

# Controlled Drugs Governance Internal Audit Briefing Paper December 2021

Swansea Bay University Health Board

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## Executive Summary

The Health Board Senior Leadership team in November 2020 agreed that the Controlled Drugs Accountable Officer (CDAO) would work with service groups to strengthen Controlled Drugs (CD) governance through a 3-phased approach to be delivered by quarter 1 2021/22;

- Phase 1: service group Directors and the CDAO will sign up to a new 'Controlled Drug Governance and Assurance Charter;
- Phase 2: The service group CD lead together with senior governance colleagues from within the service group will undertake 6 monthly CD governance and assurance meetings with the CDAO;
- Phase 3: Each service group will develop a CD management and assurance plan (CDMAP).

The intention of this methodology was to provide a flexible and practical structure via which service groups could make improvements alongside severe service pressures caused by the COVID-19 pandemic. Through a mixture of short-term actions and long-term planning, service groups would be enabled to strengthen CD governance commensurate with the nature of CD management undertaken together with controls already in place.

The overall objective of the audit, which took place in quarter 3 2021/22, was to review the health board's progress in strengthening CD Governance by assessing service group implementation of the phased measures agreed by the SLT. The key findings that emerged are outlined below, and described more fully in the report that follows:

- only three of the four service groups had submitted all the deliverables of the 3 phases by quarter 1 but these had all been submitted to the CDAO by the time the audit took place in quarter 3, excepting the CDMAP of the PCT service group;
- we were unable to determine whether service group's CD assurance plans were collectively addressing all areas of CD control weakness, due to their design being by exception, and noted that all plans contained a significant number of overdue actions;
- the development of service group CDMAPs is to be an evolving deliverable that will be taken forward through an iterative process;
- operating procedure updates are in different stages of completion across the service groups; and
- the Quality & Safety Committee have been regularly updated on the progress of the CD strengthening initiatives.

Due to the scope of our review focussing on seeking to provide an update on progress of the strengthening phases, and that this is still maturing, we have been unable to make an assessment on the health board's broader management of CDs and level of compliance with legislation.

## 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 A presentation to the Senior Leadership Team (SLT) in March 2019 identified issues in the governance surrounding the management and use of controlled drugs and it was then agreed that controlled drug governance required strengthening across the health board in order to provide the Board with the necessary assurance regarding compliance with this legislation.
- 1.3 Our own audits undertaken in 2018/19 and 2019/20 have highlighted issues with record-keeping arrangements in respect of controlled drug storage and administration too. The SLT agreed that work would proceed to address concerns in relation to CD governance and licencing.
- 1.4 An update paper presented by the CDAO to the SLT in November 2019 indicated that the systems and processes in place within the health board did not enable the CDAO to fully discharge the accountabilities set out within the guidance. It expressed concern that the limited resource allocated to the role was spent reacting to issues involving controlled drugs rather than proactively working to improve the CD governance with the aim of further minimising the potential for patient harm, misuse and criminality.
- 1.5 Work was undertaken to create a governance framework to place the responsibility for the management and use of controlled drugs with the delivery units / service groups and, more specifically, the responsibility for CD incidents and subsequent actions. Further work was required following this paper to develop, finalise and implement the framework.
- 1.6 The disruption caused by the Covid-19 pandemic had a significant impact and led to a cessation of further development of the framework which as a result was not completed and ratified.
- 1.7 In November 2020, the SLT agreed an alternative approach where action to address the need to strengthen controlled drug governance would begin with service groups introducing the following three measures:
  - Phase 1: service group Directors and the CDAO will sign up to a new 'Controlled Drug Governance and Assurance Charter;
  - Phase 2: The service group CD lead together with senior governance colleagues from within the service group will undertake 6 monthly CD governance and assurance meetings with the CDAO;
  - Phase 3: Each service group will develop a CD management and assurance plan.
- 1.8 The Advanced Pharmacist (Governance, Improvement and Transformation) was to work with each service group to develop localised arrangements in phases. The Service groups' implementation of these has progressed in parallel and all were asked to report status in April 2021.
- 1.9 The risks considered in the review were as follows:

- i. the CD Accountable Officer is unable to fully discharge their accountability as outlined in the Welsh Government Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008;
- ii. CDs are lost or stolen and not being managed / used safely resulting in patient harm; and
- iii. current CD governance arrangements do not provide the Board with the necessary assurance regarding compliance with this legislation.

