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No sneezing matter – preventing harm from drug anaphylaxis and allergy

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Drug allergy and anaphylaxis

- 4.2 per 1,000 hospital patients have drug allergies
- 0.09 per 1,000 hospital admissions die from drug allergies
- Clinical Indemnity Scheme
 - error reports, especially co-amoxiclav or piperacillin-tazobactam in penicillin allergy
 - 27% of CIS medication-related claims, including four fatalities

Prescribing and Administration of Known Allergens

All enterprises indemnified by the Clinical Indemnity Scheme (CIS) are required to notify clinical incidents and near misses to the agency using the STARWeb system. During the period January 1, 2004 - December 31, 2010, a total of 35,510 events relating to medication safety were reported. 751 of these were categorised as "adverse/allergic reaction to a known allergen". Prescribing and/or administration of Augmentin* or Tazocin* in known penicillin allergy accounted for 149 of these events.

124 claims relating to medication safety were intimated during this period, of which 33 arose as a result of prescribing/administration of a known allergen, i.e. over one quarter of all medication-related claims. This led to fatalities in 4 patients, 2 of which were accounted for by administration of Penicillin containing products. A further number of patients experienced significant morbidity leading to admission to Intensive Care Units and increased length of stay in hospital.

Medication involved in Fatal Anaphylaxis

An analysis of fatal anaphylactic reactions to medication over a 10 year period in the United Kingdom¹ found anaesthetic agents, principally neuromuscular blockers, responsible for the largest number of deaths, followed by cephalosporins, penicillins and contrast media (Table 1). This study includes reactions to known and previously unknown allergens.

Drug Class	Number	Agents involved and numbers of fatalities
Anaesthetic	35	19 suxamethonium, 7 vecuronium, 7 ^{at induction} , 6 atracurium
Antibiotic	27	12 cephalosporin, 10 aminopenicillin, 2 amphotericin, 1 benzylpenicillin, 1 ciprofloxacin, 1 vancomycin
Other drugs	15	6 NSAIDs, 5 gelatins, 3 ACE inhibitors, 2 protamine, 2 vitamin K, 2 acetazolamide, 1 etoposide, 1 pethidine, 1 diamorphine, 1 streptokinase, 1 local anaesthetic
Contrast Media	11	9 iodinated, 1 technetium, 1 fluorescein

Table 1. Deaths caused by drug-related anaphylaxis in the UK between 1992 & 2001

How to reduce the risk

1. Ensure patients understand their allergies

Patients must be aware of the medication(s) to avoid and the nature of their reaction and carry this information with them, e.g. in a Medic-Alert bracelet or similar. Referral to an allergy clinic may be helpful, particularly where there is doubt as to which medication a patient is allergic to.

2. Check allergy status immediately before prescribing, dispensing or administering medication: Every drug, every patient, every time

Failure to consider allergies when prescribing, dispensing or administering medication is the crucial contributory factor to this error type. A shift in practice is needed to ensure allergy status is considered at the essential point, i.e. immediately before prescribing, dispensing or administering any medication. A known allergen was prescribed and/or administered, despite the allergy being documented on the front of the Prescription and Administration Record in 63 of 66 reported incidents/near misses in an Irish teaching hospital².

50% of doctors and pharmacists and 35% of nurses stated they would not always check the patient's allergy status before prescribing/administering/endorsing a new antibiotic to/for a patient with no documentation in the allergies section on the Prescription and Administration Record³. This highlights the key process

issue, i.e. allergies are not always considered at the essential point.

3. Check reliable references for cross-allergies

Lack of knowledge or information regarding cross-sensitivity, i.e. which medications are contra-indicated when an allergy is documented, is common among healthcare professionals.

19/30 doctors, 11/38 nurses and 18/18 pharmacists correctly identified Tazocin* from a list of medication as being contra-indicated in penicillin allergy⁴.

