Auditing drug misuse treatment

December 2008
The National Treatment Agency for Substance Misuse

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

The NTA works in partnership with national, regional and local agencies to:

- Ensure the efficient use of public funding to support effective, appropriate and accessible local services
- Promote evidence-based and coordinated practice, by distilling and disseminating best practice
- Improve performance by developing standards for treatment, promoting user and carer involvement, and expanding and developing the drug treatment workforce
- Monitor and develop the effectiveness of treatment.

The NTA has achieved the Department of Health’s targets to:

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

It is now in the front-line of a cross-Government drive to reduce the harm caused by drugs and its task is to improve the quality of treatment in order to maximise the benefit to individuals, families and communities.

The NTA will be judged against its ability to deliver better treatment and better treatment outcomes for the diverse range of people who need it.
To provide guidance to help local drug partnerships and their clinical providers who wish to audit practice against recent clinical guidance for drug misuse treatment

Auditing drug misuse treatment

Steve Taylor, National Treatment Agency

December 2008

Local drug partnerships
Drug treatment service providers
Drug treatment commissioners
Joint commissioning managers

Initial guidance on auditing drug treatment practice against recent clinical guidance

• Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH and devolved administrations, 2007)
• Clinical Governance in Drug Treatment: A Good Practice Guide for Providers and Commissioners (NTA, 2008)
• Communication from NTA regional managers to joint commissioning managers (NTA, 2007)
• Methadone and Buprenorphine for the Management of Opioid Dependence. TA114 (NICE, 2007)
• Naltrexone for the Management of Opioid Dependence. TA115 (NICE, 2007)
• Drug Misuse: Psychosocial Interventions. CG51 (NICE, 2007)
• Drug Misuse: Opioid Detoxification. CG52 (NICE, 2007)

None required but local drug partnerships are invited to use the advice with their providers if they wish to audit against recent clinical guidance for drug misuse treatment

8th floor, Hercules House, Hercules Road, London SE1 7DU.
Tel: 020 7261 8801. Fax: 020 7261 8883
Email: nta.enquiries@nta-nhs.org.uk
Website: www.nta.nhs.uk

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1 Executive summary

This guidance is intended to help drug partnerships and treatment providers who wish to audit their drug misuse treatment in response to the recent publication of clinical guidance: Drug Misuse and Dependence: UK Guidelines on Clinical Management (2007 Clinical Guidelines) (DH and devolved administration, 2007) and NICE guidance on drug misuse (NICE 2007a, b, c, d). It contains advice designed to support the use of audit in effective implementation of this clinical guidance. It covers suitable topics for audit rather than how to conduct audit, which is covered in depth in many other publications.

This audit guidance is structured on the assumption that a stepped approach is likely to be employed at a local level in response to the recent authoritative suite of clinical guidance, including:

- A review of current service policies, protocols and procedures against the new clinical guidance
- An audit of the current clinical governance framework (at service provider, commissioner and/or partnership levels)
- Local agreements on specific topics for clinical audit that are based on the new treatment guidance (as well as other local priorities).

NICE already publishes detailed audit criteria for its technology appraisals and clinical guidelines, and many NHS organisations will have made use of these.

The 2007 Clinical Guidelines are considered an authoritative marker of good practice in the clinical management of drug misuse and are used in inspection and review, including the recent annual NTA/Healthcare Commission service reviews. These guidelines would also be considered if a service’s or individual’s professional practice was being reviewed. It will therefore clearly be of potential value for NHS and other organisations to audit their practice against the 2007 Clinical Guidelines in the same way as for NICE guidance.

Chapter Two introduces key concepts of clinical audit and reiterates its key principles but does not attempt a full description. It gives useful references and it provides an introduction for the more detailed focus of Chapter Three on particular topics.

Chapter Three includes a preliminary section that focuses on clinical topics that may be particularly suitable for including in a local review of service policies, protocols and procedures and it elaborates on these briefly. The chapter also includes its main sections, Sections A and B, which list in table form detailed criteria and data sources that may be useful in developing audits both of the clinical governance framework and of specific topic concerning treatment delivery. These sections are likely to be of interest to drug treatment providers who wish to assure themselves that key recent clinical guidance is being properly implemented as intended, and to drug partnerships involved in strategic developments and in the commissioning and delivery of effective care.

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1 NICE produces audit criteria for:
- Technology appraisal 114 (methadone and buprenorphine)
- Technology appraisal 115 (naltrexone)
- Drug misuse clinical guidelines 51 (psychosocial) and 52 (detoxification) and public health intervention guidance 4.

All are available at [www.nice.org.uk](http://www.nice.org.uk)
Section A of Chapter Three identifies criteria and data sources that can be used for a systematic audit of the clinical governance framework across a system of drug treatment. Given that clinical governance is a statutory mechanism for commissioners and providers within the NHS that is intended to help drive improvements in the quality of clinical care, this section has been kept separate from others. It is widely recognised that clinical governance is also an important mechanism for non-statutory treatment services, particularly those commissioned through the NHS. This reflects guidance in the NTA’s forthcoming good practice guide on clinical governance.

Section B of Chapter Three identifies criteria and data sources that can be used for carrying out clinical audits of a wide range of specific treatment topics:

- **B1**: The first sub-section focuses on a topic of recent clinical interest, the possible use of inappropriate prescribing practices within drug treatment – as discussed in the statement produced by the clinical guidelines independent expert working group in 2007 (appendix A). Auditing this particular topic will enable providers to assure appropriate practice locally and may be useful to enable partnerships to assure NTA regional teams about local practice.

- **B2**: This larger subsection focuses on providing support for implementation of audit for a wide range of other clinical topic areas drawn directly from the 2007 Clinical Guidelines (DH & devolved administrations, 2007) and the NICE suite of guidance (NICE 2007a, b, c, d). The subsection provides, in particular, a useful checklist of topic areas in which audit might be beneficial. The topics and the criteria and data sources are not exhaustive, and more detailed audit criteria may still need to be developed to meet local need or preferences.

This guidance has been drawn up on the assumption that audit topics will be agreed locally and normally within a wider system of clinical governance; whether that system is currently in its early stages of development, is small but appropriate to the size of the service, or part of a more highly-developed system (for example, as within some mental health trusts). This guidance on topics is not dependent on such differences in the system of governance.

Given the central role of clinical governance in improving the quality of care in drug treatment services, and the responsibilities of providers and commissioners in this, the guidance is likely to be of interest to commissioners and drug partnerships, as well as providers of care. This recognises that there is already active dialogue locally about the appropriate inclusion of specific clinical governance issues within partnership business priorities, within the work of partnership-wide provider reference groups, and explicitly in SLAs between commissioners and provider services. Any such dialogue is more likely to be effective if it is based on a clear understanding of statutory and professional expectations for clinical governance within most services and the implications for appropriate resources, capacity and support. The choice of topics and scale of audit activity locally will be influenced by dialogue on such wider issues.

While this guidance is aimed at helping services in developing particular clinical audits, the exact framework, processes and choice of topics for such audits will need to be determined locally. It is widely recognised that these are often best chosen within multidisciplinary teams and with active service user input when appropriate, and it is not intended that this guidance should be restrictive. In addition, the focus on criteria and topics is not intended to dictate any particular format. For example, the criteria suggested could be incorporated in multi-agency audits, peer audits, partnership-wide audits, and audits that allow for careful pooling of results.
2 Auditing implementation of clinical guidance

2.1 Objective

The main aim of this audit guidance is to provide assistance to drug partnerships and drug misuse treatment providers (including NHS trusts, PCTs and GP practices, the prison service, and inpatient, residential and community-based treatment settings) that wish to determine whether they are implementing particular elements of their practice consistent with the recent authoritative suite of clinical guidance on the management of drug misuse.

The implementation of a typical audit cycle allows progress to be reviewed or quality criteria appropriately amended, and this process is summarised briefly below. The audit cycle is transferable to use with a wide range of audit topics and not just those described within this document.

There are particular expectations on NHS organisations to implement and audit NICE guidance. Guidance on this can be found in NICE’s guidance, Principles for Best Practice in Clinical Audit (NICE, CHI, RCN, University of Leicester, Radcliffe Medical Press, 2002). This NTA drug misuse treatment audit guidance is intended to complement this generic guidance.

2.2 Introduction

Audit is a process to monitor and improve client care and outcomes. It involves evaluation against explicit criteria, and aims to determine whether guidelines are being followed and standards met, and whether best practice is being applied. It is distinct from research, which is conducted with the aim of generating new knowledge that determines what best practice is.

Auditing clinical governance arrangements will help partnerships to identify strengths and weaknesses of systems to support appropriate clinical governance and clinical audit locally.

An initial and important clinical governance priority for many providers in the context of new clinical guidance may be to actively review their current policies and protocols and to update these as appropriate. This is addressed in greater detail in Chapter Three.

However, in addition to reviewing policies and procedures, most drug treatment providers will also choose their own clinical audit priorities and where relevant will use criteria drawn from the most up-to-date and authoritative sources (such as the recent suite of UK and NICE clinical guidance). Audit is a key method for providers to determine whether their current practice is in line with such guidance and any other appropriate criteria determined locally.

Agreeing local priorities for audit collaborativey between providers, within or across partnerships, may help reduce duplication or waste of effort, improve opportunities for learning and, in some cases, allow for the possibility of collaboration on implementation of audits.

When feasible and appropriate, service audit priorities can usefully incorporate key external priorities, preferably through an inclusive system of discussion with service commissioners and/or with the local partnership(s). While audit is primarily a bottom-up process, priorities for commissioners will often coincide with those of providers, and can be very effectively addressed through the use of audit.
Where practicable, and to complete the full audit cycle, the audit should be repeated on a regular basis to monitor implementation and to enable comparisons of practice and results over time.

2.3 The rationale for audit

Audit can be driven by a bottom-up process of clinical governance, with teams wanting to secure improvement in client care and outcomes. It has been usual for audit priorities to be determined by provider teams in a multi-disciplinary process within a culture of clinical governance. This inclusive process has been shown to improve engagement in real change and to improve impact.

However, audit topics can also be strongly influenced by external quality assurance requirements. Priorities for audit may also be influenced by pressures arising from national, regional and wider local priorities.

In drug treatment, the NTA/Healthcare Commission service reviews are effectively external quality assurance requirements but drug treatment providers are involved in developing the criteria. The reviews have proven very successful in providing a benchmark of the quality of drug treatment and information on areas of weakness, against which improvement can be planned.

Reviews have covered:

- Community prescribing services, and care planning and coordination (2005/6)
- Commissioning drug treatment systems and harm reduction services (2006/7)
- Diversity and residential services (inpatient and rehabilitation services) (2007/8).

More broadly, the Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in Standards for Better Health (DH, 2004). The implementation of recent clinical guidance will help organisations meet developmental standard D13. Standard C5(d) states that “Healthcare organisations ensure that clinicians participate in regular clinical audit and reviews of clinical services”.

