Good Practice Guidance for Care Homes:
Handling and Reporting medication errors, incidents, near misses, concerns or adverse reactions to medicines in Care Homes

Introduction

There are an estimated 237 million 'medication errors' per year in the NHS in England, with 66 million of these potentially clinically significant.
Medication errors can be defined as **Patient Safety Incidents (PSIs)** involving medicines in which there has been an error in the process of:

- ordering,
- prescribing,
- dispensing,
- preparing,
- administering,
- monitoring,
- providing advice about medicines, or
- discrepancies with medication(s) arising/ identified following transfer of care, including that between nursing and residential care,

which could have or did lead to harm.

PSIs involving medicines can be divided into two categories:

- **errors of commission** (something which **has happened which should not have happened**)
  e.g. wrong medicine or wrong dose administered,

- **errors of omission** (something which **has not happened which should have happened**)
  e.g. a dose not administered which should have been, or a failure to monitor, e.g. international normalised ratio (INR) for a resident taking warfarin.

Policies and procedures

All medicines related PSIs including 'near misses' and incidents that do not cause any harm, should be recorded as PSIs.
The care home medicines policy should include a robust process covering the identification, reporting, reviewing, and resolving of medication discrepancies and describing how to deal with medicine-related:

- errors,
- incidents,
- concerns,
- near misses (prevented PSI),
- suspected side effects to medicines,
- how the understanding of, and learning from, medication errors, incidents, concerns and near misses will be shared.

The safety of residents should be the primary concern and care staff should first prioritise any actions that reduce risk of harm from any suspected PSI by following the advice of health care professionals where applicable.

All notifiable incidents should be reported to the Care Quality Commission (CQC).
Generally, the CQC should be notified if any of the following are involved:

- death,
- injury,
- abuse, or allegation of abuse,
- incident reported to or investigated by the police.

Care home medicines-related incident policies should cover:

- when to notify the Care Quality Commission (CQC).
- which medicines-related PSI to report to the local safeguarding authority,
- how to report the incident to the resident, their family and/ or carers,
- how to report to other regulators and agencies, such as the Nursing and Midwifery Council (NMC).

CQC advise that care home providers should:

- maintain an open 'fair blame' policy,
- encourage staff to report medicines-related errors without delay,
- have a robust process for sharing learning from incidents across the organisation,
- have mechanisms in place to make changes to practice to improve safety,
- record accurate details of medicines-related safeguarding incidents.
  Medicines-related safeguarding incidents should be recorded as soon as possible after the incident with the information available for any investigation and reporting required.

A clear process, agreed between healthcare professionals and commissioners should be available for care staff to follow. The process should include who to contact both within normal office hours and out of hours.
Information should be given to residents, their family or carers about reporting medicines-related safety incidents, errors, concerns and near misses. The care home complaints process, local authority and/ or local safeguarding processes and any relevant regulatory processes should be provided as part of this information.

Actions to be taken following identification

Following identification of a PSI involving a medication error, incident, near miss or a medication-related concern the priority is to ensure the resident is safe.
The resident's GP or other healthcare professional should be contacted.

Once satisfied that the resident is safe, consider the following:

- Could the PSI be a safeguarding issue?
  - If YES, report to safeguarding through your usual route.
- Was the PSI a notifiable patient safety incident?
  - If YES, report to the Care Quality Commission (CQC) and Local Authority commissioners.
- Did the PSI result in a death, an injury, abuse, allegation of abuse, or was it reported to or investigated by the police?
  - If YES, report to the Care Quality Commission (CQC) and Local Authority commissioners.
    Check here for the full list of situations where you are required to report to CQC.
- Did the PSI involve a Controlled Drug?
  - If YES, report to the NHS England CD Accountable Officer using the online CD Reporting Tool.

- Complete details of the PSI as soon as possible after the incident following your organisation's policy. Ensure all required and relevant information is clearly documented.
    - A suggested template for care home staff for Reporting and Learning from a medicine-related Patient Safety Incident (Appendix 2) supports recording of appropriate information.
    - This form would normally be retained in the care home, but a copy can be shared with the Medicines Optimisation in Care Homes (MOCH) team to support shared learning across the Frimley Integrated Care System (ICS).

