NATIONAL CANCER CONTROL PROGRAMME

Guidance on the Safe Use of

Intrathecal Chemotherapy

in the Treatment of Cancer

NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer
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Version	Date	Amendment	Approved By
1	November 2015	Initial Report	NCCP Oncology Medication Safety Review Implementation Steering Committee
2	December 2016	Following feedback, an amendment was made to Recommendation 37 which states "First prescription in adult hospitals is by consultant only. Subsequent prescriptions may be made by Reg/ SpR". This recommendation has been amended to state that the first prescription may be written by the Cons/ Reg/ SpR provided the decision to treat with intrathecal chemotherapy has been documented by the consultant in the patient's treatment plan.	NCCP Oncology Medication Safety Review Implementation Steering Committee
3	November 2020	Hospital names and map of Ireland updated on page 17 Recommendation 33 - the phrasing of negative labelling amended Recommendation 35 - the use of neuraxial devices updated. Appendix 1 - Terms of Reference updated to reflect the review of national guidance and development of e-learning module. Appendix 2 - new project board group membership added Appendix 6 minor amendment. Changed 'pharmacist' to 'pharmacy staff' to include all pharmacy staff in training as required.	NCCP Intrathecal Chemotherapy Project Group 2020
4	February 2025	HSE logo updated Removal of 'Oncology Medication Safety Review Implementation Resources' from cover page Footer updated with title of document Glossary – inclusion of anthracyclines Replaced 'hospital group' with 'health region' throughout document Applied Tallman lettering to drugs names	NCCP Intrathecal Chemotherapy Working Group 2025

		where appropriate Executive summary updated NCCP Oncology Medication Safety Review Key Recommendations moved to Appendix section Background section shortened Updated webpage links Methodology section removed NCCP SACT Model of Care included Section 2.12 Removed sentence re: ITC Lead responsibilities as similar sentence in same paragraph Chemotherapy unit replaced with SACT unit Rec. 1 – included 'intrathecal chemotherapy' Rec. 2 – Inclusion of CEO Rec. 3 – Inclusion of 'should align to NCCP SACT Model of Care' Rec. 4 – Inclusion of CEO; removal of 'who will be accountable to them for this issue' Rec. 7 – calculate ITC volume in hospital – wording revised Rec. 9 – Inclusion of 'How' hospital carries out ITC processes Rec. 11 – Inclusion of 'should be dedicated' for different tasks; Moved footnote re: registration lapse after one year into body of recommendation Rec. 12 – Eligible prescribers – included ANP and removed SHO. Updated note re: SHO and high volume hospitals Rec. 20 – Revised competency wording to include supervision of procedures as part of 5 competent procedures for trainers Rec. 23 – Inclusion of HSE e-learning module and word 'storage' into recommendation Rec. 24 & 25 – Inclusion of 'checking' in ITC processes Rec. 26 – Inclusion of positive wording signs Rec. 28 – Replaced pharmacy staff with	

		designated transport person Rec. 31 – revised wording & footnote regarding same day administration of ITC and non-ITC (including neurotoxins); additional safeguards & mitigating actions should be in place Rec. 32 & 33 – Inclusion of positive labelling Rec. 35 – yellow colour packaging removed; no specific colour recommended Rec. 36 – revised wording Rec. 37 – Head of Service replaced with clinical director; paediatric prescribing updated; footnote included re: SHO prescribing in high volume hospital Rec. 38 – update to include electronic prescribing Rec. 39 – Recommendation retired as Rec. 39 now includes comment on neurotoxins Rec. 40 – updated key access wording Rec. 41 – updated wording to include example of designated area Rec. 42 – wording revised and ANP included in checking step Appendices – Terms of Reference removed Appendices - Project Group Membership removed Appendices– ITC Competencies removed; available as separate document on NCCP website Appendix 1 – Removed “collect” column from sample register Appendix 2 – Pharmacist replaced with pharmacy staff Appendix 4 – Prescription check included in first step; Date of birth added to identity check Appendix 5 – Updated procedure wording to include ANP	

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Glossary and Definitions

- **ANP** – registered Advanced Nurse Practitioner
- **Anthracyclines** - a group of chemotherapeutic agents, e.g. DAUNOrubicin, DOXOrubicin. These agents are administered intravenously and are neurotoxic.
- **Chemotherapy drugs** - any systemic anticancer treatment
- **Chemotherapy order** - a written, printed or electronic order for chemotherapy to be administered in a hospital
- **Competency** - a defined skill or task which the individual is deemed capable of carrying out independently, in a safe and effective manner
- **Consultant** - consultant medical oncologist, consultant haematologist, consultant paediatric oncologist or consultant paediatric haematologist, registered on the Specialist Division of the Register of Medical Practitioners maintained by the Medical Council (of Ireland).
- **Cytotoxic** - chemicals that are directly toxic to cells preventing their replication or growth
- **Dispensing** - is the activity of preparing the dose and placing in packaging for transport.
- **Division** - A health region or cancer network may encompass more than one hospital and ITC may be administered to different categories of patients in different hospitals and within different departments within a hospital. For the purpose of implementation of these recommendations, these parts of the ITC service are termed 'divisions'. It is recognised that the term "division" may mean different things in different hospitals. The term as it is applied here is used solely for the purpose of implementation of these recommendations and health region/cancer network/individual hospitals locally may use a different term if they wish.
- **Hospital manager –** Chief Executive Officer, General Manager or other person charged with the management of a hospital
- **Intrathecal chemotherapy -** intrathecal chemotherapy or intra-ventricular chemotherapy which is injected into the intrathecal cavity of the spinal cord.
- **Prescriber** - the person authorised to order or prescribe chemotherapy
- **Proteasome inhibitor** – a neurotoxic chemotherapeutic agent which is usually administered intravenously or subcutaneously, depending on the type of drug. Bortezomib is an example of proteasome inhibitor.
- **Registrar** - A doctor, appointed to the hospital's Medical Oncology/Haematology Services, with several years' experience but who is not on a recognised specialist training programme.
- **Specialist Registrar** - A trainee specialist doctor undertaking a higher specialist training programme in Medical Oncology or Haematology with one of the recognised postgraduate training bodies.
- **Systemic anticancer therapy** - all chemotherapy, biological agents and vaccines delivered with the purpose of treating malignancy.

