



UK SACT BOARD

National Guidance on the Safe Administration of Systemic Anti-Cancer Therapies via The Intrathecal or Intraventricular Routes

(Applies to Health Care organisations in England, Wales & Northern Ireland)

Healthcare organisations in Scotland should continue to refer to CEL 21(2009) for guidance on the **SAFE ADMINISTRATION OF INTRATHECAL CYTOTOXIC CHEMOTHERAPY**.

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1. Foreword

- 1.1. This guidance has been produced by the UK SACT Board (UKSB) and is intended for use in organisations delivering SACT across England, Wales and Northern Ireland. The UK SACT Board, under the invitation of NHSE, convened a working group of experts to review and update previous guidance. Clinical experts from all devolved nations have contributed.
- 1.2. The working group felt that it was important to acknowledge the current recommendations on the dilution of vinca-alkaloids as this was one of a number of actions taken to eliminate the risk of administering vinca-alkaloids via the intrathecal route. This information can be found in Appendix B. This information also acknowledges the difference for children's cancer services.

2. Executive Summary

- 2.1 There have been multiple incidents worldwide where the anti-cancer therapies intended for intravenous administration (e.g. vinca alkaloids such as Vincristine), have been accidentally injected via the intrathecal route during the chemotherapy treatment of a cancer patient. These incidents have resulted in serious injury, paralysis and death of the patients involved.
- 2.2 As a result of such an incident in the UK in 2001, the Department of Health (DoH) published national guidance on the safe administration of intrathecal chemotherapy (HSC 2001/022, HSC 2003/101) and the final version in 2008 (HSC 2008/001) [1]. These set out what was expected of all NHS organisations that provide an intrathecal chemotherapy service. The guidance was incorporated into the NHSE National Peer Review programme through the publication of the Manual for Cancer Services Chemotherapy measures (2014) [2], with 100% compliance mandated. No further update to these guidelines or measures have since been published. The UK SACT Board, under the invitation of NHSE, convened a working group of experts to review and update previous guidance.
- 2.3 The updated guidance reflects most of the intrathecal chemotherapy measures set out in the Manual for Cancer Services Chemotherapy Measures v1.0 (2014) [2] and incorporates the recommendations for the use of **non-luer compatible neuraxial devices** to administer intrathecal and intraventricular anti-cancer therapy. The UK recommended compatible devices are the NRFit® connectors.
- 2.4 This updated guidance defines the parameters and training required to prescribe, verify, dispense, issue, check and administer intrathecal and intraventricular anti-cancer therapy. It reflects the changing roles and advanced clinical practice models operating within cancer services across the UK, allowing for tasks to be carried out by staff who have been appropriately trained and demonstrate the relevant competencies required to be included on a designated local Intrathecal Chemotherapy Register.
- 2.5 Post-graduate doctors in training, of grades F1-ST2, must not prescribe or administer intrathecal chemotherapy under any circumstances. This also applies to Physician Associates.
- 2.6 It remains the recommendation that the person checking the drugs to be administered should be from a different professional group than the person administering the dose(s) (see 7.3.1 regarding scope of practice and local risk assessments)

2.7 Each organisation providing an intrathecal chemotherapy service must document in their local intrathecal chemotherapy policy, following a governance review, which professional groups can undertake these roles locally.

2.8 This revised guidance;

- replaces the DoH national guidance issued in 2003 and 2008^[1] and the Manual for Cancer Services Chemotherapy Measures v1.0 (2014)^[2]
- Highlights that intrathecal and intraventricular anti-cancer therapies remain an important patient safety issue.
- Highlights to the executive leads of all healthcare organisations that intrathecal and intraventricular anti-cancer therapy administration remains their clinical governance responsibility.
- Sets out the updated processes and practices that need to be in place to ensure the safe administration of intrathecal and intraventricular anti-cancer therapies. This relates to intrathecal treatment given by lumbar puncture (i.e. via spinal injection) and to intraventricular anti-cancer therapies (i.e. via injection into the ventricles of the brain via a reservoir).
- Should also be read in conjunction with the following:
 - National Patient Safety Agency (NPSA) rapid response report NPSA/2008/RRR004 entitled *Using Alkaloid Minibags (Adult/ Adolescent Units)* ^[3]
 - NHS/PSA/D/2014/002 - Stage Three: Directive Non-Luer spinal (intrathecal) devices for chemotherapy 20 February 2014 supplement ^[4]

3. Background

3.1 Central Nervous System (CNS) directed systemic anti-cancer therapy (SACT) is integral to the treatment of several malignant diseases. This has commonly been administered via the intrathecal route using a lumbar puncture injection to access the spinal canal, however, there is increasing use of the intraventricular route through injection into a subcutaneous placed ventricular access device such as the Ommaya reservoir. The range of drugs utilised via these administrative routes is also expanding, with methotrexate, cytarabine and hydrocortisone being integral to the treatment of haematological malignancies. Intraventricular etoposide, topotecan are being utilised in the treatment of some CNS-based solid tumours.

3.2 For the purposes of this document, the term systemic anti-cancer therapy (SACT) and chemotherapy are used interchangeably and refer to all drugs with direct anti-tumour activity.

