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HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy

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HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy

Summary

At least 55 incidents are known to have occurred around the world (a number in England) where the intravenous vinca alkaloid drug Vincristine has been injected intrathecally during the chemotherapy treatment of a cancer patient. These incidents have resulted in the paralysis or death of the patients involved.

The Government agreed a target to reduce the number of patients dying or being paralysed by maladministered spinal injections to zero by the end of 2001. National guidance [HSC 2001/022] was issued in November 2001 to support this target. This was updated and reissued in October 2003 [HSC 2003/010].

Between November 2004-2007 all NHS Trusts providing an intrathecal chemotherapy service were peer reviewed to ensure compliance against this guidance was being maintained. The peer review process identified a number of issues that needed to be considered when the guidance was next reviewed.

This circular covers the updated *National Guidance on the Safe Administration of Intrathecal Chemotherapy* (See Annex A). **This updated guidance replaces HSC 2003/010.** It sets out the minimum that should be expected of an NHS Trust providing an intrathecal chemotherapy service. It also sets out what to do in the exceptional circumstance where an intrathecal chemotherapy procedure needs to take place in a Trust that should not normally provide this service.

The section (including the waiver) on dilutions of intravenous vinca alkaloids originally included in HSC2003/010 has been removed. The guidance now cross-refers to a new National Patient Safety Agency (NPSA) rapid response report NPSA/2008/RRR004 entitled *Using Vinca Alkaloid Minibags (Adult/Adolescent Units)* which can be found at <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr> and which should be read in conjunction with this document.

Action

All NHS Trusts in which intrathecal chemotherapy is administered should ensure that this updated guidance is fully implemented by **31 December 2008.**

Each Strategic Health Authority should ensure:

- that the updated guidance is in force across all Trusts that provide an intrathecal chemotherapy service by 31 December 2008 and confirm that this is the case to justine.windsor@dh.gsi.gov.uk by **30 January 2009**.
- that those Trusts that do not provide an intrathecal chemotherapy service are aware of the actions that would need to be taken if, in exceptional circumstances, such a procedure needs to take place in their Trust.
- that Trusts are aware that a death from intrathecal injection of a vinca alkaloid is likely to be subject to scrutiny under the Corporate Manslaughter & Corporate Homicide Act 2007 – full implementation of this guidance should reduce the risk of error as low as is reasonably practical.

Commissioning PCTs should ensure that provider contracts (including contracts with NHSFTs and any independent sector providers contracted to provide ITC services for NHS patients) are in line with this guidance by **31-December 2008** and that commissioning PCTs confirm that this is the case for their NHSFTs to justine.windsor@dh.gsi.gov.uk by **30 January 2009**.

This Circular has been issued by:

Sir Liam Donaldson
Chief Medical Officer

**UPDATED NATIONAL GUIDANCE ON THE
SAFE ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY
7th January 2008**

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Purpose of Updated Guidance

1. This guidance:
 - highlights to the NHS that intrathecal chemotherapy remains an important patient safety issue and updates the national guidance issued in October 2003;
 - asks Chief Executives and NHS Boards to continue addressing intrathecal chemotherapy as part of their clinical governance responsibilities;
 - sets out the updated processes and practices that need to be in place to ensure the safe administration of intrathecal chemotherapy. This predominantly relates to treatment given by lumbar puncture (i.e. via spinal injection) but is also relevant to intraventricular chemotherapy (i.e. via injection into the ventricles of the brain);
 - should be read in conjunction with the National Patient Safety Agency's (NPSA) rapid response report NPSA/2008/RRR004 entitled *Using Vinca Alkaloid Minibags (Adult/Adolescent Units)* which can be found at <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr>
2. A summary of the key changes between this guidance and the 2003 version it supersedes is set out at **Annex A**.
3. Updated measures for inclusion in the Manual for Cancer Services, against which Trusts can self assess their compliance with this guidance, will be available later in the year.

Action Required

4. All NHS Trusts in which intrathecal chemotherapy is administered should ensure that this updated guidance is fully implemented by **31 December 2008**.
5. Each Strategic Health Authority should ensure:
 - that the updated guidance is in force across all Trusts that provide an intrathecal chemotherapy service by 31 December 2008 and confirm that this is the case to justine.windsor@dh.gsi.gov.uk by **30 January 2009**.
 - that those Trusts that do not provide an intrathecal chemotherapy service are aware of the actions that would need to be taken if, in exceptional circumstances, such a procedure needs to take place in their trust (para 14)
 - that Trusts are aware that a death from intrathecal injection of a vinca alkaloid is likely to be subject to scrutiny under the Corporate Manslaughter & Corporate Homicide Act 2007 – full implementation of this guidance should reduce the risk of error as low as is reasonably practical.

