National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Oncology Medication Safety Review

Phase 1 Action Plan

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For circulation to hospitals

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EXECUTIVE SUMMARY

The NCCP's Oncology Medication Safety Review Report[1] presents the findings from the NCCP Oncology Medication and Safety review which was conducted across the 26 hospitals in Ireland involved in the administration of systemic cancer therapy in adults and children. The aim of the review was to assess the oncology medication policies and practices in day units nationally, from a patient safety and quality perspective.

The use of systemic cancer therapy has risen significantly in recent years, with an increase of 39% noted between 1994-2004 in Ireland (Comber and Walsh, 2008). Whilst this has brought undoubted benefits to patients, it also presents a challenge to patient safety as the number of cytotoxic drugs expands and the use of oral chemotherapy drugs increases. In addition, the increasing complexity and usage of systemic cancer therapy has raised concerns about the risks to health care workers involved in the preparation and administration of systemic cancer therapy. It is therefore prudent to take every reasonable precaution to protect staff from unnecessary exposure.

The review report set out proposed recommendations for future action which will inform the development of national policies relating to the safety and quality of systemic cancer therapy services. These forthcoming national guidelines will build on the "Guidelines for the safe administration of cytotoxic medical preparations in the treatment of patients with cancer" published by the Department of Health in 1996. The recommendations in the report were linked to the relevant standards in HIQA's National Standards for Safer Better Healthcare (HIQA, 2012).

The NCCP recommends that hospitals collaborate within the new hospital groups structure, to share good practice pertaining to systemic cancer therapy provision and to develop and implement national policies and practices for oncology medication. The NCCP plans to develop national safety policies in collaboration with stakeholders based on the learnings from this review.

The aim of this Action Plan is to provide a roadmap for the implementation of the recommendations set out in the review report.

[1] NCCP Oncology Medication Safety Review Report, January 2014. for a copy of the report, please e-mail oncologydrugs@cancercontrol.ie.

Key Findings

The review identified a number of key findings in relation to the safe delivery of systemic cancer therapy services.

Governance and Service Configuration

- Systemic cancer treatment is delivered in the 26 hospitals reviewed, which have various relationships and interdependencies. Some hospitals (including all eight designated cancer centres) have a full complement of haematology and oncology services, including designated inpatient beds for unwell patients or for in-patient chemotherapy. These often act as a hub for nurse-led units in other hospitals, where medical consultants have a sessional commitment but are not on-site each day. There are variations of both of these models, plus other examples of close collaboration across medical oncology services in some areas.

Risk Management

- Fourteen hospitals have a risk register which includes the risks of systemic cancer therapy provision. Typical risks listed include risks related to staff shortages, overcrowded treatment delivery space and risk of injury to patients and staff due to drug spillage.

Built Environment, Activity and Equipment

- Some day wards have no specified areas for preparation of medicines and only eleven units have designated isolation facilities.
- There was wide variation in the space allocated to each cubicle/treatment bay. In some units, there is less than a metre between patients receiving treatment.
- The location of the pharmacy department or the chemotherapy compounding area and the day ward varies between sites with some sites. Some sites have co-located compounding units and others having dedicated clinical pharmacy offices. Most pharmacies are located within five minutes' walk from the day ward.

Staff Training

- The review revealed that the majority of nurses working in nurse-led units have completed a higher diploma in oncology. Some smaller units link in with cancer centres for CPD (Continuing Professional Development) activities.
- Ongoing training of medical or pharmacy staff is absent in some centres.

Policies and Guidelines

- The presence of key policies related to the delivery of systemic cancer therapy is variable across hospitals.

Information for Patients and Carers

- Patients are given verbal and written information about their treatment and likely side effects by medical and nursing staff in all hospitals, before and during treatment.

Treatment Planning and Clinical Assessment

- In the charts reviewed, the treatment plan included the diagnosis and stage of disease in 93% of cases, the planned treatment regime in 90% and intended number of cycles in 80%. Details of the additional tests required pre-treatment and the results of these tests were recorded in 85% and 80% of charts respectively. Performance status was documented in approximately half of the charts reviewed. The presence or absence of allergies and history of hypersensitivity reactions was absent in 22% of patient records.
- Eleven of the 26 hospitals operate a written consent process for the provision of chemotherapy. In seven of these, this written consent process pertains to both oral and parenteral chemotherapy provision.
- The practice with regard to planned medical reviews varies across hospitals and is usually specific to the patient's treatment regime. In most cases, medical review is arranged at least once per treatment cycle, usually before treatment and often after the first cycle.

