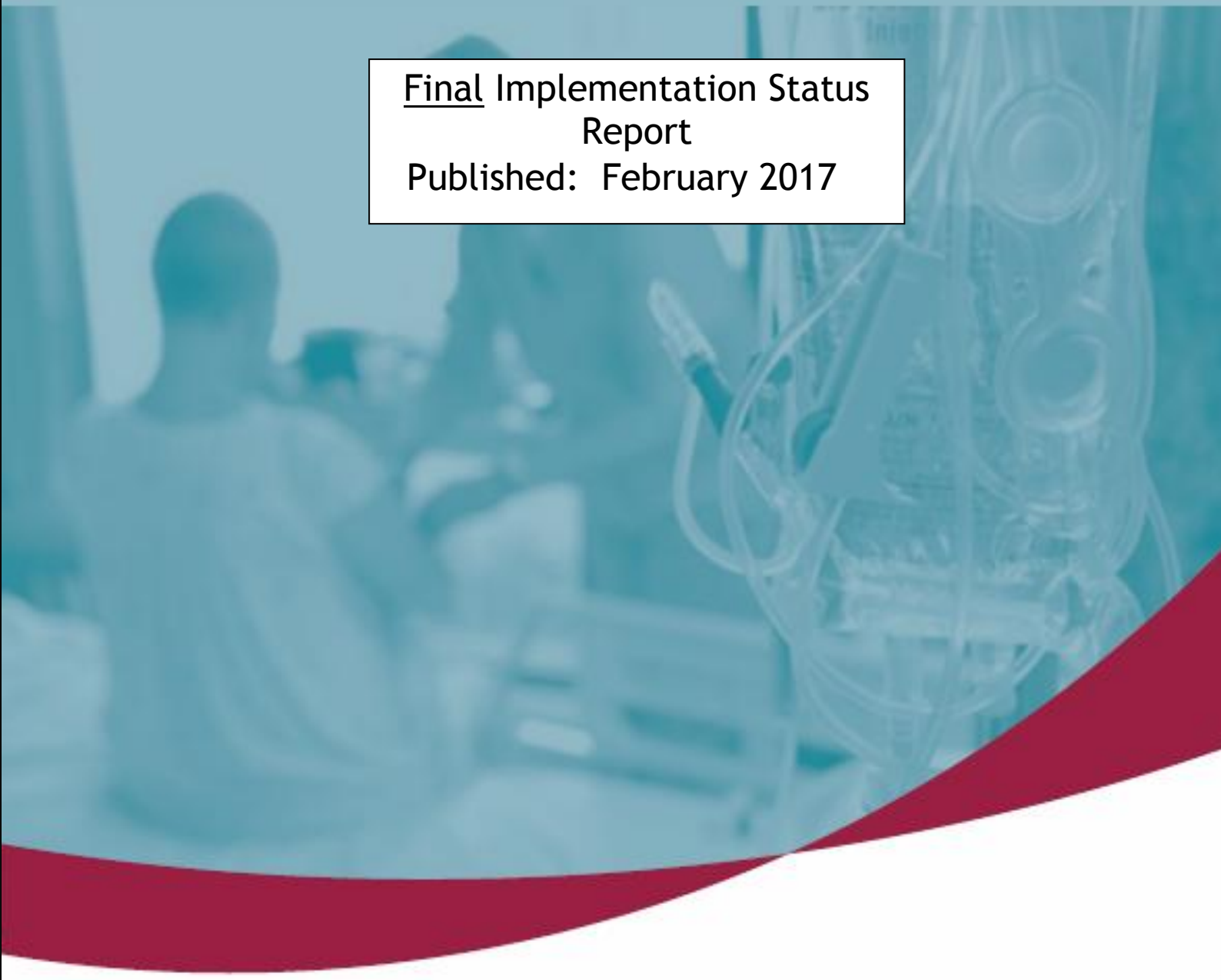
NCCP
Oncology Medication Safety Review Report



Final Implementation Status Report
Published: February 2017

National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Tús Áite do Shábháilteacht Othar
Patient Safety First

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1. Introduction

1.1 Background

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

The report presented the findings of a review of chemotherapy day wards which was conducted across the 26 hospitals in Ireland involved in the administration of systemic anti-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.

1.2 Implementation Status Reports 2014-2015

Over the past two years, data have been collected on four separate occasions from hospitals regarding their progress on implementation of the recommendations. For each assessment, hospitals were asked to provide an update on the status of each recommendation of the report, stating in each case whether the recommendation was implemented, underway, not started or not applicable. The first Implementation Status Report, published in December 2014 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. The third implementation status report in December 2015 showed sustained progress towards the implementation of the quality and safety recommendations which were contained in the original report.

1.3 Final Implementation Status Report, 2016

For the current implementation report, individual reports outlining all recommendations other than "implemented" were prepared and circulated to each hospital. Teleconferences were arranged via the hospital designated liaison contact. The discussions with NCCP focussed on all recommendations which were reported as "not started" or "underway". Any issues of concern were discussed with the hospital and clarifications provided where possible. A further report for each individual hospital, detailing changes made to the status of their recommendations during teleconference was prepared and returned to each of the 26 hospitals.

This document sets out the status of the report's recommendations relating to implementation at hospital level following these discussions with hospitals. 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 some issues which are outside of the control of the hospitals can impact the implementation of some recommendations. These issues have been raised repeatedly by hospitals as causing difficulty in implementing some recommendations, particularly those relating to the development, implementation and ongoing monitoring of policies, protocols and guidelines. These include:

- Staffing shortages
- Financial constraints
- Time constraints

With regards to policies, the NCCP is in the process of developing some of these policies for national use. It is also hoped that developments, particularly relating to information technology and the implementation of the Medical Oncology Clinical Information System (MOCIS) will facilitate enhanced quality, safety and efficiency of services. 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.

1.4 Future monitoring of implementation

Given the significant progress made by hospitals in implementing the recommendations, the NCCP has determined that ongoing monitoring of implementation is now appropriately in place in each of the hospitals. The current implementation report will therefore be the final review of the recommendations at hospital level. The working groups in place to progress the national recommendations will continue and will report to the steering group. Regular updates on these will be provided to stakeholders.

1.5 More information

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.

1.6 Acknowledgements

The NCCP would like to take this opportunity to thank all of the hospitals, hospital CEOs/Managers, designated liaison contacts and all those who were involved in the report and implementation of the recommendations over the past two years, for their hard work and ongoing efforts in the implementation of this important safety initiative.

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

The final review of implementation covered all 26 hospitals that provide public Systemic Anti Cancer Therapy (SACT) services in Ireland.

The national implementation level across all recommendations at hospital level (n=81) now stands at 81%, up from 55% in the first implementation status report in March 2014. A further 13% are underway, 1% are reported as not started and the remaining 5% are not applicable[1] (see Figure 1). The proportion of those reported as "not started" has decreased over the last two years from 13% in the first implementation report to 1% in this final report.

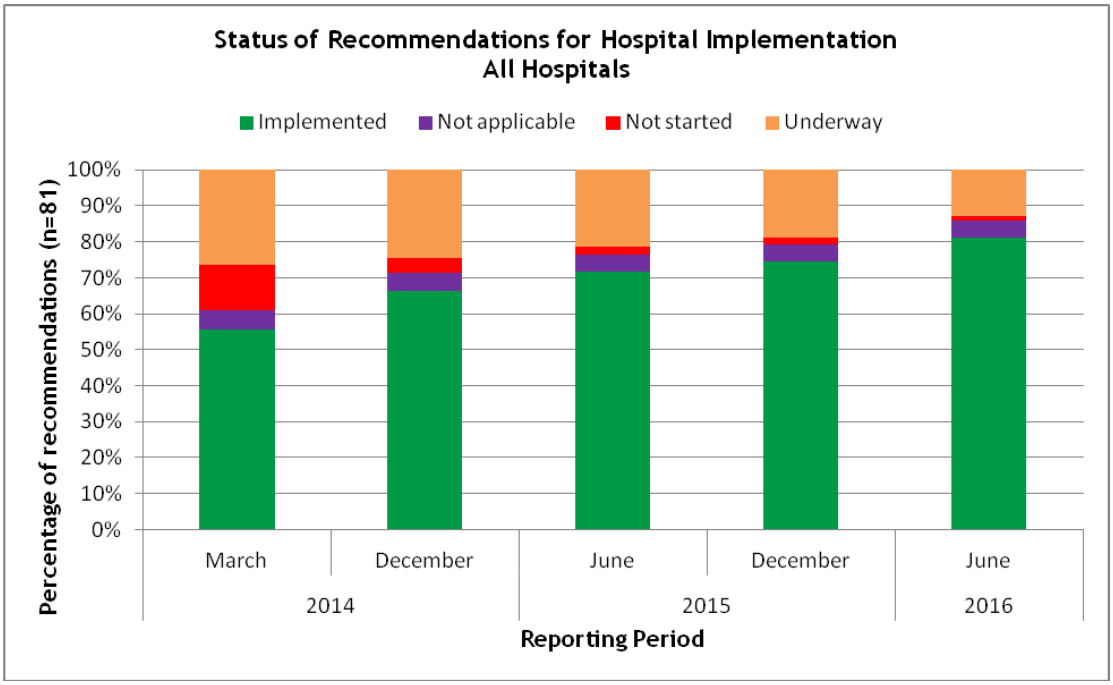

Figure 1. Comparison of status of recommendations for hospital Implementation (March 2014 - to June 2016) – All Hospitals.

Progress has been made on the implementation of recommendations across all of the areas outlined in the report, as illustrated in Figure 2, which compares the status of each group of recommendations from March 2014 with that in June 2016.

