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A review of Controlled Drug incidents reported to the NRLS over seven years

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ABSTRACT

Aim

To describe the number and types of patient safety incidents involving Controlled Drugs reported to the National Reporting and Learning System (NRLS) and the role of Accountable Officers for CDs (AOs) in incident reporting and learning.

Design and setting

All medication safety incidents concerning CDs reported from the NHS in England and Wales occurring in the seven years from 1 January 2005 to 31 December 2011 were extracted from the NRLS and subject to quantitative inspection. In addition incidents with reported outcomes of death and severe harm were also analysed qualitatively.

Results

There were 72,028 in incidents reported to the NRLS over seven years. Of 10,678 incidents of reported harm, there were 54 deaths, 74 severe harms and 10,550 incidents of other harms. The risk of death with CD incidents was found to be significantly greater than with medication incidents generally (odds ratio 1.484, 95% CI 1.015–2.169). Incidents involving overdose of CDs accounted for 89 (69.5%) of the 128 incidents reporting of serious harm (death and severe harm). Five CDs (morphine, diamorphine, fentanyl, midazolam and oxycodone) were responsible for 113 incidents (88.4%) leading to serious harm. A detailed review of the 128 incident reports associated with serious harm found that only once incident had been referred to the AO.

Conclusion

Unsafe use of CDs is the number one cause of serious harm from medication incidents reported to the NRLS; in our view, better implementation of NPSA guidance could have prevented most of these incidents from harming patients. The role of the AO should prioritise reporting and learning of incidents that have caused serious harm.

IN A previous review of all medication incidents reported to the National Reporting and Learning Service (NRLS) opioid medicines were identified as causing the greatest number of incidents with fatal and severe outcomes.[1] The National Patient Safety Agency has issued guidance intended to help minimise dosing errors with opioid medicines.[2–5]

Controlled Drugs are an essential part of modern clinical care and are used to treat a wide variety of clinical conditions. They are however, subject to special legislative controls because there is potential for them to be abused, diverted or cause possible harm.[6]

In response to the Shipman Inquiry Fourth Report,[7] the Government introduced a range of measures to strengthen the systems for managing CDs to minimise the risks to patient safety of inappropriate use. The arrangements were underpinned by the Health Act 2006 and The Controlled Drugs (Supervision of Management and Use) Regulations 2006 made under the provision of the Act. The governance arrangements embedded within the regulations are required to be implemented in a way that supports professionals, and encourages good practice in the use of these important medicines, when clinically required by patients.[6]

Accountable Officers (AOs) were given specified responsibility to minimise the risk to patients from CDs. The regulations indicate that in discharging their responsibilities, an AO must have regard to best practice in relation to the management and use of CDs.

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We have undertaken a quantitative review of all medication incidents involving CDs sent to the NRLS over a seven-year period. In addition, for those incidents with reported outcomes of death and severe harm we have undertaken a qualitative review. Our aims were to better understand the types of incidents and the role of AOs in reporting and learning.

Method

All medication safety incidents concerning CDs reported as occurring in the seven years from 1 January 2005 to 31 December 2011 were extracted from the NRLS database and subjected to quantitative inspection. In addition incidents with reported outcomes of death and severe harm were also analysed qualitatively. Where the clinical outcome of the incident description matched NRLS definitions,[8] the clinical outcome code was confirmed. Where the incident description did not match the outcome code reported, a more appropriate clinical outcome code based on the NRLS reference definition was substituted (DG), to reflect mo re accurately the details of the reported incident. The quantitative inspection was based upon the amended clinical outcome scores.

The working definition of severe harm used for the review was "a patient safety incident that appears to have resulted in permanent harm and/or a near death experience". Incidents were considered not applicable (NA) if they were adverse drug reactions where the harm was not avoidable, the incident was miscoded, there was insufficient information to make any judgement of clinical outcome or no assessment of level of harm was reported. In this text, reference to serious harm is reported death or severe harm.

