ADVERSE DRUG REACTION

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

Adverse Drug Reactions (ADRs) can occur after receiving vaccines, non-prescription medicines, alternative remedies as well as conventional prescription medication. The clinical spectrum of ADRs involve various organs, timing and severity. Avoidance of a drug suspected of causing an ADR depends both on an accurate diagnosis and communication.

ADRs reported at hospital admission

- *Nil Known Allergies Reported*
  - On the medication chart use the "Nil Known" tick box or "NKA" or "Nil known Allergies" in the ADR box accompanied with the date of review, name and signature.
  - Electronic medical record (PowerChart) "Nil known Allergies" and the date
- *Patients with reported allergies*
  - Name of the drug involved
  - Type of reaction e.g. anaphylaxis, diarrhoea
  - When the reaction occurred.
    - If a reaction has occurred over 5 years ago, consider an immunology review of the patient's current allergy status.
  - Who labelled the allergy/ADR (e.g. immunologist, GP, patient or carer)
  - Name and signature of the staff member documenting.
  - Where the reaction or date of reaction are not known this should be documented with the medication and the words "unknown" in the corresponding sections of the medication chart.

ADRs occurring during hospital admission

- The patient's allergy and ADR history must be checked before prescribing, dispensing and administering a medication. Where this does not occur and the patient receives a medication which results in an ADR this is classified as an incident that must be reported through the NSW Health Incident Information Management System (IIMS).
- ADRs should be assessed for causality and severity (e.g. confirmed or definite, probable, possible, or unlikely and mild, moderate, severe or life threatening) should be assessed and a recommendation documented.

Approved by:	SCHN Policy, Procedure & Guideline Committee	
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Team Leader:	QUM & Medication Safety Pharmacist	**Area/Dept**: Clinical Governance

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- All Staff are responsible for notifying all incidents they identify using **IIMS** and encouraging colleagues to notify incidents identified.
  - Use agreed definitions of ADR and allergy for documentation and reporting. Report ADRs into **IIMS** according to terminology Categories of ADRs [Appendix 1]

Communicating ADRs upon discharge from hospital

- Allergy and alert information are mandatory labels in referral reports to a patient's GP, specialist or community health clinician in order prevent critical information being overlooked by omission

Reporting ADRs to the TGA

- The TGA requests reports of suspected adverse events to any medicine available in Australia, including: prescription medicines, vaccines, over-the-counter medicines that are purchased without a prescription, complementary medicines including herbal medicines, naturopathic or homeopathic preparations and nutritional supplements (e.g. vitamins and minerals).
  - Nursing, Pharmacy and Medical Staff all have responsibilities in relation to ADR management at presentation to hospital, during admission and discharge.

CHANGE SUMMARY

- N/A – new document.

READ ACKNOWLEDGEMENT

- All medical, nursing and pharmacy staff are to read and acknowledge they understand the contents of this document.

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Background

Adverse Drug Reactions (ADRs) can occur after receiving vaccines, non-prescription medicines, alternative remedies as well as conventional prescription medication. The clinical spectrum of ADRs involve various organs, timing and severity. Avoidance of a drug suspected of causing an ADR depends both on an accurate diagnosis and communication.[12] The Australian Commission on Safety and Quality in Healthcare requires that the clinical workforce document a patient's previously known adverse drug reactions and update this throughout each episode of care.

In addition to reporting it is the responsibility of prescribers, pharmacists and nurses to review ADRs and alerts prior to prescribing, dispensing, ordering and administering medications to patients.[1]

Definitions

Adverse event

An unintended patient injury or complication from treatment that results in disability, death or prolonged hospital stay and is caused by health care management.[3] All ADRs are adverse (drug) events but the reverse is not true.[10]

Adverse Drug Reaction (ADR)[2]

An adverse drug reaction is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

ADRs reported at hospital admission

If a patient is taking medication the possibility of an ADR should be considered as part of the differential diagnosis at admission to hospital.[6]

