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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

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About the IMSN

The Irish Medication Safety Network (IMSN) is an independent group of pharmacists and other specialists working in the acute sector, whose principal aim is to improve patient safety with regard to the use of medicines through collaboration, shared learning and action.

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Summary

Harm from drug allergies

Serious allergic and anaphylactic reactions can occur when known drug allergens are prescribed, dispensed and administered to patients in hospitals and the community. This harm is preventable.

Anaphylaxis to drugs begins and progresses rapidly. The most common sign is severe, persistent 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 NSAIDs.

How harm occurs

The most common contributory factors to medication error with known drug allergens are:

1. Failure to consider allergies when prescribing, dispensing or administering drugs.
2. Lack of knowledge or information regarding cross-sensitivity, i.e. which drugs are contra-indicated or to be used with caution when an allergy is documented.
3. Lack of availability / accessibility of reliable information regarding a patient's allergy history at the point of prescribing, dispensing or administering drugs.
4. Assuming that a computerised prescribing system will prevent the prescribing of known allergens when the system is not configured to do so.
5. Failure to recognise, or delay in recognising, drug allergy when it occurs.

How to reduce the risk

1. **Check drug allergy status** immediately before prescribing, dispensing or administering drugs: Every drug, every patient, every time.
2. **Ensure staff understand cross-allergies:** use reliable references to check which drugs are contra-indicated or may be used with caution with particular allergies.
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 medication use (Drug Chart and all other prescription forms). Design documentation to highlight the drug / drug class and nature of the reaction. Ensure information is updated as clinical events dictate (e.g. change in allergy status) and accurately transferred through documentation.
5. **Maximise the impact of computerised prescribing:**
   a. Require input of allergy status 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**
   Request allergy information when registering a patient episode. 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 process.

7. Ensure that guidelines and facilities for the **diagnosis, treatment and follow up of allergies and anaphylaxis** are accessible, clear and that healthcare professionals are trained in their use.

8. **Purchasing for safety**
   Evaluate the prominence of information about drug class on the packaging, Patient Information Leaflets and Summaries of Product Characteristics when purchasing products with high allergy potential, e.g. “Contains penicillin”.

9. **Audit and Review**
   Allergy-related incidents and near misses should be reported according to local and national requirements and analysed locally for potential focus for improvement. Consider incorporating allergy-related parameters in local audit programmes to monitor progress with specific targets for improvement, e.g. allergy documentation rates.

The Problem

Hypersensitivity drug reactions are responsible for significant morbidity, mortality and socioeconomic costs[1]. It has been estimated that 4.2 per 1,000 hospital patients have drug allergies[2]. Mortality from allergic drug reactions in hospital is approximately 0.09 per 1,000-hospital admissions[2]. Nearly 80 per cent of emergency department visits for antibiotic-associated adverse events were the result of allergic reactions.[3]

While serious allergic or anaphylactic reactions may occur to drugs a patient has previously tolerated, serious and preventable harm to patients can occur when known allergens are prescribed, dispensed and/or administered. Reducing preventable harm to patients with a known allergy to a drug is one of the seven priorities for action identified by the UK's National Patient Safety Agency.[4]

A UK analysis of 88 deaths caused by drug anaphylaxis over a 10 year period found neuromuscular blocking agents and anaesthetics to be responsible for the largest number of deaths (40%), followed by cephalosporins (14%), contrast media (13%) and penicillins (13%)[5,6].

An analysis of fatal anaphylactic reactions[6] included 21 patients who suffered reactions to drugs or contrast media. 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 were present at post-mortem.

Food allergies may also be relevant to drug allergies as food constituents may often be found as components of various drug formulations e.g. egg (vaccines), peanuts (arachis oil) and sulphites[7].

The Clinical Indemnity Scheme (CIS) received 751 reports of "adverse/ allergic reaction to a known allergen" from indemnified enterprises from January 1, 2004 - December 31, 2010[8], 2% of the overall total of medication events reported. Prescribing and/or administration of co-amoxiclav (Augmentin®) or piperacillin-tazobactam (Tazocin®) in known penicillin allergy accounted for 149 (20%) of these events.[8]

124 medication-related claims were intimated to the CIS during the same period, of which 33 (27%) arose as a result of prescribing/administration of a known allergen, i.e. over one quarter of all medication-related claims. They included four fatalities and significant morbidity, ICU admissions and increased length of stay in a further number of patients[7].

