

NATIONAL GUIDANCE ON THE SAFE ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

Background

1. As part of the clinical governance programme, patient safety is being given a particularly high priority. The work began with the publication of *"An Organisation with a Memory"*, its recommendations becoming policy through the NHS Plan. A progress report on implementation – *"Building a Safer NHS for Patients"* was published in April 2001.
2. Since 1985 at least 13 patients have died or been paralysed as a result of the accidental intrathecal administration of Vincristine which was intended for intravenous administration. In accepting the recommendations of *"An Organisation with a Memory"*, the Government agreed a target to reduce to zero the number of patients dying or being paralysed by maladministered spinal injections by the end of 2001.
3. Two reports on intrathecal injection errors were published in April 2001. One reported on the investigation into the tragic 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. This guidance takes forward these recommendations within the NHS by building on a letter from the Chief Medical Officer issued on 27 April 2001.

Purpose

4. This guidance:
 - alerts the NHS to this important patient safety issue and asks Chief Executives and NHS Boards to address it as part of their clinical governance responsibilities;
 - sets out national guidance for safe administration of intrathecal chemotherapy (including drugs delivered by lumbar puncture and by other routes e.g. Ommaya reservoirs);
 - it must now be adopted and implemented throughout the NHS immediately;
 - should be read in conjunction with guidance issued on obtaining valid consent, issued in March 2001 - *"Reference Guide to Consent for Examination or Treatment"* (available on the Web at www.doh.gov.uk/consent).

Further Work – Finding a Design Solution

5. In parallel with issuing this guidance, work is underway to explore potential design solutions that will reduce further the risk of intrathecal injection errors. The work is looking at the recommendations made in Professor Kent Woods' report "*The Prevention of Intrathecal Medication Errors*", particularly the use of infusion bags and the design of syringes and connectors. The outcomes of the work will be reported later.

Action

All NHS Trusts in which intrathecal chemotherapy is administered must ensure that this guidance is implemented immediately. The attached checklist should be completed and returned to the Regional Office's Cancer Lead by 30 November 2001.

Each Regional Office will ensure that the checklist has been completed and where compliance with part or parts of the guidance is not in place, that action is taken in conjunction with the NHS Trust, to ensure that this is rectified. Action to be completed by 31 December 2001

Each Regional Office will then report to the Chief Medical Officer identifying the action they have taken and confirming that the guidance is in force.

Summary

The key requirements of this guidance are:

- **A register must be established which lists designated personnel who have been trained and authorised to prescribe, dispense, check or administer intrathecal chemotherapy.**
- **A formal induction programme must be introduced for all new staff and training that is appropriate to their role in the prescribing, dispensing, checking or administering of chemotherapy must be provided.**
- **Regular training programmes for all professional staff who remain on the register must also be provided.**
- **All staff involved with chemotherapy must be provided with a written protocol, which reflects both this national guidance and additional local information.**
- **Intrathecal chemotherapy must only be prescribed by a Consultant or Specialist Registrar.**
- **A purpose designed intrathecal chemotherapy chart must be used.**
- **Intrathecal chemotherapy drugs must only be issued or received by designated staff.**
- **Intrathecal drugs must be kept in a lockable designated refrigerator when they cannot be administered immediately.**
- **Intravenous drugs must be administered before intrathecal drugs are issued, unless intrathecal chemotherapy is being given to a child under general anaesthesia.**
- **Intrathecal chemotherapy must be administered in a designated, separate area and within normal working hours.**
- **Checks must be made by medical, nursing and pharmacy staff at relevant stages throughout the administration process.**
- **All drugs that have life threatening consequences must be clearly labelled.**
- **The dilution of intravenous chemotherapy drugs must be standardised.**

SAFE ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY.

Register of Designated Personnel

1. All NHS facilities providing intrathecal chemotherapy treatment must introduce and maintain a register of designated personnel who have been trained and certified competent in one or more of the following tasks: prescribing, dispensing, checking and administering of intrathecal chemotherapy.
2. Inclusion on the register of doctors authorised to **administer** intrathecal chemotherapy will be limited to Consultants, Specialist Registrars, and (exceptionally) other nominated deputies, such as career grades. Specifically, Senior House Officers (SHOs) would not normally be expected to undertake this procedure, but where the caseload means they would gain sufficient experience (such as in major Cancer Centres), they may do so subject to training and certification. SHOs should never **prescribe** intrathecal chemotherapy. This should only be done by a Consultant or a Specialist Registrar.
3. In any NHS Trusts where it is deemed locally that there is a case for allowing SHOs to administer intrathecal chemotherapy, the Chief Executive of the NHS Trust, the Clinical Director of the Cancer Service, the Medical Director, the Nurse Director and the Chief Pharmacist will need to sign a waiver to the national policy. It will be their responsibility to ensure that patients are not put at additional risk by their decision. Where a waiver is in operation, the NHS Trust must notify the Regional Office Cancer Lead of their decision. The waiver is attached to the checklist that accompanies this guidance.
4. Individuals named on the register will have to demonstrate that they are competent to fulfil their designated roles and have been certificated as such. Staff moving from one hospital to another will take with them their certification in their training logbook or other training record. However, automatic transfer of certification will not occur and on arrival, individuals named on the register will have to demonstrate their competence to their new hospital's satisfaction before being placed on the register. For doctors, it will be the responsibility of the Medical or Clinical Director to ensure that the register is maintained and kept up to date. For nurses, the responsibility will rest with the Director of Nursing and for pharmacists, the Chief Pharmacist. It will also be the responsibility of these lead professionals to ensure that all staff who are new to the ward or department are provided with a formal period of induction. This should also include the provision to the new staff of copies of the NHS Trust's protocols and guidelines

