



***National Treatment Agency  
for Substance Misuse***

**Clinical governance in drug treatment**  
A draft good practice guide for providers and  
commissioners

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Issued for consultation – 21 February 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 Government in 2001, to improve the availability, capacity and effectiveness of treatment for drug misuse in England.

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

The overall purpose of the NTA is to:

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

### Reader information

|                   |   |
|-------------------|---|
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# 1 About the consultation

## 1.1 Introduction

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Clinical governance is an important framework for ensuring the quality and safety of healthcare. Its use in drug treatment has been inconsistent but it is clearly highlighted as the key vehicle for delivering safe and effective treatment that is consistent with the recent suite of NICE clinical guidance (NICE, 2007a, b, d, c, e) and the 2007 Clinical Guidelines (or 'Orange Book'): Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH and devolved administrations, 2007).

This draft document, on which we are consulting, aims to highlight the importance of clinical governance and to provide drug treatment providers and commissioners with some of the information they need to understand clinical governance's relevance to drug treatment and how it can be implemented or improved.

Because this is a new development for some aspects of drug treatment, we are asking stakeholders to review the draft information presented here and comment back to us. The document contains a number of specific questions (in boxes with dashed lines) we would like addressed but you are welcome to comment on any other aspect of the draft. However, all comments **MUST** be entered into the proforma available on the NTA website ([www.nta.nhs.uk](http://www.nta.nhs.uk)) and returned by email. This also contains all of the questions. We will not be able to consider separate email comments or tracked changes.

The deadline for receipt of responses arising from the three-month consultation is given on the NTA website and in the proforma.

*Q1 This draft focuses on some 'formulaic' aspects of clinical governance (why it is required, what it is and the processes which drive it). Is this appropriate or would you prefer more on how clinical governance can be made to be valued and to work in real situations?*

*Q2 The draft focuses on the key elements of clinical governance for both providers and commissioners and omits the practical aspect of implementation in their organisations. Would more detailed "how to" manuals for providers and commissioners be useful?*

## 1.2 Criteria for consultation

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This consultation follows the 'Cabinet Office Code of Practice'. In particular we aim to:

- consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the code of practice
- be clear about what our proposals are, who may be affected, what questions we want to ask and the timescale for responses
- ensure that our consultation is clear, concise and widely accessible
- ensure that we provide feedback regarding the responses received and how the consultation process influenced the code of practice
- monitor our effectiveness at consultation including through the use of a designated consultation co-ordinator, and

- ensure our consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full text of the code of practice is on the Cabinet Office website at:

<http://bre.berr.gov.uk/regulation/consultation/code/index.asp>

### **1.3 Comments on the consultation process itself**

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If you have concerns or comments you would like to make relating specifically to the consultation process itself please write to:

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e-mail [clinical.governance@nta-nhs.org.uk](mailto:clinical.governance@nta-nhs.org.uk)

Please do not use this postal address for consultation responses. These should only be sent electronically and using the supplied proforma to the email address.

### **1.4 Confidentiality of information**

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

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

The NTA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

## 2 Executive summary

### 2.1 Introduction

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Clinical governance is an established system in the NHS and independent healthcare sector to deliver and demonstrate that the quality and safety of its services are of a high standard that is continually improving. However, this approach is relevant to non-NHS healthcare providers and to providers of social care, where it may currently be referred to as practice governance. For most drug treatment services, implementation of clinical governance is already a statutory or contractual obligation, and a consistent focus on clinical governance by all providers and commissioners of drug treatment will ensure higher quality services for drug misusers.

This document aims to advise on and support the effective implementation of clinical governance for all drug treatment providers, across all tiers, whether delivering health or social care, and whether public or independent (private or voluntary sector). It is intended as guidance for clinicians, commissioners and service managers in both the NHS and independent/non-statutory sector.

A clear focus on supporting services to improve their implementation of clinical governance is timely because:

- There is a wealth of new guidance on evidence-based clinical practice, including Drug Misuse and Dependence: UK Guidelines for Clinical Management, and the suite of NICE technology appraisals and clinical guidelines on drug misuse
- Clinical governance has been found to be inconsistently implemented and applied in healthcare settings, especially in drug treatment and in primary care
- Clinical governance is complex in the drug treatment sector, which crosses health, social care and criminal justice, and organisational boundaries.

Improvement in the clinical governance framework for drug treatment and for service providers is a stepwise process. This guidance is aimed at assisting with realistic improvements. It is not intended as a one-size-fits-all blueprint for delivery. Some large organisations will already have access to highly developed support systems. Other organisations will not have this but will wish to improve their current support structure. Provider groups covering local drug partnership areas present an opportunity for providers to enhance clinical governance across the partnership and to consider sharing or utilisation of resources.

### 2.2 Clinical governance content

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Clinical governance is usually conceived of as a framework containing a number of domains to be addressed. Some elements within these domains are generic to all health and social care, for example, dealing with untoward incidents, and ensuring that staff are competent to do their jobs and are adequately trained and supervised.

Focusing down on to drug treatment, there will then be particular priorities and more detailed elements within these domains that relate specifically to drug treatment. So, for example:

- Within the safety domain, local inquiry procedures in cases of drug related deaths can be an important component of the investigation of untoward incidents, and policies to address needle-stick injuries are a relevant element of patient safety standards
- Staff competence includes a doctor's or a nurse's or a drugs worker's competencies to provide specific drug treatments and will also extend to requirements for continuing professional development and clinical supervision and other mechanisms for staff development.

### 2.3 Clinical governance process

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A number of different processes will apply in any clinical governance system but one of the essential elements is clinical audit. This is a cycle for setting standards, monitoring performance against the standards, taking action to improve followed by further review. Some standards will be determined by external processes, such as the NTA/Healthcare Commission Service Reviews. Others will arise from locally-driven priorities.

Clinical governance processes can work most efficiently by fitting in with any existing and required processes and timetables for reporting or review, for example, the annual treatment planning process.

### 2.4 Responsibilities of providers and commissioners

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All providers delivering health or social care – whether NHS, local authority, criminal justice or independent sector – and commissioners of such care, have a responsibility to ensure effective clinical governance in drug treatment services. In many cases carrying out these responsibilities will be a statutory (i.e. for NHS and NHS-commissioned services) or contractual (for DAT and other non-NHS commissioned services) requirement. In others, these are not statutory or contractual obligations but are clearly recognised as best practice in providing assurance of the quality of care. The responsibilities can be summarised as follows:

- **Local drug partnerships** take the lead on planning and commissioning treatment services in their area. They should take a lead in ensuring that effective local systems for clinical governance are in place and that clinical governance is embedded within the services they commission. However, the statutory responsibility for clinical governance will usually fall to some of their member organisations.
- **Primary care trusts** are required to commission care that complies with Standards for Better Health and to have mechanisms in place to monitor compliance. NTA/Healthcare Commission substance misuse criteria are also a key driver of improvement in quality in recent years. When commissioning care within the NHS there will also be clinical governance responsibilities for the NHS provider. However, the PCT's responsibilities for standards-compliant care are especially pertinent when commissioning voluntary sector services, when the PCT commissioner has a statutory responsibility for ensuring good clinical governance. Further guidance to support effective commissioning for clinical governance is planned for 2008. **Local commissioning partnerships, and PCT commissioners especially**, take the lead in requiring services to implement or improve clinical governance, by building these requirements into service level agreements and ensuring compliance through performance management.
- **Mental health and foundation trust drug treatment services** must take part in their trust clinical governance system and should designate a clinical governance lead.

- **Primary care services** must take part in the local NHS clinical governance system. They should designate a clinical governance lead in every practice and participate in clinical governance activity across the PCT.
- **Non-statutory sector providers** should all carry out elements of clinical governance as good practice but most will also have responsibilities depending on how they are commissioned and the services they provide. These include:
  - Those registered as independent healthcare providers with the Healthcare Commission have a statutory requirement to assure themselves against the Independent Healthcare Minimum Standards.
  - Those commissioned by PCTs will be accountable to them for clinical governance, and should be assured against Standards for Better Health and NTA/Healthcare Commission criteria.
  - Registered care homes will operate within the regulation of the Commission for Social Care Inspection (CSCI) and be required to meet standards for systems of governance, although it will not be called clinical governance.
  - Services that are not regulated by the Healthcare Commissioner, CSCI or other mechanisms will also be expected to deliver services in line with national standards and guidance. They may be contractually required to provide assurance against a range of other standards, for example local authority Best Value Performance Indicators. Clinical governance is good practice for drug treatment providers whether or not it is required by contracts.
- **Services that cover multiple geographical areas or a number of different treatment modalities** may be required to meet the clinical governance requirements of multiple commissioners.
- **Prison healthcare** commissioned jointly by the PCT and prison will be subject to the same requirements as other healthcare for NHS patients. Some drug treatment, including CARATs, accredited cognitive behavioural programmes and therapeutic community programmes, will be directly commissioned by the prison service or private prisons and fall outside these requirements. The National Drug Programme Delivery Unit (NDPDU), prison healthcare managers and governors (or directors of contracted-out prisons), as appropriate, can all ensure quality and safety by ensuring that effective clinical governance is in place for these programmes.
- **Community criminal justice drug treatment** covers clinical treatment for drug misusing offenders provided by services already providing treatment to other drug misusers (in which case it will usually be subject to the same requirements as other healthcare for NHS patients) and psychosocial interventions commissioned or provided by the probation services, which may benefit from clinical governance mechanisms.

It is important to note that many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to undertake clinical governance in whichever type of service they are based. They will need to ensure that the requirements on them as professionals are reflected in organisational arrangements.

## 2.5 Standards frameworks

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Clinical governance is usually delivered through a framework of quality standards. In the NHS the key framework is now Standards for Better Health, although many providers will be more familiar with the 'seven pillars'. This can provide the basis of a framework for all drug treatment but, in practice, in order to address treatment and care priorities within drug treatment, this needs to be supplemented with drug misuse-specific standards. Examples

include the use of NTA/Healthcare Commission criteria, and the use of standards from other relevant areas of care and treatment, including statutory standards for some providers of health and social care.

## **2.6 Implementing clinical governance**

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Fully-developed clinical governance can be complex. Organisations may need to start with a simple framework and build up to a fully developed system over a number of years. Providers and commissioners intending to deliver safe and effective care and who have recognised the value and importance of clinical governance need at least to start the implementation process.

Implementation will vary depending on the size and nature of the organisation. A large mental health trust or PCT may have a clinical governance team and committees dedicated to different aspects of clinical governance. A small voluntary organisation may only need to identify a clinical governance lead and ensure that it carries out modest clinical governance activities in accordance with the requirements of its commissioner.

The drug treatment sector has the opportunity to share knowledge and experience between partners and provider services. The current range of treatment provider groups allow for such exchange and partnerships may wish to consider supporting such initiatives.

## 3 Introduction

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### Clinical governance – what’s in it for me?

“The more people grasp it the more they want to be involved. This is exciting - as chair of a big committee, it is akin to conducting an orchestra of accomplished players. ... The cardinal benefit has been the ability to form a culture that feels good. Staff [from all involved services] know that they belong to this Directorate. It has removed any sense of ‘poorer sister borough’ and allowed for the expression of local need as well as local qualities.”

Camden and North West London Mental Health Trust (William Shanahan, medical director and chair, clinical governance committee)

“The service itself benefits from the structured approach to its quality initiatives, being able to identify policy gaps, demonstrate delivery of clinical quality already established and a feeling of improved integration with the local NHS.”

Lifeline Kirklees (Bridget Hughes, service manager)

“Now that staff are engaging with the process teams will automatically come up with service improvement initiatives rather than these being imposed by managers. ... A massive vehicle for change, very exciting”

Cygnets Healthcare (Malcolm Carr, director of clinical services)

“Benefits to the organisation include ... involvement of all staff, which is empowering to more junior staff and allows a bottom-up approach.”