[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.

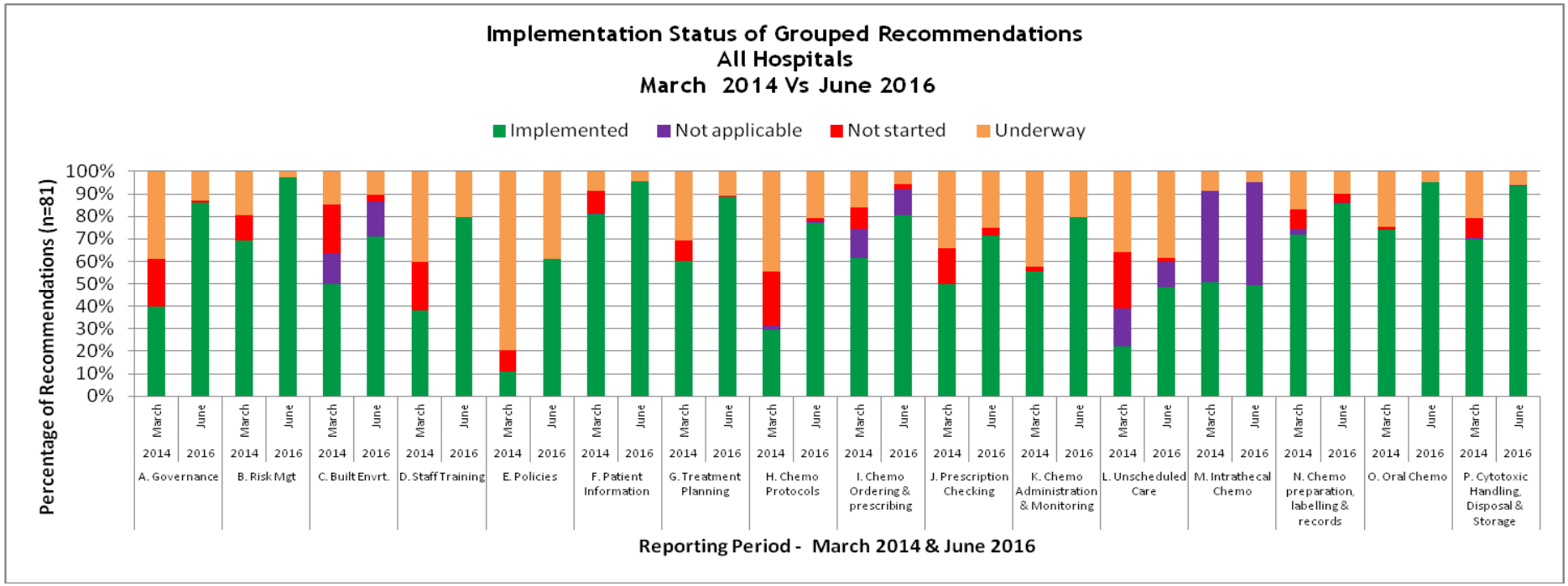

Figure 2. Comparison of implementation of grouped recommendations – March 2014 and June 2016 (All Hospitals)

The implementation level in individual hospitals ranged from 55% of recommendations implemented to 81% implementation.

In previous implementation status reports the hospitals were anonymised to give them the opportunity to address the recommendations. Each hospital was provided with the specific details relating to their hospital. Details were also provided to Hospital Group CEOs. For this final report, all hospitals have been named. All 26 hospitals provide busy SACT 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.

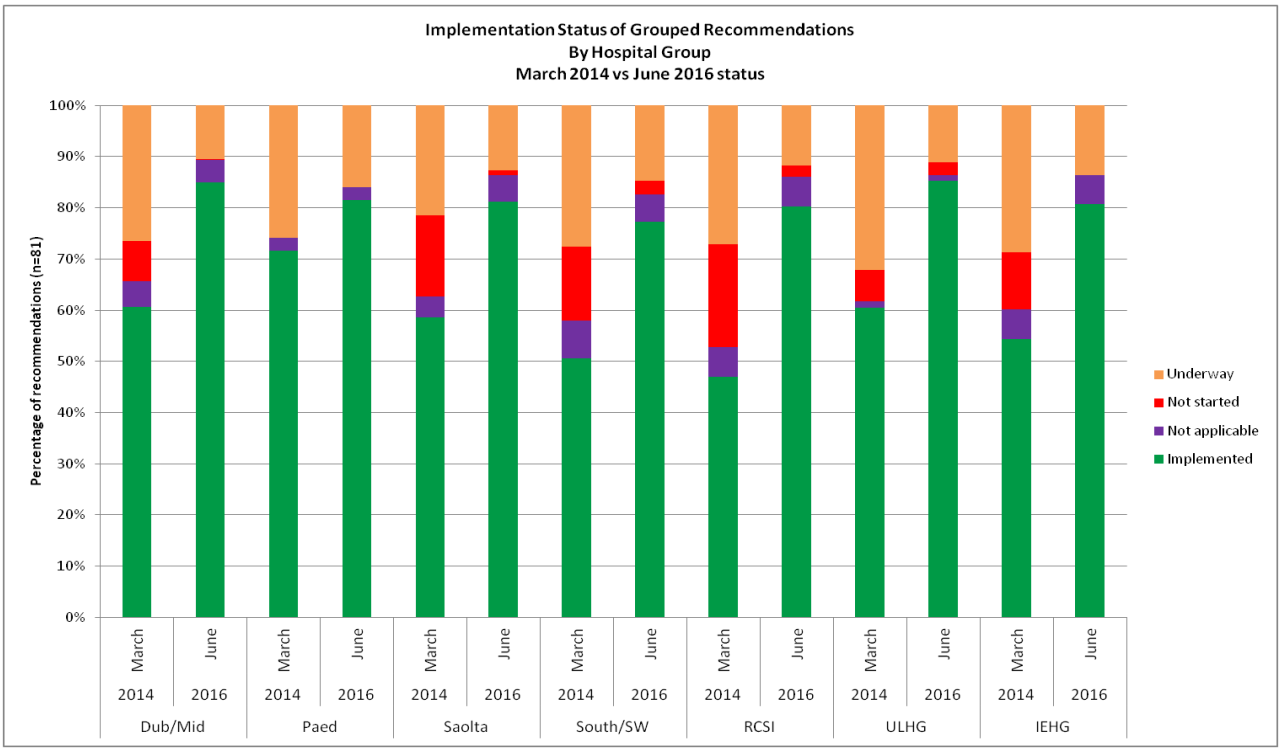

Figure 3. Comparison of implementation of recommendations – March 2014 to June 2016 – by Hospital Group

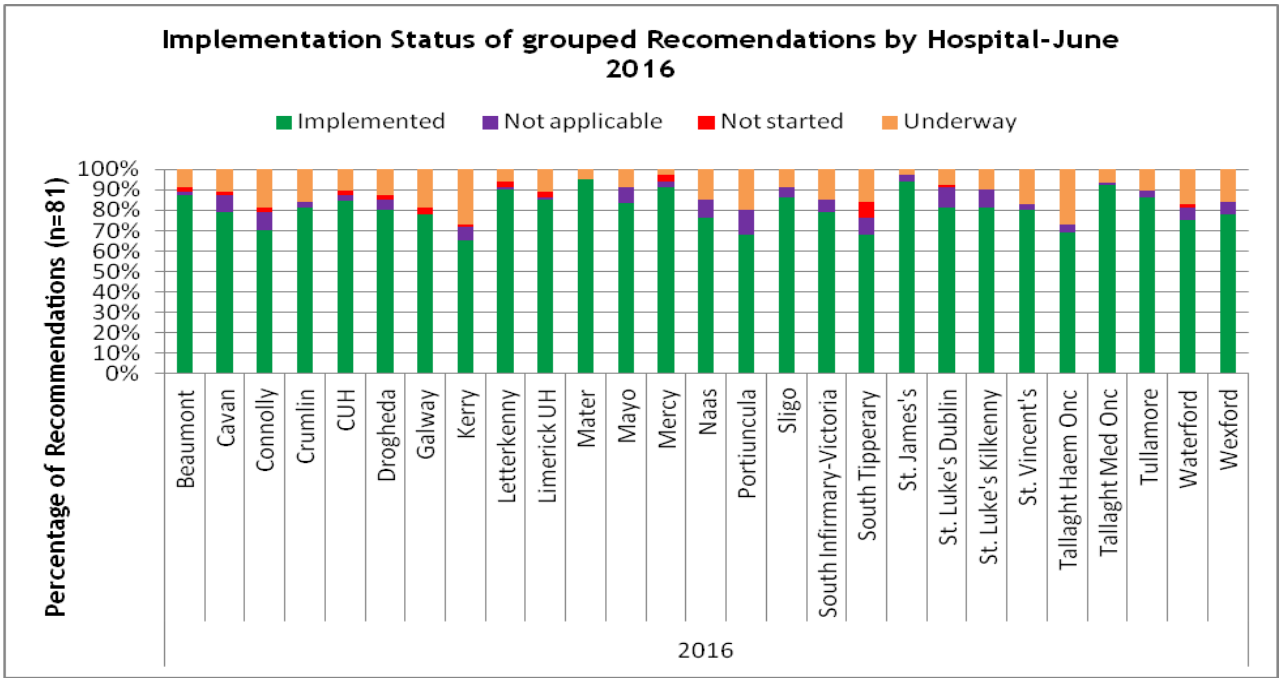

Figure 4. Implementation status of all recommendations by hospital – June 2016 (Hospitals named)

Fig 3. compares the implementation status of recommendations in March 2014 and June 2016 by Hospital Group. Fig 4. sets out the implementation status of the recommendations in each hospital. 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.
In order to illustrate the progress made in relation to some recommendations from the review report, 13 recommendations have been discussed in more detail.

