

Dear Colleague

SAFE ADMINISTRATION OF INTRATHECAL CYTOTOXIC CHEMOTHERAPY

Purpose

This circular provides revised guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy which must be implemented throughout NHS Scotland. The guidance takes into account implications for Scotland following the update of the English National Guidance on the Safe Administration of Intrathecal Chemotherapy (HSC 2008/001, 11 August 2008).

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

All NHS Boards where intrathecal cytotoxic chemotherapy is administered, must therefore ensure full implementation of this revised national guidance.

This CEL supersedes NHS HDL (2004) 30 – Safe Administration of Intrathecal Cytotoxic Chemotherapy.

Background

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

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

CEL 21 (2009)

19th June 2009

Addresses

For action

Chief Executives
Medical Directors
Directors of Pharmacy
Directors of Nursing

For information

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

Enquires to:

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

This CEL should be read in conjunction with the attached guidance, the Health and Safety Executive: Safe Handling of Cytotoxic Drugs paper, and with the recommendations of the Committee on Safety of Medicines, as detailed in the Medicines and Healthcare products Regulatory Authority, Guidance note 25. It should also be read in conjunction with CEL 22 (2009) Safe Administration of vinca alkaloids.

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

Yours Sincerely

Dr Harry Burns
Chief Medical Officer

Dr Margaret McGuire
Acting Chief Nursing Officer

Professor W Scott
Chief Pharmaceutical Officer

FURTHER READING

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

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

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

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

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

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

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

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

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

SCOTTISH GOVERNMENT HEALTH DIRECTORATES

GUIDANCE ON THE SAFE ADMINISTRATION OF INTRATHECAL CYTOTOXIC CHEMOTHERAPY

UPDATED MAY 2009

SUMMARY

REGISTER OF DESIGNATED PERSONNEL

Each NHS Board must establish and maintain a register which lists designated personnel who have been trained and authorised to prescribe, verify, dispense, transport, check and administer intrathecal chemotherapy and/or intra-ventricular chemotherapy (paragraph 1).

The register should be held by the Chief Executive who has overall responsibility for ensuring compliance with this guidance and a copy held by the Medical Director, Director of Pharmacy, Director of Nursing and the designated lead for the NHS Board (paragraph 2).

Individuals named on the register will have to demonstrate that they are competent to fulfil their designated roles and that they have been certified as such by the appropriate lead professional. For doctors, it will be the responsibility of the Medical 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 pharmacy staff, the Director of Pharmacy (paragraph 5).

Staff moving from one NHS Board to another or from a unit within an NHS Board must take with them their certification along with their training logbook or other training record as proof of their competence (paragraph 6).

Lead professionals must ensure that all these staff are provided with a formal period of induction. This should also include the provision of copies of the NHS Board's protocols and guidelines relevant to the prescribing, verification dispensing, checking, transporting and administration of chemotherapy including intrathecal therapy. Staff should confirm in writing that they have received and read the correct protocols and guidelines before being placed on the register of their new employer (paragraph 6).

EDUCATION AND TRAINING

All staff involved in the prescribing, verification, dispensing, checking, transportation and administration of chemotherapy must receive education and training appropriate to their roles (paragraph 7).

As a minimum, formal induction for those staff likely to be involved must cover all potential clinical hazards associated with intrathecal chemotherapy (paragraph 7).

WRITTEN PROTOCOLS

All staff involved with chemotherapy must be provided with a written protocol which reflects both this national standard and additional local information (paragraph 8).

In order to remain on the register, professional staff must demonstrate every two years that they are up to date on NHS Board policies for the administration of intrathecal chemotherapy (paragraph 10).

PRESCRIBING

Intrathecal chemotherapy must only be prescribed by a Consultant or ST3 and above, or staff in a non-consultant career grade who have received appropriate training (paragraph 12). The prescriber must be on the intrathecal register.

Medical staff at ST2 and below should never prescribe intrathecal chemotherapy.

A separate, purpose-designed intrathecal chemotherapy prescription form must be used (paragraph 13).

PHARMACEUTICAL VERIFICATION

All prescriptions for intrathecal chemotherapy must be pharmaceutically verified by an appropriately trained cancer care pharmacist before dispensing. (paragraph 14). The pharmacist must be named on the intrathecal register.