3.3 Throughout the guidance intrathecal chemotherapy will refer to all CNS-directed systemic anti-cancer therapy (intrathecal and intraventricular) unless indicated otherwise.

3.4 A major patient safety issue is the danger to patients if neurotoxic systemic anti-cancer therapies (SACT) are injected intrathecally or intraventricularly during the treatment of a cancer patient. There have been several reported incidents related to the inappropriate administration of neurotoxic agents intrathecally worldwide leading to patient deaths. The most widely known are those related to the vinca alkaloid drug vincristine, but incidents have also been reported related to doxorubicin, daunorubicin, dactinomycin and vindesine, and more recently bortezomib [5].

3.5 In response to such incidents, measures were developed and implemented across England in 2001 with an agreed target to reduce the number of patients dying or being paralysed by the inappropriate intrathecal administration of anti-cancer therapies to zero by the end of 2001. The Department of Health (DoH) published national guidance on the safe administration of intrathecal chemotherapy in 2001, updated in 2003 and a final version in 2008 [1]. This set out what was expected of all NHS organisations that provide an intrathecal chemotherapy service. The guidance was incorporated into the NHSE National Peer Review programme through the publication of the Manual for Cancer Services Chemotherapy Measures v1.0 (latest version 2014) [2], with 100% compliance mandated. No further update to these guidelines or measures has since been published.

3.6 Subsequently NHSE recommended NRFit® connectors for use by those organisations delivering an intrathecal chemotherapy service to be implemented not later than August 2014 [4,6]. The switch to the use NRFit® compatible neuraxial devices post-dates the publication of the chemotherapy measures leading to a very clear need to provide an updated, national consensus guideline on the delivery and management of intrathecal / intraventricular chemotherapy.

3.7 The UK SACT Board, following invitation from NHSE, convened a working group of experts to review and update the previous guidance.

3.8 This updated guidance defines the parameters and training required to prescribe, verify, dispense, issue, check and administer intrathecal and intraventricular anti-cancer therapy. It reflects the changing roles and advanced clinical practice models operating within cancer services across the UK, allowing for tasks to be carried out by staff who have been appropriately trained and demonstrate the relevant competencies required to be included on the designated Intrathecal Chemotherapy Register.

3.9 It remains the recommendation that post-graduate doctors in training, of grades F1-ST2 must not prescribe or administer intrathecal chemotherapy under any circumstances. This also applies to Physician Associates.

4. Abbreviations & Definitions

The terms 'intrathecal' and 'intraventricular' should never be abbreviated. This is to ensure there is no ambiguity with this subject matter.

Abbreviation / Term	Definition
CSF: Cerebro-spinal fluid	A clear, colourless fluid that cushions the brain and spinal cord, delivers nutrients, removes waste, and provides mechanical and immunological protection.
GA: General Anaesthetic	Is a medically induced state of unconsciousness used during surgeries and medical procedures to ensure patients are pain-free and unaware of their surroundings.
Intrathecal	Is the administration of drugs directly into the spinal subarachnoid space, typically via a lumbar puncture, allowing drugs to circulate in the cerebrospinal fluid (CSF).
Intrathecal Chemotherapy	Is the administration of chemotherapy drugs by the intrathecal route.
Intraventricular Chemotherapy	Refers to the administration of chemotherapy drugs directly into the brain ventricle through an intraventricular reservoir. This allows rapid distribution throughout the cerebrospinal fluid (CSF).
LP: Lumbar Puncture	A medical procedure used to collect cerebrospinal fluid for diagnostic purposes or to administer medications intrathecally.
SACT: Systemic anti-cancer therapy	Refers to the use of drugs that target cancer cells throughout the body, aiming to destroy or inhibit their growth.

5. Roles and Responsibilities

5.1 Health care organisations delivering cancer care should declare if intrathecal chemotherapy is delivered within their organisational policies / service specification documents.

5.2 Those delivering intrathecal chemotherapy should stipulate the following roles and responsibilities within the organisation's intrathecal policy

Note: Individuals can undertake more than one role where approved to do so (applicable to certain roles only). The named practitioners for the role(s) should be recorded within either the organisation's policy or on their local Intrathecal Chemotherapy Register.

Role	Responsibility
The Chief Executive Officer (CEO)	<p>Has overall organisational responsibility for ensuring compliance with national guidance and organisational policy.</p> <p>Must:</p> <p>Identify a single designated 'Intrathecal Chemotherapy Lead'. Ensure that the Intrathecal Chemotherapy Lead's role is reflected within the employee's job description /plans and ensure that review of accountability and responsibilities is covered during their annual appraisal.</p> <p>Ensure that the appointed Intrathecal Chemotherapy Lead is on the Intrathecal Chemotherapy Register (see section 8) and be one of the following:</p> <ul style="list-style-type: none"> • Consultant medical oncologist • Consultant clinical oncologist • Consultant paediatric oncologist or haematologist • Consultant haematologist • Senior nurse • Lead pharmacist for the cancer service / haematology-oncology service
Named Designated Intrathecal Chemotherapy Lead (single person only for the organisation)	<p>Is accountable to the CEO for ensuring compliance with the national guidelines and must be on the Intrathecal Chemotherapy Register.</p> <p>Has overall accountability for:</p> <ul style="list-style-type: none"> • Induction, training and competency assessment – see section 7.4 • Maintaining the Intrathecal Chemotherapy Register (adding and removing employees)