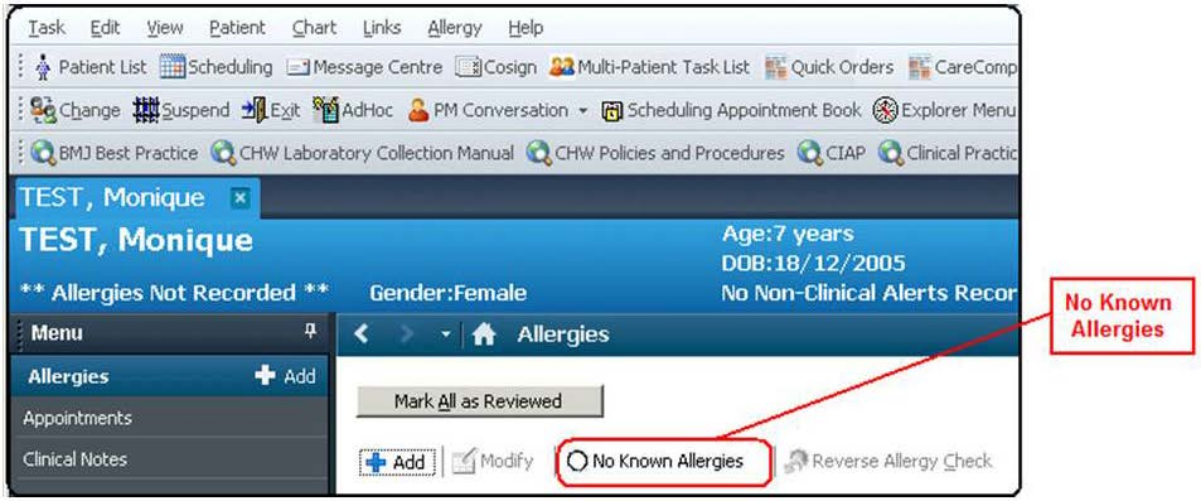
Documentation of ADRs in the medical notes and medication chart

Detailed information should be documented in order to ensure a patient is not re-exposed to a drug that may cause harm. Documentation of ADRs should comply with the local and national standards.[1,9]

Nil Known Allergies Reported [4]

- On the medication chart use the "*Nil Known*" tick box or write "*Nil known Allergies*" in the ADR box accompanied with the date of review, name and signature.
- In the patient's electronic medical record (PowerChart) the "*Nil known Allergies*" field should be selected (see Figure 1)

Figure 1: Electronic medical record (PowerChart) ADR Documentation



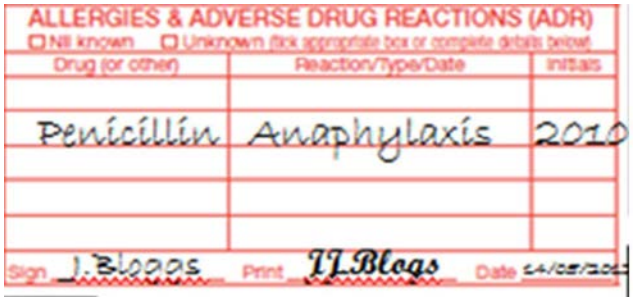
Patients with reported allergies[4]

ADRs should be recorded on the medication chart in line with Figure 2. This information should also be documented in the medical notes and the patient's electronic medical record (PowerChart) including:

- **Name of the drug** involved
- **Type** of reaction e.g. anaphylaxis, diarrhoea (see Appendix 1)
- **When** the reaction occurred.
  - If a reaction has occurred over 5 years ago, consider an immunology review of the patient's current allergy status.
- **Who** labelled the allergy/ADR (e.g. immunologist, GP, patient or carer)
- **Name and signature of the staff member documenting**.
- Where the reaction or date of reaction are not known this should be documented with the medication and the words "unknown" in the corresponding sections of the medication chart.
- Refer to Quickstart "Allergies - Viewing and Recording in PowerChart" for screen shots of how to document an allergy/ADR in the PowerChart.

Adverse Drug Reaction' stickers are available for use in hospitals to assist in the identification of patients with documented adverse drug reactions.

Figure 2: Sample ADR documentation for medication chart



Responsibilities

On admission a patient's ADR/allergy status must be confirmed and documented by the treating medical team.

Medical Staff will:

- Take a complete and accurate medication history
  - This may require more than one source of information including:
    - Referral letter
    - Previous admission
    - Patient and/or carer
    - SCH, CHW or local pharmacy dispensing systems
- Enter information about known ADRs in the patient's medical notes and the medication chart. See Documentation of ADRs in the medical notes and medication chart section above.
- Enter information about known ADRs into the electronic medical record (PowerChart), if not already entered.
- Assess whether the reason for admission relates to an ADR. If so, consideration should be made to report to the Therapeutic Goods Administration (TGA). See Reporting ADRs to the TGA section below.

