

# Handling Complaints and Incidents in Homecare

**National Homecare Medicines Committee (NHMC) Workbook**

**Ensuring Quality in Homecare**



***National Homecare  
Medicines Committee***

Endorsed by:

## **FOR PERSONAL USE ONLY**

All rights reserved. No part of this publication may be reproduced, in any form or by any means electronic, mechanical, photocopying, recording or otherwise, without the prior permission of the National Homecare Medicines Committee (NHMC).

## **DISCLAIMER**

Although great care has been taken to ensure the accuracy and completeness of the information contained in this publication, the NHMC nor any of its authors, contributors, employees or advisors is able to accept any legal liability for any consequential loss or damage, however caused, arising as a result of any actions taken on the basis of the information contained in this publication.

# CONTENTS

## PART 1

Resources	2
Useful Professional Associations	2
Useful Regulatory Information	3

## PART 2

Introduction	4
Training NHS Pharmacy Managers of Homecare Services on the Handling of Complaints and Incidents	4

## PART 3

3.1 Training Recommendations	5
3.2 Complaint and Incident Management Training	5
3.3 Patient Experience – Information for Patients	7
3.4 Receiving a Complaint and Incident Report	8
3.5 Primary and Secondary Investigator(s)	9
3.6 The Complaints and Incidents Process	12
3.7 Written acknowledgement and responses	16
3.8 Overarching process for reporting and managing complaints and incidents	18
3.9 Investigation and reporting of specific complaint and incident types	20
3.10 Process-based analysis, root cause analysis and risk assessment	23
3.11 Coding	25
3.12 National Reporting and Learning Service (NRLS)	26
3.13 Faulty medicine and faulty medical device incidents	28
3.14 Key Performance Indicators (KPIs)	30
3.15 Post Workshop Tasks	32

## PART 4

Acknowledgements	35
------------------	----

## PART 5

Practice Example Answers	36
--------------------------	----

# PART 1

## Resources

---

The National Homecare Medicines Committee (NHMC) is a sub-group of the National Pharmaceutical Supply Group (NPSG) and the Pharmaceutical Market Support Group (PMSG). NHMC acts as the national focus for developing the strategy for homecare services. NHMC is also involved in improving administration and governance processes of medicine homecare services.

NHMC supports and advises the NHS on matters relating to homecare medicine services, develops homecare contract templates suitable for medicine homecare services and ensures all supporting documentation is available to the NHS.

NHMC is working closely with the national NHS Quality Assurance representative to develop and implement an auditing framework/tool which can be used when auditing homecare providers. The NHMC will work with the homecare trade association, the National Clinical Homecare Association (NCHA), to support the development and administration of an audit programme.

NHMC liaises with homecare providers and the pharmaceutical industry, through their trade organisations, to support and co-ordinate development of the homecare market and best practise.

## Useful Professional Associations

---

NHMC

[www.sps.nhs.uk](http://www.sps.nhs.uk)

Commercial Medicines Unit (CMU)

[www.cmu.nhs.uk](http://www.cmu.nhs.uk)

Email: [Homecare@dh.gsi.gov.uk](mailto:Homecare@dh.gsi.gov.uk)

National Clinical Homecare Association (NCHA)

[www.clinicalhomecare.co.uk](http://www.clinicalhomecare.co.uk)

Association of the British Pharmaceutical Industry (ABPI)

[www.abpi.org.uk](http://www.abpi.org.uk)

Association of British Healthcare Industries (ABHI)

[www.abhi.org.uk](http://www.abhi.org.uk)

Procurement and Distribution Interest Group (PDIG)

[www.pdig.org.uk](http://www.pdig.org.uk)

Medicines and Healthcare products Regulatory Agency

[www.mhra.gov.uk](http://www.mhra.gov.uk)

Specialist Pharmacy Service

[www.sps.nhs.uk](http://www.sps.nhs.uk)

Royal Pharmaceutical Society

[www.rpharms.com](http://www.rpharms.com)

Further professional bodies can be found within the RPS Homecare Standards (Professional Standards for Homecare Services) document.

## Useful Regulatory Information

---

Please refer to Section 3 of Appendix 19: Regulation of Complaint and Incident Reporting in Homecare Services. This section contains lists of:

- Regulatory frameworks
- Standards and codes of practice
- Registration audit and monitoring

# PART 2

## Introduction

---

This workbook and associated training has been designed to assist NHS homecare teams understand and implement the recommendations of RPS Appendix 19 of the Royal Pharmaceutical Society (RPS) Handbook for Homecare Services in England i.e. 'Further guidance on managing complaints and incidents within homecare services'.