Addaction

### 3.1 Aim of this document

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The aim of this document is to advise on the effective implementation of clinical governance among all drug treatment providers, across all tiers, whether delivering health or social care, and whether public or independent (private or voluntary sector). The document:

- Clarifies and defines what is meant by clinical governance
- Outlines treatment providers’ and commissioners’ responsibilities regarding clinical governance
- Outlines senior clinicians’ and managers’ accountability for clinical governance, and raises service provider staff’s awareness of their responsibilities to work within clinical governance frameworks
- Demonstrates through case studies how aspects of clinical governance may be implemented in a range of drug treatment settings.

### 3.2 Who the guidance is for

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The guidance is aimed at clinicians, commissioners and service managers in both the NHS and independent/non-statutory sector. A clinician in this context is defined as anyone who directly provides pharmacological or psychosocial treatment to drug misusers and therefore includes doctors, nurses, pharmacists, psychologists and most drug workers.

### 3.3 What is clinical governance?

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*'A framework through which ... organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'* DH 1998

The key elements in this definition of clinical governance are:

- Framework – The various activities included in clinical governance need to be set within a framework that enables assurance for all aspects of clinical activity in a comprehensive and systematic way.
- Accountability – Public and independent sector health and social care organisations have a statutory duty to assure themselves on the quality of care they provide. Regulatory authorities ensure accountability for clinical governance. A structured accountability framework running right through the organisation can help to make everyone take responsibility for clinical governance.
- Quality – Clinical governance should aim to ensure that treatment is safe, evidence-based, effective, cost-effective, available, accessible and equitable, and that delivers the best possible service user experience.
- Environment – One in which individuals and organisations can openly and honestly examine their own practice and take responsibility for change to achieve improvement. Requires a supportive no-blame culture which focuses on systemic improvement.

Clinical governance describes a systematic approach to monitoring and improving the quality, safety and effectiveness of clinical interventions. There is no single task, structure or process that is clinical governance. Rather, it describes the totality of tasks, structures and processes implemented to improve the quality of treatment and care delivered to service users.

Most organisations will already be carrying out many of these tasks, will have many of these structures and will use many of these processes. So, clinical governance is not necessarily about doing anything new but about bringing existing quality assurance activities together.

Because it is a system for improving quality, clinical governance is relevant to all individuals and organisations providing and commissioning treatment for drug misusers, even where their interventions might not be considered as 'clinical'. In these settings it may be known as practice or service governance but this document uses the single, widely-accepted term of clinical governance. This reflects the broader definition of 'clinical' adopted by the 2007 Clinical Guidelines (DH and devolved administrations, 2007), in which 'clinicians' also covers the wide range of individuals providing treatment for drug misusers.

*Q3 We have referred to practice governance in 3.3 but only used 'clinical governance' in the publication title and throughout the text. Will non-NHS drug treatment providers who perhaps do not see their services as being clinical in nature understand that the guidance applies equally to them?*

Typically, clinical governance covers a range of general domains and, increasingly, these are drawn from Standards for Better Health (DH, 2004a), whose domains are listed in table 1. These headings provide a checklist for delivering quality, but clinical governance is more than a list – it is the means by which delivery is addressed.

And for drug misuse, the headings may take on a different priority or a different focus than in other branches of health and social care. These will be determined by, for example:

- National drivers

- statutory requirements
- national performance targets
- national clinical guidance, including NICE
- NTA/Healthcare Commission Service Review criteria.
- Local drivers
  - commissioner priorities
  - organisational priorities.

These are described in more detail in chapter 4.

#### **Domains for clinical governance**

- Safety
- Clinical and Cost Effectiveness
- Governance
- Patient Focus
- Accessible and Responsive Care
- Care Environment and Amenities
- Public Health

Standards for Better Health, DH 2004a

*Table 1. Domains for clinical governance*

### **3.4 Why this guidance is necessary**

#### **3.4.1 Clinical governance is a statutory requirement for most organisations involved in delivering drug treatment**

The Care Standards Act 2000 and the Health and Social Care (Community Health and Standards) Act 2003, established legal obligations for the entire healthcare sector and relevant parts of the social care sector to assure themselves annually on the quality of services they provide or commission. The Acts also put in place new regulatory authorities with powers to inspect health and social care, collate trusts' self reports and report their findings annually to parliament. Clinical governance is now the established mechanism by which the government is assured on quality in clinical aspects of care.

Commissioner and provider organisations falling under the umbrella of the Acts are legally required to have clinical governance frameworks and processes in place, and to comply with one of the statutory standards frameworks. The Healthcare Commission conducts a yearly assessment of the performance of every NHS trust in England: the 'annual health check'. This includes assessment against the core standards defined in Standards for Better Health.

The Healthcare Commission and NTA have been conducting annual reviews to assess against criteria for drug treatment. This generally takes drug partnerships or mental health trusts as the unit of assessment and so, between commissioned and provided services, covers the vast majority of community drug treatment provision. In 2007/8, through joint working with CSCI, the review will also assess services providing Tier 4 interventions. After

2007/8, new arrangements will apply but are expected to retain some of the criteria from previous reviews.

### **3.4.2 Clinical governance in drug treatment is patchy and inconsistent**

There are indications that commissioning for clinical governance has been poorly developed in PCTs across the board (CGST and NatPaCT, 2003) and there may be particular issues with regard to independent providers including primary care (NAO, 2007).

The NTA/Healthcare Commission Service Review in 2005/6 (Healthcare Commission/NTA, 2006) found significant inconsistencies in the implementation of one element of clinical governance in community prescribing services: clinical audit, which is regarded as a key indicator of commitment to quality. Twenty seven percent of community prescribing services had not undertaken any clinical audit in the previous 18 months.

Taken as a whole, the picture suggests only patchy or partial implementation of clinical governance at present.

### **3.4.3 Drug misuse treatment is complex and clinical governance places different demands on different organisations**

Drug treatment cuts across many organisational boundaries: health and social care, criminal justice, statutory and non-statutory. This means that clinical governance can be complex and there is wide variation in clinical governance delivery within the drug treatment sector.

The principal players in drug treatment are:

- Local drug partnerships – who take the lead on planning and commissioning treatment services in their area. They are well-placed to also take a lead in ensuring that effective local systems for clinical governance are in place and that clinical governance is embedded within the services they commission. However, the statutory responsibility for clinical governance will usually fall to some of their member organisations.
- Primary care trusts – who act as bankers for the bulk of drug treatment funding on behalf of the local drug partnership and may also be the formal commissioners for local treatment provision. They need to ensure and resource clinical governance in the services they commission and they have lead responsibility for commissioned voluntary sector services, which do not themselves have statutory clinical governance obligations. They can work with others in the local drug treatment system to ensure that clinical governance systems are complementary and do not make excessive bureaucratic demands.
- Mental health trusts – which provide much of the clinical drug treatment in some areas and have trust-wide clinical governance systems in place.
- Primary care providers – which provide an increasing amount of community prescribing and should participate in clinical governance across the PCT.
- The voluntary and private sectors – which mostly provide treatment commissioned by local commissioners but may also provide their services independently. They may have a variety of quality assurance mechanisms and will increasingly need to engage with NHS clinical governance systems.

These and other responsibilities are described in more detail in chapter 6.

One particular factor causing variation has been a lack of recognition of who is responsible for clinical governance of any service they commission. For instance it is not uncommon for a local drug partnership to commission an independent service provider to provide a part of its

drug treatment system. However it may be the PCT that actually procures the service and contracts with the service provider, in which case the PCT is statutorily accountable for the clinical governance of the independent provider.

Some interventions provided for drug misusers – and the organisations providing them – are not covered by statutory requirements for clinical governance. These may include housing and housing support, and some other interventions. They are often services provided by voluntary sector community and residential services. They may be local authority commissioned or provided services. Even where statutory requirements for clinical governance do not apply, it is important that all providers of all types of services to drug misusers strive for high quality care, and apply quality assurance and clinical governance principles outlined in this briefing. Increasingly, clinical governance will be required of all commissioned services.

## 4 The content of clinical governance

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Clinical governance is often considered in a framework of domains covered by Standards for Better Health (SfBH), although it may use – or include additional domains from – other relevant standards or guidance. Table 1 in the introduction lists the SfBH domains to be covered in a clinical governance framework. All are relevant for drug treatment services but some have more specific relevance or particular requirements.

Mental health trusts and primary care trusts are assessed against the core standards within these domains by the Healthcare Commission (Healthcare Commission, 2007a and 2007b). Drug treatment systems (and some services) are currently assessed against NTA/Healthcare Commission Service Review criteria, which also cover aspects within these domains.

*Q4 Standards for Better Health are the key standards for the NHS and, in the future, likely to form the basis of standards for both health and social care. However, would it be helpful here to explain how relationships with other quality assurance systems might work?*

*Q5 Chapter 4 only contains enough information to describe briefly how each domain relates to clinical governance in drug treatment. Would more or less information be useful under each heading?*

### 4.1 Safety

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The safety domain covers issues such as deaths and other adverse incidents, child protection, medicines safety and hazardous waste disposal. Patient safety should be enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to patients.

Proper risk management is vital in drug treatment and, in addition to the risks common to any workplace and public clinical environment, should pay special attention to:

- Safe prescribing and handling of medicines – appropriate prescribing, dispensing accuracy, on-site storage, home storage, prescription security and communication with pharmacists, etc.
- Blood-borne viruses – preventing and responding to needle-stick and other injuries, and vaccination of staff.

Risk management includes both prevention and review of untoward incidents. Review processes will include incident reporting, investigation and review (including confidential inquiries into drug related deaths). It is an important principle of effective clinical governance that an appropriate 'no-blame' culture underpins the approach to dealing with untoward incidents as they occur. Preventative processes include infection control, action on safety notices, safety and decontamination of medical devices, child protection procedures, medicines management and waste management.

NHS and independent organisations providing services that may involve the management or use of controlled drugs are required by law to appoint an accountable officer. Accountable officers are responsible for ensuring compliance with misuse of drugs legislation and the safe, effective management of controlled drugs within their organisations and within those organisations with whom they contract relevant work.

## 4.2 Clinical and cost effectiveness

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All drug treatment services should be providing interventions in line with, or that properly take account of, the latest evidence-base, including any authoritative guidance on effectiveness. This will include taking account of evidence from authoritative research and other emergent sources, NICE technology appraisals and clinical guidelines, and Drug Misuse and Dependence: UK Guidelines on Clinical Management.

Local clinical audit can monitor whether interventions are being delivered in accordance with guidance or locally determined standards and whether they are producing expected outcomes, and it can help to ensure improvement through use of the audit cycle.

Local research and analysis on the effectiveness of clinical interventions can also be useful. A range of measures, including the Treatment Outcomes Profile (TOP), can be used to compare the outcomes resulting from different treatments.

Where published evidence of effectiveness of particular interventions is not available, clinical governance processes can help to ensure on-going evaluation of such practice, including the views of service users. This can help to assure both safety and effectiveness are being properly monitored either through focused work or through general systems of governance and exception reporting.

There must be designated clinical leadership and accountability, and clear clinical protocols for effective clinical governance.

All staff must be appropriately supported and supervised, including clinical supervision for clinical staff. Underpinning principles for supervision include the need for a supportive, open and non-threatening style that recognises the need for lifelong learning for all clinicians.

*Q6 It has been suggested to us that clinical supervision is such an important topic that it might benefit from an additional appendix containing guidance. Is this needed? Would it be helpful?*

All staff should participate in continuing professional and occupational development commensurate with their work, including mandatory training programmes (NB NHS mandatory training also applies to staff from the commissioned non-statutory sector).

Team working is important in drug treatment, which involves working with clients with multiple needs and therefore the requirements to involve multiple disciplines in their treatment. Team working applies both internally, e.g. senior management, clinical and multi-disciplinary teams, and externally, e.g. across organisational boundaries and sectoral frontiers (statutory/voluntary, health/social services, etc.).

