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DRUG AND THERAPEUTICS NEWSLETTER

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In This Issue...

All formulary changes and policy/procedure updates have been approved by the Drugs and Therapeutics (D&T) Committee and Medical Advisory Council (MAC).

This and other Drug and Therapeutic Newsletters are on the Web at **www.vhpharmsci.com**

NEW ALLERGY/INTOLERANCE FORM

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Adverse drug reactions can affect 10-15% of all hospitalized patients and are the fourth leading cause of death in hospitalized patients in the US.[1] Allergic and non-immune mediated hypersensitivity reactions can represent up to 20% of all adverse drug reactions.[1] In hospital surveys, fatalities occur in 1 in 10,000 allergic drug reactions[2] To improve the documentation process and associated patient safety, a new form has been developed to document allergies or intolerance to drugs, latex, food and/or reactions to radiocontrast media.

Implementation of New Form

On February 7, 2005 the new allergy/ intolerance form will be introduced (Appendix 1) as a pilot in the Pre Admission Clinic (PAC). The form will, therefore, not be available on any patient care area but will be in the charts of patients admitted for elective surgery only from PAC. For these patients, any new adverse reactions determined to represent allergies or intolerances should be documented on the new form.

Expected Advantages of New Method of Documenting Allergy or Intolerance

1) More prominent document than existing allergy status form (pink slip).

2) Designated space to document description of reaction.

3) Allows chronology of reaction documentation.

4) Avoids inappropriately attributing a reaction to represent an allergy: allows subsequent assessment by physician and pharmacist.

5) Designated space for food, latex and radio-contrast reactions.

Pilot Phase in PAC

Surgeons will continue to document allergy information on the pink slip when patients are assessed in their office prior to the PAC visit. At the PAC visit, the nurse will review the allergy/ intolerance information with the patient and complete the new form. The nurse will remove the pink slip and place the new form at the front of the chart.

Only nursing staff in PAC can currently

document allergy/intolerance on this form - this role must be approved by the Medical Advisory Council. Physicians and pharmacists are also able to document allergy/intolerance history. All new reactions occurring during hospital admission must be documented by a physician.

Instructions on Completion of Form

1) The form must be faxed to pharmacy after initial completion and any subsequent update. This is essential to allow allergy/intolerance information to be entered into the Patient Care Information System (PCIS).

2) If allergy/intolerance status is unknown, future attempts should be made to obtain this information.

3) Reactions experienced or observed should be described with respect to:
   a) signs and symptoms
   b) time of onset following drug administration: e.g. < 1hr, < 24hr, 24-72hr, > 72hr
   c) type of intervention needed, if known. This is to allow assessment of severity of reaction.

4) Dermatologic features of reactions occurring in hospital that can be directly assessed by a physician should be fully defined e.g. urticaria, maculopapular rash vs. "skin rash".

Classification of Adverse Drug Reactions

Table 1. Classifcation of ADRs

Category	Type of Reaction
Hypersensitivity Reactions	Immune Medicated (allergy) Non-Immune Mediated
Non-Hypersensitivity Reactions	Side Effects Drug Intolerance Drug Interaction Drug Toxicity

Hypersensitivity Reactions

Allergic reactions are classified in Table 2. Understanding of the spectrum of observed allergic reactions should prompt the clinician to search for other organ system involvement in patients presenting with a dermatologic reaction.

Non-immune hypersensitivity reactions describe those that clinically resemble an allergy but the cause is not immune mediated e.g. direct release of mediators from mast cells due to opioids or radio-contrast agents. Non-immune hypersensitivity includes anaphylactoid (anaphylaxis-like) reactions caused by these agents.[2,3,5]

Table 2. Allergic Drug Reaction Classification[3]

Reaction Type	Symptoms
Type 1 (IgE mediated): Immediate (within 1hr) or accelerated (1-72 hrs)	Anaphylaxis: urticaria, angioedema, difficulty breathing, laryngoedema, hypotension, abdominal cramping, nausea/vomiting, respiratory failure, cardiac arrest
Type 2: Cytotoxic	Hemolytic anemia, granulocytopenia, thrombocytopenia
Type 3: Serum Sickness	Fever, lymphadenopathy, renal involvement
Type 4: Contact Dermatitis	Skin erythema, skin blistering
Other: Morbilliform Rash	 Maculopapular rash becoming confluent
Erythema Multiforme	Distinctive target lesions
Stevens Johnson Syndrome (Toxic Epidermal Necrolysis)	Target lesions, mucous membrane involvement, skin desquamation, renal failure
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)	Exfoliative dermatitis, fever, lymphadenopathy, eosinophilia, organ involvement (e.g. liver, kidney, lung,)

Non-Hypersensitivity Reactions

A side effect is any unintended effect of a drug occurring at therapeutic doses which is related to the pharmacological action of the drug. Side effects, depending on type and severity of the reaction and clinical context, do not necessarily preclude future use of the drug.

Drug intolerance is a side effect of drug

treatment that is experienced following administration of a low-dose of a drug or at the beginning of treatment with usual doses.[2,3,5]

Distinction Between Side Effect and Drug Allergy or Intolerance

Often expected side effects are wrongly attributed to represent allergy by patients. The full spectrum of allergic reactions are outlined in Table 2. Other symptoms would suggest a non-hypersensitivity reaction.