All patients will have their medication histories reviewed at the nursing admission and by a pharmacist as part of the chart review process. Nurses and pharmacists have an important responsibility to ensure ADRs are documented and reviewed for accuracy and any supplementary information added if appropriate.

Nursing Staff will:

- Review the patient's medication history and add relevant information about ADRs to the health care record and medication chart.
- Place alert bands on patient's wrist if they have a known ADR.
- Enter information about known ADRs into an electronic alert system or electronic medical record (PowerChart), if not already entered.

Pharmacists will:

- Review the patient's medication history and add relevant information about ADRs to the health care record and medication chart.
- Enter information about known ADRs into an electronic alert system or patient's electronic medical record (PowerChart), if not already entered.
- Enter information about known ADRs into the pharmacy dispensing system.
- Assist Medical Staff with submission of reports to the TGA if necessary.

ADRs occurring during hospital admission

The patient's allergy and ADR history must be checked before prescribing, dispensing and administering a medication. Where this does not occur and the patient receives a medication which results in an ADR this is classified as an incident that **must** be reported through the NSW Health Incident Information Management System (IIMS).[3]

Assessment of ADRs

When an ADR occurs during admission, more extensive history and investigation may be needed to fully evaluate a suspected ADR. For some patients, a consultation with an immunologist or clinical pharmacologist may be sought to assist with evaluating causality, specific diagnosis and further management of a suspected ADR. Some cases may necessitate desensitisation under the management of immunology.[12, 13]

Causality[11]

The causality of a reported or suspected ADR (e.g. confirmed or definite, probable, possible, and unlikely) should be assessed to categorise each ADR with consideration of the following:

- Was there a temporal relationship between the onset of drug therapy and the adverse reaction?
- Was the drug withdrawn and if so what was the outcome?
- Can signs and symptoms of the adverse reaction be explained by the patient's disease state?
- Were there any laboratory tests that provide evidence for the reaction being an ADR?
- What was the patient's previous general experience with the drug?
- If rechallenged, did symptoms return when the agent was readministered?

Severity

The severity of a reported or suspected ADR (e.g. mild, moderate, severe, life threatening) should be assessed and documented.

Recommendations

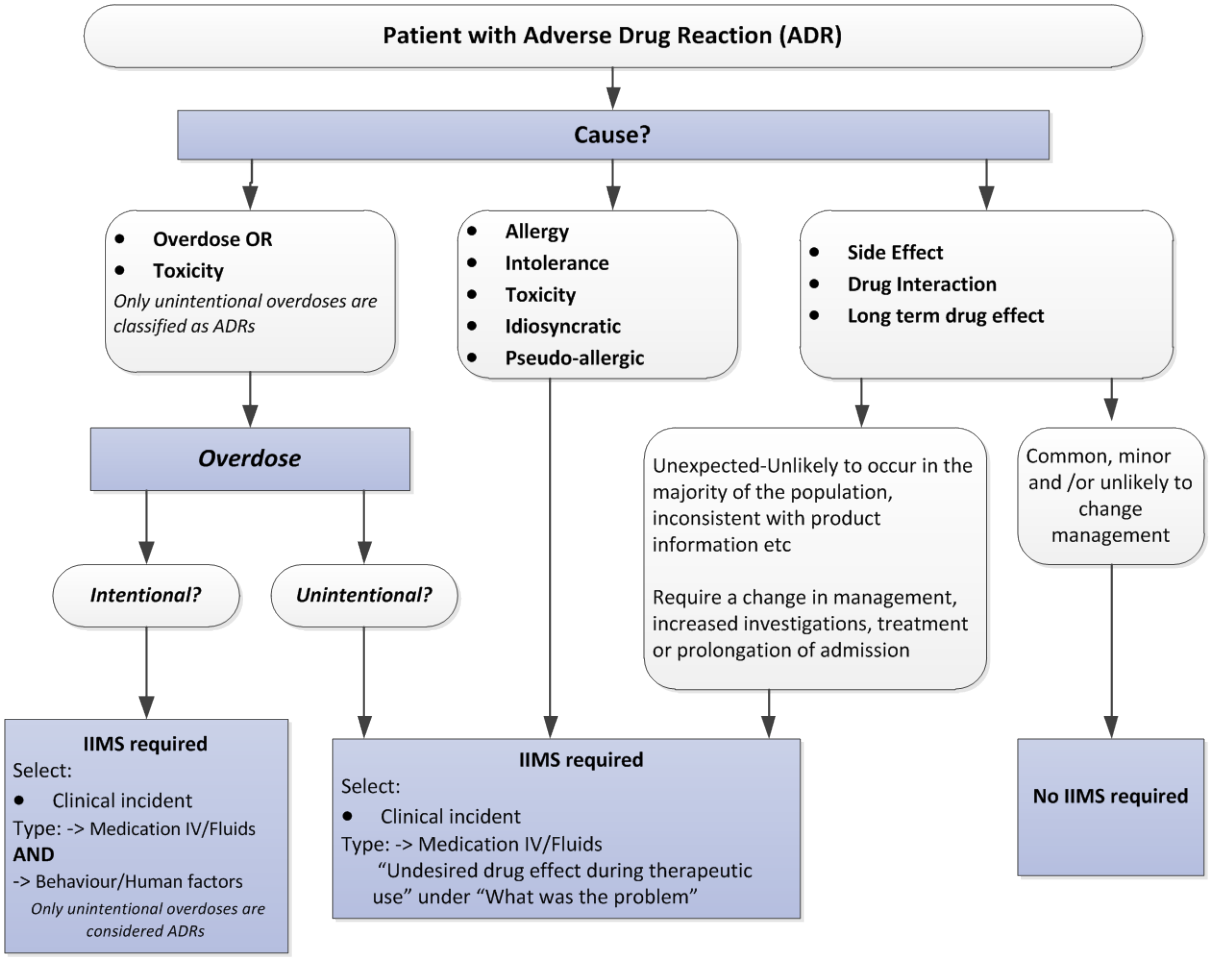
Patients and their carers should be provided with advice about avoidance and/or safe alternatives in a clear manner.[13] e.g. Avoid further use, use drugs with caution, under Immunology consultation only.