	<ul style="list-style-type: none"> Implementation of training plan /policy
Named Intrathecal Lead Trainer(s) (Can be the Intrathecal Chemotherapy Lead).	<p>Delegated responsibility by the Intrathecal Lead and must be on the Intrathecal Chemotherapy Register. Responsible for</p> <ul style="list-style-type: none"> Ensure formal induction course available and competency assessments and certification in place. <p>Their role should be reflected in their job description/plan and reviewed at their annual appraisal.</p>
Named Competency Assessor(s)	<p>Assigned by Intrathecal Lead Trainer(s) and must be on the Intrathecal Chemotherapy Register for the task(s) they are assessors for. Delegated responsibility for:</p> <ul style="list-style-type: none"> Assess and reconfirm the competency of staff seeking inclusion on the Intrathecal Chemotherapy Register for specific tasks.
Named Lead Pharmacist	<p>A dedicated 'Lead Pharmacist' should be identified. This individual will be a pharmacist currently listed on the Intrathecal Chemotherapy Register.</p> <p>Responsibilities to be agreed with the intrathecal chemotherapy lead and Chief Pharmacist and may include:</p> <ul style="list-style-type: none"> Assisting the intrathecal chemotherapy lead in the review and development of the intrathecal chemotherapy policy Ensuring drug related incidents regarding intrathecal chemotherapy are discussed on a regular basis via the organisation's governance reporting structure. Contribute to the annual risk assessment of the intrathecal chemotherapy service
All staff undertaking a given task on the intrathecal chemotherapy register.	<p>Must:</p> <p>Attend the role specific training provided at the intervals stipulated by the organisation</p> <p>Read the national guidance and associated local policies as part of their induction</p> <p>Receive a certificate or other written confirmation that they have completed the initial training and have been assessed as competent to be included on the Intrathecal Chemotherapy Register for the designated task(s). (where relevant)</p> <p>Annually sign a confirmation that they have read and understood these documents before being allowed to practice their respective roles.</p>

	<p>Undertake an annual review of competence alongside how often they carry out the task. Re-certification of competence may be dependent on refresher training (where relevant).</p> <ul style="list-style-type: none"> • Work within their scope of practice and sphere of competence for the certified task(s).
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Also See Appendix A – Accountability and responsibility Delegation Flow Chart

6. Document Purpose, Scope and Rationale

6.1 This guidance sets out the updated processes and practices that need to be in place to ensure the safe administration of intrathecal and intraventricular anti-cancer therapies within health care organisations in England, Wales and Northern Ireland.

6.2 It is intended for use in all patients receiving CNS directed systemic anti-cancer therapy (intrathecal and intraventricular).

7. Governance Aspects

7.1 Local Policies

7.1.1 Any health care organisations delivering an intrathecal chemotherapy-service must have a local intrathecal chemotherapy policy covering this national intrathecal chemotherapy guidance, clarifying specifically how the guidance applies to their organisations service. The local intrathecal chemotherapy policy should indicate:

- Who, in terms of named personnel and roles, is permitted to carry out tasks pertaining to intrathecal chemotherapy service as specified in the guidance.
- Where, in the organisation, in terms of named divisions of the intrathecal chemotherapy service, hospitals, wards, departments, pharmacies, designated areas and physical facilities, specified tasks are permissible.
- The process by which new drugs to be administered via the Intrathecal or Intraventricular route MUST go via the health care organisations local Drug and Therapeutics / Medicines Management Committee.
- The process for prescription amendments and communication of those
- That surgeons, anaesthetists and radiologists must NOT be authorised to administer or check intrathecal chemotherapy.

7.1.2 There should be an electronic copy of the local intrathecal chemotherapy policy. This must be accessible to all staff on the Intrathecal Chemotherapy Register and, in all locations as defined in 7.1.1 There must be a contingency plan for electronic failure/down time.

7.1.3 There must be a defined process to ensure local intrathecal chemotherapy policy review and update.

7.1.4. An annual risk assessment of the intrathecal chemotherapy service should be undertaken, and this should be stated in the local intrathecal chemotherapy policy.

7.1.5 Any contravention of the local intrathecal chemotherapy policy should be recorded via the organisation's incident reporting mechanism and reported to the Intrathecal Chemotherapy Lead.

7.2 Compliance, Audit and Data Collection

7.2.1 For the process of quality assurance and oversight, it is expected that audit of local adherence to these guidelines is incorporated into the annual work programme of regional cancer alliances and / or Operational Delivery Networks (ODN's), where relevant (England) or equivalent.

7.3 Scope of Practice

7.3.1 The organisation's local intrathecal chemotherapy policy should stipulate the scope of practice for different personnel, roles and grades and link this to their risk assessments where applicable.

7.4 Induction, Training and Competency Assessment

7.4.1 If the Intrathecal Chemotherapy Lead delegates named individuals to be responsible for named divisions of the service and/or named intrathecal chemotherapy training lead(s) for the organisation, these must be set out in the local intrathecal chemotherapy policy.

