

# Should known allergy status be included as a medication administration 'right'?

Manfred Mortell

## ABSTRACT

This article employs a paediatric case study, involving a 3-year-old child who had an anaphylactic reaction that occurred as a result of the multidisciplinary team's failure to identify and acknowledge the patient's documented 'known allergy' status. It examines and reconsiders the ongoing healthcare dilemma of medication errors and recommends that known allergy status should be considered the second medication administration 'right' before the prescribing, transcribing, dispensing and administration of any drug. Identifying and documenting drug allergy status is particularly important when caring for paediatric patients, because they cannot speak for themselves and must rely on their parents, guardians or health professionals as patient advocates. The literature states that medication errors can be prevented by employing a 'rights of medication administration' format, whether that be the familiar '5 rights' or a more detailed list. However, none of these formats specify known allergy status as a distinct 'right'. The medication safety literature is also found wanting in respect of the known allergy status of the patient. When health professionals employ a medication administration rights format prior to prescribing, transcribing, dispensing or administering a medication, the 'known allergy status' of the patient should be a transparent inclusion.

**Key words:** Drug allergy status ■ Medication error ■ Medication administration ■ Patient safety

The issue of medication errors (ME) is not a new concern. More than 50 years ago Barker et al's (1962) study acknowledged that ME were a much bigger problem than anyone realised and that on a daily basis patients were harmed by providers of health care. As a potentially high-risk therapy, medication administration and the associated ME remain a significant contributor to patient harm (Leape et al, 2005; Kelly et al, 2006; Aspden et al, 2007; World Health Organization (WHO), 2017a; 2017b). The Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System* (Kohn et al, 2000), stated that ME were a significant cause of morbidity and mortality, with nearly 100 000 deaths, 1 million injuries, and 17 billion dollars annually attributable to ME. In addition, the IOM identified that hospitalised patients

were potentially subjected to at least one ME a day, taking into account near misses, and that not all detected errors were reported (Aspden et al, 2007). Other studies have also indicated that up to 30% of patients will experience a harmful event such as ME or wrong procedures due to incorrect patient identification during their hospitalisation (Fowler et al, 2008; Griffin and Classen, 2008). A seminal study by Wilson et al (1999) observed that human error was a significant factor, with 81% of harmful events associated with human factors, such as non-caring attitudes and behaviour, and a lack of knowledge. Vincent et al (2001) categorised 48% of these harmful occurrences as preventable, which has been supported by other studies (Rex et al, 2000; Regenbogen et al, 2007). In the classic Harvard medical practice study, Leape and colleagues (1991) found that 1 in 4 of these harmful events was the result of negligence and 58% were deemed preventable.

Some of the most common types of harmful events that resulted in patient mortality involved administration of a drug to patient with a known allergy to that drug or a similar medication. Supplementary reports stated that 1 in 10 patients experience medication-related harm, comparably involving a documented known allergy status (Barker et al, 1962; Bates et al, 1995; Bond et al, 2002; Rothschild et al, 2005). The Joint Commission International (JCI) publishes revised National Patient Safety Goals each year to assist healthcare organisations to improve patient safety; there are specific goals relating to improving medication administration and patient identification (JCI, 2019).

This article considers the ongoing issue of ME in general and in particular the prescribing and administration of drugs to a patient with a known allergy. It considers a case involving a young child who had an anaphylactic reaction that occurred as a result of the multidisciplinary team's failure to identify and acknowledge the patient's documented 'known allergy' status.

