University Hospitals Bristol
NHS Foundation Trust

Medicines code chapter 8 – Adverse Drug Reactions

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What is in this policy?
This policy will inform users what is classified as an adverse drug reaction, and when and how they should be reported. Reporting adverse drug reactions in accordance with this policy will enable University Hospitals Bristol NHS Foundation Trust (the Trust) to increase its contribution to the national database and national patient safety.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
November 2013	2	Director of Pharmacy	Major	Review, update and re-format into trust approved policy format
September 2016	3	Director of Pharmacy	Major	Review and update in line with yellow card reporting guidance.
September 2019	3.1	Director of Pharmacy	Minor	Review, re-format into new format. Update yellow card links

Sign off Process and Dates	
Groups consulted	**Date agreed**
Medicines Governance Group	17/09/2019
Policy Assurance Group	01/12/2019
Clinical Quality Group	06/02/2020

- **Stakeholder Group** can include any group that has been consulted over the content or requirement for this policy.
- **Steering Group** can include any meeting of professionals who has been involved in agreeing specific content relating to this policy.
- **Other Groups** include any meetings consulted over this policy.
- **Policy Assurance Group** must agree this document before it is sent to the **Approval Authority** for final sign off before upload to the DMS.

Table of Contents

Do I need to read this Policy?

All Staff who administer, prescribe or talk to patients about their medicines

Must read whole policy

1. Introduction

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance in order to reduce patient risk.

Adverse drug reactions should be reported as it is important to monitor drug safety. Reporting adverse drug reactions:

- Provides “early warnings” of previously unsuspected Adverse Drug Reactions
- Can elicit factors which predispose to particular adverse drug reactions
- Can compare ADR profiles between medicines within therapeutic classes
- Permits safety monitoring throughout the duration of a product’s use

2. Purpose

The purpose of this policy is to inform users what is classified as an adverse drug reaction and when and how they should be reported.

3. Scope

This policy relates to all permanent and temporary employees, volunteers, agencies and agency staff working for and on behalf of the Trust

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4. Definitions

4.1 Adverse Drug Reaction

An adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs and is suspected to be related to the drug. The reaction may be a known side effect of the drug or it may be a new previously unrecognised ADR.

There is often confusion between the terms "adverse reaction" and "adverse event".

4.2 Adverse event

An adverse event is considered to be any untoward medical occurrence in a patient who is taking a medicine and that does not necessarily have a causal relationship with the product. An adverse event is not always the same as an adverse drug reaction as adverse events encompass ADRs but may also include cases where no association has been or can be made between drug administration and the adverse event experienced.

4.3 Serious Reaction

Serious reactions include those that are fatal, life-threatening, disabling, incapacitating or which result in or prolong hospitalisation and/or are medically significant. Other reactions that are considered serious include congenital abnormalities.

4.4 Severe Reaction

A severe reaction might be one that is not life-threatening or disabling but in the individual patient it is extreme. An example would be headache which would not normally be considered serious but may be very severe.

5. Duties, Roles and Responsibilities

5.1 All clinical staff involved in prescribing, screening, supplying or administering medicines

(a) On suspecting that an adverse drug reaction has occurred, the staff member should report the suspected reaction in line with process described in this policy.

6. Policy Statement and Provisions

6.1 Adverse event reporting

(a) The easiest method to report adverse events is by completing the form online at http://yellowcard.mhra.gov.uk/

(b) Comprehensive monitoring relies on ADR reports being made. The most commonly quoted figure for the degree of under-reporting in the UK is that around only 10% of ADRs are notified to the regulatory authorities. The number of successful notifications of rare and serious ADRs from the 'Yellow Card' and other post-marketing surveillance schemes indicates that an increase in the reported numbers will only serve to enhance the quality of information gained and increase patient safety.

(c) Adverse drug reactions have been estimated to cost the NHS £466m a year and account for 1 in 16 hospital admissions.

(d) The information included in ADR reports must be of sufficient quality to enable assessments of drug safety to be made.

(e) If a patient suffers harm due to an adverse incident involving medication, the incident is also to be reported using the Trust Incident Reporting mechanism.

6.2 What Adverse Drug Reactions to Report

The Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. Reports can be made for:

(a) All prescription and over the counter medicines

(b) Vaccines

(c) Blood factors and Immunoglobulins

(d) Herbal medicines and Homeopathic remedies

(e) Radiological Contrast media

(f) All medical devices available on the UK market

(g) E-cigarette products

(h) Prescription medicines

6.3 When to Report

Complete a Yellow Card for:

a) All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

b) All suspected ADRs associated with new drugs and vaccines (identified by the black triangle symbol: ▼). The list of Black Triangle products are updated monthly and can found on the European Medicines Agency Website.