The workbook refers to this guidance (RPS Appendix 19) extensively. The guidance can be found at:

<https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services/appendix-19>

It is worth reading Sections 1 (Introduction) and Section 2 (Scope and Purpose) of RPS Appendix 19 prior to commencing this workbook.

## Training NHS Pharmacy Managers of Homecare Services on the Handling of Complaints and Incidents

The National Homecare Medicines Committee (NHMC) teamed up with Pharmacy Management (Pharman) to hold a 'Handling Complaints and Incidents in Homecare' workshop on 28th September 2017, aimed at the pharmacy managers of homecare services. This workbook contains the necessary pre-workshop reading and tasks as well as some post workshop tasks at the end of the workbook which will help attendees complete their training to the appropriate level.

For the purposes of this training, the workbook has equal importance irrespective of attending the event on 28th September 2017 or when accessing appropriate training after that date.

# PART 3

## 3.1 Training Recommendations

---

Section 11 of RPS Appendix 19 specifically mentions three levels of training. The NHMC recommends that each organisation has at least one member of the pharmacy homecare team, usually the pharmacy homecare manager, who is trained and competent to Level 3.

The Chief Pharmacist, (or designated deputy) who is the Responsible Officer for homecare services within each NHS organisation should have sufficient knowledge of RPS Appendix 19 to be able to provide strategic oversight of the management of complaints and incidents within their organisation. Other members of the homecare team can be trained to the appropriate level by the Level 3 trainer.

Level 3 training will be attained by completion of this workbook (including all pre and post workshop tasks) and attendance at a 'Handling Complaints and Incidents in Homecare' workshop e.g. as held on 28th September 2017. A list of suggested post workshop tasks is included at the end of this workbook.

If you are accessing this workbook after the event then your regional homecare lead will be able to assist you in accessing any necessary associated training, which will help you gain the necessary competencies for the level of training required. If you do not know who your regional homecare lead is, please follow this link to the Specialist Pharmacy Service (SPS) website: [www.sps.nhs.uk](http://www.sps.nhs.uk)

If you require any further information please contact the current chair of NHMC for assistance, also available via the above link.

Pre-workshop tasks and completion of the workbook will provide the necessary competencies for NHS staff to be trained to Level 2 in the handling of complaints and incidents in homecare.

## 3.2 Complaint and Incident Management Training

---

The guidance recognises that NHS staff have regulatory responsibility to have effective processes in place to manage complaints and incidents. Training all homecare staff on how to respond to a complaint or incident is integral to the effectiveness of these processes.

Please refer to Section 11 of RPS Appendix 19, which designates 3 levels of training as follows:

- *Level 1:* all involved in the provision of homecare services
- *Level 2:* members of the complaints and incidents team
- *Level 3:* lead and specialist investigators e.g. pharmacy homecare team leaders and managers.

Please read Section 11 of RPS Appendix 19 before continuing into the main part of this workbook



iStock.com/iampartacus9

**Think about your Pharmacy Team and any other key homecare stakeholders in your organisation. Complete the table below to record the appropriate training level for each job role.**

Job Role	Homecare Complaints and Incidents Training Level Required



### 3.3 Patient Experience – Information for Patients

---

Read Section 7 of RPS Appendix 19.

The guidance states the following:

*The patient is at the heart of the complaints and incidents process. Each element of the process is focused toward ensuring patients, and/or their carers, are informed, empowered and encouraged to report any issues. The process also promotes and supports continual collaborative learning, and improvement of the service for the benefit of future patients.*

Every patient receiving medicines via a homecare service should receive a Patient Information Leaflet and a copy of the Homecare Patient Charter. In addition to this, patients should also receive a ‘welcome pack’ from the homecare provider



**Using the check list of information that should be provided to patients about complaints and incidents found in Section 7 of RPS Appendix 19, identify any gaps where required information is not currently provided. In your organisation, information may be provided to patients in organisation patient information leaflets as well as in any welcome packs from the homecare provider. Record the findings of your gap analysis and an action plan to fill any identified gaps in the table below.**

Patient information gap identified	Action Plan

## 3.4 Receiving a Complaint and Incident Report

---

The recipient of a complaint/incident report should first ensure that appropriate immediate action is taken to make the patient safe. Immediate corrective and preventative actions must be taken with the aim of resolving issues without the need for escalation as a formal complaint.

Any organisation receiving a homecare complaint/incident should capture the same information to allow effective and efficient processing. Please refer to Section 8.1 and 8.2 of RPS Appendix 19 for further details. For most homecare complaints and incidents the homecare provider will be the first point of contact for patients. Unless formally agreed otherwise the receiving organisation is responsible for managing and responding to the complaint/incident.

