Board of Directors – Public

SUMMARY REPORT	Meeting Date:	28/07/2021
	Agenda Item:	20

Report Title:	**Controlled Drugs Accountable Officer (CDAO) Report**	
Author(s):	**Abiola A-M Allinson, Chief Pharmacist and CD Accountable Officer**	
Accountable Director:	Dr Mike Hunter	
Other Meetings presented to or previously agreed at:	**Committee/Group:**	N/A
	Date:	N/A
Key Points recommendations to or previously agreed at:	N/A	

Summary of key points in report
This is the statutory Controlled Drugs Accountable Officer annual report to the Board outlining the background to the role and providing information on controlled drugs processes within SHSC NHS FT. The report highlights any concerns; ameliorating actions in place to mitigate and provides assurance with respect to the handling of Controlled Drugs.

Recommendation for the Board/Committee to consider:

Consider for Action		**Approval**		**Assurance**	**X**	**Information**	

The Board is asked to consider the content of the report and receive assurance as to the management of controlled drugs within SHSC.

Please identify which strategic priorities will be impacted by this report:				
Covid-19 Getting through safely	*Yes*		*No*	***X***
CQC Getting Back to Good	*Yes*	***X***	*No*	
Transformation – Changing things that will make a difference	*Yes*		*No*	***X***
Partnerships – working together to make a bigger impact	*Yes*	***X***	*No*	

Is this report relevant to compliance with any key standards?					**State specific standard**
Care Quality Commission	*Yes*	***X***	*No*		***Safer management of controlled Drugs***
IG Governance Toolkit	*Yes*		*No*	***X***	
Have these areas been considered? YES/NO					If Yes, what are the implications or the impact? If no, please explain why
Patient Safety and Experience	*Yes*	***X***	*No*		***Safer management of CDs improves patients safety and therefore experience***
Financial (revenue &capital)	*Yes*		*No*	***X***	***There are no directly related revenue or capital issues.***
OD/Workforce	*Yes*	***X***	*No*		***An appropriately trained workforce is essential for the safe management of all drugs.***
Equality, Diversity & Inclusion	*Yes*		*No*		*Please complete section 4.2 in the content of your report*
Legal	*Yes*	***X***	*No*		***The Misuse of Drugs Act 1971; The Misuse of Drugs Regulations 2001; The Controlled Drugs Regulations 2013***

Title	Controlled Drugs Accountable Officer (CDAO) Report

Section 1: Analysis and supporting detail

Background

1.1 Purpose of the report

To ensure that "safe management of controlled drugs" is maintained as an organisational priority.

To provide assurance on the systems and processes within SHSC that lead to the safe management of controlled drugs.

To update the BoD on the concerns raised in last year's (2020) report.

To highlight the recommendations from the Care Quality Commission (CQC) annual report on controlled drugs (published July 2020).

Background

In January 2000, Doctor Harold Shipman was convicted of the murder of 15 of his patients using the drugs diamorphine (heroin) and morphine. Reports also suggest that he may have used these drugs to kill many more of his patients, possibly around 250.

Following Dr Shipman's conviction, the Secretary of State for Health asked Dame Janet Smith to lead an independent enquiry into the case and make recommendations to protect the public from harm by relevant people using controlled drugs.

Between 2002 and 2005 six reports were published under the chairmanship of Dame Janet Smith. These led to the legislative changes which were introduced in the 2007 Health Act to strengthen the governance arrangements surrounding the use of controlled drugs by "relevant people".

As part of the statutory requirements contained within the 2007 Health Act organisations such as NHS trusts were required to appoint a Controlled Drugs Accountable Officer (CDAO), who was responsible for the assurance of safe use of controlled drugs throughout the organisation. Other requirements included the sharing of information (or intelligence) across organisational boundaries and a duty to collaborate. Where there are strong grounds for concern a CDAO must share intelligence with other bodies such as the police, the NHS counter fraud service, the CQC or registering bodies such as the General Medical Council, the Nursing and Midwifery Council, and the General Pharmaceutical Council.

In 2013 new legislation was introduced (The Controlled Drugs [Supervision of Management and Use] Regulations 2013) which brought the previous medicines and CD legislation in line with the NHS organisational changes. This legislation was put in place to ensure that the overriding aim of the CDAO continued to be to protect the public from harm in relation to controlled drug use by relevant people.

