NHS
Dorset
Clinical Commissioning Group

MEDICINES STANDARD A1:
PROCEDURE FOR REPORTING ADVERSE DRUG REACTIONS

This guidance covers all types of adverse drug reactions (ADRs) and can also be applied to incidents involving medical devices.

The national Yellow Card scheme described in this procedure can be used to report problems or incidents involving:

- side effects (also known as adverse drug reactions or ADRs)
- medical device adverse incidents
- defective medicines (those that are not of an acceptable quality)
- counterfeit or fake medicines or medical devices

This procedure does not cover medication incidents involving the unintended or inappropriate selection, administration or supply of medication; these should be reported directly to the Patient Safety team at NHS England (Wessex). See Appendix C for links to the Patient Safety Incident Report Form for NHS England.

PURPOSE

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

The purpose of this procedure is to describe the types of incidents that may be encountered in primary care, and the actions required to ensure that an adverse drug reaction (ADR) is reported correctly.

It is important to ensure that all incidents are reported correctly and in a timely way so that areas of risk can be identified, and actions can be taken to prevent recurrence, for example:

- providing 'early warnings' of previously unsuspected ADRs
- eliciting factors which predispose to particular ADRs
- comparison of ADR profiles between medicines within therapeutic classes

Appendix C of this document provides a summary of reporting routes and requirements.

DEFINITIONS

An ADR is an unwanted or harmful reaction following the administration of a medication or combination of medications that is suspected to be related to the medication.

The reaction may be a known side effect of the medicine or it may be a new previously unrecognised ADR. In general, these are the essential features of an ADR:

- there is a suspicion that at least one medicine is responsible;

- the effect is unintended;
- it iS harmful, or potentially harmful;
- the reaction is seen at normal doses used clinically (to distinguish ADRs from 'toxicity' which is used to describe the symptoms of overdose or poisoning).

Medical devices are items used to treat or diagnose a condition or an illness, or help with a disability. For example medical devices include: equipment, dressings, implants, artificial limbs, blood glucose strips and meters, low dose heparin preparations for flushing catheters, some types of eye drops, insulin pens, thermometers, wheelchairs and some software/apps. Yellow cards should be completed where a device has for example failed to function, appears of poor quality or might have hurt someone.

PROCESS FOR REPORTING ADVERSE DRUG REACTIONS TO THE CCG

If a patient experiences a known or *suspected* adverse drug reaction, even to an established drug, this must be reported. You do not have to be certain about causality - **Do not delay reporting, even if you are in doubt about causality.**

All known or *suspected* adverse drug reactions occurring in primary care should be reported using the 'Adverse incident report form (AIRS) / Significant Event Incident Form' (Appendix A)

The ADR should be reported as soon after occurring as practicable. Record the ADR in the patient's notes, and if you were not the prescriber of the drug, notify the prescriber.

Appendix C of this document highlights reporting routes for adverse incidents involving medication.

PROCESS FOR REPORTING ADVERSE DRUG REACTIONS ON A YELLOW CARD

In the UK adverse reactions are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the 'Yellow card' reporting scheme.

Paper copies of Yellow Cards can be found in the back of the BNF, or can be ordered from the MHRA. The easiest way, however, to report an adverse reaction is to visit the Yellow Card site at http://yellowcard.mhra.gov.uk/ and complete the report online. There are also forms to download and print from the website if postal submission is required.

Situations where Yellow Cards should be used for reporting adverse events include:

- a person has experienced suspected side effects to a medicine, vaccine, herbal or homeopathic remedy
- a suspected defective medicine i.e. not of an acceptable quality
- a medicine not working as it should
- a medical device is defective e.g. failed to work, broken, caused or might have caused harm or could be a counterfeit product

For an up to date list of drugs for which Yellow Cards are required consult the Yellow Card website. Assistance in selecting the appropriate option to select when reporting adverse events with medicines or medical devices is available on the Yellow Card website or by calling 020 3080 6000.

