

Dear Colleague

SAFE ADMINISTRATION OF VINCA ALKALOIDS

Purpose

This circular provides new guidance on the Safe Administration of Vinca Alkaloids which must be implemented throughout NHS Scotland. The guidance takes into account implications for Scotland following the update of the English National Guidance on the Safe Administration of Intrathecal Chemotherapy (HSC 2008/001, 11 August 2008) and the NPSA Alert (2008) Rapid Response Report. Using Vinca Alkaloid Minibags (adult/adolescent units).

This is a risk management and clinical governance issue and accords with the high priority which the Scottish Government Health Directorate places on patient safety.

All NHS Boards where vinca alkaloids are administered must therefore ensure full implementation of this new national guidance.

Background

Since 1985 at least 13 patients in the UK have died or been paralysed as a result of the accidental intrathecal administration of Vincristine which was intended for intravenous administration. Two reports on intrathecal injections errors were published in England and Wales in April 2001. One reported on the investigation into the death of a teenager in Nottingham on 2 February 2001, and the other on a review of clinical policy and the prevention of intrathecal cancer chemotherapy error. Both reports made important recommendations.

The attached document has been prepared by a working group which included members from the previous Joint Working Group of the National Pharmaceutical Forum and the Scottish Medical and Scientific Advisory Committee which forms part of the advisory structure of the Scottish Government Health Directorate. The membership of the Group is given at Annex A.

CEL 22 (2009)

19th June 2009

Addresses

For action

Chief Executives
Medical Directors
Directors of Pharmacy
Directors of Nursing

For information

Chairs of Regional Cancer Advisory Groups
Regional Cancer Advisory Groups Managers
Regional Cancer Advisory Lead Clinicians
Regional Lead Cancer Pharmacists
Scottish Cancer Taskforce
Scottish Chemotherapy Advisory Group

Enquires to:

Cancer Team
St Andrew's House
Regent Road
Edinburgh EH1 3DG

Tel: 0131-244 4773

Fax: 0131-244 2989

<http://www.scotland.gov.uk>

Implementation of the guidance will be monitored by the NHS Board Designated Lead, who will report to the NHS Board Chief Executive as part of their clinical governance procedures on compliance.

Extravasation and other incidents relating to the administration of vinca alkaloids that occur as a result of this guidance will be collected by the designated NHS Board Lead, summarised into quarterly reports and submitted to the national Chemotherapy Advisory Group.

This CEL should be read in conjunction with the attached guidance, the Health and Safety Executive: Safe Handling of Cytotoxic Drugs paper, and with the recommendations of the Committee on Safety of Medicines, as detailed in the Medicines and Healthcare products Regulatory Authority, Guidance note 25. It should also be read in conjunction with CEL 21 (2009) Safe Administration of Intrathecal Cytotoxic Chemotherapy.

By December 2009 all NHS Boards must ensure full implementation of this revised national guidance. This should be accounted for within NHS Board policies and in line with clinical governance arrangements.

Yours Sincerely

Dr Harry Burns
Chief Medical Officer

Dr Margaret McGuire
Acting Chief Nursing Officer

Professor W Scott
Chief Pharmaceutical Officer

FURTHER READING

Department of Health (2008) Health Service Circular Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy [Issued under HSC 2008/001, 11 August 2008], available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_086870

NPSA (2008) Rapid Response Report. Using Vinca Alkaloid Minibags (adult/adolescent units). Available at: www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/using-vinca-alkaloid-minibags

World Health Organisation (2007) Information Exchange system. Alert 115. Vincristine (and other vinca alkaloids) should only be given intravenously via a minibag. July 2007. Available at: www.who.int/patientsafety/highlights/PS_alert_115_vincristine.pdf

Scottish Executive Health Department (2005) Guidance for the Safe Use of Cytotoxic Chemotherapy [Issued under NHS HDL (2005) 29, 4 July 2005], available at: http://www.sehd.scot.nhs.uk/mels/HDL2005_29.pdf

Scottish Executive Health Department (2004) Safe Administration of Intrathecal Cytotoxic Chemotherapy [Issued under NHS HDL (2004) 30, 2 June 2004], available at: http://www.sehd.scot.nhs.uk/mels/HDL2004_30.pdf