Appendix 3 summarises the steps above in a flow chart.

Duty of Candour

Health and social care professionals must be open and honest with residents in their care when a medication error has occurred and has caused, or had the potential to cause, harm or distress. This means that health and social care professionals must:

- tell the resident (or, where appropriate, their advocate, carer, or family) when something has gone wrong,
- apologise to the resident (or, where appropriate, their advocate, carer, or family),
- offer an appropriate solution or support to put matters right (if possible),
- explain fully to the resident (or, where appropriate, their advocate, carer, or family) the short- and long-term effects of what has happened.
- Inform GP.

Health and social care professionals must be open and honest with:

- residents
- families
- colleagues,
- employers,
- regulator,
- relevant organisations.

They must not stop someone from raising concerns and should encourage learning from a medicines-related error, incident, near miss or concern to improve systems and processes to manage medicines-related risk more effectively.

Adverse Drug Reactions (ADRs)

Each medicine licensed for use in the UK has a Summary of Product Characteristics (SmPC) which gives information about medicines including dose, use, and possible side effects based on research and product knowledge. SmPCs, Patient Information Leaflets (PILs) and other medicines information are stored in the electronic medicines compendium (emc).

Adverse Drug Reactions (ADRs), which may be actual or suspected, are unwanted or harmful reactions which occur after administration of one or more medicines, but **not** due to human error.

Any adverse effects, suspected problems, and incidents which might be associated with administration of a medicine should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.

The Yellow Card reporting scheme is open to everyone to report suspected adverse effects from

- medicines (including herbal and homeopathic medicines),
- vaccines, and
- medical devices

which are available on the UK market.
Safety concerns with e-cigarette products can also be reported using the Yellow Card scheme.
Proactive reporting and monitoring support the safer use of medicines and devices, helping to alongside improving public health.

If care home staff suspect an adverse effect from administration of medicines, they must:

- Report/inform the prescriber as soon as possible.
- Record details in the resident's care plan.
- Report using the Yellow Card.
- Inform the supplying pharmacy (if the resident agrees that this information can be shared).

The MHRA collects and monitors information on suspected safety concerns or incidents involving medicines and medical devices to support the safe and effective use of medicines.

Transfer of care

Medication errors may occur during transfer of care, e.g., discharge from hospital and transfer or between care homes.
If there are discrepancies whereby the medicines listed on the Discharge Letter:

- do not match those the care staff understand the resident to be taking,
- appear to have been:
    - stopped
    - started
    - dose and/ or frequency changed

  without information supporting changes,
- altered, but medicines reconciliation on admission to hospital appears incorrect or has not taken place,
- duplicates other medicines the resident is taking,
- contradicts other information contained in the Discharge Letter,
- does not contain directions/ instructions for use,
- are contained within the Discharge medicines bag but not listed on the Discharge Letter,
- are contained within the Discharge medicines bag but have someone else's name on them,

these need to be resolved in a timely manner for the resident to receive their medicines correctly.

For further information refer to Good Practice Guidance Discharge Prescriptions – queries or concerns.

Completion of Reporting form

Complete your medication error reporting form as soon as possible after the event/ discovery of the event. Refer to Appendix 2 for a suggested template for Care Home staff for Reporting and Learning from a medicine-related Patient Safety Incident (PSI), (a medication error, incident, near miss, or concern).

Do NOT include the resident's identity, or any details which could identify the resident.

Once immediate actions have been taken, the learning section should be completed to:

- Identify what went well and what did not go well,
- help support open discussion and reflection at team meetings,
- support learning to improve systems and processes to manage medicines-related risk more effectively.

Share any learning with the wider team such as the Medicines Optimisation in Care Homes (MOCH) team, so that learning can be shared across the Frimley ICS.

Record keeping

Care home providers must follow the relevant legislation to ensure that appropriate records about medicines are kept secure, for an appropriate period of time, and destroyed securely when appropriate to do so. Processes should comply with the Data Protection Act 2018.

Medication errors, incidents, concerns, and any adverse effects should be recorded in the resident's care plan and clinical record at the GP practice including:

- who identified/ noted the medication error, incident, concern, or adverse effect,
- the date and time of notification.

Comprehensive records should be made detailing all actions taken following identification of the error and any additional input advised.

