also contribute indirectly to the more effective delivery of the drug treatment system. Many patients, including those involved in drug treatment through the criminal justice system, will, following appropriate discussion, be willing to consent to share appropriate personal information with others on a need-to-know basis. It is important to maintain public confidence in the confidential nature of personal health information, while at the same time optimising use of such information. Identifiable information about patients must not be given to others unless the patient consents or disclosure without consent can be justified (for example, in the public interest). Local protocols on information sharing arrangements between the criminal justice system and health and social care providers of drug treatment can be particularly useful to describe and facilitate suitable information sharing arrangements that are both consistent with legal and ethical obligations and avoid unnecessary barriers or delays.

2.5.2 Reporting of drug misusers

Except in Northern Ireland there is no longer a legal requirement for doctors in the UK to notify the authorities if they suspect that a patient is addicted to certain controlled drugs.

Prescribers are now expected to report details of drug misusers electronically or by returning special reporting forms to their regional or national drug misuse database. Details of national and regional centres can be found in annex A11 and in the *British National Formulary.*

2.5.3 Considering the needs of the children of drug-using parents

Hidden Harm (ACMD, 2003) sets out expectations that a local treatment system should work together to ensure that adequate steps are taken to protect and improve the health and wellbeing of the children of drug-

misusing parents. Clinicians and services need to take account of local frameworks, which are now in place in most areas.

Clinicians have an individual responsibility to the children of their patients. They need to take systematic steps to ensure that they assess risk to children (such as making sure that detailed knowledge of a patient's children and risks to them are ascertained as part of all assessments).

If a clinician suspects a child may be at risk they must take steps, if necessary immediately, to deal with that risk. At the core of many child protection crises is the failure to share important information between agencies. Addressing this may require referral to involve others such as social services (in accordance with relevant frameworks and protocols). This must be done with the patient's knowledge if possible but not necessarily with their consent. The safety, welfare and wellbeing of a child is paramount when making decisions to share information with, or about, them. Children have a right to express their views and to have them taken into account when decisions are made about what should happen to them. In general, information will normally only be shared with the consent of the child. However, where the child is at risk of significant harm information may need to be shared without consent, although the intention to share and the reasons for this should be notified to the child. Where appropriate, advice should be sought on the involvement of management, appropriate child protection officers and relevant professionals.

2.5.4 Young people who misuse substances

The same duties of confidentiality apply to children and young people as to adults. In addition to the usual bases for non-consensual disclosure, information might be shared about a child or young person without consent:

- to protect them from a risk of significant harm
- when it is in the best interests of a child or young person who does not have the capacity to make a decision about disclosure.

As with adults, confidentiality agreements for offenders may be different than other patients (for example, see *The National Specification for Substance Misuse for Juveniles in Custody* (YJB, 2004) for England and Wales) which states that interventions must be undertaken within clear confidentiality arrangements, and that information about a young person's medical needs and interventions should be used to inform substance misuse care plans).

2.5.4.1 Information sharing and child protection

An appropriate authority should be informed promptly of any reasonable concern that a child or young person is at risk of abuse or neglect, when that is in the child or young person's best interests or necessary to protect others from serious harm. Any decision not to share information in such circumstances must be justified and should be discussed with a named or designated doctor for child protection. The clinician should follow professional guidance and local child protection protocols.

2.5.4.2 Informed consent and competence to consent

Informed consent is a legal and ethical requirement of any investigation or treatment (other than in an emergency or when authorised by mental health legislation). At 16 young people can be presumed to have capacity to consent. Children under 16 may have the capacity to consent, depending on their maturity and ability to understand what is involved. Capacity is decision-specific. Only if a child can understand, retain, use and weigh information about the nature, purpose and possible consequences of the procedure (or refusing it) can they consent to it.

A person with parental responsibility (or the courts) can consent on behalf of a child who lacks capacity to consent for themselves. Both parents' involvement should be encouraged whether or not the child can consent for themselves. Parents cannot override the competent consent of their child to investigations or treatments that are in their best interests. Legal advice should be sought if a competent child refuses treatment necessary to save life or avoid serious deterioration in health.

There are different legal and statutory frameworks in England and Wales, Scotland and Northern Ireland in this area. Clinicians should ensure they are aware of issues relevant to their practice.

2.6 Involving patients

Involving patients as active partners in their drug treatment is good practice and is associated with better outcomes.

Patients should be fully involved in the development of their care or treatment plan, in setting appropriate treatment goals and reviewing progress in treatment. They should be informed about the benefits and risks of different treatment options so that they can be actively involved in choosing treatment appropriate to their needs.

It is also good practice to involve patients at a range of levels in the design, planning, development and evaluation of services. Competent patient representatives may also be involved at a senior level in organisations. There are formal strategies and mechanisms for patient involvement in health services in each of the countries of the UK.

Patients in drug misuse services may also be involved in peer education schemes to reduce the risks of overdose and blood-borne viruses, and in local and regional groups linked to local drug treatment systems. These groups can advise and support patients or signpost them to other sources, including a range of generic and drug-specific advocacy services. They may also inform, educate and empower patients on a range of issues and in ways that can help to improve treatment outcomes.

National patient groups can provide further information, advice and support.

2.7 Involving carers

Families and carers of drug misusers are both an important resource in treating the drug misuser and often in need of support for themselves. Depending upon the relationships between patients and their carers, and bearing in mind the patient's right to confidentiality, in as far as it is possible and practicable, information should be exchanged both ways between clinicians and carers, and carers should be active partners in drug misuse treatment.

Carers should be offered specific information and advice on:

- the risks from blood-borne viruses and overdose and, if appropriate, should be offered vaccination
- safe storage of medicines.

It is recommended that clinicians:

- make themselves accessible to family members and carers with the consent of the patient
- assess and take account of the needs of family members and carers, including the welfare of dependent children, siblings and vulnerable adults
- provide verbal and written information and advice on the impact of drug misuse and about treatment and the settings in which it may take place
- provide information about self-help, group and individual support for families and carers
- consider family or couples-based interventions.

If families and carers have been offered but not benefited from guided self-help and/or support groups and continue to have significant family problems, consideration should be given to providing formal psychosocial interventions.

National Institute for Health and Clinical Excellence (NICE) guidelines on detoxification (NICE, 2007a) and on the psychosocial management of drug misuse (NICE, 2007b) (see section 5.7 and chapter 4) detail the general and specific interventions that clinicians should offer to carers.

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CHAPTER 3
ESSENTIAL ELEMENTS OF TREATMENT PROVISION

3.1 Key points

- The needs of all drug misusers should be assessed across the four domains of drug and alcohol misuse, health, social functioning and criminal involvement.
- Risks to dependent children should be assessed for all drug-using parents.
- All drug misusers entering structured treatment should have a care or treatment plan which is regularly reviewed.
- Drug misuse treatment involves a range of interventions, not just prescribing.
- A named individual should manage and deliver aspects of the patient's care or treatment plan.
- Drug testing can be a useful tool in assessment and in monitoring compliance and outcomes of treatment.

3.2 Assessment, planning care and treatment

3.2.1 Introduction

Good assessment is essential to the continuing care of the patient. Not only can it enable the patient to become engaged in treatment but it can begin a process of change even before a full or comprehensive assessment is complete. Assessment skills are vital for all clinicians and members of the multidisciplinary team. Clinicians need sufficient competencies to be able to assess patient need.

Patients present, or are referred, to drug treatment services for a variety of reasons. Patients may consult a clinician for a medical problem without mentioning drug misuse or the full extent of their misuse. By maintaining an empathic, non-judgemental attitude, the clinician may encourage appropriate disclosure.

Assessment also provides an opportunity to provide information about treatment options and the expectations of treatment.

3.2.2 Treatment goals

For some years now, "a range or hierarchy of goals" of drug treatment has been identified in the UK (DH, 1996):

- Reducing health, social, crime and other problems directly related to drug misuse.
- Reducing health, social or other problems not directly attributable to drug misuse.
- Reducing harmful or risky behaviours associated with the misuse of drugs (for example sharing injecting equipment).
- Attaining controlled, non-dependent or non-problematic drug use.
- Abstinence from main problem drugs.
- Abstinence from all drugs.

"These goals can be interrelated, For example, they may include the attainment of abstinence at the same time as achieving improvements in psychosocial functioning in areas unrelated to drug use. The treatment goals will depend upon the motivation and circumstances of each individual. Some may be willing to commit themselves to a determined effort to become abstinent. Others may be unwilling to do so, but may still be prepared to make some changes (such as reduction in risk behaviour)." (DH, 1996.)

3.2.3 Assessment

Assessment should be seen as a process that may need to be conducted over several sessions or consultations.

It may be appropriate for concerned relatives or professionals already involved to attend with the patient. With patients under 16 years, this may be required.

After a brief initial assessment involving a risk assessment, clinicians may find it useful to develop brief initial plans of care with patients to address immediate concerns, such as access to clean injecting equipment for drug injectors together with advice to reduce risk of overdose and contracting blood-borne viruses.

For drug misusers with severe problems, the assessment process may involve a number of professionals as patients may have treatment and care needs in the domains of drug and alcohol misuse, health (physical and psychological), social functioning including housing and employment, and criminal

involvement (particularly if the clinician is working closely with the criminal justice system or providing drug treatment in prison).

3.2.3.1 Assessment of risk

Assessing risk is an important part of assessment. Drug misuse specific risks that may need to be prioritised could include risks related to overdose, polydrug and alcohol misuse, unsafe injecting practices and unsafe sex. Wider risks may include self-harm or harm to others. Risks to dependent children should be assessed as soon as possible after contact with services. This would normally include all clients being asked about their children, their ages (some service protocols may require date of birth), and the level of contact they have with them, as a minimum at initial assessment.

3.2.3.2 Aims of full or comprehensive assessment

A drug misuse assessment should include the following:

- Treating any emergency or acute problem.
- Confirming the patient is taking drugs (history, examination and drug testing).
- Assessing degree of dependence.
- Identifying physical and mental health problems.
- Identifying social problems, including housing, employment and domestic violence, and offending.
- Assessing risk behaviour.
- Determining the patient's expectations of treatment and desire to change.
- Determining the need for substitute medication (see section 3.2).
- With young people, assessing competency to consent to treatment (if required) and involving those with parental responsibility as appropriate. Local assessment proformas or processes specifically designed for young people may also need to be used and different professional competencies may be required.
- For drug-misusing parents with dependent children, obtaining information on the children and any drug-related risks to which they may be exposed.
- In private practice, establishing that the patient is able to pay for treatment through legitimate means.

If risk of significant harm to a young person is found, involve other professionals according to local child protection requirements.

The assessment process also provides an excellent opportunity for clinicians to provide brief interventions to reduce immediate harm from drug misuse including, if needed, access to sterile injecting equipment, testing for hepatitis and HIV, and immunisation against hepatitis B.

It is also important to assess the most appropriate level of expertise required to manage the patient (this may alter over time), and refer or liaise appropriately (for example, with clinicians who have more competencies in treating drug misuse and psychosocial

Full or comprehensive assessment of drug-misusing parents

The following should be taken into consideration:

- Effect of drug misuse on functioning, for example, intoxication, agitation.
- Effect of drug seeking behaviour, for example, leaving children unsupervised, contact with unsuitable characters.
- Impact of parent's physical and mental health on parenting.
- How drug use is funded, for example, sex working, diversion of family income.
- Emotional availability to children.
- Effects on family routines, for example, getting children to school on time.
- Other support networks, for example, family support.
- Ability to access professional support.
- Storage of illicit drugs, prescribed medication and drug-using paraphernalia.

With consent, information should be gathered from other professionals.

interventions). Clinicians will also need to notify the patient to the relevant national drug monitoring system using the appropriate local reporting form or system.

The assessment process should result in a written document that can be referred to and used as a basis for discussing care planning, goals and objectives with the patient.

There is an increasing trend for local areas and services to develop shared assessment processes and care pathways. For example, in Scotland, under the Joint Future process, many services are developing a process of single shared assessment (SSA) which ensures an agreed local process is in place, gathering essential information effectively and promoting information sharing in order to better co-ordinate care delivery.

Assessment is discussed in:

- *Models of Care: Update 2006* (NTA, 2006).
- *Care Planning Practice Guide: Update 2007* (NTA, 2007a).
- *Integrated Care for Drug Users: Principles and Practice* (Scottish Executive Effective Interventions Unit, 2002).
- The forthcoming In-depth Integrated Specialist Assessment Toolkit in Wales.

3.2.4 Care or treatment plan

Following taking a full history and completing an assessment, a care or treatment plan should be agreed with the patient. It should normally cover patient needs (and how these will be met) in one or more of the following domains:

- Drug and alcohol use
  - Drug use, including types of drugs, quantity and frequency of use, pattern of use, route of administration, symptoms of dependence, source of drug (including preparation), and including prescribed medication and tobacco use.
  - Alcohol use, including quantity and frequency of use, pattern of use, whether in excess of safe levels and alcohol dependence symptoms.
- Physical and psychological health
  - Physical problems, including complications of drugs and alcohol use, blood-borne infections and risk behaviours, liver disease, abscesses, overdose, enduring severe physical disabilities and sexual health. Pregnancy may need to be assessed.
  - Psychological problems, including personality problems or disorders, self-harm, history of abuse or trauma, depression and anxiety and severe psychiatric co-morbidity. Contact with mental health services will need to be recorded.
- Criminal involvement and offending
  - Legal issues including arrests, fines, outstanding charges and warrants, probation, imprisonment, violent offences and criminal activity, and involvement with workers in the criminal justice system, for example probation workers.
- Social functioning
  - Social issues, including partners, domestic violence, family, housing, education, employment, benefits and financial problems.
  - Childcare issues, including parenting, pregnancy, child protection.

It is seldom the case that a clinician will be able to meet all of a patient's needs if the patient has a serious drug misuse problem or unmet needs in a range of domains. A patient may need prescribing interventions plus psychosocial interventions, help with housing or benefits etc. This often requires clinicians to have input from or facilitate referral to a range of other professionals.

The assessment of young people will require additional components, such as comprehensive educational needs and development needs (NTA, 2007b).

Clinicians will need to be able to track progress with patients around their range of needs and record progress in the plan of care or care plan. There may be several clinicians involved in the patient's treatment – these should be named in the care plan along with a clear identified lead clinician.

3.2.5 Discharge from treatment and support to prevent relapse

If a patient has successfully completed drug treatment, they still may have ongoing needs to prevent relapse into drug and alcohol misuse. Many drug misusers relapse and it is important that they can gain speedy access back to drug

treatment if they do. Patients may also require a package of aftercare, which may include psychosocial support.

Ongoing support and help to maintain health and wellbeing from a GP may also be vital to success, together with support from social care providers (such as housing, education or employment access schemes). Advocacy and support may also be provided through organisations such as Narcotics Anonymous (NICE, 2007).

3.3 Delivery of treatment

3.3.1 Introduction

The delivery of treatment is normally through a key individual or clinician sometimes known as a keyworker. This may be a doctor, a nurse, a voluntary sector drugs worker, etc. The clinician in most regular contact with the patient is normally the keyworker and, if the patient has complex needs, it is important that this is a single named individual. Keyworking helps to ensure the delivery and ongoing review of the care or treatment plan. This would normally involve regular sessions or consultations with the patient in which progress against the care plan would be discussed and goals revised as appropriate. As good practice, keywork involves building a therapeutic relationship with the patient (see section 4.2.2).

3.3.2 Content of keywork

The content of keywork sessions is dependent on individual patient needs but would normally include the following:

- Developing and agreeing the care or treatment plan with the patient, implementation of the plan and checking progress against its milestones.
- Information and advice on drug and alcohol misuse.
- Interventions to prevent relapse.
- Harm reduction work and motivational interventions.
- Other psychosocial and medical interventions depending on the competency of the keyworker.
- Helping to address social needs, for example welfare benefits.
- For drug-misusing parents, monitoring the family situation, supporting parenting, helping patients access resources, managing the interface with social services, antenatal services and other relevant professionals, and formally monitoring child protection risk.

3.3.3 Delivering treatment in different settings

In primary care, the keyworker may be the GP or drugs worker supporting the GP in a shared care arrangement. In this setting, the keyworker will still work within a care and treatment planning framework that adheres to the principles described previously. Therefore, the care or treatment plan will describe how the specific roles and responsibilities of the GP, the shared care worker and any others involved will be shared in delivering co-ordinated care. Shared responsibilities will include monitoring of compliance and continuity of care. The GP is likely to lead on prescribing interventions, changes and additions to medication, and addressing healthcare needs. The shared care worker is likely to lead on monitoring progress against treatment goals, developing a holistic treatment plan and in ensuring multidisciplinary discussion when appropriate. For GPs working at a more specialist level (for example, a GP with a special interest) the roles may be different but in all cases this should be clear in the care plan.

In secondary care the keyworker may be a nurse or drugs worker but doctors may also keywork some patients and have an advisory or supervisory role for others, depending on local arrangements. In specialist drug treatment services, the keyworker is often part of a multidisciplinary team and responsible for co-ordinating patient care when more than one clinician or service is delivering treatment to a patient, for example a patient who is receiving psychosocial interventions from a psychologist to address specific issues, in addition to being on a methadone programme and having regular keyworking sessions.

3.3.4 Care planning in other groups with externally co-ordinated care

Individuals with severe mental health problems whose care is co-ordinated under the care programme approach (CPA), particularly those on the current 'enhanced' CPA, will have a named mental healthcare co-ordinator. Arrangements for the care programme approach are somewhat different in Scotland. Structured

drug treatment providers usually contribute to elements of the mental health CPA plan of care.

Those who are under supervision or treatment orders from the criminal justice system will need careful integration of planning of their structured treatment to optimise outcomes (for example, in the case of those on community sentences requiring drug treatment). The probation service (or Criminal Justice Social Work in Scotland) may have information (particularly regarding risk issues and offending behaviour) that may need to be incorporated into the care plan.

Patients receiving community care funding (for example, someone in residential rehabilitation) may have the co-ordination of their care and case management provided by a community care manager (sometimes drug-specific).

For young substance misusers the primary responsibility for delivery of a holistic treatment and care plan may be located with child and adolescent mental health services, social services team or young offenders team. In these situations, drug treatment clinicians may need to work closely with other professionals and participate in multidisciplinary meetings which focus on all the young person's needs and which co-ordinate care.

3.4 Drug testing

3.4.1 Introduction

Illicit and prescribed drugs and medication can be detected in a variety of biological samples using different testing methods. Selection of appropriate testing methods can complement the treatment of drug misusers.

The sensitivity and windows of detection of different drug tests can result in false negatives or false positives. Inconsistent or unexpected results should always be interpreted in the light of other clinical information.

Staff performing tests should be competent in taking samples and, if appropriate, in reading results. Laboratory testing must be done in appropriately accredited laboratories.

3.4.2 Types of drug test

Most drug testing processes consist of two separate types of analysis: a screening test and a confirmation or classification stage. The screening test is usually fairly quick, cheap and easy to do, and is designed to easily identify negative results. Frequently, an immunoassay system is used, either in the laboratory or using point of care or dipstick tests. With these tests, a negative result can usually be accepted as negative, but a positive result, particularly if substantial weight is to be placed on it, should normally be confirmed by a different type of test, usually conducted by a laboratory.

The confirmatory test is normally only done on samples that have shown positive on the screening test. It is almost always laboratory based, and frequently uses either gas or liquid chromatography coupled to mass spectrometry (GC/MS or LC/MS). These methods will detect drugs and their metabolites with greater accuracy than screening tests but are usually slower and more expensive.

3.4.3 Biological samples used in drug testing

Urine remains the most versatile biological fluid for drug testing and has the advantage of indicating drug use over the past several days. As well as being physically non-invasive, drugs are present in relatively high concentrations and large samples can quickly and safely be collected.

Oral fluid has the advantage of being easier to collect and harder to adulterate, although drugs are present in lower concentrations and the sample size is usually much smaller than for urine. The detection window for oral fluid testing is normally 24-48 hours for most drugs, so only very recent drug use can be detected. This is a relatively new method of screening, so there are fewer publications and less evidence for oral fluid compared to urine.

At the other end of the spectrum, hair testing is poor at detecting very recent use, but can be used to look at drug use over the preceding few months. Since hair grows at a relatively constant 1 cm a month, the detection window can be several months or more. Normally hair testing can detect drug use at some stage during a preceding month, and can be used to compare months, but cannot differentiate continual from sporadic use. Hair testing is much more complicated than urine or oral fluid, and is restricted to specialist laboratories.

3.4.4 Uses of drug testing

- Initial assessment and confirmation of drug use (although testing does not confirm dependence or tolerance and should be used alongside other methods of assessment).
- Confirming treatment compliance – that a patient is taking prescribed medication.
- Monitoring illicit drug use, including as a drug-specific treatment goal (for example, as part of a psychosocial intervention).

The rationale for testing and the use made of drug test results is important and must be clearly delineated to those responsible for patient care, in order to be cost effective and efficacious.

Drug testing to confirm drug use when a patient has admitted to it and is already in treatment is generally not cost-effective.

3.4.5 Choosing an appropriate drug test

Many licit and illicit drugs can be misused, but not all can be targeted by routine screening. Testing regimens generally target commonly misused drugs or drug groups. Analytical approaches need to respond to service requirements within resources available. Preliminary screening of samples, such as urine, to identify compounds below or above established negative and positive concentration cut-off values can be followed by specific confirmation of positives as appropriate.

Gas or liquid chromatography with mass spectrometry (GC/MS or LC/MS) is still the gold standard for drug testing. It is more frequently used now for confirmatory testing but its use is essential when testing is for forensic purposes or may otherwise have serious consequences for patients or their families (for example child protection).

However, alternative forms of testing may be quicker, cheaper, easier and suitable for other purposes. Qualitative screening tests for urine and saliva, such as point of care testing devices, can provide a negative or positive result at the sampling site. Presumptive positive results, which may be non-specific, can then be sent to a laboratory for confirmation testing if appropriate.

Random intermittent drug screening is probably the most practical and cost-effective option for providing reliable information about an individual's recent drug use.

3.4.6 Procedures for drug testing

It is normal practice to have written procedures for the collection and storage of biological samples, their dispatch to a laboratory and the discussion and management of reported results.

Drug or its metabolite(s)	Duration of detectability
Amphetamines/amfetamines, including methylamphetamine and MDMA	2 days
Benzodiazepines: • Ultra-short-acting (half-life 2h) (e.g. midazolam) • Short-acting (half-life 2–6h) (e.g. triazolam) • Intermediate-acting (half-life 6–24h) (e.g. temazepam, chlordiazepoxide) • Long-acting (half-life 24h) (e.g. diazepam, nitrazepam)	 12 hours 24 hours 2–5 days 7 days or more
Buprenorphine and metabolites	8 days
Cocaine metabolite	2–3 days
Methadone (maintenance dosing)	7–9 days (approximate)
Codeine, dihydrocodeine, morphine, propoxyphene (heroin is detected in urine as the metabolite morphine)	48 hours
Cannabinoids: • Single use • Moderate use (three times a week) • Heavy use (daily) • Chronic heavy use (more than three times a day)	 3–4 days 5–6 days 20 days Up to 45 days

Table 2: Approximate durations of detectability of selected drugs in urine

Note: Detection times are only very approximate and highly dependent upon dose, frequency, route of administration and urine excretion and concentration

Standard operating procedures should include, where relevant, instruction on storage of point-of-care test devices, calibration of equipment, recording of results, infection control procedures and disposal of biological fluids. Appropriate facilities should be available for sample collection and, if conducted, for testing on site.

Collection procedures should aim to ensure the integrity of specimens. The time of sample collection should always be noted and related to the consumption over the last few days of both prescribed and illicit drugs.

Samples such as urine can be prone to problems of adulteration, substitution, non-compliance and pre-collection abstinence. A negative interference can be achieved by specimen dilution, drinking large volumes of fluid, addition of chemicals (salt, soap, bleach) or direct substitution with another sample. A positive result can be achieved by direct addition of a drug to the sample or by substitution with one provided by a known positive misuser. Alternatively, pre-sample abstinence may produce a misleading negative result, while ingestion of drugs obtained licitly may be used to mask those taken illicitly.

In routine clinical practice, strict supervision, including observation of urine specimen collection, is not necessary but steps should be taken to limit the opportunities to tamper with specimens and to check their integrity, such as examining sample colour and temperature.

Where serious consequences might follow a positive (or negative) test, procedures should be more rigorous and might include greater security of the specimen collection site, further steps to reduce tampering or adulteration, and secure packaging for delivery to the testing site.

It will only very occasionally be necessary or appropriate to directly observe a urine specimen being given, and then only with informed patient consent.

In clinical practice, sampling under a 'chain of custody' protocol may be required for confirmatory testing, especially in forensic situations such as testing in relation to court orders or sentences.

3.5 General health assessment at presentation and in treatment

3.5.1 Introduction

Early assessment of the general health status of an individual revealing a drug problem is important and may be best carried out by the person conducting the initial assessment of the problem. This is not always a GP or a clinician in a drug treatment service. Increasingly the entry point into treatment or the route by which individuals are directed into specialist care begins with non-specialist staff such as a generic counsellor, pharmacist, non-statutory care agency, midwife or community or practice nurse. Presentation may be directly connected with drug taking, a complication of drug misuse or drug misuse lifestyle, or as an incidental finding.

The prescriber should ensure that healthcare assessment, screening and management are being provided for each patient – especially where specialist prescribing is being provided for patients who are not registered with a GP.

As a general principle it is good practice to do a general health assessment, within the clinician's competency, and to decide whether or not an intervention is appropriate and whether it is urgent or can wait. Sometimes it will be obvious that there is a requirement for a further and more detailed examination and perhaps laboratory or clinical testing. The most appropriate action is to refer to a medically qualified practitioner such as a GP, or from primary care to a specialist clinic. The specialist clinic may be a drug or alcohol service or a clinic dealing with, for example, liver problems, cardiac and vascular abnormalities or respiratory diseases.

The aim of a health assessment is to identify unmet healthcare needs as well as to consider the presenting symptoms and take account of health problems that could interact with drug treatment. There is also a need to take advantage of an opportunity to attract a patient into contact with health services and to improve the outcome of drug treatment by improving general health and wellbeing.

Inevitably there are some conditions which commonly affect drug misusers – questions and examinations that might help to identify these are listed in section 3.5.2. There are then examinations and tests that should be discussed and carried out on selected individuals according

to need and decisions of the patient. There are, in addition, possible health hazards connected with drug taking which might be important but which do not occur frequently and there is always the need for the clinician to be alert to other, more unusual, health issues. The clinician might like to consider covering these areas over a series of consultations rather than attempting to unearth complex and sometimes longstanding problems in a short consultation. One of the advantages of having patients in treatment is the ongoing contact and opportunities for medical and social interventions.

3.5.2 Health questions, examinations and tests

3.5.2.1 Questions

There is an overlap between the questions asked specifically in relation to health needs and those addressed as part of a full or comprehensive drug assessment (see section 3.2). History taking in relation to health should include questions about:

- presenting symptoms and perceptions of why the meeting is taking place
- past medical issues such as operations, injuries and periods in hospital
- psychiatric history and current symptoms
- drug-related complications such as abscesses, venous thrombosis, septicaemia, endocarditis and constipation
- history of accidental and deliberate overdose
- presence of current or past infection with blood-borne viruses (including assessment of risks such as previous injecting or sharing or receipt of 'homemade' tattoos), immunisations for hepatitis B and tests for hepatitis B and C or HIV
- contraception history and cervical screening, menstrual and pregnancy history in women
- sexual health and sexually transmitted infections history
- oral health
- current prescribed and non prescribed medication including cigarette, cannabis and alcohol consumption, and over the counter medicines
- any allergies or sensitivities.

3.5.2.2 Examinations and assessments

Relevant examinations and assessments early in the assessment process include:

- assessment of the patient's mental health
- assessment of injection sites in all limbs and inguinal areas, if injecting or injected in past
- measurement of weight and height
- urine testing for common conditions such as diabetes and infection
- blood pressure measurement
- general impression of respiratory, cardiovascular and other systems, paying attention to symptoms offered and complaints given.

3.5.2.3 Examinations and testing that may be required

Examinations and testing which may be required depending upon presence of history, risks, symptoms and physical signs include:

- examination of cardiovascular and respiratory systems, including chest X-rays if necessary and simple pulmonary function tests such as peak flow and FEV/FVC
- examination of gastrointestinal system including liver
- pregnancy testing (see section 7.4)
- testing for the presence of HIV, hepatitis C (including PCR testing for the presence of HCV RNA) and hepatitis B infection, and hepatitis B and A immunisation
- other blood tests to assess liver function, thyroid function, renal function and haematological indices
- ECG (see section 3.5.2.4).

3.5.2.4 Methadone and QT prolongation

The Medicines and Healthcare products Regulatory Agency (MHRA) recommended in 2006 "… that patients with the following risk factors for QT interval prolongation are carefully monitored whilst taking methadone: heart or liver disease, electrolyte abnormalities, concomitant treatment with CYP 3A4 inhibitors, or medicines with the potential to cause QT interval prolongation. In addition any patient requiring more than 100 mg of methadone per day should be closely monitored. Further advice

is included in the product information." (MHRA, 2006).

This is a story still unfolding which, with the passage of time, may prove to be a minor or a major issue measured against the many benefits afforded by methadone treatment.

Clinicians must make a balanced judgement for each patient according to the MHRA guidance (and any later expansion or revision). Monitoring will usually include checking other medications, general monitoring of cardiovascular disease (blood pressure and pulse), liver function tests and urea and electrolytes. As the risk factors for QT interval prolongation increase (such as a high methadone dose or multiple risks) clinicians will need to consider ECGs. Product information for methadone varies but, considered alongside the MHRA recommendation, suggests that an ECG might be considered before induction onto methadone or before increases in methadone dose and subsequently after stabilisation – at least with doses over 100 mg per day and in those with substantial risk factors.

There is further information in annex A2.

3.5.3 Initial management of general health and drug-related problems

The following tasks and interventions might be commenced or discussed with a drug-misusing patient. This might be a single or an ongoing task or preparatory to referral to a specialist worker or colleague. There are occasions when an opportunity should not be missed to initiate a healthcare intervention as contact can be transitory and interrupted by events in a patient's disorganised life.

- Treatment of acute episodes of illness.
- Information and advice about, and immunisation against, hepatitis B (and possibly hepatitis A) – see section 6.2).
- Counselling and advice about testing for a blood-borne virus infection.
- Testing for a blood-borne virus infection and referral for treatment if required.
- Cervical cancer screening.
- Point of contact for general health information.
- Treatment of direct complications of injecting, including deep vein thrombosis and abscesses.
- Safer injecting advice and provision of injecting paraphernalia.
- Contraception advice.
- Safer sex advice and referral to sexual health service.

It should be remembered that drug misusers, like others, are at risk from all diseases and should be included in screening programmes and health assessments. They are, in addition, susceptible to an increased range of problems and perhaps early onset of some degenerative diseases because of their lifestyle and risk activities. Consideration needs to be given to repeating the tests and investigations in those who continue to inject or to be uncontrolled in their drug use.

Drug misusers may suffer from poor nutrition but should only receive oral nutrition support if there are clear medical reasons to do so. They should be given advice on diet and nutrition, especially if drinking heavily.

Patients who are known to have injected in the past should be considered as at risk from drug-related complications and counselled and invited to be tested accordingly.

3.6 References

Department of Health (1996) *The Task Force to Review Services for Drug Misusers. Report of an Independent Survey of Drug Treatment Services in England*. London: Department of Health.

MHRA (2006) *Current Problems in Pharmacovigilance*, vol 31 May 2006. London: Medicines and Healthcare products Regulatory Agency

NICE (2007) *Drug Misuse: Psychosocial Interventions.* NICE clinical guideline 51. London: National Institute for Health and Clinical Excellence.

NTA (2006) *Models of Care for Treatment of Adult Drug Misusers: Update 2006*. London: National Treatment Agency for Substance Misuse.

NTA (2007a) *Care Planning Practice Guide: Update 2007*. London: National Treatment Agency for Substance Misuse.

NTA (2007b) *Assessing Young People for Substance Misuse*. London: National Treatment Agency for Substance Misuse.

Scottish Executive Effective Interventions Unit (2002) *Integrated Care for Drug Users: Principles and Practice*. Edinburgh: Scottish Executive Effective Interventions Unit.

CHAPTER 4 PSYCHOSOCIAL COMPONENTS OF TREATMENT

4.1 Key points

- Treatment for drug misuse should always involve a psychosocial component.
- Keyworking is a basic delivery mechanism for a range of key components including the review of care or treatment plans and goals, provision of drug-related advice and information, harm reduction interventions, and interventions to increase motivation and prevent relapse. Help to address social problems, for example housing and employment, is also important.
- A good therapeutic alliance is crucial to the delivery of any treatment intervention, especially a psychosocial one.
- Discrete formal psychosocial interventions may be provided in addition to keyworking. These should be targeted to addressing assessed need.
- Discrete formal psychosocial interventions may be provided either to treat drug misuse related problems, such as cocaine misuse, or to address common associated or co-occurring mental disorders such as depression or anxiety.
- Psychosocial interventions can be delivered alongside pharmacological interventions or alone, depending on assessed need and the goals of treatment.
- Psychosocial interventions are the mainstay of treatment for the misuse of cocaine and other stimulants, and for cannabis and hallucinogens.
- Self-help and mutual aid approaches, especially 12-Step, have been found to be highly effective for some individuals and patients seeking abstinence should be signposted to them.
- There is a strong evidence base for contingency management (CM) and family and couples interventions. Neither is commonly used in the UK. Clinicians and services will need to evaluate these approaches, and the training and support needed to provide them, before they can be implemented.

4.2 Principles of psychosocial interventions

4.2.1 Psychosocial interventions and keyworking

Treatment for drug misuse should always involve a psychosocial component. Drug misusers often present for drug treatment with a myriad of health and social problems. Psychosocial interventions encompass a wide range of actions from 'talking therapies', such as cognitive behavioural or family therapy, to supportive work such as help with benefits.

Keyworking is a basic delivery mechanism for a range of psychosocial components including:

- regular reviews of care plans and treatment goals with the patient
- provision of drug misuse related advice and information
- interventions to reduce drug-related harm (especially risk of overdose and infections such as blood-borne virus infections)
- psychosocial interventions to increase motivation
- psychosocial interventions to prevent relapse
- help to address social problems, for example family problems, housing and employment.

The keyworker is the dedicated and named clinician, usually in most regular contact with the patient, who is responsible for ensuring the patient's care or treatment plan is delivered and reviewed. This is discussed in chapter 3. This individual may also deliver some or all of the psychosocial elements of care. Keyworking usually involves regular contact between the clinician and the patient. This may range from a series of one-hour sessions to discuss cocaine problems, to the sustained relationship made during regular contact a patient may have with a GP who is treating a drug-related health problem. The strength of therapeutic alliances predicts early treatment engagement and treatment retention.