Examples

Anaphylaxis to cisatracurium in theatre with previous anaphylaxis to atracurium (UK)

A patient suffered serious bronchospasm in theatre in 1999 following injection of cisatracurium, resulting in permanent injury. The patient had a previous similar reaction in 1995 to atracurium. The court found that the first reaction should have been investigated fully and, if it had been, should have prevented the second reaction[9].

Anaphylaxis to trimethoprim with previous allergy to trimethoprim/sulfamethoxazole (Septrin®) (UK)

The antibiotic trimethoprim was prescribed and administered to a patient documented on the prescription sheet as being allergic to 'Septrin®' – this is a combination product which contains trimethoprim and sulfamethoxazole. The patient collapsed and arrested, entering into ventricular fibrillation and required defibrillation. Anaphylactic shock was given as a probable diagnosis. The patient suffered severe harm[10].

How it occurs

The following have been identified as key contributory factors in the literature and from analysis of incidents and near misses occurring in Irish hospitals[11].

1. Failure to consider allergies when prescribing, administering or dispensing drugs.

An analysis of medication errors in an Irish teaching hospital found that known allergens were prescribed and/or administered in spite of the allergy being documented on the front of the Drug Chart in 63 of 66 reports[12].

Only 50% of doctors and pharmacists and 65% of nurses stated they would always check the patient's allergy status before prescribing/ administering/ endorsing a new antibiotic where there was no documentation in the allergies section on the Drug Chart[13]. This highlights the key process issue, i.e. allergies are not always considered at the essential point, despite local policies and guidance from professional bodies (e.g. An Bord Altranais[14] and Pharmaceutical Society of Ireland[15]).

2. Lack of knowledge or information

Healthcare professionals may not be aware which drugs are contra-indicated or are to be used with caution in patients with a given allergy. This applies in particular to classes of drugs which may exhibit cross-sensitivity. In a survey in an Irish teaching hospital[13]:

- 37% of doctors and 71% of nurses did not correctly identify Tazocin® as being contraindicated in penicillin allergy.
- 7% of doctors and 50% of nurses did not correctly identify diclofenac as being contraindicated in aspirin allergy.

There are over 7,000 human medicinal products presently authorised by the Irish Medicines Board for use in this country[16]
Healthcare professionals may not be familiar with a particular brand name or know which class a drug belongs to.

3. Documentation and Communication

Lack of availability of reliable information regarding patient's allergy history at the point of prescribing, administering or dispensing can contribute to this error type. For example, the patient's record or documentation may not be accessible or may be incorrect or incomplete. The patient and/or carer's knowledge of their allergies may be incorrect, incomplete or unclear or there may be communication difficulties.

4. Computerised systems

Lack of availability or use of electronic prescribing, poor configuration of electronic prescribing systems or reliance on systems which are poorly designed to intercept errors, can contribute to the prescribing of known allergens[17].

5. Misclassification

The common use of the term 'allergy' and inadequate patient understanding and education regarding their reactions to drugs may result in misclassification of a non-allergic adverse drug reaction e.g. diarrhoea as a true drug allergy e.g. angioedema. This may result in a reduced range of potential treatment options for a patient and may lead to the use of more expensive and less effective drugs[18].

It is important that the exact nature of an adverse drug reaction is established and documented and that there is a facility to document all types of reactions.

It is critical that a careful process is followed where the patient believes they have an allergy or ADR, but the history is inconsistent with this. See Recommendations section for this process. See appendix 2 for a template for allergy history taking.

6. Problems with recognition and treatment of allergies and anaphylaxis

The recognition and diagnosis of allergy and anaphylaxis can be challenging. Life-threatening anaphylaxis frequently presents with cardiovascular collapse as the only symptom[6]. Severe, persistent hypotension +/- tachycardia are the major signs and respiratory and skin signs may be absent[6] Extreme anxiety, agitation and gastrointestinal disturbance are also common[19,20]. See Appendix 1.

Failure to have and/or to follow guidelines for the treatment of allergies or anaphylaxis appropriately and errors in treatment, particularly involving adrenaline[20] can also contribute to patient harm.

How to Reduce the Risk of Medication Error with Known Allergens - Recommendations

1. Check allergy status immediately before prescribing, dispensing or administering drugs: every drug, every patient, every time.

