The Regulation and Quality Improvement Authority

RQIA Provider Guidance 2022-23

Statutory Notification of Medication Related Incidents

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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1.0 INTRODUCTION

This guidance document has been produced for registered providers and managers of services regulated by the Regulation and Quality Improvement Authority (RQIA) and aims to:

- provide guidance on identifying and reporting medication related incidents to RQIA
- help ensure that registered providers/managers conduct a robust investigation following any medication related incident to identify learning and implement action plans, where necessary, to prevent a recurrence
- improve the quality of information submitted to RQIA, reducing the time spent requesting and resubmitting further information.

It should be noted that this document is not intended to replace the professional judgement of registered providers and managers.

This document should be read in conjunction with RQIA's Statutory Notification of Incidents and Deaths - Guidance for Registered Providers and Managers of Regulated Services (Updated: 25 March 2022) found here:

https://www.rqia.org.uk/getattachment/5b39b861-3c3b-401f-9eda-51e81bd8533e/G_Provider_Statutory_Notifications_Updated_25032022.pdf.aspx

2.0 BACKGROUND

Analysis of the medication related incidents submitted to RQIA between 1 April 2021 and 31 March 2022 highlighted that a significant number resulted in inspectors having to request further information from the registered provider/manager due to:

- insufficient detail contained within the notification concerning what had happened

  and/or

- insufficient detail regarding the actions which had been taken/were planned by the registered provider/manager to prevent a recurrence

76 nursing homes and 90 residential care homes did not report any medication related incidents between 1 April 2021 and 31 March 2022. This suggests that either these services have excellent systems in place which effectively prevent medication related incidents or the auditing systems may not be effective in identifying medication related incidents and/or staff may be unaware that medication related incidents must be reported to RQIA.

Conversely, within this timeframe, a small number of care homes and hospices reported more than 40 medication related incidents. This highlighted that while action plans had been developed as a result of the incident, these did not adequately address the cause(s) of what had occurred so as to drive and sustain improvements; this was particularly the case when systemic deficits in relation to the safe and effective management of medicines were not adequately addressed, for example:

- the stock ordering system was not reviewed and hence doses continued to be omitted due to poor stock control
- doses of weekly medicines continued to be omitted as prompts were not in place
- medicines were administered from both the monitored dosage system and a boxed supply because staff did not remove boxed medicines from the trolley
- issues with syringe drivers were not identified in a timely manner leading to missed doses

In addition, some notifications were non-reportable, for example, the service had identified that staff had not followed their procedure but the event did not need to be reported.

NHS England's national reporting and learning system (NRLS) states that 'low' reporting from an organisation should not be taken as a 'safe' organisation. This may represent under-reporting. A 'high' reporting rate should not be taken as an 'unsafe' organisation. In fact, this may represent a culture of greater openness. It is therefore important that registered providers/managers promote an open culture in which staff are encouraged and enabled to report medicine related incidents in a timely and transparent manner.

NICE Guidance SC1 on managing medicines in care homes states that care home providers "should ensure that a robust process is in place for identifying, reporting, reviewing and learning from medicines errors involving residents". It is therefore important that registered providers/managers ensure that robust and effective governance arrangements are in place to facilitate such reporting, monitoring and reflective practice; this will help to promote the quality of care delivery and service provision.

This guidance document aims to assist services to identify medication related incidents and any trends, implement effective action plans to prevent a recurrence and improve the quality of the information which is submitted to RQIA. The ultimate aim is to drive continuous quality improvement and thereby improve service user safety.

	IH (includes Hospices)	Nursing Homes	Residential Care Homes	Children's Homes	Day Care Setting
Total number services registered with RQIA	**72**	**246**	**231**	**48**	**166**
No of medication related incidents reported	**131**	**744**	**696**	**100**	**16**
No of times follow up information was requested i.e. incomplete information on initial notification form	**16**	**129**	**100**	**11**	**2**

Table 1.0 Medication Related Incidents reported to RQIA (1 April 2021 and 31 March 2022)

3.0 WHAT ARE MEDICATION RELATED INCIDENTS AND WHEN DO THEY OCCUR?

Medication related incidents can result in severe harm, disability and death. They include: medication errors, near misses and adverse drug reactions.

A 'medication error' is any service user safety incident, where there has been an error while: prescribing; preparing; dispensing; administering; monitoring or providing advice on medicines.

