Welcome to the September edition of the Clinical Communiqué. This edition marks three years and a dozen publications since the launch of our series. Over that time, we have looked at many themes central to improving safe and timely care for patients, including the importance of recognising the deteriorating patient, teamwork and communication, and effective decision-making. Medications represent another area where safety issues such as prescribing practices and modes of medication delivery are critical in many cases of avoidable patient deaths.

In this edition, we look once again at medications, this time with a focus on medication allergies. Anaphylaxis is the most severe form of allergic reaction requiring urgent medical treatment, and multiple definitions for it exist. According to the Institute of Allergy and Infectious Disease and Food Allergy and Anaphylaxis Network, anaphylaxis is highly likely when any one of the following three criteria are fulfilled:*

1. Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (e.g. generalized hives, pruritus or flushing, swollen lips-tongue-uvula), and at least one of the following:
   a. Respiratory compromise (e.g. dyspnoea, wheeze-bronchospasm, stridor, reduced peak expiratory flow, hypoxaemia)
   b. Reduced BP or associated symptoms of end-organ dysfunction (e.g. hypotonia [collapse], syncope, incontinence)

2. Two or more of the following that occur rapidly after exposure to a likely allergen for that patient (minutes to several hours):
   a. Involvement of the skin-mucosal tissue (e.g. generalized hives, itch-flush, swollen lips-tongue-uvula)
   b. Respiratory compromise (e.g. dyspnoea, wheeze-bronchospasm, stridor, reduced peak expiratory flow, hypoxaemia)
   c. Reduced BP or associated symptoms (e.g. hypotonia [collapse], syncope, incontinence)
   d. Persistent gastrointestinal symptoms (e.g. crampy abdominal pain, vomiting)

3. Reduced BP after exposure to known allergen for that patient (minutes to several hours):
   a. Infants and children: low systolic BP (age specific) or greater than 30% decrease in systolic BP
   b. Adults: systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline.

Anaphylaxis occurred in each of the three cases presented, and what is astonishing is that in every case the allergies were pre-existing, known by the patient and documented by the healthcare providers. These cases were entirely preventable. Yet although the circumstances surrounding the deaths may be astonishing, they are not unique. Hospital admissions for anaphylaxis are rising, and antibiotics make up a large proportion of the medications implicated in anaphylaxis. In many countries, medications are the most common cause of fatal anaphylaxis - not every case is an unforeseeable event. So why are patients being given medications that they are allergic to? Why are the systems failing in what would appear to be a simple and preventable cause-and-effect scenario?

In this edition, Adjunct Associate Professor Stuart Margison provides a succinct overview of effective drug allergy communication and alert systems. His expert commentary outlines the steps that every healthcare professional and organisation should take to optimize safe prescribing and dispensing of medications. Anaphylaxis to a known medication allergy should not occur. Effective alert systems must be implemented that ensure universal recognition of a medication allergy every time and in every circumstance.

Ms TD was a fit and well 34-year-old female with a previous history of allergic reactions to Septrin (trimethoprim and sulfamethaxazole – a sulphonamide antibiotic), and Ibillex (cephalexin, a cephalosporin antibiotic). She was also known to have an allergy to penicillin.

Ms TD filled her script and returned home. A short time later, her partner arrived to check on her and found her unresponsive, lying face down, with red welts on her legs. He called an ambulance and commenced cardiopulmonary resuscitation. When the ambulance arrived she had no pulse, no respiratory effort, and her Glasgow Coma Score was recorded as 3. A blister pack of cefaclor on the lounge room table was noted to have one tablet missing.

The paramedics commenced advanced life support and transported Ms TD to hospital where she was admitted to the Intensive Care Unit. After two days of monitoring, it was clear that her condition was irreversible and a decision was made to withdraw treatment.

Ms TD's hospital notes were reviewed by a forensic medical officer and forensic pathologist who, on the basis of the documentation, gave her cause of death as irreversible hypoxic ischaemic encephalopathy due to anaphylactic shock.

The materials revealed that Dr G was 83 years old at the time he saw Ms TD and that within days of her death, he had resigned from the clinic and ceased clinical practice.

Dr G had undergone his medical training in Eastern Europe and moved to Australia decades earlier. He suffered from a long history of depression which was attributed in part to being the only member of his family to survive a German concentration camp. After Ms TD's death, his health deteriorated and his depressive illness became unremitting despite medications. He experienced symptoms of anxiety, altered sleep, weight loss, and self-reproach.