6. Commissioning PCTs should ensure that provider contracts (including contracts with NHSFTs and any independent sector providers contracted to provide ITC services for NHS patients) are in line with this guidance by **31st December 2008**. and that commissioning PCTs confirm that this is the case for their NHSFTs to justine.windsor@dh.gsi.gov.uk by **30 January 2009**.

Background

Patient safety

7. Patient safety is a key strategic objective for the Department of Health. The work began with the publication of "*An Organisation with a Memory*" in 2000 and its recommendations became policy through the NHS Plan. A progress report on implementation – "*Building a Safer NHS for Patients*" was published in April 2001. Since then steps to improve patient safety across the NHS have included the publication of "*Safety First: A report for patients, clinicians and healthcare managers*" in December 2006. This followed a review into the organisational arrangements that support patient safety. The Department maintains oversight of the implementation of '*Safety First*' although the National Patient Safety Agency (NPSA) either solely or in conjunction with other organisations (such as the National Institute for Health & Clinical Excellence, the NHS Institute and the NHS) is expected to take forward the majority of the recommendations. Patient safety is also being taken forward through a programme of reform including regulation of health and social care, professional regulation and world class commissioning.

Intrathecal chemotherapy

8. A major patient safety issue is the danger to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are injected intrathecally (via spinal or intraventricular injections) during the chemotherapy treatment of a cancer patient. Vinca alkaloids are intended for intravenous use only. If injected intrathecally they cause paralysis almost always followed by death. The World Health Organisation has identified 55 intrathecal chemotherapy incidents worldwide.
9. A number of the reported incidents took place in England, the most recent in January 2001, following which the Government agreed a target to reduce the number of patients dying or being paralysed by maladministered spinal injections to zero by the end of 2001.
10. In response to this, the Department of Health established a working party, chaired by Professor Mike Richards, National Cancer Director, and including experts from all relevant clinical fields to develop national guidance. This was issued to the NHS in November 2001 so that practice would be uniform across the country and staff moving from one Trust to another would not have to adapt to a different procedure. The guidance was updated and reissued in October 2003.
11. To ensure that compliance with the updated national guidance was maintained in the longer term, a series of measures were developed for inclusion in the Manual of Cancer Services. Compliance with measures in the Manual is assessed by a process of national cancer peer review. A new round of cancer peer review was launched in November 2004 and, as part of this, each of the then 34 cancer

networks (and their Trusts) were peer reviewed once over a three year period against all the measures in the Manual including the new measures on intrathecal chemotherapy. A number of issues and queries arose during peer review and the working party was reconvened – see **Annex B** for updated membership – to advise on possible changes required to the guidance following peer review and to take into account new safety measures, such as the introduction of minibags for the administration of vinca alkaloids, that were being considered by the NPSA.

12. This is the resulting updated guidance and it supersedes HSC2003/010. It sets out the minimum that should be expected of an NHS Trust providing an intrathecal chemotherapy service. It also sets out what to do in the exceptional circumstance where an intrathecal chemotherapy procedure needs to take place in a Trust that should not normally provide this service [see para 14].

Other relevant work

13. The National Patient Safety Agency (NPSA) has issued a rapid response report NPSA/2008/RRR004 and supporting information on *Using Vinca Alkaloid Minibags (Adult/Adolescent Units)* which should be read in conjunction with this guidance. It has also confirmed that it plans to undertake a ‘purchasing for safety’ initiative, which will include work with the healthcare industry to obtain devices with safe connectors for use in the NHS.

Summary

14. The key actions of this guidance are:

- a. The Chief Executive, who has overall responsibility for ensuring compliance with this guidance, should identify a “**designated lead**” to oversee compliance within the Trust [para 17].
- b. **Low volume trusts** (10 procedures or less p.a) should look at their caseload and undertake a risk assessment to decide if the service should continue to provide an intrathecal chemotherapy service and plan appropriately – this position should be reviewed annually [para 19].
- c. **High volume trusts** (500 procedures or more p.a) should undertake a risk assessment (including an assessment of capacity to check that the daily workload does not exceed locally agreed safe levels) to ensure the safety of the service – this position should be reviewed annually [para 20].
- d. A **register** should be established and maintained which lists designated personnel who have been trained and authorised to prescribe, dispense, issue, check or administer intrathecal chemotherapy [para 20]. Staff moving from one hospital to another should not be automatically included on the new hospital’s register [para 25].
- e. The ‘designated lead’ has responsibility for **induction, training and continuing professional development** related to ITC although responsibility can be delegated to a lead trainer(s). A number of tasks should be carried out including running a formal **induction** programme, annual **reviews of competence** and **written confirmation** of competence for staff for the designated task(s) [para 29].
- f. **Tasks on the register are competency based** i.e. 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 appears on the register of designated personnel for that task. This is relevant to prescribing, dispensing, issuing, checking and administration.
- g. A purpose designed intrathecal chemotherapy **chart** – or purposed designed intrathecal chemotherapy section on a general chemotherapy chart - should be used [para 33].
- h. Intrathecal chemotherapy drugs should be kept in a **dedicated lockable container/refrigerator** in the pharmacy between dispensing and issuing [para 36] and should be stored in a dedicated lockable container/refrigerator between issuing and administration when they cannot be administered immediately [para 44-45].