7.4.2 Lead Trainer(s) for the intrathecal chemotherapy service should be identified; this can be the Intrathecal Chemotherapy Lead or senior members of staff (medical, nursing and pharmacy), that are included in

the Intrathecal Chemotherapy Register and delegated with responsibility by the Intrathecal Chemotherapy Lead and named in the local policy.

7.4.3 A formal induction should be available and attended by all staff new to the hospital, appropriate to their proposed role in the delivery or care of a patient receiving intrathecal chemotherapy, i.e. prescribing, prescription verification, dispensing, issuing, checking, and administration of intrathecal chemotherapy via a lumbar puncture, and administration of intraventricular chemotherapy via a subcutaneous ventricular access device.

7.4.4 The induction learning outcomes should cover all potential clinical hazards associated with intrathecal chemotherapy including compulsory mitigations (inclusive of but not limited to):

- The danger posed to patients if intravenous or subcutaneous SACT (e.g. vinca alkaloids) are accidentally administered intrathecally / intraventricularly
- Any new national requirements specific to the preparation and administration of SACT/Chemotherapy which impacts on intrathecal chemotherapy.
- Practice recommendations from the NPSA on the presentation of intravenous vinca alkaloids for adults and for teenagers treated in an adult or dedicated teenage setting ^[3]. (See Appendix B for details of dilution.)
- Practice recommendations on the presentation of intravenous vinca alkaloids for children and for teenagers treated in a Children's Unit. (See Appendix B for details of dilution.)
- Importance of challenging colleagues if, in their judgement, either protocols and policies are not being adhered to, or the actions of an individual may cause potential risk to a patient. Explaining that challenging a colleague should not be seen as adversarial, but as an additional check to improve patient safety and reduce risk.
- Requirement to read the national guidance and associated local policies as part of their induction and sign a written confirmation that they have read and understand these documents before completing their competency assessment.
- The need to access the training material to support local induction and training on the safe administration of intrathecal chemotherapy produced by the Department of Health Publications^[7]. ([‘Just Another day’ video guidance from the Department of Health on safe administration of intrathecal administration](#)). Note: The updated guidance has changed in some respects since the film was made; but the general messages still hold true. The film should be used as part of induction training for staff and used to highlight the risks associated with delivering an intrathecal chemotherapy service.

7.4.5 Staff should receive a certificate, or other written confirmation, that they have completed the training (or annual refresher training) and have been assessed as competent/ remain competent to be included on the Intrathecal Chemotherapy Register for the designated task(s).

7.4.6 Only 'named competency assessors', as delegated by the Lead Trainer(s) for specific tasks on the Intrathecal Chemotherapy Register, are permitted to assess and reconfirm the competency of staff seeking inclusion on the Intrathecal Chemotherapy Register. They must have been through the local intrathecal chemotherapy training programme and been assessed as competent for the tasks which they assess and be on the Intrathecal Chemotherapy Register for that task. Named Competency Assessors should be authorised by the Intrathecal Chemotherapy Lead as competent to assess and formally recorded as defined by local policy.

7.4.7 Personnel may perform a given task under constant direct supervision of a named competency assessors for that task, when it is being performed as part of the health care organisations intrathecal chemotherapy registration training programme, or competency assessment.

8. Specialist Aspects

8.1 Volume of Service

- 8.1.1. The number of intrathecal chemotherapy administrations performed in the organisation per year, should be recorded.
- 8.1.2 Following a local risk assessment of the intrathecal chemotherapy service there should be a locally agreed, maximum safe workload level and actions to address any capacity increase, should this be needed, to avoid exceeding the agreed maximum workload. This should be set out in the local intrathecal chemotherapy policy and agreed with the organisation's CEO.
- 8.1.3 If the number of administrations per year is 10 or less (low volume) there should be a risk assessment carried out on the intrathecal chemotherapy service with respect to safety issues associated with having a low volume service. Following this:
 - The results and any action arising should have been discussed and agreed with the CEO.
 - The decision to continue the service should be agreed by the CEO.

8.2 Non-Intrathecal Chemotherapy Health Care Organisations

8.2.1 Health care organisations that declare they do not provide an intrathecal chemotherapy service should have a ratified policy / pathway outlining the actions to be taken and escalation process should a patient require intrathecal chemotherapy. This should include a process to transfer to an organisation that delivers an intrathecal chemotherapy service. If not fit for transfer, the policy should outline a clear pathway on how such therapy may be delivered and drugs provided in line with this guidance. Any such action should have a documented risk assessment and written approval from the:

- Clinical Service Lead
- Chief Medical Officer (or deputy)
- Chief Executive Officer

8.3 Intrathecal Chemotherapy Register

8.3.1 There must be a dedicated Intrathecal Chemotherapy Register for the organisation, listing all personnel who are trained and certified competent to participate in intrathecal chemotherapy tasks (see section 8.3.2).

8.3.2. There must be a single Intrathecal Chemotherapy Register for the whole organisation, the minimum components of the register required are specified below. Additional components may be added at the organisation's discretion. All sections of the Intrathecal Chemotherapy Register must be kept in one document and accessible by all users.

