Partners in improving local health

North of England Commissioning Support

North of England Commissioning Support

Medicines Optimisation

Clinical Commissioning Group Controlled Drugs Responsibilities

Version issue date:	28/04/2016
Date of MO Q&G approval:	28/04/2016
Date of review:	April 2017
Circulation:	External

Author Name	**Email Address**
Lesley Angell	Lesley.Angell@cumbria.NECSU.nhs.uk

Hosted by NHS England

1. Purpose of the briefing

1.1. Remit of the briefing

This briefing paper has been prepared by the North of England Commissioning Support (NECS) Medicines Optimisation (MO) team on behalf of Dr James Gossow, Deputy NHS England (NHSE) Cumbria and North East Controlled Drugs Accountable Officer (CDAO) and takes into account recently published NICE guidance NG46 Controlled Drugs: Safe use and management.[i]

1.2. Executive Summary

Clinical Commissioning Group (CCG) responsibilities are to:

- Name an individual as Controlled Drug (CD) Lead to act as a focal point for liaison with the NHSE lead CDAO in relation to the safe use and management of CDs.
- Ensure the CCG, its governing body and member practices are aware of who represents them on the Local Intelligence Network (LIN) and how and when to raise concerns.
- Play an active part in the LIN, sharing intelligence as appropriate and taking action to improve the safe use of CDs.
- Follow guidance regarding intelligence sharing and recording with respect to well–founded concerns reported to any officer of the CCG including sharing with a responsible body.
- Report Serious Incidents in line with guidance and Serious Incident policy.
- Take part in incident panels where appropriate as agreed with the Area Team Lead CDAO.
- Participate in a system for learning from CD incidents and sharing this learning.
- Practice and prescriber level analysis of CD prescribing trends and investigation of outliers in line with assuring appropriate, safe and effective prescribing within the CCG. Report concerns to the Area Team CDAO as appropriate. The CCG is expected to take appropriate action on this analysis in keeping with the recommendations of the CDAO.
- Bring concerns about the safe use of CDs by other healthcare providers to the attention of the LIN or Area Team CDAO in line with intelligence sharing agreement.
- Alert Area Team CDAO of intelligence received regarding premises used in connection with the management or use of CDs which is not subject to inspection by other regulatory bodies.
- Support Area Team CDAO in ensuring adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe

use of controlled drugs by a person who is not providing services for any designated body, but who provides services in the LIN area.

- Work in partnership with responsible bodies to share intelligence and identify areas of concern.
- Ensure intelligence from complaints, monitoring, incidents and other concerns are effectively collated and acted upon.
- Ensure providers of commissioned services have in place arrangements for the safe management and use of CDs.

2. NHS England Controlled Drugs (Supervision of Management and Use) Single Operating Model, published Nov 13[ii]

CDs are essential to modern clinical care. As such, it is essential that NHSE enforces robust arrangements for the management and use of CDs to minimise patient harm, misuse and criminality.

As a consequence of passing the Health and Social Care Act 2012, the 2006 regulations have been revised to reflect the new architecture in the NHS in England. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force in England on 1st April 2013.

The regulations make clear that NHSE must ensure that systems are in place for the safe and effective management and use of CDs and that these systems are working effectively.

In January 2013, an operating model was drafted to outline Area Team responsibilities. It is the responsibility of the main employing organisation (NHSE) to ensure adequate governance arrangements for the lead CDAOs conduct and for registering that individual with the Care Quality Commission (CQC).

A revised operating model, published in November 2013, aims to support Area Teams in ensuring that NHSE has systems in place for the effective and safe management and use of CDs and that these systems are working effectively.

2.1. Role of the CDAO

Each CDAO is responsible for establishing and leading the LIN(s) for their Area Team geography. The LIN will be drawn from representatives of designated and responsible bodies. It is for the lead CDAO to determine the number and membership of LINs appropriate to their area. LIN membership usually comprises:

- CCGs
- Police representatives
- Acute Providers
- Community Providers
- Ambulance Trusts
- Prisons
- Armed Forces
- Private Hospitals
- Local Authority representation
- Out of hours providers
- Providers of substance misuse treatment and care
- CQC

In addition, the NHSE CDAO has local responsibility to do the following:

- Convene incident panels. The LIN must have a transparent process for establishing an incident panel if serious concerns are raised. The process should outline the responsibilities of key individuals and how the panel should be called together.
- Analyse NHS and private prescribing of CDs using Prescribing Analysis Reports provided by NHS Business Services Authority (NHSBSA).
- Request periodic declarations or self-assessments from a range of healthcare providers regarding their management and use of CDs but who are not required to appoint a CDAO, for example general medical practitioners on a medical performer's list, or providers of dental, nursing or midwifery services.
- Ensure their organisation operates arrangements for periodic inspections of premises used in connection with the management or use of CDs which are not subject to inspection by other regulatory bodies such as the CQC or General Pharmaceutical Council (GPhC).
- Ensure adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe use of CDs by a person who is not providing services for any designated body, but who provides services in the LIN area.
- Promote good prescribing practice in relation to CDs. This will include strategies to improve the safety of prescribing of controlled drugs, increase the levels of incident reporting, especially from primary care in relation to controlled drugs and reduce the harms to patients exposed to controlled drugs, working in conjunction with the NHS England patient safety team.
- Manage direct reporting of incidents reported from independent contractors.
- Promote and extend good clinical practice in respect of the management and use of controlled drugs within the LIN and supporting CDAOs in other organisations to do the same.
- Facilitate cooperation between responsible and designate bodies.
- Oversee occurrence reporting within their area.

