Recomendaciones

Uso Seguro

Potasio Intravenoso

Recomendaciones para el
Uso Seguro del Potasio Intravenoso

Plan de Calidad del Sistema Nacional de Salud

Ministerio de Sanidad y Consumo (ESPAÑA)

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Este material ha sido elaborado para proporcionar una ayuda a los profesionales sanitarios que trabajan para mejorar la seguridad en el uso de los medicamentos dentro de las instituciones sanitarias.

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Este documento debe citarse como:

Recomendaciones para el Uso Seguro del Potasio Intravenoso.
Madrid: Ministerio de Sanidad y Consumo; 2009.

"Desafortunadamente hay muchos profesionales sanitarios que creen que si no les ha sucedido a ellos, las experiencias adversas de otros no les conciernen. Este es el motivo por el que los viales de cloruro potásico concentrado pueden aún encontrarse en las unidades asistenciales".

Michael Cohen, MS, FASHP
Institute for Safe Medication Practices (1995)

RECOMENDACIONES PARA EL USO SEGURO DEL POTASIO INTRAVENOSO

La realización de estas **Recomendaciones para el Uso Seguro del Potasio Intravenoso** ha sido coordinada por el Instituto para el Uso Seguro de los Medicamentos y financiada por el Plan de Calidad para el Sistema Nacional de Salud del Ministerio de Sanidad y Consumo, a través de un convenio con la Universidad de Salamanca.

ISMP Instituto para el Uso Seguro de los Medicamentos

VNiVERSiDAD D SALAMANCA

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El Comité Técnico agradece su colaboración a Margaret Colqhoun y David U del *Institute for Safe Medication Practices*- Canada (ISMP-Canada), así como a todas aquellas instituciones que han facilitado distintos tipos de documentos para incluir en el material de apoyo de este proyecto.

Í N D I C E

1. INTRODUCCIÓN

INTRODUCCIÓN

La administración incorrecta de soluciones concentradas de cloruro potásico por vía intravenosa constituye uno de los problemas más reconocidos y tratados en el campo de la seguridad del paciente.

En distintos países han ocurrido errores de consecuencias mortales debidos a la administración accidental de cloruro potásico concentrado por vía intravenosa. Un factor contribuyente común en muchos de estos casos ha sido la disponibilidad de viales o ampollas de cloruro potásico concentrado en las áreas asistenciales.

Diversas autoridades sanitarias y organizaciones que trabajan en seguridad del paciente han emitido recomendaciones y han llevado a cabo actuaciones dirigidas a mejorar el uso del cloruro potásico intravenoso. Recientemente la Alianza Mundial para la Seguridad del Paciente de la Organización Mundial de la Salud ha considerado este problema como prioritario y lo ha incluido entre las primeras nueve "Soluciones para la seguridad del paciente".

En todas las recomendaciones emitidas, una práctica de seguridad elemental que se fomenta es la retirada de las soluciones inyectables concentradas de potasio de las unidades asistenciales, práctica que ha demostrado reducir los errores mortales. Aunque en nuestro país se desconoce la incidencia de este problema, los resultados obtenidos en el "Estudio de evaluación de la seguridad de los sistemas de utilización de los medicamentos en los hospitales españoles (2007)" pusieron de manifiesto que la mayoría de los hospitales no tenían implantada aún esta práctica para reducir los riesgos del uso de las soluciones concentradas de potasio.

Por este motivo, la Agencia de Calidad del Sistema Nacional de Salud ha financiado este proyecto, cuyo objetivo es promover en los hospitales la implantación de prácticas para reducir los posibles riesgos para los pacientes derivados de la administración intravenosa de soluciones de potasio. El proyecto ha sido desarrollado por el Instituto para el Uso Seguro de los Medicamentos, delegación en España del *Institute for Safe Medication Practices,* y ha contado con la colaboración técnica de un Grupo de Expertos de varios hospitales españoles.

El proyecto incluye unas **Recomendaciones para el uso seguro del potasio intravenoso** y un **Material de apoyo** dirigido a facilitar su divulgación e implantación en los centros hospitalarios. Entre este material puede encontrar una presentación en diapositivas y modelos de pósters y dípticos para ayudar a su difusión a los profesionales sanitarios. Asimismo se incluye un modelo de protocolo de utilización del cloruro potásico, que cada hospital puede adaptar de acuerdo a sus características. Además, junto a este material se han recopilado publicaciones y otro tipo de información que apoyan la ejecución de estas recomendaciones y que han sido utilizadas para su elaboración.

2. RECOMENDACIONES

RECOMENDACIONES PARA EL USO SEGURO DEL POTASIO INTRAVENOSO

OBJETIVO

Reducir los posibles riesgos para los pacientes derivados de la administración intravenosa de soluciones de potasio.

RECOMENDACIONES

- **Retirar los viales y ampollas de cloruro potásico concentrado de las unidades asistenciales y reemplazarlos por soluciones diluidas.**
- Definir las unidades asistenciales donde se necesite disponer de soluciones concentradas de cloruro potásico y establecer las condiciones para su almacenamiento en dichas unidades, así como para su dispensación, preparación y administración.
- Estandarizar las soluciones de cloruro potásico que deben utilizarse en la institución y establecer límites de dosis y de concentración, velocidades de infusión y situaciones en que se precise su administración con bomba de infusión.
- Adquirir soluciones diluidas de cloruro potásico y preparar en el Servicio de Farmacia aquellas diluciones que no se encuentren disponibles comercialmente y se consideren necesarias.
- Estandarizar la prescripción de cloruro potásico intravenoso, de forma que se adecue a las soluciones normalizadas disponibles en la institución.
- Supervisar periódicamente la implantación de estas recomendaciones en el hospital, controlando muy especialmente el almacenamiento de ampollas o viales de cloruro potásico concentrado en las unidades asistenciales y en el Servicio de Farmacia, para asegurar que se almacenan en los lugares establecidos y separados de otra medicación.

Las recomendaciones también se aplican a las ampollas de fosfato potásico y a otras sales concentradas de potasio.

ACTUACIONES

La implantación de las recomendaciones anteriores requiere la participación de los profesionales de todas las áreas clínicas del hospital y la realización de las actuaciones que se sugieren a continuación:

Dirección del hospital

1. Si el hospital no tiene implantadas unas recomendaciones para prevenir los errores por administración incorrecta de potasio intravenoso, el establecimiento de estas prácticas seguras para el uso del cloruro potásico intravenoso debe ser una prioridad para la institución. Para ello se recomienda:
   - Considerar la implantación de estas recomendaciones como un objetivo prioritario para el hospital, e incluirlo como tal dentro de los pactos anuales de objetivos de la dirección médica y de enfermería.
   - Constituir un equipo interdisciplinar específico con la misión de implantar estas recomendaciones y supervisar el cumplimiento de las mismas. Es conveniente que se incluyan representantes de la Comisión de Farmacia y Terapéutica, del Servicio de Farmacia y de distintas unidades asistenciales, así como del equipo directivo del hospital.
   - En aquellos hospitales donde esté constituido un Grupo de Trabajo para la Prevención de Errores de Medicación, o un Comité de Seguridad Clínica o de Gestión de Riesgos, será este grupo el encargado de constituir el equipo interdisciplinar y de aplicar estas recomendaciones, con el apoyo de la dirección.
   - Colaborar con el equipo interdisciplinar constituido para facilitar la realización de las reuniones conjuntas con los encargados de las unidades clínicas y para difundir estas recomendaciones en el hospital.

Equipo interdisciplinar para el uso seguro del potasio intravenoso

2. Desarrollar un plan estratégico para difundir y aplicar estas recomendaciones (que incluya un cronograma), e informar regularmente al Grupo de Trabajo para la Prevención de Errores de Medicación (o Comité de Seguridad Clínica o de Gestión de Riesgos) y/o a la dirección del centro de la evolución de sus actuaciones para prevenir los incidentes con el cloruro potásico intravenoso.
3. Elaborar junto con la Comisión de Farmacia y Terapéutica (véase punto 8) un protocolo de utilización del cloruro potásico en el centro que incluya, al menos, los siguientes puntos:
   - Utilizar formulaciones de potasio oral, en lugar de intravenoso, para el tratamiento de la hipokalemia, siempre que sea clínicamente posible.
   - Estandarizar la prescripción del cloruro potásico intravenoso para que se ajuste a las soluciones normalizadas disponibles en el hospital, y exigir que en la prescripción se especifiquen siempre la dosis expresada en mEq o mmol (1 mEq= 1 mmol), el volumen de dilución, y el tiempo en que se debe administrar y/o la velocidad de infusión.
   - Especificar la concentración máxima de cloruro potásico permitida en una solución intravenosa (por vía central o periférica).
   - Especificar la dosis máxima diaria de cloruro potásico que un paciente puede recibir (por vía central o periférica).
   - Especificar la velocidad de infusión recomendada, los requisitos de uso de bomba de infusión y las directrices de monitorización del paciente.
   - Establecer un procedimiento de actuación ante las prescripciones que no se adapten a las soluciones normalizadas, como por ejemplo la aplicación de un protocolo de sustitución automática.

4. En el caso de que el centro disponga de programas de prescripción electrónica y/o de hoja de administración de enfermería informatizada, revisar las aplicaciones junto con los responsables de las mismas, con el fin de:
   - Configurar el programa de prescripción electrónica, de forma que no permita la prescripción de cloruro potásico sin diluir y que facilite la cumplimentación del protocolo (alertas de dosis máximas, concentración máxima, velocidad de administración, etc.).
   - Configurar el programa de registro de administración de medicamentos, de forma que en la hoja de administración de enfermería no se presente la línea del cloruro potásico concentrado de forma independiente, sino siempre asociada a un fluido como mezcla intravenosa, y que aparezca un mensaje con las indicaciones de cómo preparar y administrar el cloruro potásico correctamente, en caso de tratarse de una unidad asistencial autorizada para ello.
5. Una vez aprobado el protocolo de utilización del cloruro potásico en el centro, asegurar que esté disponible en todas las áreas asistenciales y realizar su difusión a los profesionales sanitarios del hospital.
6. Revisar junto con los responsables de las unidades asistenciales, quirófanos, etc. (véase punto 17) el uso y almacenamiento del potasio intravenoso en cada unidad, con los siguientes objetivos:
   - Identificar si se almacenan viales o ampollas de potasio intravenoso concentrado en la unidad, incluyendo en el carro de parada. Si se dispone de existencias y es posible prescindir del potasio concentrado en esta unidad, planificar su retirada, sustituyéndolo por soluciones diluidas de cloruro potásico en cantidad suficiente.
   - Establecer sistemas de almacenamiento que permitan diferenciar las soluciones diluidas de cloruro potásico de las soluciones de fluidoterapia y de otras soluciones premezcladas con medicamentos (por ejemplo, áreas diferentes, señalizaciones, etc).
   - En aquellas unidades asistenciales donde se considere necesario disponer de cloruro potásico concentrado, establecer un procedimiento para controlar su uso que especifique las condiciones de almacenamiento y de reposición para evitar errores. Debe mantenerse siempre separado del resto de los medicamentos del stock de la unidad.

     En caso de que se almacenen ampollas o viales de cloruro potásico en armarios automatizados de dispensación se deben limitar las existencias y mantener en un cajetín de acceso restringido claramente diferenciado y que incluya una alerta de "diluir antes de administrar".
   - Asegurar que todas las dispensaciones de soluciones de potasio concentrado se efectúan directamente desde el Servicio de Farmacia y que no se transfieren entre las unidades asistenciales.
   - Establecer una relación de las unidades asistenciales donde es necesario disponer de cloruro potásico concentrado.
7. Revisar periódicamente el grado de implantación de estas recomendaciones, comprobando que la prescripción, la dispensación, el almacenamiento y la administración del potasio intravenoso se ajustan a las especificaciones establecidas en el centro.
   - Evaluar la adecuación de las prescripciones de cloruro potásico al protocolo de utilización establecido.
   - Verificar que desde el Servicio de Farmacia sólo se dispensan soluciones concentradas de potasio a las unidades autorizadas.
   - Revisar el almacenamiento del cloruro potásico concentrado en las unidades autorizadas y no autorizadas (armarios, carros de parada, áreas de preparación, etc.).
   - Verificar que la administración de las soluciones de potasio se adecua al protocolo de utilización establecido.
   - Analizar la información y proponer las medidas de mejora pertinentes.

Comisión de Farmacia y Terapéutica

8. Elaborar junto con el equipo interdisciplinar específico un protocolo de utilización del cloruro potásico en el centro (véase punto 3).
9. Establecer las soluciones normalizadas de cloruro potásico que deben estar disponibles en el hospital, limitar el número de presentaciones disponibles y evaluar las características de su etiquetado y envasado, para minimizar el riesgo de errores.
10. Seleccionar las ampollas o viales de cloruro potásico concentrado que deben estar disponibles en el hospital para aquellas situaciones en las que se considere necesario. Se recomienda disponer de una única presentación de cloruro potásico concentrado y que su apariencia no sea similar a la de otros medicamentos, particularmente cloruro sódico 0,9% o agua para inyección. Para ello se aconseja proceder a su adquisición a un proveedor diferente, para que el etiquetado se distinga, y/o en ampollas o viales de forma o volumen diferente, para facilitar su diferenciación (por ejemplo, adquirir el cloruro potásico en una presentación de 20 mL, si el suero fisiológico y el agua para inyección se adquieren en presentaciones de 10 mL). Asimismo se recomienda valorar la presencia en el etiquetado de una alerta que avise de la necesidad de "diluir antes de administrar".

Servicio de Farmacia

11. Adquirir soluciones diluidas de cloruro potásico preparadas comercialmente y establecer un sistema de almacenamiento que permita diferenciar estas soluciones de las soluciones de fluidoterapia y de otras soluciones premezcladas con medicamentos.
12. Al validar las prescripciones, verificar que la dosis, la concentración, la vía y la velocidad de administración se adecuan al protocolo de utilización establecido.
13. Preparar en el Servicio de Farmacia las soluciones de cloruro potásico que no estén disponibles comercialmente y que se consideren necesarias en el centro.
14. Designar un área específica para almacenar el cloruro potásico concentrado y otras sales concentradas de potasio.
15. Dispensar las soluciones concentradas de potasio exclusivamente a las áreas críticas autorizadas y siguiendo el procedimiento establecido.
16. Añadir a las ampollas o viales de cloruro potásico concentrado una etiqueta adicional que indique "diluir antes de administrar", en caso de que el etiquetado comercial no lo advierta claramente.

Responsables de las unidades asistenciales y supervisores de enfermería

17. Contribuir a la difusión y cumplimiento de estas recomendaciones y del protocolo de utilización del cloruro potásico en sus áreas de responsabilidad (véase punto 6).

Unidades asistenciales

18. Si es preciso preparar y administrar cloruro potásico intravenoso en la unidad a partir de viales o ampollas de cloruro potásico concentrado:
    - Aplicar los procedimientos establecidos en el protocolo de utilización del cloruro potásico del centro.

- Asegurar que la solución preparada es homogénea, invirtiéndola al menos seis veces. Nunca se debe añadir potasio concentrado a una mezcla intravenosa ya preparada que contenga potasio, ni a una solución intravenosa que ya se está administrando a un paciente.
- Asegurar que la solución esté correctamente etiquetada.
- Considerar la realización de un doble chequeo independiente por otro profesional, tanto en el momento de la preparación, para verificar que el medicamento, la dosis, la dilución y el etiquetado son correctos, como antes de la administración intravenosa, para comprobar que el paciente, el medicamento, la vía y la velocidad de administración son correctos.

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RESUMEN DE LAS ACTUACIONES PROPUESTAS

Dirección del hospital

1. Implantar en la institución prácticas seguras para el uso del potasio intravenoso. Para ello se recomienda:
   - Considerar la implantación de estas recomendaciones como un objetivo prioritario para el hospital.
   - Constituir un equipo interdisciplinar específico para su implantación y supervisión.
   - Colaborar con el equipo interdisciplinar para facilitar su implantación y difusión.

Equipo interdisciplinar para el uso seguro del potasio intravenoso

2. Desarrollar un plan estratégico para difundir y aplicar estas recomendaciones.
3. Elaborar, con la Comisión de Farmacia y Terapéutica, un protocolo de utilización del cloruro potásico que incluya, al menos, los siguientes puntos:
   - Uso de formulaciones de potasio oral, en lugar de intravenoso, siempre que sea clínicamente posible.
   - Estandarización de la prescripción del cloruro potásico intravenoso, para que se ajuste a las soluciones normalizadas disponibles en el hospital y para que especifique siempre la dosis (en mEq o mmol), el volumen de dilución, y el tiempo en que se debe administrar y/o la velocidad de infusión.
   - Concentración máxima de cloruro potásico permitida en una solución intravenosa.
   - Dosis máxima diaria de cloruro potásico que un paciente puede recibir.
   - Velocidad de infusión recomendada, uso de bomba de infusión y directrices de monitorización del paciente.
   - Procedimiento de actuación ante las prescripciones que no se adapten a las soluciones normalizadas.
4. Configurar los programas de prescripción electrónica asistida y/o de registro de administración, para que no permitan la prescripción ni administración del cloruro potásico sin diluir.
5. Difundir el protocolo de utilización del cloruro potásico en el centro.
6. Revisar el uso y almacenaniento del potasio en las unidades asistenciales, junto con los responsables de las mismas.
   - Retirar los viales y ampollas de potasio concentrado de la unidad y del carro de parada, sustituyéndolos por soluciones diluidas.
   - Establecer un sistema para almacenar las soluciones diluidas de cloruro potásico que permita diferenciarlas de otras soluciones intravenosas.
   - En aquellas unidades donde se considere necesario disponer de potasio concentrado, establecer un procedimiento para controlar su uso, almacenamiento y reposición. Almacenar separado de otros medicamentos.
   - Asegurar que la dispensación de soluciones concentradas de cloruro potásico se efectúa directamente desde farmacia y que no se transfieren entre las unidades asistenciales.
   - Establecer un relación de unidades asistenciales autorizadas para disponer de cloruro potásico concentrado.
7. Revisar periódicamente la implantación de estas recomendaciones:
   - Evaluar la adecuación de la prescripción.
   - Verificar la dispensación desde farmacia.
   - Revisar las condiciones de almacenamiento.
   - Verificar la adecuación de la administración.
   - Analizar la información y proponer medidas.

RECOMENDACIONES

Comisión de Farmacia y Terapéutica

8. Elaborar junto con el equipo interdisciplinar específico el protocolo de utilización del cloruro potásico.
9. Establecer las soluciones normalizadas de cloruro potásico que deben estar disponibles en el hospital. Limitar el número de presentaciones y evaluar el etiquetado y envasado para evitar errores.
10. Seleccionar las ampollas o viales de cloruro potásico concentrado que deben estar disponibles en el hospital. Disponer de una única presentación y evaluar su etiquetado y envasado para evitar errores.

Servicio de Farmacia

11. Adquirir soluciones diluidas de cloruro potásico y establecer un sistema de almacenamiento que permita diferenciarlas de las soluciones de fluidoterapia y de otras soluciones premezcladas con medicamentos.
12. Validar las prescripciones, verificando que la dosis, la concentración, la vía y la velocidad de administración se adecuan al protocolo de utilización establecido.
13. Preparar las soluciones de cloruro potásico necesarias en el centro que no estén disponibles comercialmente.
14. Designar un área específica para almacenar el cloruro potásico concentrado.
15. Dispensar las soluciones concentradas de potasio exclusivamente a las unidades asistenciales autorizadas y siguiendo el procedimiento establecido.
16. Añadir a las ampollas o viales de cloruro potásico concentrado una etiqueta de alerta que indique: "diluir antes de administrar", si el etiquetado no lo advierte.

Responsables de las unidades asistenciales y supervisores de enfermería

17. Contribuir a la difusión y cumplimiento de estas recomendaciones y del protocolo de utilización del cloruro potásico.

Unidades asistenciales

18. Si es preciso preparar y administrar cloruro potásico intravenoso en la unidad a partir de viales o ampollas de cloruro potásico concentrado:
    - Aplicar los procedimientos establecidos en el protocolo de utilización del cloruro potásico.
    - Asegurar que la solución preparada es homogénea. Nunca se debe añadir potasio concentrado a una mezcla intravenosa con potasio ya preparada, ni a una solución intravenosa que ya se está administrando.
    - Asegurar que la solución esté correctamente etiquetada.
    - Realizar un doble chequeo independiente durante la preparación y antes de la administración intravenosa, para verificar que el medicamento, dosis, dilución, etiquetado, paciente, vía y velocidad de la administración son correctos.

RESUMEN DE LAS PRINCIPALES ACTUACIONES POR PROCESOS

Selección y adquisición

- Seleccionar y adquirir soluciones diluidas de cloruro potásico. Limitar el número de presentaciones y evaluar el etiquetado y envasado para evitar errores.
- Seleccionar y adquirir una única presentación de viales o ampollas de cloruro potásico concentrado y asegurar que su etiquetado y envasado se distinga claramente del de otros medicamentos disponibles en el hospital. Valorar la presencia de alertas en el etiquetado.

Almacenamiento

- Retirar los viales y ampollas de cloruro potásico concentrado de las unidades asistenciales y de los carros de parada, sustituyéndolos por soluciones diluidas.
- Establecer un sistema para almacenar las soluciones diluidas de cloruro potásico que permita diferenciarlas de las soluciones de fluidoterapia y de otras soluciones intravenosas, tanto en las unidades asistenciales como en el Servicio de Farmacia.
- Almacenar el cloruro potásico concentrado en un lugar separado de otros medicamentos, tanto en las unidades asistenciales autorizadas para su uso como en el Servicio de Farmacia.

Prescripción

- Prescribir formulaciones de potasio oral, en lugar de intravenoso, siempre que sea clínicamente posible.
- Prescribir las soluciones normalizadas de cloruro potásico disponibles en el hospital.
- Especificar siempre en las prescripciones de cloruro potásico intravenoso la dosis (en mEq o mmol), el volumen de dilución, y el tiempo en que se debe administrar y/o la velocidad de infusión.
- Configurar el programa de prescripción electrónica asistida, para que no permita la prescripción del cloruro potásico sin diluir.

Validación

- Verificar que la dosis, la concentración, la vía y la velocidad de administración de potasio intravenoso se adecuan al protocolo de utilización establecido.

Preparación y dispensación en farmacia

- Preparar las soluciones de cloruro potásico necesarias en el centro que no estén disponibles comercialmente.
- Añadir a las ampollas o viales de cloruro potásico concentrado una etiqueta de alerta que indique: "diluir antes de administrar", si el etiquetado no lo advierte.
- Dispensar las soluciones concentradas de potasio exclusivamente a las unidades asistenciales autorizadas y siguiendo el procedimiento establecido.
- Asegurar que la dispensación de soluciones concentradas de cloruro potásico se efectúa directamente desde farmacia y que no se transfieren entre las diferentes unidades asistenciales.

Preparación en las unidades asistenciales

- Si es preciso preparar y administrar cloruro potásico intravenoso en la unidad a partir de viales o ampollas de cloruro potásico concentrado:
  - Verificar que no sobrepase la concentración máxima de cloruro potásico permitida en una solución intravenosa.
  - Asegurar que la solución preparada es homogénea. Nunca se debe añadir potasio concentrado a una mezcla intravenosa con potasio ya preparada, ni a una solución intravenosa que ya se está administrando a un paciente.
  - Asegurar que la solución esté etiquetada correctamente.
  - Realizar un doble chequeo independiente durante la preparación, para verificar que el medicamento, la dosis, la dilución y el etiquetado son correctos.

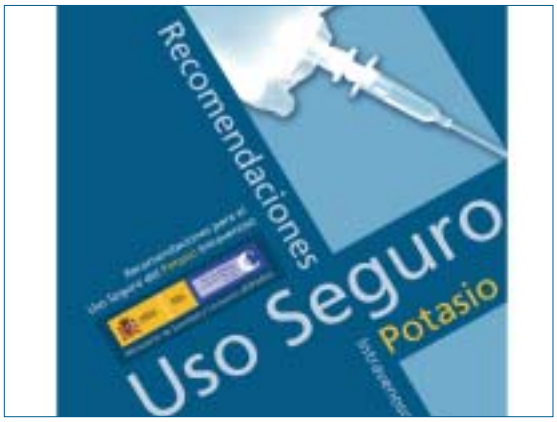
Administración

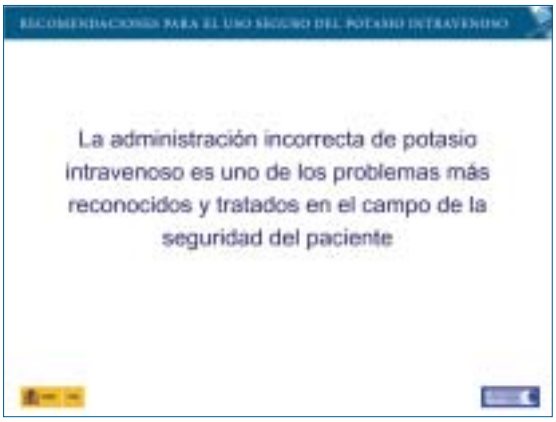
- Aplicar los procedimientos establecidos en el protocolo de utilización del cloruro potásico:
  - Verificar que la velocidad de infusión se ajusta a la recomendada.
  - Utilizar bomba de infusión siempre que sea necesario.
- Realizar un doble chequeo independiente antes de la administración intravenosa, para verificar que el paciente, el medicamento, la vía y la velocidad de la administración son correctos.
- Configurar el programa de registro de administración, para que no permita la administración del cloruro potásico sin diluir.