## 4.3 Governance

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The governance domain in Standards for Better Health covers a wide range of issues with the intended outcome that “Managerial and clinical leadership and accountability, as well as the organisation’s culture, systems and working practices ensure that probity, quality assurance, quality improvement and patient safety are central components of all the activities of the health care organisation.” (DH, 2004a)

### 4.3.1 Staff competencies

Services employing doctors can refer to Roles and Responsibilities of Doctors in the Provision of Treatment for Drug and Alcohol Misusers (RCPsych and RCGP, 2005) for

clarification of the professional consensus on the different types and levels of care delivery that medics within each professional group (GP, psychiatrist, etc.) can and do provide, and the hierarchy of competencies and qualifications for doctors providing drug and alcohol misuse treatment.

Services employing non-medical prescribers can refer to the NTA's good practice briefing on non-medical prescribing (NTA, 2007b) in order to understand the qualifications, competencies and accountabilities involved.

The competencies of all non-medical NHS staff, including drugs workers, should be matched to the NHS Knowledge and Skills Framework (NHS KSF) and to the Drug and Alcohol National Occupational Standards (DANOS), in addition to the requirements of each of their relevant professional bodies.

Competencies for non-NHS drug workers can be matched to the DANOS framework. Skills for Health is currently developing new qualifications specifically designed for those who work with drug and alcohol misusers. Skills for Justice provides a matching framework for staff in the criminal justice system.

Staff providing psychosocial interventions should be competent to provide them, as defined in recent Department of Health guidance (Roth and Pilling, 2007).

#### **4.3.2 Information management**

The management of information in drug treatment is important because of the need to both protect and share information in the client's best interests.

It includes:

- Notekeeping and records management
- Confidentiality
- Consent
- Information sharing
- Information technology quality, connectivity, networking and security.

National, NHS and local rules on confidentiality and data protection will be important to enable the effective use of information. Information sharing protocols should be consistent with guidance from the local Caldicott Guardian.

The boundaries around confidentiality and information sharing for young people will be different in some respects from adults. This is covered in more detail in Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH and devolved administrations, 2007) and NTA guidance planned for 2008 that will cover specific issues relating to the Children's Act 1989 and other legislation referring to children.

The governance domain is also where the requirement for research governance sits. The SfbH standard requires that "Health care organisations which either lead or participate in research have systems in place to ensure that the principles and requirements of the research governance framework are consistently applied".

#### **4.4 Patient focus**

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The patient focus domain covers client dignity, consent for treatment and information sharing, complaints, dietary needs and service information.

Service users should be involved in the planning and delivery of their own treatment, and in the monitoring and development of service delivery more generally. Service users may support others through peer support and advocacy. Carers should also be involved where the client agrees and their own needs should be supported.

#### **4.5 Accessible and responsive care**

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Accessible and responsive care covers prompt and equitable access to treatment and choice.

Service users and carers should be involved in the design and planning of local services. They might also be involved in, for example, interviewing for some staff or in their training.

All drug treatment services, and their commissioners, have a duty to ensure that services are accessible to their communities. They should take account of race, disability, gender, misuse of different drugs, etc in the planning, commissioning and delivery of their services. Public authorities have statutory requirements under the Race Relations Amendment Act and Human Rights Act. The NTA/Healthcare Commission Service Review in 2007/8 has diversity as one of its two themes.

Clients with health needs should be able to access care promptly and within agreed timescales. In drug treatment these timescales are represented by waiting times and the requirements to improve them to within specified limits.

#### **4.6 Care environment and amenities**

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Services should be safe, secure, well-designed and well-maintained and clean.

For drug treatment services the emphasis is likely to be on:

- Staff safety, including lone working policies, safety away from base, etc.
- Aspects of client safety not covered by the safety domain, such as protection from violence and harassment
- Clients' privacy and protection for their children while on the premises.

#### **4.7 Public health**

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Drug treatment, and harm reduction measures in particular, can make a significant impact on public health. Particular issues to be covered in this domain include, for example:

- Harm reduction, including needle exchange, and reducing overdose and drug-related deaths
- Vaccination of staff and clients against blood-borne viruses (hepatitis B and A)
- Infection control, including hazardous waste management and decontamination of medical devices
- Addressing health inequalities.

## 5 The process of clinical governance

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Clinical governance includes four key components:

- Clear lines of responsibility and accountability for the overall quality of clinical care
- A comprehensive programme of quality improvement activities – including clinical audit
- Clear policies aimed at managing risks
- Procedures for all professional groups to identify and remedy poor performance.

(Palmer, 2002)

Implementing clinical governance in drug misuse does not mean reinventing the wheel. NHS trusts and many voluntary sector providers will already have processes in place that can be adopted or adapted, or into which drug misuse-specific clinical governance can be fitted. And there is already a wide range of data sources that will provide much of the information required to audit clinical practice. Provider groups within partnerships interested in improving or enhancing clinical governance may also make use of such data or systems and may find useful opportunities for sharing knowledge, skills and systems, or may determine agreed priorities.

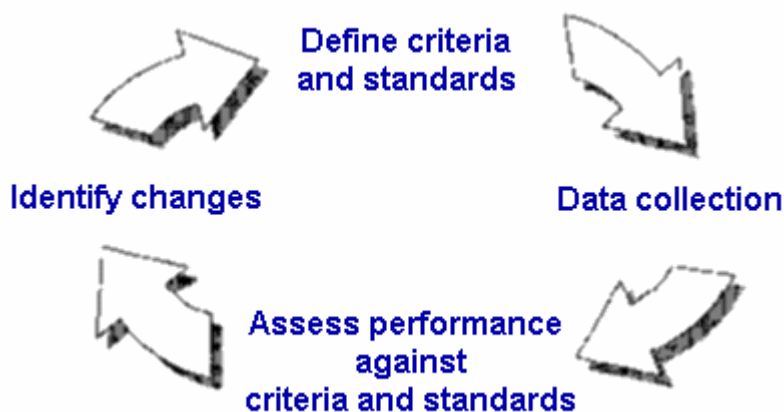
Providers and commissioners will be likely to find it helpful to aim to integrate and streamline existing processes to fit with existing timetables for data collection, needs assessment, audit and performance management, etc., where appropriate.

### 5.1 Clinical audit

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Effective clinical governance commonly relies on a clinical audit cycle in which topics to be addressed are decided (some of which may be externally imposed) and then:

- criteria and standards are set (or externally required)
- data is collected (or is provided from external sources) on how well the organisation is meeting the criteria
- the data is analysed to match performance against the expected standards
- areas for improvement are identified and action agreed.



*A simple audit cycle*

Clinical audit acts as a driver for clinical governance, because it provides evidence on the success (or otherwise) of interventions against agreed criteria and of changes needed. All clinical professional groups (doctors, nurses, pharmacists, psychologists, etc) can be expected to participate in clinical audit as part of their professional responsibilities for clinical governance.

### **5.1.1 Standards and criteria**

Criteria and standards for drug treatment come from various sources. Generic statutory standards and other requirements include:

- Standards for Better Health
- Independent Healthcare National Minimum Standards
- National Minimum Standards for Care Homes
- Race Equality Scheme duties.

There are also, importantly, drug misuse-specific standards and requirements, including:

- NTA/Healthcare Commission Service Reviews (2005-2008) and selected criteria drawn from these that may be assessed in future
- Needs assessment and annual treatment planning to inform local priorities
- Occupational standards including Drug and Alcohol National Occupational Standards (DANOS) and NHS Knowledge and Skills Framework.

Some of these standards are described in more detail in chapter 7 and appendix 3.

### **5.1.2 Data collection**

There are two main methods of acquiring the evidence needed for assuring that standards are being met. These are: firstly, collating existing policies and protocols, which match the standards, and secondly, actively monitoring the outcomes of service delivery to ensure that standards are met.

There are a number of ways of monitoring service delivery in drug services. Acquiring data to analyse outcomes may be relatively easy if they are already being collected for some other purpose, and looking for opportunities to make intelligent use of existing data is advisable wherever possible. Examples of existing data which can be used include:

- National Drug Treatment Monitoring System (NDTMS), including Treatment Outcomes Profile (TOP) data
- NTA user satisfaction surveys and internal service user surveys
- Prescribing data
- Case notes, including care plans
- Staff training, supervision and appraisal records
- Serious untoward incident (SUI) reports and complaints.

It may also be necessary to set up systems to collect specific data on explicit criteria.

### **5.1.3 Assessment of performance and reporting**

#### **5.1.3.1 Local assurance**

The assurance process examines the match of the delivery against standards using a systematic evaluation and reporting process that:

- Maintains a continuing overview of delivery on the standards framework by examining the evidence collated in each domain and making a judgement about how well standards are being achieved
- Makes recommendations for service improvements
- Is responsible for making a declaration on this self-assessment to the appropriate inspectorate.

Key to the assurance process are structures which link all participants at all levels, from individuals, through service provider organisations, DATs, commissioners and inspectorates. Typically, specific groups with remits for particular clinical areas report assurance to the provider's clinical governance overview group, which in turn may report via commissioning bodies to the inspectorates. Communication must also flow downwards, with findings and recommendations fed back to individuals so that improvements can be made.

For organisations within the NHS 'umbrella' much of this structure already exists in trusts, and the challenge is to ensure that trust clinical governance leads are aware of their responsibilities and work closely with the provider to ensure clinical governance requirements are met. However, organisations providing care entirely within the independent sector will need to establish their own reporting and assurance processes.

#### **5.1.3.2 External assurance**

External assurance for general adult health and social care is currently provided by two regulation and inspection bodies, using a range of mechanisms, described below. This will change with their merger by 2008.

##### *Healthcare Commission*

- Annual inspections of all healthcare organisations, whether NHS or independent (private or voluntary sector). NHS trusts are subject to an annual 'health check' that assesses their performance against the core standards defined in Standards for Better Health
- Investigations in response to specific incidents, such as complaints or serious service failings
- Joint NTA/Healthcare Commission Service Reviews to examine a 'theme' of care in relevant organisations
- Participation in local intelligence networks concerning controlled drugs and led by primary care trusts.

(NB Monitor regulates NHS foundation trusts but inspection of their performance against healthcare standards is carried out by the Healthcare Commission.)

##### *Commission for Social Care Inspection*

- Inspection of local authority social services covering how well local services meet people's needs, whether they provide the right specialist services and how good they are, and how effectively the council involves local people in planning services. The

inspections result in a rating of the council's overall performance in relation to social care services.

- Previously annual inspection of residential social care, now becoming targeted at higher risk services as identified in annual performance returns.

### *Future developments*

The Department of Health is planning to streamline much of the standards and reporting structures over the coming years, in line with the philosophy of 'whole system thinking' and reform. Intended developments include aligning standards and merging the Healthcare Commission and CSCI's adult social care responsibilities.

### *Young people*

Children's social care is inspected by Ofsted against national minimum standards and reported against the Every Child Matters outcomes

The NTA's regional teams also have an important role in assuring the delivery of improved capacity, availability and effectiveness of drug treatment. Their assurance processes include reviewing local drug partnership annual treatment plans and checking for compliance with improvement review action plans.

There is more information on regulation and inspection in appendix 2.

## **5.2 Timing the process**

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Some externally-driven processes – including annual treatment planning and NTA/Healthcare Commission Service Reviews (or future arrangements) – may require drug needs assessment and audit to be conducted at particular times of the year. Their results will provide useful information back to the organisation that helps determine where change is needed. It would be helpful to time internal clinical governance processes and the clinical audit cycle to fit in with these other timetables.

## **5.3 Involving others**

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Large organisations (PCTs, mental health trusts and large voluntary sector providers) may have a range of internal bodies and committees providing expertise and oversight on particular subjects in the clinical governance framework, such as health and safety, prescribing and infection control. Smaller organisations may cover all of these through simple internal mechanisms. Alternatively, commissioners might commission the involvement of these bodies as a resource to smaller providers or require them to be involved in the clinical governance processes of smaller providers through contractual arrangements. Practical examples might include:

- Medicines control – a PCT's pharmacy advisory committee provides advice, model protocols, etc. to commissioned providers around appropriate prescribing, supervised consumption, storage, etc.
- Infection control – the mental health trust's infection control nurse includes PCT-commissioned and other local providers in their annual examinations of infection control procedures.

At a more strategic level, the director of public health might provide leadership and support around, for example, infection control and harm reduction measures.

