PrescQIPP Community Interest Company

# Controlled drug monitoring in primary care - A practical guide

This bulletin focuses on controlled drug monitoring in primary care. It provides guidance and advice for Clinical Commissioning Groups (CCGs) which are required to assist the NHS England Lead Controlled Drug Accountable Officer (CDAO) with controlled drug monitoring under the Controlled Drugs (Supervision of management and use) Regulations 2013.[1] This bulletin is part of a PrescQIPP webkit which includes controlled drug prescribing data, audit templates, letter templates and a standard operating procedure template.

## Key recommendations

- Robust systems and procedures need to be in place for the safe use and management of controlled drugs.[1-3]
- Clear governance and accountability structures are required.[1-3]
- It is good practice for the CCG to nominate a Controlled Drugs CCG Lead to assist NHS England's Lead CDAO, CCGs are not required to appoint a CDAO.[1,3]
- Service Level Agreements (SLAs) for commissioned services such as Out of Hours should include requirements for controlled drug standard operating procedures and policies to be developed and implemented.[1,3]
- CCGs are required to assist with the monitoring of prescribed controlled drug.[1,3]
- CCGs are required to assist the regional NHS England CDAO with any investigations regarding controlled drugs incidents.[1,3]
- CCGs should report any concerns involving the safe use and management of controlled drugs or assist with complaints that may require further investigation from the regional NHS England CDAO.[1,3]
- Prescribing of a controlled drug should normally be to meet the person's clinical needs for no more than 30 days. If, under exceptional circumstances, a larger quantity is prescribed, the reasons for this should be documented in the person's care record.[1-3]

## Roles and responsibilities under co-commissioning

Under co-commissioning and delegated arrangements, the CDAO roles and responsibilities are reserved functions. However, the CCG must nominate a relevant senior individual within the CCG (the "CCG CD Lead") to liaise with and assist NHS England to carry out its functions under the Controlled Drugs (Supervision of Management and Use) Regulations 2013.[1]

The CCG CD Lead must, in relation to the delegated functions:

- On request provide the regional NHS England CDAO with all reasonable assistance in any investigation involving primary medical care services.
- Report all complaints involving controlled drugs to the regional NHS England CDAO.
- Ensure processes are in place to report all incidents or other concerns involving the safe use and management of controlled drugs to the regional NHS England CDAO.

- Ensure processes are in place to analyse the controlled drug prescribing data available.
- On request supply (or ensure organisations from whom the CCG commissions services involving the regular use of controlled drugs supply) periodic self–declaration and/or self-assessments to NHS England's Lead CDAO.

## Background

The monitoring of controlled drugs is a key recommendation from the Shipman Inquiry detailed in the Fourth Report in 2004.[4] The Controlled Drugs (Supervision of Management and Use) Regulations 2006 ("the 2006 Regulations") came into force on 1st January 2007 in England. As a consequence of the passing of the Health and Social Care Act 2012, these Regulations have been revised to reflect the new architecture for the NHS in England from April 2013. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Regulations") came into force in England on 1st April 2013.[1]

CCGs are required to assist with the monitoring of prescribing of controlled drugs under the Controlled Drugs regulations. This is detailed in regulation 13 of Controlled Drugs (Supervision of management and use) Regulations 2013.[1]

"Regulation 13 sets out the duties of CDAOs regarding how the use of CDs by relevant staff (referred to as "relevant individuals" or RIs) must be scrutinised. CDAOs should ensure they have appropriate arrangements in place to monitor and assess an RI's performance in respect of their management and use of CDs, to determine whether incidents or concerns require investigation and to carry out those investigations or arrange for someone else to do so on their behalf, and to take appropriate action where these concerns are well-founded. In England, CCGs are required to assist CDAOs appointed by the NHS Commissioning Board (NHSCB) for these purposes."

The NHS England Single Operating Model published November 2013 defines the roles and responsibilities of each organisation.[3] (Please note that this document is currently under review). To define the roles and responsibilities locally, each regional NHS England CDAO should have in place a Memorandum of Understanding (MoU) arrangement with individual CCGs.