Black Triangle drugs and vaccines

Report **all** suspected ADRs to drugs marked with an inverted black triangle (▼), i.e. new drugs on the market. The "Intensive Monitoring List" on the MHRA website gives details of black triangle drugs and is updated monthly. The list is maintained by the European Medicines Agency (EMA).

Established drugs

Report all suspected adverse reactions to established medicines (including over-the-counter and herbal medicines) that you consider to be **SERIOUS**. The reaction should be reported even if the effect is well recognised.

Serious reactions are those which are:

- fatal;
- life-threatening;
- disabling or incapacitating;
- have resulted in, or prolonged, hospitalisation;
- medically significant;
- resulting in congenital abnormalities.

A detailed list of reactions considered to be serious can be found in Appendix B. However, if you are unsure about the seriousness of a reaction a report should be submitted anyway.

Adverse reactions in children

The MHRA asks that all suspected adverse drug reactions in children are reported on a Yellow Card, even if they occurred with an established drug and regardless of whether or not the medicine is licensed for use in children. This is because the nature and course of illness and ADRs may differ between adults and children.

In general, children are not exposed to medicines in clinical trials, therefore very little is known about the safe use of medicines in this group. Furthermore, many drugs which are routinely used to treat children are not actually licensed for their use, so it is particularly important to focus on their safety in children.

Adverse reactions in patients that are over 65 years of age

Be particularly alert for suspected ADRs in elderly individuals. It is important to monitor the safety of medicines in this group, as older individuals may be more susceptible to developing reactions as they may metabolise medicines less effectively, and be more sensitive to their effects. For both pharmacokinetic and pharmacodynamic reasons, they may be more susceptible to developing reactions.

Delayed drug effects and interactions

Report ADRs which may seem to appear months or even years after drug exposure, e.g. cancers, retroperitoneal fibrosis – report any suspicion of such an association.

Congenital anomalies

If a baby is born with a congenital abnormality, or if a pregnancy results in a malformed aborted foetus, consider whether this might have resulted from an adverse reaction to a medicine, and report it on a Yellow Card if appropriate. In the report, give information about any medicine taken during the pregnancy, including self-medication and the date of the last menstrual period.

Complimentary remedies such as homeopathic and herbal products

There are many herbal remedies available over-the-counter from outlets other than pharmacies, or supplied by herbal practitioners, and only some of these are actually licensed for use. It is important that both licensed and unlicensed herbal products are monitored to ensure their safety; therefore, report suspected adverse reactions to **any** herbal remedy.

It is important to provide as much information as possible about the remedy, including its ingredients, the source or supplier, if known, and the condition that the product was being used for. If the remedy was supplied by a herbal practitioner, it would be useful to receive their name and address. Retain a sample of the product if the reaction is severe, in case further investigations are required.

Vaccines and biological medicines

All reactions to biological medicines such as blood products, antibodies and advanced therapies such as gene, tissue therapy as well as vaccines should be reported. The complexity and characteristics of these products will not be identical even amongst batches of the same product and therefore it is important to include the brand name and batch number in the report.

Adverse events involving Medical Devices

Yellow cards should be completed where a device has for example failed to function, appears of poor quality or might have hurt someone.

WHAT INFORMATION SHOULD BE INCLUDED ON A YELLOW CARD?

