NCCP Oncology Medication Safety Review Report



Hospital reporting period: June-November 2015

Published: December 2015







Contents:

1. Introduction	.3
2. Implementation Status Report on recommendations for	
implementation at hospital level	.5
3. Implementation Status Report on recommendations for	
implementation at national level	11
Appendix A -Status of individual recommendations (All Hospitals)	
Appendix B -Recommendations of the Oncology Medication Safety Review	
(NCCP, January 2014)1	16
List of Figures.	
List of Figures:	
Fig. 1 Comparison of status of recommendations for hospital Implementation	
(March 2014, December 2014 and June 2015) - All Hospitals. Note: No data	
for 3 hospitals for June 2015	.5
Fig. 2 Comparison of implementation of grouped recommendations -	
December 2014 and June 2015 (All Hospitals) Note: No data for 3 hospitals	
for June 2015	
Fig. 3 Comparison of implementation of recommendations - December 2014	ŀ
and June 2015 - By Hospital Group Note: No data for 3 hospitals for June	
2015	
Fig. 4 Implementation status of all recommendations by hospital - June 201	
(Anonymised) Note: No data for 3 hospitals for June 2015	.8
Fig. 5 Status of National Recommendations (June 2015)	2
Fig. 6 Implementation Status of Recommendations 1-14 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	13
Fig 7 Implementation Status of Recommendations 20-33 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	13
Fig. 8 Implementation Status of Recommendations 34-45 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	
Fig. 9 Implementation Status of Recommendations 46-61 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	
Fig. 10 Implementation Status of Recommendations 62-78 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	
Fig. 11 Implementation Status of Recommendations 81-93 (Hospital	
Implementation) June 2015, Updated November 2015. Data awaited from 3	3
hospitals1	
1105pttu15	J

1. Introduction

The National Cancer Control Programme (NCCP)'s *Oncology Medication Safety Review* was published in January 2014.

The report presented the findings of the 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 perspective. The report made a total of 93 recommendations.

An Implementation Steering Group is in place to oversee the implementation of the report.

The first Implementation Status Report, published in December provided the baseline implementation status of all recommendations. The second implementation status report, published in July 2015 showed significant progress in the implementation of the review's recommendations. This, third, implementation status report shows sustained progress towards the implementation of the quality and safety recommendations which were contained in the original report.

A similar process has been followed for each assessment of implementation status. Each hospital is asked to complete a checklist of the status of each recommendation of the report, stating in each case whether the recommendation was implemented, underway, not started or not applicable. For this (third) implementation report, the status of recommendations was requested as at the end of June 2015. The reports were submitted by hospitals over the period June to November 2015. Teleconferences were then held with each of the 26 hospitals to discuss the implementation of the report in detail.

For this round of the implementation review, the discussions with NCCP focussed on those recommendations which were reported as "not started". In addition, in line with the approach previously taken, specific areas were chosen for more indepth discussion with the hospitals. This time, the areas discussed were "policies and procedures", "protocols" and "chemotherapy administration and monitoring". Any issues of concern were discussed with the hospital and clarifications provided where possible. Progress on these will be reviewed again.

This document sets out the status of the report's recommendations following these discussions with hospitals and therefore reflect the position as at November 2015. It is clear that considerable progress has been made to address the patient safety and quality recommendations contained in the report. Overall, there has been strong support across the hospitals for the report and its recommendations.

It is important to note that financial and resource constraints can impact the implementation of some recommendations and staffing, in particular, has been raised repeatedly by hospitals as a difficulty in implementing some recommendations, particularly those relating to the development, implementation and ongoing monitoring of policies, protocols and guidelines. It is hoped that developments, particularly those relating to information technology, will facilitate appropriate change. It is also important that individual hospitals prioritise the implementation of the Review and provide the appropriate level of support to facilitate adherence to the recommendations.

Progress on the implementation of recommendations is being tracked on an ongoing basis, with updates from hospitals twice a year and follow-up discussions with each hospital. The hospitals are being be supported, where possible, by the NCCP, particularly with the exchange of learning and sharing of good practice across hospital sites, which has been helpful particularly in assisting hospitals to adopt existing policies from other hospitals and adapt them to their local needs.

Based on the feedback from hospital representatives, it is intended to establish a working group, with representation from all hospitals, to facilitate shared learning in relation to policies and procedures, in particular. It is intended to establish this group in early 2016 and to focus initially on nursing policies.

