

ORIGINAL ARTICLE

Evaluation of the implementation of the alert issued by the UK National Patient Safety Agency on the storage and handling of potassium chloride concentrate solution

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Objectives: To assess the effectiveness of the response of NHS hospital trusts to an alert issued by the National Patient Safety Agency designed to limit the availability of concentrated potassium chloride in hospitals in England and Wales, and to determine the nature of any unintended consequences.

Design: Multi-method study involving interviews and a physical inspection of clinical areas.

Setting: 207 clinical areas in 20 randomly selected acute NHS trusts in England and Wales between 31 October 2002 and 31 January 2003.

Participants: Senior managers and ward based medical and nursing staff.

Main outcome measures: Degree of staff awareness of and compliance with the requirements of the national alert, withdrawal of concentrated potassium chloride solutions from non-critical areas, provision of pre-diluted alternatives, storage and recording in accordance with controlled drug legislation.

Results: All trusts required that potassium chloride concentrate be stored in a separate locked cupboard from common injectable diluents (100% compliance). Unauthorised stocks of potassium chloride were found in five clinical areas not authorised by the trust (98% compliance). All trusts required documentation control of potassium chloride concentrate in clinical areas, but errors were recorded in 20 of the 207 clinical areas visited (90% compliance). Of those interviewed, 78% of nurses and 30% of junior doctors were aware of the alert.

Conclusions: The NPSA alert was effective and resulted in rapid development and implementation of local policies to reduce the availability of concentrated potassium chloride solutions. The success is likely to be partly due to the nature of the proposed changes and it cannot be assumed that future alerts will be equally effective. Continued vigilance will be necessary to help sustain the changes.

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It has been estimated that adverse events feature in around 10% of admissions to hospital, affecting 850 000 people a year,¹ costing the NHS in the region of £2 billion,² and causing pain and suffering to patients. It was in order to reduce the incidence of such incidents that the National Patient Safety Agency (NPSA) was established in 2001 to monitor adverse incidents and improve patient safety in England and Wales. This body, like its counterparts in the US and in Australia, made concentrated potassium products the subject of its first alert.^{3–5}

The fatal consequences of inappropriate administration of strong potassium chloride solution have been acknowledged for many years. The substance has been used inadvertently instead of sodium chloride to flush IV lines; instead of water for injection to reconstitute antibiotics; or has been confused with frusemide, a loop diuretic with which it is frequently given.^{6–7} Such confusion is exacerbated by the fact that high concentration potassium chloride is produced by a variety of manufacturers in ampoules that commonly resemble those containing sodium chloride and water for injection (fig 1). Even when diluted, the substance may give rise to problems because its hyperbaric properties make adequate mixing difficult. However, because blood potassium levels below 2.5 mmol are potentially fatal and need urgent and carefully titrated correction, many clinicians have opposed previous attempts to remove it from clinical areas. A summary of the alert is given in box 1 and full details are available from the NPSA website (http://81.144.177.110/site/media/documents/486_riskalertpsa01.pdf).

Given that this was the first directive from a new NHS organisation, it was important to study its effect so, 1 month

after the publication of the alert by the NPSA, we were commissioned to evaluate its impact. The study aims were to examine the receipt, dissemination, and management of the alert and to assess the extent of compliance with its requirements. Data collection started 1 week after the date



Figure 1 Plastic ampoules of sodium chloride, water for injection, and strong potassium chloride. Picture courtesy of Hull and East Yorkshire NHS Trust.

Box 1 Requirements of the NPSA alert on potassium products

Potassium chloride (KCl) concentrate solutions and other strong potassium solutions should be:

- restricted to intensive care environments;
- prepared in pharmacies when no commercial product of the correct concentration is available;
- subject to the same recording processes as controlled drugs;
- stored in a locked cupboard;
- signed for by a second practitioner;
- not transferred between clinical areas.

by which it was supposed to be implemented (31 October 2002) and was completed 3 months later.

