NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST

MEDICINES CODE OF PRACTICE

REPORTING OF MEDICINES INCIDENTS, MEDICINES DEFECTS, ADVERSE DRUG REACTIONS AND DRUG ALERTS

<table>
<thead>
<tr>
<th>Reference</th>
<th>CL/MM/020</th>
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<tbody>
<tr>
<td>Date approved</td>
<td>12 October 2012</td>
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<tr>
<td>Approving Body</td>
<td>Directors’ Group</td>
</tr>
<tr>
<td>Implementation date</td>
<td>12 October 2012</td>
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<tr>
<td>Version</td>
<td>3</td>
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<tr>
<td>Supersedes</td>
<td>Version 2 (August 2009)</td>
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<tr>
<td>Consultation undertaken</td>
<td>Medicines Code of Practice Review Group. Medicines Safety Group Clinical Risk Committee</td>
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<tr>
<td>Date of completion of Equality Impact Assessment</td>
<td>26th June 2012</td>
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<tr>
<td>Date of completion of Environmental Impact Assessment</td>
<td>26th June 2012</td>
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<tr>
<td>Date of completion of We Are Here For You assessment</td>
<td>26th June 2012</td>
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<tr>
<td>Target audience</td>
<td>This policy applies to all staff employed within the Trust (permanent or temporary or honorary), students, agency staff and employees of other organisations working on the Trust premises who are involved in any medication processes</td>
</tr>
<tr>
<td>Supporting Procedure(s)</td>
<td>• NUH Incident Reporting and Management Policy ref GG/CM/021</td>
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<td></td>
<td>• NUH Serious Untoward Incident Policy and Procedures ref</td>
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Reportng Of Medicines Incidents, Defects, Adverse Drug Reactions and Drug Alerts
Version3
October 2012
| **GM/CN/019** | NUH Investigating, analysing & learning from incidents, complaints & claims procedure ref GG/CN/028  
Pharmacy SOPs |
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<tbody>
<tr>
<td><strong>Review Date</strong></td>
<td>October 2015</td>
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<tr>
<td><strong>Lead Executive</strong></td>
<td>Medical Director, NUH</td>
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<tr>
<td><strong>Author/Lead Manager</strong></td>
<td>MMC, NUH</td>
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| **Further Guidance/Information** | Medicines Management Committee  
Medicines Safety Group |
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The *Here for You* standards have been introduced to ensure that employees are aware of the acceptable standards of behaviour that are expected and in doing so we have made a pledge to each other. We pledge that all day, everyday we will all do our very best to ensure:

- You are appreciated, with a polite and respectful attitude, from kind and helpful colleagues, who value everyone who takes responsibility for doing a good job
- You are supported to make the best use of your time, by simplifying processes, eliminating waste, and streamlining communication to ensure everyone can be focused on high quality care for patients
- You are encouraged to improve the quality of our service to patients, by listening to patients’ needs and through evidence-led improvement, team working, training and personal development

This chapter of the NUH Medicines Code of practice must be read in conjunction with CL/MM/002, Glossary and abbreviations
20.1 Policy Statement
The policy aims to strengthen the reporting of medication incidents and ensure uniform criteria for reporting

20.2. Reporting of Medicines Incidents
All reporting of medicines related incidents is carried out according to NUH Incident Reporting and Management Policy GG/CM/021. For all incidents and “near misses” at any stage in the medication process, an incident report form must be completed, preferably electronically.

The following gives a list of examples where medication errors can occur within the different medication processes. Near misses should also be considered. These examples have been taken from the list of medication incident codes on DATIX approved by the Trust Medicines Safety Group.

20.2.1 Prescribing

- Failure to prescribe
- Incorrect drug
- Incorrect route
- Incorrect time / frequency
- Incorrect dose / rate
- Incorrect patient
- Incorrect concentration / diluent
- Failure to acknowledge previous allergy / adverse drug reaction
- Duplication of dose
- Transcription error
- Incorrect concentration / diluent
20.2.2 Administration

- Incorrect label
- Incorrect drug
- Incorrect route
- Incorrect time / frequency
- Incorrect dose / rate
- Incorrect patient
- Duplication of dose
- Expired drug
- Significant delay in administering
- Non administration / dose omitted
- Incompatibility of drugs
- Self administration error

20.2.3 Supply of Medication

- Failure to supply
- Incorrect drug
- Incorrect form
- Incorrect strength
- Incorrect quantity
- Incorrect patient
- Incorrect label
- Expired drug
- Incorrect concentration / diluent
- Incorrect information
- Manufacturing error