### Practice Example 1

Please note that this practice example is fictitious and bears no resemblance to any actual complaint or incident reported during the provision of homecare services.

Mr X is a vulnerable adult, who has difficulty self-administering his injectable medicine (Medicine A) and has limited support from a carer. The carer notices that the patient has a box of his usual Medicine A but also another different medicine (Medicine B) in his refrigerator. The label shows both items have been dispensed by the same homecare provider but neither Mr X nor the carer is aware of a second medicine being prescribed or any recent medication change. The carer contacts the homecare provider.

The homecare provider informs the carer that there is a valid prescription for both medicines at the homecare Provider. Mr X, who is present with the carer, insists he has not been prescribed a new medicine and confirms that the carer should manage the resolution of this issue on his behalf. The homecare provider asks the carer if they have contacted the clinical team and the carer advises that they have not but shall do now.

As the patient has been identified as a vulnerable adult the homecare provider notifies the clinical team of the potential patient safety incident. The clinical nurse specialist reviews the patient notes and reports that the patient's medication has not been changed and has no record of a prescription for Medicine B.

PE1.1 - What immediate action is necessary to make the patient safe?

## 3.5 Primary and Secondary Investigator(s)

---

The organisation that first receives the notification of the complaint or incident from the complainant/reporter is referred to as the Primary Investigator. Any other organisation(s) which the Primary Investigator identifies need to be involved to complete a full and appropriate investigation will be the designated as Secondary Investigator(s).

### Practice Example 2

Think about the example of Mr X:

PE2.1 - Which organisation is the primary investigator at this stage by default?

PE2.2 - Which organisation is the secondary investigator at this stage?

Primary Investigator status can be transferred by formal, mutual agreement if an organisation different from that which first receives the complaint/incident would be best placed to undertake a full and appropriate investigation. For example, the Clinical Referring Centre is the recipient of the report but if it is more appropriate for another party (homecare provider) to handle the investigation, then the role of primary investigator can pass to the homecare provider if the homecare provider agrees to accept the status of primary investigator. The complainant/reporter must be informed of any transfer of primary investigator status as this means they will receive a response to their complaint from a different organisation from the one they first contacted. This means that if a homecare provider fails to deliver a medicine and the patient makes a formal complaint to their Clinical Referring Centre, who will be the default primary investigator. At a later stage the Clinical Referring Centre may request that the homecare provider investigate take over as primary investigator.

### Practice Example 3

PE3.1 - Should the primary investigator be changed from the default and if so explain why and describe the process that should be followed?

PE3.2 - How should the clinical team record this incident on the organisation's reporting system if they take on primary investigator status?

**Practice Example 4**

As part of its investigation, the Clinical Referring Centre requests a copy of the prescription for Medicine B from the Homecare Provider. The Clinical Referring Centre confirms that the prescription for Medicine B issued to the homecare provider is valid but identifies that the prescription for Medicine B was intended for a different patient with the same name (Mr XX).

PE4.1 - Are there any further corrective actions that need to be taken in light of the new information?

Please refer to Section 5 of RPS Appendix 19 for further details. The MHRA and EMA also provide detailed guidance on complaint handling.



***Think of an example complaint or incident within your own area of practice which was reported to the organisation.***

***Which organisation is the default primary investigator?***

***Think of examples within your own area of practice where a complaint or incident was reported by one party which required a change of primary investigator. Try to think of one example requiring a change from the homecare provider to your organisation and the other way around.***

***Was this change communicated to the patient? If so, how was this communicated to the patient?***

## 3.6 The Complaints and Incidents Process

Now we will focus on Section 8.3 and Section 8.6 of RPS Appendix 19 but it is important to have an understanding of the whole of Section 8 of RPS Appendix 19.



**TASK**

**Read Section 8 of RPS Appendix 19.**

In many cases patients will not require a written response to their complaint or incident if it is resolved quickly and efficiently. Every endeavour should be made to resolve a complaint to the satisfaction of the complainant informally as a 'concern', although patients/carers should not be deterred from making a formal complaint or requesting a written response.

Note: Duty of Candour incidents require formal, written notification to the patient whether or not requested. Duty of Candour incidents are explored in more detail in Section 9.1 of RPS Appendix 19 and in the National Reporting and Learning Service (NRLS) section of this workbook.

Where a complainant/reporter of an incident requests a written response, they should receive an acknowledgement within three business days and a full response within 30 business days unless they are notified otherwise on a case by case basis.

If the complaint or incident can be investigated and the final response sent within three business days then a separate acknowledgment is not required.