1.10 The overall objective of the audit was to review the health board's progress in strengthening CD Governance by assessing service group implementation of the phased measures agreed by the SLT in November 2020 and the health board's broader management of CDs is not in its scope.

## 2. Detailed Audit Findings

### **Audit objective 1: To assess the implementation status of the three governance strengthening measures by each of the service groups with reference to target timelines**

2.1 The health board has four service groups with responsibilities for the management of controlled drugs, all of which were in the scope of the review. These are:

- Neath Port Talbot/ Singleton (NPT/S);
- Morriston;
- Primary, Community and Therapies (PCT); and
- Mental Health & Learning Disabilities (MH&LD).

2.2 Phased CD strengthening measures required that all service groups submit the following to the Controlled Drugs Accountable Officer (CDAO) by 1<sup>st</sup> April 2021:

- a CD charter document on the template provided. Signed by the Service Group Director, CD lead and senior governance lead, this formally establishes the CD Lead role within the service group, and it's commitment to ensure the safe and appropriate management and use of controlled drugs through compliance with statutory requirements and relevant Health Board policy;
- a commitment to 6 monthly CD governance and assurance meetings with the CDAO; and
- a CD management and assurance plan (CDMAP) to align the CD governance activity of their Service Group with the statutory requirements of The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008.

2.3 We sought to establish the current delivery status of the Charter, CD assurance plans and bi-annual meeting arrangements of the four service groups and assessed this as follows:

- all service groups had submitted a CD Charter and nominated a CD lead.
- service group CDMAPs were intended to reflect their assessment of compliance with the regulatory standards so were specific to the needs of the service.

- three service groups (NPT/S, Morriston, MH&LD) had prepared and submitted a CDMAP of their own design. The CDMAP of the PCT service group was in outline only and incomplete (see audit objective 2).
- all service groups had held the first of the bi-annual meetings with the CDAO.
- a completed version of the CDMAP of the PCT service group remains pending.

#### Conclusion:

2.4 We noted that the deliverables of the three specified phases were submitted by service groups to the CDAO by the time the audit took place in quarter 3, excepting the CDMAP of the PCT service group.

### **Audit objective 2: To assess the completeness and quality of the phases' 1 (charter) and 3 (management assurance plan) deliverables of all service groups through high level review of the documentation submitted to the CDAO and the extent to which these adhere to national legislation**

2.5 We examined the documentation of the CD Charters submitted by service groups and noted the following:

- a template was devised and provided on which service groups submitted their Charters and all had submitted a charter document on the template provided.
- Charters included the nomination of a service group CD lead who was to be accountable to the CDAO for the service group's CD management compliance. They also featured a series of CD related commitments that service groups undertake to honour and through which CD governance will be strengthened.
- Whilst the sign-off and submission of charter documents demonstrated service groups commitments, we did not perform any testing to confirm that the latter were being delivered.

2.6 As has been outlined above, a process of strengthening of controls has been initiated and we examined the resulting service groups CD Management and Assurance Plans (CDMAPs), noting the following:

- the development of the CDMAPs was to be an iterative process, the requirement being that service groups prepare and submit the first draft by quarter 1 2021/22.
- service groups were asked to make their own assessment of areas where CD management control weakness was perceived and devise strengthening plans to address these.
- the brief included a steer toward sections 2 and 3 of the 2020 draft Governance framework containing the key areas and legislative obligations and service groups were expected to consider all of these in their assessment.
- these key areas were seen to feature to a greater or lesser extent in service groups plans, but as the resulting CDMAPs created by the groups by design recorded control areas by exception only it was not possible to evidence that all elements of these sections had been considered by service groups when developing the plans.