2.2. Relationships with CCGs

CCGs are not required to appoint a CDAO. However, Regulation 13(4) of the Controlled Drugs (Safe Management and Use) Regulations 2013 (SI 2013/373)[iii] states that *"A CCG…..must assist the relevant CDAO of the NHSCB (now NHSE) in the carrying out of the CDAO's functions under paragraph (1)"*.

Paragraph (1) requires NHS England CDAOs to establish and operate appropriate arrangements for those activities listed in paragraph (2).

These are:

- Monitoring and assessing a relevant individual's performance (e.g. a health professional in a GP practice) in connection with the management and use of CDs.
- Determining whether incidents or concerns that relate to that individual's performance in respect of CDs require further investigation.
- Investigating such incidents or concerns.
- Taking appropriate action with regard to such incidents or well-founded concerns.

All CCGs in England are designated as responsible bodies under Regulation 6. It is open to NHSE CDAOs to invite their CCGs to be members of the relevant LINs. LIN members have certain duties and functions set out in Regulations 14 – 16. These include a duty to co-operate with other LIN members in identifying cases where action may be appropriate, what the best course of action is and then putting it into effect.

The regulations expressly provide that LIN members can share information and intelligence, including personal confidential information where necessary. All responsible bodies are under a duty (Regulation 15(3) and (4)) to notify their local lead CDAO at NHSE and any other responsible bodies they consider relevant, where they are investigating an incident, complaint or other concern about CD management or use, or where action is being taken.

Responsible bodies are also required to assist each other in sharing relevant information about a serious concern. Area Team CDAOs should ensure that the LIN actively engages with all CCGs.

Since CCGs are not required to appoint CDAOs, CCGs may wish to consider nominating a relevant senior individual within the CCG as CD Lead, who will act as a focal point for liaison with NHSE CDAOs on CD matters locally, bringing in others as appropriate. NHSE considers it good practice for CCGs to assist its CDAOs in the following ways:

- To assist the NHSE CDAO in any investigation involving primary medical care services.
- Report all complaints involving CDs.
- Report all incidents or other concerns involving the safe use and management of CDs to the CDAO.
- Share all standard operating procedures (SOPs) in relation to the management of CDs, or ensure organisations from whom they commission services do so.
- Analyse the CD prescribing data available.

- Supply, or ensure that the organisations that CCGs commission services from, which involve the regular use of CDs, supply periodic self–declaration and/or self-assessments to NHSE CDAO as requested by the NHSE CDAO.

The CQC has responsibility for making sure that health and social care providers and other regulators maintain a safe environment for the management of CDs. As part of this responsibility for oversight of the arrangements for CDs in England the CQC is of the view that both NHSE CDAOs and CCG CD leads must be mindful of their continuing responsibilities for good governance and safe use of CDs and that this will be critical to ensure progress. It is therefore important that there is on-going, constructive dialogue between CCGs and NHSE Area Teams to ensure the system is safe.

This dialogue should include ensuring that there are sufficient authorised witnesses across primary care to ensure that there is not a build-up of obsolete CDs that could represent a threat to patient and public safety.

Many Area Teams and CCGs have already established good working arrangements underpinned by a Memorandum of Understanding.

3. Summary

3.1. CCG responsibilities

In summary CCG responsibilities are to:

- Name an individual as CD Lead to act as a focal point for liaison with the NHSE lead CDAO in relation to the safe use and management of CDs.
- Ensure the CCG, its governing body and member practices are aware of who represents them on the LIN and how and when to raise concerns.
- Play an active part in the LIN sharing intelligence as appropriate and taking action to improve the safe use of CDs.
- Follow guidance regarding intelligence sharing and recording with respect to well–founded concerns reported to any officer of the CCG including sharing with a responsible body.
- Report Serious Incidents in line with guidance and Serious Incident policy.
- Take part in incident panels where appropriate as agreed with the Area Team Lead CDAO.
- Participate in a system for learning from CDs incidents and sharing this learning.
- Practice and prescriber level analysis of CD prescribing trends and investigation of outliers in line with assuring appropriate, safe and effective prescribing within the CCG. Report concerns to the Area Team CDAO as appropriate. The CCG is expected to take appropriate action on this analysis in keeping with the recommendations of the CDAO.
- Bring concerns about the safe use of CDs by other healthcare providers to the attention of the LIN or Area Team CDAO in line with intelligence sharing agreement.
- Alert Area Team CDAO of intelligence received regarding premises used in connection with the management or use of CDs which is not subject to inspection by other regulatory bodies.
- Support Area Team CDAO in ensuring adequate steps are taken to protect patients and the public if there are concerns about inappropriate or unsafe use of CDs by a person who is not providing services for any designated body, but who provides services in the LIN area.

