PHARMACY

INTRATHECAL CHEMOTHERAPY

AUDIT

AIDE-MEMOIRE

Fourth Edition

J Hayes, on behalf of the
NHS Pharmaceutical Quality Assurance Committee
Date: 26th November 2008

This audit document is intended to be used to audit Pharmacy aspects of the safe administration of intrathecal chemotherapy, as part of the EL(97)52 Audit programme.

It is based on the requirements of HSC 2008/001. Where numbers in brackets appear at the end of each section, these indicate the relevant Paragraph of the HSC.

A record sheet for recording outcomes of audits is included in Appendix 1.

Changes since third edition:

- Complete re-numbering of references to current HSC document.
- Amendment to para 2.2, 2.3, 3.1, 3.3, 6.1, 8.3, 8.4, 10.3.
- Add section 3.6
- Complete review of section 11
- Equivalent changes to Appendix 1

1. Responsibility

1.1 There is a Trust "designated lead" for overseeing compliance with HSC 2008/001 identified by Chief Executive (17).

2. Volume of Activity

2.1 Classification of level of activity (18 - 20):

- No IT service provided.
- Low (1 - 10 procedures per annum).
- 11 - 499 procedures per annum.
- High (500 or more procedures per annum).
- Prepare chemotherapy for children
- Prepare chemotherapy out of hours

2.2 Low volume providers: Risk assessment performed to ensure the service is safe and in compliance with guidance. All staff must have the necessary competence for the task in question, training and refresher training takes place and appropriate staff are included on the register. This must be reviewed annually (19).

2.3 High volume providers: Risk assessment performed including assessment of capacity to check the daily workload does not exceed locally agreed safe levels. This should be reviewed annually (20).

2.4 No IT service provided by the Trust: Procedures in place describing actions to be taken in the case of emergencies requiring IT chemotherapy to be carried out in the Trust (15).

3. Induction, Training and Continuing Professional Development

3.1. All staff on the intrathecal chemotherapy register have completed formal induction training and an annual refresher training with review of competence. All have a current certificate of competence for their designated tasks (29). A copy of the register is available in pharmacy.

3.2. Induction/training includes challenging colleagues if in their judgement protocols are not adhered to or actions of an individual could cause potential risk to a patient.

3.3. Training includes the DVD available from the Department of Health to support the national guidance on the safe administration of intrathecal chemotherapy.

3.4. All staff sign annually to state that they have read the current national guidance and associated local protocols.

3.5. Intrathecal chemotherapy is part of CPD for all professional staff on the register.

3.6. Tasks on the register are competence based, they can be carried out by any members of staff (except for training grades) who have been appropriately trained, deemed competent by the designated lead or lead trainer(s) and whose names appear on the register of designated personnel for the task (14).

4. Local Protocols

4.1 Current protocols are available in Pharmacy and signed as read by all staff involved in intrathecal chemotherapy (67/68).

4.2 An effective document control system is in place.

5. Prescription Form

5.1 Purpose-designed IT chemotherapy prescription chart used in all instances (33).

5.2 Drug and route of administration written clearly in full on all charts. Charts include full signature of prescriber, issuer, collector, nurse checker, and administrator of the IT chemotherapy (33).

6. Prescribing and Prescription Transcription

6.1 Prescribing is only performed by those on the Trust register of approved prescribers (31 - 32). A current copy of the register is available in Pharmacy. FT1 and FT2 grades and ST1 and ST2 grades should never prescribe intrathecal chemotherapy. A waiver is not acceptable for this task. ST3 grades can prescribe intrathecal chemotherapy as long as they have been appropriately trained, deemed competent by designated lead or lead trainer(s) and their name appears on the register of designated personnel for this task.(32).

6.2 Appropriate arrangements are in place to ensure no errors occur during transcription of the prescription into pharmacy documentation.

7. Dispensing

7.1 All starting materials are appropriate for intrathecal use.

7.2 Dispensing (including preparing the dose, filling the syringe, and placing the syringe in packaging for transport) is only performed by those on the Trust register of designated personnel (34).