Chemotherapy Protocols

- Treatment protocols are generally stored electronically only. A copy of the version in use for the patient is frequently printed and filed in the patient's medical record.
- Ten of the 26 hospitals routinely review their in-house protocols at least once every two years and six hospitals reported having no formal review process. In addition, seven hospitals have no system in place to ensure that new/updated information on drugs is included in in-house protocols.

Chemotherapy Ordering and Prescribing

- The form of chemotherapy orders varies between sites, ranging from full handwritten orders, to pre-printed templates to electronic ordering systems.
- Most hospitals have standard discharge prescriptions for the prescribing of discharge supportive therapy and non high-tech oral chemotherapy.

- High-tech prescriptions were used for outpatient and discharge prescriptions when required.
- There were many instances in the chart review of hand written prescriptions/orders which were of poor quality, with many of the required fields not completed. In addition many of the written prescriptions/orders and pre-printed orders had unclear alterations.

Chemotherapy Orders and Prescription Checking

- Final check and sign off by a physician is variable across the hospitals. In most hospitals the prescriber does not sign the chemotherapy order prior to administration of chemotherapy (off-hold), to indicate that all the relevant tests and assessments had been completed and that the patient can proceed.
- Chemotherapy dose calculations are checked by a pharmacist, prior to release of parenteral treatment from the pharmacy, in all hospitals. This includes checking and continuation of dose reductions.
- Excluding dose calculations, pharmacist checks of parenteral chemotherapy orders vary between hospitals.
- Most oral prescriptions are not checked by a hospital pharmacist.

Administration and Monitoring of Chemotherapy

- All hospitals reported that the necessary checks are carried out prior to administration by a chemotherapy certified nurse and a second nurse is required for the checking process prior to administration.

Management of Unscheduled Care

- There were concerns raised in some of the smaller centres with regard to delays in transferring unwell patients to bigger centres with dedicated inpatient beds.

Intrathecal Chemotherapy

- Some hospitals where intrathecal chemotherapy is administered do not have an intrathecal policy in place.

Pharmacy – Chemotherapy Preparation, Labelling and Record Keeping

- There is variation between the chemotherapy compounding units/areas with some pharmacies having specifically designed aseptic units and some operating with stand alone isolators.
- Most pharmacies maintain a patient chemotherapy record either electronically and/or on paper.

Oral Chemotherapy

- A number of different approaches are taken across the country to minimise the potential risks associated with community-dispensed oral treatments.
- Three hospitals reported that there is no process in place between their hospital, community pharmacist and patient in relation to dispensing of oral systemic cancer therapy.
- The chart review revealed that the required clinical information was present more often on parenteral chemotherapy orders than oral prescriptions.

Handling, Disposal and Storage of Cytotoxic Drugs

- Cytotoxic drugs are stored separately from other drugs in all cases.
- Cytotoxic waste is not always stored in a secure designated area while awaiting collection from the ward.

Notes and updates

Phase 1 of the implementation process involves hospitals establishing local implementation teams on a multidisciplinary basis to proceed with implementing the recommendations contained in the report.

This Action Plan will be updated by NCCP on a quarterly basis. Details of working groups, updates and related documents will be made available on the NCCP website at www.hse.ie/nccponcsafetyreview.

Please send any feedback, comments or questions to the NCCP by e-mailing oncologydrugs@cancercontrol.ie.

Action Plan for the Recommendations of the NCCP Oncology Medication Safety Review