## 6 Roles and responsibilities in clinical governance

### 6.1 Organisations

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#### 6.1.1 Providers' responsibilities

##### 6.1.1.1 General

All providers might be expected to:

- Designate a named clinical governance lead in every service
- Operate in accordance with and participate in the clinical governance activity of their parent or commissioning body.

All drug treatment providers will be required to meet criteria set by the NTA/Healthcare Commission. In addition to these general requirements for all providers, there are specific requirements for specific providers, described below. Many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to undertake clinical governance under the terms of their professional body registration in whichever type of service they are based.

##### 6.1.1.2 Mental health and foundation trust drug treatment services

NHS healthcare services are assessed against the Standards for Better Health by the Healthcare Commission. Mental health and foundation trust substance misuse services will be required to operate in accordance with, and actively participate in, their trusts' clinical governance processes.

*Q7 The interface between the general clinical governance lead for a mental health trust and the clinical leadership in an MHT drug service may be one that would benefit from being strengthened. What advice and support can the NTA provide to facilitate this?*

##### 6.1.1.3 Primary care drug treatment services

Primary care drug services can be delivered according to a variety of models but, whether operating as independent contractors or as PCT-contracted or PCT-run services, they share common responsibilities for clinical governance and will be required to participate in clinical governance activity across the PCT.

*Q8 How can clinical governance be arranged locally so that it covers both primary and secondary care drug treatment?*

##### 6.1.1.4 Non-statutory service providers

The requirements for non-statutory service providers can be complex because of their disparate nature, the wide variety of services they provide and the different ways in which they are commissioned. Services commissioned by PCTs are likely to be accountable to the commissioner for clinical governance, and assured against the Standards for Better Health. Non-statutory services may additionally become answerable to commissioners outside healthcare organisations, funding bodies and, in the case of seconded NHS staff, NHS trusts. All will therefore benefit from a strong focus on governance within their own organisation.

Other specific requirements include:

- Independent healthcare providers will usually be required to register with the Healthcare Commission and will be assessed against the Independent Healthcare National Minimum Standards.
- Residential drug services meeting the definition of a care home will be required to register with the Commission for Social Care Inspection (CSCI) and will be required to meet standards for systems of governance, although it will not be called clinical governance.
- Residential drug services that provide detoxification and other healthcare may be required to meet additional healthcare standards, especially if they are commissioned by one or more PCTs, but will usually still be inspected by CSCI.
- Services that are not PCT-commissioned and not required to register with either the Healthcare Commission or CSCI but that do provide treatment (e.g. individual psychosocial therapies or group work) may be contractually required to carry out assurance against other standards by funding bodies, for instance against Best Value Performance Indicators as defined by the relevant Local Authority. An additional form of assurance might also be considered, such as an accreditation scheme, for example, that provided by the European Association for the Treatment of Addiction (EATA).

How these different requirements translate into the clinical governance expectations on examples of different types of non-statutory providers with different configurations of services is shown in table 2.

Large providers can usually be expected to have their own organisation-wide clinical governance frameworks, with responsibility for clinical governance resting at board level. Smaller providers may adopt or integrate with a local trust's framework and, as a minimum, be required, for example, to follow practice (or develop protocols) in line with authoritative clinical guidance, to report critical incidents and to undertake clinical audit.

Where an independent provider organisation's services are spread across a wide geographical area and encompass a number of different treatment modalities, frequent meetings of all service governance leads may not be feasible, and much of the discussion and analysis may take place at board level.

Where there are multiple purchasers or commissioners, there may be a requirement to engage in multiple clinical governance systems.

*Q9 Is the position of the non-statutory sector sufficiently covered in 6.1.1.4?*

*Q10 How do we deal with organisations operating in multiple localities that may be expected to comply with different clinical governance arrangements in each or duplicate their effort to meet multiple demands?*

| <b>Service example</b>  | <b>Clinical governance approaches</b><br>(in addition to general attention to all the elements of clinical governance listed in table 1)   |
|---|--|
| A service providing Tier 2 interventions but with no needle exchange                      | <ul style="list-style-type: none"> <li>• If commissioned by PCT, requirements for clinical governance including involvement in local processes and adherence to SfBH</li> <li>• Particular attention to: <ul style="list-style-type: none"> <li>- Competencies of staff delivering psychosocial interventions.</li> </ul> </li> </ul>  |
| A service providing Tier 2 interventions including needle exchange                        | <p>As above, plus:</p> <ul style="list-style-type: none"> <li>• Particular attention to: <ul style="list-style-type: none"> <li>- Risk management</li> <li>- Competencies of staff delivering harm reduction interventions</li> <li>- Supervision of clinical staff (e.g. nurses)</li> <li>- Infection control.</li> </ul> </li> </ul>   |
| A shared care service with GPs delivering Tier 3 interventions                            | <ul style="list-style-type: none"> <li>• PCT requirements for clinical governance including practice designated clinical governance lead, involvement in local processes and adherence to SfBH</li> <li>• Particular attention to: <ul style="list-style-type: none"> <li>- Competencies of clinical staff, training, CPD, supervision, etc</li> <li>- Clinical effectiveness of treatments</li> <li>- Safe handling of medicines.</li> </ul> </li> </ul>  |
| A structured day programme providing psychosocial interventions                           | <ul style="list-style-type: none"> <li>• If commissioned by PCT, requirements for clinical governance including involvement in local processes and adherence to SfBH</li> <li>• Particular attention to: <ul style="list-style-type: none"> <li>- Competencies of staff delivering psychosocial interventions.</li> </ul> </li> </ul>  |
| A residential service registered as a care home with nursing and providing detoxification | <ul style="list-style-type: none"> <li>• CSCI requirements: <ul style="list-style-type: none"> <li>- Adherence to National Minimum Standards for Care Homes for Adults (18–65) and, if taking clients under the age of 18, Supplementary Standards for Care Homes Accommodating Young People Aged 16 and 17</li> <li>- Plus higher and additional standards for facilities and equipment.</li> </ul> </li> <li>• PCT requirements if commissioned for detoxification</li> <li>• Particular attention to: <ul style="list-style-type: none"> <li>- Competencies of clinical staff, training, CPD, supervision, etc</li> <li>- Clinical effectiveness of treatments</li> <li>- Safety of medicines.</li> </ul> </li> </ul> |
| A residential service not registered as a care home and not providing detoxification      | <ul style="list-style-type: none"> <li>• If Supporting People-funded, will be required to meet standards laid down by central government and will be regularly reviewed by local Supporting People teams</li> <li>• Clinical governance may be required and performance managed through a contract.</li> </ul>   |

*Table 2. Examples of clinical governance approaches for different types of non-statutory sector drug treatment services*

### 6.1.1.5 Prison-based drug treatment

Providers of prison drug treatment are accountable for continuously improving quality of services and standards of care. All members of treatment teams, both clinical and psychosocial, have a role in clinical governance procedures and in decision making about improvements. As a minimum teams need to decide who is to lead on clinical governance (usually a doctor, nurse or manager), agree plans for documenting and reporting incidents, and choose priorities for improvement.

Prison healthcare commissioned by the PCT will be subject to similar clinical governance requirements as other healthcare for NHS patients. Some drug treatment, including CARATs, accredited cognitive behavioural programmes and therapeutic community-type programmes, are directly commissioned and contract-managed by the prison service and will fall outside these requirements. It will still be important to ensure that clinical governance mechanisms are in place here.

Prison healthcare managers are responsible for the coordination of all healthcare interventions delivered within the prison and will want to ensure that clinical governance arrangements are in place. In publicly-funded prisons they are accountable to the primary care trust and their employing authority. In contracted prisons they are accountable to the director of the prison or, if healthcare is contracted out to a third party organisation, jointly accountable to the clinical director of that organisation and to the director of the prison.

### 6.1.1.6 Community criminal justice drug treatment

Criminal Justice Integrated Teams (CJITs) are commissioned by local drug partnerships and delivered by a range of voluntary and statutory providers. NHS providers will usually already have clinical governance arrangements through their parent body but it may enhance quality if commissioners can ensure that clinical governance arrangements are in place in all providers.

Drug treatment for drug misusing offenders who are subject to community orders with a Drug Rehabilitation Requirement will usually be delivered by services commissioned by PCTs to provide treatment to other drug misusers and will therefore be subject to the same requirements as other healthcare for NHS patients. However, psychosocial interventions, such as cognitive-behavioural programmes like ASRO and OSAP, are commissioned or provided by the probation services and fall outside these requirements, although they are accredited by the Correctional Services Accreditation Panel against criteria that cover some of the elements of clinical governance. It may enhance quality if commissioners can ensure that clinical governance mechanisms are in place here.

*Q11 The situation in prisons is complex and fluid, with changes expected imminently. Do these current descriptions adequately capture **providers'** responsibilities for clinical governance in prisons?*

*Q12 How can criminal justice drug treatment – especially that provided in prisons – be included in local clinical governance frameworks?*

## 6.1.2 Commissioners' responsibilities

There is a difference between lines of accountability for how drug services are commissioned and managed in many areas, and for clinical governance. Although drug partnerships and their commissioners are commonly the driving force behind commissioning, it is usually the PCT – as bankers for the PTB – which provides the legal and financial mechanisms through which commissioned services are contractually bound. It is therefore the PCT that has the statutory responsibility to ensure proper clinical governance in commissioned services. This statutory responsibility should not, however, detract from the importance of the drug partnership and its commissioners playing a lead role in requiring and coordinating clinical governance mechanisms across the partnership's providers.

Practical action that all commissioners can take to support clinical governance includes:

- Recognising the resource implications of clinical governance through appropriate resource allocation. Commissioners need to recognise their role in supporting training, supervision, appraisal and accreditation of staff, staff time to implement the assurance process for clinical governance, and resources for clinical audit and research
- Ensuring contracts and service level agreements with providers explicitly specify the need for robust clinical governance structures and processes, and how compliance should be evidenced
- Putting in place robust mechanisms to monitor clinical governance implementation and compliance with standards across all the areas listed in table 1.

*Q13 How much further should the guidance go in detailing the importance of commissioners resourcing clinical governance in the services they commission, including in the voluntary sector?*

### 6.1.2.1 Primary care trusts

Services provided directly by trusts are likely to be automatically included in the clinical governance process. However trusts need to ensure that services provided indirectly, i.e. commissioned by or on behalf of the trust, are given clear contractual requirements to undertake clinical governance and that they ensure compliance with quality standards. There is some evidence to suggest that this expectation is not always acted upon. A pilot programme on implementation of clinical governance in PCTs found that: "A significant number of PCTs had failed, hitherto, to recognise that their clinical governance duties and responsibilities extend to those services that they commission, as well as services they provide." (Modernisation Agency, 2004)

Clinical governance leads in PCTs need to ensure that they support commissioned non-statutory sector drug treatment services to implement clinical governance processes and that structures exist to report on clinical governance to the trust's clinical governance overview committee.

It is important to note PCTs' new responsibilities to provide prison healthcare services. All prison healthcare services routinely treat inmates for drug problems. Clinical governance leads in PCTs need to support prison healthcare services to implement clinical governance processes, identifying clinical governance leads and teams, and commencing quality

assurance reviews against a standards framework (ideally based on SfBH). PCT clinical governance leads should also set up structures that enable regular reporting on clinical governance from prison healthcare to the PCT clinical governance overview committee.

### **6.1.2.2 Drug partnerships**

The pooled treatment budget is healthcare money usually administered through primary care trusts, which act as bankers for the drugs partnership. Any services commissioned using this money must be required to comply with Standards for Better Health and will usually be expected by commissioners to also comply with drug treatment-specific criteria from the NTA/Healthcare Commission.

As bodies with a vital role (and often taking the lead) in the commissioning process, drug partnerships are ideally placed to ensure a clinical governance framework is commissioned in all services providing treatment for drug misuse in their area. Such clinical governance requirements would need to be reflected in service level agreements. Contract managers can act as a conduit for clinical governance processes: collating evidence to assure the provider organisation against the relevant standards framework. For many this will be a new function, and it is important that they do not cut across existing healthcare and social services clinical governance arrangements, but work in collaboration with them to provide assurance on quality.