Providers and commissioners/partnerships are likely to want to consider how best to promote the development of sustainable clinical governance and audit processes within and across their provider services, and may wish to consider appropriate agreements and allocation from existing resources to support this activity. Given the importance of developing a culture of clinical governance, the role of externally-driven audits in the absence of this capacity may be likely to deliver limited and short-lived effects. A dialogue between commissioners and providers may be particularly useful in determining any such audit priorities for services and in developing appropriate capacity for delivering this as part of the wider development of effective systems of audit.

The timing of audit in response to recent clinical guidance will need to be planned alongside audits of any other relevant guidance, in order to be able to feed into appropriate reporting and planning cycles, including treatment planning.
2.4 Suggested audit topics

As part of this guidance, the NTA has identified topics that might be considered for local audit and – where these already exist – has suggested suitable audit criteria and data sources. These are developed in detail in Chapter Three. The topics for audit are organised into two main sections according to the two main approaches likely to be used by partnerships and their providers: auditing of the framework of clinical governance in which clinical audit sits; and auditing of specific treatment topics.

Section A

This covers the auditing of the clinical governance framework of the drug treatment system. Given that clinical governance is the mechanism through which many of the improvements in clinical practice suggested by recent clinical guidance will be best assured, this section is likely to be considered particularly useful by partnerships. It will assist them in the delivery of a comprehensive and systematic audit of their clinical governance structures. This reflects forthcoming NTA guidance on clinical governance in drug treatment.

Section B

This section provides assistance on the auditing of a wide range of specific treatment topics:

- **B1**: This first sub-section focuses on a topic of recent clinical interest, namely the possibility of the use of inappropriate prescribing practices, as discussed in the statement produced by the clinical guidelines independent expert working group in 2007 (appendix A). Audit of this particular topic will enable providers to assure appropriate practice locally and may be useful to enable partnerships to assure NTA regional teams about local practice.

- **B2**: This larger subsection focuses on providing support for implementation of audit for a wide range of other clinical topic areas drawn directly from the 2007 Clinical Guidelines (DH & devolved administrations, 2007) and the NICE suite of guidance (NICE 2007a, b, c, d). The subsection provides, in particular, a useful checklist of areas in which audit might be beneficial but for which more detailed audit criteria may still need to be drawn up locally.

This guidance does not include an audit template because many partnerships and providers will have their own well-developed systems for reporting audit results within the organisation and for retaining results to allow progress over time to be monitored. However, anyone wanting an example of a ready-to-use audit template could refer to the one provided by NICE in its audit criteria for technology appraisals TA114 and TA115: http://www.nice.org.uk/nicemedia/pdf/word/TA114AuditCriteria.doc (NICE 2007 e, f). Such templates are well worth reviewing as they can help develop systems that:

- Ensure clarity of inclusion and exclusion criteria

- Clearly define key terms and quality criteria

- Ensure rigour in determining data sources and data recording.

Such an approach will ensure greater ease in the systematic collection of data and its subsequent analysis against agreed criteria.
The topics for audit cover a wide range of issues and are applicable at different levels:

- Some audit topics may apply to some types of providers only (e.g. inpatient services), and some topics may not apply at all (e.g. prescribing if a service does not prescribe substitute medication). Alternatively, such topics may need to be interpreted for that service (e.g. ensuring at least that there is a clear or effective pathway into obtaining access to interventions it does not provide itself).
- Some topics will be clearly relevant to all services in a partnership area (e.g. elements of assessment) and providers may complete these individually or could consider the value of such audits across a number of providers.
- Some topics may be relevant across the partnership at a system level (e.g. auditing clinical governance frameworks) and could be audited across the whole partnership against appropriate criteria that encompass all relevant providers.

While the priority for many services is likely to be the development of effective local audit(s), partnerships and their providers might also wish to consider the potential advantages of agreeing one or more topics for audit across a number of providers. Such audits would require appropriate methodologies to ensure consistent data collection and analysis, and to ensure an agreed level of confidentiality for individual providers and their clients.

### Other NICE guidance

NICE has published a range of other guidance that is not covered in this document but against which practice may be audited.

In addition to the clinical guidelines and technology appraisals specific to drug misuse, NICE has also produced public health intervention guidance on Community-Based Interventions to Reduce Substance Misuse Among Vulnerable and Disadvantaged Children and Young People (NICE, 2007h). Audit criteria for this guidance are not covered here.

There is some limited cross-reference in this document to NICE guidelines that are not specific to drug misuse, principally those covering aspects of mental health treatment (NICE 2002, 2006a, 2007i, 2007j) and smoking cessation (NICE, 2006b). Some of NICE’s other guidance also has relevance for drug treatment services but is not covered here. This includes but is not limited to:

- One to One Interventions to Reduce the Transmission of Sexually Transmitted Infections (STIs) Including HIV, and to Reduce the Rate of Under 18 Conceptions, Especially Among Vulnerable and At Risk Groups (NICE, 2007k)

**Box 1. NICE guidance not covered in this document**

### 2.5 Planning audits

Audit topics, timetables and processes will need to be agreed within an individual service through the usual management and clinical governance mechanisms. Management teams and/or boards should agree proposed audits and it may also be appropriate to consult with commissioners or the local drugs partnership in some cases.
Agreement between services or within the partnership may be appropriate if multiprovider or partnership-wide audit is being considered.

2.6 Partnership level audits

Most focus will be on developing good practice in multidisciplinary, single-provider audits and in the development of the process of the audit cycle within those providers, where appropriate. This will take place within the framework of any local clinical governance framework that exists. Most single-provider audits will involve self-audit though this can utilise a range of perspectives and roles from within a multidisciplinary team. Some providers also use internal peer review or peer audit involving staff from different parts of a larger service where this is feasible.

Any audit of agreed topics across a partnership can be more complex than single-provider audit. Standards may need to be agreed for disparate providers, and systems will be required to ensure consistent data collection and analysis. If the results of the audit are to be shared, there may need to be an agreed level of confidentiality for individual providers.

Spreading the net of an audit beyond a single provider brings in the possibility of an external peer audit, in which a group of services (e.g. those in a particular area or of a particular service type) come together to form a group in which they will assess each other’s services using agreed standards. Peer audits can bring additional but still locally-relevant perspectives, and make good use of resources.

Within a partnership, a peer audit could involve one local treatment service being audited by staff from another. However, the inter-connectedness of services (and staff) within a partnership may make it difficult for the auditing staff to be objective or openly critical, or for the audited service to accept the results of the audit. A peer audit of a treatment service in one partnership by staff from another partnership area might also be considered.

Where an audit involves analysis of patient records, it may be necessary to either anonymise the records or for client consent to be sought if it is intended that staff from outside the treatment service will audit the records. A range of other governance processes should also be in place to ensure that client confidentiality and data protection requirements are complied with.

An example of peer audit between Devon and Torbay Drug Action Teams is described in the NTA’s guidance on Good Practice in Care Planning (NTA, 2007), which describes examples of good practice identified following the 2005/6 NTA/Healthcare Commission Improvement Review of community prescribing, and care planning and coordination.

2.7 Population groups to be included in audits

Audit against clinical guidance can include all adults and young people who misuse opioids, cannabis, stimulants or other drugs of misuse.

However, some proposed audit topics are only relevant to specific population subsets. For example, compliance with prescribing guidance will only need to be audited for clients on prescribed medication; guidance relating to drug-misusing parents and their children will only need to be audited for clients with children.
2.8 Samples for audits

Where a relevant population group has been identified, it may be appropriate to further determine a smaller, more specific cohort for audit. For example, a sample of new clients (e.g. those having entered treatment in the last six months) may give a better picture of a clinical practice under consideration. For example, levels of supervised consumption for recent entrants may be more relevant to current practice than levels of supervised consumption for all those on opioid substitution. If there were agreed criteria for both, both could be audited.

NICE recommends in its audit criteria for drug misuse (2007g) that, "If a sample of cases is selected for audit, approximately 50 are ideally needed to provide reliable evidence. However, even if organisations are unable to commit to audits of this scale there is considerable value in undertaking a structured audit of the guidance with a smaller sample". It is important to determine an appropriate sample size for each audit that will provide representative and useful results. The Clinical Governance Support Team provided additional guidance on sample sizes (see Box 2).

2.9 Data sources for audits

Audits may require data to be collected from a range of sources, including patient records, patient administration systems, local policy documents and protocols or procedures, prescription records, and drug-related death and critical incident reports.

For many topics, ‘hard’ data sources may not be available or sufficient. Those conducting audits at a partnership, trust or other provider organisational level will often need to consider additional and alternative sources of data, including discussion with service managers, staff and service users.

2.10 Frequency of audits

An audit should preferably be repeated periodically depending on the organisation’s audit strategy and the time required to implement any necessary action arising from the first audit. This will allow progress to be monitored and greatly enhances the effectiveness of audit in contributing to quality improvement. However, the frequency of repeat audits needs to be considered alongside other priorities for audit.

2.11 What happens to audit results?

In most areas there is a well-established process, within a statutory NHS framework of clinical governance, for the local analysis and discussion of audit results. Where there is an identified lack of compliance with recognised criteria this process normally includes the development of an action plan for improvement, often as part of a quality cycle. Progress against an improvement plan would usually be monitored and reported to relevant parties.

To whom audit results are reported will depend on the nature of the audit and should usually have been agreed at the outset. Reporting may only be within the local substance misuse organisation itself, within a wider system of clinical governance (e.g. in a mental health trust, PCT or voluntary sector organisation clinical governance framework) or, by agreement, to other providers, commissioners or the local drugs partnership.
As part of an effective system of clinical governance and in order to assure themselves of compliance, it is good practice for NHS and voluntary sector drug treatment service management boards to receive regular reports on the implementation of clinical guidance, highlighting areas of non-compliance and risk. It may be good practice for other stakeholders also to receive these reports because they may want to take account of the results when taking action to contribute, for example, to:

- National commitments set out in Choosing Health: Making Healthy Choices Easier (DH, 2004)
- The national drug strategy (HMG, 2008)
- Local area agreements.

### Audit sample sizes

Guidance published by the Clinical Governance Support Team (Copeland, 2005) says the following about sample sizes:

8.6 The sample chosen for audit should be small enough to allow for rapid data acquisition but large enough to be representative. In some audits the sample will be time driven and in others it will be numerical. If the data acquisition time is too long interest will be lost and data completeness will often suffer.

8.7 In numerical audits the number of cases selected should reflect the commonness of the condition or therapy, but should be of reasonable number to draw subsequent conclusions.

8.8 In time based audits of common conditions one to three months should be adequate for the majority of audits.

8.9 The IT department of a Trust or central information from the Information Centre should be able to provide an estimate of the volume of a particular clinical condition or treatment to allow the sample size to be determined. The sample size, however, must be statistically sound if the results are to be credible.