- i. **Intrathecal chemotherapy drugs should be administered after intravenous chemotherapy drugs and should only be issued following written confirmation that any intravenous chemotherapy drugs have already been administered.** The only exceptions are:
 - where intrathecal chemotherapy is being given to a child under general anaesthesia; or
 - where the paediatric protocol/ regimen requires that ITC is given first.If a regimen involves intrathecal chemotherapy combined with continuous intravenous chemotherapy, **it is only acceptable to issue intrathecal chemotherapy once there is evidence that the infusional intravenous chemotherapy has started** [paras 38-40].
- j. An **area should be designated for administration of intrathecal chemotherapy** for the entire session even if only one such procedure is to take place in that session. A permanently designated area for intrathecal chemotherapy is desirable for high volume trusts but not essential [para 49-51].
- k. **Checks** should be made in accordance with the guidance - patients should be involved in the checking process as far as they wish [52-55].
- l. **Waivers** can be signed for one situation only, to allow **ST1 and ST2 grades to administer** intrathecal chemotherapy, although not in low volume trusts. Waivers need to be signed by the Chief Executive, Medical Director, Director of Nursing and Chief Pharmacist to be valid [para 58]
- m. Under normal circumstances intrathecal chemotherapy should only be administered **within normal working hours** [para 62].
- n. A **written local protocol** covering all aspects of the national guidance from prescribing through to administration should be produced including local information identified in this guidance [para 67].
- o. The National Patient Safety Agency Rapid Response Report NPSA/2008/RRR004 and supporting information on *Using Vinca Alkaloid Minibags (Adult/Adolescent Units)* should be read in conjunction with this guidance [para 66].

NHS organisations that do not provide an intrathecal chemotherapy (ITC) service

15. An emergency requiring intrathecal chemotherapy to be carried out in a “non-intrathecal chemotherapy” hospital should be a very rare occurrence. Should this situation arise, for example if a patient is deemed to be too unwell to move, the procedure should only take place following discussion with an NHS organisation that routinely carries out intrathecal chemotherapy (usually with the designated lead for ITC or a clinician on the ITC register) and, if possible, the Strategic Health Authority. Where possible, members of the former should come over to supervise the procedure. The Medical Director and Chief Executive of the host NHS Trust would need to be involved in the decision and there would need to be clear documentation about why this situation had arisen, actions taken and outcome, which would feed into the risk management arrangements of the Trust. The SHA should be informed that such a procedure has had to take place if they could not be contacted beforehand.

NHS organisations that provide an intrathecal chemotherapy service

Overall responsibility

16. The Chief Executive of each NHS Trust providing an intrathecal chemotherapy service has overall responsibility for ensuring compliance with this national guidance.
17. The Chief Executive should identify a single lead to oversee compliance with this guidance who will be accountable to them for this issue – referred to as “**designated lead**” throughout this guidance. This lead can be a doctor, nurse or pharmacist. Where there is an adult and paediatric service, a “deputy designated lead” may also be appointed.

Volume of service

18. The 2004-2007 national cancer peer review programme showed that intrathecal chemotherapy services are delivered in 131 NHS Trusts. 18 of these Trusts were low volume trusts carrying out 10 procedures or less per annum and 11 were high volume trusts carrying out 500 procedures or more per annum. Peer review showed that average overall compliance in high and low volume trusts was slightly lower than in other trusts (90% and 87% respectively compared to 93%) but not sufficiently lower as to require low volume trusts to stop providing this service or high volume trusts to make major changes to service provision.

Low volume providers

19. Although it is acceptable for a Trust to deliver an intrathecal chemotherapy service even though it carries out a low volume of this service (10 procedures or less each year), Chief Executives of such providers will need to ensure that a risk assessment has been undertaken to ensure the safety of this service (including that all staff have the necessary competence for the task in question, training and refresher training takes place and appropriate staff are included on the register) and be sure that the service is fully compliant with this revised guidance. This position should be reviewed annually.

High volume providers

20. Where a Trust provides a high volume intrathecal chemotherapy service (500 procedures or more per annum) multiple procedures will almost inevitably be given in a single session. In these circumstances: staff can become tired, services can over run and mistakes can happen. Chief Executives of high volume providers should ensure a risk assessment is undertaken (including an assessment of capacity to check that the daily workload does not exceed locally agreed safe levels) to ensure the safety of the service. This position should be reviewed annually.

