# NATIONAL CANCER CONTROL PROGRAMME

## Oncology Medication Safety Review

## *Implementation Resources*

# Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer



NCCP Oncology Medication Safety Review *Implementation Resources*. Rec. 71 Intrathecal Policies.
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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".<br><br>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<br><br>Recommendation 33 - the phrasing of negative labelling amended<br><br>Recommendation 35 - the use of neuraxial devices updated.<br><br>Appendix 1 - Terms of Reference updated to reflect the review of national guidance and development of e-learning module.<br><br>Appendix 2 - new project board group membership added<br><br>Appendix 6 minor amendment. Changed 'pharmacist' to 'pharmacy staff' to include all pharmacy staff in training as required. | NCCP Intrathecal Chemotherapy Project Group 2020 |

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# Glossary and Definitions

- **ANP** – registered Advanced Nurse Practitioner
- **Chemotherapy drugs** - any systemic anti cancer 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 hospital group 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 hospital groups/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 anti cancer 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] or proteasome inhibitors[3] chemotherapy into the cerebrospinal fluid has resulted in death (1-4). Since 1968, this error has been reported in a variety of international settings at least 55[4] times (2). There have been repeated warnings over time and extensive labelling requirements and standards have been published (2, 5-9). However, errors related to the accidental administration of vincristine via a spinal route continue to occur (3).

This report presents the recommendations from the Project Board convened to complete the NCCP action relating to recommendation 71 of the NCCP Oncology Medication and Safety review[5] (10), where the NCCP was to lead on the development of national polices 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] There have been additional reports of this error since this publication was available.

[5] 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 draft version of this document was made available for consultation for a period of four weeks and the consultation process was notified to key stakeholders. Comments received during the consultation feedback were considered by the Project Board and incorporated, as appropriate, into the final document.

The recommendations are for implementation locally, in conjunction with the general recommendations of the NCCP Oncology Medication Safety review report on chemotherapy, and will ensure the safety and quality of intrathecal chemotherapy 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 new hospital group 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 NCCP Oncology Medication Safety Review (10). The ITC Project Board has produced the following documents which should be read in conjunction with this document:

- Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids)
- NCCP Criteria for Acting as an Assessor of Competence – Intrathecal Chemotherapy
- NCCP Guidelines for the assessment of competency for the provision of intrathecal chemotherapy.

All of these documents are available on the NCCP website at www.hse.ie/nccponcsafetyreview.ie.

**Key recommendations**

The Project Board identified a number of key recommendations in relation to the safe delivery of intrathecal chemotherapy services. Hospital CEOs/General 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 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.

# 1 Background

This policy has been produced in response to the recommendations of the NCCP Oncology Medication Safety Review Report 2014 (10). The findings of that review pertaining to intrathecal chemotherapy were:

- Some hospitals where intrathecal chemotherapy is administered do not have an intrathecal policy in place.
- Intrathecal drugs are prescribed on the same chemotherapy order forms as other parenteral chemotherapy in most hospitals.
- Some of the hospitals where intrathecal chemotherapy is administered have:
    - A specified area for administration of intrathecal chemotherapy
    - A segregated delivery for intrathecal chemotherapy or a policy on the collection of intrathecal chemotherapy by the doctor immediately prior to administration
    - Designated boxes for the transport of intrathecal chemotherapy
    - Colour differentiation to distinguish intrathecal chemotherapy from other intrathecal drugs
    - A register of doctors approved to administer intrathecal chemotherapy.

The findings of that review led to the recommendations set out in Table 1 below and the subsequent establishment of a project board to develop a national policy and detailed recommendations, similar to those developed in other countries (11-15).

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

| Recommendations | | HIQA standards(16) |
|---|---|---|
| **Rec. 68** | All hospitals administering intrathecal chemotherapy should have the following policies in place:<br>• A policy for the prescribing, preparation, delivery, storage and administration of intrathecal chemotherapy<br>• A policy on the dilution of neurotoxins (e.g. vinca alkaloids and proteasome inhibitors)[6]. | 3.1 |
| **Rec. 69** | Intrathecal chemotherapy should always be stored in a different area to other parenteral chemotherapy. | 3.1 |
| **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 |

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

In an effort to minimise these risks, the NCCP Intrathecal Chemotherapy Project Board have made a number of recommendations 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

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.

# 2 Methodology

## 2.1 Introduction

The NCCP Oncology Medication Safety review implementation steering committee established a project board in late 2014 (the terms of reference are at Appendix 1 and members are listed in Appendix 2) 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. The project board was given responsibility for key decision making in relation to project scope and key priorities. The project board met four times during the process of development of the recommendations and a further time to discuss the comments received following the consultation process on the draft report. The recommendations were published on the NCCP website for consultation in addition and the consultation process was notified to key stakeholders in the process (key stakeholders included in the consultation process are listed in Appendix 5).