- **Vinca alkaloid** – a neurotoxic chemotherapeutic agent which is always administered intravenously. The following drugs are examples in the class of drugs referred to as vinca alkaloids: vinCRIStine, vinBLAStine, vindesine, vinorelbine and vinflunine.

Abbreviations

ANP	Advanced Nurse Practitioner
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
ITC	Intrathecal Chemotherapy
NCCP	National Cancer Control Programme
NCHD	Non Consultant Hospital Doctor
Rec.	Recommendation
SHO	Senior House Officer
SOP	Standard Operating Procedure
SpR	Specialist Registrar

Executive Summary

Intrathecal Chemotherapy (ITC) is an important component of the management of malignancy and symptom control. It is a prime example of a procedure which should be identified within a clinical service as having high risk associated with it. Effective clinical governance therefore requires that there is an explicit local strategy to contain that risk.

Sentinel events associated with the inadvertent intrathecal administration of neurotoxins[1-3] have been repeatedly reported[1]. Many patients receiving these drugs also receive other medication via an intrathecal route as part of their treatment protocol. Accidental administration of neurotoxins such as vinca alkaloids[2], proteasome inhibitors[3] or anthracyclines[4] into the cerebrospinal fluid has resulted in death (1-5). Since 1968, this error has been reported in a variety of international settings at least 55[5] times (2). There have been repeated warnings over time and extensive labelling requirements and standards have been published (2, 6-10). However, errors related to the accidental administration of vinCRIStine via a spinal route continue to occur (3).

This guidance completes the NCCP action relating to recommendation 71 of the NCCP Oncology Medication and Safety review[6] (11), where the NCCP was to lead on the development of national policies for intrathecal chemotherapy and the preparation of neurotoxins.

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[1] Neurotoxins include vinca alkaloids and proteasome inhibitors. Other chemotherapeutic agents can also be neurotoxic.

[2] VinCRIStine,which is an example of a vinca alkaloid, is a widely used chemotherapeutic agents which is neurotoxic and must only be administered intravenously

[3] Proteasome inhibitors are widely used chemotherapeutic agents which are neurotoxic and must only be administered intravenously or subcutaneously, depending on the nature of the agent.

[4] Anthracyclines are widely used chemotherapeutic agents which are neurotoxic and must only be administered intravenously

[5] There have been additional reports of this error since this publication was available.

[6] The NCCP Oncology Medication Safety review was conducted across the 26 hospitals in Ireland involved in the administration of systemic cancer therapy in adults and children. The aim of this review was to assess the oncology medication policies and practices in day units nationally, from a patient safety and quality perspective.

The recommendations in this guidance are for implementation locally, in conjunction with the general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy and the NCCP Systemic Anticancer Therapy Model of Care, and will ensure the safety and quality of SACT services.

In addition, all staff involved with the care and treatment of patients receiving chemotherapy must be encouraged to challenge colleagues, no matter how senior their position, 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.

The general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy also apply to management and provision of an intrathecal chemotherapy service.

The NCCP recommends that hospitals collaborate within the health region or existing cancer network structure, to share good practice pertaining to systemic cancer therapy provision and to develop and implement national policies and practices for oncology medication.

Other relevant work

This document should be read in conjunction with the following documents:

- NCCP Oncology Medication Safety Review (10)
- NCCP Systemic Anticancer Therapy (SACT) Model of Care(12) .
- Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids) in the Treatment of Cancer
- NCCP Guidance for the assessment of Competency for the Provision of Intrathecal Chemotherapy

All of these documents are available on the NCCP website at https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/safetyreview/.

1 Background

This document has been produced in response to the recommendations of the NCCP Oncology Medication Safety Review Report 2014 (11).

The NCCP Oncology Medication Safety review implementation steering committee established a project board in late 2014 to complete the NCCP action relating to Recommendation 71 of the NCCP Oncology Medication Safety Review for the development of national policy for ITC and the preparation of neurotoxins for the treatment of cancer. Key stakeholders in the process are listed in Appendix 2.

The findings of the Oncology Medication Safety review led to the recommendations set out in Table 1 below and the subsequent establishment of a project board to develop national guidance and detailed recommendations, similar to those developed in other countries (13-17).

Table 1: NCCP Oncology Medication Safety Review recommendations on Intrathecal Chemotherapy

Recommendations		HIQA standards(18)
Rec. 68	All hospitals administering intrathecal chemotherapy should have the following policies in place: • A policy for the prescribing, preparation, delivery, storage and administration of intrathecal chemotherapy • A policy on the dilution of neurotoxins (e.g. vinca alkaloids and proteasome inhibitors)[7].	3.1
Rec. 69	Intrathecal chemotherapy should always be stored in a different area to other parenteral chemotherapy.	3.1

[7] Including the minimum recommendations of WHO (2007).

Rec. 70	All other parenteral chemotherapy should always be given at a different time to intrathecal chemotherapy.	3.1
Rec. 71	The NCCP to lead on the development of national intrathecal polices to inform the content of these local hospital policies.	3.1

This guidance document is structured according to the following headings:

- Governance and Service Configuration
- ITC administration activity
- Protocols
- The ITC Register
- Induction and Training
- ITC management - Pharmacy Department
- ITC prescribing, checking and administration

2 Recommendations

All references to intrathecal chemotherapy (ITC) in the following sections should be read as equally applicable to intra-ventricular chemotherapy.