Dr G had little recollection of his consultation with Ms TD. He described typing her notes into the computer after she had left the room, which was his usual practice. He admitted that he was not proficient on the computer and must have failed to see her allergy alert (for Ibillex) on the computer screen. He could not be certain whether he had asked Ms TD if she had any allergies and Dr G's counsel acknowledged that the question, had it been asked, would not have relieved Dr G of a duty to check the electronic record for allergy alerts.

Dr G maintained that at the time of the consultation, he was not impaired and he knew Cefaclor belonged to the same class of antibiotics as Ibillex. He would not have prescribed Cefaclor for Ms TD had he seen the alert.

**CORONER’S FINDINGS**

The coroner accepted the finding of anaphylactic shock, and agreed that there was no evidence to suggest that Dr G was physically or cognitively disabled at the time in question.

The coroner concluded by commenting – ‘it is concerning that the health system in this country has reached a point where there is such a scarcity of medical practitioners that a doctor can still be practising at the age of 83 years.’

The coroner recommended – ‘that the Minister for Health raises this case with the Minister’s Federal counterpart to investigate whether there are sufficient doctors to meet the requirements of this State.’

**KEYWORDS**

Anaphylactic shock, antibiotic allergy, cephalosporins, general practitioner, allergy alert
CLINICAL SUMMARY

Mrs CW was 68 years old when she was admitted to a small regional hospital for elective bilateral cataract removal surgery. She was in very poor health and had cataracts, raised intraocular pressure (glaucoma), and severe chronic respiratory disease which kept her house-bound. The surgery was meant to improve her quality of life at home by allowing her to enjoy craft activities and watch movies. Mrs CW had a known allergy to ‘sulphas’ (also known as ‘sulfa drugs’). Her allergy was noted in multiple sections of her medical record and on admission a red identity band was placed on her arm by nursing staff to denote her as a patient with an allergy.

Her surgeon, Dr S, was a visiting surgeon to the hospital. He had planned to perform a trabeculectomy (surgical procedure used in the treatment of raised intraocular pressure) in addition to the cataract surgery; however, on the day of surgery he decided against it as Mrs CW’s general physical condition had deteriorated. Dr S opted instead to administer medication post-operatively to lower her intraocular pressure.

The cataract surgery was uneventful. Dr S wrote up the post-operative orders, including the order for Diamox (acetazolamide, a non-antibiotic sulphonamide), to treat the raised intraocular pressure. Mrs CW returned to the ward and was clinically stable at the time. The ward nurse administered the Diamox medication as ordered. Approximately 10 minutes later Mrs CW was sweating, short of breath and tachycardic. Her anaesthetist, Dr F, was notified and told that Mrs CW had received Diamox – Dr F knew Mrs CW was allergic to ‘sulphas’ and recognised she was having an allergic reaction. Dr F stabilised Mrs CW and made arrangements for her to be transferred to a tertiary referral hospital. However, she suddenly deteriorated further and died.

PATHOLOGY

Following a post mortem examination, Mrs CW’s cause of death was given as anaphylaxis in a woman with atherosclerotic cardiovascular disease and emphysema.

INVESTIGATION

The coroner undertook an inquest into the death of Mrs CW. Questions raised during the inquest included how Mrs CW’s allergy was recorded in her file and the efficacy of how this was communicated to treating physicians. Issues regarding sulphonamide allergies were described whereby some people are allergic to all sulphonamides, or to antibiotic sulphonamides or non-antibiotic sulphonamides. The precise type of allergy Mrs CW had to sulphonamides was neither known nor documented.

The Western Australian Therapeutics Advisory Group’s position on allergic reactions to sulphonamides was referred to during the inquest. If Mrs CW had an allergy to both antibiotic as well as non-antibiotic sulphonamides then prescribing Diamox would have been contraindicated. If her allergy was to only antibiotic sulphonamides then administering Diamox was unlikely to have caused an allergic reaction, however idiosyncratic reactions have been known to occur. Dr S believed Mrs CW had suffered an idiosyncratic response however, a Professor in Ophthalmology provided an expert opinion to the court in which he suggested that the best course of action would be to follow the product advice and avoid using Diamox in somebody with a known sulpha allergy.

Regarding the communication of Mrs CW’s allergy to all her care-givers it was confirmed that her allergy had been recorded in her medical record and she was also wearing a red identity band. Though he admitted seeing it in theatre, Dr S apparently was “unaware” of the significance of the band. Dr S admitted that he had Mrs CW’s documentation with him when he wrote his post-operative orders, yet was unaware she had an allergy to ‘sulphas’.