If you are in any doubt as to whether a suspected ADR was serious or harmful, please complete a Yellow Card anyway.

Watch out for suspected ADRs in children and neonates, which can be different from those in adults. Knowledge about ADRs in children is less well established because:

- Action of a drug and its pharmacokinetics in children (especially in the very young) may be different from that in adults;
- Drugs may not have been extensively tested in children;
- Many drugs are not specifically licensed for use in children and are used either 'off-label' or as unlicensed products;
- Drugs may affect the way a child grows and develops or may cause delayed adverse reactions which do not occur in adults;
- Suitable formulations may not be available to allow precise dosing in children or they may contain excipients that should be used with caution in children;
- The nature and course of illnesses and adverse drug reactions may differ between adults and children.

It is not necessary to be certain that an adverse drug reaction (ADR) has occurred before submitting a Yellow Card report.

For more information, see the NICE Clinical Knowledge Summary for Additional information on which ADRs to report.

6.4 Who can Report

Any healthcare professional or patient can report an adverse drug reaction on a yellow card.

6.5 How to Report

Yellow cards should be completed in full electronically at
http://yellowcard.mhra.gov.uk/yellowcards/reportmediator/

Healthcare professional reporting an ADR should ensure that a full record is made in the patient's medical notes detailing the suspected adverse reaction and stating that it has been reported.

A valid suspected ADR report, which includes medication errors where harm occurs, must include 4 pieces of information:

(a) A patient identifier

(b) The name of the medicine suspected to have caused the ADR

(c) A brief description of the suspected reaction

(d) Reporter details. If reporting via NRLS do not worry about this field as a reporter Trust ID is sent to the MHRA in the NRLS dataset to validate the report.

The minimum information needed for completing a suspected ADR report:	Additional information to supply (this information helps assess a Yellow Card):
Names of the medicine(s) suspected to have caused the reaction	Details of the suspect medicine(s) if available. For example; • dose • start and stop dates • route of administration • brand and batch numbers especially for vaccines, biosimilars and biological medicines • action taken with the drug - stopped, dose change, restarted, none etc. • indication
Suspected reaction(s)	Details of the reactions if available: • report suspected reactions where there is harm or a serious reaction (e.g. fatal; life-threatening; Is incapacitating or disabling; results in a new hospital admission or prolongs hospital stay; is associated with congenital abnormalities in a child; is otherwise judged to be medically significant) • a brief description of reaction • diagnosis if relevant • start and stop dates of reaction • treatment given • reaction outcome
At least one patient identifier:	• Sex • Age • Weight • Initials • local identifier

	All should be completed if available
Reporter details:	• Your name • Qualification • Full address
Any additional information you have:	• relevant medical history • test results • other drugs taken in the last 3 months • if any re-challenge was performed • If it is a congenital abnormality, state all other drugs taken during pregnancy and date of last menstrual period • If no further information is available, please indicate this on the report

It is good practice to try and include as much of the following additional information as possible:

(e) Patient – useful information about the patient includes

(i) Age, weight, sex and ethnicity;

(ii) Relevant medical history – could recent and current medical conditions have affected the ADR reported?

(iii) Allergy status – is there a history of allergic reactions? Are there any specific substances that the patient is allergic to?

(f) Reaction/effect – be as thorough as you can in describing the reaction and include

(i) When the suspected ADR happened, how serious it was, how it was managed and what the outcome was (in many cases it might simply be that the patient recovered on stopping the medicine)

(ii) If the medicine had to be given again for any reason, whether or not the reaction recurred.

(g) Test results – results of blood tests could be valuable especially for a systemic reaction;

(h) For a congenital abnormality, all other medication taken during pregnancy together with, if available, when they were taken in relation to the last menstrual period.

(i) Details about the medicine(s) suspected to have caused the reaction or harm:

(i) Route of administration;

(ii) Dose and frequency of administration;

(iii) Date when the medicine was started and when it was stopped;

(iv) Brand name of the medicine;

(v) Batch number of the medicine – this is especially important for vaccines and biological medicines (medicines derived from 'living' biological systems).

(j) Details of any other medication the patient has taken in the last three months:

(i) Prescribed medicines;

(ii) Medicines purchased over the counter;

(iii) Complementary remedies, such as herbals and homoeopathic medicines.

(k) A reaction is considered serious by the MHRA if it:

(i) Is fatal;

(ii) Is life-threatening;

(iii) Is incapacitating or disabling;

(iv) Results in a new hospital admission or prolongs hospital stay;

(v) Is associated with congenital abnormalities in a child;

(vi) Is otherwise judged to be medically significant.

If all the information is not available, please do not let this stop you from completing a report – if you are in doubt, please do report it.