These recommendations should be implemented in conjunction with the general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy and the NCCP SACT Model of Care.

The Hospital CEO/Manager of each hospital providing an intrathecal chemotherapy service has overall responsibility for ensuring compliance with these national recommendations.

2.1 Governance and Service Configuration

2.1.1 Organisation of the service

It is recommended that the divisions of the ITC service should map, if possible, on to the general clinical chemotherapy services of the hospital, provided this is compatible with the ITC recommendations themselves. E.g. if a hospital has a combined solid tumour oncology and haemato-oncology clinical chemotherapy service it should consider having a combined division of the ITC service, which deals with the cases arising from both areas of practice. However, it should be subject to the following constraints:

- There should be no more than one division of the ITC service for adult solid tumour oncology in a given hospital and no more than one division of the ITC service for adult haemato-oncology in a given hospital.
- If number of adult patients for ITC in either solid tumour or haemato-oncology is very small, resulting in concerns about lack of experience/practice, then a single division for adult services combining both solid tumour oncology and haematology should be considered.
- There should be no more than one division of the ITC service for paediatric oncology in a given hospital.

2.1.2 Clinical Leadership

The hospital lead for ITC will have overall responsibility for clinical governance in relation to ITC. A deputy lead will also be required.

The nurse responsible for training others in the administration of general chemotherapy may or may not be the same person as the ITC lead trainer. Assessors of competency for ITC administration may or may not be the same people as competency assessors for general chemotherapy administration, provided the relevant recommendations are fulfilled in each case.

The ITC Lead can appoint others to be lead trainers in the different disciplines (medical, nursing, pharmacy). A trainer from one of these disciplines will train the portering and other staff who may be involved.

Box 1 Recommendations on Governance and Service Configuration

Recommendations on Governance and Service Configuration	
ITC Rec. 1	Hospitals with an intrathecal chemotherapy service must have an intrathecal chemotherapy policy in place. Hospitals that do not normally administer intrathecal chemotherapy should have a written policy to that effect.
ITC Rec. 2	The Hospital CEO/Manager of each hospital providing an intrathecal chemotherapy service has overall responsibility for ensuring compliance with these national recommendations.
ITC Rec. 3	These recommendations should be implemented in conjunction with the general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy and should align to the recommendations in the NCCP SACT Model of Care.
ITC Rec. 4	The Hospital CEO/Manager should identify a single lead to oversee compliance with this guidance referred to as “ITC lead” throughout this

	guidance. This lead can be a doctor, nurse or pharmacist. Where there is an adult and paediatric service or where cover is required for periods of leave etc., a “deputy designated lead” may also be appointed.
ITC Rec. 5	If a health region, cancer network or individual hospital identifies a single lead to oversee compliance in the divisions[8] into which the intrathecal chemotherapy service is divided this should be declared in the policy, naming the hospitals and categories of patient which are encompassed by each division.
ITC Rec. 6	The ITC Lead may delegate responsibility for named divisions of the service. If the ITC lead delegates named individuals (as per ITC Rec. 4 and ITC Rec. 5) to be responsible for named divisions of the service and/or a named ITC training lead, these should be declared. Each delegate declared as responsible for a named division of ITC service should have agreed a list of responsibilities with the ITC lead.

[8] A health region or cancer network may encompass more than one hospital and ITC may be administered to different categories of patients in different hospitals and within different departments within a hospital. For the purpose of implementation of these recommendations, these parts of the ITC service are termed 'divisions'. It is recognised that the term "division" may mean different things in different hospitals. The term as it is applied here is used solely for the purpose of implementation of these recommendations and health regions/cancer network/individual hospitals locally may use a different term if they wish.

2.2 ITC administration activity

Box 2 Recommendations on ITC administration activity

Recommendations on ITC administration activity	
ITC Rec. 7	The number of ITC administrations performed in the Hospital per year should be recorded[9]. This number should be averaged over the previous 2 years to establish the ITC volume / activity level in the hospital[10]. • If the number of administrations per year as recorded is 10 or less (Low Volume), a risk assessment should be carried out on the ITC service with respect to safety issues associated with having a Low Volume service, and with respect to these recommendations. The decision to continue the service should be agreed by the Hospital Manager. • If the number of administrations per year, as recorded, is 500 or more (High Volume), a risk assessment should be carried out on the ITC service with respect to the safety issues associated with having a High Volume service and with respect to the ITC guidance. It should include 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.
ITC Rec. 8	The Hospital should identify the department with responsibility for the recording of ITC activity[9].

[9] These may be recorded and audited using a form, such as the sample form in Appendix 3.

[10] Definition of low and high volume hospitals is adopted from the DOH (England) HSC 2008/001 Circular. Low volume = 10 procedures or less each year; High volume = 500 procedures or more each year

2.3 Protocols

Box 3 Recommendations on protocols

Recommendations on protocols	
ITC Rec. 9	There should be a single, written, local (i.e. Hospital) protocol covering the national ITC guidance, which clarifies how the guidance applies specifically to the Hospital's own ITC service. It should specify: • **Who,** in terms of named personnel and/or posts in the Hospital, is permitted to carry out tasks involved in ITC as specified in the guidance. • **Where**, in the Hospital, in terms of named divisions of the ITC service, hospitals, wards, departments, pharmacies, designated areas and physical facilities, specified tasks are permissible. • **Where** in the Hospital, (as above), copies of the key documents specified in the ITC guidance, may be found. • **How** the hospital carries out the ITC processes (see Rec. 38) *Note: If the local protocol and/or ITC guidance is maintained in electronic form on the Hospital intranet, there should be a method designed to ensure that these documents are kept up to date as displayed on the intranet.*
ITC Rec. 10	There should be version-controlled hard copies of the local protocol and the national ITC guidance in at least the following locations in the Hospital: • All areas where ITC is dispensed, issued or administered. • All wards (oncology in-patient area) where oncology/haemato-oncology patients are ordinarily admitted, even if not used as ITC areas. Or a decision taken by the ITC Lead that a hard copy will be available in a single location and its location known to all relevant staff. *Note: There should be a method for the Hospital, designed to ensure that the hard copies of the national ITC guidance and the local protocol, lodged in the locations in ITC Rec. 9 are kept up to date.*

2.4 The ITC Register

A sample ITC register is included in Appendix 1.