- Prescribing intrathecal chemotherapy
- Pharmacy verification of intrathecal chemotherapy prescriptions
- Dispensing intrathecal chemotherapy drugs in pharmacy
- Checking and issuing intrathecal chemotherapy drugs from pharmacy
- Checking of the prescribed intrathecal chemotherapy prior to administration
- Administration of intrathecal chemotherapy via a lumbar puncture
- Administration of Intraventricular chemotherapy via a subcutaneous ventricular access device (e.g. Ommaya reservoir). This component of the register should be clearly distinguishable from the personnel authorised to administer intrathecal chemotherapy via a lumbar puncture.

8.3.3 The Intrathecal Chemotherapy Lead has overall responsibility for reviewing and updating personnel on the Intrathecal Chemotherapy Register. Only the Intrathecal Chemotherapy Lead, or person(s) named in the local intrathecal chemotherapy policy with responsibility delegated by the Intrathecal Chemotherapy Lead for a specified task on the Intrathecal Chemotherapy Register, can authorise the entry and removal of staff from the Intrathecal Chemotherapy Register for that task. The Intrathecal Chemotherapy Register

should be updated at least annually or more frequently as required by personnel changes.

8.3.4 For individuals to be on the Intrathecal Chemotherapy Register they must have been assessed as competent, and their competency reviewed annually by a competency assessor named in the local intrathecal chemotherapy policy. (Refer to section 5 & 7.4.6)

8.3.5 Appropriate governance arrangements should be in place to ensure that a copy of the current version of Intrathecal Chemotherapy Register is available and accessible by all staff in each location where specified intrathecal tasks are permissible (as defined in the organisation's intrathecal policy). Such copies can be electronic or 'hard copy' or both. There must be a contingency plan set out in the local intrathecal chemotherapy policy for electronic failure/down time.

8.3.6 This guidance recognises the importance of extended scope of practice (e.g. non-medical prescribing and Advanced Clinical Practice) and supports the principle of roles other than solely medical staff administering intrathecal chemotherapy provided appropriate training, and competences have been demonstrated and such individuals are entered onto the Intrathecal Chemotherapy Register. Each individual organisation that delivers an intrathecal chemotherapy service must agree on the roles of those professionals with extended scope of practice in supporting the delivery of the intrathecal chemotherapy service and this must be clearly set out in the local intrathecal chemotherapy policy. This must be included in the risk assessment of the intrathecal chemotherapy service that is integral to the local intrathecal chemotherapy policy.

8.3.7 Entry onto the Intrathecal Chemotherapy Register is predicated on successful completion of designated training and being certified competent to participate in intrathecal chemotherapy task(s).

8.3.8 Post-graduate doctors in training of grades F1-ST2 should not be entered onto the Intrathecal Chemotherapy Register and therefore must not deliver any aspects of intrathecal / intraventricular anti-cancer therapy.

8.3.9 Staff moving from one hospital to another should not be automatically included on the new hospital's Intrathecal Chemotherapy Register.

8.4 Patient Consent

8.4.1 Informed consent must be obtained and recorded prior to the administration of any Intrathecal chemotherapy in line with the health care organisations consent policy

8.4.2 Consent may be obtained at the outset of treatment and applied to all intrathecal / intraventricular procedures / administration of anti-cancer therapies throughout the treatment schedule – ‘Rolling consent’.

8.4.3 If a system of rolling consent is used, confirmation of consent should be obtained prior to each individual procedure and documented accordingly.

8.4.4 The above process should be clearly set out in the health care organisations local intrathecal chemotherapy policy.

8.5 Intrathecal / Intraventricular Anti-cancer Therapy Prescription Chart

8.5.1 A purpose-designed prescription for intrathecal / intraventricular anti-cancer therapy should be generated using an electronic prescribing system.

8.5.2 The prescriptions may be used within an Electronic Prescribing and Medicines administration (ePMA) system, or the prescription chart can be printed, should the health care organisation’s policy allow.

8.5.3 The prescription chart should meet the requirements in the organisation’s medicines management policy in addition to the following minimum standards:

- The drug and route of administration should be clearly indicated – in full on the chart.
- Must allow recording of the signatures (in full) of the prescriber, verifier, issuer, collector/delivery checker and administrator of the intrathecal chemotherapy. This must be the case also where ‘paperless’ / electronic systems are in use and electronic signatures utilised. Names must match the Intrathecal Chemotherapy Register.

9. Managing Intrathecal / Intraventricular Anti-Cancer Therapy Drugs

9.1 Dispensing

9.1.1 Dispensing is the activity of preparing the dose, filling the syringe, labelling and placing the syringe in packaging and checking of the final product. It will also include transport if the drug is not issued directly to the collector.

9.1.2 This activity must only be undertaken by pharmacy staff listed on Intrathecal Chemotherapy Register as trained and competent to undertake this role.

9.1.3 All intrathecal chemotherapy drugs must be prepared and issued in NRFit® compatible devices, use of non NRFit® devices is not permitted.

9.1.4 Where the provision of intrathecal chemotherapy is outsourced, the organisation's intrathecal chemotherapy policy must clearly set out the process of validation of the provided drugs and final dispensing to the clinical area.

9.2 Labelling, packaging, and transportation

9.2.1 Labels added in pharmacy should have the route of administration printed clearly in the largest font size possible and emboldened e.g. **For Intrathecal Use Only** or alternatively use TALLman lettering such as intraTHECAL / intraVENTRICULAR.