PREPARATION AND DISPENSING

Intrathecal chemotherapy must only be prepared in a controlled environment, i.e. pharmacy aseptic departments (paragraph 15).

Only trained, designated pharmacy staff should dispense intrathecal chemotherapy (paragraph 16). The pharmacy staff should be named in the intrathecal register.

A register of pharmacy staff designated to verify, dispense and issue intrathecal chemotherapy should be held in the pharmacy and maintained by the Director of Pharmacy (paragraph 16).

LABELLING, PACKAGING AND STORAGE IN THE PHARMACY

Labels added in pharmacy must have the route of administration printed clearly in the largest font size possible and emboldened. Negative labelling must never be used (paragraph 18).

Once prepared, intrathecal chemotherapy awaiting uplift must be stored in a different area in the pharmacy from any other drug. They should never be kept as ward or theatre stock (paragraph 20).

ISSUE AND TRANSPORTATION OF INTRATHECAL CHEMOTHERAPY FROM THE PHARMACY

Intrathecal chemotherapy should only be issued from the pharmacy by and to staff designated in the local policy. 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 area (paragraph 21).

Intrathecal chemotherapy must always be packaged and transported separately from treatments for administration by other routes (paragraph 22).

TIMING OF ISSUE OF INTRATHECAL CHEMOTHERAPY FROM THE PHARMACY

Intrathecal chemotherapy must be issued at a different time from other parenteral chemotherapy for the same patient (paragraph 23).

All non-intrathecal parenteral chemotherapy must be issued first and proof of administration produced before intrathecal chemotherapy is issued (paragraph 23).

The only exceptions that can be made to the sequencing of parenteral chemotherapy before intrathecal chemotherapy are related to the treatment of children (paragraph 25).

STORAGE OF INTRATHECAL CHEMOTHERAPY

Intrathecal chemotherapy should not be routinely stored in the clinical area. Where there is no alternative, it must be stored in a lockable fridge or cupboard reserved solely for this purpose. Only one dose should ever be removed at a time (paragraph 26).

ADMINISTRATION OF INTRATHECAL CHEMOTHERAPY

Inclusion on the register of doctors authorised to administer intrathecal chemotherapy will be limited to Consultants, ST3 and above after appropriate training, and other nominated deputies, such as non-consultant career grades ("appropriate medical staff"). Specifically, all grades up to and including ST2 would not normally be expected to undertake this procedure (paragraph 3).

Checks must be made and recorded by medical, nursing and pharmacy staff at relevant stages throughout the administration process (paragraph 28).

Intrathecal chemotherapy must be administered in a designated, separate area and under normal circumstances within normal working hours (paragraphs 29 and 33). Intrathecal chemotherapy and intravenous bolus chemotherapy injections or vinca alkaloid infusions should never be administered at the same time (paragraph 30).

GUIDANCE FOR THE SAFE ADMINISTRATION OF INTRATHECAL CYTOTOXIC CHEMOTHERAPY FOR ADULTS AND CHILDREN

Background

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

This builds on intrathecal guidance issued in 2004 (HDL 2004)30 and is updated in response to guidance from the World Health Organisation, Department of Health and the National Patient Safety Agency.

The Joint Working Group of the Joint Pharmaceutical Forum and the Scottish Medical and Scientific Advisory Committee reconvened to revise implications for HDL (2004) 30 Safe Administration of Intrathecal Cytotoxic Chemotherapy in the light of these recommendations.

Register of Designated Personnel

1. All NHS Boards providing intrathecal chemotherapy must establish and maintain a register of designated personnel who have been trained and certified competent in one or more of the following tasks: prescribing, verification, dispensing, checking, transportation and administration of intrathecal and/or intra-ventricular chemotherapy. **All references to intrathecal chemotherapy in the following paragraphs should be read as equally applicable to intra-ventricular chemotherapy.**
2. The register should be held by the Chief Executive and a copy held by the Medical Director, Director of Pharmacy, Director of Nursing and lead cancer clinician.
3. Inclusion on the register of doctors authorised to **administer** intrathecal chemotherapy will be limited to Consultants, ST3 and above, after appropriate training and other nominated deputies, such as non-consultant career grades ("appropriate medical staff"). Specifically, all grades up to and including ST2 will **not normally be expected to undertake this procedure**, but where the caseload means they will gain sufficient experience (such as in major Cancer Centres), they may do so subject to training and certification and the completion of the appropriate waivers (see below). **Grades FY1, FY2, ST1 and ST2 should never prescribe intrathecal chemotherapy.**
4. In any NHS Board where it is deemed locally that there is a case for allowing ST1s and ST2s to administer intrathecal chemotherapy, the Chief Executive, the Clinical Director for the service, the Medical Director, the Nurse Director and the Director of Pharmacy and the Designated Lead 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. The waiver is attached to the checklist that accompanies this guidance. All waivers should be reviewed annually and re-signed by all parties if still required.