Recommendation 11: Day wards and outpatient clinics should facilitate appropriate desk/office space for a clinical pharmacy service.

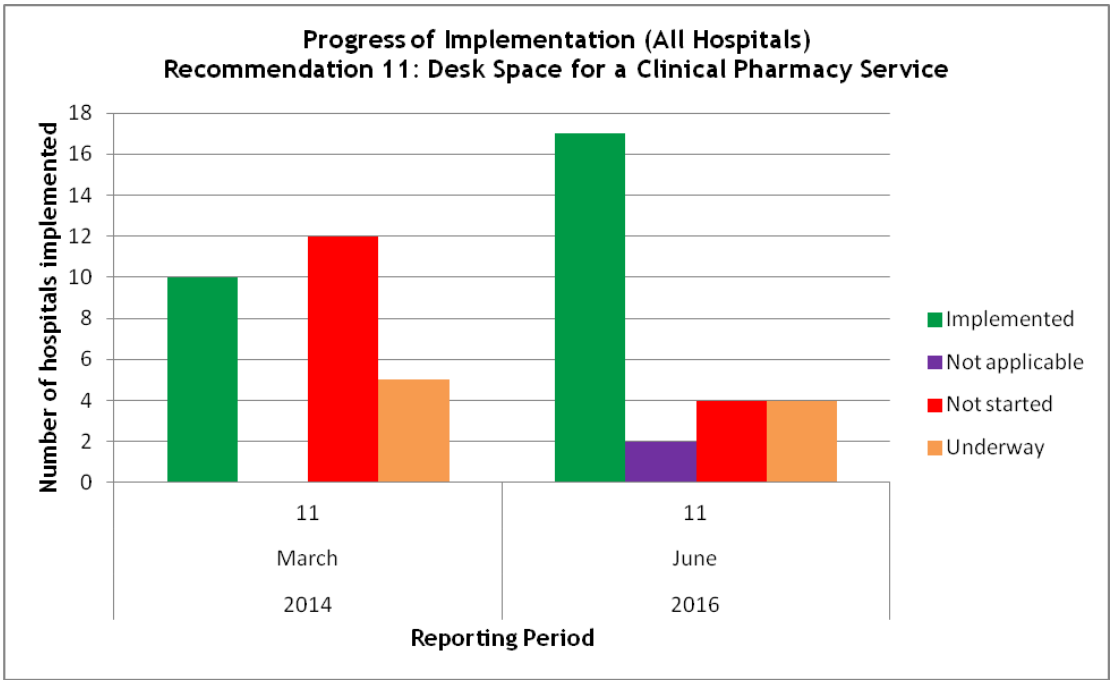

Figure 5. Progress of implementation nationally: Recommendation 11

A number of hospitals implemented this recommendation with an increase from 10 at the time of the baseline status in March 2014 to 17 in June 2016. Four hospitals stated this was underway, four not started and two as not applicable. Many of the units currently in use were not purpose built to accommodate office space for a clinical pharmacist but hospitals have put plans in place to organise space within the current unit or as part of building plans if a new build has been planned for the future. Hospitals took this opportunity to report that while desk space in some units was available, they had limited access to, or no clinical pharmacist cover due to lack of staffing resources. In some instances, business cases had been put forward seeking funding for more pharmacy staff and it had been placed on the risk register.

Recommendation 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.

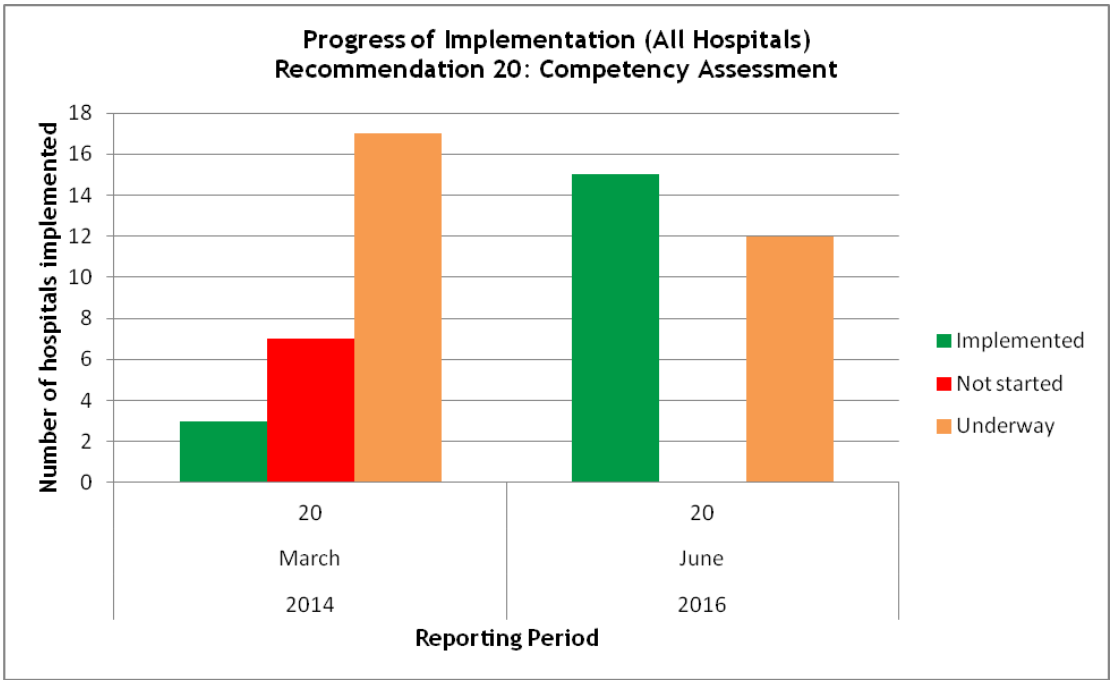

Figure 6. Progress of implementation nationally: Recommendation 20

As of June 2016, 15 hospitals had implemented this recommendation and the remainder were underway. While competency assessments for doctors in medical oncology and haematology falls under the remit of the Royal College of Physicians Ireland (RCPI), generally, nursing competencies were in place but competencies for pharmacists were still in progress in several hospitals. The final implementation status report shows considerable progress over the baseline status report in March 2014 when this recommendation was implemented in just three hospitals and not started in seven. For those underway, some hospitals were in the process of developing competency documents or incorporating existing NCCP competency documents into their competency assessments. In one hospital, all new staff were fully assessed before undertaking their assigned responsibilities but existing staff had yet to complete their competency assessments. One hospital in particular expressed concern over its means to assess competencies for all staff on an annual basis.

Recommendation 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 Oncology Medication Safety Review Report.

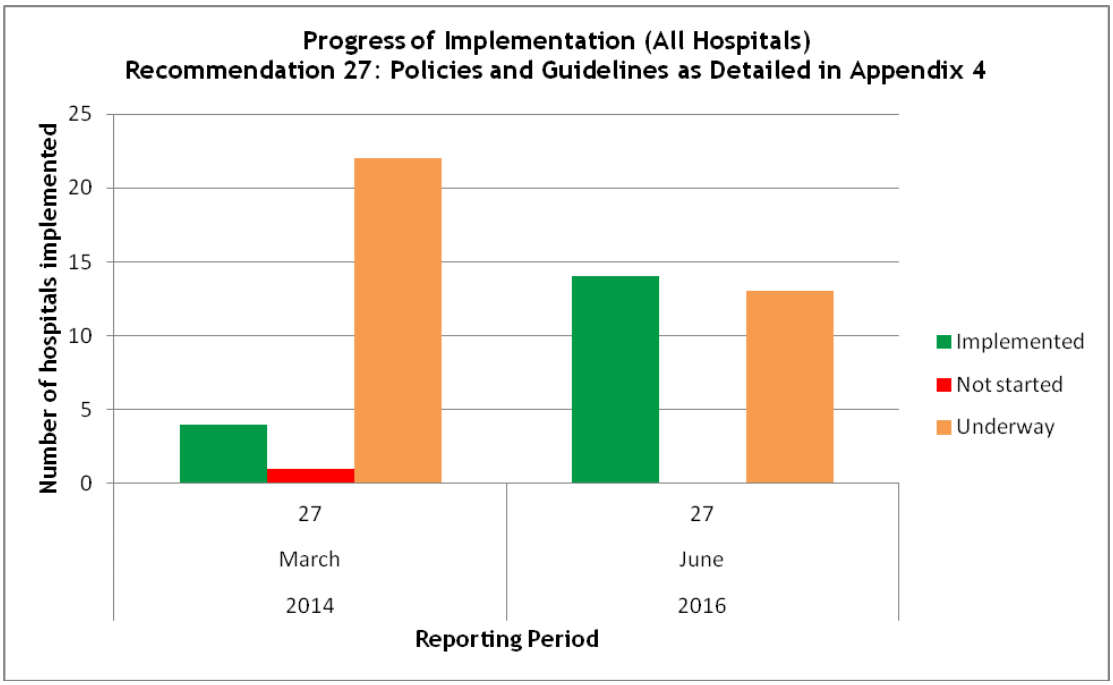

Figure 7. Progress of implementation nationally: Recommendation 27

Recommendation 27 involves guidelines/policies covering 19 different areas. Fourteen hospitals have fully implemented this recommendation. This has increased over the last two years from four hospitals at the baseline report in March 2014.

This recommendation is currently progressing well and underway in 13 hospitals with many policies in final draft form and awaiting approval and sign off. Hospitals have stated that lack of staff and time constraints have delayed the development of any outstanding guidelines and policies with a concern over the lack of administrative support to help update and maintain the policies as required.