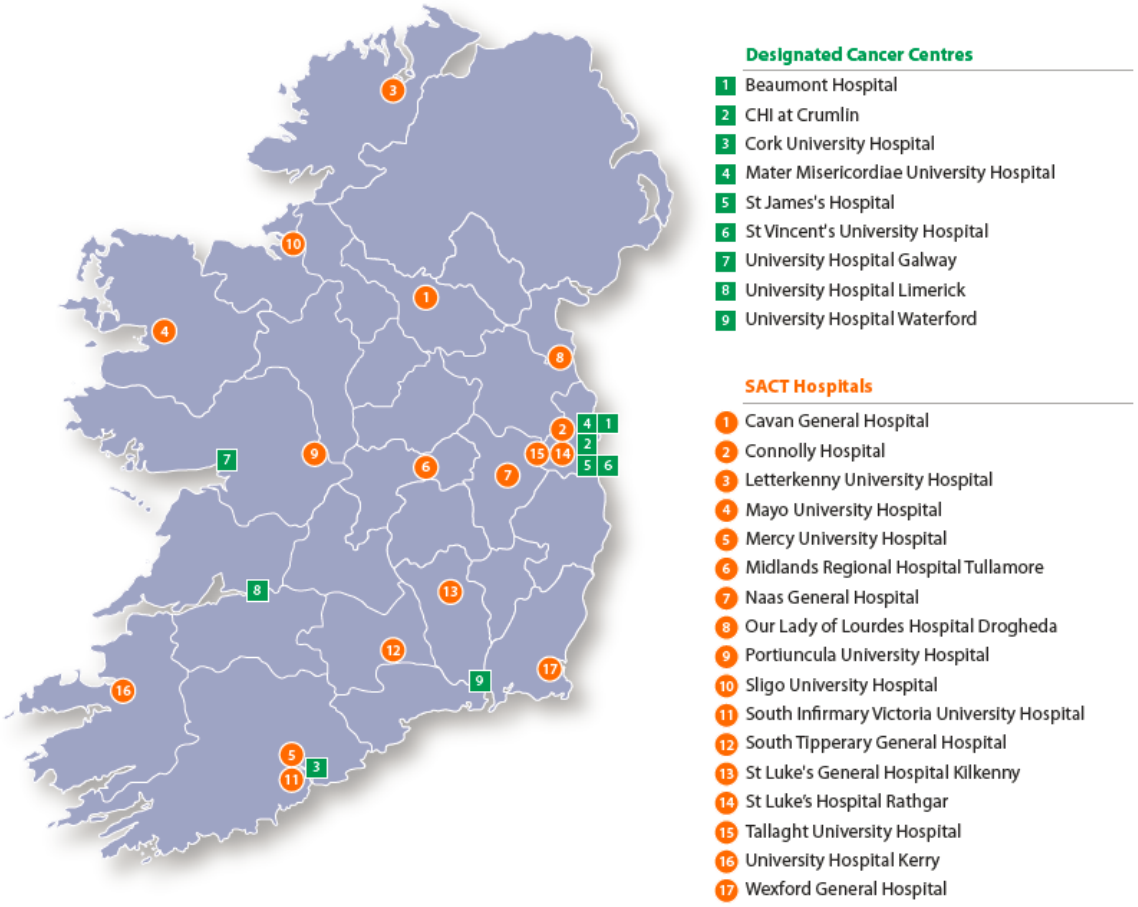
## 2.2 Data Collection

There are 26 hospitals in Ireland which deliver systemic cancer therapy (Figure 1) two of which have independent haematology and oncology day units.

In order to inform the development of an ITC policy as part of the implementation of the NCCP Oncology Medication Safety Review, a data collection template was prepared and circulated in November 2014 in order to obtain information about existing ITC services across the 25 adult chemotherapy hospitals. Information was also sought on ITC activity from Crumlin Hospital in February 2015.

Responses were received from 25 hospitals (including 2 for Tallaght – one for each of the medical oncology service and haematology service there).

**Figure 1: Location of units delivering systemic anti-cancer therapy[7]**




[7] Letterkenny General Hospital is a designated satellite of the cancer centre in Galway.

## 2.3 Response to data collection

### *2.3.1 Hospitals that administer ITC*

Of the 25 hospitals that responded to the data collection request, 14 hospitals administer ITC (including both Tallaght services) and the remaining 11 do not. See Table 2 for details.

**Table 2: Responses to data request**

| Hospital | ITC Service | Hospital | ITC Service |
|---|---|---|---|
| CONNOLLY | No | PORTIUNCULA | No |
| BEAUMONT | Yes | SLIGO | Yes |
| CAVAN | No | SOUTH INFIRMARY/VICTORIA | No |
| CRUMLIN | Yes | SOUTH TIPPERARY | No |
| CUH | Yes | ST. JAMES'S | Yes |
| DROGHEDA | No | ST. LUKE'S DUBLIN | No |
| GALWAY UH | Yes | ST. LUKE'S KILKENNY | No |
| KERRY | No | ST. VINCENTS | Yes |
| LETTERKENNY | Yes | Tallaght Med Onc | Yes |
| LIMERICK UH | Yes | Tallaght Haem Onc | Yes |
| MATER | Yes | TULLAMORE | Yes |
| MAYO | No | WATERFORD | Yes |
| MERCY | Yes | WEXFORD | no response |
| NAAS | No | | |

### *2.3.2 ITC Services for medical oncology / haematology / both*

One hospital provides ITC services for medical oncology only (this is the medical oncology service in Tallaght which is separate to the haematology service).

Four of the services are haematology-only ITC services, including Children's Health Ireland (CHI) at Crumlin.

Ten hospitals provide ITC services for both medical oncology and haematology. See Table 3 for details.

**Table 3: ITC Services provided, by hospital**

| Hospital | Medical oncology only | Haematology only | Both Medical Oncology & Haematology |
|---|---|---|---|
| BEAUMONT | | | 1 |
| CRUMLIN | | 1 | |
| CUH | | | 1 |
| GALWAY UH | | | 1 |
| LETTERKENNY | | 1 | |
| LIMERICK UH | | | 1 |
| MATER | | | 1 |
| MERCY | | | 1 |
| SLIGO | | | 1 |
| ST. JAMES'S | | | 1 |
| ST. VINCENTS | | | 1 |
| Tallaght Haemato-oncology | | 1 | |
| Tallaght Medical Oncology | 1 | | |
| TULLAMORE | | 1 | |
| WATERFORD | | | 1 |
| Total | 1 | 4 | 10 |

### *2.3.3 Combined service or separate service*

Of the ten hospitals that have services for both medical oncology & haemato-oncology, five have combined services (Galway, Limerick, Mater, Sligo & St. James's) and five

have separate services (Beaumont, CUH, Mercy, St. Vincent's & Waterford). This is in addition to Tallaght which has separate medical oncology & haematology services as listed above.

### 2.3.4 ITC policies & designated areas

Hospitals were asked to identify, separately for their medical oncology/haematology/ combined ITC services, whether (i) an ITC policy was in place, (ii) if there was a designated area for ITC administration and (iii) if a designated area was available, whether it was also used for administration of other systemic parenteral chemotherapy and/or for other purposes.

### 2.3.5 Policies

Of the 14 hospitals with ITC services, policies for ITC were in place in 8 hospitals. A further two hospitals had draft policies in development in at least one of their services. Three hospitals had no policy for their ITC services and one hospital did not answer the question. See Table 4 for details.

**Table 4: Availability of ITC policies**

| Hospital | Policy Med Onc | Policy Haem | Policy Combined |
|---|---|---|---|
| BEAUMONT | Yes | Yes | |
| CRUMLIN | | Yes | |
| CUH | No | Draft | |
| GALWAY UH | | | Draft |
| LETTERKENNY | | Yes | |
| LIMERICK UH | | | Yes |
| MATER | | | No |
| MERCY | | | Yes |
| SLIGO | not answered | not answered | not answered |
| ST. JAMES'S | | | Yes |
| ST. VINCENT'S | | | Yes |
| Tallaght Haem Onc | | No | |

| | | |
|---|---|---|
| Tallaght Med Onc | No | |
| TULLAMORE | | Yes |
| WATERFORD | No | No |

### 2.3.6 Areas for ITC administration

One hospital that responded had a designated area for both its medical oncology and haematology ITC services (Beaumont). Three hospitals (Galway, Sligo & St. James's) had a designated area for administration of ITC for the combined services in each of their hospitals. Designated ITC administration areas were also available for the haematology service in Tullamore & St. Vincent's, for the medical oncology service in CUH (but not for its haematology service) and for the Tallaght Haematology service (but not for its medical oncology service). In Crumlin, ITC is always administered under general anaesthetic in theatre, with a dedicated theatre time slot for this purpose. A further five hospitals had no designated area for any ITC service. See Table 5 for details.