8. Labelling

8.1 All labels have the route of administration printed clearly in the largest font size possible and emboldened (41).

8.2 Negative labelling is never used (41).

8.3 Drug names on labels are international non-proprietary Names and in all other respects labels comply with MHRA best practice guidance and NPSA guidance on injectable medicines (42).

8.4 All vinca alkaloids are labelled with patient name, name of product, route of administration, expiry date, and a clear warning of the consequences of administration by other routes, e.g. "For intravenous use only - fatal if given by other routes". Negative labelling is never used (NPSA/2008/RRR004, http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/using-vinca-alkaloid-minibags).

9. Storage in Pharmacy

9.1 All storage of intrathecal chemotherapy is in a dedicated lockable container/refrigerator which is never used to store intravenous drugs (36).

10. Issuing and Transportation

10.1 All issue of intrathecal chemotherapy from pharmacy is either:- (37)

a) to the doctor who will be administering the drug, or
b) by a designated member of pharmacy staff whose name appears on the register taking the drug to the ward. In this case they are either
   i) issued directly to the doctor who will be administering the drug, or
   ii) placed in the designated container/refrigerator.

10.2 In all cases the member of pharmacy staff has signed the release of the drugs, and records show to whom the drugs were released or that they have been lodged in the relevant container/refrigerator (37).

10.3 All intrathecal chemotherapy is only issued following written confirmation that any intravenous chemotherapy for the named patient for that day have already been administered (38). Intrathecal chemotherapy charts are signed by both issuer and collector (38). The only exceptions are: -

- When intrathecal chemotherapy is to be delivered to children under general anaesthesia
- When a paediatric regimen/protocol requires intrathecal drugs to be administered first[1]

[1] = the exception is intended to cover protocols that were published before the initial guidance in 2001 came into effect and international protocols where this guidance is not in use. The expectation is that new regimens/protocols will be consistent with the sequencing set out in this guidance unless there is clear clinical need to deviate from it. (40)

10.4 In all cases where regimes involve IT chemotherapy combined with continuous intravenous chemotherapy, the intrathecal chemotherapy is only issued following written confirmation that the intravenous infusion has begun (39).

10.5 All IT drugs are packed and transported separately from treatments for administration by other routes (43).

10.6 All IT drugs are transported in a distinctive bag/container that is not used for any other purpose (43).

11. Dilution of Vinca Alkaloids - FOR INTRAVENOUS ADMINISTRATION.

Table 1: Summary of recommendations for treating patients with intravenous vinca alkaloids

		Patient Type		
		Adult	**Teenager**	**Child**
Clinical Area	**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.
	Child unit	N/A	Vinca dose in a syringe (no change)	Vinca dose in a syringe (no change to current practice, as stated in HSC 2003/010) – all intravenous vincristine for patients over the age of 10 years is diluted to a maximum concentration of 0.1mg/ml and dispensed in a 10ml syringe as a minimum. All intravenous vinblastine, vindesine and vinorelbine for patients over the age of 10 years is diluted to a minimum volume of 20ml. Note: For children under the age of 10 years intravenous vincristine, vinblastine, vindesine or vinorelbine can be given at a higher concentration

Pharmacy Intrathecal Chemotherapy Audit Aide-Memoire/Record Sheet

Appendix (1)