Register of designated personnel

21. All NHS facilities providing an intrathecal chemotherapy service should 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 [para 30];
 - dispensing intrathecal chemotherapy (ie. preparing the dose, filling the syringe, placing it in packaging for transport and transporting the drug if it is not issued directly to the collector [para 33 & 36];
 - issuing intrathecal chemotherapy from the pharmacy [para 36];
 - checking intrathecal chemotherapy drugs prior to administration [para 51]; and,
 - administering intrathecal chemotherapy [para 55].
22. The “designated lead” for the Trust has 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 Chief Pharmacist for dispensing/issuing or the Director of Nursing for checking.
23. A system should be put in place to ensure that only the latest edition of the register is available to staff. The development of electronic registers maintained on Trust intranets may be the preferred method for some Trusts. However, to ensure ease of access, an up to date hard copy of the full register should be lodged, as a minimum, in each location in a Trust where intrathecal chemotherapy is dispensed/ issued and administered. This should include the oncology in-patient area, even if intrathecal chemotherapy is never administered in that location.
24. No form of “provisional” entry onto the register should be allowed for any staff.
25. Individuals named on the register will have to demonstrate that they are competent to fulfil their designated roles and have been certified as such [para 28]. Staff moving from one hospital to another will take with them their certification in their training logbook or other training record. However, automatic inclusion on the new hospital’s register should **not** occur. On arrival, individuals will have to demonstrate their competence to their new hospital’s satisfaction before being placed on the register.
26. 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.

Induction, training & continuing professional development

27. The “designated lead” for intrathecal chemotherapy in the Trust has overall responsibility for induction, training and continuing professional development related to intrathecal chemotherapy.
28. He or she may wish to designate responsibility for training to senior members of staff (medical, nursing and/or pharmacy) and should ensure that the “lead trainer(s)” role is reflected in the person’s job description and appraisal process. It should be made clear to the lead trainer(s) by the designated lead that he/she/they are accountable for ensuring the roles and tasks described below take place. The “designated lead” for intrathecal chemotherapy may take on this lead trainer role.
29. Roles and tasks that should be undertaken by the “lead trainer(s)” include ensuring that:
 - a formal induction course is available and attended by staff (nursing, pharmacy and medical - including consultants new to the hospital) appropriate to their proposed role in the intrathecal chemotherapy service ie. prescribing, dispensing, issuing, checking and administration;
 - the induction covers: all potential clinical hazards associated with intrathecal chemotherapy including the danger posed to patients if intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are accidentally administered intrathecally; and new safer practice recommendations from the NPSA on the presentation of intravenous vinca alkaloids for adults and for young people in an adult or dedicated teenage setting (para 65);
 - 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 involved in prescribing, dispensing, issuing, checking or administering intrathecal chemotherapy read the national guidance and associated local protocols as part of the induction. These staff, including consultants, should be required to sign a written confirmation that they have read and understood these documents before being allowed to practice their respective roles. This signed confirmation should be updated annually;
 - all staff on the register are able to demonstrate that 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 alongside how often staff carry out this procedure for ITC;

- staff should receive a certificate, or other written confirmation, that they have completed the training (or annual refresher training) and are competent/ remain competent to be included on the register for the designated task(s);
- clinical staff that are not involved in providing an intrathecal chemotherapy service (ie. not on the register for a given task), but are likely to work in areas where different aspects of the ITC service are provided should not take part, or be asked to take part, in any part of this process. It is the responsibility of those individuals on the register to ensure that any colleagues they involve in this process are on the register for the task in question.

30. A DVD to support local induction/training programmes in the safe administration of intrathecal chemotherapy is available. Copies of this DVD are available from:

Department of Health Publications
PO Box 777
London, SE1 6XH
Fax: 01623 724524
Email: dh@prolog.uk.com
Textphone (minicom users): 08700-102870 Mon-Fri 8am-6pm)

This DVD was produced to support the original guidance. Although the updated guidance has changed in some respects, the general messages in the DVD hold true. Additional information on using the training film can be found by searching "intrathecal chemotherapy training" on the Department's website:

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

Prescribing

31. Only staff appropriately trained, deemed competent by the designated lead or lead trainer(s) and whose names appear on the register of designated personnel for prescribing should be allowed to prescribe intrathecal chemotherapy. This includes medical staff (including consultants) and non-medical prescribers new to the hospital.
32. 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.

Charts

33. A purpose-designed intrathecal chemotherapy prescription chart should be used in all instances. This can be a dedicated chart or an area dedicated to intrathecal chemotherapy on a chemotherapy chart. The drug and route of administration should be clearly written in full on the chart. The chart should have space to allow for the signatures (in full) of the prescriber, issuer, collector, nurse checker and administrator of the intrathecal chemotherapy to enable a clear audit trail.