The NCCP was made aware of the difficulties experienced by hospitals in implementation of this recommendation during previous implementation reviews. The intention is that the NCCP will lead on the development of some of the policies and guidelines required to fully implement recommendation number 27 of the Report.

Recommendation 28: Relevant national policy recommendations and NCCP recommendations should be included in local policies and practices.

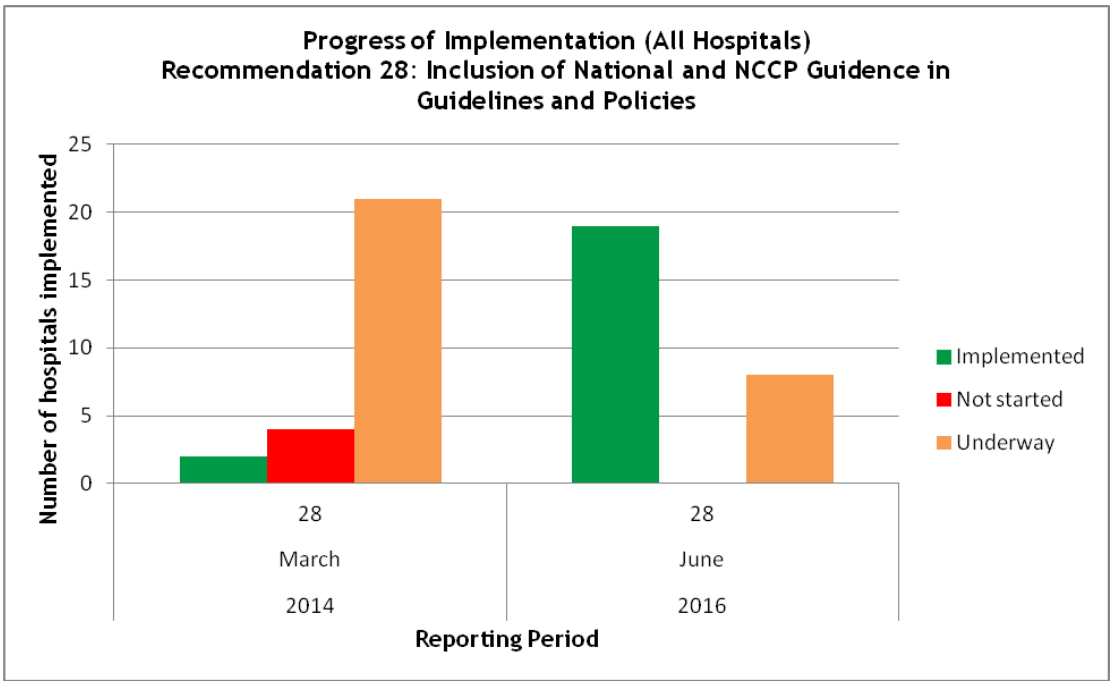

Figure 8. Progress of implementation nationally: Recommendation 28

This recommendation is directly related to recommendation 27. Huge progress has been made with 19 hospitals stating their current status as implemented which is an increase from two hospitals since the baseline report in March 2014.

There are eight hospitals with this recommendation underway. Similar to recommendation 27, hospitals have stated that lack of staff and time constraints have delayed the development of these guidelines and policies. Policies are currently being checked and re written to ensure they comply with this recommendation. Some hospitals are implementing this on an ongoing basis in parallel with the development of the policies from recommendation 27 or waiting until their existing policies are due for update to include all the required local and NCCP practices.

Recommendation 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.

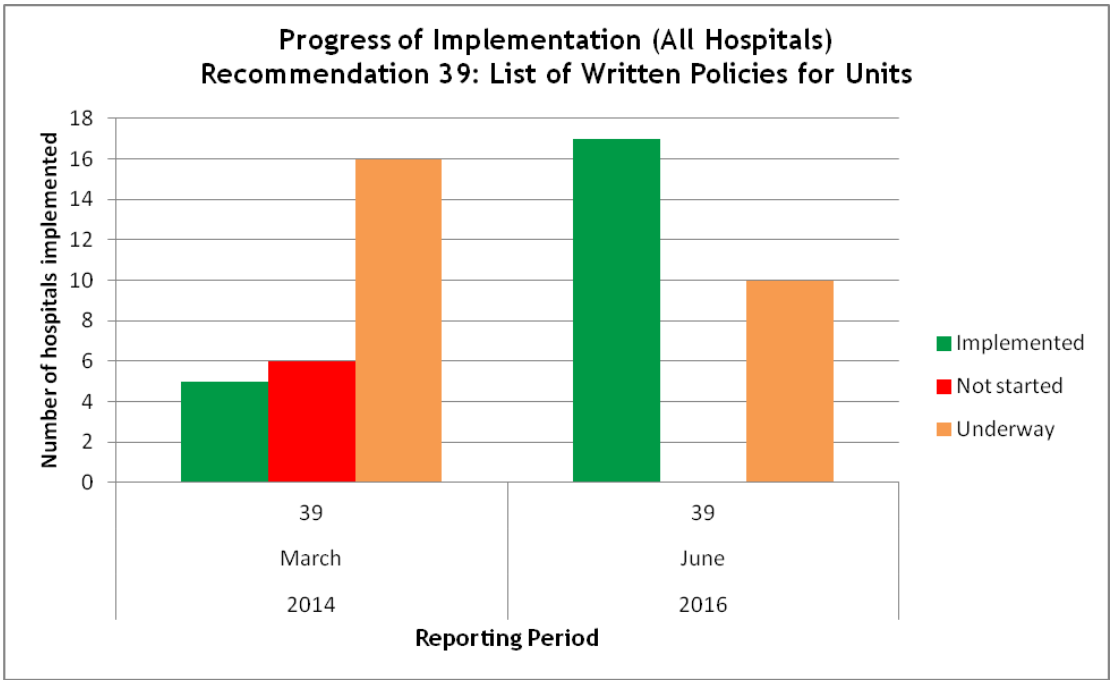

Figure 9. Progress of implementation nationally: Recommendation 39

A number of hospitals have implemented this recommendation with an increase from five hospitals at the time of the baseline status report in March 2014 to 17 in June 2016. The remaining 10 hospitals reported this recommendation as underway. There has been progress with hospitals completing many of the required policies with others in development or draft form. Many of the hospitals identified the policy on the maximum acceptable time period between pre-treatment tests as the most frequently outstanding policy. As with other policy related recommendations, lack of staff, resources and time constraints have caused delays in fully implementing this recommendation.

Recommendation 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.

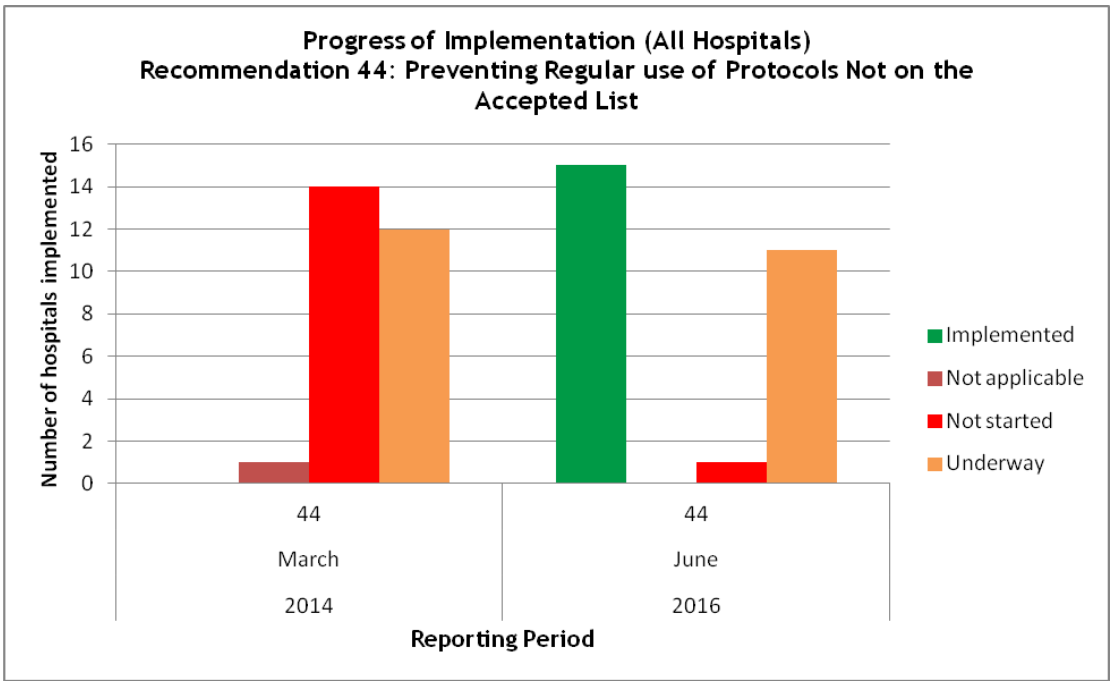

Figure 10. Progress of implementation nationally: Recommendation 44

Fifteen hospitals reported having this recommendation fully implemented showing progress compared with March 2014 when no hospital reported this recommendation as being implemented and 14 hospitals had not started. As of June 2016, 11 hospitals had this underway and only one not started. In the hospital where this recommendation is not started, time constraints and staff shortages are stated as the cause for the delay. Many of the hospitals with an "underway" status had a process in place and either had a policy written but were waiting for approval and sign off, or had yet to document their existing process.