1. National Recommendations

Rec. Number	Recommendation Details	Lead Responsibility	Others involved	Timeline	Status
	Built Environment, Activity and Equipment				
Rec. 9	Guidelines should be agreed nationally on the optimum requirements of the **built environment** of a haematology / oncology day ward. Day ward design must consider: • Current and future needs/demands • Infection control recommendations • Health and safety considerations • Patient comfort • An efficient, safe work environment	NCCP	To be determined	Target implementation: Q4 2015	Not yet commenced. Working Group required.
Rec. 15	The NCCP should develop a **space planning model** to support hospitals in their local service planning with regard to day ward spatial requirements.	NCCP	To be determined	Target implementation: Q4 2015	Not yet commenced. Working Group required.
	Staffing				
Rec. 16	There should be national agreement on the **minimum key personnel** required for an oncology/haematology day unit in relation to scope of service and the essential qualifications/ experience of these key staff.	NCCP	To be determined.	Target implementation: Q4 2015	Not yet commenced. Working Group required for Rec. 16 & 17.
Rec. 17	The NCCP should develop a **capacity-planning model** to support hospitals in their local service planning with regard to day ward activity and staffing requirements.	NCCP	To be determined.	Target implementation: Q4 2015	Not yet commenced. Working Group required for Rec. 16 & 17.

Rec. Number	Recommendation Details	Lead Responsibility	Others involved	Timeline	Status
	Staff Training				
Rec. 18	**National competencies** for all disciplines in relation to acute oncology should be developed in collaboration with the relevant colleges and professional bodies	NCCP	To be determined	Target implementation: Q4 2015	Not yet commenced. Working Groups required for Rec. 18, 19 & 21.
Rec. 19	**Specialist competency training needs** to be developed and implemented for all disciplines working in the areas of clinical oncology and aseptic manufacturing.	NCCP	To be determined	Target implementation: Q4 2015	Not yet commenced. Working Group required for Rec. 18, 19 & 21.
Rec. 21	Generic guidance should be developed on **specific oncology training programmes or competency assessments** for all nurses, pharmacists and doctors.	NCCP	To be determined	Target implementation: Q4 2015	Not yet commenced. Working Group required for Rec. 18, 19 & 21.

Rec. Number	Recommendation Details	Lead Responsibility	Others involved	Timeline	Status
	Chemotherapy Ordering & Prescribing				
Rec. 55	A rigorous **validation process for electronic ordering** is required pre-implementation of electronic ordering to ensure accuracy of calculated doses. These systems must have on-going maintenance and have suitable arrangements for supervision of their use by appropriately qualified staff.	NCCP & Individual hospitals	NCCP will lead for national system	Start (local): Q1 2014 Start (national): subject to approval to proceed Finish: Ongoing	Will be incorporated into process for national medical oncology clinical information system
Rec. 56	A **national computerised physician order entry system** agenda should be developed by the NCCP and HSE IT. *(Note: this has progressed as a project for the development of a National Medical Oncology Clinical Information System)*	NCCP	NCCP Steering Group (HSE ICT, Hospital medical, nursing & pharmacy reps.) HSE ICT GCIO[2] (formerly CMOD)	Business Case approval: Q4 2014 (subsequent stages subject to approval)	Steering Group in place. Business plan in development. Subject to HSE ICT & GCIO approval & availability of funding.
	Intrathecal Chemotherapy				
Rec. 71	The NCCP to lead on the development of **national intrathecal polices** to inform the content of these local hospital policies.	NCCP	Hospitals Others to be determined	Start: Q2 2014 Finish: Q4 2014	Not yet commenced. Working group required.
	Pharmacy Chemotherapy Preparation, Labelling & Record Keeping				
Rec. 79	The NCCP to lead on the development of **minimum standards for the preparation of parenteral chemotherapy**. This should recognise the requirements of small and large centres.	NCCP	Hospitals Others to be determined	Start: Q3 2014 Finish: Q3 2015	Not yet commenced. Working group required.

[2] GCIO: Government Chief Information Officer (role of the former CMOD in the Department of Finance)

Rec. Number	Recommendation Details	Lead Responsibility	Others involved	Timeline	Status
	Oral Chemotherapy				
Rec. 80	A national guideline is required for the **management of the prescribing and dispensing of oral chemotherapy**. This guideline should include: • Safe prescribing • Prescription checking • Prescription format • Administration • Service models for dispensing and supply Communication system between primary care and secondary care	NCCP	To be determined.	Start: Q2 2014 Finish: Q1 2015	Not yet commenced. Working group required.
Rec. 84	The NCCP will engage with the PCRS with regard to current design of the **High Tech prescription form**.	NCCP	PCRS	Start: Q2 2014 Finish: Q3 2015	Not yet commenced. Working group required

2. Local Recommendations – for implementation by individual hospitals

All recommendations are for immediate implementation by individual hospitals[3].

