NHS
National Patient Safety Agency

PATIENT SAFETY **ALERT**

PROBLEM:

Research in UK and elsewhere has identified a risk to patients from errors occurring during intravenous administration of potassium solutions.

Potassium chloride concentrate solution can be fatal if given inappropriately.

ACTION FOR NHS BY 31 OCTOBER 2002:

This alert sets out action, including initial action in the following areas:

1. **Storage and handling of potassium chloride concentrate and other strong potassium solutions**
2. **Preparation of dilute solutions containing potassium**
3. **Prescription of solutions containing potassium**
4. **Checking use of strong potassium solutions in clinical areas**

For the attention of:

Chief Executives of NHS Trusts and Primary Care Trusts

For action by:

Chief Pharmacists and pharmaceutical advisers in NHS Trusts and Primary Care Trusts

For information to:

Regional Directors of Health and Social Care
Chief Executives of Strategic Health Authorities
Directors of Public Health: Regional, StHA, PCT
Medical Directors
Directors of Nursing
Risk Managers
Lead Consultants/Clinical Directors – critical care areas
Communications Leads
Patient Advice and Liaison Service (PALS)

Date: 23 July 2002

Purpose of this alert

The purpose of this risk alert notice is:

1. to reduce the risk of accidental overdose of intravenous potassium arising from use of potassium chloride concentrate solutions and other strong potassium solutions. (see box 1 for definition of the solutions concerned)
2. to ensure that seriously ill patients in critical care units who urgently require intravenous potassium as part of their treatment can continue to receive it promptly.

Definitions

Potassium chloride (KCl) concentrate solutions and other strong potassium solutions to which the same precautions should be applied

Solutions of potassium chloride of concentrations
10% (1 gram potassium in 10 ml)
15% (1.5 grams potassium in 10 ml)
20% (1 gram potassium in 5ml)
in ampoules and vials.

Solutions of potassium hydrogen phosphate and potassium di-hydrogen phosphate in ampoules and vials.

Critical care areas.

Intensive care units, high dependency care units, cardiac care units, other specialist critical care areas such as renal units, cardiac theatres, neonatal intensive care units and some accident and emergency departments.

ACTION:

For NHS action by 31 October 2002

1. Storage and handling of potassium chloride concentrate and other strong potassium solutions

1.1 Potassium chloride concentrate solutions should be restricted to pharmacy departments and to those critical care areas where the concentrated solutions are needed for urgent use. Potassium chloride concentrate and other strong potassium solutions should be removed from routine stock in wards and clinical departments.

1.2 Potassium chloride concentrate solutions should be stored in a separate locked cupboard away from common diluting solutions such as sodium chloride (normal saline) solution.

1.3 Potassium chloride concentrate solutions should not be transferred between clinical areas. All supplies should be made directly from the pharmacy department. Documentation should follow the pattern for controlled drugs and should record the requisition, supply, receipt and administration of potassium chloride concentrate solution.

2. Preparation of dilute solutions containing potassium

2.1 Commercially prepared ready to use diluted solutions containing potassium should be used wherever possible.

2.2 Where there is a requirement for potassium solution in a dilution which is not available commercially prepared in ready to use diluted form, the solution should be prepared in the hospital pharmacy, wherever possible.

3. Prescription of solutions containing potassium

3.1 Potassium solutions for intravenous administration should generally be prescribed in those concentrations which are currently available as commercially-prepared ready to use diluted solutions.

4. Checking use of strong potassium solutions in clinical areas

4.1 A second practitioner should always check for correct product, dosage dilution, mixing and labelling during the preparation of and again prior to intravenous administration of solutions prepared from potassium chloride concentrate and other strong potassium solutions.

For NHS action by June 2003

5. Training

5.1 Risks associated with the storage, prescribing, preparation and administration of potassium chloride concentrate should be highlighted in patient safety induction training for all staff involved in the medication process and should also feature in specific training in intravenous drug preparation and administration. This includes induction schemes for locum staff.

For further action by National Patient Safety Agency (NPSA) by April 2003

6.1 The NPSA will commission an audit to determine the use of potassium chloride concentrate and ready to use diluted solutions containing potassium within the NHS. This audit will identify the range of ready to use dilutions necessary to meet the full range of clinical needs.

6.2 NPSA will work with NHS Purchasing and Supply Agency, the Medicines Control Agency and the pharmaceutical industry to facilitate the manufacture and supply of an appropriate range of ready to use solutions to minimise the need for potassium chloride concentrate ampoules and vials in clinical areas.

6.3 NPSA will work with practitioners, the Medicines Control Agency and the pharmaceutical industry to determine the best method to ensure easy identification of potassium chloride concentrate and other strong potassium solutions and to implement distinctive standardised labelling and packaging of these products.