Recommendation 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

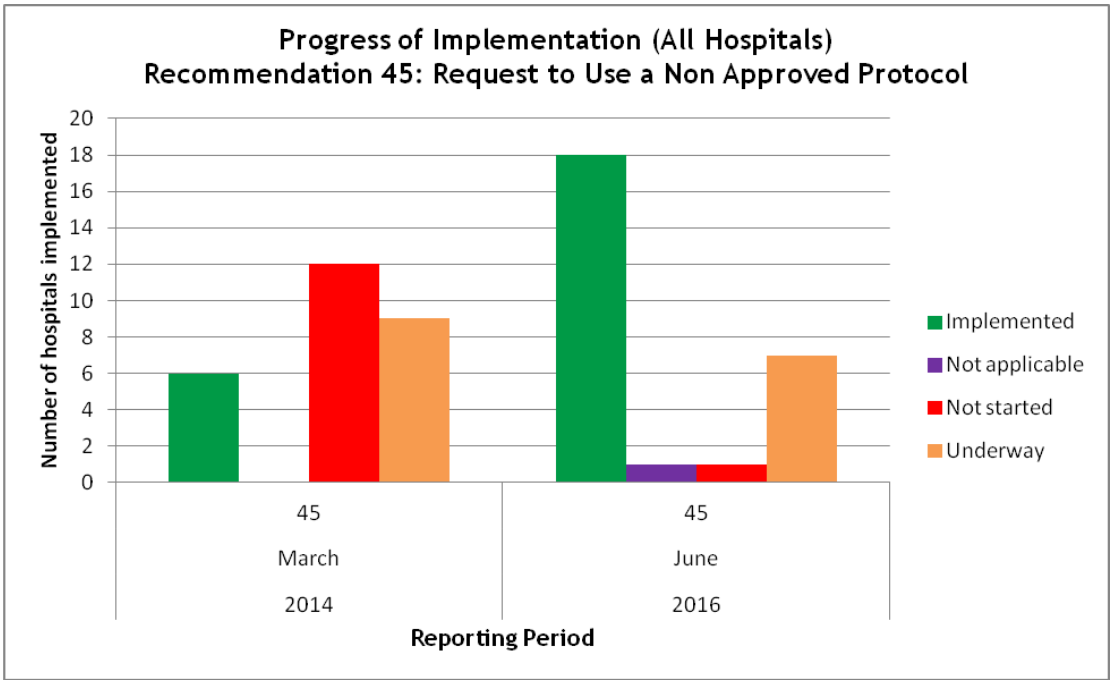

Figure 11. Progress of implementation nationally: Recommendation 45

Since the baseline status report of March 2014 implementation of this recommendation has increased from six hospitals to 18. Seven hospitals now have this recommendation underway, one not started and one not applicable. Many of the hospitals with this recommendation status as underway and not started, stated that while they have a process in place to deal with use of non approved protocols they have yet to write a policy, keep records or audit this process. One hospital stressed that while this recommendation is implemented, their pharmacy staff are finding it difficult to maintain records and audit due to time restraints, resources and staff shortages

Recommendation 52: Chemotherapy orders must be signed "off-hold" by the prescriber or the policy authorised person prior to administration of chemotherapy to the patient.

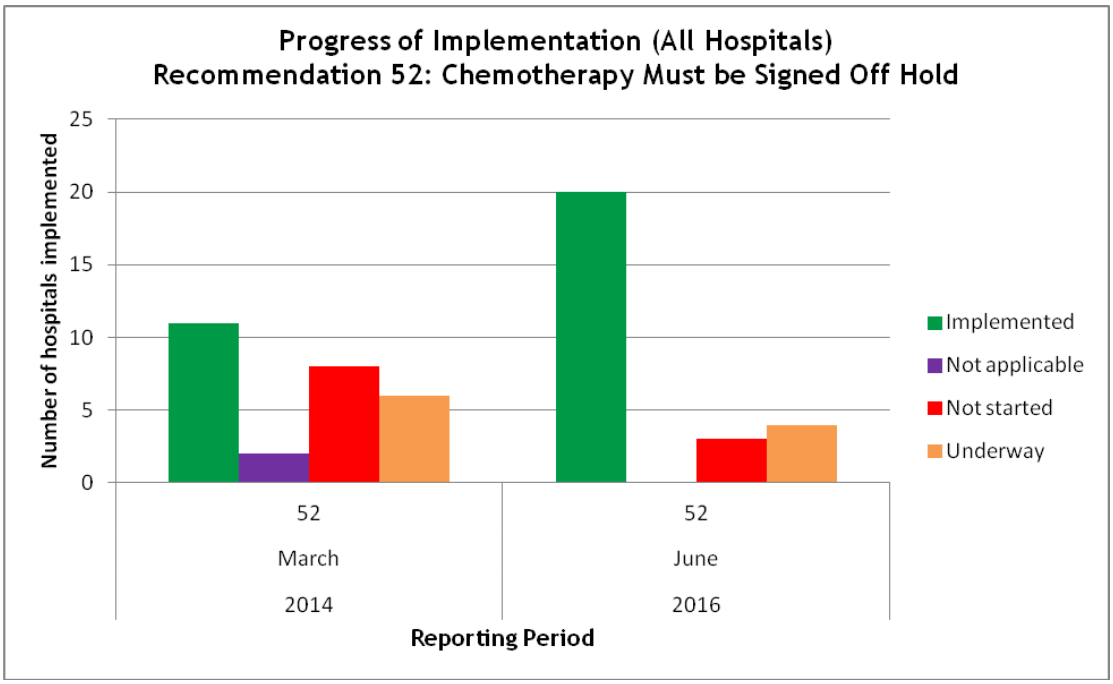

Figure 12. Progress of implementation nationally: Recommendation 52

As of June 2016, 20 hospitals have implemented this recommendation, an increase from 11 in the March 2014 report. In four hospitals this is underway and three not started. Of the hospitals that reported this recommendation as "not started" one site has a nurse led service with a consultant who visits once weekly. In the other sites, there are processes to assess and discuss the patient prior to re starting treatment but no formal document identifying who is authorised to give approval that a patient can resume treatment. For the remaining four hospitals whose status is underway, policies are in progress or waiting for approval and sign off.

Recommendation 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.

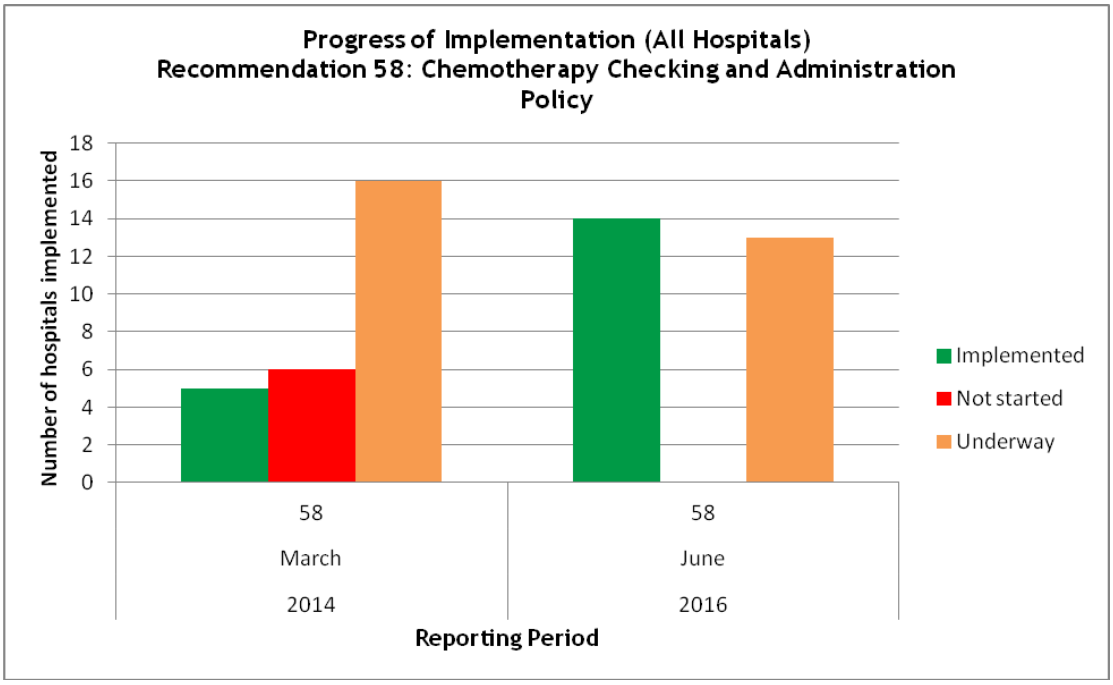

Figure 13. Progress of implementation nationally: Recommendation 58

Fourteen hospitals now have this recommendation implemented which is an increase from five in March 2014. The remaining 13 hospitals have this underway. While policies are in progress, checking of oral chemotherapy preparations by pharmacy policy appears to be frequently outstanding and is delaying the implementation of this recommendation for many hospitals. This is caused by a lack of pharmacy staffing resources. Another hospital stated that pharmacy cannot complete an assessment of interactions as they do not have access to the complete list of patient medications.

Recommendation 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.

