

# Controlled Drugs Final Internal Audit Report November 2022

Swansea Bay University Health Board



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### Acknowledgement

NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

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## Executive Summary

### Purpose

The overall objective of the audit was to review the health board’s arrangements to ensure compliance with the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008.

### Overview



We have issued reasonable assurance on this area.

The matters requiring management attention include:

- Instances of illegible or missing staff signatures in ward and theatre CD order stationery and registers.
- Instances where hospital pharmacy team CD balance checks are not recorded in CD registers.
- Service Group CDMAP action plans not up to date and varying governance and oversight arrangements across Service Groups.

Other recommendations / advisory points are within the detail of the report.

### Report Classification

		Trend
 <p>Reasonable</p>	Some matters require management attention in control design or compliance.	 2019/20
	<b>Low to moderate impact</b> on residual risk exposure until resolved.	

### Assurance summary<sup>1</sup>

Assurance objectives	Assurance
1 Policies and procedures	Reasonable
2 CD ordering controls	Reasonable
3 CD register records	Reasonable
4 CD security	Reasonable
5 CD audits	Reasonable
6 Oversight of CD management	Limited

### Key matters arising

	Assurance Objectives	Control Design or Operation	Recommendation Priority
1 CD order and register compliance	2, 3	Operation	Medium
2 Ward / theatre CD balance checks by Pharmacy	5	Operation	Medium
3 Service Group’s CDMAP updates	6	Operation	High

<sup>1</sup> The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

## 1. Introduction

- 1.1 The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 place a statutory responsibility on Swansea Bay University Health Board ('the health board') and its Controlled Drug Accountable Officer (CDAO) to ensure the safe management and use of Controlled Drugs (CDs).
- 1.2 Prompted by growing service pressures, and following internal audits in 2018/19 and 2019/20 that highlighted issues with record-keeping arrangements in respect of CD storage and administration, work has been underway within the health board to strengthen CD governance within the Service Groups, through a 3-phased approach.
- 1.3 We undertook an advisory review of the health board's progress in strengthening CD governance during 2021/22, which focussed on assessing Service Group implementation of the phased measures. One of the key limitations of our review was that it was unable to determine whether the Service Group's CD Management and Assurance plans were collectively addressing all areas of CD control weakness, due to their design being by exception. Noting that these strengthening phases were maturing at that time, we were unable to make an assessment on the health board's broader management of CDs and level of compliance with legislation.
- 1.4 This audit primarily comprised ward and theatre visits, where we conducted sample testing of CD registers and drug movements. Our review also involved meetings with Service Group Management (CD leads) to understand the oversight role they play, and to identify and test some of the controls that are operating at Service Group level.
- 1.5 Risks considered in the review were as follows:
  - breach of legislation due to non-compliance with the Policy;
  - ineffective controls and / or inaccurate records resulting in controlled drugs being lost or stolen;
  - controlled drugs are not being managed / used safely resulting in patient harm; and
  - lack of oversight of incidents / issues relating to controlled drugs within the health board.
- 1.6 Testing of Pharmacy Department operated controls over CDs was limited to the balance checks evidenced in the CD registers of the wards and theatres examined.

## 2. Detailed Audit Findings

2.1 The table below summarises the recommendations raised by priority rating:

	Recommendation Priority			Total
	High	Medium	Low	
Control Design	-	-	-	-
Operating Effectiveness	1	2	-	3
<b>Total</b>	<b>1</b>	<b>2</b>	<b>-</b>	<b>3</b>

2.2 Our detailed audit findings are set out below. All matters arising and the related recommendations and management actions are detailed in [Appendix A](#).

### **Audit objective 1: Policies and procedures are in place that set out the arrangements and responsibilities for the management of controlled drugs, and these are available to staff on wards and theatres.**

2.3 We noted health board policies and procedures in respect of CD management (Policy for the management of Controlled Drugs and the supporting Standard Operating Procedures documents) had been reviewed in 2020/2021, following concerns raised over the way controlled drugs were being managed at ward and theatre level.