8.10 … medical audits function well with both numerical and time related samples. It should be remembered particularly with regard to time related audits that seasons can have a dramatic effect on such samples. In primary care and the acute sector, process audit often shows deterioration in the winter and this should be factored into audit design.

Box 2. Audit sample sizes – guidance from the Clinical Governance Support Team.
3 Topics for auditing clinical practice against drug misuse clinical guidance

3.1 A stepped approach: a review of current policies, protocols and procedures

Services may find it helpful to conduct some simple paper-based or multidisciplinary team reviews of their current policies and procedures as a first step in response to the new suite of clinical guidance. These reviews would usually mean comparing local policies, protocols and procedures against key guidance documents, including the 2007 Clinical Guidelines and NICE guidance on drug misuse.

A staged process for this review might include:

- Mapping the new guidance and prioritising which issues to address first
- Competent staff (clinicians, managers) reading and digesting the guidance in detail
- Clinical/management team(s) discussing the key issues to be considered, the policies, protocols and procedures to be reviewed, and the changes required
- Appropriate individuals/groups being commissioned to make the changes in liaison with service users where appropriate
- Clinical/management team(s) approving changes
- The new versions of policies, protocols and procedures being disseminated to staff and service users as appropriate.

Services may see this process of reviewing policies and procedures as a higher priority than initiating related audit topics in the first phase of a stepped approach to responding to the new suite of guidance. However, these do not always need to be mutually exclusive streams of work and it is likely that all services will consider that one or more key clinical audits remain a priority alongside this activity.

Typical documents that are likely to require updating in the light of the recent suite of clinical guidance are suggested below. Audit topics which might use these documents as their principal sources of criteria and/or data are also marked in the tables in sections A and B.

Suggested topics for policy, protocol and procedure² review:

- Prescribing policies, including induction with dose titration, doses of methadone and buprenorphine within national guidelines, doses increased or decreased and antidepressants prescribed only in response to clinical need, detoxification regimens and choice of medication, benzodiazepines, injectables, etc.
- Incident reporting
- Information sharing – case management protocols with externally coordinated services; between prescriber, keyworker and pharmacist
- Multi-Agency Public Protection Arrangements (MAPPA)
- Care Programme Approach interface
- Drug testing – screening and confirmation

² ‘Policy’, ‘protocol’ and ‘procedure’ are often used interchangeably or have different definitions in different organisations so this document makes no attempt to differentiate them.
Management of drug overdoses
Responding to patients attending A&E or admitted onto wards
Risk management – serious and untoward incidents
Complaints
User and carer involvement
Supervision of staff
Infection control
Assessment, care planning and review
Care coordination (pregnancy, prisons, mental health, etc)
Drugs, drinking and driving.

3.2 Notes on the tables (pages 16-25)
As described in section 2.4, the following tables cover suggested audit topics in the following areas:


Section B covers audits of specific treatment topics:

- B1: Demonstrating the presence or absence of inappropriate prescribing practice as discussed in the statement produced by the clinical guidelines independent expert working group (appendix A)
- B2: A wide range of other clinical topic areas drawn directly from the 2007 Clinical Guidelines (DH & devolved administrations, 2007) and the NICE suite of guidance (NICE 2007a, b, c, d).

Other information in the tables includes:

- Each topic is numbered for easy reference and for cross-reference to the NTA/Healthcare Commission service reviews items in Appendix B (see below). These numbers have no meaning outside of the guidance document
- For each topic example data sources are given. Where these include policies or protocols this is also indicated in the end column
- Where the example data sources include items covered in the NTA and Healthcare Commission service reviews, a reference to the appropriate review item(s) in Appendix B is included. These items briefly describe the criteria used in the service review and include links to the relevant criteria, scoring constructions and results. Partnerships and providers may find it helpful to revisit their previous results to obtain a benchmark for future audit on these topics.
### 3.3 Section A – Clinical governance

<table>
<thead>
<tr>
<th>Topic no.</th>
<th>Topic</th>
<th>Example criteria</th>
<th>Example data sources (NTA/HC items refer to detail in appendix B)</th>
<th>Policy/Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1</strong></td>
<td>Clinical governance framework</td>
<td>The partnership has audited the current range of clinical governance mechanisms at strategic partnership level, commissioner level and provider level. &lt;br&gt;Aim: to enable the enhancement of partnership-level strategic planning and to assist commissioners and providers either in improving current clinical governance processes or in increasing awareness between stakeholders of current good practice.</td>
<td>• Annual treatment plan&lt;br&gt;• Reports from drug treatment providers, commissioners and partnerships in response to questionnaires</td>
<td></td>
</tr>
<tr>
<td><strong>A2</strong></td>
<td>Workforce planning, education and training</td>
<td>There are mechanisms for assuring effective delivery of a competent workforce: &lt;br&gt;• An appropriate range of professionals is in post with a range of competencies appropriate to the delivery of the services they provide &lt;br&gt;• Individual competencies are in line with relevant guidance: &lt;br&gt;• Doctors’ competencies are in line with Roles and Responsibilities of Doctors in the Provision of Treatment for Drug and Alcohol Misusers (RCPsych and RCGP, 2005). &lt;br&gt;• Drug workers’ competencies are in line with the appropriate Drug and Alcohol National Occupational Standards (DANOS) (Skills for Health) &lt;br&gt;• Those providing psychosocial interventions have competencies in line with those in the forthcoming NTA/BPS toolkit for psychosocial interventions in substance misuse</td>
<td>• Annual treatment plan&lt;br&gt;• NTA/HC service review (item 1)</td>
<td></td>
</tr>
<tr>
<td><strong>A3</strong></td>
<td>Clinical audit</td>
<td>There is a programme of regular, frequent clinical audit and this is adhered to</td>
<td>• Audit samples from services&lt;br&gt;• NTA/HC service review (item 2)</td>
<td></td>
</tr>
<tr>
<td><strong>A4</strong></td>
<td>Organisational culture</td>
<td>• There are mechanisms for partnerships/commissioners to assure the development of a positive organisational culture and an 'appropriate' no-blame culture of clinical governance &lt;br&gt;• There is a mission statement concerning clinical governance &lt;br&gt;• The key fora for clinical governance review have terms of reference and clear lines of communication and accountability &lt;br&gt;• There is facilitative technical support</td>
<td>• Incident reporting protocol&lt;br&gt;• ‘Whistle-blowing’ policy&lt;br&gt;• Staff survey&lt;br&gt;• Documents from clinical governance department or equivalent</td>
<td></td>
</tr>
<tr>
<td><strong>A5</strong></td>
<td>Leadership</td>
<td>• The partnership has an identified lead or formal assurance mechanisms &lt;br&gt;• Organisations have an identified clinical governance lead &lt;br&gt;• There are clearly defined clinical governance structures within the senior management processes &lt;br&gt;• There is other evidence of effective leadership</td>
<td>• Team structure document&lt;br&gt;• Trust or organisation lead for clinical governance</td>
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<tr>
<td>Topic no.</td>
<td>Topic</td>
<td>Example criteria</td>
<td>Example data sources</td>
<td>Policy/Protocol</td>
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</table>
| A6      | Risk management                           | • There is a formal mechanism for collating, reviewing and responding to serious and untoward incidents and for subsequent consideration and implementation of improvements  
• There is a mechanism for monitoring and learning from drug-related deaths  
• There is a mechanism for managing complaints | • Policy on risk management  
• DRD group terms of reference, minutes, work plan  
• Complaints policy  
• NTA/HC service review (item 3) | ✓               |
| A7      | Patient and public involvement            | There are regular processes for involvement of patients and carers to improve the quality and safety of practice                                                                                                  | • Annual treatment plan  
• Service policies on user and carer involvement                                                                                                          | ✓               |
| A8      | Research and guidance implementation      | There are agreed mechanisms for considering and implementing evidence-based practice arising from the publication of research and from authoritative clinical guidance                                                   | • Documentation from drugs and therapeutics committees or equivalent                                      |                |
| A9      | Clinical accountability                   | • There are mechanisms for clinical accountability, including regular clinical supervision  
• There are organisational and professional performance procedures for dealing with clinical performance and compliance with policies  
• Mechanisms are formalised/documented/implemented | • Documentation from job planning (consultants), appraisal, supervision  
• Supervision policies                                                                                                                                      | ✓               |
| A10     | Public health                             | There are mechanisms for ensuring that specific responsibilities around public health assurance are delivered consistently                                                                                 | • Need assessment  
• Drug-related deaths strategy  
• Infection control policies                                                                                                                                |                |
| A11     | Collection and use of 'intelligent information' | Appropriate data (including NDTMS) is systematically collected and proper use made of the results:  
• There is full compliance with NDTMS data collection requirements, including TOP items, which must be collected at treatment start, in 12-week periods of review and at treatment exit  
• NDTMS data (including TOP) and the reports generated from it are used effectively by all stakeholders, including:  
quarterly reports used for delivery assurance  
needs assessment data used for treatment system and service planning  
any exception reports used to ensure data quality and compliance | • JCG/DAT minutes/papers  
• Quarterly performance monitoring and exception reports  
• Contract monitoring  
• Business/service development plans |                |
### 3.4 Section B – Specific treatment topics

#### 3.4.1 B1 – Prescribing practice

<table>
<thead>
<tr>
<th>Topic no.</th>
<th>Topic to consider</th>
<th>Cross-reference to clinical guidance audit topics</th>
<th>Definition of terms and/or general guidance</th>
<th>Example data sources</th>
<th>Policy/Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1.1</td>
<td>Doses of methadone or buprenorphine are increased only in response to evidence of inadequate dose (e.g. positive urine results and/or client continually declaring use of illicit drugs) and as part of a patient's care or treatment plan</td>
<td>B2.22, B2.23</td>
<td>Doses are not increased solely as a reward for a negative urine test result</td>
<td>• Case note review • Prescribing protocols</td>
<td>✓</td>
</tr>
<tr>
<td>B1.2</td>
<td>Doses of methadone or buprenorphine are decreased only as part of a planned detoxification or because of concerns that the current dose is excessive for an individual's needs</td>
<td>B2.24, B2.26, B2.27, B2.29</td>
<td>Doses are not decreased solely as punishment for a urine test result that showed the patient had been taking non-prescribed illegal drugs) Doses of methadone or buprenorphine are neither increased nor decreased solely for the reason that clients continually declare no use of illicit drugs</td>
<td>• Case note review • Prescribing protocols</td>
<td>✓</td>
</tr>
<tr>
<td>B1.3</td>
<td>Antidepressants are prescribed only in response to a diagnosis of clinical depression or perhaps to assist abstinence from stimulants</td>
<td></td>
<td>Antidepressants are not prescribed as a reward for drug free urines</td>
<td>• Case note review • Prescribing protocols</td>
<td>✓</td>
</tr>
</tbody>
</table>
### 3.4.2 B2 – Other topics in the 2007 Clinical Guidelines and NICE guidance

Note: There are a large number of topics that can be considered when auditing clinical practice against the wide-ranging recommendations of the 2007 Clinical Guidelines and NICE suite of drug misuse guidance. The topics identified below are just some of those that the NTA has identified and that may be a priority for partnerships and their providers. They are in addition to and therefore do not duplicate the topics described in sections A and B1. Local priorities may well determine other topics for audit or order them differently.