3. MATERIAL DE APOYO PARA LA DIVULGACIÓN E IMPLANTACIÓN DE LAS RECOMENDACIONES

3.1. PRESENTACIÓN PARA DIVULGACIÓN EN HOSPITALES

DIAPOSITIVAS





MATERIAL DE APOYO

INCIDENTES

- Administración intravenosa directa de potasio concentrado
- Administración de potasio intravenoso a una velocidad superior a la recomendada

La preparación o administración incorrecta del cloruro potásico puede causar la muerte del paciente

INCIDENTES

CAUSAS DE LOS ERRORES

- **Administración equivocada** de cloruro potásico concentrado en lugar de otro medicamento.
  - Apariencia similar a otros medicamentos
  - Lapsus (confusión con furosemida 40 mg)
- **Preparación incorrecta** de la infusión de cloruro potásico.
  - Falta de conocimiento sobre el peligro de la administración rápida
  - Inexperiencia en el manejo del medicamento

INCIDENTES

FACTOR CONTRIBUYENTE

Disponibilidad de cloruro potásico concentrado en los botiquines de las unidades asistenciales

- Riesgo de confusión con otros medicamentos
- Riesgo de preparación incorrecta

INICIATIVAS DIRIGIDAS A MEJORAR EL USO DEL CLORURO POTÁSICO INTRAVENOSO

EE.UU., CANADÁ, AUSTRALIA, REINO UNIDO, OMS

INICIATIVAS DIRIGIDAS A MEJORAR EL USO DEL CLORURO POTÁSICO INTRAVENOSO

PRÁCTICA CLAVE

Retirar los viales y ampollas de cloruro potásico concentrado de las unidades asistenciales y reemplazarlos por soluciones diluidas

INICIATIVAS

ISMP

1995: Recomendaciones a los hospitales de EE.UU.

- Dispensar el cloruro potásico como soluciones diluidas preparadas comercialmente.
- En caso de mantener viales de cloruro potásico concentrado en las unidades asistenciales:
  - Dispensarlos con una etiqueta:

    Tiene que ser diluido
  - Almacenar en un armario cerrado

MATERIAL DE APOYO

INICIATIVAS

JCAHO

1998: Publicación de una alerta (*Sentinel Event Alert 1*).

- Retirar el cloruro potásico concentrado de las unidades asistenciales.
- Utilizar las soluciones disponibles comercialmente de cloruro potásico o preparadas en farmacia.
- Normalizar y limitar las soluciones de cloruro potásico disponibles en el hospital.

2003: Inclusión en los *National Patient Safety Goals (Goal 3)*.

INICIATIVAS

NPSA

2002: Publicación de una alerta con normas sobre almacenamiento y uso de productos con potasio intravenoso.

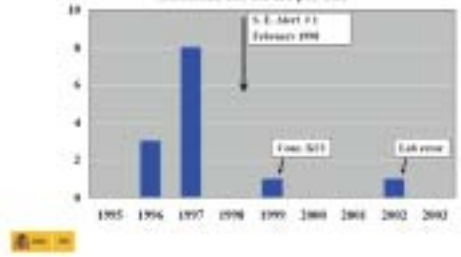
- Restringir las soluciones concentradas al Servicio de Farmacia y a áreas de cuidados intensivos.
- Utilizar soluciones diluidas disponibles comercialmente y preparar las que no se encuentren comercializadas.
- Realizar un doble chequeo en la preparación y administración, etc.

RESULTADOS

EE.UU.

1998: Publicación de la *Sentinel Event Alert 1* de la JCAHO

Incidentes con cloruro potásico



RESULTADOS

INGLATERRA Y GALES

Julio 2002: Publicación de la alerta de la NPSA

- **Grado de implantación** (Octubre 2002- Enero 2003):
  - Retirada del potasio concentrado de áreas no críticas: 98% cumplimiento
  - Almacenamiento separado del potasio concentrado en áreas críticas que lo precisan: 100% de cumplimiento
  - Conocimiento de la alerta:
    - 76% de enfermeras
    - 30% de médicos *juniors*
- **Resultados tras la implantación** (2005):
  - No se registraron nuevos incidentes con daño grave por cloruro potásico concentrado en áreas no críticas.
  - Ocurrieron 2 casos de muerte por la administración rápida en áreas críticas

SITUACIÓN EN ESPAÑA

"Evaluación de la seguridad de los sistemas de utilización de medicamentos en los hospitales españoles (2007)".

- Retirada de los viales de concentrados de electrolitos de las unidades asistenciales:

2,17± 4,15 puntos sobre valor máximo de 16 (13,6%)

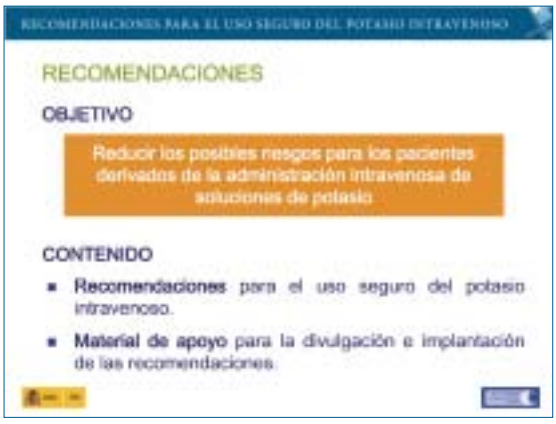
La mayoría de los hospitales no tienen implantada aún esta práctica elemental

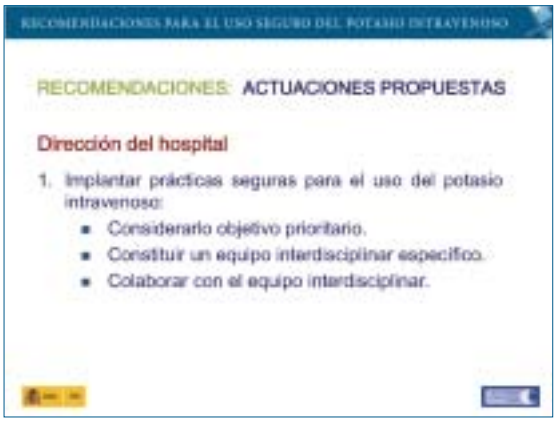
PROYECTO:
RECOMENDACIONES PARA EL USO SEGURO DEL POTASIO INTRAVENOSO

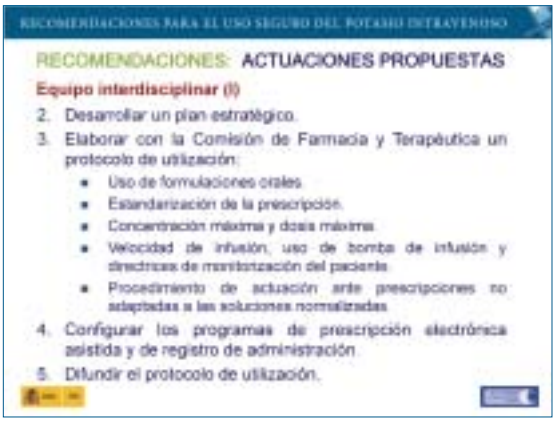
- Agencia de Calidad del Sistema Nacional de Salud
- Instituto para el Uso Seguro de los Medicamentos (ISMP-España)
- Comité Técnico:

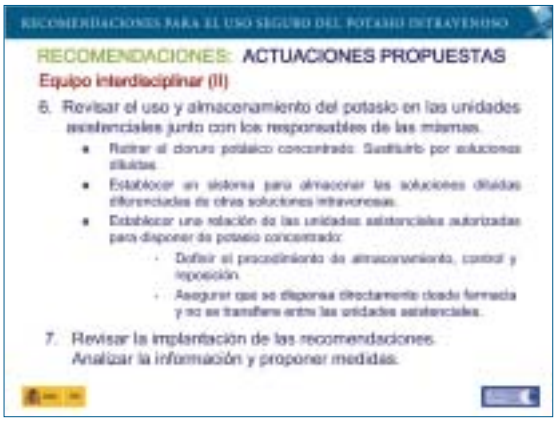
Hospital Universitario de Salamanca
Hospital Universitario Fundación Alcorcón
Hospital Clínic de Barcelona
Hospital Universitario Vall d´Hebrón de Barcelona
Instituto Oncológico de San Sebastián
Hospitales Universitarios Virgen del Rocío de Sevilla
Complejo Hospitalario Universitario de A Coruña
Hospital Universitario Dr. Peset de Valencia
Hospital Universitario Gregorio Marañón de Madrid

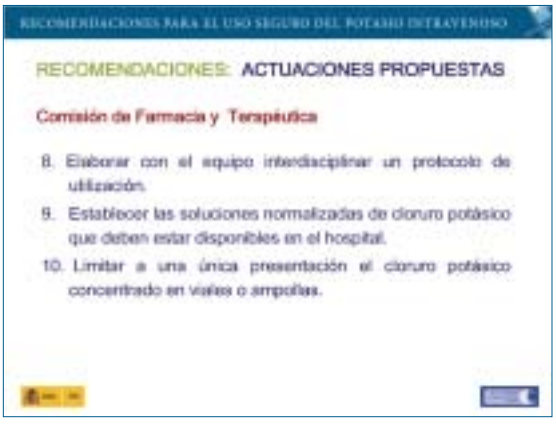
MATERIAL DE APOYO











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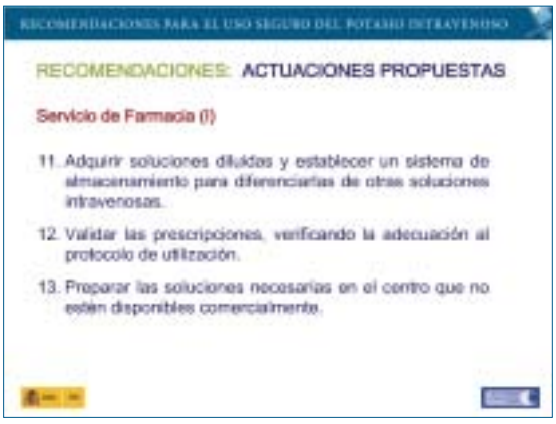

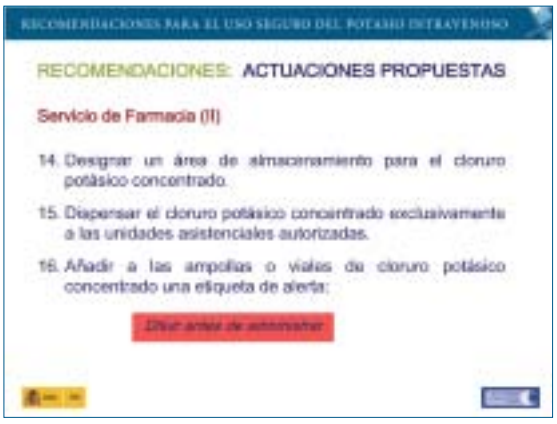

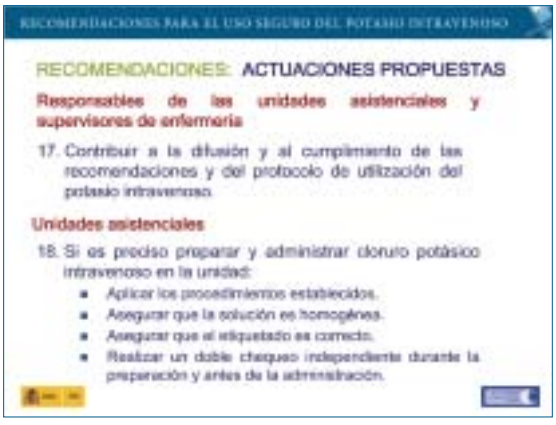

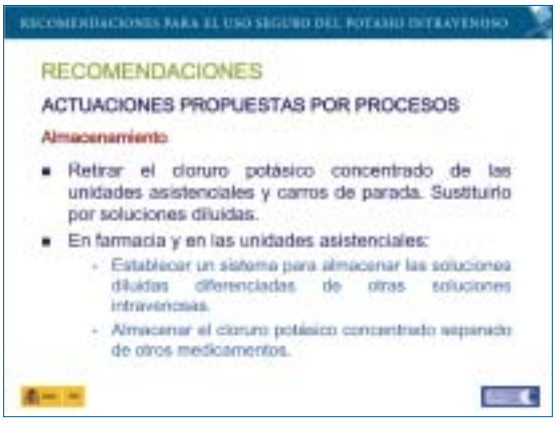

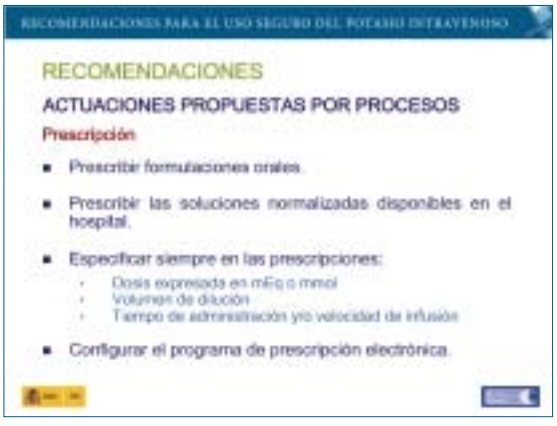

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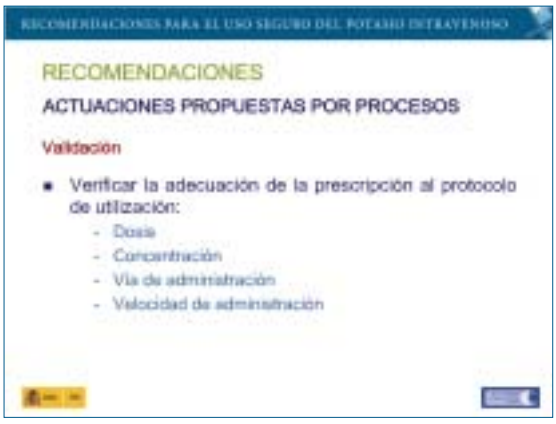

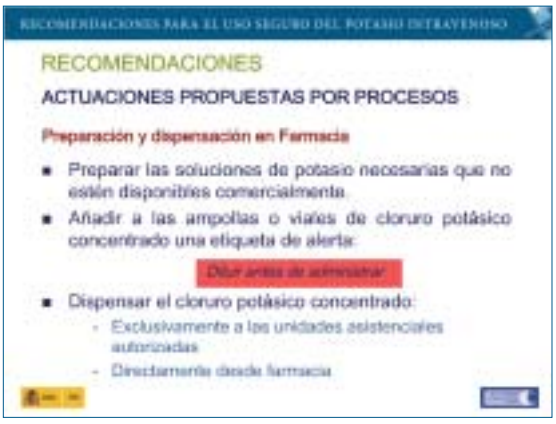

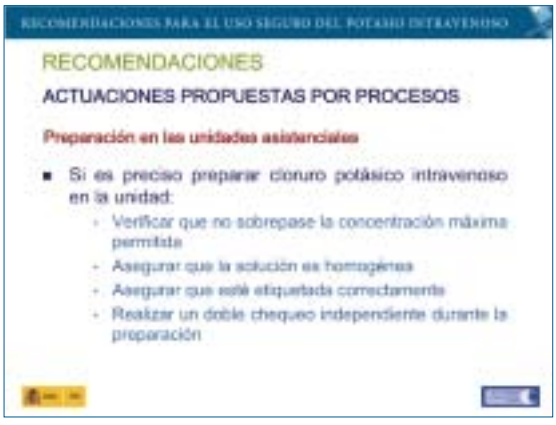

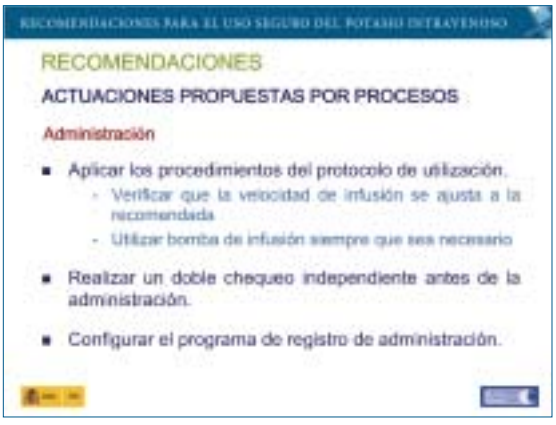

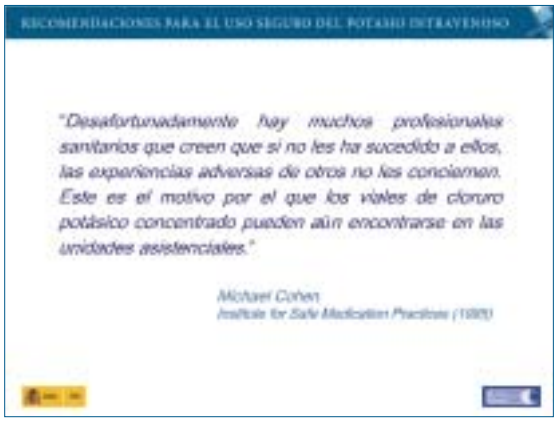

TEXTO DE LA PRESENTACIÓN

La administración incorrecta de soluciones concentradas de cloruro potásico por vía intravenosa constituye uno de los problemas más reconocidos y tratados en el campo de la seguridad del paciente.

En distintos países se han descrito casos mortales debidos a la administración accidental directa de cloruro potásico concentrado por vía intravenosa (1-7).

- En EE.UU. de diciembre de 1991 a agosto de 1996 se comunicaron al sistema de notificación de errores de medicación MERP, que mantienen el *Institute for Safe Medication Practices* (ISMP) y la *United States Pharmacopeia* (USP), 23 incidentes relacionados con el uso de soluciones concentradas de cloruro potásico (3). Veinte casos sucedieron por confundirse el cloruro potásico con otros medicamentos, llegándose a administrar el cloruro potásico en 16 ocasiones en lugar de dichos medicamentos (cloruro sódico 0,9%, furosemida y agua para inyección), lo que dio lugar a 7 muertes y a otros sucesos graves.
- En EE.UU. en los dos primeros años del programa de eventos centinela de la *Joint Commission on Accreditation of Healthcare Organization* (JCAHO) (1996-1997) se notificaron 10 muertes de pacientes por administración incorrecta de cloruro potásico, 8 de los cuales ocurrieron por la administración directa de cloruro potásico concentrado (4). En todos estos casos se identificó como factor contribuyente la disponibilidad de cloruro potásico concentrado en las unidades asistenciales. En 6 de los 8 casos, el cloruro potásico fue equivocado con otros medicamentos, principalmente por similitud en el etiquetado y envasado. El cloruro potásico fue confundido con cloruro sódico 0,9%, heparina o furosemida.
- En otros países, como Canadá, Reino Unido y Australia, han ocurrido también incidentes relacionados con la administración de cloruro potásico (5-7).
- Recientemente, en la República Dominicana falleció un niño de tres años y otros dos fueron trasladados a la Unidad de Cuidados Intensivos tras la administración de cloruro potásico en lugar de agua estéril para inyección. Un error en la dispensación, debido a la similitud en el etiquetado y envasado de ambos medicamentos, fue la causa de estos tres incidentes (8). Esto es, hay un riesgo de que sucedan errores y como no se tomen medidas para reducirlo, pueden ocurrir incidentes graves en cualquier hospital.

> *¿En qué otra industria se envasaría y almacenaría una sustancia tan potencialmente letal de forma similar a otros productos relativamente inocuos como el cloruro sódico 0,9% o el agua para inyección? La oportunidad de que ocurra un error humano es obvia. El riesgo para los pacientes es también obvio.*
>
> *Hyland SM et al, 2005 (9)*

Los incidentes descritos han consistido en una rápida infusión o en una administración intravenosa directa de potasio concentrado por vía intravenosa, lo que puede causar la muerte del paciente por parada cardíaca.
La mayoría de las veces no es clínicamente posible revertir el efecto del potasio, por lo que generalmente conducen a la muerte del paciente. En definitiva, el cloruro potásico puede llegar a ser mortal cuando no se prepara y administra correctamente (10).

Los tipos de errores más frecuentes asociados con la administración incorrecta de potasio concentrado han consistido fundamentalmente en (1-7):

- Selección y administración inadvertida o equivocada de una ampolla o vial de cloruro potásico concentrado en lugar de otro medicamento.

Estos errores han sido los más frecuentes y se han atribuido a la apariencia similar de los viales o ampollas de cloruro potásico concentrado con los de otros medicamentos, por ejemplo con los de cloruro sódico 0,9% o agua para inyección, que han llevado a la administración inadvertida del cloruro potásico para el mantenimiento de catéteres venosos o para diluir un medicamento.
También en varios casos se han debido a la administración de cloruro potásico en lugar de furosemida, por lapsus que tuvieron las enfermeras al asociar mentalmente potasio y furosemida, ya que es frecuente prescribir furosemida 40 mg por vía intravenosa directa y conjuntamente una infusión intravenosa con 40 mEq/L de cloruro potásico, y los "40" de cloruro potásico se han administrado por vía intravenosa directa en lugar de los "40" de furosemida.

- Preparación incorrecta de la infusión de cloruro potásico.
  Estos incidentes se han imputado a la falta de conocimiento sobre los peligros de una administración intravenosa rápida de potasio concentrado, ligado a una inexperiencia en el manejo del medicamento.

El análisis de estos incidentes ha revelado que un factor contribuyente común en muchos de estos casos ha sido la disponibilidad de viales de cloruro potásico concentrado en los botiquines de las unidades asistenciales.

Autoridades sanitarias y organizaciones que trabajan en seguridad del paciente de distintos países, como EE.UU., Canadá, Australia, Reino Unido y recientemente la Alianza Mundial para la Seguridad del Paciente de la Organización Mundial de la Salud, han llevado a cabo iniciativas dirigidas a mejorar el uso del cloruro potásico intravenoso (4,6,7,10-13). De hecho, este problema fue el tema de la primera alerta que lanzó en Inglaterra y Gales la *National Patient Safety Agency (NPSA) (6) y* en Australia el *Australian Council for Safety and Quality* (7).

Todas estas iniciativas se centran en la implantación de una práctica simple para prevenir estos incidentes: **retirar las soluciones concentradas de potasio intravenoso de los botiquines de las unidades asistenciales y reemplazarlos por soluciones diluidas.** Al no disponer en las unidades asistenciales de viales o ampollas almacenados de cloruro potásico concentrado, y dispensarse directamente desde el servicio de farmacia las soluciones ya preparadas, se evita el riesgo de que se confundan y se utilicen los viales de cloruro potásico concentrado en lugar de otros medicamentos y de que se administren directamente sin diluir o se diluyan incorrectamente.

- A raíz de los incidentes notificados al programa MERP del ISMP-USP relacionados con el uso de soluciones concentradas de cloruro potásico, el ISMP en 1995 envió una notificación de seguridad a los hospitales de EE.UU. recomendando:
  - Dispensar el cloruro potásico como soluciones diluidas, preparadas comercialmente o en el Servicio de Farmacia.
  - En caso de mantener viales de cloruro potásico concentrado en un área fuera del Servicio de Farmacia: a) dispensarlos con una etiqueta que indique "tiene que ser diluido" o envasado en bolsas con este etiquetado, y b) mantener el medicamento almacenado en un armario cerrado.
- Posteriormente, en febrero de 1998, después de los sucesos centinela notificados a la JCAHO, este organismo emitió una alerta (4) (la primera *Sentinel Event Alert)*, exigiendo a los hospitales:
  - Retirar el cloruro potásico concentrado de los botiquines de las áreas clínicas.
  - Preparar todas las soluciones de cloruro potásico en el Servicio de Farmacia del hospital y utilizar las soluciones disponibles comercialmente.
  - Normalizar y limitar las diluciones disponibles de cloruro potásico.

  La alerta fue difundida ampliamente para asegurar que los profesionales sanitarios comprendieran el significado de los hechos y las razones que llevaban a recomendar estos cambios en la práctica.
  En el año 2003, la JCAHO incluyó además esta práctica dentro de los *National Patient Safety Goals* (Goal 3) (12).
- La NPSA lanzó una alerta en 2002 con requisitos sobre el almacenamiento y uso de productos con potasio intravenoso (6). En ella se indica que las soluciones concentradas de cloruro potásico y otras sales de potasio deberán restringirse al Servicio de Farmacia y a áreas de cuidados intensivos,

almacenarse separadas en un armario cerrado, no transferirse entre las unidades asistenciales, etc. Recomienda el uso de soluciones diluidas disponibles comercialmente y preparar en el servicio de farmacia las que no se encuentren comercializadas. También recoge otras medidas, como el doble chequeo en la preparación y administración.

- Recomendaciones similares a las anteriores son las propuestas en Australia (7) y por la Alianza Mundial para la Seguridad del Paciente en las "Soluciones para la seguridad del paciente" (10).

La adopción de estas medidas preventivas en EE.UU., Reino Unido y otros países ha tenido un impacto positivo en la reducción de muertes por este medicamento (14, 15).

- En EE.UU., después de la publicación de la *Sentinel Event Alert* de la JCAHO, hubo una reducción importante y mantenida en los incidentes con cloruro potásico (figura) (14).
- En Inglaterra y Gales la implantación de la alerta de la NPSA fue muy amplia. Después de una semana de la fecha prevista para su implantación, en una revisión de 207 unidades clínicas en 20 centros hospitalarios seleccionados aleatoriamente se comprobó que (15):
  - El 100% de los hospitales tenían almacenado el cloruro potásico concentrado en un armario cerrado y separado de los diluyentes habituales de inyectables.
  - En el 98% de las unidades clínicas se había retirado el potasio concentrado de las áreas no críticas.
  - El 78% de las enfermeras y el 30% de los médicos *juniors* conocían la alerta.

  La implantación de esta alerta en Inglaterra y Gales fue muy efectiva, ya que la NPSA no registró ningún otro incidente de muerte o daño grave por cloruro potásico concentrado en áreas no críticas ni de incidentes en los que el potasio concentrado se confundiera con otro medicamento, como el cloruro sódico (16). Sin embargo, sí se registraron dos casos de muerte por la administración demasiado rápida de infusiones de cloruro potásico en áreas críticas.

Aunque en nuestro país se desconoce la incidencia de incidentes y muertes asociadas con la administración inadvertida de potasio concentrado, los resultados obtenidos en el "Estudio de evaluación de la seguridad de los sistemas de utilización de los medicamentos en los hospitales españoles (2007)" (17) pusieron de manifiesto que la mayoría de los hospitales no tenían implementada aún esta práctica elemental para reducir el riesgo de daños por el potasio intravenoso. La retirada de los viales de concentrados de electrolitos de las unidades asistenciales obtuvo una puntuación media de 2,17± 4,15 sobre un valor máximo de 16 puntos (13,6%).