4.2.2 Therapeutic alliance

A good therapeutic alliance is crucial to the delivery of any treatment intervention, especially a psychosocial one. The competencies of the clinician or keyworker in building and maintaining any psychosocial intervention are important in patient outcomes. A recent

Department of Health review (Roth and Pilling, 2007) cites some of the key competencies as:

- the ability to engage a patient appropriately while demonstrating satisfactory levels of warmth
- the ability to build trust, and to be able to adopt a personal style that is consistent with and meshes with that of the patient
- an ability to adjust the nature of the intervention according to the capacities of the patient
- an ability to deal with difficult emotions, understand and work with a patient's emotional context including patient motivation.

4.2.3 Formal psychosocial interventions

In addition to the basic keyworking outlined previously, discrete 'formal' psychosocial interventions may be provided:

- To treat drug misuse related problems, for example where a formal contingency management programme is used to address persistent cocaine misuse in primary cocaine users or to address crack cocaine misuse among those on methadone maintenance programmes.
- To address common associated or co-occurring mental disorders, for example, cognitive behavioural treatment to address depression.

The type of psychosocial intervention should be selected on the basis of the problem and treatment need of the specific patient, guided by the available evidence base of effectiveness, and not solely according to the interests of the clinician.

Formal psychosocial interventions or discrete packages of psychosocial interventions may be delivered alongside basic keyworking (and pharmacological interventions if appropriate). They may be delivered by a keyworker who has the required competencies or may be provided by other competent workers – for example, in a primary care setting the GP may be the keyworker, while a formal package of psychosocial interventions may be delivered by a drug worker or psychologist. Individual clinicians may or may not have the time or competencies to deliver a full range of psychosocial interventions. Whatever the local arrangements, keyworkers need to have a basic understanding of what psychosocial interventions may be required and how to access them for their patients.

4.2.4 Targeting formal psychosocial interventions

Clinical decisions to provide formal psychosocial interventions, like other interventions, depend on an assessment of need. Evidence from research can also provide indications about which populations are likely to benefit from specific psychosocial interventions.

For example, contingency management may be a useful tool to encourage patients to comply with programmes to prevent or address physical healthcare problems such as hepatitis B vaccination (NICE, 2007a). Deciding whether an individual should be offered a formal psychosocial intervention should be made in careful discussion with the individual and the wider clinical team, and the keyworker should seek advice from specialists in the field as and when necessary. It is likely that the large majority of individuals may not be in receipt of formal psychosocial interventions at any one time. For example, perhaps around 30% of people in methadone maintenance programmes may benefit from a formal psychosocial intervention to address entrenched injecting behaviour or crack cocaine misuse, at particular points in their care. In contrast, formal psychosocial interventions might be considered as a first option for all individuals considering abstinence from cocaine. Similarly, a minority of drug misusers may require psychosocial interventions focused on couples or families.

Self-help and mutual aid groups (such as Narcotics Anonymous) should be recommended for all drug misusers seeking to achieve and maintain abstinence. Patients then have a clear choice as to whether they participate in these groups outside formal treatment settings.

Psychosocial interventions may be targeted to address different drugs of misuse. With some drugs, psychosocial interventions are the only treatment available. This is discussed later in this section.

4.2.5 Individual versus group interventions

Many interventions can be provided either in groups or on an individual basis. Group interventions can be helpful and a good way of delivering effective care to a larger number of

patients. They are not popular with all patients but concerns can be mitigated by having low threshold groups, 'taster' or introductory sessions and ensuring there are alternative one-to-one interventions.

4.3 Psychosocial interventions – evidence and models

4.3.1 Psychosocial interventions currently used by keyworkers

4.3.1.1 Drug-related advice and information

Keyworkers provide patients with appropriate advice and information about their drug misuse, its consequences and the treatments available. This will assist patients in making informed choices about what their treatment goals should be and which type of treatment and support is likely to help them.

4.3.1.2 Advice and support for social problems

Keyworkers may provide practical support or referral for patients with social problems. These may include housing, childcare and child protection, employment and education.

4.3.1.3 Harm reduction

Specific advice and techniques for reducing the harm from drug misuse should be provided, such as advice on safer injecting techniques and minimising the risk of overdose.

4.3.1.4 Motivational interviewing and other motivational enhancement techniques

These include a collection of therapeutic principles, a set of counselling techniques, and more generally, a style of interaction in which the therapist takes the position of a collaborative partner in discussions with the patient about their drug use. Therapists use a set of specific skills, such as asking open questions, listening, and summarising the ideas the patient has expressed, and reflecting these back to them and providing affirmation. Underlying this approach is the principle that patients persuade themselves that change is desirable, achievable and will bring benefit. Motivational enhancement may be used to improve patient engagement in, and adherence to, treatment.

4.3.1.5 Relapse prevention

This is an individual or group-based cognitive behavioural approach. A relapse prevention programme usually includes the following (Wanigaratne, 2003): identifying high-risk situations and triggers for craving; developing strategies to limit exposure to high-risk situations; developing skills to manage cravings and other painful emotions without using drugs; learning to cope with lapses; learning how to recognise, challenge and manage unhelpful or dysfunctional thoughts about drug misuse; developing an emergency plan for coping with high-risk situations when other skills are not working; learning to recognise how one is 'setting oneself up' to use drugs; generating pleasurable sober activities and relationships, improving quality of life and attaining a lifestyle balance.

4.3.1.6 Mapping techniques

Techniques such as node-link mapping record interactions between a patient and a clinician, based on cognitive behavioural principles. The clinician and patient work together to produce visual maps of factors such as behaviours, relationships, emotions and coping strategies, which assist in planning and executing treatment. These have been found to enhance both the therapeutic relationship and treatment engagement, and to improve the patient's memory and understanding of the therapeutic session.

4.3.1.7 Other non-treatment interventions

These include sport, exercise, skills-based interventions (such as programmes teaching computer skills) and similar activities, provided as part of a structured treatment programme, which can be useful both to increase engagement in treatment and to improve physical health and wellbeing. They may be recommended in conjunction with skills-based interventions such as programmes teaching computer skills.

4.3.1.8 Complementary and alternative therapies

These may aid the building of therapeutic alliances and enable patients to learn relaxation techniques. There is little evidence that they have a significant specific impact on drug treatment outcomes although they may increase treatment retention, which has itself been linked with improved patient outcomes.

Complementary and alternative therapies should therefore be seen as an adjunct to drug treatment but are not a mainstay of treatment itself. The potential benefits and risks of any therapy should be discussed with the patient.

4.3.2 Formal psychosocial interventions to address drug misuse

The NICE guideline on psychosocial interventions in drug misuse (NICE, 2007a) identifies a number of formal psychosocial treatments as having a high-quality evidence base. It is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. Although the evidence base is rapidly expanding there are a number of gaps. These treatments are highlighted in the following sections, because the evidence would suggest, on average, that they are more likely to have a significant clinical benefit. Clinicians should refer to the full NICE guideline for the detailed findings and recommendations, noting the caveats in the foreword to this guideline about its status outside England and Wales.

4.3.2.1 Brief motivational interventions

These are brief opportunistic interventions focused on motivation. They normally consist of one or two brief sessions between ten and 60 minutes, which often focus on exploring ambivalence about changing behaviour and are offered in a non-judgemental way. They should be offered to people with no or limited contact with services if they have identified concerns about their drug misuse (for example, attendees at a needle exchange or in primary care). For people not in contact with drug treatment services, such interventions are likely to produce real benefits. However, they would not routinely be offered as the main intervention by a keyworker once a care plan for structured treatment was in place.

4.3.2.2 Contingency management

Contingency management operates by providing a variety of incentives in the form of vouchers, privileges, prizes or modest financial incentives to modify a person's drug misuse or to increase health promoting behaviours. A growing number of studies, many from the US, have found contingency management to be effective for people engaged in methadone maintenance programmes who are continuing to use illicit drugs and it is effective in promoting abstinence in stimulant misusers. The use of simple one-off incentives has proved to be highly effective in promoting engagement with and concordance with hepatitis B, hepatitis C and HIV testing, and hepatitis B vaccination programmes. Contingency management would normally be provided as part of a structured care or treatment plan in combination with other interventions provided by the keyworker.

This approach has been identified in the NICE guideline as having the strongest scientific evidence base for the most effective outcomes. However, contingency management is not commonly used formally in the UK and clinicians and services will need to identify and evaluate appropriate patient groups, incentives and the behaviours upon which incentives are contingent. Guidance on the implementation of contingency management will be made available by NICE and the National Treatment Agency.

4.3.2.3 Behavioural couples therapy

This is for patients who have an established relationship and a drug free partner who is willing to engage in treatment. There is good evidence that behavioural couples therapy focused on drug misuse can be of benefit to individuals with a range of drug misuse problems.

4.3.2.4 Family therapy

Family members may also benefit from self-help or support groups specifically focused on addressing carer needs. Support for families engaging with these groups can be a vital and important role for keyworkers. However, some families may not benefit either from guided self-help or support for families. In these cases, a rather more formal structured family therapy intervention should be provided that again focuses on drug misuse, discusses with families the sources of stress associated with drug misuse and tries to support and promote the family in developing more effective coping behaviours.

4.3.2.5 Mutual aid (self-help) approaches

These are typically provided outside formal treatment agencies, but are nevertheless one of the most commonly travelled pathways to recovery. They come in different types, with the most widely provided being mutual aid groups based on 12-Step principles, for example Narcotics Anonymous and Cocaine Anonymous. The benefits of these groups can be further

enhanced if keyworkers and other staff in services facilitate contact with them, for example by making an initial appointment, arranging transport or possibly accompanying patients to the first meeting and dealing with any subsequent concerns. These interventions can be of benefit to a wide range of people at different levels of the care and treatment system.

4.3.2.6 Other self-help approaches

Examples include user support and advocacy, self-help manuals and websites, and techniques such as relaxation and guided imagery.

4.3.2.7 Other psychosocial therapies

A variety of other psychosocial therapies have been used in drug treatment. Although the research evidence base is limited, both community reinforcement approach (CRA) and social behaviour network therapy (SBNT) may be useful approaches for some patients and therapists as they are practical and broad-based techniques.

Community reinforcement approach

This is a cognitive behavioural approach originally developed for alcohol dependence. It involves specific types of counselling and skills training, tailored to the treatment goals of the patient, and is based on the principle that individuals will have their own reinforcers in the community, which maintain their behaviour (both drug-using and non-drug-using behaviours). The outcome of altering these reinforcement contingencies (and involving the patients' social network in this process) is that the individual will make changes in their lifestyle that will support the patient's goal of abstinence from drug misuse.

Social behaviour network therapy

This form of therapy uses between four and eight treatment sessions to explore and build social network support for changing drug-using and other behaviour. It is based on the community reinforcement approach, marital therapy, relapse prevention and social skills training approaches, and aims to develop positive social support for change in drug misuse and diminish support for continuing use.

Other psychosocial therapies

Other therapies have been used in drug misuse services and these have been covered by Wanigaratne et al., in the 2005 review. Careful analysis in the NICE guideline did not suggest that there was good evidence that these should normally be offered as first line psychosocial treatments. However, they may be reserved for individuals who have not benefited from first line treatments such as brief interventions, contingency management and the self-help groups described earlier, or in cases where clinical judgement suggests this may be appropriate in the particular circumstances of the case. These other interventions include cognitive behavioural relapse prevention based therapy or psychodynamic therapy.

Where treatments have a more limited evidence base it is important for those providing the therapy to make this clear to patients and to regularly monitor the outcomes of these treatments.

4.3.3 Psychosocial intervention to address common mental disorders

Many drug misusers also have considerable co-morbid problems, particularly common mental health problems such as anxiety and depression. There is evidence that a range of evidence-based psychosocial interventions (for example, as described in relevant NICE guidelines) can be beneficial. Relevant NICE guidelines in this area include those for depression (NICE, 2007b) which recommend a stepped approach to treatment that may be increased in intensity:

- For mild forms, using simple 'watchful waiting', guided self-help or brief interventions.
- For more moderate or severe forms, more extensive psychological therapies (such as cognitive behavioural therapy) and social support, often with the addition of antidepressants (for example, SSRIs).
- For very severe cases, the infrequently-used electroconvulsive therapy (ECT).

Similarly, the NICE guideline on anxiety (NICE, 2007c) recommends a stepped approach for general anxiety disorder and panic disorder of variable severity, using various psychosocial interventions such as self-help manuals or cognitive behavioural therapy (either in primary care or a specialist therapy service) and consideration of the short-term use of tranquillisers or SSRI-type antidepressants. Other NICE guidelines provide advice on the use of psychological approaches for other disorders such as post traumatic stress disorder (NICE,

2005a), eating disorders (NICE, 2004) and obsessive compulsive disorder (NICE, 2005b) and for specific patient groups, such as antenatal and postnatal mental health (NICE, 2007d).

Refer to section 7.5 for further advice on working with mental health problems in drug misusers.

4.4 Psychosocial interventions and different drugs of misuse

For opioid, polydrug and alcohol misusers, psychosocial interventions may be provided in combination with a pharmacological intervention. There is evidence (Amato *et al.,* 2004) that the effectiveness of methadone maintenance is enhanced by the provision of psychosocial interventions.

For stimulant misuse, including cocaine, and for cannabis misuse, there is no effective substitution agent. Hence, the mainstay of treatment is evidence based psychosocial intervention.

Issues of alcohol and tobacco use and treatment are covered in sections 6.4 and 6.5.

4.4.1 Cocaine and other stimulants

The mainstay of treatment for cocaine and other stimulant misuse is psychosocial therapy. Cocaine and other stimulant misusers are a heterogeneous group whose problems have a wide range of severity. Most severe are usually those engaged in polydrug misuse, especially combining heroin and cocaine but also cocaine and alcohol, and cocaine and benzodiazepines.

A primary cocaine user with a short history of use may benefit from a brief motivational intervention. A secondary crack cocaine misuser who is using the drug in combination with opiates is more likely to benefit from keyworking in combination with contingency management.

There is evidence of the effectiveness of self-help approaches (such as Cocaine Anonymous for cocaine misusers) and contingency management.

A range of accompanying physical and psychological problems such as weight loss or cocaine-related psychiatric problems may require appropriate medical or psychiatric interventions.

4.4.2 Cannabis

Clinicians may be faced with patients seeking help for their cannabis misuse or the side-effects of such use. In part, this may be a result of increasing availability and use of stronger forms of cannabis, usually known as 'skunk'. High rates of consumption of any form of cannabis may cause physical and mental health problems.

Cannabis use can lead to significant dependence requiring appropriate treatment interventions, even though there may not be a prominent physical withdrawal syndrome.

Cannabis smokers are at risk from health-related problems. If they smoke cannabis with tobacco they are also risking all the same dependence and health problems as cigarette smokers.

Heavy cannabis users may experience symptoms such as depression, lethargy, paranoia and memory loss. Cannabis may also trigger symptoms of psychosis and may contribute to the development of longer-term problems in some individuals.

Cannabis may only be one of a range of drugs used by a patient and, like alcohol, its use may be increased by patients trying to reduce or stop using other drugs.

There are no medications suitable for treating cannabis misuse. Clinicians should consider psychosocial interventions, especially brief motivational interventions in mild cases. More heavily dependent misusers may require structured treatment with keyworking. In cases of co-morbidity with depression and anxiety, treatment will include cognitive behavioural therapies.

4.5 Competencies to deliver psychosocial interventions

Developing and supporting competencies in delivering effective planned care and in the role of the keyworker will underpin delivery of more specific interventions. Evidence suggests that a number of factors may have an impact on the performance of therapists in delivering specific interventions. These include adequate training in the delivery of the intervention, and building training programmes around the identified competencies associated with evidence based interventions (Roth and Pilling, 2007). In addition, it is essential that effective supervision is delivered. Clinical trials of effective treatments are also often associated with the provision of

effective and competent supervision (Roth *et al.*, 2007). This itself requires competencies in supervision and the associated activity of quality assurance in psychological treatment programmes. Services providing psychosocial interventions therefore need staff of sufficient seniority and competencies to provide effective supervision and to monitor the overall quality of treatment. There is also good evidence (Lambert *et al.*, 2001) that the routine monitoring of outcomes and appropriate feedback to individual clinicians can lead to significant benefits and improvements in outcome.

4.6 NICE guideline on psychosocial interventions

The National Institute for Health and Clinical Excellence (NICE) published its final guideline in July 2007 on psychosocial interventions for drug misuse (NICE, 2007a). Clinicians should refer to the full guideline for the detailed findings and recommendations noting the caveats in the foreword to these guidelines about its status outside England and Wales. What follows are NICE's key priorities for implementation.

Brief interventions

Opportunistic brief interventions focused on motivation should be offered to people in limited contact with drug services (for example, those attending a needle and syringe exchange or primary care settings) if concerns about drug misuse are identified by the service user or staff member. These interventions should:

- *normally consist of two sessions each lasting 10–45 minutes*
- *explore ambivalence about drug use and possible treatment, with the aim of increasing motivation to change behaviour, and provide non-judgemental feedback.*

Self-help

Staff should routinely provide people who misuse drugs with information about self-help groups. These groups should normally be based on 12-Step principles; for example, Narcotics Anonymous and Cocaine Anonymous.

Contingency management

Introducing contingency management

Drug services should introduce contingency management programmes – as part of the phased implementation programme led by the National Treatment Agency for Substance Misuse (NTA) – to reduce illicit drug use and/or promote engagement with services for people receiving methadone maintenance treatment.

Principles of contingency management

Contingency management aimed at reducing illicit drug use for people receiving methadone maintenance treatment or who primarily misuse stimulants should be based on the following principles:

The programme should offer incentives (usually vouchers that can be exchanged for goods or services of the service user's choice, or privileges such as take-home methadone doses) contingent on each presentation of a drug-negative test (for example, free from cocaine or non-prescribed opioids).

The frequency of screening should be set at three tests per week for the first three weeks, two tests per week for the next three weeks, and one per week thereafter until stability is achieved.

If vouchers are used, they should have monetary values that start in the region of £2 and increase with each additional, continuous period of abstinence.

Urinalysis should be the preferred method of testing but oral fluid tests may be considered as an alternative.

Contingency management to improve physical healthcare

For people at risk of physical health problems (including transmittable diseases) resulting from their drug misuse, material incentives (for example, shopping vouchers of up to £10 in value) should be considered to encourage harm reduction. Incentives should be offered on a one-off basis or over a limited duration, contingent on concordance with or completion of each intervention, in particular for:

- *hepatitis B and C, and HIV testing*
- *hepatitis B immunisation*
- *tuberculosis testing.*

Implementing contingency management

Drug services should ensure that as part of the introduction of contingency management, staff are trained and competent in appropriate near-patient testing methods and in the delivery of contingency management.

Contingency management should be introduced to drug services in the phased implementation programme led by the NTA, in which staff training and the development of service delivery systems are carefully evaluated. The outcome of this evaluation should be used to inform the full-scale implementation of contingency management.

4.7 References

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CHAPTER 5 PHARMACOLOGICAL INTERVENTIONS

5.1 Key points

- Methadone or buprenorphine, used at the optimal dose range, are effective medicines for maintenance treatment.
- Dose induction should aim to achieve an effective dose while also exercising caution about the inherent risks of too rapid an increase. Dose induction with buprenorphine may be carried out more rapidly with less risk of overdose.
- Supervised consumption should be available for all patients for a length of time appropriate to their needs and risks.
- Patients must be made fully aware of the risks of their medication and of the importance of protecting children from accidental ingestion. Prescribing arrangements should also aim to reduce risks to children.
- Clinicians should aim to optimise treatment interventions for patients who are not benefiting from treatment, usually by providing additional and more intensive interventions (pharmacological and psychosocial) that may increase retention and improve outcomes.
- Opioid detoxification, using the medication the patient has been maintained on, should be offered in an appropriate setting to patients ready for and committed to abstinence.
- Methadone, buprenorphine and lofexidine are all effective in detoxification regimens.
- Opioid detoxification should be offered as part of a package including preparation and post-detoxification support to prevent relapse.
- Benzodiazepines prescribed for benzodiazepine dependence should be at the lowest possible dose to control dependence and doses should be reduced as soon as possible.
- There are no effective pharmacological treatments to eliminate the symptoms of withdrawal from stimulants (including cocaine). Psychosocial interventions are the mainstay of treatment.
- Injectable opioid treatment may be suitable for a small minority of patients who have failed in optimised oral treatment.

NB: The principles described in this chapter apply to all patients but there are specific issues in relation to prescribing for young people described in section 7.6.

5.2 Prescribing

5.2.1 The responsibility of prescribing

Prescribing is the particular responsibility of the person signing the prescription. This includes a non-medical prescriber, whether working as a supplementary or independent prescriber.

A decision to prescribe, what and how much to prescribe will depend upon:

- the overall treatment plan for the individual patient
- clinical guidelines
- locally agreed protocols
- the clinician's experience and competencies
- discussion with other members of a multidisciplinary team
- advice, where necessary, from a specialist in drug misuse.

In the context of prescribing, it is important to note that the *British National Formulary* (BNF, 2007), which is updated twice a year, is a key reference. The dosages stated in these guidelines and in the BNF are intended for general guidance and represent (unless otherwise stated) the range of dosages that are generally regarded as being suitable for prescribing in the context of treating adults who have become dependent.

A clinician who is experienced in the treatment of drug misuse (see section 2.2.4), and in the use of a particular medication, may feel more able to operate at the outer limits of, or even to depart from, these guidelines than an inexperienced clinician. Clinicians should work within a clinical governance framework and be prepared to justify their clinical decisions, and – especially when operating outside guidelines – should keep comprehensive notes to support their decisions.

5.2.2 Deciding whether to prescribe

Before deciding whether to prescribe, the clinician should be clear as to the desired outcomes for the patient. These could be to:

- reduce or prevent withdrawal symptoms

- offer an opportunity to stabilise drug intake and lifestyle while breaking with illicit drug use and associated unhealthy risky behaviours
- promote a process of change in drug taking and risk behaviour
- help to maintain contact and offer an opportunity to work with the patient.

A prescription for substitute medication should normally only be considered if:

- opiates are being taken on a regular basis – usually daily
- there is convincing evidence of current dependence (including objective signs of withdrawal symptoms wherever possible – see Table 3)
- patients are motivated to change at least some aspects of their drug misuse
- the assessment (including history, examination and toxicology, drug diary) clearly substantiates the need for treatment
- the clinician is satisfied that the patient has the capacity to comply with the prescribing regimen
- the patient is not receiving a prescription from another clinician.

Before prescribing substitute drugs the clinician should conduct a full or comprehensive assessment and agree a care or treatment plan with the patient. This process is described in more detail in section 3.2.

5.2.3 Prescriptions for and management of controlled drugs

There are strict rules governing the writing of prescriptions for medicines controlled under the Misuse of Drugs legislation. Detailed requirements are described in the *British National Formulary* and annex A3.

NHS and independent organisations providing services that may involve the management or use of controlled drugs are required, by law, in England and Scotland, to appoint an accountable officer.

Accountable officers are responsible for ensuring compliance with misuse of drugs legislation and the safe, effective management of controlled drugs within their organisations and within services they contract. They play a key role in implementing new arrangements, monitoring systems, auditing controlled drug management, inspecting, and investigating and taking appropriate action where concerns are raised.

If prescribers have concerns about pharmacists dispensing controlled drug prescriptions or if pharmacists have concerns about the prescribing of controlled drugs then they should report their concerns to the relevant accountable officer.

Regular pharmaceutical advice can help ensure that policies and procedures concerning controlled drugs comply with current legislation.

5.2.4 Communication between prescriber and dispensing pharmacist

The relationship between the prescriber and the pharmacist dispensing – and often supervising the consumption of – prescribed medicines is important. The name and address of the dispensing pharmacist should be written in the patient notes.

Prescribers should liaise with the pharmacist when first prescribing controlled drugs for a patient:

Objective signs of opiate withdrawal	Subjective signs of opiate withdrawal
• yawning • coughing • sneezing • runny nose • lachrymation • raised blood pressure • increased pulse • dilated pupils • cool, clammy skin • diarrhoea • nausea • fine muscle tremor	• restlessness • irritability • anxiety (The signs listed above may also be useful objective signs) • sleep disorders • depression • drug craving • abdominal cramps

Table 3: Signs of opiate withdrawal

- to ensure the pharmacy has sufficient capacity to take on a new patient
- to introduce the pharmacist to a new patient, for example, by offering a brief description or history, letter of introduction, shared care agreement (in some schemes the patient may be asked to introduce themselves to the pharmacy prior to starting a prescription which can help facilitate smoother initiation of treatment)
- to ensure the pharmacist is part of a suitable local scheme (for example, a locally enhanced service) and can provide supervised consumption of the prescribed medicine if requested by the prescriber
- to ensure the pharmacist is able to confirm that the prescriber and prescription are genuine.

It is good practice that pharmacists share relevant information with prescribers and other healthcare professionals and agencies in line with locally determined confidentiality agreements:

- when the pharmacist is aware that patients are failing to comply with their treatment, for example when patients have missed scheduled pick-ups
- when there are concerns about patients' health or wellbeing
- when the patient attends the pharmacy in a state of intoxication.

It should be noted that pharmacists who are also operating a needle exchange scheme will not usually share information with the prescriber that a patient receiving prescribed medication is also obtaining supplies of injecting equipment from the pharmacy, except where the pharmacist has the permission of the patient to do so.

5.3 Induction onto methadone and buprenorphine treatment

Induction onto methadone and buprenorphine treatment is the process of starting a patient on a suitable dose of a substitute opioid and optimising the dose. NICE (NICE, 2007a) advises that induction should be monitored by a doctor or trained nurse.

It may take two to four weeks (or more) to achieve an optimal dose with methadone, less with buprenorphine.

Clinicians should be aware that there is considerable research evidence (Capelhorn and Drummer, 1999; Zador and Sunjic, 2000) that the first two weeks of methadone treatment is a time of increased risk of death due to methadone toxicity. After the first two weeks, the risk of death due to opioid overdose during maintenance treatment falls to very low levels.

Clinicians therefore need to balance three competing pressures in prescribing for opiate-dependent drug misusers.

- To prescribe an effective and appropriate dose.
- To minimise the risks of overdose or precipitated withdrawal during induction onto appropriate medication.
- To rapidly respond to the patients' needs for appropriate treatment in order to retain them in treatment and prevent harm from illicit drug misuse.

Death during induction remains a rare event but induction protocols should continue to be designed to minimise the risk of adverse events. This is the basis of the recommendations made in these guidelines.

5.3.1 Risk factors for methadone

The risk factors for overdose during induction are:

- low opioid tolerance
- use of CNS depressant drugs, including alcohol
- too high an initial dose
- increases in dose that are too rapid
- slow methadone clearance.

There is an increased risk of death during induction into methadone treatment and a consistent finding is that multiple drugs, particularly benzodiazepines and alcohol, are usually involved. Opioids induce respiratory depression and hypoventilation, and sedative drugs (including alcohol) potentiate this effect.

With methadone, toxicity is delayed, at least several hours after exposure, and often after several days of treatment. The reason for the delayed toxicity is methadone's long but variable half-life, measured at between 13 and 50 hours with chronic administration. Variation can occur between individuals and within an individual.

The half-life can be affected by other factors such as alcohol consumption or other drugs taken. It takes five half-lives, or 3–10 days, for patients on a stable dose of methadone to reach steady-state blood levels. The slower methadone is cleared, the longer it takes to reach steady state and the higher the steady state blood levels. During those 3–10 days, blood levels progressively rise even if patients remain on the same daily dose. A dose tolerated on day one may become a toxic dose on day three. Patients must therefore be carefully monitored and, if necessary, the dosage adjusted during the accumulation period.

There are many factors affecting methadone metabolism and action, and most are not currently predictable on history and examination. They mean that patients can have markedly different responses to the same dose of methadone and their responses can vary over time.

Drug interactions can slow or speed methadone metabolism, or can potentiate toxicity. See annex A5 for more information.

However, the critical factor in response to methadone is the degree of tolerance to opioids. It is in individuals with low tolerance that a starting dose that would be safe in the majority of patients can become a toxic dose.

5.3.1.1 Minimising the risks of toxicity

Risks during induction can be minimised by:

- careful initial assessment
- identification of high-risk patients
- avoiding too high starting doses
- avoiding too rapid dose increases
- frequent monitoring during induction
- supervised consumption (see section 5.4)
- alerting patients and carers to the early signs of overdose.

High-risk cases require greater supervision.

5.3.2 Risk factors for buprenorphine

The risk factors for overdose during induction are:

- low opioid tolerance
- use of CNS depressant drugs, including alcohol.

There is also a risk of precipitating withdrawal, which is increased if insufficient time is left before administering buprenorphine in patients who have:

- recently used heroin, particularly at higher doses
- recently consumed long-acting opioids such as methadone.

At low doses, buprenorphine is a potent opioid agonist, producing morphine-like effects. However, due to its mixed agonist-antagonist properties, increasing doses become self-limiting and do not produce more intense opioid effects. It is generally agreed that there is less risk of opioid overdose associated with the use of buprenorphine than with oral methadone, although the former has greater potential for misuse by injection and intranasally. These risks may be reduced by the use of a combined buprenorphine and naloxone preparation – see section 5.3.5 for more information.

However, as with methadone, concomitant use of buprenorphine with benzodiazepines, alcohol and other CNS depressant drugs can produce fatal opioid overdose, probably in individuals who lack opioid tolerance. Therefore, there is a risk of toxicity and the need for caution when initiating treatment with buprenorphine in someone misusing CNS depressant drugs.

The risks of precipitating withdrawal can be reduced by leaving sufficient time since last use of an opioid before buprenorphine is administered. This time will be longer if a long-acting opioid, such as methadone, has been used.

5.3.3 Dose optimisation

Buprenorphine and methadone are long-acting drugs. One key aim of maintenance treatment is to keep blood concentrations of these drugs within a narrow range, within which patients experience minimal intoxication and minimal withdrawal. During induction with methadone or buprenorphine, signs and symptoms of

intoxication and withdrawal fall progressively, reducing the subjective sensations that drive drug seeking and drug misuse. This is the process of dose optimisation. If doses administered during induction are too high, intoxication will result. If doses are too low, they may not prevent the emergence of withdrawal symptoms and drug cravings for the full 24 hours between doses.

5.3.4 Assessment

5.3.4.1 Introduction

Drug-misusing patients typically present at a time of crisis in their lives and may not respond well to an exhaustive interview. At the same time, clinicians need to gather sufficient information to properly and safely assess presenting problems. It is important to find a balance that obtains the necessary information without risking the patient dropping out of treatment.

Further assessment can take place over the coming weeks during treatment.

5.3.4.2 Diagnosis of opioid dependence and assessment of tolerance

It is not appropriate to offer methadone or buprenorphine maintenance treatment to patients who do not meet the diagnostic criteria for opioid dependence.

Establishing the diagnosis requires a history of the patient's drug use, including duration of use, frequency, route of administration, periods of abstinence, and past treatment. Patients should be asked to give an account of their daily activities and social functioning, and forensic history.

Corroborative evidence of opioid dependence should be sought, by physical examination, investigations, or information from other people.

Collecting a urine or oral fluid specimen for toxicological analysis is essential to confirm (or refute) recent drug misuse. However, a positive test for opioids does not establish the diagnosis of dependence, nor does a negative test exclude the diagnosis (see section 3.4). In situations of doubt it may be useful to repeat a screening test, or to conduct a confirmatory test.

The major risk factor for toxicity during induction is use of CNS depressants, especially benzodiazepines and alcohol. Each patient should be asked about all drugs used (including prescribed and over-the-counter medication) in the three days prior to the assessment interview.

5.3.4.3 Medical and psychiatric factors

At assessment, many applicants report depressed mood and disturbed sleep. However, mood usually improves after stabilisation on methadone or buprenorphine, and it is not normally appropriate to initiate antidepressant treatment during induction. Review of mental state should be part of ongoing assessment. Patients already on antidepressants, particularly tricyclic antidepressants or fluvoxamine, may need careful monitoring during induction as these medicines may interact with methadone.

Antipsychotic medicines may potentiate the hypotensive and sedative effects of methadone, and perhaps increase the risk of toxicity.

A high proportion of injecting drug users are infected with hepatitis B or C, but this seldom poses problems during induction unless they have advanced liver disease detectable at clinical examination. Patients with end-stage liver disease should only be commenced on methadone or buprenorphine with extreme care and should be referred for a specialist opinion. Many HIV medications interact with methadone and buprenorphine, and dose adjustments may need to be made (see annex A5 for more on interactions). Consultation with the clinician prescribing HIV medications is recommended.

5.3.4.4 Provision of information

At the initial visit, patients should be informed of the rationale for treatment, the expectations placed on them (such as daily attendance for supervised doses), and what they can expect. They should be told what will happen in treatment, the risks during induction, and the dangers of using benzodiazepines and other CNS depressant drugs. Many patients are anxious that they will not get enough methadone or buprenorphine to feel comfortable – the planned rate of increase should be explained, and the fact that blood levels of methadone rise during the first week of treatment.

Risks to children of ingesting prescribed medication and the importance of safe storage must be emphasised at the first appointment and repeatedly thereafter. Assessment of compliance with these safety measures should

form part of the decision-making concerning dispensing and supervision arrangements.

5.3.5 Choosing an appropriate opiate substitute

Methadone and buprenorphine are both approved for the treatment and prevention of withdrawals from opioids. Both are recommended by NICE for maintenance programmes. A number of factors should be taken into account when selecting an appropriate medication.

- Level of opioid use.
- Safety, for example likelihood of diversion and overdose risk.
- Patient experience with both illicit and prescribed medications, treatment history and response.
- Patient preference.
- Retention and treatment compliance.
- The prescriber's experience with different medications.

Drug interactions can slow or speed the metabolism of opioids and can potentiate toxicity. Buprenorphine and methadone have different drug-drug interactions, which should be taken into account when prescribing if the patient is taking other drugs or medication – see annex A5 for more information.

Evidence suggests that methadone is more likely to retain patients in treatment but the evidence for the relative effectiveness of methadone and buprenorphine at preventing illicit opioid misuse is mixed. NICE's recommendation is: "If both drugs are equally suitable, methadone should be prescribed as the first choice." (NICE, 2007a)

Clinical experience suggests that patients presenting with dependence on codeine preparations benefit from buprenorphine.