28/30 doctors, 19/38 nurses and 18/18 pharmacists correctly identified diclofenac to be contra-indicated in aspirin allergy⁵.

Referring to reliable drug references, e.g. British National Formulary or Summaries of Product Characteristics (product information) on www.imb.ie or www.medicines.ie is necessary.

4. Document/Record allergies to medication

Lack of availability/accessibility of reliable information regarding patient's allergy history at the point of prescribing, dispensing or administering medication can result in this error type. This may be due to the patient's record/documentation being inaccessible, incorrect or incomplete, or when the patient is not able to communicate or their knowledge is incorrect (e.g. state allergy to the wrong medication) or incomplete (e.g. unsure of nature of the reaction or to which medication).

The Drug Prescription and Administration Record and all prescription forms should include a section to document allergies/intolerances to medication.

The allergy section should always be completed, with the allergy or NKDA (No Known Drug Allergies) before prescribing and/or administering any medication.

Allergy wristbands are used in some hospitals as an extra warning that a patient has an allergy. They should act as a trigger to confirm the allergy status with the patient or to review the allergy history on the patient's chart. The efficacy of this strategy varies and care must be taken if implementing this to ensure that it has maximum impact and avoids the problems identified in many areas, e.g. failure to consider wristband warning when prescribing and administering known allergens, confusion with other wristband alerts, failure to apply wristbands, lack of clarity regarding responsibilities to apply wristbands.

5. Maximise the impact of computerised systems

Computerised prescribing systems can eliminate the risk of this error type, if they are configured to:

- Require the entry of allergies or NKDA (No Known Drug Allergies) before the first medication is prescribed.
- Cross-reference allergens with alerts to prescribers if an allergen is prescribed.
- Ensure that alerts cannot be overridden, or that they can be overridden only if the allergy status is updated (e.g. if documented allergy status was incorrect).

However, if systems are not configured in this way, healthcare professionals may rely on them to prevent the errors with known allergens and an error may therefore not be intercepted by the computerised system.

6. Treatment of anaphylaxis

Rapid diagnosis and evidence-based treatment of allergies and anaphylaxis can minimise the impact on the patient. Anaphylaxis to medication can be rapidly fatal. Analysis of fatal anaphylactic reactions⁶ included 21 patients who suffered reactions to drugs. They found anaphylaxis

occurred a median of 5 minutes following contact with the drug (range 1-120 minutes), with immediate deaths in 10 and delayed deaths in 11. Shock without respiratory compromise occurred in 12 of the 21 drug-related anaphylactic deaths. Pulmonary oedema was present at post-mortem in 18 of 21 deaths, but in many cases of fatal anaphylaxis, no specific findings are present at post-mortem.

- Ensure that treatment guidelines are accessible, clear and that healthcare professionals are trained in their use.
- Ensure that facilities for the treatment of anaphylaxis (including availability of oxygen, adrenaline for intramuscular injection, chlorphenamine, hydrocortisone and intravenous fluids) are available in all areas that medication is administered.

Is it a "True" Allergy?

Occasionally, a patient may believe that they have an allergy or intolerance, but the history is inconsistent with this. Healthcare professionals may be faced with a dilemma, as using the medication may risk a serious or fatal adverse reaction or anaphylaxis, while avoiding the medication unnecessarily may lead to the use of more expensive and less effective drugs. In this circumstance, healthcare professionals must ensure that medication is not prescribed, dispensed or administered unless the following process is followed:

- The allergy or intolerance has been ruled out (this may include allergy testing where available).
- A discussion has taken place with the patient detailing the risks and benefits of proposed treatments and alternatives.
- The patient expressly agrees to receiving treatment with the proposed medication.
- The discussion with the patient and

risk/benefit consideration is documented in the Healthcare Record.

- All documentation of the allergy is amended to indicate the patient's true status.
- The patient (and/or parents, carers) and healthcare professionals providing care to them (e.g. GP, nursing home, hospital) are informed of the updated information.

