



GIG
CYMRU
NHS
WALES

Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board



Meeting Date	4th October 2018	Agenda Item	4b
Report Title	Controlled Drug Accountable Officer (CDAO) Report: July 2017 – August 2018		
Report Author	Rhys Howell, Pharmaceutical Advisor. Medicines Management		
Report Sponsor	Judith Vincent, Clinical Director Pharmacy		
Presented by	Judith Vincent, Clinical Director Pharmacy		
Freedom of Information	Open		
Purpose of the Report	<ul style="list-style-type: none"> To provide an update of key controlled drug governance activity undertaken at the direction of the CDAO from July '17 to August '18. To provide an update against specific actions identified in previous CDAO reports. To outline planned activity over the coming year designed to improve controlled drug governance. 		
Key Issues	<p>Key issues from the last year that will need to be progressed and concluded over the coming year include:</p> <ul style="list-style-type: none"> Ensuring recommendations and learning outcomes from, 'The Desk Top Review into Controlled Drug Management in ABMU Health Board Theatres', have been implemented across all Service Delivery Units. Development and legal ratification of a Health Board policy regarding the requirements for Home Office Controlled Drugs and MHRA Wholesale Dealers Licenses. 		
Specific Action Required (please ✓ one only)	Information	Discussion	Assurance
			✓
Recommendations	The Committee is asked to note the content of this report including the progress made and to approve the actions prioritised for the coming year.		

Controlled Drug Accountable Officer (CDAO) Report: July 2017 – August 2018

1. INTRODUCTION

The introduction of the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 which came in to force in Wales in January 2009, made provision under the Health Act 2006 to strengthen the systems for managing controlled drugs.

Both ABMU Health Board (as a Designated Body) and the Controlled Drug Accountable Officer (CDAO) have statutory responsibilities laid out in the Regulations to ensure robust arrangements for the management and use of Controlled Drugs (CDs) to minimise patient harm, misuse and criminality.

This is the fifth report from the CDAO for ABMU Health Board. It will provide an update of activity undertaken at the direction of the CDAO throughout the intervening period since the previous such report. It also outlines planned activity over the coming year designed to improve CD governance.

2. BACKGROUND

During the last year both the Gosport War Memorial Hospital Independent Panel Report together with the annual Care Quality Commission's Safer Management of Controlled Drugs Report have been published. These provide a reminder of the importance of ensuring the Health Board has robust systems and processes in place for the safe and effective use of Controlled Drugs (CDs).

Areas of CD governance providing particular challenge for the CDAO over the last year include:

- **Multiple serious controlled drug incidents/concerns arising from ABM theatre departments.** Initially this involved oversight and investigation of the incidents and support for, 'The Desk Top Review into Controlled Drug Management in ABMU Health Board Theatres' (this was commissioned jointly by the CDAO and the Health Board Executive Team - a paper regarding the review was presented to this committee in February 2018). More recently, the focus of activity has been around providing support to, and seeking assurance from Service Delivery Units (SDUs) that the recommendations and learning outcomes of the review have been implemented.

- **Determination of Health Board license requirements.** In liaison with Health Board Risk and Legal colleagues advice has been sought from Welsh Health Legal and more recently a Barrister on behalf of all Welsh Health Boards regarding the circumstances under which the Health Board would require a Home Office Controlled Drugs and MHRA Wholesale Dealers Licenses.