Furthermore, if a provider did wish to audit practice in any one or more of these topic areas it would then be necessary to develop detailed and clear criteria, definitions (some of which will be suggested by national guidance and some determined locally), and details of assessment and analysis, using an appropriate template.

<table>
<thead>
<tr>
<th>Topic no.</th>
<th>2007 Clinical Guidelines chapter/section</th>
<th>Source(s)* (CGUK and others)</th>
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<tbody>
<tr>
<td>B2.1</td>
<td>3 Essential elements 3.2</td>
<td>3.2 Drug misusers with parental responsibility are identified at assessment and during treatment, and the risks to their children assessed</td>
<td>• Case note review • Assessment forms (contain 16 items from Hidden Harm) • NTA/HC service review (item 11)</td>
<td>Case note review</td>
<td></td>
</tr>
<tr>
<td>B2.2</td>
<td>3 Essential elements 3.2</td>
<td>3.2 Care or treatment plans are developed and agreed (signed) with the patient</td>
<td>NDTMS &amp; users survey • Case note review • NTA/HC service review (item 4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2.3</td>
<td>3 Essential elements 3.2.5</td>
<td>3.2 All patients leaving treatment have a discharge and/or aftercare plan</td>
<td>Case note review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2.4</td>
<td>3 Essential elements 3.3</td>
<td>3.3 All patients have a named keyworker</td>
<td>Case note review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2.5</td>
<td>3 Essential elements 3.3.2 4</td>
<td>3.3 Keyworking sessions contain assessment, review and core psychosocial interventions: • Harm reduction (specific advice and techniques such as advice on safer injecting and minimising the risk of overdose) • Regular care plan review and reviews of progress (including the TOP) • Identification and assessment of risk to children • Brief interventions and other psychosocial interventions according to competence • Help to address social problems, for example family problems, housing and employment</td>
<td>Case note review</td>
<td></td>
<td></td>
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<tr>
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</table>
| B2.6     | 3 Essential elements                    | 3.3.3 CG51                  | Mechanisms for effective coordination of care are in place when patients are receiving care and interventions from more than one clinician or agency | • Documentation from Models of Care implementation  
• NTA/HC service review (item 5) | ✓            |
| B2.7     | 3 Essential elements                    | 3.3.4 CG51                  | Formal case management protocols are in place relating to patients who have involvement with mental health and/or criminal justice or other externally coordinated services | • Information sharing protocols  
• NTA/HC service review (item 11)  
• Multi-Agency Public Protection Arrangements (MAPPA) protocol  
• Care Programme Approach protocol | ✓ ✓ ✓        |
| B2.8     | 3 Essential elements                    | 3.4                         | Systems and protocols are in place for drug screening and, where appropriate, confirmation testing | • Drug testing protocols  
• Case note review | ✓            |
| B2.9     | 3 Essential elements                    | 3.5                         | All patients receive regular general healthcare assessments | • Case note review |               |
| B2.10    | 4 Psychosocial                          | 4 CG51                      | A range of psychosocial interventions is available as appropriate to individual client needs and including a number of specific interventions (examples described below) | |               |
| B2.11    | 4 Psychosocial                          | 4.2.4 CG51                  | All patients are informed about local self-help groups and, if they are seeking to achieve and maintain abstinence, supported to attend them | • Case note review |               |
| B2.12    | 4 Psychosocial                          | 4.3.2.1 CG51                | Opportunistic brief interventions focused on motivation are offered to people in limited contact with drug services who have been identified as being at risk of or who are misusing substances | • Case note review  
• (NICE audit criteria) |               |
<p>| B2.13    | 4 Psychosocial                          | 4.3.2.2 CG51                | If contingency management (CM) approaches are being used, these are in line with NICE recommendations for CM to reduce illicit drug use and/or promote engagement with services for people receiving methadone maintenance treatment (Note: The NTA’s CM demonstration programme will contribute to the future shape of appropriate CM implementation, at which point it will be possible to audit against more detailed criteria arising from clinical practice in this country) | • Case note review |               |
| B2.14    | 4 Psychosocial                          | 4.3.2.4 CG51                | Guided self-help, facilitated contact with support groups and individual family meetings are offered as appropriate to families and carers of people who misuse drugs | • Case note review |               |</p>
<table>
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<tr>
<td>B2.15</td>
<td>4 Psychosocial</td>
<td>4.3.2 CG51</td>
<td>Formal psychosocial interventions are provided in line with NICE recommendations for families and couples: behavioural couples therapy is available for people in close contact with a non-drug-misusing partner</td>
<td>• Case note review</td>
<td></td>
</tr>
</tbody>
</table>
| B2.16    | 4 Psychosocial                         | 4.2.3 4.3.3 CG51 CG22 CG23 | Formal psychosocial interventions are provided (or available) for patients with common mental health problems, including CBT for patients diagnosed with anxiety and depression | • Drugs and therapeutic committee  
• Case note review                                    |                |
| B2.17    | 4 Psychosocial                         | CG51                        | Cognitive behavioural therapy and psychodynamic therapy focused on the treatment of drug misuse are not offered routinely to people presenting for treatment of cannabis or stimulant misuse or those receiving opioid maintenance treatment | • Case note review                                  |                |
| B2.18    | 5 Pharmacological: supervised consumption | 5.4.1 TA114               | Supervised consumption is available for a period of around three months for all clients commencing opioid substitution treatment | • NTA/HC service review (item 6)  
• Case note review  
• (NICE audit criteria)                    |                |
| B2.19    | 5 Pharmacological: supervised consumption | 5.4.2                      | Supervised consumption for clients on opioid substitution treatment is discontinued (and, if appropriate, recommenced) on the basis of individual assessments of risk and clinical need | • Case note review                                  |                |
| B2.20    | 5 Pharmacological                      | 5.2.4, 5.4.1               | Systems are in place to ensure effective communication between prescriber, keyworker and pharmacist | • Information sharing protocols                    | ✔             |
| B2.21    | 5 Pharmacological: induction           | 5.3                        | During induction onto methadone and buprenorphine careful dose titration is carried out and the patient is regularly reviewed | • Prescribing protocol  
• Case note review                                    | ✔             |
<p>| B2.22    | 5 Pharmacological                      | 5.5                        | Treatment is optimised for patients who are not benefiting, usually by providing additional and more intensive interventions (pharmacological and psychosocial) including careful regular assessment and monitoring of risks | • Case note review                                  |                |
| B2.23    | 5 Pharmacological: maintenance         | 5.6 TA114                  | Both methadone and buprenorphine are available as options for maintenance treatment | • NTA/HC service review (item 6)                  |                |</p>
<table>
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</table>
| B2.24     | 5 Pharmacological: maintenance         | 5.6.3 TA114                 | Maintenance doses of methadone and buprenorphine are determined in discussion with the client, taking into account evidence-based recommendations on optimal dose ranges (i.e. for methadone 60-120mg per day; and for buprenorphine 8-16mg per day, and up to 32mg when appropriate) | • NTA/HC service review (item 6)  
• Case note review  
• Prescribing policy | ✓ |
| B2.25     | 5 Pharmacological: maintenance         | 5.6.3 TA114                 | The doses prescribed to those on maintenance programmes are analysed for:  
• The proportions within or outside the suggested optimal ranges for methadone and buprenorphine  
• The average and the range prescribed  
Initial standards might be set for the first audit cycle or could be set after an initial audit and discussion of standards relevant to the service and casemix | • Case note review  
• Prescription databases  
• Prescribing policies | ✓ |
| B2.26     | 5 Pharmacological                      | 5.6.6, A8                   | Prescribing of injectable opiates is in line with the eight principles of the NTA’s injectable prescribing guidance | • Prescribing policy | ✓ |
| B2.27     | 5 Pharmacological: detoxification      | 5.7 CG52                    | Detoxification is a readily available option for opioid dependent people who have expressed an informed choice to become abstinent | • (NICE audit criteria) | |
| B2.28     | 5 Pharmacological: detoxification      | 5.7 CG52                    | Detoxification is provided only as a clear regimen distinct from maintenance or “slow reduction” | • Bespoke survey/audit (NICE audit criteria) | |
| B2.29     | 5 Pharmacological: detoxification      | 5.7 CG52                    | Detoxification is available in a choice of settings, with community-based opioid detoxification routinely offered but detoxification in an inpatient or residential rehabilitation service available for patients who might need or benefit from this | • | |
| B2.30     | 5 Pharmacological: detoxification      | 5.7 CG52                    | Clients are usually detoxified using the medication with which they have been maintained: usually methadone or buprenorphine | • Case note review  
• Prescribing protocol | ✓ |
| B2.31     | 5 Pharmacological: detoxification      | 5.7.3 CG52                  | Lofexidine is used where service users have made an informed and clinically appropriate decision to following this prescribing regimen | • Prescribing protocol  
• NTA/HC service review (item 7) | ✓ |
| B2.32     | 5 Pharmacological: detoxification      | 5.7.4 CG52                  | Ultra-rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) is not offered | • Prescribing protocol  
• NTA/HC service review (item 7)  
• (NICE audit criteria) | ✓ |
<table>
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</table>
| B2.33    | 5 Pharmacological: detoxification      | 5.7.4 CG52                  | Ultra-rapid and rapid detoxification using precipitated withdrawal are not routinely offered | • Prescribing protocol  
• NTA/HC service review (item 7) | ✓ |
| B2.34    | 5 Pharmacological: detoxification      | 5.7.1 CG52                  | Clonidine and dihydrocodeine are not routinely used in opioid detoxification | • Prescribing protocol  
• NTA/HC service review (item 7) | ✓ |
| B2.35    | 5 Pharmacological: detoxification      | 5.7 CG52                   | Aftercare is planned and provided for all patients undergoing detoxification. Specifically, continued treatment, support and monitoring designed to maintain abstinence are offered, normally for a period of at least six months following successful opioid detoxification | • Case note review  
• Care pathways  
• NTA/HC service review (item 8) | |
| B2.36    | 5 Pharmacological: detoxification      | 5.7                       | Patients undergoing detoxification have seamless pathways back to other treatments if unsuccessful | • Care pathways  
• NTA/HC service review (item 5) | |
| B2.37    | 5 Pharmacological: detoxification      | 5.8 TA115                  | Patients receiving naltrexone treatment are formerly opioid-dependent people who have undergone detoxification and are highly motivated to remain in an abstinence programme | • Bespoke audit: (NICE audit criteria)  
• Prescribing protocol | ✓ |
| B2.38    | 5 Pharmacological: detoxification      | CG52                       | If contingency management (CM) approaches are being used, these are in line with NICE recommendations for CM during and after detoxification (Note: The NTA’s CM demonstration programme will contribute to the future shape of appropriate CM implementation, at which point it will be possible to audit against more detailed criteria arising from clinical practice in this country) | | |
| B2.39    | 5 Pharmacological: benzodiazepines    | 5.9                        | Benzodiazepines prescribed to assist withdrawal from benzodiazepines are only prescribed where there is clear evidence of benzodiazepine dependency and then on a time-limited, reducing regimen, usually at doses <30mg diazepam equivalent per day | • Case note review  
• Prescribing policy | ✓ |
| B2.40    | 6 Health: BBI                         | 6.2.4.1 6.2.4.2 Green      | All drug misusers are offered vaccination against hepatitis B; and against hepatitis A, where indicated | • NTA/HC service review (item 9)  
• Patient Group Directions | |
| B2.41    | 6 Health: BBI                         | 6.2.4.3 6.2.4.4            | All drug misusers are offered testing for hepatitis C and for HIV | • NTA/HC service review (item 9) | |
| B2.42    | 6 Health: BBI                         | 6.2.4.3 6.2.4.4            | Drug misusers with hepatitis C or HIV infection are able to access appropriate treatment and management | • NDTMS & case note review  
• NTA/HC service review (item 9)  
• Care pathway | |
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<tr>
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</table>
| B2.43    | 6 Health: BBI                            | 6.2.2                        | Hepatitis B vaccination is available and encouraged for:  
• The children and sexual partners of injecting drug users  
• The children, sexual partners and close household contacts of patients with active chronic hepatitis B | • Case note review |               |
| B2.44    | 6 Health: BBI                            | 6.2.5.2                      | All injecting drug users’ tetanus immunisation status is checked and human tetanus immunoglobulin considered for patients with injection site infections | • Assessments forms  
• Case note review |               |
| B2.45    | 6 Health: BBI                            | CG51                         | If contingency management (CM) approaches are being used, these are in line with NICE recommendations for CM to improve physical healthcare  
(Note: The NTA’s CM demonstration programme will contribute to the future shape of appropriate CM implementation, at which point it will be possible to audit against more detailed criteria arising from clinical practice in this country) | • |               |
| B2.46    | 6 Health: DRD                            | 6.3.2                        | Patients who are to take home medication are required to provide details of satisfactory safe home storage of medicines, which is documented and reviewed | • Case note review |               |
| B2.47    | 6 Health: DRD                            | 6.3.2                        | All patients receive regular advice, information and risk assessments (in keyworking sessions) to reduce the risk of drug-related death | • NTA/HC service review (item 10)  
• Case note review |               |
| B2.48    | 6 Health: DRD                            | 6.3.2                        | Drug misusers and their families are advised about the risks of overdose and effective responses | • Case note review |               |
| B2.49    | 6 Health: DRD                            | 6.3.3                        | There is an emergency protocol to cover the management of drug overdoses | • Protocol | ✓               |
| B2.50    | 6 Health: DRD                            | 6.3.3                        | Suitable resuscitation training and equipment is available in clinical settings | • Survey |               |
| B2.51    | 6 Health: DRD                            | 6.3.3                        | Naloxone and staff trained to administer it are available where appropriate | • Naloxone training records  
• Review of competencies |               |
| B2.52    | 6 Health: alcohol                        | 6.4                          | All clinicians are able to detect and respond to problem drinking in drug misusers | • Case note review  
• Review of competencies |               |
| B2.53    | 6 Health: smoking                        | 6.5 PH1                      | All patients are encouraged and supported to engage in smoking cessation activities | • Smoking cessation training records  
• Case note review |               |
| B2.54    | 7 Specific situations/populations: criminal justice | 7.2                          | Information is shared, as appropriate and with patient consent, between drug treatment services and criminal justice agencies | • Information sharing protocols  
• NTA/HC service review (item 11) | ✓               |
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<tbody>
<tr>
<td>B2.55</td>
<td>7 Specific situations/populations: prisons</td>
<td>7.3.4.1</td>
<td>There are effective care pathways between prisons and the community (drug treatment service, GPs), including contingency arrangements where an individual leaves prison outside of standard working hours</td>
<td>• Care pathways • Policies • NTA/HC service review (item 11)</td>
<td>✓</td>
</tr>
<tr>
<td>B2.56</td>
<td>7 Specific situations/populations: pregnancy</td>
<td>7.4</td>
<td>The risks and needs of pregnant drug misusers are the subject of multidisciplinary assessment early in pregnancy</td>
<td>• Care pathways • Policies • NTA/HC service review (item 11)</td>
<td>✓</td>
</tr>
</tbody>
</table>
| B2.57    | 7 Specific situations/populations: mental health | 7.5.3
   CG1, CG22, CG23, CG38 | Services for clients with co-morbid substance use and severe mental health problems are delivered in line with Mental Health Policy Implementation Guidance: Dual Diagnosis good practice guide (DH 2002) | • CPA protocol | ✓ |
| B2.58    | 7 Specific situations/populations: young people | 7.6.2 (& 3.2) | Young drug users’ competency to consent to treatment is assessed and those with parental responsibility are involved in their treatment as appropriate | • Case note review | |
| B2.59    | 7 Specific situations/populations: young people | 7.6 | Young people’s specialist drug treatment is provided separately from adults | • Service review | |
| B2.60    | 7 Specific situations/populations: older drug users | 7.7 | The general and drug-related health needs of older drug users are assessed and treated | • Case note review | |
| B2.61    | 7 Specific situations/populations: pain | 7.8 | There are joint working arrangements between drug treatment services and pain management teams for drug misusers with chronic pain | • Care pathways | |
| B2.62    | 7 Specific situations/populations: hospital | 7.9 | There are protocols for how acute medical hospitals will respond to drug misusers attending A&E or admitted onto inpatient wards | • Hospital protocol | ✓ |
| B2.63    | A7 Drugs and driving | A7.1-7.5 | Policy and practice on assessing and regularly reviewing clients’ driving status, risks to self and others, and subsequent action by clinicians are in line with current DVLA and GMC guidance | • Drugs, drinking and driving policy • Case note review | ✓ |
**Key to sources:**