Managing intrathecal chemotherapy drugs

Dispensing

34. Only staff appropriately trained, deemed competent by designated lead or lead trainer(s) and whose names appear on the register of designated personnel should dispense intrathecal chemotherapy drugs. For the purposes of this guidance, dispensing is the activity of preparing the dose, filling the syringe and placing the syringe in packaging for transport. It will also include transport if the drug is not issued directly to the collector [para 36].
35. It is acceptable for batches of intrathecal chemotherapy drugs to be dispensed for high volume paediatric services (500 procedures or more per annum). However, in these cases each dose within the batch should be signed for separately by the issuer and collector.

Storage in the pharmacy

36. If storage is required between dispensing and issuing, intrathecal chemotherapy drugs should be stored in a dedicated lockable container/refrigerator in the pharmacy. This facility should **never** be used to store intravenous drugs. If such a facility cannot be made available in the pharmacy then it should be stored in a lockable container/refrigerator reserved for the purpose elsewhere prior to issue.

Issuing of drugs

37. Drugs for intrathecal chemotherapy should only be issued from the pharmacy to the doctor who will be administering the drug (the collector) or taken to the ward by a designated member of pharmacy staff whose name appears on the register. If the drugs are taken to the ward they should be either issued directly to the doctor who will be administering the intrathecal chemotherapy or placed in the designated container/refrigerator [para 43]. 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 container/refrigerator. Where a doctor does not take direct receipt of the drugs, they should check the drugs and sign on collection from the designated container/refrigerator.

Timing/sequencing of issue of drugs

38. Intrathecal chemotherapy drugs should be issued at a different time from drugs for intravenous chemotherapy. **Intravenous chemotherapy drugs should be issued first. Only following written confirmation that any intravenous chemotherapy drugs for the named patient for that day have already been administered should the intrathecal chemotherapy drugs be issued by the pharmacy.** Issuer and collector should sign in the intrathecal chemotherapy prescription chart. This will ensure that the drugs which could prove fatal if given by other routes will

have been used before the intrathecal chemotherapy drugs are issued. It is not acceptable to inconvenience patients by asking them to attend on two occasions. Trusts should consider either changing established working practices or reviewing staff hours to comply with national guidance.

39. Where a regimen involves intrathecal chemotherapy given during continuous intravenous chemotherapy, it is only acceptable to administer intrathecal chemotherapy once the intravenous infusion(s) have started. **Written confirmation that intravenous infusion(s) have begun should be given prior to issue of intrathecal chemotherapy drugs from the pharmacy.**
40. The only exceptions that can be made to the sequencing of intravenous chemotherapy before intrathecal chemotherapy are related to the treatment of children and are as follows:
 - when intrathecal chemotherapy is to be delivered to children under general anaesthesia;
 - when a paediatric regimen/protocol requires intrathecal drugs to be administered first¹.

1 - This 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 a clear clinical need to deviate from it.

Labeling, packaging & transportation

41. Labels added in pharmacy should have the route of administration printed clearly in the largest font size possible and emboldened eg. **For intrathecal Use Only**. Negative labelling (i.e. “*Not for Use*”) should **never** be used.
42. The Medicines & Healthcare products Regulatory Agency (MHRA) and the NPSA have published general guidance on labeling and packaging of medicines to improve patient safety. Although this guidance is primarily intended for the pharmaceutical industry and NHS medicines procurement groups, there are design recommendations that are pertinent to the safe labeling and packaging of intrathecal chemotherapy prepared in a ready-to-administer form in hospital pharmacy departments. The most recent publication from the NPSA (April 2007) provides detailed guidance on injectable medicines. This information is available at: <http://www.npsa.nhs.uk/patientsafety/medication-zone/design-for-patient-safety-medication-topics>
43. Intrathecal chemotherapy drugs should always be packed and transported separately from treatments for administration by other routes. Intrathecal chemotherapy drugs should be transported in a distinctive bag/container that is not used for any other purpose.

Storage once issued ie. outside the pharmacy

44. It is not desirable to store intrathecal chemotherapy drugs outside the pharmacy between issuing and administration and emergency stocks should never be held on the ward. However, if the intrathecal chemotherapy drugs have to be issued and there will be a short delay before administration the intrathecal chemotherapy drugs should be stored in a dedicated container/ refrigerator reserved for this purpose alone.
45. The container/refrigerator should be lockable and the key kept with a member of staff in-charge of the ward/location. It should be locked at all times unless an authorised member of staff is collecting drugs. Only the member of staff on the register who is designated to administer intrathecal chemotherapy drugs should remove intrathecal chemotherapy drugs from the container/refrigerator.
46. Where a batch of intrathecal chemotherapy drugs has been dispensed at a high volume paediatric service (one carrying out 500 or more intrathecal chemotherapy procedures per annum), each dose should be removed from the lockable container/refrigerator for administration individually - **never** as a batch.