Por este motivo, la Agencia de Calidad del Sistema Nacional de Salud, con la colaboración del Instituto para el Uso Seguro de los Medicamentos y un Grupo de Expertos de varios hospitales españoles, ha abordado la elaboración de estas **Recomendaciones para el Uso Seguro de Potasio Intravenoso** y ha recopilado este material de apoyo dirigido a facilitar su divulgación e implantación en los centros hospitalarios.

Para proceder a la retirada de las soluciones concentradas de potasio de las unidades asistenciales es preciso normalizar y establecer de nuevo cómo se debe prescribir, almacenar, dispensar, preparar y administrar el cloruro potásico en el hospital (18). Se requiere establecer cómo se debe prescribir y almacenar; es preciso adquirir y/o preparar en el Servicio de Farmacia soluciones diluidas para dispensar a las unidades asistenciales, y también normalizar las presentaciones disponibles, las dosis, las velocidades de administración, etc. Además, es importante establecer un procedimiento que asegure la disponibilidad del potasio concentrado para aquellas situaciones urgentes en que se necesite.

Por este motivo, para lograr la aplicación de esta práctica es preciso contar con la colaboración e implicación de todos los profesionales.

Véanse las Recomendaciones (Sección 2) (3,6,7,10,11,19-22)

Las recomendaciones incluyen actuaciones a llevar a cabo por el equipo directivo del hospital, el Comité de Seguridad, la Comisión de Farmacia y Terapéutica, el Servicio de Farmacia, los responsables de las unidades asistenciales, médicos y enfermeras.

Recogen medidas para efectuar la prescripción, almacenamiento, preparación y administración del cloruro potásico intravenoso en los hospitales, con el objetivo de reducir los riesgos derivados de su utilización y mejorar la seguridad de los pacientes.

> *"Desafortunadamente hay muchos profesionales sanitarios que creen que si no les ha sucedido a ellos, las experiencias adversas de otros no les conciernen. Este es el motivo por el que los viales de cloruro potásico concentrado pueden aún encontrarse en las unidades asistenciales".*
> *Michael Cohen, MS, FASHP, Institute for Safe Medication Practices (1995) (4)*

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3.2. MODELO DE PROTOCOLO DE UTILIZACIÓN DEL CLORURO POTÁSICO PARA UN HOSPITAL

La elaboración e implantación de un protocolo de utilización del potasio en el hospital es una de las actuaciones recomendadas en este documento. Con el fin de facilitar su elaboración, se ha incluido entre el material de apoyo este modelo de protocolo, que cada hospital puede utilizar a título orientativo y adaptar a sus peculiaridades.

Por otra parte, con fines informativos en la sección 4.2 se han recogido como ejemplo algunos protocolos y directrices de uso de potasio elaborados por algunos hospitales, que ilustran la amplia variedad de procedimientos y de documentos utilizados en los centros asistenciales.

Hay dos aspectos en particular que cada hospital debe establecer en función de sus características y posibilidades:

- las unidades asistenciales autorizadas para disponer de soluciones concentradas de potasio.
- las presentaciones de potasio que van a estar disponibles en el centro. Deben seleccionarse las formulaciones orales, las presentaciones concentradas y las presentaciones diluidas de potasio para vía intravenosa.

En la sección 3.3 se recoge una relación de los medicamentos con potasio para administración intravenosa registrados en España. Además, es recomendable que en el Servicio de Farmacia se preparen las soluciones concentradas de cloruro potásico en fluidos de pequeño volumen y aquellas soluciones diluidas en fluidos de gran volumen no disponibles comercialmente y que se consideren necesarias en el centro, siempre que se disponga de una unidad de elaboración con los recursos suficientes. De esta manera, es posible retirar por completo o reducir al máximo la disponibilidad de viales o ampollas de potasio concentrado en las unidades asistenciales.

LOGOTIPO
DEL
HOSPITAL

PROTOCOLO DE UTILIZACIÓN DEL CLORURO POTÁSICO

HOSPITAL X

Edición 1

CONTROL DE EDICIONES

Edición	Fecha	Hoja/s	Motivos de los cambios
1		Todas	Edición inicial

Elaborado por:	Revisado por:	Aprobado por:
Fdo.:	Fdo.:	Fdo.:

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1. OBJETIVO

La administración de potasio concentrado por vía intravenosa directa sin dilución previa produce hiperpotasemia y ésta puede conducir a un bloqueo y parada cardiaca. Se han comunicado casos de muerte por esta causa. Las ampollas o viales de cloruro potásico deben administrarse siempre diluidas y a la velocidad adecuada.

El protocolo tiene por objetivo definir los procedimientos que deben seguirse en el hospital para prescribir, preparar, dispensar y administrar el cloruro potásico intravenoso y garantizar la seguridad en su utilización, con la máxima eficiencia y aplicabilidad práctica.

2. ALCANCE

El protocolo implica a todos los preparados con potasio disponibles en el hospital que se administren por vía intravenosa[1]. Es de aplicación en todas las unidades asistenciales del hospital, incluyendo las áreas críticas, y afecta, por tanto, a todos los profesionales sanitarios.

3. DEFINICIONES

Soluciones concentradas de potasio.
Son aquellas que tienen un contenido en potasio superior a 40 mEq/L. Incluyen:

- las presentaciones comercializadas en viales o ampollas de cloruro potásico 1 M y 2 M.
- las soluciones de cloruro potásico en fluidos de pequeño volumen que se preparan en el Servicio de Farmacia (20 mEq y 40 mEq de potasio en 100 mL) [2].
- los viales o ampollas de fosfato potásico y otras sales de potasio para administración intravenosa.

Soluciones diluidas de potasio.
Son aquellas soluciones de cloruro potásico en fluidos intravenosos de gran volumen que tienen una concentración de cloruro potásico ≤ 40 mEq/L.

4. RESPONSABILIDADES

- La dirección del hospital tiene la responsabilidad de implantar y hacer cumplir este protocolo y las recomendaciones para el uso seguro del potasio intravenoso, con la colaboración del Grupo de Trabajo para la Prevención de Errores de Medicación [3] y la Comisión de Farmacia y Terapéutica.

- Los responsables de las unidades asistenciales y los supervisores de enfermería tienen la responsabilidad de difundir este protocolo, establecer las medidas necesarias para su implantación y revisar su cumplimiento.

- Todos los profesionales sanitarios que están implicados en alguna etapa del circuito de utilización de los medicamentos en el hospital y manejan preparados con potasio intravenoso tienen la responsabilidad de aplicar este protocolo en sus áreas de actuación: el médico en la *prescripción*, el farmacéutico en la *validación* y *dispensación*, la enfermera en la *preparación* y *administración*, y el auxiliar de farmacia en el *almacenamiento* y *dispensación*.

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[1] *El protocolo afecta también al fosfato potásico y otras sales de potasio para administración intravenosa.*

[2] *Es recomendable que la preparación de estas soluciones esté centralizada en el Servicio de Farmacia, siempre que éste disponga de los recursos necesarios. Cada hospital debe valorar este aspecto según sus características y adaptar el contenido de este apartado.*

[3] *Modificar según situación concreta del hospital.*

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5. DESCRIPCIÓN DEL PROTOCOLO

5.1. Disponibilidad de potasio intravenoso

- Soluciones concentradas de potasio

  - Presentación de cloruro potásico 1 M o 2 M[4]. Disponible en el Servicio de Farmacia. De forma excepcional, algunas unidades asistenciales autorizadas podrán disponer de un número limitado de ampollas o viales, siempre que exista un procedimiento para controlar su uso y reposición, y que se almacenen en lugares separados del resto de los medicamentos [5].

  - Soluciones de cloruro potásico en fluidos de pequeño volumen. En el Servicio de Farmacia se preparan soluciones con 20 mEq de potasio en 100 mL (200 mEq/L) y 40 mEq en 100 mL (400 mEq/L)[6]. Disponibles en aquellas unidades asistenciales autorizadas bajo control[7].

- Soluciones diluidas de potasio

  Disponibles en todas las unidades asistenciales del hospital. En el Anexo 1 se recogen las soluciones diluidas incluidas en la Guía Farmacoterapéutica del hospital.

5.2. Indicaciones

Debe aportarse potasio en situaciones clínicas que desarrollen síntomas de hipopotasemia y/o cuando la concentración plasmática de potasio es inferior a 3,5 mEq/L. La dosis y la velocidad de administración del cloruro potásico se establecen en función de la indicación y de la concentración plasmática de potasio. Las situaciones clínicas que habitualmente requieren tratamiento con potasio figuran en la siguiente tabla:

Situaciones clínicas que requieren tratamiento con potasio
1. Aporte disminuido en pacientes con nutrición parenteral total.
2. Estados de inanición, desnutrición, dieta inusual y alcoholismo
3. Causas digestivas: pérdidas de fluidos gastrointestinales (diarrea), presencia de fístulas biliares o intestinales, vómitos, aspiración nasogástrica o abuso de laxantes sin aporte controlado de potasio.
4. Pérdidas renales de potasio superiores a 20 mEq/día, no compensadas y/o tratadas, por trastornos tubulares, hipoaldosteronismo primario o secundario, síndrome de Bartter, niveles elevados de glucocorticoides, utilización de diuréticos, corticoides, L-dopa, regaliz y presencia de diuresis osmótica.
5. Pacientes edematosos con diuréticos y/o digoxina (reemplazamiento).
6. Intoxicación digitálica con arritmias cardiacas.
7. Infarto agudo de miocardio con hipopotasemia.
8. Cetoacidosis diabética tratada con insulina.

Tomada de Jiménez Torres et al (2001).

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[4] *Seleccionar una única presentación (1 M o 2 M) y consignarla en el protocolo. Incluir también las ampollas o viales de fosfato potásico y acetato potásico.*

[5] *Relacionar las unidades asistenciales autorizadas.*

[6] *Consignar las presentaciones disponibles, en caso de que se preparen en el Servicio de Farmacia.*

[7] *Relacionar las unidades asistenciales autorizadas.*

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- Siempre que sea clínicamente posible, el potasio se debe administrar por vía oral. En este caso, no se debe administrar con el estómago vacío. Se prefieren las formas líquidas o las efervescentes de sales de potasio.

- La dosis diaria máxima es generalmente de 150 mEq. Ciertos pacientes, debido a su condición clínica o medicación concomitante, pueden requerir dosis mayores (hasta 300 mEq/día), como son los pacientes con hipopotasemia severa (< 2,5 mEq/L), leucemia en terapia de inducción, administración de diuréticos, anfotericina B o corticoides, pérdidas gastrointestinales severas (vómitos, diarrea, ostomía, drenajes), etc.

- Los requerimientos de potasio en la gran mayoría de los pacientes oscilan entre 30 y 80 mEq/día, y las necesidades de fluidos entre 2.000 y 3.000 mL diarios. Por tanto, las soluciones diluidas disponibles con una concentración de 20 a 40 mEq/L garantizan las necesidades descritas.

- El balance del potasio es dependiente de la homeostasis del magnesio. Una hipopotasemia refractaria puede resultar de una hipomagnesemia, y esta condición debería ser tratada para facilitar la corrección del potasio.

- El aporte de potasio está absolutamente contraindicado en situaciones de hiperpotasemia. Puede estar contraindicado o debería administrarse en pequeñas dosis con monitorización en insuficiencia adrenocortical, insuficiencia renal, oliguria post-operatoria, shock con reacción hemolítica y/o deshidratación, tratamiento con inhibidores de la enzima convertidora de la angiotensina y diuréticos ahorradores de potasio, etc.

- En situaciones de emergencia (potasio < 2,5 mEq/L) no se deben utilizar soluciones de glucosa 5% como vehículo para la administración de potasio, ya que la glucosa origina una distribución intracelular de potasio que, ocasionalmente, provoca un empeoramiento paradójico de la depleción de potasio existente en el paciente.

- En determinadas situaciones clínicas el fluido más recomendable es la solución de glucosalino 1/3 (GS1/3), por su adecuado contenido en glucosa y baja cantidad de cloruro sódico (ClNa) [5].

- **Todas las prescripciones de cloruro potásico deben indicar:**
  - **la dosis de potasio expresada en mEq o mmol (1 mEq = 1 mmol) y nunca en ampollas, viales o mililitros.**
  - **el volumen de dilución.**
  - **el tiempo en que se debe administrar y/o la velocidad de infusión.**

[5] *A fecha 1 de Diciembre de 2008, no están registrados en España preparados de glucosalino con cloruro potásico, pero se encuentran en fase de registro y algunos laboratorios los preparan como fórmula magistral.*

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5.3. Preparación de las soluciones de potasio intravenoso

En aquellas unidades específicas autorizadas para disponer de ampollas o viales de cloruro potásico concentrado, se deben seguir las siguientes instrucciones cuando se preparen soluciones intravenosas de potasio[9]:

- Diluir el cloruro potásico siempre en fluidos compatibles: cloruro sódico 0,9% (ClNa 0,9%) y cloruro sódico 0,45% (ClNa 0,45%), glucosa 5% (G5%), y soluciones glucosalinas.
- Preparar las soluciones concentradas de cloruro potásico en fluidos de pequeño volumen con ClNa 0,9%. Las concentración habitualmente utilizada es la de 200 mEq/L (20 mEq de potasio en 100 mL) y excepcionalmente la de 400 mEq/L (40 mEq de potasio en 100 mL). Estas soluciones se administrarán exclusivamente por vía central.
- Homogeneizar adecuadamente la solución. Para ello se invertirá al menos seis veces.
- Nunca añadir potasio extra a una mezcla intravenosa ya preparada que contenga potasio, para evitar confusiones en la concentración final.
- Nunca añadir potasio a una solución intravenosa que ya se esté administrando al paciente.
- Etiquetar la solución correctamente, consignando: dosis, volumen final, velocidad de infusión y/o periodo de administración.
- Las soluciones para administración por vía central deben incluir un aviso: "sólo para administración por vía central".
- Se debe realizar un doble chequeo independiente por otro profesional en el momento de la preparación, para verificar que el medicamento, la dosis, la dilución y el etiquetado son correctos.

5.4. Administración de las soluciones de potasio intravenoso

La cantidad de cloruro potásico a administrar está limitada por la concentración y la velocidad de infusión, y depende del tipo de acceso venoso (periférico o central) y de la localización del paciente (unidad de hospitalización o área crítica).

Se debe confirmar la permeabilidad absoluta de la vena por la que se va a administrar el potasio, ya que la extravasación puede causar necrosis.

- Por vía periférica, la concentración máxima habitual de potasio es de 40 mEq/L y la velocidad de 10 mEq/h. Se aceptan como límites de concentración y velocidad para la administración intravenosa de potasio por esta vía 60 mEq/L y 20 mEq/h, respectivamente. Concentraciones superiores puede producir dolor local y flebitis.

- Por vía central, la concentración de potasio en la solución intravenosa puede llegar hasta 100 mEq/L en fluidos de gran volumen y se puede alcanzar una velocidad máxima de infusión de 20 mEq/h y excepcionalmente de 40 mEq/h. Cuando se administra en fluidos de pequeño volumen habitualmente se utiliza la preparación de 20 mEq en 100 mL y en caso necesario de 40 mEq en 100 mL.

- Las soluciones diluidas de potasio (≤ 40 mEq/L de potasio) pueden administrarse con un sistema de regulación de flujo (p.ej. dial-a-flo®), mientras que las soluciones que contengan más de 40 mEq/L y/o que se administran por vía central deben administrarse utilizando bombas de infusión.

[9] *Adaptar el contenido de este apartado a las soluciones que se preparen y a las unidades o situaciones autorizadas para ello.*

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- Se recomienda realizar un doble chequeo independiente antes de la administración, para verificar que el paciente, la dosis, la vía y la velocidad de administración son correctos.

LÍMITE SUPERIOR DE CONCENTRACIÓN, VELOCIDAD Y DOSIS DIARIA DE POTASIO EN ADULTOS

	Infusión IV continua Fluidos de gran volumen		Infusión IV intermitente Fluidos de pequeño volumen
	Vía periférica	Vía central	Vía central
Concentración	40 mEq/L [a]	100 mEq/L	20 mEq en 100 mL 40 mEq en 100 mL
Velocidad (mEq/h)	10 [b]	20 [c]	20 [c]
Dosis (mEq/día)	150	300 [d]	60 mEq en 3 h [e]

[a] *Excepcionalmente 60 mEq/L durante períodos cortos de tiempo y/o en unidades especiales.*
[b] *Excepcionalmente 20 mEq/h en unidades especiales.*
[c] *Excepcionalmente hasta 40 mEq/h.*
[d] *Necesaria la monitorización continua del paciente.*
[e] *No es conveniente administrar más de tres dosis consecutivas de 20 mEq.*

5.5. Intercambio terapéutico

Las prescripciones de potasio intravenoso deben adaptarse a las soluciones disponibles en el hospital (véanse apartado 5.1 y Anexo 1).

En pacientes adultos con función renal normal, para aquellas situaciones en que se prescriba una solución diluida de potasio que no se adapte a las presentaciones disponibles, se ha establecido el siguiente protocolo de sustitución:

ADULTOS Concentración prescrita	Sustituir por
1-30 mEq/L, perfusión continua	20 mEq/L, perfusión continua
31-59 mEq/L, perfusión continua	40 mEq/L, perfusión continua

El farmacéutico podrá reemplazar directamente la prescripción recibida con la sustitución propuesta y lo indicará en las observaciones de la línea prescrita, a no ser que la prescripción indique específicamente "no cambiar".

La enfermera podrá reemplazar automáticamente la prescripción a la sustitución propuesta en el protocolo, a no ser que la prescripción indique específicamente "no cambiar".

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5.6. Monitorización del tratamiento

- Se requiere monitorización cardiaca para velocidades de administración de potasio total superiores a 10 mEq/h, considerando todas las fuentes de potasio (nutrición parenteral, infusión intravenosa continua, infusión intravenosa intermitente, etc).

- En pacientes que reciben dosis ≥ 60 mEq/día se deben monitorizar las concentraciones plasmáticas de potasio, al menos cada 24 horas.

- Los pacientes adultos con un peso superior a 40 Kg y función renal normal (Cr plasmática < 2 mg/L) que reciben dosis de mantenimiento de potasio < 59 mEq/día, no necesitan monitorización diaria de concentraciones de potasio.

- Para la extracción de la muestra de sangre se debe esperar al menos 60 minutos después de la administración de potasio, tanto por vía oral como intravenosa.

- Puede ser necesario monitorizar las concentraciones de magnesio y aportar en caso necesario, pues en situación de hipomagnesemia puede no resultar efectiva la reposición de potasio para corregir la hipopotasemia.

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ANEXO 1. Presentaciones con cloruro potásico incluidas en la Guía Farmacoterapéutica del hospital.

Presentaciones disponibles de potasio para administración oral [10]:

Nombre comercial	Composición	Potasio mEq/ unidad
Potasión 600® cáps	Cloruro potásico 600 mg	**8 mEq/cáps**
Potasión® solución	Glucoheptonato potásico 1,32 g/5 mL	**5 mEq/5 mL**
Boi-K® comp eferv	Bicarbonato potásico 1001 mg + ácido ascórbico 250 mg	**10 mEq/comp eferv**
Boi-K aspártico® comp eferv	Bicarbonato potásico 2502 mg + ácido ascórbico 500 mg + ácido L-aspártico 350 mg	**25 mEq/comp eferv**

Soluciones diluidas disponibles de potasio para administración intravenosa [11]:

Presentación	Composición	Potasio mEq/envase	Potasio mEq /L
Cloruro sódico 0,9% y cloruro potásico 0,15%, envase 500 mL	Cloruro sódico 0,9% 500 mL + ClK 10 mEq	**10 mEq**	**20 mEq/L**
Cloruro sódico 0,9% y cloruro potásico 0,3%, envase 500 mL	Cloruro sódico 0,9% 500 mL + ClK 20 mEq	**20 mEq**	**40 mEq/L**
Cloruro sódico 0,9% y cloruro potásico 0,3%, envase 1000 mL	Cloruro sódico 0,9% 1000 mL + ClK 40 mEq	**40 mEq**	**40 mEq/L**
Glucosa 5% y cloruro potásico 0,15%, envase 500 mL	Glucosa 5% 500 mL + ClK 10 mEq	**10 mEq**	**20 mEq/L**
Glucosa 5% y cloruro potásico 0,15%, envase 1000 mL	Glucosa 5% 1000 mL + ClK 20 mEq	**20 mEq**	**20 mEq/L**
Glucosa 5% y cloruro potásico 0,3%, envase 500 mL	Glucosa 5% 500 mL + ClK 20 mEq	**20 mEq**	**40 mEq/L**
Glucosa 5% y cloruro potásico 0,3%, envase 1000 mL	Glucosa 5% 1000 mL + ClK 40 mEq	**40 mEq**	**40 mEq/L**
Glucosalino 3,3%/ 0,3% y cloruro potásico 0,15%, envase 500 mL	Glucosalino 3,3%/ 0,3% 500 mL + ClK 10 mEq	**10 mEq**	**20 mEq/L**
Glucosalino 3,3%/ 0,3% y cloruro potásico 0,3%, envase 500 mL	Glucosalino 3,3%/0,3% 500 mL + ClK 20 mEq	**20 mEq**	**40 mEq/L**
Glucosalino 3,3%/ 0,3% y cloruro potásico 0,15%, bolsa 1000 mL	Glucosalino 3,3%/ 0,3% 1000 mL + ClK 20 mEq	**20 mEq**	**20 mEq/L**
Glucosalino 3,3%/ 0,3% y cloruro potásico 0,3%, bolsa 1000 mL	Glucosalino 3,3%/ 0,3% 1000 mL + ClK 40 mEq	**40 mEq**	**40 mEq/L**

[10] *Consignar las presentaciones disponibles en el hospital.*

[11] *Consignar las presentaciones disponibles en el hospital. A fecha 1 de Diciembre de 2008, no están registrados en España preparados de glucosalino con cloruro potásico, pero se encuentran en fase de registro y algunos laboratorios los preparan como fórmula magistral.*

3.3. RELACIÓN DE MEDICAMENTOS CON POTASIO PARA ADMINISTRACIÓN INTRAVENOSA DISPONIBLES EN ESPAÑA

Tabla 1. Soluciones diluidas con potasio para administración intravenosa comercializadas en España*.

Presentación/ Laboratorios	Composición	Potasio mEq/envase	Potasio mEq/L
Cloruro sódico 0,9% y cloruro potásico 0,15%, envase 500 mL *(Baxter, S.L.) (G.E.S. Genéricos Españoles S.A.) (Laboratorios Grifols S.A.)*	Potasio 10 mEq en 500 mL de Cloruro sódico 0,9%	**10 mEq/envase**	20 mEq/L
Cloruro sódico 0,9% y cloruro potásico 0,3%, envase 500 mL *(Baxter, S.L.) (G.E.S. Genéricos Españoles S.A.) (Laboratorios Grifols S.A.)*	Potasio 20 mEq en 500 mL de Cloruro sódico 0,9%	**20 mEq/envase**	40 mEq/L
Cloruro sódico 0,9% y cloruro potásico 0,3%, envase 1000 mL *(Baxter, S.L.)*	Potasio 40 mEq en 1000 mL de Cloruro sódico 0,9%	**40 mEq/envase**	40 mEq/L
Glucosa 5% y cloruro potásico 0,15%, envase 500 mL *(Baxter, S.L.) (G.E.S. Genéricos Españoles S.A.) (Laboratorios Grifols S.A.)*	Potasio 10 mEq en 500 mL de Glucosa 5%	**10 mEq/envase**	20 mEq/L
Glucosa 5% y cloruro potásico 0,3%, envase 500 mL *(G.E.S. Genéricos Españoles S.A.) (Laboratorios Grifols S.A.)*	Potasio 20 mEq en 500 mL de Glucosa 5%	**20 mEq/envase**	40 mEq/L
Glucosa 5% y cloruro potásico 0,15%, envase 1000 mL (Baxter, S.L.)	Potasio 20 mEq en 1000 mL de Glucosa 5%	**20 mEq/envase**	20 mEq/L

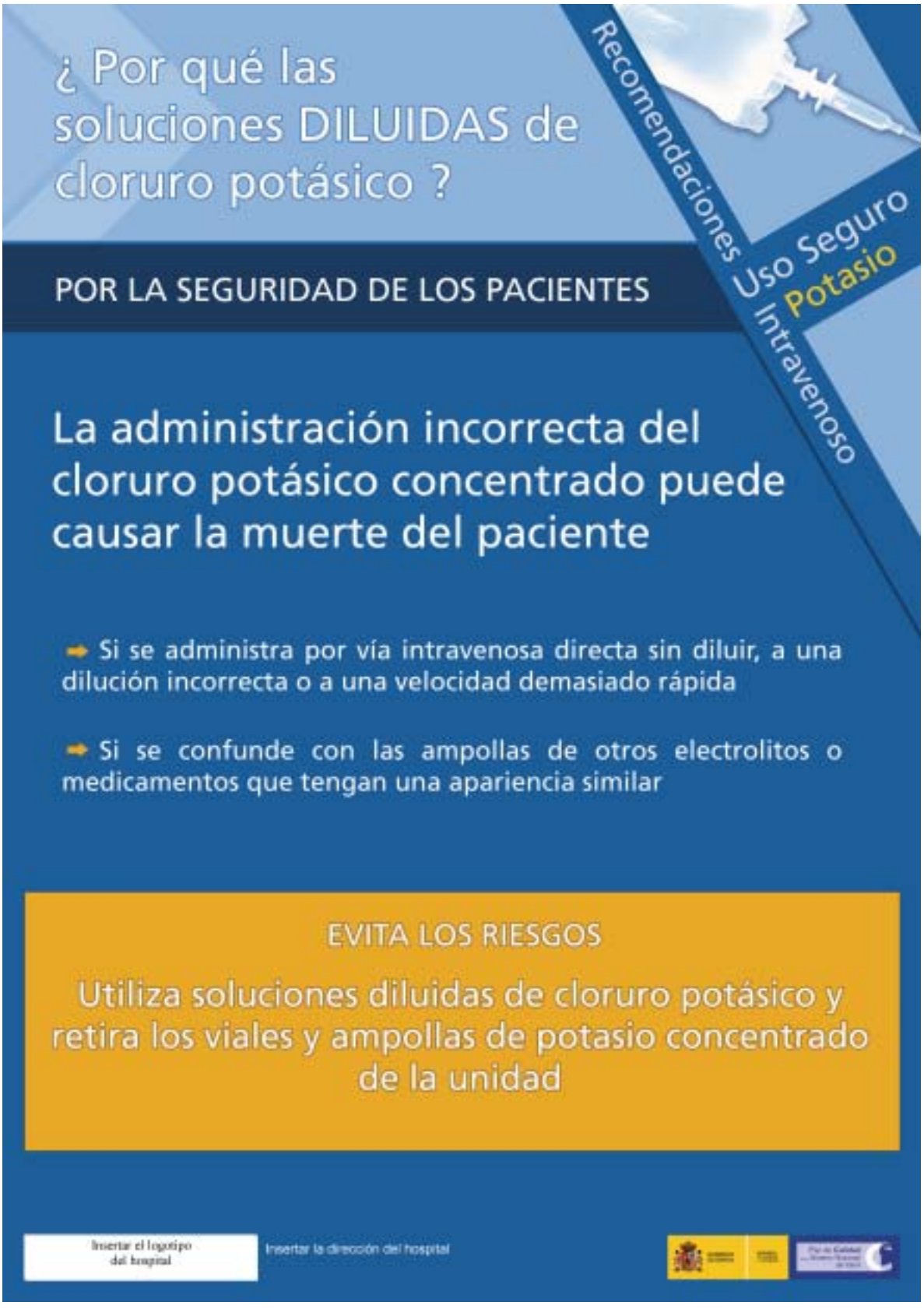
(*) **Nota aclaratoria:** En esta tabla se recogen las soluciones diluidas con potasio registradas y comercializadas en España a fecha 1 de diciembre de 2008. No se han incluido los preparados comercializados como fórmulas magistrales.