CORONER’S FINDINGS

The coroner heard that the hospital had improved its ‘team timeout process’ immediately prior to surgery so that it was mandatory for all team members to acknowledge a patient’s allergy. The coroner commented that this step would increase the awareness of allergies but there was a need for, “precision when describing a patient’s allergy. The term sulphas is not sufficiently precise to provide a nurse, doctor or surgeon with sufficient information as to the nature of the allergy.”

Two recommendations were made by the coroner. Firstly, that all nurses, doctors and surgeons working at the hospital were to be reminded about the necessity of recording the precise nature of patients’ allergies and this precise nature was to be known by the prescriber of medication.

The second recommendation was that a protocol be developed to mandate the minimum acceptable standards of practice which doctors and surgeons, not employed by the Department of Health, agree to adopt before being allowed to practice in the hospital. The protocol should cover the existence of any protective procedures or systems such as the wearing of a red allergy alert band.

Research has demonstrated issues with clinicians overriding alerts indicating that continuous quality improvement and usability of electronic systems are of paramount importance.

AUTHOR’S COMMENTS

Mrs CW’s case illustrates the importance of standardised, accurate recording of allergies and the effective communication of this information for health professionals. It also highlights the confusion that can arise from inconsistent reporting of the details of allergies. Examples include the frequency with which patients disclose their allergies, the nature of their allergy (ranging from mild intolerance to anaphylaxis), and the specificity of the substance which causes an adverse reaction (one medication or a whole class of medications). Research has demonstrated issues with clinicians overriding alerts indicating that continuous quality improvement and usability of electronic systems are of paramount importance.

RESOURCES


KEYWORDS

Antibiotic allergy, sulphonamides, communication, ophthalmologist, alert bands.
CASE #3 AN ALERT UNSEEN IS A RISK UNKNOWN

Case Number: 2010/2516 QLD

Case Précis Author: Dr Ian Summers MBBS, DRANZCOG, GCHEP, FACEM

CLINICAL SUMMARY

Mrs ML was a 74 year old female who had a past history of diabetes, glaucoma, and chronic obstructive airways disease. She was on a number of medications including aspirin and hypoglycaemic tablets. She was known to be allergic to penicillin for approximately 20 years as well as Minomycin (a tetracycline class antibiotic), Cefclor and Keflex (antibiotics of the class cephalosporin related to penicillin). It is not clear what type or severity of allergic reaction had been provoked in the past. These drugs reactions were listed on her medical alert bracelet that she wore on the day of her presentation to the emergency department of a regional base hospital. She had attended the receiving hospital many times before.

The events that led to the time of her death began when Mrs ML presented to her GP with chest and abdominal pain, and phlegm irritating her throat. She was given clarithromycin (a macrolide antibiotic) by her GP. Over the next two days her condition worsened and she called an ambulance.

At that stage, Mrs ML’s blood pressure was low, her heart rate was severely elevated and she was confused, distressed and struggling to breathe. The treating team felt that she was suffering shock as a result of infection (septic shock) and an urgent chest x-ray showed a pneumonia.

Intravenous ampicillin (a penicillin beta-lactam antibiotic) was ordered as part of the treatment of her septic shock and administered by the nursing staff. Mrs ML rapidly deteriorated and the penicillin allergy alert was then noted on her medical alert bracelet. There was no rash or swelling of her face or airway to signal to the treating team that anaphylaxis was the cause of her deterioration, but this was considered nonetheless, and adrenaline was given intra-muscularly to reverse a potential reaction. She had a cardiac arrest shortly afterwards. Despite return of her pulse and an admission to the intensive care unit, Mrs ML did not regain consciousness and died four days later.

At inquest, a professor of emergency medicine, who explained that penicillin is the most common cause of drug-induced anaphylaxis, which can manifest as sudden cardiovascular collapse, without associated cutaneous features. The expert also pointed out that tryptase does not always rise following anaphylaxis and has a short half-life of two hours, so may have already returned to normal when the blood tests were taken. Ultimately, the coroner accepted the opinions that the rapid temporal relationship between administration of a known allergen and cardiac arrest left “no doubt” that the arrest was due to an anaphylactic reaction. The same experts also suggested that Mrs ML’s illness was so severe that the gall bladder infection, septic shock and subsequent multi-organ failure would almost certainly have resulted in death regardless of anaphylaxis.