METHODS

We planned to carry out this research in a random sample of 20 NHS hospital trusts. Forty NHS trusts were initially identified by applying computer generated random numbers to a Department of Health list of acute trusts. After taking mergers into account, the Chief Executives and Medical Directors of 37 trusts were invited to take part in two studies, the second of which (evaluation of the implementation of NICE guidance) entailed a detailed audit of patient records.⁸ Twenty trusts finally agreed to take part in both studies, the remainder citing as a reason the workload implications of the NICE study. The sample exhibited features of good geographical spread, size distribution, and performance rating (see Appendix 4 available online at <http://www.qshc.com/supplemental>). The study was exempted from ethics approval by the South East MREC who classified it as an audit.

Semi-structured interview schedules for senior managers and structured schedules for ward staff were developed and administered by experienced nurse teachers from the University of York (see Appendices 1 and 2 available online at <http://www.qshc.com/supplemental>). Documentary evidence of action and consultation was collected to form an “audit trail”. The same researchers also undertook an inspection of 10 clinical areas in each trust selected for the likelihood of regular potassium use.

Interviews with senior managers

All medical directors, clinical governance leads, chief pharmacists, chief nurses and clinical risk managers were approached for interview using a semi-structured format. We also interviewed others identified as having a key role in the dissemination and implementation process. Specific data were recorded on the interview schedules with these 70 senior managers to enable the development of descriptive statistics, but interviews were also recorded and transcribed.

Data analysis was concurrent and clear thematic categories and subcategories emerged.^{9–10} These categories were developed by two researchers working independently, and differences compared and reconciled by discussion. Differences between trusts and groups of respondents were examined using analytical matrices.¹¹

Ward audits

Although the NPSA alert named some specific clinical areas that would require continued access to the concentrate, it also referred to “other specialist critical care areas” and it was found that most pharmacy departments held their own list of

“authorised areas”. In each trust at least five authorised and five unauthorised wards were visited and audited for availability, storage, and recording of potassium chloride using an audit checklist (see Appendix 3 available online at <http://www.qshc.com/supplemental>). Researchers inspected all drug cupboards, drug trolleys, other storage facilities, and preparation surfaces in both patient areas and in clinical preparation rooms. In addition, they examined opened boxes and containers holding sterile water and sodium chloride for injection and examined books used for recording the use of potassium. In total, 207 areas were inspected.

Ward staff interviews

A convenience sample of eight registered nurse ward managers and two junior doctors in each trust was interviewed to ascertain their awareness of the NPSA requirements and to explore any problems that had arisen since the implementation of the alert (see box 2 for definitions of staff types). In total, 166 ward managers (or their nominees) and 37 junior medical staff were interviewed in addition to 14 others including night nursing staff. A structured interview schedule was used for these interviews and these were coded and analysed using SPSS.

Audit trail

Trusts were asked to provide evidence of action taken in advance of and immediately following the alert. These data—consisting of policies, memos and minutes of meetings—were used to triangulate the information given in the interviews.

RESULTS

The results reported here represent a distillation of data from all sources. The themes emerging from the senior manager interviews and the open questions in the structured interviews with ward staff related to previous action, dissemination, awareness and reaction, implementation of the guidance (storage, recording and authorisation), actual and potential unintended consequences and unresolved issues.

Previous action taken

Interviews with senior managers revealed that 19 trusts (95%) had previously taken some prior action to reduce dependence on the concentrated solution although only one was fully compliant with all aspects of the guidance at the

Box 2 Definitions of professional roles

- Medical director: trust board member representing doctors
- Clinical governance lead: executive member of trust board with responsibility for clinical quality
- Ward manager/ward sister/charge nurse: registered nurse in charge of ward
- Junior doctor: all non-consultant grades
- Clinical risk manager: person responsible for undertaking risk assessments and identifying and addressing potential and actual clinical risk.
- House officer: newly qualified doctor in pre-registration year
- Senior house officer: registered doctor who has completed a minimum of 1 year’s practice after qualifying.

Table 1 Percentage of each staff group reached by stated means of communication

Staff group	Guidance/policy circulated	Memo	Email	Routine meeting	Orally by pharmacist	Other	Educational event
Ward sister/Charge nurse	27.0%	25.2%	15.3%	12.6%	27.9%	27.9%	3.6%
Staff nurse	18.2%	47.3%	3.6%	14.5%	12.7%	21.8%	0.0%
House officer	5.6%	61.1%	0.0%	5.6%	5.6%	50.0%	5.6%
SHO	0.0%	7.1%	0.0%	0.0%	14.3%	50.0%	0.0%
Specialist registrar	20.0%	0.0%	20.0%	20.0%	20.0%	40.0%	0.0%
Other	50.0%	28.6%	28.6%	21.4%	21.4%	21.4%	0.0%

Figures do not sum to 100% as some respondents quoted more than one source of information.

time the alert was published. All managerial claims were substantiated by the audit trail.

