New Zealand HealthCare Pharmacists' Association

quality safe use of medicines

RECOMMENDATIONS FOR THE SAFE ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY & INTRAVENOUS VINCA ALKALOIDS

In New Zealand

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Key requirements

- National Guidelines should be prepared based on the recommendations of a multi-disciplinary working group representing all parties involved in the use or administration of intrathecal chemotherapy and intravenous vinca alkaloids.
- Any agreed guideline must be fully implemented across all DHBs to ensure national consistency. Those DHBs that do not provide an intrathecal chemotherapy service would need to be aware of the required actions if cytotoxics are prescribed by this route in the future.
- A national standardised training programme and competency assessment should be implemented to ensure national consistency.
- There should be a national audit of all DHB's to confirm the implementation of any national guideline.
- In line with any national guidance a local protocol covering all aspects of prescribing through to administration of intrathecal chemotherapy should be developed.
- A register must be established and maintained in each DHB that lists designated personnel who have been trained and authorised to prescribe, prepare, dispense or administer cytotoxic medication.
- A formal induction/education programme must be provided for all new staff (including medical consultants) including training that is appropriate to their role in the prescribing, dispensing, checking, issuing or administering intrathecal chemotherapy, supported by the national training programme.
- Competence reviews by the DHB are required for all professional staff (including consultants) who remain on the register including written confirmation that they have read local protocols and any national guidance.
- Intrathecal chemotherapy must only be prescribed by a Medical Consultant, Associate Specialist or Specialist Registrar whose name is on the register. Prescriptions written by other Oncology/Haematology medical staff must be counter-signed by a Medical Consultant on the register.
- A purpose designed chemotherapy chart should be developed and disseminated.
- Intrathecal chemotherapy drugs must only be transported from the pharmacy by the administering doctor or designated personnel.
- Intrathecal chemotherapy drugs must be kept in a dedicated refrigerator or compartment between issuing and administration when they cannot be administered immediately.
- Intrathecal drugs must be packaged separately for delivery to the ward in designated containers and clearly labelled both on the syringe and outer container "For intrathecal use".
- Prior to administration, checks must be made in accordance with the "5 Rights" - patients should be involved in the process as far as they wish.
- Under normal circumstances intrathecal chemotherapy should only be administered within standards working hours, and in an area where no other cytotoxic drugs are given or stored concurrently.
- All intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) must be clearly and appropriately labelled.

- The dilution of vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) for intravenous injection must be to a volume of 50mL.

Background

To date, more than 23 incidents have occurred world-wide where the intravenous vinca alkaloid drug, vincristine, has been injected by the intrathecal route (via spinal injections) during a course of chemotherapy treatment for a cancer patient. As Vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are intended for intravenous use only, the intrathecal injection of vinca alkaloids can cause paralysis, almost always followed by death. The dangers of inadvertent administration of intrathecal vinca alkaloid administration were initially highlighted in 1963[(1)] with the first case report published in 1978[(2)] and the most recent event occurring in 2003. [(3)] Many of the reported cases resulted in fatalities. All reported cases have involved a combination of human and systems errors at all stages in the medicine supply chain

Although reports have been published, the true frequency of this type of event is unknown. However, in the UK it has been postulated that an event occurs 3 times in 100,000 treatments.[(4)] This order of magnitude is significant due to its rarity. The hazard is further compounded by its invariable fatal consequences, and that available recovery methods are of little or no benefit. In response to these incidents several strategies have been identified to minimise the risk of inadvertent intrathecal administration of Vinca alkaloids.[(5, 6, 7, 8)] The UK has produced national guidance on the administration of intrathecal chemotherapy [(9)] based on the external inquiry into the Nottingham incident during 2001.[(10)]

Aim

This document is intended to:

- Re-emphasise nationally that intrathecal chemotherapy is an important ongoing patient safety issue.
- Ensure that DHBs review and address intrathecal chemotherapy as part of their clinical governance responsibilities.
- Provide recommendations to ensure the safe administration of intrathecal chemotherapy. Predominantly relating to intrathecal treatment (ie. via spinal injection) but is also relevant to intraventricular chemotherapy (ie. via injection into the ventricles of the brain).
- Recommend national uniformity for the labelling and dilution of vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine). If other intravenous vinca alkaloids become available for chemotherapy in the future, they should be deemed to be covered by the principles of this guidance.
- Identify and address the issues around labelling and presentation of intrathecal doses.
- Identify the requirements for further national guidelines and educational resources.