Table 1 below is an extract from Section 4.4 of RPS Appendix 19, which you should refer to for full details of the timelines for investigation and responding to complaints and incidents.

**Table 1: Extract from 'Summary of complaint and incident timelines'**

Type of incident or complaint	Action Required	Timescale
Complaints and incidents (no written response requested)	Simple investigation and corrective/preventative actions	Usually by next business day
Complaints and incidents (written response requested)	Written acknowledgement	Within 3 business days of the complaint raised
	Final written response to the complainant (copy to clinical referring centre)	Within 30 business days (unless agreed otherwise by the complainant and the primary investigator)

Type of incident or complaint	Action Required	Timescale
Appeals against a written response	Written acknowledgement	Within 3 business days of the complaint raised
	Final written response to the complainant (copy to clinical referring centre)	Within 30 business days (unless agreed otherwise by the complainant and the primary investigator)
Patient Safety Incident Duty of Candour	Inform the patient and/or carer	As soon as reasonably practicable
Safeguarding referrals	Followed up by the provider safeguarding lead	Within 24 hours or the next business day
Information Governance Serious Incidents Requiring Investigation (IG SIRI)	Initial report, updates and closure	Initial report within 24 hours and updated with full details within 5 days of an incident becoming known. Closure expected within 90 days.

## Practice Example 5

Despite being given information via the carer as previously requested, Mr X contacts the homecare provider directly to complain as he is very unhappy that he has received medication not intended for him. Mr X requests a written response.

PE5.1 - What action should the homecare provider take?

PE5.2 - Which organisation is responsible for sending the formal acknowledgement and final response? What are the timelines for these?



**Check that the timelines in your organisation's Complaints Policy align with the timelines specified in Section 4.4 of RPS Appendix 19?**

**If not, identify what elements of your organisation's policy may require change or provide a justification for any deviation.**



**Find your organisation's template letter for the acknowledgement of complaints and incidents and compare the contents of the template with the suggested list of contents of the letter and with the sample template as detailed in Section 8.3 of RPS Appendix 19.**

**If the organisation receives a complaint/incident in the first instance and sends an acknowledgement to the complainant, but then the homecare provider takes over responsible as primary investigator for the incident, describe how you would communicate the change of responsibility to the patient.**

**Note any deviations from this list and template letter including what changes may be required to the organisation's template.**



***Identify the appropriate contact in the organisation to facilitate the required changes identified above.***

***How will you follow this up to ensure compliance and under what timescale?***

***Note the process and record the date of completion of this task.***

***Who in the organisation is responsible for sending acknowledgements?***

## 3.7 Written acknowledgement and responses

---

Please make sure that you have read Section 8.6 of RPS Appendix 19.

We have already seen that complainants/reporters should receive an acknowledgement of their complaint/incident within three business days of the report. For complaints and incidents that are straightforward, the acknowledgement and the written response can be one and the same letter. Where more complex or detailed investigation is needed then patients should receive an acknowledgement followed by a more detailed response. In all cases the written response must include a number of elements.



***Find your organisation's template letter for formal response to complaints and incidents and compare the contents of the template with the suggested list of contents of the letter and with the sample template as detailed in Section 8.6 of RPS Appendix 19.***

***Note any deviations from this list and template letter including what changes may be required to the organisation's template.***

***Identify the appropriate contact in the organisation to facilitate the required changes identified above.***

***How will you follow this up to ensure compliance and under what timescale?***

***Note the process and record the date of completion of this task.***

***Who in the organisation is responsible for approving the response letters?***

***Who approves and signs the letters?***

## 3.8 Overarching process for reporting and managing complaints and incidents

Complaints and incidents can be classified into different incident types. The guidance details five key incident types and highlights that incidents may meet the definition of more than one incident type. Please refer to Section 4 of RPS Appendix 19 for further details and then to Section 6 of RPS Appendix 19 for further guidance around the use of the terms 'serious incidents' and 'notifiable incidents'.

### Practice Example 6

Prior to the uplift of Medicine B taking place, the carer discovers that Mr X has self-injected with Medicine B instead of Medicine A. Mr X informs the carer that he tried to self-administer Medicine A but that he was unable to activate the device and so he used Medicine B instead. Mr X feels well but the carer immediately telephones the clinical team to inform them and to seek advice. The clinical team advises that there should be no risk of harm from the single dose of Medicine B Mr X has taken and that Mr X should take his usual dose of Medicine A.

PE6.1 - Classify the events in these practice examples into the different incident types identified in the section above and complete the table below. You will see that as the investigation progresses and more information becomes available the categories that the incident falls into may need to be amended.

You may wish to complete the table with your final incident categorisation on completion of this workbook. A similar table can be found at the end of this workbook for that purpose.