Further Information

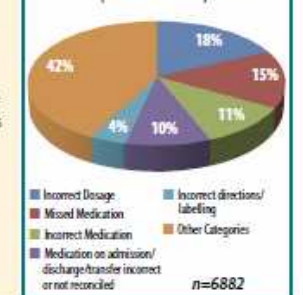
The Irish Medication Safety Network is preparing 'Best Practice Guidelines for Reducing Preventable Harm to Patients with Known Drug Allergies in Irish Hospitals', which will be available shortly on their website, www.imsn.ie

References

- Pumphrey R. Anaphylaxis: can we tell who is at risk of a fatal reaction? *Curr Opin Allergy Clin Immunol* 2004; 4 (4):285-90
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- Pumphrey RSH, Roberts ISD. Post-mortem findings after fatal anaphylactic reactions. *J Clin Pathol* 2000; 53:273-276.

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Medication Events reported to the State Claims Agency (Jan - Dec 2010)



Safety Alert

Allergy and Anaphylaxis to Known Drug Allergens

Issue

Serious allergic and anaphylactic reactions can occur when known drug allergens are prescribed, dispensed and administered to patients. This harm is preventable. Rapid recognition and treatment of drug allergy is essential. Anaphylaxis to drugs begins and progresses rapidly. The most common sign is severe hypotension +/- tachycardia. Extreme anxiety, agitation and gastrointestinal disturbance are also common. Respiratory and skin signs may be absent. The most common causes of fatal drug anaphylaxis are neuromuscular blockers, cephalosporins, contrast media, penicillins and NSAIDs¹.

Evidence of Harm

Over one-quarter of all medication-related claims intimated to the Clinical Indemnity Scheme from January 2004-December 2010 arose as a result of a known allergen being prescribed / administered. Four patients died as a result of these errors, with others experiencing significant morbidity².

How to Reduce the Risk

1. Check allergy status immediately before prescribing, dispensing or administering drugs:

Every drug, every patient, every time.

- Documentation must be referred to if it is to be effective. However, the allergy was documented on the front of the drug chart in 63 of 66 reported incidents where known drug allergens were prescribed in an Irish hospital³.
 - 50% of hospital doctors, 50% of pharmacists and 35% of nurses stated they did not always check allergy status before prescribing/administering/endorsing a new antibiotic in an Irish hospital staff survey⁴.
2. **Understand cross-allergies:** Use reliable references to check which drugs are contra-indicated. 27% of doctors and 70% of nurses were unable to identify Tazocin® as contra-indicated in penicillin allergy⁴.
 3. **Ensure patients understand their allergies:** which drug(s) to avoid and the nature of their reaction. Referral to an allergist/immunologist may be required where there is difficulty determining the drug allergen.
 4. **Ensure drug allergies are clearly documented** at the point of drug use (Drug Chart and all other prescription forms) before any drug is prescribed or administered. Document the drug/drug class and nature of the reaction.
 5. **Maximise the impact of computerised prescribing**, where available:
 - a. Require input of allergies or NKDA (No Known Drug Allergies) before the first prescription.
 - b. The system should generate automated alerts to prescribers if an allergen is selected.
 - c. Ensure that alerts for contra-indicated allergens cannot be overridden without amending the allergy status.
 6. **Configure healthcare databases to allow recording of allergy information.** Clarify who is responsible for completing this step. Ensure that allergy information automatically displays on any documents/screens which may be referred to during medication-related processes.
 7. **Ensure that guidelines and facilities for diagnosis, treatment and follow up of allergies and anaphylaxis** are accessible, clear and that healthcare professionals are trained in their use.

See Briefing Document: on www.imsn.ie for further information.