Allergy status should be available at the point of drug use, i.e. the patient and/or the front of the Drug Chart should be the primary sources consulted for in-patients. If information is not available from the primary sources, other sources may need to be consulted, e.g. carers/family members, Healthcare Record, GP records, community pharmacy, nursing home.

2. Understand cross-allergies

Healthcare professionals must have a clear understanding of cross-sensitivities. Some drug classes may be contra-indicated in particular allergies, while others may be used with caution.

Check reliable references such as the British National Formulary (BNF)[7] - check 'Contra-Indications' and 'Cautions' sections for entry stating "Hypersensitivity to x" - or product literature - Summary of Product Characteristics (SPC) available on www.medicines.ie or www.imb.ie for cross-allergies.

Traffic-light posters have been developed in some organisations to highlight some cross-allergies (See example in Appendix 3). For example:

- Patients allergic to aspirin or another NSAID (non-steroidal anti-inflammatory drug) should usually not be given aspirin or any other NSAID.

- Patients with a history of hypersensitivity or true allergy to penicillins should not be given any penicillin antibiotics, e.g. co-amoxiclav (Augmentin®) Patients with a history of hypersensitivity or true allergy to cephalosporins should not be given any cephalosporin antibiotics.

- 0.5 - 6.5% of penicillin-allergic patients will also be allergic to cephalosporins.[7] Local policy should guide management of patients with allergies to penicillins in whom therapy with cephalosporins is indicated. In general, patients with a history of immediate hypersensitivity to penicillins should not receive a cephalosporin[7]. If a cephalosporin is essential in these patients, then third generation cephalosporins such as cefixime, cefotaxime, ceftazidime, ceftriaxone or the second-generation cephalosporin cefuroxime may be used with caution. First-generation cephalosporins such as cefaclor, cefalexin, cefradine and cefadroxil should be avoided. [7]

- Anaphylactic reactions to contrast media are more common in patients with a history of asthma, or history of allergies (e.g. food, medication, hay fever) [21].
  A patient who has a reaction to contrast may not react on subsequent exposure. A risk-benefit decision should be made with the patient if they have a history of asthma, allergy or anaphylactic reaction to contrast, with pre-treatment if necessary[21].

3. Patient Education

Patients need to have a clear understanding of which drugs(s) to avoid and the nature of their reaction in order to empower them to avoid the culprit drugs in future.[22] The patient is the one constant factor irrespective of where healthcare is delivered (e.g. patient's home, GP surgery, hospital out-patient department, dentist). See further details under 'Diagnosis, treatment and follow-up of allergies and anaphylaxis' below.

4. Allergy History Taking & Documentation

The aim of allergy/adverse drug reaction history taking and documentation is to determine:
- the drug(s) and drug class(es) the patient has reacted to previously,
- the nature of the reaction(s),

in order to help determine the most appropriate drug therapy for that patient subsequently, i.e. which drugs are contra-indicated and which may be used with caution.

See flow chart in Appendix 2.

a. All Drug Charts and prescription forms should include a section to document allergies and adverse drug reactions to drugs, which is clearly defined and highlighted, preferably on the front of the Drug Chart. It should contain sections for at least the following:

   - Drug name / drug class
   - Nature of reaction
   - Signature of the healthcare professional documenting the reaction
   - Date of documentation

b. The allergy/s section of the Drug Chart should always be completed before prescribing and/or administering any drugs. Responsibilities for taking and documenting the allergy history should be specified in local policy. Documentation should be updated in the case of a new allergic or adverse drug reaction, e.g. to contrast media.

c. Allergy status should be documented on the pharmacy computer system, Patient Medication Record (PMR) [14] and all other computerised systems, where possible and where appropriate.

d. Allergies and adverse drug reactions should be documented on all out-patient and discharge prescriptions as well as on the patient discharge summary which is sent to the GP. Allergy to contrast media should be documented on the GP Radiology report for ambulatory day patients so that the GP can communicate this information onwards if referring the patient for another examination elsewhere.

e. The HSE Code of Practice for Healthcare Records Management[23] requires recording of "Allergies/ Alerts or Adverse Drug Reactions" on the inside front cover of the Healthcare Record.

f. Specific patient identification bands or allergy bracelets may be used by health care organisations to denote patients with a drug allergy. However, it must be noted that the presence of such a band will not prevent a known allergen being prescribed or dispensed to a patient and may have limited effect on whether a known allergen is administered to a patient. Likewise over-dependence on such a system may result in a greater chance of error where a patient has not been given this identifier or has removed it[24,]

g. Where the patient believes they have an allergy or experienced an ADR to a medication, but the history is inconsistent with this, ensure the drug is not prescribed, dispensed or administered unless:

- The allergy or ADR has been out-ruled or is thought to be very unlikely. Rarely, allergy testing or desensitisation may be required for a limited patient group under expert immunology guidance.
- 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 drugs.
- The discussion with the patient and risk / benefit consideration is documented in the Clinical Record.
- Pre-medication is considered if appropriate.
- The re-challenge is carried out with close monitoring of the patient and appropriate facilities available should a reaction occur, e.g. im adrenaline, oxygen etc.