**Table 5: Designated areas for ITC administration**

| Hospital | Designated area Medical Oncology ITC | Designated Area Haematology ITC | Designated Area Combined ITC |
|---|---|---|---|
| BEAUMONT | Yes | Yes | |
| CRUMLIN | | Yes | |
| CUH | Yes | No | |
| GALWAY UH | | | Yes |
| LETTERKENNY | | No | |
| LIMERICK UH | | | No |
| MATER | | | No |
| MERCY | | | No |
| SLIGO | | | Yes |
| ST. JAMES'S | | | Yes |

| | | |
|---|---|---|
| ST. VINCENT'S | | Yes |
| Tallaght Haem Onc | | Yes |
| Tallaght Med Onc | No | |
| TULLAMORE | | No |
| WATERFORD | No | No |

### *2.3.7 Uses of designated area*

Of the eight services with designated areas for ITC administration:

- **Galway, Sligo & St. James's** each had combined medical oncology & haematology ITC services. The designated ITC areas in Galway & Sligo are also used for the administration of other systemic parenteral therapy (the area in St. James's is not). The designated ITC area in Galway is not used for other purposes but the areas in Sligo and St. James's are used for other purposes.
- **Beaumont** had separate medical oncology and haematology services and the designated areas were also used for the administration of other systemic parenteral therapy and for other purposes.
- **CUH** has separate services but only has a designated area in relation to medical oncology ITC administration, which is used for the administration of other systemic parenteral therapy but not for other purposes.
- In the case of **Tallaght Haematology**, the designated ITC area is not used for the administration of other systemic parenteral therapy but is, however, used for other purposes.
- In Crumlin, a dedicated theatre time slot is provided for ITC and no other parenteral chemotherapy is administered.
- St. Vincent's service is primarily for haematology. The designated area is not used for administration of other systemic parenteral chemotherapy but is used for other purposes.

### 2.3.8 ITC administrations per month & per annum

The number of ITC administrations per month and per annum varied across hospitals, as set out in Table 6. Just one of the hospitals that responded – Crumlin - would be classed as high volume in terms of the DOH (England) HSC circular definitions[8] (>500 procedures per annum). No other hospital in Ireland would be classed as high volume or low volume (<10 procedures per annum) under these criteria, although two hospitals (Sligo & Mercy) were close to the low volume level.

(Note: where ranges were provided by hospitals due to the variable nature of the ITC service, the upper range was recorded for the purposes of this data collection. All figures are approximate)

[8] The working group adopted the definition of "low" and "high" volume hospitals from the DOH (England) HSC circular definitions. Low volume hospital = 10 procedures or less each year), high volume hospital = 500 procedures or more per annum. (1. DOH. H**SC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy**. 2008.)

**Table 6: ITC Administrations per month and per annum (approximate; self-reported data)**

| Hospital | ITCs per month Med Onc | ITCs per month Haem | ITCs per month Combined | **Total ITCs per month** | ITCs per annum Med Onc | ITCs per annum Haem | ITCs per annum Combined | **Total ITCs per annum** |
|---|---|---|---|---|---|---|---|---|
| CRUMLIN | | 100 | | **100** | | 1300 | | **1300** |
| BEAUMONT | | | 20 | **20** | | | 240 | **240** |
| ST JAMES'S | | | 15 | | | | 184 | **184** |
| MATER | | | 12 | **12** | | | 160 | **160** |
| CUH | 1 | 7 | | **8** | 10 | 86 | | **96** |
| Tallaght | 0 | 8 | | **8** | 0 | 80 | | **80** |
| GALWAY UH | | | 5 | **5** | | | 60 | **60** |
| ST. VINCENT'S | | | 4 | **4** | | | 49 | **49** |
| LIMERICK UH | 1 | 2 | | **3** | 13 | 22 | | **35** |
| WATERFORD | | 2 | | **2** | 2 | 30 | | **32** |
| LETTERKENNY | | 2 | | **2** | | 25 | | **25** |
| TULLAMORE | | 2 | | **2** | | 24 | | **24** |
| SLIGO | | | 1 | **1** | 5 | 10 | 15 | **15** |
| MERCY | | | 1 | **1** | | | 12 | **12** |

Note: All figures are separately estimated; the annual estimate is not necessarily the monthly figure multiplied by twelve.

### *2.3.9 Colour coding of ITC*

All 26 chemotherapy hospitals were contacted and were asked to provide information on:

- The standardised colour, if any, in their hospital for cytotoxics, neurotoxins (e.g. vinca alkaloids and proteasome inhibitors), intrathecal and monoclonal antibodies.
- In relation to each drug type, the colours of printed labels, additional labels, packaging bags, secondary outer bags and transport or delivery bags and boxes were sought.

Eleven responses were received to the request for information on colour coding. The responses were considered by the group and it was clear that there was no consensus

across the hospitals. It was agreed that a recommendation on colour would be made only in relation to intrathecal chemotherapy **(see ITC Rec. 35).**

# 3 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.

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

## 3.1 Governance and Service Configuration

### *3.1.1 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 that 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.

### 3.1.2 Clinical Leadership

The hospital lead for ITC and the named persons with delegated responsibilities may or may not be the same people as the Heads of Service of general chemotherapy services in the hospital. 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 a documented policy in place. Chemotherapy hospitals that do not normally administer intrathecal chemotherapy should have a written policy to that effect. |
| **ITC Rec. 2** | The Hospital 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. |

| | |
|---|---|
| **ITC Rec. 4** | The Hospital Manager should identify a single lead to oversee compliance with this guidance who will be accountable to them for this issue – 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 hospital group, cancer network or individual hospital identifies a single lead to oversee compliance in the divisions[9] 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. |

[9] A hospital group 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 hospital groups/cancer network/individual hospitals locally may use a different term if they wish.

## 3.2 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[10]. This should be averaged over the 2 years prior to establish the volume activity level of the hospital.<br>• If the number of administrations per year as recorded for recommendation 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.<br>• 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[10]. |

[10] These may be recorded and audited using a form, such as the sample form in Appendix 6.

## 3.3 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:<br>• **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.<br>• **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.<br>• **Where** in the Hospital, (as above), copies of the key documents specified in the ITC guidance, may be found.<br>*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:<br>• All areas where ITC is dispensed, issued or administered.<br>• All wards (oncology in-patient area) where oncology/haemato-oncology patients are ordinarily admitted, even if not used as ITC areas.<br>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.<br>*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.* |

## 3.4 The ITC Register

A sample ITC register is included in Appendix 4.