Box 4 Recommendations on the ITC register

Recommendations on the register	
ITC Rec. 11	There should be a register for the Hospital of named personnel who are trained and certified competent[11] to participate in ITC tasks. The register should fulfil the following criteria: • There should be a single register for the whole Hospital. Different parts of the Register should be dedicated for different tasks, as specified below, and copies of these parts may be kept in separate locations, but for each task there should be a unique list of registered personnel, each list being a distinct part of the register. • It should cover the following separate tasks, making up the entire ITC process: - Prescribing ITC - Verification of ITC - prescriptions - Dispensing ITC drugs - Issuing ITC drugs from the pharmacy - Collecting ITC drugs from the pharmacy - Transporting ITC drugs to the location where they will be administered - Checking ITC drugs prior to administration - Administering the ITC. *Note:*

[11] Minimum competencies are defined in the "NCCP guidance for the assessment of Competency for the Provision of Intrathecal Chemotherapy"

Recommendations on the register	
	(1) *A given person may appear as registered for more than one task, but the register should specify all the named staff who are competent for each task.* (2) *The registration status of any registered staff member never lasts for more than 2 years. Registration will lapse after one year where fewer than five ITC competent procedures are performed and/or supervised (supervised relates to the trainer observing a trainee). Their name is deleted from the register unless their competence is reviewed and re-certified within that time. Re-certification may be dependent on refresher training.* (3) *Persons transferring from another hospital who are deemed ITC competent in that hospital can be included on the hospital register once the local induction training is complete and they have been assessed as competent, according to their new Hospital's own protocol – see ITC Rec. 13.*
ITC Rec. 12	The following procedures regarding registration should be incorporated in the local protocol: • Only those staff members named on the Hospital's own register for a given task in the ITC process are permitted to perform that task in the Hospital, except for those personnel as detailed in the next bullet point. • Personnel may perform a given registerable task under the direct supervision of, and in the constant presence when performing it, personnel who are agreed as Hospital competency assessors for that task when it is being performed as part of the Hospital ITC registration training programme, competency review or refresher training. • Only those staff members who have been trained and assessed as competent in that task, according to the Hospital's ITC training procedure, are eligible to be registered for that task. See “NCCP

Recommendations on the register	
	guidance for the assessment of Competency for the Provision of Intrathecal Chemotherapy" for minimum agreed competencies. • Only medical staff of the following levels of seniority (following training and the attainment of competence) are eligible to be registered for prescribing ITC[12]; Consultants, SpRs, Registrars[13] and ANPs. • Only medical staff of the following levels of seniority (following training and attainment of competence) are eligible to be registered to administer ITC; Consultants, SpRs, Registrars and ANPs. Note: (i) In a Hospital that is a high volume hospital, as defined[10], SHOs can be registered to prescribe and administer ITC (following training and attainment of competence) in line with the hospital's local policy. (iii) Radiologists who position lumbar puncture needles are not permitted to perform any other part of the ITC process or procedure.
ITC Rec. 13	All staff transferring to the hospital who at the time of transfer were on the ITC register of their previous hospital are only eligible for entry onto the register of the hospital under review when they have provided written confirmation from that hospital of their entry on the previous hospital's register, current at the time of transfer and have been inducted, and have been assessed as competent, according to their new hospital's own protocol.

[12] Prescribing in the paediatric setting is by consultants only. First prescription in adult hospitals may be written by Cons/Reg/SpR provided the decision to treat with intrathecal chemotherapy has been documented by the consultant in the patient's treatment plan. Subsequent prescriptions may be by a Registrar / Specialist Registrar.

[13] Registrars working in the discipline of medical oncology or haematology who have been deemed competent to administer ITC.

Recommendations on the register	
ITC Rec. 14	The following procedures regarding holding and maintaining the register should be incorporated in the local protocol: • Only the ITC lead (or their deputy in their absence) or the single named person with responsibility delegated by the ITC lead for a specified part of the register, can authorise the entry of an eligible person onto that part of the register for that respective task. • If applicable, the people delegated to have responsibility for authorising entry onto the register for specified tasks, should be named in the policy, against the respective tasks. • At their biennial review of competence, or at any other time, the ITC lead is authorised to remove a staff member from the register, if they are assessed by the ITC lead as performing their registered task(s) insufficiently often to maintain competence or are no longer employed at the organisation. • The initial assessment of competence and its biennial reconfirmation includes there being written confirmation that the staff member has read the ITC national guidance and associated local protocols.
ITC Rec. 15	There should be a method for the Hospital designed to ensure that the competence of registered personnel is reviewed biennially[10] and then (i) Reconfirmed or (ii) Refresher training is initiated or (iii) They are removed from the register.
ITC Rec. 16	It should be confirmed in writing, (or by email), every two years[14] that registered staff have read the latest versions of the national ITC guidance and associated local protocol.

[14] Registration will lapse after one year where less than five ITC competent procedures are performed

Recommendations on the register	
ITC Rec. 17	There should be a method for the Hospital, designed to ensure that registered personnel have the frequency with which they perform registered tasks monitored and their competence subsequently reviewed from this point of view.
ITC Rec. 18	There should be a method for the Hospital (to be determined locally) designed to ensure that: • An electronic version of the most up-to-date register is available to all relevant staff. In addition, at least one controlled version hard copy of the register must be available and its location known to all relevant staff.