## Practical elements of controlled drug monitoring

There are no national guidelines on practical elements of how to deliver controlled drug monitoring within an organisation. Key points to take into account when starting to implement controlled drug monitoring within your organisation are:

- Is there a MoU with the the regional NHS England CDAO? If so, what does it say?
- What are the local reporting mechanisms for controlled drug incidents, concerns and complaints?
- Do the SLAs for commissioned services have controlled drug standard operating procedures and policies in place?
- Is there a nominated person within the CCG or the Medicines Optimisation Team that leads on controlled drugs?
- Does the CCG Controlled Drug Lead attend the Controlled Drug Local Intelligence Network (LIN)?

## What are the practical areas to consider when starting to implement controlled drug monitoring?

### Frequency of monitoring

What time period do you want to look at?

- Monthly
- Bi-monthly

- Quarterly
- Six monthly
- Annually.

### Hints and tips

- The greater the time period, the more data you need to review.
- The number of localities/GP practices the CCG cover will increase the data you need to review.
- Review the medicines optimisation team capacity to analyse the data.
- ePACT is always two to three months behind - does this fit in with your schedule?
- Frequency of reports required for the Controlled Drug LIN, Quality Committee etc.

## Prescribing data source to be used

- PrescQIPP CCG level: https://www.prescqipp.info/datahub#controlled-drugs-monitoring
- PrescQIPP Practice level: https://www.prescqipp.info/resources/viewcategory/320-practice-level-data-reports
- PrescQIPP Controlled Drugs Threshold Support Snapshot tool (Excel): https://www.prescqipp.info/datahub#controlled-drugs-thresholds-support-snapshot
- PrescQIPP Controlled drug threshold snapshot and visual analytics for commissioner and practice level: https://www.prescqipp.info/datahub#controlled-drugs-thresholds-snapshot-and-visual-analytics

Please note that for all PrescQIPP data you will need to be logged into the website to view it and for practice level data you must have practice level data available to you.

- ePACT drop down tags for schedule 1-5 drugs: http://www.epact.ppa.nhs.uk/systems/sys_main_epact.htm

Please note you will need to log in to the NHS Business Service ePACT website to view this data.

- NHS Business Service Information portal: https://apps.nhsbsa.nhs.uk/infosystems/welcome

Please note you will need to login to the NHS Business Service Information portal website to view this data.

- Remote GP clinical system searches.

### Hints and tips

- The greater number of GP practices covered by the CCG, the more data you need to review.
- Check your MoU - does it have any specific requirements?
- If you want to compare growth to identify anomalies in controlled drug prescribing within your NHS England Area, nationally or ONS clusters – use the PrescQIPP CCG level data or Visual Analytics at commissioner level: https://www.prescqipp.info/datahub#controlled-drugs-monitoring https://www.prescqipp.info/datahub#controlled-drugs-thresholds-snapshot-and-visual-analytics
- If you want to compare growth to identify anomalies in controlled drug prescribing at practice level within your organisation - use PrescQIPP Practice level data Visual Analytics at Practice level: https://www.prescqipp.info/resources/viewcategory/320-practice-level-data-reports https://www.prescqipp.info/datahub#controlled-drugs-thresholds-snapshot-and-visual-analytics
- If you need prepared graphs for reports then use:
  - PrescQIPP CCG level data: https://www.prescqipp.info/datahub#controlled-drugs-monitoring

  - PrescQIPP Practice level data: https://www.prescqipp.info/resources/viewcategory/320-practice-level-data-reports
  - PrescQIPP Controlled drug threshold snapshot and visual analytics at commissioner and practice level data: https://www.prescqipp.info/datahub#controlled-drugs-thresholds-snapshot-and-visual-analytics
  - NHS Business Service Information portal: https://apps.nhsbsa.nhs.uk/infosystems/welcome
- If you want live data; not prescribing data that is potentially two to three months behind – use remote clinical searches; both EMIS web and SystmOne have the ability for remote searches that produce patient anonymised data.
- If you want to analyse controlled drug private prescriptions and requisitions issued, then use the NHS Business Service Information portal: https://apps.nhsbsa.nhs.uk/infosystems/welcome

## Criteria for raising prescribing queries

- Non–formulary prescribing.
- Unusual growth either in cost or items compared to previous years prescribing.
- Unusual growth either in cost or items compared to other GP practices within the CCG locality.
- Potentially exceeding 30 days prescribing.
- Shared care prescribed medicines.
- Medicines required for short term use only.
- Recurrent quantities/high strength medicines suggesting long term prescribing of opioids.
- Other local specific issues.