If a patient no longer exhibits an allergic reaction on re-challenge, their allergy status should be updated appropriately on all relevant documentation and the patient clearly counselled that they are not allergic to the agent.

5. Maximise the impact of computerised prescribing

Ensure computerised prescribing systems are configured to:

i. Require the entry of an allergy/allergies, previous adverse drug reaction(s) or NKDA before the first drug is prescribed. The drug/drug class and the nature of the reaction should be documented.
ii. Drugs should be selected from a drug database to avoid misspelling. The drug database should link all drugs to a drug class.
iii. Alert prescribers if an attempt to prescribe an allergen is made.
iv. Ensure that alerts contra-indicating drugs cannot be overridden without amending the allergy status. Alerts cautioning a drug e.g. cephalosporins in penicillin allergy, may be overridden if a risk-benefit decision has been made and the reason for prescribing the drug is documented.

v. It should be possible to update the allergy/adverse drug reaction for new reactions or where the allergy/reaction has been excluded. A history of previous entries should be retained.

6. Configure healthcare databases to allow recording of allergy information

Configure healthcare databases to request allergy information when registering a patient episode. 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 process.

7. Diagnosis, treatment and follow-up of allergies and anaphylaxis

Healthcare professionals need to have a clear understanding of the types of allergy (see appendix 1) and the diagnosis, treatment and follow-up of patients with allergies and anaphylaxis.

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

Where an allergy is identified during the hospital admission, it is recommended that the facility has a locally agreed procedure, which includes the following:

- Diagnosis and treatment of allergies and anaphylaxis (a medical emergency).
  Include advice to continue anti-histamines and/or steroid therapy for 72 hours, to suppress delayed or biphasic allergic reactions.
- Follow-up of patients suffering allergies and anaphylaxis, including:
  - Roles and responsibilities for patient counselling, which may include advice on accessing and using MedicAlert or similar bracelets, 'Personal Information Packs' (available from community[25]) or Allergy Alert cards (See example in Appendix 4).
  - Circumstances where referral to an allergy clinic/immunologist is appropriate and details of how and to whom to refer patients.
- Documentation in prominent position in the patient's Clinical Record and Drug Chart that an allergy/anaphylaxis has occurred, the type of reaction and the suspected / proven cause.
- Documentation of patient education and advice given.
- Communication of allergic reaction to other healthcare providers, in particular the patient's GP or extended care facility, if applicable.

8. Purchasing for safety

- Evaluate the prominence of information about drug class on product packaging when purchasing products with high allergy potential, e.g. "Contains penicillin", "Do not take if you are allergic to aspirin or to any other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)".

- Evaluate the clarity of information about allergy potential in Patient Information Leaflets and Summaries of Product Characteristics.

9. Audit and Review

All medication incidents and near misses which involve allergy and/or anaphylaxis should be recorded, reported and dealt with according to local and national requirements, e.g.

- Local medication safety incident reporting,
- Reporting to the Irish Medicines Board[26], where indicated, in accordance with their guidance
- Reporting to the Clinical Indemnity Scheme for indemnified hospitals.

It is recommended that these incidents and near misses are regularly reviewed to monitor for trends to identify potential focus for corrective action[27,28].

Consider incorporating allergy-related parameters in local audit programmes to monitor progress with specific targets for improvement, e.g. allergy documentation rates.

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Glossary of Abbreviations

ACE	Angiotensin Converting Enzyme
ADR	Adverse Drug Reaction
BNF	British National Formulary
CIS	Clinical Indemnity Scheme
IMB	Irish Medicines Board
IMSN	Irish Medication Safety Network
IV	Intravenous
NHS	National Health Service (UK)
NKDA	No Known Drug Allergies
NPSA	National Patient Safety Agency (UK)
NSAIDs	Non Steroidal Anti- Inflammatory Drugs
PIP	Personal Information Pack
PMR	Patient Medication Record
SPC	Summary of Product Characteristics
WHO	World Health Organisation

Appendix 1: Classification of Allergy

A **drug allergy** is a state of hypersensitivity induced by exposure to a particular drug antigen resulting in harmful immunologic reactions on subsequent drug exposures[28].