Other key areas of CD governance that have been progressed over the last year:

- ***Maintenance of the Local Intelligence Network (LIN)*** – The Western Bay Controlled Drug LIN which is supported and chaired by the CDAO continues to meet quarterly. The CDAO is grateful to all the members representing many different organisations and professions who participate in this group. A LIN newsletter was produced this year to highlight key CD issues but also to raise awareness of the group. To further support participation and visibility, the LIN has undertaken to meet in a variety of different settings over the coming year throughout the community.
- ***Controlled Drug Authorised Witness Programme*** – The CDAO continues to operate this programme to ensure the timely and appropriate destruction of CDs that are no longer required or are out of date. There has been an increased turnover of Controlled Drug Authorised Witnesses (CDAWs) this year due to a number of staff changes in partner organisations. This has placed additional demand on the programme to train and accredit new staff to ensure timely access to CDAWs.
- ***Review of Controlled Drug Policy*** – The CDAO led a successful multidisciplinary review and update of the CD Policy and associated assurance audit arrangements for ABM theatres over the last year. A review of ward CD policy has now begun to ensure that this remains fit for purpose going forward together with a review of the Health Board's, Policy for the Handling/Disposal of Illicit Substances.'

3. GOVERNANCE AND RISK ISSUES

There continues to be a number of competing priorities to be delivered over the coming year within the resource available to support the CDAO (currently sourced from within the Pharmacy and Medicines Management Service Group), including:

- Ensuring that each SDU has produced and is working through an action plan to implement the recommendations and learning outcomes from, 'The Desk Top Review into Controlled Drug Management in ABMU Health Board

Theatres.’ Following early discussions and submission of action plans in recent weeks it has become apparent that ongoing support will be required from the CDAO, working closely with SDUs to provide the assurance required regarding CD management.

- Successful resolution of an ongoing CD Incident Panel regarding multiple serious controlled drug incidents/concerns on a Health Board site.
- Development and legal ratification of a Health Board policy regarding the requirements for Home Office Controlled Drugs and MHRA Wholesale Dealers Licenses.
- Development, in liaison with key stakeholders, of a CD incident template for Datix to improve quality and consistency of investigations. This is in direct response to a recommendation of, ‘The Desk Top Review into Controlled Drug Management in ABMU Health Board Theatres.’
- Supporting closer working with other Health Board CDAOs and Welsh Government to ensure where appropriate a ‘Once for Wales’ approach is taken.
- The need to liaise closely with the Cwm Taf CDAO and their team to ensure a seamless transition of CD governance for the Bridgend Locality as they move from one Health Board to another.

A progress report against actions identified in the previous CDAO report as well as new actions identified over the last year can be found in Appendix 1.

A CD Governance Dashboard developed by the CDAO can be found in Appendix 2. CD related incidents now make up more than a quarter of all incidents reported on Datix. The increase seen over the last year may be due to an increased awareness of the need to report, a genuine rise in CD related incidents, or a combination of both factors. Missing and damaged CDs have been identified specifically in the Dashboard because incidents in these categories have been associated with suspected diversion of CDs in the past. Finally the Dashboard also shows the significant work associated with the Controlled Drug Authorised Witness Programme as well as the number of CD Incident Panels held between July 2017 and August 2018 due to serious concerns regarding CD governance.

4. FINANCIAL IMPLICATIONS

There is no impact on the Health Board financial bottom line however funding for training (including updates) and ad hoc resources need to be considered in line with CD Regulations.

5. RECOMMENDATION

The Committee is asked to note the content of this report including the progress made and to approve the actions prioritised for the coming year.

Governance and Assurance										
Link to corporate objectives <i>(please ✓)</i>	Promoting and enabling healthier communities		Delivering excellent patient outcomes, experience and access		Demonstrating value and sustainability		Securing a fully engaged skilled workforce		Embedding effective governance and partnerships	
			✓						✓	
Link to Health and Care Standards <i>(please ✓)</i>	Staying Healthy	Safe Care	Effective Care	Dignified Care	Timely Care	Individual Care	Staff and Resources			
		✓	✓				✓			
Quality, Safety and Patient Experience										
<p>Safe and effective management of Controlled Drugs (CDs) is essential to prevent patient harm, misuse and criminality, both within the Health Board and in the wider community.</p>										
Financial Implications										
<p>There is no impact on the Health Board financial bottom line however funding for training (including updates) and ad hoc resources need to be considered in line with CD Regulations.</p>										
Legal Implications (including equality and diversity assessment)										
<p>Both ABMU Health Board (as a Designated Body) and the Controlled Drug Accountable Officer (CDAO) have statutory responsibilities laid out in the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 to ensure robust arrangements for the safe management and use of Controlled Drugs.</p> <p>In relation to the determination of Health Board requirements for MHRA and Home Office licenses (outlined above) - The Health Board has received legal advice that the consequences of not having the necessary licenses in place for both individuals and the Health Board are very serious both in terms of criminal and civil liabilities.</p>										
Staffing Implications										
<p>There are no staffing implications at this time.</p>										
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)										