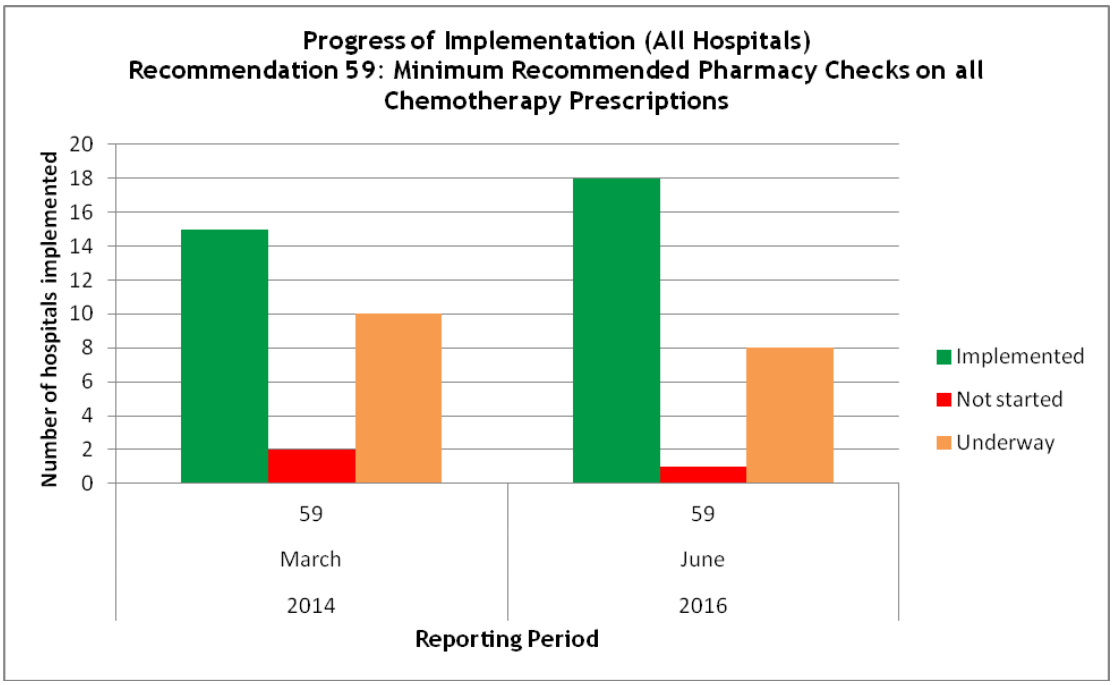

Figure 14. Progress of implementation nationally: Recommendation 59

Eighteen hospitals have implemented this recommendation, an increase from 15 in the March 2014 report. Eight hospitals have this underway and one hospital reported that implementation had not started. The hospital that has "not started" stated that a lack of pharmacy resources had prevented implementation. The remainder of hospitals who have this recommendation underway report that the recommendation, in part, has been implemented. Lack of pharmacy checks on drug interactions, oral chemotherapy preparations and a shortage of fully trained pharmacy staff dedicated to this task, have delayed full implementation.

Recommendation 61: All units should have a policy in place that defines the persons authorised to give approval to proceed with treatment (off-hold).

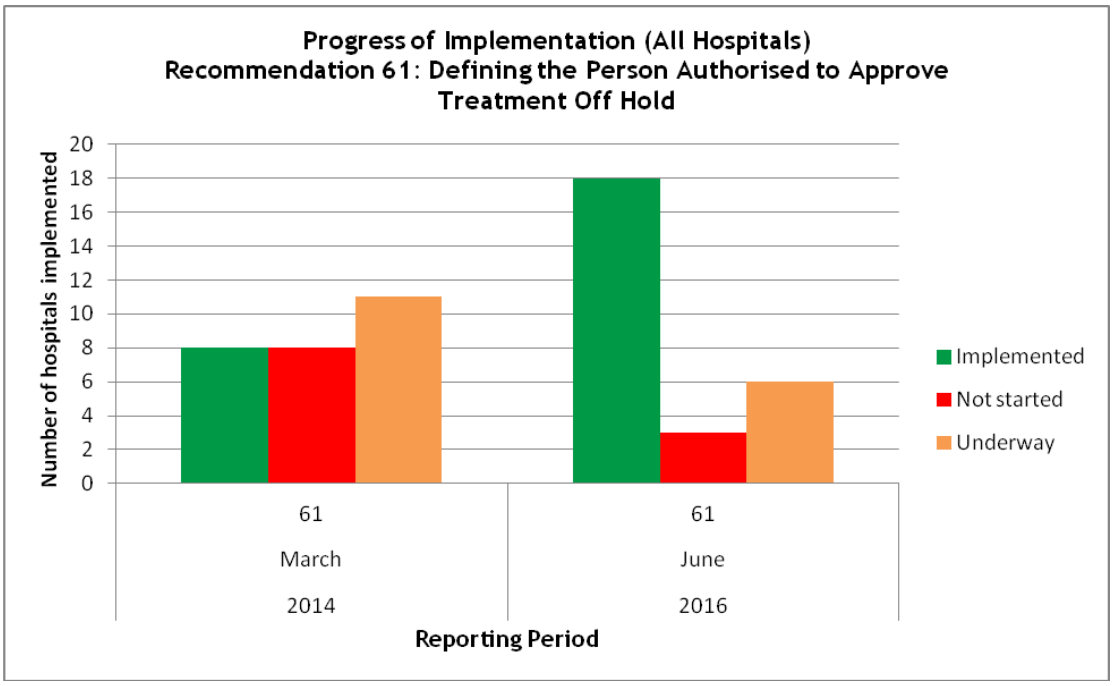

Figure 15. Progress of implementation nationally: Recommendation 61

As of June 2016, 18 hospitals had implemented this recommendation, an improvement from eight in March 2014. Six hospitals are underway and three not started. While the three hospitals that have not started implementation of this recommendation have a process in place to discuss and assess the patient fully prior to treatment, there is no formal written policy. Those that are underway are waiting for their policies to be completed or have drafts in place.

Recommendation 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 etc (list given – see Appendix B for details)

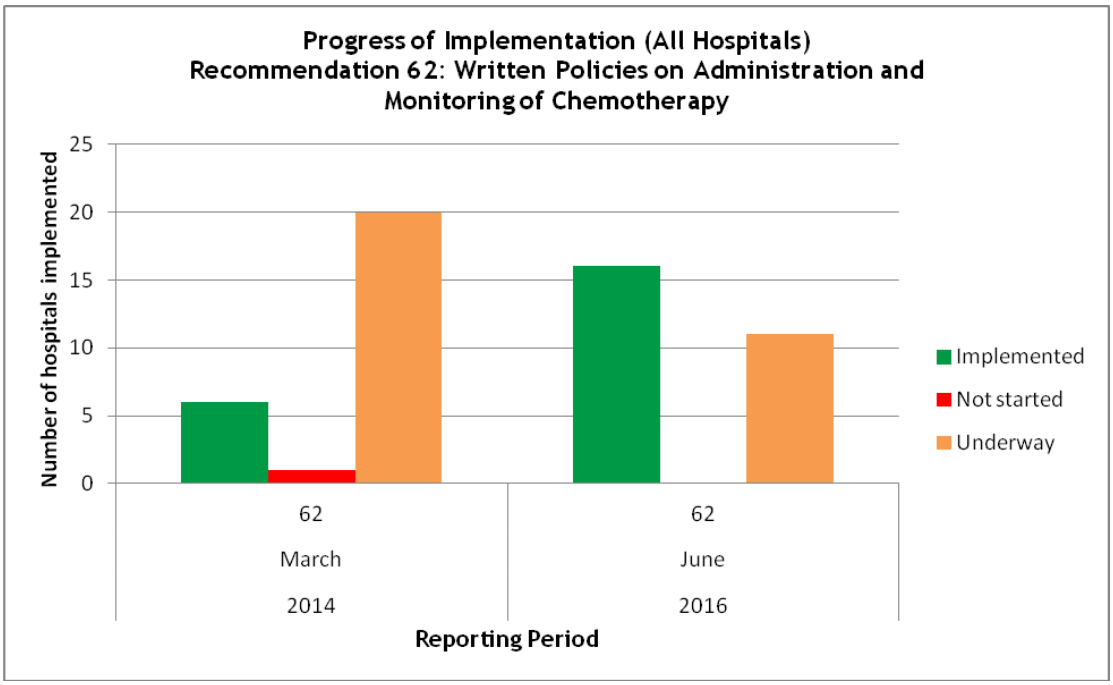

Figure 16. Progress of implementation nationally: Recommendation 62

Recommendation 62 involves guidelines/policies covering five different areas. While 16 hospitals have this recommendation fully implemented; an increase from six in the March 2014 report, 11 hospitals currently remain underway. While policies are in place for many of the required areas in these hospitals, others are in draft form or waiting for development. This is due to staff time constraints and resource issues preventing their completion. This is a common issue and has been raised during the previous implementation reviews.

Recommendation 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.