AIDE MEMOIRE	COMMENTS
1. Responsibility **1.1** There is a Trust "designated lead" for overseeing compliance with HSC 2008/001identified by Chief Executive (16). **2. Volume of Activity** 2.1 Classification of level of activity (18 - 20): • No IT service provided • Low (1-10 procedures per annum) • 11-499 procedures per annum • High (500 or more procedures per annum • Prepare chemotherapy for children • Prepare chemotherapy out of hours 2.2 Low volume providers: Risk assessment performed to ensure the service is safe and in compliance with guidance, reviewed annually. (19). 2.3 High volume providers: Risk assessment performed including assessment of capacity to check the daily workload does not exceed locally agreed safe levels, reviewed annually. (20). 2.4 No IT service provided by the Trust: Procedures in place describing actions to be taken in the case of emergencies requiring IT chemotherapy to be carried out in the Trust (15). **3. Induction, Training and Continuing Professional Development** 3.1 All staff on the intrathecal chemotherapy register have completed formal induction training and an annual refresher training with review of competence. All have a current certificate of competence for their designated tasks (29). A copy of the register is available in pharmacy. 3.2 Induction/training includes challenging colleagues if in their judgement protocols are not adhered to or actions of an individual could cause potential risk to a patient. 3.3 Training includes the DVD available from the Department of Health to support the national guidance on the safe administration of intrathecal chemotherapy. 3.4 All staff sign annually to state that they have read the current national guidance and associated local protocols. 3.5 Intrathecal chemotherapy is part of CPD for all professional staff on the register. 3.6 Tasks on the register are competence based, they can be carried out by members of staff (except for training grades) who have been appropriately trained, deemed competent by the designated lead or lead trainer(s) and whose names appear on the register of designated personnel for the task (14). **4. Local Protocols** 4.1 Current protocols are available in Pharmacy and signed as read by all staff involved in intrathecal chemotherapy (67/68). 4.3 An effective document control system is in place. **5. Prescription Form** 5.1 Purpose-designed IT chemotherapy prescription chart used in all instances (33). 5.2 Drug and route of administration written clearly in full on all charts. Charts include full signature of prescriber, issuer, collector, nurse checker, and administrator of the IT chemotherapy (33).	

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7.2 Dispensing (including preparing the dose, filling the syringe, and placing the syringe in packaging for transport) is only performed by those on the Trust register of designated personnel (34).

8. Labelling
8.1 All labels have the route of administration printed clearly in the largest font size possible and emboldened (41).
8.2 Negative labelling is never used (41).
8.3 Drug names on labels are international non-proprietary Names and in all other respects labels comply with MHRA best practice guidance and NPSA guidance on injectable medicines (42).
8.4 All vinca alkaloids are labelled with patient name, name of product, route of administration, expiry date, and a clear warning of the consequences of administration
by other routes, e.g. "For intravenous use only - fatal if given by other routes". Negative labelling is never used (NPSA/2008/RRR04).

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i) issued directly to the doctor who will be administering the drug, ii) placed in the designated container/refrigerator.
10.2 In all cases the member of pharmacy staff has signed the release of the drugs, and records show to whom the drugs were released or that they have been lodged in the relevant container/refrigerator (37).
10.3 All intrathecal chemotherapy is only issued following written confirmation that any intravenous chemotherapy for the named patient for that day have already been administered (38). Intrathecal chemotherapy charts are signed by both issuer and collector (38).
There are two exceptions (1) when intrathecal chemotherapy is to be delivered to children under general anaesthesia (2) when a paediatric regimen/protocol requires intrathecal drugs to be administered first. – see statement in main body of text. (40)
10.4 In all cases where regimes involve IT chemotherapy combined with continuous intravenous chemotherapy, the intrathecal chemotherapy is only issued following written confirmation that the intravenous infusion has begun (39).
10.5 All IT drugs are packed and transported separately from treatments for administration by other routes (43).
10.6 All IT drugs are transported in a distinctive bag/container that is not used for any other purpose (43).

11. Dilution of Vinca Alkaloids FOR INTRAVENOUS ADMINISTRATION For each clinical area Adult unit: Adult 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 hould be undertaken to determine the safest method of treatment Adolescent unit – Teenager 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 Child unit – Childrens vinca doses to be delivered in a syringe (no change to current practice as stated in HSC 2003/010) – all intravenous vincristine for patients over the age of 10 years is diluted to a maximum concentration of 0.1mg/ml and dispensed in a 10ml syringe as a minimum. All intravenous vinblastine, vindesine and vinorelbine for patients over the age of 10 years is diluted to a minimum volume of 20ml. Note: For children under the age of 10 years vincristine, vinblastine, vindesine or vinorelbine can be given at a higher concentration	