In some cases, where national policies are subsequently developed, they should be incorporated into local policies. In situations where an individual hospital does not have the recommended policy / information / documentation in place, there may be examples from other hospitals that would be useful. Hospitals may contact NCCP at oncologydrugs@cancercontrol.ie for relevant contact details.

Rec. Number	Recommendation Details	Comments
	Governance and Service Configuration	
Rec. 1	All HSE hospitals providing elective chemotherapy services should ensure that they have an appropriate **leadership team** in place. The lead of the service could be from any of the professional groups, a consultant oncologist/haematologist, a nurse, or a pharmacist.	
Rec. 2	The specified lead of the chemotherapy service, in association with hospital drugs and therapeutics committees, should be explicitly charged with ensuring that the required hospital **policies/guidelines are in place and adhered to**.	
Rec. 3	The responsibility of different staff in relation to **safe chemotherapy ordering and prescribing, administration and handling of hazardous drugs** should be outlined in a written policy and disseminated to all staff involved in these activities.	
Rec. 4	Hospitals should collaborate, within the new hospitals group structure, to share good practice pertaining to systemic cancer therapy provision and to work towards the **standardisation of oncology medication policies and practices**.	
Rec. 5	In line with national policy, all units are encouraged to have a written policy in place on **incident reporting** (HSE, 2008) and open disclosure (HSE, 2013). Services are encouraged to continue with routine reporting of all medication safety incidents, including near misses.	
Rec. 6	The medical oncology and haematology services should actively engage with hospital **risk management and quality improvement**. Consideration should be given to regular scheduled multidisciplinary meetings, with risk management and supported by senior management, to discuss medication safety reports, review recurring trends and identify areas for improvement.	

[3] Please see letter of January 21st 2014 from Dr. Susan O'Reilly, attached at Appendix 1.

Rec. Number	Recommendation Details	Comments
Rec. 7	Issues which are considered to potentially compromise the safe delivery of systemic cancer therapy should be included on the department or hospital **risk register** and reviewed annually using the HSE risk assessment tool and guidance (HSE, 2011). Processes should be in place to review recurring trends and there should be clear guidance on when incidents need to be addressed nationally.	
Rec. 8	**Chemotherapy administration should be commenced during normal working hours** wherever possible, when support services and expert advice are available. When chemotherapy continues outside normal working hours, staff skilled in chemotherapy administration and access to expert medical advice must be available.	
	Built Environment, Activity and Equipment	
Rec. 10	If restructuring of the hospital built environment is planned, consideration should be given to **co-locating the oncology day ward and the preparation area** for oncology drugs/pharmacy aseptic units, particularly where the pharmacist(s) involved in the service are shared between the clinical oncology service and drug compounding.	
Rec. 11	Day wards and outpatient clinics should facilitate appropriate desk/office **space for a clinical pharmacy service.**	
Rec. 12	A **risk-based approach** should be taken locally to ensure that the environment is appropriate for carrying out clinical activities and undertaking manual handling operations, while maintaining a good standard of infection control.	
Rec. 13	Day wards/units should have within them, or adjacent to them, a **separate and identified area for the temporary storage of chemotherapy agents** which have been dispensed from pharmacy, and for additional tasks involved in preparation and delivery of treatment. Note: These tasks refer to the preparation of treatment which the local service has deemed safe to prepare at ward level and which does not need to be carried out in pharmacy or outsourced.	
Rec. 14	Patients, if appropriate, should be offered a **two day treatment model**, whereby patient assessments and/or blood tests are conducted on the day prior to treatment to improve patient flow and decrease wait times.	

Rec. Number	Recommendation Details	Comments
	Staff Training	
Rec. 20	**Competency should be assessed** at a minimum annually or in line with relevant national or professional guidelines for all disciplines. Staff must be deemed competent before undertaking their assigned roles and responsibilities. In the absence of national policies, local guidelines should be agreed on competencies.	
Rec. 22	**Induction training** in the delivery of systemic cancer therapies should be mandatory for doctors, nurses and pharmacists. (Also see Rec. 90 All personnel handling, preparing, transport or administering cytotoxics require training in the relevant areas).	
Rec. 23	**Onsite training** in relation to chemotherapy prescribing should be provided for doctors and nurses working in oncology, with appropriate supervision and competency assessment.[4]	
Rec. 24	**Medical Council requirements** in relation to prescriber documentation and to continuing professional development should be implemented in all sites.	
Rec. 25	**Training and CPD records** should be maintained by staff in line with the recommendations of their professional and/or regulatory bodies.	Individual staff members responsible
Rec. 26	Sharing of **educational sessions on a multidisciplinary basis** should be promoted between centres and learning opportunities maximised by using technologies such as video linkage, webinars and e-learning.	