The NHS England and NHS Improvement – (NE and Yorkshire) team CDAO is responsible for coordinating the sharing of information through Local Intelligence Networks (LINs). To support the CDAO in this task the Sheffield CCG has a designated lead who co-ordinates the functions of the Sheffield LIN.

Information concerning all incidents relating to controlled drugs is reported by the SHSC CDAO to the North East and Yorkshire CD LIN on a quarterly basis.

Controlled Drugs

In August 2012, the legislation covering medicines for human use was revised and consolidated into a new act – The HUMAN MEDICINES REGULATIONS 2012. This legislation updated the 1968 Medicines Act and incorporated various changes introduced by EU legislation together with all the updates and variations to the original act.

There is a degree of complexity surrounding the laws relating to medicines and CDs but in general terms the main legislative points to note are:

The Misuse of Drugs Act 1971 (MDA 1971)
This act primarily covers the illegal use of drugs and provides a schedule system for classification of these drugs. This system of classification provides the courts with guidance on the maximum sentences to be imposed if this law is broken (Schedules A, B & C).

The Misuse of Drugs Regulations 2001 (MDR 2001) (and subsequent amendments)

Covers the medical use of those drugs listed within the MDA 1971. Within the context of MDR 2001 the classification system for the medical use these drugs defines the drugs by a different system of schedules (1, 2, 3, 4 & 5). Within this context these drugs are classified according to their likelihood of harm vs therapeutic benefit. With Schedule 1 drugs being the most tightly controlled in terms of prescribing, dispensing, storage & transportation and Schedule 5 having the least control. Schedule 4 also includes anabolic steroids.

The British National Formulary (BNF) gives details of the legal status of most of the medicines used in the UK. The Chief Pharmacist/CDAO would be expected to intervene in all cases where there may be a concern about the use of these drugs by relevant people. Further details can be found on the home office website http://www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-licences/controlled-drugs-list.

Management of Controlled Drugs (CD's)

Following the activities of Dr Harold Shipman in the 1990's, it became clear that the systems and process of control that were in place at the time to govern the use of CDs were inadequate. Following the fourth report of the Shipman enquiry in 2004, the chairman Dame Janet Smith concluded that the governance arrangements for these drugs needed to be strengthened.

Many of her recommendations from the enquiry were incorporated into part three of the 2007 Health Act and statutory instrument No. 3148 The Controlled Drugs (Supervision of Management and Use) Regulations.

http://www.legislation.gov.uk/ukpga/2006/28/pdfs/ukpga_20060028_en.pdf

http://www.legislation.gov.uk/uksi/2006/3148/pdfs/uksi_20063148_en.pdf

One of the key changes introduced by the 2007 Health Act was the statutory requirement for NHS trusts (and other relevant bodies) to appoint an Accountable Officer for Controlled Drugs (CDAO).

In December 2015 further changes to legislation took place which enforced the use of new controlled stationary by anyone ordering stocks of controlled drugs. An unintended consequence of this legislation resulted in additional bureaucratic requirements for anyone receiving – or supplying controlled drugs outside of the legal entity of an NHS Trust. No exemption can be applied to NHS trusts such as SHSC where small quantities of controlled drugs are supplied to other NHS trusts and all NHS trusts are required to submit standard requisitions in order to transfer stocks of controlled drugs between themselves.

Statutory role of the Controlled Drugs Accountable Officer (CDAO)

The requirement for designated bodies to appoint a CDAO was made in the 2007 Health Act and has been reiterated in subsequent legislation. The CDAO must ensure that their designated body has adequate arrangements for the safe and legal management and use of controlled drugs throughout the organisation.

The overriding concern of the CDAO is to protect the patients and public from harm due to controlled drugs by relevant people. There are a number of specific duties of the CDAO. Full details of the duties of the CDAO are laid down in Part 2 of The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (http://www.legislation.gov.uk/uksi/2013/373/part/2/made).

The CQC are required to hold a record of all CD accountable officers (and ensure all relevant organisations are registered with them. See http://www.cqc.org.uk/content/controlled-drugs-accountable-officers)

Duties of the CDAO include ensuring that:

- The organisation is following “adequate and up-to-date” Standard Operating Procedures (SOPs).

- Appropriate arrangements for monitoring and auditing the management and use of controlled drugs.