20.2.4 Monitoring

- Incorrect monitoring / failure to monitor therapeutic levels

20.2.5 Adverse drug reactions

- Adverse drug reaction

20.2.6 Discharge
• Patient discharged from ward with incorrect / incomplete / without TTOs

20.2.7 Storage and Security

• Discrepancies in controlled drug numbers / counts / records
• Incorrect storage / transportation / missing medication (not controlled drugs)
• Lost drugs / drug cupboard keys

20.2.8 Clinical Trials

• Clinical Trial Error (Prescribing, Dispensing, Administration, Protocol Violation)

20.2.9 Financial loss

• Drug wastage (financial loss) WASTE

20.2.10 Defective Product

• Faulty Medicinal product

20.3 Medication supply or administration via a PGD or under a local agreement approved by MMC

An incident form must be completed if a patient is administered or supplied a medication by PGD without regard to the exclusion criteria, outside the inclusion criteria or by mis-selection of the product, dose frequency, or if the total number of doses allowed on the PGD has been exceeded.

The Assistant Chief Pharmacist Clinical Governance /Medicines Management, Chair of Medicines Management Committee must be informed.

20.4 Pharmacist Interventions

Pharmacists can report on DATIX any medication incidents listed above discovered in the normal course of their clinical pharmacy activity. In particular they are required to report all prescribing
errors listed in Appendix 1, whether or not the patient received medication or their intervention prevented a “near miss”.

20.5 Serious incidents
The NUH Serious Incident Policy and Procedure must be followed.

20.6 Management of Reported Medicines Incidents
All reported medication incidents will be investigated according to Management of Medicines Incidents and Staff involved in a medication incident policy (policy in development), and NUH Investigating, analysing & learning from incidents, complaints & claims procedure GG/CM0/28.

20.7 Adverse drug reaction reporting
An Adverse Drug Reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use and is suspected to be related to the medicine.

Any member of staff who suspects a patient is experiencing or has experienced an adverse drug reaction must bring this to the attention of the patient’s medical team.

For documentation of adverse drug reactions experienced during patients’ treatment at NUH refer to the Prescribing chapter of the Medicines Code CL/MM/006 section 6.5 ‘RECORDING OF ALLERGIES OR ADVERSE DRUG REACTIONS (ADRs)’. For action to be taken for ADRs experienced during administration of clinical trial drugs, including breaking of codes for double blind studies, refer to the Clinical Trials chapter of the Medicines Code CL/MM/019 section 19.13.

All ADRs must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the “yellow card” system. Any health care professional, the patient or their family/carers may report a suspected ADR.

Refer to the BNF or contact Medicines Information for practical guidance on reporting ADRs.
20.8 Reporting of Defective Medicinal Products

A Trust incident form must be completed for all suspected defects.

The following are examples of possible medicine defects:

- particulate matter in iv fluids
- cracks in fluid bottles
- hairline cracks in ampoules
- labelling on containers which does not correspond to the outer wrap
- a different odour than normal
- unexpected clinical reaction
- quality of dressings lower than normal
- microbial growth on IV fluids or in other injectables
- colour change in a medicine.

All suspected medicine defects must be reported within 24 hours, to the Pharmacy Governance Team (email via DATIX), and the nurse in charge of the area at the time. If a medicine defect is suspected outside the normal pharmacy opening hours, the on-call pharmacist must be contacted.

If a suspected defective item is being administered to a patient, use of the item must be immediately discontinued. The item must be stored separately from other medicines, clearly labelled as defective, and what the suspected defect is.

The doctor in charge of the patient must be notified if any medicine has been administered. If further medicine is required, this must be taken from a different batch. If an intravenous infusion has been set up both the administration set and the infusion fluid must be replaced from a different batch.

The defective material must be sent to the pharmacy store labelled clearly for the attention of the Pharmacy Governance Team.

The Pharmacy Governance Team will take charge of the investigation and reporting of the incident.
20.9 DRUG ALERTS
Refer to local pharmacy procedures for the management of drug alerts from the MHRA.
APPENDIX 1
Pharmacists are required to record onto DATIX all of the following of their interventions