Tabla 2. Soluciones concentradas con potasio para administración intravenosa comercializadas en España*.

Nombre comercial/ Laboratorio	Composición	Potasio mEq /envase	Potasio mEq /mL
Acetato potásico 1 M Braun amp 10 mL *(B. Braun Medical S.A.)*	Acetato potásico 980 mg/10 mL	**10 mEq/10 mL**	1 mEq/mL
Cloruro potásico Braun 7,45% (1 M) miniplasco 10 mL *(B. Braun Medical S.A.)*	Cloruro potásico 745 mg/10 mL	**10 mEq/10 mL**	1 mEq/mL
Cloruro potásico 1 M Grifols amp 10 mL *(Laboratorios Grifols, S.A.)*			
Cloruro potásico 1 M Fresenius Kabi amp 10 mL *(Fresenius Kabi España)*			
Cloruro potásico Braun 14,9% (2 M) miniplasco 5 mL *(B. Braun Medical S.A.)*	Cloruro potásico 745 mg/5 mL	**10 mEq/5 mL**	2 mEq/mL
Meinsol cloruro potásico 2 M 14,9% amp 5 mL *(Fresenius Kabi España)*			
Cloruro potásico Braun 14,9% (2 M) miniplasco 10 mL *(B. Braun Medical S.A.)*	Cloruro potásico 1,49 g/10 mL	**20 mEq/10 mL**	2 mEq/mL
Meinsol cloruro potásico 2 M 14,9% amp 10 mL *(Fresenius Kabi España)*			
Cloruro potásico Braun 14,9% (2 M) miniplasco 20 mL *(B. Braun Medical S.A.)*	Cloruro potásico 3 g/20 mL	**40 mEq/20 mL**	2 mEq/mL
AP-Inyect solución de cloruro potásico vial 20 mL *(Fresenius Kabi España)*			
Cloruro potásico Grifols 18,5% amp 10 mL *(Laboratorios Grifols, S.A.)*	Cloruro potásico 1,85 g /10 mL	**24,8 mEq/10 mL**	2,5 mEq/mL
Fosfato dipotásico 1 M Fresenius Kabi amp 10 mL *(Fresenius Kabi España)*	Fosfato dipotásico 1742 mg/10 mL	**20 mEq/10 mL**	2 mEq/mL

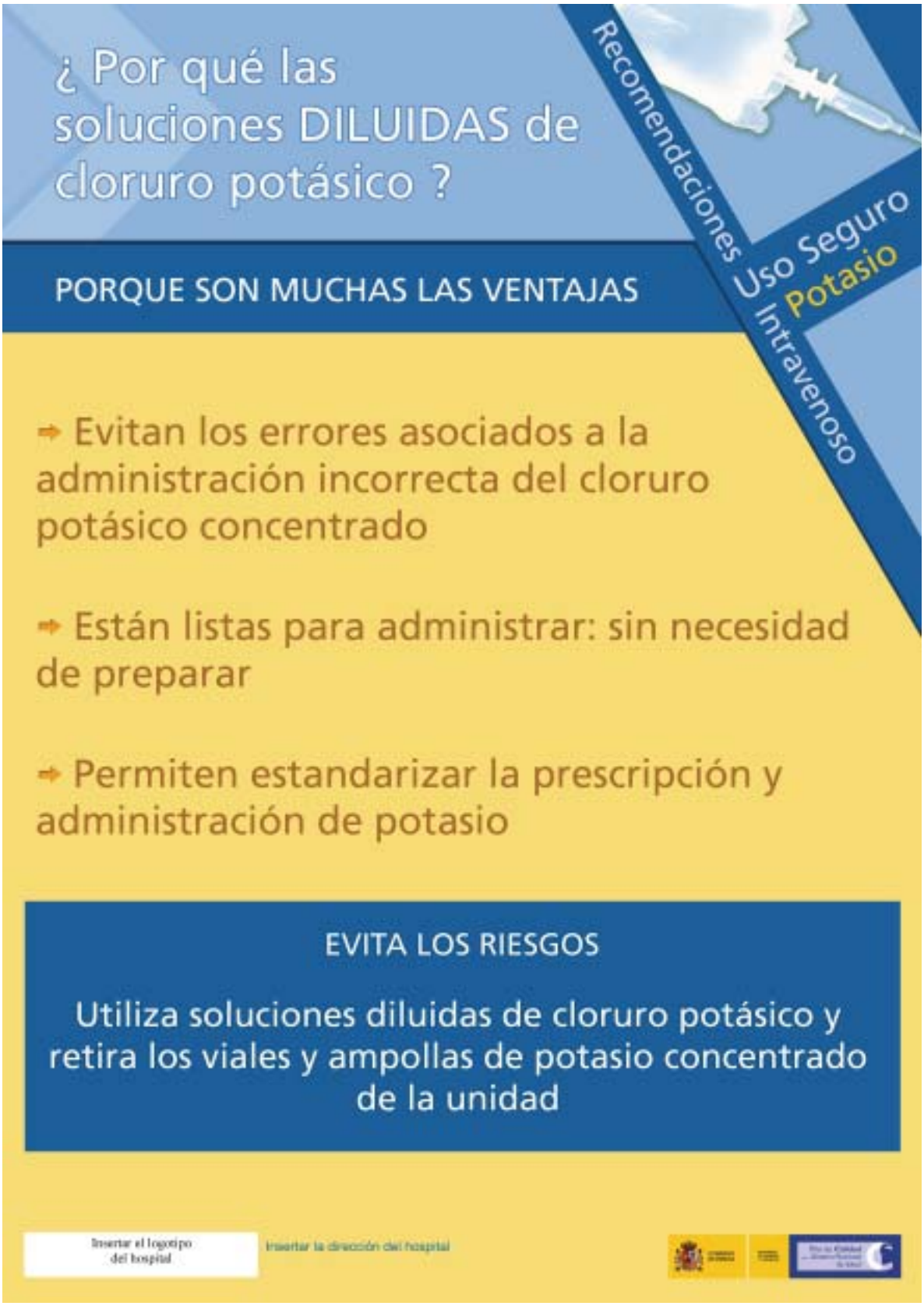
(*) **Nota aclaratoria:** En esta tabla se recogen las soluciones con potasio concentrado registradas y comercializadas en España a fecha 1 de diciembre de 2008. No se han incluido los preparados comercializados como fórmulas magistrales.

3.4. MODELOS DE PÓSTERS



MATERIAL DE APOYO

MATERIAL DE APOYO



3.5. MODELOS DE DÍPTICOS

POR LA SEGURIDAD DE LOS PACIENTES

La administración incorrecta del cloruro potásico concentrado puede causar la muerte del paciente

- Si se administra por vía intravenosa directa sin diluir, a una dilución incorrecta o a una velocidad demasiado rápida
- Si se confunde con las ampollas de otros electrolitos o medicamentos que tengan una apariencia similar

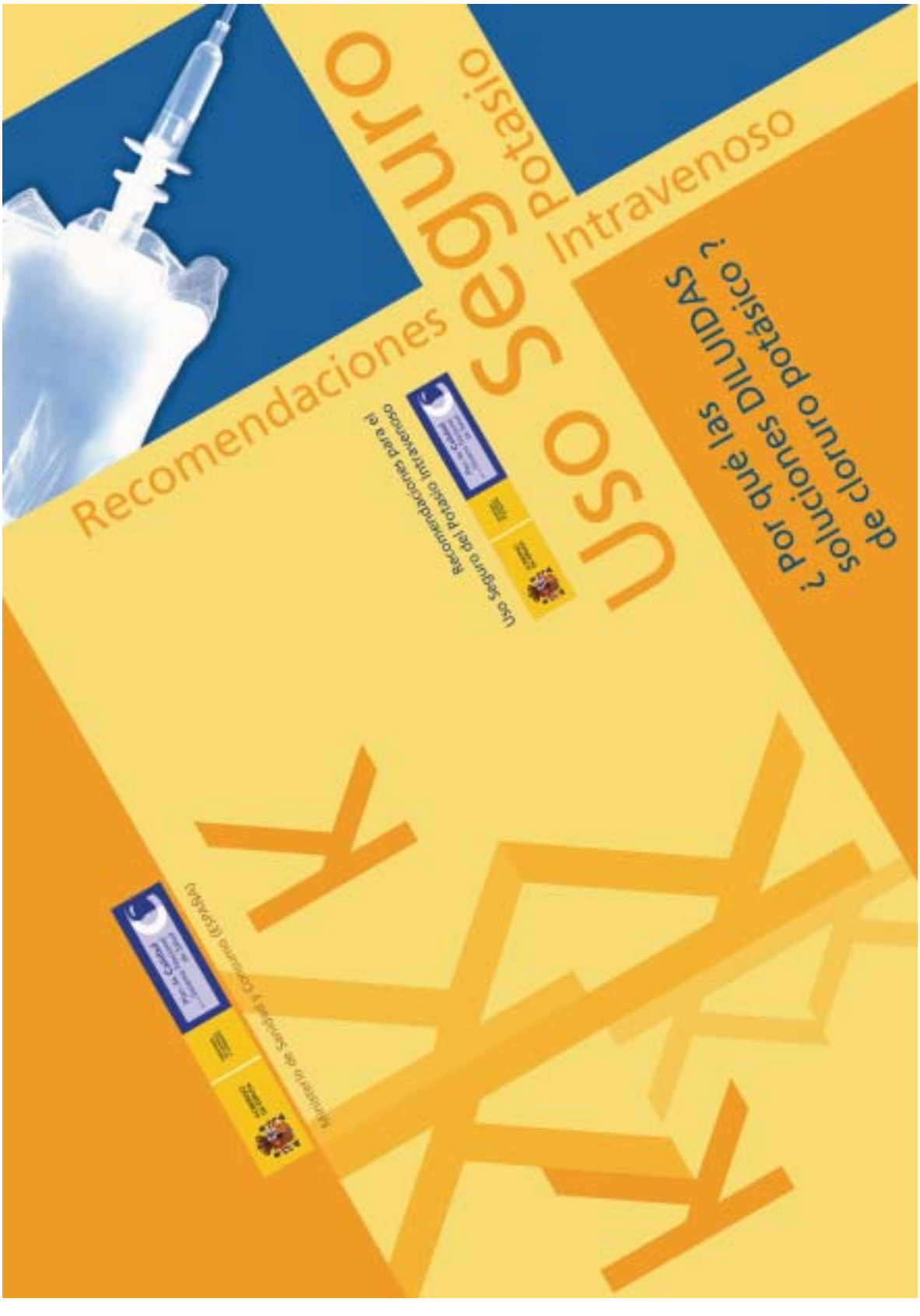
EVITA LOS RIESGOS

Utiliza soluciones diluidas de cloruro potásico y retira los viales y ampollas de potasio concentrado de la unidad

Insertar el logotipo del hospital

Insertar la dirección del hospital

MATERIAL DE APOYO



PORQUE SON MUCHAS LAS VENTAJAS

- Evitan los errores asociados a la administración incorrecta del cloruro potásico concentrado
- Están listas para administrar: sin necesidad de preparar
- Permiten estandarizar la prescripción y administración de potasio

EVITA LOS RIESGOS

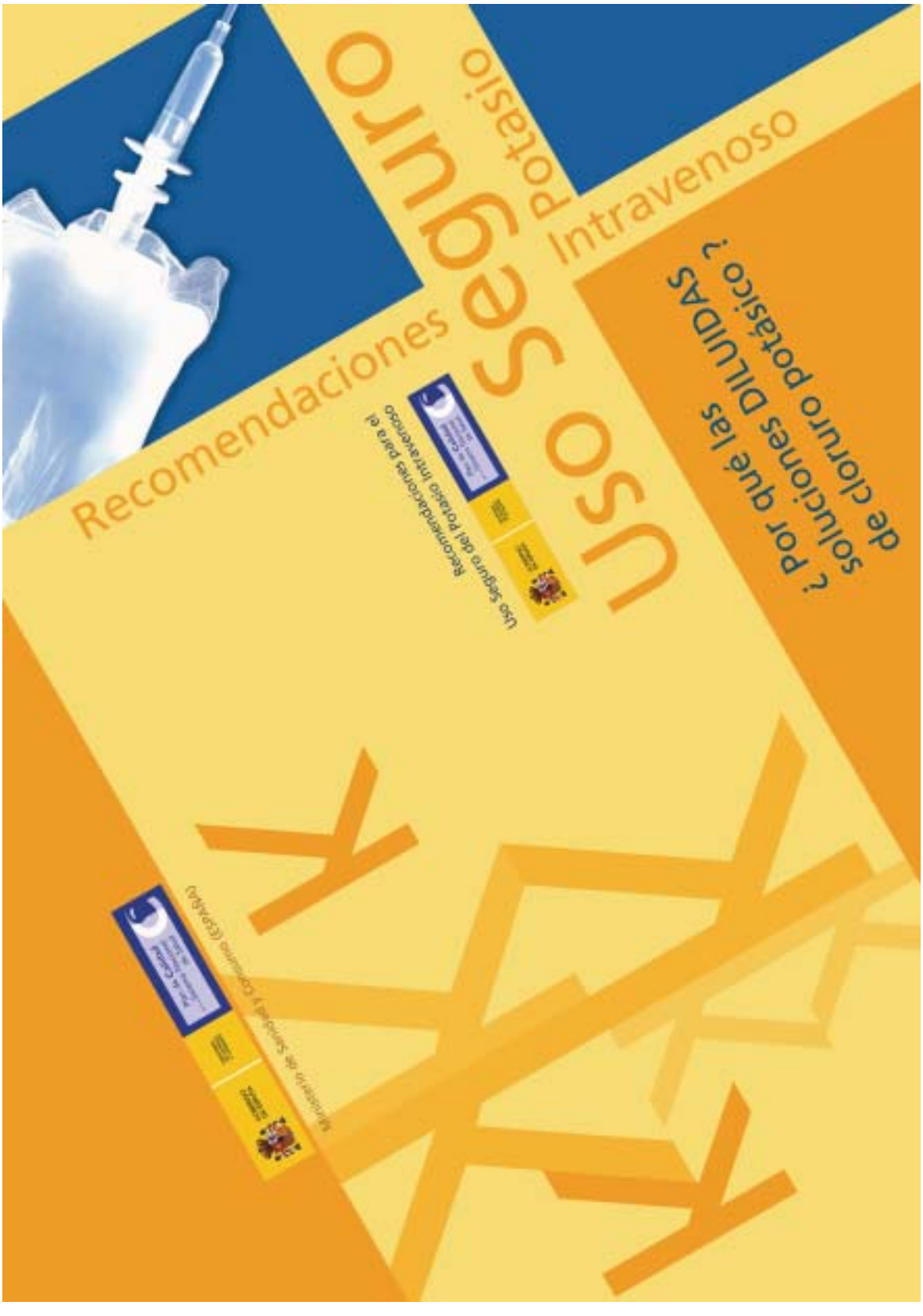
Utiliza soluciones diluidas de cloruro potásico y retira los viales y ampollas de potasio concentrado de la unidad

PRESENTACIÓN	COMPOSICIÓN	mEq POTASIO POR ENVASE
Incluir datos del hospital	Incluir datos del hospital	Incluir datos del hospital
Incluir datos del hospital	Incluir datos del hospital	Incluir datos del hospital
Incluir datos del hospital	Incluir datos del hospital	Incluir datos del hospital
Incluir datos del hospital	Incluir datos del hospital	Incluir datos del hospital

Insertar el logotipo del hospital

Insertar la dirección del hospital

MATERIAL DE APOYO



PORQUE SON MUCHAS LAS VENTAJAS

- Evitan los errores asociados a la administración incorrecta del cloruro potásico concentrado
- Están listas para administrar: sin necesidad de preparar
- Permiten estandarizar la prescripción y administración de potasio

EVITA LOS RIESGOS

Utiliza soluciones diluidas de cloruro potásico y retira los viales y ampollas de potasio concentrado de la unidad

Insertar el logotipo del hospital

Insertar la dirección del hospital

4. DOCUMENTOS DE INTERÉS

4.1. RECOMENDACIONES EMITIDAS POR ORGANISMOS Y AGENCIAS

The Joint Commission | Joint Commission International | World Health Organization

WHO Collaborating Centre for Patient Safety Solutions | Aide Memoire

Control of Concentrated Electrolyte Solutions

Patient Safety Solutions
volume 1, solution 5 | May 2007

▶ 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 burettrol 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.

DOCUMENTOS DE INTERÉS

- 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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ISMP Medication Safety Alert! Acute Care

DESPITE KNOWLEDGE OF ACCIDENTS, OPPORTUNITIES FOR POTASSIUM ADE'S PERSIST IN SOME US HOSPITALS

From the August 28,1996 Issue

PROBLEM: Despite widespread coverage of potassium chloride-related deaths in professional journals, newsletters, and the lay press (ABC 20/20, August 23, 1996), some US hospitals still have not established necessary controls to optimize the safe administration of this drug. A close call last week at a children's hospital illustrates why hospitals must be proactive rather than reactive when addressing this issue. A pharmacist received a call from a pediatric nurse who wanted to know if there wer e smaller IV bags for 0.45% saline than 1000 mL. The pharmacist informed her that there were and asked why she wanted to know. The nurse stated that she had to give an IV medication and wanted to use the least expensive bag. The pharmacist told her that there was little difference between the costs of the various IV bags, and not enough to justify sending up a smaller bag specifically for her purpose. As the nurse was about to hang up she mentioned: "It's just that I have 20 mEq of potassium to give in 30 mL over one hour and don't want to waste all that fluid." Instant chaos!

The pharmacist asked who the potassium was for and was told that a surgical resident had written this order for a 23 day-old. A child of this size and age would ordinarily receive just 3 mEq of potassium per kg per day! The nurse was instructed not to hang the IV and to wait until the pharmacist called the surgical resident. Although the resident initially failed to see what the problem was, when told of the correct dose and the possible consequences of a 20 mEq dose of potassium given over one hour, he readily agreed to cancel the order and check with the pediatric attending physician regarding what dose of potassium, if any, should be given.

Administering 20 mEq of potassium most likely would have killed the child. The fact that the potential medication error was intercepted by the pharmacist is commendable, but the situation begs the bigger question of how this even came so close to being a serious adverse drug event. Obviously, the surgical resident was not completely familiar with fluid and electrolyte therapy in children. Still, that is probably not all that uncommon among non-pediatricians. The information was passed on to the Medical Director for Pediatrics, and that matter will be handled there.

How did the nurse happen to have 20 mEq of potassium? The answer is quite simple - she took it from another patient's medication drawer. For dehydrated pediatric patients, orders are commonly written at the hospital to "add 20 mEq of potassium to I V after child begins to urinate". The pharmacy in the hospital where this happened routinely sends vials of 20 mEq potassium chloride injection to the floor for such patients. Potassium injection is also readily available for dispensing from automated dispensing modules (in this case Pyxis), located near many of the pediatric nursing floors.

SAFE PRACTICE RECOMMENDATION: The pharmacy recently instituted a new potassium policy for this hospital. Potassium will not be kept as floor stock anywhere in the hospital except in the neonatal & pediatric intensive care unit Pyxis machines where s pecial packaging and controlled storage is used. Further, potassium will not be sent to the nursing floors for patient orders, and all potassium-containing IVs must be either manufacturer prepared or, when the desired concentration is not available commercially, pharmacy-prepared. A policy is being written that will specify exactly what amounts of potassium may be safely administered on the nursing floor. In addition, pediatric nursing will receive in-servicing on the policy and the safe administration of potassium.

Will any of this totally eliminate the possibility of potassium being administered in an incorrect, and possibly dangerous manner? Experience suggests that the answer to that is "no", but even if you can't stop the train at least you can drag your legs. Will this policy meet with some resistance from nurses who feel, and rightly so, that there are more and more restrictions to performing patient care? Yes, it probably will. However, any of us would be willing to suffer the slings and arrows of an angry professional if it means a patient, and particularly a young child, is a little safer. [D, N, P, Q, T]

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Acute Care

ISMP MedicationSafetyAlert!®

KCl DEATHS: ART IMITATES LIFE

From the November 20, 1996 issue

On November 7th a med-surg nurse with a temporary assignment to work in the ER mixed up unlabeled syringes of saline and potassium chloride and nearly killed a patient by injecting KCl by IV push. This won't make the medication errors database because it happened on NBC-TV's ER. But another KCl error, sent to ISMP by USP on the very same day was all too real.

The Arkansas State Board of Nursing is investigating two nurses who last month accidentally gave a 71-year-old man IV push KCl instead of IV furosemide. The patient arrested, was resuscitated, but died six hours later. Neither nurse had been previously involved in a serious error. Both have been suspended pending an investigation. ISMP is aware of over a dozen cases of mix-up between potassium and furosemide. Investigations by us indicate that some incidents may be the result of a mental slip which occurs when nurses mentally associate potassium excretion with furosemide administration and subsequently have potassium in mind and at hand while preparing what they believe to be furosemide whose mg dose overlaps with potassium's mEq dose. If needed, please call us for support to better control potassium chloride concentrate vials.

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ISMP MedicationSafetyAlert! Acute Care

SYSTEMS THINKING: TAP INTO STAFF CREATIVITY TO UNLEASH INNOVATION

From the October 3, 2001 issue

Last week, a letter to the editor was published in the New England Journal of Medicine (Landrigan C. Preventable deaths and injuries during magnetic resonance imaging. N Engl J Med. 2001;345:1000-1) from a physician who suggested using metal detectors to prevent the risk of injuries from metal objects during magnetic resonance imaging (MRI). Unfortunately, his suggestion was spurred by the recent tragic death of a six-year-old child in New York who suffered a skull fracture and intracranial hemorrhage after an oxygen tank was pulled by the magnet into the machine at high speed.

As noted by the author, injuries from undetected or misplaced metal objects (e.g., IV drug poles, sandbags containing metal filings, defibrillators, wheelchairs, etc.) brought into MRI exam rooms are not uncommon. Yet, staff training and patient questionnaires to detect metal implants remain the most common methods used to prevent such incidents.

In fact, education has been healthcare's bread and butter for preventing errors and injuries. And while education may prevent some errors, its success is limited because it relies heavily upon human memory and vigilance. More to the point, education alone fails to change the system in a way that would make it impossible for people to make mistakes.

More effective solutions require systems thinking. The suggestion to use highly sensitive walkthrough metal detectors (which are available commercially for about $2,000-$5,500 and require minimal maintenance) to prevent accidental introduction of a metal object into a MRI exam room is an excellent example of systems thinking. This coupled with staff education and patient screening has a high likelihood of preventing injuries. But how did the physician come up with such a powerful suggestion? In retrospect, it seems so obvious. Yet systems thinking is not as easy as it seems.

Our history of errors with potassium chloride concentrate for injection in patient care units demonstrates this very well. Until systems thinking prevailed, many organizations relied upon staff education and manufacturer label warnings to prevent administration of potassium chloride concentrate without proper dilution. Although lessened, errors persisted until the pharmaceutical industry manufactured premixed solutions, physicians standardized potassium replacement therapy to maximize use of commercially available solutions, and vials of potassium chloride were removed from patient care units. Unfortunately, it took years for the healthcare industry to come up with and implement such an effective system-based solution that now seems so simple and intuitive.

To become more proficient at systems thinking, multidisciplinary teams must openly discuss medication errors and refuse to settle for old familiar (and ineffective) ways of solving problems. If education is identified as an error reduction strategy, we can't stop there. Instead of just building inspections into processes to detect errors before they reach patients, we need to find ways to actually prevent them. We must always ask, "Are there ways to make it impossible, not just unlikely, for people to make such a mistake?" Systems thinking is the key needed to bridge the gap between understanding the causes of errors and selecting error reduction strategies that have the greatest likelihood of success. With practice and a little creativity, we can become more skillful and innovative in identifying system-wide strategies that work continuously and automatically to prevent errors and injuries.

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ISMP Medication Safety Alert! Acute Care

POTASSIUM MAY NO LONGER BE STOCKED ON PATIENT CARE UNITS, BUT SERIOUS THREATS STILL EXIST!

From the October 4, 2007 issue

PROBLEM: In the 1980s and 1990s, ISMP, the United States Pharmacopeia (USP), The Joint Commission (TJC), and the Institute for Healthcare Improvement (IHI) drew much-needed attention to the removal of concentrated potassium chloride vials from patient care areas. A 2002 TJC National Patient Safety Goal sustained this effort, and now, virtually all US hospitals have removed the drug from floor stock on typical patient care units. The tragic errors that gave rise to this system change were caused by knowledge deficits about the dangers of rapid IV administration of concentrated potassium or, more often, mental slips or selection errors when grabbing a vial of medication. There's no doubt that limiting access to this drug has reduced fatal errors. However, healthcare providers should not be complacent about the risks associated with this high-alert medication. Below we have detailed some lingering problems associated with concentrated potassium chloride that still represent serious threats to patients.