- CGUK – Drug Misuse and Dependence; UK Guidelines on Clinical Management (DH & devolved administration, 2007) (column gives relevant section number)
- Green – Immunisation Against Infectious Disease (The Green Book) (DH, 2006)
- TA – NICE technology appraisal:
  - 114 = methadone and buprenorphine (NICE, 2007a)
  - 115 = naltrexone (NICE, 2007b)
- CG – NICE clinical guideline:
  - 51 = Drug Misuse: Psychosocial Interventions (NICE, 2007c)
  - 52 = Drug Misuse: Opioid Detoxification (NICE, 2007d)
  - 1 = Core Interventions in the Treatment and Management of Schizophrenia in Primary & Secondary Care (NICE, 2002)
  - 22 = Management of Anxiety in Adults in Primary, Secondary & Community Care (NICE, 2007i)
  - 23 = Management of Depression in Primary & Secondary Care (NICE, 2007j)
  - 38 = Management of Bipolar Disorder in Adults, Children and Adolescents, in Primary and Secondary Care (NICE, 2006a)
- PH – NICE public health intervention guidance
  - 1 = Brief Interventions and Referral for Smoking Cessation in Primary Care and Other Settings (NICE, 2006b)
Appendix A: Clinical guidelines statement on appropriate prescribing and chair’s explanatory note

Clinical Guidelines on Drug Misuse and Dependence Update 2007 Working Group

Statement on medication choice and dosing in drug misuse treatment
23 October 2007

The objective in prescribing is to give the patient the right medication at a dose that produces the greatest therapeutic benefit, without incurring unnecessary risk of harm. It is inappropriate for medications to be used as a reward, or to be withheld or dose reduced solely as a punishment or sanction.

1. What do the Clinical Guidelines 2007 say?
Drug Misuse and Dependence: UK Guidelines on Clinical Management (2007) do not specifically address the question of choice of medication and dose as a “reward”. This is simply because it should be obvious to any competent clinician that medication and dose should be determined only on the basis of clinically assessed need. However, this principle is present as an undercurrent throughout the relevant sections of the guidelines, including:

- Balancing drivers behind prescribing for drug misuse:
  - “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.” (5.3)
- Dose optimisation: (methadone at) “a level at which the patient reports feeling comfortable and is no longer using illicit heroin.” (5.3.7.2)

The Clinical Guidelines also stress the importance of proper clinical governance in services and localities – a systematic approach to quality, safety and effectiveness – which would prevent inappropriate prescribing.

2. How is appropriate medication determined?
Medicines should only be prescribed on the basis of clinical need. Clinicians must choose appropriate medications that treat the patient’s presenting condition or prevent a condition arising. It is inappropriate to prescribe or withhold a clinically-indicated medication to reward or punish a patient’s behaviour. This principle applies to medication used directly to treat drug misuse, such as methadone and buprenorphine, and to medications used to treat other conditions and symptoms in the drug misusing patient, such as depression.

3. How is the right dose of medication determined?
The nature and duty of prescribing is for clinicians to individually tailor dose for each patient, basing their decisions on research evidence or clinical evidence of effectiveness, and seeking the optimal balance between clinical improvement and minimising the dangers intrinsic in any medication. Methadone and buprenorphine are medicines being prescribed as treatment for drug misuse and for which the decision about the right dose for each patient is
one about optimising the therapeutic benefit for that patient while minimising dangers such as overdose and withdrawal.

It is inappropriate for such medications and their dose level to be used as a reward, or for them to be withheld or dose reduced solely as a punishment or sanction.

**Why might dose of medication be changed?**

Dose of prescribed medication must be monitored and may need to be changed for a number of reasons:

- altered metabolic handling: e.g. when a patient commences some other new medication, or suffers deteriorating liver function, or becomes pregnant.
- re-emergence of drug misuse problem: a patient may relapse at times of stress, and the clinician may increase medication dose to produce a greater therapeutic effect or reduce it to lower the risk of overdose.
- disengagement from a failing treatment: if the patient continues to misuse drugs at the same level as prior to treatment, with no demonstrable benefit from the prescribed treatment, or is no longer taking the medication as prescribed, the clinician may decide to stop the medication and consider, with the patient, alternative and perhaps more intensive ways of tackling the drug misuse problem.
- adjusting a properly planned programme of detoxification: in which the patient gradually reduces their dose of methadone or buprenorphine. If urine test results and self-report show resumed heroin use, then reduction may be slowed, held steady, or even briefly go back up a step.
- interruption of medication: if the patient misses doses, a dose reduction may be required to avoid possible overdose if tolerance has decreased.