Any medications which have been stopped should be appropriately disposed of as stated in the care home Medicines Policy (refer to Good Practice Guidance: Disposal of medicines in care homes for further information and support).

An action plan should be agreed and documented, including any changes, support, follow up, monitoring, sign posting, referral, and safety netting.

References

- Care Quality Commission Reporting medicine related incidents
  Reporting medicine related incidents - Care Quality Commission (cqc.org.uk)
- Data Protection Act 2018
  Data Protection Act 2018 (legislation.gov.uk)
- Good Practice Guidance: Medicines Reconciliation
  file (icb.nhs.uk)
- Good Practice Guidance: Structured Medication Review for Care Home Residents
  NHS Frimley - Care Homes (icb.nhs.uk)
- electronic medicines compendium
  Home - electronic medicines compendium (emc)
- NICE Managing medicines in care homes
  Overview | Managing medicines in care homes | Guidance | NICE
- CQC: Reporting medicine related incidents
  Reporting medicine related incidents - Care Quality Commission (cqc.org.uk)
- The Framework for Enhanced Health in Care Homes, Version 2 (march 2020)
  the-framework-for-enhanced-health-in-care-homes-v2-0.pdf (england.nhs.uk)
- NICE NG5: Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes
  Overview | Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes | Guidance | NICE
- Medicines & Healthcare products Regulatory Agency
  Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)
- Nursing and Midwifery Council: Openness and honesty when things go wrong
  Openness and honesty when things go wrong: the professional duty of candour (nmc.org.uk)
- NHS Devon: Caring for Care Homes
  Caring for Care Homes: Resources for Care Homes across Devon - One Devon
- NICE NG56: Multimorbidity: clinical assessment and management
  Overview | Multimorbidity: clinical assessment and management | Guidance | NICE
- NHS England Safety culture: learning from best practice
  NHS England » Safety culture: learning from best practice
- Prevalence and economic burden of medication errors in the NHS in England
  medication-error-report-edited-27032020.pdf - Google Drive
- Specialist Pharmacy Service: Resources to support learning from medication incidents and harms
  Resources to support learning from medication incidents and harms – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- World Health Organisation: Medication Without Harm
  Medication Without Harm (who.int)

Appendix 1 Example of errors involving medicines

Error Type	Examples
Prescribing Errors	• Resident known to be allergic to medication, but the medication was prescribed. • Resident prescribed the wrong medication, dose, route, or rate. • Time critical medicine not administered within appropriate time frame. • Incomplete information e.g. no strength or route specified. • Medication omitted from prescription. • Medication prescribed to the wrong resident. • Transcription errors, this would include errors when hand-writing a MAR chart entry. • Prescribing without considering the resident's clinical condition. • Prescribing without taking into account resident's clinical parameters e.g. weight. • Not prescribing according to up-to-date guidelines.
Dispensing Errors	• Resident known to be allergic to medication, but the medication dispensed. • Resident dispensed the wrong medication or dose or route. • Medication dispensed and issued for the wrong resident. • Medication dispensed is out-of-date medicine. • Medication is labelled incorrectly.
Preparation Errors	• Medication incorrectly prepared. • Crushing and mixing inappropriately with foods or fluids • Medication prepared for administration down a Percutaneous Endoscopic Gastrostomy (PEG) tube incorrectly.

Administration Errors	• Resident known to be allergic to medication, but medication administered.
	• 6 Rs of administration not followed:
	  ○ Right resident.
	  ○ Right medicine.
	  ○ Right route.
	  ○ Right dose.
	  ○ Right time - time critical medicine requires administration within appropriate time frame.
	  ○ Right to refuse.
	• Resident administered an expired medicine.
	• Medication omitted without a clinical rationale (consider if this should be reported as safeguarding).
	• Unauthorised administration e.g. medicines being administered covertly without following correct procedure (consider if this should be reported as safeguarding).
	• Administration of medication recorded incorrectly or not recorded at all (administration box left blank) on Medicines Administration Record (MAR) chart or on e-MAR.
	• Medication deliberately not administered without good reason (consider if this should be reported as safeguarding).

