### Safe Prescribing, Handling and Administration of Hazardous Drugs Guidelines

**Reference Number:**

NHSCT/11/406

**Target audience:**

This document is primarily aimed at staff delivering anti-cancer treatment for patients with malignant disease.

**Sources of advice in relation to this document:**

Pat McClelland, General Manager Cancer Services  
Ewan McGrattan, Principal Pharmacist

**Replaces (if appropriate):**

Any legacy policies on safe prescribing, handling and administration of hazardous drugs

**Type of Document:**

Trust Wide

**Approved by:**

Policy, Standards and Guidelines Committee

**Date Approved:**

16 September 2010

**Date Issued by Policy Unit:**

19 May 2011

---

**NHSCT Mission Statement**

To provide for all, the quality of service we expect for our families, and ourselves.
Safe Prescribing, Handling and Administration of Hazardous Drugs Guidelines

September 2010

Adopted NICaN (Northern Ireland Cancer Network) Policy
## Contents Pages:

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Introduction</td>
<td>4</td>
</tr>
<tr>
<td>2 Purpose</td>
<td>5</td>
</tr>
<tr>
<td>3 Scope of document</td>
<td>5</td>
</tr>
<tr>
<td>4 Health &amp; safety</td>
<td>5</td>
</tr>
<tr>
<td>4.1 Staff monitoring</td>
<td>6</td>
</tr>
<tr>
<td>4.1.1 Personnel records</td>
<td>7</td>
</tr>
<tr>
<td>4.2 Pregnancy and breastfeeding</td>
<td>7</td>
</tr>
<tr>
<td>4.3 Minimising exposure</td>
<td>8</td>
</tr>
<tr>
<td>4.4 Personnel protective equipment/clothing to be used when</td>
<td>8</td>
</tr>
<tr>
<td>handling hazardous drugs</td>
<td></td>
</tr>
<tr>
<td>4.4.1 Disposable gloves</td>
<td>9</td>
</tr>
<tr>
<td>4.4.2 Eye and face protection</td>
<td>10</td>
</tr>
<tr>
<td>4.4.3 Armlets</td>
<td>10</td>
</tr>
<tr>
<td>4.4.4 Gowns</td>
<td>10</td>
</tr>
<tr>
<td>5 Clinical governance</td>
<td>11</td>
</tr>
<tr>
<td>5.1 Senior management at individual trusts</td>
<td>11</td>
</tr>
<tr>
<td>5.2 Department managers and supervisors</td>
<td>11</td>
</tr>
<tr>
<td>5.3 Employees and medical staff</td>
<td>12</td>
</tr>
<tr>
<td>6 Staff responsibilities and standards</td>
<td>12</td>
</tr>
<tr>
<td>6.1 Prescribers' responsibility</td>
<td>12</td>
</tr>
<tr>
<td>6.2 Pharmacists responsibility</td>
<td>13</td>
</tr>
<tr>
<td>6.3 Nurses responsibility</td>
<td>14</td>
</tr>
<tr>
<td>6.4 Prescriptions</td>
<td>15</td>
</tr>
<tr>
<td>6.5 Consent for treatment</td>
<td>17</td>
</tr>
<tr>
<td>6.6 Chemotherapy 'Off Protocol' prescribing</td>
<td>17</td>
</tr>
<tr>
<td>7 Preparation, supply and storage of chemotherapy</td>
<td>18</td>
</tr>
<tr>
<td>7.1 Preparation</td>
<td>18</td>
</tr>
<tr>
<td>7.2 Supply of hazardous drugs</td>
<td>19</td>
</tr>
<tr>
<td>7.2.1 Labels requirements for dispensed hazardous drug</td>
<td>20</td>
</tr>
<tr>
<td>preparations</td>
<td></td>
</tr>
<tr>
<td>7.3 Transportation</td>
<td>20</td>
</tr>
<tr>
<td>7.4 Storage in clinical areas</td>
<td>21</td>
</tr>
<tr>
<td>8 Out of hours initiation and administration of chemotherapy</td>
<td>22</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>9  Prescribing, dispensing and administration of oral hazardous drug preparations</td>
<td>22</td>
</tr>
<tr>
<td>9.1 Prescribing</td>
<td>22</td>
</tr>
<tr>
<td>9.2 Dispensing and labelling</td>
<td>22</td>
</tr>
<tr>
<td>9.3 Administration of oral hazardous drug preparations</td>
<td>23</td>
</tr>
<tr>
<td>9.4 Advice for patients and carers</td>
<td>24</td>
</tr>
<tr>
<td>10 Preparation of hazardous drugs</td>
<td>24</td>
</tr>
<tr>
<td>10.1 Pharmacy hazardous drug preparation services</td>
<td>24</td>
</tr>
<tr>
<td>10.2 Out of hours preparation of chemotherapy doses in clinical areas</td>
<td>25</td>
</tr>
<tr>
<td>11 Administration of hazardous drugs</td>
<td>25</td>
</tr>
<tr>
<td>11.1 General comments</td>
<td>25</td>
</tr>
<tr>
<td>11.2 Facilities</td>
<td>25</td>
</tr>
<tr>
<td>11.3 Equipment</td>
<td>26</td>
</tr>
<tr>
<td>11.4 Preparing to give hazardous drugs</td>
<td>26</td>
</tr>
<tr>
<td>11.5 Chemotherapy information for general practitioners</td>
<td>27</td>
</tr>
<tr>
<td>11.6 Chemotherapy information for patients</td>
<td>28</td>
</tr>
<tr>
<td>12 Administration of intravenous chemotherapy</td>
<td>28</td>
</tr>
<tr>
<td>12.1 Venous access</td>
<td>28</td>
</tr>
<tr>
<td>12.1.1 The vascular access device</td>
<td>28</td>
</tr>
<tr>
<td>12.1.2 Central venous catheters</td>
<td>28</td>
</tr>
<tr>
<td>12.1.3 Peripheral venous cannulation</td>
<td>29</td>
</tr>
<tr>
<td>12.1.4 Selection of cannulation site</td>
<td>29</td>
</tr>
<tr>
<td>12.2 General comments on intravenous administration</td>
<td>30</td>
</tr>
<tr>
<td>12.3 Administration of vesicant drugs</td>
<td>32</td>
</tr>
<tr>
<td>13 Administration via specific routes</td>
<td>32</td>
</tr>
<tr>
<td>13.1 Administration of chemoembolism</td>
<td>32</td>
</tr>
<tr>
<td>14 Extravasation</td>
<td>33</td>
</tr>
<tr>
<td>14.1 Definition</td>
<td>33</td>
</tr>
<tr>
<td>14.2 Prevention of extravasation</td>
<td>33</td>
</tr>
<tr>
<td>14.3 Treatment of extravasation with hazardous drugs</td>
<td>33</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>15 Disposal of cytotoxic waste</td>
<td>33</td>
</tr>
<tr>
<td>15.1 Used disposable equipment</td>
<td>33</td>
</tr>
<tr>
<td>15.2 Contaminated non-disposable equipment/items</td>
<td>34</td>
</tr>
<tr>
<td>15.3 Protective clothing and wipes</td>
<td>34</td>
</tr>
<tr>
<td>15.4 Part used doses</td>
<td>34</td>
</tr>
<tr>
<td>15.4.1 A damaged or leaking parenteral dose</td>
<td>35</td>
</tr>
<tr>
<td>15.5 Unused oral doses</td>
<td>35</td>
</tr>
<tr>
<td>15.6 Patient waste / Body fluids</td>
<td>35</td>
</tr>
<tr>
<td>15.7 Soiled bedding / linen</td>
<td>36</td>
</tr>
<tr>
<td>15.8 Nappies</td>
<td>36</td>
</tr>
<tr>
<td>16 Personal accidents</td>
<td>36</td>
</tr>
<tr>
<td>16.1 Skin</td>
<td>36</td>
</tr>
<tr>
<td>16.2 Eyes</td>
<td>37</td>
</tr>
<tr>
<td>16.3 Needlestick injuries</td>
<td>37</td>
</tr>
<tr>
<td>16.4 Clothing</td>
<td>37</td>
</tr>
<tr>
<td>17 Cytotoxic spillages</td>
<td>38</td>
</tr>
<tr>
<td>17.1 Immediate action</td>
<td>38</td>
</tr>
<tr>
<td>17.2 Subsequent action</td>
<td>39</td>
</tr>
<tr>
<td>18 Ambulatory and home chemotherapy treatment</td>
<td>39</td>
</tr>
<tr>
<td>18.1 Home chemotherapy</td>
<td>39</td>
</tr>
<tr>
<td>18.1.1 Assessment of suitability for home chemotherapy</td>
<td>40</td>
</tr>
<tr>
<td>18.1.2 Commercial home chemotherapy providers</td>
<td>40</td>
</tr>
<tr>
<td>18.1.3 Administration of home chemotherapy</td>
<td>42</td>
</tr>
<tr>
<td>18.1.4 Disposal of home &amp; ambulatory chemotherapy</td>
<td>42</td>
</tr>
<tr>
<td>18.1.5 Management of side effects and complications</td>
<td>42</td>
</tr>
<tr>
<td>18.2 Hospital based chemotherapy with intermittent administration in home or community setting</td>
<td>42</td>
</tr>
<tr>
<td>18.2.1 Continuous intravenous infusions</td>
<td>43</td>
</tr>
<tr>
<td>18.2.2 Intravenous or subcutaneous cytotoxic boluses</td>
<td>43</td>
</tr>
<tr>
<td>19 Education &amp; training</td>
<td>44</td>
</tr>
<tr>
<td>20 Implementation</td>
<td>44</td>
</tr>
<tr>
<td>21 References</td>
<td>44</td>
</tr>
<tr>
<td>22 Bibliography</td>
<td>45</td>
</tr>
<tr>
<td>23 Consultation process</td>
<td>45</td>
</tr>
<tr>
<td>24 Equality, Human Rights and DDA</td>
<td>46</td>
</tr>
<tr>
<td>25 Alternative formats</td>
<td>46</td>
</tr>
<tr>
<td>26 Sources of advice in relation to this document</td>
<td>46</td>
</tr>
<tr>
<td>Appendix 1 Guidance on dosing in children</td>
<td>47</td>
</tr>
<tr>
<td>Appendix 2 Advice for patients and carers for the disposal of cytotoxic waste &amp; the management of cytotoxic spillages in the home</td>
<td>48</td>
</tr>
</tbody>
</table>
Guidelines for the safe prescribing, handling and administration of hazardous drugs

1 Introduction

This document has been produced by the Northern Ireland Cancer Network (NICaN). It is intended for use across each of the cancer units and the cancer centre. It is based on a document produced by the North and North East London Cancer networks to which we express our sincere gratitude for granting us permission to adapt their guidelines.

