Medication Safety Alerts

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This column draws on US and Canadian experience and may include, with permission, material from the *ISMP Medication Safety Alert!*, a biweekly bulletin published by the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pennsylvania.

STERILE WATER: ERROR REPORT LEADS TO CHANGE FOR CANADIAN HOSPITALS

The Incident

After completing a patient care procedure, a health care professional intending to connect normal saline to a patient's IV line inadvertently connected a 1-L bag of sterile water for injection. Approximately half of the contents of the litre bag were infused before the error was noted. IV administration of a solution for hydration is routine and is generally without risk for error-induced injury. However, because of the hypotonicity of water, accidental IV administration of sterile water can cause serious morbidity and is potentially deadly. In this case, significant renal complications occurred.

Finding

Serious harms that can be attributed to medical care require careful examination. In this incident a contributing factor was the fact that the sterile water product and the sodium chloride IV solution product had similar labelling and packaging (Figure 1).

The error was alarming for all involved, and there was a sense that the same error might have happened before and could happen again, in any hospital. The incident was reported to a national voluntary error-reporting program (administered by the Institute for Safe Medication Practices Canada) with the goal of alerting other hospitals (https://www.ismp-canada.org/err_report.htm). A warning bulletin was distributed to Canadian hospitals,[1] which led to the reporting of similar incidents from elsewhere in North America.[2-4] In one US incident, a patient died as a result of IV administration of plain sterile water.[2]

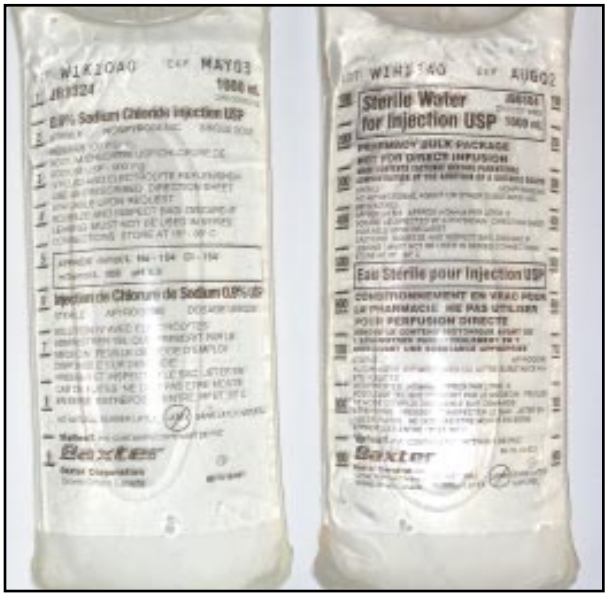

Figure 1. Left: Sodium chloride 0.9% for injection (intended for direct IV use). Right: Sterile water for injection (not intended for direct IV use).

The decision to report such events illustrates a new approach among health care providers to errors and adverse events. In addition to disclosing information about such events to patients, there is a recognition of the need to warn others and to seek system improvements. There is a new ethos of openness and accountability.

Systems Thinking

The concept that errors are linked to faulty systems and not faulty people is the foundation of the patient safety movement.[5-7] It is new thinking for many and is the reverse of what we were taught in medical, nursing, and pharmacy schools.[8] As health care professionals we are taught to maintain competence, practice due diligence, and take care to avoid mistakes. Systems theory states that although these steps are necessary, they are not enough. The way to prevent mistakes and to mitigate harm from mistakes that do occur is to redesign systems with integrated safeguards, in addition to practising due care.

Evidence indicates that a large percentage of medication errors are attributable, at least in part, to commercial labelling, packaging, and nomenclature.[9] Therefore, ISMP Canada worked with Baxter Corporation (Canada) to enhance labelling for the sterile water product and continues to work with manufacturers and Health Canada to further improve labelling and review packaging of all sterile water products. Descriptions of the labelling changes and the rationale for them were communicated in a bulletin to hospitals.[10] Brief descriptions are included here, with permission.

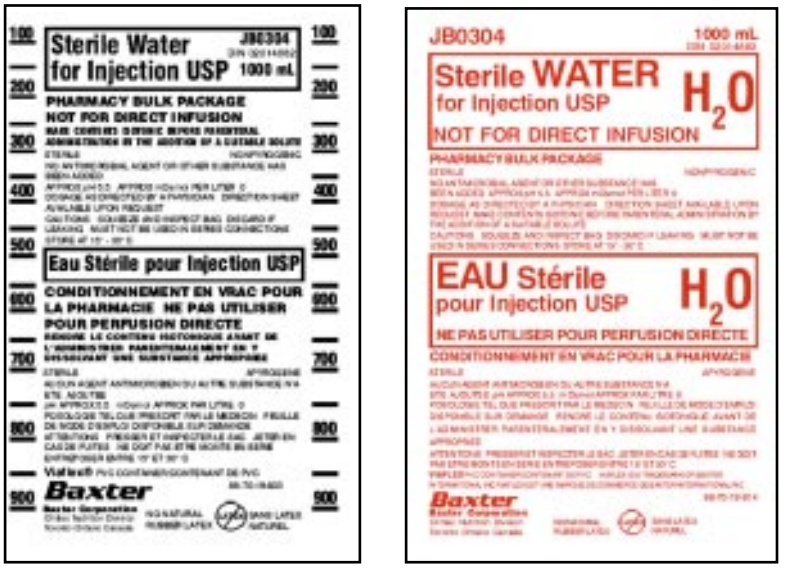

Figure 2. The recently implemented label for sterile water for injection (at right) uses colour, information display, and redundant cues to help differentiate the product from IV solutions. The previous label for this product is shown at left.

Use of Colour

Studies indicate that the colour red conveys the highest level of perceived hazard, followed by orange, black, green, and blue.[11] The change from black print to all red print on the label (Figure 2) sends a message of warning to the health care professional.

Prominence of Critical Information

The words "Not for Direct Infusion" have been given prominence on the new label. The word "WATER" appears in larger print size, in uppercase lettering.

Use of Redundant Cues

The use of the international chemical symbol H_20 adds a "redundant cue" to the label, assisting the user to identify the product as water.

Discussion

To our knowledge, there are no other reports of a hospital, a pharmaceutical manufacturer, and a voluntary error-reporting program working together in the early stages of error analysis to systematically identify improvement opportunities. The shared information led to the identification of several unusual events that lined up in such a way that the error could have been predicted by human factors specialists. It is recognized that effective error prevention in complex systems requires a multipronged approach. Error analysis can identify improvement opportunities both within and outside the immediate workplace. Strong emotions elicited after an error and a belief that human error must, by definition, have a preceding cause can be powerful motivators for system redesign, and such redesigns can only be fully realized through team efforts. Reporting the error was the first step.

The US Institute of Medicine report[12] summarized findings from various medical adverse event studies to create awareness that health care is a high-risk industry. It proposed that "a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations."[12] The recently released Canadian Adverse Events Study concluded that "Efforts to make patient care safer will require leadership to encourage the reporting of AEs" [adverse events].[13]

The sterile water story illustrates a heightened level of interest in working together across boundaries and between organizations to enhance safety within our health care systems.

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