There are no direct implications on the Well-being of Future Generations (Wales) Act. However, the specific updates in this report will be subject to full impact against the act where necessary.

Report History

This is the fifth report to the Committee by the Controlled Drug Accountable Officer. The reports have been presented annually (the last report in August 2017).

A separate update entitled, 'Outcome and learning from the, 'Desk Top Review: Controlled Drug Management in ABMU Health Board Theatres,' was presented to the Committee in February 2018.

Appendices

- Appendix 1: Action Plan
- Appendix 2: CDAO CD Governance Dashboard (July 2017 – August 2018)

Appendix 1: Action Plan

The table below provides a progress report against actions identified in the previous CDAO report as well as new actions identified over the last year. Whilst progress has been made in the majority of cases, competing priorities and limited resources have meant that it has not been possible to fully complete in all cases and therefore further action required going forward is noted.

Action/ regulation	Status	Progress	Further action required
Regulation 4: Accountable Officer			
Action 1: Liaise with the Cwm Taf CDAO and their team to ensure a seamless transition of CD governance for the Bridgend Locality as they move from one Health Board to another.	Ongoing	Will form part of ongoing boundary change discussions.	Initial meeting between CDAO support teams required.
Action 2: Welsh Government will be approached to highlight the need for an all Wales CDAO forum	Ongoing	A survey of CD LINs in Wales by Public Health highlighted a number of concerns expressed by the Welsh Health Boards including sharing information across LINs, consistency of approach across Wales and professional support for CDAOs. A meeting of Health Board CDAOs was held in March 2017 with the Chief Pharmaceutical Officer for Wales. A	Monitor & review.

		number of CD issues that are common to all Health Boards were discussed and the desire to deliver a 'Once for Wales' approach as far as possible. Follow up meetings to progress these issues have not occurred to date.	
Regulation 9: Safe Management and Use of CDs			
Action 3: Ensure that each Delivery Unit has produced and is working through an action plan to implement the recommendations and learning outcomes from, 'The Desk Top Review into Controlled Drug Management in ABMU Health Board Theatres.'	Ongoing	Discussions between CDAO team and Delivery Units during early Summer 2018. Submission of 5/6 Delivery Unit action plans. It is anticipated that ongoing support will be required from the CDAO, working closely with Delivery Units to provide the assurance required regarding CD management.	Continue to monitor progress and provide support.
Action 4: Development of Health Board policy regarding the requirements for Home Office Controlled Drugs and MHRA Wholesale Dealers Licenses.	Ongoing	Legal advice received. Next step is to translate the legal advice into policy.	Continue to work with Health Board Risk and Legal colleagues to develop the policy
Action 5: Review ward CD policy to ensure that this remains fit for purpose going forward	Ongoing	Pharmacy Patient Services Transformation Work stream undertaking review of current policy	Await outcome of review
Action 6: Continue to use CD Incident Panels to address serious CD concerns	Ongoing	Conclude current ongoing CD Panel. Currently awaiting additional information from Delivery Unit regarding CD	Follow up meeting with Delivery Unit senior staff to be scheduled following review

