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How to Use 'Failure Mode and Effects Analysis' to Prevent Error-Induced Injury with Potassium Chloride

In this bulletin we will briefly describe reports of sentinel events and near miss incidents with potassium chloride that have been reported to ISMP Canada during the past two years. The literature is replete with reports of similar errors worldwide (Medline search) and selected case reports are referenced.¹⁻⁵ We will present the concept of Failure Mode and Effects Analysis (FMEA) and show how it can be used to prevent injury with potassium chloride in hospital medication use systems. We conclude this bulletin with a recommendation for change.

The following incidents with potassium chloride have been reported to ISMP Canada:

1. 10 mL potassium chloride (KCl) concentrate was administered direct IV when the intended action was to flush an intravenous line with 10 mL 0.9% sodium chloride. Result: patient fatality.
2. 10 mL KCl concentrate was used to reconstitute a drug for parenteral administration when the intended diluent was sterile water. Result: Near miss (error was noted before administration).
3. 10 mL KCl concentrate was administered as a bolus injection by a health care professional who was unaware that KCl concentrate cannot be given as a bolus but must be diluted in a minibag and given as an infusion. Result: patient fatality.
4. A one-liter IV solution was prepared with 400 mEq of potassium chloride and although it was administered at a very low rate, the incident was felt to be a near miss because of the potential for accidental overdose.(error was noted during administration).
5. IV solutions containing KCl were administered as a fluid replacement in a patient requiring several liters of fluid in a short time frame. Result: hyperkalemia, patient fatality.

Many Canadian hospitals continue to have weaknesses in their medication use systems that place their patients at risk of serious consequences from errors with potassium chloride. The purpose of FMEA is to discover the potential for risk in a product or system by analysis of the possible failures, their consequences and their possible risk factors. The questions one asks in order to perform failure mode and effects analysis are: "What could fail and how?" and "Given the various possibilities for failure, what are the potential consequences of each?" The concept was first introduced in the engineering literature in the early 1960's⁶. It is now a standard procedure in many industries. The

time for its application to the Canadian healthcare industry is overdue. The application of this mode of analysis to the use of potassium chloride could have forestalled the accidents and near-accidents described above.

The following examples of post accident analysis, showing what would have been detected by FMEA, will serve as a guide to you for use in your hospital, in order to identify risks to your patients and to assist in targeting areas for improvement.

In the KCl incidents #1 and #2, the fundamental human failure (error mode) was an error of substitution. The substitution was expressed in the picking up of a vial of KCl when the intent was to pick up sodium chloride or sterile water. The effect of such a substitution error, if injection follows, is almost always fatal.

System Remedy:

The system remedy is to remove potassium chloride concentrate from all patient care areas; to purchase pre-mixed IV solutions containing potassium chloride; and to standardize prescribing practices to match available pre-mixed solutions. Most medical conditions can be appropriately treated with the commercially available pre-mixed solutions. For those solutions determined to be necessary, but unavailable commercially, have Pharmacy prepare admixed solutions.

There are many references^{3,7,8} that describe similar errors with concentrated KCl and advocate for removal of potassium chloride concentrate from patient care areas.

Concentrated potassium chloride, even if stocked only in the Pharmacy, has the potential for error-induced injury. We suggest the following stratagems aimed at making the potassium chloride concentrate product 'look and feel different' from other products:

- (i) Add an auxiliary label to the concentrated KCl product such as:

**** CAUTION ****
Concentrated KCl
Fatal if Injected Undiluted
DILUTE before use

- (ii) Remove the 10 mL size of the potassium chloride concentrate from all hospital inventories. The larger 20 mL size "looks and feels different".

In the KCl incident #3 where KCl concentrate was administered as a bolus dose, the failure mode was determined to be an error of omission: forgetting about the lethality of concentrated KCl.

System Remedy:

In addition to the system remedy described above, clearly stated and easily accessible information on the prescribing, the administration and the monitoring of potassium chloride should be readily available. Orders such as “KCl 40 mEq IV now” must be considered incomplete and unacceptable. Guidelines for the maximum rate of infusion, the required frequency of serum potassium monitoring, the use of an infusion pump and cardiac monitoring, along with renewed and continuous training, provide system safeguards.

In the KCl incident #4, the failure mode was determined to be an error of omission: a failure to institute and/or apply a safe potassium chloride use policy. In addition to the system remedies described above, a clear policy on a maximum content of potassium chloride in an IV bag should be developed and well communicated.

In the KCl incident #5, the failure mode is difficult to ascertain because of the lack of detailed information in the report submitted.

Recommendation:

ISMP Canada recommends that hospitals create a ‘high-level’ multidisciplinary Task Force dedicated specifically to identifying the system weaknesses that could potentially result in patient injury with the use of potassium chloride. The Task Force needs to develop a mandate to reduce the error potential with potassium chloride and to define a strategy to implement the necessary changes in your organization, with target timelines. In addition, efforts to educate all hospital staff about the safety initiatives will serve as an example of a system re-design and will demonstrate a culture of patient safety.

If you would like assistance from ISMP Canada with your hospital initiatives please write to us at info@ismp-canada.org. If you have system improvement ideas or ‘successes’ to share we would appreciate hearing from you. ISMP Canada believes that one person can make a difference. If you have read this bulletin, you can lead the way for change in your place of work!

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