Reporting ADRs in IIMS

All Staff are responsible for notifying all incidents they identify using IIMS and encouraging colleagues to notify incidents identified.[3]

- Use agreed definitions of ADR and allergy for documentation and reporting.
- Report ADRs into IIMS according to terminology Appendix 1
- These are reviewed at the facility's Patient or Medication Safety Committee.

Figure 3: Decision making algorithm ADR entry into IIMS within SCHN



Medication Alert Card (MAC)

Detailed information should be documented in order to ensure a patient is not re-exposed to a drug that may cause harm.

Where possible a **MAC should be provided to the patients and their carers** documenting the drug name, type of reaction, date and level of verification (immunologist, GP, patient or carer) with action of this documented in the medical notes. See Appendix 2; example of a MAC

Responsibilities

Medical Staff will:

- Present information of suspected ADRs to their consultant. The consultant can then decide if further action is to be taken.
- Document the ADR and course of action in the patient's medical record and electronic medical record (PowerChart) (see Quickstart - Allergies).
- Document the ADR in the patients medication chart according to Documentation of ADRs in the medical notes and medication chart section above.

- Enter information about known ADRs into the patient's electronic medical record (PowerChart), if not already entered.
- Enter ADRs that occur during treatment into IIMS where necessary. See Reporting ADRs in IIMS section above.
- Notify all suspected ADRs to Pharmacy.
- Report reactions to the TGA via the blue card scheme where necessary with the assistance of pharmacy staff. See Reporting ADRs to the TGA section below.
- Discuss verified allergies/ADRs and their avoidance with patients and/or carers and give written advice e.g. future avoidance, risk with medications in the same pharmacological group. This process should be documented in the medical notes.

Nursing Staff will:

- Review the patient's medication history and add relevant information about ADRs to the health care record, including the medication chart and electronic medical record (PowerChart).
- Place alert bands on patient's wrist upon confirmation of the ADR.
- Enter ADRs that occur during treatment into IIMS if not already entered. See Reporting ADRs in IIMS section above.

Pharmacists will:

- Enter ADRs that occur during treatment into IIMS and PowerChart, if not already entered.
- Enter ADRs into the pharmacy dispensing system
- Update ADRs on any pharmacy specific forms e.g. Medication Reconciliation Form
- Assist medical staff in reporting to the TGA and provide an additional copy for collation and reporting at the SCH Medications Advisory Group and CHW Drug Committee.