Nursing access to pharmacy or night cabinet stock of concentrated potassium. In hospitals where 24-hour pharmacy services are not available, nurses may obtain medications from a night/weekend cabinet or a discrete, secured area in the pharmacy. Vials of concentrated potassium chloride may be available in these areas, risking accidental selection of this medication when attempting to obtain another medication. As recently as 6 months ago, this occurred in a critical access hospital and led to a patient's death. The patient was extremely short of breath, and his physician had prescribed an IV dose of furosemide. The pharmacy was closed, so a nurse entered the secured section of the pharmacy to obtain the drug. She mistakenly selected a vial of potassium chloride instead of furosemide, both of which were kept on nearby shelves just above the floor. She took the vial to the unit, withdrew the medication, and administered it to the patient. A mental slip-erroneous association of potassium on the label with the potassium-excreting diuretic-likely resulted in the nurse's failure to recognize the error until she went back to the pharmacy to document removal of the drug.

Vials dispensed for specific patients. Since TJC prohibits floor stock of concentrated potassium chloride vials, some hospitals now dispense vials of the drug as needed for specific patients, particularly pediatric patients, to be added to existing parenteral solutions. This dangerous practice exposes the patient to the risk of receiving undiluted potassium if the nurse selects the wrong vial when preparing medications. The vial or an unlabeled syringe containing potassium could also be placed on the counter in common medication areas, exposing other patients to the risk of a similar error.

Vials available in specialty areas. Potassium chloride vials are sometimes stocked in specialty areas such as the cardiac bypass surgical suite for use during surgery. However, the availability of concentrated potassium chloride in the operating suite risks accidental IV administration of the undiluted drug.

Vials available in outpatient settings. During onsite hospital visits, ISMP staff occasionally find vials of concentrated potassium chloride in hospital-associated adult ambulatory care clinics and women's centers. The drug is used to prepare IV solutions or treatments, such as bladder instillations to diagnose interstitial cystitis (a controversial practice in recent years). The presence of these vials represents a serious risk since some patients in these clinics also receive IV medications or solutions. In some cases, nurses did

not know the vials were in the clinic, further increasing the risk of an error. Another risk factor is that clinic staff sometimes order the potassium chloride vials along with other medications and solutions directly through a wholesaler. In these cases, when the drug supplies reach the pharmacy, they may be delivered directly to the clinic without pharmacy staff's awareness that the box contains concentrated potassium vials.

Mix-ups in the pharmacy. ISMP has previously published reports of serious errors associated with concentrated potassium chloride that originated in the pharmacy. For example, in one report, a pediatrician prescribed an IV infusion of 3.5 mEq of potassium chloride for a 3.5 kg infant. The order was entered into the computer properly as 3.5 mEq/17.5 mL using the hospital's standard 0.2 mEq/mL concentration. The drug was typically withdrawn from a premixed 20 mEq/100 mL bag, but in this case, a pharmacist inadvertently obtained the drug from a vial of concentrated potassium chloride. A 35 mEq dose was drawn into a syringe labeled 3.5 mEq. The infant developed ventricular tachycardia, which was treated successfully with cardioversion and amiodarone. However, patients have died as a result of similar errors, including one in which a batch of dialysis solutions was prepared using a look-alike carton of potassium chloride vials instead of sodium chloride vials.

SAFE PRACTICE RECOMMENDATIONS: Removing concentrated potassium chloride vials from floor stock is not enough to prevent all tragic errors with this high-alert medication. Consider the following additional strategies:

Use premixed solutions. Standardize electrolyte replacement therapy. Use premixed solutions or commercially out-sourced admixtures whenever possible.
Prohibit nursing access to pharmacy. Nurses should not enter the pharmacy when it is closed. A discrete stock of carefully selected, after-hours medications, including premixed small and large volume potassium chloride solutions, should be available in a secured area, preferably a controlled-access cabinet.

Segregate and label. In the pharmacy, store bulk supplies and immediate inventory of concentrated electrolytes in an area segregated from other drugs, and distinctly separated by product type. On all storage shelves and bins, affix warning labels about the need to dilute these products.
Prohibit the dispensing of vials. Vials of potassium chloride should not be dispensed for individual patients. Pharmacy should dispense premixed solutions or prepare patient-specific admixtures as needed. Vials also must not be provided as floor stock. While some hospitals may make an exception for perfusionists in the cardiac bypass surgical suite, please be aware that many hospitals have been able to eliminate vials in all areas by providing premixed or pharmacy-prepared mini-bags of selected concentrations. If vials are dispensed to a cardiac bypass surgical suite, they should carry bold auxiliary warnings. Upon delivery, two individuals should independently verify that the correct product has been received, that it is labeled properly with auxiliary warnings, and that it has been placed in the proper, secured storage area.
Perform double-checks. Require a pharmacist to perform a final, independent check of all products used for IV admixtures of electrolyte solutions.
Procure through pharmacy. For clinics associated with hospitals, medications should be purchased through the pharmacy. All packages delivered to the pharmacy should be inspected before distribution to the clinics.
Conduct safety rounds. Conduct regular rounds at affiliated outpatient facilities and on inpatient units to verify floor stock and ensure safe storage of medications.
Perform failure mode and effects analysis (FMEA). Inventory all concentrated electrolytes in the organization and perform an FMEA. Be sure to evaluate the look-alike potential of product containers. When possible, purchase concentrated electrolytes from different vendors to avoid packaging similarities.

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The Joint Commission

Sentinel Event Alert

Issue 1 - February 28, 1998

New Publication

We are pleased to introduce the first issue of Sentinel Event Alert, a periodic publication dedicated to providing important information relating to the occurrence and management of sentinel events in Joint Commission-accredited health care organizations. Sentinel Event Alert, to be published when appropriate as suggested by trend data, will provide ongoing communication regarding the Joint Commission's Sentinel Event Policy and Procedures, and most importantly, information about sentinel event prevention. It is our expectation and belief that in sharing information regarding the occurrence of sentinel events, we can ultimately reduce the frequency of medical errors and other adverse events.

Initially, Sentinel Event Alert will be mailed to the organization chief executive officers and Joint Commission survey coordinators, however, it is expected that eventually Sentinel Event Alert will be sent via broadcast fax. In the future, staff from the Joint Commission will be contacting your organization to collect appropriate fax and E-mail addresses.

While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple -- organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function' -- a procedure that makes a certain type of error impossible."

Lucian L. Leape, M.D. Harvard School of Public Health

Medication Error Prevention -- Potassium Chloride

In the two years since the Joint Commission enacted its Sentinel Event Policy, the Accreditation Committee of the Board of Commissioners has reviewed more than 200 sentinel events. The most common category of sentinel events was medication errors, and of those, the most frequently implicated drug was potassium chloride (KCl). The Joint Commission has reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the result of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

Issue For Consideration

In light of this experience, the Joint Commission suggests that health care organizations NOT make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. That is why potassium chloride concentrate vials can still be found in patient care areas."

Michael Cohen, MS, FASHP, President, Institute for Safe Medication Practices

PHARMACY PRACTICE

Medication Safety Alerts

David U and Sylvia Hyland

This column draws on US and Canadian experience and may include, with permission, material from the *ISMP Medication Safety Alert!*, a biweekly bulletin published by the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pennsylvania.

PHARMACISTS' ROLE IN PREVENTING MEDICATION ERRORS WITH POTASSIUM CHLORIDE

A recently announced coroner's inquest will review the case of Frances Marie Tanner, who died in an Ontario hospital on January 21, 2002, as a result of accidental injection of concentrated potassium chloride. As health care professionals, we are spurred to action to take steps to prevent future tragedies of this nature. On the basis of previous documentation of cases of error-induced injury with potassium chloride and the resultant recommendations,[1-5] we can anticipate the system remedies that will be highlighted in the upcoming inquest. There is thus no need to await the outcome of the inquest — we can start to implement more safeguards in our medication-use systems today, to prevent mishaps with potassium chloride.

Successful implementation of system changes to prevent error-induced injury with potassium chloride entails multidisciplinary commitment. Pharmacists are in a position to lead the way, and, if initiatives are already in place in a hospital, they are in a position to move these measures forward, to ensure implementation to the fullest extent possible. Michael Cohen, a pharmacist in the United States, has long advocated for changes in the manner in which potassium chloride products are stored and dispensed (and manufactured), and his writings provide guidance and direction.[3,4]

ISMP Canada is aware of several Canadian hospitals that have implemented strategies to prevent injury with potassium chloride. These examples of system redesign demonstrate a movement toward a culture of patient safety. We hope that the suggestions below will serve as a useful checklist for system improvements to prevent injury with potassium chloride in your institution.

1. If your hospital has not already done so, pull together a high-level multidisciplinary team that can forward recommendations to the Medical Advisory Committee and help move hospital-wide patient safety initiatives forward promptly. Representatives from the Pharmacy and Therapeutics Committee, the Risk Management Department, the Quality Department, and the patient care teams are suggested starting points for identifying team members. The team should develop a mandate to reduce the error potential of potassium chloride, define an implementation strategy (including timelines), and provide regular updates to the hospital board's Quality Committee, outlining progress toward preventing tragic accidents with concentrated potassium chloride.
2. Recommend that each patient care unit, program, department, and clinic undertake a specific multidisciplinary review (by physicians, nurses, and pharmacists) with the following aims:
   (a) Identify if potassium chloride concentrate is ever available in the respective patient care area and, if so, under what circumstances.
   (b) Identify any barriers to the complete removal of potassium chloride concentrate from the patient care area. If no barriers exist, remove all potassium chloride concentrate from the patient care area. Storage of potassium chloride concentrate in patient care areas, automated dispensing units, and emergency (crash) carts should be discouraged.

(c) Ensure that standardized premixed IV solutions incorporating potassium chloride are available in adequate quantities in the medication rooms.
(d) Ensure that prescribing practices are standardized to match the available premixed solutions containing potassium chloride.

3. Recommend that the Pharmacy and Therapeutics Committee develop clear guidelines for the use of potassium chloride. Such guidelines should address the use of oral potassium instead of IV potassium for the treatment of hypokalemia whenever clinically feasible; the prescribing of standardized solutions containing potassium chloride; the clear definition of the maximum concentration of potassium chloride allowable in an IV solution; the recommended maximum hourly and daily limits of potassium chloride that a patient may receive; and infusion rate, infusion pump requirements, and patient monitoring.
4. Once the guidelines describing safe administration of potassium chloride are approved, ensure that they are readily available and accessible in all patient care areas.
5. Consider removing the 20 mEq/10 mL size of potassium chloride concentrate from the hospital drug inventory. The 40 mEq/20 mL size concentrate has a different "look and feel" from other products, such as 10 mL sterile water and 10 mL sodium chloride, which have so often been confused with potassium chloride. This measure can help staff to differentiate between these products.
6. Consider adding an auxiliary fluorescent warning label to the potassium chloride concentrate product, which would read as follows:

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

Ideally, the label would be added at the time of receipt of the drug into inventory, before it is placed on the shelf in the pharmacy.

7. If your hospital is purchasing premixed minibags containing potassium chloride, consider adding an auxiliary warning label to these products as well. The warning label on the minibag products should provide instructions as to the recommended route of administration (e.g., "central line only") and the recommended duration of infusion (e.g., "Infuse over at least 1 hour"). Minibag products containing potassium chloride should be dispensed and controlled by the pharmacy department rather than through a stores or central supply department, to help prevent confusion with other minibag products.
8. Advocate for pharmacist intervention whenever a nonstandard order for an IV solution with potassium chloride is prescribed. Intervening on all nonstandard orders can be an opportunity to educate physicians and nurses about system improvements for patient safety and will help to engender a culture of safety. Several hospitals have implemented automatic substitution policies for nonstandard orders. Other hospitals have opted for direct communication as the method of order intervention. Prescribing practices must take into consideration the premixed IV solutions containing potassium chloride that are available.
9. Orders such as "KCl 40 mEq IV now" or "give KCl 20 mEq IV bolus" should be considered incomplete and unacceptable. Orders without instructions for dilution and infusion rate should not be accepted. The word "bolus" should never be used for IV potassium chloride solution orders. These are examples of opportunities to educate about prescribing with safety in mind.
10. Advocate having the pharmacy prepare any nonstandard solutions that are deemed necessary but are unavailable commercially in a premixed format. This measure would include reviewing dialysis solutions requiring the addition of potassium chloride.
11. Evaluate practices for storing potassium chloride in the pharmacy. Choose a designated area for storage of this drug to reduce the likelihood of substitution errors.
12. Recommend that the issue of potassium chloride injury and preventive system safeguards be included as an item for discussion during orientation programs for nurses, physicians, and pharmacists. The video *Beyond Blame*, which can be obtained through Bridge Medical (http://www.mederrors.com), can be a powerful communication tool for effecting system improvements.

The suggestions listed above emphasize the shared responsibility of multidisciplinary professionals to ensure the safe storage and use of potassium chloride. Pharmacists are in a position to identify the system weaknesses that could result in patient injury, and they have a key role in the development of potassium chloride error-prevention strategies. Pharmacists have the knowledge, the experience, and, in most Canadian hospitals, the influence to ensure that medication safety initiatives are defined and implemented. Although many

pharmacists are aware of the concerns and risks related to potassium chloride products, leadership and action are needed to ensure that the necessary changes are made. We are confident that many pharmacists are willing to take up this challenge and are determined to make safe medication practices a high priority when providing pharmaceutical care to Canadian patients.

To accomplish all of the suggested strategies for system improvements, some changes in pharmacy services, and a review of priorities and resources, may be necessary. Additional resources may be required for strategies such as in-house preparation of selected potassium chloride solutions and possibly a 24-hour on-call service for unexpected situations. The purchase of commercially available premixed solutions containing potassium chloride may have cost implications. Ultimately, specific persons or groups must take responsibility and be accountable for the decisions required to prevent accidents with potassium chloride, as well as for decisions to weigh the risks and benefits if potassium chloride concentrate remains accessible in patient care areas. Senior management must be advised of the risks associated with potassium chloride concentrate, the financial considerations associated with improving safety, and the potential impact of not implementing system improvements.

Pharmacists are encouraged to inform the manufacturer when look-alike and sound-alike product packaging and labelling problems are identified. Manufacturers are not always aware of front-line experiences with their products, and educating manufacturers about product problems will help to improve our health care system.

Finally, pharmacists, in conjunction with the hospital's Product Evaluation and Pharmacy and Therapeutics Committees, must invest time in performing failure mode and effects analysis (FMEA) on existing potassium chloride products, as well as for other products considered for purchase in the future. The concept of FMEA was first introduced in the engineering literature in the early 1960s, and it is now recognized as a good method to proactively identify the risks and potential patient injuries associated with existing or new pharmaceutical products. The following questions are asked in this type of analysis: What could fail and how? Given the various possibilities for failure, what are the potential consequences of each? More information about FMEA and how it relates to medication safety can be found in the textbook *Medication Errors*.[7] In addition, ISMP Canada recently published a Safety Bulletin entitled "How to use 'failure mode and effects analysis' to prevent error-induced injury with potassium chloride."[8] The bulletin briefly describes reports of sentinel events and near-miss incidents with potassium chloride that have been reported to ISMP Canada during the past 2 years. A copy of this bulletin can be obtained by request to info@ismp-canada.org.

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The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

Volume 3, Issue 11

ISMP Canada Safety Bulletin

November, 2003

More on Potassium Chloride

In this issue:

- ISMP Canada shares the results of an Ontario potassium chloride project carried out in conjunction with the Ontario Hospital Association and the Ontario Ministry of Health and Long-Term Care. The success of the project can be attributed directly to the initiatives undertaken by Ontario hospitals and to the support of an Advisory Group representative of key stakeholders.
- ISMP Canada and AstraZeneca Canada Inc. worked together to re-design the packaging and labelling of AstraZeneca's 10 mL size of concentrated potassium chloride for injection, within the limitations of manufacturing equipment. The changes are briefly described in this bulletin.
- Two unique errors involving potassium chloride oral liquid, as reported to ISMP Canada, are discussed.

Potassium Chloride Project in Ontario

The deaths of two Ontario patients that were related to the accidental injection of concentrated potassium chloride (KCl) prompted the Ontario Ministry of Health and Long-Term Care (MoHLTC), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Ontario Hospital Association (OHA) to take action designed to prevent a repeat tragedy. That action took the form of the establishment of the Medication Safety Support Service. The first project of the Medication Safety Support Service was to assist Ontario hospitals in implementing safeguards to prevent further incidents with concentrated KCl. The project provided suggested interventions and guidance to hospitals for the removal of concentrated KCl from patient care areas, thereby reducing the potential for inadvertent administration and subsequent patient harm from concentrated KCl.

The project began with a pre-intervention survey distributed to Ontario hospitals in November, 2002. The results identified that 62% of Ontario hospital respondents stored concentrated KCl in patient care areas. Next, a resource kit, prepared by ISMP Canada, was made available to all Ontario hospitals. The resource kit includes safe medication practice recommendations pertaining to the prescribing, distribution, storage and preparation of KCl solutions in hospitals. Hospitals were also communicated with directly, at conferences, through the North Network and via an interactive website.

In July, 2003, Ontario hospitals were re-surveyed. The respondents' results indicated that between November, 2002 and June, 2003:

- The number of Ontario hospitals storing concentrated KCl in patient care areas decreased from 62% to 26%.
- The number of Ontario hospitals storing concentrated KCl in Emergency Departments decreased from 65% to 35%.
- The number of Ontario hospitals storing concentrated KCl in Intensive Care Units decreased from 50% to 35%.
- 71% of hospitals indicated that they had made changes to KCl distribution in the 6-month period (i.e., during the time of the project).
- 63% of hospitals planned to make changes in the near future.
- 63% of hospitals had used the resources of the Medication Safety Support Service.

ISMP Canada continues to receive communication from Ontario hospitals regarding ongoing system enhancements being made. It is ISMP Canada's goal to provide similar services to hospitals in other provinces.

Upcoming Changes to Packaging and Labelling by AstraZeneca Canada

As part of patient safety enhancement strategies, ISMP Canada has worked with AstraZeneca Canada Inc. to make changes to the packaging and labelling of their 10 mL size of concentrated potassium chloride for injection. The new product packaging and labelling have been deliberately designed to reduce the potential for substitution errors with sodium chloride for injection and sterile water for injection (also provided by AstraZeneca). The new 10 mL concentrated potassium chloride product will be available to Canadian hospitals by mid-2004 or earlier. ISMP Canada acknowledges and commends AstraZeneca's initiative in re-designing a product for enhanced patient safety.

Two Error Reports Involving Potassium Chloride Oral Liquid:

Error Description One: A nurse received an order for KCl 20 mEq/L in Ringer's Lactate to be administered at 100 mL/h. The nurse found only the KCl 40 mEq/L bags of Ringer's Lactate available on the nursing unit. She then went to the automated dispensing cabinet for 'potassium chloride'. Since the order had not yet been profiled by Pharmacy, and since an

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override was allowed, the nurse was able to obtain "K-10 20MEQ/15ML LIQ". The nurse removed the potassium chloride oral solution 20 mEq/15 mL (pre-packaged in a 50 mL amber bottle by Pharmacy and sealed with a cellulose seal). The nurse then proceeded to withdraw 15 mL of the oral potassium chloride liquid using a needle and syringe and injected the volume into a one-litre Ringer's Lactate IV bag. Approximately one hour later, a second nurse noticed that the IV had an unusual yellow colour and stopped the infusion. No serious harm to the patient was reported.

Recommendations:

- Ensure widespread education (during implementation and ongoing orientation sessions) about system changes, such as the removal of the concentrated KCl for injection product, so that all nurses know that IV solutions with potassium chloride are either available pre-mixed or must be prepared by Pharmacy.
- Ensure that Pharmacy labels on repackaged products highlight and emphasize important information such as "for oral use". Consider an auxiliary label **"For ORAL USE only".**
- Review the screens of automated dispensing cabinets to ensure that important information such as 'for oral use only' is easily identifiable by the nurse obtaining the medication.
- Review the automated dispensing cabinet 'override' list on a regular basis with an interdisciplinary team, such as a Safe Medication Practices Committee.
- Avoid repackaging oral liquids in 'stock bottles'. Where possible, prepare unit dosed oral liquids.

Error Description Two: An infant requiring short-term ventilation and sedation was admitted to a Neonatal Intensive Care Unit. Chloral hydrate oral liquid 70 mg was ordered for administration on an "as needed" basis. Pharmacy inadvertently prepared and dispensed potassium chloride oral liquid instead. A dose of 0.93 mmol of KCl might have been administered to the patient. The hospital, in investigating and analyzing the incident, identified that the two stock bottles of liquid preparation (chloral hydrate and potassium chloride) appear very similar. Both products, as manufactured by Pharmascience, are illustrated in the photograph in Figure 1.

Figure 1. Chloral Hydrate *vs* Potassium Chloride

Recommendations:

- In order to prevent a similar mix-up, consider purchasing one of the products from an alternate supplier. This will prevent the two products from having a similar appearance.
- Apply auxiliary labels on products that have similar labelling and packaging to warn of a potential mix-up. Use TALL-MAN lettering on these labels, e.g., POTASSIUM chloride and chloral HYDRATE.

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To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org or (ii) email us at info@ismp-canada.org or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent Canadian non-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

Volume 4, Issue 3

ISMP Canada Safety Bulletin

March, 2004

Concentrated Potassium Chloride: A Recurring Danger

ISMP Canada has worked with hospitals across Ontario and other hospitals in other provinces to identify and implement strategies to promote the safe use of potassium chloride (KCl). A key example safeguard is the removal of concentrated KCl from all patient care areas. Even if hospitals have removed stock of this dangerous drug from their nursing units they must remain vigilant and not let their guard down. We have received reports of sentinel events involving other situations where potassium is used. These include inadvertent injection of other potassium salts (acetate, phosphate); wrong rates of infusion; and the use of potassium chloride as an incorrect additive.

ISMP Canada has recently learned of an adverse drug event resulting from the inadvertent addition of potassium chloride to a renal dialysis fluid for Continuous Renal Replacement Therapy (CRRT). The hospital has shared information about this case recognizing that a similar error could occur in other hospitals:

- A pharmacy technician, in the process of setting up a batch preparation of dialysis solution, picked up a carton of 12 x 250 mL Concentrated Potassium Chloride 2 mmol/mL bottles, instead of a carton of 12 x 250 mL bottles of 23.4 % Sodium Chloride (NaCl) for Injection. Since 85 mL of sodium chloride solution was needed for each 3-litre dialysis solution, and because one batch preparation was 35 bags, an entire carton of 12 bottles of 250 mL of NaCl solution was required. The cartons of stock potassium chloride solutions were located near the sodium chloride solutions.
- The selected items for dialysis preparation were checked against the manufacturing or ingredient worksheet by a second pharmacy technician in the preparation area. The second technician did not notice that the carton was the wrong one.
- During the manufacturing process, 85 mL of potassium chloride 2 mmol/mL were added to the 3-litre bags of dialysis solution.
- A third technician later checked the completed batch of dialysis solutions. Again, the incorrect ingredient went unnoticed.

Each of the 3-litre solutions contained a total of 170 mmol potassium chloride. This amount given over a short period of time, such as 3 hours, is lethal. When one of the renal dialysis patients died suddenly, the physician identified a serum potassium of almost 8 mmol/L. An immediate laboratory test carried out on the dialysis solution revealed the error. The hospital then recalled the remaining bags of dialysis solution. Officials reviewed the charts of all other patients who had received continuous dialysis since the batch had been produced. It was determined that a second patient was probably exposed to this same batch and had died as a result of hyperkalemia. Five of the dialysis bags had been utilized for two patients and the other 30 bags were successfully retrieved from the patient care area.

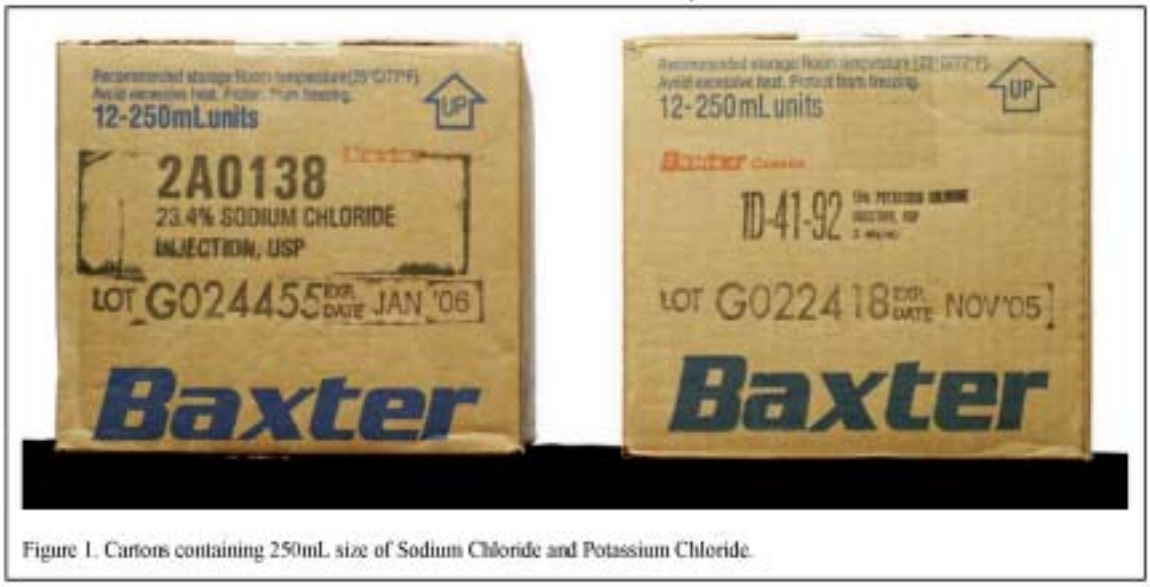

Figure 1. Cartons containing 250mL size of Sodium Chloride and Potassium Chloride.