2.4 Policy and procedure review by the Service Groups was included as part of a three-phased approach introduced to strengthen CD Governance and this development was the subject of an earlier internal audit advisory review. We noted actions recorded at that time to review documentation are now recorded as complete, and that current policy and procedure documents are in date. Both record the latest review date of November 2021 and the next review date of December 2022.

2.5 We noted the SOP has a wide scope and includes sections on the following key elements:

- individuals access arrangements for CDs and assigned responsibilities;
- storage of CDs;
- security of storage and transport as per Misuse of Drugs legislation;
- disposal and destruction of CDs;
- alerting mechanism for incidents or arising complications;
- record keeping process for CDs;
- maintenance of CD register; and
- maintenance of CDs returned by patients.

**Conclusion:**

2.6 CD Policy and Procedures documents are current, recently reviewed, and have an appropriate scope that incorporates the key areas for good CD management and we have provided **Reasonable** assurance for this objective.

**Audit objective 2: The ordering, delivery and administration of controlled drugs is carried out in accordance with the policy and operating procedures, by authorised individuals, with records completed as required.**

2.7 We reviewed CD management practice operating on the wards and theatres visited and confirmed the following in discussion with senior ward staff prior to confirming the practices through substantive testing:

- CD cabinet stocklists are recorded on the first page of the CD register;
- Stationery in use at the wards and theatres sampled for the recording of CDs, including CD registers, order books, key logs (theatres), are standard documentation which are issued by the Pharmacy department;
- Only qualified staff on wards and theatres are authorised to order, receive, log, issue, count and otherwise record CD movements. The same staff member may not receive CDs they have ordered;
- Hospital based pharmacy teams maintain a signatory list of these staff and may review and challenge signatures when orders are placed or collected. We did not observe or conduct testing of this specific control during our visits to a sample of wards and theatres;
- CD orders are collected by ward and theatre staff, or in some cases delivered by pharmacy staff. They are transferred in a secure manner to wards and theatres, within sealed bags which are identified by a unique serial number; and
- CDs are signed out of pharmacy delivery log books and recorded within the ward and theatre registers on receipt.

2.8 We tested a sample of 40 CD orders, across the four wards and four theatres, where we examined order and register documents for compliance with requirements. The following key control exceptions were identified (see **Matters Arising 1**):

- five instances where the order had been raised and received by the same individual;
- the ward signature in the 'Received by' section of the order slip was illegible in two instances and absent in two instances;
- six instances where the delivery bag seal number was absent from the orders' entry in the ward/theatre CD register;
- five instances where the signature in the order entry section of the ward/theatre CD register was illegible; and
- four orders where the second (witness) signature section on the CD register was illegible.

We noted that some of the wards/ theatres in our sample recorded a second (witness) signature in the 'Received by' section of the order slips we examined. Whilst this is not at present a requirement stated in the policy or procedure documentation, nor does the current order stationery include a position to record a second signatory, the health board should consider introducing into the CD order documentation this good practice step to strengthen further the existing controls.

#### Conclusion:

2.9 We record control exceptions in the sample of CD orders examined and noted that audits conducted in 2018/19 and 2019/20 had also reported similar issues with CD register completion. We have provided **Reasonable** assurance for this objective.

### **Audit objective 3: There are controlled drugs registers in place on each ward and theatre, which are completed accurately and reconcile to stock levels.**

2.10 We examined the CD registers on the sample wards and theatres and noted the following features (although the previous section records exceptions to some of these processes identified during testing):

- CD registers were of the prescribed format, hard back standard stationery issued by the Pharmacy department;
- each drug type had a separate page within the CD register;
- CD orders / CDs dispensed to patients are entered into the respective page in accordance with the drug type, and evidenced by two staff signatures;
- dispensing entries on register pages record the amount where a part of the drug measure taken for a patient is not used. Wasted drugs are disposed of in the sharps bin and witnessed.
- drug balances are updated and recorded at the end of each entry on the register.
- drug balances are carried over to a new page on the register each time a page for a drug type is complete.
- daily CD balance checks undertaken by the ward or theatre, in which register balances and cabinet drug counts are agreed and reconciled, are recorded in a separate section in the back of the register, evidenced by two staff signatures.
- periodic CD balance checks are conducted by hospital pharmacy teams every 3 - 6 months and, in some cases, recorded in the pages of the registers (examined further under audit objective 5).