A 'near miss' is an event not causing harm but has the potential to cause severe harm, disability and death. Review of 'near misses' by registered providers/managers can be used to help inform reflective practice and identify areas for improvement.

An 'adverse drug reaction' is an unwanted or harmful reaction which occurs after administration of a medicine or medicines. These should be reported through the Medicines Health Products Regulatory Agency (MHRA) yellow card scheme.

Medication related incidents tend to occur when there are weak medication systems or when human factors adversely affect processes.

In contrast, robust medication systems deliver care in a way that minimise things going wrong and maximise things going right. Poor medication systems, processes, and conditions can lead people to make mistakes or can fail to prevent them occurring. Following any medication related incident, registered providers/managers should review their medication systems to determine if changes are necessary to prevent a recurrence.

Examples of human factors that can adversely affect processes include:

- poor communication, distraction
- lack of resources
- stress
- complacency
- lack of team work
- pressure
- lack of awareness
- lack of knowledge
- lack of assertiveness and norms (adopting poor routine practice or routinely failing to follow procedures)

Addressing these factors can help lead to a reduction of medicine related incidents and therefore better outcomes for service users.

4.0 HOW ARE MEDICATION RELATED INCIDENTS IDENTIFIED?

Medication related incidents and trends may not be detected if services do not have an effective auditing system.

Robust and consistent quality assurance audits which focus on all aspects of medicines management are therefore an important tool in assisting with the effective identification and prevention of medication related incidents.

Medication related incidents may sometimes be identified immediately by the person who was involved/another staff member. Such information should be used to help develop and enhance the quality of any quality assurance audit systems which are in place.

A sample medicines management audit tool can be found on the Business Services Organisation (BSO) website, linked here: Community Pharmacy Care Home Support Service (CPCHSS) (hscni.net)

5.0 WHAT SHOULD HAPPEN WHEN A MEDICATION RELATED INCIDENT IS IDENTIFIED?

An up to date policy and procedure for managing medicines related incidents should be available for staff and include details of who to contact during and outside normal office hours. The service user and/or their next of kin/representative should be informed in keeping with agreed arrangements at the time of the incident.

The safety of the service user should be the registered provider's/ manager's primary concern. Where necessary, the prescriber or emergency services should be contacted for guidance.

In order to learn from medication related incidents and implement improved systems registered providers/ managers should:

- encourage staff to report medicines errors, near misses and adverse drug reactions without delay
- provide support for the staff and the service user/next of kin/representative involved
- investigate all medication related incidents, errors, near misses and adverse drug reactions to identify any learning. By examining the events that led to an error or near miss, services can take a learning approach to responding to errors and unintended events. They can look for reasonable system changes to prevent the same problems from happening again.
- review their medication management systems and implement any necessary improvements

- have mechanisms in place to make changes in practice to improve safety
- have mechanisms in place to identify any trends and implement further action plans/systems changes to reduce the likelihood of a recurrence
- have a robust process for sharing learning from incidents with all staff and across the organisation
- record accurate details of medicines-related incidents and report to the appropriate authorities, including RQIA (see Regulations relevant to your service)
- incidents involving the loss or theft of controlled drugs must be reported to the Accountable Officer and Police Service of Northern Ireland. Accountable Officer
- Safeguarding: NICE Guidance SC1 indicates that a safeguarding issue in relation to managing medicines could include: deliberate withholding of a medicine without a valid reason; incorrect use of a medicine for reasons other than the benefit of a resident; deliberate attempt to harm through use of a medicine, and accidental harm caused by incorrect administration or a medication error. If the medication error falls into any of these categories it must therefore be reported to the Safeguarding team within the appropriate Trust.

6.0 WHEN SHOULD A MEDICATION RELATED INCIDENT BE REPORTED TO RQIA?

Any incident involving medicines where there has been an error (which has the potential to affect the health and well-being of the service user) while:

- prescribing
- preparing
- dispensing
- administering
- monitoring
- providing advice on medicines

All notifications should include the following 'essential information':

- any effect the error has had on the service user's health and well-being
- what medicine was administered/omitted in error, and why
- how many incorrect doses were administered/doses were missed
- how the error was identified
- the changes in the medicines systems which have/will be been implemented to reduce the likelihood of a recurrence with relevant timescales clearly outlined
- confirmation that learning from this incident has been shared with all relevant staff
- confirmation that all relevant person(s) and/or statutory bodies have been informed

For any incidents which involve staff provided by a nursing agency please include the name of the nursing agency and confirm that the agency have been informed of the discrepancy. Please also advise what induction processes were followed with the agency staff member prior to the incident occurring and the support provided following the incident. .