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Figure 2. Bottles of Sodium Chloride and Potassium Chloride, by Baxter.

The hospital is undertaking an in-depth incident review of this tragic event. Interim findings have identified a number of contributing factors: (1) The cartons containing the 250 mL size bottles are similar in appearance. (2) The drug name text (critical information) on the carton has significantly smaller font size than both the product identification number and the manufacturer logo (Figure 1). (3) The glass bottles are identical in shape and size (Figure 2). (4) The cardboard box cartons were stored in close proximity to each other in the pharmacy storage area.

The hospital has instituted a number of immediate steps to safeguard against a similar error.

- The concentrated potassium chloride solutions have been moved to a completely separate and secured area.
- The sodium chloride solution is now purchased from a different vendor to avoid packaging similarities and thus help to better differentiate between the potassium and sodium products.
- A full review of the preparation and checking processes and workflow are being undertaken.

ISMP Canada has previously recommended the use of visible auxiliary labels and separate storage location of concentrated potassium chloride.[1] Hospitals may also wish to explore the use of commercially available dialysis solutions. The Hospital Medication Safety Self-Assessment™ (available from ISMP Canada) is also recommended as a reference tool for evaluating and implementing medication system safeguards.

There has been a movement in some Canadian hospitals toward a "tech-check-tech" approach, where pharmacy technicians are responsible for checking the work performed by other technicians. This trend has been accelerated by the shortage of pharmacists and the concurrent demand for direct patient care pharmacy services. However, in order to delegate duties and responsibilities, it is important that protocols and supports be in place to ensure that processes are carried out accurately and safely. Pharmacy regulatory authorities need to work with professional organizations to better define the scope and standards of pharmacy technician practice in hospitals. ISMP Canada recommends that a pharmacist oversee the operations and be readily available to technicians.

Regardless of the type of personnel involved, it is crucial that a safety infrastructure be established. This should include appropriate policies and procedures, adequate staff training, competency validation and regular recertification. Particular attention should be paid to policies, procedures and ongoing staff training required for high alert drugs.[2] The training should include information about such drugs, how they can be hazardous, and the rationale for the safeguards.

ISMP Canada emphasizes the need for "***independent check processes***"[3] in the preparation of batched products. Designing workflow to ensure that the checks are truly independent of each other is an ongoing challenge and a critical endeavour for all healthcare practitioners.

This incident brings to attention the benefits of bar coding. Ironically, in the year of 2004, grocery and sporting goods stores have implemented bar coding technology, but healthcare continues to function without it. Healthcare practitioners, administrators, manufacturers and regulatory authorities must move bar coding technology forward as a priority for implementation.

ISMP Canada has met with Baxter Corporation (Canada) to address the concern and discuss possible changes to the bottle label and carton of the concentrated potassium chloride product. Health Canada has also been informed of this important issue.

ISMP Canada acknowledges and is grateful to the hospital that provided the information about this event to allow for sharing and learning throughout our community.

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3. The virtues of independent double checks – they really are worth your time! Available at http://www.ismp.org/msaarticles/time.htm. Accessed March 26, 2004.

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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

NHS
National Patient Safety Agency

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.

NHS
National Patient Safety Agency

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.

NHS
National Patient Safety Agency

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.

NHS
National Patient Safety Agency

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

NHS
National Patient Safety Agency

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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Ref: PSA 01

Safety+Quality COUNCIL
www.safetyandquality.org

MEDICATION ALERT!

From the Medication Safety Taskforce of the Australian Council for Safety and Quality in Health Care

The purpose of this alert is to provide frontline health professionals and administrators with information on high risk medications that have the potential to cause serious or catastrophic harm to patients. The intention is to raise awareness of the potential harm and provide a strategy for local level response.

Alert 1, October 2003

Intravenous POTASSIUM CHLORIDE can be fatal if given inappropriately

For the attention of *Chief Executive Officers* and *Directors of Nursing*, *Pharmacy*, and *Medical Services*; *Doctors*, *Nurses* and *Pharmacists*

For implementation immediately

Wrong ampoule (Australia)

A patient indicated that the cannula site in her hand was becoming painful. An ampoule of normal saline was selected from the medication cupboard in order to flush the cannula site. The patient quickly became distressed and stopped breathing within a few minutes. The ampoule that was thought to be normal saline was actually potassium chloride. The patient could not be resuscitated.[1]

Preparation error (Australia)

Two ampoules each containing 10 millimoles of potassium chloride were added directly to a running large-volume parenteral fluid without mixing. The patient received a bolus dose of potassium chloride and had a cardiac arrest.[2]

Overseas Experience

The risks associated with intravenous potassium chloride are well known. It has been identified as the drug most commonly implicated in fatal incidents in acute care facilities. This alert is based on similar recommendations from the UK[3], USA[4] & Canada[5].

Tools and Tips

Tools to action this alert can be found on the Council website at www.safetyandquality.org

Critical incidents have been associated with the preparation and administration of intravenous (IV) potassium chloride indicating that patients are at risk. **Ampoules of potassium chloride must be diluted before use.**

Three types of error have been identified routinely[6]

- **Wrong ampoule**
  Potassium chloride ampoules are mistaken for ampoules of similar appearance, such as sodium chloride 0.9% (normal saline) when reconstituting a drug for injection. Consequently, the patient is administered an accidental overdose of potassium.
- **Cognitive mix-up**
  The intent is to select frusemide (a diuretic), but a potassium chloride ampoule is selected by mistake and administered. This type of cognitive error is thought to arise due to the frequent use of potassium chloride in patients who are taking frusemide, conditioning staff to the familiar pairing of the two drugs.
- **Preparation error**
  An intravenous infusion of potassium chloride is prepared incorrectly.

Errors have a single common cause

Incidents have a common root cause—potassium chloride ampoules are available as medication stock in wards and other patient care areas.

Recommendations

1. **REMOVE AMPOULES OF POTASSIUM CHLORIDE FROM WARD STOCK AND REPLACE WITH PREMIXED SOLUTIONS.**
   Due to the risk associated with intravenous potassium chloride, ampoules of potassium chloride SHOULD NOT be kept as a stock item in wards.
2. In critical areas where high concentrations and doses of potassium chloride are necessary, do a risk assessment to determine whether it is appropriate to keep the ampoules as a stock item and develop a protocol for safe preparation and use.
3. Assess the storage of potassium chloride ampoules and premixed solutions to ensure they are stored separately and are readily identifiable from preparations with similar packaging.

The recommendations also apply to ampoules of potassium phosphate or other concentrated potassium salts.

ACTION

Successful implementation of the actions below requires the commitment of personnel from all clinical areas.

Many acute care facilities have already implemented safety controls for IV potassium chloride in their institution—it is recommended that all facilities evaluate their current safety controls for IV potassium chloride against the actions recommended below.

CHIEF EXECUTIVE OFFICERS

1. Form and resource a multidisciplinary team to action the recommendations in this alert, and review and evaluate progress (see review and evaluation below). Team members would include representatives from the Drug and Therapeutics Committee, the Risk Management Department or Quality Department, and patient care teams.

2. The team should be given a mandate to reduce the error potential of potassium chloride and define an implementation strategy (including timelines). The team should provide regular updates to the CEO and/or the appropriate hospital committee outlining progress toward preventing incidents with intravenous potassium chloride.

DRUG AND THERAPEUTICS COMMITTEES

3. Develop clear therapeutic guidelines for the use of potassium chloride. Sample guidelines are available on the S&Q Council website. Guidelines should include the following points:

   3.1 Oral, instead of IV potassium chloride should be used for the treatment of hypokalemia whenever clinically feasible.

   3.2 Prescribing of all IV potassium chloride should be in millimoles (mmol).

   3.3 Prescribing and use of standardised premixed solutions containing potassium chloride should be encouraged.

   3.4 Provide a clear definition of the maximum concentration of potassium chloride allowable in an IV solution.

   3.5 Specify the maximum hourly rate and daily limits of potassium chloride that a patient may receive (by central or peripheral lines); and recommended infusion rate, infusion pump requirements, and patient monitoring.

4. Once the guidelines describing safe administration of potassium chloride are approved, ensure that they are readily available and accessible in all wards. Review regularly. Consider developing summary charts of key messages for ready reference; see the S&Q Council website for examples.

5. Review the concentrations of potassium chloride ampoules and premixed solutions available hospital-wide. Consider rationalising the range of concentrations (eg only stock the '10 mmol in 10 mL' ampoules).

DIRECTORS OF MEDICAL SERVICES, PHARMACY AND NURSING

Where commercially prepared premixed potassium chloride infusions are available, these products should be procured and introduced, and IV potassium chloride ampoules withdrawn from use. Where this is not feasible, safe on-site preparation and administration protocols should be developed.

6. Undertake a specific multidisciplinary review (by doctors, nurses, and pharmacists) in each ward, department, and clinic with the following aims.

   6.1 Identify if potassium chloride ampoules are available. Identify any barriers to the removal of the ampoules. If no barriers exist, remove all potassium chloride ampoules from the area and replace with premixed solutions. In critical areas where potassium chloride ampoules are to be retained, a risk management policy should be developed and staff education on strategies to minimise risk should be undertaken.

   6.2 Ensure that appropriate concentrations of premixed IV solutions are available in adequate quantities in wards.

   6.3 Ensure prescribing practices are standardised to match the available premixed solutions.

PHARMACISTS

7. Evaluate practices for storing IV potassium chloride preparations in the pharmacy and on wards to reduce the likelihood of substitution errors.

8. Assess the range of premixed potassium chloride solutions available and ensure adequate supply for each area.

9. *Where facilities and staff are available*, have the pharmacy aseptic dispensing service prepare premixed potassium chloride products that are not available commercially. Otherwise, follow the protocol for safe on-site preparation.

DOCUMENTOS DE INTERÉS

NURSES

10. Prescriptions with directions such as "KCl 20 mmol IV now" or "give KCl 10 mmol IV bolus" should be considered incomplete and unacceptable. Orders without instructions for dilution and infusion rate should not be accepted. The word "bolus" should never be used for IV potassium chloride solution orders.
11. Consider instituting a double-check policy for administration of IV potassium chloride—have two practitioners check the correct product, dose, dilution, labelling, route and rate before administration, as per the safe on-site preparation protocol.
12. Consider adding auxiliary fluorescent warning labels to IV potassium chloride preparations.
13. Question any nonstandard order for an IV solution with potassium chloride.
14. *Where facilities and staff are available*, advocate having the pharmacy prepare any nonstandard solutions that are deemed necessary but are unavailable in a premixed form.
15. When the above options are not available, keep potassium chloride ampoules on the ward in a medicine cupboard (preferably locked) and store separately from other ampoules with similar appearance.

DOCTORS

16. Standardise prescribing of IV potassium chloride—prescribe in millimoles rather than 'milligrams per litre' or 'percent'.
17. Ensure orders for IV potassium chloride have rate, route, dilution and administration instructions fully specified.
18. Prescribe premixed (standard concentration) potassium chloride infusions where possible.

TRAINING

19. Include the issue of potassium chloride injury and preventive system safeguards as an item for discussion during orientation programs for nurses, doctors, and pharmacists, and as part of continuing education training.

REVIEW AND EVALUATION AT FACILITY LEVEL

Resources must be made available to evaluate progress at an appropriate time, eg after 6 months. For example:

- *Are premixed solutions being used?* Audit the distribution of potassium chloride ampoules & premixed solutions pre and post system change.
- *Are doctors prescribing, and nurses administering premixed solutions? If not, why not?* Communicate with staff.
- *Are doctors prescribing in millimoles? Are orders complete?* Evaluate prescribing.
- *Are 'near miss' incidents relating to IV potassium chloride reported and assessed?* Communicate with staff.
- *Are ampoules or premixed solutions being transferred between clinical areas?* Assess protocols.
- *Which areas have retained potassium chloride ampoules, and why?* Assess safety controls in these areas.
- *To what extent are non-standard IV potassium solutions (ie solutions not available as commercially prepared premixes) being used? How and where are they prepared?* Assess the range of products available.
- Have regular meetings and monitor progress. Survey staff regarding knowledge of policies and guidelines.
- Comment on this alert system, your experience in implementation and share your knowledge and tools via the feedback form on the S&Q Council website.

FURTHER INFORMATION

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The Australian Council for Safety and Quality in Health Care thanks the following organisations and government agencies for their input and/or dissemination of this alert notice: ACHSE, ADRAC, ADSA, AHA, AIMS, AMA, ANF, APHA, CHA, CHF, Commonwealth DoHA, HPCA, Medicines Australia, MUNCCI, NPS, NSWTAG, NTD&TC, PGA, PHIQS, PSA, QHDAC, RACMA, RACP, RACS, RCNA, SATAG, SHPA, S&Q State and Territory Quality Officials Forum, TSTDC, VicTAG, WADTC.

4.2. PROTOCOLOS Y DIRECTRICES DE ALGUNOS HOSPITALES

Hospital Costa del Sol
CONSEJERÍA DE SALUD

Procedimiento de Manejo de Potasio Intravenoso

Fecha: 20 de Octubre de 2008

PROCEDIMIENTO ESPECÍFICO

PROTOCOLO DE MANEJO DE POTASIO INTRAVENOSO

Elaborado por:	Revisado por:	Aprobado por:
Vicente Faus. DAIG Farmacia	Comisión de Farmacia y Terapéutica	Comisión de Farmacia y Terapéutica
Fecha 20/10/2008	Fecha 3/12/2008	Fecha 3/12/2008

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Utilizado con permiso del Hospital Costa del Sol

Hospital Costa del Sol
CONSEJERÍA DE SALUD

Procedimiento de Manejo de Potasio Intravenoso

Fecha: 20 de Octubre de 2008

1. OBJETIVO.

La administración de potasio por vía intravenosa, en forma de cualquiera de sus sales, tiene un efecto directo sobre la contractilidad cardiaca. La administración de soluciones concentradas (viales ó ampollas sin diluir) puede producir flebitis, arritmias e incluso la muerte. Se han comunicado errores de medicación consecuencias fatales asociados a una utilización inadecuada. Diversos organismos internacionales, entre ellos JCI, obligan entre otras medidas, a eliminar de la unidad de hospitalización la presencia de estos medicamentos para evitar su administración intravenosa directa por error. La preparación centralizada en farmacia supone por, otra parte, un complicado proceso logístico de que debe articularse y complementarse con una serie de medidas.

Objetivo del procedimiento

El objetivo del proceso de manejo del potasio intravenoso es garantizar la seguridad en la utilización del fármaco dentro del centro.

Intención del objetivo

La administración de soluciones concentradas de potasio intravenoso puede producir la muerte. Este fármaco es uno de los más utilizados en el centro, principalmente como componente en la fluidoterapia de mantenimiento. El procedimiento trata de evitar errores de medicación que no solo se refieran a la confusión entre la cantidad prescrita y la administrada sino también: confusión entre pacientes, confusión con otro fármaco o diluyente para reconstituir fármacos, confusión con cloruro sódico para salinizar vías venosas ó cualquier otra circunstancia que pueda derivar en la administración parenteral del mismo.

2. ALCANCE.

A) Todos los centros hospitalarios dependientes de la Empresa Pública Hospital Costa del Sol.

B) Todos los profesionales sanitarios con responsabilidad asistencial que tienen contacto directo y asistencial en algún momento con pacientes.

C) Está fuera del alcance de este procedimiento el manejo del cloruro potásico que figura como aditivo en las nutriciones parenterales, el utilizado para los circuitos de las máquinas de diálisis ó la utilización de suplementos de potasio oral o en la dieta.

3. TÉRMINOS y DEFINICIONES.

Potasio concentrado: es cualquier envase comercializado de ClK con concentración igual ó superior a 1 mEq/ml. Incluye todos los envases en ampollas o viales de Cloruro Potásico, Acetato Potásico y Fosfato potásico, pero no las bolsas de fluidoterapia que incluyen potasio como componente.

Mezcla intravenosa (MIV): es un preparado para uso intravenoso compuesto de un diluyente (normalmente un fluido intravenoso que aporta el volumen para la dilución) y un componente o fármaco activo (en este caso, un electrolito)

Mezcla normalizada: es cualquier mezcla definida en el protocolo para su utilización en una unidad de hospitalización concreta, que dispone de una concentración y diluyente constante. Las mezclas normalizadas son las siguientes:

S.Glucosalino 500 ml + 10 mEq ClK
S.Glucosalino 500 ml + 20 mEq ClK
S.Glucosalino 500 ml + 30 mEq ClK
S.Glucosalino 500 ml + 40 mEq ClK

S.Fisiológico 500 ml + 10 mEq ClK
S.Fisiológico 500 ml + 20 mEq ClK
S.Fisiológico 500 ml + 30 mEq ClK
S.Fisiológico 500 ml + 40 mEq ClK

S.Glucosado 5% 500 ml + 10 mEq ClK
S.Glucosado 5% 500 ml + 20 mEq ClK
S.Glucosado 5% 500 ml + 30 mEq ClK
S.Glucosado 5% 500 ml + 40 mEq ClK

En pediatría las soluciones normalizadas son las siguientes:

Soluciones de para fluidoterapia de mantenimiento:

S. Glucosalino 1/5 500 ml + 10 mEq ClK

Soluciones utilizadas para tratamiento de debut diabético:

S. Salino hipotónioco 500 ml + 20 mEq ClK
S. Glucosado 5% 500 ml + Cloruro Sódico 20% 12 ml + 20 mEq ClK
S. Glucosado 5% 500 ml + Glucosmon R50 25 ml + Cloruro Sódico 20% 12 ml + 20 mEq ClK
S. Glucosado 10% 500 ml + Cloruro Sódico 20% 12 ml + 20 mEq ClK

En UCI se dispondrá, además de;

S.Fisiológico 100 ml + 20 mEq ClK
(Esta MIV dispone de un procedimiento específico de administración)

4. RESPONSABILIDADES.

- Serán responsables de la aplicación de este procedimiento, todos los profesionales sanitarios médicos, farmacéuticos, enfermeros, auxiliares de clínica y técnicos en farmacia, con responsabilidad asistencial sobre pacientes.
- Será responsable de hacer cumplir este procedimiento la Dirección del Centro.

5. DESCRIPCIÓN.

Selección: Guía Farmacoterapéutica.

El Hospital Costa del Sol dispondrá en el centro de las siguientes especialidades con contenido en potasio de uso intravenoso:

Nomenc.	Denominación	Concentración	Presentaciones disponibles
ClK	Cloruro Potásico	2 mEq/ml	viales 40 mEq, amp 10 mEq
PO_4K_2H	Fosfato dipotásico	2 mEq/ml	amp 10 mEq
Ac K	Acetato Potásico	1 mEq/ml	amp 10 mEq

El acetato potásico sólo se permite como aditivo para la adición a nutriciones parenterales preparadas en farmacia.

Disponibilidad y almacenamiento.

La presencia y utilización de envases concentrados de *potasio parenteral* en las unidades de hospitalización del centro, está prohibida. En las unidades sin dosis unitarias, donde se precise disponer de éstos en stock, se encontrarán diluidos en forma de **mezclas normalizadas;** en las situaciones donde la prescripción médica no se ajuste a la concentración normalizada disponible en la unidad de hospitalización se resolverán enviando a farmacia la prescripción médica para su preparación individualizada (**mezclas individualizadas**).

Se exceptúan a dicho procedimiento las unidades de hospitalización de UCI (Marbella) y Urgencias del H.A.R. de Benalmádena, que dispondrán **dentro del dispensador automatizado** de un pequeño stock de ampollas de 10 mEq de cloruro potásico. Estas ampollas podrán ser utilizadas sólo cuando en una situación de urgencia, no dispongan de una MIV normalizada adecuada. El acceso a esta medicación está limitado con los siguientes criterios:

1. En **UCI**, la dispensación de una ampolla se realizará con un enfermero que ejercerá como testigo, y que validará introduciendo su código en el dispensador automatizado que la utilización se realiza de acuerdo a lo descrito en este documento, y comprobará los cálculos realizados para la preparación son correctos.

2. En **Urgencias del H.A.R. de Benalmádena**, el acceso al CIK está limitado a un facultativo médico, que entregará al enfermero para su preparación las ampollas y supervisará que el manejo y control sea adecuado.

3. La **preparación de la mezcla debe realizarse de forma inmediata**, y debe ser etiquetada MIV de acuerdo al procedimiento general descrito en este documento.

4. Está prohibido el estocaje fuera del armario dispensador de ningún envase de cloruro potásico.

5. Si el fármaco no es utilizado debe devolverse inmediatamente al dispensador.

Prescripción .

La prescripción de electrolitos en el centro se adecuará a las siguientes recomendaciones:

La prescripción de Cloruro Potásico o Fosfato Potásico **se realizará siempre en miliequivalentes** (mEq) **de potasio**, y nunca en ampollas, viales ó mililitros. Se exceptuarán a esta norma, la prescripción en pediatría, que para mantener la coherencia con el resto de electrolitos de uso en dicha unidad se realizará siempre en mililitros. La prescripción de potasio en una nutrición parenteral seguirá el formulario específico.

En unidades con DOSIS UNITARIAS en ADULTOS la preparación de CIK se realizará siguiendo los siguientes criterios::

- El aporte total diario será siempre múltiplo de 10 mEq.

  Ej: 15 mEq/ 8 h → 45 mEq diarios → se dispensan 40 mEq /día

- la adición de CIK se realizará preferentemente en las mezclas de 1 litro

  Ej: 2500 ml SF + 50 mEq CIK
  → 1000 ml SF + 30 mEq CIK
  → 1000 ml SF + 20 mEq CIK
  → 500 ml SF (sin CIK)

- Se potenciará la fluidoterapia de gran volumen (volumen igual o superior a 1 litro). En pautas de 500 ml alternas se racionalizará el número de envases diarios según los siguientes criterios:

  - similar cantidad de agua libre
  - igual volumen total

Para ello se ha protocolizado un **intercambio terapéutico** que se aplicará de forma automática salvo indicación expresa del médico en la prescripción, para las siguientes pautas alternas:

1500 GS+ 1500 SF (3000 ml volumen; 1000 ml agua libre)
→ 2000 GS + 1000 SF (3000 ml volumen; 1300 ml agua libre)

1500 G5% + 1500 SF (3000 ml volumen; 1500 ml agua libre)
→ 2000 GS + 1000 SF (3000 ml volumen; 1300 ml agua libre)

1500 GS + 1500 G5% (3000 ml volumen; 2500 ml agua libre)
→ 2000 GS + 1000 G5% (3000 ml volumen; 2300 ml agua libre)

En la comprobación de la trascripción médica, el enfermero comprobará la coincidencia entre la cantidad total de ClK adicionado al día, y la composición de la fluidoterapia, de acuerdo a la prescripción ó al anterior protocolo de intercambio.

Preparación

La preparación de las MIV con ClK ó PO_4K_2H se realizará en el área de farmacia por Técnicos especialistas en farmacia, según los procedimientos generales de preparación estéril. La preparación de cualquier MIV con potasio precisará la comprobación de un segundo TEF ó farmacéutico que validará el proceso.

La preparación de mezclas individualizadas se realizará siempre a partir de la prescripción médica ó la etiqueta extraída de la aplicación de dosis unitarias. La preparación de ClK deberá tener especial cuidado de no ser confundida con una prescripción de ClNa, cuya fonética es parecida. Por este motivo, no está permitida la preparación de una orden verbal.

Identificación

Las MIV con electrolitos deben ser identificadas completamente en el etiquetado y en todo momento contendrán la siguiente información:

- Diluyente y volumen
- Fármaco (electrolito) y cantidad

En las mezclas preparadas en farmacia se incluirá también el lote y fecha de caducidad. En MIV individualizadas se añadirán a éstos los datos de identificación del paciente: nombre y apellidos, NHC y cama.

Las MIV de **cloruro potásico normalizadas** se etiquetarán con un código de color distinto en función del contenido total de CLK, para cualquiera que sea el diluyente a emplear:

amarillo: 10 mEq
verde:20 mEq
rojo: 40 mEq

estos códigos de color sólo se utilizarán para mezclas normalizadas; el resto de etiquetas de MIV individualizadas se realizarán sobre papel blanco, aunque su cantidad coincida con alguna de estas concentraciones.

Administración.

La administración de soluciones de potasio intravenosa se realizará conforme a los criterios generales del uso de medicación y, particularmente, de acuerdo a los siguientes parámetros:

- Concentración máxima: 60 mEq/l (puede superarse por vía central)
- Dosis diaria máxima: 100 mEq día. No administrar más sin confirmar con médico prescriptor (puede llegar a 300 mEq/día)
- Velocidad de máxima de administración:
  - Adultos: 15 mEq/h (excepcionalmente en pacientes con $K_{sérico}$<2 mEq/l con complicaciones puede administrarse hasta 40 mEq/h)
  - Pediatría: 0.5 mEq/kg/h. Con monitorización continua puede llegar a 1 mEq/kg/h
- Pacientes con insuficiencia renal: precaución por menor eliminación.

Las mezclas que contengan electrolitos diluidos preparados en el área de farmacia no sufrirán la adición de ningún otro componente en la unidad de hospitalización.

Las **MIV de 20 mEq en 100 ml** ó **cantidades de CIK prescritas superiores a 100 mEq/día** precisarán de los siguientes controles en la primera administración:

- **comprobación previa de la analítica del paciente**. El objeto de este control previo a la administración es garantizar que no exista una confusión en la identificación del paciente, que, de producirse, dejaría al paciente con hipopotasemia sin tratamiento, y administraría una dosis masiva a un paciente con una kaliemia normal o incluso elevada.
- Si la velocidad de administración es superior a 15 mEq/hora, monitorización electrocardiográfica continua durante su administración.

6. INDICADORES.

- % de utilización de MIV individualizadas referidas al total de MIV con potasio preparado
  Fuentes de datos: Base de datos de Dosis Unitarias. Aplicación de Gestión del Área de Farmacia.
  Periodicidad del indicador: anual.