1. Protocols

1.1 A written protocol for local use covering all aspects of the recommendations from prescribing through to administration should be produced. It should, additionally, include the following local information:

- Who, in the DHB, can do what (the register);
- Where, in the DHB things should be done (e.g. names of wards/designated areas, location of refrigerators etc);
- Location of copies of key documents such as other relevant protocols and any national guidance.
- Who is the designated lead responsible for overseeing compliance in the DHB with regard to this issue.

1.2 The local protocol should be read by all members of staff directly and indirectly involved in any aspect of the intrathecal chemotherapy procedure and form part of their training process/records. Information in the protocol about intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) should be kept separate from information about intrathecal chemotherapy wherever possible and should include clear warnings that they must only be administered intravenously and are almost always fatal when administered by other routes.

1.3 Local protocols should complement any national guidance produced and not contradict or change recommendations. Local protocols on intrathecal chemotherapy may be covered as part of the local protocol on the general chemotherapy service.

2. Register

2.1 All facilities providing an intrathecal chemotherapy service 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 intrathecal chemotherapy;
- Dispensing intrathecal chemotherapy (ie. preparing the dose, filling the syringe and placing it in packaging for transport);
- Delivery of intrathecal chemotherapy from the pharmacy;
- Checking intrathecal chemotherapy drugs prior to administration; and,
- Administering intrathecal chemotherapy.

2.2 The “designated lead” for the DHB has an overall responsibility for holding the register and ensuring that it is maintained and kept up to date. He or she may delegate day to day responsibility for maintaining individual aspects of the register to other senior staff, for example, the Pharmacy Service Leader for dispensing/delivery or the Director of Nursing for checking of administration.

2.3 A system must be put in place to ensure that only the most recent version of the register is available.

2.4 No form of "provisional" entry onto the register should be allowed. Individuals named on the register will have to demonstrate that they are competent to fulfil their designated roles and have been certified as such.

2.5 Staff moving from one hospital to another, or coming from overseas, will take with them their certification in their training logbook or other training record. However, automatic inclusion on any new hospital's register should **not** occur. On arrival, individuals will have to demonstrate their competence to their new DHB's satisfaction before being placed on the register.

All references to a "register" in this guidance refer to the intrathecal chemotherapy register. They do not refer to any other register such as the medical register.

3. Prescribing

3.1 Only Consultant Medical Staff, Associate Specialists or Specialist Registrars should be allowed to prescribe intrathecal chemotherapy, and only then if their names appear on the register of designated personnel and are deemed competent to prescribe intrathecal chemotherapy.

3.2 Intrathecal chemotherapy **cannot** be prescribed until staff have received appropriate induction and training; their competency is agreed and documented; and, their name has been included on the register.

3.3 House surgeons (HSs) and Senior House Officers (SHOs) should **never** prescribe intrathecal chemotherapy.

4. Chemotherapy Prescription Charts

4.1 The requirement of a purpose-designed national chemotherapy prescription chart should be explored. This could have an area dedicated to intrathecal chemotherapy.

4.2 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 (in full) of the prescriber, nurse checker and administrator of the intrathecal chemotherapy to enable a clear audit trail.

4.3 For computer generated prescriptions a digital signature that clearly identifies the prescriber, can be used as an adjunct to handwritten signatures.

5. Manufacture and Supply

5.1 Dispensing:

Only pharmacy staff whose names appear on the register should dispense (or package for transport to the ward) intrathecal chemotherapy drugs.

5.2 All Vinca Alkaloid doses in adults and children are to be diluted in a 50mL minibag for IV infusion.[13-27]

5.3 All Intrathecal doses must be diluted to a concentration of 2.5mg/ml or a final volume of 5ml to allow adequate volume of distribution across the CNS.[28-33]

5.4 Due to the inherent risk of intrathecal chemotherapy, with regard to the route of administration, doses should be manufactured on an individual patient basis and expiry should be limited to 24 hours.

5.5 All practices in the manufacturing unit should be in accordance with current GMP guidelines.

6. Storage of Intrathecal Chemotherapy

6.1 If storage is required between dispensing and delivery to the ward/clinic/theatre, intrathecal chemotherapy drugs must be stored in a dedicated location in the pharmacy.