2.11 We conducted further CD register substantive testing of the process of drug dispensing to patients, examining a sample of 40 register page entries. Our testing identified instances where the ward signatures in the register dispensing entries were illegible: eleven cases first signatory, nine cases second (witness) signatory (see **Matters Arising 1**).

2.12 During our examination of sample ward and theatre CD registers, we also carried out our own balance checks of the drug pages examined in the earlier CD order test, and found no discrepancies between register and CD cabinet counts.

**Conclusion:**

2.13 We noted only a small number of control exceptions in our examination and sample testing of CD registers and have provided **Reasonable** assurance for this objective.

**Audit objective 4: Controlled drugs are securely stored, with the keys held by an appropriate person.**

2.14 The requirements for the security of CD cabinets and the management, recording and safe-keeping of cabinet keys is captured within the health board's Standard Operating Procedure (SOP). We reviewed these processes and documentation during our visits across a sample of wards and theatres. The following was noted:

- ward staff confirmed that CD cabinet keys were kept separately from general keys, are at all times held on the person of the designated person in charge of the ward, and are kept securely when cabinets are locked and not being accessed;
- key log books are maintained in theatres, to record which staff member is holding the CD keys at any point in time. Separate key logs are in operation for both the master key to the safe (which typically holds a range of CD cabinet keys) and for each individual CD cabinet key;
- key logs record the issue of theatres CD cabinet keys at the beginning of a theatre list, handovers from one staff member to another during the day, and return of the key to safe or cabinet when the theatre closes; and
- entries in key logs are signed by two members of staff.

2.15 We note that it is not the practice of this nor other health boards for wards to maintain CD cabinet key logs to replicate the arrangements in place at theatres (wards do not have frequent lengthy periods when keys are not being held by a staff member), although would consider it to be good practice provided it is not impractical to implement. Due to the absence of a log at the wards we are unable to provide assurance that the CD cabinet key is held by an appropriate person at all times. Whilst we reviewed the theatre key logs to confirm what was being described to us by theatre staff, we did not perform any sample testing of individual key log entries to confirm the accuracy of these.

2.16 We noted in the CD cabinet balance checks we carried out on all visits (reported above under audit objective 3), that cabinets were secure and locked when our check began. We noted too that no drugs other than CDs were held in them and where patients own drugs were held in the ward's CD cabinets these were stored on a separate shelf (theatres do not store patient's own drugs).

**Conclusion:**

2.17 We noted no control exceptions in our examination and sample testing of CD cabinet security and have provided **Reasonable** assurance for this objective.

**Audit objective 5: Appropriate checks and audits are undertaken by health board staff in line with the policy and acted upon accordingly.**

2.18 Daily CD balance checks are conducted by staff on wards and theatres and we confirmed this operating across the sample examined during our site visits (recorded above under objective 3).

2.19 Health board Policy requires that Hospital pharmacy teams conduct periodic CD balance checks on wards (every 6 months) and theatres (every 3 months). Template documents are provided to record these and accepted practice is to record in the pages of the CD registers an entry evidencing the balance check. In 2020, the Pharmacy department introduced a process whereby their audits are captured in a database / dashboard tool. By referring to this, we were able to confirm that these audits were taking place for each unit in our sample, although we did not conduct any structured sample testing of the records in this database. However, our sample testing across the wards and theatres of our sample revealed the following exceptions (see **Matters Arising 2**):

- Pharmacy CD balance checks not evidenced in the CD register in six out of eight instances (but all eight were seen in the CD dashboard); and
- In a broader sample of pharmacy CD audits we noted some instances where documentary records were not retained to support that the audit and balance check had been undertaken.