**About this statement**

This brief statement was agreed by prescribing clinician members (in England) of the Clinical Guidelines on Drug Misuse and Dependence Update 2007 Working Group.

A more detailed explanatory note to the statement has also been produced.

Professor John Strang, Chair for the Clinical Guidelines on Drug Misuse and Dependence Update 2007 Working Group

**References**


Statement on medication choice and dosing in drug misuse treatment

Explanatory note from Professor John Strang, Chair

23 October 2007

The objective in prescribing is to give the patient the right medication at a dose that produces the greatest therapeutic benefit, without incurring unnecessary risk of harm. It is inappropriate for medications to be used as a reward, or to be withheld or dose reduced solely as a punishment or sanction.

Finding the right medication dose for a patient, and reasons why it might change

In this brief note, the issue of medication dose is considered specifically with regard to dose of methadone or buprenorphine – in the context of methadone maintenance or buprenorphine maintenance treatment for opiate addiction.

Three questions will be answered:
1. How is the right dose of medication determined?
2. Why might the dose of medication be changed?
3. When might medication dose be varied as a result of urine test results (or other measures of progress/benefit)?

1. How is the right dose of medication determined?

Methadone maintenance and buprenorphine maintenance are both treatments with a strong evidence base, as recently endorsed by NICE (2007). Methadone mixture and buprenorphine tablets are the medications used in these treatments. The authority to prescribe medicine as treatment is precisely what it says: an authority to prescribe medicine in order to treat a condition. The recent Clinical Guidelines 2007 give clear guidance about careful induction onto maintenance doses, and about the ongoing maintenance doses that are most likely to achieve greatest benefit (in summary, recommending doses of 60 to 120mg daily of oral methadone, and 8 to 16mg daily of sublingual buprenorphine). These recommendations are based on research evidence or clinical evidence of effectiveness. With this guidance, the clinician must then individually tailor dose for each particular patient, looking for the optimal relationship between clinical improvement and the intrinsic dangers of the medication itself – and if they determine that the maintenance dose is outside these recommended ranges, then they are advised to pay particular attention to their careful assessment of the criteria on which they are reaching this more unusual conclusion (applicable to the decision to prescribe above this recommended dose range, and also applicable to the decision to prescribe below this recommended dose range).

It is inappropriate for such medications to be used as a reward, a bonus or a present, and it is also inappropriate for them to be withheld (or dose reduced) solely as a punishment or sanction. There may be occasions when the treating clinician forms the opinion that the dose is no longer correct, and concludes that they should adjust it (see next paragraph), but this is in order to optimise the therapeutic benefits of the medication. But it is important to be clear that methadone and buprenorphine are medicines which are being prescribed as treatment and for which the decision about the right dose for each individual patient is a decision about optimising the therapeutic benefit for that patient. To give extra doses as a bonus or reward is wrong. To withhold doses and make the treatment less effective as a punishment or sanction is wrong.
2. Why might dose of medication be changed?

Dose of prescribed medication may be changed for a number of reasons, including the following:

(a) altered metabolic handling: There will be occasions when an individual patient's dose may need to be increased (when the clinician judges that a higher dose will result in more therapeutic beneficial effects without introducing unacceptable increase in the danger from the increased dose); and there will be occasions when an individual patient's dose may need to be decreased (when the clinician judges that the current dose is causing toxicity or other such actual or potential danger to the patient). We now have a greater understanding of the factors which influence the optimal dose for an individual patient, although our understanding is still incomplete: these influences include genetic factors (e.g. different enzyme activity and metabolic breakdown), the influence of other medications (e.g. medication for TB or HIV disease), other medical conditions (e.g. liver disease and pregnancy) as well as different body mass. When one of these changes (e.g. when a patient commences some other new medication, or suffers deteriorating liver function, or becomes pregnant), and then the clinician needs to pay particular attention to the possible need adjustment of dose.

(b) re-emergence of addiction problem: it is not uncommon for patients to suffer a partial relapse at times of stress or difficulty, and the treating doctor may conclude that the dose should be increased to produce a greater therapeutic effect, even though the patient had previously been adequately maintained on a lower dose. The reason for such dose increase is directly in order to increase the therapeutic benefit, just as might be done with a patient whose pain is no longer adequately controlled, whose epileptic fits are no longer adequately controlled, or for whom depressive symptoms re-emerge.

(c) disengagement from a failing treatment: sadly it occasionally transpires that maintenance treatment fails to provide any benefit to a particular patient. It is not uncommon for heroin addicts commencing treatment to have difficulty completely disengaging from their previous heroin use, or to suffer occasional relapses, and this is part of the nature of providing treatment to this patient population. However, if the patient is deriving no benefit from the treatment and, for example, is continuing to use street heroin, and doing so with the same intensity and regularity as prior to treatment and with no demonstrable benefit from treatment, then it is possible that the addition of the prescribed methadone or buprenorphine is either pointless, or may even be making the situation worse. The patient may also be failing to comply with the prescribed treatment regime: taking their medication irregularly or not at all.

In these circumstances, fortunately rare, the treating doctor may decide that they should stop the failing treatment. Typically the doctor would conclude that it was unreasonable to abruptly stop the methadone or buprenorphine, since this would precipitate a withdrawal syndrome and would probably further aggravate the situation, and hence the doctor would often conclude that they should rapidly taper the dose down to zero over a brief period of time. But these dose reductions are not being done as a punishment or sanction – they are being done in order to terminate a failing treatment. (The doctor and the patient must then jointly consider alternative and perhaps more intensive ways of tackling the addiction problem).

(d) interruption of medication: if the patient misses one or more doses of medication, tolerance to the effects of the medication may have reduced and so a dose reduction may be required to avoid possible overdose.

Dose might also be appropriately changed in a client on a programme of detoxification from methadone or buprenorphine, either directly or after a period of maintenance treatment. If the client relapses back into heroin use as the medication is reduced, then the clinician may suggest to the client that the dose be held for a longer period of time before the next reduction takes place, or may suggest the dose be increased until on-top heroin use ceases. However, if the client does not relapse back into heroin use, and urine drug screens confirm this, planned dose reduction can continue.
3. When might medication dose be varied as a result of urine test results (or other measures of progress/benefit)?

There are occasions when the treating clinician will legitimately alter the dose of medication in the light of urine test results, or in the light of other possible measures of benefit/progress (or lack of it). For example, the preceding section deals with the situation where the clinician may increase dose in order to get greater therapeutic power, and also the situation where no benefit is occurring and they decide to terminate a failing treatment.

There is also the situation where the level of regulatory scrutiny of treatment provision may deliberately be relaxed, when the patient is progressing well with their treatment. This is not a situation in which the daily dose is increased, even though it may sometimes involve the provision of a larger amount of medication in each instalment (e.g. if the patient is doing sufficiently well that it is appropriate for them to pick up their medication on alternate days, instead of daily, when they will obviously receive double the dose on alternate days, instead of the single day's dose on a daily basis).

The new Clinical Guidelines 2007 give clear guidance about the caution that must be exercised when commencing maintenance treatment with either methadone or buprenorphine, and they recommend that the treating clinician should typically arrange for the new patient to attend daily (either at the clinic or at a local dispensing pharmacy) to take the prescribed medication under direct supervision. Once it is clear that the patient is doing well in treatment (after a period of time which varies from one patient to the next, but may be around three months), it is then appropriate to relax the intense regulatory scrutiny and, as a first step, to permit that patient to collect their medication to take as they wish throughout the day (perhaps retaining some to take in the evening, for example); and then, as the patient shows continued progress and improvement, it is then appropriate to further relax the scrutiny – for example by allowing the patient to collect a two-day supply at each attendance at the clinic/pharmacy.

The treating clinician will typically look at the results from urine testing, as well as other measures of progress, to help determine whether it is appropriate to relax the regulatory scrutiny. And it is in this area that it would be possible to introduce a more clearly articulated protocol in which the demonstrable improvement and adherence to the treatment plan, as evidenced by negative urine test results, might be "rewarded" by a relaxation of the requirement for supervision of consumption and, at a later stage, by a relaxation of the requirement for daily attendance. No extra drug is being given, but the requirements for regulatory scrutiny are being relaxed in a deliberate manner – to the benefit of the patients who then have more possibility of engaging in a more normal way of life, and to the benefit of clinical staff and funders who no longer need to incur the extra time and financial investment in this regulatory scrutiny.

About this statement
This explanatory note supports a brief statement agreed by prescribing clinician members in England of the Clinical Guidelines on Drug Misuse and Dependence Update 2007 Working Group.

Professor John Strang
Chair, Clinical Guidelines on Drug Misuse and Dependence Update 2007 Working Group

References
Appendix B: NTA/HC improvement review criteria

The following appendix gives further information on the Healthcare Commission/NTA joint service review questions that serve as potential data sources for some of the audit topics suggested in the tables in section 3 of this guidance. The data submitted by partnerships or services for the service reviews may be useful as a baseline against which to benchmark progress.

The items listed below are extracts from the following reviews:

- 2005/6 community prescribing and care planning
- 2006/7 commissioning and harm reduction

Each item below lists:

- The relevant review
- The relevant criteria and question number
- The overarching question relevant to the audit topic/section
- The specific questions asked against which data will have been collected.

General information about the service reviews and links to the scores attained by your partnership or service, the data submitted and an explanation of how scores were constructed can be found on the NTA and Healthcare Commission substance misuse service review web pages:

- NTA – [www.nta.nhs.uk/areas/standards_and_inspections](http://www.nta.nhs.uk/areas/standards_and_inspections)

Where data has been published (2005/6 and 2006/7 review only at the time of publication), this is available by following relevant links from the web pages listed above.

The data used to construct review scores was:

- National data sets, available at the links listed above
- Partnership and provider questionnaire responses. PDF versions of these were generated and sent to partnership and provider review leads at the time of submission. Copies of these submissions are also available on request from [substance.misuse@nta-nhs.org.uk](mailto:substance.misuse@nta-nhs.org.uk)
## Item 1 (audit topic A2)

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workforce planning, education and training: A2 – There are mechanisms for assuring effective delivery of a competent workforce</td>
<td>2006/7 service review on commissioning and harm reduction, Criterion 4 Question 3: Does the partnership have a workforce development strategy to respond to the needs identified for developing the workforce?</td>
</tr>
</tbody>
</table>

The local drug partnership submitted data in relation to the following questions:

- **JCM questionnaire, question 8a**: Does the partnership have a workforce development strategy to respond to the needs identified for developing the workforce?
- **JCM questionnaire, question 8b**: Is the partnership responding to identified needs for developing the workforce?

