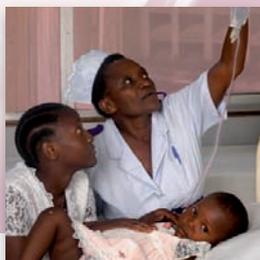


Control of Concentrated Electrolyte Solutions

Patient Safety Solutions

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► STATEMENT OF PROBLEM AND IMPACT:

Concentrated potassium chloride has been identified as a high-risk medication by organizations in Australia, Canada, and the United Kingdom of Great Britain and Northern Ireland (UK) (1-8). In the United States of America, ten patient deaths from misadministration of concentrated potassium chloride (KCl) solution were reported to the Joint Commission in just the first two years of its sentinel event reporting programme: 1996–1997 (1). In Canada, 23 incidents involving KCl mis-administration occurred between 1993 and 1996 (2). There are also reports of accidental death from the inadvertent administration of concentrated saline solution (3).

While all drugs, biologics, vaccines, and contrast media have a defined risk profile, concentrated electrolyte solutions for injection are especially dangerous. Reports of death and serious injury/disability related to the inappropriate administration of these drugs have been continuous and dramatic. Most of the time, it is not clinically possible to reverse the effects of concentrated electrolytes when not administered properly (e.g. not properly diluted, confused with another drug, etc.), and hence, patient death is usually the observed outcome. In short, these agents are deadly when not prepared and administered properly.

It is especially critical that the availability, access, prescribing, ordering, preparation, distribution, labeling, verification, administration, and monitoring of these agents be planned in such a way that possible adverse events can be avoided, and, hopefully, be eliminated. Standardizing the dosing, units of measure, and terminology are critical elements of safe use of concentrated electrolyte solutions. Moreover, mix-ups of specific concentrated electrolyte solutions must be avoided (e.g. confusing sodium chloride with potassium chloride). These efforts require special attention, appropriate expertise, inter-professional collaboration, processes of verification, and several forcing functions that would ensure safe use.

► ASSOCIATED ISSUES:

Removal of concentrated electrolyte solutions, specifically potassium chloride, from patient care units has had a marked positive impact on the reduction of death and disabling injury associated with these agents. Several forcing functions are inherently implemented when these agents are removed from patient care units; namely, the drug must be prescribed and ordered; it must be properly prepared (e.g. diluted), packaged, and labeled; and it must be administered with appropriate care and expertise. By not having these products on the patient care unit, they cannot simply be reached for, drawn up, and injected.

While some might suggest that such procedures impede rapid-action to meet patient care needs in case of emergency, it is important to know that plans and procedures for such eventualities can be put in place to make concentrated electrolytes safely available in such cases. Collaborative efforts in this regard between physicians, nurses, and pharmacists are recommended. Institutional and cultural change may be required to ensure that fail-safe systems are in place in order to avoid death or disabling injury associated with the inappropriate use of concentrated electrolyte solutions.

Although concentrated KCl is the most common medication implicated in electrolyte administration errors, potassium phosphate concentrate and hypertonic (>0.9%) saline also have lethal consequences if improperly administered. Until recent concerns prompted revised practices, it was common to find concentrated electrolyte solutions in the unit/clinic stock located in close proximity to other less hazardous, similarly packaged and labeled solutions. This situation, coupled with the practice of having ward or clinic staff prepare the intravenous solution, increased the possibility of inadvertent administration of concentrated electrolytes, leading to fatalities in some cases. Fortunately, such catastrophic errors can be eliminated by adopting simple precautionary measures.

► SUGGESTED ACTIONS:

The following strategies should be considered by WHO Member States.

1. Ensure that health-care organizations have systems and processes in place wherein:
 - a. The promotion of safe practices with potassium chloride and other concentrated electrolyte solutions is a priority and where effective organization risk assessments address these solutions.
 - b. Potassium chloride is treated as a controlled substance, including requirements that restrict ordering and establish storage and documentation requirements.
 - c. Ideally, removal of concentrated electrolyte solutions from all nursing units is accomplished, and these solutions are only stored in specialized pharmacy preparation areas or in a locked area. Potassium vials, if stored in a specialized patient care area, must be labeled individually with a visible florescent warning label that states **MUST BE DILUTED**.
 - d. When a pharmacist or pharmacy preparation area is not available to store and prepare these solutions, only a trained and qualified individual (physician, nurse, pharmacy technician) prepares the solutions.
 - e. After solution preparation, there is independent verification of the electrolyte solution by a second trained and qualified individual. The organization should establish a checklist that is used for the independent verification. Checklist items should include concentration calculations, infusion pump rates, and correct line attachments.
 - f. The prepared solution is labeled with a **HIGH RISK WARNING** label prior to administration.
 - g. An infusion pump is used to administer concentrated solutions. If an infusion pump is not available, other infusion devices, such as buretrol administration tubing (tubing with an inline receptacle that limits the volume that will flow into the patient), may be considered for use, but infusions of concentrated solutions must be monitored frequently.
 - h. An organizational safety infrastructure supports the training of qualified individuals through policies, procedures, best practices, and annual recertification.
 - i. Physician orders include the rates of infusion for these solutions.

► LOOKING FORWARD:

Member states recommend that:

1. Concentrated electrolyte solutions be purchased by the health-care organization only in standardized and limited drug concentrations.
2. The health-care organization purchases and uses only premixed parenteral solutions.
3. The organization petitions the drug manufacturing industry to utilize **HIGH RISK WARNING** labels on all concentrated electrolyte solutions.
4. Regulatory agencies and drug manufacturers should be engaged to improve the safety of manufacturing these types of concentrated electrolyte solutions.

► STRENGTH OF EVIDENCE:

- Expert consensus.

► APPLICABILITY:

- Hospitals, ambulatory care facilities, ambulatory surgical centers, dialysis centers, and any other facilities that use and administer concentrated electrolyte solutions.

► OPPORTUNITIES FOR PATIENT AND FAMILY INVOLVEMENT:

- Ask what medications are being given and why they are being given.
- Learn to recognize that potassium chloride solutions and other high concentration electrolyte solutions may create dangerous situations. Ask for clarification regarding their need and route of administration if they are to be given.
- Ensure positive identification before receiving medication.

► POTENTIAL BARRIERS:

- Some organizations have limited pharmacy services.
- Perceived need to have electrolyte concentrates immediately available—especially for urgent or emergent situations.
- Economics (current low cost of pharmaceutical production of concentrated products—having pre-mixed KCL bags will increase cost).
- Lack of technology required for safe administration (e.g. infusion devices).
- Lack of staff awareness of the risk.

- ▶ Insufficient generally accepted research, data, and economic rationale regarding cost-benefit analysis or return on investment (ROI) for implementing these recommendations.

▶ RISKS FOR UNINTENDED CONSEQUENCES:

- ▶ Unacceptable delays in obtaining needed electrolyte solutions from the pharmacy.
- ▶ Gradual stockpiling of unused solutions on the nursing units for future use.

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