Background to this Patient Safety Alert

IDENTIFYING AND REDUCING RISKS FROM POTASSIUM CHLORIDE CONCENTRATE SOLUTIONS

Potassium chloride concentrate solution can be fatal if given inappropriately.

Potassium chloride is widely used and administered intravenously in diluted solutions to treat low potassium levels (hypokalaemia) in more seriously ill patients. Patients with low potassium levels may require intravenous potassium very quickly, within minutes. A delay in administering this therapy could compromise patient care and risk cardiac arrest. Some patients in critical care settings may require potassium in the form of a very small volume of the concentrated solution.
Potassium chloride concentrate ampoules can look very similar to sodium chloride, water for injection and other injectable medicines. Reports from the United States of America, Canada and the UK have identified a number of incidents where potassium chloride concentrate has been accidentally administered to patients with fatal results. A common cause of such incidents was a member of staff mistaking potassium chloride concentrate solution for sodium chloride (normal saline) solution when reconstituting a drug for injection and thereby administering to the patient an accidental overdose of potassium.

These reports have prompted recommendations for safe practice from organisations in the USA, Canada and the UK. The most recent of these was a Statement on the storage and prescribing of potassium chloride concentrate injection issued by the UK Guild of Healthcare Pharmacists in December 2000.

Relevant experience in USA and Canada

After two years of data collection on clinical errors, it became clear to the Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) in the USA that the most major category of sentinel events was medication errors and of those, the drug most frequently implicated in fatal incidents was potassium chloride concentrate. Ten incidents were reviewed in detail, where patient death occurred as a direct result of misadministration of potassium chloride concentrate. Eight of these were the result of direct infusion of potassium chloride concentrate. In all these cases, a contributing factor was the availability of potassium chloride concentrate in wards and clinical areas. In six of the eight cases, the potassium chloride concentrate was mistaken for some other medication, primarily due to similarities in packaging and labelling. Most often, the potassium chloride concentrate was mistaken for sodium chloride, heparin or furosemide (Lasix).
In summary, the risk factors were:

- Storage of potassium chloride concentrate outside the pharmacy
- Extemporaneous mixing of potassium chloride concentrate in clinical areas.
- Requests for unusual concentrations of potassium chloride solutions.

In Canada, 23 incidents were examined which took place between 1993 and 1996, and there were similar findings to those described by JCAHO.

These risk factors exist despite the dangers of potassium chloride concentrate being well known. In 1997 as part of the development of their protocol, JCAHO identified through survey that potassium chloride concentrated was kept as ward stock in:

- 59.4% of all emergency rooms
- 71.9% of all intensive care units

The JCAHO risk alert (1998) requires:

- Removal of potassium chloride concentrate from ward stock.
- Transfer the preparation of potassium chloride dilutions from clinical areas to the hospital pharmacy and use commercially available potassium chloride dilutions.
- Standardise and limit the range of potassium chloride dilutions available.

JCAHO both issued a risk alert notice and amended their accreditation standards, so that all health care organisations when visited were checked for compliance. The risk alert notice was widely published, with public relations support, to ensure that front line staff understood the significance of the findings and the reason behind the changes in practice.

Where there is no 24 hour access to pharmacy and it is felt necessary to keep potassium chloride concentrate in critical care areas, the JCAHO recommended protocols for the storage and use of undiluted potassium chloride

on care units, which have been developed in the light of scrutiny if the root cause analyses of all sentinel events, are as follows:

- Management in the care areas concerned should sign a liability release for the pharmacy. This acts to focus the mind of those concerned
- Potassium chloride concentrate ampoules and vials should be kept in amber heat sealed bags bearing the warning "Must be diluted before administration"
- Potassium chloride concentrate should be kept in a separate area in the clinical area to other ward stock medications. The controlled drug cupboard should be considered as a suitable storage location for the concentrate.
- The injection of potassium chloride in any situation where it is kept in concentrated form on the nursing unit should require the signatures of two nurses

There has been a substantial and sustained reduction in incidents involving potassium chloride in USA following release of the JCAHO alert.

Risks inherent in current control measures for potassium chloride concentrate in the NHS.

NPSA commissioned a survey between March to May 2002 on arrangements for the storage and use of potassium chloride concentrate in the NHS. The main findings of the survey demonstrate that:

- In the overwhelming majority of hospitals in the United Kingdom undiluted potassium chloride is being stored and diluted in solutions outside pharmacy areas.
- The majority of hospitals have not developed local policies regarding the storage of potassium chloride concentrate or its dilution in patient care areas.
- The majority of United Kingdom hospitals do not have 24 hour staffing by pharmacists in order to prepare dilutions of potassium chloride outside the clinical areas.
- Neither critical care physicians nor pharmacists are confident that pharmacy departments in every hospital could always prepare and deliver all the required dilutions of potassium solutions to critical care areas fast enough to ensure good patient care.

Further details

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