References: 1. Pumphrey, RS. Anaphylaxis: Can we tell who is at risk of a fatal reaction? *Curr Opin Allergy Clin Immunol*, 2004; 4 (4)
 2. Clinical Indemnity Scheme Newsletter, March 2011
 3. Personal communication, IMSN member, 2010
 4. Morris, C, Gowing C, Seolghie A, Kirke C. Hospital Pharmacists' Association of Ireland Annual Educational Meeting, April 2008

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Briefing Document: Reducing Preventable Harm to Patients with Known Drug Allergies

This document is intended as a briefing document and is not to be regarded as a document offering definitive legal advice in relation to the subject matter

Reducing preventable harm

1. Recognise and treat drug anaphylaxis rapidly and correctly
2. Knowledgeable patients
3. Check drug allergy status immediately before prescribing or administering, with IT if possible
4. Understand cross-allergies
5. Documentation and use of IT

Drug anaphylaxis

Drug anaphylaxis

- Begins and progresses rapidly.
 - Onset median 5 minutes (1-120 mins)
 - Immediate death in 10/21
- Cardiovascular: Severe hypotension +/- tachycardia
 - Shock without respiratory compromise in 12/21 drug-related anaphylaxis deaths
- Other: Extreme anxiety, agitation +/- GI disturbance common
- +/- Respiratory +/- skin signs


Fatal drug anaphylaxis

- Most fatalities in theatre
 - Neuromuscular blockers/at induction (35),
 - Cephalosporins (12)
 - Contrast (11)
 - Penicillins (11)
 - NSAIDs (6)
 - Gelatins (5)
 - ACE inhibitors (3)
- Fatal reaction first in 84%

Avoiding known allergens

Knowledgeable patients

- Drug(s) to avoid
- Nature of reaction
- What to do if occurs

	<p>Allergy Alert Card See www.imsn.ie for more info</p>	<p>Allergies:</p>			
	<p>Name: Date of Birth: Address: Tel: Next of kin: Tel: GP:</p>	<table border="1"> <thead> <tr> <th data-bbox="1136 980 1318 997">Drugs</th> <th data-bbox="1325 980 1661 997">Reaction, when, where</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table> <p>Source of Information: Date Signed: Contact details:</p>	Drugs	Reaction, when, where	
Drugs	Reaction, when, where				

Check drug allergy status

- Check drug allergy status immediately before
 - Prescribing
 - Administering
 - Dispensing drugs
- Every patient, every drug, every time