This policy is intended to safeguard patients and staff, by defining best practice for all disciplines involved in chemotherapy.

For the purposes of this document, the term hazardous drug is used to refer to all drugs with direct anti-tumour activity including conventional cytotoxic drugs, monoclonal antibodies, partially targeted treatments (such as imatinib, gefitinib) and drugs such as thalidomide.

The term ‘hazardous drug’ is generally used to refer to any agent that may be genotoxic, oncogenic, mutagenic or teratogenic. The health risk of any procedure involving hazardous drugs stems from the inherent toxicity of the drug and the extent to which workers and patients are exposed. Although in therapeutic doses some of these drugs are known to produce neoplastic changes in the long term, there is conflicting evidence on the effect of the much lower level of occupational exposure.
Chemotherapy administration for cancer patients throughout the network should be provided by a multidisciplinary team in which doctors, chemotherapy competent nurses and pharmacy staff work to approved written protocols to provide integrated care both within the hospital and the community.

The handling and administration of hazardous drugs is potentially harmful to both the healthcare professionals involved in their preparation and administration, and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical. It is therefore prudent with the present state of knowledge to take every reasonable precaution to protect staff from unnecessary exposure.
These guidelines aim to minimise these risks by promoting the safe handling of hazardous drugs throughout the NICaN. It should be read in conjunction with relevant policies and procedures available in each individual Trust.

We are grateful to the pharmacists, clinicians, nurses and other healthcare professionals who have contributed to the production of this document.

2 Purpose

The guideline is intended to safeguard patients and staff by defining best practice for all disciplines involved in the delivery of chemotherapy for malignant disease.

3 Scope of the document

This document is primarily aimed at staff delivering anti-cancer treatment for patients with malignant disease. It does not deal with chemotherapy specifically for immunosuppressive purposes, or for the treatment of non-malignant disease. Individual Trusts should, where necessary, develop supplementary policies and guidelines to cover these circumstances. In these circumstances it is hoped this document would provide a useful reference source and we would recommend that any policies and guidelines are consistent with this guideline.

4 Health and Safety

Hazardous drugs interfere with cell division, but as this action is not specific to tumour cells, normal cells may also be damaged. Hazardous drugs may produce significant side effects in treated patients, or others exposed. This, together with the increasing complexity and usage of anti-cancer therapy, has raised concerns about the risks to health care workers involved in the preparation and administration of chemotherapy and/or the care of patients undergoing treatment. 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. Hence, all staff involved in the delivery of services to cancer patients should be aware of all 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.
The more common routes of exposure are contact with skin or mucous membranes (e.g. spillage and splashing), inhalation (over-pressurising vials), and ingestion (e.g. through eating or drinking in contaminated areas or from poor hygiene). Less likely routes of exposure include needle-stick injuries, which can occur during the preparation or administration of these drugs.

Some hazardous drugs can cause acute or short term health effects including irritation to the skin, eyes and mucous membranes. Information on chronic, or long-term, health effects of hazardous drugs mainly comes from data in animals and from patients given therapeutic doses. It is not certain how relevant this is to workers and any occupational exposures are likely to be at much lower levels. Health workers preparing cytotoxic doses without adequate precautions have been shown to contaminate themselves and their work environment. Reports of increased foetal loss and birth abnormalities, as well as anecdotal reports of toxicity unrelated to genetic damage have been published. It should be emphasised that these reports relate to exposure occurring prior to the introduction of cytotoxic drug handling precautions and guidelines. However, recent studies have shown evidence that contamination of the working environment with cytotoxics may still occur even with current safe handling procedures. Therefore it cannot be guaranteed that such adverse effects will not occur, although the likelihood should be greatly reduced with safer working systems.

The adoption of improved handling techniques and the use of isolators has reduced the potential for exposure to hazardous drugs significantly.

4.1 Staff monitoring

All relevant new employees, as outlined above, should receive an orientation to the current ‘Guidelines for the safe prescribing, handling and administration of hazardous drugs’ as soon as is feasible after commencement of employment.

There is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to adequately predict the effect of chronic long-term exposure. It is therefore recommended that staff monitoring (e.g. blood or urine testing) is not routinely undertaken until improved methodology and means to interpret the data are available. Hence, the primary focus of safety during the preparation and administration of hazardous drugs should be on control of the working environment, minimizing exposure and safe practice.

4.1.1 Personnel records
Records should be kept of all designated posts that require nursing, pharmacy or medical staff to reconstitute or administer hazardous drugs. This is the responsibility of the relevant manager. The Health and Safety Executive recommends that the records should contain at least the following: surname, forename, gender, date of birth, permanent address and postcode, National Insurance number, date when present employment started and a historical record of jobs in this employment involving exposure to hazardous drugs.

4.2 Pregnancy and breastfeeding
This is a particularly complex and emotive issue, which is of importance to staff and managers in areas with a high proportion of female staff. As some pregnancies are unplanned, or staff may be unwilling to discuss plans for conception, the emphasis should be on clear guidelines to reduce occupational exposure to all staff at all times. Most of the published evidence refers to pregnancy however all principles and recommendations should be applied to those staff who are breastfeeding.

Refer to local Trust policy and procedural arrangements relating to new and expectant mothers.

Evidence
Various studies have demonstrated links between occupational exposure to cytotoxic drugs and menstrual dysfunction, infertility, miscarriages and stillbirths, low birth weight and congenital abnormalities. However these studies were mostly carried out either in the 1980s, or based on staff exposure in the 1980s; a time when the use of personal protective equipment and safe handling techniques were not well established. These studies do not on the whole reflect current working practices.

Other studies have failed to find a statistically significant association with spontaneous abortion and congenital malformation. This may be due to the increased awareness of the risk, leading to the use of protective clothing and equipment, or the avoidance of cytotoxic handling by staff if they are pregnant.

Risk
The time of greatest risk to the unborn child is during the first three months of pregnancy, being the time of most rapid cell division and differentiation. As most staff will not disclose their pregnancy until well into this period any policy for the handling of cytotoxics by pregnant staff should therefore consider the needs of those trying to conceive and indeed those who may not be aware that they are pregnant. Guidance
from the Health and Safety Executive for new and expectant mothers emphasises that ‘a safe level of exposure cannot be determined for these drugs, so you should avoid exposure or reduce it to as low a level as is reasonably practicable’.9,10.

**Recommendations**

1. A comprehensive method of staff education and assessment in safe handling of cytotoxics should be in place. Regular audit should take place to ensure compliance.
2. Managers should ensure that a risk assessment is carried out in all areas where hazardous drugs are handled. This risk assessment should assume that there may be pregnant staff working in the environment at any given time.
3. Staff should be encouraged to discuss plans for pregnancy with their manager in confidence, and to inform them as soon as pregnancy is suspected or confirmed.
4. To comply with HSE guidance, all pregnant/breastfeeding staff should be removed from duties involving the preparation of cytotoxics. Under these circumstances, staff should be offered alternative duties.

**4.3 Minimising exposure**

A full COSHH (Control of Substances Hazardous to Health) assessment should be undertaken in all areas handling hazardous drugs and this is the responsibility of the relevant line manager.

*The following guidance applies to all staff handling hazardous drugs during administration of treatment, handling of patient waste and cleaning of spillage.*

**4.4 Personal protective equipment/clothing to be used when handling hazardous drugs**

The correct use of personal protective equipment can shield staff from exposure to hazardous drugs and minimise the health risks.

Pharmacy staff preparing hazardous drugs within pharmacy preparation units will wear personal protective clothes as defined by local standard operating procedures. The following recommendations are considered to be the absolute minimum protective clothing/equipment that should be worn, in clinical areas, for the defined work tasks. Local policy, or specific and individual staff needs, may dictate the use of further supplementary protection. Effective protection will only be obtained if the personal protective equipment chosen is:

- Suitable for the task and fit for purpose
• CE/kite mark and use within expiry date
• Suited to the wearer and the environment
• Compatible with other personal protective equipment in use
• In good condition
• Worn correctly.