9.2.2 Intrathecal chemotherapy drugs must always be packed and transported separately from treatments for administration by other routes. Intrathecal chemotherapy should be transported in a distinctive bag/container that is not used for any other purpose.

9.3 Storage in Pharmacy / Designated clinical area

9.3.1 If storage is required between dispensing and issuing, intrathecal chemotherapy must be stored in a dedicated lockable container/refrigerator in the pharmacy. This facility should only be used for intrathecal chemotherapy drugs.

9.3.2 If the intrathecal chemotherapy needs to be stored between issuing and administration, the drugs should be stored in a lockable dedicated container/refrigerator reserved for this purpose alone in the designated clinical area where the intrathecal chemotherapy will be administered. The key must be held by a member of staff on the Intrathecal Chemotherapy Register in-charge of the location.

9.3.3 Only the member of staff on the Intrathecal Chemotherapy Register who will be administering the intrathecal chemotherapy dose must remove the intrathecal chemotherapy dose(s) from the container/refrigerator.

9.4 Issuing and Receipt of Drugs

9.4.1 Intrathecal chemotherapy must only be issued from the pharmacy by staff on the Intrathecal Chemotherapy Register:

- Directly to the healthcare professional who will be administering the drug (the collector).
- Or to a nominated member of pharmacy staff (whose name appears on the Intrathecal Chemotherapy Register) and delivered directly to the clinical area where intrathecal chemotherapy will be administered and either placed into a designated container/refrigerator or delivered directly to the healthcare professional who will be administering the intrathecal chemotherapy.

9.4.2 The member of pharmacy staff must sign for the issue of the intrathecal chemotherapy, identifying to whom they were issued. If relevant; the pharmacy staff delivering the intrathecal chemotherapy should sign to confirm that the intrathecal chemotherapy has been locked in the designated container / refrigerator in the designated clinical area.

9.4.3 The healthcare professional who will be administering the intrathecal chemotherapy must sign for receipt of the individual intrathecal chemotherapy dose; this includes if collected from the designated container/refrigerator.

9.5 Location of Administration of Intrathecal / Intraventricular anti-cancer therapy

9.5.1 The Health care organisation's intrathecal chemotherapy policy must set out the physical locations within the organisation where it has been agreed such therapy can be safely delivered. The area must be designated for intrathecal chemotherapy administration for the entire session and must not be used for any other purpose during this time. This will comprise of a separate room with walls and a door (a curtained off area is not acceptable). Permanent designation of an area for intrathecal chemotherapy is desirable but not essential.

9.5.2 There may be exceptional circumstance when a patient cannot be moved to a designated area for intrathecal chemotherapy administration eg patient unwell on intensive care unit. In these circumstances the local intrathecal chemotherapy policy should indicate the procedure to be followed to ensure this can be done safely.

9.5.3 During the administration of intrathecal chemotherapy, no other anti-cancer therapy or cytotoxic drugs are allowed in the designated location during the entire session (with the exception of a continuous intravenous SACT infusion that has already been started, see 9.8.5)

9.5.4 Other anti-cancer therapy or cytotoxic drugs must never be stored in the designated location at any time, even when the area is not in use.

9.6 Pre-administration Checks

9.6.1 A formal checking procedure should be carried out to ensure:

- The correct drug is being administered.
- To the correct patient.
- At the correct dose.
- Via the correct route.

9.6.2 Checking is undertaken, and signed on the prescription, by at least the healthcare professional administering the intrathecal chemotherapy and another healthcare professional on the Intrathecal Chemotherapy Register for the relevant task. It remains the recommendation that the person checking the drugs to be administered should be from a different professional group from the person administering the dose(s).

9.6.3 The patient or, if relevant the parent, or guardian of the patient, should be offered the opportunity to take part in the checking process if they so desire and this should be recorded.

9.6.4 Where general anaesthesia is used to facilitate the administration of intrathecal chemotherapy, the local intrathecal chemotherapy policy must set out the process by which all relevant checks are completed in alignment with the WHO's (World Health Organisation) Safe Surgery Saves Lives principles. [8].

9.7 Administration

9.7.1 Administration of intrathecal chemotherapy should only take place during normal working hours as defined in the local intrathecal chemotherapy policy

9.7.2 Administration of intrathecal chemotherapy outside of these normal working hours is only by exception and requires special authorisation (which should be over and above normal procedure).

9.7.3 Compliance with all other parts of the intrathecal chemotherapy policy must be maintained. Details of the special authorisation procedure must be specified in the local intrathecal chemotherapy policy.

9.7.4 Any administration taking place outside this definition of normal working hours or in contravention of the local intrathecal chemotherapy policy should be recorded via the local incident reporting mechanism and reported to the Intrathecal Chemotherapy Lead.

9.7.5 Such incidents should be reviewed on a regular basis via the organisation's governance reporting structure and the Intrathecal Chemotherapy Lead and form part of the annual risk assessment.

9.7.6 Administration of any intrathecal chemotherapy will only be undertaken by individuals certified to do so as listed on the Intrathecal Chemotherapy Register.

9.7.7 Individuals undertaking training or competency assessments towards inclusion on the Intrathecal Chemotherapy Register can administer intrathecal chemotherapy only under direct supervision of a named competency assessor for intrathecal or intraventricular administration (see 7.4.7).

