Sheffield Health and Social Care NHS Foundation Trust

Board of Directors – Open

Date: 12th August 2020 **Item Ref:** 16

TITLE OF PAPER	**Controlled Drugs Accountable Officer (CDAO) report to the Board of Directors**
TO BE PRESENTED BY	Abiola Allinson CD Accountable Officer
ACTION REQUIRED	1) To review the report 2) Raise questions and challenge if necessary
OUTCOME	BoD is assured that 1) The governance arrangements for the management of controlled drugs and relevant people are fit for purpose 2) CDAO acts in line with statutory requirements to prevent the harm from controlled drugs by relevant people.
TIMETABLE FOR DECISION	August Board
LINKS TO OTHER KEY REPORTS / DECISIONS	Patient safety Medicines optimisation risks and processes CQC assurance processes
LINKS TO OTHER RELEVANT FRAMEWORKS BAF, RISK, OUTCOMES	To ensure the safe use of controlled drugs by relevant people. To ensure shared intelligence to prevent harm from controlled drugs
IMPLICATIONS FOR SERVICE DELIVERY AND FINANCIAL IMPACT	Delivered within allocated resources
CONSIDERATION OF LEGAL ISSUES	The Human Medicines Regulations 2012 http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916.pdf The Health Act 2006 and subsequent updates. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 The Controlled Drugs (Supervision of Management and Use) Regulations 2013 http://www.legislation.gov.uk/uksi/2013/373/pdfs/uksi_20130373_e.pdf

Author of Report	Abiola Allinson
Designation	Chief Pharmacist and CD Accountable Officer
Date of Report	August 2020

Sheffield Health and Social Care
NHS Foundation Trust

SUMMARY REPORT

1. Purpose

For Assurance	For Approval	collective decision	To report progress	To seek input from	For information	Other (please state
X		X			X	X

2. Summary

- There has been an increase in the number of Controlled Drug (CD) incidents that are reported to the CDAO, though with regards schedule 4 controlled drugs this has remained steady.
- The majority of Schedule 2 incidents relate to primary care interface issues.
- The largest number of reports relate to schedule 4 controlled drugs (as in previous years). CD Standard Operating Procedures (SOPs) have been reviewed and a new way of working instigated on the wards to support better recording and accountability. There have also been timeliness issues in receiving details of investigations. The Medicines Safety Officer (MSO) has implemented a system for review by ward /team pharmacists to speed up the investigation process and review trends in relation to schedule 4 incidents to ensure the timeliness of reports
- SOP's for CDs have been updated and has lead to a decrease in unaccounted losses of Schedule 4 benzodiazepines.
- ADIoS – (A programme devised to support NHS Trust Accountable Officers with a robust system for monitoring and reporting on controlled and abusable drugs including schedules 4+ 5 Controlled drugs) is in use within SHSC. Program supports early tracking of trends in unusual transactions that warrant investigation.

3 Next Steps

Board to note the report and be assured of robust monitoring and management of controlled drugs in SHSC

4 Actions

Continue to monitor the impact of the changes to the CD SOPs and the investigations process Continue to use the intelligence in ADioS to monitor CD usage and trends.

5 Monitoring Arrangements

CDAO to continue to monitor and ensure all incidents relating to controlled drugs are investigated and information shared.

Medicines Safety Group monitors all medicines related incidents – including those relating to controlled drugs.

Quarterly reports submitted to Regional CD accountable officer

Annual Assurance report to SHSC board of directors.

CDAO reports issues of major or serious concern to Trust Chief Executive and Executive medical director.

6 Contact Details

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Controlled Drugs Accountable Officer (CDAO) report to the Board of Directors (BoD)

July 2020

Abiola A-M Allinson, Chief Pharmacist and CD Accountable officer

Purpose of the report

To ensure that "safe management of controlled drugs" in 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 describe the range of incidents reported to the CDAO from April 2019 – March 2020.

To update the BoD on the major concerns raised in last years (2019) report.

To highlight the recommendations from the Care Quality Commission (CQC) 2018 annual report on controlled drugs (published July 2019).

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 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 (LIN's). 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 CD's, 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. Although the full list of controlled drugs is currently under review, 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 – including contact details for advice on whether or not a specific substance is a controlled drug. (DLCUCommsOfficer@homeoffice.gsi.gov.uk)

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 CD's 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. It appears that 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 his/her 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 (SOP's).
- 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 s/he is a "fit, proper and suitably experienced person" who does not 'routinely supply, administer or dispose of controlled drugs as part of his or her 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 at August 2020) of the CDAO for SHSC as follows:

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

Note: Current DAO was appointed in September 2018.