**Conclusion:**

2.20 We noted a small number of control exceptions in our examination and sample testing of periodic hospital pharmacy team CD audits where, although the Pharmacy dashboard indicates these are being undertaken, they are not always being recorded in CD registers. We have provided **Reasonable** assurance for this objective.

**Audit objective 6: There is appropriate oversight of controlled drugs within the health board, including incidents.**

2.21 Finally, we discussed with Service Group CD leads a range of Service Group level CD oversight controls that are prescribed across the health board, to confirm these were in place and in operation, and to establish their current status.

2.22 We noted each of the Service Groups oversee their management of CDs through service group level monitoring groups. The governance structures of the service Groups vary, but typically these comprise a CD management group and a quality and safety group, meeting monthly, bi-monthly or quarterly. We examined

example related materials evidencing their activity during this audit, but did not carry out any structured detailed testing of the work of these groups.

- 2.23 CD management groups are typically chaired by the Service Group CD lead and attended by Service Group quality & safety, pharmacy and senior ward and theatre staff. These receive notification and review the results of both the regular CD audits conducted by ward / theatre staff and the periodic audits conducted by pharmacy teams, as well as any discrepancies that are identified in the CD registers of their wards and theatres following the daily register balance checks. We noted too service level CD management and quality & safety groups escalate key matters to health board level oversight groups, including the Quality, Safety & Patient Experience sub-committee and the Nursing and Midwifery Group.
- 2.24 Introduced in 2021 as an element of the three-phased approach to strengthen CD governance within the health board, Service Groups maintain a CD Management and Assurance Plan (CDMAP) to align their CD governance activity with the statutory requirements of The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008. CDMAPs record any weaknesses in CD management practices and include an action plan to address these. This is an evolving deliverable that will be taken forward through an iterative process, through regular review by Service Level oversight groups.
- 2.25 All Service Group CD leads meet bi-annually with the Controlled Drugs Assurance Officer (CDAO), to discuss any emerging/current concerns regarding CD governance and to provide an update on the progress of the CDMAP tasks or actions. The latest of these meetings took place in June 2022 and we reviewed the minutes to understand current issues. We undertook our own review of the Service Group's CDMAPs but noted instances where these were not being regularly updated and reviewed by Service Group level oversight groups. We also noted that CDMAPs scopes / contents do not appear to have been reviewed against current legislation (an action raised in our previous advisory review), and that the CD lead role in the Murrison Service Group was vacant. (see **Matters Arising 3**).
- 2.26 We discussed the oversight of CD errors and incidents by the Service Groups and reviewed example documentation evidencing the activities described (although we have not reviewed Datix records, incident investigations etc. in detail). In this we noted the following to be in action:
- Wards and theatres and other areas across the health board holding and administering CDs, record any incidents and errors that arise by raising entries in the DATIX system.
  - Service Group management oversee CD incidents and errors in their wards and theatres through sight of DATIX incidents they are notified.
  - Staff in the divisions, departments, sections or teams of the Service Groups submit review and monitor their incidents and submit highlight reports of these to their Service Group's regular CD group meetings.
  - Staff monitoring DATIX incidents maintain logs in which these cases are held and where actions to address them are recorded.

- Incident highlight reports of these cases are submitted to Service Group level CD and Quality & Safety oversight groups where they are discussed, assessed and resolved.
- Service Group level CD oversight groups escalate high risk incident cases, or those they cannot themselves resolve, to the health board level Medicines Management and Quality & Safety groups.

#### Conclusion:

2.27 We noted each of the Service Groups have monitoring groups whose remit includes the overseeing of the management of CDs. The governance structures of the oversight groups varies, but typically these comprise a CD management group and a quality and safety group, meeting monthly, bi-monthly or quarterly and escalating matters to health board level sub-committees and groups accordingly. We noted that CDMAPS are not routinely reviewed and updated by all Service Groups at CD management group meetings, and that there was a lack of clarity over actions and target dates in these documents. We have therefore provided **Limited** assurance for this objective.