<table>
<thead>
<tr>
<th>Activity (When to Wear)</th>
<th>Personal Protective Equipment</th>
<th>Nitrile Gloves</th>
<th>Eye &amp; Face*</th>
<th>Respiratory Protection</th>
<th>Armlets</th>
<th>Apron</th>
<th>Disposable Gown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration &amp; Disconnection of Parenteral Hazardous drugs</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes or gown</td>
<td>Yes or gown</td>
<td>Yes or armlets and apron</td>
<td></td>
</tr>
<tr>
<td>Handling contaminated patient waste</td>
<td>Yes</td>
<td>If waste not contained</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Handling oral Preparations Of Hazardous drugs</td>
<td>Yes</td>
<td>No for Solid preps Yes for liquid preps</td>
<td>No</td>
<td>No -tabs /caps Yes – liquids</td>
<td>No-tabs /caps Yes – liquids</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Distribution &amp; Stores activities</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes(^{13})</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Spill clean up</td>
<td>For hazardous drug spillages of less than 100mls a ‘Cytox 5 Emergency Cleaning Kit’ or equivalent is recommended. For cytotoxic spillages of more than 100mls a ‘Berner Cytotoxic Drug Spill kit’ or equivalent is recommended. Cleaning of a hazardous drug spillage should follow local standard operating procedure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Eye protection should meet British Standard EN 166 (RCN)

4.4.1. Disposable gloves (single use only)
• Cuts and scratches on the skin should be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged. Staff with dermatological conditions (e.g. eczema) should be referred to occupational health for assessment of fitness to operate in their role.
• Permeation of hazardous drugs depends upon glove material, thickness and integrity, the properties of the drug/solvents and the contact time with the drug. Since no material is completely impermeable to hazardous drugs and permeability increases with time, users should minimise contact and change their gloves regularly, approximately every hour.
- Gloves should be worn at all times appropriate to the task being undertaken. Powder free, disposable nitrile gloves should be used for the administration of hazardous drugs or for handling hazardous waste.
- Gloves should always be changed between patients.
- Double glove when dealing with spillage or administration of carmustine, mustine, amsacrine or thiotepa.
- If the inner surface of a glove becomes contaminated, exposure will occur. Therefore once disposable gloves are removed, they should not be re-applied, but disposed of as detailed in section 14.3.
- Gloves should be changed immediately if damaged or if any contamination occurs.
- Decontaminate hands as per local infection control policy before and after each glove application.
- Individuals suffering from nitrile allergy should be dealt with as per local policy and may be referred to Occupational Health.

4.4.2 Eye and face protection
- Safety glasses and visors are satisfactory to protect against splashes but goggles are recommended when exposure to vapours or aerosols may occur.
- Eyewash kits should be readily available in all areas where handling of hazardous drugs occurs. For action to be taken in the event of a splash injury see 15.2

4.4.3 Armlets (single use only)
- Non absorbent armlets and a plastic apron, or a disposable protective gown should always be worn when administering chemotherapy. Cuffs should be tucked under the gloves.

4.4.4 Gowns (single use only)
- Protective disposable gowns should be made of low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs. Cuffs should be tucked under gloves.

All personal protective equipment (PPE) should bear the European CE mark which ensures that the article complies with European regulations. All personal protective equipment should be certified as such according to the European directive 89/686/EEC.

5 Clinical governance
The responsibilities of different staff groups in relation to the safe prescribing, administration and handling of hazardous drugs are outlined below.

5.1 **Senior management at individual Trusts should;**
- Designate responsibility for the implementation and maintenance of the “Guidelines for the safe prescribing, handling and administration of hazardous drugs”.
- Ensure that all managers and supervisory staff are familiar with, and adhere to, the “Guidelines for the safe prescribing, handling and administration of hazardous drugs”.
- Be accountable for clinical and corporate governance.

5.2 **Department managers and supervisory staff should**
- Ensure that all relevant staff are fully familiar with the NICaN “Guidelines for the safe prescribing, handling and administration of hazardous drugs”, the individual Trust intrathecal policy, and that they are properly trained in, and comply with, all policies and procedures.
- Ensure that the health and safety of patients, public and staff are given primary consideration when implementing or altering processes, programs, or physical facilities related to hazardous drugs.
- Make every effort to ensure that all requests to change work assignments from staff that are pregnant, breastfeeding or trying to conceive, are accommodated.
- Ensure that appropriate and properly maintained facilities and equipment are available to all staff in employment handling hazardous drugs.
- Ensure personnel records, as outlined in section 3.1.1, are maintained for the duration of employment of each employee plus thirty years, and training records for three years from the date training occurred.
- Ensure that the service is reviewed against the current COSHH regulations with an authorised Trust COSHH assessor.
- Ensure that the training, education and competence assessment of all staff is subject to periodic review.
- Ensure that any member of staff transporting hazardous drugs has received training on dealing with a spillage and appropriate access to spillage kit.
- Ensure that standard operating procedures are in place for all likely activities involving hazardous drugs describing safe systems of work that meet all current legislative requirements.

5.3 **Employees and medical staff should**
• Ensure that all safety requirements according to COSHH guidelines and the NICaN “Guidelines for the safe prescribing, handling and administration of hazardous drugs” are followed.
• Only carry out potentially hazardous activities when competent or trained to do so.
• Follow departmental standard operating procedures where available.
• Report all unsafe acts and conditions.
• Actively participate in the training programs provided.
• Ensure that equipment and facilities provided to enable safe working are used correctly and any defects are reported promptly to the appropriate person.
• Inform managers/supervisors if they are pregnant, breastfeeding or trying to conceive.

6 Staff responsibilities and standards

The recommendations outlined in this document are supplementary to those measures within the Northern Ireland Chemotherapy Service Standards12.

6.1 Prescribers responsibility

• The decision to treat a patient with chemotherapy should be made by a Consultant, and the patient should be discussed at an appropriate Multidisciplinary Team Meeting (MDT). The decision and proposed plan of treatment should be documented in writing in the patient’s notes.
• Only appropriately qualified and competent Consultant Medical Oncologists, Clinical Oncologists, Haematologists, Paediatric Oncologists or Paediatric Haematologists may prescribe first courses of chemotherapy. Staff Grade / Specialist Registrars in training who have demonstrated the required level of competency may also prescribe first courses of chemotherapy for the treatment of cancer patients.
• Authorisation of second or subsequent courses may be delegated to F2/ST1/ST2 doctors (who have demonstrated the required level of competency or completed their chemotherapy competency card) or supplementary/independent prescribers according to local policy, but only if there are clear written instructions available, in the form of a Trust/ directorate protocol or entry into the patients’ medical notes. If modification of a dose is required, the Consultant or Specialist Registrar should document this in the medical notes.
• Only appropriately qualified Consultant urologists can prescribe first and subsequent course of intravesical anti-cancer therapies for bladder cancers.
• F1 doctors are not allowed to prescribe chemotherapy.

• The prescriber is responsible for:
  – Ensuring the patient has appropriate venous access appropriate to the drugs being administered
  – Completing the prescription as per section 5.4
  – Selecting the appropriate protocol and ensuring correct sequencing for alternating type regimens
  – Ensuring that maximum cumulative doses of anthracyclines and bleomycin have not been exceeded.

• If a patient is to be treated with a chemo-radiation protocol, it is essential that the prescriber makes this clear on the prescription, and notifies the relevant nursing, radiotherapy and/or pharmacy staff.

• If a patient is to be treated ‘off protocol’, refer to section 5.6. (Off protocol may be defined as any regimen not included in the relevant Clinical Management Guideline (CMG)).

• After the final cycle is given in a course, the prescriber should ensure that there is a treatment record for each patient that states whether the course was completed or not. If the course was not completed, the reasons for cessation should be documented. For completed courses of non-adjuvant treatment, a reference to the response should be included.

• Wherever possible, chemotherapy should be administered during normal working hours when access to specialist staff is more likely to be available.

6.2 Pharmacists responsibility

• An appropriately trained pharmacist should clinically check all prescriptions for hazardous drugs prescribed for the treatment of malignant disease.

• Prior to a cytotoxic dose being released for administration the pharmacist should verify the prescription according to the protocol or treatment regimen, clarify and resolve any discrepancies and check:
  – That the appropriate protocol has been selected.
  – The appropriateness of each element of the prescription as specified in 5.4
  – That all relevant safety parameters such as complete blood counts, renal and hepatic function have been checked.
  – That dose modifications to previous treatments are maintained if appropriate.
  – That maximum cumulative doses of anthracyclines and bleomycin have not been exceeded.
- That the volume and medium of infusion is appropriate with respect to the patient, protocol and pharmaceutical stability.

- If the prescription is for a new chemotherapy protocol, not included on the current relevant CMG, or is prescribed ‘Off Protocol’, the oncology/haematology pharmacist should discuss the case with the responsible Consultant. A copy of an original paper(s) from the responsible consultant detailing the protocol should be obtained, or the pharmacist should satisfy themselves that the prescription is appropriate in the individual patient’s circumstances before the prescription can be dispensed. If there is any doubt, a senior oncology/haematology pharmacist should be consulted. For further details, refer to section 5.6.

- In the absence of local policy, discrepancies exceeding plus or minus 5% of the dose, calculated according to the patient’s treatment plan, should be clarified with the doctor.

- The pharmacist will resolve any discrepancies identified with the prescribing doctor prior to dispensing the medication(s). The actual prescription, and electronic prescribing systems, will be amended, and any changes will be communicated to other team members as appropriate. The pharmacist will complete documentation of the discrepancy and the resolution.

- The pharmacist should sign the prescription to indicate that it has been verified and validated for the intended patient and that all safety checks have been undertaken.