They can take a role in overseeing the whole treatment system and in particular the intra-organisational interfaces by bringing together all commissioned (and even non-commissioned) service providers to share clinical governance learning and develop interagency referral and care pathways.

Partnership commissioners can assist services to identify clinical governance leads and teams, and to commence quality assurance reviews against a standards framework (ideally based on SfBH). They may also assist in setting up structures which enable regular reporting on clinical governance from commissioned non-statutory services to the PCT clinical governance overview committee.

DAT partners, including PCTs and local authorities, may also have specific responsibilities, described below.

### **6.1.2.3 Local authorities**

Generally local authorities will commission within a DAT framework, but occasionally they may not have this support. In either case they must ensure a contractual obligation for governance from the service provider. Local authorities will set Best Value Performance Indicators relevant to the services they commission and the outcomes they want to see.

### **6.1.2.4 Prisons**

Primary care trusts are responsible for the commissioning of healthcare services within publicly funded prisons in England and should therefore ensure proper clinical governance as for other healthcare for NHS patients.

In contracted prisons, managers of healthcare services provided by the contractors themselves are accountable to the Director of the prison. Where a clinical service is contracted out to a third party organisation, the healthcare manager is jointly accountable to the clinical director of that organisation and to the Director of the prison. The quality and safety of these healthcare services will be better ensured if the Director of the prison or the clinical director or both ensure proper clinical governance is in place.

Some drug treatment, including CARATs, accredited cognitive behavioural programmes and therapeutic community programmes, is directly commissioned and contract-managed by the prison service. Governors and Directors could ensure that these psychosocial contributions to the overall treatment care plan are included in clinical audit and improvement processes.

The National Drug Programme Delivery Unit (NDPDU) is responsible for coordinating the delivery of non-clinical drug treatment programmes in prisons, including CARAT services, and could ensure proper clinical governance is in place.

*Q14 The situation in prisons is complex and fluid, with changes expected imminently. Do these current descriptions adequately capture **commissioners'** responsibilities for clinical governance in prisons?*

#### **6.1.2.5 Community criminal justice treatment**

Treatment interventions for offenders (DIP and DRR) are all commissioned through local drug partnerships and subject to the same clinical governance arrangements as mainstream treatment. Local probation managers and Regional Offender Managers need to play a proactive role in the joint commissioning process and can help to ensure clinical governance arrangements are in place.

#### **6.1.3 Employers' responsibilities**

Mental health, foundation and primary care trusts' accountability for clinical governance can extend to trust employees on secondment, with trusts being accountable for assuring the quality of the places of work of their employees.

#### **6.1.4 Clinical governance interface - clinical governance quality or audit groups**

Healthcare trusts, and some non-statutory services, have clinical governance groups or departments, with nominated leads for key areas and an overall lead. Governance structures generally comprise several committees for various aspects of governance, such as prescribing, psychological therapies, treatment effectiveness, risk management and so on reporting to a clinical governance overview committee.

Trust clinical governance leads should liaise continually with clinical leads and service managers of provided and commissioned drug services in order to collate evidence confirming that they are providing safe and effective care. Trust clinical governance departments can provide practical support to drug services, for instance by:

- Enabling them to devise drug misuse specific standards frameworks
- Providing policy frameworks, for example for risk management, SUI analysis, descriptions of care pathways and any relevant other clinical guidelines, etc.
- Facilitating clinical audit, by providing training, expertise and devising data collection tools. Data analysis may also be provided by trusts if they are also the provider.

Clinical governance oversight and coordination across drug treatment will be important in every drug partnership area in delivering an effective system of high quality care. This is because service users will often use a number of the statutory and non-statutory health and social care providers within the partnership and because the various providers will have an opportunity to share knowledge and skills and, possibly, resources at this level. This would also assist a co-ordinated provider input on clinical governance to the annual treatment planning process. Unless there are already suitable mechanisms, a partnership-wide clinical governance committee/subcommittee may be required to address this issue most effectively. This may be a role for a current partnership-wide drug reference group, or a reinvigorated or

reconstituted shared care monitoring group, or other suitable local group. However it is constituted, it is likely to be vital that such a group includes adequate representation from non-statutory providers as well as statutory clinical services. Such a group might also formally feed back progress and plans to the drug partnership as well as supporting clinical governance priorities of the services.

*Q15 Inclusive statutory and voluntary sector representation on area and treatment system-wide clinical governance groups is vital. How can it best be achieved?*

## 6.2 Individuals and teams

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*'Clinical governance is everyone's business'*

NHS Clinical Governance Support Team

Clinical governance affects individuals and teams at all tiers of health and social care – this section sets out the different parts people play and the responsibilities they have at each level for ensuring and improving quality in services.

NB Many clinical staff (doctors, nurses, clinical psychologists and pharmacists) have a professional duty to undertake clinical governance under the terms of their professional body registration in whichever type of service they are based.

### 6.2.1 Individual staff

Individuals' roles and responsibilities for clinical governance are discharged through doing the best job they can in the light of service user and public interest, for example:

#### **Clinical leads and managers:**

- Champion clinical governance and provide motivation and direction
- Implement and standardise safe and effective practice through service guidelines and protocols
- Enable training, supervision, and appraisals as appropriate for whole team
- Set up and lead clinical audit teams to run clinical audits
- Set up and lead clinical governance teams to run clinical governance processes
- Make clinical governance reports against standards frameworks.

#### **Clinical staff:**

All staff delivering treatment interventions have a general responsibility to engage in clinical governance. Staff with professional clinical responsibilities, such as doctors, nurses, clinical psychologists and pharmacists, have mandatory registration with their professional bodies. Through these they must adhere to particular professional codes which require them to engage in key clinical governance activities that help to promote and maintain high quality clinical care. These include requirements to:

- Adhere to good practice guidelines and protocols
- Maintain skills and knowledge through continuing professional development
- Report serious untoward incidents (SUIs) and participate in SUI reviews
- Participate in clinical audit.

Some staff may be voluntarily registered with a professional organisation – such as the Federation of Drug and Alcohol Professionals (FDAP) – that requires them to adhere to codes of conduct for safe and effective practice.

**Reception and administration staff:**

- Maintain data quality and ensure data collection
- Ensure clear and timely communication
- Enable service user access to information, and treatment
- Facilitate service user feedback and complaints.

**Cleaners and caretakers:**

- Adhere to protocols regarding infection risk, and health and safety
- Maintain a safe and secure environment.

**Service users and carers**

Service users and carers have a vital role to play in clinical governance. In addition to being on the ‘receiving end’ of, for example, the patient focus elements of clinical governance, they need to be actively involved in clinical governance processes, including participating in:

- Feedback mechanisms to services
- Strategic planning for improved service delivery
- Service user support, advocacy and peer-led training.

Additional information on carer involvement is contained in the NTA publication, Supporting and Involving Carers (NTA 2006c)

As part of their clinical governance arrangements services also need to actively consider, for example:

- Service user volunteer policies
- Service user rights
- Service user involvement in recruitment
- Service user payments.

*Q16 User and carer involvement are vital in clinical governance. We have tried to address this in the roles and responsibilities chapter but it is quite different from the roles of individual staff. Would it be better considered elsewhere in the document? And what more should the document say, without duplicating detailed information more properly contained in user and carer involvement publication?*

**6.2.2 Teams**

Collaborative and open team-working is essential for good clinical practice, and this is especially important for management of drug misuse where multidisciplinary team working is

the cornerstone of effective treatment, and is usually multi-agency. Teams that deliver high quality care:

- Ensure that the interests of service users are always the focus of their actions
- Understand each others' roles and responsibilities and ensure appropriate designation of tasks
- Share information and knowledge on a 'need-to-know' basis where this is in the interests of the service user
- Support each other to deliver the best possible care
- Monitor and audit their practice and are not afraid to challenge poor practice, without blaming individuals
- Work together to learn lessons, and change practice to improve the quality of service.

## 7 Standards for drug treatment

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A number of NHS clinical governance frameworks and standards have been developed over the years. NHS bodies may already use one of these or a modified version and commissioners and providers will need to take this into account. However, they will also need to ensure that standards relevant to drug treatment are reflected in the clinical governance framework they adopt.

Appendix 3 describes a number of health, social care and other standards and frameworks, including two of the best-known in healthcare services: the 'Seven Pillars' model, and the Department of Health Standards for Better Health. Standards for Better Health are mandatory standards for NHS healthcare, and all drug services should – in the long term – aim to adopt them as a suitable standards framework and comply with them.

Key drug-specific standards include the criteria developed for the NTA/Healthcare Commission Service Reviews.

### 7.1 NTA/Healthcare Commission Service Review criteria

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The joint Service Reviews by the NTA and Healthcare Commission have specified criteria for the delivery of drug treatment, some of which may continue to be audited by the NTA and Healthcare Commission but may also be used by services to review progress within their internal governance processes.

#### 7.1.1 2005/06 review of community prescribing services, and care planning and care coordination

##### Community prescribing services

- Community prescribing services are commissioned in line with Models of Care for substance misuse treatment - promoting quality, efficiency and effectiveness in drug misuse treatment services (Models of Care) and Drug Misuse and Dependence - Guidelines on Clinical Management (the Clinical Guidelines).
- Service users have prompt, equitable and flexible access to community prescribing services.
- Service users have a personalised care plan that incorporates a comprehensive assessment of their physical, psychological, social and legal needs and preferences.
- Prescribing practice is in line with Models of Care.
- Community prescribing services have procedures in place to ensure controlled drugs are administered and managed in accordance with best practice.
- Community prescribing services are delivered by competent practitioners who are appropriately trained and supervised and work in a supported and managed environment.

##### Care planning and care coordination

- Service users are integrated partners in the entire treatment planning process and are fully informed about the range of treatment options, choice and access available.
- Service users have prompt, equitable and flexible access to an appropriate range of drug treatment services.

- Service users have a personalised care plan that incorporates a comprehensive assessment of their physical, psychological, social and legal needs and preferences.
- The pathways of service users through treatment are clear, coordinated and continuous.
- Services have systems in place to minimise client did not attend/drop out rates and support clients being retained in treatment.

### **7.1.2 2006/07 review of commissioning and systems management, and harm reduction**

#### **Commissioning and systems management**

- Local commissioning partnerships have formal strategic partnerships with key stakeholders including health, social care, housing and employment services, drug treatment providers, and local drug user and carers.
- Local commissioning partnerships have a shared understanding of the local need for drug treatment, based upon annual needs assessment reports in line with a nationally agreed methodology. This methodology requires the needs assessment to profile the diversity of local need for drug treatment, including rates of morbidity and mortality (e.g. infection with blood borne viruses), the degree of treatment saturation or penetration, and impact of treatment on individual health, public health and offending.
- Local commissioning partnerships develop local drug treatment system plans annually in line with the Models of care update 2006 with focus on reducing harm to individuals and communities, improving clients' journeys through treatment, predicting client flow through local systems and improving the effectiveness of local drug systems.
- Local commissioning partnerships demonstrate best practice in handling public money, contracting with providers and monitoring service level agreements.
- Local commissioning partnerships performance manage local systems of drug treatment by using data and key performance indicators in partnership with local strategic partners and plans.
- Local commissioning partnerships are 'fit for purpose', have involvement from key stakeholders at an appropriate level of seniority and ensure commissioners are competent against national quality standards and other relevant professional frameworks.

#### **Harm reduction**

- Service users have prompt and flexible access to needle exchange services, vaccination, testing and treatment for blood borne viruses.
- Service providers deliver harm reduction interventions embedded in the whole treatment system.
- Service providers take action to reduce the number of drug-related deaths.
- Service providers have staff competent to deliver effective harm reduction services.

### **7.1.3 2007/08 review of diversity and Tier 4 services**

#### **Diversity**

- Local commissioning partnerships ensure that the requirements of the Race Relations Amendment Act (2000) are complied with in the local treatment system.
- Local commissioning partnerships carry out needs assessments and treatment planning which includes the identification of and response to the needs of diverse populations.