## Appendix A: Management Action Plan

### Matter arising 1: CD order and register compliance (Operation)

### Impact

We tested a sample of 40 CD orders, across the four wards and four theatres, where we examined order and register documents for compliance with requirements. The following key control exceptions were identified:

- five instances where the order had been raised and received by the same individual;
- the ward signature in the 'Received by' section of the order slip was illegible in two instances and absent in two instances;
- six instances where the delivery bag seal number was absent from the orders' entry in the ward/theatre CD register;
- five instances where the signature in the order entry section of the ward/theatre CD register was illegible; and
- four orders where the second (witness) signature section on the CD register was illegible.

Potential risk that loss or misappropriation of CDs may go undetected.

We noted that some of the wards/ theatres in our sample recorded a second (witness) signature in the 'Received by' section of the order slips we examined. Whilst this is not at present a requirement stated in the policy or procedure documentation, nor does the current order stationery include a position to record a second signatory, the health board should consider introducing into the CD order documentation this good practice step to strengthen further the existing controls.

We conducted further CD register substantive testing to test the process of drug dispensing to patients, examining a sample of 40 register page entries. Our testing identified instances where the ward signatures in the register dispensing entries were illegible: eleven cases first signatory, nine cases second (witness) signatory.

### Recommendations

### Priority

- 1.1 We recommend that the exceptions above are addressed and that rules requiring double signatories for all CD register movements are applied without exception (signatures should always be accompanied by printed names in order that they may clearly identify the individual signing). Additionally, we recommend that the health board consider introducing the requirement to provide a second (witness) signature on CD order stationery to strengthen further the existing controls.

Medium

Management response	Target Date	Responsible Officer
<p>1.1 The Controlled Drug Accountable Officer will work with Service Group Controlled Drug Leads to review controlled drug policy in respect of witness signatures for the receiving of CDs and for existing controls in place.</p> <p>Where exceptions have been noted above to Health Board policy/SOPs, the Service Group Controlled Drug Lead will direct the Service Group's response to the above recommendation. This will include as a minimum:</p> <ul style="list-style-type: none"> <li>• Making all staff involved in the management of controlled drugs aware of the above findings in order to help staff reflect on current practice.</li> <li>• Drawing staff attention to the Health Board's controlled drug policy and in particular the relevant sections relating to the above recommendation with the aim of improving adherence to policy requirements.</li> <li>• Ensuring performance relating to the above recommendation is re-audited by the Service Group within 6 weeks to provide the Service Group, the Executive team and the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful and that practice is fully compliant with policy.</li> <li>• Ensuring that the above findings and recommendation are discussed at the relevant Service Group controlled drug governance and quality &amp; safety forums together with the outcome of mitigating actions.</li> </ul>	<p>Response to recommendations to add additional controls to Health Board policy/SOPs: 31st March 2023</p> <p>Response to exceptions to existing Health Board policy/SOPs: 6th January 2023</p>	<p>Service Group Controlled Drug Leads &amp; Controlled Drug Accountable Officer</p>

Matter arising 2: Ward / theatre CD balance checks by Pharmacy (Operation)		Impact
<p>Testing on the four sample wards and four theatres selected confirmed hospital pharmacy teams were conducting and documenting periodic CD audits, but in doing so we noted instances of the following:</p> <ul style="list-style-type: none"> <li>Pharmacy CD balance checks not evidenced in the ward / theatre CD register (six of eight cases).</li> <li>in a broader sample of pharmacy CD audits we noted some instances where documentary records were not retained to support that the audit and balance check had been undertaken.</li> </ul>		Potential risk that loss or misappropriation of CDs may go undetected.
Recommendations		Priority
2.1	We recommend that hospital pharmacy team CD balance checks are recorded on the individual drug pages of the CD registers and in the Pharmacy CD dashboard tool for all audits undertaken. The latter should then be used to support a more formal management review of the audit findings, the results of which could be shared with stakeholders across the health board.	Medium
2.2	Pharmacy should retain original audit documentation for all audits they perform in order that they are available for examination in the event of enquiry.	
Management response	Target Date	Responsible Officer
2.1 & 2.2	31 <sup>st</sup> March 2023	Pharmacy Leads & Service Group Controlled Drug Leads
	<ul style="list-style-type: none"> <li>All staff involved in the joint controlled drug checks are made aware of the above findings in order to help staff reflect on current practice.</li> <li>Staff are made aware of the requirements around undertaking the joint controlled drug checks, including appropriate recording of such checks.</li> <li>The results of such audits are being captured and acted upon accordingly to improve controlled drug governance.</li> <li>Ensuring performance relating to the above recommendation is re-audited by pharmacy leads and the Service Group following the next scheduled joint CD checks, to provide the Chief Pharmacist, the Service Group, the Executive team and the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful.</li> </ul>	