5. Individuals named on the register will have to demonstrate that they are competent to fulfil their designated roles and have been certified as such by the appropriate lead professional. For doctors, it will be the responsibility of the Medical 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 Director of Pharmacy.

6. Staff moving from one NHS Board to another or to a different unit within an NHS Board must take with them their certification along with their training logbook and other training record as proof of their competence. In addition they must demonstrate their competence to the satisfaction of their employer before being placed on the register. Additionally, it will be the responsibility of lead professionals to ensure that these staff are provided with a formal period of induction. This should also include the provision of copies of the NHS Board's protocols and guidelines relevant to the prescribing, verification, dispensing, checking, transporting and administering of chemotherapy including intrathecal therapy. Staff should confirm in writing that they have received and read the correct protocols and guidelines before being placed on the register of their new employer.

Education, and Training

7. Staff involved in the prescribing, verification, dispensing, transportation, checking and administration of intrathecal chemotherapy must receive education and training appropriate to their roles. Formal induction programmes for all staff likely to be involved in intrathecal chemotherapy, must cover at the very minimum all potential clinical hazards associated with intrathecal chemotherapy.

8. A written local protocol which covers prescribing, verification, dispensing, transportation, 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 using the minibag according to the guidance in CEL 22 (2009)** and are almost always fatal when administered by other routes. The use of vinca alkaloid minibags in children and adolescents treated in a paediatric unit is not recommended. 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.
- a list of all drugs and doses locally approved to be administered by the intrathecal route.

The provision of local information should complement this 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.

10. In order to remain on the register, professional staff must demonstrate every two years that they are up to date on NHS Board and local policies for the administration of intrathecal chemotherapy.

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

Prescribing

12. Only a Consultant, ST3 or above, or staff in a non-consultant career grade (appropriate medical staff) should prescribe intrathecal chemotherapy. 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. **Grades up to FT1, FT2, ST1 and ST2 should never prescribe intrathecal chemotherapy, a waiver is not acceptable for this task.**

13. Intrathecal chemotherapy drugs should continue to be recorded on the master chemotherapy chart. However, a separate prescription form for the intrathecal drug must be used. This should preferably be printed, typed or computer-generated. The entry must be legible, indelible, and signed and dated by the doctor who is on the NHS Board register. The intrathecal chemotherapy prescription form should be adapted to record: the issuer of the intrathecal chemotherapy; the verifier; the collector; the person administering the intrathecal chemotherapy and the person who verifies the administration (the checker) (see paragraph 26). All personnel involved in the procedure should be on the NHS Board register.

Pharmaceutical Verification

14. All prescriptions for intrathecal chemotherapy must be pharmaceutically verified by an appropriately trained cancer care pharmacist designated on the register to do so, before preparation.

Preparation and Dispensing

15. Intrathecal chemotherapy must only be prepared in a pharmacy controlled environment.

16. Only trained, designated pharmacy staff can dispense intrathecal drugs. A register of pharmacy staff designated to dispense and issue drugs for intrathecal chemotherapy should be held in the pharmacy and maintained by the Director of Pharmacy. A copy of this register should be held by the Chief Executive of the NHS Board. 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 Board protocols relating to intrathecal chemotherapy should be lodged in the pharmacy.

17. 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 are administered by an inappropriate route. There should be a formal local assessment to ensure all staff have read and understood this guideline and all NHS Board guidelines and protocols before their names are added to the register.

Labelling, Packaging and Storage in the Pharmacy

18. Labels added in pharmacy must have the route of administration printed clearly in the largest font size possible and emboldened. For example:

"Methotrexate- FOR INTRATHECAL USE".