## Item 2 (audit topic A3)

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical audit: A3 – There is a programme of regular, frequent clinical audit and this is adhered to</td>
<td>2005/6 service review on community prescribing and care planning, Criterion 3 Question 4: Prescribing practice is in line with Models of Care for treatment of adult drug misusers and Drug misuse and dependence – guidelines on clinical management</td>
</tr>
</tbody>
</table>

Community prescribing services submitted data in relation to the following question:

- **Community prescribing service questionnaire, question 4**: What are the title(s) of clinical audits completed by the substance misuse service (or trust wide audits which specifically inc. SM) in last 18 months?

## Item 3 (audit topic A6)

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<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
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<tbody>
<tr>
<td>Risk management: A6</td>
<td>2006/7 service review on commissioning and harm reduction, Criterion 9 Question 1: Does the partnership have a written multi-agency strategic plan for reducing drug related deaths?</td>
</tr>
</tbody>
</table>
- There is a formal mechanism for collating, reviewing and responding to serious and untoward incidents and for subsequent consideration and implementation of improvements
- There is a mechanism for monitoring and considering drug-related deaths
- There is a mechanism for managing complaints

The local drug partnership submitted data in relation to the following questions:

- **JCM questionnaire, question 22a**: Does the partnership have a written multi-agency strategic plan for reducing drug-related deaths?
- **JCM questionnaire, question 22b**: Does the partnership have an agreed strategy to communicate messages about acute risks from contaminated or very strong consignments of drugs?
- **JCM questionnaire, question 22c**: Does the partnership have an agreed protocol for confidential inquiries relating to drug related deaths, which is in line with Department of Health guidance or exceeds the guidance?
- **JCM questionnaire, question 22d**: Does the partnership have agreed protocols on dealing with overdose incidents and/or other drug-related acute emergency problems (e.g. cocaine induces heart failure) for staff groups dealing with overdose incidents?

### Item 4 (audit topic B2.2)

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<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential elements: B2.2 – Care or treatment plans are developed and agreed (signed) with the patient</td>
<td>2005/6 service review on community prescribing and care planning, Criterion 9: Service users have a personalised care plan that incorporates a comprehensive assessment of their physical, psychological, social and legal needs and preferences.</td>
</tr>
</tbody>
</table>

The partnerships’ community prescribing services’ assessment, care planning and risk assessment tools were assessed against a good practice template.

- **Question 1**: Are assessment tools and care plans comprehensive covering the full range of needs based on measurable goals?
- **Question 2**: Is there a comprehensive risk assessment as part of the assessment process?

### Item 5 (audit topics B2.6, B2.36)

<table>
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<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential elements: B2.6 – Mechanisms for effective care coordination are in place when patients are receiving care and interventions from more than one clinician or agency</td>
<td>2005/6 service review on community prescribing and care planning, Criterion 10 Question 3: Are there clear and appropriate protocols for care planning and coordination across agencies?</td>
</tr>
<tr>
<td>Pharmacological – detox: B2.36 – Patients undergoing detoxification have seamless pathways back to other treatments if unsuccessful.</td>
<td></td>
</tr>
</tbody>
</table>

Scores were constructed using data from the following sources:

- Drug action team annual treatment plans
- Drug action team self-assessment for care-coordination arrangements for all four tiers
- Drug action team self-assessment for models of care: integrated care pathways arrangements
- Drug action team self-assessment for models of care: care coordination
- Survey of service users (all respondents): questions on care plan review and having a care plan.
**Item 6 (audit topics B2.18, B2.23, B2.24, B2.25)**

<table>
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<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
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</thead>
</table>
| Pharmacological – supervised consumption: B2.18 – Supervised consumption is available for a period of around three months for all clients commencing opioid substitution treatment | 2005/6 service review on community prescribing and care planning, Criterion 4 Questions 1 & 4:  
- Question 1 – Is the agency’s prescribing policy and practice in line with models of care and guidelines on clinical management?  
- Question 2 – What is the service users’ experience of prescribing practice? |
| Pharmacological – maintenance: B2.23 – Methadone and buprenorphine are both available as options for maintenance treatment |  |
| Pharmacological – maintenance: B2.24 – Maintenance doses of methadone and buprenorphine are determined in discussion with the client taking into account evidence-based recommendations on optimal dose ranges (i.e. for methadone 60-120mg per day; and for buprenorphine 8-16mg per day, and up to 32mg when appropriate). |  |
| Pharmacological – maintenance: B2.25 – The doses prescribed to those on maintenance programmes are analysed for:  
- The proportions within or outside the suggested optimal ranges for methadone and buprenorphine  
- The average and the range prescribed. Initial standards might be set for the first audit cycle or could be set after an initial audit and discussion of standards relevant to the service and casemix. |  |

Scores were constructed using data from the national prescribing audit (March 05 – June 05) or, if the services did not take part, additional questions on the bespoke data collection tool (October 05).

The data items used were:

- The mean daily dose for methadone
- The range of doses prescribed
- The range of supervised consumption for methadone undertaken within the first 12 weeks
- The range of supervised consumption for methadone undertaken after the first 12 weeks
- The range of methadone treatment options (i.e. tablets/ oral methadone/ mixture/ampoules) offered
- The range of buprenorphine doses prescribed
- The range of supervised consumption for buprenorphine undertaken within the first 12 weeks
- The range of supervised consumption for buprenorphine undertaken after the first 12 weeks.
Item 7 (audit topic B2.31, B2.32, B2.33, B2.34)

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacological – detoxification:</td>
<td>2007/8 service review on diversity and tier 4 services, Criterion 10 Question 3: Are prescribing regimens in line with NICE clinical guidelines? (Only in-patient detox/stabilisation services were reviewed against this question)</td>
</tr>
<tr>
<td>• B2.31 – Lofexidine is used where service users have made an informed and clinically appropriate decision to following this prescribing regimen</td>
<td></td>
</tr>
<tr>
<td>• B2.32 – Ultra-rapid detoxification under general anaesthesia or heavy sedation (where the airway needs to be supported) is not offered</td>
<td></td>
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<tr>
<td>• B2.33 – Ultra-rapid and rapid detoxification using precipitated withdrawal are not routinely offered.</td>
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</tr>
<tr>
<td>• B2.34 – Clonidine and dihydrocodeine are not routinely used in opioid detoxification</td>
<td></td>
</tr>
</tbody>
</table>

Tier 4 inpatient detoxification services submitted data in relation to the following question:

- **Tier 4 questionnaire, question 9:** Are prescribing regimens in line with NICE clinical guidelines?

<table>
<thead>
<tr>
<th>Guideline recommendation</th>
<th>Regimens are in line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone or buprenorphine are the primary medications used</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Ultra-rapid, rapid and accelerated detoxification is NOT used</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Lofexidine is used where service users have made an informed and clinically appropriate decision to following this prescribing regimen</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Clonidine is NOT routinely used in opioid detoxification</td>
<td>Yes/no</td>
</tr>
<tr>
<td>Dihydrocodeine is NOT routinely used in opioid detoxification</td>
<td>Yes/no</td>
</tr>
</tbody>
</table>

Item 8 (audit topic B2.35)

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacological – detoxification: B2.35 – Aftercare is planned and provided for all patients undergoing detoxification. Specifically, continued treatment, support and monitoring designed to maintain abstinence are offered, normally for a period of at least six months following successful opioid detoxification</td>
<td>2007/8 service review on diversity and tier 4 services, Criterion 7 Question 5 &amp; Criterion 9 Question 4: Criterion 7 Question 5 – How integrated are community care pathways with Tier 4 in-patient detoxification/stabilisation/maintenance interventions? Criterion 9 Question 4 – Does the service prepare exit strategy plans prior to, or on, admission?</td>
</tr>
</tbody>
</table>

Tier 4 services submitted data in relation to the following questions:

**Criterion 7 Question 5:**

- **JCM questionnaire, question 15:** How are community care pathways\(^3\) integrated with Tier 4 interventions?

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Are care pathways into and out of Tier 4 services required in service level agreements with Tier 3 providers?  Yes/no  Yes/no

If yes, do these care pathways include:

- Requirements for Tier 3 providers to assess need for, and either refer directly to Tier 4 in-patient provision or for a Community Care Assessment  Yes/no  Yes/no
- The designation of a Tier 3 based care coordinator for service users going to Tier 4 provision  Yes/no  Yes/no
- Procedures for liaison with community care managers while service users are in residential rehabilitation provision  Yes/no  Yes/no
- Procedures for assessment of risk by Tier 3/Community Care Manager following planned discharge from Tier 4 provision  Yes/no  Yes/no
- Procedures for assessment of risk by Tier 3/Community Care Manager following unplanned discharge\(^4\) from Tier 4 provision  Yes/no  Yes/no
- A care plan which identifies aftercare needs and progress towards meeting these needs while the service user is in Tier 4 provision  Yes/no  Yes/no

**Criterion 9 Question 4:**

*Tier 4 questionnaire, question 5:* Does your service prepare exit strategy plans prior to or on admission?

Yes/no

If yes, does the exit strategy plan include:

- Procedures for notification to the care coordinator, or named contact, as specified in the care pathway of a service user’s unplanned discharge\(^5\)  Yes/no
- Procedures for ensuring the provision of drug-related support after discharge  Yes/no
- Procedures for ensuring the provision of non-drug related support after discharge  Yes/no

---

\(^4\) Definition of unplanned discharge: The discharge of a service user which occurs at a date earlier than that expected in the service user’s care plan. This may be due to:
- The service user deciding to leave before treatment is completed and doing so before early discharge can be planned
- ‘Disciplinary’ discharge of a service user for breaching service rules or behavioural requirements
- The death or serious injury of the service user.

\(^5\) Definition of unplanned discharge: The discharge of a service user which occurs at a date earlier than that expected in the service user’s care plan. This may be due to:
- The service user deciding to leave before treatment is completed and doing so before early discharge can be planned
- ‘Disciplinary’ discharge of a service user for breaching service rules or behavioural requirements
- The death or serious injury of the service user.
Item 9 (audit topics B2.40, B2.41, B2.42)

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
</table>
| Health – BBI: B2.40 – All drug misusers are offered vaccination against hepatitis B and against hepatitis A where indicated (injecting) | 2006/7 service review on commissioning and harm reduction, Criterion 8 Questions 5 & 6:  
• Question 5 – How many service users have been tested and/or vaccinated against HBV?  
• Question 6 – What is the partnership’s response for HCV? |
| Health – BBI: B2.41 – All drug misusers are offered testing for hepatitis C and for HIV                                                                 |                                                                                                                                 |
| Health – BBI: B2.42 – Drug misusers with hepatitis C or HIV infection are able to access appropriate treatment and management |                                                                                                                                 |

**Question 5:**

Local drug partnerships submitted data against the following questions:

- **JCM questionnaire, question 20:** Has the partnership an agreed protocol for HBV vaccination of injecting drug misusers?

NDTMS data was also used to score this question. The data related to the second quarter of 2006/07:

- What is the proportion of service users offered HBV vaccinations?
- What is the proportion of service users taking up HBV vaccination against locally set targets?