- Ensuring that the above findings and recommendations are discussed at the relevant Pharmacy and Service Group controlled drug governance and quality & safety forums together with the outcome of mitigating actions.

**Matter arising 3: Service Group's CDMAP updates (Operation)****Impact**

We noted the following issues with the CDMAPs of the Service Groups we were provided with:

- CDMAPS are not routinely reviewed and updated at CD management group / Quality & Safety meetings by all Service groups.
- There is no evidence that CDMAP scopes have been reviewed against legislation to ensure all key aspects are covered (an action raised in our previous advisory review).
- Mental Health & Learning Difficulties: the document we examined was dated June 2022, but we noted that actions were not dated and there were many of amber status denoting that they were not completed.
- Singleton / NPT: the document we examined was dated April 2021 (although we were advised of, but did not see, a later revision in November 2021). The document has a narrative format without clear actions or target dates so it wasn't possible to determine status of the former.
- Morrison: the latest revision of the CDMAP was dated April 2022 and we noted actions of the action plan largely completed, excepting three where revised target dates had expired (implementing a comprehensive training programme, structured review of the CD "Potential Diversion" Log, developing and implementing a comprehensive performance monitoring framework.)

Potential risk that some of the CD related management responsibilities of Service Groups are not delivered.

**Recommendations****Priority**

- 3.1 We recommend that all Service Groups review and update their CDMAP action plans to give clarity over those actions that are outstanding, their significance rating and target dates for completion and going forward, that these should be monitored and updated at each of the respective Service Group CD management group review meetings.
- 3.2 CDMAPs scope should be reviewed against current legislation to ensure that all key aspects are covered, and against the findings reported in this audit and updated where necessary.

High

**Management response****Target Date****Responsible Officer**

- 3.1 The Service Group Controlled Drug Lead will direct the Service Group's response to the above & recommendation. This will include as a minimum:
- 3.2
- Ensuring that the Service Group reviews their Controlled Drug Management & Assurance Plan (CDMAP) in line with the above recommendations.

6<sup>th</sup> January  
2023






Service Group Controlled Drug  
Leads

- Discussing the Service Group's updated CDMAP, or latest draft if ongoing, at the Service Group Controlled Drug Lead/Controlled Drug Accountable Officer biannual meeting in late November/early December 2022, to provide the Controlled Drug Accountable Officer with the necessary assurance that mitigating action has been successful.
- Ensuring that the above findings and recommendations are discussed at the relevant Service Group controlled drug governance and quality & safety forums, together with the outcome of mitigating actions.

## Appendix B: Assurance opinion and action plan risk rating

### Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	<b>Substantial assurance</b>	Few matters require attention and are compliance or advisory in nature. <b>Low impact</b> on residual risk exposure.
	<b>Reasonable assurance</b>	Some matters require management attention in control design or compliance. <b>Low to moderate impact</b> on residual risk exposure until resolved.
	<b>Limited assurance</b>	More significant matters require management attention. <b>Moderate impact</b> on residual risk exposure until resolved.
	<b>No assurance</b>	Action is required to address the whole control framework in this area. <b>High impact</b> on residual risk exposure until resolved.
	<b>Assurance not applicable</b>	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

### Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

\* Unless a more appropriate timescale is identified/agreed at the assignment.



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