Negative labelling (i.e. *"Not for Intrathecal Use"*) must **never** be used.

19. This guidance should be read in conjunction with the recommendation of the Committee on Safety of Medicines, as detailed in the Medicines and Health Care Products Regulatory Authority Guidance Note 25.

20. Once prepared, intrathecal chemotherapy awaiting uplift must be stored in a different area in the pharmacy from any other drugs. They should **never** be kept as ward or theatre stock. Intrathecal chemotherapy should not be made up on wards, except in exceptional circumstances (such as emergency cases of central nervous system relapse leukaemia outside of normal working hours and where there is no available designated pharmacist) (See paragraph 31).

Issue and Transportation of Intrathecal Chemotherapy from the Pharmacy

21. Intrathecal chemotherapy should only be issued from the pharmacy by and to staff designated in the local policy. If the drugs are taken to the ward they must be either issued directly to the doctor who will be administering the intrathecal chemotherapy (the collector) or placed in a designated area (which in areas other than theatres is a lockable fridge or cupboard solely reserved for this purpose). In both instances, the member of pharmacy staff should sign for the release of the drugs, identifying to whom the drugs were released or that they have been placed in the designated area. Where a doctor does not take direct receipt of the drugs, s/he must check the drugs and sign for them on retrieval from the designated area.

22. Intrathecal chemotherapy must always be packaged and transported separately from treatments for administration by other routes. Intrathecal doses should be packaged in such a way as to highlight that the product is different from intravenous drugs. For example, the transport containers should be clearly labelled for intrathecal use. The packaging of intrathecal chemotherapy must comply with the manufacturer's recommendations. Colour coding of containers and syringes is unreliable and could result in error.

Timing of Issue of Intrathecal Chemotherapy from the Pharmacy

23. Intrathecal chemotherapy must be **issued** at a different time from other parental chemotherapy drugs for the same patient. Non intrathecal parenteral chemotherapy should be issued first. Only following written proof that any non intrathecal cytotoxic drugs for the named patient for that day have already been administered should the intrathecal chemotherapy be issued. Issuer and collector must sign the intrathecal chemotherapy prescription form.

24. 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.

25. The only exception that can be made to the sequencing of parenteral 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 first.*

* This exception is intended to cover protocols that were published before the initial guidance in 2002 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.

Storage of Intrathecal Chemotherapy

26. After being issued from the pharmacy, intrathecal chemotherapy should **not** be stored in the clinical area. Where there is no alternative, they must be stored in a lockable fridge or cupboard reserved solely for this purpose. The key should be kept with the nurse-in-charge. These areas must be locked at all times unless an authorised member of staff is retrieving drugs. Only the administering doctor on the register of designated personnel should remove drugs from the designated area for intrathecal chemotherapy. Only one dose should ever be removed at any one time.

Patient Review

27. 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.

Administration of Intrathecal Chemotherapy

28. Appropriate medical staff, when preparing to treat a patient with intrathecal chemotherapy, must verify details to ensure that the right drug and the right dose is given to the right patient. These details must be verified by a second, experienced person (eg. a designated chemotherapy-trained nurse, designated pharmacist or designated theatre staff) who are trained in the procedure and included on the register. The checks made must be recorded. Patients, and / or their carers, should be explicitly told the nature of the procedure, the route of administration, and the drug to be administered. The intrathecal chemotherapy prescription form should be adapted to record signatures and printed names of: the issuer of the intrathecal chemotherapy, the collector, the doctor administering and the person who verifies the administration (see paragraph 13).

29. Intrathecal chemotherapy must be administered in an area where no other cytotoxic drugs are being given or stored. When intrathecal chemotherapy is being administered, that area should **not** be used for any other purpose. Under no circumstances should any other cytotoxic drugs be stored in this area.

30. Intrathecal chemotherapy and intravenous bolus injections or vinca alkaloid infusions should **never** be administered at the same time. In general, **in-patients** should not be scheduled to receive intravenous bolus chemotherapy or vinca alkaloid infusions and intrathecal chemotherapy on the same day; **out-patients** may be scheduled to receive intravenous and intrathecal chemotherapy on the same day, but pharmacy should **only** issue the intrathecal doses when the administration record has been received to confirm that the

intravenous therapy has been administered. This should be risk assessed and local incident documentation completed. **The only exceptions that can be made to the sequencing of parenteral 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 first.