Communicating ADRs upon discharge from hospital

Allergy and alert information are mandatory labels in referral reports to a patient's GP, specialist or community health clinician in order to prevent critical information being overlooked by omission.[7]

Responsibilities

Medical Staff Will:

- Communicate with GPs, relevant health professionals and families about verified allergies:
  - In discharge summaries according to Figure 4 Sample GP Summary. [7]
  - Use the Medicines Alert Card (**MAC**) to document the drug name, type of reaction, date and level of verification. See Appendix 2 for how to complete MAC and document actions in the medical notes.
  - On all discharge prescriptions

Figure 4: Sample required information for GP Summary[7]

No allergy: <No allergy flag> Adverse reaction: <adverse reaction type> to <allergen description> Reaction severity: <severity> Symptoms: <reaction description>

Pharmacy and nursing staff will ensure:

- Discharge prescriptions include any documented ADRs
- The PowerChart and IIMS are updated with documented ADRs
- Parents and caregivers have been provided with information and supporting documentation e.g. MAC

Pharmacists will:

- Update dispensing systems to reflect any ADRs
- Ensure TGA reporting has been completed ("blue card system" or MIMMS online)
- Ensure pharmacist specific documentation including medication reconciliation forms are updated with ADRs
- Compile ADRs for collation and reporting to the Sydney Children's Hospital Medication Advisory Group or CHW Medication Safety Committee and/or other relevant committees.

Reporting ADRs to the TGA [9,10]

The Advisory Committee on the Safety of Medicines (ACSOM) makes recommendations on the safety of medicines risk assessment and risk management of medicines.

All reports received by ACSOM are entered onto the Australian Adverse Drugs Reactions System which is then publicly accessible via the Database of Adverse Event Notifications (DAEN) and Medicines Safety Updates published in the Australian Prescriber and online to educate health professionals about adverse drug reactions and drug interactions.

The TGA requests reports of suspected adverse events to any medicine available in Australia, including: prescription medicines, vaccines, over-the-counter medicines that are purchased without a prescription, complementary medicines including herbal medicines, naturopathic or homeopathic preparations and nutritional supplements (e.g. vitamins and minerals).

ACSOM requests reports for:

- All suspected reactions to new medicines and vaccines (see drugs of current interest listed in the Medicines Safety Update)
- All suspected drug interactions
- Unexpected reactions, i.e. not consistent with product information or labelling
- Serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing:
    a) death or danger to life
    b) admission to hospital or prolongation of hospitalisation
    c) absence from productive activity
    d) increased investigations or treatment
    e) birth defects.

Reports should include the following information[9,10]:

- A patient identifier (such as initials, hospital record number, date of birth or age),
- Contact details for the reporter (name, address, telephone number),
- A description of the event,
- Medicines or vaccines suspected of causing the event,
- Any other medicines the patient was taking or vaccines administered,
- Date of onset of the adverse event,
- Date of starting and stopping the suspected medicines,
- Date of starting and stopping any other medicines,
- Details of how the adverse event was treated,
- The outcome of the event, and the date of the outcome.

If available, reporters are also asked to provide:

- Details of patient age and sex,
- Information about the patient's medical history,
- Relevant laboratory data (haematology, biochemistry, imaging, serology, biopsy, etc),

- For complementary medicines, AUST L number, which can be found on the medicine packaging,
- For vaccines and any problems thought to be related to a manufacturing fault, the batch number.

In cases where the outcome is death, the TGA requests information such as the circumstances, date and cause of death and a copy of any post-mortem examination or coroner's enquiry that may have been conducted.

Reports can be made to the TGA online through the Adverse Drug Reaction Reporting System, via “Blue Card” or MIMS Online. See the TGA website for links and information: http://www.tga.gov.au/safety/problem.htm#medicine