- Partnerships commission services to meet the needs of diverse populations.
- Service providers comply with the requirements of the Race Relations Amendment Act (2000).
- Service providers provide services which meet the needs of diverse populations.
- Service providers plan and provide services in a way that considers and respects the views of service users and other service providers.

#### **Tier 4**

- Local commissioning partnerships strategically commission Tier 4 interventions.
- Service users have prompt and flexible access to Tier 4 interventions.
- Service providers deliver Tier 4 interventions in line with an up to date evidence base that relates to the type of intervention or programme being delivered.
- Service providers provide Tier 4 interventions in a safe environment.

## **7.2 Race Equality Schemes**

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All public authorities have a duty to implement a Race Equality Scheme, as defined by the Commission for Racial Equality (CRE, 2002). In brief the duties are: eliminating unlawful racial discrimination, promoting equality of opportunity and promoting good relations between people of different racial groups. All statutory inspectorates, including the Healthcare Commission and CSCI, have a duty to inspect and assure RESs. They must assess policies for relevance, monitor existing policies for adverse impact, and assess for potential adverse impact of proposed policies.

## 8 Making clinical governance happen

### 8.1 General

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Clinical governance is a multi-faceted framework and its full implementation in an organisation not already doing it can be a long and complex business. However, all organisations can and should start the process and it can be relatively simple to get the basics right:

- Appoint a clinical governance lead if not already in place
- Clarify your responsibilities for clinical governance as a provider or commissioner
- Audit your existing clinical governance practice and consider the interface with clinical governance in other parts of your organisation and in other local organisations
- Consider the demands and timetables of external assurance mechanisms (such as NTA treatment planning and NTA/Healthcare Commission Service Reviews) and how these mesh with local processes
- Consider the audit tools already available for drug treatment (for example, NICE's audit tools for its drug misuse technology appraisals and clinical guidelines, available at [www.nice.org.uk](http://www.nice.org.uk))
- Ensure the existence of and participation in a multiagency group with a remit to consider clinical governance for the drug treatment system as a whole, sharing information and good practice.

*Q17 In addition to this document what other guidance, tools or support do you need from the NTA, local drug partnerships, your service, etc. in order to ensure proper implementation of clinical governance in your service or organisation or across your treatment system?*

### 8.2 Special considerations

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Clinical governance within a single provider is relatively straightforward. But clinical governance within and across the many and varied services that make up the drug treatment system can be more complex. In developing clinical governance, special attention needs to be paid to, for example, the following:

- Clinical governance arrangements also cover services for young people and will need to take into account the interface between the local authority and drug services. The NTA is planning to produce guidance in 2008 that will cover specific issues relating to the Children's Act 1989 and other legislation referring to children.
- Clinical governance mechanisms across a local drug partnership area
- Clinical governance expectations on large third sector providers, which provide services in multiple partnership areas and may therefore have multiple incompatible demands for clinical governance systems and mechanisms.

*Q18 For young people's substance misuse services the interface between the local authority and drug service is key – how do we manage this interface in relation to clinical governance when the concept is not one used in local authorities?*

## 9 Conclusion

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Clinical governance is a systematic way of ensuring and improving quality of care. Until now, the extent to which it has been implemented in drug services has been variable, yet it has been a duty of both the NHS and services which it commissions, and independent healthcare, enshrined in law since 2004. It can no longer be seen as solely the domain of the NHS: non-NHS and social care services have an equal responsibility to provide the best possible care to their service users. It applies equally to all tiers involved in drug treatment, and is the task of primary as well as secondary care services.

Implementing clinical governance requires a whole system approach, from commissioners commissioning for quality, service providers implementing robust clinical governance frameworks and processes, to individual clinical teams and clinical and non-clinical staff working together to systematically evaluate and improve practice. It requires too a cultural shift - a collaborative and open approach and an environment in which there is recognition that blame is unhelpful and focusing on system change is the constructive approach required to truly improve client care. Strong leadership is key to achieving cultural change, and is the responsibility of commissioners, service managers and clinical leads.

For partnerships and services that have not used this approach, a long-term view is recommended. Setting up the necessary structures and processes takes time. Cultural transformation may evolve only gradually. Taking an incremental approach is sensible: best practice advice is to benchmark current procedure and policy to start with and prioritise tasks according to clinical needs. Continual evaluation and monitoring through clinical audit cycles allows clinical governance processes to be built up year on year until they are woven integrally into every aspect of the work.

Service user involvement is invaluable in enabling prioritisation to be grounded in their needs and should be enlisted from the start. Keeping the focus on the service user will allow the best opportunity for genuine and visible improvement, allowing all involved to embrace it as a meaningful and highly constructive undertaking.

Experience of clinical governance, as illustrated in the case studies in appendix 1, shows that, when fully implemented, all involved – from commissioners to service providers and users – feel energised and motivated, and that they have gained a real tool with which they can drive change to achieve excellence in clinical care.

## 10 Appendix 1: Case studies

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*Q19 Appendix 1 contains a number of case studies that illustrate how different organisations have responded to the need to implement clinical governance. Are they helpful and sufficiently detailed? What other examples might it be useful to include?*

This appendix contains four case studies that illustrate how different organisations have responded to the need to implement clinical governance. They include:

- A DAT-commissioned voluntary sector community drug treatment provider and its integration into PCT clinical governance (8.1)
- A large mental health trust and its clinical governance for eight London boroughs (8.2)
- A large voluntary sector provider with a long history of clinical governance development (8.3)
- A DAAT overseeing clinical governance for the whole of their treatment system (8.4).

The case studies are based upon information and opinions supplied by the organisations themselves and have not been verified by the NTA. They are intended only as examples of how some organisations have implemented clinical governance. Situations may vary from area to area and from organisation to organisation, and appropriate clinical governance implementation is for local determination. They are included here for the purposes of consultation but may not be retained in the final version of the publication.

### 10.1 DAT-commissioned voluntary sector community drug treatment provider and PCT clinical governance

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#### Lifeline Kirklees

Kirklees DAT has commissioned drug and alcohol treatment services for many years from Lifeline, a voluntary provider. Lifeline had no overarching corporate clinical governance policy. In 2006, the need to include Lifeline and other DAT-commissioned services within the remit of the PCT clinical governance process was identified. A period of restitution lasting several months followed, with Lifeline Kirklees submitting some 57 policies, standard letters and forms.

The DAT have found the PCT clinical governance department to be very supportive, for instance they have provided useful tools and support around developing care pathways.

The PCT Clinical Governance Overview Group requires each policy to be presented in person, accompanied by a briefing paper written to the local standard format, which includes matching the policy to Standards for Better Health, and delineation of measurable performance indicators. To save time all the policies from DAT-commissioned services are to be presented in two bundles (employment-related and practice-related policies).

It has been observed that the DAT is already undertaking unrecognised clinical governance activity (for instance, audit) so arrangements have been put in place to ensure the PCT's clinical governance will be copied into all relevant documentation.

A further impact on the service was the need to gain clinical governance approval before any new therapies could be introduced into practice, following the Kerr-Haslam report (into how NHS services in Yorkshire dealt with concerns raised about two doctors' abuse of patients).

As a result of the process, in less than a year, Lifeline reported that:

- Commissioners have made progress towards being assured on many aspects of quality, and can identify others to be addressed
- The PCT is making progress towards fulfilling its statutory obligations to evidence compliance with SfBH, and improve annual ratings
- The service itself benefits from the structured approach to its quality initiatives, being able to identify policy gaps, demonstrate delivery of clinical quality already established and a feeling of improved integration with the local NHS
- Closer working relationships have been built up between the PCT and commissioners, and between the commissioners and service managers, and it is felt that this will be beneficial in the long term, leading to a better understanding of each others' roles and a shared vision for patient care.

## **10.2 Mental health trust clinical governance for eight London boroughs**

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### **Central and North West London NHS Foundation Trust (formerly Central and North West London Mental Health NHS Trust)**

The substance misuse service developed a quality framework and data management system in 1994 in response to the introduction of an injectable service.

The framework comprised the original seven pillars (see appendix 3), three of their own, and national directives.

Eight clinical governance sub-committees were set up, covering clinical audit, risk management, infection control, medicines management, NICE implementation, research and development, therapeutics, and training and development. All link with local clinical governance groups.

Problems identified by the trust included:

- **Resistance to change** was seen in organisations that had not been familiar with being accountable, and those with no clear leadership, permanent staffing or team structure. In contrast, those with strong leadership and teamworking adopted the framework readily.
- **Loss of autonomy** – the trust expects cooperation with existing practice when joined by outside bodies, scrutinising and even rewriting policies that have already been ratified. Some non-statutory agencies perceived threat at the idea of being 'taken over' by the NHS.
- **Information sharing** – sharing protocols, serious untoward incidents reports, quality information and budget lines can be difficult due to lack of structures or because they are seen as too sensitive to share.
- **Unwieldy procedure** – it is difficult to use a single process to assure on governance for such a large and multifaceted organisation. Appointing chairs of shared clinical governance committees is problematic without approved qualifications for the role.

Solutions found by the trust included:

- **Clear leadership** has been hugely influential in the success of the clinical governance process.
- **Staff engagement** – building friendly and caring relationships with staff has been helpful. In part this has been achieved by meeting all staff regularly en masse to provide simple, contemporary information, demonstrate the purpose of clinical governance and share experiences.
- **Holding responsible people to account** – asking for an explanation of action plans and holding chairs to account for these.
- **Local control** – each borough has its own clinical governance committee and the primary care and prison sector has its own managerial and governance arrangements. All are linked through an overarching strategic clinical governance committee chaired by the medical director.

### **Resource implications**

Resources are needed for management courses for senior personnel and to implement quality improvements. CG is tied into commissioning meetings and commissioners usually respond.

### **Advantages of clinical governance reported by staff in the trust**

- “The cardinal benefit has been the ability to form a culture that feels good. Staff know that they belong to this Directorate. It has removed any sense of ‘poorer sister borough’ and allowed for the expression of local need as well as local qualities.”
- “The more people grasp it the more they want to be involved. This is exciting - as chair of a big committee, it is akin to conducting an orchestra of accomplished players.”
- “The Trust has found that implementing clinical governance well has led to invitations to help out regions in trouble or need and this can assist with overheads and CIPs within the Directorate as a whole”.

## **10.3 Large voluntary sector provider with a background of clinical governance development**

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### **Addaction**

As an organisation Addaction has a long-held vision of wanting to monitor and demonstrate the quality of its services. The key drivers for this were:

- The vision and values of its previous chief executive
- Historically having had to be scrupulously accountable to funders and commissioners due to its voluntary, non-statutory status
- Increasing interest in quality noticed when tendering for new business.

Accountability and monitoring against standards was a complex business in the early days as so many different funding bodies needed different (if only slightly) information e.g. Best Value reviews by Local Authorities, commissioners, CSCI. However, joint commissioning resolved much of this multiplicity of standards and reporting systems.

Addaction’s quality assurance framework was first established in 1995.

In 1999, when QuADS was published, some drug partnerships requested that Addaction services be compliant with the standards. In some areas partnerships commissioned external audits of the QuADS standards to see level of compliance. DrugScope acted as consultants and sent QuADS assessors in on request. However, there was no consistency of approach since some partnerships did not request it. Addaction's corporate response was:

- The organisation's quality assurance strategy encompassed the need for all projects to undertake QuADS self-assessment, in line with their quality values template
- The quality assurance strategy required all staff at every level to understand QuADS and to be involved in self-assessment

The purpose of including all staff was to promote wider understanding of QuADS standards and to demystify them, thus ensuring that the standards were part of everyday work and not seen as something additional.

The next natural step was to look at the clinical governance framework: the quality assurance strategy and framework was reviewed against existing clinical governance principles and framework. As a result:

- Addaction's Clinical Governance Committee was set up
- The organisation established systems for examining clinical incidents and other parts of clinical governance.

An unexpected positive outcome from this was bringing more closely together the work of support services and senior managers, e.g. human resources operations (who had a remit for health and safety) and the quality assurance team.