2.5 Induction and Training

Box 5 Recommendations on Induction and Training

Recommendations on Induction and Training	
ITC Rec. 19	There should be an ITC Lead Trainer for the Hospital, either the ITC Lead or a named individual delegated with the responsibility by the ITC Lead. The Lead Trainer should be drawn from one of the following: Consultant Medical Oncologist or Paediatric Oncologist, Consultant Haemato-oncologist, Consultant Paediatric Haematologist; Nurse on the ITC register or Pharmacist on the ITC register. The Lead should be particularly aware of the challenges at the time of the changeover of NCHD staff.

ITC Rec. 20	The Lead Trainer should have agreed a list of responsibilities with the ITC lead or if the latter is acting as the Lead Trainer, with the Hospital Manager. The responsibilities should include: Ensuring that: (i) For all clinical staff who are not yet on the ITC register involved in ITC: • They undertake an induction course which includes the potential clinical hazards associated with ITC, reading the national ITC guidance and the Hospital local protocol and explains that they are prohibited from becoming involved in any registered task associated with ITC. (ii) For all staff to be included on the Hospital ITC register: • they are trained in, and can demonstrate competence in, their expected registerable ITC task prior to inclusion on the register; • once registered they have their competence reconfirmed every two years or annually where fewer than five ITC competent procedures are performed and/or supervised (supervised relates to trainer observing a trainee) and they receive this confirmation in writing; • practical experience of the ITC task is part of continuing professional education for registered staff.
ITC Rec. 21	There should be an induction course, which includes the potential clinical hazards associated with ITC, reading the national ITC guidance and the Hospital local protocols and explains which staff are prohibited from becoming involved in any registered task. This should be taken into account by hospitals when planning induction for new staff, including the changeover of NCHDs.

ITC Rec. 22	A HSeLanDe-learning module is available to hospitals to facilitate the training of all healthcare staff involved in the delivery of intrathecal chemotherapy. The module integrates key learning points from NCCP guidance documents on intrathecal chemotherapy and neurotoxic drugs to promote safe practices in the prescribing, supply, handling and administration of intrathecal chemotherapy. The training from this module is transferable between hospitals and ensures that staff possess an appropriate level of training in line with the national guidance. There should be a mandatory training course provided locally, and competency criteria which are prerequisite for eligibility for inclusion on the register. The timing of training courses should take account of scheduled changeover of NCHDs. The training and the competency criteria should include material needed for all registered staff, including the subjects in the induction course as in ITC Rec. 21, with additional material as relevant only to the specific ITC task which the staff member is seeking registration for, out of the following: • Prescribing ITC • Verification of ITC prescriptions • Dispensing ITC drugs • Issuing ITC drugs from the pharmacy • Collecting ITC drugs from the pharmacy • Storage • Transporting ITC drugs to the location where they will be administered • Checking ITC drugs prior to administration • Administering the ITC

ITC Rec. 23	There should be named competency assessors for the Hospital, specific for the register of ITC tasks. • They, and only they, should be permitted to assess and reconfirm the competency of staff seeking inclusion on the register. • They should have fulfilled the following criteria: Either: they have been through the Hospital's agreed training programme and have themselves been assessed as competent by it for the tasks which they assess; Or: (for those who were the initial assessors of competence for the Hospital) they have been deemed competent directly by the ITC lead.
ITC Rec. 24	Staff working in areas involved in the prescribing, preparation, dispensing, checking, storage, distribution and administration of ITC must sign a written confirmation that they are aware that they cannot carry out any ITC related duties unless their name is included on the ITC register. This should form a component of the induction training of these staff.

2.6 ITC management - Pharmacy Department

The responsibility for recommendations ITC Rec. 25 to ITC Rec. 36 lies with the ITC Lead and they should be applied separately to, and compliance recorded separately for, each pharmacy, including any central pharmacy if relevant.

Box 6 Recommendations for ITC management - Pharmacy Department

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 25	The dispensing of ITC drugs should only be undertaken by staff currently registered for this task. Note: For the purpose of this guidance, 'dispensing' is the activity of preparing the dose, checking and placing in packaging for transport.
ITC Rec. 26	There should be storage facilities in the pharmacy for ITC drugs, if needed, for the time between dispensing and issuing of ITC drugs, which fulfil the following: • They should be lockable • They are always available • They are only ever be used for ITC drugs[15] and this is made clear Note: • *These should ideally be in the pharmacy.* • *Positive signs should be used (i.e. "For storage of intrathecal drugs only". Negative signs (i.e. "Not for ... use") should be avoided in relation to the storage of ITC drugs.*
ITC Rec. 27	The issuing of ITC drugs should only be undertaken by staff currently registered for this task.

[15] Where spatial/storage restrictions apply, pharmacies may utilise compartments or sections of existing storage. A risk assessment should be completed locally and documented to support this with particular focus on drugs which may be stored in the same areas.

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 28	When issuing ITC drugs, it should be carried out only in one of the following ways: Either: Physically handed over in the pharmacy to the person who will be administering the ITC on the ward. (In this case this person is referred to as 'the collector'). Or: Transported by a person, whose name appears on the register, to the ward where the ITC will be administered and there, physically handed to the person who will be administering the ITC or placed by the a designated transport person into a designated storage facility as specified in ITC Rec. 40. Note: This is distinct from the storage facilities in the pharmacy, specified in ITC Rec. 26.
ITC Rec. 29	When issuing ITC drugs, there should be a clear record (signatures) that the named issuer released the drugs from the pharmacy. Or, if relevant, there should be a clear record (signature) that the named issuer placed them into the designated storage facility specified in ITC Rec. 40, and when this was done.
ITC Rec. 30	When issuing an individual dose of ITC which has been prepared as part of a batch, each individual dose should be separately issued and separately signed for by the issuers before they are released from the pharmacy or separately signed into the designated storage specified in ITC Rec. 40.