**Question 6:**

Local drug partnerships submitted data against the following questions:

- **JCM questionnaire, question 21a:** Have clinical pathways or protocols been agreed for the assessment and treatment of HCV viral infection in drug misusers?

- **JCM questionnaire, question 21b:** Have clinical pathways or protocols been agreed for the assessment and treatment of HIV viral infection in drug misusers?

NDTMS data was also used to score this question. The data related to the second quarter of 2006/07:

- What proportion of current or ever injecting service users have a record in NDTMS of their last test date for HCV?
**Item 10 (audit topic B2.47)**

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
</table>
| Health – DRD: B2.47 – All patients receive regular advice, information and risk assessments (in keyworking sessions) to reduce the risk of drug-related death | 2006/7 service review on commissioning and harm reduction, Criterion 7 Questions 2, 3 & 4:  
  - Question 2 – Does the local needs assessment establish the levels of need for harm reduction interventions?  
  - Question 3 – Where in the treatment system are harm reduction interventions provided?  
  - Question 4 – Which harm reduction interventions are provided in specialist community prescribing services? |

**Question 2:**

Local drug partnerships submitted data against the following questions:

- *JCM questionnaire, question 15:* Does the local needs assessment establish the levels of need for the following drug-related harm reduction interventions?
Question 3:
Local drug partnerships submitted data against the following questions:

- *JCM questionnaire, question 16:* Where in the treatment system are harm reduction interventions provided?

- The following table was presented to joint commissioning managers and they were asked to state whether this intervention was available in “None”, “Some” or “All” services under the Tier in question.

<table>
<thead>
<tr>
<th>Harm reduction intervention</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle and syringe exchange services</td>
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<tr>
<td>Advice and information on safer injecting practice</td>
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<tr>
<td>Advice and information on reducing sexual risk-taking behaviour</td>
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<tr>
<td>Advice and information on overdose prevention</td>
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<tr>
<td>Wound care in substance misuse services</td>
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<tr>
<td>General healthcare assessments and referral to general/sexual health services</td>
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<tr>
<td>Testing for HIV infection with pre- and post-test counselling</td>
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<tr>
<td>Referral to other services for treatment for HIV infection</td>
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<td></td>
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<tr>
<td>Testing for HBV infection with pre- and post-test counselling</td>
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<tr>
<td>Vaccination for HBV</td>
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<tr>
<td>Referral to other services for treatment for HBV infection</td>
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<tr>
<td>Testing for HCV infection with pre- and post-test counselling</td>
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<tr>
<td>Referral to other services for treatment for HCV infection</td>
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<tr>
<td>Testing for other infections with pre- and post-test counselling</td>
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<tr>
<td>Referral to other services for treatment for other infections</td>
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</tr>
<tr>
<td>Identification of drug-users with hazardous or harmful drinking practices</td>
<td></td>
<td></td>
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<tr>
<td>Advice to drug-users about reducing their risk of alcohol-related harm</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Provision of specialist alcohol-addiction services</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Advice and support for responding to overdose situations</td>
<td></td>
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</tr>
</tbody>
</table>
Question 4:

Local drug partnerships submitted data against the following questions:

*JCM questionnaire, question 3:* How many specialist community prescribing services, that your organisation is responsible for, provide the following harm reduction information?

Please tick 'All', 'Some' or 'None' as applicable. If there is only one provider, please tick 'All'

<table>
<thead>
<tr>
<th>Harm reduction interventions</th>
<th>Provided by</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
</tr>
<tr>
<td>Needle and syringe exchange services</td>
<td>☐</td>
</tr>
<tr>
<td>Advice and information on safer injecting practice</td>
<td>☐</td>
</tr>
<tr>
<td>Advice and information on reducing sexual risk-taking behaviour</td>
<td>☐</td>
</tr>
<tr>
<td>Advice and information on overdose prevention</td>
<td>☐</td>
</tr>
<tr>
<td>Substance misuse related wound care</td>
<td>☐</td>
</tr>
<tr>
<td>General healthcare assessments and referral to general/sexual health services</td>
<td>☐</td>
</tr>
<tr>
<td>Testing for HIV infection with pre- and post-test counselling</td>
<td>☐</td>
</tr>
<tr>
<td>Referral to other services for treatment for HIV infection</td>
<td>☐</td>
</tr>
<tr>
<td>Testing for HBV infection with pre- and post-test counselling</td>
<td>☐</td>
</tr>
<tr>
<td>Vaccination for HBV</td>
<td>☐</td>
</tr>
<tr>
<td>Referral to other services for treatment for HBV infection</td>
<td>☐</td>
</tr>
<tr>
<td>Testing for HCV infection with pre- and post-test counselling</td>
<td>☐</td>
</tr>
<tr>
<td>Referral to other services for treatment for HCV infection</td>
<td>☐</td>
</tr>
<tr>
<td>Identification of drug users with hazardous or harmful drinking practices</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical audit topic to consider</th>
<th>Related NTA/Healthcare Commission service review criteria/question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential elements:</td>
<td>2005/6 service review on community prescribing and care planning, Criterion 10 Question 1: Do formal partnership agreements exist for the following inter-agency policies?</td>
</tr>
<tr>
<td>B2.1 – Drug misusers with parental responsibility are identified at assessment and during treatment, and the risks to their children assessed</td>
<td>Information Sharing Policy</td>
</tr>
<tr>
<td>B2.7 – Formal case management protocols are in place where patients have involvement with mental health and/or criminal justice or other externally coordinated services</td>
<td>Child Protection Policy</td>
</tr>
<tr>
<td>Specific situations/populations – criminal justice: B2.54 – Information is shared, as appropriate and with patient consent, between drug treatment services and criminal justice agencies</td>
<td>Care Coordination Policy</td>
</tr>
<tr>
<td>Specific situations/populations – prisons: B2.55 – There are effective care pathways between prisons and the community (drug treatment service, GPs), including contingency arrangements where an individual leaves prison outside of standard working hours</td>
<td></td>
</tr>
<tr>
<td>Specific situations/populations – pregnancy: B2.56 – The risks and needs of pregnant drug misusers are the subject of multidisciplinary assessment early in pregnancy</td>
<td></td>
</tr>
</tbody>
</table>

Information was collected from local drug partnerships in relation to the following service pathways:

- Information sharing policy: Defines appropriate parameters for confidentiality and information sharing and has local strategic sign up (Ref: Dept of Health 1999 – working together to safeguard children).
- Child protection policy: A joint working arrangement which is agreed, implemented and reviewed through the mechanism of the area child protection committee.
- Care coordination policy as defined in Models of Care, 2002.
### Appendix C: Extracts from NICE drug misuse audit criteria

**NICE audit criteria for drug misuse clinical guidelines 51 (psychosocial interventions) and 52 (detoxification)**

Extracted from full drug misuse audit criteria (NICE, 2007g), which additionally includes PHI4 (NICE, 2007h) and has exceptions, standards, definitions, etc.

<table>
<thead>
<tr>
<th>No.</th>
<th>Criterion</th>
<th>CG</th>
</tr>
</thead>
</table>
| 1   | Percentage of service users offered evidence-based written information about:  
  • Their condition  
  • The treatment and care they should be offered  
  • The service providing their treatment and care.                                                                                             | 51 & 52     |
| 2   | Percentage of carers offered evidence-based written information about:  
  • the service user’s condition  
  • the treatment and care the service user should be offered  
  • the service providing the service user’s treatment and care.                                                                                | 51 & 52     |
| 4   | For those people in limited contact with drug services (such as those attending primary care settings) who have been identified as being at risk of misusing substances, the percentage who are offered opportunistic brief interventions focused on motivation. | 51          |
| 10  | For those people in limited contact with drug services (such as those attending primary care settings) who are misusing substances, the percentage who are offered opportunistic brief interventions focused on motivation. | 51          |
| 11  | Percentage of people who misuse drugs who are provided with information about self-help groups.                                                                                                           | 51          |
| 12  | Detoxification as a treatment option is readily available to people who are opioid dependent and have expressed an informed choice to become abstinent.                                                      | 52          |
| 13  | Percentage of people who are considering detoxification given detailed information about detoxification and the associated risks. This should include:  
  • 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). | 52          |
| 14  | Percentage of people offered either:  
  a) methadone or  
  b) buprenorphine  
  as the first-line treatment in opioid detoxification.                                                                                         | 52          |
| 15  | If the service user is currently being maintained on either methadone or buprenorphine, the percentage who start their opioid detoxification using the same medication.                                             | 52          |
| 16  | The service user’s preference for either methadone or buprenorphine is taken into account when the healthcare professional decides between these medications for first-line treatment in opioid detoxification. | 52          |
| 17  | Percentage of people offered ultra-rapid detoxification under general anaesthesia or heavy sedation.                                                                                                       | 52          |
| 18  | Percentage of people considering opioid detoxification who have been offered a community-based programme.                                                                                                   | 52          |
## NICE audit criteria for drug misuse technology appraisals 114 (methadone and buprenorphine) and 115 (naltrexone)

Extracted from full technology appraisal audit criteria (NICE 2007e and NICE 2007f), which include exceptions, standards, definitions, etc.

<table>
<thead>
<tr>
<th>No.</th>
<th>Criterion</th>
<th>TA</th>
</tr>
</thead>
</table>
| 1   | The percentage of people who have been prescribed methadone or buprenorphine (oral formulations), who have previously had an assessment that included:  
  - The person’s history of opioid dependence  
  - The person’s commitment to a particular long-term management strategy  
  - An estimate of the risks and benefits of each treatment made by the responsible clinician in consultation with the person. | 114 |
| 2   | The percentage of people for whom, following assessment, methadone has been prescribed as the first choice over buprenorphine.                                                                              | 114 |
| 3   | The percentage of people who are supervised daily for at least the first 3 months while receiving methadone or buprenorphine.                                                                                  | 114 |
| 4   | The percentage of people who are receiving methadone or buprenorphine treatment as part of a programme of supportive care (irrespective of receiving psychosocial care as part of this programme). | 114 |
| 1   | The percentage of formerly opioid-dependent people receiving naltrexone treatment who have undergone detoxification and are highly motivated to remain in an abstinence programme. | 115 |
| 2   | The percentage of people receiving naltrexone treatment who are under adequate supervision while receiving this treatment.                                                                                  | 115 |
| 3   | The percentage of people receiving naltrexone treatment who have been fully informed of the potential side effects of the treatment.                                                                      | 115 |
| 4   | The percentage of people who are receiving naltrexone treatment as part of a programme of supportive care.                                                                                         | 115 |
| 5   | The percentage of people receiving naltrexone treatment who are regularly reviewed.                                                                                                                      | 115 |
| 6   | The percentage of people receiving naltrexone treatment for whom there is an agreed plan of action in the event that they use opioids while receiving naltrexone treatment. | 115 |
Appendix D: References