6.2 The storage location for intrathecal chemotherapy doses should be clearly identified and **never be** used to store other chemotherapy dosage forms.

7. Labelling of Vinca Alkaloids and Intrathecals

7.1 Vinca Alkaloids should be clearly labelled both on the dosage form and outer container *"For intravenous use only — fatal if given by other routes".* Negative labels, such as "Not for intrathecal use", must never be used.

7.2 Intrathecal doses must have the route of administration printed clearly e.g. **For Intrathecal Use Only**. Negative labelling (i.e. "*Not for …… Use*") must **never** be used.

8. Delivery to the Ward/Clinic from Pharmacy

8.1 When dispensed to the wards from pharmacy all intrathecal chemotherapy drugs must be packaged separately from treatments for administration by other routes in a distinctive bag/container that is not used for any other purpose.

8.2 Drugs for intrathecal chemotherapy should only be issued from the pharmacy to the doctor who will be administering the drug, a chemotherapy trained nurse, or taken to the ward by a designated member of pharmacy staff whose name appears on the register.

8.3 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 a designated storage location that is clearly identified and **never** used to store other chemotherapy dosage forms.

9. Administration

9.1 Administration of intrathecal medication should only occur when there is sufficient qualified staff available to assist.

9.2 Under normal circumstances, intrathecal chemotherapy should be administered only within “normal” working hours i.e. at times when a full range of specialist expertise, knowledge and support is readily accessible. Only in the most exceptional circumstances (such as CNS relapse of leukaemia requiring emergency treatment) should intrathecal chemotherapy be given out of hours.

9.3 Medical staff, when preparing to treat a patient with intrathecal chemotherapy, must use a formal checking procedure to ensure that the patient identifiers, drug, dose, volume, route and rate is in concordance with the medication order. These checks should include a chemotherapy trained nurse or pharmacist.

9.4 If possible the checking process should be in a designated medicines room as a “time-out”, with both parties signing the administration documentation, immediately before administration.

9.5 The timing and location of any other chemotherapy administration should be such that it is separate from all medicines intended for intrathecal administration.

Note: A chemotherapy trained nurse is a nurse who has been assessed to be competent both to administer intravenous chemotherapy and check both intravenous and intrathecal chemotherapy.

10. Induction, training & continuing professional development

10.1 A national standardised training programme to ensure consistency of training across New Zealand should be established.

10.2 The “designated lead” for intrathecal chemotherapy in the DHB has overall responsibility for induction, training and continuing professional development related to intrathecal chemotherapy.

10.3 The “designated lead” may in turn wish to designate responsibility for training to a senior member of staff (medical, nursing or pharmacy) and ensure that this “lead trainer” role is reflected in that person’s job description and appraisal process. The “designated lead” may take on this lead trainer role.

10.4 The roles and responsibilities that should be undertaken by the “lead trainer” include ensuring:

- all staff (including consultants) who are new to a ward or department involved in intrathecal chemotherapy are provided with a formal induction;
- a formal induction course, covering all potential clinical hazards associated with intrathecal chemotherapy and the danger posed to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally, exists for all staff (nursing, pharmacy and medical - including consultants new to the hospital), appropriate to their proposed role in the intrathecal chemotherapy service i.e. prescribing, dispensing, issuing, checking, administration;
- as part of the induction/training it is made clear to all staff involved with the care and treatment of patients receiving intrathecal chemotherapy that they should 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;
- staff read local protocols as part of the induction. All staff, including consultants, should be required to sign a written confirmation that they have read these documents before being allowed to practise their respective roles. This signed confirmation should be updated at a designated time;
- the practical administration of intrathecal chemotherapy (from prescription onwards) is a regular part of continuing professional education and training for all professional staff who remain on the register. This can form part of continuing professional development in relation to chemotherapy more generally;
- all staff on the register are able to demonstrate they are competent for the roles they will be expected to undertake in providing an intrathecal chemotherapy service and that this competence is reviewed annually;

- staff should receive a certificate, or other written confirmation, that they have completed the training (or refresher training) and are competent/ remain competent to be included on the register for the designated task(s);
- staff that are not involved in providing an intrathecal chemotherapy service, but are likely to work in areas where different aspects of the service are provided, are aware that there is strict local protocols (or were applicable national guidance) for this service which prohibit their involvement in any aspect of this procedure.

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