- service groups were asked to cross reference the entries in their CDMAPs to sections 2 and 3 of the CD Framework document. These are not included in the documents of any of the service groups but the health board have identified the need for an assessment of CDMAP content against the CD legislation to ensure that key areas are adequately covered (we are advised this will require additional resource as there are capacity constraints within the current team).
- CDMAP action plans of three (Morrison, NPT/S, MH&LD) of the four service groups include a significant number of overdue actions. The fourth (PCT) is unpopulated in respect of officers tasked with action delivery and action target dates.
- we noted that only one of the service groups CDMAP (MH&LD) includes actions to address the areas of concern notified by the CDAO that preceded the strengthening work in late 2020 (i.e. safe keeping of CD cabinet keys, safe destruction and disposal of CDs), but were advised all service groups have been reminded to consider these as they further develop their CDMAPs.

#### Conclusion:

- 2.7 Service groups had submitted their charters on the template provided and made their own assessment of their CD arrangements but we were unable to determine whether service group's CD assurance plans were addressing all areas of control weakness and noted that all plans contained a significant number of overdue actions. The health board has recognised a piece of work is now needed to conduct an assessment of CDMAPs against CD legislation to ensure that key areas are adequately covered.

### **Audit objective 3: To ensure that related service group procedure documents have been updated and communicated to relevant staff accordingly**

- 2.8 We noted all CD assurance plans cover procedure documents and include actions to review and process any amendments that arise from the strengthening initiatives but we noted status of these varies across the service groups:
- for one service group (PCT) the action plan is unpopulated throughout and as such we cannot establish whether any necessary updates are being progressed to timescale.
  - in two other of the four service group's CDMAPs (NPT/S, MH&LD), actions to update operating procedures that are impacted by the strengthening changes have passed their target dates and are overdue.
  - in the fourth service group (Morrison), actions are being progressed and are within target timescale.
- 2.9 CDMAPs did not specify how service groups planned to communicate changes to procedures to officers who may be affected but we recognise there will be existing pathways to facilitate their cascade.

#### Conclusion:

- 2.10 Operating procedure updates to reflect the strengthening initiatives are in different stages of completion across the service groups. Target action dates have passed in the majority of

cases, with the exception of one service group. The revised operating procedures will need to be communicated to staff once finalised.

#### **Audit objective 4: To assess the oversight arrangements in place within the health board to manage and monitor the implementation of the 3 phases**

2.11 We noted the following governance framework in respect of oversight by the health board of the implementation of the CD strengthening initiatives, although, noting in particular that the health board is currently reviewing service group governance arrangements more broadly, we have not conducted formal audit testing across the period to confirm they are fully operating:

- service groups report the progress of their strengthening plans to their Quality & Safety groups, which typically meet monthly.
- Service group Quality & Safety groups also report to the Quality & Safety Governance Group (QSGG), a sub-group of the Quality & Safety Committee of the board.
- the CDAO meets bi-annually with service group leads who provide assurance status of their CD compliance.
- the CDAO reports status to the health board's Quality & Safety Committee which reports to Board.

2.12 Ongoing CD management assurance activity is embedded across the health board and continues to operate in the normal way (but note was not tested in this review). This includes regular ward (6 monthly) and theatre (3 monthly) audits overseen by the individual service group's incident review function and ongoing CD incident capture and investigation through the Datix system.

2.13 Whilst these ongoing activities were outside of the scope of this review, reports provided to us indicate these processes are active.

2.14 The CDAO provides a twice yearly update to the Quality & Patient Safety Committee and provided a paragraph for the health board's 2021/22 annual governance statement on the progress with CD assurance strengthening measures.

#### **Conclusion:**

2.15 CD management oversight structures / groups are in place in the health board and are updated on the progress of the CD strengthening initiatives, although we have not conducted formal audit testing across the period to confirm they are fully operating in all service groups.



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