Information on the Oncology Medication Safety Review, including the report, action plan and implementation status reports are available on the NCCP website at www.hse.ie/nccponcsafetyreview.

2. Implementation Status Report on recommendations for implementation at hospital level

A total of 26 responses were received, from 25 of the 26 chemotherapy hospitals including one hospital which has separate oncology and haematology services and therefore made two submissions.

The national implementation level across all recommendations for implementation at hospital level (n=81) now stands at 71%, up from 55% in the first implementation status report in December 2014 and 65% in the second implementation report in July 2015. A further 21% are underway, 2% were reported as not started and the remaining 4% were not applicable¹ (see Fig. 1). The proportion of those reported as "not started" decreased from 12% in the first implementation report to 2% in this period.

Status of Recommendations for Hospital Implementation All Hospitals

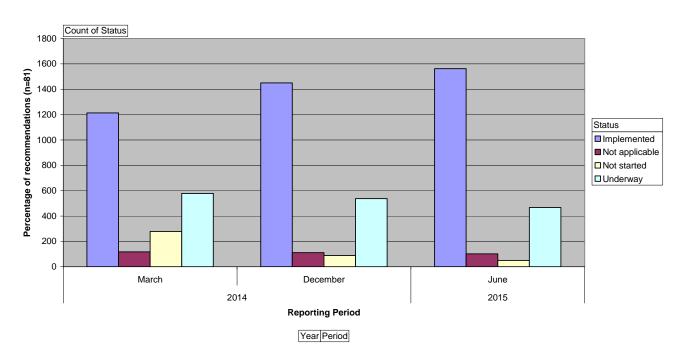


Fig. 1 Comparison of status of recommendations for hospital Implementation (March 2014, December 2014 and June 2015) - All Hospitals.

Progress has been made on the implementation of recommendations across all of the areas outlined in the report, as illustrated in Fig. 2, which compares the status of each group of recommendations in December 2014 and June 2015. In relation to one area, intrathecal chemotherapy, the level of "not applicable" responses has increased since the baseline report due to some hospitals reviewing their current practice of intrathecal chemotherapy administration and one hospital opting to

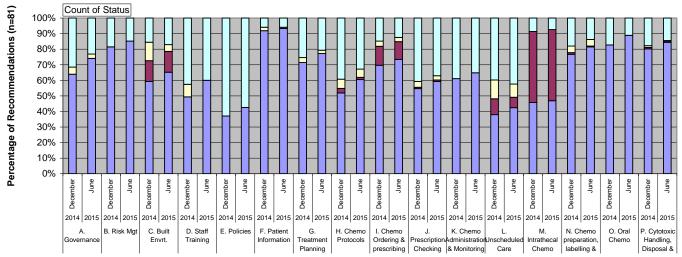
5

¹ A recommendation may not be applicable to hospital if, for example, a particular service is not provided by that hospital e.g. intrathecal chemotherapy services.

cease administration for patient safety reasons due to small volumes. A separate national NCCP intrathecal policy is due to be published shortly(see Section 3).

Implementation Status of Grouped Recommendations All Hospitals December 2014 vs. June 2015





Reporting Period - Dec 2014 & June 2015

Rec Group Year Period

Fig. 2 Comparison of implementation of grouped recommendations - December 2014 and June 2015 (All Hospitals)

The implementation level in individual hospitals ranged from 54% of recommendations implemented to 94% implementation.

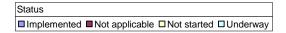
For the purposes of this report, the hospitals have been anonymised. However, it is intended to name the hospitals in 2016, when hospitals will have had two years to address the recommendations of the report. Each hospital has been provided with the specific details relating to their hospital. Details are also being provided to Hospital Group CEOs.

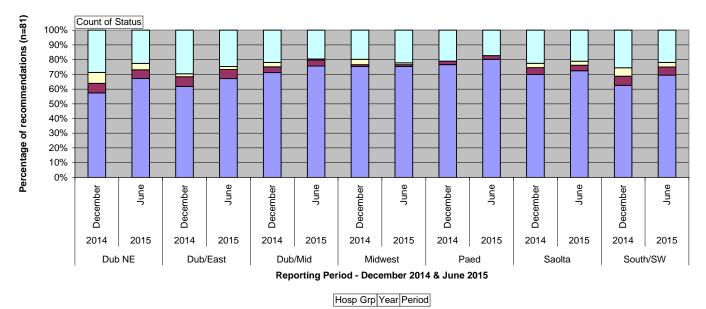
All 26 hospitals provide very busy systemic anti-cancer therapy services to their patients. A key issue emerging for several hospitals was the availability of pharmacy staffing to address many of the recommendations, the availability of nursing staffing to develop guidelines and policies and the availability of administrative staffing, particularly for the purposes of maintaining version control and ongoing updating of policies, protocols and operating procedures.