Monitoring Errors	• Monitoring medication effects but not taking action e.g. BP low and on antihypertensive but not raised with healthcare professional. • Adverse effects to medication but not raised with healthcare professional. • Failure to monitor resident who is undertaking self-medication. • Failure to react appropriately to signs of ill health, pain, or requests for help due to being unwell associated with medication administration (consider if this should be reported as safeguarding).
Providing advice about medicines	
Transfer of Care	• New admission from own home to a care home. • New admission from supported living environment to a care home. • Discharge from hospital to a care home. • Transfer of care from one care home to another care home. • Transfer of care from a residential care home to a nursing home.
Other errors	• Poor or inadequate communication. • Poor, inadequate, or incorrect recording/ documentation. • Inappropriate or inadequate disposal of medicines

Appendix 2

Template for Care Home staff for Reporting and Learning from a medicine-related Patient Safety Incident (PSI) *(error/ incident/ near miss/ concern)*

PART 1: REPORTING a MEDICINE-RELATED PSI		
Name and organisation of person completing this form:	**Date form completed:**	
Name & organisation of person identifying error/ incident/ near miss/ concern		
Date medication error/ incident/ near miss/ concern took place:	**Date Incident Identified:**	
Location of Incident:		
Own Home ☐	Residential Care Home ☐	Nursing Home ☐
Learning Disability Home ☐	Supported Living ☐	Out of Hours Centre ☐
GP practice ☐	Community Hospital ☐	Community Pharmacy ☐
Other (please describe) ☐.....……..		
Type of medication error		
Error ☐	Incident ☐	
Near miss ☐	Concern ☐	
Stage of medication process:		
Documentation/ communication ☐	Prescribing ☐	Administration ☐
Dispensing ☐	Monitoring ☐	Advice ☐
Other (please describe) ☐.....		
Name of medication(s) involved:		
Description of medication error / incident/ near miss/ concern. What happened?		
Resident Date of Birth:		**Sex:** Male ☐ Female ☐ Not stated / unknown ☐
Ethnicity of Resident:		
White ☐	Black or Black British ☐	Mixed ☐
Asian or Asian British ☐	Other ☐	Not stated / unknown ☐
What was the actual effect on the resident and/ or service?		
Action taken at the time of the medicines-related event		