### Hints and tips

- Keep your criteria small and achievable.
- Check your MoU – does it have any specific requirements?
- Get advice from the NHS England Controlled Drug Team - what are they looking for?
- What are the main local controlled drug issues in prescribing?
- Check previous controlled drug incidents, concerns and complaints – any themes that need to be focussed on?

## How are the queries going to be answered?

- Letters sent centrally from the CCG to GP practices and a response is required.
- Medicines optimisation team performs audits at GP Practice level.

### Hints and tips

Review medicines optimisation team capacity.

Keep robust timelines for responses to be resolved.

Be pragmatic with your queries so GP practices do not get overwhelmed with letters.

Do not repeatedly ask about the same query, try and match queries with previous responses.

Work with the NHS England controlled drug team on recalling prescriptions from the NHS Business Service Authority, if practices are unable to identify patients.

## Accountability structure

If queries are not answered satisfactorily or not answered at all – who needs to know and when?

- Head of Medicines Optimisation.

- Clinical Commissioning Group GP Chair.
- Clinical Commissioning Group Quality Committee.
- NHS England Lead CDAO.
- Controlled Drug LIN.

### Hints and tips

- Check your MoU - does it have any specific requirements?
- How are you going to report controlled drug incidents following your monitoring? Does your NHS England Controlled Drug Team have procedures for reporting controlled drug incidents, concerns and complaints?
- Get the support from your CCG GP Chair to encourage GP practices to answer queries in a timely manner.
- Discuss the process at GP forums within the CCG to ensure commitment and understanding of the importance of controlled drug monitoring.

## Documents required

### Formal documents

- MoU - authored by NHS England, agreed and signed by the CCG.
- Policy or Standard Operating Procedure for reporting controlled drug incidents, concerns and complaints - authored by NHS England.
- Service Level Agreements (SLAs) for commissioned services to include Controlled Drug Standard Operating Procedures and policies.
- Standard Operating Procedure for Controlled drug monitoring.

### Practical documents

- Template GP letters.
- Templates for recording queries and outcomes.
- Audit templates.

### Hints and tips

Use the PrescQIPP materials within the controlled drug webkit.

## Summary

- Under co-commissioning and delegated arrangements, the CCG must perform the delegated functions.
- The CCG are required to assist the regional NHS England CDAO with controlled drug monitoring under the Controlled Drugs (Supervision of management and use) Regulations 2013.[1]
- Check local arrangements, in particularly the MoU with the the regional NHS England CDAO.
- It is good practice for the CCG to nominate a Controlled Drugs CCG Lead to assist the regional NHS England CDAO.
- The CCG is required to assist the regional NHS England CDAO with any investigations, concerns and complaints regarding controlled drugs.[1,3]
- Ensure correct documentation and monitoring are in place for commissioned services, such as Out of Hours that prescribe controlled drugs.
- Ensure clear governance and accountability structures are in place for the safe use and management of controlled drugs.

## References


1. Department of Health Controlled Drugs (Supervision of management and use) Regulations 2013. February 2013. Accessed 21/04/16. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf
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4. Dame Janet Smith DBE. Harold Shipman Fourth Report - The Regulation of Controlled Drugs in the Community. Published 15 July 2004. Accessed 21/04/16. http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/images/fourthreport/SHIP04_COMPLETE_NO_APPS.pdf


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## Additional PrescQIPP resources

 Briefing

 Data pack

 Audit, letters, tools

Available here: https://www.prescqipp.info/resources/category/352-controlled-drugs-monitoring


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