Practice Example	Incident Category(s)	Reasoning
Practice Example 1		
Practice Example 4		
Practice Example 6		
What if Mr X had not made the complaint in Practice Example 4 but in Practice Example 6 had required admission to hospital following taking Medicine B?		



*Please refer to Section 4.1 of RPS Appendix 19 and list the key types of incidents.*

*Think of some examples of incidents from your own practice that can be categorised into each of the complaint/incident types. (Sometimes it is not easy to think of an incident that falls into just one category.)*

## 3.9 Investigation and reporting of specific complaint and incident types

---

When a report of an incident or complaint is received by the organisation, it may be necessary to inform certain specialists within the organisation. Please refer to Section 9 of RPS Appendix 19 for further details.



***Who is your organisation's Responsible Officer for Homecare?***

***Who is your organisation's Pharmacy Clinical Governance Lead?***

***Who sits on your Pharmacy Clinical Governance Group?***

***Who is your organisation's Device Safety Officer DSO?***

***Who is your organisation's Information Governance (IG) Lead?***

**Who is your organisation's Caldicott Guardian?**

**Who is your organisation's Safeguarding Lead for adults?**

**Who is your organisation's Safeguarding Lead for paediatrics?**

**Who is your organisation's Risk Management Lead?**

## Practice Example 7

Think about the example of Mr X:

PE7.1 – Which individuals would need to be involved in the investigation and reporting of this incident at the Clinical Referring Centre?

Where required, regional support may be available from your regional homecare specialist.



***Who is your Regional Homecare Specialist?***

Often, your regional homecare specialist will be able to provide support and assistance.



## 3.10 Process-based analysis, root cause analysis and risk assessment

---

Please refer to Section 10 of RPS Appendix 19. The guidance states that all complaints, incidents and non-conformances should be subject to appropriate root cause analysis (RCA).

Further details can be found in Sections 10.1 and 10.2 of RPS Appendix 19 and further guidance is available from the NRLS using the link in the RPS Appendix 19. The organisation's Level 3 homecare specialist should be competent to identify the stage of the homecare process which initiated the cascade of actions which led to the incident and the contributory factors. Pharmacy homecare teams will not usually be solely responsible for undertaking a full detailed root cause analysis as your organisation will have specialists trained in this area to help and guide you if need further assistance.

In the NHS, following an incident and implementation of corrective actions identified as a result of that incident, if you consider that risk remains within the homecare service it is advisable to report this risk to the Responsible Officer for homecare (usually the Chief Pharmacist). In all organisations this should include consideration for inclusion in the Organisation Risk Register. Please refer to Section 10.3 of RPS Appendix 19 for further details.

### Practice Example 8

Think about the example of Mr X above:

PE8.1 – In your own words, complete the table below to identify at which stage(s) of the process errors occurred that were the root cause of, or contributed to, the incident.

Refer to Section 10 of RPS Appendix 19: Further Guidance on Managing Complaints and Incidents in Homecare to help you.

Process step	Error description	Root cause or contributory factor

PE8.2 - Considering this incident complete the table below to identify the risks related to these errors, the preventative actions that should be taken to mitigate these risks?

Error description	Risk	Preventative action	Residual risk

## 3.11 Coding

---

To facilitate learning within and between organisations, it is important to use standard terminology so trends can be identified. The master code list is intended to support this process.

Please refer to Section 13 of RPS Appendix 19 for further details and use the link in the RPS Appendix 19 to locate the master code list. The master code list can also be located as Appendix 22 to the RPS Handbook for Homecare Services in England.

Datix and Ulysses are two of the most commonly used incident reporting systems in the NHS. Collaboration between the pharmacy homecare team and the reporting system lead will help ensure that coding is consistent with master code list and therefore the NRLS reporting system (for further information, see below). Using the same language and the same codes will improve the clarity of reporting and support analysis of trends and improve learning.

Typically, NHS organisation reporting systems can be configured to fit the NRLS codes. RPS Appendix 19 recognises the need to be able to distinguish between reports that are related to homecare services and those that occur elsewhere within a referring centre.



**Which incident reporting system does your organisation use?**

**Who is the organisation's lead for the IT complaint and incident reporting system?**

**Link up with them and ask them to review the coding to ensure that the system codes match the master code list as described in the link in the guidance. You may wish to signpost them to the whole of RPS Appendix 19.**

**Think of an example of a simple incident (take one of your previous examples or all of them) and code it.**

## 3.12 National Reporting and Learning Service (NRLS)

---

Please refer to Section 9.1 of RPS Appendix 19 for further details.