**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:<br>• There should be a single register for the whole Hospital. Different parts of the Register 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.<br>• It should cover the following separate tasks, making up the entire ITC process:<br>- Prescribing ITC<br>- Verification of ITC - prescriptions<br>- Dispensing ITC drugs<br>- Issuing ITC drugs from the pharmacy<br>- Collecting ITC drugs from the pharmacy<br>- Transporting ITC drugs to the location where they will be administered<br>- Checking ITC drugs prior to administration<br>- Administering the ITC.<br>*Note:*<br>*(1) A given person may appear as registered for more than one task,* |

[11] Minimum competencies are defined in Appendix 3

| Recommendations on the register | |
|---|---|
| | *but the register should specify all the named staff who are competent for each task.*<br>*(2) The registration status of any registered staff member never lasts for more than 2 years[12]. Their name is deleted from the register unless their competence is reviewed and re-certified within that time. Re-certification may be dependant on refresher training.*<br>(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:<br>• 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.<br>• 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.<br>• Only those staff members who have been trained and assessed as competent in that task, according to the Hospital's ITC training |

[12] Registration will lapse after one year where less that five ITC competent procedures are performed.

| Recommendations on the register | |
|---|---|
| | procedure, are eligible to be registered for that task. See Appendix 3 for minimum agreed competencies.<br>• Only medical staff of the following levels of seniority (following training and the attainment of competence) are eligible to be registered for prescribing ITC[13]; Consultants, SpRs and Registrars[14]. SHOs can never be registered to prescribe ITC.<br>• 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, SHOs and ANPs.<br>Note:<br>(i) SHOs and ANPs can only be registered to administer ITC (following training and attainment of competence) if the Hospital is a high volume hospital, as defined[8].<br>(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 |

[13] 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.

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

| Recommendations on the register | |
|---|---|
| | been assessed as competent, according to their new Hospital's own protocol. |
| **ITC Rec. 14** | The following procedures regarding holding and maintaining the register should be incorporated in the local protocol:<br>• 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.<br>• 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.<br>• 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.<br>• 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<br>(i) Reconfirmed or<br>(ii) Refresher training is initiated or<br>(iii) They are removed from the register. |
| **ITC Rec. 16** | It should be confirmed in writing, (or by email), every two years[12] that |

| Recommendations on the register | |
|---|---|
| | registered staff have read the latest versions of the national ITC guidance and associated local protocol. |
| **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:<br>• 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. |

## 3.5 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.<br>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.<br>The Lead should be particularly aware of the challenges at the time of the changeover of NCHD staff. |

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| **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:<br><br>Ensuring that:<br><br>(i) For all non-registered clinical staff new to wards and departments involved in ITC:<br><br>• 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.<br><br>(ii) For all staff to be included on the Hospital ITC register:<br><br>• they are trained in, and can demonstrate competence in, their expected registerable ITC task prior to inclusion on the register;<br><br>• once registered they have their competence reconfirmed every two years, and they receive this confirmation in writing;<br><br>• 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.<br><br>This should be taken into account by hospitals when planning induction for new staff, including the changeover of NCHDs. |

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|---|---|
| **ITC Rec. 22** | 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.<br><br>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:<br>• Prescribing ITC<br>• Verification of ITC prescriptions<br>• Dispensing ITC drugs<br>• Issuing ITC drugs from the pharmacy<br>• Collecting ITC drugs from the pharmacy<br>• Transporting ITC drugs to the location where they will be administered<br>• Checking ITC drugs prior to administration<br>• Administering the ITC. |
| **ITC Rec. 23** | There should be named competency assessors for the Hospital, specific for the register of ITC tasks.<br>• They, and only they, should be permitted to assess and reconfirm the competency of staff seeking inclusion on the register.<br>• They should have fulfilled the following criteria:<br>Either:<br>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;<br>Or: (for those who were the initial assessors of competence for the Hospital) they have been deemed competent directly by the ITC lead. |

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| **ITC Rec. 24** | Staff working in areas involved in the prescribing, preparation, dispensing, 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 if the induction training of these staff. |

## 3.6 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.<br><br>Note:<br><br>For the purpose of this guidance, 'dispensing' is the activity of preparing the dose, 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:<br>• They should be lockable<br>• They are always available<br>• They are only ever be used for ITC drugs[15] and this is made clear<br><br>Note:<br>• *These should ideally be in the pharmacy.*<br>• *Negative signs (i.e. "Not for ... use") should not occur on or in relation to the storage* |

[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. 27** | The issuing of ITC drugs should only be undertaken by staff currently registered for this task. |
| **ITC Rec. 28** | When issuing ITC drugs, it should be carried out only in one of the following ways:<br><br>Either:<br><br>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').<br><br>Or:<br><br>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 member of the pharmacy staff into a designated storage facility as specified in ITC Rec. 40.<br><br>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.<br><br>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. |

| Recommendations for ITC management - Pharmacy Department | |
|---|---|
| **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** | 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[16]. There should be written confirmation[17,18] that either<br>i. All other non-ITC parenteral chemotherapy for a given patient for a given day, has been administered to that patient before any ITC for that patient are issued by pharmacy for administration on that day. (Where a regime 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.)<br>or<br>*ii.* All ITC for a given patient for a given day, has been administered to that patient before any non-ITC chemotherapy is issued by pharmacy for administration on that day.<br>*Note: The only exception to this sequencing is where ITC is to be given to children under general anaesthetic.*<br>*Specific safeguards should be put in place, and documented by the hospital, to facilitate this exception.* |

[16] See ITC Rec. 39 - neurotoxins must never be administered on the same day as intrathecal chemotherapy

[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. 32** | There should be a written policy in the local protocol for 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:<br>• They should clearly show the patient's name and the name of the product.<br>• The route of the administration should be clearly printed in the largest font size possible and emboldened.<br>• Negative labelling (i.e. "Not for ... use") must never be used. |
| **ITC Rec. 33** | There should be a written policy[19] in the local protocol for 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:<br>• Clearly show the patient's name and the name of the product and the route of administration (2).<br>• 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).<br>• Negative labelling (i.e. "Not for ... use") must be avoided. |

[19] This recommendation should be read in conjunction with the NCCP guidance on the safe use of neurotoxic drugs including vinca alkaloids, available at www.hse.ie/nccponcsafetyreview.ie .

| Recommendations for ITC management - Pharmacy Department | |
|---|---|
| **ITC Rec. 34** | There should be a written policy[19] in the local protocol, for the pharmacy department and implemented in each pharmacy, to the effect that:<br>• ITC drugs should be packed and transported separately from treatments which are to be administered by other routes.<br>• ITC drugs should be transported in bags/containers which are distinct from bags/containers used for any other purposes. |
| **ITC Rec. 35** | • Neuraxial devices (e.g. NRFit®) are recommended for ITC. Hospitals should transition to these devices. During the transition period where Luerlock syringes are being used these should have yellow barrels and/or a yellow label placed on the individual syringe stating that it is for intrathecal administration only. ITC should be placed in a sealed bag, which is then placed in a secondary yellow bag or placed in a sealed yellow bag.<br>• Hospitals should ensure, where possible, that yellow packaging is not used for other (non-ITC) chemotherapy.<br>• Arrangements for transport and delivery should be in line with local hospital policies, as per ITC Rec. 34. |
| **ITC Rec. 36** | There should be a written policy[19] in the local protocol for the pharmacy department and implemented in each pharmacy, to the effect that:<br>• The dilution of neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) should follow the instructions in the national ITC guidance(17).<br>*Note: This may be over-ridden for paediatric centres who are compliant with the dilution waiver (Neurotoxin Rec. 3).* |