Appendix 1 contains examples of notifications reported to RQIA which contained insufficient detail to enable a thorough assessment.

For information on how to submit a notification and timescales please see "Statutory Notification of Incidents and Deaths, Guidance for Registered Providers and Managers of Regulated Services."

https://www.rqia.org.uk/getattachment/5b39b861-3c3b-401f-9eda-51e81bd8533e/G_Provider_Statutory_Notifications_Updated_25032022.pdf.aspx

Prescribing errors/interface issues

Any errors identified in the prescribing of medication for service users, for example:

- by the service user's GP
- on hospital discharge
- any issue with medication which has arisen due to care of service user transferring between services, for example, on admission from another care facility

Registered providers/managers should report all prescribing errors to RQIA, including near misses (the medication was not administered because the error was identified by staff in the service prior to administration).

RQIA should be notified of any error identified in the service user's prescription chart (independent hospitals/hospices), prescription or hospital discharge letter which has or could have led to medicines being administered incorrectly; this also includes incorrect allergy status.

The notification should include details of the name and address of the prescriber (GP) or hospital and ward (hospital discharge). RQIA may pass the details of the incident on to the appropriate Trust/ Strategic Planning and Performance Group (SPPG) for review with the prescriber or facility involved if appropriate.

If the incorrect medicine/medicine dose was administered, the service should review their systems for receiving medicines to ascertain why the error was not identified by staff in the service prior to administration. The system for receiving medicines should be reviewed to reduce the likelihood of a similar event occurring. These details should be included in the notification.

If trends are identified in prescribing errors/interface issues systems should be reviewed further so as to meaningfully address any deficits and prevent recurrence.

In addition, please also provide 'essential information' as outlined above.

Dispensing Errors

Any dispensing errors in prescribed medication dispensed by the community pharmacy or from hospital, for example, incorrect medication, incorrect strength, incorrect dosage directions, out of date medicine.

Registered providers/managers should report all dispensing errors to RQIA, including near misses (i.e. the medication was not administered because the error was identified by staff in the service prior to administration).

The notification should include details of the name and address of the community pharmacy or hospital and ward (hospital discharge). RQIA may pass the details of the incident on to the appropriate Trust/SPPG for review with the pharmacist or facility involved if appropriate.

If the incorrect medicine/medicine dose was administered, the service should review their systems for receiving medicines to ascertain why the error was not identified by staff prior to the administration. The system for receiving medicines should be reviewed to reduce the likelihood of a similar event occurring.

These details should be included in the notification. In addition, please provide 'essential information' as outlined above.

Medicines Record

RQIA should be notified of any error identified in the service user's records which has led to medicines being administered incorrectly. This may include the incorrect allergy status and discrepancies in the controlled drug record book.

Please provide 'essential information' as outlined above.

Keys

This may include the loss or theft of keys used for access to medicine storage areas including controlled drug safes, medicines trolleys and medicine refrigerators.

The notification should include details of when the keys went missing, any potential access to medicines by service users/visitors/unauthorised persons and confirmation that locks have been replaced to prevent unauthorised access. It should also specify if this had an impact on service users receiving their medicines due to lack of access to trolleys/cupboards.

Please provide 'essential information' as outlined above.

Out of Stock Medicines

RQIA should be notified if a prescribed medicine is out of stock and this has resulted in *more than one missed dose.

In addition to the 'essential information' the notification should include details of:

- confirmation that the medicine is now available for administration
- why the medicine was out of stock and for how many days/doses
- the action which had been taken to obtain a supply of the medicine prior to the medicine being out of stock
- the changes made in the stock ordering system to ensure that all service users have a continuous supply of their prescribed medicines
- confirmation that medicines are available for all other service users in the service
- confirmation that the registered provider/manager is made aware of any stock control issues at the daily handover for escalation
- confirmation that learning from this incident has been shared with all relevant staff

* one missed dose of a **critical medicine** or controlled drugs in Schedule 2 and Schedule 3 should be reported to RQIA.