3.2. Commissioners (including NHSE and CCG) responsibilities

Commissioners (Including NHSE and CCGs) must also:

- Work in partnership with responsible bodies to share intelligence and identify areas of concern.

- Ensure intelligence from complaints, monitoring, incidents and other concerns are effectively collated and acted upon.
- Ensure providers of commissioned services have in place arrangements for the safe management and use of CDs including:
    - Compliance with the Misuse of Drugs Act 1971 and other medicines legislation.
    - SOPs being in place for the safe management, use, transportation and disposal of CDs including the prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed CDs.
    - Education and training in relation to these SOPs, good practice and the law in relation to the safe management and use of CDs.
    - A system for recording concerns, incidents, intelligence and complaints in respect to CDs and for raising concerns with others as appropriate.
    - A system for monitoring, assessing, investigating and taking action in relation to relevant individuals with regard to well-founded concerns.
    - A system for assessing and investigating concerns, incidents, intelligence and complaints.
    - A system for monitoring and assessing individual health professional's performance in relation to the safe management of CDs.
    - A system for reviewing the effectiveness of the above arrangements.

CCGs can meet their obligations internally or may commission support for some of these from other sources.

NECS MO team are commissioned to provide services which support the NHSE Cumbria and North East CDAO in his responsibilities. These services include but are not limited to:

- Provide senior pharmacist pharmaceutical advice to support responsibilities of the CDAO.
- Establish and co-ordinate the LIN, drawn from designated and responsible bodies to include meeting management, minute taking, distribution of papers, development of supporting documents and papers and senior pharmaceutical and administrative attendance at meetings.
- Establish and manage a single standardised system for the reporting, recording and risk assessment of incidents and concerns involving CDs including complaints.
- Provide quarterly occurrence report detailing incidents reported to the CDAO.

- Risk assess concerns and provide senior pharmaceutical input to support investigation of serious concerns. Provide senior pharmaceutical input to incident panels convened by the CDAO to address serious concerns raised.
- Analyse and interpret NHS and private prescribing of CDs using ePACT data to support investigation of concerns.
- Manage process for targeted periodic declarations or self-assessments from a range of healthcare providers regarding their management and use of CDs as agreed with CDAO, which includes general medical practitioners and dental, nursing and midwifery practitioners. Analyse returns and prepare reports.
- Carry out any required inspections of premises not inspected by regulatory bodies at the request of the CDAO.
- Oversee systems to ensure there are appropriate witnesses for the destruction of stock CDs in GP practices and community pharmacies, including the co-ordination, training and authorisation of witnesses where necessary.
- Handle queries from GP practices, community pharmacies and other providers regarding safe management of CDs.
- Support development and implementation of initiatives to improve the safety of CD use and quality of prescribing.
- Publish quarterly newsletter to highlight issues relating to safe practice with regard to use of CDs.

These functions are carried out by the NECS MO governance team. The governance team produce quarterly reports on behalf of the CDAO analysing CD prescribing at Area Team, CCG and practice level, identifying outliers and prescribing trends.

The reports consist of nationally available comparator data which set Area Team prescribing in a national context, CCG prescribing in context with other CCGs in the Area Team and identify practices where prescribing is significantly outlying in comparison to other practices within the Area Team. This is done for Schedule 2 CDs excluding methadone, Schedule 2 injectable CDs and Schedule 3 CDs. The report also presents data at a practice level for CDs of Limited Clinical Value, Drugs used in Substance Dependence and Benzodiazepines with a similar analysis of a selected drug or presentation (e.g. diazepam 10mg tablets) each quarter.

Trends in volume of prescribing for individual drugs at CCG level complete the report; rising trends are highlighted to CCGs. There are limitations in the national comparator measure used, i.e. per 1000 items and variations in the services provided by GP practices, e.g. some practices participate in shared care arrangements with drug and alcohol treatment providers. For this reason, local interpretation of these reports is necessary.

The report highlights areas of prescribing that the CDAO wishes the CCG to investigate as part of their responsibility for improving clinical quality within their constituent practices.

The CCG is responsible for carrying out detailed analysis at prescriber level in order to identify, investigate and rectify poor prescribing practice or provide justification to support that practice where it has been identified as outlying.

[i] https://www.nice.org.uk/guidance/ng46 *Accessed: 27th April 2016*

[ii] https://www.england.nhs.uk/wp-content/uploads/2013/11/som-cont-drugs.pdf *Accessed: 27th April 2016*

[iii] http://www.legislation.gov.uk/uksi/2013/373/contents/made *Accessed: 27th April 2016*