relevant to prescribing, dispensing, checking and administering chemotherapy. Staff should verbally confirm they have received and read the correct protocols and guidelines, and sign to acknowledge receipt.

Being Prepared to Challenge

5. All staff involved with the care and treatment of patients receiving chemotherapy must be encouraged to challenge colleagues if, in their judgement, either protocols are not being adhered to or the actions of an individual may cause potential risk to a patient. Challenging of a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.

Training, Education and Induction

6. A formal induction course should be created for all staff, including nursing and pharmacy staff as well as SHOs and Specialist Registrars, appropriate to their needs with regard to prescribing, dispensing, storage, checking and practical administration of chemotherapy. Consideration is being given to the introduction of a national training package, including aids to support training such as videos and CD-ROM based evaluation tools. However, in the interim, as a minimum, formal induction must cover all potential clinical hazards associated with chemotherapy and the danger posed to patients if vinca alkaloids (e.g. Vincristine) are accidentally administered intrathecally. There should be a formal assessment to ensure all staff have read and understood all NHS Trust guidelines and protocols before allowing them to practise their respective roles in intravenous and intrathecal chemotherapy. It should be made clear to all new medical staff that they do **not** prescribe or administer intravenous or intrathecal chemotherapy until they have received appropriate training and their competency is agreed and documented.
7. Formal training and updating about the practical administration of intravenous and intrathecal chemotherapy should be a regular part of continuing professional education and training for all professional staff who remain on the register.
8. A written local protocol for prescribing, dispensing, storage, checking and administration of chemotherapy, including intrathecal chemotherapy, should be produced and given to all members of staff involved with chemotherapy. It must warn that vinca alkaloids (e.g. Vincristine) must only be administered intravenously and are almost always fatal when administered by other routes. The local protocol should cover all aspects of this guidance – from training,

through prescribing, dispensing, transportation, storage, checking and administration. It will additionally include the following local information:

- who can do what (the register);
- where things should be done (e.g. names of wards/other designated area, location of refrigerators etc);
- where to find key documents such as national guidance and local relevant protocols.

The provision of local information should complement the national guidance. It **should not change** elements described in this guidance.

9. A system must be put in place to ensure that only the latest editions of this guidance and local protocols are available to staff. Copies should be lodged in appropriate locations to ensure ease of access. Regular reviews of protocols by ward staff should be carried out and documented.

Prescribing

10. Only a Consultant or Specialist Registrar should be allowed to prescribe *intrathecal* chemotherapy.
11. A purpose-designed intrathecal chemotherapy chart should be used in all instances. The drug and route of administration must be clearly written in full on the chart. The chart should have space to allow for the signatures of the prescriber, dispenser, collector and administrator.

Preparation and Dispensing

12. Only trained designated oncology pharmacy staff should dispense intrathecal drugs (and vinca alkaloids). A register of pharmacy staff designated to dispense and issue drugs for intrathecal chemotherapy should be held in the pharmacy and maintained by the **Chief Pharmacist**. There should be a copy of the register of designated personnel eligible to prescribe and administer intrathecal chemotherapy held in the pharmacy and a mechanism introduced to ensure that the copy is always up-to-date. All relevant, approved NHS Trust protocols relating to chemotherapy should be lodged in the pharmacy.
13. Individuals named in the register will have to demonstrate that they are competent to dispense and/or issue intrathecal chemotherapy and have been

certified as such. As a minimum, training must cover all potential clinical hazards associated with chemotherapy and the danger posed to patients if vinca alkaloids (e.g. Vincristine) are accidentally administered intrathecally. There should be a formal assessment to ensure all staff have read and understood all NHS Trust guidelines and protocols before allowing them to practise their respective roles. Staff moving from one hospital to another will take with them their certification. On arrival at the new hospital they will still need to demonstrate their competence before being placed on the register of designated personnel of the new hospital.