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Trust IV Potassium Policy

Applicable to:	Trust Staff
Date Issued:	November 2005
Principle Author(s):	Stephanie Barnes, Principle Pharmacist
Expiry date/ Review date:	November 2006
Version:	1 (Second Edition)
Updated on:	November 2006

D&T Approved reference: 05103e Approved: October 2005 Review Date: November 2006
Author: S. Barnes

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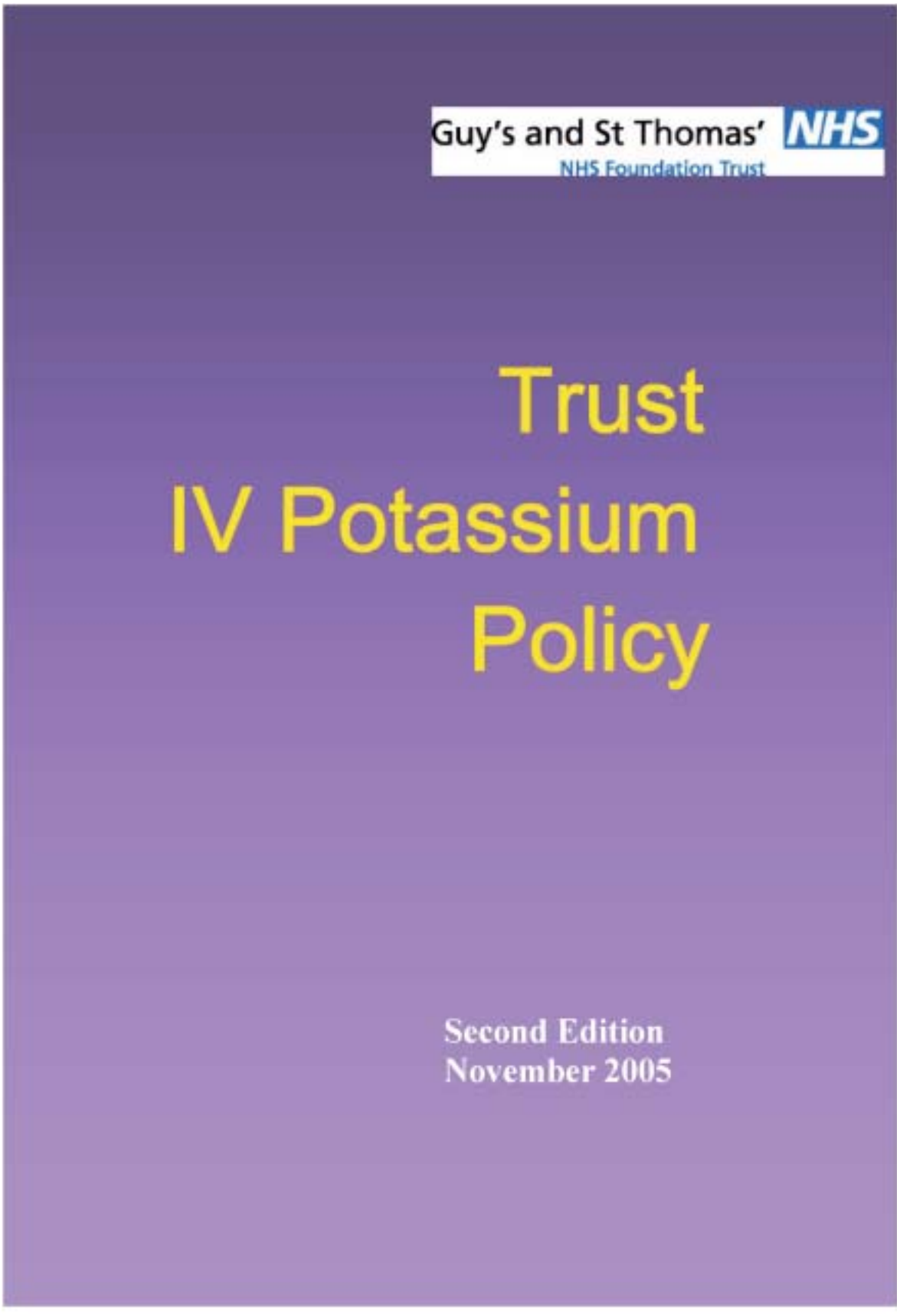
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IV Potassium
Policy
Second Edition
November 2005

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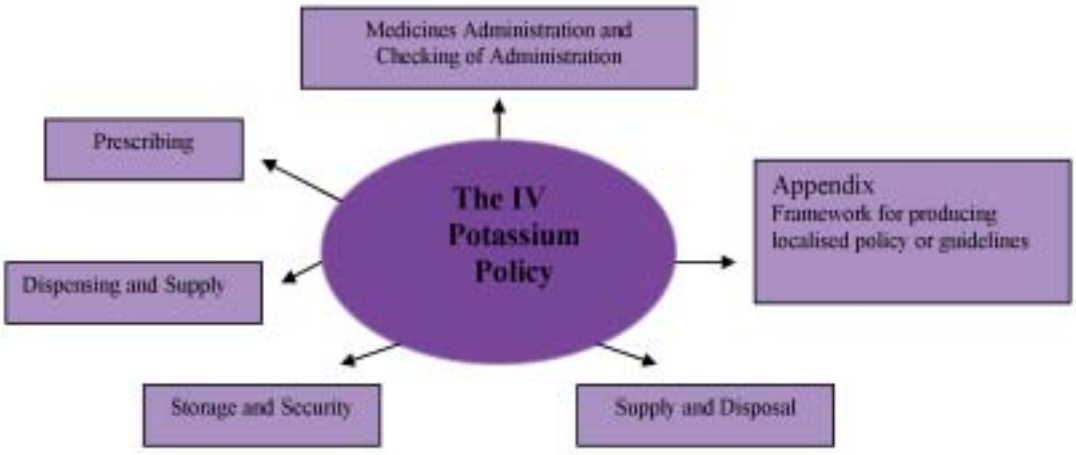
SUMMARY PAGE



Purpose	The IV Potassium Policy lays down the guidelines for managing this medicine within the Trust. It fulfils the National Patients Safety Agency requirements. The aims of the document include: • safeguarding the interests of patients • implementing best practice in administration • provide a framework for producing documented local standard practice and policy A concise leaflet is available as a quick reference guide for members of staff both permanent and temporary. The IV Potassium Policy in also available on the Intranet under Clinical Services/Clinical Policies.
Applies to	All members of staff who deal in any way with potassium products (e.g. prescribing, supplying, administering, ordering and storing).
Consultation Process for Original Policy (2002)	• Pharmaceutical working group • Drug & Therapeutics Committee members • Heads of Service for Anaesthetics, ITU Team leader • Clinical Governance Committee
Professional Groups Involved in Approval	• Trust Clinical Governance and Risk Management Committee • Trust Drug & Therapeutics Committee
Accountable Officer	• Trust Chief Executive
Revised Policy Approved by	• Trust Drug and Therapeutics Committee – 25th October 2005
Implementation date	• November 2005
Policy Review	• Two years – November 2006
Version number	• Second Edition (version 1)

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TRUST POLICY FOR IV POTASSIUM COMPOUNDS

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  - Monitoring
- References
- Monographs
- Appendix (framework for local policy making)

D&T Approved ref: 05103e

Approved date: October 2005
Review date: November 2006

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Foreword

It has been known for over 30 years that strong potassium chloride injections can be inappropriately administered with fatal consequences.

In the NHS alone there have been 33 serious incidences (including 3 deaths) reported to the NPSA due to use of strong intravenous potassium. The Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) in the USA reported ten incidents where patient death occurred as a direct result of misadministration, eight of which were the result of direct infusion of potassium chloride. In six out 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.

The NPSA website (www.npsa.org.uk) has detailed information concerning the risks revealed in both the NHS and North American Hospitals attributable to poor storage leading to misadministration of strong potassium.

In order to secure patient's safety it is important to have safe systems for the prescription, preparation, administration, supply and storage of intravenous potassium.

Following National Patient Safety Agency's alert to the dangers posed by strong potassium compounds in July 2002, all CEO's of NHS and Primary Care Trusts are instructed to implement new clinical good practice throughout all hospital trusts. As a result the National Patient Safety Agency (NPSA) has issued national guidance. This policy applies these national recommendations to the Guy's and St Thomas' Hospital Trust. Compliance with this policy is mandatory.

Edward Baker
Medical Director
Chairman,
Trust Clinical Governance
and Risk Management Committee

Dr Jonathan Michael
Chief Executive

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Overview

This policy is in addition to the principles laid out in the Trust Medicines Policy. The critical guidelines for iv potassium to be adhered to throughout the Trust are:

ISSUE	GUIDELINE Potassium Dilutions (K+)
Prescription	K+ dilutions for intravenous administration should generally be prescribed in those concentrations that are currently available as commercially-prepared, ready-to-use diluted solutions. If a K+ dilution is not commercially available, the solution should be prepared in the hospital pharmacy whenever possible. Prescribing of strong K+ ampoules/vials will be the same as a controlled drug; record the requisition, supply, receipt and administration.
Administration	A second practitioner should always check for correct product, dosage, dilution, mixing and labelling during the preparation and again prior to iv administration of solution.
Ordering	All supplies should be requisitioned directly from the pharmacy stores. Documentation should follow the pattern for controlled drugs, (except no CD labelling), and record the requisition, supply, receipt and in the clinical areas the administration of strong K+ ampoules/ vials.
Storage	Strong K+ ampoules/vials should be restricted to pharmacy departments and critical care areas and removed from routine stock in wards and clinical departments. They must be stored separately in a locked cupboard or unit. The same storage safety measures are recommended for the 20mmol and 40mmol of potassium in 100 ml mini-bags. These should be stored separately and must not be stored next to other infusion bags.
Borrowing	NO borrowing between wards. Strong K+ ampoules/vials and concentrated dilutions of intravenous K+ (e.g. 20mmol and 40mmol in 100 ml mini-bags) should not be transferred between clinical areas. All supplies should be obtained directly from the pharmacy department.
Monitoring	Each area that stocks strong K+ ampoules/vials must complete a proforma that justifies use and is approved by the Clinical Governance Committee. Concentrated dilutions of intravenous K+ (e.g. mini-bags or specially manufactured dilutions) require a completed unlicensed medicine form for either a clinical area or individual patient.
Training	Risk associated with all aspects of strong K+ ampoules/vials and concentrated dilutions prescribing, preparation, administration and storage should be highlighted in patient safety induction training for all staff involved in the medication process. This should also feature in specific training in iv preparation and administration, including induction schemes for locum staff

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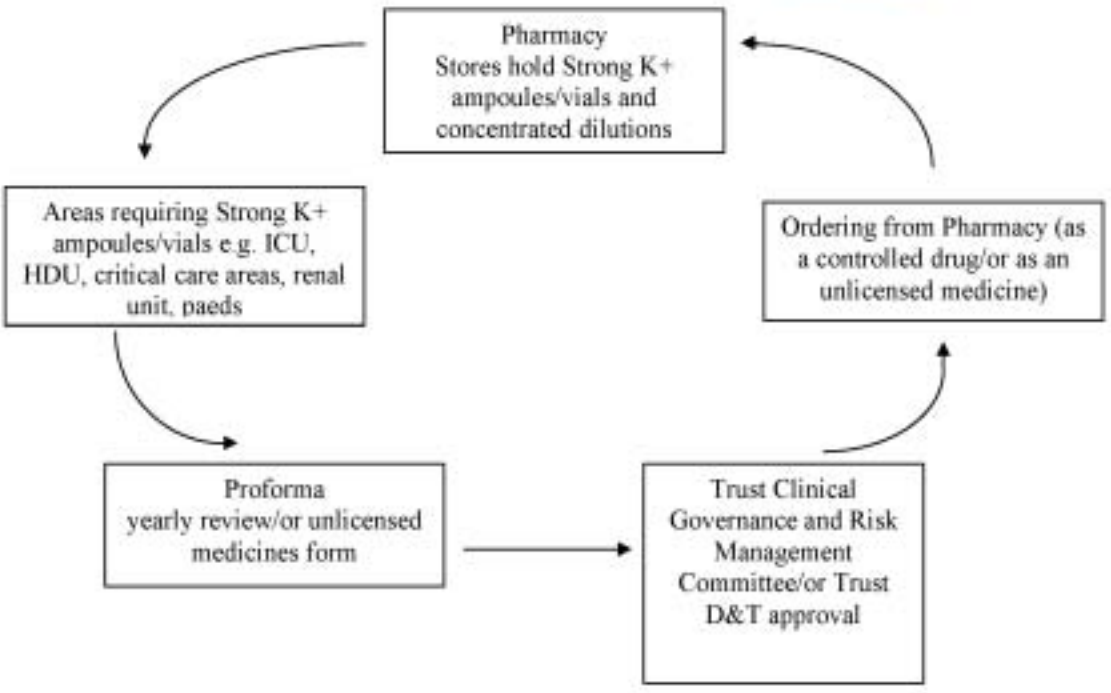

General Policy

All clinical areas that administer and store potassium, whether the standard commercially-prepared dilutions, strong K+ ampoules/vials, or concentrated dilutions, must put into place a documented local guideline for their use within their clinical area (see Appendix).

The Appendix contains a framework for producing a local guideline with two tables listing the Trust potassium products in stock and the various storage options that can be utilised for these preparations.

In addition, some of the key points of this Trust policy are explained in greater detail below.

PRESCRIBING

All prescribing of intravenous potassium dilutions must be expressed in terms of millimoles and include the rate of infusion and volume.

ADMINISTRATION

The principal areas that use strong K+ ampoules/vials or concentrated dilutions are the critical care areas e.g. ICU, HDU, Peri-operative and Renal.

- All concentrated potassium dilutions, whether made up with strong K+ ampoules/vials, or the 20mmol and 40mmol in 100 ml mini-bags, must be administered by the central route. These should be administered accurately using either a volumetric infusion pump, a burette, or a syringe driver. All

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intravenous potassium solutions whether in a syringe or infusion bag need to be fully labelled with rate, volume and millimoles.

- Each administration of a strong K+ ampoule/vial will be checked by two staff members one being a registered nurse/midwife (for full details refer to the section on controlled drug administration in the Trust Medicines Policy page 32) and recorded with both practitioner's initials on the patient's record or prescription chart (or in ICU the Clinical Information System CIS).
- A running total of strong K+ ampoule/vial use will be recorded in the IV Potassium record book, or in the case of ICU the Clinical Information System Carevue. This will be checked in ICU and OIR once per shift, other critical areas once every 24 hours and pharmacy will take a stock check once a week to account for any discrepancies.
- There will be a distinction on the patient charts or CIS between administration of strong potassium for parenteral supplementation, CVVH administration and continuous infusion

Strong K+ ampoules/vials are used in the following situations:

1. patient care areas level 2 or above - to maintain patient's cellular potassium levels due to co-morbidity e.g. fluid restriction, renal function and co-prescription, notably digoxin or antiarrhythmics
2. adult and paediatric dialysis – whilst undergoing dialysis the potassium levels may drop causing co-morbidity
3. paediatric care areas – to provide potassium at a specific ratio
4. theatres – post-operative care when there is an urgency of potassium replacement e.g. presence of cardiac arrhythmia, very low serum potassium

ORDERING

To avoid the mistake of misadministration or non-recognition, all strong K+ ampoules/vials are treated as a controlled drug:

- All orders will be made directly to pharmacy. (Orders for standard diluted preparations will be via the normal pharmacy ordering system).
- Each order of strong K+ ampoules/vials or concentrated K+ dilutions will require appropriate documentation and will correspond to either the Clinical Governance approved list of areas to be supplied, or the unlicensed medicine directorates list for concentrated dilutions.
- Requisitions for supply of strong K+ ampoules/vials from the pharmacy will be recorded as a controlled drug (CD) i.e. with a IV Potassium order book and record book. Orders are to be checked and signed for by a registered nurse or midwife and witnessed with second signature in the record book, by either pharmacy technician, registered nurse or midwife, ODA/ODP, doctor, student nurse or radiographer.
- The ICU and OIR areas will order strong K+ ampoules/vials as a controlled drug, but it will then be issued from the ICU/OIR central IV Potassium record to each bedside cabinet assigned for K+ ampoule/vial use only.
- Any "one-off" orders for a particular patient for a ward area not on the approved lists will be treated as an unlicensed medicine whether for an ampoule, vial,

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mini-bag, or specially manufactured dilutions and will require the completion of a patient specific non-proforma order form held by stores/dispensary. If the order is urgent or out of hours then the prescription can be dispensed by a pharmacist or site practitioner and the paperwork completed retrospectively.

STORAGE

One of the most critical risk management aspects of dealing with strong potassium ties in directly with storage security. However, following a Trust survey it was discovered that a number of wards were keeping strong K+ ampoules/vials on a 'just in case' basis or because they had ordered a box for one particular patient and still had some remaining ampoules. In the future no other wards except the approved critical care areas will be allowed to store strong K+ ampoules/vials.

Therefore to minimise the risk of storing strong K+ ampoules/vials the following guidance must be adhered to by all departments and wards:

- Strong K+ ampoules/vials and concentrated dilutions must be restricted to pharmacy departments and to those critical care areas where the clinical need has been approved. All strong K+ ampoules/vials should be removed from routine stock in non-approved wards and clinical departments.
- Strong K+ ampoules/vials should be stored in a separate locked cupboard. The same good practice of storing separately away from other intravenous solutions is recommended for storage of the 20mmol and 40mmol potassium in 100ml mini-bags.
- Each receipt of the strong K+ ampoules/vials will be recorded by two practitioners in the IV Potassium ward record book, with a running balance similar to controlled drugs.
- In ICU and OIR areas for individual patient use, strong K+ ampoules/vials will be signed out of the ICU's central K+ cupboard to the bedside cabinets, used only for storage of strong K+ ampoules/vials and no other medicine.

BORROWING

In the past a ward requiring a small amount of strong potassium e.g. a few ampoules or one or two infusion bags for a particular patient has sometimes borrowed a supply from another ward rather than pharmacy.
In future there must be NO borrowing between wards. Borrowing increases the risk of misadministration and indeed one of the deaths reported was due to borrowing, where the packaging was not identified and misadministration occurred.

IF a ward has a patient with a particular requirement for a concentrated K+ dilution or strong K+ ampoule/vial they should ideally be in a level 2 care area, but if not, then the potassium should be ordered through the pharmacy and clearly accounted for. For areas not approved to stock strong K+ ampoules/vials or concentrated K+ dilutions a patient specific non-proforma order form will need to be completed.

Out of hours requirements are to be addressed through either the on-call pharmacist or the site practitioner who will consult with the on-call pharmacist.

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D&T Approved reference: 05103e

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MONITORING

If a misadministration or "near-miss" occurs, this should be recorded as an adverse incident and logged through your line manager or site practitioner according to the Trust Risk Management Policy.

Compliance with this iv potassium policy will be monitored annually. A proforma has been circulated to all areas requesting strong K+ ampoules/vials, this requires a statement as to clinical need of strong K+ ampoules/vials. The proforma will need to be countersigned by the clinical directorate head of service, clinical governance lead, lead nurse, and the clinical pharmacist. The proformas will be forwarded to Clinical Governance for ratification and a database and hard copy record kept.

Every year following the initial circulation of proformas in October 2002, there will be a review of the areas holding strong K+ ampoules/vials and each area will be sent a new proforma requesting justification. These again will need to be ratified by Clinical Governance.

Any ward area found to be storing strong K+ ampoules/vials without Clinical Governance permission will be held in breach of Trust policy.

All unlicensed concentrated dilutions will need either a directorate signed unlicensed medicine form to be held on record, or for individual requests, a patient specific non-proforma order form will need to be completed. If the individual request is urgent and/or out of hours, this form can be completed retrospectively.

All completed proformas, unlicensed medicine forms and non-proforma order forms should be returned to Principal Pharmacist, Clinical Governance (Medicines), MI, Pharmacy, Thomas Guy House, Guy's Hospital.

References

National Patient Safety Agency guidance as issued July 2002.

The Guy's and St Thomas' Hospital Trust Medicines Policy

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Appendix

FRAMEWORK FOR LOCAL GUIDELINE

Local policies or guidelines should be developed to assist in the training of new staff, locums and junior doctors.

To assist you in putting together the document please utilise the following tables of Trust potassium products and recommended storage, along with the tick boxes to assist you in pinpointing your requirements. This table will be updated as new requests are received.

Justification of Clinical Use
Training to be implemented

All intravenous strong potassium should only be administered via a central route either with a volumetric infusion pump, burette or syringe driver.		
Tick Box	**Preparations in ampoules and vials**	**Storage (circle option chosen or write in system to be implemented)**
	15% (1.5 grams potassium in 10 ml)	Locked cupboard/cabinet
	10mmol and 10mmol acid phosphate in 10 ml ampoule	Locked cupboard/cabinet
	40mmol phosphate, 30mmol sodium, 30mmol potassium in 20 ml ampoule	Locked cupboard/cabinet
	Preparations of mini-bags will be available by the end of 2002	
	20mmol in 100 ml Sodium Chloride solution	Locked cupboard/separate clearly marked shelf

11/10

IV Potassium: Approved date: October 2005: Review date: November 2006: Author, S Barnes D&T Approved reference: 05103e

Guy's and St Thomas' NHS
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Standard potassium dilutions available in ready made bags or bottle concentrates that are administered peripherally, are:		
Tick Box	**Preparations of dilutions available**	**Storage**
	13.5% KCL in 100 ml bottled concentrate	Separate cupboard/clearly marked shelf
	10mmol 0.15% in 500 ml Sodium Chloride 0.9% solution	Separate cupboard/clearly marked shelf
	10mmol 0.15% in 500 ml Sodium Chloride 0.18% and Glucose 4%	Separate cupboard/clearly marked shelf
	10mmol 0.3% in 500 ml Sodium Chloride 0.45% and Glucose 5% (Unlicensed)	Separate cupboard/clearly marked shelf
	10mmol 0.15% in 500 ml Glucose 10% (Unlicensed)	Separate cupboard/clearly marked shelf
	20mmol in 500 ml Sodium Chloride 0.9% solution	Separate cupboard/clearly marked shelf
	20mmol in 500 ml Glucose 5% solution	Separate cupboard/clearly marked shelf
	40 mmol in 500 ml Sodium Chloride 0.9% solution (Unlicensed)	Separate cupboard/clearly marked shelf
	20mmol in 1000 ml Sodium Chloride 0.5% solution	Separate cupboard/clearly marked shelf
	20mmol in 1000 ml Glucose 5% solution	Separate cupboard/clearly marked shelf
	40mmol in 1000 ml Sodium Chloride 0.9% solution	Separate cupboard/clearly marked shelf
	40mmol in 1000 ml Glucose 5% solution	Separate cupboard/clearly marked shelf

12/10
IV Potassium: Approved date: October 2005: Review date: November 2006: Author, S Barnes
D&T Approved reference: 05103e

The Pharmacy and Therapeutics Committee

Brigham and Women's Hospital

POTASSIUM CHLORIDE POLICY

Intravenous (IV)/Oral (PO)

Please note., ***The acetate and phosphate salts of potassium are RESTRICTED to Total Parenteral Nutrition solutions and to use in the Neonatal Intensive Care unit. Sodium salts will be substituted in all other settings and clinical applications.***

I. DESCRIPTION

Potassium (K+) is the principal intracellular caution: serum potassium levels are only approximately 3% of intracellular levels. Potassium is essential for maintenance of intracellular tonicity, muscle contraction, and maintenance of normal renal function. It is a critical component of cardiac nerve conduction and muscle contraction and has a narrow therapeutic/toxic range.

II. MAJOR USES

Potassium chloride can be given orally or intravenously for the prevention or treatment of potassium depletion.

III. DOSAGE AND ADMINISTRATION

A. ROUTES OF ADMINISTRATION

1. INTRAVENOUS

a. Continuous IV infusion

- **Maintenance solutions**

- Total Parenteral Nutrition (TPN) solutions

b. Intermittent IV INFUSION ("bolus")

- For administration via peripheral line

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- For central line administration

WARNING. POTASSIUM SHOULD NEVER BE GIVEN VIA "IV PUSH"

2. ORAL

a. Immediate Release Products

- K-Lor powder for oral solution

- Potassium chloride oral solution

b. Sustained Release Products

- Micro-K Extencaps

B. DOSAGE

1. - IMPORTANT CONSIDERATIONS

• REQUIREMENTS

♥ Cardiac monitoring for all infusion rates of >10 mEq/hour

Exception: *Patients on 6th Floor Hematology/Oncology/BMT programs who meet the "3-70/12 Rule " (see below).*

* All Potassium infusions required an infusion pump

• RECOMMENDATION: Administer via large bore angiocath (i.e.. 18-20G)

2. POTASSIUM SCALES ("K-scales"):

Please see Attachment I

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C. PREPARATION/ADMINISTRATION

WARNING! POTASSIUM CAN CONCENTRATE INTO LAYERS IN I.V. SOLUTIONS!

POTASSIUM CAN CONCENTRATE IN LAYERS WITHIN ADMIXTURES IF IT IS ADDED WITHOUT ADEQUATE MIXING. THIS MAY CAUSE SOME PORTIONS OF THE ADMIXTURE TO CONTAIN SIGNIFICANTLY HIGHER CONCENTRATIONS OF POTASSIUM THAN OTHERS.

1. Reconstitution - Not Applicable: All admixtures are either premixed or prepared by Pharmacy. PLEASE NOTE: *Undiluted vials of potassium chloride are NOT available for IV admixture preparation outside of Pharmacy Services.*

- Premixed *KCl* for *intermittent bolus* is available from *Pharmacy Services* as:

  10 mEq/100mL sterile water (preferred peripheral solution)

  10 mEq/50mL sterile water (maximally concentrated peripheral solution)

  20mEq/50mL sterile water (central line ONLY)

- Premixed *KCl* for *continuous infusion* is available from *Service Center* as:

  20 mEq/1000 mL D5W

  20 mEq/l1000 mL D5NS

  40 mEq/1000 mL D5NS

  20 mEq/1000 mL D5 1/2NS

  40 mEq/1000 mL D5 1/2NS

  20 mEq/1000 ml NS

- *KCl* for *continuous infusion* for *non-standard solutions is* available

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from *Pharmacy*

2. Stability - As labelled on premixed products or on Pharmacy Services I.V. Label.

3. Who May Administer

RNs

LPNs

4. Special Equipment

An infusion pump is *required* for all Potassium infusions

Cardiac monitoring *is required for* all dosage rates > 10 mEq/hour.