5.3.5.1 Buprenorphine-naloxone (Suboxone®)

A new form of buprenorphine has been developed that includes the opioid antagonist naloxone (buprenorphine:naloxone 4:1) in a combined sublingual tablet. This new form is for use at the same buprenorphine dose (the current 8 mg sublingual buprenorphine being considered as the same therapeutic dose as the new combination of 8 mg buprenorphine plus 2 mg naloxone). It has been presented as a new product, under the trade name Suboxone®, and received product approval for addiction treatment throughout the European Union in December 2006. The rationale is that, when taken sublingually as intended, the naloxone has very low bioavailability and does not diminish the therapeutic effect of the buprenorphine. However, if injected, the naloxone has high bioavailability and is liable to precipitate withdrawal in an opiate-dependent patient, therefore discouraging further misuse. If taken intranasally, the effect of the naloxone appears to be variable. The combination tablet is therefore expected to provide the same therapeutic benefit while preventing or reducing the liability for misuse. Clinical experience with this new combination product is, at the time of publication, extremely limited in the UK, and it is too early to indicate the relative positions of these two versions of buprenorphine.

5.3.5.2 Other medications

Other medications, and treatment for non-opioid drug misuse, are covered in sections 5.3.3 and 5.7.

5.3.6 Converting from other opioids

For patients who are using other opioids it is sometimes necessary to stabilise them onto methadone or buprenorphine. It is not possible to accurately predict equivalent doses in most cases. This is especially true for street drugs where purity is notoriously variable. It is also problematic to convert from one drug to another when the half lives are not equivalent. For these reasons, the working group decided that it would not be desirable to include an equivalence table in the 2007 guidelines.

Clinicians must apply careful clinical judgment and monitor the progress of treatment carefully, especially during the early stages of treatment. Reference to any conversion table is insufficient on its own, and can only ever be a partial contribution to the necessity of ongoing clinical assessment and monitoring.

Safe conversion from another opioid involves carefully following the dose induction process.

5.3.7 Methadone dosing

The guidance given here applies to patients within normal ranges of body weight, body mass index and liver and kidney function. Patients outside the normal ranges may need to have their dose adjusted up or down accordingly,

although variations are usually small and taken care of by normal induction.

5.3.7.1 Commencement dose

Methadone should normally be prescribed as a 1 mg in 1 ml oral solution. Oral concentrates, containing methadone hydrochloride 10 mg/ml or 20 mg/ml, should normally be dispensed only after dilution as appropriate (BNF, 2007). Methadone tablets are not licensed for the treatment of drug dependence and should not normally be prescribed due to the increased potential for diversion.

Inappropriate dosing can result in overdosing in the first few days: as cumulative toxicity develops to methadone, this can lead to death. There is no uniquely fatal dose of methadone and deaths have occurred following doses as little as 20 mg. The commencement dose should aim to achieve an effective level of comfort, both physical and psychological, while minimising the likelihood of overdose.

- In general, the initial daily dose will be in the range of 10–30 mg.
- If tolerance is low or uncertain then 10–20 mg is more appropriate.
- With heavily dependent misusers who are tolerant, and where the clinician is experienced or competent, a first dose can be up to 40 mg but it is unwise to exceed this dose.

A supplementary dose on the same day may be considered where there is evidence of persistent opioid withdrawal. These cases need to be assessed by a prescriber with appropriate competencies.

The process of dose induction requires clinical judgement from the prescriber. Clearly those prescribers with more experience may feel able to take more and proportionate risks following thorough assessment. In general more caution should be taken with high-risk patients. More caution should be applied if the patient cannot be well supervised, for example seen only weekly.

5.3.7.2 Optimal dose

First seven days

It is critically important to provide adequate information regarding the recognition of methadone toxicity and management to patients and accompanying carers (with consent).

Opiate-dependent patients being managed in the community should attend frequently at the beginning of treatment in order that their dose can be titrated against withdrawal symptoms and evidence of intoxication monitored. With patients who can only attend infrequently, dose induction will take longer.

Where doses need to be increased during the first seven days, the increment should be no more than 5 mg to 10 mg on one day. In any event, a total weekly increase should not usually exceed 30 mg above the starting day's dose.

Subsequent optimisation

Following the first week, doses can continue to be increased incrementally up to a total of between 60 and 120 mg a day, and occasionally more – a level at which the patient reports feeling comfortable and is no longer using illicit heroin. Caution needs to be exercised and it may take several weeks to reach the desired dose. There should be a few days between each dose increase.

5.3.8 Buprenorphine dosing

The guidance given here applies to patients within normal ranges of body weight, body mass index and liver and kidney function. Patients outside the normal ranges may need to have their dose adjusted up or down accordingly, although variations are usually small and taken care of by normal induction.

Most dosing regimens involve starting with a low dose (4–8 mg) and rapidly increasing.

The two identified problems during buprenorphine induction are:

- the risk of precipitated withdrawal
- the risk of premature dropping out of treatment.

Following recommended cautious schedules will reduce the risk of precipitated withdrawal. Higher doses at an earlier stage in induction might in some cases improve retention in treatment, but at the risk of precipitating more marked withdrawal in others. Clinical judgement is required that takes into account all relevant factors in a particular case.

5.3.8.1 Precipitated withdrawal

Precipitated withdrawal occurs when buprenorphine is first administered to an opiate-dependent person with circulating opioid

agonist drugs present. In this situation, buprenorphine can inhibit the agonist, leading to the appearance of withdrawal signs and symptoms. Precipitated withdrawal is unpleasant and may deter patients from continuing participation in treatment. There are three measures to minimise precipitated withdrawal:

- Administer the first dose of buprenorphine when the patient is exhibiting signs of withdrawal. The pharmacist needs to emphasise this point when supervising medication.
- If withdrawal is difficult for the patient to tolerate, delay the administration of buprenorphine until at least 6–12 hours after the last use of heroin (or other short-acting opioid), or 24–48 hours after the last dose of low-dose methadone.
- In all cases, patients should be provided with information about precipitated withdrawal and informed that they can switch to methadone.

Patients on more than 30 mg of methadone daily are less likely to be able to tolerate a transfer to buprenorphine.

5.3.8.2 Starting dose and increments

Effective maintenance treatment with buprenorphine involves doses in the range of 12-16 mg for most patients, with some needing up to 32 mg. It makes sense to work towards this dose rapidly, so long as this does not produce side-effects or precipitated withdrawal.

A cautious approach is to initiate treatment with 4 mg on day one, then 8–16 mg on day two and thereafter. An experienced and competent clinician may increase the starting dose to 8 mg on day one, then 16 mg on day two and thereafter increase the dose more slowly if necessary. Dividing the daily dose may be useful.

Ongoing assessment, monitoring, regular clinical review and reassurance are likely to improve retention.

5.3.8.3 Symptomatic prescribing

There is limited evidence for the effectiveness of adjunctive medications for the management of symptoms associated with withdrawal. The prescribing of other opioids, or any other respiratory depressant drugs, during induction onto buprenorphine treatment is therefore not recommended.

5.4 Supervised consumption

5.4.1 When and how to use supervised consumption

Supervision of consumption by an appropriate professional provides the best guarantee that a medicine is being taken as directed. Since the advent of supervised consumption, the number of drug-related deaths involving methadone has reduced, during a period when more methadone is being prescribed, providing indirect evidence that supervising the consumption of medication may reduce diversion.

Other guidance, such as the ACMD report on drug-related deaths (ACMD, 2000), the NICE technology appraisal on methadone and buprenorphine (NICE, 2007a) and the 1999 Clinical Guidelines (UK health departments, 1999) have described recommended practice for supervised consumption in slightly different ways. For the 2007 Clinical Guidelines the working group agreed the following recommendations.

In most cases, new patients being prescribed methadone or buprenorphine should be required to take their daily doses under the direct supervision of a professional for a period of time that may be around three months, subject to assessment of patients' compliance and individual circumstances. There may be variation in practice across the UK and a range of durations of supervised consumption is likely to be seen for different patients, ranging from just a couple of weeks in highly compliant patients to much longer in patients who fail to respond to conventional treatment. The clinical need for supervised consumption should be reviewed regularly and the decision on when to relax the requirement for supervised consumption is one for the individual clinician.

Long-term, daily supervised consumption would probably not be appropriate for a patient in regular, full-time work where supervision would be a clear barrier to engagement in treatment.

When a patient restarts methadone or buprenorphine after a break, or receives a significant increase in the methadone dose, daily dispensing – ideally with supervised consumption – should be reinstated for a period of time agreed in local guidelines and protocols.

In patients whose treatment is failing, a period in supervised consumption can improve

observation of progress and increase interventions to improve outcomes. A good example is to enable daily breathalyser readings or monitoring of other indicators of alcohol intoxication in patients who are drinking heavily while taking methadone (see section 6.4).

Supervised consumption may have a role in contingency management. Relaxation of supervision can be regarded as an incentive if progress, such as drug-free urine samples, can be demonstrated.

Supervised consumption is often a situation where therapeutic relationships can be built with patients and efforts should be made to stop it being viewed as a punishment.

In the majority of cases the person supervising will be a community pharmacist, although some specialist services and dispensing doctors may employ their own pharmacy or nursing staff to provide on-site supervised consumption. There should be multi-agency protocols in place to ensure a consistent high standard of service is provided. As part of the service, there should be systems in place to ensure information about patients can be fed to and from the prescriber and keyworker, as well as agreement from the patient that confidential information can be shared between the pharmacist and named members of the multidisciplinary team. Much of this is described in *Best Practice Guidance for Commissioners and Providers of Pharmaceutical Services for Drug Users* (NTA, 2006).

5.4.2 Stopping supervision

Relaxation of requirements for supervised consumption and for instalment dispensing should be a stepped process in which a patient first stops taking doses observed by a professional but remains on daily dispensing. Later, after further progress, the frequency of dispensing may be gradually reduced. The relaxation of supervision can be seen as an important component of rehabilitation.

Supervised consumption should only be relaxed if the prescriber has good reason to believe that compliance will be maintained. The assessment of compliance and clinical progress is covered in section 5.5. In general the prescriber needs to assess the following: changes in drug-taking behaviours (such as injecting), compliance with prescribed drug treatment, abstinence from or significant change in drug misuse and compliance with other elements of a care plan, for example attendance at appointments. Arrangements for daily consumption through instalment prescribing and, where appropriate, supervised consumption of other medicines should also be made.

Take-home doses should not normally be prescribed where:

- a patient has not reached a stable dose
- the patient shows a continued and unstable pattern of drug misuse, including a significant increase in alcohol intake, the use of illicit drugs, benzodiazepines or other tranquillisers
- the patient has a significant, unstable psychiatric illness or is threatening self-harm
- there is continuing concern that the prescribed medicine is being, or may be, diverted or used inappropriately
- there are concerns about the safety of medicines stored in the home and possible risk to children.

In some of these cases, especially the latter, take-home doses might be permitted but the dose taken home limited by frequent dispensing.

5.4.3 Issues in supervised consumption

A range of different medications can be supervised. Oral methadone mixture consumption can most easily be observed. Buprenorphine, as a sublingual tablet, can be more difficult to supervise because of the length of time taken for the tablet to dissolve. Some pharmacists have been crushing buprenorphine tablets before consumption to make the supervision process more straightforward. This practice, while technically off-licence, can be undertaken with appropriate clinical governance approval and protocols (also see annex A3).

Other medication can be observed being consumed such as benzodiazepines, antidepressants, antipsychotics and medication for conditions such as tuberculosis and HIV.

Patients' privacy and dignity should be taken into account when making arrangements for supervised consumption.

5.4.4 Competencies for supervised consumption

Supervised consumption can take place in a pharmacy, drug treatment service or other clinical environment. In whatever environment,

staff supervising the consumption of medication need to be competent to do so.

5.5 Assessing and responding to progress and failure to benefit

5.5.1 Principles

It is clear from the available evidence that drug treatment offers protection against a range of harms including risk of contracting or spreading blood-borne viruses, risk of overdose and risk of offending.

Treatment should seek to maximise treatment outcomes across a range of domains including drug and alcohol misuse, health, crime and social functioning.

While drug treatment has been shown to be effective in reducing drug misuse, patients may not cease all illicit drug use immediately on entering treatment – eliminating all illicit drug misuse and alcohol misuse may take months or years. Clinicians will frequently be faced with decisions concerning what action to take if a patient is failing to benefit from a treatment programme. Such assessments should be based on the assessment of relative risks to the patient and staff, while maintaining the integrity of the treatment programme.

If a patient is not benefiting from treatment, clinicians should consider optimising treatment by increasing the intensity of the programme rather than reducing it. Optimising treatment may include ensuring medication is provided within evidence-based optimal levels, changing to another substitute medication, increasing keyworking or psychosocial interventions and increasing supervised consumption.

Use of illicit drugs or alcohol misuse may indicate that the patient requires discrete treatment for these substances. Relapse or lapse into illicit use may provide an opportunity for discussion and for the patient to learn about what triggers a relapse and how they can develop techniques to avoid such situations.

A good therapeutic relationship between the clinician and the patient should allow for discussion about drug misuse without fear of expulsion from treatment. A clinician should ensure a patient is fully aware of their roles and responsibilities while in drug treatment including correct use of medication.

Care planning and regular review should provide a vehicle to check patient progress and agree a course of action in partnership with the patient.

Clinicians are encouraged to chart progress in treatment systematically under the four domains of care planning – drug and alcohol misuse, physical and mental health, social functioning and criminal justice.

5.5.2 What constitutes failure to benefit?

A number of different scenarios may constitute failure to benefit from treatment, each of which may require a different response. It will be beneficial for clinicians to be aware of the behaviour of patients prior to drug misuse treatment in order to assess whether improvements (albeit slow) are being made. A good therapeutic relationship will enable illicit drug use to be discussed and interventions agreed accordingly. If this does not exist, or if a clinician or service is perceived as rigid or having a punitive response to illicit use, a patient may not disclose such use and may not be able to elicit the help they require.

5.5.3 Common scenarios in failure to benefit

5.5.3.1 Drug and alcohol misuse on top of a prescription

Common drug misuse scenarios leading to failure to benefit are outlined in Table 4, together with their risks and some proposed responses.

5.5.3.2 Patient misses appointments

In instances where a patient is collecting their medication but failing to attend appointments, as arranged with the clinician in line with the agreed care or treatment plan, the clinician will be unable to monitor progress against identified needs. If this situation persists and the patient does not respond to requests to contact the clinician, the patient may be offered incentives to attend or evening appointments. An urgent review needs to take place to enable prescribers to review patients and satisfy themselves that the medication is optimised and safe.

5.5.3.3 Patient misses daily pick-up of medicines for more than three days

After three days without their regular prescribed dose of opioid, patients may have lost their tolerance to the drug and may be at risk of

Scenario	Risks	Possible reason	Proposed response
Opiate misuse on top of an opioid prescription	Overdose Blood-borne viruses and other infections if injecting Continued offending and involvement in drug-misusing lifestyle Impaired engagement	Inadequate dose	Dose assessment, increase dose, give injecting equipment
		Medication unsuitable	Change medication regimen
		Patient on reducing regimen	Swap patient to maintenance regimen
		Patient using heroin and/or cocaine for 'high' on high dose opioids	Increase psychosocial interventions, e.g. contingency management plus urine tests and supervised consumption, provide injecting equipment and address negative social problems such as housing if applicable
Crack cocaine and cocaine misuse on top of an opioid prescription	Blood-borne viruses and infections if injecting More chaotic drug misuse Increased crime Psychological problems Overdose	Patient using for 'high'	Increase keywork/psychosocial interventions, provide injecting equipment if injecting drug misuser
		Patient dependent on cocaine or crack cocaine	
Alcohol or benzodiazepine misuse on top of an opioid prescription	Alteration of methadone metabolism Deterioration of hepatic functioning in those with hepatitis C Street drinking Intoxicated presentations Overdose or 'near misses' Drug interactions	Patient using to get intoxicated	Increase keywork/psychosocial interventions plus supervised consumption of opioid prescriptions with breathalyser test
		Patient dependent	Alcohol/benzodiazepine detoxification and/or reduction regimen plus increase keywork/psychosocial interventions and supervised consumption of opioid prescriptions with breathalyser test

Table 4: Responses to drug and alcohol misuse on top of an opioid prescription

overdose if the usual dose is then taken. The risks of loss of tolerance are less with buprenorphine than with methadone. Prescribers must ensure that pharmacists are part of a local scheme with protocols that include this scenario. Where a patient has not picked up for more than three days, a pharmacist is normally (under the terms of a local agreement) unable to dispense the next day's dose unless they have confirmed with the prescriber that it is safe to do so. Usually this will trigger urgent assessment by the prescriber. Efforts should be made to limit the impact on the patient of being without prescribed medication until a new prescription can be established. The patient should be asked about pick-up details and the clinician should check this aligns with the patient's lifestyle, when appropriate.

Arrangements for patients on daily pick-ups who miss a pick-up can be written into prescriptions. See the prescriptions annex A3.

5.5.4 Clinical responses to patients failing to benefit from treatment

Where patients are not progressing or are failing to benefit from drug treatment it is important that clinicians demonstrate and actively participate in regular monitoring, which should include:

5.5.4.1 Repeated risk assessment using a consistent and validated approach

Careful record keeping that accurately details responses to treatment, details the risks and benchmarks progress across the four care planning domains, informs clinical decision making and provides a clear audit trail for individual patient and clinician alike.

5.5.4.2 Information and feedback on risks

Patients who may be struggling in treatment are informed of the risks and consequences of continued chaotic drug misuse while established on a substitute opioid prescription.

5.5.4.3 Informed drug testing regimens

Drug testing (for example, once or twice weekly as part of a care plan) provides an opportunity to reflect back to the individual real evidence of poor progress and share the risks and concerns as a prescribe, such as the negative consequences of use on top, polydrug misuse and missed pickups.

5.5.4.4 Application of safe prescribing boundaries

Prescribers have a responsibility to make individuals aware of the criteria they apply as healthcare professionals, when deciding whether or not it is safe to continue to prescribe or when it is necessary to make a change to a prescription in order to manage documented risk.

5.5.5 Suspension and exclusion

It may be necessary on the basis of a careful assessment of the risks to the patient and staff to come to the conclusion that a prescription must be suspended or in rare cases withdrawn. Such decisions must involve the prescribing clinician and other members of the multidisciplinary team. Patients must be forewarned of the potential actions and consequences that the prescriber and the team may take where there is a failure to optimise treatment and be offered the opportunity to set new goals or identify contingencies that might influence their progress from this point.

A decision to temporarily or permanently exclude a patient from a drug treatment service or provide coerced detoxification should not be taken lightly. Such a course of action can put the patient at an increased risk of overdose death, contracting a blood-borne virus or offending. It may also increase the level of risk to children and vulnerable adults in the home. If at all possible, patients excluded from a service should be offered treatment at another local service or setting in a way that minimises risks and maximises opportunities for patients to be retained in treatment. Other steps in line with *Good Medical Practice* paragraphs 38-40 (GMC, 2006) must also be followed.

5.6 Opioid maintenance prescribing

5.6.1 Introduction

While a few patients can achieve abstinence rapidly, most require the support of prescribed medicines for longer than just a few months. The decision to maintain a patient on a long-term opioid prescription should be an active decision agreed between the clinician and patient. Longer-term prescribing should be reviewed at regular intervals (usually at least three-monthly) and should be part of a broader programme of care planned social and psychological support.

5.6.2 Maintenance treatment with methadone and buprenorphine

Opioid maintenance treatment is increasingly recognised as an effective management strategy and oral methadone remains the most commonly used medicine. However, there is an increasing body of work on the effectiveness of buprenorphine – a NICE technology appraisal (NICE, 2007a), which compared the two medicines in 2007, is summarised in section 2.3.

Maintenance treatment should be provided in the context of high-quality, care-planned, well-supervised and well-organised treatment services.

Any doctor or treatment service prescribing for opiate users must be competent to provide maintenance treatment, and local protocols and guidelines should be provided to assist in this.

If a decision to provide a long-term maintenance prescription is being considered, a number of factors that assist treatment effectiveness need to be incorporated:

- Patients may need to be seen at least fortnightly initially and then, if stable, at least monthly or less frequently if very stable.
- Random urine or oral fluid tests may be helpful, at least twice a year.
- Co-existing physical, emotional, social and legal problems, as well as drug and alcohol misuse, should be addressed as far as possible.
- A more thorough review every three months may be useful to consider what has been achieved and to set new goals.

5.6.3 Dosing regimen for maintenance treatment

After careful dose induction (see section 5.3) and dose stabilisation, there is a consistent finding of greater benefit from maintaining individuals on a daily dose between 60 and 120 mg of methadone. In some instances, due to a patient's high tolerance, higher doses may be required but this is exceptional. The clinician may need to ensure that there is good compliance through supervised consumption. High doses can reduce heroin and other opiate consumption, but caution over high doses needs to be observed if there is associated alcohol or benzodiazepine dependence. If patients miss methadone doses for three or more days, for whatever reason, they need to be reassessed for intoxication and withdrawal before methadone administration is recommenced. It may be appropriate to reduce the dose and titrate back up to the original dose if the patient has not had methadone for more than three days, as their tolerance may be reduced. If patients have abstained from methadone for five days or more, they will require an assessment of their tolerance before they are re-inducted onto methadone.

There is less consensus about the effective dose levels of buprenorphine required to optimise outcome once dose induction and stabilisation have taken place. Trials have shown that higher doses result in lower levels of opiate use and higher treatment retention. In general, daily doses of between 12 and 16 mg (and up to 32 mg in some cases) would seem appropriate for long-term prescribing. Alternate day dosing may suit some patients. Like methadone, if patients miss more than three days of buprenorphine the dose may need to be reduced and retitrated. If missed for five days, patients may need an assessment of their opiate misuse before they are re-inducted onto buprenorphine to minimise the risk of precipitating withdrawal.

5.6.4 NICE technology appraisal

The National Institute for Health and Clinical Excellence (NICE) completed a technology appraisal in January 2007 on the use of methadone and buprenorphine for managing opioid dependence (NICE, 2007a). Clinicians should refer to the full appraisal for the detailed findings and recommendations.

NICE's summary of its guidance is as follows:

- *Methadone and buprenorphine (oral formulations), using flexible dosing regimens, are recommended as options for maintenance therapy in the management of opioid dependence.*
- *The decision about which drug to use should be made on a case by case basis, taking into account a number of factors, including the person's history of opioid dependence, their commitment to a particular long-term management strategy, and an estimate of the risks and benefits of each treatment made by the responsible clinician in consultation with the person. If both drugs are equally suitable, methadone should be prescribed as the first choice.*
- *Methadone and buprenorphine should be administered daily, under supervision, for at least the first 3 months. Supervision should be relaxed only when the patient's compliance is assured. Both drugs should be given as part of a programme of supportive care.*

In addition to its status in England and Wales as NICE guidance, this technology appraisal has been validated by NHS QIS for Scotland.

The Clinical Guidelines update working group supports the key messages contained in the guidance. The following points are supplementary to NICE's guidance:

- The process of and factors involved in setting and reviewing periods of supervised consumption are covered in detail in section 5.4. The thrust of the working group's recommendation is that the majority of patients will benefit from a period of supervised consumption but this period should be determined according to clinical need rather than any fixed timescale. Some patients will not require three months of supervised consumption, others may need more and all should be reviewed regularly and, if necessary, returned to supervised consumption.
- The importance of programmes of support and other interventions alongside prescribing is described in chapter 4.

5.6.5 Other oral opioids sometimes used for maintenance

Methadone and buprenorphine are the oral opioids with most evidence of effectiveness in maintenance, and should continue to be the mainstay of treatment. Oral opioids other than methadone and buprenorphine, such as dihydrocodeine and slow release oral morphine (SROM) preparations, are not licensed in the UK for the treatment of opiate dependence and should not normally be used in the community.

5.6.5.1 Dihydrocodeine

There is a small evidence base that dihydrocodeine can be used effectively for maintenance although none that it is superior to other opioid medicines (Robertson *et al.*, 2007). The problem with dihydrocodeine tablets is that they are difficult to supervise, are short acting (so need frequent dosing) and can be easily diverted. Dihydrocodeine may occasionally be prescribed:

- for some patients unable or unwilling to consider or to tolerate methadone or buprenorphine
- in some circumstances where the clinician chooses to prescribe an alternative in particular circumstances (for example, in police custody or some prisons) and after considering the requirements for safe prescribing.

Dihydrocodeine should only be prescribed by clinicians with appropriate specialist competencies. The clinician will need to ensure an adequate dose and frequency of consumption because of dihydrocodeine's short half-life, and the patient will need to be carefully monitored.

5.6.5.2 Slow release oral morphine

Research from elsewhere in Europe has shown slow release oral morphine (SROM) preparations to be useful in treating patients who fail to tolerate methadone and several studies have show them to be effective in maintaining patients. There is also some evidence that the medicine may be useful in patients who are 'not held' on methadone. SROM should only be prescribed by clinicians with appropriate specialist competencies.

5.6.6 Injectable opioid treatment

There is a small section of the treatment population who, despite treatment with oral opioid maintenance, fail to make adequate progress and continue to be involved in high levels of injecting drug misuse and other risk-taking behaviour. These patients may benefit from specialist assessment and in some instances, clinical benefit can be improved by correcting sub-optimal dosing, although for other patients specialists could decide to initiate a trial of injectable maintenance treatment.

Injectable opioid maintenance treatment is a less established and less accepted form of treatment, which requires greater commitment of time and resources from the patient, the clinician and the service. It is a second-line treatment that should only be considered when optimised oral methadone and buprenorphine maintenance treatment are available and are found not to be suitable or, after proper trial, fail to deliver the expected benefit. Provision of optimised treatments using oral methadone and buprenorphine can be expected to be the more appropriate form of maintenance treatment for the majority of patients, and should remain the major clinical approach.

The situation in the UK with regard to injectable prescribing is complex. A number of long-term patients are still receiving injectable opioids under what is often called the 'British System'. There are also some areas of England in which a new form of injectable opioid treatment is being introduced, modelled on the recent Swiss and Dutch supervised injectable maintenance clinics. These were established to treat heroin dependent patients who had failed to benefit from orthodox treatments. The trials in Europe have shown very promising results and these models do have advantages as a result of the higher levels of supervision and safety; however results from the UK are not yet available. Injectable opioid treatment is not currently available in all specialist services and in all parts of the country.

Patients should only be considered for injectable opioid prescribing in line with the eight key principles described in *Injectable Heroin (and Injectable Methadone): Potential Roles in Drug Treatment* (NTA, 2003). The principles are described at annex A8, which also describes models of delivery of injectable dispensing and discusses some issues relating to different levels of supervision of consumption that may be applied to patients in receipt of such treatment.

5.7 Opioid detoxification

5.7.1 Introduction

In dependent opiate users, detoxification is usually thought of as being a clearly defined process supporting safe and effective discontinuation of opiates while minimising withdrawals. The process varies in duration from person to person, usually lasting about 28 days as an inpatient or up to 12 weeks as an outpatient.

The assessment process can establish whether a patient is suitable for detoxification. It should be remembered that detoxification alone is rarely successful especially at the first attempt. Patients who do not successfully detoxify should be offered seamless access back into maintenance or other treatment.

The following factors can guide the clinician and patients' opinions about whether they are suitable for detoxification:

- The patient is fully committed to and informed about the process.
- The patient is fully aware of the high risk of relapse.
- The patient is either in a stable and supportive social situation or able to go into one following detoxification.
- Plans for continuing support and treatment are in place.

There is clear evidence that coerced detoxification against a patient's express will is likely to lead to relapse and increased risks of harms such as overdose and blood-borne viruses.

A full programme of psychosocial support needs to be in place during detoxification. Access to a range of drug-free support services is vital following detoxification.

Some patients and prescribers agree to reduce doses slowly over many months or years. This is not really detoxification but can be useful as a way to work towards a formal detoxification. It reduces the dose at which the detoxification process is started and can improve a patients' confidence in their abilities to manage on lower opioid doses.

NICE found that there was no evidence for any superiority of clonidine over lofexidine and, because of its greater side effect profile, suggests that clonidine is not used in routine practice. Alpha agonists are not useful in detoxification for patients with substantial dependence but may be helpful in relieving symptoms of withdrawal in those who are using small amounts of opioids and are keen to achieve abstinence.

5.7.2 Dosing regimen for detoxification

5.7.2.1 Methadone

Following stabilisation on methadone the dose can be reduced at a rate which will result in zero in around 12 weeks. This is usually a reduction of around 5 mg every one or two weeks. Patients often prefer a faster reduction at the beginning although there is no research evidence to indicate the superiority of a linear or exponential dose reduction.

5.7.2.2 Buprenorphine

Buprenorphine doses can be reduced initially by 2 mg every two weeks or so, with final reductions being around 400 micrograms. Patients report being able to reduce buprenorphine doses more quickly than methadone.

NICE guidelines found that neither opioid medicine was more effective than the other in achieving good outcomes from detoxification. They concluded that detoxification should be carried out with the medicine on which the patient had stabilised.

5.7.3 Symptomatic treatment of withdrawal

5.7.3.1 Lofexidine

Lofexidine is a non-opioid alpha-adrenergic agonist and is not a controlled drug. It is authorised for the management of opioid withdrawal.

The treatment course is between 7–10 days with doses starting at 800 micrograms daily and rising to a maximum of 2.4 mg in divided doses. The dose is then reduced over subsequent days. It is most likely to be successful for patients with uncertain dependence, young people and shorter drug and treatment histories. NICE's guidance (NICE, 2007b) is that lofexidine may be considered for those who have decided not to use methadone or buprenorphine for detoxification, have decided to detoxify within a short time period or have mild or uncertain dependence (including young people).

Reported side effects are a dry mouth and mild drowsiness. Sedation is increased with concomitant use of alcohol or central nervous system depressants. Hypotension and bradycardia can be clinically significant.

The patient should be seen daily in the early stages of treatment to check for withdrawal symptoms, for blood pressure monitoring and to provide general encouragement. One of the disadvantages of lofexidine is that additional short-term medications may be needed to control other effects of opioid withdrawal, such as stomach cramps and diarrhoea.

The patient should be advised to take at least part of their dose at bedtime to offset insomnia associated with opiate withdrawal.

5.7.3.2 Other symptomatic treatment

Prescribing symptomatically can reduce some of the physical effects of withdrawal. There is no systematic evidence that any of these medicines work to improve outcome but they may be useful for the clinician in situations where it is not possible to prescribe effective opioid substitution. Particular care is needed concerning the risks of polypharmacy and ensuring appropriate supervision and support in such cases.

- Diarrhoea – loperamide 4 mg immediately followed by 2 mg after each loose stool for up to five days; usual dose 6-8 mg daily, maximum 16 mg daily.
- Nausea, vomiting, may also be useful for stomach cramps – metoclopramide 10 mg eight-hourly or prochlorperazine 5 mg three times a day or 12.5 mg intramuscularly 12-hourly.
- Stomach cramps – mebeverine 135 mg three times a day.
- Agitation and anxiety, sleeplessness – diazepam (oral) up to 5-10 mg three times daily when required (or zopiclone 7.5 mg at bedtime for patients who have been dependent on benzodiazepines). In severe cases of anxiety and agitation, obtain suitable psychiatric advice from an addiction psychiatrist or the on-call duty psychiatrist.
- Muscular pains and headaches – paracetamol, aspirin and other non-steroidal anti-inflammatory drugs. Topical rubefacients can be helpful for relieving muscle pain associated with methadone withdrawal.

5.7.4 NICE guideline

The National Institute for Health and Clinical Excellence (NICE) published its final guideline in July 2007 on opioid detoxification for drug misuse (NICE, 2007b). Clinicians should refer to the full guideline for the detailed findings and recommendations.

NICE's key priorities for implementation are as follows:

Providing information, advice and support

Detoxification should be a readily available treatment option for people who are opioid dependent and have expressed an informed choice to become abstinent.

In order to obtain informed consent, staff should give detailed information to service users about detoxification and the associated risks, including:

- *the physical and psychological aspects of opioid withdrawal, including the duration and intensity of symptoms, and how these may be managed*
- *the use of non-pharmacological approaches to manage or cope with opioid withdrawal symptoms*
- *the loss of opioid tolerance following detoxification, and the ensuing increased risk of overdose and death from illicit drug use that may be potentiated by the use of alcohol or benzodiazepines*
- *the importance of continued support, as well as psychosocial and appropriate pharmacological interventions, to maintain abstinence, treat comorbid mental health problems and reduce the risk of adverse outcomes (including death).*

The choice of medication for detoxification

Methadone or buprenorphine should be offered as the first-line treatment in opioid detoxification. When deciding between these medications, healthcare professionals should take into account:

- *whether the service user is receiving maintenance treatment with methadone or buprenorphine; if so, opioid detoxification should normally be started with the same medication*
- *the preference of the service user.*

Ultra-rapid detoxification

- *Ultra-rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) must not be offered. This is because of the risk of serious adverse events, including death.*

The choice of setting for detoxification

Staff should routinely offer a community-based programme to all service users considering opioid detoxification. Exceptions to this may include service users who:

- *have not benefited from previous formal community-based detoxification*
- *need medical and nursing care because of significant co-morbid physical or mental health problems*
- *require complex polydrug detoxification, for example concurrent detoxification from alcohol or benzodiazepines*
- *are experiencing significant social problems that will limit the benefit of community-based detoxification.*

The Clinical Guidelines update working group supports the key messages contained in the guideline. The following point is supplementary to NICE's guideline.

- There are cases in which detoxification in an inpatient or residential rehabilitation service might benefit a patient who has not previously attempted detoxification in the community.

5.8 Naltrexone for relapse prevention

5.8.1 Introduction

Naltrexone is an opioid antagonist which, when taken regularly, blocks a former opiate user from experiencing the effects of opiates. It can be helpful following detoxification in enabling a patient to maintain abstinence.

In the UK naltrexone is only licensed for use orally. A depot formulation is available but it is not licensed for drug treatment and safety information is missing.

5.8.2 Dose regimen

Due to the potentially hepatotoxic nature of naltrexone, liver function tests should be conducted before and during naltrexone treatment.

If uncertain whether the patient has used opiates, it may be necessary to conduct a naloxone dose challenge before administering naltrexone. If opiates have been used then severe and prolonged withdrawal symptoms will result if naltrexone is administered.

Following a negative urine or oral fluid test for opiates the patient is given a single dose of naltrexone (25 mg) orally or naloxone (400 micrograms) intramuscularly or subcutaneously. If the patient does not experience any withdrawal symptoms after a few hours, a 50 mg tablet of naltrexone can be given. Patients can be commenced on naltrexone within a few days of finishing a buprenorphine detoxification. The usual maintenance dose is then 50 mg a day.

It is good practice to give patients a card indicating that they are maintained on naltrexone.

The outcome of naltrexone treatment is improved by a programme of supervision, which can involve carers, to ensure compliance with the regimen.