When Standards for Better Health was launched, QuADS became less relevant.

As a result of its previous work on standards, Addaction felt well prepared in terms of audit for NTA/Healthcare Commission Service Reviews.

#### **Reported benefits of quality assurance and clinical governance to Addaction:**

- Ability to demonstrate quality to commissioners at tender and performance review and also to produce internal management information
- Ability to demonstrate quality to NTA/Healthcare Commission at Service Review
- Bringing together support services and senior management teams
- Involvement of all staff, which is empowering to more junior staff and allows a bottom-up approach.

## **10.4 DAAT overseeing clinical governance for whole treatment system**

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### **Plymouth Drug and Alcohol Action Team**

#### **Context**

In Plymouth, all services are managed by the voluntary sector, with statutory services seconding both statutory health and social care staff in to the teams.

Plymouth Drug and Alcohol Action Team (Plymouth DAAT) needed assurance on the quality of the services they were commissioning after a period of massive local reorganisation and requirement to implement Models of Care.

In 2004, therefore, Plymouth DAAT appointed a clinical and service governance manager to its team to establish an inclusive governance framework committed to by all provider agencies.

### **Initial scoping**

The governance manager found no specific models for drug and alcohol misuse agencies to follow and, in particular, none that cut across both health and social care, and both statutory and non-statutory services.

There were recurrent challenges in the everyday language of clinical governance: for instance, the traditional definition does not include social care and only covers the NHS, and the very word 'clinical' may not be seen sufficiently inclusive to encompass social care.

Performance management is a shared task between governance manager and commissioner to ensure that performance change is managed in line with clinical governance standards.

In order to achieve maximum engagement with non-statutory agencies, it was felt important to avoid a top-down approach or anything that was derived solely from a health model of clinical governance. Therefore the standards had to be drawn up afresh, and in broad-based local consultation.

Underpinning the standards were the principles that they should concentrate on areas that directly impact on service users, with the main focus being on safety and effectiveness, and supporting systems.

### **Agreeing the framework**

Key domains of the framework were drafted in the light of knowledge and experience of drug treatment services. Between four and ten standards were set for each domain according to local priorities.

This draft document was sent out for a very broad-based, inclusive three-month consultation. The fact that it referred throughout to SfBH made it far more acceptable to statutory healthcare organisations.

### **Implementing the governance process**

A governance lead for each service was identified. These people need to have the authority necessary to implement change in their organisations, and therefore tend to be chief executive or deputy chief executive level. Those from larger organisations may appoint domain-leads to report to them on specific areas such as audit, research and training.

A Service Governance Leads Group was then established, with monthly meetings chaired by the DAAT. Non-specialist agencies are also invited to send a representative, for example, police, probation, CAMHS etc, and are copied into all minutes.

Seven standards were chosen from the framework by the DAAT to be met within the first year. Service governance leads were invited to choose three more from the framework to address priorities of their own organisations. This had the further beneficial effects of allowing ownership of the process by all services, and introducing an audit and governance culture into services.

After a few months it became clear that a separate prescribing and pharmacy forum was needed because of the level of expertise and detail needed in dealing with these issues–

includes prescribing specialists, pharmacists, drug specialists from police. This forum has proved very effective in bringing about change and addressing poor practice.

### **Benefits of clinical governance**

#### **Practical:**

- Local NTA now better assured on quality and governance
- DAAT ownership of the process, real engagement of providers and partners
- All statutory and non-statutory services are monitored against same standards and participate in common audit cycle
- PCT able to be easily assured on quality of Plymouth drug and alcohol services, as are SHA and DH
- Process has anticipated recent NTA/Healthcare Commission Service Reviews – much of the work to bring services up to required standard already been done
- Real improvements seen in harm reduction measures.

#### **Organisational culture:**

- Placing governance firmly at the heart of DAAT business – now addressed in all DAAT meetings
- Assisting whole-systems approach to managing change, because it makes it safer to proceed
- Service users all involved in governance and all organisations have systems to engage them from level of becoming trustees to signing care plans
- Cooperative relationships between organisations, e.g. on training and sharing policies
- Closer relationship with local health services.

#### **Examples of specific improvements reported by the partnership**

- Prescribing and pharmacy governance forum has devised a system which enables it to track poor prescribing and address this directly with prescriber
- Adoption of a common prescribing policy for the whole DAAT.

# 11 Appendix 2: Legal framework for clinical governance

## 11.1 Legislation

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Two key pieces of legislation have determined the structures and processes of clinical governance that guide current practice in drug treatment:

### 11.1.1 Care Standards Act (2000)

This act applies to independent health and social care – whether private or voluntary sector. It established the principle of an autonomous statutory regulatory authority and legally obliges any independent service where treatment or nursing care is provided to register with the regulatory authority (the Healthcare Commission) and legislates for publication of national independent healthcare standards (see 3.2.1)

### 11.1.2 Health and Social Care (Community Health and Standards) Act 2003

#### 11.1.2.1 Health

This Act establishes a parallel legal framework for statutory sector health and social care. For healthcare, trust boards (i.e. mental health, primary care or acute trusts) that hold accountability – they must have arrangements to monitor and improve the healthcare they provide. Statutory health services are inspected by the Healthcare Commission against statutory standards frameworks (see section 12.2.1).

PCT model standing orders (DH, 2006) require the PCT and their chief executive officer to ensure that they explicitly commission for SfBH compliant care, and that they have appropriate mechanisms in place to monitor contract compliance.

#### 11.1.2.2 Social care

The Act also covers social care for drug and alcohol treatment, but only where ‘nursing or personal care’ is provided, and not ‘healthcare’. For these organisations, registration and inspection is with the Commission for Social Inspection (CSCI). It is not possible for a service to be registered with and inspected by both the Healthcare Commission and CSCI. (Contact CSCI for further information on definitions, which are under review at the time of going to press).

Social care organisations which fall outside the Act do not have the same statutory duty for quality as that for healthcare, but all public sector bodies have a ‘duty of care’ enshrined in statute. For social care organisations there are now a variety of models of provision, varying between different Local Authorities, and this duty will be vested with whichever organisation they sit within, whether independent or statutory.

## 11.2 The legal framework for DH standards

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### 11.2.1 Standards expected from healthcare organisations

Independent healthcare organisations continue to be obliged to meet Independent Healthcare National Minimum Standards Regulations (2002) – see appendix 3.

The following applies to public sector healthcare trusts, which are legally obliged to:

- Meet Standards for Better Health (SfBH)
- Continue to meet targets previously set by the Department of Health
- Work towards compliance with NICE guidelines and NSFs.

### **11.2.2 Standards expected from social care organisations**

Social care organisations have to meet the National Minimum Standards Care Homes Regulations (2003) underpinned by the legal framework of the Care Standards Act 2000 and Care Home Regulations 2001 (see appendix 3).

## **11.3 Scrutiny by regulatory bodies**

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### **11.3.1 Scrutiny and inspection by the Healthcare Commission**

#### **11.3.1.1 Annual inspections**

All healthcare organisations are statutorily subject to annual inspection by the Healthcare Commission, whether NHS or independent (private or voluntary sector). This requires all NHS trusts, PCTs and Foundation Trusts (FTs) to submit a self assessment, which is a report on compliance with each element of each of the core standards that is then assessed by the Commission against a range of other data sources including the organisation's use of resources. This assessment against quality of services and use of resources is known as the 'Annual Healthcheck' and generates an Annual Performance Rating for each NHS organisation, which is published. In addition, the Healthcare Commission reports directly to Parliament on the state of healthcare in England and Wales for NHS Trusts, and to Monitor, the independent regulatory authority, for foundation trusts.

Where the Healthcare Commission has assessed the poor performers and judged them to be failing to meet the core standards and will need to improve, the Healthcare Commission would either:

- Agree an action plan with the strategic health authority, or
- If serious failings are identified, recommend to the Secretary of State (or Monitor) that special measures should be taken.

The Healthcare Commission also inspects non-commissioned independent healthcare providers at least once every five years against standards set out in Independent Healthcare National Minimum Standards Regulations. Those judged to be failing standards may be subject to variation in regulation conditions, de-registration or even prosecution.

#### **11.3.1.2 Investigations**

In addition to the annual inspections, the Healthcare Commission undertakes thorough investigations in response to specific incidents, such as complaints or serious service failings, particularly where there are concerns for the safety of patients. An investigation involves developing an understanding of, and obtaining evidence on the reasons for a serious failing, and making recommendations to prevent recurrence. The Commission may carry out unannounced visits, or audits in specific cases.

#### **11.3.1.3 Controlled drugs**

The Healthcare Commission is responsible for regulating the management of controlled drugs by healthcare providers in England, using information in the annual self-declaration

forms submitted by all NHS trusts and foundation trusts and monitoring the management of controlled drugs by independent healthcare providers.

The Healthcare Commission also takes part in local intelligence networks led by primary care trusts. These networks bring together organisations from the NHS and independent health and social care sectors, and other regulators including the Commission for Social Care Inspection, the Royal Pharmaceutical Society of Great Britain, and NHS counter-fraud services and police services.

The Healthcare Commission makes annual reports on how safely organisations manage controlled drugs and the findings of its national intelligence group on themes and trends in controlled drugs management.

#### **11.3.1.4 Service Reviews**

As part of its system of assessment for healthcare organisations, the Healthcare Commission undertakes a number of Service (previously called 'Improvement') Reviews each year. A review is an in-depth examination of one aspect or 'theme' of care, and is carried out in every relevant organisation. Specific criteria are developed regarding the particular theme(s) chosen and these are used to make judgements about performance. The lowest performers are assisted to draw up an action plan to ensure standards are met.

The Healthcare Commission and NTA work in partnership on substance misuse Service Reviews. These examined:

- Care planning and prescribing (2005-6)
- Commissioning and harm minimisation (2006-7)
- Diversity and Tier 4 treatment (2007-8).

Information about the results of the Service Reviews can be found on the NTA website ([www.nta.nhs.uk](http://www.nta.nhs.uk)). The lowest scoring 10-12% of DATs are required to agree an action plan in conjunction with their regional NTA teams, who then monitor delivery of the plan.

The Healthcare Commission also has an interface with the NTA through national retention targets.

#### **11.3.2 Scrutiny and inspection by the Commission for Social Care Inspection**

Responsibility for social care inspection rests with the Commission for Social Care Inspection (CSCI). CSCI has interpreted the national minimum standards specifically for drug and alcohol misuse in its Guidance for Inspectors: Residential Services for Drug and Alcohol Addiction (CSCI, 2006). Inspections have traditionally been annual, but are now becoming targeted at higher risk services as identified in annual performance returns.

#### **11.3.3 Combined scrutiny and inspection for health and social care**

The government recognises the significant impact of inspection on those in the frontline of health and social care. In June 2004 a concordat was reached: there is now agreement between health and social care regulatory authorities to streamline inspection timetables and criteria so as to reduce burden on care commissioning and provider organisations, and avoid duplication of work. This is led/coordinated by the Healthcare Commission, and an increasing number of bodies are involved – currently around twenty.

## **11.4 Future developments**

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The Department of Health is planning to streamline much of the standards and reporting structures over the coming years, in line with the philosophy of 'whole system thinking' and reform. Subject to Parliamentary approval, the Health and Social Care Bill will create a new, integrated regulator for health and adult social care; the Care Quality Commission. This will bring together the functions of three existing bodies: the Healthcare Commission (HC), the Commission for Social Care Inspection (CSCI), and the Mental Health Act Commission. From 2009 the new regulator will build on the expertise of these three bodies, and will register all health and social care activities.

## 12 Appendix 3: General frameworks and standards

### 12.1 Seven pillars model

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The seven pillars model was developed by the Commission for Health Inspection (CHI) in the 1990s. In this model the domains in which quality is to be assured are conceptualised as supporting pillars for a temple. The seven pillars in this model are:

- Risk management
- Clinical effectiveness
- Education, training and continuing personal and professional development
- Use of information
- Staffing and staff management
- Clinical audit
- Service user involvement.

