Clinical review

Best practices for safe handling of products containing concentrated potassium

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In February 2004, two fatal medication errors occurred in the Calgary health region, Alberta, Canada, when two different dialysis patients received dialysate solution containing formulations. The story of patients dying unnecessarily in this way had a powerful effect on the public. Numerous (often sensationalistic) accounts in the lay media across the country speculated on possible causes of the errors, publicly chastised the pharmacy technicians and other professionals involved, and called into question the safety of all of Canada's healthcare institutions. As a result of these events, an independent inquiry of the incident was conducted, a new patient safety position was created for the region,[1] a review of best practices was commissioned, and many changes were made to ensure "this would never happen again." Often it is the public response to a story about an adverse event or medical error that drives changes in practice, rather than careful attention to the available evidence.[2]

Since the publication of the Institute of Medicine's report, *To Err is Human: Building a Safer Health Care System*,[3] the safety of medications, and of patients in general, has caught the attention of the general public and hospital healthcare practitioners. This report identified medication errors as the single largest cause of medical errors in hospitals, accounting for some 7000 deaths each year in the United States. Another report estimated that more than one million medication errors occur every year in US hospitals,[4] and about 5% of all admissions to hospital are related to adverse drug events.[5] Since the report, most safety research has focused on measuring the incidence of adverse events, including medication errors, rather than evaluating the effectiveness of current or proposed safety practices relating to medication and patients. The use of potassium supplements and safe handling of potassium are examples of the kind of practice affecting the safety of patients that is common and ought to be improved through the rigorous application of evidence based practices. Surveillance systems in US hospitals report that potassium chloride concentrate is the drug most often implicated in fatal incidents.[6]

We conducted a qualitative systematic review of the literature evaluating best practices for handling products containing potassium in hospital settings, at all stages of the process by which medications are used, to help frontline personnel improve patients' safety in the hospital setting. We identified and summarised the evidence supporting practices for handling products containing potassium safely, to provide policy makers and healthcare practitioners with guidance to facilitate best practice.

Summary points

Recommendations for improved patients' safety, specifically the safety of products containing potassium, are often based on practice guidelines and untested recommendations widely endorsed by various experts or organisations

Valid and empirical evidence to support or discourage implementation of even the most widely identified potassium safety practices is completely lacking

Research aimed at evaluating healthcare systems as a whole, accompanied by implementation of effective evidence based medication safety practices, is essential and urgently needed

Methods

We searched the reference lists of major reviews already completed on the safety of medication and known bibliographies relevant to patients' safety and medication error. We supplemented this by searching the Cochrane Central Register of Controlled Trials (2nd quarter 2004), Medline (1966 to May 2004, week 4), Embase (1988 to 2004, week 22), and International Pharmaceutical Abstracts (1970 to May 2004). We used broad search terms to ensure that we identified all studies related to the safe use of potassium. Searches were not limited to specific study designs, to allow us to identify research encompassing all levels of evidence. We examined the reference lists of all related articles for relevant studies. We considered only English language reports.

We also examined sources of relevant grey literature for information about medication safety. We searched the internet to identify pertinent government agencies and non-governmental organisations, special interest groups or lobby groups, accreditation agencies, key informants, and other websites of interest. We contacted key informants from these organisations.

In recognition of the current early state of literature about the safety of patients and medications and the importance of practices that are relevant to existing systems, we systematically searched for publications that would provide a comprehensive set of best practice information across a continuum of evidence. We did not include reports that were simply descriptive in nature or that lacked any supporting evidence. We examined the entire medication process, from production in the pharmaceutical companies to direct administration of drugs to patients, to identify potential interventions. Although each stage of the medication process offers opportunities for improving patients' safety, the primary focus of this review is on those interventions that are directly applicable to the administration of potassium.

Results

Of the 2533 citations identified in the literature search, we retrieved 238 that seemed potentially relevant. We excluded all from this analysis because they were case reports, anecdotal papers, or opinion papers. We did not find a single study that evaluated the effectiveness of any of the practices routinely recommended for the safe use of products containing potassium, nor for the use of analysis of healthcare systems, including organisational culture and structure, in medication safety. The literature discussing the safety of potassium consists largely of case reports of errors resulting from the improper use of potassium, and expert recommendations for preventing these case specific errors. These recommendations are not based on evidence on the relative effectiveness of various corrective practice options but rather on expert consensus, the experience of various hospitals that have implemented specific practices, and practices endorsed by well respected patient safety and medication safety organisations. These organisations, found largely in the United States, Australia, and the United Kingdom, provide support, expertise, and resources for improving the safety of medications. Box 1 shows the spectrum of recommendations for potassium safety that we found, not as an endorsement of any particular practice, but to illustrate the broad scope of practices commonly implemented—practices that, as far as we were able to ascertain, have no evidence basis indicating they might actually reduce harm.