5.8.3 NICE technology appraisal

The National Institute for Health and Clinical Excellence (NICE) completed a technology appraisal in January 2007 on the use of naltrexone for the management of opioid dependence (NICE, 2007c). Clinicians should refer to the full appraisal for the detailed findings and recommendations.

NICE's summary of its guidance is as follows:

- *Naltrexone is recommended as a treatment option in detoxified formerly opioid-dependent people who are highly motivated to remain in an abstinence programme.*
- *Naltrexone should only be administered under adequate supervision to people who have been fully informed of the potential adverse effects of treatment. It should be given as part of a programme of supportive care.*

- *The effectiveness of naltrexone in preventing opioid misuse in people being treated should be reviewed regularly. Discontinuation of naltrexone treatment should be considered if there is evidence of such misuse.*

In addition to its status in England and Wales as NICE guidance, this technology appraisal has been validated by NHS QIS for Scotland.

The Clinical Guidelines update working group supports the key messages contained in the guidance. The following point is supplementary to NICE's guidance:

- The importance of programmes of support and other interventions alongside prescribing is described in chapter 4.

5.9 Benzodiazepines

5.9.1 Introduction

These medicines have their own potential for misuse and dependence and are often taken in combination with opiates or stimulants. Many drug misusers misuse benzodiazepines but the majority do not require long-term replacement prescribing or high doses. For those who are benzodiazepine dependent, sudden cessation in their use can lead to a recognised withdrawal state.

Good assessment and care planning – and adherence to local protocols – are prerequisites for considering prescribing benzodiazepines. Prescribing benzodiazepines to drug misusers requires competencies in this form of treatment and appropriate supervision. It is therefore more likely to be considered an appropriate approach in secondary rather than in primary care.

5.9.2 Prescribing regimen

There is little evidence to suggest that long-term substitute prescribing of benzodiazepines reduces the harm associated with benzodiazepine misuse and there is increasing evidence that long-term prescribing (especially of more than 30 mg diazepam equivalent per day) may cause harm. Clinicians may be faced with requests to continue a prescription for maintenance benzodiazepines. To prevent symptoms of benzodiazepine withdrawal, the clinician should continue the prescription but the dose should be gradually reduced to zero. Only very rarely should doses of more than 30 mg diazepam equivalent per day be prescribed.

Prescribing to assist withdrawal should only be initiated where there is clear evidence of benzodiazepine dependency from the patient's history, observed symptoms and drug testing. The aim should be to prescribe a reducing regimen for a limited period of time.

Longer-term prescribing of benzodiazepines should adhere to the general principles of management, including clear indications of benzodiazepine dependence, clear intermediate treatment goals and milestones, regular review and methods to prevent diversion.

If the patient is also receiving a long-term prescription of methadone for concomitant opioid dependency, the methadone dose should be kept stable throughout the benzodiazepine reduction period. Concurrent detoxification from both medicines is not recommended in a community setting.

Insomnia in patients receiving prescribed methadone may be best alleviated by reviewing methadone dose, encouraging cessation of any stimulant misuse and guidance on management of sleep disturbance.

NICE guidance (NICE, 2004) is that the choice of shorter-acting benzodiazepine or Z-drug (zaleplon, zolpidem and zopiclone) for the short-term "management of severe insomnia interfering with normal daily life" should be determined by cost. Patients who have not responded to one of these hypnotic drugs should not be prescribed any of the others.

There is no evidence that intermittent, 'pulse' regimens (such as one week on and one week off) prevent dependence and these should be avoided.

5.9.3 Reduction of sedative hypnotics

Sedative hypnotics include benzodiazepine and 'z-drugs'.

5.9.3.1 Dose regimen

The following guidelines are suitable for a long-term sedative hypnotics withdrawal regimen in the community. It is good practice initially to convert all sedative hypnotics into an appropriate dose of diazepam. Table 5 lists the conversions to be used for selected medicines.

Diazepam has several advantages over other benzodiazepines. It has a relatively long half-life

and is available in different strength tablets. It can be given as a once-a-day dose, which may need to be adjusted against withdrawal symptoms. The clinician should aim for the lowest dose of diazepam that will prevent withdrawal symptoms.

The rate of withdrawal is often determined by an individual's capacity to tolerate symptoms. Benzodiazepines, including diazepam, can be withdrawn in proportions of about one-eighth (between one-tenth and one-quarter) of the daily dose every fortnight. In dependence on therapeutic doses, the dose can be reduced initially by 2–2.5 mg and if withdrawal symptoms occur, then the dose can be maintained until symptoms improve. If the patient is not coping and is experiencing severe withdrawal symptoms, it may be necessary to increase the dose to alleviate the symptoms.

If very high dose prescribing is required the patient should be referred for specialist assessment. Specialist practitioners then need to exercise caution in their assessments and prescribing. If the patient is stable and free of withdrawal symptoms, at for example 50 mg a day, the dose should be gradually reduced at a faster rate than suggested, for example by half over six weeks and then the planned rate of reduction should be again reviewed in line with the guidance outlined previously. This faster rate of reduction from very high doses led to no convulsions even in a group who had a high incidence of these during previous benzodiazepine withdrawals (Scott, 1990).

Drug	Dose
Chlordiazepoxide	15 mg
Diazepam	5 mg
Loprazolam	500 micrograms
Lorazepam	500 micrograms
Nitrazepam	5 mg
Oxazepam	15 mg
Temazepam	10 mg
Zaleplon	10 mg
Zopiclone	7.5 mg
Zolpidem	10 mg

Table 5: Approximate dosages of common benzodiazepines and Z-drugs equivalent to 5 mg diazepam

5.9.3.2 Adjunctive therapies

While reducing the dose, structured psychosocial interventions, counselling, support groups and relaxation techniques can be helpful.

5.9.4 Monitoring

It is important to note that, because of long-term effects, all patients on a benzodiazepine prescription must be regularly reviewed, on at least a three-monthly basis.

5.9.5 Dispensing and supervision

Where practicable, this should follow a schedule similar to that for other drugs of dependence, including daily dispensing and supervised consumption where appropriate.

5.10 Stimulants

5.10.1 Introduction

Clinicians will see stimulant users with a wide range of severity of problems. The mainstay of treatment is psychosocial and non-pharmacological. These approaches are described in chapter 4. Many pharmacological agents have been tested to assess their utility in treating withdrawal from stimulants, particularly cocaine, and none have convincingly been demonstrated to be useful in promoting abstinence.

5.10.2 General measures

General principles of management, such as giving preventive advice about safer injecting practice, must be applied. Psychiatric complications need to be treated on a symptomatic basis. Studies have found that an abstinence-based psychosocial treatment approach, linking counselling and social support, has the greatest impact on cocaine misuse. Approaches incorporating contingency management (CM) have been found to be more successful at promoting abstinence, both with regard to primary cocaine use and also for patients in opioid maintenance treatment programmes who also use cocaine (see chapter 4 and the NICE guideline, *Drug Misuse: Psychosocial Interventions* (NICE, 2007d)).

Where a patient exhibits persistent anxiety and agitation, the clinician should attempt to focus on stress reduction procedures. Patients who display persistent and severe psychotic symptoms may require admission to and treatment in a psychiatric unit. Withdrawal may

be associated with significant depression and the patient's mood should be monitored and the risk of suicide assessed. Special efforts may be required to attract hard-to-reach populations into treatment.

5.10.3 Antidepressants

Antidepressants, such as fluoxetine, can be effective in the management of major depressive episodes associated with stimulant use. There is no evidence that antidepressants have any effect on the withdrawal symptoms from stimulants. Care should be taken if selective serotonin re-uptake inhibitors are prescribed while cocaine or amphetamines continue to be taken, as toxic reactions have been described.

5.10.4 Substitute prescribing

There is no indication for the prescription of cocaine or amfetamines in the treatment of stimulant withdrawal and it is not recommended that other stimulants, such as methylphenidate or phentermine, are prescribed. However, there is evidence that, when providing maintenance treatments (methadone or buprenorphine) to patients with opiate dependence problems who also take cocaine, this cocaine use can be expected to decrease or stop with the provision of effective opioid maintenance treatment, and, when it persists, it may respond positively to improvement of the opioid maintenance treatment.

There was previously thought to be a limited place for the prescription of dexamfetamine in the treatment of amphetamine misuse, and this still occurs in some parts of the UK. The evidence is from reports that are typically small in number and weak in design, and the evidence of benefit is not convincing. Even though there may be individual patients for whom existing treatment should be continued for the time being, substitute stimulant prescribing does not have demonstrated effectiveness and, accordingly, should not ordinarily be provided.

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CHAPTER 6
HEALTH CONSIDERATIONS

6.1 Key points

- Reducing potential harm due to overdose, blood-borne viruses and other infections should be a part of all patient care.
- All drug misusers should be offered vaccination against hepatitis B and against hepatitis A where indicated.
- All drug misusers should be offered testing and, if required, treatment for hepatitis C and HIV infections.
- Retaining patients in high-quality treatment is protective against overdose. This protection may be enhanced by other interventions including training drug misusers and their families and carers in the risks of overdose, its prevention and how to respond in an emergency.
- Drug misusers who are also misusing alcohol should be offered alcohol treatments.
- Drug misusers who smoke tobacco should be offered smoking cessation interventions.

6.2 Blood-borne infections

6.2.1 Introduction

Four viruses are currently of particular concern in the context of drug misuse: hepatitis C, hepatitis B, HIV, and to a lesser degree or more sporadically, hepatitis A. Tetanus has also been a concern for injecting drug users.

There have been recent increases in the levels of blood-borne viruses among drug misusers (particularly those who inject). This increase is more marked in certain groups, including those injecting crack cocaine with heroin, and homeless drug users. Blood-borne virus incidence has also increased among new (predominantly younger) injectors and there has been a rise in the rate of sharing of injecting equipment.

Overall, approximately one in two injecting drug users in the UK have been infected with hepatitis C but there are marked regional variations. The overall prevalence of hepatitis C infection among injecting drug users has probably increased in recent years and levels of hepatitis C transmission remain elevated (HPA, 2006).

Risks can be reduced by providing an optimised range of drug services, including access to:

- needle exchange services
- adequate doses of opiate substitution treatments
- structured psychosocial interventions.

6.2.2 Prevention and testing

In addition to the virus-specific recommendations, there are some general measures that clinicians working with drug misusers should take.

- Injecting equipment and education to reduce equipment sharing should be made available to all injecting drug users.
- Opiate-dependent patients, whether injecting or not, should be encouraged to access relevant advice and information or counselling which includes strategies for avoiding exposure to blood-borne virus infection and contamination.
- All patients, and especially those engaged in sex work, should be made aware of the risk of infection from sexual contact.
- Sexual partners and household contacts should be supported and tested where appropriate.
- All injecting drug users and their partners should be offered testing for hepatitis C and hepatitis B infection even if they regard themselves as unlikely to have acquired these infections. Patients should be made aware that a test in general practice may have to be disclosed if they give permission for a medical report for financial purposes, and that confidential test facilities are available, usually in sexual health (GUM) clinics.
- Testing may have to be repeated when the risk of exposure continues.

6.2.3 Responding to exposure to infection

Prevention of avoidable exposure to infection is of prime importance. When exposure to infection does occur, it is vital to respond urgently and for appropriate protocols to be in place for dealing with incidents. The risk of transmission of infection, from an infected individual as a result of an injury caused by a used needle or other sharp object contaminated by blood or body fluids, is affected by a number of factors.

The degree and source of an injury will influence the level of risk. A superficial wound or one resulting from an old piece of injecting equipment carries only a small risk. A deep injury with a sharp instrument or needle from a known infected individual carries a higher risk.

When the specific infection carried by the source can be determined, this will help to assess risk as some viruses are more likely to lead to infection. When the infection status of the source cannot be determined – for example, where the source is unknown or refuses testing – risk assessment is influenced by the prevalence of infection in at-risk populations.

Understanding the implications of these risks also involves knowledge of the relative risks of harm from being infected by the virus involved. Sexual exposure is also an important issue, for example in sex workers.

In most areas a detailed protocol for dealing with infection exposure will be in place in the local A&E department or occupational health department. The protocol for an individual service might only cover first aid and immediate transfer to A&E. Protocols might cover some or all of the following.

- First aid measures at the site of the injury.
- Assessment of the severity of the problem and route of referral to an appropriate specialist for further advice.
- The need for post-exposure prophylactic immunisation with, for example, hepatitis B vaccine.
- Information, advice and counselling, testing and retesting.
- Wound care.
- Provision, or not, of antiviral chemotherapy for HIV infection.

6.2.4 Viral infections

The main route of transmission in this context is the blood-borne route, through the sharing of injecting equipment or paraphernalia. However, hepatitis A is commonly transmitted through the oral-faecal route, and hepatitis B and C, and HIV infections can spread through sexual contact. Vaccination is currently available against hepatitis A and hepatitis B viruses but not against hepatitis C virus and HIV.

Hepatitis B and C viral infections may be followed by complete recovery without treatment or may develop into longer-term infection and illness. Hepatitis A infection is not usually associated with a chronic carrier state and usually requires no specific treatment, unless occurring with other disease. There are specific treatment regimens to be considered for the chronic infections that are commonly found with hepatitis C virus and with HIV infection.

6.2.4.1 Hepatitis A

Based on current evidence it is recommended that injecting drug users are vaccinated against hepatitis A and B. A combined vaccine is available that may improve uptake. However, the benefits of hepatitis A vaccination are modest and the benefits of hepatitis B vaccination are substantial. If there are pressures against vaccinating for both viruses, injecting drug users should be vaccinated against hepatitis B as a priority.

6.2.4.2 Hepatitis B

Hepatitis B is in many cases sub-clinical or may only present with a flu-like illness. In patients who do not develop symptoms suggestive of hepatitis the illness will only be confirmed by abnormal liver function tests or the presence of serological markers of hepatitis B infection.

Hepatitis B vaccination should be carried out as soon after initial presentation as possible in all drug misusers, regardless of the presence of injecting. Pre-vaccination testing for antibodies indicating past exposure is not necessary. Incentives for completion of hepatitis B vaccination could be offered as part of a package of treatment. Sexual partners and children of injecting drug users should also be vaccinated, as should sexual partners and close household contacts of patients with chronic active hepatitis B infection. A record of vaccinations given should be kept.

Opinions and protocols for testing after vaccination courses are varied. The European Consensus Group considers that post-vaccination testing and repeated boosters are not necessary even when antibody responses are poor, unless there is concern regarding any immunological deficiency (European Consensus Group on Hepatitis B Immunity, 2000). The Green Book (DH, 2006) also recommends against testing except those at risk of occupational exposure and patients with renal

failure. Accelerated courses may be appropriate in drug misusers depending upon timing of appointments and assessments.

A combined vaccine formulation for both hepatitis A and B viruses is available. It can be given as three standard-spaced doses (initial dose with subsequent doses one and six months later) or on an accelerated schedule (initial dose followed by doses seven and 21 days later) when early protection against hepatitis B is required or patients may not return for the later doses of the standard schedule.

Patients who have received the standard schedule vaccination and are at continuing risk of infection should be offered a single booster dose of vaccine, once only, around five years after primary immunisation. Individuals who have received combined hepatitis A and B vaccine in an accelerated schedule require a booster dose at one year.

6.2.4.3 Hepatitis C

Diagnosis

The uptake of testing for hepatitis C for those in contact with drug services has increased in recent years but it is estimated that almost half of injecting drug users with hepatitis C and in contact with these services still remain unaware of their infection.

Patients should be given information and advice on the hepatitis C virus (HCV), the risks of infection and its effects, and the role of testing and treatment. Those at risk should be offered access to screening tests and tests to confirm hepatitis C infection. Local pathways need to be in place for additional assessment and advice on management of chronic infection.

Acute infection and chronic infection

During initial infection with the hepatitis C virus, individuals may suffer from an acute illness resulting from inflammation of the liver. Symptoms include nausea, vomiting, fever and jaundice lasting for a variable amount of days but usually resulting in recovery and improvement in symptoms. Many patients become infected with few or only minor transitory symptoms that pass unnoticed.

If blood tests are taken at this time, there will be signs of liver inflammation and the appearance of antibodies to the virus. These antibodies persist in the blood for life, providing a marker for anyone who has been infected with hepatitis C. In 75–80%, the illness may become chronic, while 20–25% will eliminate the active virus. Ongoing active infection is measured by the polymerase chain reaction (PCR) test, which measures the presence of active viral RNA indicating the presence of replicating viral particles.

Chronic infection may persist for many years and damage to the liver is variable depending on individual factors and additional problems such as alcohol use and other liver diseases. Hepatitis C is slowly progressive over many years and 5–15% of patients with chronic hepatitis will develop liver cirrhosis over 20 years. Most studies indicate that the proportion developing cirrhosis continues to rise after 20 years. Of the patients with cirrhosis, 4–9% will develop liver failure and 2–5% of patients with cirrhosis will develop primary hepatocellular carcinoma.

Genotypes

Many different strains of HCV have been recognised by virological testing. These have been grouped into six categories known as genotypes 1 to 6. There are significant geographical variations in the prevalence of the different genotypes in different parts of the world. In the UK, genotype 1 is the most common, followed by genotype 3 and genotype 2. There are small numbers of patients in the UK infected with hepatitis C virus of genotypes 4, 5 and 6, most of whom acquired the infection overseas.

Routes of transmission

The majority of cases in developed countries are infected by sharing of injecting equipment. Observational studies indicate a very small risk of people with diagnosed HCV infection transmitting infection to their families, close contacts and sexual partners. Expert opinion acknowledges the small risk of transmission by close contact or sexual intercourse but nevertheless advises that condom use should be considered where the infected case is PCR positive. The risks of transmission to others by sharing equipment when injecting drugs should be explained to those that are infected.

Transmission by needlestick injuries to health or social care workers is probably less than 2% and depends on the severity of the injury.

The risk of women who are HCV infected and RNA positive transmitting infection to their babies *in utero* or during childbirth is

approximately five percent. The rate is twice as high for those co-infected with HIV. The baby's risk of acquiring HCV from a mother infected with HCV is not increased by mode of delivery or breastfeeding.

Investigations
Blood tests including HCV antibody, PCR and liver function tests are used to diagnose the disease and to assess the current state of progression. Additionally, an ultrasound scan of the liver or a liver biopsy may be recommended to determine the stage of the disease, depending on blood test results. Antibody tests should be available in general practice surgeries and increasingly in drug treatment services. The PCR test, which was previously expensive and confined to specialist liver clinics, is now usually available at the same time as the antibody test and requires only an additional small EDTA blood sample. A negative PCR test indicates lack of active ongoing disease and means unnecessary referrals to specialist hepatology services can be avoided. Repeat liver biopsies may be considered in patients with mild disease who remain untreated, if progression of liver fibrosis would influence the decision to opt for antiviral therapy.

Before and after testing, information, advice or counselling for patients, relatives and carers is always necessary and might be undertaken by an interested clinician or with the help of an outreach worker from a specialist clinic or an agency with expertise. A range of written materials and information helplines are now available across the UK.

Shared care
A common problem for drug misusers is lack of engagement or failure to attend initial assessment clinics. This may be for a variety of reasons including lack of understanding of hepatitis and its risks, low priorities given to personal health problems and the practical difficulties of getting to specialist clinics. Increasing efforts are being made to share the care of patients with hepatitis C who are in need of testing and follow up. Antibody and PCR testing can be carried out in GP surgeries by an interested doctor or nurse or an outreach worker from a specialist clinic, as can follow up of patients under observation or who have finished active treatment.

Treatments
There is specific guidance in the relevant NICE technology appraisals from 2004 and 2006, which makes clear that those who continue to inject drugs or misuse alcohol should not, simply because of those behaviours, be excluded from provision of antiviral treatments for the management of hepatitis C infection, although clearly not addressing such issues may impact on the effectiveness of treatment in particular cases.

The Scottish Intercollegiate Guidelines Network has also produced a guideline (SIGN, 2006), which states: "Current injecting drug users infected with HCV should not be excluded from consideration for HCV clinical management, including antiviral therapy, on the basis of their injecting status."

Specific antiviral treatments for mild, moderate and severe cases of hepatitis C infection should always be explored, including referral for specialist advice. Early referral of all active disease is now commonly recommended, irrespective of injecting status, as the disease is more responsive to treatment earlier in disease progression and reinfection rates are low. Patient choice about treatment is important and "the decision on whether a person with mild chronic hepatitis C should be treated immediately or should wait until the disease has reached a moderate stage ('watchful waiting') should be made by the person after fully informed consultation with the responsible clinician." (NICE, 2006).

Provision of active antiviral treatments and specialist investigations is often carried out in specialist centres although, increasingly, treatment may be provided in primary care. Improved drug combinations are giving better results and, depending upon the genotype, success rates are increasing and length of treatment courses reducing.

Advanced disease
Hepatocellular carcinoma, cirrhosis and transplantation are all longer-term consequences for a minority of patients with hepatitis C. In individuals who have had active infection for many years screening may be necessary to detect early liver cancer.

6.2.4.4 HIV

Diagnosis

HIV infection is diagnosed with a blood test, but this generally only shows the presence of the virus once it has become established (three months or so after infection). Testing can be done by a GP or in a specialist GUM (genito-urinary medicine) clinic. GPs may be asked to disclose (with patient consent) details of test results to institutions such as insurance companies. Tests conducted at GUM clinics are subject to stronger legal confidentiality rules.

Acquired Immune Deficiency Syndrome (AIDS) is usually only diagnosed on the basis of an AIDS-related condition combined with a positive HIV result.

Routes of transmission

Men who have sex with men remain the behavioural group at greatest risk of acquiring HIV within the UK. Since 1999, the HIV epidemic in the UK has seen a rapid increase in the number of diagnoses among heterosexuals, with many probably contracting the disease in Africa.

HIV diagnoses among injecting drug users (IDUs) in the UK have remained low and constant. However, the prevalence of HIV infection among IDUs in England and Wales has increased in recent years. Overall, around one in 50 IDUs is now infected, which is still low compared to many other countries. The prevalence remains elevated among IDUs in London with around one in 25 HIV infected. The recent increase in HIV prevalence has been greatest elsewhere in England and Wales, where the prevalence has risen from around one in 400 in 2003 to about one in 65 in 2005 (HPA, 2006). This is thought to be associated with a combination of risk factors:

- Combined heroin and cocaine injecting (speedballing).
- Injecting into the groin (femoral vein).
- Homelessness.

Sharing of injecting equipment remains higher than in the mid-1990s with more than half of current injectors reporting sharing injecting equipment in the previous month (HPA, 2006). Women may transmit HIV infection to their babies in the uterus, at birth and through infected breast milk. However, early diagnosis is now much more common and allows interventions to prevent mother to child transmission during pregnancy, labour and delivery. Transmission by needlestick injuries to health or social care workers remains very low.

Investigations

Blood tests are used to diagnose the disease and to assess the current state of progression. Antibody tests should be available in general practice surgeries and increasingly in specialist drug treatment services.

Counselling for patients, relatives and carers is always necessary and might be undertaken by an interested clinician or with the help of an outreach worker from a specialist clinic or an agency with expertise. A range of written materials and information helplines are available across the UK.

Shared care

Increasing efforts are being made to share the care of patients with HIV. Antibody testing can be carried out in GP surgeries by a doctor or nurse, or an outreach worker from a specialist service.

Treatment

Treatment for HIV infection has improved markedly since the publication of the 1999 Clinical Guidelines. Disease progression is slowed by combinations of antiretroviral drugs and survival rates have increased accordingly. However, the UK has some of the highest rates of resistance to anti-HIV drugs (Dunn, 2005) and there are fears of a new epidemic of drug-resistant HIV.

6.2.5 Bacterial infections

6.2.5.1 Tuberculosis

Drug misusers account for only a small number of cases of tuberculosis (TB) in the United Kingdom but they have a higher prevalence of TB compared with the general population (Story *et al.,* 2007). Together with a substantial general rise in UK notifications of TB – from a plateau of 5,100 in 1987 to around 8,113 in 2005 – this will mean increased numbers of drug misusers with TB. However, national and regional distribution of TB is varied, with London accounting for 43% of the national total in 2005. Almost all cases of TB in the UK are acquired through the respiratory route, by breathing in infected respiratory droplets from a person with infectious respiratory TB, often after prolonged close contact (DH, 2006).

Immunisation against TB, with BCG vaccine, is now a risk-based programme targeted at protecting newborn children most at risk of exposure to TB and is not usually recommended for people aged over 16 years. Older unvaccinated, tuberculin-negative individuals are recommended to receive the vaccine if they are more likely than the general population to come into contact with someone with TB through their work or are a contact of someone with respiratory TB. BCG is contraindicated in symptomatic HIV-positive individuals and not recommended in those known to be or suspected to be HIV positive, regardless of clinical status.

The symptoms of TB are varied and depend on the site of infection. General symptoms may include fever, loss of appetite, weight loss, night sweats and lassitude. Pulmonary TB typically causes a persistent productive cough, which may be accompanied by blood-streaked sputum or, more rarely, frank haemoptysis. Untreated, TB in most otherwise healthy adults is a slowly progressive disease that may eventually be fatal.

Screening and diagnosis of TB usually involves a chest X-ray. Other tests include examination of a sputum sample for TB bacteria and a tuberculin skin (Mantoux) test to determine to assess evidence of infection or immunity to TB. A positive result from a Mantoux test is recommended to be confirmed with an interferon gamma release blood assay. Tuberculosis screening by chest X-ray may be another candidate, alongside hepatitis B immunisation, for contingency management and was recommended as such by NICE (NICE, 2007).

Substitute opioid doses may need to be increased in patients taking antitubercular medicines such as rifampicin which increase drug clearance and reduce the half-life of many drugs. Conversely, doses may need to be reduced when antitubercular medication is discontinued. Adherence to anti-tuberculosis therapy in drug-misusing patients prescribed substitute opioids may be significantly improved if the consumption of both medicines is supervised together. This is known as directly observed therapy (DOT) and may be especially useful in custodial settings.

6.2.5.2 Tetanus

There was an outbreak of tetanus among injecting drug users in 2003 and, although the numbers affected have dropped since then, injecting drug users are still at risk and the consequences of infection can be very serious. Tetanus immunisation status should be actively checked in injecting drug users and the use of human tetanus immunoglobulin considered for patients with injection site infections.

6.2.6 Further information

Detailed information about immunisations is contained in *Immunisation Against Infectious Disease 2006* (the 'Green Book') available to download from the Department of Health website at www.dh.gov.uk or to order from The Stationery Office at www.tso.co.uk. Individual sections are also available to view online or download from the NHS immunisation website at www.immunisation.nhs.uk.

Details of testing and treatment for hepatitis C are available from NICE (the National Institute for Health and Clinical Excellence) and in the current guideline from the Scottish Intercollegiate Guideline Network:

- *Peginterferon Alfa and Ribavirin for the Treatment of Mild Chronic Hepatitis C*. TA106. NICE, 2006.
- *Interferon Alfa (Pegylated and Non-Pegylated) and Ribavirin for the Treatment of Chronic Hepatitis C*. TA75. NICE, 2004.
- *Management of Hepatitis C: A National Clinical Guideline*. SIGN 92. SIGN, 2006.

The Royal College of GPs has also provided *Guidance for the Prevention, Testing, Treatment and Management of Hepatitis C in Primary Care* (RCGP, 2007).

The British Liver Trust provides a range of publications on individual liver conditions and offers support to patients with liver disease and those who care for them.

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6.3 Preventing drug-related deaths

6.3.1 Introduction

The four main causes of drug-related deaths are:

- overdose
- suicide
- accidents
- physical health complications of drug misuse

Rates of recorded drug-related overdose deaths among UK drug misusers are among the highest in Europe. Drug-related overdoses are most commonly caused by opioid drugs (heroin or methadone) and remain the second most common cause of years of life lost in young men. Overdoses often involve the use of opioids with other depressant drugs like alcohol and benzodiazepines.

Drug-related deaths are especially high in the first weeks following release from prison. Those at most risk have a history of injecting drug use immediately prior to entry to prison, and a long history of opioid dependence or polydrug dependence (Farrell and Marsden, 2005).

Clinicians have an important role in minimising the risks of all four causes of drug-related deaths among drug misusers and the risks of death to others due to diversion or due to unsafe storage of prescribed medication.

Since the publication of the Clinical Guidelines in 1999, there has been greater attention to daily dispensing and supervised consumption for patients in the early stages of methadone treatment. Over this period the number of overdose deaths associated with prescribed methadone has halved despite a substantial increase in the number of methadone prescriptions and an increase in average daily dose. In England, for example, deaths have halved while the number of prescriptions has doubled.

6.3.2 Reducing drug-related deaths

Clinicians can help to reduce drug-related deaths in their patients by:

- identifying and assessing patients at greatest risk of drug-related death
- providing education and training to drug misusers and their families on the risks of overdose and how to respond effectively
- advising drug misusers of the dangers of combining drugs, especially alcohol and benzodiazepines
- educating drug misusers that the use of methadone, outside its medical purpose, is extremely dangerous
- educating new patients starting on methadone and buprenorphine on the risks of loss of tolerance
- using supervised consumption, especially in the early stages of methadone and buprenorphine treatment, flexibly and in line with the protocols described in section 5.4
- adjusting dispensing frequency according to risks
- requiring that patients moving on to take-home methadone and buprenorphine provide details of satisfactory home storage arrangements and recording these in the patient's notes, especially when children are in the home
- conducting or arranging for mental health assessments in patients who present a suicide risk
- making use of local specialist support and referral in complex cases, such as cases of poly-pharmacy requiring specialist review
- contributing to effective care pathways between prisons and the community.

6.3.3 Dealing with overdose

All services working with drug misusers should have an emergency protocol in place that covers the management of drug overdoses. This should include rapid ambulance call and competent preservation of a clear airway, and may include protocols for the emergency administration of interim naloxone while awaiting the arrival of the ambulance.

Suitable resuscitation training and equipment should be available for clinical settings. Naloxone, and staff competent to administer it, may usefully be made available in suitable services working with drug misusers. Naloxone is a prescription-only medicine and must be prescribed for a named patient or supplied to an individual by means of a patient group direction. However, it can be administered by anyone to another person for the purpose of saving life.

Evidence for the effectiveness of take-home naloxone in preventing overdose-related deaths in opiate misusers is largely anecdotal at present. It is permissible to prescribe take-home naloxone to named patients and is established practice in some parts of the country. It would be reasonable for services to pilot take-home naloxone locally, with suitable training for its users – and for relatives and carers, if appropriate.

There is a need to provide a range of overdose measures to carers of opiate misusers. These might include information, advice and training on avoiding overdose, recognising the signs of overdose and first aid, and might also include the use of naloxone.

6.4 Alcohol

6.4.1 Introduction

There is a common belief that alcohol-related problems occur predominately in middle aged or older people and alcohol deaths are typically from physical diseases such as cirrhosis of the liver, cardiovascular disease, and gastrointestinal disorders. In reality alcohol is a significant cause of death among young people through alcohol overdose, inhalation of vomit, hypoglycaemia, and accidents or violence. More generally alcohol increases the risk of dropout from treatment and exacerbates mental health problems. Alcohol increases the risk of hepatic cancer in people who are hepatitis C positive. Most of these risks are increased when alcohol and other drugs are taken in combination (ACMD, 2000).

6.4.2 Drinking and drug misuse

The National Treatment Outcomes Research Study (Gossop *et al.,* 2001) found 24% of the cohort at the start of the study were drinking above Department of Health recommended sensible limits and 25% were doing so at the five year follow-up. Eight percent were drinking at definitely harmful levels. About one-third of patients receiving methadone have been identified as having a current drink problem and a further one-sixth have a history of a drinking problem (Senbanjo *et al.,* 2006). It follows that clinicians working with drug misusers require:

- an awareness that alcohol misuse is not separate from misuse of other drugs
- competence at detecting problem drinking
- to be able to give harm reduction and educational messages regarding misuse of alcohol
- to be able to manage alcohol misuse emerging alongside pharmacotherapies such as substitute prescribing.

It may be clinically helpful to think of different patterns of drinking associated with drug misuse:

- Drinking that is substantially independent of other drug misuse.
- Drinking that is interchangeable with the use of other psychoactive drugs.
- Drinking, and often other drug misuse, as a supplement to a substitute prescription.

Assessment of the cumulative effects of high-risk behaviours and polydrug use requires some clinical experience and the application of clinical judgements.

Opiate misusers who are chronically intoxicated with alcohol are difficult to manage. Some strategies to deal with the problems are outlined in the section on responding to failure to benefit from treatment (section 5.5). The risks of prescribing opioids in conjunction with high levels of alcohol use need to be balanced against the benefits of retaining the patient in treatment. Specialist competencies are required.

6.4.3 Treatment interventions

Drug misusers who are dependent on alcohol should be offered alcohol interventions. This usually involves detoxification either in the community or as an inpatient followed by a range of psychological and pharmacological interventions to prevent relapse. The following may be helpful in planning treatment:

- The standard treatments for alcohol dependence and misuse apply to those who also misuse other drugs (Raistrick *et al.,* 2006). These include psychological interventions specifically directed at alcohol misuse and pharmacology to prevent relapse such as acamprosate and disulfiram, or naltrexone (although outside the approved product licence in the UK) if not maintained on methadone.
- The more drinking behaviour is intertwined with drug misuse, the more the two need dealing with together, probably by a more intensive intervention.

- The stability of what is prescribed and taken is of greater importance than the total amount taken, at least in the short term – accidental or intended overdose is more likely when irregular high doses of a drug are consumed.
- Minimise polypharmacy and consider in what order to address withdrawal from multiple drugs of misuse – it is usual to focus first on detoxification from alcohol and sedative-hypnotics, while maintaining a stable dose of substitute opioids before moving on to opioid detoxification.
- Consider the degree of supervision required for the safe management of alcohol detoxification – inpatient or daycare services are likely to be needed.
- Regular use of breathalyser readings may be useful in monitoring the amount of alcohol consumed and in assisting patients to reduce their use. Many services only issue substitute prescriptions when the breathalyser reading is below a certain level, often the drink driving limit. There is no evidence that this does reduce the amount a patient drinks but it may contribute to the safety of prescribing opioids in patients who are dependent on alcohol.
- Patients drinking heavily may suffer from vitamin deficiencies and associated health consequences. Providing appropriate supplements may help prevent future problems.

Further information on the treatment of alcohol dependence can be found in *Clinical Topics in Addiction: Updates from Advances in Psychiatric Treatment* (Day, 2007).

6.4.4 Non-drug interventions

Advice should be given on the location of Alcoholic Anonymous (AA) meetings, and patients should be encouraged to attend AA meetings as part of their initial treatment programmes. Posters with information on NA and AA should be prominently displayed in patient waiting areas and leaflets on such programmes should be available. Knowledge of other local support groups and day programmes, and active links with such programmes, can facilitate patient uptake.