- Failure to record serious allergy (throat swelling / collapse etc)
- Prescribing of drug documented as causing serious allergy e.g. anaphylaxis to penicillin
- Failure to carry out timely TDM for drugs with potential to cause severe toxicity -vancomycin and gentamicin
- Critical dose adjustments in TDM / renal failure not made for narrow therapeutic range drug with high toxicity
- Failure to administer/ prescribe treatment dose LMWH or warfarin in patient with PE /DVT/mechanical heart valve
- Failure to follow anticoagulant advice / guidelines results in far too high INR/APTT/factor Xa in bleeding patient
- Failure to prescribe or administer effective dose of IV antibiotic for severe life threatening infection e.g. meningitis, aspiration pneumonia, HAP
- Failure to administer/ prescribe treatment dose LMWH or warfarin in patient with PE /DVT/mechanical heart valve
- Failure to follow anticoagulant advice / guidelines results in far too high INR/APTT/factor Xa in bleeding patient
- Prescribing or administering a drug where a serious side effect has previously occurred and this has not been considered in the prescribing decision
- Errors involving cytotoxic medication prescribing or administration where drug in regime has been unintentionally omitted or wrong dose administered (dependent on situation)
- Ten times prescribing errors
- Failure to prescribe insulin in IDDM
- Infusion which must only be administered centrally is prescribed/ administered peripherally.

- Misidentification of patient - medicines prescribed for wrong patient/on wrong prescription chart

- Wrong route administration of chemotherapy

- Inappropriate administration of daily oral methotrexate or where prescription is written

- Overdose of opiates, particular in opiate naïve patients, off guideline

- IV potassium maladministration with potential to cause death or severe harm (selection of concentrated form when not intended, wrong route administration and infusion rate greater than intended)

- Prescribing that could contribute to overdose of midazolam for conscious sedation (over the dose in guidelines)

- Maladministration of insulin caused by use of abbreviations for units, omission of prescribed insulin, or failure to draw up correct insulin dose by not using insulin syringe/needle or pen

- Wrongly prepared high risk injectable medication with potential to cause death or severe harm

- Intravenous administration of epidural injection/infusion

- Inappropriately prescribed or administered daily methotrexate
APPENDIX 2. EQUALITY IMPACT ASSESSMENT REPORT OUTLINE

1. Name of Policy or Service

Medicines Code of Practice-Reporting of medicines incidents, medicines defects, adverse drug reactions and drug alerts

2. Responsible Manager

Medical Director, NUH

3. Name of Person Completing Assessment

Sue Ellis

4. Date EIA Completed

26th June 2012

5. Description and Aims of Policy/Service

This chapter of the Medicines Code of Practice has been developed to strengthen the reporting of medicine related incidents and to ensure consistency in what is reported.

6. Brief Summary of Research and Relevant Data

7. Methods and Outcome of Consultation

Medicines Code of Practice Review Group, Clinical Risk Committee

8. Results of Initial Screening or Full Equality Impact Assessment:

<table>
<thead>
<tr>
<th>Equality Group</th>
<th>Assessment of Impact</th>
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<tbody>
<tr>
<td>Age</td>
<td>No Impact Identified</td>
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<tr>
<td>Gender</td>
<td>No Impact Identified</td>
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<tr>
<td>Race</td>
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<td>Sexual Orientation</td>
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<td>Working Patterns</td>
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<tr>
<td>Social Deprivation</td>
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9. Decisions and/or Recommendations

Following the initial impact assessment, it is my recommendation that this document does not require a full impact assessment.

10. Equality Action Plan

N/A

11. Monitoring and Review Arrangements

It is recommended that once implemented, this chapter is reviewed in line with NUH guidelines.

Equality Statement
All patients, employees and members of the public should be treated fairly and with respect, regardless of age, disability, gender, marital status, membership or non-membership of a trade union, race, religion, domestic circumstances, sexual orientation,
ethnic or national origin, social and employment status, HIV status, or gender re-assignment.

**Environmental Impact Assessment**
This policy has no detrimental environmental impact
### Appendix 3
CERTIFICATION OF EMPLOYEE AWARENESS

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Medicines Code of Practice: Reporting of medicines incidents, medicines defects, adverse drug reactions and drug alerts</th>
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<tbody>
<tr>
<td>Version (number)</td>
<td>3</td>
</tr>
<tr>
<td>Version (date)</td>
<td>12 October 2012</td>
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</table>

I hereby certify that I have:
- Identified (by reference to the document control sheet of the above policy/procedure) the staff groups within my area of responsibility to whom this policy/procedure applies.
- Made arrangements to ensure that such members of staff have the opportunity to be aware of the existence of this document and have the means to access, read and understand it.

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<th>Signature</th>
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<tr>
<td>Date</td>
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<tr>
<td>Directorate/Department</td>
<td>[Directorate/Department]</td>
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</table>

The manager completing this certification should retain it for audit and/or other purposes for a period of six years (even if subsequent versions of the document are implemented). The suggested level of certification is:

- Clinical directorates - general manager
- Non clinical directorates - deputy director or equivalent.

The manager may, at their discretion, also require that subordinate levels of their directorate/department utilise this form in a similar way, but this would always be an additional (not replacement) action.