## 3.7 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 Head of Service for chemotherapy that ITC should only be prescribed by registered medical practitioners according to the local protocol.<br>• Prescribing in the paediatric setting is by consultants only.<br>• First prescription may be written by Cons/Reg/SpR provided the decision to treat with Intrathecal chemotherapy has been documented by the consultant in the patients treatment plan. |

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|---|---|
| **ITC Rec. 38** | There should be a purpose-designed ITC prescription chart. This may be a chart uniquely for ITC, separate from the general chemotherapy chart, or a dedicated area on the general chemotherapy chart uniquely reserved for recording ITC[20].<br><br>There should be areas on the chart for people to authorise, by their full signatures[21] that they have carried out the following tasks: prescribing, issuing, collecting, checking by nurse and administering doctor[22].<br><br>There should be areas for the drug and route of administration to be clearly indicated in full. |
| **ITC Rec. 39** | Ideally, a patient's ITC should be administered on a separate day to the patient's other non-ITC parenteral chemotherapy. If it is necessary to administer the ITC chemotherapy on the same day as the patient's other systemic chemotherapy then ITC Rec. 31 applies. Neurotoxins must never be administered on the same day as intrathecal chemotherapy. |

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

[21] 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 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.

[22] 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 6).

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|---|---|
| **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.<br><br>The facility and its use should fulfil the following criteria:<br><br>• It should be kept locked except for the depositing or withdrawal of ITC drugs.<br><br>• The key should be kept with the nurse in charge<br><br>• It should be used exclusively for ITC drugs stored between their being issued and administered. This should be clearly indicated.<br><br>Note:<br><br>• *Negative signs (i.e. "Not for ... use") should be avoided on or in relation to the storage facility*<br><br>• *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, where ITC chemotherapy is given which should fulfil the following criteria:<br>• When ITC is being administered in the area it should not be used for any other purpose for at least the entire session. This precludes its use for any other form of chemotherapy for that session.<br>• Chemotherapy drugs for administration by other parenteral routes may never be stored in the area even when it is not in use.<br>*Note: Any plans for 'new build' chemotherapy units or the updating of existing chemotherapy 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:<br>• The checking of drugs prior to their ITC administration (as specified below) should only be done by staff who are registered for this task.<br>Note:<br>The exception to this is checking, if desired, by patients or their parents or guardians - as specified below.<br>• 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.<br>• It is carried out by at least the following staff members: a nurse registered for the checking of ITC and the registered doctor who will be administering the ITC.<br>• 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.<br>• An additional check to the minimum specified above, should be made by the nurse checking the ITC in theatre when ITC is given under general anaesthetic in theatre (as the parent or guardian is normally unable to participate).<br>• The checks made are recorded.<br>*Note: Two doctors checking is not an appropriate substitute for a nurse taking part in the checking procedure.*<br>A sample checking format is included in Appendix 7 and a sample patient information leaflet is included in Appendix 8. |

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|---|---|
| **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:<br>• Normal working hours should have an agreed local definition for the purposes of this policy.<br>• The exceptional circumstances in which ITC may be administered outside this definition of normal working hours should be specified.<br>• 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.<br>• Following such administration:<br>(i) A record should be kept, specifying each out of hours administration, enabling their frequency to be monitored.<br>(ii) Documentation should be provided on why each had to take place out of hours, the remedial action taken and the outcome. |

# 4 CONCLUSION

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

# Appendix 1. NCCP ITC Project Board Terms of Reference

**Background**

The Intrathecal Chemotherapy Project Group was originally convened to develop and agree a national guidance document for the use of intrathecal chemotherapy (ITC). The ITC Project Board was a sub-group of the NCCP Oncology Medication Safety Implementation Steering Group. The Project Group was then disbanded following the completion of the national guidance document. It was agreed that the Project Group could be re-convened as required to review the guidance in place as required and also to consider any additional projects relating to the area of intrathecal chemotherapy.

A second Intrathecal Chemotherapy Project Group was convened in 2020 to oversee the development and roll out of a formal education programme on the use of ITC.

**Membership**

1) The composition of the Group will be determined by the NCCP.
2) The Chair/s of the Group will be appointed by and report to the Director of the NCCP.
3) Membership will be for the duration of the project.
4) Additional members may be co-opted to the group from time to time

**Objective**

1. To review and refresh the national guidance as required, considering any new evidence of relevance to the recommendations contained.

2. To advise, approve and ensure that the e-learning module content is aligned to the NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer and is suitable for use by all hospitals. UHW have agreed to develop the content and incorporate the feedback of the editorial board.

**Frequency of meetings**

It is envisaged that the group will meet approximately three times and the work of the group will conclude when the e-learning programme is finalised.

**Secretariat**

The Secretariat to the group will be provided by NCCP.

# Appendix 2. Members of NCCP ITC Project Board

### Project Group Membership 2014

| Role of group | Name and professional title |
|---|---|
| NCCP | Dr Maccon Keane, Clinical Lead, Medical Oncology<br>Ms Patricia Heckmann, NCCP Chief Pharmacist<br>Ms Ciara Mellett, Medical Oncology Programme Manager |
| Consultant medical oncologist (ISMO rep.) | Dr. Cliona Grant, Consultant Medical Oncologist, St. James's Hospital. |
| Consultant haemato-oncologist – paediatrics | Aengus S. O'Marcaigh, Consultant Paediatric Haematologist, Crumlin. |
| Nursing Representatives | Ms. Lorna Cosgrave, CNM2, Beaumont Hospital.<br>Ms. Teresa Meeneghan, RANP in Haematology, Galway<br>Ms. Lorna Storey, RANP, Paediatric Haematology, Crumlin<br>Ms. Frieda Clinton, RANP, Paediatric Haematology Oncology, Crumlin |
| Pharmacy Representatives | Ms AnnMarie de Frein – Chief II Pharmacist SVUH<br>Ms. Keira McQuaid – Oncology Pharmacist, Beacon Hospital<br>Mr. Nuno Silva – Chief II Pharmacist St. Vincent's Private Hospital |