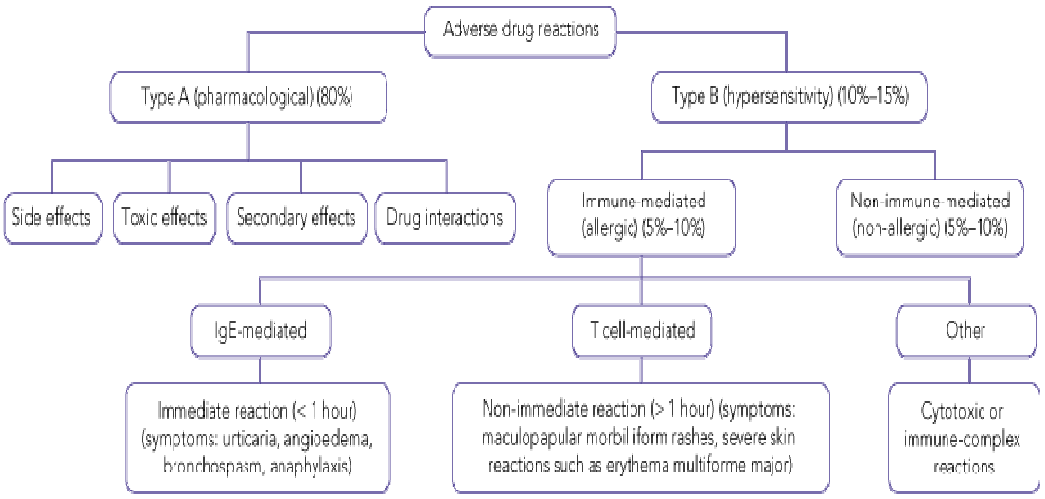
An allergic reaction is a hypersensitivity reaction that involves an immune mechanism. This can be IgE- or T cell-mediated, or rarely, involving an immune complex or cytotoxic reaction[18].

Allergic or hypersensitivity reactions may result in very minor, limited reactions or more severe reactions, including anaphylaxis, which may be fatal.

Non-immune mediated hypersensitivity reactions may also occur to drugs, including anaphylactoid reactions, e.g. to contrast media. Although the aetiology of these reactions is different, the symptoms and treatment can be identical to anaphylactic reactions[21]

Adverse drug reactions may also occur, the symptoms of which overlap with the symptoms of hypersensitivity reactions, e.g. skin reactions.

Figure 1. Classification of adverse drug reactions, including hypersensitivity and immune-mediated drug allergy[18].



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Allergic or immune-mediated reactions

Type 1 - IgE-mediated reactions

Most drug allergies belong in this category, e.g. allergies to neuromuscular blockers, penicillins and some but not all reactions to non-steroidal anti-inflammatory drugs.

Initial IgE-mediated reactions may be mild, e.g. skin rash or one or more of the symptoms below. Subsequent exposure may result in some or many of the following symptoms and signs of anaphylaxis[19]**:**

- **Skin:** Generalised erythema, urticaria or angio-oedema (localised swelling of face, mouth, etc)
- **Respiratory:** Cough, wheeze, stridor, tachypnoea, recession, cyanosis.
- **Cardiovascular:** Tachycardia, weak/absent pulse. Sustained hypotension unless specific treatment.
- **Neurological:** Severe anxiety and distress. Loss of consciousness.
  Gastro-intestinal: Nausea and vomiting.[20]

Anaphylactic reactions typically occur within minutes of exposure, but delayed presentations (1-72 hours) have been reported[29].

Type 2- Cytotoxic hypersensitivity

Type 2 reactions are mediated by IgG or IgM and result in the destruction of host cells, usually blood cells e.g. Methylene Blue-induced haemolytic anaemia and Heparin-Induced Thrombocytopenia (HITS) [29].

Type 3 - Immune-complex deposition

Type 3 reactions are where antigen-antibody complexes are deposited in tissues and small blood vessels, causing a local inflammatory response, which may result in serum sickness or vasculitis e.g. serum sickness caused by beta-lactams, quinidine-induced lupus erythematosus and minocycline-induced vasculitis[29].