Fig. 3 compares the implementation status of recommendations in the December 2014 and June 2015 submissions by Hospital Group. Fig. 4 below sets out the implementation status of the recommendations by hospital (anonymised). The status across all hospitals for each individual recommendation is set out in

Appendix A. The text of each recommendation is provided at Appendix B for reference purposes.

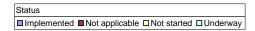
Implementation Status of Grouped Recommendations By Hospital Group December 2014 vs June 2015 status





 $\begin{tabular}{ll} Fig. 3 Comparison of implementation of recommendations - December 2014 and June 2015 - By Hospital Group \\ \end{tabular}$

Implementation Status of Recommendations By Hospital (Anonymised) June 2015



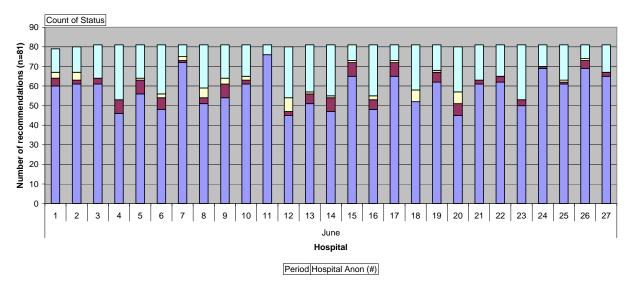


Fig. 4 Implementation status of all recommendations by hospital - June 2015 (Anonymised)

In order to illustrate the progress made in relation to some specific recommendations of the Review report, details on three specific areas are shown in more detail below -

- The identification of a lead for the chemotherapy service (Rec. 2)
- The inclusion of relevant chemotherapy issues on the hospital Risk Register (Rec. 7)
- The use of an informed patient consent form for chemotherapy (Rec. 37)

Recommendation 2: Identification of a Lead for the chemotherapy service

The number of hospitals which have identified a lead for the chemotherapy service has increased from 9 to 20 over the period March 2014 to June 2015. Five hospitals reported that this recommendation was underway. One hospital indicated that the implementation of this recommendation had not started as there was no agreement locally as to who would take on this responsibility. This issue has been raised previously with the management of the hospital concerned.

Progress of Implementation (All Hospitals) Recommendation 2: Identification of a lead for the chemotherapy service

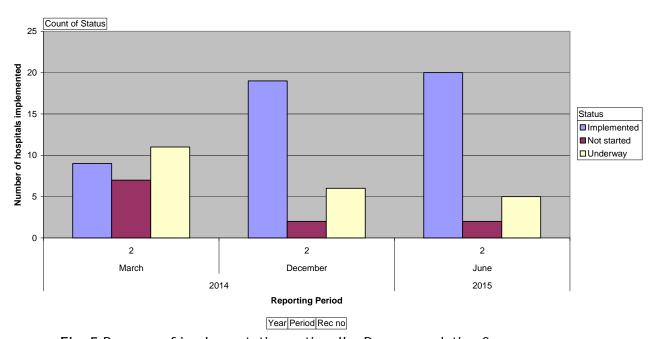


Fig. 5 Progress of implementation nationally: Recommendation 2

Recommendation 7: Inclusion of issues relating to systemic cancer therapy included on risk register

The number of hospitals which were including issues relating to the systemic therapy service on their Risk Registers increased from 13 at the time of the baseline status in March 2014 to 21 in June 2015.