### 12.2 Standards for Better Health

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The Department of Health's Standards for Better Health (SfBH, often simply referred to as 'the Standards') were formally issued to the NHS in July 2004. They are more complex than the earlier models for several reasons:

- The Standards include financial governance and corporate governance in addition to 'pure' clinical governance
- The Standards address the need to balance current performance and future development by setting out two subsets within each domain: the core and the developmental standards:
  - Core standards relate to *existing provision*, deemed to be the minimum requirement
  - Developmental standards provide a framework for NHS bodies to plan the delivery of services that continue to improve in line with increasing patient expectations and the NHS Improvement Plan (DH, 2004b).
- SfBH were explicitly designed to synthesise an integrated framework from other national standards and reduce the burden of legislation on service providers. This process has created a new balance between types of standards which some have found problematic (Shaw, 2004).

The 44 standards are set out in seven domains:

- Safety
- Clinical and cost-effectiveness
- Governance
- Patient focus
- Accessible and responsive care
- Care environment and amenities

- Public health.

Each domain contains several core standards and some developmental standards. Services which do not use SfbH at the outset may find it useful to map their standards to SfbH, in order to assist correlation in the future.

The clear intention of the Department of Health is that SfbH is the future destination of all health and social care standards frameworks. In the coming years, there will be a phasing in of the standards to apply to services provided entirely by the independent sector and, as the Healthcare Commission and CSCI work more closely together and eventually merge, for relevant social care services too. Clearly therefore, it is important to have an overview of the SfbH framework. However governance as a whole is a major undertaking – a process rather than an event – that needs to be undertaken incrementally. Organisations introducing clinical governance for the first time are recommended to start with a simple framework and develop it in subsequent years.

The Standards for Better Health (SfbH) can be found at the Health Care Standards Unit website ([www.hcsu.org.uk](http://www.hcsu.org.uk)).

### **12.3 Independent healthcare standards**

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National minimum standards for independent healthcare acquired legal status in 2000 but are to be redesigned in alignment with SfbH by March 2008. Until then, independent healthcare providers will continue to be inspected against them by the Healthcare Commission. They comprise 32 core standards in eight domains and additional service-specific standards, including for mental health establishments. Mental health service-specific standard M19 covers “treatment for addictions”.

In drug misuse treatment, independent healthcare standards mostly apply to non-NHS detoxification units.

Independent Health Care: National Minimum Standards can be found at the Department of Health website ([www.dh.gov.uk](http://www.dh.gov.uk)).

### **12.4 Social care standards**

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Within drug misuse treatment, national minimum standards for social care apply mainly to residential rehabilitation services registered as care homes (with or without nursing). The key standards are those contained in National Minimum Standards for Care Homes for Adults (18–65) and Supplementary Standards for Care Homes Accommodating Young People Aged 16 and 17 (DH, 2003). The standards cover eight domains, including socially-focused ones such as lifestyle and personal healthcare and support. The Commission for Social Care Inspection (CSCI) Guidance for Inspectors: Residential Services for Drug and Alcohol Addiction (CSCI, 2006) helps to clarify how each standard should be interpreted.

Drug care and treatment provided by social services will be covered by CSCI’s inspection and rating of how well councils serve adults who use social care services. Most children’s services are now inspected by Ofsted.

National minimum standards for social care can be found at CSCI’s website ([www.csci.org.uk](http://www.csci.org.uk)).

## **12.5 Quality in Alcohol and Drugs Services standards (QuADS)**

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Quality in Alcohol and Drugs Services (QuADS) standards (SCODA and Alcohol Concern, 1999) predate much of the current health service clinical governance infrastructure. QuADS standards concentrate on organisational and management quality. They are not clinical standards, in particular lacking specific requirements for safety or effectiveness in clinical treatments.

There is no statutory obligation to implement QuADS. Nonetheless it has historical value, as it was for many services the first set of quality standards by which they could assure themselves, or to which they were contractually obliged, and for commissioners the first framework against which they could ensure quality in services they commissioned.

QuADS can be found at Drugscope's website ([www.drugscope.org.uk](http://www.drugscope.org.uk)).

## 13 Appendix 4: Sources of information and support for clinical governance

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A large number of agencies can support services in implementing clinical governance. It is important to remember the local support that can be offered by the DAT partnership, PCT or MHT. In addition there are many national organisations whose input may be valuable. This appendix briefly describes these, firstly for general advice, and then for some specific clinical governance domains.

### 13.1 Drug treatment specific

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#### National Treatment Agency

The NTA has a number of roles in relation to elements of clinical governance. These include:

- Ensuring partnership commissioning structures take full account of governance requirements of treatment systems
- Incorporation of unit costs / Value for Money in the commissioning process
- NDTMS and other treatment information governance.

Supporting information is available on the NTA's website at [www.nta.nhs.uk](http://www.nta.nhs.uk).

### 13.2 General

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#### 13.2.1 Clinical governance implementation

##### National Clinical Governance Support Team (NCGST)

<http://www.cgsupport.nhs.uk/>

Will close in March 2008 but website has a useful electronic library of catalogues, articles, case studies and other resources.

##### Healthcare Commission

[www.healthcarecommission.org.uk](http://www.healthcarecommission.org.uk)

An independent body that promotes improvement in the quality of the NHS and independent healthcare. It has a statutory duty to assess the performance of healthcare organisations and does this through an annual health check. The Commission reviews formal complaints about the NHS and independent healthcare that have not been resolved locally.

##### The Health Care Standards Unit (HCSU)

[www.hcsu.org.uk](http://www.hcsu.org.uk)

Works with the NHS and the Department of Health to ensure the Standards for Better Health are useful to staff, patients and other stakeholders.

##### The Information Centre for Health and Social Care

[www.icservices.nhs.uk/clinicalgovernance](http://www.icservices.nhs.uk/clinicalgovernance)

A special health authority which provided facts and figures to help health and social services to run effectively.

### **Clinical Governance Bulletin**

[www.rsmppress.co.uk/cgb.htm](http://www.rsmppress.co.uk/cgb.htm)

The Royal Society of Medicine's online bulletin is a bi-monthly publication for clinicians and managers working in the NHS which highlights and disseminates best practice.

## **13.2.2 Safety and risk management**

### **NHS Litigation Authority (NHSLA)**

[www.nhsla.com](http://www.nhsla.com)

A special health authority responsible for handling negligence claims made against NHS bodies in England, and works to prevent claims through an active risk management programme.

The NHSLA runs the Clinical Negligence Scheme for Trusts (CNST), which handles all clinical negligence claims against member NHS bodies. All NHS Trusts (including Foundation Trusts) and Primary Care Trusts (PCTs) in England currently belong to the scheme although membership is voluntary. While Independent sector organizations cannot join CNST in their own right, they can benefit from cover when treating NHS patients via the membership of their referring PCT.

### **National Patient Safety Agency (NPSA)**

[www.npsa.nhs.uk](http://www.npsa.nhs.uk)

A special health authority with a remit to learn from patient safety incidents occurring in the NHS. Central to this is the mandatory National Reporting and Learning System (NRLS) for adverse health care events and near misses within the NHS. The NPSA excludes private and voluntary providers. The NPSA's work also encompasses other areas, including:

- Ensuring research is carried out safely, through its responsibility for the National Research Ethics Service ([www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk)) (formerly COREC)
- Responsibility for the National Clinical Assessment Service (NCAS) (see below).

## **13.2.3 Clinical and cost effectiveness**

### **13.2.3.1 Evidence base**

#### **The National Institute for Health and Clinical Excellence (NICE)**

[www.nice.org.uk](http://www.nice.org.uk)

An independent organisation responsible for providing national guidance on the best practice cost-effective promotion of good health and the prevention and treatment of ill health based on available best quality evidence.

### **13.2.3.2 Clinical audit**

#### **National Audit and Governance Group (NAGG)**

[www.nagg.co.uk](http://www.nagg.co.uk)

An umbrella organisation linking all the separate, sector specific, local and national clinical audit groups and associations through quarterly meetings and regular conferences. NAGG represents clinical audit at strategic level.

### **13.2.3.3 Professional education and training**

#### **Royal College of General Practitioners (RCGP) Substance Misuse Unit (SMU)**

[www.rcgp.org.uk](http://www.rcgp.org.uk)

The RCGP sets standards for the training and qualifying examinations for GPs, as well as a programme of postgraduate Continuing Professional Development. The SMU, a faculty of the RCGP, educates and certifies GPs and other disciplines in management of drug and alcohol misuse through its certificate programme, and issues guidance on specific areas of drug misuse treatment.

#### **Royal College of Psychiatrists (RCPsych) - Faculty for Addictions**

[www.rcpsych.ac.uk/college/faculties/addictions.aspx](http://www.rcpsych.ac.uk/college/faculties/addictions.aspx)

The Faculty is committed to education and training, setting clearly defined standards for future addiction specialists, influencing the training of medical students and other doctors.

#### **British Psychological Society (BPS) Division of Clinical Psychology – Faculty for Addictions**

[www.bps.org.uk/dcp-addiction.cfm](http://www.bps.org.uk/dcp-addiction.cfm)

The Faculty has a programme of CPD events as well as defining the standards and competencies for addiction psychology specialists and providing BPS national assessors for consultant psychologist appointments in specialist addiction posts.

### **13.2.4 Governance**

#### **13.2.4.1 Professional and performance issues**

##### **National Clinical Assessment Service (NCAS)**

[www.ncaa.nhs.uk](http://www.ncaa.nhs.uk)

Provides confidential advice and support to the NHS in situations where the performance of doctors (and dentists) is giving cause for concern.

##### **General Medical Council (GMC)**

[www.gmc-uk.org](http://www.gmc-uk.org)

The regulator of the medical profession. Their purpose is to protect, promote and maintain the health and safety of the community by ensuring proper standards in the practice of medicine. Registration with the GMC is mandatory for all medical practitioners in the UK.

## **Nursing and Midwifery Council (NMC)**

[www.nmc-uk.org](http://www.nmc-uk.org)

An organisation set up by Parliament to protect the public by ensuring that nurses and midwives provide high standards of care. To achieve its aims, NMC functions include: maintaining a register, setting standards for conduct, performance and ethics and considering allegations of misconduct, lack of competence or unfitness to practise due to ill health.

## **British Psychological Society (BPS)**

[www.bps.org.uk](http://www.bps.org.uk)

The representative body for psychology and psychologists in the UK. It has a national responsibility for the development, promotion and application of psychology for the public good. It provides accreditation and standards for individuals, and maintains a register and licensing of psychologists as practitioners.

## **Royal Pharmaceutical Society of Great Britain (RPSGB)**

[www.rpsgb.org.uk](http://www.rpsgb.org.uk)

The professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. Professional regulation functions include: registration, setting professional standards, and dealing with performance and misconduct issues

## **General Social Care Council**

[www.gsccl.org.uk](http://www.gsccl.org.uk)

The workforce regulator and guardian of standards for the social care workforce in England, established in October 2001 under the Care Standards Act 2000.

## **Health Professions Council (for Allied Health Professions)**

[www.hpc-uk.org](http://www.hpc-uk.org)

A statutory regulator that works to protect the health and well-being of people using the services of the health professionals registered with us. The HPC currently registers professionals from 13 disciplines, the most relevant of which are Arts therapists and occupational therapists.

### **13.2.4.2 Information governance**

#### **Information Commission**

[www.ico.gov.uk](http://www.ico.gov.uk)

Promotes access to official information and protects personal information by promoting good practice, ruling on eligible complaints, providing information to individuals and organisations, and taking appropriate action when the law is broken.

#### **Department of Health policy and guidance information governance section**

[www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/fs/en)

The 'Policy and guidance' section of the DH website has pages on health and social care information governance with links to many useful publications and related organisations.

### **Connecting for Health**

[www.connectingforhealth.nhs.uk/systemsandservices/infogov/policy](http://www.connectingforhealth.nhs.uk/systemsandservices/infogov/policy)

Oversees development of new NHS computer systems and services that link GPs and community services to hospitals. There is a very useful information governance section accessible from the 'systems and services' section of their website.

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