- Systems exist to alert the accountable officer of any complaints or concerns involving the management or use of controlled drugs.

- The incident reporting system captures untoward incidents involving the management or use of controlled drugs.

- Appropriate arrangements in place for analysing and responding to untoward incidents involving the management or use of controlled drugs.

- Relevant individuals receive appropriate training in relation to controlled drugs.

- Arrangements are appropriate for monitoring and auditing the management and use of controlled drugs by relevant individuals and assessing their performance.

- The recording of any concerns raised in relation to the management or use of controlled drugs by a relevant individual.

- The assessment and investigating of any concerns raised regarding the management or use of controlled drugs by a relevant individual. The CDAO must determine whether these concerns should be shared with a responsible body.

- Appropriate action is taken to protect patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a relevant person appear to be well-founded.

- Appropriate arrangements for ensuring the proper sharing of information.

The designated body (Board of Directors) has a responsibility to ensure that they notify the CQC of the name of the CDAO and that they are a “fit, proper and suitably experienced person” who does not ‘routinely supply, administer or dispose of controlled drugs as part of their duties’.

Notification to the CQC should be done through the relevant section of the CQC website (http://www.cqc.org.uk/content/controlled-drugs-accountable-officer-notifications) -This notification section is password protected.

The BoD can be assured that the CQC hold details as of July 2021 of the CDAO for SHSC as follows:

TAH	Sheffield Health and Social Care NHS Foundation Trust	Abiola	Allinson	Abiola.allinson@shsc.nhs.uk	0114 2718630	Sheffield	S10 3TH

Designated bodies are required to ensure that the CDAO is provided with the necessary funds and resources to carry out their responsibilities.

CD Recommendations from the Care Quality Commission (CQC)

The CQC scrutinise and report on how well NHS trusts and other agencies work together to ensure the sharing of intelligence/information on the safe management and use of controlled drugs by relevant people.

As part of this work, the CQC publish their findings annually, together with recommendations on how the safe use and management of CDs can be improved.

In July 2020, the CQC published their latest annual report

https://www.cqc.org.uk/publications/themes-care/safer-management-controlled-drugs-annual-update-2020

Of the five recommendations made by the CQC in their 2020 report, the BoD are advised the following that relate to SHSC;

Recommendations

1. Providers should enable all health and care staff to freely engage and participate in activities that support reflection and learning

- The post COVID-19 recovery period for health and care providers is an important opportunity to reflect on and share learning. This should include positive experiences, innovative and good practice, as well as when things have gone wrong. The opportunity to improve safety is rooted in this process.

2. Those leading and working in local health and care systems need to collaborate to reduce risks

of avoidable harm associated with controlled drugs

- We know that people have better experiences and outcomes when local providers of health and care services work well together.

From the 2018 CQC CD report recommendations identified, the current SHSC progress updates are as below:

1. CDAO and nominated CD leads must have oversight of the use of controlled drugs and follow up any unusual use to assure themselves that the arrangements for controlled drugs in the organisation are safe. This should include timely audits and considering treating controlled drugs as high-risk medicines

Progress: Scheduled 3 monthly CD audits on the SHSC inpatient wards are undertaken and unexplained discrepancies are followed with affected wards/teams. CD storage regimes have been simplified to standardise across the organisation. Use of the ADioS (Abusable Drugs Investigational Software) programme highlights any unusual trends that could warrant an investigation.

2. CDAOs and nominated controlled drugs leads need to share controlled drug related concerns about health care professionals with their NHS England CDAO. Although it is important to be aware of General Data Protection Regulations requirements, these do not remove this responsibility in the interest of patient and public safety

Progress: There have been no concerns raised about any individual that required details to be shared with NHS England CDAO in the last year**.**

SHSC Assurance Statement

1) Any serious concerns relating to controlled drugs are investigated and actions taken to prevent recurrence.
2) All reported losses/discrepancies are reviewed, investigated, and followed robustly with teams and managers
3) The CDAO will share any serious concerns relating to controlled drugs and relevant people with NHS England, Yorkshire, and Humber LIN and CDAO
4) The CDAO attends the Regional CD LIN meetings which in the times of COVID have been on-line

Update on issues reported to the BoD in the previous annual CDAO reports (2016-2020)

Update 2014 There has been a considerable improvement in this over the past year, and it is expected to improve further with the continued roll out and refinement of the electronic incident reporting system throughout the trust.