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 31	Ideally, a patient's ITC should be administered on a separate day to the patient's other non-ITC parenteral chemotherapy. Each hospital should have a policy in place which indicates the order of administration if a patient is to receive ITC chemotherapy on the same day as other non-ITC parenteral chemotherapy. Where neurotoxins are being administered on the same day as intrathecal chemotherapy, additional safeguards must be sanctioned and documented by the hospital[16]. Safeguards include the use of neuraxial devices, minibags for vinca alkaloids, segregated transport, segregated storage and segregated administration area. There should be written confirmation[17,18] that either: i. All non-ITC parenteral chemotherapy for a given patient on a given day, has been administered to that patient before any ITC for that patient is issued by pharmacy for administration on that day. (Where a regimen involves ITC combined with continuous intravenous infusion, there should be written confirmation that IV infusion has already begun before ITC is issued from the pharmacy.) or *ii.* All ITC for a given patient on a given day, has been administered to that patient before any non-ITC parenteral chemotherapy is issued by pharmacy for administration on that day. *Note: There may be exceptions to the locally agreed sequencing where ITC is to be given to patients under general anaesthetic or according to current / future protocols which should have additional safeguards and mitigating actions in place. Specific safeguards should be put in place, and documented by the hospital, to facilitate this exception.*

[16] Where pragmatically possible, neurotoxins should be administered on a separate day to intrathecal chemotherapy.

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 32	There should be a written policy in the pharmacy department and implemented in each cytotoxic reconstitution unit to the effect that, for labels on individual doses of ITC drugs, the following apply: • They should clearly show the patient's name and the name of the product. • The route of the administration should be clearly printed in the largest font size possible and ideally emboldened if possible • Positive labelling should be used to ensure associations between the product and its intended use, e.g. vinca alkaloids must be clearly labelled with the intended route of administration. For example, ‘‘FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES.’’ The use of negatively worded labels such as ‘‘Not for XY’’ must be avoided as XY may be misread as being the recommended instructions.

[17] Written confirmation could include paperwork such as the signed administration record or a stand-alone declaration that the intravenous chemotherapy administration is complete.

[18] Where an electronic administration system is in use for chemotherapy the confirmation on the electronic record that the intravenous chemotherapy administration is complete, or in the case of an intravenous chemotherapy infusion that the infusion has commenced, will replace the requirement for written confirmation.

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 33	There should be a written policy[19] in the pharmacy department and implemented in each cytotoxic reconstitution unit or dispensing pharmacy department to the effect that labels on individual doses of neurotoxins (e.g. vinca alkaloids and proteasome inhibitors), should: • Clearly show the patient's name and the name of the product and the route of administration (2). • Provide a clear warning of the consequences of administration by other routes. (For example, - "for intravenous use only - fatal if given by other routes") (2). • Positive labelling, e.g. FOR INTRAVENOUS USE ONLY, should be used. Avoid the use of negatively worded labels, e.g. “Not for XY”, which can be misread.
ITC Rec. 34	There should be a written policy[19] in the pharmacy department and implemented in each pharmacy, to the effect that: • ITC drugs should be packed and transported separately from treatments which are to be administered by other routes. • ITC drugs should be transported in bags/containers which are distinct from bags/containers used for any other purposes.
ITC Rec. 35	• Neuraxial devices i.e. NRFit® are recommended for ITC. Hospitals should transition to these devices as soon as possible. In the absence of the use of neuraxial devices, a label should be placed on the individual syringe stating that it is for intrathecal administration only. • Arrangements for transport and delivery should be in line with local hospital policies, as per ITC Rec. 34.

[19] This recommendation should be read in conjunction with the NCCP Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids) in the Treatment of Cancer, available at https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/safetyreview/itc.html

Recommendations for ITC management - Pharmacy Department	
ITC Rec. 36	There should be a written policy[19] in the pharmacy department and implemented in each pharmacy, to the effect that: • The dilution of neurotoxins should follow the instructions in the NCCP Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids) in the Treatment of Cancer(19).

2.7 ITC prescribing, checking and administration

Box 7 Recommendations for the Declared Divisions of the ITC Service

Recommendations	
These recommendations are specifically with regard to the management of ITC and should be implemented in conjunction with the general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy.	
ITC Rec. 37	There should be a written policy for the ITC division in the local protocol, agreed with the relevant Clinical Director for chemotherapy that ITC should only be prescribed by registered medical practitioners according to the local protocol. • Prescribing in the paediatric setting is under the written direction of the attending consultant. • First prescription should be prescribed by Cons/Reg/SpR/SHO[20] provided the decision to treat with intrathecal chemotherapy has been documented by the attending consultant.

[20] SHOs can only be registered to prescribe ITC (following training and attainment of competence) if the hospital is a high volume hospital in line with local policy

ITC Rec. 38	There should be a dedicated ITC prescription template (either on paper or electronically) with processes in place according to local arrangements and considerations. For example, there may be a paper chart uniquely for ITC, separate from the general SACT paper chart, or a dedicated area on the general paper chart uniquely reserved for recording ITC[1]. For electronic systems a separate prescription or therapy plan may be utilised, or after local risk assessment it may be reasonable to prescribe ITCs with other medications provided the specific ITC procedures are followed. The local processes should also include details for people to record, by handwritten or electronic signature[2] that they have carried out the following tasks: prescribing, issuing, collecting, checking by nurse and administering doctor[3]. The drug and route of administration to be clearly indicated in full.
ITC Rec. 39	Recommendation retired. Refer to Rec. 31.

[1] The requirement for a separate or integrated prescription for intrathecal drugs should be conducted locally and the results documented.

[2] Where the prescription format does not allow for sufficient space for a full signature, an initial box will be acceptable where there is a signature bank available on the SACT unit and a signature archive maintained for historical purposes. This is applicable only to written signatures. Systems in use for computerised prescribing and administration of intrathecal chemotherapy must maintain an audit trail of the persons prescribing and administering intrathecal chemotherapy.