Commonly encountered controlled drugs:
https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation

Wrong Medicine

RQIA should be notified if the wrong medicine was administered to a service user(s).

Please provide 'essential information' as outlined above.

Wrong Service User(s)

RQIA should be notified if a medicine prescribed for one service user was administered to another in error.

In addition to the 'essential information' the notification should include details of any effect the error has had on both service users' health and well-being.

Wrong Dose

RQIA should be notified if the incorrect dose of a prescribed medicine was administered to a service user.

Please provide 'essential information' as outlined above.

Wrong Frequency/Time of Administration

RQIA should be notified if the prescribed medicine was administered at the wrong frequency (for example three times daily instead of twice daily) or was administered at the wrong time (for example a medicine prescribed to be taken at night was administered in the morning).

Please provide 'essential information' as outlined above.

Missed/Delayed Doses

RQIA should be notified if a prescribed medicine was omitted in error or there was a delay in the administration for *more than one dose of a prescribed medicine.

Please provide 'essential information' as outlined above.

* one missed dose of a **critical medicine** or controlled drug in Schedule 2 and Schedule 3 should be reported to RQIA.

Commonly encountered controlled drugs:
https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation

Discrepancy/Loss

RQIA should be notified if a discrepancy is identified whereby the quantity of prescribed medication in stock differs from the quantity which would remain if medicine was administered as prescribed. This is usually identified through the service's audit processes.
In addition to the 'essential information' the notification should include details of:

- the quantity of medicine unaccounted for/missing
- whether/not this led to missed doses for the service user
- any discrepancies in the quantity of controlled drugs should be reported to the Accountable Officer in The Trust

7.0 FURTHER INFORMATION

For further information or advice, please contact a member of the pharmacy team at RQIA, by telephone: 028 9536 1111 or email: info@rqia.org.uk

References

Statutory Notification of Incidents and Deaths, Guidance for Registered Providers and Managers of Regulated Services" Updated: 25 March 2022
https://www.rqia.org.uk/RQIA/files/5b/5b39b861-3c3b-401f-9eda-51e81bd8533e.pdf

Reporting Medication Incidents, Care Quality Commission (CQC) Updated 2 August 2022
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Managing Medicines in Care Homes, National Institute for Health and Care Excellence (NICE)
https://www.nice.org.uk/Guidance/SC1

Dealing with mistakes, National Institute for Health and Care Excellence (NICE)
https://www.nice.org.uk/Guidance/SC1

Managing medicines for adults receiving social care in the community
https://www.nice.org.uk/guidance/ng67

Medication without harm, World Health Organisation, 15 May 2017
https://www.who.int/publications/i/item/WHO-HIS-SDS-2017.6

Institute of Healthcare Improvement (IHI)
https://www.ihi.org/about/Pages/default.aspx

Care Standards for Nursing Homes, Department of Health, Social Services and Public Safety, April 2015
https://www.rqia.org.uk/RQIA/files/7d/7dec5d24-796a-440a-9a60-7deb7112c994.pdf

Residential Care Home, Minimum Standards, Department of Health, Social Services and Public Safety, August 2021
https://www.rqia.org.uk/RQIA/files/ea/ea7c184c-8bb5-41e3-a270-db34fc2fad9a.pdf

Useful web-links

Medicines Health Products Regulatory Agency (MHRA) yellow card scheme
https://www.gov.uk/report-problem-medicine-medical-device

Business Services Organisation (BSO) website.
Community Pharmacy Care Home Support Service (CPCHSS) (hscni.net)

https://www.gov.uk/government/publications/controlled-drugs-list--2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation

Critical medicines
https://hscbusiness.hscni.net/pdf/Critical%20medicines%20Final%20March%202019.pdf

DoH Accountable officer:
Microsoft Word - Accountable Officer contact list - 26 July 2022 (health-ni.gov.uk)

Appendix 1

Examples of notifications received by RQIA which resulted in a request for further information

Part 4 of the RQIA Web portal allows the service to provide information under three headings:

- details of the event
- any action taken following the event
- any action taken to prevent a recurrence

The person completing the web portal notification should ensure that the 'essential information' is detailed clearly; not doing so may lead to further correspondence with the pharmacy team. (See Section 6.0)

Listed below are examples of notifications which did not contain the 'essential information' or action plans to prevent a recurrence were insufficient. It was therefore necessary to request further information from the registered provider/manager.