It is essential that all reports of complaints and incidents that occur within homecare services are reported on the organisation's reporting system; this is particularly true for patient safety incidents. It is also important that these incidents can be identified by the organisation as having occurred within the homecare service.

All patient safety incidents occurring in the NHS are further reported externally to the National Reporting and Learning Services (NRLS) provided that they are appropriately recorded. The current NRLS guidance recommends that the keyword 'homecare' is included in the incident description as there is no specific 'homecare' setting code.

Some organisation reporting systems can also be configured to 'flag' homecare incidents to ensure that these are escalated to the NRLS routinely.

Note: at the time of writing, work is ongoing to implement the successor to the NRLS system which will be called Development of the Patient Safety Incident Management system (DPIMS).



***Who is your Pharmacy contact within the organisation's Complaints and Incidents reporting team?***

***Do you regularly report homecare incidents on your organisation's incident reporting system?***

***Is your organisation's incident reporting system configured to aid the identification of homecare incidents as having occurred during the provision of homecare services?***

**Is your reporting system configured to separate the following categories?**

- *complaints with local resolution*
- *formal complaints*
- *incidents*

**Can secondary investigator status or transfer of primary investigator status to another organisation be recorded?**

**Does your Pharmacy Clinical Governance Group or Medicines Safety Group or equivalent identify and review all homecare incidents?**

**Are all homecare patient safety incidents reported to NRLS?**

**If not, how can you ensure that Pharmacy is involved in reviewing all homecare related incidents? (For example, you can suggest that the homecare lead is involved into the section of the meeting that discusses the homecare incidents.)**

### 3.13 Faulty medicine and faulty medical device incidents

---

Please refer to Section 9.4 of RPS Appendix 19 for further details. In particular refer to the process flow (Figure 5) in Section 9.4.1 of RPS Appendix 19.

The guidance states that any clinically significant faults must also be classified as patient safety incidents and therefore reported to the clinical team at the clinical referring centre.

Clinical Referring Centres routinely report Faulty Medicine and device incidents to the NHS AIC database on a monthly basis via their Regional QA contact with the escalation of individual serious faults direct to the MHRA via the Yellow Card Scheme. Where homecare providers report directly to the NHS AIC database, there is no need for the Clinical Referring Centres to duplicate reporting and where duplicate reporting is possible other report references should be included so duplicates can be easily identified.



**Who is your NHS Regional Quality Assurance (QA) contact?**

### Practice Example 9

Think about the example of Mr X in Practice Example 6:

PE9.1 – What immediate action should be taken based on the information regarding Mr X being unable to activate the Medicine A device?

PE9.2 - Where should this be reported?



*Do you have policies and procedures in place to enable pharmacy staff, medical staff, nurses and other AHP and patients to report faulty products to your organisation?*

*Who is responsible in your organisation for reporting faulty products to suppliers and the MHRA?*

*Who is responsible in your organisation for collating trend reports?*

## 3.14 Key Performance Indicators (KPIs)

---

The new governance KPIs have been developed for use in addition to the existing operational KPIs. For the avoidance of doubt the same reporting processes and timelines currently used for the operational KPIs will apply and the updated template includes both dataset. Please refer to Section 12 of RPS Appendix 19 and use the links provided for the national templates to compare the reports that you receive against the national template.

All organisation staff involved in the provision of homecare services, including clinical specialists, should have access to the key performance indicator (KPI) data for services relevant to them and their patients. All pharmacy homecare team leaders and managers should have access to the KPI data for services within the organisation.

Where available it is strongly recommended that regional homecare leads are granted access by a local NHS organisation to their homecare KPI data to allow oversight for appropriate support to be provided. With appropriate permission from local NHS organisations, homecare KPI data may be captured centrally by the regional homecare lead and disseminated locally.

All homecare providers are expected to deliver the standard KPIs for all homecare services.

All pharmacy homecare leads should have an understanding of the KPIs, should be able to interpret them and identify trends and any appropriate follow up actions that are required. Further support may be available from your regional homecare specialist.

### Practice Example 10

Think about the example of Mr X

PE10.1 – Assuming that the required acknowledgement and formal response is provided within the specified timelines and the complaint/incident is raised and closed within the same reporting period. Which KPI dataset(s) should this example be captured under?





**What homecare services does your organisation offer to patients and from which homecare providers?**

**List any homecare services for which you do not currently receive a monthly KPI report. These should be requested from the relevant homecare provider representative.**

Homecare Provider	Therapy Area/Service Type	Date KPIs requested

Congratulations, you have now attended the Handling Complaints and Incidents in Homecare Workshop event and have completed this workbook up to this point. Now is the time to put your learning into practice with the final tasks that follow.