To complete a Yellow Card, include the following information as a minimum:

- suspect drug(s) – the name of the medicine which you suspect to be associated with the reaction;
- the route of administration, the daily dose, dates of administration and the reason for which the medicine was given, if known;
- if it is clear that only one drug could be involved in the reaction then only enter this drug. If, however, two or more drugs are suspected (or in the case of suspected drug interactions) then all possible drugs should be entered;
- describe the suspected drug reaction(s), including a diagnosis, if relevant;
- if the reaction is serious, tick the appropriate reason;
- give the start and finish dates of the suspected reaction, if known;
- patient details;
- gender,
- age at the time of the reaction,
- weight (if known);
- patient's initials and any number or code that will identify the patient to you, but not to MHRA. For instance, you could use the patient's local practice or hospital number or you may want to set up a file specifically for Yellow Cards. (This will help you in identifying the patient in any future correspondence with the MHRA, confidentiality will not be breached by doing this);
- your name and full address. This will enable the MHRA to acknowledge receipt of the report, and follow up for further information if necessary;
- any other relevant details, Including:
    - other drugs: please indicate whether or not a patient was on any other medication in the last three months
    - if the patient was not taking any other medicines, or if no other information is available on the case, please state this.
    - include any re-challenges, relevant medical history, test results, known allergies or suspected drug interactions, if relevant.
    - for congenital anomalies please state all other drugs taken during the pregnancy and the date of the last menstrual period. Attach additional pages (including print-outs of test results) if necessary.

Place a copy of the Yellow Card in the patient's notes; if you were not the prescriber of the drug, send a copy to the prescriber.

PROCESS FOR REPORTING DEFECTIVE MEDICINES, COUNTERFEIT OR FAKE MEDICINES OR MEDICAL DEVICE ADVERSE INCIDENTS

The MHRA Yellow Card website should also be used to report incidents around:

- Medical devices – items used to treat or diagnose a condition or illness or help with a disability. For example medical devices include: equipment, dressings, implants, artificial limbs, blood glucose strips and meters, low dose heparin preparations for flushing catheters, some types of eye drops, insulin pens, thermometers, wheelchairs and some software/apps. Examples of incidents to report would be where an item is broken or failed to work and caused harm or might harm someone, seems faulty / of poor quality or is not working as it should. Some products which may appear to be medical devices are actually medicines, for example pre-filled syringes, hormonal contraceptives, or hormonal contraceptive coil.

- Counterfeit or fake medicines or medical devices – you suspect the medicine you used is counterfeit or otherwise not genuine

- Defective medicines – where a medicine is not of an acceptable quality

APPENDIX A

ADVERSE INCIDENT/SIGNIFICANT EVENT INCIDENT FORM

Patient details	
Patient name	
Identifying number on system for patient:	
NHS No. (if known)	
Hospital No. (if known)	
Date of Birth	
Gender	
Ethnicity of patient (if known)	

Incident details	
Date of incident	
Time of incident	
Date of reporting	
Reported by	
Job title	
Name of surgery or pharmacy	
Address	

Description of incident *Record fact and not opinion. Include a description of any medicines involved / injuries sustained / equipment problem / tests given.*

Persons involved (witnesses or attending staff)			
	Person 1	**Person 2**	**Person 3**
Name			
Status			
Job title			

Additional considerations		
Person directly affected by incident (harmed or prevented harm)	☐ Yes	☐ No
Does this incident have child protection/vulnerable adult issues?	☐ Yes	☐ No

Does this incident involve controlled drugs?	☐ Yes	☐ No

What was the CONSEQUENCE of what happened as a result of the incident? (circle)				
None/Negligible (no harm)	Minor (low harm)	Moderate (moderate harm)	Major (serious harm)	Catastrophic (death)

What is the LIKELIHOOD of the incident occurring again? (circle)				
Rare	Unlikely	Possible	Likely	Almost certain
This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur, possibly frequently

Using the risk matrix below, what is the risk score?					
Consequence score =		Likelihood Score =		C x L =	

Risk Matrix

Likelihood / ***Consequence***		Rare	Unlikely	Possible	Likely	Almost certain
		1	2	3	4	5
1	No harm	1	2	3	4	5
2	Low harm	2	4	6	8	10
3	Moderate harm	3	6	9	12	15
4	Serious harm	4	8	12	16	20
5	Death	5	10	15	20	25

Low Risk Green 0-5	Moderate Risk Yellow 6-8	Significant Risk Orange 9-12	High Risk Red 15-25

Actions taken			
Signature:		Date:	

Serious/Major incidents should be reported immediately. Complete this form and send it to the Patient Safety and Risk team within 24 hours: avril.brown@dorsetccg.nhs.uk or laura.limm@dorsetccg.nhs.uk Please complete all of the form; if not completing electronically, please use black ballpoint pen and block capitals.