Removing potassium chloride from clinical areas

The single most often suggested strategy for reducing medication errors involving potassium chloride is to remove all stocks of concentrated potassium chloride from clinical areas. Rather than being based on specific research studies that have determined the efficacy of this, and other, recommendations, this suggestion is based on forcing function concepts (whereby the system is designed to force healthcare professionals to act in a certain way, preventing adverse events) drawn from research literature into human factors. Although safety organisations strongly recommend removing concentrated potassium chloride from wards, many hospitals continue to stock this medication in clinical areas. A 1997 survey of US hospitals determined that concentrated potassium chloride was kept in 59.4% of all emergency departments and 71.9% of all intensive care units.[6] The same survey indicated that the primary reason that hospital staff found it necessary to maintain stocks of potassium chloride in these departments was because patients requiring this medication often need it very quickly, and any delay in administering it could severely compromise patients' care. In addition, many hospital pharmacies have limited hours of operation, necessitating storage of potassium chloride in clinical areas. For this reason, several agencies specify that stocks of potassium chloride can remain in critical care areas, but care must be taken to avoid transferring ampoules between clinical areas.[6 7] In addition, it is often recommended that when potassium chloride must be kept on the wards it should be kept in a locked cupboard, separate from all other solutions.[6–8] Proper protocols should be developed to monitor the removal, use, and restocking of potassium chloride, including the checking of drug use against prescription orders, and to reduce unauthorised transfer of drugs across clinical departments.[9]

Packaging and preparation of potassium chloride

Mistakes are often made during the preparation of dilute solutions containing potassium. Similar packaging to other solutions, storage of potassium chloride in close proximity to other solutions, and a lack of effective independent double checking have all

Box 1: Recommendations for safe handling of potassium products

Drug storage
- Remove concentrated potassium chloride from clinical areas
- Store potassium products in locked cupboards in clinical areas
- Eliminate the transfer of potassium products between wards and other clinical areas

Drug preparation
- Have pre-prepared intravenous infusion available that contains potassium
- Prepare needed infusions in the pharmacy

Drug packaging
- Ensure ampoules of potassium chloride are distinguishable from other injectable preparations

Prescribing
- Prescribe potassium chloride in concentrations available as ready made infusions
- Avoid "incomplete" and illegible prescribing
- Prescribe oral potassium chloride to treat hypokalaemia when clinically feasible

Drug administration
- Develop clear therapeutic guidelines defining the maximum concentration of potassium in an intravenous solution
- Develop clear therapeutic guidelines defining infusion rates for the administration of intravenous potassium
- Institute a double check policy
- Ensure safe use of infusion pumps

Pharmaceutical industry standards
- Encourage distinct, standardised labelling and packaging as an industry standard

contributed to medication errors involving potassium chloride.[10] For this reason, commercially prepared dilute solutions are often recommended.[6 8 11] Some literature on safe medication recommends that healthcare providers should prescribe potassium solutions in standardised concentrations, available as commercially prepared products.[7] However, when premixed solutions are not feasible, required dilutions should be made only in the pharmacy and never in clinical areas.[12] It is recommended that in the pharmacy, efforts should be made to ensure potassium products are easily distinguishable from similar products.[8 9 13] This can be accomplished by having a separate storage area for products containing concentrated potassium and adding auxiliary fluorescent warning labels to both concentrated potassium chloride and diluted intravenous solutions.[13] In addition, some hospitals purchase concentrated potassium solutions from a different vendor from the one they use to supply dilute solutions to avoid errors caused by packaging similarities.[14]

Development of guidelines for appropriate administration

Many people recommend that therapeutic guidelines be developed for the administration of potassium chloride[13] and once developed, continuous training of healthcare staff should be implemented to ensure these guidelines are understood and implemented. The Safety and Quality Council of Australia has summarised the recommended components of potassium chloride guidelines (box 2).[9]

Most medication errors occur at the prescribing and administration level.[15 16] For this reason, clear guidelines should be developed to ensure that safe prescribing practices are used for products containing potassium. Common recommendations include ensuring that all prescriptions include instructions for dilution and infusion rates, and avoiding the term "bolus" for intravenous orders.[9] In terms of administering products containing potassium, the universal recommendation is to develop double check policies (similar to those used for blood transfusion) for every step in the process of administering medications. For example, it is often suggested that two healthcare providers always check for the correct product, dose, dilution, labelling, route, and rate before administering any medication, to ensure it complies with the therapeutic guidelines.[9]

Box 2: Recommendations for guidelines for administration of potassium chloride

- Oral potassium should be used to treat hypokalaemia when clinically feasible
- Prescribing should be standardised to ensure all intravenous potassium chloride is ordered in millimoles (mmol)
- Prescribing should be standardised, and premixed solution should be encouraged
- Clear definitions should be developed to indicate the maximum concentration of potassium chloride in an intravenous solution
- The maximum hourly rate and daily limits that a patient may receive, in addition to infusion rates and infusion pump requirements, should be specified

Discussion

It is not, perhaps, surprising to find a complete lack of valid evidence to support or discourage implementation of even the most widely recommended, identified practices for administering medication safely, with respect to the safe administration of potassium. However, considerable debate surrounding the current state of the science occurs in the literature on patients' safety and a recurrent theme consistently emerges: what role (if any) does evidence have in medication safety?