## 3.15 Post Workshop Tasks

---

Choose an example, from your own experience, of an incident which included patient safety implications. Follow through the entire complaint and incident process for the example. The questions below are there to support you on the root cause analysis.

What is the most likely root cause of each incident?

Start by asking yourself at which stage of homecare process did the incident 'cascade' start?

Which root cause category code would this fall under?

What were the contributory factors e.g. internal checks which should have, but did not, stop the incident occurring?

What is the risk of a similar incident happening again and if it did, could the harmful consequences be minimised?

What actions could you take to prevent recurrence or minimise the consequences of a similar incident?

Note: two layers of robust checking are usually optimum for safety e.g. prescriber plus one clinical check of prescriptions. Adding more layers of checking rarely improves safety as each layer of check is likely to be less robust and added layers will decrease efficiency.



***In addition to complaints and incidents handling training or equivalent, what other training within your organisation should you attend? List the training/courses:***

<b>Course/Training</b>	<b>Date completed</b>	<b>Evidence of completion</b>
Complaints and Incidents workbook		
Attendance at a Complaints and Incidents training workshop		
Competency assessment <sup>1</sup>		
Investigating Officer training <sup>2</sup>		
Complaint Handling <sup>2</sup>		
Incident Handling <sup>2</sup>		
Report writing training <sup>2</sup>		
Complaint and Incident Reporting System Training <sup>2</sup>		

1 Being developed by NHMC.

2 These are examples of courses that should be available in your organisation; however, each organisation may have different titles for these.

***If you are a pharmacy homecare manager please ensure that you have completed the training needs analysis for your team.***

***Describe how you will ensure that the members of your team will be trained to the appropriate level.***

*Is there any further training required which is offered either by your own organisation or an external organisation that is accessible?*

# PART 4

## Acknowledgements

---

Editorial Team:

- Joe Bassett
- Jackie Eastwood
- Susan Gibert
- Carol McCall
- Liz Payne

# PART 5

## Practice Example Answers

---

PE1.1 - What immediate action is necessary to make the patient safe?

*Homecare provider should agree with the clinical team who is to advise the carer to move medicine B to a secure location where it is inaccessible to Mr X. The homecare provider should also contact the carer to arrange uplift of Medicine B and ask if they would like to be informed of the outcome of the investigation.*

PE2.1 - Which organisation is the primary investigator at this stage by default?

*The homecare provider is the primary investigator as they were original recipient of the potential incident report.*

PE2.2 - Which organisation is the secondary investigator at this stage?

*The Clinical Referring Centre is a secondary investigator with the clinical team acting as lead contact at this stage as the homecare provider (Primary investigator) has approached the Clinical Referring Centre to input into the investigation of the incident report.*

PE3.1 - Should the primary investigator be changed from the default and if so explain why and describe the process that should be followed?

*Yes, when the homecare provider has confirmed they have a valid prescription for Medicine B they should request that the Clinical Referring Centre takes over primary investigator status. The Clinical Referring Centre should accept primary investigator status. The homecare provider should notify the carer that the Clinical Referring Centre is continuing the investigation and that, if requested, they should expect further communication from the Clinical Referring Centre. In this example the carer is contacted rather than the patient as they are the original reporter of the incident and additionally as the patient is a vulnerable adult.*

PE3.2 - How should the clinical team record this incident on the organisation's reporting system if they take on primary investigator status?

*Where the clinical referring centre takes on primary investigator status it should record the incident on the clinical referring centre's incident management reporting system. Whilst local systems may vary in their design, the information fields detailed in section 8.2 of the RPS Handbook for Homecare Services RPS Appendix 19 should be recorded.*

PE4.1 - Are there any further corrective actions that need to be taken in light of the new information?

*Yes – The Clinical Referring Centre should check whether there has been any impact on Mr XX's treatment.*

PE5.1 - What action should the homecare provider take?

*The homecare provider should provide an apology and explain that, as previously discussed, the Clinical Referring Centre is already investigating following report of the incident from Mr. X's carer and therefore the homecare provider will notify the Clinical Referring Centre that the patient would like a written response to both Mr X and his carer following conclusion of this investigation. The homecare provider should advise the patient that formal acknowledgement of the complaint should be received from the Clinical Referring Centre within the next 3 business days. The homecare provider should confirm Mr X is satisfied with this.*

PE5.2 - Which organisation is responsible for sending the formal acknowledgement and final response? What are the timelines for the these?