6.5 Tobacco

6.5.1 Introduction

Most patients in drug treatment smoke and this is often the only drug dependence that is not addressed. This is despite smoking-related diseases being highly prevalent in drug misusers, with a likelihood of causing premature death. Smoking may act as a cue for the misuse of other drugs that are consumed in the same way. Therefore smoking may increase the risk of relapse into drug misuse.

6.5.2 Smoking cessation in drug treatment

Evidence suggests that smoking cessation help may be associated with improved drug treatment outcomes. Similar processes apply to smoking cessation treatment as to treatment for other types of drugs, for example coping with cravings and preventing relapse.

Despite this, most drug treatment services do not offer smoking cessation to drug misusers. This may be because staff have not been appropriately trained, believe that it will interfere with drug treatment or are tobacco smokers themselves. Or it may result from a lack of evidence and clinical experience of using smoking cessation treatments in this patient group.

However, societal attitudes are changing and the smoking bans introduced across the UK in 2006 and 2007 may increase the demand for treatment for tobacco dependence in drug misusers.

6.5.3 Treatment options

There is a large evidence base for the effectiveness of smoking cessation treatment in the general population and in prisons, with the best outcomes from a combination of behavioural support and pharmacological interventions such as nicotine replacement therapies, bupropion and varenicline (Champix®). In the absence of evidence to the contrary, it seems likely that drug misusers will respond to the same treatments as the general population although they may need more intensive options to achieve the same results.

Given the high rates of smoking and the low quit rates in drug misusers, it may be reasonable to consider harm reduction approaches to smoking such as replacing cigarettes with clean

nicotine in the form of patches for some of the day. This may be particularly useful in alleviating the symptoms of tobacco withdrawal while a patient is in a residential or inpatient drug treatment facility.

Clinicians should encourage patients to stop or reduce their smoking and refer them to smoking cessation services. This may be particularly easy in primary care drug treatment where many GPs and pharmacists have smoking cessation services provided within the same premises. Specialist services may need to consider providing smoking cessation interventions as part of standard drug treatment. Staff will need to be competent in providing smoking cessation interventions.

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CHAPTER 7
SPECIFIC TREATMENT SITUATIONS AND POPULATIONS

7.1 Key points

- Quality of treatment should be consistent regardless of how patients enter treatment. This includes treatment for those in the criminal justice system, including those in prison.
- Appropriate communication and transfer of information between a wide range of professionals coming into contact with or providing interventions for drug misusers is vital to ensure seamless care.
- Assessment and evidence-based care provided by liaison or a multidisciplinary team is appropriate in many clinical situations, including, for example, with pregnant women, young people, older drug misusers, those with a dual diagnosis, drug misusers with acute and chronic pain, and drug misusers being admitted to or discharged from hospital.
- Clinicians working with pregnant women should strike a balance between reducing the amount of prescribed drugs, in order to reduce fetal withdrawal symptoms, and the risk of the patient returning to or increasing their misuse of illicit drugs.
- Common mental health problems are typical in drug misuse treatment populations. Interventions for these may need to be provided in drug misuse services. Those with severe mental health problems should have high-quality, patient-focused care integrated with mental health services.
- Young people are likely to need interventions which are different from those in adults and specific competencies are required to deliver them.
- As drug misusers become older they will have increasing drug-related and non-drug-related health needs.
- Drug misusers in pain will have needs for pharmacological and other interventions similar to non-drug users.
- Drug misusers in hospital will need interventions that facilitate their medical treatment and, if possible, improve their engagement with drug misuse treatment.

7.2 Criminal justice

The criminal justice systems of England and Wales, Scotland and Northern Ireland vary. What follows is a general summary of the ways in which clinicians might be involved with drug misusers in the criminal justice system.

7.2.1 Introduction

There is considerable overlap between those misusing drugs and those committing crimes, especially acquisitive crime and drug dealing. Clinicians should make treatment decisions on clinical grounds but drug misusers – especially those who commit crimes to fund their drug misuse – may come into contact with, and increasingly be offered treatment in, the criminal justice system at various points and through a number of different arrangements. Clinicians need to understand the nature of these and where their involvement lies.

Drug misusers in the criminal justice system should neither receive higher priority for their treatment nor should their legal status deny them access to care equivalent to that available in the community.

7.2.2 Criminal justice intervention points and arrangements

7.2.2.1 Co-ordinated solutions

Increasingly, there are co-ordinated solutions for those who commit crimes to fund their drug misuse; engaging with problematic drug users at every stage of the criminal justice system and moving them into appropriate drug treatment and support. Case management begins at first point of contact with the criminal justice system and continues through custody, court, sentencing and beyond, into resettlement.

In England and Wales this co-ordinated case management is provided by criminal justice intervention teams (CJITs) through the Drug Interventions Programme (DIP).

The Drug Interventions Programme does not extend to Scotland or Northern Ireland, although similar work linking criminal justice and treatment agencies aims to reduce the number of people who commit crime as a result of their drug misuse.

7.2.2.2 Police custody

Accurate assessment of drug misuse problems in detainees, including the degree and severity of dependence, and of the need for medical intervention, is essential because both intoxication and withdrawal can put detainees at risk of medical, psychiatric and even legal complications.

There is detailed guidance for forensic physicians in *Substance Misuse Detainees in Police Custody – Guidelines for Clinical Management* (AFP and RCPsych, 2006). This recognises that the assessment and treatment of drug misusers presents particular challenges, which require certain skills and experience to ensure appropriate management. The guidelines stress the importance of good communication, working closely with custody officers and sharing responsibility for the safety and care of detainees with drug misuse problems.

Criminal justice drug workers working in police custody suites provide information and, where appropriate, referral to treatment or other means of assistance. The involvement of the accused is voluntary. It is not an alternative to prosecution or due process.

It may sometimes be appropriate to ensure continuity of pharmacological treatment for drug misusers taken into custody, for example ensuring that a prescription for methadone can be continued. Further guidance is contained in *Pharmaceutical Care of Detainees in Police Custody* (RPSGB, 2007).

7.2.2.3 Arrest and bail

Those arrested for a 'trigger' offence in Great Britain (one associated with dependent drug misuse, such as burglary) may be drug tested. If the test is positive, they can be required to undergo an assessment of their drug misuse or, in England and Wales, their bail can be restricted.

7.2.2.4 Drug courts

In some areas, dedicated drug courts are aimed at offenders for whom there is an established relationship between a pattern of serious drug misuse and offending. They aim to reduce the level of drug-related offending behaviour and to reduce or eliminate offenders' dependence on or propensity to use drugs. Multi-professional and multi-agency working are key characteristics of drug courts, as is continuity of the sentencer who monitors the offender's progress.

7.2.2.5 Community sentences

A number of community sentences now exist that incorporate requirements to undergo treatment (with consent). They are usually targeted at offenders with a significant number of previous convictions and custodial sentences.

For any of these sentence options, it is important for clinicians to note that the involvement of the offender is voluntary, although an impetus for the patient's agreement to treatment may be the hope of influencing the outcome of any criminal justice proceeding, for example, reducing the risk of a custodial sentence.

In England and Wales, the Drug Treatment and Testing Order (DTTO) has largely been superseded by the more flexible Drug Rehabilitation Requirement, which is itself being subsumed as one of the options in the new Community Order.

DTTOs are available to the High Court and all Sheriff Courts in Scotland and were announced in Northern Ireland in December 2006, as part of a new sentencing framework yet to be introduced.

7.2.2.6 Civil orders

In addition to the sentences for criminal activity described previously, there are civil orders designed to get antisocial drug misusers in the community into treatment, if they are not already receiving it.

An Intervention Order, for example, compels recipients to undergo drug treatment to tackle the root cause of their nuisance behaviour, or face a fine.

7.2.2.7 Targeting programmes

There are also programmes aimed at identifying, targeting, monitoring and rehabilitating offenders believed to cause most harm to themselves and the local community.

7.2.2.8 Prison

The treatment of drug misusers remanded in prison or given a custodial sentence is covered in the next section.

7.2.3 The role of the clinician

In all of the cases described previously, the clinician is still required to act in the best

interests and according to the needs of the patient, and to provide a standard of treatment equal to that available to other members of the community.

Clinicians may be asked to share some information with other members of the multidisciplinary team providing interventions to drug misusers through the criminal justice system. This is intended to assist the patient to receive consistent and appropriate care and treatment throughout their journey through the criminal justice system. Patient consent to treatment and to sharing of appropriate and limited information will be required as in other circumstances.

Although all of these issues are determined by professional and ethical considerations, they should also be covered by the clinical governance and other arrangements described in local protocols.

7.3 Prisons

7.3.1 Introduction

There is a high concentration of people with a history of drug misuse in prison. Over one-third of the people received into British prisons each year are treated for opiate dependence. In Scotland the figure is closer to two-thirds. Of these, 40% report injecting drug use within the 28 days preceding imprisonment (Home Office, 2003). Opiate dependence and injecting are more common still among women entering prison. Many in prison have a wide range of mental and physical health and social care needs (Singleton *et al.,* 1998; Social Exclusion Unit, 2002).

The average pattern of drug misuse alters markedly when an offender enters prison, with reductions in drug misuse (NOMS, 2006) and injecting (Singleton *et al.,* 1998). Although clinicians should regard drug misuse management in prisons as equivalent to any other setting, there are some particular differences they will need to take into account:

- The lower availability of drugs and alcohol in prisons, leading to intermittent intoxication and unanticipated withdrawal episodes.
- Less injecting behaviour but, where it does occur, potentially much higher risk behaviours due to the scarcity of injecting equipment.
- The high volume and frequency of movement of patients.
- The risk of overdose on release due to diminished opioid tolerance (Farrell and Marsden, 2005).
- A correlation between drug withdrawal and suicide in the first week of prison custody (Shaw *et al.,* 2003).
- The high value, relative to the patient's limited income, of drugs.
- Limited continuous access for clinicians to prisoners and therefore difficulty monitoring treatment.
- The particular needs of prisoners in custody for very short periods of time.

These factors have been taken into account in the formulation of prison drug treatment policy.

7.3.2 Blood-borne viruses

The general principles outlined in chapter 6 in relation to blood-borne viruses and other infections apply equally to prisons and perhaps more so because of some of the factors described previously.

In some parts of the country, including Scotland, prisons provide (or will shortly provide) condoms to all prisoners and packs to injecting prisoners containing citric acid, water ampoules, stericups and filters, along with one-to-one sessions to raise awareness of safer injecting. This would be good practice throughout the country.

7.3.3 Meeting the needs of drug-dependent prisoners

7.3.3.1 Integrated treatment

As with drug misuse management in other settings, there is a need to integrate prescribing practice with psychological, medical and social interventions (Amato *et al.,* 2004). Integration with mental health and primary healthcare services is also very important to address the high levels of complex needs within the prison population.

Clinicians should familiarise themselves with the integrated care pathways that operate in the prison in which they work. In the case of a patient with serious mental illness, the mental health service within the prison will lead on the integration of the services the patient requires

via the Care Programme Approach or, in Scotland, Integrated Case Management.

Clinical supervision provided by a specialist with experience of work in a secure environment will assist clinicians to gain the competence and confidence they require for working in a prison.

Prison presents an opportunity and a challenge to address a wide range of clinical needs of drug misusers, especially harm reduction interventions such as hepatitis B vaccination and hepatitis C treatment.

7.3.3.2 Women prisoners and pregnancy

Women of child-bearing age who give a recent history of substance misuse should be encouraged to have a pregnancy test along with a urine drug screen upon reception into prison.

The clinical stabilisation of opiate-dependent women should be in accordance with general guidance on the management of drug dependence in prisons (for example, *Clinical Management of Drug Dependence in the Adult Prison Setting* (DH, 2006)). However, the period of stabilisation should be extended to allow for previous antenatal records to be obtained or for a dating scan to be undertaken, before a clinical management plan is agreed. The involvement of a specialist drug liaison midwife is desirable at this stage.

The ongoing clinical management of opioid dependence and other drug misuse during a pregnancy should proceed as described in section 7.4 of these guidelines. The options for pregnant drug-using women in prison with regard to the care of their baby post-delivery will depend on the recommendations of a childcare review involving social services. In the postnatal period women should be offered opioid substitute maintenance treatment for a duration that meets their individual needs. If the mother and baby are leaving prison together, there is a particular need to ensure that maintenance prescribing is sufficient to protect against a return to opiate misuse upon release. It is also essential that this prescribing is continued once the mother is back in the community.

7.3.3.3 Appropriate prescribing

Prescribing protocols may provide a solution to the clinical challenges presented by the prison environment.

Patients may stabilise on lower doses in prison than they would in the community (DH, 2006), but clinicians should be prepared to increase doses where needed to a level that achieves appropriate clinical stability.

Polydrug use is common among offenders entering custody. In cases of co-dependency on any combination of alcohol, opiates and benzodiazepines, more than one reduction regimen may be required, with additional caution necessary due to the interaction of these drugs. Detoxification from more than one drug should not take place concurrently, with alcohol commonly the initial priority when this is required. As with practice in community services, non-medical prescribing should be encouraged and developed.

Opiates

In view of the potentially rapid onset of withdrawal effects in prison and a heightened risk of suicide among drug misusers during the early days of custody, a clinical response to physical dependence is essential.

Where detoxification from illicit opiates is indicated, methadone or buprenorphine are commonly prescribed over two to three weeks. Dihydrocodeine is used in Scottish prisons for patients who did not have a community substitute prescription prior to imprisonment. Alternatively, the patient may elect to simply reduce their currently prescribed opioid or, if available, to commence a lofexidine detoxification programme. Detoxification should be provided in association with psychosocial support. When an opioid substitute is prescribed, a period of stabilisation over the first five days is advisable, rather than immediate reduction of the dose, because of the risk of self-harm in this period. There may also be an increased risk of suicide close to the end of, or just following, completion of a detoxification regimen.

Where drug users are received into prison having had their community dose continued in police custody (AFP and RCPsych, 2006), this treatment should be continued in prison, subject to regular review. Time spent in police and court custody often results in a break in patients receiving substitute medication between the day of their arrest and their subsequent reception into prison. Sometimes this break can extend to three days or more. In such cases, clinicians will need to take potential diminishment of opioid tolerance into account when deciding on a

starting dose. Clinicians should seek to verify prescriptions (and consumption) with community services, the police or both, and use appropriate drug tests to verify the presence of opioids in the body. As offenders frequently arrive in prison in the evening, it may not be possible to secure this information during an initial assessment. Prescribing will therefore need to be circumspect enough to address the risks related to this absence of corroboration.

Some prisons prescribe sublingual buprenorphine tablets as an alternative to oral methadone mixture. Where this treatment is offered, care needs to be taken to ensure adequate supervised consumption. The relatively long time required for the tablet to be absorbed sublingually (compared to the time needed to swallow methadone mixture) and the reduced supply of drugs in prison mean that sublingual buprenorphine is more amenable to diversion into the prison shadow economy. See section 5.4.3 and annex A3 for advice on the crushing of buprenorphine, and section 5.3.5.1 for the possible benefits of using a buprenorphine-naloxone combined formulation.

Stimulants

Stimulant withdrawal should be treated according to clinical indications. Emerging symptoms, such as depressed mood and insomnia, are likely to be short-lived and any prescribing for this should generally be short-term and reviewed before renewal. Patients arriving in prison with a recent history of stimulant use should be observed during the first three days of custody for any sign of emerging acute physical or psychological problems. Patients demonstrating symptoms of psychological distress should continue to be monitored and referred for mental health assessment if they are showing signs of psychosis or other serious mental health problems.

7.3.3.4 Treatment exits

Treatment exits should be negotiable and revisited. As in all other environments, treatment should not be discontinued punitively. In the event of relapse in prison, the clinician should explore the reasons for this with the patient and discuss treatment options.

7.3.3.5 Working with patients and their carers

When deciding on ongoing clinical management of opioid dependence, clinicians should take into account the patient's informed wishes, the opinion of any current prescriber, and the recommendation of the patient's drug or case worker (if applicable). Where possible, and with the consent of the patient, the help of a supportive family member or significant other should be sought to assist with treatment.

7.3.4 Preparing for release

Research has found a seven-fold increase in overdose deaths in the fortnight after release from prison (Bird and Hutchinson, 2003). The principle objective in preparing a drug-misusing prisoner for release should be to prevent overdose. Preventing relapse and facilitating continuation in treatment (if needed) or access to suitable aftercare provision or support are important in themselves and as a means of preventing overdose. The following interventions can all help achieve these objectives.

7.3.4.1 Continuing care

Preparations for drug treatment post-release, if required, should be planned wherever possible. Where release is unanticipated (when a patient is released following an order from the court, for instance, or where an individual leaves prison outside of standard working hours), clinicians should operate a contingency arrangement, which may involve making a direct referral to a community drug treatment service.

In addition to a drug treatment service referral (via a prison drug worker if applicable), it is recommended that clinicians attempt to secure GPs for their patients before they leave prison, and that both the drug treatment provider and GP are advised of discharge medications and, if appropriate, the need to quickly take over prescribing.

7.3.4.2 Reviewing dose

Patients in prison will commonly achieve stability on doses lower than those commonly prescribed in the community, although some will require equivalent doses to achieve clinical stability. However, prior to release, consideration should be given to reviewing the current dose of methadone with the patient, to optimise their likely retention in treatment upon return to the community (Bellin *et al.,* 1999; Dolan *et al.,*

2003). This may entail increasing the dose prior to release – in consultation with the community prescriber – and explaining to the patient why this is appropriate.

7.3.4.3 Re-induction

Prior to release some patients request re-induction onto opiate substitution treatment. Re-induction should be considered for patients who are about to leave prison and for whom there is a clearly identifiable risk of overdose. Those with the most significant risk of death have a history of injecting opiate misuse immediately prior to custody, longstanding opioid dependence and polydrug dependence (Farrell and Marsden, 2005). They may also have a history of non-fatal overdose. Re-induction may be offered after the patient has been offered and has declined relapse prevention interventions, and once the implications of restarting opiate misuse have been explained.

7.3.4.4 Naltrexone

Naltrexone provided prior to release from prison for users abstinent from opiates and committed to abstinence may be a useful adjunct to psychosocial treatment. However, it is not generally recommended where psychosocial support cannot be secured (Minozzi *et al.,* 2006), as drop-out from such treatment is associated with a heightened risk of drug-related death.

The outcome of naltrexone treatment is improved by a programme of supervision, which can involve carers, to ensure compliance with the regimen.

7.4 Pregnancy and neonatal care

7.4.1 Introduction

The number of women misusing drugs has increased considerably in the past 30 years, and many are in their child-bearing years. Two to three percent of children under the age of 16 in England and Wales are known to have a parent with problematic drug or alcohol misuse, the majority being polydrug misusers (ACMD, 2003).

Though pregnancy may act as a catalyst for change and present a 'window of opportunity', drug misusers may not use general health services until late into pregnancy and this increases the health risks for both the mother and child.

Long-term outcomes in women who enter methadone treatment programmes during pregnancy are better in terms of their pregnancy and outcomes for the neonate. Women attending treatment services usually have better antenatal care and better general health than drug-using women not in treatment, even if they are still using illicit drugs. Therefore, services are advised to fast-track pregnant women into drug treatment to allow for the earliest engagement possible. Engagement of drug-misusing partners in treatment is also important in enabling pregnant women to achieve progress at the earliest possible stage.

At the time of writing, NICE is developing guidance on *Management of Pregnant Women Who Misuse Drugs and/or Alcohol, and Their New Born Babies*. This may change what services are recommended to do in this area of patient management.

There are some special considerations in relation to the treatment of pregnant drug misusers in prison and these are covered in section 7.3.3.3.

7.4.2 Pregnancy unknown, unwanted or lost

Some women patients may be unaware they are pregnant because amenorrhea is common in female opiate users and, if withdrawing, withdrawal symptoms can mimic signs of early pregnancy. All women of child-bearing age who give a recent history of substance misuse should therefore be encouraged to have a pregnancy test. Some women may know or suspect they are pregnant but may not have engaged with antenatal care and so their stage of gestation may be unknown. If a woman is considering or has had a termination of pregnancy, or miscarries, appropriate drug treatment should be maintained rather than any change considered, until the woman is fully recovered.

7.4.3 Management by a multidisciplinary team

Local multidisciplinary policies are recommended to improve communication and reduce risks to children of drug-misusing parents (ACMD, 2003).

The type of service in each area will depend on local circumstances, the number of pregnant drug misusers presenting for care, expertise of the obstetric and primary care services, and availability of specialist or shared-care support.

Midwifery services need competencies in assessing and managing drug-misusing pregnant women.

Obstetric departments should develop good links with local drug specialists, GPs and local social services. Local statutory authorities should have a written policy on drug-misusing parents, including the need for planning early in pregnancy, and all professionals involved should be aware of the policy.

7.4.4 Management of antenatal care

The objectives of management are to achieve stability – pharmacological, social, medical and psychological. Engagement with and close monitoring in antenatal care and drug treatment are integral to achieving stability.

Good co-ordination between relevant parties is imperative. Risks and needs should be assessed as early as possible in the pregnancy, goals set and support networks planned. This assessment should be multidisciplinary. Agencies should consider convening case conferences around unborn children if there appears to be a significant risk of harm when they are born. This should reduce the need for emergency child protection proceedings at birth. Prospective parents should be informed about all meetings and invited to attend.

7.4.5 Maternal health problems

There are a number of health problems in pregnancy that need to be discussed with the woman and reviewed throughout the pregnancy. These include general nutrition, risks of anaemia, alcohol and nicotine consumption, oral hygiene and complications from chronic infection related to injection practice. These all contribute to the increased rate of obstetric complications and premature delivery found in drug-misusing women. It is also appropriate to consider socio-economic factors and domestic violence. Drug-misusing women are at high risk of antenatal and postnatal mental health problems.

7.4.6 Effects of drugs on the fetus and baby

It is important for clinicians to note that some of the effects of different drugs of misuse during pregnancy are broadly similar and are largely non-drug specific. Intra-uterine growth retardation and pre-term deliveries contribute to increased rates of low birth-weight and increased perinatal mortality rate. These outcomes are multifactorial and are also affected by factors associated with socio-economic deprivation, including smoking (Kaltenbach and Finnegan, 1997).

Higher rates of early pregnancy loss and third-trimester placental abruptions appear to be major complications of maternal cocaine use. Increased rates of stillbirth, neonatal death and sudden infant death syndrome are found in cocaine misusers. Heroin misusers have a higher rate of small-for-date babies and pre-term delivery, even when allowing for other confounding factors. There appears to be a correlation between methadone dose and severity of neonatal abstinence syndrome, (NAS) but this is not always the case (Ostrea, 1976; Archie, 1998).

7.4.7 Prescribing for pregnant drug misusers

Substitute prescribing can occur at any time in pregnancy and carries a lower risk than continuing illicit use. It has the advantage of allowing engagement and therefore identification of health and social needs, as well as offering the opportunity for brief interventions and advice to improve outcomes.

7.4.7.1 Opioids

Opioid treatment will depend on the general principles outlined in these guidelines. Maintenance, at a dose that stops or minimises illicit use, is most appropriate for ensuring continuity of management of pregnancy and aftercare. Many mothers request detoxification, although during the first trimester the patient should normally be stabilised as there is an increased risk of spontaneous abortion. Detoxification in the second trimester may be undertaken in small frequent reductions – for example 2–3 mg methadone every 3–5 days – as long as illicit opiate use is not continuing.

If illicit opiate use continues, strenuous efforts should be made to stabilise the patient on a prescribed opioid, which may involve increasing its dose. Further detoxification should not generally be undertaken in the third trimester because there is evidence that maternal withdrawal, even if mild, is associated with fetal stress, fetal distress, and even stillbirth. However, for some, slow, carefully monitored reductions may safely be continued as long as there are no obstetric complications or resumption of illicit

drug misuse. The metabolism of methadone is increased in the third trimester of pregnancy and it may occasionally be necessary to increase the dose or split it, from once-daily consumption to twice-daily consumption, or both.

Methadone has been used safely for many years but buprenorphine is not licensed for use with pregnant women. However, an increasing number of women who are stable on buprenorphine are having babies delivered in the UK. The research evidence demonstrates no adverse effects on the pregnancy or neonatal outcomes, with incidence of NAS similar to methadone exposure (Johnson *et al.,* 2003). Therefore, in a pregnant woman who is stable on buprenorphine and informed of the risks it is reasonable to leave her on a prescribed dose of buprenorphine, rather than transfer to methadone with the risk of inducing withdrawal in the fetus. If detoxification is unsuccessful and the patient's drug use becomes uncontrolled at any stage of pregnancy, reduction should be stopped or the opioid dose increased until stability is regained.

7.4.7.2 Cocaine

Women using cocaine during their pregnancy should be advised to stop altogether, as there is no safe drug for substitute prescribing. Psychological therapies, including family interventions, should be offered to this group of women.

7.4.7.3 Benzodiazepines

Women who are dependent on benzodiazepines should be stabilised on diazepam and, where this can be tolerated without restarting illicit use, the dose reduced. A woman being maintained on methadone should have her dose maintained during benzodiazepine reduction.

7.4.7.4 Nicotine

Smoking cessation programmes in pregnancy reduce smoking and the incidence of low birth weight and pre-term delivery, and are therefore recommended for all pregnant women.

7.4.7.5 Alcohol

Updated Department of Health alcohol advice says that "pregnant women or women trying to conceive should avoid drinking alcohol" and "if they do choose to drink, to minimise the risk to the baby, they should not drink more than one to two units of alcohol once or twice a week and should not get drunk" (DH, 2007).

Pregnant women who drink alcohol at hazardous and harmful levels have high rates of co-morbidity and social problems and while the neonates of very heavy drinkers are well known to be at risk from fetal alcohol syndrome, there may be a significant risk of related problems (such as described by fetal alcohol spectrum disorder) at lower levels of consumption. Pregnant women using alcohol should be offered brief and, if appropriate, extended interventions to reduce their alcohol use completely, or to very low levels.

7.4.8 Management of labour

This is similar to any other woman, but pain relief needs special attention especially as full opioid agonists such as diamorphine and methadone, or partial agonists such as buprenorphine, determine the choice of analgesia in the individual pregnancy. Therefore, there should be a low threshold for considering the use of an epidural, clear local guidance on partial vs. full agonist effects explained both to the pregnant woman and the antenatal services, and forward planning as to how the pregnancy is to be managed. In addition, there may be increased placental insufficiency in pregnancies of drug-misusing women, leading to an increased risk of intrapartum hypoxia, fetal distress and meconium staining.

7.4.9 Early neonatal care and withdrawals

Many babies will not need paediatric interventions, but it is important to have access to skilled neonatal paediatric care.

Signs of withdrawal from opioids are vague and multiple, and tend to occur 24–72 hours after delivery. They include a spectrum of symptoms such as a high-pitched cry, rapid breathing, hungry but ineffective sucking, and excessive wakefulness. At the other end of the spectrum, symptoms include hypertonicity and convulsions but these are not common. Neonatal withdrawal can be delayed for up to 7–10 days if the woman is taking methadone in conjunction with benzodiazepines. Maternal benzodiazepine use also causes more prolonged symptoms in the neonate, including respiratory problems and respiratory depression.

7.4.10 Postnatal management

The care of the pregnant drug misuser and the safe delivery of the baby is just the start of care. Continuing support, which may need to include parenting advice and skills training, and mental health advice and interventions, should be provided if the ideal outcome of maintaining mother and child together is to be achieved.

Breastfeeding should be encouraged, even if the mother continues to use drugs, except where she uses cocaine or crack cocaine, or a very high dose of benzodiazepines. Specialist advice should be sought if she is HIV positive or hepatitis C positive. Methadone treatment is not a contraindication to breastfeeding but the dose should be kept as low as possible, while maintaining stability, and the infant monitored to avoid sedation.

7.5 Mental health

7.5.1 Introduction

There are high rates of psychiatric disorders among individuals misusing or dependent on drugs and alcohol. These patients present with a range of problems and disorders, chiefly anxiety and mood disorders. Others have personality disorders, some with significant personality traits that may negatively impact upon their presentation and compliance with treatment. Patients with coexisting mental health and drug (or alcohol) misuse problems are generally regarded as having a 'dual diagnosis' or 'co-morbidity'. Whatever the term used, the nature of co-occurring drug misuse and mental health problems is complex, with a number of interacting continuums such as severity, type of mental health problem, and type and amount of substance misused, as well as change over time. Those with co-morbidity have a poorer prognosis. Co-morbidity is associated with negative and often complex factors including higher rates of relapse, increased hospitalisation, higher rates of completed suicide, housing instability, poorer levels of social functioning, such as poverty, violence, criminality and marginalisation, less compliance with treatment, greater service utilisation and higher costs to services. It is important they receive appropriate assessment of need and risk and then relevant and evidenced treatments.

7.5.2 Prevalence

Many large epidemiological surveys demonstrate the high prevalence of co-morbidity in those attending mental health services and drug and alcohol treatment services (Regier *et al.,* 1990, Kessler *et al.,* 1994, Menezes *et al.,* 1996). Weaver *et al.,* (2003) found that 44% of community mental health patients had reported problem drug use or harmful alcohol use in the previous year. In drug and alcohol treatment services, 75% and 85% of patients respectively had a past year psychiatric disorder – most had affective disorders (depression) and anxiety disorders (see Table 6).

Almost 30% of the drug treatment population and over 50% of those in treatment for alcohol problems experienced 'multiple' morbidity (co-occurrence of a number of psychiatric disorders or substance misuse problems). In the National Treatment Outcome Research Study, 29% of new admissions reported having suicidal thoughts in the previous three months and 10% reported having a psychiatric hospital admission (Gossop *et al.,* 1998). Personality disorder was reported in 37% of those attending drug services and in 53% of alcohol service users. The usefulness of personality disorder in diagnoses is in marking severity of personality traits, and in pointing to appropriate treatment, complex needs and possible requirements for pharmacotherapy and structured psychotherapies.

	Drug services (total=16)	Alcohol services (total = 62)
Schizophrenia	3%	3%
Bipolar affective disorder	1%	5%
Non-specific psychosis	5%	11%
Personality disorder	37%	53%
Affective and anxiety disorders	68%	81%
Severe depression	27%	34%
Mild depression	40%	47%
Severe anxiety	19%	32%

Table 6: Presence of co-morbidity in drug and alcohol services (adapted from Weaver et al., *2004)*

7.5.3 Mental health policy

In 2002, the Department of Health's *Mental Health Policy Implementation Guide: Dual Diagnosis Good Practice Guide* (DH, 2002) summarised policy and good practice ingredients in the provision of mental health services to people with severe and enduring mental health problems and problematic substance misuse. It charged local implementation teams (LITs) in partnership with DATs with implementing the policy requirements.

In Scotland there have been many policy developments in the field of mental health provision, including *Mind the Gaps: Meeting the Needs of People with Co-occurring Substance Misuse and Mental Health Problems* (SACDM & SACAM, 2003) and *A Fuller Life – Report of the Expert Group on Alcohol Related Brain Damage* (Scottish Executive, 2004). A further report on substance misuse and mental health, building on these earlier documents and making practical recommendations for services, is expected in 2007.

In Wales a *Service Framework to Meet the Needs of People with Co-occurring Substance Misuse and Mental Health Problems* (Welsh Assembly Government, 2007) has been reviewed and reissued. The strategy emphasises the importance of unambiguous clinical responsibility for individuals with a dual diagnosis and appropriate access to the services they need.

However, there is still a need for more collaborative planning, delivery and accountability of services for people with co-morbidity, including those with mild-to-moderate mental ill-health, early traumatic experiences, and personality traits and disorders. Further concerns are of the lack of specified core competencies, inadequate assessment and communication between services, and the need for greater integrated care.

Individuals with these severe mental health problems should have high-quality patient-focused and integrated care with mental health services, often referred to as mainstreaming (DH, 2002). For those with, for example, schizophrenia, mental health services usually manage the care of these individuals, often leading the co-ordination of their care, although more often they work in partnerships with drug treatment services in a shared care model. Here, the mental health problems are managed within mental health services, sometimes with management of the dependence. More often, drug treatment services care for and treat the drug misuse, and provide elements of care alongside advice and support to the mental health team. The emphasis is on good communication and ensuring patients do not fall between gaps. Patients who meet the diagnostic criteria for personality disorders may present in drug treatment services and have difficulties accessing appropriate interventions for their mental health difficulties. Patients in drug treatment services with common mental illness problems additional to their drug misuse are often treated in drug treatment services, although clarity on competencies and shared care models is important. For all those with mental health problems, it is important that adequate assessment is made by competent practitioners and appropriate treatment organised.

The guidance in England (DH, 2002) also emphasised the importance of local definitions of dual diagnosis being agreed locally by all relevant agencies. Different models of services designed to support patients with dual diagnosis exist. Services may be parallel (individuals attending mental health and substance misuse services) or sequential (individuals attending one service at a time depending on their needs), with little evidence to support a particular model, although anecdotal evidence favours an integrated or shared care approach. Service models need to be geared to delivery of integrated psychosocial interventions and integrated pharmacotherapies, and to access wraparound services. The guiding principle should be to match the needs of the patient to the clinical team and its competencies, minimise multiple referrals and movements within multiple teams, and prevent exclusion from services (Raistrick *et al.,* 2006).

7.5.4 The care programme approach

Patients with mental health problems of sufficient severity and risk to need monitoring under the enhanced care programme approach should have care plans that meet care programme approach (CPA) requirements (or other arrangements in Scotland). The CPA arrangements should normally sit within mental health services although local policies may change this. Whatever the local arrangement,

the CPA should ensure that patients' care is planned and co-ordinated by individuals with the competencies to do so within sufficiently resourced service. The individual patient may also have a substance misuse care plan, which incorporates the CPA requirements, and there must be adequate co-ordination. In addition, all those attending substance services should have a care plan that identifies and plans management of their mental health needs.

7.5.5 Treatment for mental health problems

Systems of assessment and care planning that ensure services are designed to meet the needs of individuals must be in place. Given the high prevalence of mental health difficulties, the majority attending substance misuse services will have mental health needs that need treatment and if not appropriately managed may affect outcome and retention in services.

Proper assessment is the key to establishing a comprehensive care plan. Adequate risk assessment of mental health should be undertaken at initiation of treatment and at appropriate times during management. There needs to be a culture of identifying these mental health needs, for example, assessing risks of suicide, self-harm and violence. In addition, there needs to be adequate care planning and interventions with an emphasis on assertive outreach, engagement and retention in treatment, specific psychological management in line with appropriate guidance, such as NICE and other psychiatric and drug misuse guidelines, and pharmacological interventions (for example, psychosocial interventions (NICE, 2007a), anxiety (NICE, 2007b), self-harm (NICE, 2004a), bipolar disorder (NICE, 2006) and depression (NICE, 2007c)). Other key features of service provision are early intervention, provision of broad-based interventions, interventions based on need and advocacy.