Patient consent, reviews, location, checks and administration to patients

Patient consent

47. Full patient consent (See “Reference Guide to Consent for Examination or Treatment” at www.dh.gov.uk/consent) is required for a course of chemotherapy rather than each dose within the course. However, when attending for each dose, patients should be explicitly told the nature of the procedure, the route of administration, and the drug to be administered.

Patient reviews

48. A member of staff who is on the register of designated personnel who can administer intrathecal chemotherapy should 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 intrathecal chemotherapy to be administered by the appropriate member of staff. As part of this review, the member of staff should check that any staff assisting in the procedure are also on the register for the task they are carrying out. Confirmation that the review has taken place should be written in the patient’s medical notes or intrathecal prescription.

Location

49. Intrathecal chemotherapy should be administered in an area where no other chemotherapy drugs are being given or stored. An area should be designated for administration of intrathecal chemotherapy for the entire session even if only one such procedure is to take place in that session. This area should be a separate room (ie. with walls and a door). A curtained off area with a sign is not a suitable alternative. It is accepted that exceptions will need to be made for patients in an operating theatre or intensive care unit – in these circumstances extra caution will be needed to ensure that no other chemotherapy is in the vicinity at the time of the procedure and that the right drug is administered intrathecally.
50. When intrathecal chemotherapy is being administered the designated area should **not** be used for any other purpose. **Under no circumstances** should any other form of chemotherapy take place in this area during that session. Chemotherapy drugs for intravenous use should **never** be stored in this area, even when the area is not in use.
51. Permanent designation of an area for intrathecal chemotherapy is desirable (particularly in high volume trusts) but not essential.

Checks

52. Clinical staff, when preparing to treat a patient with intrathecal chemotherapy should use a formal checking procedure to ensure that the right drug and the right dose is given by the right route to the right patient. These checks should include a member of staff (not the member of staff who will be administering the ITC on that occasion) appropriately trained, deemed competent and on the register to carry out this check, the patient and, if appropriate, a relative or guardian.
53. Some patients may choose to check the name, dose and route of the drug(s) written up on the chart with those on the label of the syringe. They should be enabled to do this if they so wish. However it is not the intention of the guidance to make patients take on a greater burden of responsibility than that with which they are comfortable. The intention of involving patients is not to remove the responsibility of clinicians for ensuring that the patient receives the required treatment, or to put responsibility at the patient's door but rather, through their engagement, add another safety check to the process. As a minimum the member of staff administering the intrathecal chemotherapy should confirm the identity of the patient, explain the nature of the procedure, the drug that is to be administered and the route of administration. 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 should be made for an additional check to be undertaken in theatre by another member of staff such as a senior theatre nurse or an Operating Department Practitioner.
54. As a further check, staff may find it helpful to bear in mind that Methotrexate, the drug most commonly given intrathecally, is yellow.
55. The checks made should be recorded.

Administration of drugs

56. Administration of intrathecal chemotherapy should only be undertaken by staff appropriately trained, deemed competent by designated lead or lead trainer(s) and whose name is included on the register of designated personnel to carry out this task. This also applies to medical staff (including consultants) new to the hospital.
57. A technically difficult lumbar puncture may need the assistance of staff not on the register, for example, a radiologist to position the needle under imaging control. This is acceptable - however, these staff should **never** be involved in any other aspect of the process and should never administer the intrathecal chemotherapy unless they have received appropriate training, been deemed competent by the designated lead or lead trainer(s) and their name included on the register of designated personnel for the task in question.

Waivers for junior and middle grades to administer intrathecal chemotherapy

58. It is not usually appropriate for junior grades to administer intrathecal chemotherapy as they may not have the necessary experience and expertise to carry out this procedure safely:
- a waiver for staff at FT1 and FT2 level to administer intrathecal chemotherapy should never be given;
 - ST1 and ST2 grades should not normally be expected to undertake this procedure. However, where the caseload means they would gain sufficient experience (such as in major cancer centres), they may do so subject to suitable training, being deemed competent by designated lead or lead trainer(s) and having had their name placed on the register for this task. In any NHS Trusts where it is deemed, by the “designated lead”, that there is a case for allowing ST1 and ST2 grades to administer intrathecal chemotherapy a **waiver** to the national policy will need to be signed by **all** of the following:
 - Chief Executive of the NHS Trust;
 - Medical Director;
 - Nurse Director; and
 - Chief Pharmacist.
 - ST3 level doctors may administer intrathecal chemotherapy after suitable training, being deemed competent by designated lead or lead trainer(s) and having had their name placed on the register for this task - a waiver is not needed.
59. A template for the ST1 and ST2 grade waiver is attached at **Annex C**. In signing the waiver, the Chief Executive and all relevant senior clinicians are confirming that they have considered the position for the Trust and made a balanced judgement of the risks and benefits of implementing this recommendation in their local services. In signing the waiver they are confirming that they believe that the Trust’s systems are safe and that patient safety will not be adversely affected by the decision to allow ST1s and ST2s to administer intrathecal chemotherapy. It will be their responsibility to ensure that patients are not put at additional risk by their decision. It is **not** acceptable to issue a waiver for ST1s and ST2s to deliver intrathecal chemotherapy in a low volume trust (10 procedures or less per annum).
60. Although the waiver covers the ST1 and ST2 grades in general, individual ST1 and ST2 grade staff will still need to undertake training and be certified competent to carry out this task before their name can be placed on the register.
61. Where a waiver is in operation, the NHS Trust should notify, in writing, the SHA Medical Director of their decision. The waiver needs to be reviewed annually and if it is to be renewed it should be signed again by all parties and sent to the SHA for information.