6.6 Reporting unexpected or severe adverse reactions to illicit substances

Healthcare professionals can also report cases of unexpected or severe adverse reactions to illicit substances via the Report Illicit Drug Reactions (RIDR) website.

6.7 Further information

Reports of suspected adverse drug reactions (ADRs) received in the UK by the MHRA through the Yellow Card Scheme are provided in lists for each medicine. These are known as drug analysis prints and can be accessed at Drug Analysis Prints

Standards and Key Performance Indicators

6.8 Applicable Standards

(a) All suspected adverse drug reactions should be reported in line with the MHRA yellow card reporting scheme.

7. References

7.1 MHRA Yellow card website http://yellowcard.mhra.gov.uk/

7.2 MHRA Yellow card scheme http://yellowcard.mhra.gov.uk/the-yellow-card-scheme/

7.3 NICE Clinical Knowledge Summaries http://cks.nice.org.uk/adverse-drug-reactions#!topicsummary

8. Associated Internal Documentation

Medicines Code Policies

9. Appendix A – Monitoring Table for this Policy

The following table sets out the monitoring provisions associated with this policy. Please ensure any possible means of monitoring this policy to ensure all parts are fulfilled are included in this table. **The first line is an example for you and should be removed prior to submission**.

Objective	Evidence	Method	Frequency	Responsible	Committee
Monitoring of incidents to identify learning.	Incident reports from Datix Incident Reporting System.	Data extraction from incident reporting system.	Quarterly, Annually and Ad hoc as required.	Divisional Health and Safety Leads/Divisional H&S (site/service) Advisors	Trust Health and Safety Committee/Divisional H&S Forums.
Monitoring of ADR reports via the yellow card reporting system.	Report from MHRA of number of ADRs reported cross referenced with the Datix reports.	Email report from MHRA. Data extraction from Datix.	Annually	Medication Safety Officer	Medicines Governance Group

10. Appendix B – Dissemination, Implementation and Training Plan

The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Director of Pharmacy
Is this document: A – replacing the same titled, expired policy, B – replacing an alternative policy, C – a new policy:	A
If answer above is B: Alternative documentation this policy will replace (if applicable):	[DITP - Existing documents to be replaced by]
This document is to be disseminated to:	All clinical staff
Method of dissemination:	Newsbeat
Is Training required:	No
The Training Lead is:	[DITP - Training Lead Job Title]

Plan Elements	Plan Details
Additional Comments	
[DITP - Additional Comments]	

11. Appendix C – Equality Impact Assessment (EIA) Screening Tool

Further information and guidance about Equality Impact Assessments is available here:
http://nww.avon.nhs.uk/dms/download.aspx?did=17833

Query	Response
What is the main purpose of the document?	To ensure that all adverse drug reactions are reported via the yellow card reporting scheme.
Who is the target audience of the document? Who is it likely to impact on? (Please tick all that apply.)	Add ☑ or ☒ **Staff** ~~**Patients Visitors Carers Others**~~

Could the document have a significant negative impact on equality in relation to each of these characteristics?	YES	NO	Please explain why, and what evidence supports this assessment in relation to your response.
Age (including younger and older people)		✓	
Disability (including physical and sensory impairments, learning disabilities, mental health)		✓	
Gender reassignment		✓	
Pregnancy and maternity		✓	
Race (includes ethnicity as well as gypsy travelers)		✓	
Religion and belief (includes non-belief)		✓	
Sex (male and female)		✓	
Sexual Orientation (lesbian, gay, bisexual, other)		✓	
Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)		✓	
Human Rights (particularly rights to privacy, dignity, liberty and non-degrading treatment)		✓	

Will the document create any problems or barriers to any community or group? ~~YES /~~ NO

Will any group be excluded because of this document? ~~YES /~~ NO

Will the document result in discrimination against any group? ~~YES /~~ NO

If the answer to any of these questions is YES, you must complete a full Equality Impact Assessment.

Could the document have a significant positive impact on inclusion by reducing inequalities?	**YES**	**NO**	**If yes, please explain why, and what evidence supports this assessment.**
Will it promote equal opportunities for people from all groups?		✓	
Will it help to get rid of discrimination?		✓	
Will it help to get rid of harassment?		✓	
Will it promote good relations between people from all groups?		✓	
Will it promote and protect human rights?		✓	

On the basis of the information/evidence so far, do you believe that the document will have a positive or negative impact on equality? (Please rate by circling the level of impact, below.)

Positive impact				**Negative Impact**		
~~Significant~~	~~Some~~	~~Very Little~~	NONE	~~Very Little~~	~~Some~~	~~Significant~~

Is a full equality impact assessment required? ~~YES~~ / NO

Date assessment completed: 11.12.19

Person completing the assessment: Georgina Holmes