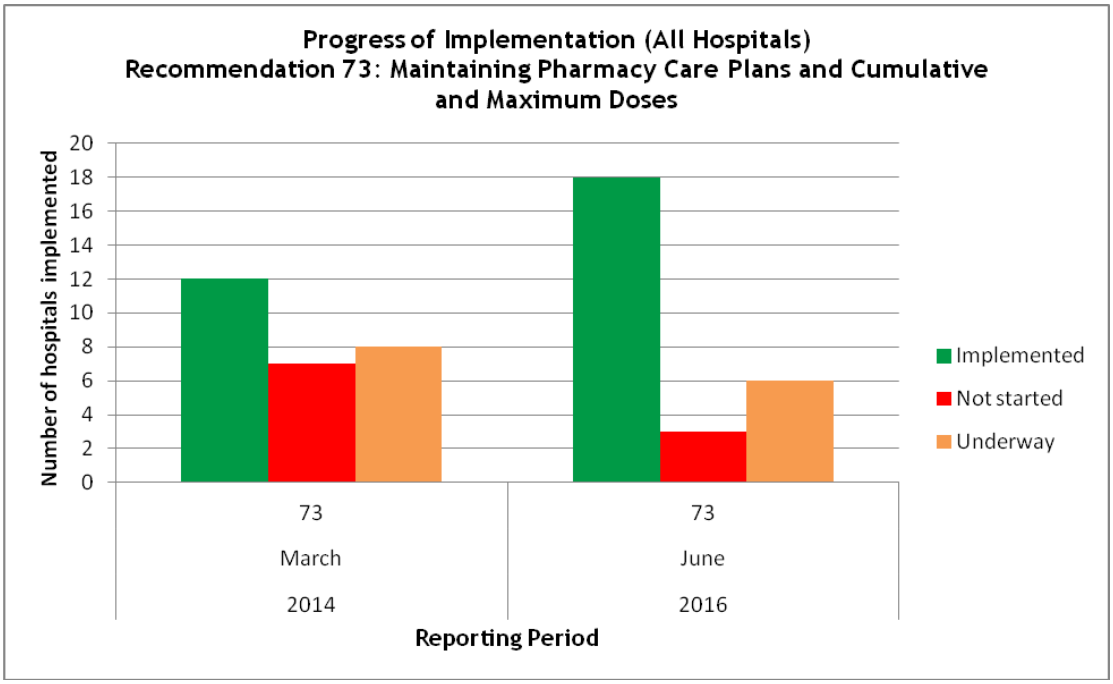

Figure 17. Progress of implementation nationally: Recommendation 73

Since the baseline status report in March 2014 implementation of this recommendation has increased from 12 hospitals to 18. It is underway in six and not started in three. In some hospitals, pharmacy staffing and resource issues have prevented this from being fully implemented. Pharmacy staff is limited so maintenance with regards to updating of care plans is not possible. The hospitals in which this recommendation is not started, reported that the lack of resources and staff along with increased clinical workload in the pharmacy departments had prevented implementation.

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.

Overall, of the national recommendations (n=13), 15% are implemented, 69% are underway and the remaining 15% are not started. This is partially due to delays in formal establishment of some groups and prioritisation of other areas.

The national implementation status of each of the national recommendations is provided in Fig. 18. The NCCP will continue to monitor these recommendations and their implementation status will be updated on an annual basis.

Period				Nov-16	
NCCP Rec	N.	Recommendation details	HIQA	Nov-16	
				Status	Comments
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	Underway	Recommendations are being progressed. It is expected that a document will be available for consultation late in 2016/early 2017
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	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	Existing capacity planning tools are being explored.
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 progressing national competencies. RCPI curricula for medical oncology and haematology (SpR) are comprehensive.
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 are completed
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	Procurement process for MOCIS completed. Implementation to commence 2017
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	Completed	Guidance documents published late 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	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		2	15%
		Number underway		9	69%
		Number not started		2	15%

Figure 18. Status of National Recommendations (June 2016)

Appendix A-Status of individual recommendations (All Hospitals)

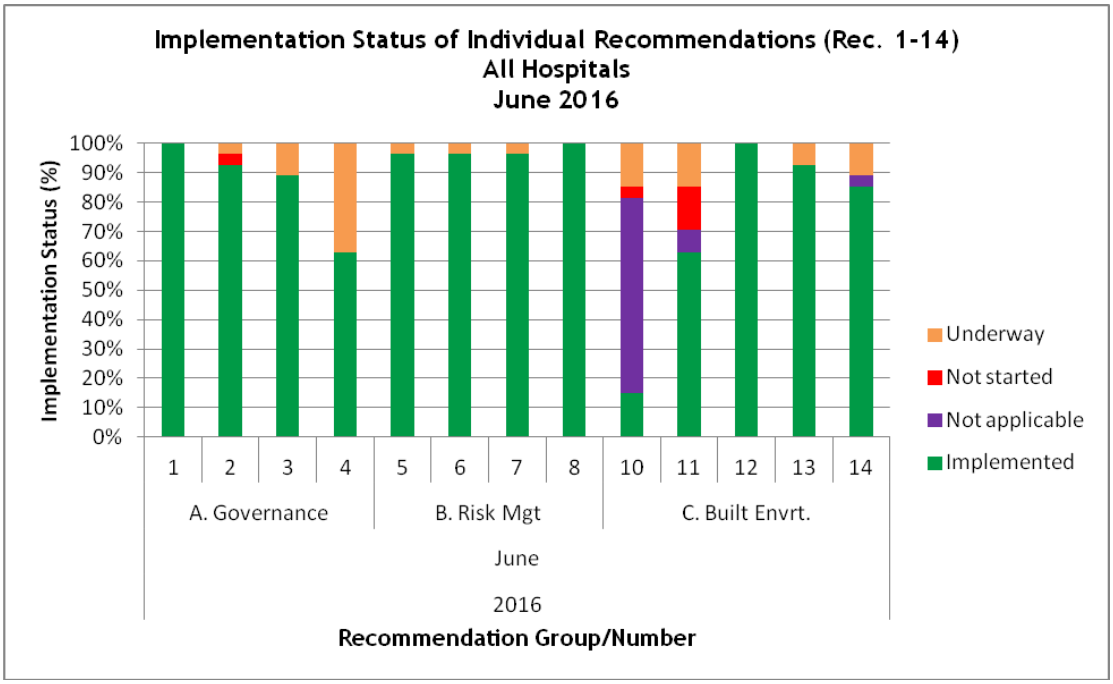

Figure 19. Implementation Status of Recommendations 1-14 (Hospital Implementation) June 2016, Updated December 2016.

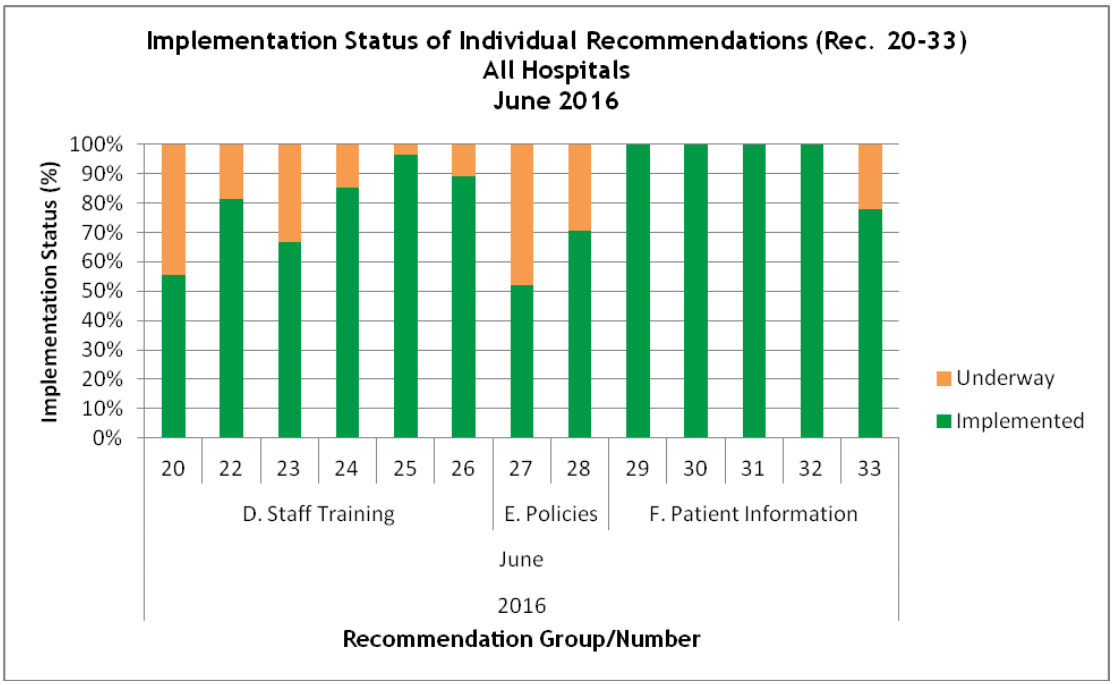

Figure 20. Implementation Status of Recommendations 20-33 (Hospital Implementation) June 2016, Updated December 2016.

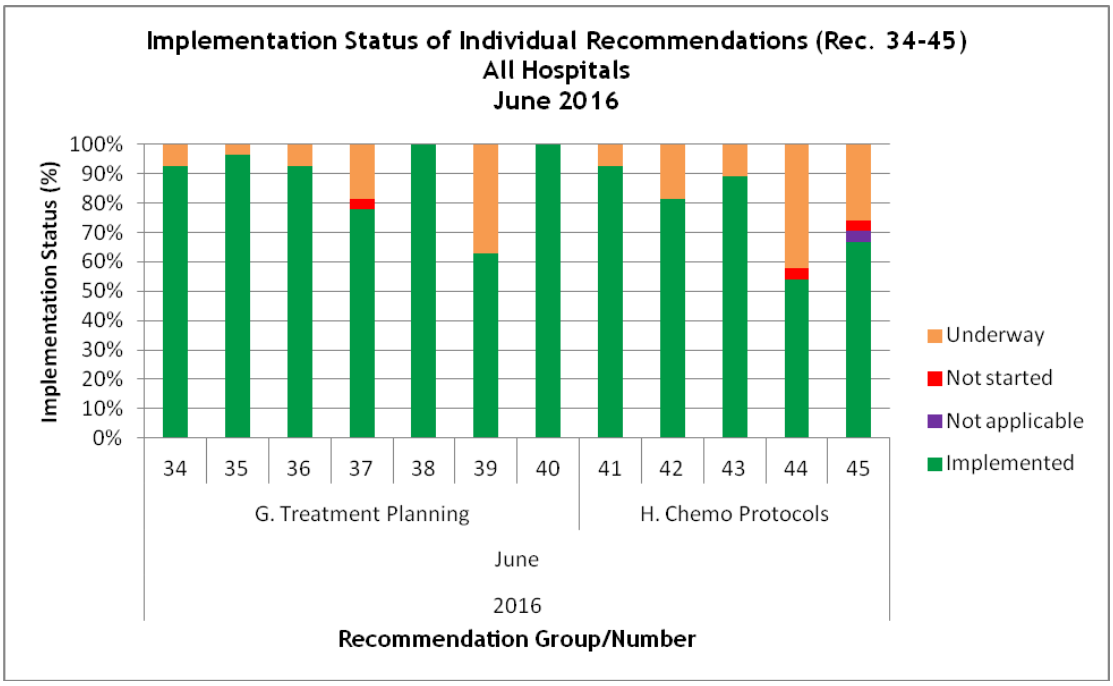

Figure 21. Implementation Status of Recommendations 34-45 (Hospital Implementation) June 2016, Updated December 2016.