Progress of Implementation (All Hospitals) Recommendation 7: Inclusion of issues with chemotherapy on Risk Register

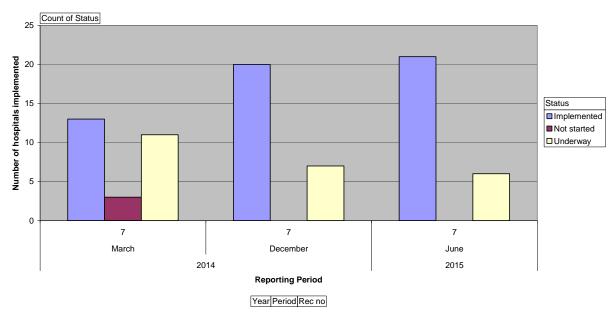


Fig. 6 Progress of implementation nationally: Recommendation 7

Recommendation 37: Use of informed consent form

As of June 2015, the informed consent form has been implemented in 17 hospitals, is underway in 6 hospitals and was reported as "not started" in 2 hospitals. This was discussed with the hospitals involved and those which were "not started" were hospitals linked with a larger centre where piloting of the consent form was underway. The status reported in June 2015 shows considerable progress over the baseline status when an informed consent form was in place in 10 hospitals.

Progress of Implementation (All Hospitals) Recommendation 37: Use of informed consent form

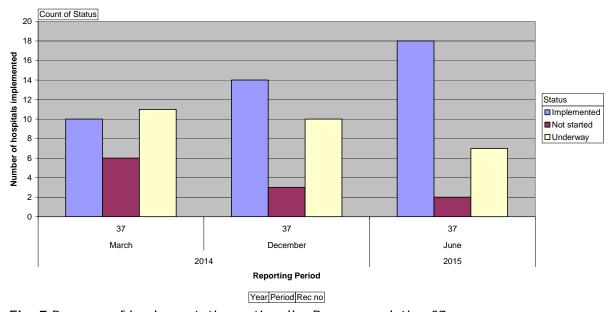


Fig. 7 Progress of implementation nationally: Recommendation 37

3. Implementation Status Report on recommendations for implementation at national level

A number of the recommendations of the report required the establishment of national representative groups to develop national guidelines and policies.

Two particular areas were identified by the Implementation Steering Group as being priority recommendations:

- (i) The development of national policies on intrathecal chemotherapy.
- (ii) A national guideline on the management for the prescribing and dispensing of oral chemotherapy.

Separate working groups were established for these two areas. The national guidelines on intrathecal chemotherapy and neurotoxic drugs are nearing completion.

Overall, of the national recommendations (n=13), 7% are implemented, 77% are underway and the remaining 15% are scheduled to commence in 2016. This is partially due to delays formal establishment of some groups and prioritisation of other areas.

The national implementation status of each of the national recommendations is provided in Fig. 8.

Period				Jun-15	1
NCCP Rec	N.	Recommendation details	HIQA		Apr-15
9	1	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	2.7	Status Underway	Comments Recommendations are being progressed. It is expected that a dtaft document will be available for consultation around the end of 2015.
15	1	The NCCP should develop a space planning model to support hospitals in their local service planning with regard to day ward spatial requirements.	2.7	Underway	
16	1	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.	6.1 6.2 6.3		Completed and has been circulated to hospitals
17	1	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.	6.1 6.2 6.3	Underway	C-PORT on hold in UK. May include capacity planning as an element in MOCIS to inform a planning model based on activity
18	1	National competencies for all disciplines in relation to acute oncology should be developed in collaboration with the relevant colleges and professional bodies.	6.3	Underway	National nursing group is meeting to discuss competencies. RCPI curricula for medical oncology and haematology (SpR) are comprehensive. Any additional requirements to be discussed.
19	1	Specialist competency training needs to be developed and implemented for all disciplines working in the areas of clinical oncology and aseptic manufacturing.	6.3	Underway	Competencies for pharmacy to be presented to Steering Group November 2015.
21	1	Generic guidance should be developed on specific oncology training programmes or competency assessments for all nurses, pharmacists and doctors.	6.3	Not started	To be informed by Rec. 18 & 19.
55	1	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.	3.1	Underway	Approval in principle received from GCIO (formerly CMOD). Statement of requirements developed. Invitation to tender expected to issue around the end of 2015.
56	1	A national computerised physician order entry system agenda should be developed by the NCCP and HSE IT.	3.1	Underway	
71	1	The NCCP to lead on the development of national intrathecal polices to inform the content of these local hospital policies.	3.1	Underway	Guidance documents issued for public consultation in October 2015. Draft document to be presented to Steering Group in November 2015.
79	1	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.	2.1	Not started	Establishment of group delayed due to industrial action of IMPACT affecting HPAI members
80	1	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	I 2.1 3.1	Underway	Policy is in development and expected to be submitted to Steering Group shortly.
84	1	The NCCP will engage with the PCRS with regard to current design of the High Tech prescription form.	2.3	Underway	
Total	13				
		Number completed Number underway		10	7%
		Number not started		2	15%
		Number not relevant		0	0%