### Project Group Membership 2020

| Role of group | Name and professional title |
|---|---|
| Chair | Prof Patrick Thornton, Consultant Haemato-oncologist, Beaumont |
| NCCP | Ms Patricia Heckmann, Assistant National Director, & Chief Pharmacist, NCCP<br>Ms Anne Marie De Frein, NCCP Deputy Chief Pharmacist<br>Elizabeth Breen, NCCP Chief II Pharmacist<br>Tracy Folliard, NCCP Project Manager Systemic Therapy |
| NCCP Medical Oncology Advisor | Prof. Maccon Keane, Consultant Medical Oncologist at Galway University Hospital. |

| | |
|---|---|
| Consultant medical oncologist (ISMO rep.) | Dr. Deirdre O'Mahony, Consultant Medical Oncologist, Bons Secours, Cork |
| Consultant haemato-oncologist – paediatrics | Prof Aengus S. O'Marcaigh, Consultant Paediatric Haematologist, Childrens Health Ireland at Crumlin (CHI at Crumlin). |
| HSE Quality Improvement | Ms Ciara Kirke, Medication Safety National Lead, Quality Improvement Lead, HSE |
| Nursing Representatives | Ms. Rachel Fox, Beaumont Hospital<br>Ms. Lorna Storey, Paediatric Haematology ANP, CHI at Crumlin |
| Pharmacy Representatives | Ms Catriona Collins, Pharmacist, Galway University Hospital<br>Ms Nessa Fahy, Pharmacist, Galway University Hospital<br>Mr Enda Molloy, Pharmacist, CHI at Crumlin |

# Appendix 3. ITC Competencies

See also separate document entitled "NCCP Guidance for the assessment of competency for the provision of intrathecal chemotherapy".

## 1. Introduction

This document should be read in conjunction with the NCCP Oncology Medication Safety Review[23]. The Intrathecal Chemotherapy (ITC) Project Board has produced the following documents which should be read in conjunction with this document:

- Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer
- Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids)
- NCCP Criteria for Acting as an Assessor of Competence – Intrathecal Chemotherapy

The sections that follow set out the recommended competencies for medical doctors, advanced nurse practitioners, nurses and pharmacists involved in the provision of intrathecal chemotherapy services.

## 2. Requirements relating to all disciplines

2.1. All units providing intrathecal chemotherapy treatment must introduce and maintain a register of designated personnel who have been trained and certified competent to prescribe, check and administer intrathecal chemotherapy ("the Register"). Individuals placed on the register must have demonstrated that they are competent to fulfil their designated role and have been certified as such.

[23] Available: www.hse.ie/nccponcsafetyreview

2.2. All staff must be trained, deemed competent and entered on the register before any task related to ITC is undertaken. Under no circumstances may a person not entered on the register perform any task related to ITC.

2.3. All staff on the register must be re-accredited every two years or annually where less than five ITC competent procedures are performed.

2.4. Ensure patient is informed of procedure and written consent is obtained in line with national guidelines for informed consent for chemotherapy, for both adults and children.

2.5. A patient assessment is carried out prior to the procedure and the patient must be deemed fit for ITC. Ensure any necessary blood results are available prior to procedure e.g. platelet count, coagulation screen.

2.6. Ensure drug is checked at the bedside in front of patient with doctor or ANP administering the drug and nurse assisting: check chemotherapy protocol, drug, dose, administration date, expiry date, patient name, patient ID number. Both the doctor/ANP and the nurse must sign the chemotherapy prescription following administration.

2.7. Ensure the patient is given the opportunity to check the details, if appropriate, as set out in Appendix 8 of the NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer.

2.8. All staff should read and understand the following documents, as appropriate:

- The hospital's and department's policies on the safe provision of intrathecal chemotherapy and others as deemed relevant.
- NCCP Oncology Medication Safety review
- NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer

- NCCP Guidance on the safe use of neurotoxins in the treatment of cancer
- Using Vinca Alkaloid minibags (Adult/Adolescent Units) Rapid Response Report NPSA/2008/RRR04 (United Kingdom)

# 3. Medical Doctors

3.1. All medical practitioners[24] wishing to be included on the register of competent personnel for the provision of ITC must fulfil the requirements set out in Section 2 above and the following requirements.

a) Must be on the ITC Register before performing any activity relating to ITC.

b) Read and understand the institutional intrathecal chemotherapy policy and national Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer.

c) Be aware of the risks of intrathecal chemotherapy including the fatal consequences when intravenous neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) have been mistakenly administered via the intrathecal route.

d) Demonstrate competence in the following areas under the direct supervision of the consultant[25] who is assessing competence:

- Ensuring that the chemotherapy is prescribed correctly.
- Correct patient identification.
- Ensuring that the patient's coagulation profile and platelet count are satisfactory.
- Checking the chemotherapy with an authorised person prior to administration.
- Technical ability to perform lumbar puncture and administration of intrathecal chemotherapy under aseptic conditions

[24] Including any practitioners who have recently been on an intrathecal register in another institution.

[25] The supervising consultant should specify the number of procedures that will be supervised, particularly in the case of staff not recently on an intrathecal register in another institution.

- Reassure patient throughout procedure.
- If during any part of the procedure the doctor, nurse or patient has any concerns or questions the doctor may stop the procedure, if safe to do so, and seek appropriate advice e.g. medical/pharmacy.
- Safe disposal of procedural materials according to hospital policy
- Documentation of the procedure in the patient's medical chart

e) Is aware of action to be taken in the event of a near miss/incident or serious adverse event.

3.2 The certificate of procedural competence must be renewed every two years or annually where less than five ITC competent procedures are performed in a year. Such renewal requires the demonstration of the above competencies to the satisfaction of the supervising consultant, and must be documented on the certificate of competence, and the intrathecal register. Hospitals should take into account the timing of the changeover of NCHDs when scheduling training and competency assessments.

## Medical Doctor Assessment of Competence to prescribe or administer ITC

| |
|---|
| Name of doctor being assessed: |
| Grade of doctor being assessed: |

*To be completed as an initial assessment and be reviewed every two years or annually where less than five ITC competent procedures are performed in a calendar year.*

## To be assessed by the supervising Consultant Medical Oncologist or Haematologist / Consultant Paediatric Oncologist or Paediatric Haematologist

| No | Competency Criteria | Attained | Deferred |
|---|---|---|---|
| 1. | Read and understand the institutional intrathecal chemotherapy policy, and national guidance, particularly NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer and NCCP Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids). | | |
| 2 | Understands and can access the ITC Register | | |
| 3 | Be aware of the risks of intrathecal chemotherapy including the fatal consequences of intrathecal neurotoxin administration. | | |
| 4 | Demonstrate competence in the following areas under the direct supervision of the consultant assessing competence: | | |
| 4a | Ensuring that the chemotherapy is prescribed correctly and for the correct patient. | | |

| | | | |
|---|---|---|---|
| 4b | Ensuring that the patient is informed of the procedure and informed written consent is obtained. | | |
| 4c | Correct patient identification. | | |
| 4d | Ensuring that the patient assessment is carried out prior to the procedure and the patient is deemed fit for ITC. Ensure that the patient's coagulation profile and platelet count are satisfactory. | | |
| 4e | Checking the chemotherapy with an authorised person prior to administration. | | |
| 4f | Ensuring that the patient is given the opportunity to check the details, if appropriate. | | |
| 4g | Technical ability to perform lumbar puncture and administration of intrathecal chemotherapy under aseptic conditions | | |
| 4h | Reassure the patient throughout the procedure. If during any part of the procedure the doctor, nurse or patient has any concerns or questions the doctor may stop the procedure, if safe to do so, and seek appropriate advice e.g. medical/pharmacy. | | |
| 4i | Safe disposal of procedural materials according to hospital policy | | |
| 4j | Documentation of the procedure in the patient's medical chart | | |
| 5 | Is aware of action to be taken in the event of a near miss/incident or serious adverse event | | |

| Further Comments and Recommendations: |
|---|
| |

| | | |
|---|---|---|
| Signature of Assessor; | Print Name: | Date signed: |
| Signature of Doctor being assessed: | Print Name: | Date signed: |