9.7.8 Should problems be encountered accessing the intrathecal space or accessing the intraventricular access device, assistance may be sought from another member of staff to position the needle. This additional member of staff must not undertake any other aspects of the procedure and never administer intrathecal chemotherapy unless on the Intrathecal Chemotherapy Register for that task.

9.8 Sequencing of Intravenous and Intrathecal / Intraventricular Anti-cancer Therapy

For each patient:

9.8.1 Where at all possible, intravenous SACT known to be neuro-toxic (e.g. vinca-alkaloids) should not be scheduled to be administered on the same day as the intrathecal chemotherapy.

9.8.2 Where administration of intravenous SACT is scheduled on the same day as intrathecal chemotherapy, the intravenous SACT should be issued and administered separately both in time and location space to any intrathecal chemotherapy.

9.8.3 Intrathecal chemotherapy should be scheduled for administration after intravenous SACT. Any intrathecal chemotherapy should only be issued by

pharmacy once they have received confirmation that all intravenous SACT for the patient has been completed.

9.8.4 In paediatric patients where general anaesthesia is often used, administration of intrathecal chemotherapy may be scheduled prior to intravenous SACT. Any intravenous SACT should only be issued from pharmacy once they have received confirmation that the intrathecal chemotherapy for the patient has been completed

9.8.5 Where a regimen involves intrathecal chemotherapy combined with continuous intravenous SACT there should be confirmation that intravenous infusion has started or is still running before intrathecal chemotherapy is issued from the pharmacy.

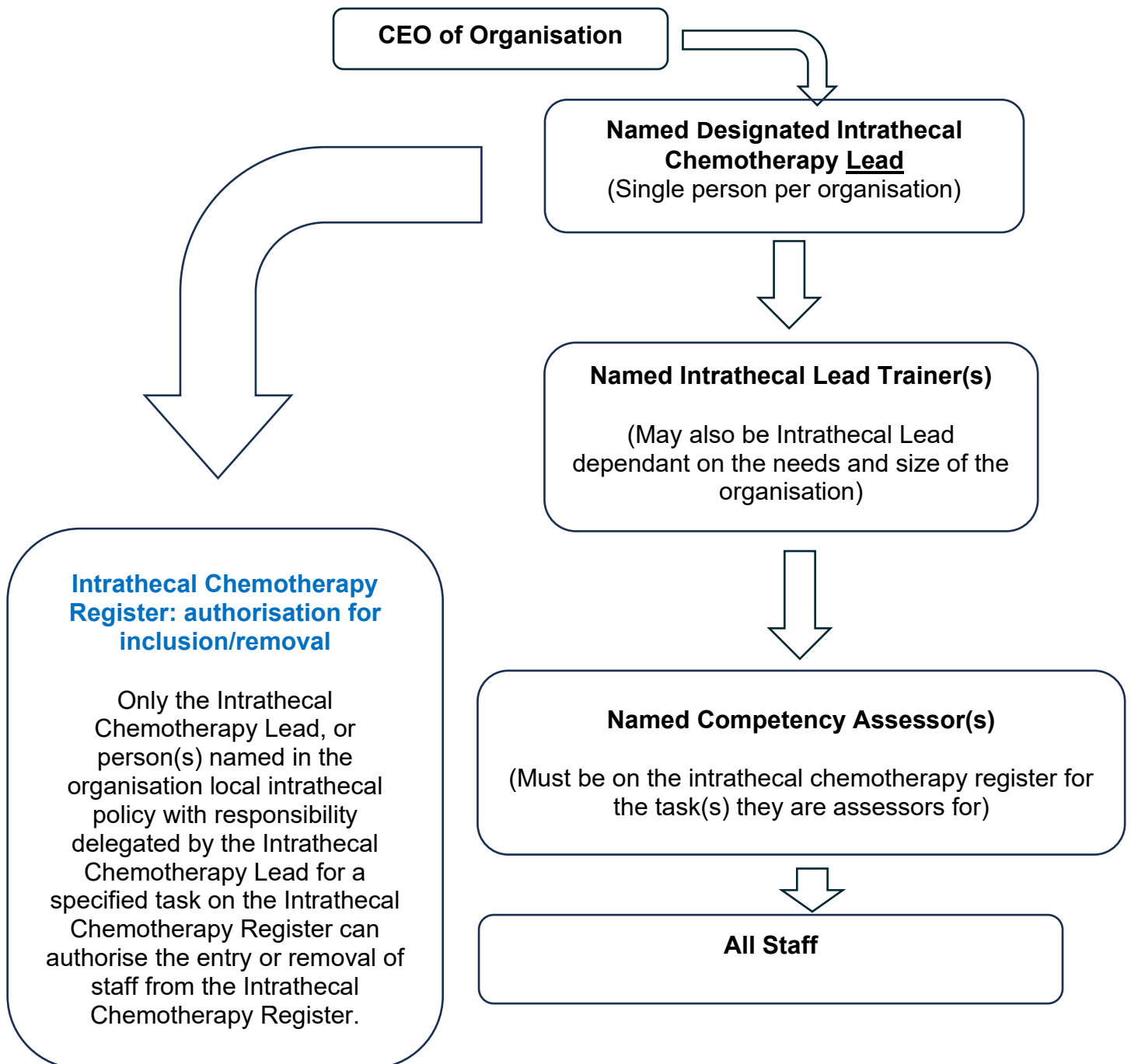
9.8.6 Where a regimen requires intravenous SACT to be given before and after the intrathecal chemotherapy (e.g. twelve hourly dosing of Intravenous cytarabine) the intrathecal chemotherapy must be retained in pharmacy until confirmation the first dose of intravenous SACT has been administered. The release of the second intravenous SACT dose may only occur once pharmacy has confirmed the intrathecal chemotherapy has been administered.