[3] Where the prescription format does not allow for sufficient space for the signatures of the person/s issuing and collecting the ITC an audit trail record may be utilised (Appendix 3).

ITC Rec. 40	There should be a facility available outside the pharmacy, in an appropriate location, for the storage of ITC drugs between issuing and administration, if administration has to be delayed. The facility and its use should fulfil the following criteria: • It should be kept locked except for the depositing or withdrawal of ITC drugs. • Swipe key access or physical key (acquired from ward CNM) should be required to lock and unlock the ITC storage facility. • It should be used exclusively for ITC drugs stored between their being issued and administered. This should be clearly indicated. Note: • *Negative signs (i.e. "Not for ... use") should be avoided on or in relation to the storage facility* • *The facility may be a locked box as a component of a general storage area e.g. dedicated lockable box within a chemotherapy fridge.*
ITC Rec. 41	There should be a designated area or areas for the division of the service (e.g. designated room on a ward), where ITC chemotherapy is given which should fulfil the following criteria: • When ITC is being administered in the area it should not be used for any other purpose until the completion of administration. This precludes its use for any other form of chemotherapy for that session. • Chemotherapy drugs for administration by other parenteral routes should never be stored in the area even when it is not in use. *Note: Any plans for 'new build' SACT units or the updating of existing SACT units must include provision for a permanently designated area for administration of ITC if the Hospital wishes to provide this service. This does not preclude its use for other activities when not required for ITC administration.*

ITC Rec. 42	There should be a written ITC checking procedure for the division in the local protocol, which specifies the following: • The checking of drugs prior to their ITC administration (as specified below) should only be done by staff who are registered for this task. • It ensures that the correct drug at the correct dose is to be given to the correctly identified patient by the correct administration route, prior to administration. • It is carried out by at least the following staff members: a nurse registered for the checking of ITC and the registered doctor or ANP (see ITC Rec. 12) who will be administering the ITC. • All checks made are recorded. *Note: Two doctors checking is not an appropriate substitute for a nurse taking part in the procedure.* A sample checking format is included in Appendix 4 and a sample patient information leaflet is included in Appendix 5. *Note:* *This checking procedure, if desired, may also include the patient or their parents or guardians as an additional check to Dr/ANP - as specified above. It allows and offers the opportunity for the patient or, if relevant (e.g. in the case of patients who are minors), the parent, or guardian of the patient, to take part in the checking process if they so desire.*
ITC Rec. 43	The administration of ITC should be carried out only by persons registered for this task.

ITC Rec. 44	ITC should be given during normal working hours and should only be given outside normal working hours in exceptional circumstances. There should be a written policy for the division designed to ensure that ITC is administered within normal working hours wherever possible. It should fulfil the following: • Normal working hours should have an agreed local definition for the purposes of this policy. • The exceptional circumstances in which ITC may be administered outside this definition of normal working hours should be specified. • The special authorisation procedure (which should be over and above normal procedure) which is then necessary to allow it, should be specified in line with the guidance. • Following such administration: (i) A record should be kept, specifying each out of hours administration, enabling their frequency to be monitored. (ii) Documentation should be provided on why each had to take place out of hours, the remedial action taken and the outcome.

3 CONCLUSION

The implementation of the above recommendations should ensure a safe and quality intrathecal chemotherapy service for patients.

Appendix 1. Sample ITC Register

The following staff have been deemed competent in the documented areas and have been approved by the relevant ITC lead for addition to the ITC register

Name	Role/Specialisation	Registration Number[21]	Date added to register	Assessed by	Prescribe	Verify	Prepare / Dispense	Issue	Transport	Check	Administer
A Registrar	Registrar	123445			✓				✓	✓	✓
A Nurse	Nurse – e.g. CNS	123445							✓	✓	
A Porter	Porter	N/A							✓		
A Pharmaceutical technician	Pharmaceutical technician	N/A					✓		✓		
A Pharmacist	Pharmacist	123445				✓	✓	✓	✓		
AN Other	Other -	N/A or 123445					✓	✓	✓		

[21] Professional registration number where applicable, otherwise N/A

Appendix 2. Key stakeholders in the intrathecal chemotherapy process

Department of Health

HSE (Acute Hospitals, Clinical Programmes, Quality Improvement, Nursing & Midwifery Services, National Doctor Planning and Training)

Hospital Group Management

Hospital management

Doctors

Nurses

Pharmacy Staff

Clinical Indemnity Scheme

Patients and Patient Advocacy Groups

NCCP

Relevant education and training bodies

Relevant regulatory bodies

Relevant professional bodies

Appendix 3. Sample form for ITC audit trail

Date of administration:	
Patient Demographics:	
ITC prescriber:	
ITC prescription clinically checked by:	
ITC collected/delivered by:	
ITC delivered to:	
ITC administered by:	
ITC administration where:	
Comments:	

Please return the completed form to the Pharmacy Department[22] following administration for the purposes of audit and quality control.

NOTE: Hospitals may wish to amend this form locally to include the names or roles of the person registered to complete each task.

[22] The Pharmacy Department may be replaced by another Department/Ward within the hospital as required. This should be identified in the policy.

Appendix 4. Sample Checking Procedure

1. The doctor or ANP administering the ITC must check the prescription to identify if there is other chemotherapy to be administered on the same day.
2. The doctor or ANP administering the ITC must check the following details on the ITC label against the chemotherapy prescription:
   - Patient's name
   - medical record number (M.R.N.)
   - drug
   - dose
   - route of administration
   - expiry date and time.
3. These details are also to be checked independently by the nurse assisting the procedure.
4. The patient[23] is given the opportunity to check the details, as set out in Appendix 5.
5. The volume in the syringe must be confirmed against the label and also that the syringe is intact and the cap is sealed tight.
6. The patients' identity (name, date of birth and MRN) must be formally confirmed and checked against the patients' wristband.
7. All mobile phones must be turned off and responsibility for answering bleeps transferred to other staff for the duration of the procedure.
8. Ensure a "Do Not Disturb" notice is on the door in the designated areas for administration of ITC (see sample inFigure 1).