References

1. National Standards National Safety and Quality Health Service Standards September 2012 p39; Australian Commission on Safety and Quality in Health Care: http://www.safetyandquality.gov.au/publications/national-safety-and-quality-health-service-standards/ Accessed 01/07/2013
2. World Health Organisation Glossary Accessed online: http://www.who.int/medicines/areas/coordination/English_Glossary.pdf Accessed 02/07/2013
3. NSW Ministry of Health Incident Management Policy [PD2007_061]: http://www0.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_061.pdf Accessed 02/07/2013
4. Indicators for Quality Use of Medicines in Australian Hospitals: NSW Therapeutic Advisory Group, 2007: http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/QUMIndicators/Manual0408.pdf Accessed 01/07/2013
5. Reidl MA, Casillas AM. (2003). Adverse Drug reactions: types and treatment options. Am Fam Physician 68:1781-90.
6. Edwards IR, Aronson JK. (2000). Adverse drug reactions: definition, diagnosis and management. Lancet 356:1255-59.
7. NSW Ministry of Health Medical Discharge Referral Reporting Standard (MDRRS) [GL2006_015]: http://www0.health.nsw.gov.au/policies/gl/2006/pdf/GL2006_015.pdf Accessed 01/07/2013
8. NSW Ministry of Health Patient Safety and Clinical Quality Program [PD2005_608]: http://www0.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_608.pdf Accessed 01/07/2013
9. NSW Therapeutics Advisory Group (NSW TAG) Adverse Event Reporting: Frequently Asked Questions: http://www.ciap.health.nsw.gov.au/nswtag/pages/faq-adr-reporting.html Accessed 03/07/2013
10. Australian Government Department of Health and Ageing –Therapeutic Goods Administration : Reporting medicine and vaccine adverse events: http://www.tga.gov.au/safety/problem-medicine.htm [Last updated 17/01/2013] Accessed 8/07/2013
11. American Society of Health System Pharmacists(1995) ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting; Am J Health Sys Pharm; 52, 417-9
12. World Allergy Organization (2011) WAO White Book on Allergy 2011-2012: Executive Summary: http://www.worldallergy.org/UserFiles/file/WAO-White-Book-on-Allergy_web.pdf Accessed 05/07/2013
13. BMJ: Estelle F Simmons R (2013) Anaphylaxis: The acute episode and beyond BMJ 346: 602

Appendix 1: Categories of Adverse Drug Reactions

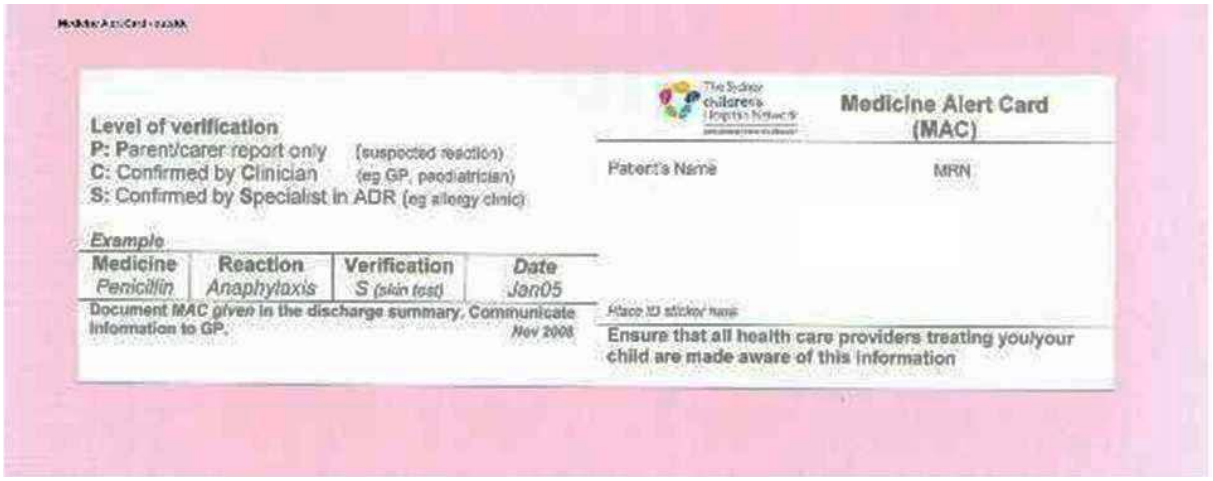
Category	Definition[5,6]	Examples
Allergy (Unpredictable)	Adverse reaction occurring in a susceptible patient involving an immunological mechanism	• *Penicillin anaphylaxis* • *Stevens-Johnson syndrome due to sulfonamide* • *Cefaclor serum-sickness like reaction*
Side effect (Predictable, dose-related)	Any unintended effect of a pharmaceutical product, occurring at doses normally used and is related to the pharmacological properties of a drug	• *Augmentin causing diarrhoea* • *Anticholinergic causing dry mouth* • *Cytotoxic causing nausea*
Drug interaction (Predictable, dose-related)	Interaction with another medicine causing variation in its metabolism or pharmacological effect. May increase or decrease a medicine's effects	• *Increased cyclosporin levels/toxicity with erythromycin* • *Decreased cyclosporin levels with concurrent carbamazepine*
Intolerance (Unpredictable)	A lower threshold to the normal pharmacologic action of a drug	• *Tinnitus after a single dose of aspirin*
Toxicity/overdose (Predictable, dose-related) *Only unintentional overdoses are classified as ADRs i.e. due to error*	Always dose-related and usually occurs by the same mechanism as the therapeutic effect	• *Morphine-induced sedation/respiratory depression* • *Paracetamol overdose causing liver toxicity* • *Seizure from excessive lignocaine*
Idiosyncratic (Unpredictable)	Adverse reaction occurring in susceptible patients. Mechanism usually unknown	• *Anticonvulsant hypersensitivity* • *Haemolytic anaemia due to Glucose-6-Phosphate dehydrogenase deficiency*
Other	**Pseudo-allergic** reaction (clinically resembling allergic reaction but mechanism not immunological)	• *Vancomycin red man syndrome* • *Ampicillin rash with viral illness (vs. true ampicillin allergy)* • *Morphine itch* • *Reaction to radio-contrast media*
	Long-term drug effects • chronic use • latent or delayed effects	• *Growth suppression secondary to chronic steroid use* • *Secondary malignancy after cancer chemotherapy*