31. A technically difficult lumbar puncture may occasionally 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 must **never** be involved in any other aspect of the process and, specifically, must **never** administer the intrathecal chemotherapy.

32. Scheduling of intrathecal therapy must take account of the availability of trained staff. Should trained staff be unavailable, the intrathecal procedure should be cancelled.

Out of Hours Procedures

33. Under normal circumstances intrathecal chemotherapy should only be administered within normal working hours. Only in the most exceptional circumstances (such as central nervous system relapse of leukaemia, requiring emergency treatment) should intrathecal chemotherapy be given out-of- hours or at weekends. In these instances, there should be a clear medical need for the procedure to be undertaken. A local policy must be in place detailing the circumstances where out of hours administration of intrathecal chemotherapy is acceptable. All instances of out of hours administration must be recorded and audited.

INTRATHECAL CYTOTOXIC CHEMOTHERAPY ADMINISTRATION CHECKLIST

Please answer all questions - either "Yes" or "No" and return the completed questionnaire to your NHS Board designated lead. This checklist provides a snapshot of the current position in your NHS Board. Staff completing this questionnaire must ensure that they can answer "YES" to all questions on this checklist if their NHS Board provides intrathecal chemotherapy. If the answer to any question from "5" onwards is "No", please give an explanation in the comments section at the end of the checklist. Answering "No" to any question from "6" onwards indicates non-compliance with National guidance.

- 1 Name of NHS Board:
- 2 Do you provide chemotherapy at this NHS Board? YES/NO

If the answer to this question is NO, no further questions need be answered.

The Chief Executive should sign this form below and return it to their designated lead:

Chief Executive:

Date: / /

- 3 Is **INTRAVENOUS** chemotherapy ever given in this NHS Board:
 - (i) to adults? YES/NO
 - (ii) to adolescents? YES/NO
 - (iii) to children? YES/NO
- 4 Is **INTRATHECAL** chemotherapy ever given in this NHS Board:
 - (i) to adults? YES/NO
 - (ii) to adolescents? YES/NO
 - (iii) to children? YES/NO

If the answer to question 4 (i) (ii) and (iii) is NO, no further questions need be answered.

The Chief Executive should sign this form below and return it to their designated lead:

Chief Executive:

Date: / /

Register of Designated Personnel

Will only Consultants, ST3 and above after appropriate training, and other nominated deputies, such as non-consultant career grades administer INTRATHECAL chemotherapy?

- 5 YES/NO

If the answer is NO please sign the attached waiver and inform your designated lead of your decision and the reasons for that decision.

- 6 Is a register of personnel authorised to prescribe, verify, dispense, check, transport and administer intrathecal chemotherapy maintained in this NHS Board? [paragraph 1] YES/NO

Education and Training

- 7 Does the NHS Board provide a formal training programme related to the safe administration of chemotherapy? [paragraph 7] YES/NO