[23] Or, if relevant, (e.g. in the case of patients who are minors), the parent or guardian of the patient.

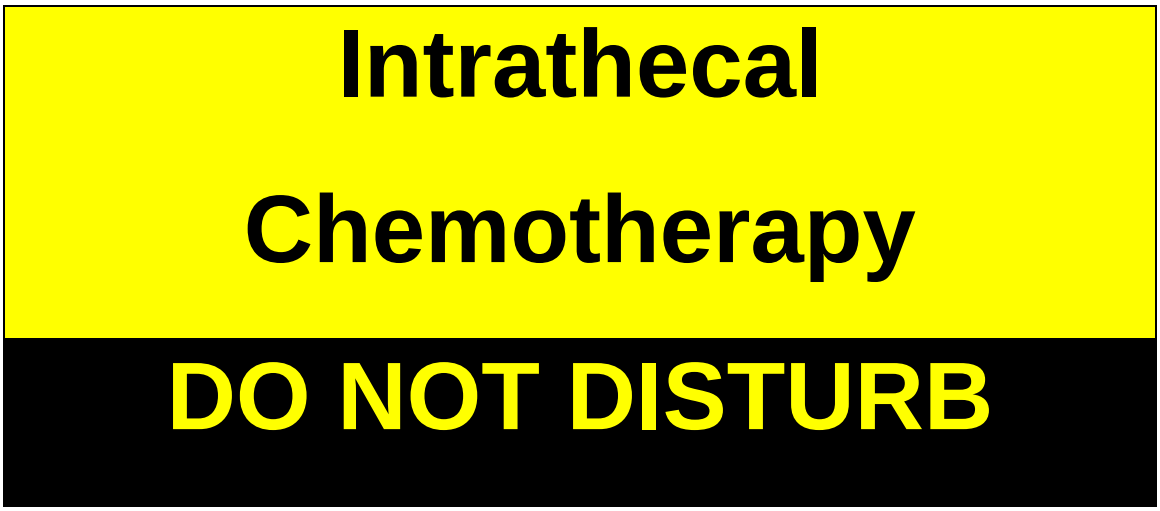

Figure 1: Sample sign to be attached to the door where ITC is being administered

Appendix 5. Sample Patient Information – Intrathecal Chemotherapy

Your doctor has prescribed intrathecal chemotherapy called _____ (which is cytotoxic or cell toxic treatment) for your condition. This means that you will have cell toxic drugs given by injection into the fluid around the spinal cord by a lumbar puncture.

What will happen?

- Because this is a special procedure you will be moved to a designated area whilst it takes place. Only specially trained staff will be involved.
- If you wish, you may check the drug yourself before it is given. You should check that the label states your name, the drug name that you are expecting to get intrathecally, the dose, and that the word "intrathecal" is on the label. If you read these out loud, you can check that they are as you expect and the nurse/doctor can check against the prescription.

- If you have any concerns before the drug is given to you, ask the nurse/doctor/pharmacist. If you are still concerned, ask to speak to a separate member of the team (nurse/doctor/pharmacist). If you are still concerned after speaking to two healthcare professionals, ask for the procedure to be stopped until your concerns can be addressed to your satisfaction, if it is safe to do so.

Lumbar Puncture Procedure for the Administration of Intrathecal Chemotherapy

There are two usual positions for this procedure.

Lying Down

- You will be asked to lie on your side, with your knees drawn up to your tummy and held in place by your hands.
- The nurse will support you in this position by gently holding you behind your knees and neck.

Sitting

- You will be asked to sit with your back facing the doctor or ANP, your arms folded, supported over some pillows or the back of a chair, with your head resting on your arms.

The procedure in either position continues as follows:

It is important that you remain very still, but do tell the doctor or nurse how you are feeling throughout the procedure.

- The skin will be cleaned with antiseptic cleansing agents.
- Local anaesthetic may be put onto the area of skin that is being punctured.

- The spinal needle will be inserted into your spine.
- The intrathecal chemotherapy will be put in with a small syringe.
- The needle will be taken out and a small dressing put over the area.
- You will be asked to lie flat on your back on the bed for about 4 to 6 hours after the procedure.

Appendix 6. Key recommendations from NCCP Oncology Medication Safety Review 2014

A number of key recommendations in relation to the safe delivery of intrathecal chemotherapy services were identified below. Hospital CEOs/Managers should determine appropriate responsibility for the implementation of recommendations locally.

The key recommendations are:

- A local protocol covering all aspects of governance of intrathecal chemotherapy use must be in place.
- A register must be established and maintained in each hospital, which lists designated personnel who have been trained and authorised to prescribe, prepare, dispense, transport or administer intrathecal chemotherapy.
- Only persons trained, deemed competent and with a current registration on the register may prescribe, prepare, dispense, transport or administer intrathecal chemotherapy.
- A formal induction/education programme must be provided for all new staff (including medical consultants) including training that is appropriate to their role in the prescribing, dispensing, checking, issuing or administering intrathecal chemotherapy, supported by the relevant national training programme.
- Competence reviews by the hospital are required for all professional staff. See the NCCP Guidance for the assessment of competency for the provision of intrathecal chemotherapy.
- A purpose-designed paper or electronic chemotherapy chart should be used.
- Intravenous neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) must be clearly and appropriately labelled, packaged and transported so as to minimise the risk of error.
- Intrathecal chemotherapy should only be administered within standard working hours, and in an area where no other parenteral chemotherapy drugs are given or stored concurrently

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