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 2019 the CQC published their latest (2018) annual report see

https://www.cqc.org.uk/sites/default/files/20190708_controlleddrugs2018_report.pdf

Of the five recommendations made by the CQC in their 2018 report, the BoD are advised of the following that relate to SHSC and the CDAO

1) CDAOs and nominated controlled drug 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 their organisation are safe. This should include timely audits and considering treating controlled drugs as high-risk medicines.

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

3) All healthcare professionals need to remember their responsibility to speak up on areas of concern that might negatively affect patient safety, including prescribing, administering, dispensing, supplying and disposing of controlled drugs.

From the 2017 CQC CD report recommendations identified and progress updates are as below

1. Healthcare professionals should keep their personal identification badges and passwords secure and report any losses as soon as possible to enable organisations to take the necessary action -
   Progress: Diversion and misuse of lower schedule controlled drugs are still a concern and we continue to encourage localised monitoring where appropriate.

2. Health and care staff should consider regular monitoring and auditing arrangements for controlled drugs in the lower schedules, such as Schedules 4 and 5, to identify and take swift action on diversion.
   Progress: We continue to raise this through NHS England CD LINs and in our controlled drug newsletters. However, it remains an issue and we must all continue to be vigilant as the diversion of controlled drugs is becoming increasingly sophisticated. Use of the ADioS programme highlights any unusual trends that could warrant an investigation.

SHSC Assurance statement

The CDAO makes the following statements of assurance to the BoD in relation to controlled drugs and relevant people.

BoD should note the following.

1) Serious concerns relating to controlled drugs are investigated and actions taken to prevent recurrence.
2) The CDAO shares any serious concerns relating to controlled drugs and relevant people with NHS England ,Yorkshire and Humber LIN and CDAO
3) The CDAO attends the Regional CD LIN meetings

Update on Issues reported to the BoD in the previous annual CDAO report (2016-2019)

1) Delays in reporting/awareness concern (all incidents). There were, at times, delays between the occurrence of an incident and the CDAO being informed.

Update 2014 There has been a considerable improvement in this over the past year, and it is expected to improve further with the continued role 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 pharmacists 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.

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
Incidents relating to schedule 2 CD's	49	20	29	18	23	22
Incidents relating to schedule 3 CD's	26	62	24	7	8	10
Incidents relating to schedule 4 CD's	173	146	154	97	55	60
Incident relating to schedule 5 CD's	5	2	3	2	3	1
Unscheduled or not listed because of other reasons e.g. multiple drugs/schedules	13	12	10	19	7	22

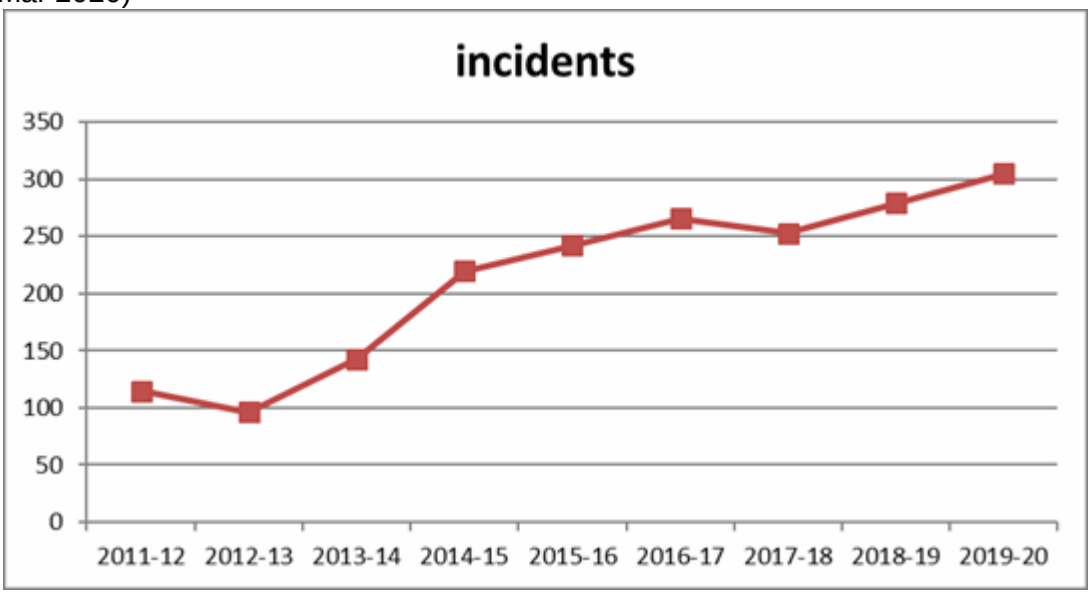
Trends in incident reported to CDAO October 2017 to March 2020

	2017-2018	2018-2019	2019-2020
Total CD incidents reported to CDAO	253	279	305
Incidents relating to schedule 2 CD's	30	29	29
Incidents relating to schedule 3 CD's	27	18	25
Incidents relating to schedule 4 CD's	181	207	213
Incident relating to schedule 5 CD's	0	2	3
Unscheduled or not listed because of other reasons e.g. multiple drugs/schedules/illicit/unknown	15	23	35

A total of 305 reports were received in the period April 2019 – March 2020

Incidents identified as moderate and above as per the CD LIN protocol have been shared with the NHS England and NHS Improvement – (NE and Yorkshire) CD LIN.