# 4. Advanced Nurse Practitioners

4.1. All advanced nurse practitioners[26] wishing to be included on the register of competent personnel for the provision of ITC must fulfil the requirements set out in Section 2 above and the following requirements.

a) Must be on the ITC Register before performing any activity relating to ITC.
b) Read and understand the institutional intrathecal chemotherapy policy and national Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer.
c) Be aware of the risks of intrathecal chemotherapy including the fatal consequences when intravenous neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) have been mistakenly administered via the intrathecal route.
d) Attend local chemotherapy administration study day and complete chemotherapy work book.
e) Ensure the intrathecal chemotherapy is delivered separately from other chemotherapy drugs. In the paediatric setting where ITC is administered in theatre under general anaesthetic the nurse transferring the patient to theatre will bring the ITC for that patient to the theatre in a closed hard box labelled “cytotoxic medication for intrathecal use”.
f) Reassure patient throughout procedure.
g) If during any part of the procedure the ANP or patient has any concerns or questions, the ANP should stop the procedure, if safe to do so, and seek appropriate advice e.g. medical/pharmacy.
h) Demonstrate competence in the following areas under the direct supervision of the ANP/consultant[27] who is assessing competence:

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[26] Including any ANPs who have recently been on an intrathecal register in another institution.

[27] The supervising ANP/consultant should specify the number of procedures that will be supervised, particularly in the case of staff not recently on an intrathecal register in another institution.

- Correct patient identification.
- Ensuring that the patient's coagulation profile and platelet count are satisfactory.
- Checking the chemotherapy with an authorised person prior to administration.
- Technical ability to perform lumbar puncture and administration of intrathecal chemotherapy under aseptic conditions.
- Safe disposal of procedural materials according to hospital policy.
- Documentation of the procedure in the patient's medical chart.

i) Is aware of action to be taken in the event of a near miss/incident or serious adverse event

4.2. The certificate of procedural competence must be renewed every two years or annually where less than five ITC competent procedures are performed in a year. Such renewal requires the demonstration of the above competencies to the satisfaction of the supervising consultant/ANP, and must be documented on the certificate of competence, and the intrathecal register.

## ANP Assessment of Competence to administer ITC

| |
|---|
| Name of ANP being assessed: |
| Grade of ANP being assessed: |

*To be completed as an initial assessment and be reviewed every two years or annually where less than five ITC competent procedures are performed in a calendar year.*

## To be assessed by the supervising Consultant Medical Oncologist or Haematologist / Consultant Paediatric Oncologist or Paediatric Haematologist or assessing ANP.

| No | Competency Criteria | Attained | Deferred |
|---|---|---|---|
| 1. | Read and understand the institutional intrathecal chemotherapy policy, and national guidance, particularly NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer and NCCP Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids). | | |
| 2 | Understands and can access the ITC Register | | |
| 3 | Be aware of the risks of intrathecal chemotherapy including the fatal consequences of intrathecal neurotoxin administration. | | |
| 4 | Attend local chemotherapy administration study day and complete chemotherapy work book. | | |
| 5 | Ensure the intrathecal chemotherapy is delivered separately from other chemotherapy drugs. In the paediatric setting where ITC is administered in theatre under GA the nurse transferring the patient to theatre will bring the ITC for that patient to the theatre in a closed hard box labelled "cytotoxic medication". | | |

| | | | |
|---|---|---|---|
| 6 | Reassure patient throughout procedure. | | |
| 7 | If during any part of the procedure the ANP has any concerns or questions, the ANP should stop the procedure, if safe to do so, and seek appropriate advice e.g. medical/pharmacy. | | |
| 8 | Demonstrate competence in the following areas under the direct supervision of the consultant assessing competence: | | |
| 8a | Correct patient identification. | | |
| 8b | Ensuring that the patient's coagulation profile and platelet count are satisfactory. | | |
| 8c | Checking the chemotherapy with an authorised person prior to administration. | | |
| 8d | Technical ability to perform lumbar puncture and administration of intrathecal chemotherapy under aseptic conditions | | |
| 8e | Safe disposal of procedural materials according to hospital policy | | |
| 8f | Documentation of the procedure in the patient's medical chart | | |
| 9 | Is aware of action to be taken in the event of a near miss/incident or serious adverse event | | |

| Further Comments and Recommendations: |
|---|
| |

| Signature of Assessor; | Print Name: | Date |
|---|---|---|
| | | |

| | | |
|---|---|---|
| | | signed: |
| Signature of ANP being assessed: | Print Name: | Date signed: |

# 5. Nurses

5.1. All nurses[28] wishing to be included on the register of competent personnel for the provision of ITC must fulfil the requirements set out in Section 2 above and the following requirements.

5.2. Must be on the ITC Register before performing any activity relating to ITC.

5.3. Be aware of the risks of intrathecal chemotherapy including the fatal consequences when intravenous neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) have been mistakenly administered via the intrathecal route.

5.4. Nurses assisting with intrathecal chemotherapy treatment have to be on the hospital's ITC register. All such nurses are required to have undergone specific training and have read the national "Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer" and the "Chemotherapy Policy" within their unit. They will have attended local chemotherapy administration study day(s) and completed their chemotherapy work book.

5.5. Ensure the intrathecal chemotherapy is delivered separately from other chemotherapy drugs. In the paediatric setting where ITC is administered in theatre under general anaesthetic the nurse transferring the patient to theatre will bring the ITC for that patient to the theatre in a closed hard box labelled "cytotoxic medication".

5.6. Reassure patient throughout procedure.

[28] Including any nurses who have recently been on an intrathecal register in another institution.

5.7. If during any part of the procedure the nurse or patient has any concerns or questions the nurse should request the procedure to be stopped, if safe to do so, and seek appropriate advice e.g. medical/pharmacy.