Miscellaneous

Out of hours

62. 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.
63. 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 must be a clear clinical need for this procedure to be undertaken without delay to the next working day. If such a case can be made a member of staff on the register for prescribing should prescribe the intrathecal chemotherapy. Only if the dose cannot be made up in pharmacy should it be prepared on the ward by a chemotherapy trained nurse.
64. The “designated lead” for the Trust would need to be notified that such a procedure had had to take place out of hours and there would need to be clear documentation about why this situation had arisen, actions taken and outcome. A record should be maintained of the number of times this procedure has to take place outside of normal working hours.

Prescribing intraventricular chemotherapy

65. There are differences of opinion as to whether the doses of chemotherapy drugs such as methotrexate and cytarabine should be the same or different whether given by the lumbar intrathecal route or intraventricularly by a system such as an Ommaya reservoir. The clinical trial protocol or guideline in use should always be followed carefully.

Minibags & dilutions of intravenous vinca alkaloids

66. A Rapid Response Report on the dilution and method of administration of vinca alkaloids has been issued by the NPSA. It is essential that this report NPSA/2008/RRR004 is read in conjunction with this guidance. It can be found at <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/rapidrr>

Local protocols

67. A written local protocol covering all aspects of the national guidance from prescribing through to administration should be produced. It should, additionally, include the following local information:
 - who, in the Trust, can do what (the register);
 - where, in the Trust, things should be done (e.g. names of wards/designated areas, location of lockable containers/refrigerators etc);
 - where, in the Trust, to find copies of key documents such as national guidance, relevant local protocols and the full register.
68. The local protocol should be read by all members of staff directly involved in any aspect of the intrathecal chemotherapy procedure.
69. The provision of local protocols should complement the national guidance. Local protocols **should not change** elements described in this guidance. However, local protocols can enhance national guidance where that is thought helpful.
70. A system should be put in place to ensure that only the latest edition of the national guidance and associated local protocols are available to staff. The development of electronic protocols maintained on Trust intranets may be the preferred method for some Trusts. However, to ensure ease of access, up to date hard copies of the national guidance and associated local protocols should be lodged, as a minimum, in each location in a Trust where intrathecal chemotherapy is dispensed/issued and administered. This should include the oncology in-patient area, even if intrathecal chemotherapy is never administered in that location.
71. The local protocol on the intrathecal chemotherapy service may form part of the local protocol on the general chemotherapy service.

Updated Guidance: Key Changes from HSC/2003/010

The majority of the guidance is unchanged but some revisions have been made following feedback from peer review and developments by the National Patient Safety Agency. The key changes are summarised below:

- The guidance is now competency based ie. the various tasks on the register can be carried out by any member 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 that task. References to specific staff groups or combinations of staff being able to carry out certain tasks have been removed from sections on prescribing, dispensing, issuing, checking and administration.
- Clinical staff that are not involved in ITC process no longer have to receive an induction about ITC or confirm in writing that they understand not to get involve in any aspect of ITC process. Responsibility now rests with staff on the register to ensure that they only involve others in the process who are also on the register for relevant tasks [para 28 & 47].
- An additional exception has been included for sequencing in relation to children. It relates to paediatric regimens/protocols that require intrathecal drugs to be given first [para 39].
- The patient review should now include a check by the person to administer the drug that any staff assisting them are on the register [para 47].
- References to SHOs have been updated to take into account the new FT1 and 2 and ST1,2 and 3 grades. Specific references are made to these grades in relation to prescribing [para 31] and administration [para 57-60].
- There is clarification about what a designated area for administration of ITC is and is not classed as. Also, the need to include a permanent designated area in longer term building plans has been removed [para 48-50].
- The local protocols section has been moved to the end of the guidance [para 66-70].
- The section (including the waiver) on dilutions of intravenous vinca alkaloids has been removed. The guidance now cross refers to a new NPSA rapid response report on this subject [para 65].