Fig. 8 Status of National Recommendations (June 2015)

Appendix A -Status of individual recommendations (All Hospitals)

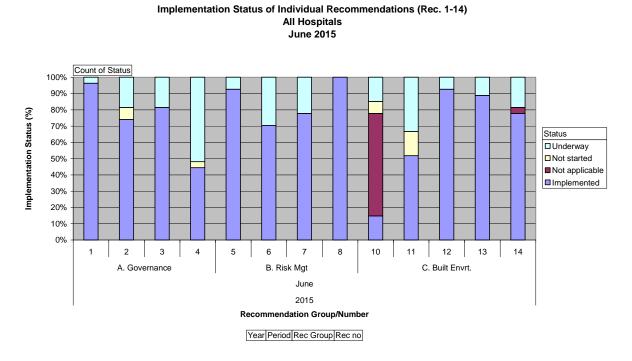


Fig. 9 Implementation Status of Recommendations 1-14 (Hospital Implementation) June 2015, Updated November 2015.

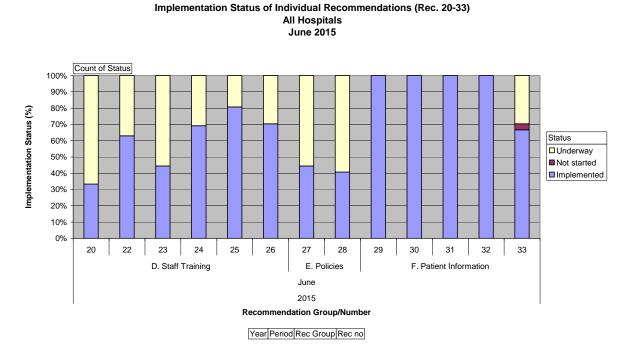


Fig 10 Implementation Status of Recommendations 20-33 (Hospital Implementation) June 2015, Updated November 2015.

Implementation Status of Individual Recommendations (Rec. 34-45) All Hospitals June 2015

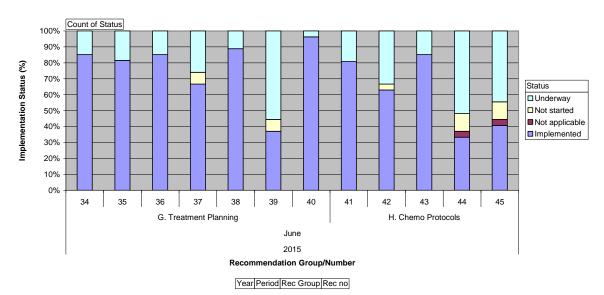


Fig. 11 Implementation Status of Recommendations 34-45 (Hospital Implementation) June 2015, Updated November 2015.

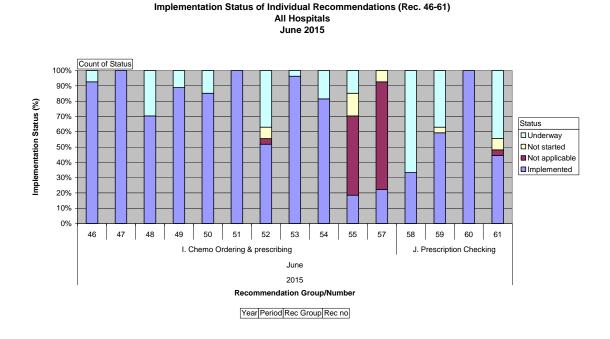


Fig. 12 Implementation Status of Recommendations 46-61 (Hospital Implementation) June 2015, Updated November 2015.

Implementation Status of Individual Recommendations (Rec. 62-78) All Hospitals June 2015

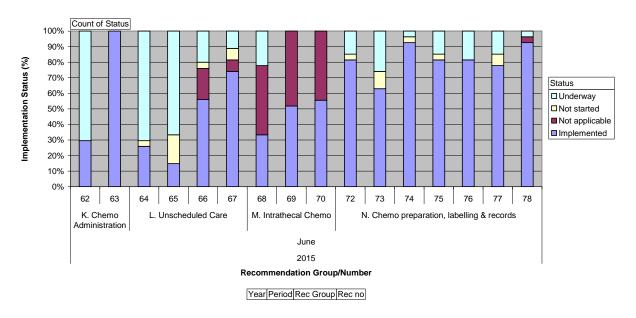


Fig. 13 Implementation Status of Recommendations 62-78 (Hospital Implementation) June 2015, Updated November 2015.