Update 2015 Improvements in the timely reporting of CD incidents continue. The trust MSO continues to work with the risk department to improve the quality of reporting and learning from CD incidents.

Update 2016 The timeliness of reporting of incidents has improved – but the overall increase in the number of incidents has led to delays in fully investigating incidents. *The interim Chief Pharmacist (in agreement with the CDAO) has agreed to update the SOP relating to the investigation of small discrepancies of schedule 3,4 & 5 controlled drugs in an attempt to create the capacity for timely investigation of incidents.*

Update 2018 The improvements in the timeliness of reporting and investigation of incident not considered serious, have not been maintained. Systems for tracking low level discrepancies have not been introduced. It is expected the support systems will be strengthened by the appointment of the new Trust chief pharmacist and medication safety officer in July 2018.

Update 2019 – Close scrutiny of the reported low-level incidents has led to a review of Standard operating procedures of management of Controlled drugs on the wards. These updates and implementation plan should improve the management of CDs in those areas.

Update 2020 – Updated SOPs implemented in September 2019. This has led to a decrease in unresolved medication losses and closer scrutiny of the CD processes.

Update 2021- The number of incidents reported have increased and this shows transparency and needs to be encouraged. There has conversely been an increase percentage wise in the resolution of CD discrepancies.

Trends in Incidents reported to the CDAO (October 2012 to September 2017)

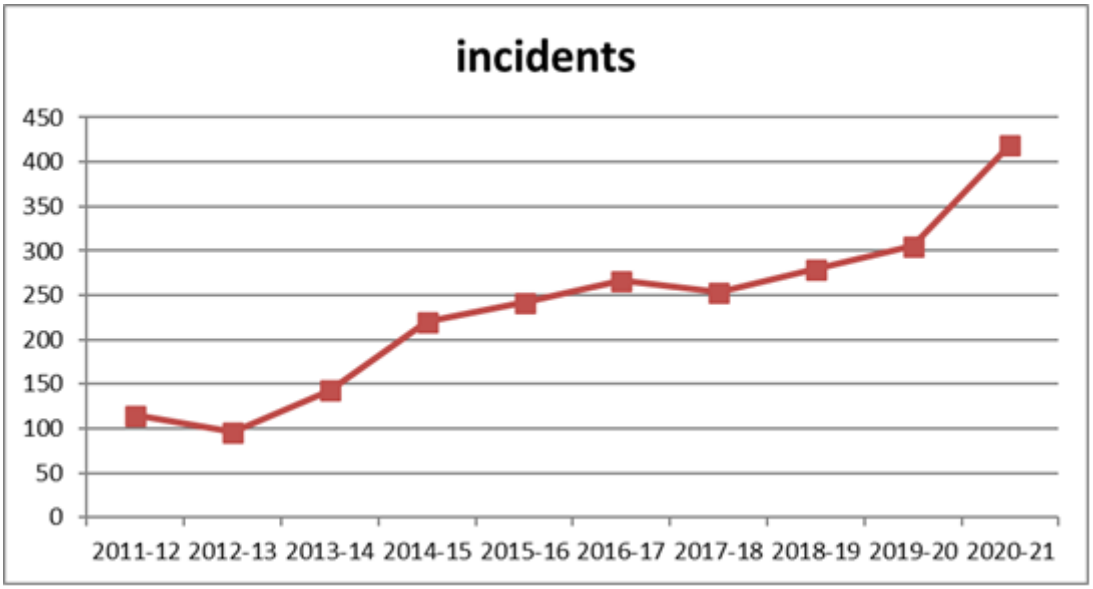
(Note" year" relates to period ending September i.e. reporting period Oct to Sept)

	2017	2016	2015	2014	2013	2012
Total CD incidents reported to CDAO	266	242	220	143	96	115

Trends in incident reported to CDAO October 2017 to March 2021

	2017-2018	2018-2019	2019-2020	2020- 2021
Total CD incidents reported to CDAO	253	279	305	419

The annual trend in reported incidents involving all controlled drugs in shown below (Oct 2012 to Mar 2021)



Review and investigation of incidents

Incidents were reported to the CDAO through the trust electronic incident reporting and management system – "Ulysses".