There is evidence of much unmet need and high prevalence. Substance misuse services need to ensure all individuals have appropriate identification and management of their difficulties and appropriate care pathways in place, with specialist addiction psychiatric services and mainstream mental health services that work jointly and flexibly with these individuals.

Practitioners in mental health and substance misuse teams should be competent to identify and understand people with co-occurring problems, with the addition of specialist practitioners with competencies in delivery of psychiatric assessment and care, and psychosocial structured interventions, and working in an integrated model. Training and continuous professional development should address these issues. Effective staff supervision, both clinical and managerial, is important.

7.6 Young people

7.6.1 Differences in substance misuse patterns

While a significant minority of under-18s will experiment with or use illegal drugs occasionally (often in conjunction with alcohol), most illicit drug use is short-term cannabis use. Alcohol use in young people is generally experimentation or episodic bingeing. Fewer under-18s use drugs regularly, or to an extent where drugs and alcohol have a harmful impact on their lives. While most drug and alcohol use carries increased risks, few young people experience significant harm. Some do experience harm, related to intoxication or excessive consumption, but dependence (especially opiate or stimulant dependence) and drug injecting are uncommon. Evidence indicates that young people with other problems are more likely to misuse drugs and alcohol, such as young offenders, young people with mental health problems and those excluded from school.

7.6.2 Differences in specialist drug treatment

Drug treatment goals for young people who regularly misuse substances should be to reduce immediate harms from substance misuse, stabilise the young person and enable them to move to abstinence from illegal drug misuse (though some drug use may still occur). Given the shorter history of substance misuse in the under-18s, and their continuing development and maturation, there is often the potential for rapid improvements to be made.

Evidence and clinical experience suggest that young people's specialist drug treatment is different from adult treatment and should be provided separately from adults. It will also vary according to the severity of the drug use and associated problems.

- Brief interventions may be useful to divert young people with less-severe substance misuse problems away from developing more severe problems and substance-related harm.
- More intense substance misuse treatment episodes may be required for those with more severe problems, perhaps involving family and the young person.
- A minority of under-18s are likely to require longer-term retention in treatment. For those with complex needs, substance misuse treatment should be set within the context of a wider package of treatment delivered by mainstream children and family health, social and education services.

Policy and clinical governance issues for substance misuse treatment for those under 18 are also different and require different action from clinicians. These include:

- consideration of the young person's ability to consent to treatment and competence (or capacity to consent)
- involvement of those with parental responsibility
- confidentiality and information sharing
- child protection needs in line with local guidelines
- developmental needs of the child
- the competence of the clinician to work with the young substance misuser
- whether and how to involve other professionals to ensure a holistic approach to the young person's needs
- particular considerations in prescribing for under-18s, including drug licensing considerations (see annex A6)
- the different legal, statutory and policy framework for young people and families.

Many of these issues are covered in the clinical governance chapter (2) and annex A9.

7.6.3 Research evidence on treatment effective for under-18s

The evidence-base for substance misuse treatment for under-18s is not extensive and almost non-existent in UK and US populations. Consequently, guidance based on this literature has limited applicability. However, some cautious extrapolation from evidence of effective drug treatment for young adults is reasonable.

Specific substance misuse treatment for young people should normally involve psychosocial interventions that address the pattern of substance misuse in the context of a package of care planned interventions to a range of identified needs.

The NICE guidance, *Community-Based Interventions to Reduce Substance Misuse Among Vulnerable and Disadvantaged Children and Young People* (NICE, 2007d) provide guidance on recommended interventions, including the use of motivational interviewing for problematic substance misusers.

There is scant research on specific pharmacological treatments for drug dependence and withdrawal for young people, although extrapolation from the adult literature may be cautiously considered. Buprenorphine and methadone are used in both detoxification and long-term stabilisation. Lofexidine is used in detoxification.

7.6.4 Assessment

Assessment for young people with substance misuse problems should be comprehensive and multidisciplinary. This may involve other professionals such as child and adolescent mental health services (CAMHS), social services or a young offenders' team. As with adults, all domains of functioning should be assessed, but this should also include developmental needs, educational and language attainment, and emotional and physical health and safety. Young substance misusers require a risk assessment to assess areas such as self-harm, suicide intent, dangerousness, and child protection needs. Clinicians may need to follow local or national protocols and assessment procedures, such as the *Common Assessment Framework* (DfES, 2006) in England. (See section 3.2.)

7.6.5 Psychosocial treatment interventions for substance misuse

7.6.5.1 Brief interventions

Brief psychosocial interventions are indicated for young people misusing alcohol, cannabis and stimulants (see section 4.4).

7.6.5.2 Structured substance misuse interventions

Structured treatment by specialist young people's substance misuse treatment services is recommended for under-18s who have significant substance misuse problems (normally polydrug and alcohol misuse). This would normally comprise specific harm reduction interventions, psychosocial treatments (motivational therapies, cognitive behavioural treatments, family based supports and treatment) delivered in the context of a care plan which is part of a wider package of interventions to address all the young person's health, social, family and educational needs and perhaps offending behaviour. It may occasionally involve pharmacological interventions, both for drug misuse and co-morbid conditions. These specific substance interventions will normally require co-ordination with interventions provided by other children's agencies. The involvement of a young person's family or those with parental responsibility is considered good practice and may be required with regard to consent.

7.6.5.3 Interventions to reduce specific drug-related harm

A young person should be assessed and receive interventions to prevent and reduce harm such as blood-borne virus infection, unwanted pregnancy, sexually transmitted diseases, weight loss and mental health problems. Provision of hepatitis B vaccination, sexual health advice and interventions such as smoking cessation may be appropriate. The provision of injecting equipment for a young injecting drug user may be required, but specialist assessment and frequent review are advised to prevent escalation of risk.

7.6.6 Pharmacological treatment

7.6.6.1 Multiple dependencies

Pharmacological treatment will be required if a young person is dependent on a combination of alcohol, opiates and benzodiazepines. This may require more than one pharmacological reduction regimen sequentially over time.

7.6.6.2 Alcohol dependence

The recommended medication for alcohol detoxification is chlordiazepoxide. The usual regimen will be 20 mg chlordiazepoxide four times a day initially then reducing over seven days, but this will vary depending on assessment and monitoring of severity. The dose of chlordiazepoxide should be titrated until withdrawal symptoms cease.

If withdrawal symptoms do not stabilise, or there are seizures or delirium symptoms, the young person should be transferred to a hospital. Acamprosate or disulfiram may have a role, but only where supported by specialist community substance misuse teams and the young person's family, with an emphasis on compliance and perhaps supervision.

7.6.6.3 Benzodiazepine dependence

Benzodiazepine use among young people is more often characterised by bingeing rather than dependence. Benzodiazepine maintenance prescribing is not recommended for this age group. Detoxification, if required, should be gradual according to the length and severity of dependence. Diazepam at 30 mg per day is usually a sufficient initial stabilisation dose before reduction, even where previous use was higher. Benzodiazepine dependence and withdrawal can be associated with suicidal and self-harming behaviours in young people so monitoring of mental state is important.

7.6.6.4 Stimulants

Substitute pharmacological treatment of cocaine or amphetamine is not advocated for children or young people. Stimulant withdrawal may precipitate significant psychological symptoms such as self-harm and suicide, violence, agitation and depression – these may require a full mental health assessment, treatment and careful monitoring, with close liaison with a child and adolescent or other mental health team. Psychosocial interventions in line with NICE guidelines are recommended for stimulant users.

7.6.6.5 Cannabis

Withdrawal from cannabis may precipitate decreased appetite, weight loss, sleep problems, craving, irritability and vivid dreams, and these may require management. Cannabis can contribute to and exacerbate mental health problems. Where there is any evidence of psychosis a full mental health assessment must be completed; anti-psychotic medications and careful monitoring may be required with close liaison with a child and adolescent or other mental health team. Psychosocial interventions consistent with NICE guidelines are recommended for young cannabis misusers.

7.6.6.6 Inhalants

For very frequent inhalant users withdrawal may precipitate agitation that should be monitored as it may require treatment. Interventions to prevent deaths may be required as these are mostly related to 'sudden sniffing' or accidental injury while intoxicated.

7.6.6.7 Nicotine

Many young substance misusers are regular and dependent cigarette smokers. While bupropion is not licensed for use in adolescents, nicotine replacement products have a strong evidence base, though evidence is lacking in adolescents. Nicotine patches in adolescents appear to be safe. Smoking cessation programmes should be used to enhance nicotine replacement therapy.

7.6.6.8 Opioid dependence

Regimens

Unless the decision to proceed with dose induction, immediate reduction and detoxification is clear, clinicians suggest a period of stabilisation with buprenorphine or methadone to allow time to stabilise and assess all domains of functioning, and organise a future care plan. The use of methadone, buprenorphine and lofexidine (if detoxification is required) is recommended in the treatment of young people who are opioid dependent. Day care titration and inpatient units may be useful for stabilisation and commencement of therapy in those with unclear tolerance, with co-morbid problems, with multiple drug use, with less family and social support, and for assessment of all other domains of functioning. All opioid medication should normally be consumed under supervision.

Dose induction

Toxicology is essential to assess and confirm opioid use and to monitor adherence to treatment. Methadone or buprenorphine should not be prescribed in the absence of positive drug testing and care should be taken on assessment of tolerance and dependence in young people. Non-opioid medication, such as lofexidine, should be used as an alternative if tolerance is unclear and prescribing is deemed necessary. Dose induction is similar to that in adults, although care must be taken about assessment of tolerance, which can be more uncertain in the young person, and greater care needs to be taken with dose in relation to body mass.

Induction on to methadone is generally commenced at doses under 30 mg a day and much lower if tolerance is not clear. It is unclear if the evidence for the value of induction onto higher dose in adults is applicable to adolescents, so close regular clinical review and titration in response to progress are good practice.

Buprenorphine should normally be commenced at 4 mg, increased to 8 to 12 mg rapidly and increased according to response. All doses must be carefully titrated and adjusted for height, weight and age.

Stabilisation and short-term maintenance

Anecdotal evidence would suggest that stabilisation on to substitute medication with retention in treatment is greater if the young person's parents are involved and supportive. Treatment in daycare settings may initially allow greater compliance and encourage greater retention, particularly if parental support is less.

Assisted withdrawal and detoxification

Detoxification should be considered in the context of the young person's progress in their holistic care plan, taking into account health, social functioning, family context, accommodation, education and offending behaviour.

For those young people who make a clear decision for immediate detoxification without a period of substitution treatment, lofexidine is the drug of choice. This may also be the choice for those with presumably low or unknown tolerance. If young people have been stabilised on opioid medication, they would normally undergo detoxification using the same medication (for example, methadone or buprenorphine).

Preventing relapse

Naltrexone should be considered in young people where there is community support from both substance misuse specialists and family. Young people should also be motivated and understand the full implications of the medication.

7.6.7 The management of co-morbid disorders

Substance misuse in young people is sometimes associated with co-morbid psychiatric disorders. Substance misuse may also contribute to and

exacerbate mental illness. Psychological treatments are the mainstay of treatment but pharmacology may be required on occasions, for example attention deficit hyperactivity disorder (ADHD). Treatment should be in conjunction with other professionals, including child and adolescent mental health services (CAMHS) and child and adolescent psychiatrists, and consistent with NICE and SIGN guidelines on ADHD (NICE, in development; SIGN, 2001), NICE guidelines on adolescent depression (NICE, 2005) and national guidelines on autism (NICE, forthcoming) and early onset psychoses. Careful co-ordination of care and structured care planning with clear identification of goals, and roles and responsibilities between practitioners and services are particularly important in young people with co-morbid disorders.

7.7 Older current and ex-drug misusers

As the number of drug misusers entering treatment services increases and the number receiving evidence-based substitute medication rises, so do the number of drug misusers maintained over long periods of time on substitute medication. It is not unusual now for clinicians to be caring for patients aged in their 40s, 50s and 60s receiving methadone or buprenorphine treatment. Between 2004/05 and 2006/07, National Drug Treatment Monitoring System figures for the proportion of over-40s in drug treatment in England rose from 13.3% to 16.4%.

Older drug misusers need all the usual screening and monitoring that a non-drug misuser might be offered appropriate to their age and general health status. However, older drug misusers may also have special health needs and it is important that, as their patients age, clinicians are mindful of underlying problems caused either by complications of lifelong drug (and alcohol) misuse or by the problems associated with substitute treatment (see Table 7). One of the most significant of these problems in the future is likely to be hepatic damage caused by hepatitis C.

Statistics indicate a greater risk of drug misusers over 35 dying from drug-related causes than for younger drug misusers, with older intravenous drug users two to six times more likely to die because of drug misuse than young misusers (Bird *et al.,* 2003). Older male injecting drug users are at highest risk of drug-related death. Overdose death incidence can be represented as a U-shaped curve, most common in the young and older age groups.

There are many reasons why increasing age may affect the individual's vulnerability to the effects of drugs (prescribed or non-prescribed) and alcohol. Health problems resulting from prolonged drug (including tobacco and cannabis) and alcohol misuse can exacerbate the decline in health that older adults already experience. Loneliness, loss of loved ones, or a declining sense of purpose can also lead older adults to return to drugs they used casually as young people or to or alcohol. As chronic illness increases with advancing age, older people are more likely to have conditions that require medical treatment. Advanced age, frailty, and an increased need for prescription medications are all factors that contribute to a patient's risk of developing a drug-related problem.

Complications related to long history of drug and alcohol misuse	Examples: ■ hepatic damage due to hepatitis B or C and excess alcohol use (or a combination of these) ■ HIV infection with or without antiviral chemotherapy ■ chronic airways disease from cigarette and cannabis smoking ■ chronic lung damage from inhaling drugs ■ increased cardiovascular disease risk due to alcohol, smoking and lifestyle ■ chronic venous and/or arterial damage making IV access difficult or impossible ■ past cardiac valve destruction.
Poly-pharmacy	Risk of drug interactions between methadone or buprenorphine and treatments used to modify other diseases (e.g. antihypertensive, hypoglycaemic).
Normal ageing process	Patients on methadone can also develop any of the diseases common in the elderly community, including hypertension, diabetes, and chronic airways disease. Interpreting memory loss or cognitive function may be difficult in individuals with longstanding drug-related neurological damage.

Table 7: Special health needs of ageing drug-misusing patients

Alcohol use disorders in elderly people are associated with widespread impairments in physical, psychological, social, and cognitive health. Age-related changes in body composition mean that, while absorption, metabolism, and excretion of alcohol are largely unchanged, equivalent amounts of alcohol produce higher blood alcohol concentrations in older people.

Drug misusers of any age may have mental health problems and, at any age, are likely to have had more than average contact with mental health services. Combined with experience of conflict with the criminal justice system and many years of negotiating with a healthcare system that is not always sympathetic, the older drug misuser may often seem suspicious, manipulative or hostile to change. An understanding of their lifestyle difficulties is sometimes necessary to manage these attitudes constructively.

7.8 Pain management for drug misusers

7.8.1 Introduction

Pain, both chronic and acute, is a complex biopsychosocial experience and both drug dependence and chronic pain are common conditions with long-term consequences. Chronic pain is estimated to affect 13% of the UK population. Pain can be either acute or chronic. Chronic pain leaves the individual susceptible to mood disorders and reduces their ability to function across domains. The commonest causes are back pain, arthritis and headache – all increasing in prevalence with age. Acute pain occurs commonly in drug misusers as they are at a higher risk of physical illness and traumatic injury as a consequence of their lifestyle. Pharmacological intervention is only one aspect of pain management and non-pharmacological interventions, for example, CBT, should be considered for drug misusers although considerable support may be needed for these patients to engage in them.

7.8.2 Acute pain

Acute pain requires full analgesic management in patients dependent on opioids. These patients may have a lower tolerance of pain together with a higher tolerance of opioid analgesic effects. If pain is mild to moderate, non-opioid analgesia (as used in the general population) is the initial treatment of choice together with appropriate education and advice. For more severe pain, if opioid analgesia is indicated, the treatment will depend on whether the patient is taking full agonist opioids such as methadone, partial agonist opioids such as buprenorphine, or opioid antagonists such as naltrexone.

If the patient is dependent on full agonists the opioid pain relief should be in addition to the usual opioid treatment dose and the amount of pain relief medication titrated against pain while monitoring respiratory function. Sub-therapeutic doses should be avoided.

If the patient is dependent on a partial agonist, such as buprenorphine, specialist advice should be sought but, if the buprenorphine is continued, especially high doses of full agonist opioids will be required initially, with careful monitoring and anticipated dose reduction in the subsequent 36 to 72 hours. Opioid antagonists such as naltrexone will render opioid analgesia ineffective.

All patient and carers should be informed of and understand the effects of opioid substitution and opioid blockade on pain management, and are advised to carry a card stating their current medication.

Pregnant women dependent on opioids and in labour should have full pain management as indicated. Once they are tolerant to their maintenance opioid they will need additional analgesia. However the need for monitoring of the respiratory function of the woman and the fetus or neonate should be taken into account.

7.8.3 Chronic pain

Opioid-dependent patients who develop chronic pain report lower pain thresholds than controls (Compton, 1994). Practitioners should investigate complaints of pain to exclude physical co-morbidity and mood disorder. Therefore, these patients frequently require assessment by medical, primary care, psychiatric and pain services. The development of joint working arrangements across services for this population is desirable. It should be remembered that complete symptomatic relief of chronic pain is seldom possible and an acceptable balance between improved function and side-effects should be seen as the goal. Non-pharmacological interventions must be considered for all patients, including occupational therapy assessments.

Patients should have:

- a full joint assessment of their pain, incorporating either information from other professionals involved or joint assessment
- a jointly agreed treatment plan including agreement by the patient
- a lead agency to manage their treatment
- a single prescriber to avoid multiple prescribing
- prescriptions dispensed in ways which minimise over use and diversion
- regular reviews
- a plan for responding to non-compliance or if outcomes are not met.

Patients with pain resulting from terminal illness should be managed by palliative care services. Advice on current good practice in pain management and addiction medicine, and practical pharmacological and non-pharmacological solutions for the treatment of pain in drug-dependent patients can be found in *Pain and Substance Misuse: Improving the Patient Experience* (British Pain Society, 2006) which contains common clinical scenarios and solutions.

7.9 Hospital admission and discharge

7.9.1 Introduction

Drug misusers may attend A&E or be admitted to hospital for treatment of conditions common to other patients or directly related to their drug misuse. In either case, hospital medical staff should take proper account of any drug misuse and any treatment being provided in the community.

The objective of drug treatment in hospital should be to stabilise drug misuse as rapidly as possible in order that the patient can have appropriate treatment for drug-related and non-drug-related medical conditions.

On occasions patients may wish to take the opportunity of a hospital admission to reduce their drug doses or even to detoxify fully. This may occasionally be useful, but if unplanned is likely to result in relapse on leaving hospital, which in turn exposes the patient to overdose risks.

The transfer of care on admission and discharge requires understanding of the issues involved and a co-ordinated response by all professional staff concerned in the care of the patient. Planned admissions will provide greater opportunities for preparation and effective transfer of care. A&E treatment and emergency admissions may present greater challenges.

Protocols should be in place for how hospitals will respond to drug misusers attending A&E or admitted onto wards. The admitting wards and departments should have the contact details of local drug treatment services to hand.

7.9.2 Opiate-dependent patients

7.9.2.1 Assessment

The doctor must ensure that an adequate assessment has been made before prescribing substitute opioids or other controlled drugs. Full or comprehensive assessment of drug misusers requires specialist knowledge and expertise, and all doctors are strongly encouraged only to initiate opioid substitution prescribing as part of a multidisciplinary team. Appropriate senior advice should be sought. Aims of assessment include the following:

- Enabling treatment of any emergency or acute problem or enable an elective procedure to take place.
- Confirming patient is taking drugs (history, examination and urine analysis).
- Identifying degree of dependence – confirming the presence of opioid withdrawal symptoms (and particularly observing objective signs) can be very helpful to support a diagnosis of dependence. See section 5.2.2.
- Identifying complications of drug misuse and evaluate risk behaviour. This may include confirming HIV status, risk of hepatitis B and C infections, general nutrition and alcohol intake. Appropriate pre- and post-test, information and advice, or counselling, should be provided concerning blood-borne virus infections.
- Psychiatric co-morbidity may also need to be considered.

Hospital staff responsible for the assessment of an opiate-dependent patient are advised to contact their local drug treatment service for advice and support.

For patients currently being prescribed methadone or buprenorphine for treatment of

opiate dependency, good communication between hospital and community is essential for safe patient care. Patients will usually have a named keyworker and a named pharmacy. They will be receiving treatment from either their GPs or local drug treatment services. Prescribing in these cases should be a relatively straightforward matter of continuing the usual dose while in hospital. The hospital doctor should ascertain by independent means (through communication with the patient's specialist prescriber or GP, or with the community pharmacist or the keyworker, or by consulting electronically the emergency care summary (ECS) in Scotland) the prescribed daily dose and, if possible, when the last dose of substitute medication was taken or, at least, when the last prescription was issued and how many days have been supplied.

For patients not on opioid substitution treatment, or where there is uncertainty about recent compliance, it is appropriate to exercise particular care in initiating opioid substitution treatment.

7.9.2.2 Initial dosing schedule for opiate-dependent patients admitted to hospital

Safety first

- Only prescribe following an assessment. Do not give in to undue pressure to prescribe immediately. Take time to assess if necessary. However, remember a patient who is experiencing withdrawal symptoms may not be able to co-operate fully with medical or surgical treatment.
- Polydrug and alcohol misusers may develop multiple withdrawal syndromes and hospital doctors will need to differentiate these to prioritise treatment. Methadone may initially mask alcohol and benzodiazepine withdrawal symptoms.
- Exercise particular care in cases of respiratory disease, head injury and liver diseases.
- It is important to be extremely careful when prescribing additional drugs such as sedatives. It may be necessary, in some cases, to contact the relevant pain control team for further advice on improving pain control.

When it is concluded that it is appropriate to initiate opioid substitution in hospital, to manage the risk of withdrawal, methadone is usually preferred over buprenorphine, as the latter acts as a partial agonist and may interfere with acute pain management. However, the choice of an appropriate substitute will depend on the circumstances of the individual case (especially, for example, if respiratory depression is a particular concern).

Induction should broadly follow the protocols described at section 5.3. However the close supervision available in a hospital environment may allow for a modified protocol:

- Prescribe a small dose of methadone in divided doses (for example, four times a day) under conditions of supervised consumption and titrate against opiate withdrawal symptoms. Initial dose should be no more than 10 mg four times a day. Final total daily doses may be as little as 30 mg or as much as 120 mg.
- After initial induction (over three to four days) allow time for methadone levels to reach a steady state (and so minimise the risk of an excessive cumulative increase in blood levels in the early days of treatment), then reassess and give the medication as a supervised single daily dose.

Signs of intoxication such as drowsiness, slurred speech or constricted pupils indicate a need to discontinue the drug or reduce dosage. Patients may also be finding ways to continue to misuse illicit drugs on the ward and this may also cause such intoxication. The hospital pharmacist can provide advice on drug interactions and the prescribing of controlled drugs.

7.9.2.3 Dealing with emergency overdose

Treat opiate overdose with standard resuscitation techniques and with the use of naloxone. Naloxone is given 0.4-2.0 mg parenterally (IV/IM/SC) and this can be repeated after every 3–4 minutes, up to a maximum dose of 10 mg.

It is important to remember the half-life of naloxone is much shorter than methadone and other opioids. This fact should be made clear to patients, particularly in A&E and in other situations where the patient may leave the hospital suddenly. Patients should be helped to understand that they are at risk of re-emergence of life-threatening sedation when the naloxone wears off. Given that some patients may find it difficult to cope with the precipitated discomfort that can occur on administering naloxone, and

may choose to leave, it is important that they are helped to understand this risk.

7.9.3 Other drugs of misuse

Opiate-dependent patients may commonly also be taking other drugs and misusing alcohol. It is not uncommon for opioid users (prescribed or illicit), for example, also to be prescribed or taking illicit benzodiazepines. The misuse of these drugs may lead to associated withdrawal symptoms and to seizures.

Benzodiazepine prescribing should only be done once dependence has been established by history taking and exploring the presence of withdrawal symptoms. In the inpatient setting it is appropriate to provide a slow withdrawal regimen over one to four weeks, with diazepam starting at a daily dose of no more than 30 mg, and usually less, given in divided doses. Patients may also require detoxification from alcohol. Routine prescribing of benzodiazepines as hypnotics and as anxiolytics should be avoided.

7.9.4 Discharge

7.9.4.1 Drug misusers not previously in treatment

Attendance at A&E or admission into hospital may present a window of opportunity to put drug misusers in touch with other services and consider their drug misuse. On discharge the following information should be given as a minimum:

- General health promotion advice.
- Contacts for further help (such as needle exchange services, drug treatment services or self-help groups).
- Advice on preventing overdose.
- Advice on reducing the risk of blood-borne virus infection and its consequences (including support for hepatitis B vaccination).

This information is available from local drug treatment services.

7.9.4.2 Patients prescribed substitute opioids prior to discharge

If the patient was admitted on an opioid prescription from the community, this should ordinarily be continued on discharge and prescribing responsibility transferred back to the local drug treatment service or GP.

- At least 24 hours before discharge – and preferably on admission – hospital staff should contact the local drug treatment service, or the patient's GP, regarding discharge date and agree how much methadone or buprenorphine should be prescribed to the patient on discharge. This may be influenced by local treatment policies.
- On the day of discharge, confirm to the GP or drug treatment service:
  - whether or not that day's dose has been administered at the hospital, and if so how much
  - the number of days' supply that the patient is taking home (minimising this usually to around one day's supply depending on availability of appointment – larger amounts run the risk of overdose or being pressured to hand over or sell their supply)
  - any other drugs that the patient is being prescribed.
  - if the patient's drug misuse is being treated by a GP and the GP cannot be contacted, contact the patient's community pharmacist who should be able to advise what the patient's prescription is and whether it is still current.

Take care in prescribing take-home doses. Generally, they should be avoided although one or two days' supply may be necessary to ensure continuity of care, for example at weekends. For longer periods it is important to limit availability by ensuring daily or frequent pick-up (through instalment dispensing or by provision of multiple appropriately dated prescriptions).

7.10 References

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ANNEXES

A1 Doctors' job titles and involvement in drug treatment

Terminology used for a practitioner at this level	Brief description
Specialists	
Consultant in addiction psychiatry	Doctors on the specialist register in psychiatry, with endorsement in substance misuse working exclusively to provide a full range of services to substance misusers.
Substance misuse specialist (primary care)	Doctors with a general practice background and an extensive postgraduate training in substance misuse working as a specialist GP lead or director employed by a primary care organisation or mental health trust.
Substance misuse specialist (other professional backgrounds)	Doctors from a range of professional backgrounds particularly public health. They may have a specialist qualification in their own field. They will be on the specialist register.
Associate specialist, senior clinical medical officer, staff grades and other doctors	Doctors working in specialist services under the supervision of a consultant in addiction psychiatry.
Doctors with a special interest	
Consultant in general psychiatry with a special interest in addiction	Doctors on the specialist register in psychiatry with some training in substance misuse, who spend a proportion of their time providing services to substance users in specialist services.
GP with special clinical interest (GPwSI) providing enhanced services	GPwSIs have received specific higher-level training in the management of substance misusers in primary care, usually the GP Certificate in Management of Drug Use Part 2. GPwSIs delivering locally enhanced services or nationally enhanced services are able to work more autonomously and take responsibility for more complex cases in substance misuse than other GPs.
GP providing enhanced services	Doctors providing basic medical care plus care to substance misusers, in accordance with local enhanced service agreements.
Other doctors caring for substance misusers	
GP providing core services	Doctors providing general medical care only to substance users.
Consultant in general psychiatry	Doctors on the specialist register in psychiatry, who provide non-specialist services to substance misusers attending general adult psychiatry services (usually alcohol).

Table 8: Doctors' job titles and involvement in drug treatment, adapted from Roles and Responsibilities of Doctors in the Provision of Treatment for Drug and Alcohol Misusers (RCPsych and RCGP 2005).

A2 Cardiac assessment and monitoring for methadone prescribing

A2.1 Drug-induced prolongation of the QT interval

The QT interval is measured on an ECG* from the beginning of the QRS complex (caused by contraction of the ventricular mass) until the end of the T wave (caused by the return of the ventricular mass to the resting state). The QT corrected (QTc) interval is the QT interval (in milliseconds) corrected for heart rate using a standard formula (for example, Bazett's formula: QTc (ms) = QT (ms) / $RR^{½}$ – QT divided by the square root of the R-R interval). QTc calculators are available on the internet.

The QTc interval is a useful indicator of risk of polymorphic ventricular tachycardias, or torsade de pointes which can be fatal. QTc interval prolongation beyond normal limits (440 ms for men and 470 ms for women) is associated with increased risk of cardiac arrhythmias and sudden death, especially above 500 ms (Botstein, 1993).

Various psychotropic medications have recently been identified as causing QT prolongation and sudden death. In the past decade this has become the most common reason for a drug to be withdrawn from the market. In the drug treatment field, this was the reason for levacetylmethadol (LAAM or ORLAAM) being withdrawn (EAEMP, 2001).

A2.2 Methadone and risk of QT prolongation

Methadone may prolong the QTc interval and induce torsade de pointes (Lipski *et al.,* 1973). However increases in QTc interval following methadone induction may not exceed specified thresholds (440 ms in adult males and 470 ms adult females). Findings in relation to the effect of methadone dose have been varied but recently there have been a number of case reports of patients on high-dose methadone experiencing QT prolongation and torsade de pointes. Reducing or stopping methadone was followed by reduction in the QT interval.

Cocaine has been shown to increase QT intervals acutely (Haigney *et al.,* 2006). Other confounding factors may be the use of antipsychotics and tricyclic antidepressants (www.torsades.org; Schmittmer *et al.,* 2004).

In summary the evidence, as currently available, points towards methadone as a risk factor for QT prolongation and torsade de pointes, with a possible dose-dependent action.

A2.2.1 MHRA guidance 2006

In May 2006 the Medicines and Healthcare Products Regulatory Agency (MHRA) drew attention to reports in Europe and elsewhere which "highlighted the risk of QT prolongation in patients taking methadone, especially at high doses". The MHRA recommended that: "patients with the following risk factors for QT interval prolongation are carefully monitored whilst taking methadone: heart or liver disease, electrolyte abnormalities, concomitant treatment with CYP 3A4 inhibitors, or medicines with the potential to cause QT interval prolongation. In addition any patient requiring more than 100 mg of methadone per day should be closely monitored." (MHRA, 2006).

A2.3 Patient consent and information

The patient should be fully informed of the available evidence, the reasons for the clinical assessment and fully involved in the decision making process for their treatment. A patient information leaflet may be useful to inform the patient of the available evidence.

A2.4 Clinical assessment of patients on methadone maintenance

A standard physical health assessment and physical examination should be carried out on all patients entering methadone maintenance treatment. For patients already in methadone treatment, the clinical assessment should cover assessment of heart or liver disease, concomitant treatment with CYP 3A4 inhibitors, other drugs with the potential to cause QT interval prolongation and the presence of electrolyte abnormalities. Please also refer to the general section on clinical assessment for drug misuse patients before proceeding.

A2.5 Clinical assessment of patients when initiating methadone

At present, the decision to perform an ECG prior to commencing methadone treatment should be based on a risk-benefit analysis. A baseline ECG should be considered in patients with evidence

* Clinicians wanting to refresh their understanding of ECGs might start with Hampton JR (2003). *The ECG Made Easy, 6th edition*. London: Churchill Livingstone.

of heart or liver disease, concomitant treatment with CYP 3A4 inhibitors, use of other QTc prolonging drugs or electrolyte abnormalities.

If QT prolongation is detected, alternatives to methadone should be considered, and other QTc risk factors (such as cocaine use) should be re-assessed. It is important that the patient is fully informed and involved in the decision making process.

A2.6 Summary

- Methadone may be a risk factor for QT prolongation and torsade de pointes with a possible dose-dependent action.
- The MHRA recommends monitoring for patients on high dose methadone (>100 mg daily) and with other QT interval prolongation risk factors where appropriate.
- Patients should be fully informed of the reasons for the clinical assessment and involved in the decision making process for their treatment.
- Screening before commencing methadone treatment is not currently advocated but may be considered.
- Any QT prolongation needs full investigation, consideration of specialist referral, identification of options for QT risk factor modification as well as ongoing ECG monitoring.

A2.7 References

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A3 Writing prescriptions

NB: This annex covers the requirements for writing prescriptions for controlled drugs for the treatment of drug dependence for dispensing by a community pharmacist.

A3.1 General considerations

Writing prescriptions for controlled drugs is complicated as it is necessary to consider:

- the safety of the patient and others, for example, dependants and partners
- communication between the prescriber and the dispensing pharmacist
- the legal requirements as required by the Misuse of Drugs legislation, NHS legislation and the legal and good practice requirements implemented as a result of the Shipman inquiry
- additional requirements when prescribing relating to instalment prescriptions
- the requirements for NHS pricing.

A3.2 Patient safety

Patients must be warned:

- that methadone and other prescribed medicines must be kept out of reach and out of sight of children and vulnerable individuals
- of the risks of overdose and death if opiates are taken by an opiate naïve person.

Children (under 18) of patients prescribed controlled drugs must not be authorised to collect their parents' (or others') medication from the pharmacy.

The person collecting the medicine from the dispensing pharmacy will be required to sign the back of the prescription form when collecting Schedule 2 (for example, methadone) or Schedule 3 (for example, buprenorphine) controlled drugs. Legislation states that the pharmacist must ascertain whether the person collecting is the patient, patient's representative or healthcare professional. In the case of Schedule 2 prescriptions (for example, methadone), the person will be asked to present some form of identification, unless they are already known to the pharmacist. If the person collecting the Schedule 2 controlled drug is a healthcare professional acting in their professional capacity on behalf of the patient, the pharmacist must also obtain the name and address of the healthcare professional and evidence of it.

Note the requirements for signing the prescription and identification on collection do not apply to instalment prescriptions except the first time the patient presents. It is at the discretion of the pharmacist who, in special circumstances, may dispense without these requirements.