*The Clinical Referring Centre is responsible for sending the formal acknowledgement within 3 business days from the original complaint to the homecare provider and final response within 30 business days unless Mr X and his carer are informed of a need for an extended investigation and advised of the alternative timeline.*

PE6.1 - Classify the events in these practice examples into the different incident types identified in the section above and complete the table below. You will see that as the investigation progresses and more information becomes available the categories that the incident falls into may need to be amended.

You may wish to complete the table with your final incident categorisation on completion of this workbook. A similar table can be found at the end of this workbook for that purpose.

Practice Example	Incident Category(s)	Reasoning
Practice Example 1	<i>Patient safety incident Safeguarding</i>	<i>Potential harm if Mr X had taken Medicine B. Patient is a vulnerable adult.</i>
Practice Example 5	<i>Formal complaint</i>	<i>The Mr X has requested written response to his complaint.</i>
Practice Example 6	<i>Patient safety incident  Faulty product</i>	<i>Mr X has taken a prescription medicine which he was prescribed in error.  Mr X has identified that he was unable to activate the Medicine A device.</i>
What if Mr X had not made the complaint in Practice Example 5 but in Practice Example 6 had required admission to hospital following taking Medicine B?	<i>Duty of Candour</i>	<i>Mr X's condition following taking Medicine B incorrectly prescribed to him warranted admission to hospital. Under Duty of Candour the Clinical Referring Centre would be required to provide Mr X a written report of the incident investigation even where no complaint was raised.</i>

PE7.1 – Which individuals would need to be involved in the investigation and reporting of this incident at the Clinical Referring Centre?

PE8.1 - Complete the table below to identify at which stage(s) of the process errors occurred that were the root cause of, or contributed to, the incident.

<b>Process step</b>	<b>Error description</b>	<b>Root cause or contributory factor</b>
<i>Prescribing</i>	<i>Incorrect patient selected in clinical referring centre ePrescribing system due to similar patient name.</i>	<i>Root cause</i>
<i>Dispensing</i>	<i>Clinical check by the clinical referring centre failed to identify Medicine B was not intended for Mr X, specifically absence of previous history or 'new item' annotation on prescription</i>	<i>Contributory factor</i>
<i>Dispensing</i>	<i>Prescription check by the homecare provider failed to identify Medicine B was not intended for Mr X, specifically absence of previous history or 'new item' annotation on prescription</i>	<i>Contributory factor</i>



PE8.2 - Considering this incident complete the table below to identify the risks related to these errors, the preventative actions that should be taken to mitigate these risks?

<b>Error description</b>	<b>Risk</b>	<b>Preventative action</b>	<b>Residual risk</b>
<i>Incorrect patient selected in clinical referring centre ePrescribing system due to similar patient name.</i>	<i>Prescription generated for incorrect patient</i>	<i>NHS number established as standard practice to load patient file</i>	<i>Staff not following established procedure leaves residual risk of incorrect prescription generation</i>
<i>Clinical check by the clinical referring centre failed to identify Medicine B was not intended for Mr X, specifically absence of previous history or 'new item' annotation on prescription</i>	<i>Prescription not intended for the patient not intercepted</i>	<i>Introduce prescriber check in the absence of previous history of medicine use and 'new item' annotation on prescription.</i>	<i>Staff not following established procedure leaves residual risk of failure to intercept an incorrectly prescribed item.</i>
<i>Prescription check by the homecare provider failed to identify Medicine B was not intended for Mr X, specifically absence of previous history or 'new item' annotation on prescription</i>	<i>Prescription not intended for the patient not intercepted</i>	<i>Introduce prescriber check in the absence of previous history of medicine use and 'new item' annotation on prescription.</i>	<i>Staff not following established procedure leaves residual risk of failure to intercept an incorrectly prescribed item.</i>

PE9.1 – What immediate action should be taken based on the information regarding Mr X being unable to activate the Medicine A device?

*The homecare provider, as the initial recipient of the information, should ascertain whether the product is available for inspection and arrange it's uplift as well as gather any further information about the issues experienced with the Medicine A device.*

PE9.2 - Where should this be reported?

*NHS organisations report to regional QA who reports it onto the AIC database*

PE10.1 – Assuming that the required acknowledgement and formal response is provided within the specified timelines and the complaint/incident is raised and closed within the same reporting period. Which KPI dataset(s) should this example be captured under?

- *D51 – Number of Formal Complaints and Incidents opened*
- *D56c - Number of Formal Complaints and Incidents attributed to Prescribing process*
- *D57 – Number of Patient safety incidents*
- *D61 - Number of faulty medicinal product incident reports*
- *D63 - Number of safeguarding incidents*

*A single complaint/incident can often be captured under multiple KPI datasets due to the often multifaceted nature of any given complaint/incident.*