Clinical

Medication Errors and Medicine Defect Reporting SOP

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Contents

1. Introduction .......................................................................................................................... 3
2. Purpose ............................................................................................................................... 3
3. Scope .................................................................................................................................. 3
4. Body Text ............................................................................................................................
5. Process For Monitoring Compliance And Effectiveness ................................................... 6
6. References ........................................................................................................................... 6
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<table>
<thead>
<tr>
<th>Version</th>
<th>Dates</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Feb 2016</td>
<td>SOP created from existing Medicines Code V6.10</td>
</tr>
</tbody>
</table>
1. Introduction
This SOP provides a framework for knowing how to report medication errors and medicine defects. This SOP will let clinical staff know exactly what to do should a medication error occur or a defective medication be encountered.

2. Purpose
The purpose of this SOP is to minimize delays in reporting medication errors and to familiarise staff in what to do if a defect is found in a medication.

3. Scope
This SOP is applicable to all nursing and clinical staff who are involved with the administration of medications and all clinical staff who handle medication.
4. Procedure

4.1 Drug Error Reporting System for Nursing Staff

**DRUG ERROR Report**

immediately to:

The Senior Person in your Team, or the next most Senior Person on call. The Senior Person will support you with the process of reporting the error

- You, or the Senior Person in your Team discuss immediately with GP or Medical Practitioner responsible for patient
  
  Discuss with Pharmacy

- Either you or the Senior Person in your Team inform:
  
  Locality manager who will manage incident

  - Assess and report as Critical Incident
  
  - Report to Quality Risk and Effectiveness Committee

  - Before going off Duty you should complete risk management adverse event report and document error in the Progress notes on RiO
  
  - Following discussion, identify training needs/systems failure. Report findings to Locality Manager

**Other health professionals** should complete incident report, document error in patient records, inform line manager and liaise with other health professionals caring for the patient as appropriate. Patient/relatives should be informed of error and informed of complaints procedure (if appropriate). The line manager and health professional should assess whether the incident constitutes a critical incident, which needs to be reported to the Quality Governance Committee.
4.2 Medicine Defect Reporting

The following procedure applies when a defect is found or is suspected in any medicine.

1. Inform the Pharmacy who will advise on all reporting, recording and investigating on the defect.
2. Retain any remaining product and any associated products or equipment (e.g. administration sets, infusion devices etc.).
3. Record the details of the product and defect.
4. If the product has been administered to a patient inform the medical practitioner responsible for the patient and record the defects in the patients' notes.
5. Report the incident to the Appointed Practitioner in Charge of the ward or department.
6. If a drug defect is suspected after the Pharmacy Department's normal opening hours, the pharmacy department should be contacted as soon as it is next open to inform them of the defect.

Suspected defective medicinal products are notifiable by doctors and pharmacists to:

The Defective Medicines Report Centre, 
Medicines and Healthcare products Regulatory Agency, 
Room 1801, 
Market Towers, 
Nine Elms Lane, 
London, 
SW8 5NQ

The Medicines Optimisation Committee will ensure that appropriate report takes place. The MHRA collects information on suspected adverse drug reactions and suspected defects in medicinal products.

The Defective Medicines Report Centre (DMRC) receives and assesses complaints and reports of actual or suspected defects in medicinal products for human use and co-ordinates the necessary actions.

The Centre provides an assessment and communication system between suppliers (manufacturers and distributors), users of medicines and other regulatory authorities.

Where a defect is considered to be a risk to public health, the marketing authorisation holder withdraws the affected product from use and the MHRA issues a 'drug alert' letter. This alert is classified from 1 to 4 depending upon the risk presented to the public health by the defective product. Class 1 is the most critical, for example serious mislabelling, microbial contamination or incorrect ingredients, and requires immediate recall; Class 4 is the least critical and advises 'caution in use'.

Patients or members of the public who have concerns about the quality of a medicine should in the first instance refer the matter to their pharmacist or doctor, who may then decide to contact the MHRA. Should this not be possible, patients and members of the public may contact the DMRC directly. Telephone 020 7084 2574 (during office hours Monday to Friday 0900 -1700). Telephone 020 7210 3000 for urgent calls outside of normal working hours, at weekends or on public holidays.
5. Process For Monitoring Compliance And Effectiveness

Incident Reports and reports from MHRA
Audit

6. References

Medicines Code