Patients should collect the controlled drug in person. If they are unable to collect prescriptions in person, they may arrange for a representative to collect it. In such circumstances, pharmacists will require a letter on each occasion from patients, stating that a named person is authorised to collect the medicine on their behalf. The pharmacist will keep the letter. Such authorisation is also recommended, for example when a patient is in custody, to authorise a named police officer to collect an instalment from the pharmacy. Authorisation letters are necessary to allow people to carry controlled drugs, since they are not the people for whom it was intended – otherwise they are in unlawful possession. It may also prevent misunderstandings or deceit. The person collecting may then be asked to sign in a record book. It is at the pharmacist's discretion whether to supply to another person if for any reason the pharmacist is concerned the request is not genuine.

A3.3 Legal and good practice requirements

Do not leave blank prescription forms unattended. When not in use, keep in a suitable place. The NHS Security Management Service is issuing guidance on the security of prescription forms.

It is an offence for a prescriber to issue an incomplete prescription and a pharmacist is not allowed to dispense a controlled drug unless all the information required by law is given on the prescription. This means the pharmacist cannot agree alterations by telephone or authorisation letter. All the correct relevant information must be on the prescription before it can be dispensed. If an incomplete prescription is returned by the pharmacist then the prescriber signing the prescription must make the necessary alteration. In an emergency, the Home Office has stated that it would be acceptable for another doctor or health professional, who is

allowed to prescribe CDs under the legislative rules, to amend a controlled drug prescription provided that he or she signs and dates the whole prescription – not just the amendment and therefore accepts responsibility for the prescription in its entirety. Prescriptions must satisfy the following criteria:

- They must be indelible
- They must be signed by the prescriber with their usual handwritten signature – the dispensing pharmacist must be acquainted with the prescriber's signature or must be able to be satisfied that the signature is genuine.
- They must be dated (a computer-generated date or rubber stamp is acceptable)
- They must specify the prescriber's address which must be in the UK (does not include the Channel Islands or the Isle of Man). Although one prescriber in a practice may stamp the prescription and another prescriber in the same practice may write and sign it because the prescriber's address will be the same, the Department of Health does not consider this to be good practice.

The prescriber's name should be legible for example by printing the name in block capitals after the signature or by ensuring the name is pre-printed on the prescription. It is good practice to include the prescriber's registration number and the profession of the person signing the prescription.

Non-medical prescribers must include particulars on the prescription to indicate the type of non-medical prescriber, the relevant wording for non-medical prescribers together with the PIN or RPSGB registration number, as appropriate. Subject to Home Office consultation, only nurse and pharmacist supplementary prescribers are allowed to prescribe controlled drugs used in the treatment of addiction, in accordance with a clinical management plan, although independent nurse prescribers can currently prescribe from a limited list of controlled drugs for specific indications (generally palliative care and diazepam and chlordiazepoxide in the treatment of alcohol withdrawal).

Prescribers can now issue computer generated prescriptions – only the signature needs to be in the prescriber's own handwriting. Prescription requirements for the total quantity to be in words and figures, and for the strength, form and full dose to be included all remain in place.

Handwritten prescriptions should be written by an appropriate healthcare professional. 'Own handwriting' requirements for Schedule 2 and 3 controlled drugs were removed in November 2005. Carbon copied or faxed prescriptions are not acceptable for Schedule 2 and 3 controlled drugs. The prescription must always state the following

- The name and address of the patient. An email address or PO Box is not acceptable. 'No fixed abode' is acceptable as an address for homeless people.
- In the case of a preparation, the form and where appropriate the strength of the preparation.
- The total quantity of the preparation, or the number of dose units, in both words and figures (for liquid methadone preparations, the total quantity must be stated as a volume in millilitres, not a weight in milligrams).
- The daily dose, or dose of each amount to be taken, and the frequency (note that 'as directed' is not acceptable – see Table 9).

Other points:

- As a general principle, substitute opioid medicines should be prescribed in daily instalments (see section 5.2).
- In England, Wales and Northern Ireland, use the special instalment prescription forms where more than one pick-up is required. In Scotland forms GP10 and HBP(A) can be used for prescribing instalments.
- When prescribing in instalments, the prescription must contain a direction specifying the amount of the instalment which may be supplied and the intervals observed when supplying. It is not a legal requirement for the number of instalments to be specified.
- The prescription must specify amounts to be collected on days to cover when the pharmacy is closed. See Table 9 for specific wording which can be added to prescriptions if the prescriber is unsure of the days a pharmacy is closed over a bank holiday.
- The pharmacist must only dispense the prescription on the date on which it is due. If the patient does not collect an instalment when it is due, that supply is no longer valid – the patient cannot collect that instalment on another day. Part instalments may be collected provided the

approved Home Office wording is included on the prescription (see Table 9).

- Additional wording can be added to the prescription to allow the pharmacist to dispense part of an instalment; for example, if the patient is required to collect more than one day's supply at a time and misses the specified day for collection, the patient will be able to collect the remaining balance of the instalment provided additional wording authorising this is included on the prescription. This wording must be specifically approved by the Home Office. Examples of Home Office approved wording are given in Table 9. Pharmacists will need to be informed through official channels (such as their own professional networks) when new wording has been approved by the Home Office.

- Only medical practitioners who hold a special licence issued by the Home Secretary may prescribe, administer or supply diamorphine, dipipanone or cocaine in the treatment of drug addiction. Currently, non-medical prescribers are not considered to be 'medical practitioners' and so may not prescribe these drugs or obtain a special licence.

- In most circumstances, when prescribing substitute opioid medicines, no more than one week's total supply should be dispensed at one time, except for holidays and special arrangements.

- Prescribers should restrict prescriptions for Schedule 2, 3 and 4 controlled drugs to amounts of no more than is sufficient to meet the patient's clinical needs for up to 30 days, except in exceptional circumstances.

- It is good practice to write a start date on the prescription which is clear and unambiguous. Prescriptions for Schedule 2, 3 and 4 controlled drugs are only valid for 28 days from the date of signing if no start date is specified. A start date, even if more than 28 days after the date of signing, will ensure the prescription is still valid. The pharmacist will not be able to dispense the prescription before the start date or date of signing. Where a start date is not included, in the case of instalment prescriptions, the first instalment must be dispensed within 28 days of the date of signing, with the remainder instalments dispensed in accordance with the instructions.

- Alterations are best avoided but if any are made they should be clear and unambiguous. The NHS Security Management Service recommends that alterations should be signed and dated by the prescriber.

- The name of the dispensing pharmacy (chosen by the patient) may be added to the top of the prescription. However, the patient will still retain the right of choice to take their prescription elsewhere.

- The name and address of the dispensing pharmacy should be written in the patient's notes.

A3.4 Minor amendments (applicable in England, Wales and Scotland)

New regulations from 7 July 2006 allow pharmacists – where the prescriber's intentions are clear – to make minor technical amendments to CD prescriptions for Schedule 2 or 3 drugs, except temazepam which is exempted from the Schedule 2 and 3 CD prescription requirements. The error must be a minor spelling or typographical error or the omission of either words or figures in the total quantity (but not both). The pharmacist making the amendment must make it clear they are responsible for it and should:

- ensure the prescription is genuine

- be sure they are supplying what the prescriber intended

- amend the prescription in ink so that the amendment made is attributable to the pharmacist.

A3.5 Additional country-specific rules

A3.5.1 England

- Do not write prescriptions for durations of longer than 14 days on FP10MDA forms.

- Instalment prescriptions (FP10MDA) can only be used for the treatment of addiction using schedule 2 controlled drugs (for example, methadone), buprenorphine (schedule 3), buprenorphine-naloxone (Suboxone®) (Schedule 3) and diazepam (Schedule 4). Single supplies of water for injections can also be prescribed where appropriate, for example when diamorphine dry powder injection is prescribed to be dispensed in instalments.

- The FP10MDA instalment prescription forms cannot be used for other Schedule 3, 4 or 5 controlled drugs; for example, dihydrocodeine 30 mg tablets (Schedule 5) or temazepam

(Schedule 3) cannot be prescribed in instalments using this form.

- FP10MDA forms are available as either pads of 10 prescriptions or as FP10MDA SS (single sheet). FP10MDA SS are intended for computer generated prescribing although they can also be used for handwritten prescribing.
- Hospital FP10MDA forms are overwritten with the words 'hospital prescriber'. Hospital prescribers (only) can also prescribe single supplies of any other medicine prescribable on FP10 using FP10MDA SS forms.
- FP10NC forms can only be used to order a single supply. Patients should be warned that, in the case of Schedule 2 CDs, they may be required to show photo identification to the dispensing pharmacist when collecting their CDs.
- It is good practice to include the patient's identifier on the prescription; in England this is the patient's NHS number. This is likely to become a mandatory requirement at a later date.

A3.5.2 Wales

- Do not write prescriptions for durations of longer than 14 days on the WP10(MDA) or WP10HP(AD) forms.
- Instalment prescriptions WP10(MDA) and WP10HP(AD) can be used to order any Schedule 2, 3, 4 and 5 controlled drug in instalments.
- Pharmacists in England can only dispense Welsh instalment prescriptions for Schedule 2 controlled drugs, buprenorphine, buprenorphine-naloxone (Suboxone®) and diazepam and therefore cannot dispense instalment prescriptions for other Schedule 3, 4 and 5 controlled drugs.
- WP10 forms can only be used to order a single supply. Patients should be warned that, in the case of Schedule 2 CDs, they may be required to show photo identification to the dispensing pharmacist.
- It is good practice to include the patient's identifier on the prescription. This is likely to become a mandatory requirement at a later date. (In Wales, the patient identifier to be used is yet to be decided).

A3.5.3 Scotland

- There is no 14-day instalment restriction (as separate instalment prescriptions are not used). Prescriptions for Schedule 2, 3 and 4 CDs will be valid for 28 days from the date signed by the prescriber or from the date specified by the prescriber. The 30 days supply stated in the guidance is good practice.
- Form GP10 can be used to prescribe any medicine (including non-schedule prescription only medicines) to be dispensed in instalments.
- Form HBP(A) is issued in Scotland by drug dependence clinics and can be used to order any medicine used in the treatment of addiction.
- It is good practice to include the patient's identifier on the prescription; in Scotland this is the Community Health Index (CHI) number. This is likely to become a mandatory requirement at a later date.

A3.5.4 Northern Ireland

- In the community, form HS21 is used by prescribers in Northern Ireland treating drug misusers.
- SP forms are used by specialist drug treatment services.
- SP and HS21 forms can be used to prescribe methadone mixture 1mg in 1 ml, methadone tablets (methadone hydrochloride 5 mg) or sublingual buprenorphine (including buprenorphine-naloxone (Suboxone®)) for instalment dispensing, subject to Department of Health, social services and public safety (DHSSPS) guidelines.
- It is good practice to include the patient's identifier on the prescription. This is likely to become a mandatory requirement at a later date. (In Northern Ireland, the patient identifier to be used is yet to be decided.)

A3.6 Other considerations

For liquid preparations, for example methadone mixture 1 mg in 1 ml, it is important to ensure the patient will be able to accurately measure their daily dose. When more than one dose is to be given to the patient, for example on weekends and bank holidays, the dispensing pharmacist will dispense each day's dose in individual containers only if specifically instructed to do so. The NHS Business Services Authority has approved the following specific wording to be added to prescriptions: "Dispense daily doses

in separate containers and in advance". Otherwise the pharmacist may supply all take home doses in a single large container and only supply the patient with the Drug Tariff 5 ml spoon.

Tablet forms, especially of methadone and buprenorphine, carry a risk of being inappropriately crushed, dissolved and injected. Buprenorphine-naloxone (Suboxone®) carries a lower risk of being abused in this manner by opiate dependent users on account of its naloxone component.

If local policies support pharmacists crushing buprenorphine tablets (an unlicensed use of the medicine) then the local policy and lines of accountability should be clearly indicated in the policy or protocol. Pharmacists may need to take out additional insurance to cover this procedure (the National Pharmacy Association will indemnify members provided they comply with the NPA model protocol). Procedures prescribing the crushing of doses must be evidence based, fully supported by the local shared care monitoring group, the prescriber, and clinical governance leads, and informed patient consent must be obtained. A risk assessment must be made to minimise or remove any risks to the operator or patient as a result of crushing (examples of potential risks include danger to staff from inhaling the powder, danger from crushing the tablets so finely that they create a sludge that sticks to the buccal mucosa). Patients should be offered a drink of water before taking their dose.

Colour-free or higher-strength methadone mixture is not recommended for routine use due to the possible increased potential for misuse.

Local dental policies may advocate always prescribing sugar-free preparations. However, sugar-free methadone mixture may have unacceptable gastrointestinal side effects due to the high sorbitol content present in some brands. Sugar-free methadone mixture has not been shown to be less likely to cause dental caries than the sugar-containing methadone oral mixture as methadone itself is acidic. If prescribed, patients should still be advised to rinse their mouths with water, and preferably brush their teeth after consuming their methadone to minimise adverse effects on their teeth. Pharmacists can only dispense sugar-free methadone oral mixture if specifically prescribed.

It is good practice, when prescribing Schedule 4 CDs, such as benzodiazepines, and Schedule 5 CDs, such as dihydrocodeine tablets, to state the total quantity to be dispensed in words and figures.

A3.7 Examples of what to write on a prescription

See Table 9.

(M) indicates mandatory requirements for a controlled drug prescription

(R) indicates things that are not legally required but are strongly recommended to help prevent missed doses and errors, and ensure the patient receives optimum care.

A3.7.1 Private prescriptions

Standardised private prescription forms must now be used for the private prescribing of all Schedule 2 and 3 CDs dispensed in community pharmacies or in dispensing practices.

- In England – forms FP10(PCD).
- In Scotland – forms PPCD(1).
- In Wales – forms WP10PCD and WP10PCD SS.
- In Northern Ireland – forms PCD1 (issued by the CSA).

In England private prescriptions for Schedule 2 and 3 CDs must include the prescriber's six-figure identification number. Forms are obtained from the local primary care organisation.

In Scotland, valid NHS prescriber codes will be used where available. New private prescriber codes will be issued where necessary. Private prescribers of Schedule 2 and 3 controlled drugs must register with their local health board. Private prescribers will be allocated a prescriber code. Valid NHS prescriber codes will be used where available.

In Wales, unique prescriber identification codes will be issued for all private prescribers of Schedule 2 and 3 CDs. The number is issued by the relevant NHS agency (the primary care organisation) for the purpose of that person's private prescribing. This number is not the person's professional registration number.

Private prescribers may also issue prescriptions for instalment dispensing but may not prescribe repeat prescriptions for Schedule 2 and 3

controlled drugs. Private repeat prescriptions for Schedule 4 and 5 CDs are allowed.

A3.8 Further information

Refer to *Controlled Drugs and Community Pharmacy*, Fitness to Practise and Legal Affairs Directorate, fact sheet one. The latest edition is available from the Royal Pharmaceutical Society of Great Britain website www.rpsgb.org.

What you want to prescribe (M) mandatory CD requirement (R) not legally required but strongly recommended	Examples of what to write on the prescription (notes in italics)	
Drug (M)	Methadone	Buprenorphine *NB: The Temgesic® brand is available as 200 and 400 micrograms tablets and is licensed for analgesia, not substitute opioid prescribing. Temgesic should not be prescribed or dispensed for treatment of addiction as the patient information leaflet supplied will not give appropriate information.*
Form (M)	Mixture	Tablets *(can be done as part of total quantity below). The word 'tablets' must still be included even if implicit in the name)*
Strength (M) (where appropriate)	1 mg in 1 ml *(10 mg in 1 ml only to be dispensed after dilution)*	400 micrograms, 2 mg, 8 mg or a combination *Can be done as part of total quantity – see below.* *NB: Subutex® brand is not available as 200 microgram strength and this strength should not be prescribed in the treatment of opioid addiction as the patient information leaflet will not give appropriate information.*
Sugar-free (must not be supplied unless specifically prescribed)	SF	*n/a*
Dose (M)	60 mg daily *(60 ml daily is also acceptable for liquids as the strength must be included on the prescription)*	12 mg daily (as one 8 mg tablet plus two 2 mg tablets)
	'To be taken as directed' is not acceptable *'One as directed' is acceptable for solid dose formulations*	
For how long (R)	14 days	7 days
Start date (R)	Start date: 21 November 2007	Start date: 2 October 2007
Total quantity of dose units in WORDS and FIGURES (M)	840 ml eight hundred and forty ml (or millilitres) *(Milligrams or mg is NOT acceptable)*	7 (seven) x 8 mg tabs 14 (fourteen) x 2 mg tabs *The prescriber must list the individual strengths and quantities required.* *For clarity, the name of the drug should also appear each time for each different strength so that there can be no ambiguity.*
Supply in instalments – this may be written against individual dates	60 ml daily in instalments	12 mg daily (as one 8 mg tablet plus two 2 mg tablets) in instalments
If you want supervised consumption (R) *(Local enhanced service agreement must be in place.)*	Please supervise consumption *(The frequency of supervised consumption may also be added if necessary.)*	

Table 9: Examples of what to write on a prescription

What you want to prescribe (M) mandatory CD requirement (R) not legally required but strongly recommended	Examples of what to write on the prescription (notes in italics)	
If you want the buprenorphine tablets crushed *(Local policy or agreement must be in place.)*		Please crush
To cover daily pick-ups due on Sundays and bank holidays (R)	Supply Sunday and bank holiday doses on preceding pick-up day immediately prior to closure.	
If you want pick-up to be less than daily state days for collection or, alternatively, amounts to be dispensed can be specified for individual dates If a patient misses a pick-up one day they cannot collect their medicine until the next specified collection day unless the wording in the line below is added.	Collect on Monday, Wednesday and Friday.	Collect on Tuesday each week.
	21.11.07 120 ml 23.11.07 180 ml 26.11.07 120 ml 28.11.07 120 ml 30.11.07 180 ml 3.12.07 120 ml	2/10/07 36 mg (3 x 8 mg plus 6 x 2 mg) 5/10/07 48 mg (4 x 8 mg + 8 x 2 mg)
If you want methadone to be measured in individual bottles for the patient (otherwise patient will be supplied with multiple take home doses in a single container)	Dispense daily doses in separate containers and in advance *A rubber stamp may be used for this.*	*Not needed as the tablets are easily counted.*
If you want patients who pick up their medicine less frequently than daily to be able to collect a part instalment as soon as possible after they miss a dose	If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days missed may be supplied. Or alternative wording permitted: Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e. the instalment less the amount prescribed for the days missed) may be supplied.	
If you want the patient to be supervised consuming their dose on the days that they collect from the pharmacy but still want them to be able to obtain a part instalment of their medicine if they miss their prescribed collection day	Supervised consumption of daily dose on specified days; the remainder of the supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the days missed may be supplied.	
If you want to ensure that the patient is not supplied with their dose if they have missed collecting for three days	Instalment prescriptions covering more than one day should be collected on the specified day. If this collection is missed, the remainder of the instalment (i.e. the total amount less the instalments for the days missed) may continue to be supplied in the specified instalments at the stated intervals, provided no more than three days are missed.	
For bank holidays when unsure which days the pharmacy is closed	Instalments due on days when the pharmacy is closed should be dispensed on the day immediately prior to closure.	

A4 Travelling abroad with controlled drugs

A4.1 General

When travelling abroad for any length of time, controlled drugs are carried at the risk of the individual, who is subject to legal requirements and restrictions of the country or countries of transit and destination. These can be checked with the relevant embassies and consulates to enquire about any restrictions in the country to be visited (contact details can be found at www.drugs.gov.uk). In general medicines should:

- be carried in original packaging
- be carried with a letter from the prescriber confirming the patient's name, destination, and details and amounts of medicine
- meet carriers' requirements for hand and hold luggage (for example restrictions on volumes of liquids in hand luggage on aeroplanes).

A4.2 Travelling for 28 days or less

Drug misusers in receipt of a prescription for a controlled drug can travel abroad with their supply. A Home Office licence is not necessary for planned stays of 28 days or less. The requirements listed previously still apply.

A4.3 Travelling between 28 days and three months

A Home Office personal export licence is required for planned stays of more than 28 days. The patient should complete a form, available from Home Office Drugs Licensing, and return it to them along with a letter from the prescriber stating:

- the name and address of the person
- the person's date of birth
- the strength
- the form
- the quantity of the medicine
- the daily dose prescribed
- the person's date of departure and return
- countries being visited.

There is nothing laid down about the maximum amounts that individuals may travel with and the Home Office advises that each case is treated on its merits.

The export licence is to allow the carriage of the medicine out of the UK and any surplus back in. It does not mean that the holder of the licence has the right to take the medicine into the country to be visited. Therefore, it is important that the patient checks with the embassy or consulate before departure, to establish that the country or countries to be visited will accept the Home Office licence.

Anyone applying for a licence should allow at least two weeks, assuming all the information needed is contained in the letter from the prescriber, for the processing of the application.

A licence is obtainable from:

Home Office Drugs Licensing
6th Floor, Peel Building
2 Marsham Street
London SW1P 4DF
Tel: 020 7035 0467

Email: licensing_enquiry.aadu@homeoffice.gsi.gov.uk

The form can be downloaded from www.drugs.gov.uk/publication-search/drug-licences/Personal

The requirements described in this section are similar for all/most prescribed medicines contained in Schedules 2, 3 and 4 of the Misuse of Drugs Regulations 2001 (as amended).

A4.4 Travelling for more than three months

Patients are advised to register with a doctor in the country they are visiting for the purpose of receiving further prescriptions.

A5 Interactions

A5.1 Medicinal interactions

Two or more drugs taken at the same time (whether prescribable, obtained over the counter, herbal, or illicit) may exert their effects independently or may interact. The interaction may be potentiation or antagonism of one drug or another, or occasionally some other effect. Alcohol and nicotine can also interact with other drugs.

Refer to appendix 1 of the latest edition of the *British National Formulary* (BNF) for an up to date list of drug interactions.

Drug interactions may be pharmacodynamic or pharmacokinetic and an explanation of these terms is included in BNF appendix 1. Drugs are organised in the appendix by approved name and by pharmacological classification. Interactions with alcohol are also listed.

The sections in BNF appendix 1 of most relevance to the drug misuse field are:

- alcohol
- anabolic steroids
- anaesthetics, general (such as ketamine)
- antidepressants, SSRI
- antidepressants, tricyclic
- antihistamines
- antipsychotics
- anxiolytics and hypnotics
- barbiturates
- disulfiram
- opioid analgesics
- sympathomimetics (such as dexamfetamine)
- tobacco
- opioid interactions.

A5.1.1 Opioid interactions

Compared to most other street drugs, there is more data on the potential interactions between opioids and medicines because opioids are so widely used therapeutically. Factors which may pre-dispose opioids to interact may include the following:

- All of them are central nervous system depressants and so will have at least additive effects with medicines (and other illicit drugs) that have this property.
- Methadone and buprenorphine are both metabolised by the enzyme CYP3A4.
- The enzyme CYP2D6 is occasionally important in interactions. For example, it is responsible for the metabolism of oxycodone, and for the transformation of codeine and tramadol into active metabolite. Methadone inhibits CYP2D6.

A5.2 Interactions with illicit drugs

Interactions between illicit drugs and conventional medicines have not been systematically studied in humans. Most data has been derived from case reports and small-scale laboratory research and so should be interpreted cautiously. In addition, there are the added complications that many illicit drugs are often 'cut' (diluted) with unknown compounds; some of which may have pharmacological actions that also may interact adversely with the illicit drug or any other drug taken.

Many drug misusers are polydrug users and the potential for these drugs to interact should not be overlooked.

Drug misusers may not report all drugs – such as cannabis, benzodiazepines, alcohol, over-the-counter drugs and nicotine – all of which may interact with each other and other drugs.

Drug misusers may be taking counterfeit or fake drugs, for example anabolic steroid misusers and benzodiazepine misusers who buy drugs over the internet (which may not contain what it says on the label).

A5.3 Further reading

Drugs of Abuse – Second Edition. Simon Wills, Pharmaceutical Press.

Table 10: Some important interactions with opioids

Opioid interaction	Examples	Opioids affected	Mechanism	Effect
Other medicines (and substances) that depress the CNS	Other opioids Benzodiazepines Many tricyclic antidepressants Many antipsychotics Older antihistamines Alcohol	All	Increased CNS depression	Additive effect – potentiation of respiratory depression
Medicines that increase opioid levels	Cimetidine Ciprofloxacin Erythromycin Clarithromycin Fluconazole Ketoconazole Fluvoxamine and possibly other SSRIs	Methadone Buprenorphine	Increased blood levels of methadone or buprenorphine by inhibition of the enzyme CYP3A4	Dose of methadone or buprenorphine may need to be decreased to prevent toxicity or overdose AND may need to be increased to prevent withdrawal symptoms when the enzyme inhibitor is stopped
Medicines that decrease opioid levels	Anticonvulsants (e.g. barbiturates, carbamazepine, phenytoin) HIV medicines (e.g. efavirenz, nevirapine) Rifampicin Spironolactone St John's Wort	Methadone Buprenorphine	Decreased blood levels of methadone or buprenorphine by induction of enzyme CYP3A4	Dose of methadone or buprenorphine may need to be increased to prevent withdrawal symptoms AND decreased to prevent overdose when the enzyme inducer is stopped
Opioids that act as partial agonists	Buprenorphine and other partial opioid agonists	Methadone Diamorphine Other full agonists	Buprenorphine is a partial agonist and displaces other opioids from receptor sites	Can precipitate withdrawal symptoms – advise waiting until opioid is excreted (confirmed by presence of withdrawal symptoms) before taking buprenorphine
Opioid antagonists	Naltrexone (active orally) Naloxone (active by injection – IV, IM and SC)	All	Naltrexone and naloxone are full antagonists and displace other opioids from receptor sites	Will precipitate withdrawal symptoms if taken when agonist or partial agonists have recently been taken
Medicines affecting QTc interval	Tricyclic antidepressants Antipsychotic medicines	Methadone	Prolongation of QTc interval	Can cause torsades de pointes. Use cautiously with methadone – see section 3.5 and annex A2
Medicines affecting urine pH	Vitamin C Sodium bicarbonate (antacids)	Methadone	Affects excretion of methadone – increased excretion in acidic urine, decreased excretion in alkaline urine	Increased excretion may cause withdrawal Decreased excretion may cause toxicity

A6 Marketing authorisations

When the Clinical Guidelines were last published in 1999 the Medicines Control Agency was responsible for licensing medicines under the Medicines Act 1971. European Community (EC) legislation now takes precedence over the Medicines Act, and the Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for issuing marketing authorisations. A marketing authorisation lasts for five years and covers all the main activities associated with the marketing of a medicinal product.

A6.1 Adults

See Table 11.

A6.2 Young people

Absence of a marketing authorisation licence does not necessarily mean the absence of evidence for the proposed interventions. Most medicines have only been tested for safe and effective use in the adult population. Few medicines used in adults are specifically authorised for use in the treatment of children. Medicines prescribed for a child that are not authorised for that age group or for their health problems are referred to as 'off label' and medicines that do not have an authorisation at all as 'unlicensed'.

Children are different from adults: their bodies metabolise medicines differently and young children respond differently than older children. Detailed care and attention therefore needs to be taken when making prescribing decisions for children and young people, taking into account their age, weight and developmental stage (HM Government, 2004). When making the clinical decision to prescribe these drugs, the risks and benefits of the treatment must be considered and fully documented.

The informed use of 'unlicensed' or 'off label' medicines is often unavoidable if children are to have access to the most effective medicines. Both scenarios are quite common and allowed for in legislation if prescribed by a registered doctor.

The Medicines Act 1968 and its regulations provide exemptions that enable doctors to use or advise the use of licensed medicines outside the recommendations for the licence, or to override the warnings and precautions given in the licence. In these circumstances, the doctor must be able to justify this action in accordance with a respectable, responsible body of professional opinion.

Information must be given to the young person and their parents on the nature of the drug to be used, the likely effect, the timing of this effect and the safety and licensing of the

Markers of good practice in the prescribing of medication for young people (in England)
National Service Framework for Children, Young People and Maternity Services: Medicines (2004) Department for Education and Skills and Department of Health

- The use of medicines in children is based on the best available evidence of clinical and cost-effectiveness and safety, ideally derived from clinical trials, but also including, where appropriate, medicines that are not licensed for their age group or for their particular health problem ('off-label'), or those that do not have a licence at all ('unlicensed') in order to achieve the best possible health outcomes and minimise harm and side effects.
- In all settings and whatever the circumstances, children and young people have equitable access to safe, clinically and cost-effective medicines in age appropriate formulations.
- Appropriate information and decision support is available for professionals who prescribe, dispense and administer medicines for children and young people.
- Children, young people and their parents and carers receive consistent, up-to-date, comprehensive, timely information on the safe and effective use of medicines.
- In all settings, professionals enable parents, young people and, where appropriate, children to be active partners in the decisions about the medicines prescribed for them.
- Primary care trusts, NHS trusts and other organisations ensure that the use of medicines in children is incorporated in their clinical governance and audit arrangements.
- The contribution of pharmacists in the effective and safe use of medicines in children is maximised.

Pharmacological group	Drug	Marketing authorisation status for the treatment of drug dependency
Opioid agonists and antagonists	Methadone oral solution 1 mg in 1 ml Methadone oral solution 1 mg in 1 ml sugar-free	Authorised
	Methadone oral concentrate (blue) 10 mg in 1 ml Methadone oral concentrate (brown) 20 mg in 1 ml Methadose® diluent	Authorised (NB The final strength of the methadone mixture to be dispensed to the patient must be specified on the prescription)
	Methadone injection 25 mg in 1 ml – ampoules of 2 ml Methadone injection 50 mg in 1 ml – ampoules of 1 ml	Authorised
	Naltrexone (oral)	Authorised as adjunct for relapse prevention
	Naltrexone (depot)	Not authorised
	Buprenorphine (sublingual)	Authorised
	Buprenorphine-naloxone (Suboxone®) (sublingual)	Authorised
	Dihydrocodeine (any route) Codeine (any route)	Not authorised
	Diamorphine (heroin) (any route)	Not authorised
Benzodiazepines	Diazepam (oral)	Authorised for benzodiazepine and alcohol withdrawal
	Chlordiazepoxide (oral)	Authorised for alcohol withdrawal
Amphetamines	Dexamfetamine (any route)	Not authorised
Alpha-adrenergic agonists	Lofexidine (oral)	Authorised for management of opioid withdrawal
Cigarette smoking	Bupropion (oral)	Authorised as adjunct to smoking cessation in combination with motivational support
	Nicotine (patches, gum, lozenges, nasal spray, inhalator)	Authorised as adjunct to smoking cessation
	Varenicline (Champix®)	Authorised as adjunct to smoking cessation

Table 11: Marketing authorisations for medicines used in the treatment of drug misuse in adults

medication. It would be useful if this information was available in leaflet form as well as discussed verbally. Any difficulties in literacy skills need to be acknowledged. This information is important for a number of reasons:

- Young people need to feel their dosage adjustments are for their own comfort and safety, rather than any punishment system.
- It ensures informed consent can be given.
- It facilitates understanding of treatment given including likely outcomes.

NHS bodies, prescribers, dispensers and those administering medicines must take precautions to ensure that the use of 'off label' or 'unlicensed' medications is managed properly. There should be local safety standards and arrangements in place to monitor the use of unlicensed and off label medicines.

Pharmacological group	Drug	Marketing authorisation status for the treatment of drug dependency
Opioid agonists and antagonists	Methadone oral solution 1 mg in 1 ml Methadone oral solution 1 mg in 1 ml sugar-free	Not authorised for children. 'Children' in this context is generally recognised to mean those aged 13 and younger, however, manufacturers note the lack of evidence for adolescents.
	Naltrexone (oral)	Authorised as adjunct for relapse prevention over 18 years. Not authorised for the management of relapse prevention for alcohol misuse.
	Buprenorphine (sublingual)	Authorised for those aged 16 plus with opiate dependence
	Buprenorphine-naloxone (Suboxone®) (sublingual)	Authorised for those aged 15 plus with opiate dependence
	Dihydrocodeine (any route) Codeine (any route)	Not authorised for the treatment of dependence and not recommended
Alpha-adrenergic agonists	Lofexidine (oral)	Authorised for management of opioid withdrawal from age 18
Alcohol dependence	Acamprosate (oral)	Authorised for maintenance of abstinence in alcohol dependence in over-18s
Cigarette smoking	Bupropion (oral)	Not recommended in those under 18 years
	Nicotine (patches, gum, lozenges, nasal spray, inhalator)	Authorised as adjunct to smoking cessation in those aged 18 years upwards. Some gums authorised for use in those aged 12 and over.

Table 12: Some marketing authorisations for medicines used in the treatment of drug misuse in young people

A7 Drugs and driving

A7.1 Driving licence requirements

The Driver and Vehicle Licensing Agency (DVLA) regularly publishes new editions of its *At a Glance Guide* (DVLA, 2007), which sets out the medical standards required for the holding of driving licences. This document outlines the regulations on persistent misuse of and dependence on drugs.

Under the terms of the Road Traffic Act, holders of a driving licence are required to inform the Driver and Vehicle Licensing Agency (DVLA) in Great Britain or Driver and Vehicle Agency (DVA) in Northern Ireland of "… any disability likely to affect safe driving".

Drug misuse, whether or not amounting to dependency, is regarded as a disability in this context. However, the focus and emphasis is on dependent and persistent misuse that is likely to impair driving. If dependent, then the use of prescribed medication to treat drug misuse constitutes a relevant disability and is subject to specific rules in order to obtain permission to continue to retain a licence.

The responsibility to inform the licensing agency of their current medical status lies with the licence holder, not the prescribing clinician or drug service.

There are detailed rules for revocation and refusal of licences for different types of vehicles in relation to different drugs of misuse, and for the reinstatement of driving entitlement. "Consultant supervised oral methadone maintenance" or "an oral buprenorphine programme" are, at the time of writing, the only drug treatments under which a patient may be licensed, subject to specified conditions.

A7.2 Driving under the influence of drugs

It is an offence to be in charge of a vehicle if "unfit to drive through drink or drugs".

A patient taking a prescribed drug like methadone would not automatically be considered by the courts to be unfit to drive.

The General Medical Council's guidance states that doctors "should explain to patients that they have a legal duty to inform the DVLA about their condition. If patients refuse to accept the diagnosis or the effect of the condition on their ability to drive, you can suggest that the patients seek a second opinion, and make appropriate arrangements for the patients to do so. You should advise patients not to drive until the second opinion has been obtained. If patients continue to drive when they may not be fit to do so, you should make every reasonable effort to persuade them to stop. This may include telling their next of kin, if they agree you may do so. If you do not manage to persuade patients to stop driving, or you are given or find evidence that a patient is continuing to drive contrary to advice, you should disclose relevant medical information immediately, in confidence, to the medical adviser at the DVLA. Before giving information to the DVLA you should try to inform the patient of your decision to do so. Once the DVLA has been informed, you should also write to the patient, to confirm that a disclosure has been made." (GMC, 2007)

A7.3 Disclosure and breaching confidentiality

Whether clinicians should take the step of breaching confidence and informing the driver licensing agency without a patient's consent – if they are concerned about a patient's ability to drive or if the patient is driving passenger or heavy goods vehicles – is a complex but real ethical issue. Clinicians should make and document an assessment of risk before deciding whether to break confidentiality in the public interest.