[4] A mandatory chemotherapy prescribing module for medical oncology and haematology SpRs is planned by the RCPI.

Rec. Number	Recommendation Details	Comments
	Policies and Guidelines	
Rec. 27	All units involved in the prescribing/ordering and administration of systemic anticancer therapy must have **guidelines/policies** in place covering the essential areas as detailed in Appendix 4 of the Review Report.	Policies are not required if the services listed are not provided in your hospital e.g. intrathecal.
Rec. 28	Relevant national policy recommendations and NCCP recommendations should be included in **local policies and practices**.	
	Information for Patients and Carers	
Rec. 29	All units should have **patient information** on cancer e.g. cancer treatment, local support groups and support services.	
Rec. 30	Decisions to treat a patient with chemotherapy should involve the patient and carer on an **informed choice** basis.	
Rec. 31	**Written information should be available for patients and carers** for each treatment protocol on the hospital's agreed list.	
Rec. 32	There should be **written information for patients and carers** covering the action they should take, whom they should contact for advice, and the symptoms that should prompt this, with regard to treatment related side-effects of systemic cancer therapy.	
Rec. 33	All units should have written policies in place on information for patients on **safe handling of cytotoxic drugs** in the community including: • Spillage information • Disposal information • Safe storage information Also see Rec. 93 regarding supply of spill kits to patients on home parenteral chemotherapy.	

Rec. Number	Recommendation Details	Comments
	Treatment Planning and Clinical Assessment	
Rec. 34	The patient's **treatment plan** should include the following information at a minimum: Diagnosis and staging according to an internationally recognised staging system Performance status and co-morbidities Treatment intent Treatment protocol Pre-treatment investigations where required Planned numbers of cycles Frequency and method of assessment if appropriate Any deviation from protocol and rationale for deviation	
Rec. 35	There should be detailed documentation of the patient's systemic cancer therapy in the **patient's treatment record**, fulfilling the minimum criteria as detailed in Appendix 5 of the review report for each patient: Prior to the start of a course of chemotherapy Prior to the administration of each cycle After the final cycle is given in a course	
Rec. 36	**Patient consent** or understanding of adverse events should be documented.	
Rec. 37	The **consent form**, signed prior to starting a course of chemotherapy, should contain the minimum criteria as specified in the NCCP Template Patient Consent Form for Systemic Therapy Treatment.	Consent form is available on the NCCP website[5]
Rec. 38	**Reassessment** is required before the start of any subsequent cycle of treatment. Assessment requirements should be detailed in the treatment protocols and should, at a minimum: • Document any serious toxicity (e.g. grade 3 or 4 toxicities) • Indicate appropriate blood tests and other tests, as required • Outline circumstances and details of dose modifications when required • Document response to treatment at appropriate intervals	

[5] http://www.hse.ie/eng/services/list/5/nccp/profs/medonc/safetyreview/

Rec. Number	Recommendation Details	Comments
	(Treatment Planning and Clinical Assessment)	
Rec. 39	Each unit should have a written policy on: • The **maximum time period** acceptable between pre-treatment tests, including patient weight, and chemotherapy administration • **Patient assessment** using validated tools such as Early Warning Score and Common Criteria Toxicity Scale	
Rec. 40	**Pre-treatment tests** should be undertaken a maximum of three days prior to Day 1 of each cancer medicines cycle (excluding cycle 1) and at intervals designated in the treatment plan. Local arrangements may need to be made to consider bank holiday weekends.	
	Chemotherapy Protocols	
Rec. 41	Each unit should have access to an agreed list of **chemotherapy protocols**. This list should be updated at a minimum every two years.	
Rec. 42	Each protocol should contain the **minimum protocol specific information** as detailed in Appendix 3 of the Review Report. Each protocol should be reviewed at a minimum every two years.	
Rec. 43	**Protocols should be readily available** to multiple users. At a minimum there should be hard copies of the local protocols in all wards (including day wards, and out-patient clinics) where oncology/haematology patients are admitted or reviewed. The unit should have a policy in place designed to ensure that the hard copies of the local protocols are kept up to date and versions are controlled. Master copies should be signed by the approving consultant. If the local protocols are maintained in electronic form on the unit's intranet or computerised physician order entry system, there should be a method designed to ensure that these documents are kept up to date as displayed on the electronic system. Note: An electronic form of the protocols does not preclude the requirement for hard copies as above.	