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CORONER’S FINDINGS
The coroner found that Mrs ML did suffer an anaphylaxis which resulted in her cardiac arrest. However, in view of her significant co-morbidities, the effect of the cardiac arrest did not hasten her death.

The coroner commented that aside from the incorrect administration of ampicillin, the medical management of Mrs ML in the emergency department had been appropriate and in accordance with best practice.

The coroner made a number of recommendations including that:

1. Manufacturers, retailers, and promoters of medical identification products only make available those items which distinctly place function over fashion in their design, and which bear a readily recognisable medical symbol and prominent wording.

2. Education material about atypical presentations of anaphylaxis, especially the possibility of anaphylaxis occurring without a rash, should be disseminated to medical personnel.

3. The Department of Health and Ambulance Service investigate and implement (if feasible) the option of a red alert wrist band being applied by pre-hospital staff as soon as a significant medical condition (such as a known allergy) is noted.

AUTHOR’S COMMENTS
In addition to the important issues explored at inquest, it is also worth considering the cognitive load, noise or other environmental circumstances that can impact on the ability of healthcare professionals to accurately relay and receive critical information. Alert systems must be robust enough to ensure that they work even in the face of extreme external pressures and distractions.

RESOURCES


KEYWORDS
Anaphylaxis, medical alert bracelet, emergency department, penicillin, antibiotic allergy
EXPERT COMMENTARY
MEDICATION ALLERGIES
- A SYSTEMS APPROACH

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Medications are the most common intervention in health care. In most circumstances, medications improve patient outcomes, but occasionally things go wrong. An anaphylactic reaction to a medication is a rare but serious event that warrants serious attention.

The cases presented in this edition highlight examples where a medication was prescribed and administered to patients with known allergies. These incidents are avoidable when adequate systems and processes are in place.

There is large variation in the medication safety systems used in Australian hospitals, including the system to alert clinicians to pre-existing medication allergies. The variation is largely technology driven.

The introduction of new National Standards for Safety and Quality in Healthcare in 2010, for which all hospitals have since been required to meet accreditation, defines a set of minimum requirements for providing safe patient care. The National Standards include the pertinent standards to medication allergy alert systems: Medication Safety - Standard 4; and, Patient Identification and Procedure Matching - Standard 5. These standards are augmented with the National Inpatient Medication Chart (NIMC) User Guide, published by the Commission on Safety and Quality for Healthcare.

In hospitals where there is limited technology, these standards would see a red patient identification arm band used (in place of the standard white patient identification arm band) signalling that the patient has an allergy. A ‘Best Possible Medication History’ would have been taken that saw the relevant medication allergies documented in the clinical notes. The patient would have had a medication reconciliation completed for them confirming the allergy status. The NIMC would specify not only the medication allergy, but also the reaction type and date, which is visible every time a medication is prescribed, has a pharmacy review or, is administered.

Hospital pharmacy dispensing software has the ability to record allergies, and issue an alert at the point of dispensing.

This is not a reliable standalone system because: 1) not all medications are dispensed - many commonly used medications are available as imprest; and 2) not all patients are seen by a pharmacist to input this data into the dispensing software.

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Whatever the current medication alert system in place at your organisation may be, you have an obligation to know what it is, and how it is used. The Clinical Excellence Commission urges all hospitals to participate in the Medication Safety Self-Assessment Program, which will highlight the weaknesses of your system in terms of alerts, allergies and medication safety more broadly.

The aim of these systems is to provide clinicians with the information they need at the time they need it, and to provide decision support tools to facilitate the best possible evidence based care.

Hospitals all over the country are implementing electronic health records (EHR) and/or electronic medication management (EMM), to varying degrees and with varying success. At the same time, the Commonwealth continues the implementation of the ‘My Health Record’. The aim of these systems is to provide clinicians with the information they need at the time they need it, and to provide decision support tools to facilitate the best possible evidence based care. The ideal system has many requirements that are not easily attained such as:

- interoperability with other systems to ensure that information flows between systems
- accurate input of data
- easy and intuitive to use for the end-user
- a mechanism to reduce the possibility of alert over-rides or alert fatigue

In any of the cases presented, the patient’s My Health Record would have provided accurate allergy information that seamlessly integrated with the electronic health record or electronic medication management system of the hospital or patient’s general practitioner clinic. At the point of prescribing, the system would trigger an alert, notifying the prescriber of the allergy status. The system could then provide alternative therapies for the indication. The prescriber could then make an informed decision, in consultation with the patient, to treat.

RESOURCES