### 6.3 Nurses responsibility

- Registered nurses are responsible for safe administration of chemotherapy prescribed to the correct patient as outlined in the individual Trusts Policy for Administration of Medicines by Nurses/Midwives, the Nursing and Midwifery Council (NMC) Guidelines\(^{11}\) and the Northern Ireland Chemotherapy Service Standards\(^ {12}\) 2006. The nurse is also responsible for the handing over of this information to other nursing staff as required to ensure continuity of care.

- All prescriptions for parenteral hazardous drugs should be checked by one chemotherapy competent nurse, another registered nurse or a competent pharmacist. The chemotherapy competent nurse (as defined in NICaN Chemotherapy Competence Framework) is responsible for ensuring that:
  - The correct weight and height have been recorded.
  - Dose modifications to previous treatments are maintained if appropriate.
  - All hazardous drugs and supportive therapies including anti emetics have been prescribed.
- The route of administration and the duration of infusion have been specified on the prescription.
- The patient has appropriate venous access prior to administering hazardous drugs.
- There is an appropriate interval between treatments.
- All relevant safety parameters such as complete blood counts, renal and hepatic function are checked.
- The patient is fully informed of their treatment and has given written consent.

- Patients should also be assessed for the need of any additional psychological, social or spiritual support.
- A nurse should not accept verbal orders for hazardous drugs or for adjustments to doses of hazardous drugs.

**6.4 Prescriptions**

- The initial decision to prescribe chemotherapy should be made by a consultant.
- The decision and proposed plan of treatment should be documented in writing in the patient's notes.
- Prescriptions for hazardous drugs should be complete, clear and simple to follow.

Each prescription should contain the following:

- Date prescribed
- Patient name, date of birth, hospital number and address
- Patient’s weight, height, body surface area (BSA) if applicable (NB: Height is not necessary for paediatric prescriptions. Height and weight are not necessary for intrathecal chemotherapy prescriptions or flat doses)
- Ward / clinic
- Consultant name
- Protocol code, regimen name or clinical trial name
- The condition being treated
- The intended number of cycles, where appropriate
- The cycle frequency
- Name of drug(s) - use approved generic drug names; no abbreviations.
- The individual dose in appropriate units (e.g. mg, micrograms or units, and target AUC (area under the curve) for carboplatin etc)
- 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
In the absence of specific instruction in a particular protocol, guidance was
issued through the UKALL2003 newsletter (Jane Buckham Paediatric Oncology
Pharmacists Group) in Sept 2004 (Details in Appendix 1).

For carboplatin prescriptions, uncorrected glomerular filtration rate (GFR) should
be stated for adult patients and Creatinine ethylene diaminetetraacetic acid
(EDTA) half life should be stated for paediatric patients.

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.

Investigations and critical tests required.

Critical test results such as blood counts, renal and hepatic function, as stated on
the prescription should be recorded and endorsed by the prescriber for each
treatment.

All dose reductions, additions or amendments endorsed with prescribers’
signature and date.

Reason for any dose modifications.

Signature of the prescriber and the date prescribed.

Record of drug administration.

- Prescriptions for oral chemotherapy should contain clear directions, including the
dose, frequency, and duration including start and stop dates where applicable. This
is to avoid patients being treated for longer than intended. For further details refer to
Section 8.1.

- Oncology, haematology and paediatric oncology/haematology staff should prescribe
hazardous drugs for all patients using electronic prescribing systems where these
are available.

- In those Trusts where electronic prescribing systems are not currently available,
chemotherapy should ideally be prescribed by using appropriate pre-printed
prescription proformas.

6.5 Consent for treatment
• All patients receiving chemotherapy regardless of route should be fully informed of their treatment and should have given full written consent.
• The name and grade of the doctor taking consent should always be stated on the consent form.
• Consent should only be taken by a clinician sufficiently experienced to judge that the patient’s decision has been made after consideration of the potential risks and benefits of the treatment, and that the treatment is in the patient’s best interest.
• Consent should be documented on the appropriate form, or a protocol/trial specific consent form. A copy of the completed form should be kept in the patient’s medical notes and a copy given to the patient. The chemotherapy regimen should be documented on the form.
• If a change in chemotherapy regimen is necessary, patients should be re-consented, after having received regimen specific details. This should be documented as before.
• Paediatric patients/carers should be given a copy of the signed consent form to keep in their patient held record, and be advised to take this when receiving treatment at Paediatric Oncology Specialist Cancer Units (POSCU’s).

6.6 Chemotherapy ‘Off Protocol’ prescribing
• In exceptional circumstances, it may be necessary to treat a patient with a protocol not included in the relevant CMG. This situation may arise, for example, in a patient for whom none of the current network approved regimens are appropriate due to pre-existing organ toxicity.
• If an ‘Off Protocol’ treatment is to be used, the consultant should document the intended regimen in the patient’s notes. This should include the following details:
  - The name of each drug.
  - The condition to be treated.
  - The intended dose of each drug in mg, micrograms or units per sq. metre or per kg. For carboplatin the desired AUC should be quoted.
  - The schedule on which each drug is given and the route of administration.
  - The length (in days) of each cycle should be stated as well as the interval between courses.
  - The total number of courses to be given as appropriate.
  - The reason for prescribing a protocol not included on the relevant current CMG or ‘Off Protocol’.
- An ‘Off Protocol’ or “Introduction of new regimen form” should be completed, and the treatment schedule should be discussed with Pharmacy. Where available, any published protocol details should be provided to Pharmacy.
- Confirmation of the indication, treatment details and in particular the dose and administration details should be checked and confirmed with published papers or published regimens (at a minimum details should be obtained from the hospital site from which the treatment details originated)

- Refer to Trust policy for further guidance.

7 Preparation, supply and storage of chemotherapy

7.1 Preparation

- All prescriptions should be received in pharmacy in a timely fashion according to local Trust policy.
- Dispensing and preparation of hazardous drugs should take place in Pharmacy (see section 9).
- Preparation of hazardous drugs should take place in filtered vertical laminar flow air cabinet or isolators situated in a specifically controlled and monitored environment. The equipment should be certified at least annually.
- All pharmacy staff preparing hazardous drugs will follow the individual Trust pharmacy procedures.
- An appropriately trained pharmacist will clinically check all prescriptions as per section 5.2 and 5.4.
- To facilitate drug preparation, changes to a previously written prescription may be made by an oncology/haematology pharmacist upon verbal confirmation from a doctor. Any changes on the prescriptions should be appropriately annotated by the pharmacist or prescriber, as per local policy.
- The pharmacist performing the clinical checking will document that the prescription is approved for preparation on the appropriate form.
- Appropriately trained pharmacy staff are responsible for the accurate preparation, documentation, labelling, determining and allocating the correct expiry and storage conditions for a hazardous drug.
- The pharmacist or accredited technician performing the final product check will ensure correct documentation, computer entry, ensure appropriate preparation, and release the medication for the patient.
7.2 Supply of hazardous drugs
Hazardous drugs are supplied as follows, depending on the form, which is most appropriate:

Bolus IV, IM or SC doses - in labelled luer-lock syringes
IV infusions - in sterile labelled bags of infusion fluid or appropriate infusion device/ambulatory infusion pump
Intrathecal doses - in labelled luer-slip syringes
Bladder instillation - in labelled ‘urotainers’ or 50ml luer-lock syringes, or a commercially available closed system device.
Intrapleural - in labelled luer-lock syringes
Intraperitoneal - in labelled luer-lock syringes or infusion bags
Chemoembolisation - in labelled luer-lock syringes or infusion bags
Tablets & capsules - in clearly labelled bottles or skillets
Oral liquids - in clearly labelled bottles
Topical - in clearly labelled tubes, ointment jars, dropper bottles or original packs
7.2.1: Label requirements for dispensed hazardous drug preparations

Labels should comply with all statutory and professional requirements, and should include the following information:

<table>
<thead>
<tr>
<th></th>
<th>Parenteral preparations &amp; other aseptically prepared doses</th>
<th>Oral preparation</th>
<th>Topical preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved drug name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Amount of drug in container</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(micrograms, mg, g, units)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength of preparation or</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>concentration of oral liquid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infusion solution (inc volume)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infusion time</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of tablets, capsules or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>volume of oral liquid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full directions &amp; indication of</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>length of treatment (e.g. for x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>days then stop)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quantity of preparation (weight</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>for creams or ointments, or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>volume for topical solutions)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation date</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hospital number</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward / Location</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Batch number</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiry date &amp; time</td>
<td>✓</td>
<td>✓ (date only)</td>
<td>✓ (date only)</td>
</tr>
<tr>
<td>Storage conditions</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Warning: Cytotoxic Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(if applicable)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other drug specific warnings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eg. for vinca alkaloids</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>For External Use Only</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Name &amp; address of Pharmacy dept</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

7.3 Transportation

- Containers of prepared cytotoxic agents should be transported in appropriately labelled, sturdy and leak-proof transport boxes or bags.
- All Trust staff involved in the transportation of hazardous drugs should be trained to follow their Trust procedure for cytotoxic spillage and have appropriate access to spill kits. The frequency of training will be defined by local Trust policy.
- Intrathecal doses should be transported separately to all other medication. Refer to local Trust Intrathecal Policy.

\[\text{Where appropriate}\]
• Pneumatic tubes should not be used for transporting cytotoxic agents.
• If a product has reached the administration area and a leak has occurred during transport and the product remains within the transport box then contact Pharmacy for advice. The transport box should contain any leak and the spill should be dealt with as per local policy. If the leak and any subsequent spillage occur after removal from the transport box, this should be dealt with promptly following local standard operating procedures. Contact Pharmacy who will log that a leak has occurred and that all waste was disposed of appropriately.
• Hazardous drugs that are to be transported outside of the hospital should be placed in sturdy, leak proof transport bags or boxes. They should be clearly labelled as 'Cytotoxic - handle with care’. Details of the recipient and delivery address should be clear. The label should also contain the name and address of the originating hospital and a direct contact in pharmacy in case of an emergency. A spillage kit should be made available to those involved in transporting the chemotherapy.