Rec. Number	Recommendation Details	Comments
	(Chemotherapy Protocols)	
Rec. 44	Each unit should have a **written policy for preventing regular use of protocols not on the accepted list.** The policy should state: • The exceptional circumstances under which such a regimen could be used. • The procedure which is then required to authorise it.	
Rec. 45	**Requests to use a non-approved protocol** should be made to hospital pharmacy by a medical consultant and accompanied by supporting references and a completed proforma request. A record should be kept of all such requests which result in off-protocol treatment. Annual audits should be conducted to examine the reasons why such off-protocol treatments were necessary.	
	Chemotherapy Ordering and Prescribing	
Rec. 46	There should be regular **multidisciplinary team meetings** (e.g. weekly) to discuss patients' treatment, including chemotherapy treatment.	
Rec. 47	The **first cycle of a course of systemic cancer therapy** must be written by a consultant medical oncologist or haematologist, Specialist Registrar (SpR) or Registrar based on the consultant's written treatment plan. Subsequent cycles may be written by a Consultant, SpR or Registrar.	
Rec. 48	All units should maintain a list and **signature bank*** of those staff deemed competent to prescribe/order, check, dispense and administer systemic cancer therapy. The list and signature bank should be updated annually. *A signature bank is not required for those functions where electronic systems have replaced paper processes.	
Rec. 49	**Approved drug names** should be used when prescribing/ordering chemotherapy. Trade names should only be utilised where the use of an approved name may result in an error.	

Rec. Number	Recommendation Details	Comments
	(Chemotherapy Ordering and Prescribing)	
Rec. 50	**Prescriptions/orders for all parenteral or oral chemotherapy must be written** and should not be given as verbal or telephone orders. If a prescription/order is amended, the changes must be signed and dated on all copies of the prescription/order by the physician before the treatment is administered or supplied by the Pharmacy Department. Electronic orders must be clearly attributed to the prescriber and all changes to the order must be maintained in an audit log.	
Rec. 51	Writing of **chemotherapy orders in advance of day of treatment** should be introduced for a large majority of elective chemotherapy treatments. This does not remove the need for patient assessment and sign off (off-hold) prior to administration.	
Rec. 52	Chemotherapy orders must be signed "**off-hold**" by the prescriber or the policy authorised person prior to administration of chemotherapy to the patient.	
Rec. 53	A copy of the chemotherapy order and/or prescription must be kept in the **patient's medical record**.	
Rec. 54	In the absence of electronic ordering systems, chemotherapy should be ordered on **designated order forms**. Ideally these should be pre-printed and regimen specific. A standardised blank order form should be available to cater for situations where non approved protocols are utilised and where pre-printed order forms are not yet available for infrequently used protocols. The minimum data required are detailed in Appendix 9 of the Review Report.	Individual Hospitals
Rec. 55	A rigorous **validation process for electronic ordering** is required pre-implementation of electronic ordering to ensure accuracy of calculated doses. These systems must have on-going maintenance and have suitable arrangements for supervision of their use by appropriately qualified staff.	NCCP & Individual hospitals NCCP will lead on this in the proposed national medical oncology clinical information system; individual hospitals with existing CPOE must ensure in place for their current system
Rec. 57	Hospitals using computerised physician order entry systems should ensure that these systems are fully validated and, as for paper based prescribing/ordering, a clinical pharmacy check is required to authorise the prescription. This needs to be auditable. In addition there should be clear medical, pharmacy and nursing checks of the electronic ordering template for each chemotherapy regimen.	Individual Hospitals that have CPOE