In response to the medical error data published in *To Err is Human*,[3] the Agency for Healthcare Research and Quality (AHRQ) commissioned the University of California, San Francisco-Stanford University Evidence-Based Practice Center to produce a report summarising the literature surrounding practices relevant to improving patients' safety. This landmark report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, contains summaries of the evidence supporting 83 safety practices.[17] Only six of these practices concern medication safety,[18] and none of them deals with practices specifically relating to the safe administration of products containing potassium. This report generated controversy in the literature on patients' safety, largely because most of the practices advocated by leading patient safety agencies were not tackled nor even considered. In addition, this report sparked new interest in the continuing debate surrounding the principles of evidence based medicine and its role in patients' safety.

Safety practices

Many leading medication safety experts and agencies believe that the safety of medications, indeed of patients in general, is primarily a "systems" issue. Unfortunately, this hypothesis has not been tested rigorously, and it is often claimed that changes to systems are not as easily evaluated as specific, individual practices and technologies. In addition, several practices that are widely endorsed were not mentioned in the report of the Agency for Healthcare Research and Quality but are nevertheless directly relevant to the safe handling of potassium. These include[19]:

- Instituting pharmacy based intravenous admixture systems
- Removing concentrated potassium chloride vials from areas where patients are being cared for and stocking premixed solutions on wards
- Developing special procedures for high risk drugs by using a multidisciplinary approach (written guidelines, checklists, preprinted orders, double checks, special packaging, special labelling)
- Providing doctors, nurses, pharmacists, and all other clinicians involved in the medication process with education on ordering, dispensing, administering, and monitoring medications
- Having a pharmacist available on call after hours of pharmacy operation.

Many of these practices reflect the basic tenets of the systems based approach, such as building in system redundancies ("double checks"), reducing options, and standardising or simplifying processes.[7]

Investigations of fatalities and injuries caused by the misuse of potassium need to take into account the full range of systems based factors that might affect the safety of medications, including the priority and

resources given to patients' safety in general. Furthermore, to reduce the incidence of potassium related (and other medications) errors—many of which are preventable—effectively, hospitals must go beyond investigating individual incidents and focus more on identifying and implementing effective, systems based improvements that are grounded in evidence of reasonable quality.

Conclusions

This systematic review highlights the lack of strong evidence in support of specific best practice initiatives related to the safe handling of potassium containing products. The quality and quantity of evidence in support of best practices related to other patient safety issues is likely in a similar state. If the aim is to identify and implement the most effective medication safety practices, then systems oriented evaluation research accompanied by implementation of evidence based medication safety practices is essential. The need is especially urgent given our main finding that no valid studies evaluate the effectiveness of any of the practices currently recommended for the safe handling of products containing potassium.

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Additional educational resources

Making health care safer: a critical analysis of patient safety practices (www.ahrq.gov/clinic/ptsafety/)—The report of an evidence based project, funded by the Agency for Healthcare Research and Quality, that collected and critically reviewed the existing evidence on practices relevant to improving the safety of patients, including medication safety (primarily pertaining to heparin and warfarin)

National Patient Safety Agency (www.npsa.nhs.uk)—This UK agency aims to foster a culture in which errors in the NHS healthcare system can be investigated and innovative solutions developed. In addition to providing resources, the agency collects reports of medical errors and "near misses"

Institute for Safe Medication Practices (United States: www.ismp.org; Canada: www.ismp-canada.org)—This non-profit agency's mission is to understand the causes of medication errors and provide time critical strategies for reducing errors to the healthcare community, policy makers, and the public. The institute runs a voluntary error reporting programme

Australian Council for Safety and Quality in Healthcare (http://www.safetyandquality.org/index.cfm)—Leads national efforts to improve the safety and quality of healthcare provision in Australia. Primary initiatives include medication safety, incident management, and reporting of sentinel events

Endpiece

A scientist's fiancée wants to tidy his desk in 1861

How I shall have to struggle with myself and subdue my natural inclinations before I can become a really useful wife! Do not lose patience with me, Hermann, I am easily discouraged; but I must tell you that your writing table is frightfully untidy. If I were not far too well brought up in regard to learned confusion, I should take the liberty of sorting out all the written papers from the blank sheets, with energetic hand, and putting away all the letters in a drawer—NB unread—and then go over everything with a damp cloth, on Miss Nightingale's principle. But as it is I must leave things as they are and only thankful to have discovered one human failing in you.

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