7.4 Storage in clinical areas
• 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.
• A member of nursing staff should receive the hazardous drug in the transit bag/box at its destination. Bags/boxes will not be left unattended or with untrained staff on arrival.
• Nurses are responsible for the correct storage of hazardous drugs delivered to wards and clinics prior to use. The storage should be in appropriate and designated areas.
• Hazardous drugs should be stored separately from other drugs.
  - Parenteral doses of chemotherapy should be stored in a designated locked chemotherapy refrigerator or cupboard.
  - Intrathecal doses should be stored in a designated locked intrathecal storage area or refrigerator. Refer to local Trust policy.
  - Oral doses can be stored in a locked drug trolley, cupboard or refrigerator with other medication, as long as they are clearly labelled as cytotoxic.
• Any refrigerators used for the storage of chemotherapy doses should be monitored at least daily to ensure that the temperature is maintained between 2 to 8 degrees
Centigrade. Maximum, minimum and current temperature should be recorded. A record of monitoring should be kept.

8 Out of hour’s initiation and administration of chemotherapy

Hazardous drug administration should be commenced during normal working hours wherever possible when support services and expert advice is available. When chemotherapy continues outside normal working hours, staff skilled in chemotherapy administration and access to expert medical advice must be available.

In a medical emergency, hazardous drugs should be prescribed by a Consultant Oncologist/ Haematologist. 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 to local arrangements and local policy. (See section 9.2)

9 Prescribing, dispensing and administration of oral hazardous drug preparations

9.1 Prescribing
- The prescribing of oral hazardous drugs should be carried out and monitored to the same standards as those for parenteral hazardous drugs.
- Electronic systems, or prescription templates, similar to those for parenteral hazardous drugs should be used.
- Prescriptions should state the dose, route, frequency, start date, duration of treatment and the intended schedule for treatment.
- The prescribing and dispensing of oral hazardous drugs should remain the sole responsibility of the hospital-based oncologist or haematologist and pharmacist respectively.

9.2 Dispensing and labelling
- Prescriptions should be clinically checked by a pharmacist who has been appropriately trained before dispensing.
- Relevant protocols should be available to all pharmacy staff who may be involved with dispensing oral hazardous drugs.
- Specialist oncology/haematology pharmacists should be accessible to advise dispensary staff dealing with oral hazardous drug prescriptions / requisitions.
- Dispensary staff should work to detailed standard operating procedures.
• A dedicated area should be reserved for the dispensing of oral hazardous drugs.
• All prescriptions dispensed for oral hazardous drugs should be labelled as per section 6.2.1.
• All containers of oral hazardous drug preparations for inpatients should be labelled as an outpatient prescription including full instructions and a ‘Cytotoxic’ warning label should be attached.
• Blister packed tablets should be ordered into the pharmacy department where they are available.
• If a liquid formulation is required, the pharmacy department should try to source a commercially available product.
• Loose tablets or capsules should be counted on designated counting triangles. Triangles should be cleaned with an alcohol wipe after each use which should be disposed of as cytotoxic waste.
• Automated tablet counting machines should NEVER be used to count oral hazardous drug preparations.
• When dispensing tablets or capsules, the complete course of treatment should be supplied.
• Patient information leaflets should be supplied to all patients.
• When dispensing cytotoxic liquid formulations the exact quantity required for the course (plus a small overage) should be supplied. For maintenance therapy it is more appropriate to dispense the drug in its original container.
• During normal working hours all oral hazardous drug quantities should have a second check prior to packaging.

9.3 Administration of oral hazardous drug preparations
• Oral formulations of hazardous drugs should not be handled directly.
• Protective gloves should be worn if handling loose tablets, capsules or liquid formulations.
• Loose tablets / capsules should be dispensed into a medicine cup and given to the patient.
• Where the tablet / capsule is presented in a blister pack the tablet / capsule should be pushed out into a medicine cup using a ‘non touch’ technique.
• Tablets / capsules should be swallowed whole and not chewed.
• Tablets should never be crushed or split. Capsules should never be opened.
• If medicine cups are used for the administration of hazardous drug tablets or capsules then they should be disposed of as cytotoxic waste. In the community patients should use a designated medicine cup and wash after each use.
• Medicine cups, spoons or oral syringes used to measure doses of liquid oral cytotoxics should be disposed of as cytotoxic waste.
• For patients with swallowing difficulties an alternative liquid formulation may be available. Contact Pharmacy department for details.

9.4 Advice for patients and carers
• Patients and their carers should be given adequate verbal and written information about their chemotherapy regimen, how to take their medication and for how long.
• Education should be given with regards to recognising adverse effects and what to do if these arise.
• Contact information should be supplied with telephone numbers of the chemotherapy unit and an out of hour’s emergency contact.

10 Preparation of hazardous drugs
10.1 Pharmacy hazardous drug preparation services
The Pharmacy departments at the cancer centre and each of the cancer units operate a hazardous drug preparation service providing parenteral hazardous drugs individually dispensed and ready for administration to named patients. The work is carried out within isolators or vertical laminar flow cabinets situated in a specifically controlled and monitored environment. These facilities provide operator protection, as well as ensuring maintenance of the sterility of the products. These units are subject to regular inspection from the Regional Pharmaceutical Laboratory Service.
Trained pharmacists and technicians, whose aseptic techniques are regularly validated, carry out all the preparation operations following standard operating procedures. Trained pharmacists carry out clinical checks of all chemotherapy prescriptions.

During normal working hours, preparation of hazardous drugs in a clinical area, outside pharmacy, is unacceptable.
10.2 Out of hour’s preparation of chemotherapy doses in clinical areas
There is no out of hours pharmacy preparation services or scheduled on call service at the Cancer Centre or at the Cancer Units however, some units will provide emergency chemotherapy if required, this is by local arrangement. Whenever possible, all cancer chemotherapy should be initiated, and as much as is feasible, administered, within normal working hours. The risk of accidents is increased when complex hazardous drug regimens are given outside normal working hours.
Emergency doses may be required out of hours in some instances e.g. for specific medical emergencies.
A Consultant Oncologist, Haematologist or Paediatric Oncologist should determine that it would be absolutely inappropriate to delay chemotherapy. The decision should be recorded in the medical notes by the responsible Consultant. Refer to local policy for further advice.

11 Administration of hazardous drugs

11.1 General comments
Pregnant staff should refer to section 3.
Chemotherapy should only be given in wards, clinics or theatres where it is agreed as part of, or the whole of, the wards allowed activity.

Double-checking of chemotherapy doses is recommended. All prescriptions for parenteral hazardous drugs should be checked by one chemotherapy competent nurse and another registered nurse or a competent pharmacist. The chemotherapy competent nurse is defined in NICaN Chemotherapy Competence Framework. Staff who are not competent to give hazardous drugs may only give hazardous drugs under the direct supervision of a competent staff member. Staff administering hazardous drugs should have an assessed current knowledge of the drugs being given, with respect to:

• The appropriate method of administration, following an agreed protocol.
• The usual dose ranges for each drug.
• Possible immediate, short and long term systemic and local side effects.

11.2 Facilities
Hazardous drugs should be administered in a dedicated environment with appropriate facilities for safe administration. Areas designated for the administration of hazardous drugs should have all relevant policy and protocol documents available. Facilities should
include easy access to expert help and all the equipment necessary for the management of emergencies.

11.3 Equipment

All areas in which hazardous drugs are administered should have the following equipment:

- Emergency alert system.
- Resuscitation equipment (or access to it as defined by local practice).
- Drugs for the management of emergencies – cardiac arrest and anaphylaxis.
- Access to drugs/equipment required to treat cytotoxic extravasation.
- Cytotoxic spillage kit. (Cytox 5 and Berner kit are recommended)
- Eye wash / access to running water.
- Electro-mechanical equipment used to assist administration should be appropriately installed, validated, and have a current maintenance certificate. The practitioner should observe the equipment for consistent performance. They should also be appropriate for the prescribed purpose and used by a competent practitioner only (as defined by local written policy) at all times. Staff should use the Medicines and Healthcare products Regulatory Agency (MHRA) for reporting adverse incidents, and act upon MHRA hazard and safety notices.

11.4 Preparing to give hazardous drugs

- Check the patient/carer has been fully informed and has given written consent to receive the proposed treatment.
- Check the prescription is dated correctly, signed, written clearly and unambiguously and is in accordance with the chemotherapy protocol.
- Check pre-chemotherapy investigations have been completed and results reviewed by an Oncology / Haematology doctor, designated chemotherapy trained nurse or an appropriate specialised pharmacist.
- Be aware of the side effects of all the drugs to be administered.
- Check cumulative doses have not been exceeded for anthracyclines and bleomycin.
- Check appropriate antiemetics have been prescribed and given.
- When the protocol contains premedications (e.g. with paclitaxel) or hydration, ensure that these are prescribed and given in line with the protocol.
- For parenteral doses, if the injections or infusions have been stored in a refrigerator they should be allowed to reach room temperature before administration to a patient.
This is to reduce the risk of infusion bags splitting during insertion of the giving set, and to reduce venous spasm.

- Explain the procedure to the patient/carer and ensure written information has been provided.
- With a second person (as defined earlier), check the following details (if there is a discrepancy contact the Pharmacy):
  - The patient’s name and hospital number correspond with the prescription chart and pharmacy label.
  - Commencement of administration of hazardous drugs should be on the date stated on the prescription.
  - The name of the drug, the dose and for parenteral doses, the infusion fluid: the prescription and pharmacy label should be identical.
  - For parenteral doses the volume of fluid prescribed should correspond to the volume stated on the label or the volume of fluid in a syringe should correspond to the volume stated on the label.
  - Check the name on the patient's wristband corresponds to the prescription chart. In day chemotherapy areas where patients may not be wearing a wristband, the patient must state their name, home address and date of birth.
  - Check the route of administration is the same on the hazardous drug product label and the prescription.
  - Check the expiry of all drug doses.
  - Check all parenteral doses for particulate contamination e.g. precipitation before administration.
  - Where an infusion pump is required ensure that it is set to the correct rate according to prescription and protocol and checked by two nurses.
  - For intravenous doses, flush well with appropriate compatible solution in between drugs.

11.5 Chemotherapy information for general practitioners (GP).
There should be available written guidelines for General Practitioners covering advice to give and action to take when patients undergoing cancer chemotherapy consult them with symptoms that may be related to complications. Conditions to be covered include neutropenic sepsis, extravasation injury, nausea and vomiting.

These guidelines should be sent to each individual GP each time one of their patients commences a course of cancer chemotherapy.
It is the responsibility of the Trust staff member giving the chemotherapy to ensure the appropriate guideline is sent to the GP.

11.6 Chemotherapy information for patients
Patients undergoing chemotherapy will be provided with written information related to their treatment. The information should cover advice and action to be taken if and when they develop symptoms that may be related to side effects or complications. Conditions to be covered should include neutropenic sepsis, nausea and vomiting.

It is the responsibility of the Trust staff member giving the chemotherapy to ensure that the patient/guardian has been provided with the appropriate information via the appropriate team member(s).

12 Administration of intravenous chemotherapy

12.1 Venous access
Cannulation of a patient and administration of hazardous drugs should be carried out by nursing or medical staff that have been trained and assessed as competent.

12.1.1 The venous access device
- An appropriate venous access device should be selected by a competent practitioner to fulfil the requirements of the proposed treatment plan. Butterflies should not be used for the administration of any chemotherapy.
- Hazardous drugs should NOT be given if there is any doubt regarding the safety of the venous access device.

12.1.2 Central venous catheters
- Central venous access should be considered if the drugs or fluids are to be administered over a long duration, are irritant to the peripheral veins, or have the potential to cause tissue necrosis.
- Where the recipient of therapy has insufficient or unsuitable peripheral veins, insertion of a central venous catheter may be indicated.
- Some therapies will justify the placement of a Peripheral Inserted Central Catheter (PICC). However, several months of intensive therapy may indicate the need for tunnelled central catheters or implantable devices.

The care and maintenance of central venous catheters should follow local guidelines.
12.1.3 Peripheral venous cannulation
Small gauge non ported vialon cannula, which preserve vein integrity and cause least pain to the patient, are recommended. A closed system with luer-lock attachments should be used. Peripheral cannulae should be changed every 72 hours or more frequently if there is any doubt about the integrity.

- The care of cannulae should follow local guidelines.

12.1.4 Selection of cannulation site
When choosing a suitable site, both the required cannula size and the size and condition of available veins should be taken into consideration. The following need to be considered:

- The purpose of the cannulation. For example:
  - A large vein required for high flow rate.
  - Irritant solutions or drugs require good flow to assist haemodilution.
- The condition of the accessible vein, the lumen and blood flow.
- Small visible but impalpable superficial veins are rarely suitable for cannulation.
- In the elderly patient particularly, prominent, superficial veins may be sclerosed, tortuous, fibrosed or fragile and therefore maybe unsuitable for cannulation.
- The large superficial veins of the forearm are commonly chosen for the cannulation as they are numerous, easily detectable with wide lumens and thick walls and the skin is less sensitive. Most common are: median cubital, basilic and cephalic veins.
- Veins in the lower limbs must be avoided in adults.
- Avoid use of dominant arm in order to maintain patient mobility and independence whenever possible.
- Avoid areas of joint flexion.
- For the administration of cytotoxic chemotherapy, use the back of the hand or the antecubital fossa only as a last resort.
- Avoid sites distal to recent cannulation or venepuncture to minimise the risk of fluid extravasation.
- Avoid areas proximal to skin lesions or wounds.
- Avoid areas affected by invading tumour, haematoma, inflamed or sclerosed areas, cardiovascular access etc.
- Avoid limbs where there is lymphatic impairment following surgery, chemical occlusion or radiotherapy even if there is no obvious lymphoedema.
- Most difficulties arise when few or no veins in good condition are available. Heat may be used to dilate difficult veins, following local protocol.
• Follow local policy for cannulation.

12.2 General comments on intravenous administration

• Thoroughly wash and dry hands prior to glove application. (Refer to local Infection Control Policy).
• Ensure appropriate protective clothing is worn (see section 3.4), prior to handling syringes or infusion bags containing hazardous drugs.
• Hazardous drugs should be administered as per protocol, or according to the manufacturers’ instructions.
• Prior to commencing administration check the patency of the cannula or central catheter, by aspirating for blood and flushing with 10mls of sodium chloride 0.9%. **Caution**: remember to check drug compatibility with the fluid used for flushing.
• If there are any doubts regarding cannula patency, recannulate the patient.
• Access of central catheters should follow local policy and guidelines.
• If the placement or patency of central access is in doubt, appropriate investigations should be requested prior to commencing treatment. Use of non touch technique should be maintained throughout intravenous administration.
• Inspect sealed bags before opening to ensure no spillage has occurred within the bag.
• Carefully insert the giving set into the hazardous drug infusion at waist height to minimise the risk of personnel contamination in the event of a spillage.
• Ensure that the infusion solution is covered to protect it from light if the drug is prone to photo degradation (See manufacturers guidelines).
• If a special giving set or filter is required, (e.g. paclitaxel, dacarbazine), use only those recommended.
• Checking should follow procedure previously described in section 5.3., immediately prior to administration by the person giving the treatment and the person performing the second check.
• Check for blood return every 2-5mls during peripheral administration and before and after each drug during bolus administration.
• Advise patient to immediately report local or systemic adverse events.
• Use sterile compatible fluid, which is appropriate to the drug being administered, to test and flush the vein and vascular access devices during administration. This should also be done between different drugs, and after hazardous drug administration.
• Place a sterile gauze swab under the injection port during administration. Administration should be performed over a protective pad with waterproof backing to protect skin and surfaces from potential cytotoxic leakage.
• Maintain a closed system by using luer-lock syringes. Use intravenous administration sets and syringes with luer-lock fittings.
• To ensure visibility at all times, bandages should not be applied to cannula sites when chemotherapy is in progress.
• On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 14.
• Wash hands thoroughly following the removal of gloves.
• Record the administration on the prescription sheet, in the medical, nursing notes, and electronic prescribing system if available.

The patient should be monitored frequently throughout administration for:
• Leakage at the site.
• Swelling.
• Pain.
• Venous irritation.
• Phlebitis.
• Flare reaction.
• Allergic reaction.
• Anaphylaxis.
• Extravasation.
• Known side effects.

Stop administration if:
• There is any doubt about the checks that have been carried out.
• The patient requests the treatment to stop.
• The patient demonstrates side effects or complications, particularly signs of anaphylaxis or extravasation.
• The equipment fails to function effectively.

12.3 Administration of vesicant/exfoliant drugs
Adhere to the following when administering a vesicant/exfoliant drug:
• Use a new cannula if possible, or one that was sited less than 48 hours since insertion. Ensure that it is patent and that there are no obvious signs of
extravasation. (Note: Presence or absence of venous return is not an absolute indication of patency.)

- Central venous catheters are recommended for administration of large volume vesicant/exfoliant infusions, but if vesicants/exfoliants are to be administered peripherally, infuse under gravity control or use a pump set to low pressure. A fast running, free flowing infusion of sodium chloride 0.9% must be used for administration of vesicant boluses. In the paediatric setting, vesicant/exfoliant drugs are not generally given peripherally, except for vincristine, and in this situation a fast running infusion is not usually used.

- For peripheral administration give any vesicant drugs first when administering multiple drugs, as vein integrity is greatest at this time.

- For central venous access, ensure patency before administration. A fast running drip is not required for vesicant boluses.

**13 Administration via specific routes**

Other routes of administration include subcutaneous, intramuscular, intravesical and topical. Follow 3.4 (personal protective equipment) 10.4 (preparing to give hazardous drugs), and local appropriate administration and disposal procedures. (Information also in section 5).

**13.1 Administration of chemoembolisation**

- Prescriptions for chemoembolisation should only be written by designated Consultants experienced in its administration.

- Chemoembolisation can only be carried out by, or under the direct supervision of, a designated consultant radiologist who has expertise in the technique and who has received training in the safe handling of hazardous drugs.

- The hazardous drug used in the procedure is Doxorubicin which is loaded onto the DC bead delivery system. Planning and co-ordination with the Pharmacy department is essential.

**14 Extravasation**

**14.1 Definition**

Extravasation is defined as the unintended administration of a pharmaceutical into the tissue spaces surrounding a vein during intravenous injection. The
consequences are often pain, erythema, inflammation and discomfort. Damage can continue for months and involve nerves, tendons and joints. If left undiagnosed, or if treatment is delayed, surgical debridement, skin grafting, and even amputation may result, depending on drug classification.

14.2 Prevention of extravasation
The most important issue in managing extravasation injury is prevention. When administering intravenous drugs precautions should be taken to minimise the risk. (See section 11 Administration of intravenous chemotherapy).

- Some patient groups are at increased risk of extravasation. These include elderly and paediatric patients, patients with fragile veins, thrombocytopenic patients, and unconscious or sedated patients, patients with superior vena cava obstruction and diabetics with peripheral neuropathy. Extra care should be taken with these patient groups.

- Vesicant drugs should routinely be given as an intravenous bolus when given peripherally. There may be exceptions to this e.g. amsacrine, dacarbazine, carmustine, vinca alkaloids and streptozocin. This list is not exhaustive; refer to local policy and procedure. Intravenous infusions administered peripherally should be infused under gravity control or a pump set to low pressure.

14.3 Treatment of extravasation with hazardous Drugs
Refer to local Trust policy.

15 Disposal of cytotoxic waste
The recommendations in this section act as a guide, and are supplementary to those detailed in Individual Trust Waste Disposal policies.

15.1 Used disposable equipment
While wearing gloves and plastic apron/gown place any needles, syringes, giving sets, empty ampoules/vials or infusion bags into a rigid cytotoxic burn bin (A yellow burn bin with a purple lid designated for cytotoxic waste). Giving sets should be closed off and not be removed from infusion bags prior to disposal. Sharps boxes for cytotoxic waste are yellow in colour with purple lids. The method of disposal shall be in accordance with the requirements for the disposal of hazardous drugs by high temperature incineration to ensure degradation of the cytotoxic agents. Sharps disposal boxes containing cytotoxic waste should be regularly collected.
15.2 Contaminated non-disposable equipment/items
Re-usable plastic or metal trays should be cleaned with a large wipe containing 70% isopropyl alcohol between patients and then cleaned with a detergent disinfection solution or 70% isopropyl alcohol wipe at the end of each shift. Wear eye protection, gloves and gown, or disposal apron and armlets. If non-disposable equipment or items are sent to another department for terminal cleaning, they should be transported in sealed leak-proof bags or containers. These should be clearly labelled indicating that they are potentially contaminated by hazardous drugs.

15.3 Protective clothing and wipes
Contaminated protective clothing, wipes, plastic aprons and gloves worn during the administration of chemotherapy should be placed in a yellow burn bin with a purple lid. No bin should be filled more than two thirds full and no burn bin or sharps box should weigh more than 9kg.

After a cytotoxic spillage (dealt with according to the cytotoxic spillage procedure), arrangements should be made for collection of the rigid cytotoxic sharps/burn bin for incineration as per local Trust policy. (See Section 16 for further details).

15.4 Part used doses
While still wearing protective clothing, attach a luer-lock cap to the syringe or to the end of an infusion line. If disposing of an infusion bag leave the giving set in place and clamp it off. Place the syringe/bag in a yellow bag and place into a rigid cytotoxic sharps box (purple lid). It should be clearly documented how much of the dose was administered and the reasons for discontinuation of treatment. Medical staff should also be notified. Contact the Pharmacy who will log that the product has been partially used and disposed of appropriately.

15.4.1 A damaged or leaking parenteral dose
See section 6.3
If a leak occurs at commencement or during administration of an infusion, discontinue administration and deal with as per cytotoxic spillage procedure. (See section 16 for further details).
15.5 Unused oral doses
Any unused oral doses (e.g. tablets or oral liquids that have been dropped that have been refused etc) should be disposed of in a cytotoxic burn bin (yellow bin with purple lid). To minimise the risk of damage and potential contamination, they should be discarded as follows:

• Loose tablets/capsules: Put into a sealable plastic bag or a medicine bottle / sample pot securing the lid, before placing in a cytotoxic burn bin.
• Oral liquids: Pour into a medicine bottle / sample pot securing the lid, before placing in a cytotoxic burn bin.

15.6 Patient waste/body fluids
Patient waste e.g. urine, faeces, vomit may contain high concentrations of hazardous drugs or active metabolites both during administration and up to seven days after treatment has ceased. Particular care should be taken with patients receiving high dose chemotherapy or intravesical treatment.

It has been shown that these unchanged hazardous drugs or active metabolites can be irritant to the skin, eyes and mucous membranes. Although evidence of long-term toxicity is inconclusive and conflicting, all staff handling waste should take reasonable precautions to limit exposure and ensure absorption does not occur.

The use of standard infection control precautions applies here as with all body fluids.

• Wear disposable gloves and disposable protective aprons or gowns.
• Double flushing of sluices after emptying potentially cytotoxic contaminated matter from bedpans, catheter bags, dialysis bags etc is recommended. Bedpans should be put through a bedpan washer twice at high temperature.
• Staff are advised to follow the precautions described in individual Trust Control of Infection Policy Manuals.
• Ideally patients should use separate toilet facilities to staff. Men should be advised to void sitting down to minimise splashing. Following voiding, toilets should be flushed twice, with the lid down (again to minimise splashing). A strong bleach based detergent should be poured into the toilet after voiding, for patients who have received intravesical BCG therapy. The bleach and urine should be left to stand in the toilet for 15 minutes before flushing.
15.7 Soiled bedding / linen
Soiled bedding and linen should be treated as infected linen and double bagged and sent to the hospital laundry/ relevant licensed contractor according to the procedures described in the individual Trusts Control of Infection Policy Manual.

15.8 Nappies
Non-disposable nappies should be treated as infected linen and handled according to the procedures described in the individual Trusts Control of Infection Policy Manual. In hospital disposable nappies and stoma bags should be disposed of in a cytotoxic burn bin.

16 Personal accidents

If a patient, member of staff or visitor is involved in a spillage of hazardous drugs or potentially contaminated patient waste the following procedures should be followed. All such events/accidents should be reported to a senior member of staff and fully documented on the local Trust Incident Report form.

16.1 Skin
- Remove any contaminated clothing immediately using disposable gloves.
- The contaminant should be removed as rapidly as possible by flushing the affected area with a large volume of cold water. If running water is not immediately available, bottles or bags of sterile water or normal saline should be kept as an alternative.
- After initial copious flushing with water, the contaminated skin should be thoroughly washed with liquid soap or antiseptic scrub and water. After rinsing, the process should be repeated.
- Shower facilities should be available for use if large areas of skin are contaminated.
- Do not use hand creams and emollients as these may aid absorption of the drug.
- Medical attention should be sought from the nearest Accident & Emergency Department.
- A Trust Incident report form should be completed, and the Head of Department & Occupational Health informed.

16.2 Eyes
- In the case of contact with eye(s), hold back the eye lid and flush the affected eye(s) with copious amounts of water or sodium chloride 0.9%. Use Emergency Eye Wash
Equipment available or alternatively cold tap water can be used if necessary. When anthracycline contamination occurs, flush eye(s) for at least 15 minutes. Refer to relevant Summary of Product Characteristics and Product Safety data sheet for further details.

- Medical attention should be sought immediately from the nearest Eye Clinic or Accident & Emergency Department.
- A Trust incident report form should be completed and the Head of Department & Occupational Health informed.

16.3 Needlestick injuries

- When a needlestick injury results in contamination, first squeeze the area until it bleeds.
- Wash the puncture site/wound thoroughly with copious amounts of cold water and cover with a waterproof dressing.
- If the needle contained any cytotoxic drug contaminant, check the vesicant status of the drug by referring to, 'The Management of Extravasation' policy, or by seeking advice from a senior oncology or haematology pharmacist.
- Report the incident immediately to a senior member of staff.
- Follow the Trust’s Needle stick injury procedure, and consider seeking advice from the Accident & Emergency Department or Occupational Health, especially if the needle had been in contact with a patient.
- A Trust incident report form from should be completed.

16.4 Clothing

- Any contaminated clothing should be removed immediately. Put on gloves and an apron. Rinse the clothing under running tap water. Squeeze dry and place in a plastic bag.
- Uniforms or hospital linen should be double bagged in the appropriate laundry bags and sent to the hospital laundry according to the procedures described in the individual Trusts Control of Infection Policy Manual.
- Personal clothing should be taken home for laundering. Such items should be laundered twice where possible. The first wash should be separate from other clothing. They may be laundered with other items for the second wash.
- Dispose of gloves and apron into a double yellow clinical waste bag.
• If there is a likelihood that the drug has soaked through the outer clothing, underwear should be removed and treated as above, and the area of skin treated as in section 15.1 above.

17 Cytotoxic spillages

A cytotoxic spillage kit should be available, at all times, in all clinical areas where hazardous drugs are administered, and in all pharmacy areas where hazardous drugs are handled or stored. All staff should know how to use it and where it is stored. If a kit is used it should be replaced immediately. Cytotoxic spillage kits are available from Pharmacy or Supplies Departments, depending on local practice. Commercially available spillage kits are used in all hospitals providing a chemotherapy service to Oncology and Haematology patients in Northern Ireland. Information aimed at patients and carers regarding cytotoxic spillages in the home or community environment is outlined in Appendix 2.