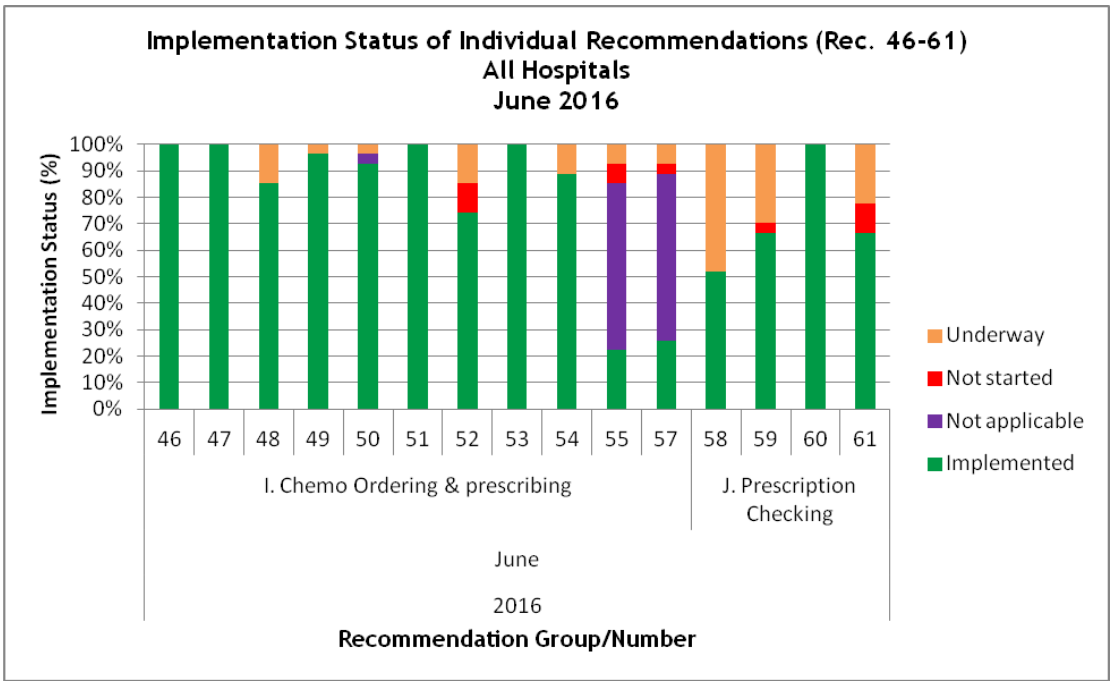

Figure 22. Implementation Status of Recommendations 46-61 (Hospital Implementation) June 2016, Updated December 2016.

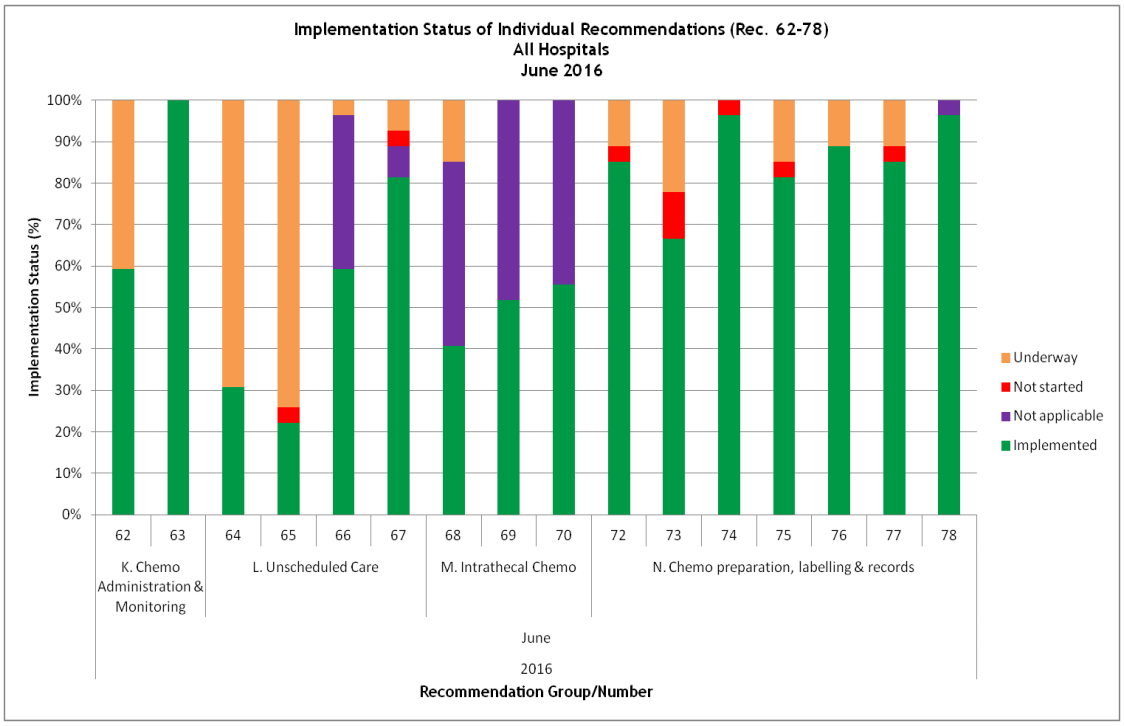

Figure 23. Implementation Status of Recommendations 62-78 (Hospital Implementation) June 2016, Updated December 2016.

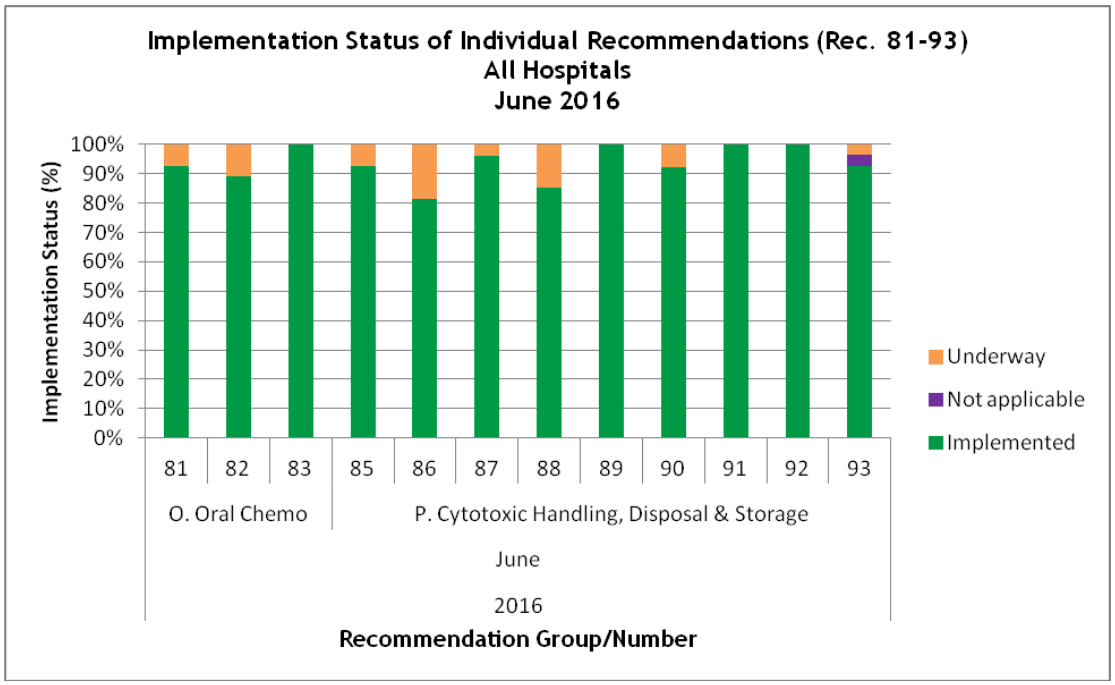

Figure 24. Implementation Status of Recommendations 81-93 (Hospital Implementation) June 2016, Updated December 2016.

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

Recommendations 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.
Recommendations 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.
Recommendations 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 considerations • Patient 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.
Recommendations 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.
Recommendations 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.
Recommendations 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 Appendix 4 of the review report.
Rec 28.	Relevant national policy recommendations and NCCP recommendations should be included in local policies and practices.

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

Recommendation 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 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.
Recommendations 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.
Recommendations 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 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 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.
Recommendations 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.
Recommendations on 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.
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).
Administration and 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: ○ Neutropenia/neutropenic sepsis ○ Cytotoxic-induced emesis ○ Cytotoxic extravasation ○ Allergic reactions including anaphylaxis ○ 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.
Recommendations 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.
Recommendations 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 alkaloids[3].
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.
Recommendations 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.

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

Recommendations 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 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.
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.
Recommendations 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.
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.