Dissemination, awareness, and reaction

Interviews with ward based personnel revealed that an average of 135 nurses (79%) and 11 doctors (30%) were aware of the alert and could provide information concerning the provisions. Most nurses welcomed the action taken, typical comments being:

"It's not about making our jobs more difficult, it's about protecting us. It's been quite reassuring and improved safety. It recognises that we are humans and we do make mistakes." (Ward sister)

"The guidance has resulted in the benefit of having peace of mind." (Staff nurse)

There was considerable variation in the means by which nursing and medical staff at ward level had become aware of the policy or its provisions (table 1). Circulation of the policy, staff meetings, and oral communication by pharmacists appeared to be the most effective mechanisms for communicating with nursing staff, whilst memos, emails, and overheard conversations were the means by which most junior doctors had received the information. The ward interviews revealed that doctors were, almost without exception, unaware of any procedures relating to storage and recording of drugs or of obtaining them out of hours, claiming that these were nursing responsibilities.

Authorisation of areas

Four pharmacists reported having discussions with the NPSA to determine whether they could authorise theatres or paediatric units to hold the concentrated solution and had been told that this was possible, subject to a full risk assessment. The range in the number of areas authorised to

hold the concentrate was 2–11 for small trusts; 4–11 for medium trusts, and 5–27 for large trusts.

Eighty seven of the 207 areas visited were found to be in possession of concentrated potassium chloride solution (table 2). Eighty two of these were named in trust policies as authorised. Of the five areas in three trusts that were not authorised, two (accident and emergency and renal unit) lay within the NPSA's definition of critical care areas and two were theatre recovery areas, which had been authorised in other trusts. Strong potassium chloride solution was found on only one general medical ward (from which it was promptly removed by the lead pharmacist) and no potassium phosphate was found outside intensive care units.

Storage

The audit revealed that, of the 87 wards and departments in which strong potassium chloride was found, in 70 cases it was stored in the controlled drug cupboard, in seven in the outer drug cupboard, and in 10 in a separate locked cupboard (100% compliance). Storage of potassium dihydrogen phosphate was also in line with the alert. Overall, it was clear that in the majority of areas the storage space for controlled drugs was inadequate for its purpose and, had potassium chloride been made a true controlled drug under the provisions of the act, many trusts would have required a wholesale replacement of these cupboards. As it is, in most wards these tiny cupboards are piled high with drugs, frequently necessitating the removal of several boxes to locate the drug required.

Recording

Fifty seven (65%) of the areas in which the strong solution was found were recording its use in a controlled drug register and 25 (29%) were using a separate potassium register. Five (6%) were not making any record. The failure to record the use of strong potassium chloride was an error in four cases

Table 2 Wards audited indicating whether or not authorised to stock strong potassium chloride solution

Wards and departments	No of authorised areas visited	No of unauthorised areas visited	Total visited	KCl found in unauthorised area	Recording error found in at least one entry in book
Accident & emergency	5	5	10	1	4
Coronary care	12	4	16		1
High dependency	6	4	10		2
Intensive care	28	1	29		4
Medical	2	53	55	1	1
Obstetrics	3	2	5		3
Paediatric	5	6	11		
Renal unit	2	2	4	1	
Surgical	0	35	35		2
Special care baby unit	10	0	10		
Theatre – recovery	7	6	13	2	2
Theatre – anaesthetics	2	2	4		1
Other	0	5	5		
Total	82	125	207	5	20

and a deliberate strategy in one intensive care area where the staff maintained that they already recorded and double signed the administration of potassium chloride in the patient's care plan and so refused to sign the controlled drug register for the preparation, citing pressure of time.

"The hardest bit of the guidance has been the double checking and signing for ... given that they already had to double sign the treatment card and double sign the label and what they were very concerned about was taking a one to one nurse away from a patient to go to a cupboard." (Clinical risk manager)

In addition to these five wards, auditors noted 13 cases in which second signatures were missing and two in which patients' names were not recorded.