9.8.7 A process should be agreed and set out in the local intrathecal chemotherapy policy as to how confirmation of administration of intravenous SACT or intrathecal chemotherapy is communicated to pharmacy. Confirmation must be written or digital. Verbal confirmation is not permitted.

9.8.8 The local intrathecal chemotherapy policy should include details of actions to follow where intrathecal chemotherapy dose has been issued but not administered.

10. Appendices

Appendix A: Delegation of Accountability / Responsibilities Flow Chart



Appendix B: Dilution of Vinca Alkaloids for Intravenous use

The UK SACT Board has not altered or amended the archived guidance below, this is provided for information and to signpost healthcare organisations to undertake risk assessments rather than waivers in this area of practice.

The following information reflects the National Patient Safety Agency's rapid response report NSPA/2008/RRR004 entitled Using Vinca Alkaloid Minibags (Adult/Adolescent Units)^[3] and Manual for Cancer Services Chemotherapy Measures v1.0. (2014)^[2]

The statements on the dilution of vinca alkaloids presented in syringes are in accordance with the advice from DoH HSC2003/010 & HSC2008/010.

1. Vinca alkaloids should be supplied in the form of **minibags** to adult and teenagers treated in adult and also Teenage and Young Adults cancer services ^{[9][10]}. The following points apply:
 - a. The prescribed dose of vinca alkaloids should be supplied **ready to administer in a 50ml minibag** of sodium chloride 0.9% (for some brands of vinorelbine, glucose 5% solution for injection may be used instead of sodium chloride 0.9%).
 - b. All vinca alkaloid doses should be labelled '**For Intravenous Use Only - Fatal If Administered by Other Routes**'.
 - c. There should be consideration of **design on the label**, outer packaging and delivery bags to further differentiate minibags containing vinca alkaloids from other minibag infusions.
 - d. The **vinca minibag should be infused intravenously** over 5 - 10 minutes.

This does not apply to children or teenagers being treated in a children's cancer service ^{[11][12]} where syringes should be used.

2. Vinca alkaloids should be supplied to **children's cancer services ^{[11][12]} only in syringes**.**

The following points apply regarding dilution:

- Patients **over the age of 10 years**, the pharmacy should dilute the volume of intravenous **vincristine** to a maximum concentration of 0.1mg/ml and dispense it in a 10ml syringe as a minimum.

- Patients **over the age of 10 years**, the pharmacy should dilute the volume of intravenous **vinblastine, vindesine or vinorelbine** to a minimum volume of 20ml.
- Children **under the age of 10 years** intravenous **vincristine, vinblastine, vindesine or vinorelbine** can be given at a higher concentration

****See point 4 for exceptions following a risk assessment**

3. The full range of options for treatment by patient type and place of care are summarised in Table 1. Note that this advice provides consistency by place of care i.e. only minibags given in adult, adolescent or adult/adolescent units. This is taken from NPSA/2008/RRR04 [2]

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

Clinical Area/ Unit	Patient Type			
		Adult	Teenager	Child
	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 to current practice).	Vinca dose in a syringe (No change to current practice).

4. Risk Assessments:

- Children's cancer services: Principal Treatment Centres^[11] may decide, following a risk assessment, to give intravenous vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) to children of any age at concentrations higher than those specified above. This practice must be clearly defined in the organisation's local intrathecal chemotherapy policy, covered in intrathecal chemotherapy induction and training and approved by the Chief Executive, Medical Director, Director of Nursing & Chief Pharmacist.

- Children should not be treated in adult or adolescent clinical areas (see references 9 –12 for guidance on age definitions). In the unlikely situation that this requirement should arise, a local risk assessment should be undertaken to determine the safest method of intravenous vinca alkaloid treatment.

11. About the UK SACT Board

11.1 The UK SACT Board provides guidance, oversight and support for the continuing development of SACT services in the UK. Its core membership comprises representatives of the Association of Cancer Physicians, The Royal College of Radiologists, the Royal College of Physicians, the British Oncology Pharmacy Association, the UK Oncology Nursing Society, and the British Society of Haematologists. The Board also has representation from the four UK nations, a patient representative and from other organisations closely involved in SACT services.

12. Disclaimer

12.1 While every reasonable care has been taken to ensure the accuracy of the material, the UKSB cannot accept any responsibility for any action taken, or not taken, on the basis of it. As publisher, the UKSB shall not be liable to any person for any loss or damage which may arise from the use of any of the material.

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14. Version History

Version No.	Date	Lead Author	Brief Description of Changes
1.0	October 2026	Dave Hobin	First version

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