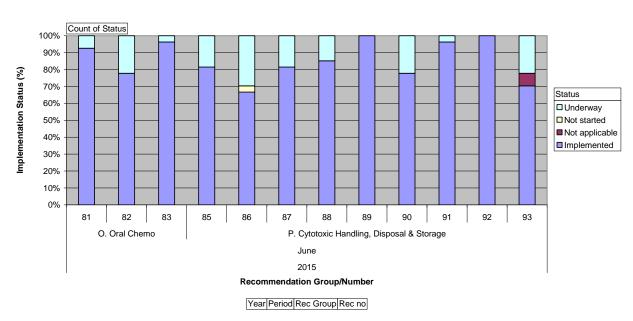


Fig. 14 Implementation Status of Recommendations 81-93 (Hospital Implementation) June 2015, Updated November 2015.

Appendix B -Recommendations of the Oncology Medication Safety Review (NCCP, January 2014)

Recomme	ndations on 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.
Recomme	ndations on Risk Management
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.
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.
Recomme	ndations on 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 considerationsPatient comfort
	An efficient, safe work environment
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 15.	The NCCP should develop a space planning model to support hospitals in their local service planning with regard to day ward spatial requirements.
Recomme	ndations on 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.
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.
Recomme	ndations on 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.
Rec 19.	Specialist competency training needs to be developed and implemented for all disciplines working in the areas of clinical oncology and aseptic manufacturing.
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 21.	Generic guidance should be developed on specific oncology training programmes or competency assessments for all nurses, pharmacists and doctors.
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. ²
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.
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.
Recomme	ndations on Policies/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 Error! Reference source not found
Rec 28.	Relevant national policy recommendations and NCCP recommendations should be included in local policies and practices.
Recomme	ndation on 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

² A mandatory chemotherapy prescribing module for medical oncology and haematology SpRs is planned by the RCPI.

	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.
Recomme	endations on 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.
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
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.

Recomme	ndations on 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 outpatient 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 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.
Recomme	ndations on 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, SpR or Registrar based on the consultant's written treatment plan. Subsequent cycles may be written by a Consultant, Specialist Registrar (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 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.
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.
Rec 56.	A national computerised physician order entry system agenda should be developed by the NCCP and HSE IT.
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.
Recommer	ndations on Prescription Checking
D 50	Hospitals should ensure that their chemotherapy prescription checking and administration policy includes:
Rec 58.	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.
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.
Rec 60.	All patient treatment, assessment and prescription checking areas should have access to the most recent relevant laboratory test results.
Rec 61.	All units should have a policy in place that defines the persons authorised to give approval to proceed with treatment (off-hold).
Administra	ation and Monitoring of Chemotherapy
Rec 62.	Each unit should have a written policy on:
100 02.	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).
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.
Recomme	ndations on 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.
Recomme	ndations on 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 alkaloids³.
Rec 69.	Intrathecal chemotherapy should always be stored in a different area to intravenous chemotherapy.
Rec 70.	Intravenous chemotherapy should always be given at a different time to intrathecal chemotherapy.
Rec 71.	The NCCP to lead on the development of national intrathecal polices to inform the content of these local hospital policies.
Recomme	ndations on 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 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 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.

.

 $^{^{\}rm 3}$ Including the minimum recommendations of WHO (2007).

_	
Recomme	ndations on 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
Rec 81.	Monitoring of adherence to oral chemotherapy by medical/nursing personnel is recommended while patients
Rec or.	are on their treatment.
Rec 82.	Structured education is required for patients and their carers in relation to safe handling, administration and
NOU UZ.	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.
Rec 83.	Patients on oral chemotherapy should have 24hr access to appropriately trained medical oncology staff.
Rec 84.	The NCCP will engage with the PCRS with regard to current design of the High Tech prescription form.
Recomme	ndations on 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. Refrigerators used for the storage of chemotherapy doses should be monitored according to hospital policy.
Rec 88.	
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.
	1

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.