Out of hours arrangements

No pharmacy in any of the 20 trusts visited was open for 24 hours. Typically, out of hours arrangements, as described by senior managers and confirmed by policy documents, indicated that the first action was to borrow a stronger commercially prepared solution from another ward area or, through the nurse in charge, to access these from an emergency drug cupboard. If these measures proved insufficient, the on-call pharmacist was to be contacted. In one trust the nurse in charge had authority to dispense with the on-call pharmacist in specific life threatening clinical emergencies, providing certain conditions were met.

Actual and potential unintended consequences

Senior managers were asked whether they had concerns about any unintended consequences of the implementation of the guidance. Five stated that there was a need to monitor whether restrictions were impeding access to potassium for patients who required it. This was of particular concern in cardiac theatres and cardiac intensive care units where potassium levels can fall quickly.

"In cardiac surgery you do actually use large volumes of potassium and some of it is actually not prescribed by doctors but perfusionists – the people who drive the cardiopulmonary bypass. Their role includes putting potassium into the heart lung machine. In a way, cardiopulmonary perfusionists are practitioners in their own right and they have their own system of registration." (Consultant anaesthetist)

Concern was also expressed at the potential for deskilling staff in non-authorized areas, bearing in mind that all but four trusts retained the right to make the strong solution available for named patients on unauthorised areas. Some managers pointed out the need for constant vigilance lest the concentrate find its way back into unauthorised areas as a result of lack of storage space for, or non-availability of, commercially produced solutions or for reasons of cost or access. Finally, two were anxious about inappropriate use of the stronger solutions (40 mmol in 100 ml; 50 mmol in 50 ml) of which clinicians had no prior experience.

"There was a fear that we were changing the risk from the ampoules to the 40 mmol in the 100 ml bags. Firstly, they are unlicensed and, secondly, although not as concentrated as the injection, they can still cause harm so we had to demonstrate that we weren't merely transferring the risk from one preparation to another." (Chief pharmacist)

One pharmacist reported a recent case of a consultant giving the stronger solution as a bolus injection through a peripheral vein.

Unresolved issues

Both managers and ward staff were invited to comment on any issues arising from the alert and some of their responses have been embedded in sections above.

There had been a few recorded instances of problems encountered since the implementation of the guidance. Staff

on paediatric and other wards with specific patient groups (cardiac surgery) were concerned about having to go through complex processes in the middle of the night to obtain the concentrate, although these were not common complaints.

"Fluid-restricted patients present a major challenge. The rigmarole to get hold of the concentrate in the middle of the night is ridiculous." (Ward sister)

There were also issues for manufacturers. Eighteen managers and ward staff stressed the need to address the packaging and labelling of ampoules and of IV solutions containing potassium to clearly differentiate them and so avoid confusion (fig 1).

"After all that has been said about this, it is obscene that the ampoules are so similar to water and sodium chloride. You would have thought that they would have done something about it by now." (Registered nurse)

"The red writing on the IV bags is on the side of the bag. You need it on the front of bag in red." (Registered nurse)

Others stated that the sudden rise in demand for 40 mmol potassium chloride in 100 ml solutions of sodium chloride or glucose was creating problems for manufacturers and stressed the importance of these substances being constantly available.

"We had to wait three months for the glucose bags – there is no point in doing all this unless we can ensure a constant supply, otherwise people will go back." (Assistant chief pharmacist)

DISCUSSION

There are a number of limitations to this study. The 20 NHS trusts that agreed to take part may not be an unbiased sample even though the given reasons for non-participation were unrelated to the research study reported here. Trusts had around 6 weeks warning of our audit which may have prompted implementation of the alert, although in all cases the audit trail revealed activity from the date of the alert or earlier, rather than commencing after our first contact. Finally, the audit was carried out immediately after the implementation date and thus we may have failed to identify problems that had yet to surface, and conversely identified easily resolvable problems. The main strengths of the study lie in the physical inspection and audit trail which verified both the accuracy of interview data and the effectiveness of the management action.

Overall, the dissemination process from the NPSA to the trusts and thence to senior managers had worked well. The alert was welcomed by all pharmacists interviewed who felt that it had lent authority to their efforts to restrict the availability of concentrated ampoules and to promote the use of commercially available dilutions. This illustrates a potential value of these communications in providing strong central backing for the views of a significant professional group which may stimulate more action from senior managers than would otherwise be the case.