Example 1

Part 4 Web portal entry received by RQIA:

Resident was administered simvastatin 40mg instead of 20mg because wrong label on box supplied by community pharmacy.

Contacted pharmacy for a new supply

Staff to be more vigilant

Further information requested by pharmacist inspector:
Did the resident suffer any ill effects?
How many incorrect doses were administered?
Is the correct medicine now available?
How was the error identified?
Why did staff not identify the dispensing error prior to administration?
Has the medication system been reviewed to identify any improvements/changes which could have prevented this error?
Has any learning been shared with staff?
What is the name and address of the community pharmacy?
Has this happened before? Is there a trend?

Example 2

Part 4 Web portal entry received by RQIA:

Nurse was assisting a resident who had fallen. Care assistant administered medications to the wrong resident.
Clinical observations taken and commenced hourly; resident remained under close observation. GP OOH contacted and informed. NOK contacted and informed of above. Nurse in charge and manager informed. Encouraged with fluids following incident

Supervised medication practice was carried out by deputy manager.
Nurse competent at time of practice.

Further information requested by pharmacist inspector:
Did the resident suffer any ill effects?
Which medicines were administered in error?
Do care assistants administer medicines in the nursing home?
If not, why did a care assistant administer medicines on this occasion?
Has the medication system been reviewed to identify any improvements/changes which could have prevented this error?
Has any learning been shared with staff?

Example 3

Part 4 Web portal entry received by RQIA:

A BuTec patch was placed on this resident in error.

When the matter was detected it was reported to the manager and the on call GP, and all steps the GP suggested were then followed.

A discussion of errors has taken place with the staff member and increased observation of her practice until the manager is satisfied of her competence.

Further information requested by pharmacist inspector:
Did the resident suffer any ill-effects?
What strength was the BuTec and how long did it remain in situ?
Is the resident prescribed BuTec?
How/why was the BuTec administered to the wrong resident?
How was the error identified?
Do two staff witness the administration of controlled drugs?
Why were staff unable to follow the home's procedure for administering controlled drugs?
Has the medication system been reviewed to identify any improvements/changes which could have prevented this error?
Has the learning been shared with all staff to prevent a recurrence?

Example 4:

Part 4 Web portal entry received by RQIA:

At controlled drug balance check, nurse realised she had administered incorrect dose of temazepam. Four tablets were administered instead of one. Resident was agitated at time of administration.
GP out of hours contacted immediately and advice taken.
Resident admitted to hospital for observation.

Nurse has been advised to be more vigilant when administering medicines. She will complete a reflective practice form.

Further information requested by pharmacist inspector:
Did the resident suffer any ill effects?
Why was the incorrect dose administered?
How was the error identified?
Was the administration of this controlled drug witnessed by a second member of staff?
If not, why did staff not follow the home's procedures?
Are any changes in the home's systems necessary to facilitate the safe administration of medicines?
Has any learning been shared with all staff to prevent a recurrence?

Example 5:

Part 4 Web portal entry received by RQIA:

At pharmacy advice visit it was noted that resident's eye drops were signed as administered but the bottle had not been opened.

GP advised and optician arranged to call to assess eye pressure. No concerns noted in this area.

Review of administration records as all signed as being administered.

Further information requested by pharmacist inspector:
What follow up action taken with staff?
What lessons have been learned?
Have any training needs been identified?

Example 6:

Part 4 Web portal entry received by RQIA:

Resident missed doses of the following medications:
Adcal D3 750mg
Bisoprolol 1.25mg
Atorvastatin 10mg
Lercanidipine 10mg
Folic Acid 5mgs
Edoxaban 30mg
Omeprazole 20mg
Lidocaine patch

Prescription was ordered on 25/07/2022 and staff notified pharmacy on 26/07/2022.
Pharmacy committed to deliver the medication 27/07/2022 failed to do so.
Staff notified GP that medication had not been supplied.

Staff to ensure a continuous supply of all resident's medication.

Further information requested by pharmacist inspector:

Did the resident suffer any ill effects?
How many doses were omitted?
How many days were the medicines out of stock?
Are the medicines now available?
Are staff aware that Edoxaban is a critical medicine?
Has the medication ordering system been reviewed to identify any improvements i.e. will medicines be ordered at least seven days before they run out?
Has this learning and change in practice been shared with staff?