Those incidents identified as causing serious harm were inspected for underlying themes. The full dataset was filtered for occurrence of the words "Accountable Officer" or "AO" and the resulting subset inspected and grouped under the themes identified for incidents associated with death or severe harm. The role of the AO was reviewed in all incidents where death or severe harm occurred.

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TABLE 1: CONTROLLED DRUG INCIDENTS

The number of reported Controlled Drug incidents 2005–11 by stage of the medication process

	Level of harm							
Stage	**Death**	**Severe**	**Moderate**	**Low**	**No harm**	**N/A**	**Incident total**	**%**
Administration supply of a medicine from a clinical area	29	45	1,440	4,887	30,375	15	36,791	51.1
Prescribing	9	16	349	1,102	7,605	5	9,086	12.6
Dispensing and preparation of medicines	4	4	234	700	7752	2	8,696	12.1
Monitoring/follow-up of medicine use	1	2	199	510	4,718	3	5,433	7.5
Supply or use of over-the-counter medicine			9	22	380		411	0.6
Advice	3		10	31	258		302	0.4
Blank*				6	11	4	21	0
Other†	8	7	282	769	10,220	2	11,288	15.7
Total	54	74	2,523	8,027	61,319	31	72,028	100

**Indicating the reporter did not select an NRLS code to indicate the stage of the medication process*

†Previous analysis has shown that the majority of "other" patient safety incidents can be reassigned to the available categories in similar proportions to those reported.

TABLE 2: CONTROLLED DRUG INCIDENTS BY TYPE OF ERROR

The number of reported Controlled Drug incidents 2005–2011 by type of error

Error category	**Incidents**	**%**
Wrong/unclear dose or strength	10,630	14.8
Wrong quantity	7,142	9.9
Omitted medicine/ingredient	6,022	8.4
Wrong drug/medicine	5,442	7.6
Wrong storage	3,657	5.0
Wrong frequency	3,320	4.6
Unknown	2,052	2.8
Wrong formulation	1,720	2.4
Wrong method of preparation/supply	1,634	2.3
Mismatching between patient and medicine	1,539	2.1
Wrong/transposed/omitted medicine label	1,267	1.8
Wrong/omitted/passed expiry date	1,230	1.7
Contra-indication to the use of medicine in relation to drugs or conditions	1,025	1.4
Wrong route	963	1.3
Adverse drug reaction (when used as intended)	704	0.9
Patient allergic to treatment	694	0.9
Wrong/omitted verbal patient directions	87	0.1
Wrong/omitted patient information leaflet	81	0.1
Blank*	19	0.1
Other†	22,890	31.8
Total	72,028	100

**Indicating the reporter did not select an NRLS code to indicate the stage of the medication process*

†Inspection of incidents reports categorised as "other" shows a preponderance for audit and documentation error.

The full dataset was inspected for incidents according to the stage of the medication process and reporting from community pharmacy and general (medical) practice.

Results

There were 72,028 in incidents reported to the NRLS over seven years (Table 1). Of 10,678 incidents of reported harm, there were 54 deaths, 74 severe harms and 10,550 incidents of other harms. Over 50 per cent of the CD incidents involved medicines administration. The category "other" was the second largest category. The level of reported serious harms involving CDs was compared with results of our previous review of all medication incidents (271 deaths, 551 severe harms) over the same time period.[1] The risk of death as a serious harm with CD incidents was found to be significantly greater than with medication incidents generally [odds ratio 1.484, 95 per cent CI 1.015–2.169].

The largest type of error category was "other". Some 22,890 incidents (31.8 per cent) were not allocated to common patient safety categories by the reporters (Table 2). Inspection of these reports indicated that errors in CD documentation and storage were the most frequently reported types of incident in this category. It was not always clear how these types of error had caused harm or had the potential to cause harm to patients. "Wrong or unclear dose" received the next largest number of incident reports 7,142 (14.8 per cent).

Incidents involving overdose of CDs accounted for 89 (69.5 per cent) of the 128 incidents of serious harm (death and severe harm) (Table 3). More detailed analysis of these reports indicates that simple overdose errors were responsible for 41 (46.1 per cent) of these incidents followed by over-infusion involving an infusion device, overdose from a transdermal patch, and "10x" errors (Table 4).