Exception: Patients on 6th Floor Hematolgy/Oncolog/BMT programs who meet the "3-70/12 Rule" (see below).

1. INTRAVENOUS ADMINISTRATION

CONTINUOUS INFUSION

ROUTE	MAX. CONCENTRATION (mEq/L)	MAX. RATE (cc/ hr, mL/hr)
Peripheral	40 *	250 * ♥
Central	40 *	250 * ♥

INTERMITTENT INFUSION (BOLUS)

ROUTE	MAX. CONCENTRATION	MAX.RATE
Peripheral	10mEq/100mL * 10mEq/50mL for fluid restricted *	10 mEq/hr * ♥

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Central	20mEq/50mL*	20 mEq/hr ♥ *

♥ CARDIAC MONITORING: Required for rates > 10mEq/hr regardless of route

Exception: 6th Floor Heme/Onc/BMT pts. who meet the "3-70/12 Rule" (see below)

* INFUSION PUMPS: Required for all potassium infusions

EXCEPTION TO THE CARDIAC MONITORING REQUIREMENT

" HEMATOLOGY/ONCOLOGY PATIENTS (Including Bone Marrow Transplant) ONLY

Patients on a Hematology/Oncology (inc. BMT) inpatient unit (currently Tower+6), whose clinical condition falls under the "3-70/12 Rule" may receive up to 20 mEq/ hour of potassium chloride without the requirement of concomitant cardiac monitoring.

The rule is as follows:

"3" Serum potassium is <= 3 mmol/L (mEq/L)

AND

"70/12" Total potassium excretion is >= 70 mEq during a 12-hour urine collection

This exception applies only to these locations, patients, clinical conditions (i.e., serum potassium < 3 mmol/L AND total potassium excretion is >= 70 mEq during a 12-hour urine collection) , and infusion rates.

This exception will be valid until the serum potassium becomes > 3 mmol/L and may be resumed if the serum potassium returns to <= 3 mmol/L and the underlying cause (s) of persistent high potassium excretion is/are still present (i.e., amphotericin B, high-dose corticosteroids, acute leukemia induction).

2. ORAL ADMINISTRATION

A. GENERAL All oral potassium products can cause GI upset:

administer after meals or with food and with water/Juice (below).

DO NOT CRUSH sustained-release capsules or tablets

COMPARISON CHART: IMMEDIATE vs. SUSTAINED-RELEASE PRODUCTS

Product Type	Time to Peak K+	Maximum Dosage	BWH Product	Availability	***Notes***
Immediate Release	*1-2* Hours	40mEq q2h	K-Lor Powder for Oral Solution	20mEq/ packet	Must be added to at least 4 ounces cold water or juice and stirred until dissolved. Sugar free.
			Oral solution	20mEq/15mL (unit-dose cups)	Must be diluted With at least 3 to 8 ounces (90 - 240mL) water or juice before administration. Sugar free. Contains 5% alcohol.
Sustained Release	8-10 hours	40 mEq q8h	Micro-K 10 Extencaps	10mEq Capsules	Administer with 3 to 8 ounces (90-240mL) fluid. ***DO NOT CRUSH.***

MONITORING CONSIDERATIONS

NOTE:
Consider ALL sources of potassium (i.e., tube feeds, TPN, boluses, other infusions, etc.) when evaluating strategies for potassium replacement

1. Precautions/Contraindications

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HYPERKALEMIA:

Three primary causes of hyperkalemia:

1 Decreased renal excretion (e.g., renal impairment, drug interaction)

2 Redistribution of potassium from the intracellular to the vascular space

3 Increased potassium intake

SEE ATTACHMENT II FOR SIGNS/ SYMPTOMS OF HYPERKALEMIA AND GUIDELINES FOR MANAGEMENT.

ADRENAL INSUFFICIENCY:

Use cautiously in patients *with untreated* adrenal insufficiency (Addison's Disease)

DIGOXIN:

Careful monitoring required (e.g., daily)

POTASSIUM-SPARING DIURETICS:

Careful monitoring required (e.g., daily)

ACE INHIBITORS:

Careful monitoring is required (eg., daily)

CARDIAC CONDUCTION DISORDERS:

Careful monitoring is required (e.g., daily)

RENAL IMPAIRMENT:

Careful monitoring is required (e.g., daily). Potassium scales cannot be used for patients with significant renal impairment (see above).

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ACED-BASE DISORDERS:

Alkalosis: As serum pH increases, serum K+ decreases due to the potassium ion shifting from the plasma into the cell. Consider whether a low or falling potassium level is truly due to depletion in the alkalotic patient.

Acidosis: As serum pH decreases, serum K+ increases due to the potassium ion shifting from the cell into the plasma.

GI TRACT (ORAL)

Oral potassium tablets have been shown to produce lesions of the small intestine and death. -These lesions are caused by a concentration of the potassium ion in the area of the tablet, causing injury, obstruction, hemorrhage, and/or perforation.

Patients at greatest risk:

Elderly

Immobile

Medical history of:

Scleroderma

Diabetes mellitus

Mitral valve replacement

Cardiomegaly

Esophageal stricture/ compression

OTHER GI DISTURBANCES:

Loss of appetite, nausea, vomiting

2. Other Adverse Reactions

POTENTIALLY LETHAL ARRHYTHMIAS AND CONDUCTION DELAYS WITH RAPID I.V. ADMINISTRATION AND/OR OVERDOSAGE

THROMBOPHLEBITIS

3. Therapeutic Levels

Adults/Children (>= I year-old): 3.5 - 5 mmol/L (mEq/L)

Infants (< 1 year-old): 5 - 7 mmol/L (mEq/L)

4. Dosage Modifications Required

RENAL DISEASE: Use with caution (if at all) in patients with renal dysfunction

NOTE: See Drug Interactions Section (below) for further modifications

5. Drug Interactions

POTASSIUM-SPARING DIURETICS:

These agents conserve potassium, and include

- Amiloride

- Spironolactone

- Triamterene

ACE INHIBITORS:

These agents conserve potassium, and include

- Benazepril
- Captopril
- Enalapril/enaprilat
- Fosinopril
- Lisinopril
- Quinapril
- Ramipril.

DIGOXIN:

Low serum potassium (hypokalemia) may result in digoxin toxicity even though digoxin levels may be normal (0.9 - 1.7 mg/ dL). Therefore, use caution if discontinuing a potassium preparation in patients maintained on digoxin.

References available on request from the Drug Information Service (x3696).

Author: Pharmacy and Therapeutics Committee Date: 4/96

Approvals: Pharmacy and Therapeutics Committee Date: 4/96

BWH Care Improvement Council Date: 4/96

ATTACHMENT I: POTASSIUM DOSAGE SCALES ("K-Scales")

A. IMPORTANT CONSIDERATIONS

The Pharmacy and Therapeutics Committee must approve all "K-scales" for

potassium chloride. Requests for different scales should be addressed to the P& *T Committee Chairperson c/o Department of Pharmacy Services.*

K.scales cannot be used and potassium dosages must be individualized for patients who have:

-A serum creatinine >= 2.0 mg/dL; or

-A serum creatinine a 1.5 mg/dL and an increase of 0.5 mg/ dL within 24 hours

Potassium, like all other medications at BWH, cannot be ordered using "slashed routes" (i.e., "IV/PO"). BWH policy requires that separate orders be written for each route for every drug, and that parameters be specified by the prescriber for when each route should be chosen. Only immediate-release potassium chloride products can be ordered or administered under orders for K-scale.

K-scales must be renewed daily.

All scales for Hematology/Oncology patients are limited to those patients located on Tower +6.

ORAL K-SCALE		I.V K-SCALES	
TARGET LEVEL: > 4.0 mEq/L		TARGET LEVEL: > 4.0 mEq/L	
Serum Potassium (mEq/L)	*Potassium Dosage (mEq)*	*Serum Potassium (mEq/L)*	*Potassium Dosage (mEq)*
< 3.1	Call H.O.	< 3.1	CALL H.O.
< 3.4	60 mEq	< 3.4	30 mEq
< 3.7	40 mEq	< 3.7	20 mEq
< 4	20 mEq	< 4	10 mEq
TARGET LEVEL > 4.5 mEq/L		TARGET LEVEL: > 4.5 mEq/L	
Serum Potassium (mEq/L)	*Potassium Dosage (mEq)*	*Serum Potassium (mEq/L)*	*Potassium Dosage (mEq)*
< 3.4	CALL H.O.	< 3.7	CALL H.O.
< 3.7	60 mEq	< 4.1	30 mEq
< 4.1	40 mEq	< 4.6	20 mEq

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< 4.6	20 mEq	< 5.1	*CALL H.O.* IF KCl IS *INDICATED (e. g., if high* urine output)
HEME/0NC (TARGET LEVEL > 4.0 mEq/L)		HEME/ONC (TARGET LEVEL: > 4.0 mEq/L)	

Serum Potassium (mEq/L)	*Potassium Dosage (mEq)*	*Serum Potassium (mEq/L)*	*Potassium Dosage (mEq)*
< 3	CALL H.O.	< 3	CALL H.O.
< 3.4	80 mEq	< 3.4	80 mEq
< 3.6	60 mEq	< 3.6	60 mEq
< 3.8	40 mEq	< 3.8	40 mEq
< 4	20 mEq	< 4	20 mEq

ATTACHMENT II: HYPERKALEMIA

I. Signs/Symptoms

Characteristic ECG Changes:

Peaking of T waves (can occur with mild hyperkalemia (e.g., K<6])

Loss of P wave

ST segment depression

QT prolongation

P-R interval lengthening

Widening of QRS complex

Other Signs/Symptoms:

Cardiac arrhythmias, heart block, asystole

Paresthesias

Muscle weakness and flaccid paralysis of extremities

Listlessness, mental confusion

Hypotension

II. Guidelines to management

There are three basic interventions to manage patients with hyperkalemia. These are outlined in the table below.

1.) PREVENTION OF POTASSIUM-INDUCED CARDIOTOXICITY

Calcium chloride	1 gm IV over 5-10 min	*DOES NOT CHANGE K+ LEVEL* *Onset 1-3* min. *Duration: 30-60* min. *Use with caution in patients on digoxin:* *hypercalcemia may precipitate dig. toxicity.*

2.) REDISTRIBUTION OF POTASSIUM FROM EXTRACELLULAR TO INTRACELLULAR

Sodium bicarbonate	*50* mEq IV over 2-5 min. Repeat PRN.	*Onset 30* min, *Duration: 2-6* hours.
Insulin	10 U regular insulin IV	*Onset 30* min. *Duration: 2-6* hours.

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Glucose	Dextrose 50%: 50mL IV over 5 min.	*Not necessary if patient already has high serum glucose. Onset 30* min. *Duration: 2-6* hours.

3.) BINDING/REMOVAL OF POTASSIUM

Kayexalate (sodium polystyrene sulfonate)	15-60 gm PO or PR	*Onset ~1* Hour. *Duration:* Variable. *Absorption of sodium may precipitate CHF if Pt has fluid overload and/or impaired cardiac output.*
Hemodialysis		*Onset* Immediate *Duration:* Variable

Reviewed by Pharmacy and Therapeutics Committee: 12/16/00

Updated: 08/2005

WILLIAM OSLER HEALTH CENTRE

Etobicoke Hospital Campus
Brampton Memorial Hospital Campus
Georgetown Hospital Campus

www.williamoslerhc.on.ca

Memorandum

To: Patient Care Managers WOHC
Educators
Pharmacists and Pharmacy Technicians
All Physicians
Clinical Directors
KCl Standardization Task Force
Philip Smith
Vicki Truman, Brenda Elsbury, Ruth Yates, Don Trant
Safe Medication Practice Committee
Pharmacy Nursing Liaison Committee

From: Nancy Henderson

Date: May 22, 2002

Re: IMPLEMENTATION OF STANDARDIZED PREMIXED I.V. KCl SOLUTIONS

ON **JUNE 4 @ BMHC and JUNE 5 @ EHC and GHC**, Potassium Chloride Polyamps will be removed from patient care units. Premixed IV KCl solutions will be provided. KCl infusion orders will be standardized.

Please see the attached education package.

EDUCATORS – Please use this information when coaching unit staff.

PATIENT CARE MANAGERS – You will also find attached laminated sheets to post in med rooms and clean supply rooms.

PHYSICIANS – page 4 is devoted to specific Physician practice issues.

GENERAL INFORMATION SESSIONS WILL BE HELD:

EHC	May 29	1330 – 1630 h	EHC Boardroom
GHC	May 30	0900 – 1200 h	GHC Boardroom
BMHC	May 30	1330 – 1630 h	BMHC Pharmacy Dept.

ALL ARE WELCOME – PLEASE DROP IN FOR 10 MINUTES.

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Potassium Chloride Intravenous Solutions
WOHC Automatic Substitution Policy

Effective June 4/02 @ BMHC, June 5/02 @ EHC & GHC

Premixed KCl Solutions will be run at the same rate as originally ordered.

ORDERED AS:		SUPPLIED AS:	
KCl concentration	***Base Solution***	***KCl concentration***	***Base Solution***
ADULT:		**ADULT:**	
1 – 30 mmol/L	0.9% NaCl Ringers Lactate* Unspecified	20 mmol/L	0.9% NaCl * In ICU, if Ringers Lactate is ordered for a metabolic indication, nurse to admix.
1 – 30 mmol/L	D5W	20 mmol/L	D5W
1 – 30 mmol/L	2/3 & 1/3	20 mmol/L	2/3 & 1/3
1 – 30 mmol/L	D5W / 0.45% NaCl	20 mmol/L	D5W / 0.45% NaCl
31 – 59 mmol/L	0.9% NaCl Ringers Lactate* Unspecified	40 mmol/L	0.9% NaCl * In ICU, if Ringers Lactate is ordered for a metabolic indication, nurse to admix.
31 – 59 mmol/L	D5W	40 mmol/L	D5W
31 – 59 mmol/L	2/3 & 1/3	40 mmol/L	2/3 & 1/3
31 – 59 mmol/L	D5W / 0.45% NaCl	40 mmol/L	D5W / 0.45% NaCl
ADULT BOLUS:	***(Via Central Line, using Infusion Pump)***		
1–15 mmol bolus		10 mmol / 100mL	Sterile Water for Inj
16-30 mmol bolus		20 mmol / 100 mL	Sterile Water for Inj
31-40 mmol bolus		40 mmol / 100 mL	Sterile Water for Inj
PEDIATRICS:		**PEDIATRICS:**	
1-20 mmol/500mL	2/3 & 1/3 unspecified	10 mmol/500mL	2/3 & 1/3
1-7 mmol/500mL	D5W / 0.45% NaCl	5 mmol/500mL	D5W / 0.45% NaCl
8-20 mmol/500mL	D5W / 0.45% NaCl	10 mmol/500mL	D5W / 0.45% NaCl
1-20 mmol/500mL	D5W / 0.2% NaCl	10 mmol/500mL	D5W / 0.2% NaCl

Nurse will automatically initiate Autosub Policy unless order states "no sub". Pharmacy will ensure standard order is documented on the chart directly or through autosub notice.

STOCKING: **Infusion solutions** stocked on patient care unit **supply cart.**
Bolus solutions stocked by Pharmacy on **medication cart / cupboard.**
Polyamps available in the night cupboard.

1

STOCKING LOGISTICS:

Premixed KCl intravenous solutions will be stocked by Materials Management on the patient care unit supply carts. They will be strategically separated from IV base solutions on the cart and a coloured label will be used to identify a drug admixture. The majority of these solutions will be 1000mL = 1 L. Some solutions are available in 500mL and 250mL.

KCl bolus infusions will be provided premixed in a 100mL minibag of Sterile Water. (10, 20 and 40 mmol/100mL SWI) These concentrated minibags will be stocked by Pharmacy and located on the medication carts.

In the event a physician orders a nonstandard solution and requests no automatic substitution, the nurse will be required to admix the solution. Pharmacy will send a patient specific supply of polyamps. After hours, **KCl polyamps will be available from the Night Cupboard.**

KCl Polyamps will also be available for nurse admixture in the following areas:

a) ICU/IMU/CCU at EHC and BMHC – need polyamps when KCl ordered to be added to dialysate, or Ringers Lactate solutions.
b) Emerg at EHC for bolus orders Eg. 40 mmol/100mL. (Not required at BMHC, Emerg will stock premixed minibags instead. EHC will convert once usage increases)
c) SCN - doses difficult to standardize, very few orders. Double check of calculations and admixture recommended.

***Pediatrics at EHC and BMHC for 2 months after go live.*

When stocked on a patient care unit, KCl Polyamps will be treated in a similar manner as a controlled drug requiring sign-out for tracking and safety purposes.

NURSING PRACTICE CHANGES:

- PCA Documentation
  When documenting an IV with a KCl additive in PCA, select **mmol** from the dosage look-up rather than mEq. (1 **mmol** KCl = 1 **mEq** KCl**)
  ***This 1:1 equivalency does not apply to polyvalent electrolytes Eg. Ca++, Mg++*
- Starting an IV
  IV nurses will start a new IV with manufacturer prepared premixed KCl solutions. IV nurses cannot start an IV with any medication mixed by another RN.
- Implementing Autosubstitution Policy
  STANDARD concentrations of KCl infusions are 20 or 40 mmol KCl / L.
  If a nonstandard KCl order is written, implement the automatic substitution policy to hang a premixed solution, unless the physician has specified "no substitution". Pharmacy will supply an automatic substitution notification which must be added to the chart.
- Admixing KCl and another medication
  Premixed KCl IV solutions from Baxter have an injection port to be used for admixture, if a compatible drug is ordered to be given with the KCl solution. Normal IV labelling (red) requirements will apply.

2

PHYSICIAN PRACTICE CHANGES:

I.V. KCl should be ordered using mmol instead of mEq. (1 mEq = 1 mmol KCl)

Please refer to the **Automatic Substitution Policies** to guide standardized prescribing.

Premixed Solutions (for Adults) include **20 or 40 mmol per L** of:

- 0.9% NaCl
- D5W
- 2/3 & 1/3
- D5W / 0.45% NaCl

For metabolic acidosis patients requiring Ringers Lactate, KCl will be prepared by the nurse. These orders are expected in Critical Care.

CRITICAL CARE

The KCl protocol has been changed

From: 40 mEq / 50 cc normal saline

To: 40 **mmol / 100 mL Sterile Water**

Although Sterile water provides the lowest osmolarity, a central line is still required for bolus administration.

SURGERY and OBSTETRICS

Post-op: 0.9% NaCl is the solution of choice for KCl infusion in the post-op setting. If Ringers Lactate is ordered, the automatic substitution policy will apply unless "no Sub" is written.

MEDICINE and SURGERY

NG Losses – Standard order is 20 mmol KCl / L 0.9% NaCl

PEDIATRICS

In children under 2 years the largest volume which will be hung is **250mL.**
A premixed solution of 5 mmol / 250 mL 2/3 & 1/3 will be provided.

In children over 2 years, the following **500 mL** solutions will be stocked:

5 mmol in	D5W 0.45% NaCl
10 mmol in	2/3 & 1/3
	D5W 0.45% NaCl
	D5W 0.2% NaCl

Note to all: 20 mmol / L = 10 mmol / 500 mL = 5 mmol / 250 mL.

These are all the same order, just the bag volume differs.
Patient age usually determines bag volume.
An automatic substitution policy is not required.
Conversion is done via calculation. Physicians are encouraged to order appropriate volume eliminating the need for calculation.

bayside|health **GUIDELINES**

Title: Administration of Intravenous Potassium Chloride (KCl) Replacement

Campus:	The Alfred	**Number:**
Accreditation Standard:	Safe Practice and Environment	**Related to Policy number:**
Responsibility for Review:	Melita Van de Vreede	
Date Approved: March 2004		**Review Dates:** March 2007

GUIDELINES:
These guidelines should be read in conjunction with The Alfred Drug Formulary Policy.

PURPOSE/EXPECTED OUTCOME
These guidelines define the use of intravenous potassium in general wards and critical care areas. They sets out maximum strengths, concentrations and rates and preferred products.

THESE GUIDELINES SUPERSEDE ALL OTHER POTASSIUM CHLORIDE GUIDELINES AT THE ALFRED

A) Indication: Correction of hypokalaemia and maintenance of potassium requirements, where oral potassium supplements are unsuitable.

- Potassium supplements are to be given orally whenever possible since the relatively slow absorption from the gastrointestinal tract prevents sudden large increases in plasma potassium concentrations.

All intravenous potassium (to be given as potassium chloride (KCl) is to be prescribed in millimoles (mmol).

- The preferred product is premixed 30mmol potassium chloride in one litre bags of normal saline (0.9% sodium chloride), 5% dextrose, Hartmans' solution or 0.18% sodium chloride/ 4% dextrose (see below).
- The other product available is premixed 10mmol potassium chloride in 100ml bags of sodium chloride (see below).
- If required 10mmol potassium chloride in 10ml sodium chloride ampoules are available.

B) Premixed intravenous solutions of Potassium Chloride

- 30mmol potassium chloride solutions in 1000ml- available with 4 diluents (see below)
- 10mmol potassium chloride solutions in 100ml – available with sodium chloride only
  - Pre-mixed potassium chloride bags have red outer packaging and are written in red print.
  - Pre-mixed potassium chloride solutions must be used.
  - Pre-mixed solutions must be prescribed using *millimoles* (NOT grams) (eg. 30mmols KCl in 1000mls 5% dextrose; rate @ 120mls/hour) or 10mmol KCl in 100ml sodium chloride).

EXTRA POTASSIUM CHLORIDE MUST NEVER BE ADDED TO PREMIXED SOLUTIONS as this may lead to confusion regarding the final concentration

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Products Available and Conversion Table

Standard Intravenous Solutions *	KCL Dose (millimoles)	KCL Dose (grams)	KCL percentage
Sodium Chloride 100ml	**10 mmol**	**0.75g**	**0.75%**
Sodium Chloride 0.9% 1000ml	**30mmol**	**2.24g**	**0.224%**
Sodium Chloride 0.18% & Glucose 4% 1000ml			
Hartmann's 1000ml			
5% Glucose 1000ml			

*All solutions are isotonic with the exception of 30mmol potassium chloride in 0.9% sodium chloride which is slightly hypertonic and labelled as such to comply with TGA regulations

C) **Guidelines for potassium chloride administration**

- All 30mmol potassium chloride solutions/1000mls must be administered via burette, to control the hourly rate.
- All potassium chloride solutions at concentrations greater than 30mmol/1000mls must be administered via infusion pump

For unmonitored patients on general wards:

- Potassium chloride 30mmol in one litre solutions are to be used.
- Potassium chloride ampoules are not be used, due to the possibility of inadvertent intravenous administration.
  - The maximum rate for intravenous potassium chloride administration must not exceed 10mmol per hour.
  - The maximum concentration of a solution for a peripheral line must not exceed 10mmol potassium per 100ml (in 100ml bags).
  - Lignocaine 20mg (ie 2ml of 1% Lignocaine HCl) may be added to 10mmol potassium chloride per 100ml for peripheral administration.

For critical care areas (ICU,ED, CCU, Anaesthetics, Cardiothoracics):

- Intravenous potassium chloride administered at rates at or exceeding 10mmol per hour may be appropriate for selected patients at the discretion of the treating clinician. A central line is preferable to prevent phlebitis and patient discomfort. Cardiac monitoring, frequent serum potassium measurements (2-hourly recommended), and regular assessment of renal function are required.

For resuscitation use

- Potassium chloride boluses (pushes) may be given only during cardiac arrest in the setting of recurrent ventricular fibrillation or electro-mechanical dissociation via a peripheral line according to specific unit protocols.

CAUTION: PHOSPHATE AMPOULES ALSO CONTAIN POTASSIUM IN VARYING AMOUNTS.

The treating specialist has to approve the administration of intravenous potassium chloride that does not meet the requirements of this guideline.

Authorised by: Lea Pope	
Date: March 04	
Signed:	
Contact person: Melita van de Vreede pharmacist	*Position: Quality Use of Medicines*
E-Mail : m.vandevreede@alfred.org.au	*Phone:92763308*

4.3. OTRAS PUBLICACIONES DE INTERÉS

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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Qual Saf Health Care 2005;14:196–201. doi: 10.1136/qshc.2004.011874

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Accepted for publication 5 April 2005

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.

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-authorised 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 implantation 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.

ACKNOWLEDGEMENTS

The authors acknowledge the help of the following steering group members who are not authors: Professor N Cullum, Department of Health Sciences, University of York; Dr P West, Director, York Health Economics Consortium; and the audit team (Alison Foster-Lill, Celia Grant, Dawn Harrison, and David Stevenson).

Appendices 1–6 are available online at http://www.qshc.com/supplemental

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This study was commissioned by the Patient Safety Research Programme. There were no competing interests. The full report can be located at: http://pcpoh.bham.ac.uk/publichealth/psrp/pdf/lankshear_kcl_final.pdf

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Clinical review

Best practices for safe handling of products containing concentrated potassium

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BMJ 2005;331:274–7

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.[3] 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.[4–7] 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.[4–6] 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.[3]

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.[8 9 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 11] 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[15] 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).[8]

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.[8] 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.[8]

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[18]:

- 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.

We thank Michael Plumb of the Health Quality Council of Alberta for guidance and expertise in preparing this paper. We also thank Lisa Hartling of the Department of Pediatrics, University of Alberta, for methodological and administrative support.

Contributors: All authors contributed to conception and design of the study, analysis and interpretation of the data, revising the manuscript critically for important intellectual content, and all gave final approval of the version to be published. In addition, MT coordinated the project, screened articles for inclusion, and drafted the manuscript; SRM co-wrote and revised the manuscript and provided professional expertise to the project; DL screened articles for inclusion, collected articles, and contributed to the searching. CF conducted the search and co-wrote the Methods section. TPK co-wrote and edited the manuscript and provided methodological and administrative support. He is the guarantor.

Funding: This report was produced under contract to the Health Quality Council of Alberta. SRM is a population health investigator supported by the Alberta Heritage Foundation for Medical Research and a new investigator supported by the Canadian Institutes of Health Research.

Competing interests: None declared.

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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.

Koenigsberger L. *Hermann von Helmholtz* [1905]. New York: Dover Publications, 1965:205

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