Cross-allergies

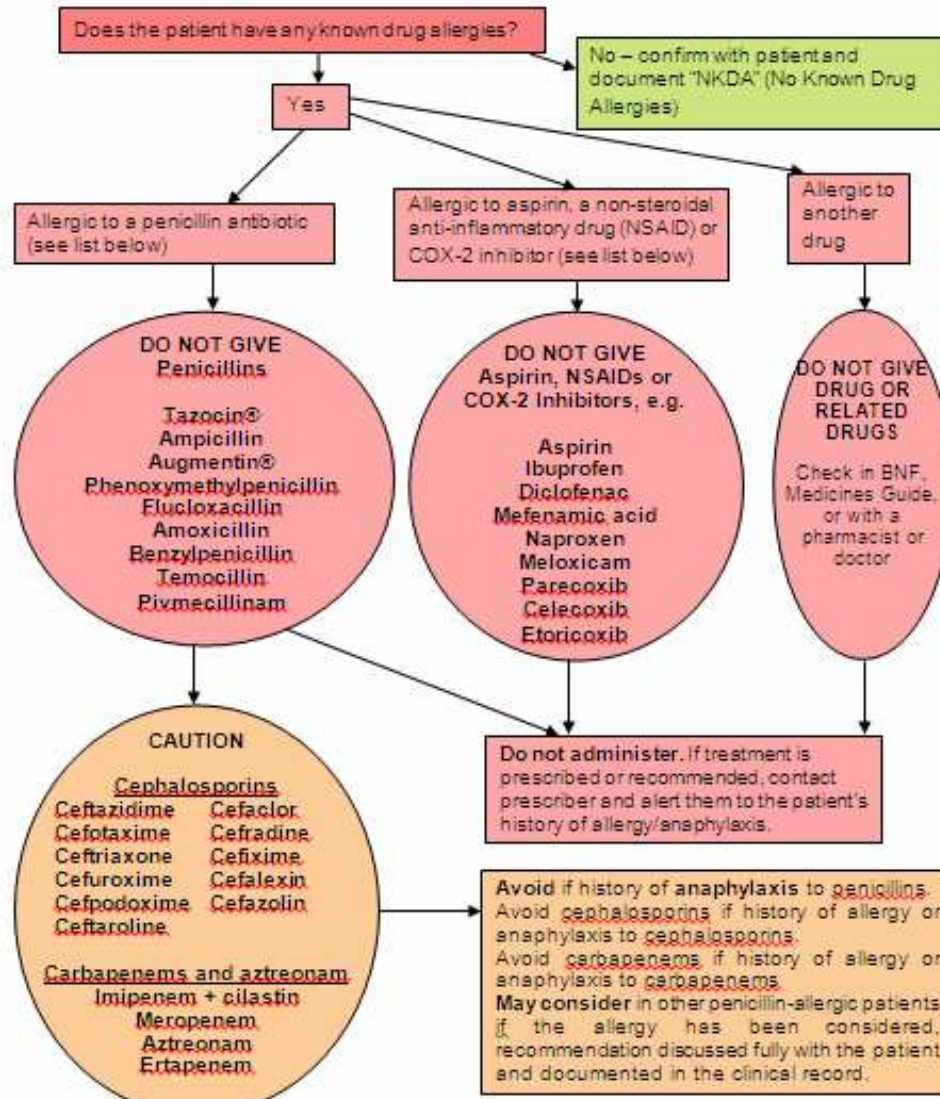
- Ensure patients and staff understand cross-allergies
- Reliable references – check for “hypersensitivity to...” in contra-indications section
- Allergist/immunologist if unclear which drug patient allergic to, or future management (e.g. anaesthesia)



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ALWAYS CHECK FOR ALLERGIES BEFORE PRESCRIBING/ADMINISTERING



Documenting

- At the point of medication use
 - Drug chart
 - Prescriptions
- Drug/class, nature
- Update, Transfer
- But known allergens prescribed +/- administered despite documentation on front of drug chart in 63/66 incidents

Maximise effectiveness of IT

- Prescribing
 - Require allergy status before first prescription
 - Automated alert if allergen selected
 - Cannot override without amending allergy status
- Other systems
 - Configure to record and display allergies

Management of allergies

- Clear, accessible guidelines
- Facilities
- Staff education/information
 - Diagnosis
 - Treatment
 - Follow up

Other measures

- Purchasing for safety
 - “Contains penicillin”
- Measurement & Improvement
 - Incident reporting, analysis
 - Process, e.g. nursing audit
 - Documentation completion rate

Is the patient truly allergic?

Is the patient truly allergic?

- Type 1 IgE-mediated reactions
 - Usually rapid onset
 - Anaphylaxis or milder
 - Contra-indication to challenge
- Type 4 T cell-mediated reactions
 - Slower onset (days), usually skin only
 - Rarely, Stevens-Johnson Syndrome/ TEN
- Non-immune mediated anaphylactoid
 - Mild to life-threatening
 - No previous sensitisation needed, may not recur

Rechallenge?

- Do not prescribe, dispense or administer unless
 - Allergy/ adverse drug reaction outruled or very unlikely
 - Discussion with patient detailing risks and benefits of proposed drug(s) and alternatives
 - Express patient agreement
 - Documented discussion and agreement
 - Pre-medication if appropriate
 - Close monitoring and full facilities
- Rechallenge with no adverse effect
 - Patient understanding, update all records of allergy status

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