Working Party: Updated Membership

	Role
Mike Richards	<ul style="list-style-type: none"> ▪ National Cancer Director [Chair]
David Cousins	<ul style="list-style-type: none"> ▪ Head of Safe Medication Practice and Medical Specialties (NPSA)
Kent Woods	<ul style="list-style-type: none"> ▪ CE, Medicines & Healthcare products Regulatory Agency (MHRA)
Clive Bray	<ul style="list-style-type: none"> ▪ Director, Device Technology & Safety, MHRA
Brian Toft	<ul style="list-style-type: none"> ▪ Independent Consultant
Tim Root	<ul style="list-style-type: none"> ▪ Specialist Pharmacist, Clinical Governance & Technical Services, London Eastern & South East Specialist Pharmacy Services c/o Chelsea & Westminster Hospital, ▪ Past Chair, British Oncology Pharmacy Association (BOPA)
David Webb	<ul style="list-style-type: none"> ▪ Consultant in Paediatric Haematology, GOSH
Tim Eden	<ul style="list-style-type: none"> ▪ Professor of Teenage & Young Adult Cancer, University of Manchester, ▪ Honorary Consultant, Christie Hospital NHS Trust & Central Manchester & Manchester Children's University Hospitals NHS Trust & Former Professor of Paediatric Oncology, Manchester
Julie Bayliss	<ul style="list-style-type: none"> ▪ Paediatric modern matron – haematology, oncology, palliative care, GOSH
Denise Blake	<ul style="list-style-type: none"> ▪ Senior Lead Clinical Pharmacist, Paediatric Oncology, Newcastle upon Tyne Hospitals NHS Foundations Trust ▪ Past Chair, BOPA
Lisa Dougherty	<ul style="list-style-type: none"> ▪ Nurse Consultant IV Therapy & Lead Chemotherapy Nurse, The Royal Marsden Hospital
Ann Cuthbert	<ul style="list-style-type: none"> ▪ Consultant Haematologist, Airedale General Hospital
Lisa Newton	<ul style="list-style-type: none"> ▪ Consultant Haematologist, Bradford Royal Infirmary
Michel Thompson	<ul style="list-style-type: none"> ▪ Matron, Rotherham General Hospital
Nic Ketley	<ul style="list-style-type: none"> ▪ Consultant Haemato-oncologist, QEH
Naim Akhtar	<ul style="list-style-type: none"> ▪ Haematologist, Whipps Cross Hospital
George Hughes	<ul style="list-style-type: none"> ▪ Haematologist, WMUH
Meena Hunjan	<ul style="list-style-type: none"> ▪ Pharmacist, WMUH
Tony Nunn	<ul style="list-style-type: none"> ▪ Clinical Director of Pharmacy, Alder Hey
Martin English	<ul style="list-style-type: none"> ▪ Consultant Paediatric Oncologist, Birmingham Children's Hospital ▪ Chair of Chemotherapy Standardisation Group of UK Children's Cancer and Leukaemia Group. ▪ Member of NCRN Oncology, Pharmacy and Chemotherapy Standardisation Committee.
Chris Mitchell	<ul style="list-style-type: none"> ▪ Paediatric Oncologist & Chair of ALL Working Group (representing President of British Society of Haematology and the Chair of the Leukaemia Working Party)
Robert Marcus	<ul style="list-style-type: none"> ▪ Consultant Haematologist, Addenbrookes Hospital, Cambridge University Hospitals NHS Trust
Peter Clark	<ul style="list-style-type: none"> ▪ Consultant in Medical Oncology, Clatterbridge
David Thomson	<ul style="list-style-type: none"> ▪ Lead Pharmacist, Yorkshire Cancer Network
Wendy Harris	<ul style="list-style-type: none"> ▪ Patient Safety & Investigations Branch, Dept of Health
Cheryl Cavanagh	<ul style="list-style-type: none"> ▪ Cancer Policy Team, DH (secretariat)
Justine Windsor	<ul style="list-style-type: none"> ▪ Cancer Policy Team, DH (secretariat)

Updated national guidance on safe administration of intrathecal chemotherapy:

Waiver to allow administration of intrathecal chemotherapy by ST1 & ST2 Grades

Having read the 2008 updated “*National Guidance on the Safe Administration of Intrathecal Chemotherapy*”, we the undersigned, have decided that at NHS Trust, there are compelling reasons for the inclusion of trained and supervised ST1 and ST2 grades on the register of designated personnel who can administer intrathecal chemotherapy.

We confirm that we are not a low volume trust (undertaking 10 intrathecal chemotherapy procedures or less per annum) and that patient safety will not be adversely affected by the decision.

Signatures

Chief Executive _____

Date: / /

Medical Director (on behalf of Clinical Directors) _____

Date: / /

Director of Nursing _____

Date: / /

Chief Pharmacist _____

Date: / /

Note: This waiver expires 12 months from the date of the latest signature.