APPENDIX B

WHAT IS A SERIOUS ADVERSE DRUG 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.

Examples of serious reactions

Blood	**Gastrointestinal**	**Musculoskeletal**
Bone marrow dyscrasias	Colitis	Arthropathy
Coagulopathies	Haemorrhage	Aseptic bone necrosis
Haemolytic anaemias	Hepatic cirrhosis	Osteomalacia
	Hepatic dysfunction	Pathological fracture
Cardiovascular	Hepatic fibrosis	
Arrhythmias	Ileus	**Renal**
Cardiac arrest	Pancreatitis	Renal dysfunction
Cardiac failure	Perforation	Urinary retention
Cardiomyopathy	Peritonitis (inc. fibrosing)	
Circulatory failure	Pseudo-obstruction	**Reproduction**
Hypertension		Spontaneous abortion
Hypotension	**Immunological**	Antepartum haemorrhage
Myocardial	Anaphylaxis	Congenital abnormalities
Ischaemia/infarction	Arteritis	Eclampsia, pre-eclampsia
Sudden death	Drug fever	Infertility
	Graft rejection	Uterine haemorrhage, perforation
Central nervous system	Lupus syndrome	
Anorexia nervosa	Polyarteritis nodosa	
Catatonia	Vasculitis	**Respiratory**
Cerebrovascular accident		Alveolitis (allergic, fibrosing)
Coma	**Malignancy**	Bronchospasm (inc. exacerbation)
Confusional state	Any	
Dependence		Pneumonitis
Depression	**Metabolic**	Respiratory failure
Epilepsy (inc. exacerbations)	Acidosis	Thromboembolism
	Adrenal dysfunction	
Extrapyramidal reactions	Diabetes	**Skin**
Hallucinations	Hypercalcaemia	Angioedema
Hyperpyrexia	Hyperkalaemia	Bullous eruptions
Intracranial pressure	Hypokalaemia	Epidermal necrolysis
Myasthenia	Hyponatraemia	Exfoliation (generalised)
Neuroleptic malignant		
		Special senses
		Cataract

This list is updated frequently. The current suggested list of serious reactions can be found on the MHRA website.

APPENDIX C

Summary of Reporting of medication incidents in primary care

What to report?		How to report?
Adverse drug reactions	• Reactions that are serious, medically significant or result in harm* • Caused by errors in the way a medicine has been given • Caused by NEW medicines & vaccines (identified by black triangle) • Caused by herbal preparations, homeopathic remedies or unlicensed medicines	**Yellow Card to MHRA** https://yellowcard.mhra.gov.uk/ **&** **Adverse Incident / Significant Event Incident Form to CCG**
Defective medicines (or devices)	• Medicines that are not of an acceptable quality • Medicines not working as expected • A medicine you suspect is counterfeit or otherwise not genuine • A medical device broke or failed to work and caused or might have caused harm / the device seems faulty, of poor quality or is not working as it should	
Prescribing, dispensing and administration errors	• All incidents that result in patient harm* • Any error where no harm* has occurred, even when the patient has taken (or been given) the medication.	**NRLS** via e-form https://report.nrls.nhs.uk/GP_eForm **Tick "Share with CCG" in Question 1**
Prescribing problems relating to:	• Inadequate safety monitoring e.g. no INRs with warfarin • Problems at transfer of care • Updating repeat medicines following hospital admission • Contra-indications or documentation of allergy information • High risk medicines e.g. anticoagulants, opiates, methotrexate, NSAIDS, insulin, amiodarone	