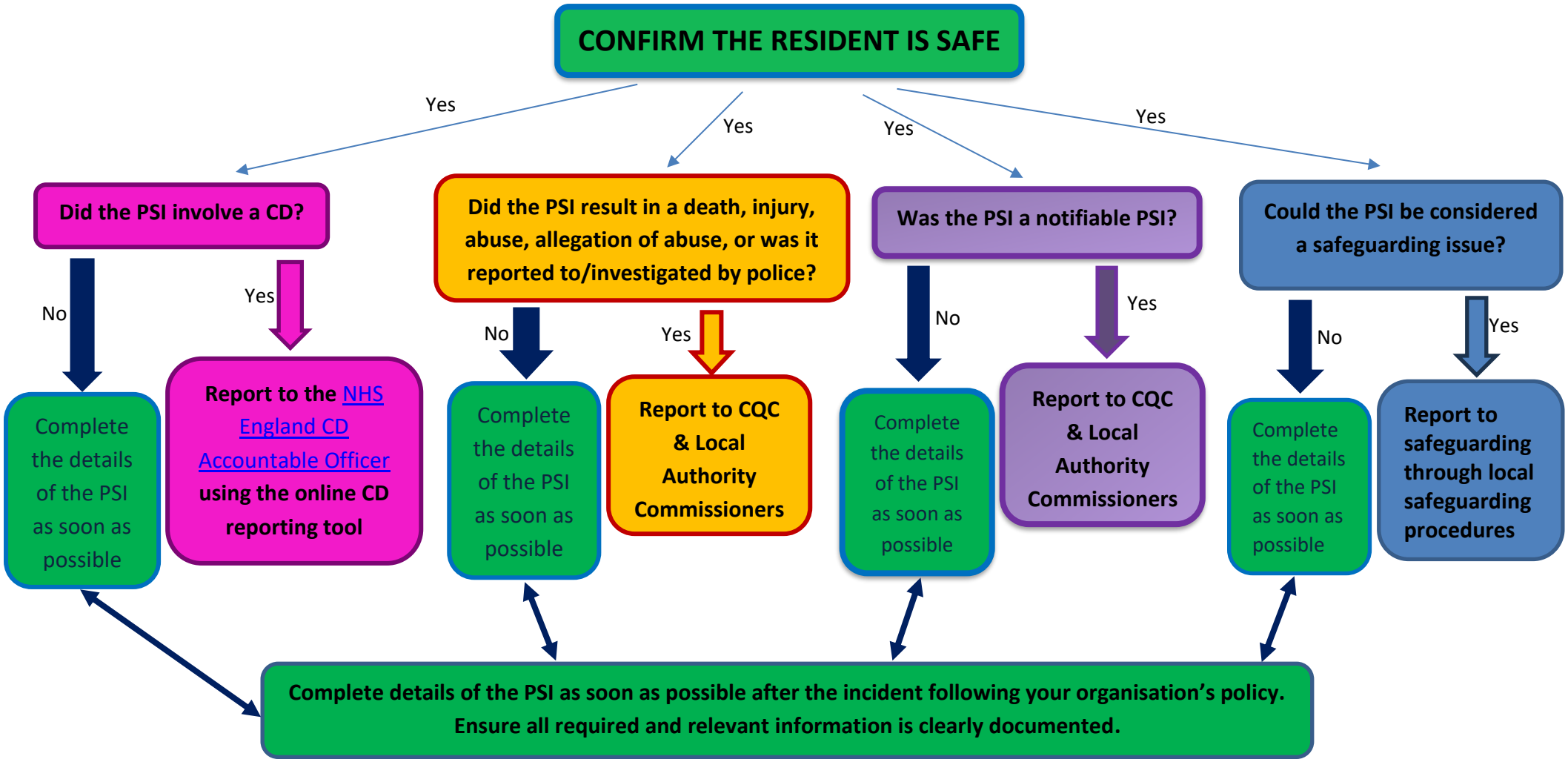
PART 2: LEARNING from a MEDICINE-RELATED PSI	Date of meeting
What could have been done better?	
What went well?	
Key risk issues identified:	
Lessons learned:	
Names and organisations of persons present at meeting:	
Date to review actions:	
Care Home to return completed form to NHS Frimley MOCH Team via email: frimleyicb.moch@nhs.net	

Care Home Medicines Safety Champion contact name and email address:
Please tick here if you consent for any learning from this event to be shared: ☐

For completion by Medicines Optimisation in Care Homes (MOCH) Team only		
What impact or potential impact did the event have on the patient?		
Degree of harm to the patient (severity)	**Potential Harm**	**Actual Harm**
• **None**	☐	☐
• **Low Harm** (patient(s) required extra observation or minor treatment)	☐	☐
• **Moderate Harm** (patient(s) required further treatment, or procedure)	☐	☐
• **Severe Harm** (permanent or long-term harm)	☐	☐
• **Death** (related to the incident)	☐	☐

Appendix 3

Actions to be taken following identification of a medicine-related PSI



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Good Practice Guidance documents are believed to accurately reflect the literature at the time of writing.

Appendix 4

Discharge Team Contact Information

Hospital	Contact Details and Hours of Operation
Berkshire Healthcare Foundation Trust (BHFT)	8am to 6pm (Monday – Friday) 8am to 1pm (Saturday and Sunday) 8am to 4pm (Bank Holidays) 0118 322 8729 0118 322 8680 0118 322 5603 0118 322 8920 HospitalDischargeTeam@berkshire.nhs.uk
Frimley Park (FPH, part of FHFT)	8am to 4pm (7 days a week) 0300 6133649 0300 6136771 Senior Duty Nurse • Medicine 07818 578212 • Surgery 07827 841073 Fph-tr.dischargeteam@nhs.net Fhft.iris@nhs.net
Royal Berkshire Foundation Trust (RBH)	8am to 4pm (Monday – Friday) 07385 406925 hospitaldischargeteam@berkshire.nhs.uk rbb-tr.complex.discharge@nhs.net No discharge-specific contact. Ward. Pharmacy.
Wexham Park (WPH, part of FHFT)	8am to 4pm (7 days a week) 01753 633853 01753 633539 Senior Duty Nurse 07899 876564 Fhft.clinicaldischargeteamwxm@nhs.net