The list of areas permitted to stock potassium ampoules left trusts some room for manoeuvre and, on advice from the NPSA, most trusts had carried out a risk assessment and had added general theatres, labour wards, and paediatric wards to their list of authorised areas. There was wide variation in the number of wards authorised within trusts of the same size, which may indicate further room for removal of the concentrate from clinical areas.

The only opposition to the requirements of the alert came from intensive care staff, and particularly from those involved with cardiac surgery patients, who cited as a problem the time consuming nature of the new procedures caused by the location of some controlled drug cupboards and the fact that the drugs could only be checked out ampoule by ampoule to address the immediate need of the patient.

Key messages

- The potentially fatal consequences of the inappropriate administration of concentrated potassium chloride have been acknowledged for many years.
- In 2002 the newly formed National Patient Safety Agency (NPSA) made the substance the subject of its first alert.
- All 20 trusts visited had taken action in response to the alert (100% compliance).
- The substance was found in five clinical areas which were not authorised by the trusts to stock it, although only one of these was a general ward (98% compliance).
- 78% of nurses and 30% of junior doctors were aware of the alert and could describe at least some of its requirements.
- Recording errors were found in 20 of the 207 areas visited (90% compliance).
- Senior staff welcomed the intervention of the NPSA in assisting the implementation of a policy widely held to be in the interests of patient safety.

Given that the literature is peppered with tales of patient deaths arising from the confusion of potassium chloride with sodium chloride and water for injection, it seems inappropriate that the packaging and labelling has not been made more distinctive.

Poor awareness on the part of junior doctors, despite the commendable efforts of some pharmacists to communicate, was a source of concern. The numbers interviewed in this study are too small to justify recommendations in relation to this finding, nor did any of the senior manager respondents have any suggestions as to how to cope with this constantly changing resource. However, there may be strength in the prevailing view of the junior doctors that the management of drugs was purely the province of nursing staff. Nurses may both figuratively and literally “hold the key” to this problem and, if they are provided with prescribing guidance in relation to the administration of the potassium, they can challenge prescriptions that they perceive to be inappropriate.

Our research suggests that strong potassium chloride has been successfully removed from nearly all inappropriate clinical areas and there is reason for optimism that this may result in a marked reduction in sentinel events, as was reported in the US.^{7, 12} The finding is compatible with those from the NPSA’s “learning and sharing” initiative with trusts.¹³

The rapid and comprehensive impact of the safety alert is likely to have been influenced by several factors that have been shown in the literature to influence the uptake of guidelines and other innovations.^{14–16} Most importantly in this context, the proposed change is strongly supported by evidence in the literature showing a clear advantage to patients, a factor recognised by the key players. Unlike many guidelines and efforts for behaviour change aimed at clinicians alone, the approach adopted by the alert led to action by senior management. This is vital, because change does not take place in isolation from the organisational context.¹⁶ The proposed changes were given strong backing by hospital pharmacists and by senior nurses and clinicians, who acted as opinion leaders and champions (though this by itself had not hitherto been sufficient to produce the change observed in this study). The safety alert was compatible with

the shared norms and values of health professionals and was relatively simple to implement, in that no new skills were required, nor significant resources entailed. New directives such as that aimed at reducing the risk of wrong site surgery which are more complex and which also challenge professional styles, may prove more difficult to implement. For most staff there are likely to be few response barriers. However, the indifference of junior doctors suggests that sustaining the policy implementation may be challenging with some groups. Continuing vigilance of pharmacy departments, with annual random monitoring checks, may be required to ensure that ampoules do not effect a gradual return to unauthorised wards by prescription on a named patient basis. Cost, lack of storage space, inconsistent availability of some of the newer stronger solutions, and the difficulties in accessing concentrated potassium chloride out of hours may also contribute to its return.

CONCLUSION

The NPSA alert was effective, resulting in a rapid implementation of local policies to reduce the availability of concentrated potassium chloride solutions. The success is likely to be partly due to the nature of the proposed changes and future alerts may not be equally effective. Continued vigilance will be necessary to help sustain the changes.

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Appendices 1–4 are available online at <http://www.qshc.com/supplemental>

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