Rec. Number	Recommendation Details	Comments
	Prescription Checking	
Rec. 58	Hospitals should ensure that their **chemotherapy prescription checking and administration policy** includes: • Both oral and parenteral chemotherapy • A description of the integrated multidisciplinary checking process and details of each team member's responsibility in this process. An example is included in Appendix 8 of the Review Report. • The pharmacy verification practice where different levels of verification are in place.	Individual Hospitals
Rec. 59	All **chemotherapy prescriptions** should be checked by a pharmacist, who has demonstrated their appropriate competence and is locally authorised/accredited for the task. Minimum recommended pharmacy checks are detailed in Appendix 6 of the Review Report.	Individual Hospitals
Rec. 60	All patient treatment, assessment and prescription checking areas should have access to the most recent relevant **laboratory test results**.	Individual Hospitals
Rec. 61	All units should have a policy in place that defines the **persons authorised to give approval** to proceed with treatment (off-hold).	Individual Hospitals

Rec. Number	Recommendation Details	Comments
	Monitoring of Chemotherapy	
Rec. 62	Each unit should have a written policy on: • Management of **skin penetrating injuries** with cytotoxic drug exposure • The **prevention, recognition and management of treatment related side effects** such as: o Neutropenia/neutropenic sepsis o Cytotoxic-induced emesis o Cytotoxic extravasation o Allergic reactions including anaphylaxis o Stomatitis, other mucositis and diarrhoea • The use of **mechanical drug delivery devices** used by the unit, such as infusion pumps etc. • The **use of devices** to prevent alopecia, if used by the unit. • The **care of aids** to venous access for use in the unit (e.g. Hickman lines, PICC lines).	Policies are not required if the services listed are not provided in your hospital e.g. intrathecal.
Rec. 63	Prescription drugs to be administered must be checked by two chemotherapy competent nurses prior to administration. Minimum recommended verification information is included in Appendix 7 of the Review Report.	

Rec. Number	Recommendation Details	Comments
	Management of Unscheduled Care	
Rec. 64	Each unit should have a **written policy on the management of unscheduled care** including: • Emergency department policies e.g neutropenic sepsis, cytotoxic induced emesis, extravasation etc. • Inter hospital patient transfers • Telephone triage • Acute admission of patients from other hospitals • Data requests from other hospitals	
Rec. 65	**Telephone triage protocols**, using evidence based scoring/assessment, should be utilised to facilitate accurate and standardised patient assessments.	
Rec. 66	Chemotherapy should be written by a consultant medical oncologist/haematologist in the event of it being required as an emergency outside of normal working hours. A record of the number of times that this procedure has taken place outside normal hours should be maintained. Preparation of hazardous drugs out-of-hours should be in accordance with local arrangements and local policy.	
Rec. 67	**Guidelines/polices on the management of symptoms pertaining to treatment and oncology emergencies** should be accessible to general physicians/ED staff, if there is no direct access to oncology services out-of-hours.	
	Intrathecal Chemotherapy	
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 **vinca alkaloids**[6].	This does not apply to hospitals that do not provide intrathecal services.
Rec. 69	**Intrathecal chemotherapy** should always be stored in a different area to intravenous chemotherapy.	This does not apply to hospitals that do not provide intrathecal services.
Rec. 70	**Intravenous chemotherapy** should always be given at a different time to intrathecal chemotherapy.	This does not apply to hospitals that do not provide intrathecal services.

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

Rec. Number	Recommendation Details	Comments
	Pharmacy Chemotherapy Preparation, Labelling and Record Keeping	
Rec. 72	Each unit should have a written policy in place on **drug preparation** including labelling and packaging (see Appendix 10 of the Review Report for minimum recommendations on labelling).	
Rec. 73	Pharmacy departments should maintain: • Structured **pharmaceutical care plans**, either electronically or on paper, for each patient • A **patient history** for each patient that allows the verification of cumulative and maximum patient doses.	
Rec. 74	All hospital pharmacy departments should have a dedicated area reserved for the **preparation/ dispensing/supply of hazardous drugs**, both oral and parenteral.	
Rec. 75	All hospital pharmacy departments should utilise a **specialised computer system** for the preparation and/or dispensing or issuing of cancer medicines to enable batch tracking, cumulative dose monitoring, and a complete electronic patient history.	
Rec. 76	**Labels** should comply with all statutory and professional requirements, and should include the minimum information as detailed in Appendix 10 of the Review Report.	
Rec. 77	Outsourced products should be **overlabelled** where the label does not comply with the minimum requirements as detailed in Appendix 10 of the Review Report.	
Rec. 78	Hospitals **outsourcing the production of parenteral chemotherapy** should ensure that the chosen suppliers comply with best practice and/or any statutory/regulatory requirements.	