## Background Medication errors

The phenomenon of ME is among the most frequent and widespread of healthcare-related mistakes that cause iatrogenic patient harm (Rothschild, 2005; Aspden et al, 2007; Dhawan et al, 2017). ME have also been clarified as any preventable event that may cause or lead to patient harm while the medication is in the control of the health professional, patient or consumer (Leape, 2005; da Silva and Krishnamurthy, 2016). These potentially harmful events may be related to professional practice, healthcare products, procedures and systems (National Coordinating

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Council for Medication Error (NCCME), 2007). Essentially, it is a failure in the medication method that has the potential to lead to patient harm and can be classified as ‘errors’, ‘fault’, ‘slip-ups’ or ‘lapses’ (Reason, 1990). The varieties of ME have included the wrong patient, wrong drug, wrong dose, wrong frequency, wrong route, and wrong allergy status. All ME can be considered a sentinel event when associated with patient harm (Reason, 1990; Joint Commission for Accreditation of Healthcare Organizations, 2001; Burke, 2005). In the 1990s, research into ME focused on systems and nurses as being crucial to intercepting ME before they reached the patient; however, as the number of medications prescribed, transcribed, dispensed and administered increased, so did the number of ME. The IOM established that ME were not acceptable in a healthcare system that is intended to comfort, heal and reassure (Kohn et al, 2000; Aspden et al, 2007). Nonetheless, ME remain common and occur with increasing frequency. The literature on ME, conversely, remains in conflict as indicated by the academic declarations that ME are unavoidable (Etchells et al, 2008; Dhawan et al, 2017), or that they are always avoidable (da Silva and Krishnamurthy, 2016).

Despite the academic conflicts, evidence-based practice maintains that health professionals are informed and are educated on the ‘right’ medication theory, which affects medication practices in health care. Another consideration suggested by academics is that contributing factors such as health professional competence and compliance attitudes must also be considered when reviewing issues with ME and ‘known allergy’ status (Anderson et al, 2010). Previous work by the author (Mortell, 2012; 2013) offered an alternative concept to reflect on, a ‘theory-practice-ethics gap’ that pertains to practice ethics, and suggested that non-compliance or non-conformity with organisational policies and procedures could be an issue when concerned with medication prescription, transcribing, dispensing and administration.

### Ethics and duty of care

The word ethics has Greek origins—*Ta Ethika*: into good and evil; *ethos*: personal character—a code of ethics defines basic principles to determine what constitutes ‘right’ behaviour, united with a moral duty and obligation. Ethics are moral values and behaviours that express ideals for other human beings (Certo and Certo, 2009), comprising commitments to remove harm or promote benefit (Twomey, 2010). These basic principles of safety management, *primum non nocere* (first, do no harm) and *in dubio abstine* (in case of doubt, do not intervene) go back to ancient times. Historically, Hippocrates, a Greek physician born circa 460 BC is acknowledged as the father of medicine and was concerned with alleviating human suffering while pledging ethical values and moral conduct. The Hippocratic Oath reminds doctors to practise medicine ethically, and ensure safe, effective care and never doing harm. In part, the ionic Greek version of the Hippocratic Oath translated into English, reads: ‘According to my ability and judgement I will never do harm, I will never give a deadly drug to anybody.’

Similarly, nurses abide by an equivalent oath, referred to as the Nightingale pledge, which acts to remind them of their responsibilities to the patient and, in part, states that nurses ‘will

not administer any harmful drug’ (Marples, 2010; Reid, 2011). As perceived by Florence Nightingale more than 150 years ago, and remaining applicable today, the greatest threat to patient safety are the ‘frailties of the human condition, complacent attitudes and unconscious behaviours’ (Reid, 2011). The medical profession focuses on the clinical, scientific and ethical competence aimed at curing and healing those unwell, while the nursing profession concentrates on the moral work of the health experience for a human being by caring for them physically, emotionally, and spiritually.

### Safety in health care

Patient safety is a fundamental facet of health care because, when human beings are admitted to hospital, they expect to have their illness or disease treated, receive high-quality health care and not be harmed in the process. The primary goal of health care is to maximise wellbeing, and therefore optimise the quality of people’s lives (Williams, 2007). The culture of patient safety acknowledges seven key elements: leadership, teamwork, evidence-based health care, communication, learning, just culture, and patient-centredness (Sammer, 2010). The organisational safety climate is linked directly to patient safety and care behaviour outcomes; the greater the safety climate, the lower the rate of ME (Fogarty, 2006; Hofmann, 2006). However, in the traditional literature, O’Shea (1999) cautioned that, despite the placement of structured safety policies, ME and medication safety may not improve due to the high incidence of violations by health professionals, which precede patient harm.

A global consideration in health care is medication safety and, based on the literature reviewed, there is a general consensus that ME still occur frequently and compromise patient safety (Hughes and Blegen, 2008; Anderson et al, 2010). The strategies employed to reduce or eliminate ME have included medication education, the introduction of independent double-checking, a computerised physician order entry, automated pharmacy dispensing systems, bar coding, ‘smart’ intravenous (IV) pumps, and electronic medication administration records (Kaushal, 2001; Rothschild, 2005; Schneider, 2006; Franklin, 2007; Cohen, 2008; Early, 2011). However, despite the implementation of these patient safety strategies, ME continue to occur, with consequent effects on patient safety (Leape 2005; Kelly et al, 2006; Aspden et al, 2007).

The healthcare education programmes that have been introduced to improve professionals’ medication knowledge, and practices to decrease ME, have demonstrated negligible improvement, with ongoing practice violations (O’Shea, 1999; Schneider, 2006). Franklin (2007) reported that use of barcoding with medication administration demonstrated a decline in ME from 8.6% to 4.4%. However, Early (2011), contradicted that study, stating that health professionals override these safety systems, which created significant ME (Koppel, 2008). ‘Smart’ IV pumps are a technology that can reduce ME; however, Rothschild et al (2005) discovered that drug libraries and IV pump alerts were frequently bypassed by health professionals and therefore did not reduce ME. Electronic medication systems have also been advocated as an effective strategy to reduce ME and increase patient safety (Franklin, 2007). However, alternate

research studies have found that ME have continued to occur despite use of electronic medication systems (Leape et al, 1995; Englebright et al, 2005). These ME, again, could be explained by the attitudes of health professionals toward the recommended organisational policies on safe practice, non-compliance, or deliberate violations regarding organisational guidelines (Dean et al 2002 ;Williams,2007).As organisations adopt more complex and costly technologies to prevent ME to improve patient safety, success of these strategies depends on professional responsibility, accountability, and practice ethics.

### The medication administration rights

The medication administration rights typically incorporate the '5 rights': 'right patient, right drug, right dose, right route, and right time for administration'. Health professionals have acknowledged and taught the medication administration rights as an important strategy to reduce ME and keep patients safe from harm (Grissinger, 2010). However, Pepper (2006) argued that the '5 rights' do not acknowledge the complexity of the nurse's role and lack an evidence base to support their use to prevent ME. Regardless of the academic debate pertaining to the validity of the '5 rights', they are fundamental rules that are taught to health professionals, and if observed offer a simple methodology that has the potential to reduce ME and improve patient safety. However, because of its significance and implication the known allergy status of a patient must be acknowledged as the second medication administration right in the checking sequence (*Table 1*). In doing so, a potential contributor to ME with sentinel event consequences may be averted.

All health professionals have a vital role in the prevention of ME, and that is to verify that other health professionals have not made an error in the prescription, transcription, dispensing and administration chain. The nurse's role is usually the final verification and safeguard to prevent an ME (Rothschild et al, 2005; Davey et al, 2008; Adams and Koch, 2016). Therefore, nurses as patient advocates have a vital responsibility to ensure that the medication administration rights are implemented correctly (*Table 1*).

### Case study

A 3-year-old child was brought into the emergency department (ED) of a hospital in the Middle East by his parents. The father informed the ED nursing staff that the young child had been unwell with a cough and fever for several days. The ED nursing staff recorded the following observations: a fever with a core temperature (tympanic) 38.5 °C, rigor-like shivering, tachypnea, SpO<sub>2</sub> 88% on room air, chest retractions, shallow breathing and fatigue. During the ensuing history-taking by the ED physician, when asked about allergy status, the parents stated that the child had developed a severe rash and breathing difficulties following the administration of an oral penicillin suspension on a previous occasion. The penicillin allergy status of the child was documented and flagged in the physician's handwritten and electronic medical records. Succeeding investigations included laboratory tests, such as nasopharyngeal bacterial swabs, blood cultures, and a complete blood count, which highlighted a high white cell count of 15 000/mm<sup>3</sup>; neutrophils 70%, bands

**Table 1. A medication administration rights format that includes 'known allergy' status**

| No. | Medication administration rights |
|-----|----------------------------------|
| 1   | Right patient                    |
| 2   | Right known allergy status       |
| 3   | Right drug                       |
| 4   | Right dose                       |
| 5   | Right route                      |
| 6   | Right time                       |

15%, lymphocytes 15%. An anterior-posterior chest X-ray was also recorded.

The child was started on oxygen therapy, which elevated the SpO<sub>2</sub> to 94%, and was subsequently transferred to the paediatric high-dependency unit (PHDU) for specialist care, close monitoring and the commencement of prophylactic antibiotic therapy. On arrival in the PHDU, the physical examination findings by nursing staff revealed that the child was drowsy, had a pulse rate of 138 beats per minute, a blood pressure of 104/63 mmHg, a respiratory rate of 45 breaths per minute with associated shortness of breath, and an SpO<sub>2</sub> of 92% on oxygen 40% non-rebreather mask. Pulmonary auscultation revealed wheezing and decreased air entry on the right side of the chest. The chest X-ray verified a right-sided middle and lower lobe abnormality and probable pneumonia.

Once the child was settled, the PHDU physician prescribed IV amoxicillin as antibiotic prophylaxis until the culture and sensitivity report from laboratory was available to prescribe the specific antibiotic regimen. Following the medical prescription of IV amoxicillin for the child it was transcribed by the PHDU nurse, and subsequently dispensed from the satellite pharmacy to the PHDU. The IV amoxicillin was then prepared for administration by the primary nurse caring for the child. The antibiotic was connected to the child's IV site and about to be administered when the parents, who were still present at the bedside, queried the medication. The father restated to the nurse that their child had a medication allergy to penicillin. The nurse informed the parents that this medication was not penicillin, it was amoxicillin and that they need not worry because 'she knew what she was doing'. Following the start of the IV amoxicillin as prescribed, transcribed, dispensed and administered, the child had an anaphylactic reaction and subsequently had a cardiopulmonary arrest. A paediatric 'code blue' (PCB) was announced over the public address system, the PCB team arrived within minutes and the child was successfully resuscitated. The child was then intubated with an oral tracheal tube and was transferred to the paediatric intensive care unit (PICU) for mechanical ventilation and stabilisation.

### Discussion

As a health professional, knowledge about pharmaceuticals is a fundamental requirement for all registered nurses in their daily practice (WHO, 2016; Nursing and Midwifery Council, 2018). Before administering any medication to a patient, the nurse

must know about the medication administration ‘rights’ and establish the ‘known allergy’ status of the patient (Powrie, 2018). The nurse must also know the rationale for the prescription of the medication, the generic name of the medication, the related medication ‘families’, the actions, and potential adverse effects of the medication. These are fundamental medication principles that are established as a nursing practice responsibility. This praxis applies to all medications, whatever the intended route of administration. The benchmark in healthcare practice, before the administration of any medication, is to verify the patient’s full name, medical record number and the documented ‘known allergy’ status. This practice ensures patient safety and prevents any potential ME-related harm (JCI, 2019). Nurses, as professionals and patient advocates, are aware that there are no routine medical procedures in health care; every medication prescribed and administered could place the patient at risk and in harm’s way.

Antibiotics such as penicillin are often used to treat *Streptococcus* infections, because they damage the bacterial cell, inhibit cell wall synthesis, and stop bacterial growth. Penicillin is a medication known to cause allergic reactions in many people and is interrelated to a ‘family’ of antibiotics known as the beta-lactams, which includes amoxicillin. Amoxicillin is therefore termed a ‘penicillin-like-antibiotic’. If someone is allergic to penicillin, they may be allergic to other types of beta-lactams, such as amoxicillin.

This case study involved a 3-year-old child who was admitted to the hospital with presumed pneumonia. During the medical examination by the ED physician it was noted and documented that the child was allergic to penicillin. An allergy status alert (such as the one in *Figure 1*) was applied to the medical records documentation hard copy and was immediately flagged electronically to the pharmacy department.

The child was subsequently transferred and admitted to the PHDU by the nursing staff. This was followed by a review of the ED medical records documentation and a targeted physical assessment by the PHDU physician. The antibiotic that was subsequently prescribed by the PHDU physician was IV amoxicillin, this medication was then transcribed by the primary nurse and relayed electronically to the satellite pharmacy. The IV amoxicillin was dispensed by the pharmacist to the PHDU primary nurse caring for the child. The IV amoxicillin was administered, which resulted in an anaphylactic reaction and a cardiopulmonary arrest.

The process of identification and acknowledgement of the child’s known allergy status in this case study progressed through four stages of safeguards that should have identified the risk. These were:

- The physician prescribing the medication
- The nurse transcribing the medication order
- The pharmacist dispensing the medication
- The nurse administering the medication.

However, all of the stages failed to identify the patient’s known allergy status prior to prescribing, transcribing, dispensing and administering the medication, and resulted in the near-fatal cardiopulmonary arrest of a 3-year-old child.

The practice of correct patient identification with medication

# ALLERGIC TO PENICILLIN

**Figure 1.** An example of an ‘allergic to penicillin’ label affixed to patient records

administration is a standard practice and complies with the recommended JCI patient safety goal number 1: ‘Improve the accuracy of patient identification’ (JCI, 2019). All patients must therefore be correctly identified by their full name and medical record number (MRN), in addition to confirming the ‘known allergy’ status and medication administration ‘rights’ for that drug. This is a standard safety practice required of all health professionals who are involved with patient medications.

It does not matter what name we give to the contributing issues, whether they are ‘attitudinal behaviours’, ‘medical errors’, ‘faults’, ‘slips’, or ‘non-compliance problems’, the health professionals in this case study neglected to follow the standard policies and practices related to known allergy status, which ensure a patient’s safety when receiving a medication. The safeguard failures occurred at multiple levels—the PHDU physician; the PHDU nurse, the pharmacist, and the parents’ concerns about their child’s allergy status (*Figure 2*). The failure to acknowledge the known allergy status could have resulted in fatal consequences associated with the cardiopulmonary arrest for the child. In a perfect world, health care would occur in an exceedingly reliable system where no one is hurt and everyone receives the high-quality care they need. But, in reality, patients continue to be harmed, with the professionals choosing to state that ‘we’re all human’ and ‘to err is human’ (Fowler et al, 2008; Hinno et al, 2011; James, 2013).

The safety academics offer in explanation the Swiss cheese model (Reason, 1990). This compares human systems to layered slices of Swiss cheese, which are fixed side by side. In the Swiss cheese model, an organisation’s defences against failure are modelled as a series of barriers, represented as slices of cheese. The holes in the slices represent weaknesses in individual parts of the system and are continually varying in size and position across the slices. The system produces failures when holes in multiple slices momentarily align, permitting ‘a trajectory of accident opportunity’, so that a hazard such as an ME passes through holes in all of the slices, leading to a failure (Reason, 1990).

Although the Swiss cheese model is considered a useful method of relating error concepts (Reason, 1990), the author of this article deems there to be a ‘theory-practice-ethics gap’, when health professionals are aware of evidence-based practice, but fail to provide ethical care (Mortell, 2012; 2013).

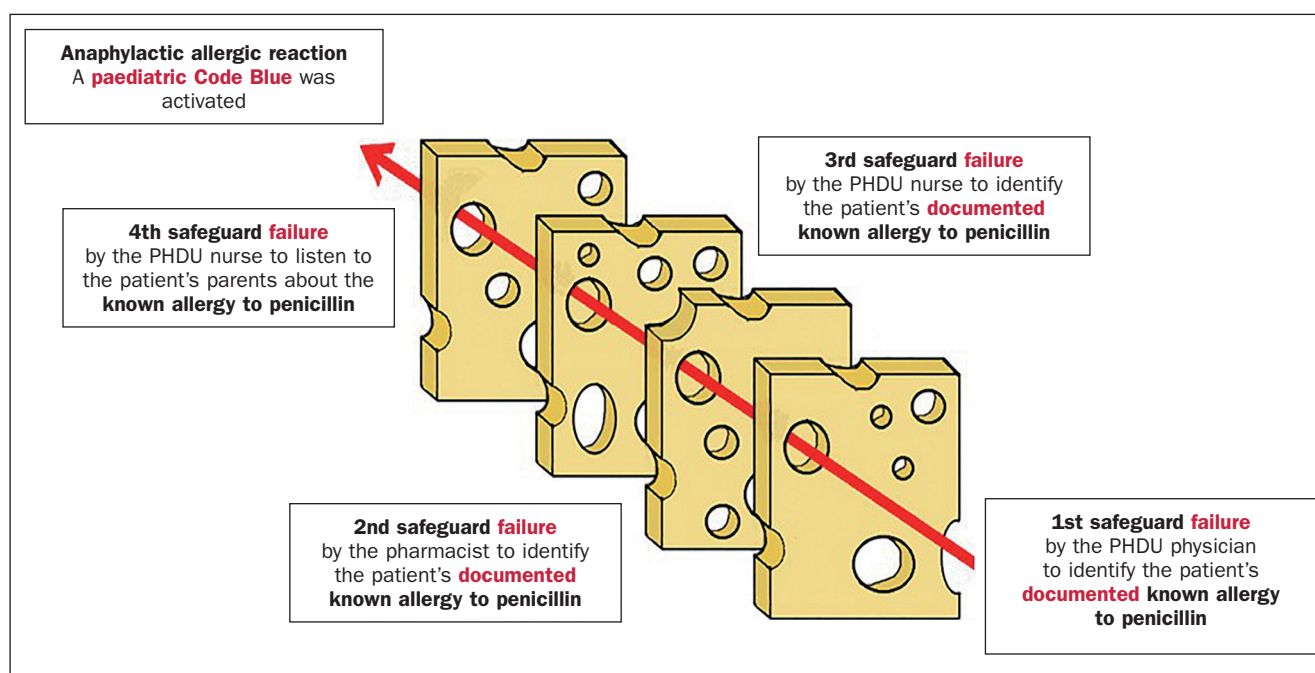


Figure 2: The Swiss cheese model (Reason, 1990) applied to this case study

## Conclusion

This case study focused on two issues relating to patient safety, the first was an ongoing medical predicament, which involved the identification of a young child's known allergy status. The second was a potential conflict of professional ethics within a paradigm called the 'theory-practice-ethics gap' (Mortell, 2012; 2012). This paradigm acknowledges that all health professionals are provided with theoretical knowledge and practical skills to perform competently and safely, yet continue to be ethically non-compliant. The situation presented here serves as a reminder that everything we do to or for the patient has potential consequences. Ultimately, the goal of all health professionals is to provide safe, evidence-based high-quality care to all patients. Healthcare dynamics are complex and involve care processes that include sophisticated technologies and therapeutic interventions. Endeavours must be made to encourage health professionals to reflect on their moral duty, which is to provide safe, high-quality patient care. Only by creating a culture of ethical care can we hope to decrease morbidity and mortality from ME related to known allergies. **BJN**

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## KEY POINTS

- Medication administration practices within healthcare organisations must be effective for patient safety
- All health professionals have a moral obligation to 'do the right thing' to ensure patient safety
- Given that health professionals understand the theory related to their clinical practices, ethical responsibilities require more emphasis
- For patient safety to be a valid goal, health professionals such as nurses must embrace their role as patient advocates

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## CPD reflective questions

- Think about what 'patient safety' means to you
- Reflect on your role as a healthcare provider, and as a patient advocate, in patient safety
- Consider how poor communication between members of the healthcare team, and between health professionals and patients/families, can have an adverse effect on patient safety

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