The annual trend in reported incidents involving all controlled drugs in shown below (Oct 2012 to Mar 2020)



Review and investigation of incidents

Almost all incidents were reported to the CDAO through the trust electronic incident reporting and management system – "Ulysses". Occasionally the CDAO is informed through other routes such as the CD LIN or personal contact/intelligence. As soon as the CDAO is informed about an incident involving controlled drugs and relevant people, a judgement about the potential seriousness of the issue and the need to protect people from harm is made.

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 he 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 in order 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 these 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 2019 to March 2020)

There have been no issues of serious concern in the year.

Other issues (April 2019 to March 2020)

Not all reported incidents concerned people who were employees of the Trust. Some incidents involving schedule 2 drugs were “interface” issues with community pharmacies or others not employed by the trust. Details of these incidents were shared with the Regional CDAO and/or the relevant organisation’s CDAO and the CCG.

Schedule 2 CD’s

The number of incidents has been similar to the previous year. Most incidents reported were outside SHSC. The information was shared with Local and Regional CD LIN in relation to interface issues.

Schedule 4 controlled drugs

As noted in previous years, many incidents relate to schedule 4 drugs. The majority relating to a small number of tablets or liquid. To address some of the liquid discrepancies, the Medicines Optimisation Committee (MOC) have reviewed the measuring processes for liquid benzodiazepines and approved a standard operating procedure relating to overages to support better management.

Finding the root cause for these minor discrepancies often remains elusive. The previous CDAO had reached an agreement with the executive team that the focus of investigating these small-scale stock discrepancies should switch from an attempt to scrutinise in detail every report – but instead look for anomalies arising from plotting patterns of supply and discrepancies.

A review was undertaken by the MSO and new CDAO in 2019 of the low-level reporting and the continual loss of medication though low grade was of concern. Following an internal audit investigation, the process for recording CD and checking CDs was reviewed and changed in September 2019 to ensure there is a double signature on medication administration of CDs inclusive of benzodiazepines and Z-Drugs. Increased stock checks brought in to encompass all handovers to be able to closer pinpoint the time of discrepancy and support the investigation and resolution process.

	Q1	Q2	Q3	Q4
Accounted for losses	3	5	5	11
Unaccounted for losses	12	10	25	10
Total	15	15	30	21
Record keeping	12	6	5	18

The increased scrutiny with Schedule 4 and 5 incidents is in line with the recommendations from the CQC report in 2017.
There has been a noted improvement in accounted for losses which is indicative of better scrutiny and checking processes. There is also a noted increase in reports of record keeping concerns.

This indicates an open and honest reporting culture highlighting when SOPs are not able to be followed. One of the concerns are the numbers of accredited second checkers. This is currently being addressed by rolling out a program for training to support the in-patient wards.

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

Clover group

Scrutiny and monitoring of the staff within Clover Group's use of CD's continues to be undertaken by Clinical Support Unit at the CCG. This is done as part of their overall arrangements for the monitoring of CD's in general practice and primary care.

If there are reported causes for concern about the management of controlled drugs by relevant people within Clover group, the monitoring arrangements through NHS England will continue in line with the rest of the GP practices within the CCG.

Outstanding themes that remain under review.

1) Timeliness of investigation relating to low level CD incidents.
2) Intelligence gathering with the full implementation of the ADIoS programme for monitoring medicines of abuse.
3) Monitoring of a change in practice post implementation of new CD SOPs in the in-patient areas
4) Reaching a critical number of approved CD's checkers to reduce the incidents of not conforming to the SOPs

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.

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) Higher percentage of CD discrepancy incidents reported are now able to be resolved to a satisfactory conclusion

5) The largest number of reports relate to schedule 4 controlled drugs (as in previous years). The Medicines Safety Officer (MSO) has implemented a system for review by ward /team pharmacists to speed up the investigation process and trends in relation to schedule 4 incidents to ensure the timeliness and appropriate level of investigation.

6) The ADIoS monitoring system provide more timely information of any discrepancies with respect to Schedule 4 and 5 CDs.

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