Type 4 - T cell-mediated reactions

These reactions have a slower onset (occurring more than one hour after drug administration) and typically have dermatological manifestations. On exposure to the antigen, memory T calls become activated and elicit an inflammatory response. Initial and subsequent reactions may be mild, although severe skin reactions may result. This reaction is used for diagnostic purposes in the tuberculin skin test[29].

Non-allergic or non-immune-mediated reactions

Adverse reactions to radiographic iodinated contrast media include idiosyncratic reactions, which typically begin within 20 minutes of contrast injection, independent of the dose that is administered. Although reactions to contrast media have the same manifestations as allergic or anaphylactic reactions, these are not true hypersensitivity reactions and IgE antibodies are not involved. Previous sensitization is not required, nor do these reactions consistently recur in a given patient. They are commonly referred to as anaphylactic reactions. Symptoms range from mild, e.g. urticaria, rhinorrhea etc, to life-threatening, e.g. arrhythmias, hypotension, bronchospasm etc[19,21]. These reactions are treated in the same way as IgE-mediated anaphylaxis.

Adverse reactions to NSAIDs can include reactions due to COX-1 inhibition, resulting in urticaria and angioedema, in addition to IgE-mediated allergy and T cell-mediated reactions[30].

Appendix 2: Taking and Documenting a Drug Allergy and ADR History [18, 31]

- No drug should be prescribed or administered until allergy history is complete, except in extreme urgency, e.g. life threatening situations. If it is not possible to establish an allergy history (e.g. a comatose emergency admission), ALL drugs should be considered as a potential allergen and healthcare staff should make sure that treatment is readily available in the event of a reaction.
- Responsibility for taking, documenting and communicating onwards of the allergy history should be clearly designated in local hospital policy.

Before taking an allergy history, healthcare professionals should:

1. Know the clinical features of allergic drug reactions (See Appendix 1)
2. Know and be familiar with drugs commonly associated with allergies, particularly fatal anaphylaxis (See The Problem, page 5)

Patients Able to Give an Allergy History

Step 1: Ask patient if they have ever experienced a reaction to a drug or ever been told to avoid certain drugs.

If No: Document "No Known Drug Allergies" or "NKDA" on Allergies section of Drug Chart and patient's Healthcare Record.

If Yes: Proceed to Step 2.

→

Step 2: Ask patient the name of the drug(s) and the specific nature of the reaction

- What type of reaction?
- Any rash, swollen tongue, difficulty breathing?
- Did the reaction happen the first time you were given the drug?

↓

Step 3: Likely allergy / ADR

- Date of reaction
- Was patient taking other drugs at the same time?
- How soon after taking the medicine did it occur?
- Has patient recently received drug in question again without incident?
- Could an underlying condition cause this reaction?
- Assess likely nature of reaction

←

Step 4: Clinical Decision & Documentation

- Document drug allergy and/or adverse drug reaction, according to local policy.
- Document the drug (and any related drugs) to be avoided and the nature of the reaction on the Drug Chart and in the patient's healthcare record.

Patients Unable to Give a Drug Allergy History

If an adequate history of drug allergy cannot be provided as patient is incapacitated / unconscious, disorientated or there is a language comprehension barrier, then the prescriber must make all reasonable efforts to establish their drug allergy status.

- Look for allergy band / bracelet, Personal Information Pack etc.
- Seek information from a family member, the Healthcare Record, GP, community pharmacy, etc.
  If / when further information becomes available the allergy status should be reviewed & documented.
- If it is not possible to establish an allergy history, ALL drugs should be considered as potential allergens and treatment should be readily available in the event of a reaction.