Health and Safety Executive (2003) Safe Handling of Cytotoxic Drugs. September 2003, available at: <http://www.hse.gov.uk/pubns/misc615.pdf>

Medicines and Healthcare products Regulatory Authority (2003) Guidance Note 25: Best Practice Guidance on the labelling and packaging of medicines, available at: <http://www.mhra.gov.uk/home/groups/commsic/documents/publication/con007554.pdf>

Department of Health (2001). The Prevention of Intrathecal Medical Errors. [The Kent Woods Report] London, available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065044

Toft, B. (2001) Report of an Independent Investigation into the Death of a Teenager from an Intrathecal Injection Error at the Queen's Medical Centre, Nottingham.

SAFE INTRAVENOUS ADMINISTRATION OF VINCA ALKALOIDS

Background

Since 1985 at least 13 patients in the UK have died or been paralysed as a result of the accidental intrathecal administration of vincristine which was intended for intravenous administration. **Vinca alkaloids must only be administered intravenously.** Two reports on intrathecal injections errors were published in England and Wales in April 2001. One reported on the investigation into the death of a teenager in Nottingham on 2 February 2001 and the other on a review of clinical policy and the prevention of intrathecal cancer chemotherapy errors. Both reports made important recommendations. Since these reports there have been further reports of fatal and serious incidents from outside the UK in which doses of vinca alkaloids, intended for intravenous administration, were administered by the intrathecal route in error. This new guidance builds on the subsequent advice from the WHO, DH and NPSA.

The Joint Working Group of the Joint Pharmaceutical Forum and Scottish Medical and Scientific Advisory Group was reconvened to review the current national guidance on intrathecal chemotherapy as a result recommended the separation of vinca alkaloids from the intrathecal guidance. This guidance should be read in conjunction with CEL 21 (2009) - Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy.

A key change is the recommendation that all vinca alkaloids are administered by intravenous infusion for all adults and adolescents treated in adult or adolescent units. This must be implemented by all NHS Boards regardless of whether or not intrathecal chemotherapy is administered within the NHS Board.

They have also advised that the practical difficulties of preparing and administering intravenous infusions of vinca alkaloids to treat children outweigh the benefits. For this reason the use of minibags to administer vinca alkaloids to children and adolescents in children's units is **NOT** recommended.

1. When vinca alkaloids are prescribed for administration in adult or adolescent units:
 - Doses in syringes should no longer be used.
 - The prescribed dose should be supplied from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9% or glucose 5% according to stability
 - The vinca minibag should be infused intravenously over 5 - 10 minutes and the patient closely monitored for signs of extravasation.
 - A full risk assessment should be undertaken locally to determine the method of intravenous infusion
 - Chemotherapy protocols, policies and procedures should be amended to reflect these requirements.
 - Staff should be alerted and trained to follow the new practice.
 - Practice should be audited to ensure compliance with the revised safety procedure.

2. The use of minibags to administer vinca alkaloids to children and adolescents treated in a children's unit is not recommended.

3. For children and adolescents treated in a children's unit, intravenous vinca alkaloids can be given undiluted. It is however considered good practice, as far as possible, to dilute all vinca alkaloids and dispense in a 10ml or greater syringe size.

Labelling of Vinca Alkaloids

4. For all vinca alkaloids, labels should have patient name, name of product, dose, route of administration (always intravenous) and a clear warning of the consequences of administration by other routes -for example:

"Vincristine -FOR INTRAVENOUS USE ONLY - FATAL IF GIVEN BY OTHER ROUTES".

Reporting Arrangements

5. Since this is a change in practice it is important that information is collected on any incidents including extravasation. For the first year following introduction of this new guidance extravasation incidents reports involving vinca alkaloid minibags must be collated by the NHS Boards Head of Chemotherapy Service and a summary report sent quarterly by each network to the Chemotherapy Advisory Group.

6. All other incidents should be reported as normal through the local NHS Board system.

7. After one year from the publication of this CEL the Chemotherapy Advisory Group will advise on further reporting required.