Rec. Number	Recommendation Details	Comments
	Oral Chemotherapy	
Rec. 81	**Monitoring of adherence to oral chemotherapy** by medical/nursing personnel is recommended while patients are on their treatment.	
Rec. 82	**Structured education** is required for patients and their carers in relation to safe handling, administration and the identification and management of side-effects pertaining to their oral chemotherapy medications. A pre-treatment education checklist should be developed for patients on each oral chemotherapy agent.	See Rec. 31 also.
Rec. 83	Patients on oral chemotherapy should have 24hr **access to appropriately trained medical oncology staff.**	
	Cytotoxic Handling, Disposal and Storage	
Rec. 85	All hospitals should have clear **protocols/guidelines to reduce the occupational exposure** of staff to cytotoxics and should have written policies on the safe handling of cytotoxic agents including: • Segregated storage • Spill management of cytotoxic agents • Transportation of cytotoxics • Disposal of cytotoxic waste • Needle stick injuries • Preparation of cytotoxics	
Rec. 86	All hospitals should maintain a **list of hazardous drugs** in line with the hospital's waste policy, relevant legislation and best practice.	
Rec. 87	**Hazardous drugs** should be stored separately from other drugs. Access to hazardous drug storage areas on wards or day units should be limited to authorised staff. Storage should be designed in a manner that will prevent containers of hazardous drugs from falling or being punctured. Such storage areas should be clearly labelled with cytotoxic warning labels. High-risk drugs, such as intrathecal chemotherapy, should be stored in a segregated manner in line with local hospital policy, best practice and relevant legislation.	

Rec. Number	Recommendation Details	Comments
	(Cytotoxic Handling, Disposal and Storage)	
Rec. 88	**Refrigerators** used for the storage of chemotherapy doses should be monitored according to hospital policy.	
Rec. 89	Containers of prepared cytotoxic agents should be transported in appropriately labelled, sturdy and leak-proof transport boxes or bags. They should be clearly labelled as 'Cytotoxic - handle with care'. Intrathecal chemotherapy should be transported separately to all other medication. Pneumatic tubes should not be used for transporting any non-solid cytotoxic agents, including creams and ointments.	
Rec. 90	All personnel **handling, preparing, transporting or administering cytotoxics** require training in the relevant areas.	
Rec. 91	A member of staff should receive the hazardous drug in the transit bag/box at its destination. Bags/boxes must not be left unattended or with untrained staff on arrival.	
Rec. 92	**Disposal** of cytotoxic waste should comply with the hospital's waste policy, relevant legislation and best practice.	
Rec. 93	Hospitals should supply **spill kits** to patients who are on home parenteral chemotherapy.	

Appendix 1

21 January 2014

NCCP Oncology Medication Safety Review

Dear CEO/Hospital Manager,

The National Cancer Control Programme (NCCP) conducted an Oncology Medication & Safety Review in the last 12 months across all 26 hospitals in Ireland involved in the administration of systemic cancer treatments. The aim of the review was to assess the oncology medication policies and practices nationally from a patient safety and quality perspective.

I've attached a copy of the final review report (a hard copy will be circulated shortly). This report presents the combined review findings across all 26 participating hospitals. The report also sets out proposed recommendations for future action, some of which will inform the development of national policies relating to the safety and quality of systemic cancer therapy services.

We recommend that your relevant managers and multi-disciplinary clinical staff review the recommendations in the report, identify areas where any improvements are required and implement accordingly. The next steps in fostering continuous improvements in medication safety will be to develop national policies, based on the learning from this report. The NCCP will endeavour to engage with you and your hospital in the coming months on the development of these national policies.

Overall I am very pleased with the findings of the review. I would like to take this opportunity to thank you and your staff for participating in this review.

Yours sincerely,

Dr. Susan O'Reilly MB, FRCPC, FRCPI, MB, BCH, BAO
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Appendix 2 – References

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