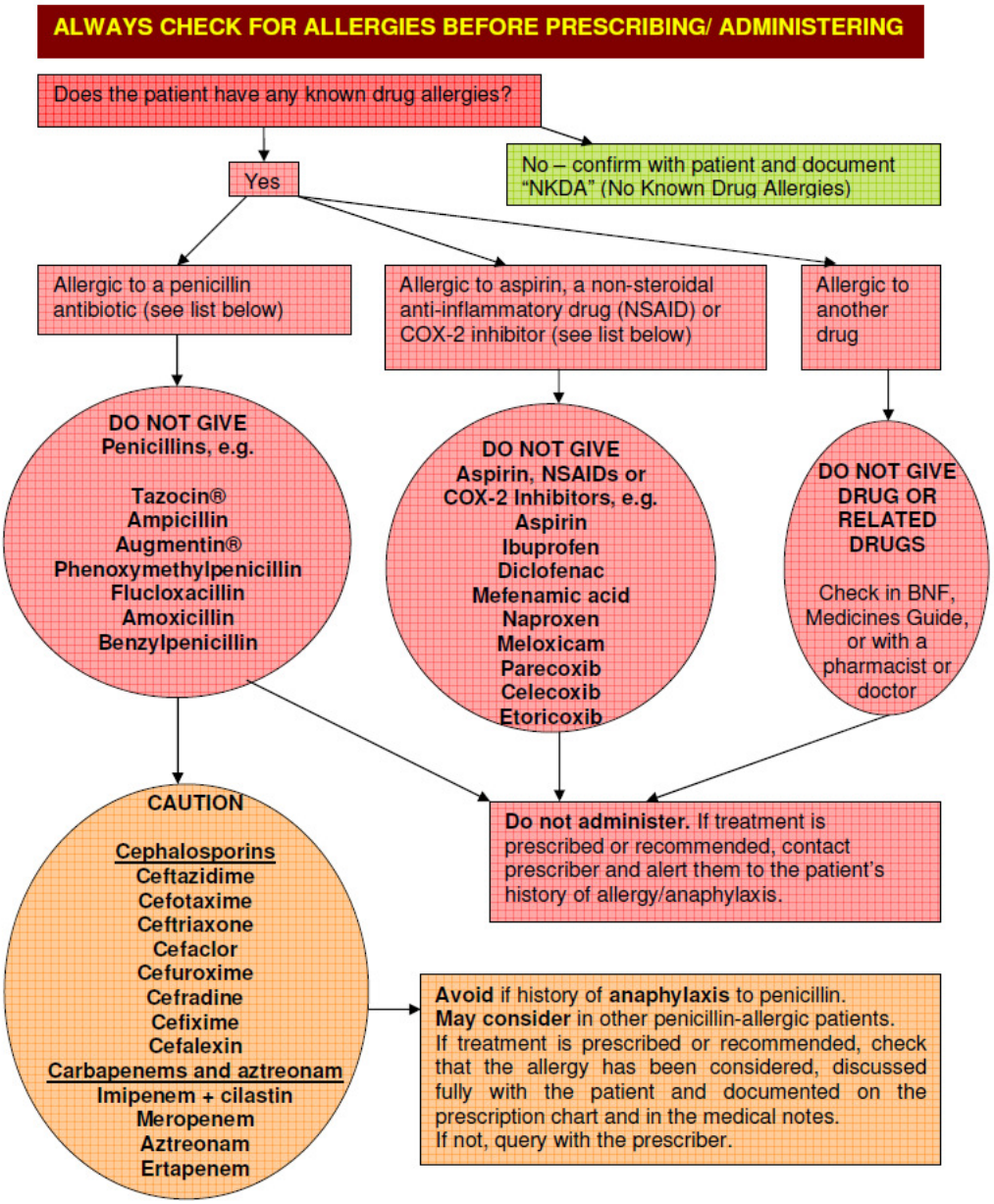
Patients Reporting Allergies or ADRs Where the History is Inconsistent with This

Where the patient believes they have an allergy or ADR, but the history is inconsistent with this, ensure the drug is not prescribed, dispensed or administered unless:

- The allergy or ADR has been outruled or is thought to be very unlikely. Rarely, allergy testing or desensitisation may be required for a limited patient group under expert immunology guidance.
- 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 drug.
- The discussion with the patient and risk / benefit consideration is documented in the Healthcare Record)
- Pre-medication is considered if appropriate.
- The rechallenge is carried out with close monitoring of the patient and appropriate facilities available should a reaction occur, e.g. adrenaline for intramuscular use, oxygen.

  If a patient no longer exhibits an allergic reaction on challenge, their allergy status should be updated appropriately on all relevant documentation and the patient clearly counselled that they are not allergic to the agent.

Appendix 3: Cross-Allergy



Appendix 4: Sample Allergy Alert Card

STOP	**Allergy Alert Card** See www.imsn.ie for more info	**Allergies**:
Name: Date of Birth: Address: Tel Next of kin: Tel: GP:		Drugs Reaction , when, where Source of Information: Date Signed: Contact details: