NCCP Oncology Medication Safety Review Report







Tús Áite do Shábháilteacht Othar Patient Safety, First





NATIONAL CANCER CONTROL PROGRAMME

ONCOLOGY MEDICATION SAFETY

REVIEW REPORT

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TABLE OF CONTENTS

| Tab | ole Of Co | ontents | 2 |
|-----|-----------|------------------------------------|----|
| Exe | ecutive S | Summary | 7 |
| 1 | Backgr | round | 12 |
| 2 | Method | dology | 14 |
| 3 | Results | S | |
| 3.1 | Govern | nance And Service Configuration | |
| | 3.1.1 | Findings | 17 |
| | 3.1.2 | Recommendations | |
| 3.2 | Risk M | anagement | |
| | 3.2.1 | Recommendations | |
| 3.3 | Built E | nvironment, Activity And Equipment | |
| | 3.3.1 | Findings | |
| | 3.3.2 | Recommendations | |
| 3.4 | Staffing | g | 24 |
| | 3.4.1 | Findings | 24 |
| | 3.4.2 | Recommendations | |
| 3.5 | Staff T | raining | 29 |
| | 3.5.1 | Findings | |
| | 3.5.2 | Recommendations | |
| 3.6 | Policie | s And Guidelines | |
| | 3.6.1 | Findings | |
| | 3.6.2 | Recommendations | |
| 3.7 | Informa | ation For Patients And Carers | |
| | 3.7.1 | Findings | |
| | 3.7.2 | Recommendations | |

| 3.8 | Treatment Planning And Clinical Assessment | | | |
|------|--|---|----|--|
| | 3.8.1 | Findings | 35 | |
| | 3.8.2 | Recommendations | 36 | |
| 3.9 | Chemot | herapy Protocols | 37 | |
| | 3.9.1 | Findings | 37 | |
| | 3.9.2 | Recommendations | 38 | |
| 3.10 | Chemot | herapy Ordering And Prescribing | 39 | |
| | 3.10.1 | Findings | 39 | |
| | 3.10.2 | Recommendations | 43 | |
| 3.11 | Chemot | herapy Orders And Prescription Checking | 45 | |
| | 3.11.1 | Findings | 45 | |
| | 3.11.2 | Recommendations | 46 | |
| 3.12 | Adminis | stration And Monitoring Of Chemotherapy | 47 | |
| | 3.12.1 | Findings | 47 | |
| | 3.12.2 | Recommendations | 48 | |
| 3.13 | Manage | ment Of Unscheduled Care | 49 | |
| | 3.13.1 | Findings | 49 | |
| | 3.13.2 | Recommendations | 49 | |
| 3.14 | Intrathe | cal Chemotherapy | 50 | |
| | 3.14.1 | Findings | 50 | |
| | 3.14.2 | Recommendations | 51 | |
| 3.15 | Pharma | cy – Chemotherapy Preparation, Labelling And Record Keeping | 52 | |
| | 3.15.1 | Findings | 52 | |
| | 3.15.2 | Recommendations | 54 | |
| 3.16 | Oral Ch | emotherapy | 55 | |
| | 3.16.1 | Findings | 55 | |
| | 3.16.2 | Recommendations | 57 | |

| 3.17 | Handling | g, Disposal And Storage Of Cytotoxic Drugs58 |
|------|------------|---|
| | 3.17.1 | Findings |
| | 3.17.2 | Recommendations59 |
| 4 | Conclus | sion61 |
| Арр | pendix 1. | Additional Review Findings62 |
| Арр | pendix 2. | Members Of Steering Committee And Site Visit Team64 |
| Арр | pendix 3. | Minimum Treatment Protocol Specific Information Requirements66 |
| Арр | pendix 4. | Guidelines/Policies Required67 |
| Арр | pendix 5. | Minimum Criteria For Treatment Record69 |
| Арр | pendix 6. | Recommended Minimum Pharmacist Checks For Chemotherapy |
| | | Orders And Prescriptions71 |
| Арр | pendix 7. | Minimum Nursing Verification Checks Prior To Chemotherapy |
| | | Administration74 |
| Арр | pendix 8. | Sample Guide To Prescription/Order Checking Responsibilities 75 |
| Арр | pendix 9. | Recommended Minimum Data For Chemotherapy Prescriptions76 |
| Арр | pendix 10 | Recommended Minimum Labelling Requirements For Pharmacy. |
| | | Prepared Chemotherapy Preparations78 |
| Glo | ssary | |
| Abb | previation | ıs80 |
| Bib | liography | |

List of Tables and Figures

Figure 1: Location of units delivering systemic cancer therapy......15

| Table 1 Patient episodes and treatment spaces (oncology and haematology combined) |
|---|
| |
| Table 2: Medical staffing levels - these data pertain to WTE on site in the hospital per |
| week26 |
| Table 3: Pharmacy staffing levels (haematology and oncology combined; including |
| pharmacy staff in inpatient and ambulatory services) |
| Table 4: Nursing staffing levels (haematology and oncology combined - day ward only) |
| |
| Table 5: Status of key policies in relation to delivery of systemic cancer therapy |
| Table 6: Prescription formats in use in the hospitals |
| Table 7:Chemotherapy order and prescription documentation - percentage of |
| prescriptions/orders across all hospitals that contained specified detail outlined below.42 |
| Table 8: Additional review findings: pharmacy62 |

| Box 1 Recommendations on Built Environment and Activity and Equipment | |
|--|------------|
| Box 2: Recommendations on Staffing | |
| Box 3: Recommendations on Staff Training | |
| Box 4: Recommendations on Policies/Guidelines | |
| Box 5: Recommendations on Information for Patients and Carers | |
| Box 6: Recommendations on Treatment Planning and Clinical Assessment | |
| Box 7: Recommendation on Chemotherapy Protocols | |
| Box 8: Recommendations on Chemotherapy Ordering and Prescribing | |
| Box 9: Recommendations on Prescription Checking | |
| Box 10: Recommendations on Administration and Monitoring of Chemotherapy | 48 |
| Box 11: Recommendations on Management of Unscheduled Care | |
| Box 12: Recommendations on Intrathecal Chemotherapy | 51 |
| Box 13: Recommendations on Pharmacy Chemotherapy Preparation, Labo | elling and |
| Record Keeping | 54 |
| Box 14: Recommendation on Cytotoxic Handling, Disposal and Storage | |

EXECUTIVE SUMMARY

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

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

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

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

Key Findings

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

Governance and Service Configuration

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

Risk Management

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

Built Environment, Activity and Equipment

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

Staff Training

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

Policies and Guidelines

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

Information for Patients and Carers

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

Treatment Planning and Clinical Assessment

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

Chemotherapy Protocols

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

Chemotherapy Ordering and Prescribing

- The form of chemotherapy orders varies between sites, ranging from full handwritten orders, to pre-printed templates to electronic ordering systems.
- Most hospitals have standard discharge prescriptions for the prescribing of discharge supportive therapy and non high-tech oral chemotherapy.
- High-tech prescriptions were used for outpatient and discharge prescriptions when required.
- There were many instances in the chart review of hand written prescriptions/orders which were of poor quality, with many of the required fields not completed. In addition many of the written prescriptions/orders and preprinted orders had unclear alterations.

Chemotherapy Orders and Prescription Checking

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

Administration and Monitoring of Chemotherapy

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

Management of Unscheduled Care

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

Intrathecal Chemotherapy

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

Pharmacy- Chemotherapy Preparation, Labelling and Record Keeping

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

Oral Chemotherapy

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

Handling, Disposal and Storage of Cytotoxic Drugs

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

1 BACKGROUND

The National Cancer Control Programme (NCCP) was established in 2007 to implement the Strategy for Cancer Control in Ireland (Department of Health, 2006). The NCCP is striving to deliver a comprehensive cancer control programme involving an integrated and cohesive approach to cancer on a whole population basis. The NCCP National Medical Oncology Programme incorporates a number of initiatives aimed at coordinating and managing cancer drug services, ensuring appropriate access to and monitoring of cancer drug use and ensuring that appropriate forward-planning is undertaken to meet future requirements. A key deliverable output of the NCCP National Medical Oncology Programme is a review of Medical Oncology Services from a quality assurance and patient safety perspective. This review is co-sponsored by the HSE Quality & Patient Safety Directorate.

This review was a national baseline assessment of systemic cancer therapy cancer services in day units from a patient safety perspective. The information gathered enabled the NCCP to establish a broad understanding of the existing policies and practices nationally and will inform the development of national policies relating to safety and quality of systemic cancer therapy services. The process has also allowed participating hospitals the opportunity to highlight examples of good practice pertaining to systemic cancer therapy provision.

The review was conducted across all 26 hospitals in Ireland involved in the administration of systemic cancer treatments in adults and children¹ and included both oncology and haematology services. However findings are reported for 28 units, due to the separate reporting of the independent haematology and oncology day wards in Beaumont and Adelaide and Meath Hospital, Tallaght. The scope included the following steps of the oncology medication pathway: pre-treatment assessment, documentation in patient records, chemotherapy ordering and prescribing, dispensing and supply, administration checks and management of risks.

¹ Our Lady's Children's Hospital Crumlin (OLCHC) was included in the review. Hospitals that operate a shared care agreement with OLCHC for the delivery systemic cancer treatment to children were not included in the review and will be dealt with under a separate process.

The review findings are structured according to the following headings:

- Governance and Service Configuration
- Risk Management
- Built Environment, Activity and Equipment
- Staffing
- Staff Training
- Policies and Guidelines
- Information for Patients and Carers
- Treatment Planning and Clinical Assessment
- Chemotherapy Protocols
- Chemotherapy Ordering and Prescribing
- Chemotherapy Orders and Prescription Checking
- Administration and Monitoring of Chemotherapy
- Management of Unscheduled Care
- Intrathecal Chemotherapy
- Pharmacy– Chemotherapy Preparation, Labelling and Record Keeping
- Handling, Disposal and Storage of Cytotoxic Drugs

2 METHODOLOGY

A steering committee was established in 2012 (members listed in Appendix 2) with responsibility for key decision making in relation to project scope and key priorities, directing the work of the project team and sign off on data collection processes and content. The project team (members listed in Appendix 2) were responsible for developing the data collection tools and conducting data collection across the participating hospitals.

The review methodology was a two-step process which consisted of:

- A self-administered questionnaire completed by each hospital
- A site visit to each hospital by a NCCP review team

The self-administered questionnaire was developed based on tools used in similar studies in the UK and Canada and with reference to international best practice guidelines for the safe preparation and provision of systemic cancer therapy (Cancer Care Nova Scotia, 2011; National Chemotherapy Advisory Group, 2009; NICAN, 2009). The topics covered in the questionnaire included staffing, quality and safety practices, and existing policies and processes related to systemic cancer therapy provision. A pilot study was conducted in September 2012 in both Beaumont Hospital and St. Luke's Hospital Kilkenny. Minor changes were made to the questionnaire based on feedback received from the pilot hospitals.

The review commenced in November 2012 and continued until May 2013. The site review team was multidisciplinary, typically consisting of a pharmacist, and either two nurses or a nurse and a doctor. All site review team members are listed in Appendix 2. The team used a standardised approach for the site visits which included a walk-through of the oncology/haematology day ward and hospital pharmacy to verify items stated in the questionnaire. 182 patient charts across all participating hospitals were reviewed during the site visits to assess the level of documentation outlined in the treatment plan, pre-treatment assessment prior to first cycle and subsequent cycles and the patient's systemic cancer therapy prescription. A mix of oncology, haematology, oral, parenteral and clinical trials patient charts were included in this review. Finally, the site visits also

allowed an opportunity for the review team to meet with key members of staff and discuss medication safety aspects in greater detail.

A round-up meeting was held at the end of each visit which allowed the team to clarify any points from the visit and provided an opportunity for questions for the team. Feedback was not provided on the day of the site visit. If any practices of concern were observed during the site visit these were raised either during the round-up meeting or in the days immediately after the site visit. The NCCP advised hospitals on a course of action in order to minimise risk and maximise staff and patient safety with regard to practices of concern.

3 RESULTS

The review was carried out in all 26 hospitals in Ireland which deliver systemic cancer therapy (Figure 1), two of which have independent haematology and oncology day units. Findings² are presented in line with common themes and followed by the associated recommendations of the steering committee.



Figure 1: Location of units delivering systemic cancer therapy³

² Where possible, quantitative data is presented in the findings section. Additional observations were made during the course of the site visits, which were of a more subjective nature, and therefore not easily quantifiable.

³ Letterkenny General Hospital is a designated satellite of the cancer centre in Galway.

3.1 Governance and Service Configuration

3.1.1 Findings

- Systemic cancer treatment is delivered in the 26 hospitals reviewed (Figure 1), which have various relationships and interdependencies. Some hospitals (including all eight designated cancer centres) have a full complement of haematology and oncology services, including designated inpatient beds, for unwell patients or for in-patient chemotherapy. These often act as a hub for nurse-led units in other hospitals, where medical consultants have a sessional commitment but are not on-site each day. There are variations of both of these models, plus other examples of close collaboration across medical oncology services in some areas.
- The sharing of regime-specific treatment protocols between hospitals generally falls to the individual consultant who is treating on both sites. Other clinical management guidelines, standard operating procedures or protocols are occasionally shared between sites but often formally ratified by management in each hospital.
- Some established networks of medical oncology services cross the boundaries of the new hospital trusts. This was raised as an issue in the hospitals concerned.
- Very few hospitals have a designated lead individual for all aspects of systemic cancer treatment within their hospital. Many have multiple leads, for each of the disciplines involved.

3.1.2 Recommendations

Box 1 Recommendations on Governance and Service Configuration

| Recomm | HIQA framework standards ⁴ | |
|--------|---|---------------|
| 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. | 5.1, 5.2 |
| 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. | 5.1, 5.2 |
| 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. | 5.2 |
| 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. | 2.3, 5.5, 5.6 |

⁴ Recommendations are linked to the relevant standards in HIQA's National Standards for Safer Better Healthcare (HIQA, 2012)

3.2 Risk Management

- Medication safety incidents are graded using either NCC Merp (2001) or the HSE Risk Assessment Matrix (2011).
- Fourteen hospitals have a risk register which include the risks of systemic cancer therapy provision. Typical risks listed include risks related to staff shortage, overcrowded treatment delivery space and risk of injury to patients and staff due to drug spillage.
- A number of hospitals have regular scheduled meetings between senior members of the oncology multidisciplinary team and management to review incidents, near misses and items on the risk register and to work towards identifying solutions.
- All hospitals have a policy on incident reporting.
- In the event of a medication safety incident, common practice is such that an incident form is completed, the medical team is notified and the patient is assessed clinically. In some hospitals the pharmacist is also notified routinely.
- All incident report forms are collated by hospital risk management and feedback is given on a hospital or departmental level at regular intervals.

3.2.1 Recommendations

Box 2 Recommendations on Risk Management

| Recomm | endations | HIQA framework |
|--------|---|--------------------|
| 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. | 3.2, 3.3 |
| 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 | 3.2, 3.3, 3.6, 3.7 |

| | 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. | 3.1, 3.2, 3.6 |
| 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. | 3.1 |

3.3 Built Environment, Activity and Equipment

3.3.1 Findings

Built environment

- Most day wards are combined, delivering systemic cancer treatment to both oncology and haematology patients in the one facility.
- Some hospitals share day ward facilities with other specialities insofar as they do not operate a 5-day week, and on other days the same area is used by different specialities.
- Some hospitals have adapted facilities and others have purpose built units.
- It was apparent that the designated day ward space in some hospitals was never intended to cater for the volume of patients currently attending the service.

- There was wide variation in the space allocated to each cubicle/treatment bay. In some units, there is less than a metre between patients receiving treatment.
- Some day wards have no specified areas for preparation of medicines.
- Eleven units have designated isolation facilities.
- The space available for waiting areas also varied, with patients in some units waiting in corridors, while other units had designated waiting areas.
- Patient charts are generally easily accessible in a dedicated secure area, adjacent to the reception desk or nurses station and a tracking system is in place.

Pharmacy location/Adjacency to day ward

- The location of the pharmacy department or the pharmacy department chemotherapy compounding unit/area and the day ward varied between sites, with some sites having co-located compounding units and some sites having dedicated clinical pharmacy offices. Most pharmacies are located within 5 minutes' walk from the day ward.
- In the absence of electronic ordering, the chemotherapy order is typically collected by pharmacy (n=14) or is delivered to pharmacy by a porter (n=15).

Activity

- Treatment spaces, activity levels and staff numbers are included in Table 1, Table 2, Table 3 and Table 4. This is to provide context, as capacity planning was considered outside the remit of this review. Units are not directly comparable, given the variation in complexity of treatments.
- Units vary in their management of patients on oral treatments, as detailed further in section 3.16. In some hospitals patients are assigned a day ward space, whereas in others they are seen in separate oral chemotherapy clinics. There is also variation in the use of day ward treatment spaces for clinical assessment or phlebotomy.

Equipment

 All hospitals have access to a crash call number and trolley, drugs for the management of anaphylaxis, drugs/equipment required for the treatment of cytotoxic extravasation and a spill kit. All hospitals have access to an eye wash either as an eye wash bottle or as a sterile normal saline preparation.

| Hospitals | Average monthly | Patient episoo 201 | Treatment spaces (beds | |
|---------------------|--|-----------------------|---------------------------|--------------------|
| | systemic drug preparations ⁵ | Parenteral | Oral ⁷ | and recliners) |
| Beaumont | 900 | 604 ⁸ | 119 ⁸ | 27 |
| Castlebar | 320 | 155 | 5 | 10 |
| Cavan | 227 | 129 in total | (Oral & IV) | 7 |
| Clonmel | 102 | 47 | 4 | 10 |
| Connolly | 58 | 12 | 1 | 12 |
| Crumlin | 800 | 318 ⁹ | 53 | 13.1 ¹⁰ |
| CUH | 770 | 333 | 49 | 17 |
| Drogheda | 350 | 164 | 30 | 9 |
| Letterkenny | 400 | 216 | 46 | 15 |
| Mater | 840 | 321 | 25 | 14 |
| Mercy | 503 | 287 | missing | 16 |
| MWRH Limerick | 784 | 596 | 75 | 21 |
| Naas | 46 | 31 | 2 | 6 |
| Portiuncula | 164 | 148 | 3 | 6 |
| SIVUH | 250 | 212 | 28 | 18 |
| Sligo | 430 | 217 | 20 | 10 |
| St James's | 1000 | 603 | 91 | 18 |
| St Luke's, Kilkenny | 145 | 76 | 18 | 6 |
| St Luke's, Rathgar | 191 | 120 | 0 | 20 |
| St Vincent's | 909 | 832 | 36 | 19 |
| Tallaght | 815 | 330 | 35 | 36 |
| Tralee | 204 | 166 | 23 | 8 |
| Tullamore | 500 | 316 | missing | 15 |
| UCHG | 1290 | 482 | 54 | 19 |
| Wexford | 50 | 48 | 18 | 13 |
| WRH | 678 | 380 | 43 | 14 |

Table 1 Patient episodes and treatment spaces (oncology and haematology combined)

⁵ These data were provided in response to the question: *What is the average number of systemic drug preparations a month based on the last 6 months?* This data encompasses both day ward and inpatient preparations.

⁶ Patient episode defined as individual patient episodes e.g a patient attending for 6X3 day cycle = 18 patient episodes.

⁷ Oral patient episodes refer only to those seen in the day ward. It does not capture all oral chemotherapy activity, as many are seen in a separate clinic/ out patient setting.

⁸ Beaumont data for patient episodes relates to July 2012

⁹ 86 patient episodes were based in the ALL maintenance clinic. In addition, The paediatric patient episodes in hospitals operating a shared care agreement with OLCHC for the delivery of systemic cancer treatment are not included in this data.

¹⁰ The 0.1 space refers to the ALL maintenance clinic which operates in a separate location to the day ward for one half day per week".

Note: these figures are based on self-reported data. These data were collected from September 2012 to May 2013.

3.3.2 Recommendations

Box 2 Recommendations on Built Environment and Activity and Equipment

| Recomm | HIQA framework | |
|---------|--|-----|
| 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 | 2.7 |
| 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. | 2.7 |
| Rec 11. | Day wards and outpatient clinics should facilitate appropriate desk/office space for a clinical pharmacy service. | 2.7 |
| 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. | 2.7 |
| Rec 13. | Day wards/units should have within them, or adjacent to them, a separate and identified area for the temporary | 2.7 |

| | 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. | 2.6, 1.1 |
| 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. | 2.7 |

3.4 Staffing

3.4.1 Findings

- Information was gathered on the staffing of day ward units, in relation to nursing, health care assistants and other administrative and support roles. It is often difficult to estimate the time commitment to the day ward unit only, as roles are configured in many different ways – e.g. shared with inpatient ward duties, out patients, clinical trials, other services.
- From a medical and pharmaceutical perspective, it is not possible to define time allocated to day ward activity and the data collected refer to the WTE commitment to that hospital's medical oncology/haematology service overall.
- Staffing information was collated for the purpose of context but no attempt was
 made to define staff activity ratios etc. This was considered outside the remit of
 this baseline review, given the number of variables that would need to be taken
 into consideration, such as complexities of treatment, training levels,
 appropriateness of the physical environment etc.

• The concerns raised in relation to staffing focussed mainly on increasing activity levels and availability of the appropriate skill-mix.

| | ONCOLOGY | | | | HAEMATOLOGY ¹¹ | | | |
|---------------------|------------|-------------|------------|--------|---------------------------|-------------|-----|--------|
| Hospitals | Consultant | SpR/ Reg | SHO | Intern | Consultant | SpR/ Reg | SHO | Intern |
| Beaumont | 2.6 | 4 | 2 | 2 | 2.5 | 2.5 | 3 | 0 |
| Castlebar | 0.4 | 1 | 0 | 0 | 0.2 | 0 | 0 | 1 |
| Cavan | 1.0 | 0 | 0 | 0 | 0.2 | 0 | 0 | 0 |
| Clonmel | 0.2 | 0.2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Connolly | 0.2 | 0 | 0 | 0 | 0.9 | 1.5 | 0 | 0 |
| Crumlin | 3 | 2 | 2 | 0 | 4 | 4 | 2 | 0 |
| CUH | 1.8 | 2 | 2 | 0 | 2.6 | 3 | 1 | 2 |
| Drogheda | 0.65 | 1.6 | 0 | 0 | 1.7 | 2 | 0 | 0 |
| Letterkenny | 2 | 2 | 1.5 | 0 | 1 | 1 | 1.5 | 0 |
| Mater | 3 | 5 | 2 | 0 | 2.5 | 4 | 0 | 1 |
| Mercy | 2 | 1 | 2 | 0 | 1 | 1 | 1 | 0 |
| MWRH Limerick | 2 | 2 | 1 | 0 | 3 | 2 | 2 | 0 |
| Naas | 0.1 | 0.1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Portiuncula | 0.2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| SIVUH | 0.27 | 0.5 | 0 | 0 | 0 | 0 | 0 | 0 |
| Sligo | 1 | 1 | 1 | 1 | 1 ¹² | 1 | 1 | 0 |
| St James's | 4 | 6 | 4 | 0 | 8 | 6 | 3 | 0 |
| St Luke's, Kilkenny | 0.2 | 0.2 | 0 | 0 | 0 | 0 | 0 | 0 |
| St Luke's, Rathgar | 0.79 | 1 | as reqd | 0 | 0 | 0 | 0 | 0 |
| St Vincent's | 5 | 1 | 1 | 2 | 3 | 1 | 2 | 0 |
| Tallaght | 1.7 | 4 | 2 | 0 | 1.8 | 2 | 3 | 0 |
| Tralee | 0.2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tullamore | 1 | 1 | 1 | 0 | 1.7 | 1.6 | 1 | 0 |
| UCHG | 2.7 | 5 | 4 | 1 | 4.75 | 4 | 4 | 1 |
| Wexford | 0.2 | 0.2 | 0 | 0 | 0 | 0 | 0 | 0 |
| WRH | 3 | 4 | 2 | 0 | 3 | 1 | 3 | 0 |

Table 2: Medical staffing levels – these data pertain to WTE on site in the hospital per week

¹¹ Haematology WTE includes staff working with malignant and non-malignant conditions

¹² Shared with laboratory services

 Table 3: Pharmacy staffing levels (haematology and oncology combined; including pharmacy staff in inpatient and ambulatory services)

| HOSPITALS | Pharmacist (compounding) | Pharmacist (ward) | Pharmacist technician (compounding) | Pharmacist technician (ward) |
|---------------------|-----------------------------|----------------------|---|------------------------------------|
| Beaumont | 3 | 1 | 3 | 0 |
| Castlebar | 1 | 0 | 1 | 0 |
| Cavan | 0.65 | 0 | 0.5 | 0 |
| Clonmel | 0 | 0.4 | 0 | 0.3 |
| Connolly | 0 | 0.5 | 0 | 0 |
| Crumlin | 1.08 | 1 | 3.5 | 0.08 |
| CUH | 1.9 | 0.2 | 1.8 | 0 |
| Drogheda | 1.0 | 0 | 0.4 | 0 |
| Letterkenny | 2 | 0.8 | 1.7 | 0.2 |
| Mater | 2 | 1 | 2 | 0 |
| Mercy | 2 | 0 | 3 | 0 |
| MWRH Limerick | 2.75 | 0.25 | 2 | 0 |
| Naas | 0 | 0.5 | 0 | 0 |
| Portiuncula | 0 | 0.5 | 0 | 0 |
| SIVUH | 0.5 | 0 | 1 | 0 |
| Sligo | 2 | 1 | 3 | 0 |
| St James's | 3.2 | 5 | 12 | 14.4(whole hospital) |
| St Luke's, Rathgar | 0 | 2 | 0 | 2 |
| St Vincent's | 2.5 | 0.5 | 3 | 0.1 |
| St. Luke's Kilkenny | 0.1 | 0.2 | 0 | 0 |
| Tallaght | 2.4 | 2.6 | 4 | 0.3 |
| Tralee | 0 | 0.25 | 0 | 0 |
| Tullamore | 2 | 0.5 | 2.5 | 0.5 |
| UCHG | 2 | 1.5 | 4 | 0.2 |
| Wexford | 0 | 0 | 0 | 0 |
| WRH | 1 | 1 | 2.5 | 0.5 |

| Table 4 | 1: | Nursing | staffing | levels | (haematology | and | oncology | combined | - | day | ward |
|-----------------------|----|---------|----------|--------|--------------|-----|----------|----------|---|-----|------|
| only) ^{13,1} | 14 | | | | | | | | | | |

| Hospitals | CNM | CNS | Staff nurse |
|---------------------|------|------|--------------------------|
| Beaumont | 5 | 0 | 7 |
| Castlebar | 0 | 1 | 4.8 |
| Cavan | 0 | 3 | 1 |
| Clonmel | 0 | 1.8 | 0 |
| Connolly | 0.5 | 0.8 | 2.5 |
| Crumlin | 2 | 0 | 6.5 |
| CUH | 4.8 | 0 | 6.3 |
| Drogheda | 2 | 1.95 | 5.6 |
| Letterkenny | 2 | 0 | 6.98 |
| Mater | 3 | 0 | 5 |
| Mercy | 0 | 0 | 4 (day ward & inpatient) |
| MWRH Limerick | 2.75 | 0 | 6.3 |
| Naas | 1 | 1 | 0.4 |
| Portiuncula | 1 | 1.5 | 2.5 |
| SIVUH | 0 | 2.8 | 0 |
| Sligo | 1 | 0 | 4.79 |
| St James's | 5 | 5 | 14 |
| St Luke's, Rathgar | 1 | 0 | 4 |
| St Vincent's | 2 | 0 | 7.7 |
| St. Luke's Kilkenny | 0 | 1.4 | 1.4 |
| Tallaght | 2 | 7.25 | 9.35 |
| Tralee | 2 | 0.2 | 5 |
| Tullamore Hospital | 3.37 | 1.5 | 8 |
| UCHG | 1 | 0 | 8.75 |
| Wexford | 0 | 2.6 | 0 |
| WRH | 2 | 2 | 5.5 |

¹³ Note: While some hospitals have CNS liaison posts these are not exclusively linked to the day unit and therefore not captured above.

¹⁴ Hospital practice may vary in terms of scope of day ward functions.

3.4.2 Recommendations

Box 3: Recommendations on Staffing

| Recommendations | | HIQA framework |
|-----------------|--|----------------|
| 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. | 6.1, 6.2, 6.3 |
| 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. | 6.1, 6.2, 6.3 |

3.5 Staff Training

3.5.1 Findings

- The review revealed that the majority of nurses working in nurse led units have completed a higher diploma in oncology. Some smaller units link in with cancer centres for CPD (Continuing Professional Development) activities.
- There is variation in relation to record keeping of qualifications, training and CPD in each centre, ranging from absent to complete records.
- Variability was noted in the record keeping of personnel competent to order and prescribe, prepare, check and administer chemotherapy.
- Ongoing training of medical or pharmacy staff is absent in some centres.
- Most hospitals have training processes in place for new staff and existing staff on issues relating to systemic cancer therapy provision.
- Nine hospitals have training processes for new consultants. These processes include induction, training on policies, procedures and out-of-hours administration. A number of hospitals hold regular journal clubs and case presentations.

- The vast majority of hospitals that employ SpRs (or SHOs) have training processes in place which include: induction, journal clubs and case presentations, intrathecal training, RCPI chemotherapy prescribing course and central line training.
- In many cases CNSs/CNMs and some staff nurses are chemotherapy trained and deemed competent in the administration of chemotherapy when they commence in post.
- Staff nurses who work in oncology receive education and training on the safe administration of chemotherapy and are signed off as being competent by a mentor who is normally a senior oncology nurse.
- A number of hospitals also run chemotherapy administration courses. Other training processes include study days, journal clubs, mentoring and in-service education on local policies and procedures.
- All hospitals have either formal or informal training processes in place both for their clinical and aseptic pharmacy services, provided to pharmacists and pharmacy technicians. Formal processes typically take place during induction where new pharmacy staff receive training on medication management, policies/procedures, SOPs, use of software systems and ordering processes. Informal training typically takes place on-the-job under the supervision of a specialist oncology pharmacist. Pharmacists also attend conferences and aseptic courses. There is currently no Irish accredited training course for pharmacists in this speciality area.

3.5.2 Recommendations

Box 4: Recommendations on Staff Training

| Recommendations | | HIQA framework |
|-----------------|---|----------------|
| Rec 18. | National competencies for all disciplines in relation to acute oncology should be developed in collaboration with the relevant colleges and professional bodies. | 6.3 |
| Rec 19. | Specialist competency training needs to be developed and implemented for all disciplines working in the areas of clinical oncology and aseptic manufacturing. | 6.3 |

| 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. | 6.3 |
|---------|---|------------|
| Rec 21. | Generic guidance should be developed on specific oncology training programmes or competency assessments for all nurses, pharmacists and doctors. | 6.3 |
| 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). | 6.3 & 6.4 |
| 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. ¹⁵ | 6.3 |
| Rec 24. | Medical Council requirements in relation to prescriber documentation and to continuing professional development should be implemented in all sites. | 5.10 & 6.3 |
| Rec 25. | Training and CPD records should be maintained by staff in line with the recommendations of their professional and/or regulatory bodies. | 6.3 |
| 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. | 6.3 |

¹⁵ A mandatory chemotherapy prescribing module for medical oncology and haematology SpRs is planned by the RCPI.

3.6 Policies and Guidelines

3.6.1 Findings

Oncology staff were asked to report on the status of key policies related to the delivery of systemic cancer therapy within their hospitals. Responses are summarised in Table 5.

| Table 5: Statue of key no | ligion in relation to deliver | v of ovotomi | h concer thereby ¹⁶ |
|---------------------------|--------------------------------|---------------|--------------------------------|
| Table 5: Status of key po | plicies in relation to deliver | y of systemic | c cancer therapy |

| Policy/Guideline | Policy in place (n) | Policy under development (n) | Policy not in place (n) |
|--|---------------------|---------------------------------|----------------------------|
| Drug prescribing/ordering | 15 | 5 | 3 |
| Prescription checking process | 17 | 2 | 7 |
| Drug preparation | 18 | 0 | 4 |
| Labelling and packaging in pharmacy | 18 | 1 | 3 |
| Administration of intravenous systemic cancer therapy | 23 | 4 | 0 |
| Administration of intrathecal systemic cancer therapy ¹⁷ | 8 | 5 | 4 |
| Administration of oral systemic cancer therapy | 18 | 5 | 3 |
| Administration of intramuscular systemic cancer therapy | 7 | 3 | 9 |
| Safe handling of cytotoxic agents | 26 | 1 | 0 |
| Patient monitoring during systemic therapy administration of named drugs | 14 | 1 | 9 |
| Management of anti-emesis | 23 | 1 | 1 |
| Management of neutropenic sepsis | 20 | 2 | 3 |
| Management of immediate side effects such as hypotension | 14 | 3 | 10 |
| Management of systemic therapy anaphylaxis | 21 | 3 | 2 |
| Prevention and management of extravasation | 27 | 0 | 0 |
| Management of skin penetrating injuries with cytotoxic drug exposure | 20 | 0 | 5 |
| Spill management of cytotoxic agents | 26 | 1 | 0 |
| Patients on purine analogs receiving irradiated blood | 11 | 0 | 8 |
| Incident reporting | 26 | 0 | 1 |
| Disposal of cytotoxic waste | 24 | 1 | 0 |
| Transportation of cytotoxics | 22 | 1 | 4 |
| Segregated storage of high risk drugs | 14 | 1 | 10 |

¹⁶ Figures do not add up to 28 in all instances due to missing data or responses that stated "not applicable"

¹⁷ The centres not administering intrathecal chemotherapy are not expected to have a policy in place.

3.6.2 Recommendations

Box 5: Recommendations on Policies/Guidelines

| Recommendations | | HIQA framework |
|-----------------|--|----------------|
| 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. | 3.1 |
| Rec 28. | Relevant national policy recommendations and NCCP recommendations should be included in local policies and practices. | 2.1 |

3.7 Information for Patients and Carers

3.7.1 Findings

- Patients are given verbal and written information about their treatment and likely side-effects in all hospitals by medical and nursing staff before and during treatment. The documentation of informed consent is discussed further in section 3.8.
- Patient information literature varies from hospital to hospital. Some hospitals have developed very detailed unit-specific materials. However, the majority use Irish Cancer Society literature or Macmillan/Cancer Backup materials all of which were easily accessible to patients and staff in the units.
- All patients are given the contact details of their medical oncology day ward and the relevant after hours support services.
- Some centres had excellent initiatives with regard to patient information. One example is a fridge magnet detailing the contact information of the centre and key points relating to the actions to be taken in the management of febrile episodes.

3.7.2 Recommendations

Box 6: Recommendations on Information for Patients and Carers

| Recomme | endation | HIQA framework |
|---------|--|----------------|
| Rec 29. | All units should have patient information on cancer e.g. cancer treatment, local support groups and support services. | 1.4 |
| Rec 30. | Decisions to treat a patient with chemotherapy should involve the patient and carer on an informed choice basis. | 1.4 |
| Rec 31. | Written information should be available for patients and carers for each treatment protocol on the hospital's agreed list. | 1.4 |
| 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. | 1.4 |
| 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. | 3.1 |

3.8 Treatment Planning and Clinical Assessment

3.8.1 Findings

- In the charts reviewed, the treatment plan included the diagnosis and stage of disease in 93% of cases, the planned treatment regime in 90% and intended number of cycles in 80%. Additional tests that were required pre-treatment and the results of these tests were recorded in 85% and 80% of charts respectively. Performance status was documented in approximately half of the charts reviewed. The presence or absence of allergies and history of hypersensitivity reactions was absent in 22% of patient records.
- Documentation of patient consent was absent from 20% of patient charts.
- Eleven of the 26 hospitals operate a written consent process for the provision of chemotherapy. In seven of these, this written consent process pertains to both oral and parenteral chemotherapy provision.
- The pre-treatment assessment prior to the first cycle was documented by a consultant (72%), SpR, CNS or staff nurse. This assessment generally included vital signs (88%), medical history (89%), allergic reactions (76%), current medications and possible interactions with drugs (78%), co-morbid conditions (73%), full blood count (93%), renal (96%) and hepatic function (94%), height (88%), weight (94%) and body surface area (83%).
- Assessments prior to subsequent cycles were carried out mainly by the SpR or nursing staff and included documentation in relation to adverse effects/toxicities in 91% of cases.
- The practice with regard to planned medical reviews varies across hospitals and is usually specific to the patient's treatment regime. In most cases medical review is arranged at least once per treatment cycle, usually before treatment and often after the first cycle.
- All patients receiving systemic cancer therapy have access to clinical trials although sometimes this requires attendance at bigger centres, typically under the management of the same consultant.
3.8.2 Recommendations

| | D | | | |
|--------|--------------------|----------------------|----------------|------------|
| BOX /: | Recommendations of | n Treatment Planning | g and Clinical | Assessment |

| Recomm | HIQA framework | |
|---------|---|-----|
| 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 | 8.1 |
| 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 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 | 8.1 |
| Rec 36. | Patient consent or understanding of adverse events should be documented. | 1.5 |
| 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. | 1.5 |
| Rec 38. | Reassessment is required before the start of any subsequent cycle of treatment. Assessment requirements should be detailed in the treatment | 8.3 |

| | 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: | 2.2 |
| | • 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 | 2.2 |
| | 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. | |

3.9 Chemotherapy Protocols

3.9.1 Findings

- Eight of the 26 hospitals have hospital specific treatment protocols for each systemic cancer treatment regimen in their unit. Sixteen have written protocols for some but not all treatment protocols.
- Treatment protocols are generally stored electronically only. A copy of the version in use for the patient is frequently printed and filed in the patient's medical record.
- Ten hospitals routinely review their in-house protocols at least every two years and six hospitals reported having no formal review process. In addition, seven

hospitals have no system in place to ensure that new/updated information on drugs is included in in-house protocols.

• A large number of hospitals use protocols from external organisations such as NCCN and BCCA.

3.9.2 Recommendations

Box 8: Recommendation on Chemotherapy Protocols

| Recomme | Recommendations | |
|---------|--|---------------|
| 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. | 2.5 |
| Rec 42. | Each protocol should contain the minimum protocol specific information as detailed in Appendix 3. Each protocol should be reviewed at a minimum every two years. | 2.5 |
| 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. | 2.5, 8.1, 8.2 |
| | 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: | 5.2 |
| | 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. | 5.2 |

3.10 Chemotherapy Ordering and Prescribing

3.10.1 Findings

- 18 of the 26 hospitals have a policy on chemotherapy prescribing/ordering.
- Chemotherapy ordering and prescribing is mainly undertaken by Consultant Medical Oncologists/Haematologist or SpRs.
- The format of chemotherapy orders varies between sites, ranging from full handwritten orders, to pre-printed templates to electronic ordering systems, as presented in Table 6.
- The Mid-Western Regional Hospital, Limerick and Adelaide and Meath Hospital, Tallaght (oncology service) were the only hospitals that had implemented a computerised physician order entry system at the time of the review.

A duplicate chemotherapy order form was used in some sites while others used a single copy form.

- There were many instances in the chart review of hand-written prescriptions which were of poor quality, with many of the required fields not completed. In addition, many of the written prescriptions and pre-printed prescriptions had unclear alterations.
- Some units do not have ready access to their chemotherapy protocols when prescribing/ordering chemotherapy.
- The environment where chemotherapy orders and prescriptions are written varies between the sites with some sites having a scheduled multidisciplinary prescribing meeting and others prescribing following patient review, in OPD or on the day ward.
- The results of the chemotherapy order and prescription documentation review are outlined in Table 7.

Table 6: Prescription formats in use in the hospitals

| Hospitals | Handwritten | Pre-printed** | Electronic |
|------------------------|-------------|---------------|------------------------|
| Beaumont (haematology) | Yes | Yes | No |
| Beaumont (oncology) | Yes | Yes | No |
| Castlebar | Yes | Yes | No |
| Cavan | Yes | Yes | No |
| Clonmel | Yes | Yes | Yes* |
| Connolly | Yes | No | No |
| Crumlin | No | Yes | No |
| CUH | Yes | No | No |
| Drogheda | Yes | No | No |
| Letterkenny | No | Yes | No |
| Mater | Yes | No | No |
| Mercy | Yes | No | No |
| MWRH Limerick | Yes | No | Yes (oncology only) |
| Naas | Yes | Yes | No |
| Portiuncula | No | Yes | No |
| SIVUH | Yes | No | No |
| Sligo | No | Yes | No |
| St James's | Yes | Yes | No |
| St Luke's, Rathgar | Yes | Yes | No |
| St Vincent's | Yes | Yes | No |
| St. Luke's, Kilkenny | No | No | Yes* |
| Tallaght (haematology) | Yes | No | No |
| Tallaght (oncology) | Yes | No | Yes |
| Tralee | Yes | No | No |
| Tullamore | Yes | Yes | No |
| UCHG | Yes | Yes | No |
| Wexford | Yes | Yes | Yes* |
| WRH | Yes | Yes | Yes** |

Note: these figures are based on self-reported data. These data were collected from September 2012 to May 2013.

*Prescribing is done utilising preformatted spreadsheet or word documents

**Main protocols only

 Table 7: Chemotherapy order and prescription documentation – percentage of prescriptions/orders across all hospitals that contained specified detail outlined below

| DETAIL ON PRESCRIPTION | ORAL% (N=58) | IV % (N=126) |
|--|--------------|--------------|
| Date | 91 | 99 |
| Patient name | 98 | 100 |
| Patient hospital number | 83 | 94 |
| Diagnosis | 39 | 75 |
| Patient weight | 55 | 88 |
| Patient height | 56 | 88 |
| Patient body surface area | 57 | 89 |
| Protocol, regimen name or clinical trial name | 66 | 88 |
| Name of drug(s) | 94 | 100 |
| Dose in mg or mg/m ² | 94 | 100 |
| Route of administration | 94 | 98 |
| For infusions, details of solution and volume | NA | 97 |
| Duration of infusion | NA | 91 |
| Starting dates (and times when appropriate) | 81 | 93 |
| Cycle or course number | 60 | 89 |
| Renal and hepatic function | 38 | 58 |
| Signature of the prescriber | 90 | 99 |
| Date prescribed/ordered | 91 | 93 |
| Medical Council number of prescriber | 25 | 22 |
| Contact bleep or phone number of prescriber | 44 | 17 |

3.10.2 Recommendations

Box 9: Recommendations on Chemotherapy Ordering and Prescribing

| Recommendations | | HIQA framework |
|-----------------|---|-------------------|
| Rec 46. | There should be regular multidisciplinary team meetings (e.g. weekly) to discuss patients' treatment, including chemotherapy treatment. | 2.3 |
| 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. | 5.1 & 5.2 |
| 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. | 5.1 & 5.2 |
| 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. | 3.1 |
| 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. | 3.1 |

| 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. | 3.1 |
|---------|---|-----|
| 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. | 3.1 |
| Rec 53. | A copy of the chemotherapy order and/or prescription must be kept in the patient's medical record. | 3.1 |
| 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. | 3.1 |
| 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. | 3.1 |
| Rec 56. | A national computerised physician order entry system agenda should be developed by the NCCP and HSE IT. | 3.1 |
| 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. | 3.1 |

3.11 Chemotherapy Orders and Prescription Checking

The process for checking chemotherapy orders and prescriptions refers to a triple checking process whereby the treatment protocol is checked by a doctor and the prescription is checked by a pharmacist and nurse before administration.

3.11.1 Findings

Most hospitals have a policy for chemotherapy prescription checking and administration. These policies often lack a description of the integrated multidisciplinary checking process and details of each team member's responsibility in this process. A suggested sample is included in Appendix 8.

Prescriber checking

 Final check and sign off of prescriptions by a physician is variable in hospitals with full-time consultants. In most hospitals, the prescriber does not sign the prescription prior to administration of chemotherapy to indicate that all of the relevant tests and assessments have been completed.

Pharmacist checking

- Eighteen hospitals have access within pharmacy to a list of staff locally approved to prescribe systemic cancer therapy. Fewer sites maintain a signature bank of those staff.
- Chemotherapy dose calculations are checked by a pharmacist, prior to release of parenteral treatment from the pharmacy, in all hospitals. This includes checking and continuation of dose reductions.
- Other pharmacist checks for parenteral prescriptions vary between hospitals in areas, such as checking of routine and protocol specific laboratory tests. All hospital pharmacies had access to lab results from within the pharmacy, or can arrange to have access. Most pharmacies checking laboratory results have a procedure in place regarding lab results that fall outside normal limits.

- All hospital pharmacies verify the parenteral prescription according to the protocol or treatment regimen.
- 22 hospitals check that maximum cumulative doses of drugs are not exceeded.
- In all but one hospital, the parenteral prescription is signed in pharmacy to indicate it has been verified and validated for the intended patient.
- Most oral prescriptions are not checked by a hospital pharmacist.

Nursing checks are listed in section 3.12.

3.11.2 Recommendations

Box 10: Recommendations on Prescription Checking

Note: These recommendations apply to both oral and parenteral treatments

| Recomme | HIQA framework | |
|---------|--|-----------|
| 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 The pharmacy verification practice where different levels of verification are in place. | 3.1 |
| 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. | 3.1 & 5.2 |
| Rec 60. | All patient treatment, assessment and prescription checking areas should have access to the most recent | 2.5 |

| | 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). | 5.1 |

3.12 Administration and Monitoring of Chemotherapy

3.12.1 Findings

- All hospitals reported that the following checks are carried out prior to administration by a chemotherapy certified nurse:
 - o Verification of patient identification using at least two identifiers
 - o Weight has been recorded
 - o Height has been recorded
 - o Correct body surface area has been calculated and recorded
 - o Full blood count
 - o Renal and hepatic function (if indicated)
 - o A second nurse is required for the checking process prior to administration.
- In the case of all hospitals, where an infusion pump is required, checks are conducted to verify that the pump was set to the correct rate according to prescription and protocol. The infusion rate is verified by another nurse or pharmacist in 17 hospitals.
- In all hospitals, patients are monitored frequently throughout administration for complications and side effects which are documented in charts.
- Port-a-caths (n=24) are the most commonly used central venous access devices followed by PICC lines (n = 23) and Hickman lines (n = 20).
- Some hospitals have implemented the Early Warning Score as per National Recommendations.

3.12.2 Recommendations

| Box 11: Recommendations or | Administration and | Monitoring of | Chemotherapy |
|----------------------------|--------------------|---------------|--------------|
| | | | |

| Recomme | ndations | HIQA framework |
|---------|--|----------------|
| 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 use of the | 2.1 |
| 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. | 3.1 |

3.13 Management of Unscheduled Care

3.13.1 Findings

- A physician is always available in case of emergency during the administration of treatment in the case of all hospitals in the review. Some units have access to a dedicated NCHD or contact a member of the team if an urgent clinical assessment is required during treatment. Where there is no on-site medical oncology/haematology service, arrangements exist with the Medical Assessment Unit or the medical team on-call, if such a situation arises.
- Most units experience a high volume of phone calls from patients. Practice is variable with regard to documentation on assessment and advice.
- In general there are systems in place in Emergency Departments with regard to the management of oncology/haemato-oncology patients including:
 - Clear identification that they are patients of the oncology/haematooncology service
 - o Contact details of key personnel of the service.
- There were concerns raised in some of the smaller centres with regard to delays in transferring unwell patients to bigger centres with dedicated inpatient beds.
- Most hospitals do not initiate chemotherapy outside of normal working hours except in exceptional circumstances. Some of the hospitals have policies and training in place detailing the persons permitted to prescribe/order, compound, supply/dispense, check and administer in such circumstances.

3.13.2 Recommendations

Box 12: Recommendations on Management of Unscheduled Care

| Recomm | endations | HIQA framework |
|---------|--|----------------|
| Rec 64. | Each unit should have a written policy on the management of unscheduled care including: Emergency department policies e.g neutropenic sensis cytatoxic induced emesis extravasation | 2.3 & 2.5 |
| | 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. | 2.3 |
| 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. | 5.1 |
| 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. | 6.3 & 6.4 |

3.14 Intrathecal Chemotherapy

3.14.1 Findings

- Some hospitals where intrathecal chemotherapy is administered do not have an intrathecal policy in place.
- Intrathecal drugs are prescribed on the same chemotherapy order forms as other parenteral chemotherapy in most hospitals.
- Some of the hospitals where intrathecal chemotherapy is administered have:
 - o A specified area for administration of intrathecal chemotherapy

- A segregated delivery for intrathecal chemotherapy or a policy on the collection of intrathecal chemotherapy by the doctor immediately prior to administration
- o Specific boxes for the transport of intrathecal chemotherapy
- Colour differentiation to distinguish intrathecal chemotherapy from other intrathecal drugs
- o A register of doctors approved to administer chemotherapy.

3.14.2 Recommendations

Box 13: Recommendations on Intrathecal Chemotherapy

| Recomme | ndations | HIQA framework |
|-------------------------|---|--------------------|
| The chem intrathecal | notherapy ordering and prescribing recommendations in 3. I chemotherapy prescribing/ordering. | 10.2 also apply to |
| 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 alkaloids¹⁸. | 3.1 |
| Rec 69. | Intrathecal chemotherapy should always be stored in a different area to intravenous chemotherapy. | 3.1 |
| Rec 70. | Intravenous chemotherapy should always be given at a different time to intrathecal chemotherapy. | 3.1 |
| Rec 71. | The NCCP to lead on the development of national intrathecal polices to inform the content of these local hospital policies. | 3.1 |

 $^{^{\}rm 18}$ Including the minimum recommendations of WHO (2007).

3.15 Pharmacy– Chemotherapy Preparation, Labelling and Record Keeping

3.15.1 Findings

Preparation areas

- Many pharmacy departments operate a chemotherapy compounding unit/area. Other pharmacy departments outsource the production of some, or all, of their parenteral chemotherapy requirements to a third party supplier. All but one hospital outsource some of their chemotherapy requirements. This outsourcing is driven by specific product stability or preparation requirements or circumstances where units are deemed to be beyond their maximum capacity, as determined by limited availability of equipment or staffing levels.
- Biologics are prepared in the day ward area in some hospitals by pharmacy department and/or nursing staff.
- There is variation between the chemotherapy compounding units/areas with some pharmacies having specifically designed aseptic units and some operating with stand alone isolators. Variations include:
 - o The standards applied to areas where cancer medicines were prepared
 - o The grading of the preparation rooms in aseptic units
 - o The equipment used
 - o The space allocated
 - o The level of environmental monitoring
 - o The expiry dates assigned to a medicine once compounded
 - o The sharing of vials.
- Loose tablets or capsules are counted on designated counting triangles in 25 hospital pharmacies and on electronic tablet counters in 3 hospital pharmacies.

Pharmacy records

 The patient records of cancer medicines treatment maintained in pharmacy vary. The majority of pharmacy departments utilise specific pharmacy compounding software to maintain an electronic record of the cancer medicines and other medications issued to individual patients. Other sites use the pharmacy department dispensary systems to issue these products. Some pharmacy departments also maintain structured pharmaceutical care plans, either electronically or on paper.

Pharmacy Labelling

- The information on sample labels requested as part of the review varied between hospitals:
 - 30% of drug labels provided by hospitals did not include a cytotoxic warning¹⁹.
 - o All labels either include the patient's name or other patient identifier.
 - All drug labels included:
 - the full generic drug name
 - the amount of drug in container and
 - the route of administration.
 - The majority of drug labels included: duration of infusion (if applicable) (87%), batch number (88%) and date of administration (87%).
 - In the case of oral drugs, the strength of preparation and number of tablets or volume of liquid was stated in all cases.
 - o 39% of hospitals did not include the hospital name on the label.
- There is variation in the practice of labelling of outsourced products with some hospitals overlabelling these products and some not.

See Appendix 1 for additional review findings pertaining to pharmacy

¹⁹ Supplementary labelling is frequently used to notify the user that the drug is cytotoxic. The questionnaire did not specifically request supplementary labelling. As a result this figure may be overstated.

3.15.2 Recommendations

Box 14: Recommendations on Pharmacy Chemotherapy Preparation, Labelling and Record Keeping

| Recomm | nendations | HIQA framework |
|---------|--|----------------|
| 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). | 3.1 |
| 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. | 8.3 |
| Rec 74. | All hospital pharmacy departments should have a dedicated area reserved for the preparation/ dispensing/supply of hazardous drugs, both oral and parenteral. | 2.7 |
| 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. | 2.5 |
| Rec 76. | Labels should comply with all statutory and professional requirements, and should include the minimum information as detailed in Appendix 10. | 5.11 |
| Rec 77. | Outsourced products should be overlabelled where the label does not comply with the minimum requirements as detailed in Appendix 10. | 3.1 |

| 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. | 5.11 |
|---------|---|------|
| 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. | 2.1 |

3.16 Oral Chemotherapy

3.16.1 Findings

- There is variation in the prescription formats used for oral chemotherapy in different hospitals. A small number of hospitals utilised prescriptions similar to those for parenteral treatment in addition to issuing a prescription for the community pharmacy.
- In general, oral chemotherapy is dispensed in community pharmacies as it is outpatient treatment and available on the PCRS reimbursement schemes. There are a small number of hospital pharmacies which dispense oral chemotherapy or a subset of such medicines, which are not high cost. One of the barriers identified to hospital dispensing of oral chemotherapy was the high cost of some of the drugs involved.
- The review team noted a number of different approaches taken across the country to minimise the potential risks associated with community-dispensed treatments:
 - o Prescribing of one cycle's treatment at a time.
 - Contact with community pharmacy made by CNS/pharmacist to ensure understanding of treatment +/- provision of treatment protocol to the community pharmacist.

- Requiring patients to attend the day ward/clinic with their dispensed medication to ensure they have the correct treatment and understand how to take it.
- Different models for patient review while on treatment include attendance at day ward, in oncology/haematology OPD, at a nurse-led oral chemo clinic, or in an oral chemo clinic with nurse, pharmacist and consultant in attendance.
- Three hospitals reported that there is no process in place between their hospital, community pharmacist and patient in relation to dispensing of oral systemic cancer treatments.
- There is variation in the prescription checking process. For example:
 - o Some centres have a second prescription check
 - o In some centres a doctor writes the prescription and it is checked by a nurse and pharmacist
 - In some centres a prescriber writes the prescription and it is checked by a nurse and pharmacist
- The chart review revealed that the required clinical information was included more often on parenteral prescriptions than oral prescriptions. Examples include:
 - o Diagnosis 40% of oral prescriptions vs 75% of parenteral prescriptions
 - Patient weight 55% of oral prescriptions vs 88% of parenteral prescriptions
 - Cycle number 61% of oral prescriptions vs 90% of parenteral prescriptions

This was attributed in part to the format of the high tech and standard hospital prescriptions.

- Some patient charts did not contain a copy of their oral chemotherapy prescription. Some of the oral chemotherapy prescriptions in the patient charts were difficult to read due to the quality of the copy.
- Many units were of the opinion that the current prescription for high tech chemotherapy medicines was not suitable for chemotherapy prescribing.

3.16.2 Recommendations

| Recomme | ndation | HIQA framework |
|-----------------------|---|------------------------------------|
| The chem oral chem | otherapy ordering and prescribing recommendation otherapy prescribing/ordering. | ns in 3.10.2 also apply to |
| Rec 80. | A national guideline is required for the management of the prescribing and dispensing of orac chemotherapy. This guideline should include: Safe prescribing Prescription checking Prescription format Administration Service models for dispensing and supply Communication system between primar care and secondary care | ^{nt} 2.1 & 3.1 al |
| Rec 81. | Monitoring of adherence to oral chemotherapy b medical/nursing personnel is recommended whil patients are on their treatment. | y 3.1 e |
| Rec 82. | Structured education is required for patients an their carers in relation to safe handling administration and the identification an management of side-effects pertaining to their ora chemotherapy medications. A pre-treatmer education checklist should be developed for patients on each oral chemotherapy agent. | d 3.1 g, d al nt pr |
| Rec 83. | Patients on oral chemotherapy should have 24h access to appropriately trained medical oncolog staff. | nr 2.3 Iy |
| Rec 84. | The NCCP will engage with the PCRS with regar to current design of the High Tech prescription form | rd 2.3 1. |

3.17 Handling, Disposal and Storage of Cytotoxic Drugs

Exposure of personnel to cytotoxic agents is potentially hazardous. Proper procedures must be put in place to avoid exposure (Department of Health, 1996). For healthcare personnel, the potential for exposure exists during tasks such as drug reconstitution and preparation, administration and disposal of waste equipment or patient waste.

Therefore, all staff involved in the delivery of services to cancer patients should be aware of health and safety procedures. This applies to clinicians, nursing, pharmacy and domestic staff in the relevant pharmacy and clinical areas, transport and portering staff carrying hazardous drugs or hazardous waste.

3.17.1 Findings

- Few hospitals differentiate between cytotoxic drugs and other cancer medicines which are not cytotoxic.
- Cytotoxic drugs are stored separately from other drugs in all cases.
- In all but two cases, sealed sturdy containers with appropriate leak-proof packaging and labelling are used for the transport of cytotoxic drugs.
- In 22 out of 28 units, personnel involved in transport of cytotoxics are trained in necessary precautions should a spill occur.
- Cytotoxic drugs are always prepared in the pharmacy department or the preparation is outsourced to a third party.
- There is variation in the location of the preparation of monoclonal antibodies (MAbs).
- Cytotoxic waste is not always stored in a secure designated area while awaiting collection from the ward.
- In all applicable cases, health care personnel preparing and administering chemotherapy wear protective clothing.
- In all but one hospital, instances of staff being exposed to a spill are reported to occupational health.
- All hospitals have a policy in place or under development for the management of needle stick injuries.

3.17.2 Recommendations

Box 15: Recommendation on Cytotoxic Handling, Disposal and Storage

| Recomm | endations | HIQA framework |
|---------|---|----------------|
| 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 | 3.1 |
| | 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. | 5.10 |
| 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. | 3.1 |
| Rec 88. | Refrigerators used for the storage of chemotherapy doses should be monitored according to hospital policy. | 3.1 |

| 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. | 3.1 |
|---------|--|-----------|
| Rec 90. | All personnel handling, preparing, transporting or administering cytotoxics require training in the relevant areas. | 6.3 |
| 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. | 3.1 & 6.3 |
| Rec 92. | Disposal of cytotoxic waste should comply with the hospital's waste policy, relevant legislation and best practice. | 3.1 |
| Rec 93. | Hospitals should supply spill kits to patients who are on home parenteral chemotherapy. | 3.1 |

4 CONCLUSION

This Oncology Medication Safety Review was conducted to evaluate oncology medication policies and practices nationally from a patient safety and quality perspective. The review also facilitated the development of recommendations which will inform the development of national policies and practices for oncology medication. These standards will be developed in consultation with multidisciplinary teams, acute hospitals and hospital groups and the Department of Health, Cancer Policy Unit and will be in line with the HIQA National Standards for Safer Better Healthcare.

The NCCP would like to sincerely thank all of the 26 hospitals who contributed to this review.

Appendix 1.Additional ReviewTable 8: Additional review findings: pharmacy Additional Review Findings

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| 2013. | Мау | to | 2012 | September | from | collected | were | data | These | data. | reported | self- | on | based | are | figures | these | Note: |
|---------------------------------|----------------------------|------------|----------------|--|--------------|-----------------------------|---------------------------|------|------------------------------------|------------------|---------------------|---------------|-------------|---------------------|-----------------|---------|-------|---------|
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Appendix 2. Members of Steering Committee and Site Visit Team

Steering committee

- Dr. Susan O' Reilly, Director National Cancer Control Programme (Chair)
- Dr. Miriam O' Connor, Consultant Medical Oncologist, Waterford Regional Hospital
- Dr. Maccon Keane, NCCP Clinical Lead for Medical Oncology and Consultant Medical Oncologist, University College Hospital Galway
- Dr. Janice Richmond, Advanced Nurse Practitioner, Letterkenny General Hospital
- Dr. Patrick Thornton, Consultant Haematologist, Beaumont Hospital
- Mr. Tim Delaney, Programme Lead Medication Safety, Quality & Patient Safety Directorate, HSE
- Ms. Eileen Butler, Chief 2 Pharmacist (Haematology / Oncology), Our Lady's Children's Hospital, Crumlin
- Ms. Anne Marie De Frein, Chief 2 Pharmacist (Aseptics), St. Vincent's University Hospital
- Ms. Ciara Mellett, National Programme Manager for Medical Oncology and Haemato-oncology, NCCP (joined January 2013)
- Dr. Marie Laffoy, Consultant in Public Health Medicine, NCCP
- Dr. Triona McCarthy, Consultant in Public Health Medicine, NCCP
- Ms. Patricia Heckman, Chief Pharmacist, NCCP (joined January 2013)
- Ms. Orla Walsh, Project Manager, NCCP
- Ms. Terry Hanan, Nursing Development Co-ordinator, NCCP

Members of site visit team

- Dr. Marie Laffoy, Consultant in Public Health Medicine, NCCP
- Dr. Triona McCarthy, Consultant in Public Health Medicine, NCCP
- Ms. Patricia Heckman, Chief Pharmacist, NCCP (joined January 2013)
- Ms. Orla Walsh, Project Manager, NCCP
- Ms. Terry Hanan, Nursing Development Co-ordinator, NCCP

- Ms. Ciara Mellett, National Programme Manager for Medical Oncology and Haemato-oncology, NCCP
- Ms. Carmel O' Keefe, Oncology Nurse, St. Luke's Hospital, Kilkenny
- Ms. Anne Marie De Frein, Chief 2 Pharmacist (Aseptics), St. Vincent's University Hospital
- Mr. Paul Troy, CNM3, Beaumont Hospital
- Ms. Mary Egan, Oncology Nurse

Appendix 3. Minimum Treatment Protocol Specific Information Requirements

Each treatment protocol should be accompanied by the following minimum protocol specific information, or a clinical trial protocol:

- Cancer type (ICD10)
- Indications
- Name of regimen
- Cytotoxic drugs
- Doses (per m² or kg as applicable).
- Routes of administration
- Number of cycles or whether this is indeterminate
- Length of cycle and schedule of administrations within a cycle
- Mandatory tests prior to a course and individual cycle
- Mandatory supportive drugs with each cycle
- Mandatory cytotoxic dose modifications and their indications
- NCCP national protocol reference number, when available
- Local protocol reference number
- Version number
- Review date
- Approving consultant signature on master copy
- Supporting references.

Appendix 4. Guidelines/Policies Required

All units involved in the prescribing and administration of systemic anticancer therapy must have guidelines/policies in place, covering the areas listed below. These guidelines/policies may be produced as separate guidelines/policies, or amalgamated, where appropriate, to reflect workflow and the multidisciplinary nature of this service.

- 1. Chemotherapy prescribing
- 2. Consent policy
- 3. Management of chemotherapy requirements outside of normal working hours
- 4. Prescribing, preparation, labelling, storage and administration of intrathecal chemotherapy
- 5. Management of vinca alkaloids and other chemotherapy drugs with similar life threatening consequences if administered by the incorrect route
- Chemotherapy prescription checking process including a description of the integrated multidisciplinary checking process and details of each team member's responsibility (see Appendix 8)
- 7. Chemotherapy administration techniques, including intravenous, intrathecal, oral, intramuscular and other routes
- 8. The care of those aids to venous access in use in the unit (e.g. Hickman lines, PICC lines)
- Policies on patient assessment using validated evidence based tools, for example Early Warning Score and Common Terminology Criteria for Adverse Events (CTCAE)
- 10. Policy for preventing regular use of protocols not on the accepted list
- 11. The use of mechanical drug delivery devices used by the unit, such as infusion pumps etc.
- 12. The use of devices to prevent alopecia, if used by the unit
- 13. The use of haemopoietic growth factors and patient support using blood and blood products, including guidance on the use of irradiated blood when administering purine analogs
- 14. The prevention, recognition and treatment of:
 - o Neutropenia and neutropenic sepsis
 - o Cytotoxic-induced emesis
 - o Cytotoxic extravasation

- o Allergic reactions including anaphylaxis
- o Stomatitis, other mucositis and diarrhoea
- 15. The treatment and/or prevention of protocol-specific complications, not included in the above measures and relevant to the protocols on the unit's agreed list of protocols, for example:
 - o Additional patient monitoring during administration of named drugs
 - o IV pre- and post-hydration
 - o Folinic acid rescue
 - o The use of mesna
 - o The prevention of serious hypersensitivity reactions
- 16. Safe handling of cytotoxic agents including:
 - o Segregated storage
 - o Management of skin penetrating injuries with cytotoxic drug exposure
 - o Spill management of cytotoxic agents
 - o Transportation of cytotoxics
 - o Disposal of cytotoxic waste
 - o Information for patients on safe handling in the community including:
 - Spillage information
 - Disposal information
 - Safe storage information
- 17. Drug preparation, including labelling and packaging see Appendix 10 for minimum recommendations on labelling
- 18. Incident reporting and open disclosure
- 19. Management of unscheduled care including:
 - o Emergency department policies
 - o Inter hospital patient transfers
 - o Telephone triage
 - o Acute admission of patients from other hospitals
 - o Data requests from other hospitals

Appendix 5. Minimum Criteria for Treatment Record

The patient's record should document details of the patient's systemic cancer therapy. This should fulfil the minimum criteria listed below.

Prior to the start of a course of chemotherapy

- Patient identification
- Patient's performance status
- Weight, height, body surface area
- Cancer type and stage/grade
- Treatment intention palliative, curative, adjuvant, neo-adjuvant, other *
- Specify the treatment regimen and related drug protocol
- Route of administration (oral, IV, IV infusion, IM, SC)
- Number of cycles intended
- Frequency of cycles and of administrations within a cycle
- Investigations necessary prior to starting the whole course
- Investigations to be performed serially during the course (to detect/monitor both toxicity and response) and their intended frequency
- For palliative, curative and neoadjuvant treatments, i.e. any treatment other than adjuvant; the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course
- Attendances managed by agreed non-medical staff e.g. nurse led attendances

*Note: Some treatment situations are difficult to categorise - being intended to prolong life or induce remission as much as to palliate symptoms, but not expected to cure, e.g. some treatments for ovarian, small cell lung, and some haematological cancers

Prior to each cycle

- The results of essential serial investigations applicable to that cycle (and prior to an administration within a cycle, if applicable)
- Any dose modifications and whether or not they are intended to be permanent
- Any cycle (or administration) delays
- Any introduced support drugs not recorded prior to the start of a course of chemotherapy

After the final cycle is given in a course:

- Whether the course was completed or not
- If not completed the reasons for cessation
- For completed courses of non-adjuvant treatment a reference to the response should be included.

Appendix 6. Recommended Minimum Pharmacist Checks for Chemotherapy Orders and Prescriptions

All chemotherapy prescriptions should be checked by an oncology pharmacist who has demonstrated their appropriate competence and is locally authorised / accredited for the task. The minimum recommended pharmacy checks are provided below.

Ideally the verification of prescriptions and all pharmaceutical care issues should be documented within a structured pharmaceutical care plan/patient record. At a minimum, significant care issues and interventions should be documented in the clinical notes or locally agreed system for recording.

Dispensing of outpatient medication requires compliance with the statutory requirements for prescription dispensing and maintaining a retail pharmacy business.

Pharmacists must review and verify the following information prior to prescription verification and further preparation and release of cancer medicines:

Check the Prescription:

- 1. Has the drug or regimen been prescribed in line with legislation and local prescribing policy?
 - Check the prescriber details and signature are present and confirm they are authorised to prescribe cancer medicines as appropriate
 - Check that the prescription is clear, legible, and unambiguous and includes all details required for dispensing, labelling and administration.
- 2. Check the prescription against the protocol and treatment plan:
 - Ensure that the regimen has local approval e.g. clinical governance and financial approval and/or is included on a list of locally approved regimens
 - Where there is access to either clinical notes, treatment plan or electronic record, on first cycle check the regimen is the intended treatment and is appropriate for patient's diagnosis, medical history, performance status and chemotherapy history.
- 3. Check patient details:
 - Check patient demographics (age, height and weight) have been correctly recorded on prescription, as appropriate
- 4. Check administration details. This will include the following as appropriate/ relevant (see note below)²⁰:
 - Checking there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s), where patient's existing medication history is available
 - Checking the timing of administration is appropriate, i.e. interval since last treatment and/or start and stop dates for oral chemotherapy
 - Checking appropriate supportive care is prescribed
 - Checking method of administration is appropriate.
- 5. Check Calculations:
 - Check all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance, e.g. dose rounding / banding as appropriate. There should be a general maximum dose variation agreed locally and ideally this should be less than 5% (in circumstances were a variation of 5% is not a measurable dose, an agreed dose variation of 10% could be considered). If there is an agreed dose variation policy locally, any protocols where dose variation is prohibited must have this information explicitly detailed in that protocol.
 - Check prescribed dose is in line with previous dose reductions
 - Check BSA is correctly calculated if needed for dose calculation. There should be local agreement for frequency of monitoring and checking patient's weight
 - Check cumulative dose and maximum individual dose as appropriate

²⁰ As chemotherapy services are varied, it is recognised that there will be differences in pharmacists' responsibilities depending on the agreed service provided. Some pharmacies may not operate a clinical service and so may not be in a position to review drug interactions, allergies etc. This should be clearly defined in the organisation's process where it identifies the person with ultimate responsibly for these checks as per the sample in Appendix 8.

- 6. Check Laboratory Results as appropriate (see note below²¹):
 - Check laboratory values FBC, U&E's and LFT's are within accepted limits, if appropriate
 - Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities
 - Check other essential tests have been undertaken, if appropriate
 - NOTE: For new patients or patients beginning a new course of cancer treatment, baseline tests must have been conducted within four weeks of the start of therapy. For subsequent cycles, patients must have their pretest observations on the day of treatment. Serum blood/urine analysis should be within acceptable parameters, no more than 72 hours prior to commencement of the next cytotoxic drug administration.
- 7. For cyclical chemotherapy, no more than one cycle of medication will be issued at a time.
- 8. Sign and date prescription as a record of verification and/or issue of cancer medicines as appropriate.

Adapted with permission from: BOPA Standards for Pharmacy Verification of Prescriptions for cancer medicines 2.4.13

²¹ As chemotherapy services are varied, it is recognised that there will be differences in pharmacists' responsibilities depending on the agreed service provided. Some pharmacies may not prepare or release cancer medicines until the pharmacist has checked the full blood count and other relevant test results. However due to lack of staff or as pre-prescribing and pre-preparation of chemotherapy becomes more widespread (to reduce waiting times and increase flexibility) there may be a requirement for drugs to be released from pharmacy to a clinical area before the results of the relevant tests are known. In these circumstances, pharmacists must still verify the prescription and allow the drugs to be released provided the organisation has a policy in place clearly defining the process and identifying who is responsible for checking full blood count results as per the sample in Appendix 8.

Appendix 7. Minimum Nursing Verification Checks Prior to Chemotherapy Administration

There should be a verification procedure, which is carried out by nursing staff before each physical administration of chemotherapy, to ensure that the following aspects have been checked and are correct prior to proceeding to administration:

- All pre-treatment tests and assessments have been completed
- Critical test results have been checked by a minimum of two people
- Patient's identity on the chemotherapy order, the chemotherapy drug labels and the patient's identity band are correct and patients are identified using a minimum of two identifiers and in line with local policy
- The drugs prescribed for the patient are those for the designated treatment protocol and day of cycle and are correct with regard to:
 - o Dose, including dose reductions
 - o Route and rate of administration
 - o Diluents and volumes
 - o Are within the expiry date
 - o The dosage per kg or m² should be rechecked.
- All necessary premedication has been administered as per the protocol and prescription
- All necessary prehydration and other therapies have been administered as per the protocol and prescription
- Correct body surface area has been calculated and recorded using the patient's most recent weight and height
- That there has been a final check and authorisation to proceed for the prescriber (off hold)

IF IN DOUBT - DO NOT PROCEED WITH TREATMENT

| Appendix 8. | Sample Guide to Prescription/Order Checking |
|-------------|---|
| | Responsibilities ²² |

| Primary Responsibility | | Ultimate Responsibility |
|------------------------|--------------------------------------|----------------------------|
| D,P | Prescription for Chemotherapy - | D |
| | Standard Regimen and non | |
| | standard regimens | |
| N | Height and weight patient | N |
| N,P,D | Check and record patient allergies | D |
| N,P,D | Calculate Body Surface Area | Р |
| N,P,D | Check doses with respect to: | Р |
| | Protocol/ Proforma | |
| N,P,D | FBC, U + E and LFT's | D |
| N,P,D | EDTA/Creatinine Clearance & | D |
| | additional tests if specified | |
| N,P,D | Drug induced dosage reduction | D |
| N,P,D | Are all drugs prescribed (including | Р |
| | supportive meds) | |
| D,P | Check drug interactions with | Р |
| | existing medicines | |
| D,P | Prescription signed and dated | D&P |
| | (Prescriber and Verifier) | |
| N,D | Suitable venous access | N |
| N,P,D | Course number & lifetime | D |
| | cumulative dose (if applicable) | |
| N,P,D | Check sequence & timing of | Р |
| | regimen (** see note) | |
| N,P,D | Check appropriate day/week of | N |
| | regimen | |
| N,P,D | Check appropriate pharmaceutical | Р |
| | stability | |
| N,P,D | Check appropriate dilution & rate of | N |
| | administration | |
| N,P,D | Check | P |
| | - hydration | |
| | - antiemetics | |
| | - adjuvant treatments | |
| | - other supplementary medicines | |
| N,P,D | Final authorisation and "off hold" | ט |

ii. Peripheral administration, give vesicant drugs firstiii. Oral drugs to have start and stop date indicated as appropriate

N = Nurses, P = Pharmacist, D = Doctors

 $^{^{\}rm 22}$ Adapted with permission from: Guidance to support BOPA Clinical Verification Standard v1.5

Appendix 9. Recommended Minimum Data for Chemotherapy Prescriptions

In the absence of electronic prescribing systems, chemotherapy should be prescribed on designated prescription forms. Ideally these should be pre-printed and regimen specific. The minimum data required are listed below.

Prescription sheets must contain the following data:

- 1. Date prescribed
- 2. Patient's name, date of birth, hospital number and address (for prescriptions to be dispensed in retail pharmacy businesses)
- Patient's height, weight, body surface area (BSA) as a calculated value (NB: Height is not required for paediatric prescriptions. Height and weight are not required for intrathecal chemotherapy prescriptions or flat doses)
- 4. Ward/Clinic
- 5. Name of supervising consultant
- 6. Diagnosis
- 7. Protocol code, regimen name or clinical trial name
- 8. The intended number of cycles, where appropriate
- 9. The cycle frequency
- 10. Information on the drugs prescribed including:
 - Drug's generic name (and brand name where the generic name does not adequately describe the product, e.g. doxorubicin which is available in multiple formats)
 - Protocol dose, e.g. per kg or m² BSA, or target area under the curve (AUC)
 - Absolute drug dose as a calculated value. For children, the doses should be calculated according to the relevant protocol, i.e. in mg/kg or based on BSA using the UKCCSG BSA chart
 - The frequency per day and the number of days of treatment
 - The dosing sequence

- Route of administration (the abbreviations for intrathecal, intraperitoneal or intrapleural are not acceptable and should be written in full)
- For infusions, details of solution and volume
- Duration of infusion and any other administration instructions
- Starting dates (and times when appropriate)
- Cycle or course number
- Antiemetics, hydration and any additional drugs as defined by the protocol
- All dose reductions, additions or amendments endorsed with the prescribers' signature and date
- 11. Off hold/On hold signature boxes
- 12. Signature of the prescriber, their identification number²³ and the date prescribed
- 13. Appropriate space for pharmacist verification, including the pharmacists' signature, identification number and date
- 14. Appropriate space for endorsing that all critical test results have been checked
- 15. Appropriate space for recording of administration

iii. The National Nursing and Midwifery Board (formerly ABA) Professional Identification Number (PIN) for nurses.

²³ In the absence of nationally agreed health professional identifiers, the following identifiers are recommended:

i. Medical Council Registration Number (MCRN) for doctors

ii. Pharmaceutical Society of Ireland (PSI) registration number for pharmacists

Appendix 10. Recommended Minimum Labelling Requirements for Pharmacy Prepared Chemotherapy Preparations

Each hospital pharmacy unit should have a written policy in place on drug preparation including labelling and packaging. Labels should comply with all statutory and professional requirements, and should include the following minimum information:

| | PARENTERAL PREPARATIONS & OTHER ASEPTICALLY | ORAL PREPARATIONS | TOPICAL PREPARATIONS |
|--|---|----------------------|-------------------------|
| | PREPARED DOSES | | |
| Approved drug name | \checkmark | | |
| Amount of drug in container | \checkmark | | |
| (micrograms, mg, g, units) | | | |
| Strength of preparation or | \checkmark | \checkmark | |
| concentration of liquids (inc volume) | | | |
| Infusion solution (inc volume) | | | |
| Infusion time | \sim | | |
| Route of administration | \checkmark | \checkmark | |
| Number of tablets, capsules or | | \checkmark | |
| volume of oral liquid | | | |
| Full directions & indication of length | | \checkmark | |
| of treatment (e.g. for x days then | | | |
| stop) | | | |
| Quantity of preparation (weight or | | | \checkmark |
| volume) | 1 | | |
| Preparation date** | N | | |
| Patient's name | N | N | N |
| Hospital number | N | 1. | 1. |
| Ward / Location | N | √* | \ \ * |
| Batch number | √ | √* | √* |
| Expiry date & time | √ | √(date only) | √(date only) |
| Storage conditions | √ | N | N |
| Warning: Cytotoxic Drug (if | \checkmark | | \checkmark |
| applicable) | | | |
| Other drug specific warnings, e.g. | \checkmark | N | |
| tor vinca alkaloids, intrathecal drugs | | | |
| etc. | | | |
| For External Use Only | 1 | 1 | N |
| Name & address of Pharmacy dept | \checkmark | \checkmark | \checkmark |

*where appropriate

**Where possible

NOTES:

- Labels added in pharmacy must have the route of administration printed clearly in the largest font size possible and emboldened.
- Negative labelling (i.e. "Not for Intrathecal Use") must never be used.
- For vinca alkaloids and for drugs with similar life threatening consequences, labels should have patient name, name of product, route of administration and a clear warning of the consequences of administration by other routes – for example, "For Intravenous Use Only – fatal if given by other routes".

Glossary and Definitions

- Chemotherapy drugs any systemic anti cancer treatment
- **Chemotherapy order** a written, printed or electronic order for chemotherapy to be administered in a hospital
- Chemotherapy prescription a written or printed prescription for dispensing in a retail pharmacy business ²⁴
- **Competency** a defined skill or task which the individual is deemed capable of carrying out independently, in a safe and effective manner
- Consultant consultant medical oncologist or haematologist
- Cytotoxic chemicals that are directly toxic to cells preventing their replication or growth
- Hazardous drugs drugs that adversely affect the health and safety of people in the workplace
- High Tech the High Tech Arrangement of the PCRS Drugs Scheme provides for the supply and dispensing of high-tech medicines through Community Pharmacies on foot of prescriptions written in hospitals.
- Medical record patient case history (hard copy or electronic)
- Prescriber the person authorised to order or prescribe chemotherapy
- Registrar A doctor, appointed to the hospital's Medical Oncology/Haematology Services, with several years' experience but who is not on a recognised specialist training programme.
- Specialist Registrar. A trainee specialist doctor undertaking a higher specialist training programme in Medical Oncology or Haematology with one of the recognised postgraduate training bodies.
- **Systemic cancer therapy** all chemotherapy, biological agents and vaccines delivered with the purpose of treating malignancy
- Treatment spaces all day ward chairs/recliners/beds which are used for the assessment of patients, supportive care and the delivery of systemic cancer therapy.

²⁴ Some hospital pharmacies also operate as a retail pharmacy business.

Abbreviations

| HOSPITALS | ABBREVIATION USED IN TABLES | |
|--|-----------------------------|--|
| Mater Misericordiae University Hospital, Dublin | Mater | |
| St. Vincent's University Hospital, Dublin | St Vincent's | |
| Beaumont Hospital, Dublin | Beaumont | |
| St. James's Hospital, Dublin | St James's | |
| Cork University Hospital | СИН | |
| Waterford Regional Hospital | WRH | |
| Mid-Western Regional Hospital Limerick | MWRH Limerick | |
| University College Hospital Galway | UCHG | |
| Letterkenny General Hospital | Letterkenny | |
| Adelaide and Meath Hospital, Tallaght | Tallaght | |
| Midlands Regional Hospital Tullamore | Tullamore | |
| Our Lady of Lourdes Hospital, Drogheda | Drogheda | |
| Sligo General Hospital | Sligo | |
| Naas General Hospital | Naas | |
| Mercy University Hospital, Cork | Mercy | |
| South Infirmary/Victoria University Hospital, Cork | SIVUH | |
| St. Luke's Hospital, Dublin | St Lukes, Rathgar | |
| Kerry General Hospital, Tralee | Tralee | |
| South Tipperary General Hospital, Clonmel | Clonmel | |
| Mayo General Hospital, Castlebar | Castlebar | |
| Portiuncula Hospital, Ballinasloe | Portiuncula | |
| St. Luke's Hospital, Kilkenny | St Lukes, Kilkenny | |
| Wexford General Hospital | Wexford | |
| Connolly Hospital, Blanchardstown | Connolly | |
| Cavan General Hospital | Cavan | |
| Our Lady's Children's Hospital Crumlin | Crumlin | |

- ABA An Bord Altranais
- BCCA British Columbia Cancer Agency
- BSA Body Surface Area
- CNM Clinical Nurse Manager
- CNS Clinical Nurse Specialist
- CPD Continuing Professional Development
- ED Emergency Department
- EDTA Ethylene diamine tetra acetic acid.
- FBC Full Blood Count
- GMP Good Manufacturing Practice
- HIQA Health Information and Quality Authority
- HSE Health Service Executive
- ICD10 International Statistical Classification of Diseases and Related
- Health Problems 10th revision
- IM Intramuscular
- IV Intravenous
- LFTs Liver Function Tests
- MAbs Monoclonal antibodies
- MCRN Medical Council Registration Number (MCRN)
- NA Not Applicable
- NCCN National Comprehensive Cancer Network
- NCCP National Cancer Control Programme
- NCHD Non Consultant Hospital Doctor
- **OPD** Outpatients Department
- PCRS Primary Care Reimbursement Scheme
- PIN Professional Identification Number
- RCPI Royal College of Physicians in Ireland
- **Rec** Recommendation
- **Reg** Registrar
- SC Subcutaneous
- SHO Senior House Officer
- SOP Standard Operating Procedure
- SpR Specialist Registrar.
- U&E's Urea and Electrolytes

Bibliography

BOPA, 2013. Standards for Pharmacy Verification of Prescriptions for Cancer Medicines. British Oncology Pharmacy Association.

Cancer Care Nova Scotia, 2011. Administration of Cancer Chemotherapy Competency. Safe Handling of Chemotherapy Competency Checklist.

Comber, H., Walsh, P., 2008. Patterns of care and survival of cancer patients in Ireland 1994 to 2004. National Cancer Registry of Ireland.

Department of Health, 1996. Guidelines for the Safe Administration of Cytotoxic Medical Preparations in the Treatment of Patients with Cancer. Department of Health.

Department of Health, 2006. A Strategy for Cancer Control in Ireland. Department of Health.

Department of Health, UK, 2013. Health Building Note 00-09: Infection control in the built environment.

Government of Ireland, 2003. Statutory Instrument No. 540 of 2003 Medicinal Products (Prescription and Control of Supply) Regulations.

Government of Ireland, 2007. Medical Practitioners Act 2007, Number 25 of 2007.

Government of Ireland, 2001. Safety, Health and Welfare at Work (Carcinogens) Regulations 2001 (S.I. No. 78 of 2001).

Government of Ireland, 2001. Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 (S.I. No. 619 of 2001).

Government of Ireland, 2000. Safety, Health and Welfare at Work (Pregnant Employees etc.) Regulations 2000 (S.I. No. 218 of 2000).

Government of Ireland, 2008. Statutory Instrument S.I. No. 495 of 2008 Pharmacuetical Society of Ireland (Retail Pharmacy Business) (Registration) Rules.

Government of Ireland, 1989. The Safety, Health and Welfare at Work Act (No. 7 of 1989) and the Safety, Health and Welfare at Work (General Application) Regulations 1993 (S.I. No. 44 of 1993 - as amended).

HIQA, 2012. National Standards for Safer Better Healthcare.

HSE, 2008a. HSE Incident Management Policy and Procedure.

HSE, 2008b. Best Practice Guidance For Developing a Site Specific Safety Statement.

HSE, 2011. HSE Risk Assessment Tool and Guidance.

HSE, 2013. Quality and Patient Safety Directorate.

Jacobson, J.O., Polovich, M., Gilmore, T.R., Schulmeister, L., Esper, P., LeFebvre, K.B., Neuss, M.N., 2012. Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings, in: Oncology Nursing Forum.pp.31-38. Medical Council, 2009. Guide To Professional Conduct and Ethics for Registered Medical Practitioners.

National Chemotherapy Advisory Group, 2009. Chemotherapy Services in England: Ensuring quality and safety.

NCCMerp, 2001. National Coordinating Council for Medication Error Reporting and Prevention.

NHS, 2008. Rapid Response Report. Using Vinca Alkaloid Minibags (Adult/Adolescent Units).

NICAN, 2009. Guidelines for the safe prescribing, handling and administration of hazardous drugs.

Queensland Government Department of Industrial Relations, 2006. Guide for Handling Cytotoxic Drugs and Related Waste.