		governance.	of CD governance data
<p>Action 7: A Policy and procedure will be drafted to ensure reporting, investigation and management of incidents and concerns is in line with the regulations. This has differing requirements to the current arrangements for investigating other (non-CD related) incidents</p>	On-going	<p>This action was developed several years ago. In line with learning from recent incidents and guidance from Welsh Government regarding implementation of the Regulations (i.e. that strengthened governance should work within and alongside existing governance arrangements) it is now thought appropriate that this action is amended.</p> <p>Datix is used to report CD incidents. Datix continues to have a CD mandatory field where reporters are asked to confirm if the incident is related to a CD. In addition work has begun to develop a standardised template for the management of CD incidents on Datix</p> <p>As previously reported arrangements have been made to ensure that Delivery Units take ownership of their own medication incidents and ensure that any lessons learnt are shared within the Units via their own Quality & Safety Committees.</p> <p>Information has been cascaded to staff regarding how to report</p>	<p>Development, pilot and roll out of standardised Datix CD template to ensure quality and appropriateness of investigation.</p> <p>Completion of Handling/Disposal of Illicit substances policy review.</p>

		<p>CD related incidents and concerns.</p> <p>The Health Board policy for the Handling/Disposal of Illicit substances is currently under review in liaison with South Wales Police.</p>	
<p>Action 8: Adequate multidisciplinary support is required for the Accountable Officer to address the significant risk to the organisation and patient safety</p>	On-going	<p>Resources to support the CDAO are dependent on the existing pharmacy and medicines management department establishment.</p>	Monitor & review.
Regulation 18: Local Intelligence Network (LIN)			
<p>Action 9: The Accountable Officer will identify an appropriate escalation route for non-attendance, poor sharing and non-submission of occurrence reports. Adequate multidisciplinary support is required for the LIN to function effectively.</p>	On-going	<p>Following the re-launch of the Western Bay LIN in April 2016 the group have continued to meet quarterly.</p> <p>The Terms of Reference have been updated to reflect changes in membership particularly around national bodies that are no longer able to attend meetings routinely.</p> <p>A new deputy chair of the LIN has been appointed during the last year who represents an external organisation. It is hoped that this appointment will continue to encourage multi-disciplinary/multi-organisational</p>	<p>Monitor & review. The LIN is functioning well with good levels of attendance to date.</p>

		engagement.	
Regulation 12 :Declarations and Self Assessments			
Action 10: The process for obtaining declarations and self assessments will be reviewed.	On-going	There is potential for this to be an all Wales solution via NWIS and needs to be progressed on an All Wales basis. The CDAO will continue to raise this issue with the Chief Pharmaceutical Officer for Wales.	Monitor & review.
Regulation 10: Adequate destruction and Disposal arrangements			
Action 11: All contractors will be reminded of the obligation to share destruction reports with the Accountable Officer.	Ongoing	An exercise to review the register of authorised witnesses has been completed during 2016/17. Reminders have also been sent to Authorised Witness's regarding destruction reports.	Monitor and review. Re-fresher training for all CDAWs is planned for the coming year where this key message will be re-iterated.
Action 12: Authorised Witness Guideline/SOP review and associated training programme refresh required	Complete	Authorised witness Guideline/SOP reviewed and agreed by CDAO during 2017. Associated training programme refreshed in line with the above during the last year.	Action complete
Action 13: Additional authorised witnesses will be trained from acute site pharmacies during 2017/18	Complete	Training complete and staff accredited as Controlled Drug Authorised Witnesses	Action complete
Regulation 11: Monitoring and Audit of the use of Controlled Drugs			
Action 14: Adequate resourcing of previously identified areas of work will be required to free capacity within the	Ongoing	In Primary Care, a review of CD prescribing data by a pharmacist has continued to form part	Monitor & review

<p>Medicines Management Team to undertake monitoring</p>		<p>of the annual QoF prescribing visits to GP Practices during the last year.</p> <p>In Acute Care pharmacy departments continue to undertake a 6 monthly audit of CD stock/registers on wards/theatres.</p>	
--	--	--	--

Appendix 2: CDAO CD Governance Dashboard (July 2017 – August 2018)