Five CDs (morphine, diamorphine, fentanyl, midazolam and oxycodone) were responsible for 113 incidents (88.4 per cent) leading to serious harm (Table 5).

A detailed review of the 128 incidents associated with serious harm revealed that in 112 reports (87.6 per cent) better compliance with previously issued NPSA guidance[2–5] would have helped prevent these incidents. The review of these same incidents found that 125 (97.7 per cent) of them should have been referred to the AO. A surprising finding was that referral to the AO was only mentioned in one report (0.8 per cent).

Of the full dataset, 301 reports (0.4 per cent) included reference to the "Accountable Officer" or "AO" (Table 6) Only 32 incidents (10.6 per cent) that had been referred to AOs, had caused harm. This indicated that evidence that AOs had been informed that a patient had been harmed from use of a CD in 32 (0.3 per cent) out of a total of 10,678 incidents reported to the NRLS. Most incidents that were referred to AOs concerned breaches of safe custody and documentation procedures, with only 3.0 per cent of incidents involving the safe clinical use of CDs.

Qualitative analysis of the incidents that did include mention of the "AO" is shown in Panel 1. Results from qualitative analysis supports the findings in both Table 1 concerning incidents categorised as "Other" and in Table 6, which indicate the focus of the current role of an AO is on safe custody and documentation, rather than on reports and learning arising from the clinical use of a CD where a patient has died or been harmed.

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TABLE 3: INCIDENTS WITH SERIOUS OUTCOMES AND CAUSE

The number of reported Controlled Drug incidents 2005–2011 with outcomes of serious harm outcomes and cause

	Level of harm		Incident total	%
Cause	**Death**	**Severe**		
Overdose	37	51	89	69.5
Wrong medicine	1	8	9	7.0
Possible never event (opoid naive patient)	3	5	8	6.3
Known adverse drug event	2	2	4	3.2
Self-harm (abuse)	3		3	2.3
Wrong medication name	1	2	3	2.3
Omitted and delayed medication administration	1	2	3	2.3
Medication administration by carer	2		2	1.6
Communication failure	1	1	2	1.6
Precipitated withdrawal	2	2	1.6	
Poor clinical management	1	1	0.7	
Known drug-drug interaction	1		1	0.7
Insufficient information to specify	1		1	0.7
Total	54	74	128	100

TABLE 4: INCIDENTS CAUSED BY OVERDOSE

The number of reported Controlled Drug incidents 2005–2011 caused by overdose by type

	Level of harm		Incident total	%
Breakdown of overdose type	**Death**	**Severe**		
Overdose (simple)	17	24	41	46.1
Overdose infusion device	7	11	19	21.4
Overdose transdermal patch	4	5	9	10.1
Overdose x 10	3	6	9	10.1
Overdose inadvertant	1	4	5	5.6
Overdose calculation	3	1	4	4.5
Overdose label	2		2	2.2
Total	37	51	89	100

TABLE 5: SERIOUS HARM OUTCOMES BY MEDICINE

The number of reported Controlled Drug incidents 2005–2011 with outcomes of serious harm outcomes by medicine

	Level of harm		Incident total	%
Medicine	**Death**	**Severe**		
Morphine	19	27	46	36.0
Diamorphine	13	8	21	16.4
Midazolam	9	12	21	16.4
Fentanyl	5	13	18	14.1
Oxycodone	4	3	7	5.5
Methadone	1	3	4	3.1
Pethidine		3	3	2.4
Remifentanil		2	2	1.7
Phenobarbital		2	2	1.6
Buprenorphine		1	1	0.8
Dexamfetamine	1		1	0.8
Temazepam	1		1	0.8
Blank*	1		1	0.8
Grand total	54	74	128	100

**Indicating the reporter did not select an NRLS code to indicate the stage of the medication process*

From the total of 72,028, only 2,558 reports (3.5 per cent) were from community pharmacy and general medical practice (Table 7). As expected, there was a dominance of dispensing incident reports. This relatively low incident reporting rates from primary care is consistent with our previous review of all medication incidents, indicating a poor safety reporting culture in this healthcare sector.[1]

PANEL 1: QUALITATIVE ANALYSIS

Qualitative analysis of Controlled Drug incidents 2005–11 with outcomes of serious harm which included mention of the Accountable Officer

Management procedure
Cases where written procedures were not followed including storage, transfer between different locations, identification of faulty or leaking stock, identification of out-of-date stock, incorrect dispensing, supply to the wrong patient and, dominantly, supply of the wrong strength.