The distinction between drug intolerance and side effect is based on context of the dose and or timeline following drug initiation. Examples of drug intolerance would be: severe bradycardia with very low dose metoprolol, parkinsonism with initiation of metoclopramide. A report of isolated nausea and vomiting during opioid therapy can be interpreted as an expected side effect and should not necessarily preclude the future use of opiates.

Reactions to Radiocontrast Media

Radiocontrast media may cause the following reactions[6]:

1) Vasomotor: includes self-limited warmth, nausea and emesis
2) Vagal-type reactions: includes hypotension associated with bradycardia
3) Anaphylactoid (anaphylaxis-like) reactions

The new allergy/intolerance form prompts documentation of the type of procedure the patient was having and treatment needed (if any) for the reaction.

References

1. Demoly P et al. Classification and epidemiology of hypersensitivity drug reactions. Immunol Allergy Clin North Amer 2004;24:345-56.
2. DeShazo RD et al. Allergic reactions to drugs and biologic agents. JAMA 1997;278:1895-1906.
3. Volcheck GW. Clinical evaluation and management of drug hypersensitivity. Immunol Allergy Clin North Amer 2004;24:357-71.
4. Lieberman P. Anaphylaxis and anaphylactoid reactions. In: Middleton E. (ed). Allergy, Principles and Practice. 5th ed. St Louis,Mosby-Year Book 1998:1079-1093.
5. Gruchalla RS. Drug allergy. J Allergy Clin Immunol 2003;111: S548-59.
6. Hagan JB. Anaphylactoid and adverse reactions to radiocontrast agents. Immunol Allergy Clin North Amer 2004;24:507-19.

REPORTING ADVERSE DRUG REACTIONS

Adverse drug reactions (ADR) that should be reported include all suspected adverse drug reactions (ADRs) (including allergies or non-immune hypersensitivity) which are:

- unexpected, regardless of severity (i.e. not consistent with product information)
- serious, whether expected or not
- reactions to drugs on the market in Canada less than 5 years regardless of severity.

A serious ADR is defined as "a noxious and unintended response to a drug, which occurs at any dose and requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life threatening or results in death".[1]

A temporal or possible association is sufficient for a report to be made. The World Health Organization (WHO) defines possible association as: " a clinical event.., with a reasonable time sequence to administration of the drug, but which also could be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear".[1]

How to Report an Adverse Drug Reaction

Health professionals should obtain and complete the ADR Reporting Form form available from:

1) Canadian Compendium of Pharmaceuticals and Specialities (CPS)
2) http://www.hc-sc.gc.ca/hpfb-dgpsa
3) CSU Pharmaceutical Sciences

All completed ADR forms should be sent to the B.C. Regional ADR Centre (FAX: 604-806-8262). This Centre then forwards all reports to the Canadian ADR program in Ottawa who then forward them to the WHO.

Reference

1. World Health Organization, Uppsala Monitoring Centre. http//www.who-umc.org/defs

DANGEROUS ABBREVIATIONS

The Medication Safety Committee of Vancouver Acute published a list of high-risk abbreviations in their March 2003 bulletin (see VCH website at vcha.ca/policynet). Clear and safe order communication has been promoted in the past and many prescribers have already adopted good practices; however, further improvement is required in reducing the use of dangerous abbreviations. Representatives of the Drugs and Therapeutics Committees across Vancouver Coastal Health and Providence Health Care have identified three abbreviations that have the highest risk of causing patient harm.

1. Write out "units"

A "u" or "iu" (in the case of international units) can be easily misinterpreted as an additional 0 or 10.

e.g. NPH insulin 4U misread as 40 units

Considering the potential consequences of a 10-fold increase in the dosage of either insulin or heparin (both measured in units), "units" should always be spelled out to protect the patient.

2. Write out "daily"

Common abbreviations such as q.d. may be misinterpreted as q.i.d., resulting in a fourfold increase in the daily dose.

e.g. Methadone 40mg q.d. misread as 40mg q.i.d.

These potential errors can be easily avoided by writing out "daily".

3. Always precede a decimal point with a 0 and never add a trailing 0 unnecessarily.

Failing to follow either of these rules sets a patient up to receive a 10 or 100 fold increase in dosage over what was intended. There are numerous reported cases of inappropriate doses being administered with catastrophic consequences.

e.g. Warfarin .5mg misread as 5mg
Morphine 10.0mg misread as 100mg

This awareness campaign is the first step in adopting the recommendation made by the Institute for Safe Medication Practices (ISMP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that hospitals develop a standardized list of prohibited abbreviations, acronyms, and symbols.

PHARMACY AWARDS

The Awards Committee of the Canadian Society of Hospital has honoured several members of Pharmaceutical Sciences CSU with the following research awards:

- **Robert Balen, Pharm.D., Nilufar Partovi, Pharm.D., Peter Loewen, Pharm.D.**
  Baxa Award (Innovative Practitioner) and Bristol Myers Award (Clinical Pharmacy Program). Their research paper, co-authored with Sumit Raybardhan B.Sc. (Pharm) and Peter Jewesson is entitled "Implementation of a personal digital assistant-based drug-related problem documentation tool for pharmacy practice in a multi-site healthcare organization setting."

- **Karen Shalansky, Pharm.D.**
  Merck Frosst Award (Rational Drug Therapy). Her research paper, co-authored with Jacek Jastrzebski MD, FRCP (C), is entitled "Complete switch to darbepoetin in a hemodialysis unit".