DILUTION OF DRUGS

Summary of recommendations for treating patients with intravenous vinca alkaloids

Patient Type				
Clinical Area/ Unit				
		Adult	Adolescent	Child
	Adult unit	Vinca dose in a 50ml minibag	Vinca dose in a 50ml minibag.	Children should not be treated in adult clinical areas. In the unlikely situation that this requirement should arise a local risk assessment should be undertaken to determine the safest method of treatment.
	Adolescent unit	n/a	Vinca dose in a 50ml minibag.	Children should not be treated in adolescent clinical areas. In the unlikely situation that this requirement should arise a local risk assessment should be undertaken to determine the safest method of treatment.
Children's unit	n/a	Vinca dose in a syringe. Further dilution according to NHS Board practice.	Vinca dose in a syringe. Further dilution according to NHS Board practice. (No change to current practice).	



MEMBERSHIP OF THE WORKING GROUP

Chairman:

Dr B Cowan, Medical Director, NHS Greater Glasgow and Clyde

Members:

Ms G Caldwell, Director of Pharmacy, NHS Forth Valley

Dr M Cornbleet, Chair of Chemotherapy Advisory Group

Dr J Currie, Consultant in Paediatric Anaesthesia and Pain Management, Royal Hospital for Sick Children, Glasgow

Mrs M Dolan, National Services Scotland, Edinburgh

Dr P Johnson Consultant Haematologist, Western General Hospital, Edinburgh

Mr S McIntosh, Lead Nurse (Anaesthesia), Ninewells Hospital, Dundee

Mrs F MacLean, Lead Cancer Care Pharmacist, South Glasgow, NHS Greater Glasgow and Clyde

Ms M Maclean, Regional Cancer Care Pharmacist, West of Scotland Cancer Network

Mr J Milne, Lead Oncology Pharmacist, NHS Lanarkshire

Dr D Murphy, Consultant Paediatric Oncologist, Royal Hospital for Sick Children, Glasgow

Mr J Wallace, Lead Directorate Pharmacist – Women's and Children's Services, NHS Greater Glasgow and Clyde

Mr N Richardson, Paediatric Oncology Lead Pharmacist, Royal Hospital for Sick Children, Edinburgh.

Dr A Bowman, Consultant Medical Oncologist, Edinburgh Cancer Centre.

Scottish Government:

Mrs P Warrington, Deputy Chief Pharmaceutical Officer, Scottish Government Health Directorates.

Ms R Dunk, Team Leader: Cancer Strategies, Scottish Government Health Directorates (Secretariat)

References

Department of Health (2008) Health Service Circular Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy [Issued under HSC 2008/001, 11 August 2008], available at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_086870

NPSA (2008) Rapid Response Report. Using Vinca Alkaloid Minibags (adult/adolescent units). Available at:

www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/using-vinca-alkaloid-minibags

World Health Organisation (2007) Information Exchange system. Alert 115. Vincristine (and other vinca alkaloids) should only be given intravenously via a minibag. July 2007. Available at:

www.who.int/patientsafety/highlights/PS_alert_115_vincristine.pdf

Scottish Executive Health Department (2005) Guidance for the Safe Use of Cytotoxic Chemotherapy [Issued under NHS HDL (2005) 29, 4 July 2005], available at:

http://www.sehd.scot.nhs.uk/mels/HDL2005_29.pdf

Scottish Executive Health Department (2004) Safe Administration of Intrathecal Cytotoxic Chemotherapy [Issued under NHS HDL (2004) 30, 2 June 2004], available at:

http://www.sehd.scot.nhs.uk/mels/HDL2004_30.pdf

Health and Safety Executive (2003) Safe Handling of Cytotoxic Drugs. September 2003, available at: <http://www.hse.gov.uk/pubns/misc615.pdf>

Medicines and Healthcare products Regulatory Authority (2003) Guidance Note 25: Best Practice Guidance on the labelling and packaging of medicines, available at:

<http://www.mhra.gov.uk/home/groups/commsic/documents/publication/con007554.pdf>

Department of Health (2001). The Prevention of Intrathecal Medical Errors. [The Kent Woods Report] London, available at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065044

Toft, B. (2001) Report of an Independent Investigation into the Death of a Teenager from an Intrathecal Injection Error at the Queen's Medical Centre, Nottingham.