Audit of Controlled Drugs records
Cases where the audit process revealed discrepancies in stock levels, which often resulted in retrospective identification of incorrect administration of medication. In some cases audit of drug charts and reconciliation with the Controlled Drugs register identified medication safety incidents.

Prescribing documentation
Cases where failure to provide an accurately completed prescription form or CD requisition resulted in delays in treatment.

Clinical
Rare cases where the Accountable Officer was involved in a patient safety incident where clinical decisions involving CDs had put patients at risk of harm.

Other
Cases of deliberate abuse of CDs, excessive quantities of CDs prescribed and dispensed. Lack of available storage facilities, deliberate theft of CDs and trafficking.

Discussion

There is an important limitation to this study and that concerns our assumption that if the AO was not mentioned in the NRLS reports of serious harm arising from the use of CDs, then they were not informed of the incident and did not have the opportunity to review it and take the necessary actions to make local systems safer or suggest national action.

Similarly, we cannot confirm the validity of reports stating AOs were informed because there are no national data available to use for this purpose. In support of these assumptions there have been very few occasions when an AO has contacted the NPSA over the time frame of the study to raise concerns over risks or share learning concerning the safe use of CDs.

This review has several implications for practice:

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TABLE 6: MENTION OF ACCOUNTABLE OFFICER

The number of reported Controlled Drug incidents 2005–11 with outcomes of serious harm which included mention of the Accountable Officer

	Level of harm				Incident	%
Theme	**Death**	**Moderate**	**Low**	**No harm**	**total**	
Management procedure		2	13	139	154	51.2
Audit of CD records		1	7	102	110	36.5
Other			3	13	16	5.3
Prescribing documentation			1	11	12	4.0
Clinical	1		4	4	9	3.0
Total	1	3	28	269	301	100

TABLE 7: REPORTED CONTROLLED DRUG INCIDENTS

Stage of medication safety process	**Community pharmacy**	**GP surgery**	**Incident total**
Preparation of medicines in all locations/ dispensing in a pharmacy	1,747	59	1,806
Prescribing	145	169	314
Administration/supply of a medicine from a clinical area	139	58	197
Other	91	69	160
Monitoring/follow-up of medicine use	29	30	59
Supply or use of over-the-counter medicine	11	1	12
Advice	6	4	10
Total	2,168	390	2,558

- Unsafe use of CDs is the main cause of serious harm from medication incidents reported to the NRLS.
- In our view, better implementation of NPSA guidance could have prevented most of these incidents from harming patients. In particular all practitioners who prescribe, dispense or administer CDs should routinely confirm the intended dose is safe for the patient; for example, any new dose of diamorphine or morphine more than 50 per cent higher than the previous dose should be queried.
- In our opinion prioritising efforts on safe custody and documentation of CDs may distract from ensuring the safe use of these potent medicines.
- Improvements are required to ensure more reporting of and learning from CD incidents in primary care.
- The role of the AO for CDs should prioritise reporting and learning of incidents that have caused serious harm.
- For reasons of improving the focus on the safe clinical use of CDs, transparency and quality improvement, we recommend an annual report is produced by individual AOs that summarises serious harms that have arisen from the use of CDs and the actions that have been taken to make the systems of use safer, to minimise these risks in the future. The report should also include a review of the use of antidotes naloxone, and flumazenil.[9] These reports can be shared with the NRLS for national learning.
- A clinical subgroup to promote safer clinical use of CDs has been established to report to the National Care Quality Commission Accountable Officers for Controlled Drugs Group.

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