## Nursing Assessment of Competence to check, store or collect ITC

| |
|---|
| Name of nurse being assessed: |
| Grade of nurse being assessed: |

*To be completed as an initial assessment and be reviewed every two years or annually where less than five ITC competent procedures are performed in a calendar year.*

## To be assessed by the supervising Consultant Oncologist/haematologist or supervising Nurse

| No | Performance Criteria | Assessment Method | Attained | Deferred |
|---|---|---|---|---|
| 1. | **Background reading**<br>Read and understand the institutional intrathecal chemotherapy policy, and national guidance, particularly NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer and NCCP Guidance on the Safe Use of Neurotoxic Drugs (including Vinca Alkaloids).<br>Completed Chemotherapy study Day | | | |
| 2 | Understands and can access the ITC Register | | | |
| 3 | **Experience**<br>Witnessed intrathecal chemotherapy being administered | | | |
| 4 | Complete questions on cytotoxic chemotherapy | | | |
| 5 | **Checking**<br>Checks prescription matches protocol and according to Chemotherapy policy | | | |

| | | | | |
|---|---|---|---|---|
| 6. | Checks that all intrathecal chemotherapy correctly labelled | | | |
| 7. | **Knowledge of Cytotoxic drugs Involved**<br>Actions and possible side effects/interactions | | | |
| 8. | Knowledge of appropriate doses | | | |
| 9. | Checks that intrathecal chemotherapy has been appropriately packaged | | | |
| 10. | Ensures that intrathecal chemotherapy is collected by an appropriate person | | | |
| 11. | Ensures that the prescription is signed by the administrator and counter signed by the nurse checker once intrathecal chemotherapy has been administered | | | |
| 12 | Is aware of action to be taken in the event of a near miss/incident or serious adverse event | | | |

| Further Comments and Recommendations: |
|---|
| |

| Signature of Assessor; | Print Name: | Date signed: |
|---|---|---|
| Signature of Nurse being assessed: | Print Name: | Date signed: |

# 6. Pharmacy

6.1. All pharmacy staff[29] wishing to be included on the register of competent personnel for the provision of ITC must fulfil the requirements set out in Section 2 above and the following requirements.

6.2. Must be on the ITC Register before performing any activity relating to ITC.

6.3. Pharmacy staff on the register will have undergone specific training, including but not limited to

- Undergone local systemic therapy and intrathecal chemotherapy induction and training and has been deemed competent in the relevant areas
- Be aware of the risks of intrathecal chemotherapy including the fatal consequences when intravenous neurotoxins (e.g. vinca alkaloids and proteasome inhibitors) have been mistakenly administered via the intrathecal route, and how to minimise the risk of error.
- Demonstrate an understanding of
  - The Intrathecal Chemotherapy Register
  - The procedure for ordering/prescribing, compounding, storing and dispensing/release of intrathecal chemotherapy preparations
  - Who is allowed prescribe and administer intrathecal chemotherapy
  - How intrathecal chemotherapy should be prescribed
  - The measures for risk reduction in place
  - The consequences of incorrect administration of neurotoxins

6.4. Complete and sign an assessment of competency.

[29] Including any pharmacy staff who have recently been on an intrathecal register in another institution.

## Pharmacy Assessment of Competence to Issue, Dispense and Check Intrathecal Chemotherapy

*To be completed as an initial assessment and be reviewed every two years or annually where less than five ITC competent procedures are performed in a calendar year.*

**To be assessed by the supervising[30] Pharmacist, who is approved to act as an Assessor of Competence[31]**

| |
|---|
| Name of pharmacy staff member being assessed: |
| Role and grade of pharmacy staff member being assessed: |

To be completed as an initial assessment and be reviewed every two years thereafter

- I have read and understood the "insert Hospital intrathecal chemotherapy policy reference here" ☐
- I have read the following national and international documents ☐
    - NCCP Oncology Medication Safety review
    - NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of cancer
    - NCCP Guidance on the safe use of Neurotoxic Drugs (including vinca alkaloids) in the treatment of cancer
    - Using Vinca Alkaloid minibags (Adult/Adolescent Units) Rapid Response Report NPSA/2008/RRR04 (United Kingdom)

**To be assessed by Haematology/Oncology Pharmacist:**

[30] Refers to the pharmacist supervising the person being assessed

[31] See NCCP Document "NCCP Criteria for Acting as an Assessor of Competence – Intrathecal Chemotherapy.

| | | |
|---|---|---|
| **1** | **Understands and can access the Intrathecal Chemotherapy Register** | |
| **2** | **Can describe the following procedures for intrathecal chemotherapy** | |
| 2a | ○ Ordering/prescribing including prescription formats | |
| 2b | ○ Compounding | |
| 2c | ○ Storing | |
| 2d | ○ Dispensing / release to ward/unit | |
| **3** | **Knows who** | |
| 3a | ○ Can prescribe intrathecal chemotherapy | |
| 3b | ○ Can administer intrathecal chemotherapy | |
| 3c | ○ Can collect/deliver intrathecal chemotherapy | |
| **4** | **Can explain the measures for risk reduction in place** | |
| **5** | **Can explain the consequences of incorrect administration of neurotoxins** | |

| Further Comments and Recommendations: |
|---|
| |

| | | |
|---|---|---|
| Signature of Assessor; | Print Name: | Date signed: |
| Signature of Pharmacy Staff Member being assessed: | Print Name: | Date signed: |

# Appendix 4. 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[32] | Date added to register | Assessed by | Prescribe | Verify | Dispense | Issue | Collect | Transport | Check | Administer |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A Registrar | Doctor - 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 | | | | | ✓ | ✓ | ✓ | ✓ | | |

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

# Appendix 5. 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

Pharmacists

Clinical Indemnity Scheme

Patients and Patient Advocacy Groups

NCCP

Relevant education and training bodies

Relevant regulatory bodies

Relevant professional bodies

# Appendix 6. Sample form for ITC audit trail

| | |
|---|---|
| Date of administration: | |
| Patient Demographics: | |
| ITC prescriber: | |
| ITC prescription clinical 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[33] 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.

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

# Appendix 7. Sample Checking Procedure

1. The doctor administering the ITC must check the following details on the ITC label against the chemotherapy prescription:
   - patients' name
   - medical record number (M.R.N.)
   - drug
   - dose
   - route of administration
   - expiry date and time.
2. These details are also to be checked independently by the nurse assisting the procedure.
3. The patient[34] is given the opportunity to check the details, as set out in Appendix 8.
4. The volume in the syringe must be confirmed against the label and also that the syringe is intact and the cap is sealed tight.
5. The patients' identity (name and MRN) must be formally confirmed and checked against the patients' wristband.
6. All mobiles phones must be turned off and responsibility for answering bleeps transferred to other staff for the duration of the procedure.
7. Ensure a "Do Not Disturb" notice is on the door in the designated areas for administration of ITC (see sample at Figure 2).

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


**Figure 2: Sample sign to be attached to the door where ITC is being administered**

# Appendix 8. 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, 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 how you are feeling throughout the procedure.

- The skin will be cleaned with antiseptic cleansing agents.
- The area to be punctured and local anaesthetic will be put onto the skin.

- 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.

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# Acknowledgement

The recommendations in this document are adapted from the recommendations developed by National Cancer Action Team for the NHS Manual for Cancer Services: Chemotherapy Measures. 2011 (11), available at https://www.rcplondon.ac.uk/sites/default/files/final-chemotherapy-measures_0.pdf