14. Once dispensed, intrathecal and intravenous drugs must be stored in different areas. Cytotoxic drugs should **never** be made up on wards, except in exceptional circumstances (such as emergency cases of central nervous system (CNS) relapse leukaemia outside of normal working hours and where there is no available oncology pharmacist. See paragraph 22).

Issuing of Drugs

15. Drugs for intrathecal chemotherapy should only be issued from the pharmacy to the doctor or taken to the ward by a designated member of pharmacy staff. If the drugs are taken to the ward they must be either issued directly to the doctor who will be administering the intrathecal chemotherapy or placed in the designated refrigerator. In both instances, the member of pharmacy staff should sign the release of the drugs, identifying to whom the drugs were released or that they have been lodged in the relevant refrigerator. Where a doctor does not take direct receipt of the drugs, they must check the drugs and sign on retrieval from the refrigerator.

Timing of Issue of Drugs

16. Intrathecal drugs should be issued at a different time from drugs for intravenous chemotherapy. Intravenous drugs should be issued first. Only following written proof that any intravenous cytotoxic drugs for the named patient for that day have already been administered should the intrathecal drugs be issued. Issuer and collector must sign in the intrathecal area of the dedicated chemotherapy prescription chart. The only exception that can be made to the sequencing of intravenous therapy before intrathecal chemotherapy is when intrathecal chemotherapy is to be delivered to children under general anaesthesia (see paragraph 21).

Packaging and Transportation

17. Intrathecal chemotherapy drugs must always be packed and transported separately from treatments for administration by other routes.

Storage, Checking and Administration to Patients on Wards and in Clinics

Storage

18. Intrathecal chemotherapy drugs must be stored in a dedicated refrigerator reserved for this purpose alone. The refrigerator must be lockable and the key kept with the nurse-in-charge. All ward refrigerators must be locked at all times unless an authorised member of staff is retrieving drugs. Only a doctor on the register of designated personnel should remove drugs for intrathecal chemotherapy.

Patient Reviews

19. A consultant or an appropriately trained and nominated deputy from the register of designated personnel must review patients before intrathecal chemotherapy is administered. This is to ensure that the patient is fit for treatment, the correct tests have been conducted, the correct chemotherapy has been prescribed and that arrangements have been clearly made for the chemotherapy to be administered by the appropriate medical staff.

Checking and Administration of Drugs

20. Intrathecal chemotherapy must be administered in an area where no other cytotoxic drugs are being given or stored. An area should be designated for intrathecal chemotherapy and when intrathecal chemotherapy is being administered the area should **not** be used for any other purpose. This does **not** mean that an area should be put aside solely for the administration of intrathecal chemotherapy – this will not be practical in many units. Under no circumstances should cytotoxic drugs for intravenous use be stored in this area.
21. Medical staff, when preparing to treat a patient with intrathecal chemotherapy, must use a formal checking procedure to ensure that the right drug and the right dose is given to the right patient. These checks should include a chemotherapy trained nurse, the patient and, if appropriate, a relative or guardian in the checking procedure. Patients should be explicitly told the nature of the procedure, the route of administration, and the drug to be administered. The

checks made must be recorded. The intention of involving patients is not to remove the responsibility of clinicians for ensuring that the patient receives the required treatment, but rather through their engagement add another safety check to the process. It is recognised that where intrathecal chemotherapy is being given under general anaesthesia, the patient or guardian will not be able to participate in the final checking. In such cases, arrangements must be made for an additional check to be undertaken in theatre by the senior theatre nurse.

Out of Hours procedures

22. Under normal circumstances intrathecal chemotherapy should only be administered **within normal working hours**. Only in the most exceptional circumstances (such as CNS relapse of leukaemia, requiring emergency treatment) should intrathecal chemotherapy be given out-of-hours. In these instances, there should be a clear medical need for the procedure to be undertaken. If a medical case can be made, a consultant must undertake the prescribing.

Technical Issues

Labelling and Packaging

23. Labels added in pharmacy must have the route of administration printed clearly in the largest font size possible and emboldened. Negative labelling (i.e. "*Not for Intrathecal Use*") must never be used. For vinca alkaloids and for drugs with similar life threatening consequences, labels should have patient name, name of product, route of administration and a clear warning of the consequences of administration by other routes – for example, "***For Intravenous Use Only – fatal if given by other routes***". This guidance should be read in conjunction with the recommendation of the Committee on Safety of Medicines, as detailed in the Medicines Control Agency consultation letter MLX 275 dated 21 August 2001. (available on the Web at www.open.gov.uk/mca)

Dilution of Drugs for Intravenous Use

24. For patients over the age of 10 years, the pharmacy should dilute the volume of Vincristine to a maximum concentration of 0.1mg/ml. The drugs should be dispensed in a 10ml syringe **as a minimum**.

For children under the age of 10 years the Vincristine can be given undiluted at a concentration of 1.0mg/ml.