A7.4 Risk assessment

The responsibility for determining whether or not a patient's driving is putting the public at risk is not a clinician's alone but also that of the treatment service, although a prescriber cannot deflect their responsibility. A review (Tunbridge *et al.,* 2000) for the European Union categorised the overall risk to traffic safety caused by different drugs and combinations as follows:

- High risk – alcohol, benzodiazepines, cannabis and alcohol.
- High-to-moderate risk – cocaine.
- Moderate risk – cannabis, amphetamines.
- Low-to-moderate risk – opiates, methadone, antihistamines.
- Low risk – antidepressants.

There are also stages in treatment when a patient may be at greater risk of their driving being impaired. These include:

- dose induction and dose adjustment
- detoxification
- change to injectable opioid treatment.

A7.5 Action with patients

Some services find it helpful to issue patients with an information leaflet on their rights and responsibilities in relation to driving (and other issues). It may also be appropriate to record the fact that this information has been given (especially where there are concerns).

In situations where patients continue to drive they should be advised that they:

- should not drive for 4–5 days after beginning an opioid treatment or after a dose increase
- should not drive if they ever feel sedated
- should report sedation, unsteadiness or cognitive decline immediately to the physician so that reduction in dosage can be initiated
- should not use alcohol or other drugs that impair performance, such as cannabis and antihistamines, and drive
- should not make any changes in their medication regimens without consulting with the prescribing service.

Further information can be obtained from:

The senior medical adviser
DVLA, Driver Medical Unit
Longview Road
Morriston
Swansea SA99 1TU
www.dvla.gov.uk

or the Driver and Vehicle Agency in Northern Ireland
www.dvani.gov.uk

A7.6 References

Driver and Vehicle Licensing Agency (2007). *At a Glance Guide to Medical Aspects of Fitness to Drive*. Swansea: DVLA.

Tunbridge R, Clark A, Ward BN, Dye L, Berghaus G (2000) *Prioritising Drugs and Medicines for Development of Roadside Impairment Testing*. Project Deliverable DR1, CERTIFIED EU Research Project (Contract No RO-98-3054). Leeds: School of Psychology, University of Leeds.

A8 Injectable opioid treatment

A8.1 Principles of injectable opioid prescribing

Patients should only be considered for injectable opioid prescribing in line with the eight key principles that were outlined in the NTA guidance, *Injectable Heroin (and Injectable Methadone): Potential Roles in Drug Treatment* (NTA, 2003). These were established through an expert consensus process. Applying these principles in practice sets a high standard for delivery of this treatment intervention in recognition of the risks involved in providing injectable treatments.

Both injectable diamorphine and injectable methadone are effective and, at present, our guidance is that selection of one or the other should be on the basis of assessment of the individual patient, rather than there being any specified hierarchy.

Clinicians providing injectable opioid treatment should encourage patients not to regard it as a lifelong treatment option and should regularly review their patients and the continuing necessity for this unusual and expensive treatment, particularly in view of the significant inherent risks.

Principles guiding injectable maintenance prescribing from NTA guidance, *Injectable Heroin (and Injectable Methadone): Potential Roles in Drug Treatment* (NTA, 2003):

1. *Drug treatment comprises a range of treatment modalities which should be woven together to form integrated packages of care for individual patients.*
2. *Substitute prescribing alone does not constitute drug treatment. Substitute prescribing requires assessment and planned care, usually with other interventions such as psycho-social interventions. It should be seen as one element or pathway within wider packages of planned and integrated drug treatment.*
3. *Within the substitute prescribing modality, a range of prescribing options are required for heroin misusers requiring opioid maintenance. Some options may carry more inherent risks than others (for example, injectable versus oral options). Patients who do not respond to oral maintenance drug treatment should be offered other options in a series of steps. This would normally include:*
   - *oral methadone and buprenorphine maintenance, specifically optimised higher dose oral methadone or buprenorphine maintenance treatment, then*
   - *injectable methadone or injectable heroin maintenance treatment (perhaps in combination with oral preparations).*
4. *Injectable maintenance options should be offered in a local area that can offer optimised oral methadone maintenance treatment including adequate doses, supervised consumption and psycho-social interventions. This is essential to ensure oral drug treatment options have been fully explored prior to a trial of injectable maintenance treatment and to ensure smooth transition back to oral treatment if required.*
5. *Injectable and oral substitute prescribing must be supported by locally commissioned and provided mechanisms for supervised consumption. Injectable drugs may present more risk of overdose than oral preparations and have a greater value on illicit markets and hence may require greater levels of supervision.*
6. *Injectable maintenance treatment is likely to be long-term treatment with long-term resource implications. Clinicians should consider the move from oral to a trial of injectable preparations carefully, including long-term implications for the patient and drug treatment systems and involvement of services.*
7. *Specialist levels of clinical competence are required to prescribe injectable substitute drugs. Heroin prescribing also requires a Home Office licence.*
8. *The skills of the clinician should be matched with good local systems of clinical governance, supervised consumption and access to a range of other drug treatment modalities.*

The NTA guidance also recommends that there is need for further work around identifying the most effective models of delivery. Suggested eligibility criteria are outlined in the NTA guidance.

A8.2 Models for delivery of injectable opioid treatment

A8.2.1 The nature of new injectable opioid treatments

The current evidence for successful injectable opioid treatment programmes comes from Swiss, Dutch and German programmes (Rehm *et al.,* 2001, van den Brink *et al.,* 2003, Haasen *et al.,* 2007). These differ in several crucial ways from how injectable opioids have been prescribed in the past in the UK. They include the absolute requirements that the patient must:

- attend in person for their prescribed injectable opioid maintenance treatment – daily or more frequently, according to the treatment plan
- inject their dose under the direct supervision of a member of staff who is competent to do so
- be given no take-away injectable medication.

On occasions and in circumstances where it is not feasible to provide this close supervision, patients may be issued with a take-home alternative supply of oral opioid medication. These occasions and circumstances might include rural areas where it is not feasible to supervise consumption every day, and days when the patient cannot come into the service.

A8.2.2 Advantages and disadvantages of supervised injectable opioid treatment

Advantages:

- Supervised environment permits prescription of higher doses with less concern about potential acute hazards.
- Supervised environment permits higher doses to be prescribed without concern about potential misuse or diversion.
- Structured setting and supervised environment permit treatment of higher-risk and more complicated patients.
- It removes the potential for prescribed injectable medication to be diverted onto the illegal market by patients.
- Patients can be advised on safer injecting techniques and sites, for example, moving from groin or neck injecting to safer sites.
- It provides opportunities for building therapeutic relationships, brief interventions and for daily observation and monitoring.
- The restrictive nature of supervised IOT may encourage patients to work towards other treatments which give them more freedom – for example, encouraging the return to oral maintenance.

Disadvantages:

- Inconvenience to patients of the necessity for daily (or more frequent) attendance.
- Limited compatibility with workplace requirements if the patient secures gainful employment.
- Challenges around childcare if the patient is the sole carer for a child or children and does not have any support.
- Financial and human resources costs to the service provider of establishing, maintaining and delivering such a specialist facility and service.
- Difficult to provide in rural areas, especially as patients on injectable medication are typically considered not fit to drive.

A8.2.3 Patients already receiving unsupervised injectable opioid treatment

There are a small but significant number of patients who are already in receipt of injectable maintenance prescriptions, on an unsupervised basis. The number who receive such treatment is steadily dwindling, having been about 10% of prescribing to this group in the mid-1990s, it now represents about 2% of all maintenance prescribing (Strang, Sheridan *et al.,* 1996; Strang, Manning *et al.,* 2007). Patients usually receive a prescription regularly and pick up sometimes very large doses of medicines from community pharmacists. There is some evidence that quality of care planning and treatment for many of these patients is variable and often poor (Metrebian *et al.,* 2006). Many have long-term chronic health problems.

The quality of care for such patients is often in need of renewed attention and should be reviewed regularly. Where there is clear evidence of benefit, then treatment should continue and be improved for these patients.

There may be some difficulty for service providers in continuing to provide for such 'old system' patients while, within another part of local development, the service is moving to supervised-only IOT for new patients. 'Old system' patients should not have their treatment withdrawn but should be reviewed to consider whether their current treatment optimally meets their needs.

A8.3 References

Haasen C, Verthein U and Degkwitz P (2007) Heroin-Assisted Treatment for Opioid Dependence: Randomised Controlled Trial. *Br J Psychiatry* 2007 191: 55-62.

Metrebian N, Carnwath Z, Mott J, Carnwath T, Stimson G and Sell L (2006) Patients Receiving a Prescription for Diamorphine (Heroin) in the United Kingdom. *Drug and Alcohol Review* 25 (2) 115 – 121.

NTA (2003) *Injectable Heroin (and Injectable Methadone): Potential Roles in Drug Treatment*. London: National Treatment Agency.

Rehm J, Gschwend P, Steffen T, Gutzwiller F, Dobler-Mikola A and Uchtenhagen A (2001) Feasibility, Safety and Efficacy of Injectable Heroin Prescription for Refractory Opioid Addicts: A Follow-up Study. *The Lancet* 358:1417-1420.

Strang J, Manning V, Mayet S, Ridge G, Best D and Sheridan J (2007) Does Prescribing for Opiate Addiction Change After National Guidelines? Methadone and Buprenorphine Prescribing to Opiate Addicts by General Practitioners and Hospital Doctors in England, 1995-2005. *Addiction* 102 (5), 761–770.

Strang J, Sheridan J, Barber N (1996) Prescribing Injectable and Oral Methadone to Opiate Addicts: Results From the 1995 National Postal Survey of Community Pharmacies in England and Wales. *BMJ* 313:270–272.

Van den Brink W, Hendriks VM, Blanken P, Koeter MWJ, van Zwieten BJ and van Ree JM (2003) Medical Prescription of Heroin to Treatment Resistant Heroin Addicts: Two Randomised Controlled Trials. *BMJ* 2003; 327:310-312.

A9 Policy considerations for under-18s

Children and young people (under 18 years) are considered in this document in two distinct ways:

- As the children of drug-misusing parents.
- As young substance misusers in need of treatment in their own right.

Evidence suggests that children of drug-misusing parents are at higher risk than other children of significant harm and of developing substance misuse problems themselves. *Hidden Harm* (ACMD, 2003) has provided a powerful policy driver to ensure that the needs of this group of children and young people receive due attention, including specific consideration of the needs of the children of drug-using parents by clinicians providing drug treatment for their parents.

Young substance misusers may or may not have drug-misusing parents. If they do, they may be at risk of significant harm due to their own and their parents' substance misusing behaviour and lifestyle. The legislative framework concerning child protection is relevant to both the children of drug-using parents and young substance misusers themselves.

The legislative frameworks concerning the provision of interventions, treatment and care for children and young people are relevant to both young substance misusers in treatment and the children of drug-misusing parents who are receiving generic interventions, support or care.

The following section outlines each of the administrations' key legislative and policy frameworks concerning child protection and the provision of services for young people.

A9.1 England

The legislative and policy framework for under-18s is different to that for adults. Inter-agency collaboration is often required to assess and respond to the needs of vulnerable children and young people. Partnership working is a fundamental principle and is encompassed in the Children Act 1989 and 2004, and *Working Together to Safeguard Children: A Guide to Inter-agency Working to Safeguard and Promote the Welfare of Children* (HM Government, 2006).

The National Service Framework for Children, Young People and Maternity Services (DH, 2004) states that drug education should be provided for young people in schools and pupil referral units; primary care trusts (PCTs) should provide information and services on substance use to children and parents; and staff from all agencies should identify young people at risk of misusing drugs or alcohol and provide them with access to prevention and treatment services.

Every Child Matters: Change for Children (HM Government, 2004) and guidance related to the *Every Child Matters* programme state that all professionals working with children should be trained to identify, assess and respond to those with drug use problems; PCTs, local authorities and drug and alcohol action teams (DAATs) should work together to identify vulnerable young people through the common assessment framework (CAF); local behaviour and education support teams (BESTs) should work with children and young people, families and schools to intervene early and prevent problems developing further.

National Specification for Substance Misuse for Juveniles in Custody (Youth Justice Board, 2004) requires that drug use needs are assessed and identified as part of the reception into a facility; that drug education and prevention programmes are provided; and that support programmes acknowledge the needs of young people.

A9.2 Scotland

Children in need of care and protection require a response that addresses their particular needs in a way which protects them and removes or reduces future risk of harm. Existing guidance published in 1998, *Protecting Children – A Shared Responsibility* (Scottish Office, 1998; 2000) remains the crucial reference for all agencies working with children and families who may have to respond to information or allegations that a child is at risk of significant harm or abuse. It should inform local agency guidelines and procedures.

More recently, in Scotland, as part of a three-year programme of sustained activity to reform child protection services, multi-agency child protection committees in all local authority areas have been strengthened to ensure that all relevant partners play their part in identifying and responding to child protection concerns. The reform programme also developed guidance

for children, professionals and their agencies including:

A9.2.1 The Children's Charter

Protecting Children and Young People: The Charter (Scottish Executive, 2004a) sets out what children and young people need and expect to help protect them when they are in danger of being, or already have been, harmed by another person.

It was developed through talking to children and young people who have experienced the need to be protected and supported – but what they are saying is how any child facing difficulties could expect to be treated.

The response to the 13 statements from children is a set of 11 pledges and an outline of work to be done to help deliver on these.

A9.2.2 Framework for Standards

Protecting Children and Young People: The Framework for Standards (Scottish Executive, 2004b) was developed for children and young people, their parents and for all adults and agencies that work with children in Scotland. It is a means for translating the commitments made to children in the Charter into practice. It sets out what each child in Scotland can expect from professionals and agencies to ensure that they are adequately protected and their needs are met. It also sets out what parents or other adults who may report abuse and neglect can expect.

A9.2.3 Child protection committees

Child protection committees in Scotland are equivalent to local safeguarding boards in England and Wales. The Scottish Government has developed a new model for child protection committees focusing on strengths and weaknesses highlighted in earlier reviews. *Protecting Children and Young People: Child Protection Committees* (Scottish Executive, 2005) contains comprehensive details on the role, remit and functions of the committee.

There are 30 child protection committees (CPCs). The structure of each committee emphasises the requirement for leadership and acceptance of responsibility by senior management. Agencies within each CPC area (in particular health, police and the local authority) should work singly and collectively in order to promote the best interests of children and young people. The child protection committee is the inter-agency mechanism to support this work.

A9.2.4 Getting Our Priorities Right

Getting Our Priorities Right (Scottish Executive, 2003) sets out national guidance for all relevant agencies to assess the needs of children of drug-misusing parents, and provide services to safeguard their welfare. It recommends that local ADATs work closely with their local child protection committees to put in place joint policies and procedures for addressing the needs of the children and prevent substance misuse from destroying the lives of more children. It also builds on working together, in planning and delivering services, in assessment and care planning with families, and in multidisciplinary training.

A9.2.5 Getting it Right for Every Child

Getting it Right for Every Child (www.scotland.gov.uk/Topics/People/Young-People/childrensservices/girfec) is a national reform programme that is changing the way adults think and act to help children and young people to grow, develop and reach their full potential. Over the coming years, Getting it Right for Every Child will help practitioners working with children and those associated with them, to remove all of the obstacles that can block children's paths on their journey from birth to adulthood. It is recognised that some of these obstacles are rooted in the different cultures, systems and practices that have emerged through single agency developments. The Getting it Right approach promotes the consideration of children's needs through holistic assessment that identifies the strengths, risks and pressures faced by children. Key information should be shared as appropriate across relevant agencies, based on consent of the child and family wherever possible. Those agencies working directly with adults who are parents are expected to consider the impact on children. Where appropriate, integrated planning should be undertaken with the child and family, developing one plan to which all agencies subscribe. Responses by agencies to need must be appropriate, proportionate and timely.

A9.2.6 Information sharing

At the core of many child protection crises is the failure to share important information between agencies. At the time of writing, Scottish ministers are considering a draft code of practice

on information sharing when there are concerns about a child.

A9.2.7 Definition of a child

For the purposes of support for children in need and their families under the Children (Scotland) Act 1995 'child' means a person under the age of eighteen years. 'Family', in relation to a child, includes any person who has parental responsibilities for a child and any other person with whom the child has been living.

A9.3 Wales

The Welsh Assembly Government's strategic policy with respect to children and young people is governed by the 2004 Children Act, section 25, which creates a statutory framework for local co-operation between local authorities, key partner agencies and other relevant bodies, including the voluntary and community sectors, in order to improve the wellbeing of children in the area.

The Act requires local authorities in Wales to work with their partners to prepare and publish a single children and young people's plan setting out their agreed strategy for discharging their functions in relation to all children and young people. Current statutory duties and responsibilities for the delivery of services remain.

Implementation of the 2004 Act is supported by the development and piloting of a common assessment framework (CAF). The Welsh CAF is being developed for use by all agencies working with children, including those whose primary focus is on adults. It is intended for use with children and young people who have additional needs and those at risk of poor outcomes.

The Welsh Assembly Government published its *National Service Framework for Children, Young People and Maternity Services in Wales* in September 2005. As in England, this is a ten-year strategy that sets national standards to improve services for children and young people.

A9.3.1 Child Safeguarding in Wales

In Wales the Welsh Assembly Government has adopted seven core aims through which it will work to ensure that all children and young people:

- have a flying start in life
- have a comprehensive range of education and learning opportunities
- enjoy the best possible health and are free from abuse, victimisation and exploitation
- have access to play, leisure, sporting and cultural activities
- are listened to, treated with respect, and have their race and cultural identity recognised
- have a safe home and a community which supports physical and emotional wellbeing
- are not disadvantaged by poverty.

These aims are also embodied in the five key outcomes for improving the wellbeing of children from conception to adulthood that are set out in section 25(2) of the Children Act 2004

The document *Safeguarding Children: Working Together Under the Children Act 2004* issued in 2007 sets out how all agencies and professionals should work together to safeguard and promote children's welfare and protect them from harm. It is addressed to all statutory partners on local safeguarding children boards and others whose work brings them into contact with children and families. It is relevant to those working in the statutory, voluntary and independent sectors.

The guidance:

- describes how actions to safeguard children fit within the wider context of support to children and families
- summarises some of the lessons learned from research and experience to date on the nature and impact of abuse and neglect, and how best to operate child protection processes
- sets out the role and responsibilities of different agencies and practitioners
- outlines the way in which joint working arrangements should be agreed, implemented and reviewed through the mechanism of local safeguarding children boards
- sets out the processes which should be followed when there are concerns about a child, and the action which should be taken to safeguard and promote the welfare of children who are suffering, or at risk of suffering, significant harm
- provides guidance on child protection in specific circumstances, including children living away from home

- outlines some important principles which should be followed in work with children and families
- sets out the processes which should be followed if a tragedy occurs, in order to learn lessons and make any necessary improvements in practice to safeguard children
- discusses the importance of multi-agency training, and considers training requirements for effective child protection.

The guidance reflects the principles contained within the United Nations Convention on the Rights of the Child, ratified by the UK Government in 1991 and takes account of the European Convention of Human Rights, in particular Articles 6 and 8. It further takes account of other relevant legislation at the time of publication, but is particularly informed by the requirements of the Children Act 1989 and the Children Act 2004, which provide a comprehensive framework for the care and protection of children.

A9.4 Northern Ireland

The Northern Ireland Assembly Government's strategic policy with respect to children and young people is set out in the document *Our Children and Young People – Our Pledge* (OFMDFM, 2006). This document provides the overall vision for children and young people's lives in Northern Ireland as well as identifying key principles that should underpin children's services and the outcomes that services should be working to achieve. Among the key indicators selected to measure progress towards the achievement of the strategy's outcomes are levels of alcohol and illegal drug use among children and young people.

A9.5 References

ACMD (2003) *Hidden Harm: Responding to the Needs of Children of Problem Drug Users*. London: Advisory Council for the Misuse of Drugs.

DH (2004) *National Service Framework for Children, Young People and Maternity Services*. London: Department of Health.

HM Government (2004) *Every Child Matters. Change for Children*. London: Department for Skills and Education.

HM Government (2006) *Working Together to Safeguard Children: A Guide to Inter-agency Working to Safeguard and Promote the Welfare of Children*. London: The Stationery Office.

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Scottish Office (1998) *Protecting Children – a Shared Responsibility: Guidance on Inter-Agency Co-operation*. Edinburgh: The Scottish Office.

Scottish Office (2000) *Protecting Children – a Shared Responsibility: Guidance for Health Professionals in Scotland: September 1999*. Edinburgh: The Scottish Office. www.scotland.gov.uk/library/documents-w3/pch-00.htm

Youth Justice Board (2004) *National Specification for Substance Misuse for Juveniles in Custody*. London: Youth Justice Board.

A10 Useful documents

A10.1 NICE technology appraisals and guidelines relevant to drug misuse

NICE (2007) *Naltrexone for the Management of Opioid Dependence.* NICE technology appraisal guidance 115. London: National Institute for Health and Clinical Excellence.

NICE (2007) *Methadone and Buprenorphine for the Management of Opioid Dependence.* NICE technology appraisal guidance 114. London: National Institute for Health and Clinical Excellence.

NICE (2007) *Drug Misuse: Opioid Detoxification.* NICE clinical guideline 52. London: National Institute for Health and Clinical Excellence.

NICE (2007) *Drug Misuse: Psychosocial Interventions.* NICE clinical guideline 51. London: National Institute for Health and Clinical Excellence.

NICE (2007) *Community-based Interventions to Reduce Substance Misuse Among Vulnerable and Disadvantaged Children and Young People.* NICE public health intervention guidance 4. London: National Institute for Health and Clinical Excellence.

All documents are available at www.nice.org.uk.

A10.2 Other drug misuse clinical guidelines

A10.2.1 Prisons

Department of Health (2006) *Clinical Management of Drug Dependence in the Adult Prison Setting*. London: Department of Health.

A10.2.2 Police custody

AFP and RCPsych (2006) *Substance Misuse Detainees in Police Custody: Guidelines for Clinical Management (third edition)*. London: Royal College of Psychiatrists and Association of Forensic Physicians.
Available at www.rcpsych.ac.uk/files/pdfversion/cr132.pdf

A10.3 Service guidance

A10.3.1 England

National Treatment Agency (2006). *Models of Care for Treatment of Adult Drug Misusers: Update 2006*. London: National Treatment Agency for Substance Misuse.

National Treatment Agency (2006). *Care Planning Practice Guidance: Update 2007*. London: National Treatment Agency for Substance Misuse.

Available at www.nta.nhs.uk

A10.3.2 Scotland

Scottish Executive (2006) *Good Practice Guide on Consent for Health Professionals in NHSScotland*. Edinburgh: Scottish Executive. Available at http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf

Scottish Executive Effective Interventions Unit (2003) *Integrated Care for Drug Users: Digest of Tools Used in the Assessment Process and Core Data Sets.* Edinburgh: Scottish Executive Effective Interventions Unit. Available at http://www.scotland.gov.uk/Publications/2003/05/17143/21872.

Scottish Executive (2006). *National Quality Standards for Substance Misuse Services.* Edinburgh: Scottish Executive. Available at http://www.scotland.gov.uk/Publications/2006/09/25092710/0.

NHS Quality Improvement Scotland (2005) *Clinical Governance & Risk Management: Achieving Safe, Effective, Patient-Focused Care and Services – National Standards* . Edinburgh: NHS Quality Improvement Scotland 2005. Available at http://www.nhshealthquality.org/nhsqis/files/CGRM_CSF_Oct05.pdf.

SACDM and SACAM (2003) *Mind the Gaps: Meeting the Needs of People with Co-occurring Substance Misuse and Mental Health Problems*. Report of the joint working group. Edinburgh: Scottish Executive.

Scottish Executive (2003) *Getting our Priorities Right – Good Practice Guidance for Working with Children and Families Affected by Substance Misuse*. Edinburgh: Scottish Executive.

Scottish Executive (2005) *Getting it Right for Every Child: Proposals for Action*. Edinburgh: Scottish Executive.

A10.3.3 Wales

Substance Misuse Treatment Framework for Wales (Welsh Assembly Government). Available at http://new.wales.gov.uk/topics/housingandcommunity/safety/substancemisuse/treatframe/?lang=en

A10.4 Other issues

British Pain Society (2006) *Pain and Substance Misuse: Improving the Patient Experience, a Consensus Document*. London: British Pain Society. Available at www.britishpainsociety.org.

A range of RCGP guidance for working with drug misusers in primary care is available on the SMMGP website at www.smmgp.org.uk

Møller L, Stöver H, Jürgens R, Gatherer A and Nikogosian H (eds) (2007) *Health in Prisons. A WHO Guide to the Essentials in Prison Health*. Geneva: World Health Organization.

A11 Contacts

A11.1 Drug treatment monitoring systems

A11.1.1 England

National Drug Treatment Monitoring System
Tel: 020 7261 8902
www.nta.nhs.uk/areas/ndtms/regional_NDTMS_contacts.aspx for regional contacts

A11.1.2 Scotland

The Scottish Drug Misuse Database
Tel: 0131 275 7097
www.drugmisuse.isdscotland.org/sdmd/sdmd.htm

A11.1.3 Wales

Welsh National Database
Tel: 02920 503343
www.wales.gov.uk/substancemisuse

A11.1.4 Northern Ireland

Northern Ireland Drug Misuse Database
Tel: 02890 522501
www.dhsspsni.gov.uk/index/stats_research/stats-drugs.htm

A11.2 Other contacts

ADFAM (families, drugs and alcohol)
25 Corsham Street
London N1 6DR
Tel: 020 7553 7640
Fax: 020 7253 7991
Email: admin@adfam.org.uk
www.adfam.org.uk

Alcohol Concern
First floor, 8 Shelton St
London WC2H 9JR
Tel: 020 7395 4000
Fax: 0202 7395 4005
E-mail contact@alcoholconcern.org.uk
www.alcoholconcern.org.uk

Alcohol Focus Scotland
Second Floor
166 Buchanan Street
Glasgow G1 2LW
Tel: 0141 572 6700
Fax: 0141 333 1606
Email: enquiries@alcohol-focus-scotland.org.uk
www.alcohol-focus-scotland.org

ASH Scotland
8 Frederick Street
Edinburgh EH2 2HB
Tel: 0131 225 4725
Fax: 0131 225 4759
Email: ashscotland@ashscotland.org.uk

Association of Nurses in Substance Abuse
37 Star Street
Ware SG12 7AA
Tel: 0870 241 3503
Fax: 01920 462730
Email: ansa@profbriefings.co.uk,
ansa@fsmail.net (admin)
www.ansa.uk.net

Association of Nurses in Substance Abuse Scotland
Email: chair@ansa-scotland.org

Department of Health Substance Misuse Team
6th Floor Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7972 2000
Fax: 020 7972 4998
Email: drugs@dh.gsi.gov.uk
www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/SubstanceMisuse/fs/en

Department of Health, Social Services and Public Safety Alcohol and Drug Policy Branch
Email: nidast@dhsspsni.gov.uk
www.dhsspsni.gov.uk

DrugScope
40 Bermondsey Street
London SE1 3UD
Tel: 020 7928 1211
Fax: 020 7928 1771
Email: info@drugscope.org.uk
www.drugscope.co.uk

Home Office Drug Strategy Directorate
Horseferry House
Dean Ryle Street
London SW1P 2AW
Tel: 020 7035 4848
Fax: 020 7035 4745
Email: public.enquiries@homeoffice.gsi.gov.uk
www.homeoffice.gov.uk/drugs

Know the Score – Scotland's drugs information gateway
Tel: 0800 587 5879

Narcotics Anonymous (NA)
202 City Road
London EC1V 2PH
Helpline: 0845 3733366
Tel: 020 7251 4007
Fax: 020 7251 4006
Email: ukso@ukna.org
www.ukna.org

National Institute for Health and Clinical Excellence (NICE)
MidCity Place
71 High Holborn
London WC1V 6NA
Tel: 020 7067 5800
Fax: 020 7067 5801
Email: nice@nice.org.uk
www.nice.org.uk

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
www.nta.nhs.uk

Pharmacy Misuse Advisory Group (PharMAG)
Email: marion.walker@berkshire.nhs.uk
(secretary)

Release (legal and heroin helplines)
388 Old Street
London EC1V 9LT
Helpline: 0845 4500 215
Tel: 020 7729 5255
Fax: 020 7729 2599
Email: ask@release.org.uk
www.release.org.uk

Royal College of General Practitioners Substance Misuse Unit
14 Princes Gate
London SW7 1PU
Tel: 0845 456 4041
Fax: 020 7225 3047
E-mail info@rcgp.org.uk
www.rcgp.org.uk/continuing_the_gp_journey/substance_misuse.aspx

Royal College of General Practitioners Scotland
25 Queen Street
Edinburgh EH2 1JX
Tel: 0131 260 6800
Fax: 0131 260 6836
www.rcgp.org.uk/councils__faculties/rcgp_scotland.aspx

Royal College of Psychiatrists Substance Misuse Faculty
17 Belgrave Square
London SW1X 8PG
Tel: 020 7235 2351
Fax: 020 7245 1231
Email: rcpsych@rcpsych.ac.uk
www.rcpsych.ac.uk/college/faculties/addictions.aspx

Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London SE1 7JN
Tel: 020 7735 9141
Fax: 020 7735 7629
Email: enquiries@rpsgb.org
www.rpsgb.org.uk

Scottish Drugs Forum
91 Mitchell Street
Glasgow G1 3LN
Tel: 0141 221 1175
Fax: 0141 248 6414
Email: enquiries@sdf.org.uk
www.sdf.org.uk

Scottish Government Public Health and Substance Misuse Division
Area 3EN
St Andrews House
Regent Road
Edinburgh EH1 3DG
Tel: 0131 244 2576
www.scotland.gov.uk/topics/health

Scottish Government Drugs Policy Unit
Area 1W South
St Andrew's House
Regent Road
Edinburgh EH1 3DG
Tel: 0131 244 2208
www.scotland.gov.uk

Specialist Clinical Addiction Network (SCAN)
(National network for UK addiction specialists)
8th Floor. Hercules House
Hercules Road
London SE1 7DU
Tel: 020 7261 8728
Fax: 020 7261 8883 (marked "for the attention of SCAN")
Email: amy.wolstenholme@nta-nhs.org.uk
www.scan.uk.net

Substance Misuse Management in General Practice
c/o Bolton, Salford and Trafford Mental Health NHS Trust
Bury New Road
Prestwich
Manchester M25 3BL
Tel: 0161 772 4641
Fax: 0161 772 3783
Email: smmgp@freeuk.com (Jim Barnard)
www.smmgp.org.uk

TACADE (Personal, Social, Health and Citizenship Education for Children and Young People)
Old Exchange Buildings
6 St Ann's Passage
King Street
Manchester M2 6AD
Tel: 0161 836 6850
Fax: 0161 836 6859
Email: ho@tacade.co.uk
www.tacade.com

Tackling Drugs, Changing Lives (cross-government website for clinicians)
www.drugs.gov.uk

Talk to Frank (national drugs helpline)
Tel: 0800 77 66 00
Email: frank@talktofrank.com
www.talktofrank.com
Free confidential drugs information and advice 24 hours a day, including information on local services.

Wales Drug and Alcohol Helpline
Tel: 0800 633 5588

Welsh Assembly Government Substance Misuse Policy Development Team
Merthyr Tydfil Office
Rhydycar
Merthyr Tydfil CF48 1UZ
Tel: 01685 729067
Fax: 01685 729547
Email: john.lenaghan@wales.gsi.gov.uk
http://new.wales.gov.uk/topics/housingandcommunity/safety/substancemisuse/?lang=en

To find out the contact details for the nearest drug action team partnership in England, see the www.drugs.gov.uk website.

GLOSSARY

Amfetamine (including dexamfetamine) is used in line with 2004 MHRA changes to bring the British Approved Name (BAN) of medicinal products in line with the recommended International Nonproprietary Name (rINN). The convention is extended to methylamfetamine where it is used to describe a medicinal product, although this is not specifically named in the BAN or rINN lists. It is not used to describe non-medicinal products (illicit drugs) – in these cases the established "ph" spellings (amphetamine(s), dexamphetamine, methamphetamine) are used.

Carer is used only to describe a partner, child, relative, friend or neighbour who, without payment, provides help and support for a drug-misusing patient. Paid, professional carers provided under a care plan are not included.

Clinician is used throughout the 2007 Clinical Guidelines to refer to the range of professionals working in treatment settings with drug misusers. In the past, the Clinical Guidelines were targeted principally at doctors and, while doctors are still the primary audience, clinicians increasingly covers other professions, including nurses, pharmacists, psychologists and drug workers.

Dependence vs. addiction. Dependence is the preferred term in these 2007 Clinical Guidelines. The term 'addiction' has generally been avoided except in relation to addiction psychiatry.

Drug is used to describe a psychoactive substance (other than alcohol) used illicitly or illegally, except in the term 'controlled drug' where it refers to a substance defined by and controlled under the Misuse of Drugs Act.

Drug misuse is the generally preferred term in the 2007 Clinical Guidelines for illicit or illegal drug use which is causing sufficient harm to require treatment. Someone who engages in drug misuse is called a 'drug misuser'. However, some generally accepted compound terms, such as 'injecting drug user' (or IDU), have been kept. 'Problem drug user' (or PDU) is also retained where it has the specific definition of a heroin or crack cocaine misuser.

Medicine is used to describe a substance made up into a suitable formulation for use in treatment, except where the term 'controlled drug' is used to describe a substance defined by and controlled under the Misuse of Drugs Act.

The term 'drug' may also be used when describing the properties of a chemical used as a medicine, or when used in a widely accepted compound term such as 'non-steroidal anti-inflammatory drug' or Z-drug.

Opiate vs. opioid. Opioid is used in line with the WHO definition to refer to the whole group of natural, semi-synthetic and synthetic compounds that act on opioid receptors. Opiate is used for substances derived from the poppy plant and for the semi-synthetic drug diamorphine (heroin). Although drug misusers may use a range of opioids, most will have developed problems while using heroin therefore, in line with common usage, we refer to opiate misusers.

Substance is used to describe the wider range of drugs, volatile substances and alcohol often misused by young people.

These conventions may not be maintained where the text is quoted from elsewhere.

NHS
National Treatment Agency
for Substance Misuse

Production supported by the NTA