- 8 Does this training programme cover the safe delivery of INTRATHECAL chemotherapy? [paragraph 7] YES/NO
- Written Protocols**
- 9 Does this NHS Board have a local written policy / protocol related to the administration of INTRATHECAL chemotherapy? [paragraph 8] YES/NO
- 10 If yes, does the policy / protocol comply with all aspects of the national guidance? [paragraph 8] YES/NO
- 11 Does the local policy / protocol specify designated areas where INTRATHECAL chemotherapy may be:
- Prepared? [paragraph 8] YES/NO
- Stored? [paragraph 8] YES/NO
- Administered? [paragraph 8] YES/NO
- 12 Are professional staff required to demonstrate every two years that they are up to date on NHS Board policies for the administration of intrathecal chemotherapy? [paragraph 10] YES/NO
- Prescribing**
- 13 Does this NHS Board have a separate, purpose-designed prescription form for INTRATHECAL chemotherapy? [paragraph 13] YES/NO
- 14 For INTRATHECAL drugs, are there spaces for the signatures of:
- the prescriber?[paragraph 13] YES/NO
- the dispenser?[paragraph 13] YES/NO
- the verifier? [paragraph 13] YES/NO
- the collector?[paragraph 13] YES/NO
- the checkers?[paragraph 13] YES/NO
- the administrator?[paragraph 13] YES/NO
- Preparation, Verification and Dispensing**
- 15 Are only trained designated cancer care pharmacists allowed to verify intrathecal chemotherapy [paragraph 14] YES/NO
- 16 Are intrathecal doses only prepared in a controlled environment? [paragraph 15]
- 17 Are only trained, designated pharmacy staff allowed to dispense intrathecal drugs? [paragraph 16] YES/NO
- 18 Does this NHS Board have a register of pharmacy staff designated to verify and dispense and issue drugs for intrathecal chemotherapy? [Paragraph 16] YES/NO
- 19 Is the register held in the pharmacy and maintained by the Director of Pharmacy? [paragraph 16] YES/NO
- Labelling, Packaging and Storage in the Pharmacy**
- 20 Do labels added in pharmacy have the route of administration clearly marked? [paragraph 18] YES/NO
- 21 Does the labelling of drugs in pharmacy comply with the requirements of the national guidance? [paragraph 19] YES/NO
- 22 Are intrathecal and intravenous chemotherapy awaiting uplift stored in different areas in the pharmacy? [paragraph 20] YES/NO
- Issue and Transportation of Drugs from Pharmacy**
- 23 Are intrathecal chemotherapy drugs only issued by and to staff designated in the local policy? [paragraph 21] YES/NO
- 24 Are intrathecal chemotherapy drugs always packaged and transported separately from treatments for administration by other routes? [paragraph 22] YES/NO

Timing of Issue of Drugs from Pharmacy

- 25 Is intrathecal chemotherapy issued at a different time from other parental chemotherapy drugs? [paragraph 23] YES/NO
- 26 Is a process in place to ensure that intrathecal chemotherapy is only issued from the pharmacy when written evidence is presented to show that any prescribed parenteral intravenous chemotherapy has already been given or vice versa for exceptions [paragraph 23] YES/NO

Storage of Drugs

- 27 Is intrathecal chemotherapy ever stored between collection and administration? [paragraph 26] YES/NO
- 28 If yes, is intrathecal chemotherapy stored in a designated lockable fridge or cupboard which is reserved for this purpose alone? [paragraph 26] YES/NO

Administration of Drugs

- 29 Are the details of intrathecal chemotherapy always verified by a second, experienced person who is trained in the procedure and included on the register? [paragraph 28] YES/NO
- 30 Are intrathecal chemotherapy drugs always administered in a location which is different from that for intravenous chemotherapy? [paragraph 29] YES/NO
- 31 Are intrathecal chemotherapy drugs always administered by an individual who is named on the NHS Board's register of designated personnel (Consultant, ST3 and above)? [paragraphs 1 and 3] YES/NO
- 32 A local policy is in place detailing the circumstances where out of hours administration of intrathecal chemotherapy is acceptable YES/NO
- 33 Has intrathecal chemotherapy been administered out of hours? (paragraph 33) YES/NO
- 34 If yes, were exceptional circumstances demonstrated in all cases? YES/NO

Signatures

Chief Executive
Designated Intrathecal Lead
Job Title:
Medical Director
Director of Nursing
Director of Pharmacy

Date

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INTRATHECAL CHEMOTHERAPY ADMINISTRATION WAIVER TO GUIDANCE ON THE SAFE ADMINISTRATION OF INTRATHECAL CYTOTOXIC CHEMOTHERAPY

Having read and understood the *Guidance on the Safe Administration of Intrathecal Cytotoxic Chemotherapy*, we the undersigned, have decided that within unit at Hospital in NHS Board, there are compelling reasons for the inclusion of trained and supervised Grades ST1 and ST2 in the administration of intrathecal chemotherapy. We confirm that patient safety will not be adversely affected by the decision and that we have notified the designated lead of our decision.

Signatures

Date

Chief Executive
Designated Intrathecal Lead
Job Title:
Clinical Director
Medical Director
Director of Nursing
Director of Pharmacy

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MEMBERSHIP OF THE WORKING GROUP

Chairman:

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

Members:

Ms G Caldwell, Director of Pharmacy, NHS Forth Valley

Dr M Cornbleet, Chair of Chemotherapy Advisory Group

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

Mrs M Dolan, National Services Scotland, Edinburgh

Dr P Johnson Consultant Haematologist, Western General Hospital, Edinburgh

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

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