Appendix 2: Medicine Alert Card (MAC)

Figure 5 Example of MAC

Double business card size, folds to single sized (not to scale).

Actual card from CHW or SCH may have slight variations.



Level of verification
P: Parent/carer report only (suspected reaction)
C: Confirmed by Clinician (eg GP, paediatrician)
S: Confirmed by Specialist in ADR (eg allergy clinic)

Medicine Alert Card (MAC)

Patient's Name MRN

Example

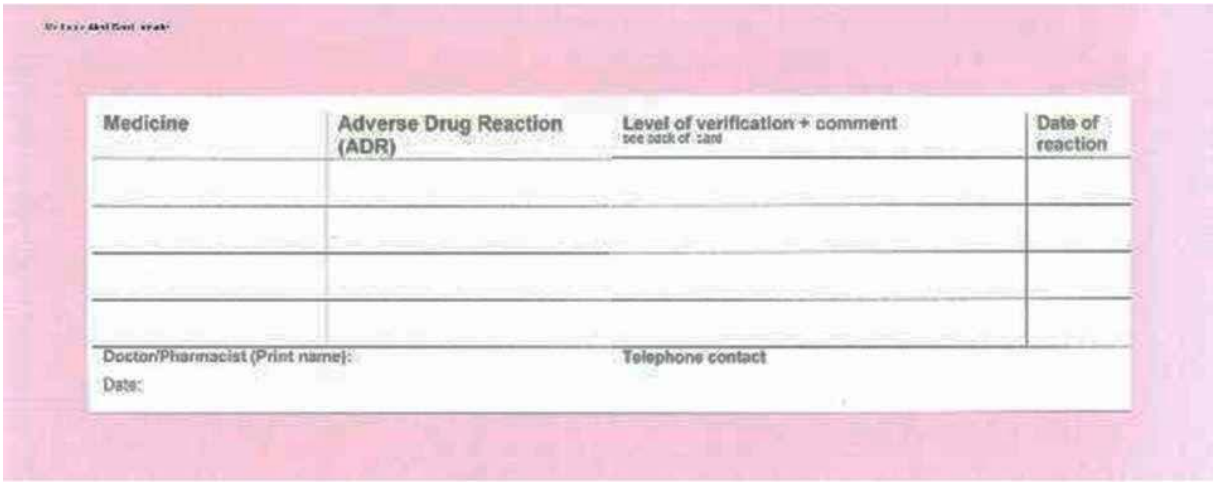
Medicine	Reaction	Verification	Date
Penicillin	Anaphylaxis	S (skin test)	Jan05

Document MAC given in the discharge summary. Communicate information to GP.

Nov 2008

Place ID sticker here

Ensure that all health care providers treating you/your child are made aware of this information



Medicine	Adverse Drug Reaction (ADR)	Level of verification + comment see back of card	Date of reaction

Doctor/Pharmacist (Print name): Telephone contact

Date: