

Open School

Case Study: (AHRQ) Misread Label

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Case Study from [AHRQ WebM&M](#); Discussion questions submitted by Andrew Carson-Stevens, Medical Student, Cardiff University, Cardiff, United Kingdom; Jennifer Boehne, PharmD, Masters in Health Informatics, University of Minnesota, Minneapolis, Minnesota, USA

Learning Objectives

At the end of this activity, you will be able to:

- Explain how human error can result in adverse events.
- Identify the dangers associated with look-alike/sound-alike drugs.
- Discuss the benefits of apologizing to a patient (or a patient's family) after an adverse event.

Description

An infant born with sluggish breathing is given Lanoxin® instead of naloxone, and dies of digoxin toxicity.

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- [PS 102: Human Factors and Safety](#)
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Key Topics

Patient safety, perinatal care, engage patients and families in care, patient- and family-centered care, redesign processes and systems, reliable processes, adverse event, culture of safety, medication safety, adverse drug event.

The Case

An infant was born with sluggish respirations. During labor the infant's mother had received meperidine [Demerol, a pain medication], a narcotic with a half-life of 2.5–4.0 hours in adults and 12–39 hours in neonates. The physician started resuscitation and ordered naloxone [an opiate antagonist]. Shortly after administration of the medication, the infant's condition began to deteriorate further.

Prompted by the proximity of the deterioration to the administration of the naloxone the physician checked the packaging of the drug. The syringe had inadvertently been filled with Lanoxin® [digoxin, a cardiac medication] instead of naloxone. The packages of both drugs, made by the same manufacturer, were almost identical. ECG revealed bi-directional ventricular tachycardia, consistent with digoxin toxicity.

Approximately 1 hour later the infant died. A post-mortem digoxin level was 17 ng/ml (therapeutic range 0.8 to 2 ng/ml).

The Commentary

Bryony Dean Franklin, PhD, Director, Academic Pharmacy Unit, Hammersmith Hospitals NHS Trust and The School of Pharmacy University of London

What does this tragic case tell us, and more importantly, what can we learn from it? Following symptoms of meperidine toxicity, a doctor prescribed naloxone, an appropriate antidote. However, digoxin, a cardiac glycoside, was administered instead, and the baby died of digoxin toxicity.

On face value, it is almost impossible to imagine how this could have occurred. However, when one realizes that the brand name of digoxin is Lanoxin®, and that in this case both drugs were made by the same manufacturer and presented in similar packaging, it may be slightly easier to understand how the error happened. Both are drugs that would be stocked on a typical neonatal unit, and the doses used are similar. The intravenous dose of naloxone recommended for use in newborn babies is 10 mcg/kg every 2-3 minutes, and a digoxin loading dose is 10 mcg/kg to 17.5 mcg/kg depending on the age of the baby and whether he was full term. If whoever administered the drug confused naloxone with Lanoxin, either because she thought this was the brand name for naloxone, or simply because the name on the packaging was misread, there would be few cues to suggest that the wrong drug had been selected until after it had been administered.

Observational studies in hospitals have reported administration errors in 3-8 percent of doses in the United Kingdom (UK) (1,2), and in 0.6-14.6 percent in the United States (US) (3), excluding wrong time errors. Methods and definitions vary, so it is difficult to compare studies directly, but it is clear that administration errors are not uncommon. Wrong drug errors are typically a smaller proportion of these, occurring in about 0.2% of all doses given. (4) Fortunately, most administration errors do not result in outcomes as tragic as in this case.

There are various approaches to investigation. For example, the Clinical Risk Unit in the UK has developed a protocol for the investigation and analysis of adverse events in clinical practice (8) based on a well-known model of human error. (9) This method requires training to be used effectively, but involves interviewing staff involved to identify care management problems and why each occurred.

The investigation aims to identify contributing factors at the level of the institution, organization and management, work environment, team, individuals, task, and the patient. (10) Such an approach would likely be useful in investigating this incident, and would highlight more wide-reaching issues than the simple fact that someone gave the wrong drug.

Discussion Questions

1. **What systems do you think might prevent or minimize this type of error?**

Consider:

- **Do you think health care facilities should restrict the forms available or the concentrations available in pediatric units?**
- **Should practitioners be required to include indications for all medication orders?**
- **Do you think independent double-checks would have prevented this incident?**
- **Both of the medications involved may be used emergently in an acute situation. What can be done in a high stress emergent setting to prevent incidents like this?**

Defenses could be built in at many stages, depending on the outcome of the investigation. These may include purchasing products from different manufacturers, reviewing how look-alike and sound-alike products are stored, and highlighting drugs that could potentially be confused. Another approach may involve improving systems of communication between prescribers and nursing staff. It has been proposed that all medication orders should include the indication for which the drug is being used, as this may prevent some errors (though probably not in an urgent situation such as this one). In this case, had the physician indicated that the baby was being treated for opiate toxicity, the nurse might have hesitated to draw up a cardiac glycoside.

More global changes are needed to increase the risk assessment carried out when naming medicinal products, to minimize the risks of mix-ups occurring. The Institute for Safe Medication Practices provides proprietary reviews of proposed names, trademarks, packaging, and labeling for pharmaceutical industry clients (<http://www.ismp.org/Pages/MedErrs.html>) in an attempt to prevent potentially confusing names. Unfortunately, such reviews are not yet compulsory.

Little is known about the true causes of administration errors like this one. However, studies have examined the causes of prescribing errors (5) and other types of medical error (6) using psychological models of human error. In addition to exploring why the error occurred at the level of individuals at the “sharp end,” such studies also aim to identify the organizational and environmental factors that make errors possible. The objective of identifying these latter factors is that actions here are likely to have the most impact in preventing future errors. While there have been no in-depth studies of the causes of administration errors, similar packaging, and look-alike or sound-alike names (7) are considered important contributing factors.

2. In your opinion, should this error be disclosed to the parents? If so, what would that look like?

Experts in medical ethics and professional organizations all endorse disclosure of errors. A recently published exploration of both patients' and physicians' attitudes toward medical error disclosure, which used scenarios with errors specifically involving medication, found that patients wanted disclosure of all harmful errors and sought information about what happened, why, and how similar errors will be prevented in the future.(11) There was less agreement over whether near misses should be disclosed. Physicians agreed that harmful errors such as this one should be disclosed, but the report found that they "chose their words carefully" when telling patients about errors. Although physicians disclosed the adverse event, they often avoided stating that an error had occurred, why it happened, and how it would be prevented. These findings back up those of other studies (12) from the viewpoints of both doctors and patients.

Take-Home Points

- Errors in drug administration occur relatively often.
- Packaging and look-alike/sound-alike drugs are thought to be important contributing factors.
- Risk assess look-alike and sound-alike products and consider how they are stored.
- Improving communication between medical and nursing staff may help to prevent errors.
- Patients and their families want disclosure of errors, along with information on how similar errors will be prevented in the future.

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AHRQ WebM&M is produced for the Agency for Healthcare Research and Quality by a team of editors at the University of California, San Francisco. The AHRQ WebM&M site was designed and implemented by Silverchair.