In cases of known or suspected serious or major concern, the CDAO will act immediately and inform the Chief Executive and Medical Director and where possible will put systems in place to prevent further harm. If the CDAO believes that there are strong grounds for major concern they will share information with other relevant bodies e.g. Local Intelligence Network (LIN), professional bodies, Police, Care Quality Commission (CQC), etc.

All reported CD incidents are subject to a brief initial assessment by the Medicines Safety Officer (MSO) and team/ward pharmacist as a triaging process for the CDAO. A prioritised investigation is triggered if the CDAO or others suspect that the incident may be a major concern.

In cases where the management investigation of a reported incident is considered insufficient, the MSO will oversee a more granular investigation and if required interview the staff involved, their manager and any other relevant people to triangulate and verify the information received. Details of individuals' behaviour in relation to relevant SOP's, their medicines related training and their involvement with other CD or medicines related incidents are all considered and recorded as part of the investigation process.

The investigation/review continues until the CDAO is satisfied that there is a complete picture of what went wrong, why it went wrong and what action is necessary to prevent further occurrence. The incident will then be classed as "closed" by the CDAO

There are cases where there is insufficient information, or it is impractical to gather more details. Rather than leaving these as open, or on-going, but where there is little prospect of gathering more detailed information e.g. staff leaving, then these incidents will be classed as "technically closed" but would be re-opened if further information comes to light through other incidents. Details of all incidents and subsequent investigation are held by the CDAO in electronic format. The trust incident recording system also contains details of the incident, but currently it is not possible for this system to capture any associated information (e.g. copies of paper records).

The CD LIN reporting tool is used to submit quarterly data to the CD LIN. The MSO has reviewed the incident review process; it has been streamlined; pharmacists are working with their teams to address poorly completed incident forms as well as supporting the investigation to reach a conclusion. Timeliness of reporting is key in order that incidents are investigated contemporaneously and resolved.

Issues of serious or major concern (April 2020 to March 2021)

There were two issues reported of major concern. Both incidents triggered serious incident investigations.

1) Related to a leaflet produced by the Chronic Fatigue Syndrome service with incorrect information relating to incorrect maximum daily dose of prescribed pregabalin
2) Related to a medication administration error- clonazepam 4mg administered instead of diazepam 4mg

Other issues (April 2020 to March 2021)

Finding the root cause for some of the CD discrepancies often remains elusive; 133 out of a total of 419 incidents reported were attributed to discrepancies. Of the 133 discrepancies reported; 63 (47%) were resolved in 2020/21 (compared to 30% in 2019/20) (*See table below*)

	Q1 (19/20)	Q2 (19/20)	Q3 (19/20)	Q4 (19/20)	Total
Accounted for losses	16 (3)	20 (5)	14 (5)	13 (11)	63 (24)
Unaccounted for losses	25 (12)	8 (10)	20 (25)	17 (10)	70 (57)
Total	41 (15)	28 (15)	34 (30)	30 (21)	133 (81)

There has been a noted improvement in accounted for losses which is indicative of better scrutiny and checking processes. This improvement is supported by the checks at shift changes (to narrow down the time frame of discrepancy occurrences -this supports quicker resolutions) and training at ward level on CD management by pharmacy staff.

<u>The NHS England and NHS Improvement – (NE and Yorkshire) CD LIN</u>
This body continues to function and is well attended by CDAO's. Meetings are held 6 monthly and reports requested quarterly.

<u>Clover Group</u>

The Clover Group scrutiny and monitoring of staff is undertaken by the Clinical Support Unit at the CCG. As the Clover Group transferred out of management of SHSC in April 2020, there will be no further inclusion of management information of the Group in CDAO future reports.

Outstanding themes that remain under review.

1) Timeliness and quality of investigation relating to some low-level CD incidents is still an on-going issue

2) Embedding of the change in practice with the updated CD SOPs in the in-patient areas

Conclusion

The overall pattern of incidents involving CD's and relevant people within the Trust indicate that:

1) Safeguarding and information sharing relating to serious concerns across the NHS England and NHS Improvement – (NE and Yorkshire) CD LIN is continuing to work well even in the COVID environment.

2) The CD incidents reporting rate rates continue to increase. This supports an open culture of reporting within SHSC.

3) Assurance that the CDAO is aware of and acted on incidents in relation to any concerns about controlled drugs.

4) A higher percentage of CD discrepancy incidents reported are now able to be resolved to a satisfactory conclusion .