17.1 Immediate action

• Restrict access to the spillage area.
• Alert other members of staff in the vicinity and inform a senior member of staff.
• If you have been injured or contaminated, another member of staff should deal with the spillage while you receive attention for the injury or contamination following the procedure detailed in Section 15.
• Untrained and pregnant staff should not have direct involvement in the management of a cytotoxic spillage.
• Turn off all fans and reduce any draughts.
• Open a Cytotoxic Spillage Kit (refer to local policy).
• If protective clothing has been contaminated during the spillage, remove the contaminated items and put on fresh protective clothing from the spillage kit. Place all contaminated items in a cytotoxic burn bin.
• Before dealing with the spillage ensure you have put on:
  - a disposable protective gown
  - A pair of protective plastic armlets
  - A pair of gloves (Tuck the armlet sleeves inside the glove cuffs)
  - A mask (preferably a respirator)
  - Protective eye wear
  - put on a pair of plastic overshoes (only if spillage is on the floor).
• For dry powder spills also refer to local procedures.

17.2 Subsequent action
The procedure as outlined in the spillage kit or the local standard operating procedure should be followed. Such procedures should also be accessible in all relevant ward, clinic and pharmacy areas. A Trust incident report form should be completed.

18 Ambulatory and home chemotherapy treatment

Chemotherapy is usually given in an appropriate hospital based facility, either on the wards as an in-patient or on a day care unit. However, current practice of chemotherapy and cancer management means that many patients now receive chemotherapy in settings outside of conventional hospital facilities.

The hospital-based team, regardless of the place of chemotherapy drug delivery retains the overall responsibility for the patient. It is essential however that the patient’s GP is informed of the method and place of chemotherapy delivery and the support package available, including 24 hour contact numbers.

18.1 Home chemotherapy
For the purposes of this document, home chemotherapy is the delivery of a complete cycle of chemotherapy usually in the patient’s home, but occasionally in a local community setting.

Chemotherapy delivery in this setting is usually by commercial companies specialising in home treatment. It is essential that the prescribing, dispensing and administration of home chemotherapy should be carried out and monitored to the same standards as those for hospital based parenteral chemotherapy.

Certain chemotherapy administration procedures are not suitable for home delivery. These include intrathecal, intrapleural and intraperitoneal administration. At any point during a treatment plan, the patient should be able to opt out of home treatment, and continue with hospital based treatment, if they wish to do so.

18.1.1 Assessment of suitability for home chemotherapy
All patients need to be referred to the home chemotherapy hospital team for a formal assessment. Although the actual assessments tools used in practice may vary, the following factors should be considered as a minimum requirement.
Patients should be assessed to ensure that:

- They have consented to chemotherapy.
- The chemotherapy regimen is appropriate for home administration.
- The routes of chemotherapy administration are appropriate.
- They wish to receive treatment at home.
- They have a good understanding of their disease and the treatment side effects.
- They understand when to contact the hospital if unwell.
- The family and carer are aware of the home treatment.
- They have a permanent address.

The patient’s home environment should be assessed to ensure that:

- There is a working telephone.
- There is running water.
- There is a safe area clear of obstacles and hazards for the nurse and patient.
- There is place for the patient to be comfortable whilst receiving treatment.
- The patient is happy for treatment to be administered in this environment.
- The nurse feels happy and safe in the environment.

18.1.2 Commercial home chemotherapy providers

There are a number of companies that provide home chemotherapy services. This may be on an individual patient basis or as part of a hospital home care policy. Before embarking on a home chemotherapy programme, it is essential that any service provider be formally assessed. When assessing a commercial company the following factors should be taken into account and considered as a minimum requirement:

- The company should be experienced in home chemotherapy administration.
- Company facilities and services should be open to inspection by hospital based staff if felt necessary.
- There should be a patient assessment that is used to check that the patient is fit for treatment prior to administration.
- Policies and procedures for the management of anaphylaxis, allergic reactions and extravasation should be the same as that of the requesting Trust.
- There should be a policy relating to patient data, and who can access individual patient details.
• The recruitment and training of nursing staff administering the chemotherapy doses should be of a similar standard to Trust staff.
• The company should hold indemnity insurance.

Once a tender from a commercial company is agreed, a number of processes and pathways need to be agreed upon before a home chemotherapy programme can commence. These include:

• A procedure for the initial referral of the patient to the company homecare team.
• The referral policy for an unwell patient. This should usually state that the patient is referred back to the medical team as per local arrangements, and not to the GP.
• Appropriate pathways for feedback and handover of documentation to the hospital based team. A reasonable time frame would need to be agreed with the Trust involved.
• An agreement should be in place concerning the supply of medications. This should include the dispensing of the hazardous drugs as well as the dispensing of any supportive drugs such as antiemetics. Pharmacy verification of the prescription (see section 5.4) must be performed before chemotherapy is made for homecare patients. If the company is supplying the medication, it is essential that there is a process for a prescription to be available in advance for the preparation and dispensing of the doses.
• A pathway should exist for the prescription to be available in advance for the nursing staff to administer from.

18.1.3 Administration of home chemotherapy
The procedure for the actual administration of any cytotoxic drug in the home setting should be as outlined in sections 11.
18.1.4 Disposal of home and ambulatory chemotherapy
Refer to Appendix 2 and local arrangements.

18.1.5 Management of side effects and complications

- All patients and health care providers involved in the administration of home chemotherapy should be aware that any side effects and complications should be managed by referral to the base hospital.
- Guidelines for the management of infusion related reactions and hypersensitivity should be agreed between the commercial chemotherapy provider and the individual Trust.
- In the event of an extravasation, refer to section 13.

18.2 Hospital based chemotherapy with intermittent administration in the home or community setting

Some patients within Northern Ireland may be treated with regimens in which most of the chemotherapy doses are administered within the hospital setting, but may involve some part of their treatment also being managed or delivered at home or in the community setting.

Such patients should be regularly reviewed by the hospital based medical or nursing team to ensure that they are still fit for treatment. The frequency of review will be dependant on local practice and the chemotherapy regimen.

Patients should be provided with all appropriate supplementary equipment. This should include gloves, aprons, syringe tip covers, cytotoxic sharps and/or burn bins and cytotoxic spillage kits.

It is essential that for all these settings the patients and carers have received full information and advice concerning their chemotherapy treatment. They should also have been given adequate training and support regarding safe handling, storage and disposal of the drug doses and management of spillages. (Refer to Appendix 2).

Patients, carers or community nurses will not be expected to prepare or reconstitute any hazardous drugs at home. All hazardous drugs for administration will be in a ready to administer form such as pre-filled syringes, infusion bags or prepared infusor devices.
Disconnection and disposal of chemotherapy infusor systems will be undertaken by appropriately trained personnel.

18.2.1 Continuous intravenous infusions
The hospital based nursing or medical staff will undertake an assessment of patient suitability for continuous infusional chemotherapy before a patient is allocated to receive treatment.
Disposable elastomeric infusors are the device of choice for delivery of continuous infusions in the home setting.
Patients, carers or community nursing staff should be provided with information regarding their treatment as well as how to care for the central venous access device.

The following information should be given to the patient, carer, GP and/or community nurse:
I. The name of the drugs(s), dose(s) and duration of infusion.
II. The name of the pump or infusion device and how it operates.
III. Care of the central venous access device.
IV. Potential problems and management.
V. Safe handling, storage and disposal.
VI. Spillage procedure and spillage kit.
VII. 24-hour contact telephone numbers.

The patients or carers understanding of the above will be assessed using a teaching checklist. Additional supplementary written information will also be provided.

18.2.2 Intravenous, subcutaneous or intramuscular cytotoxic boluses
The hospital based nursing or medical staff will undertake an assessment of patient suitability for treatment in the home or community setting. The actual administration of intravenous cytotoxic boluses in this setting will be by an appropriately trained nurse.

The following information should be given to the patient, carer and/or community nurse:
- The name of the drug(s) and dose(s)
- Potential problems and management
- As per (IV-VII) in 17.2.1

The patients understanding of the above will be assessed using a teaching checklist. Additional supplementary written information will also be provided.
19 Education and training

Training of all medical, nursing, pharmacy, portering, domestic, transport and any other staff who handle hazardous drugs or cytotoxic waste is essential. Such staff should understand the potential hazards associated with hazardous drugs and be familiar with relevant procedures. All managers should ensure that staff have completed training as per local Trust policy prior to working with hazardous drugs and that training is up to date and relevant to their role.

20 Implementation

The guideline should be available to all staff working with hazardous drugs for the treatment of malignant disease, within the Trust. Dissemination of the guideline to service groups via Medical Director, Clinical Directors and co-directors for service groups.

21 References

1. Safe Handling of Hazardous Drugs. HSE Information Sheet MISC615.
3. COSHH (NI): A brief guide to the Regulations. What you need to know about Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 (COSHHH (NI)).
12. Northern Ireland Chemotherapy Service Standards.
13. MARCH guidelines (www.marchguidelines.com) (latest access November 2009)

22 Bibliography

1. A Guide to Risk Assessment Requirements. HSE.
5. NMC, 2005 Guidelines for records and record keeping. London. NMC
6. NMC, 2008 Standards for medicines management. London. NMC

23 Consultation process

The first consultation was with the multi professional sub group of the NICaN Pharmacy group and the full NICaN Regional Pharmacy group. The second and final consultation included NICaN Regional Chemotherapy group, Regional Nursing group and NICaN Regional Pharmacy group with onward dissemination to other stakeholders and interested parties.

24 Equality, Human Rights and DDA
The policy is purely clinical/technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

25 Alternative Formats
This document can be made available on request on disc, larger font, Braille, audio-cassette and in other minority languages to meet the needs of those who are not fluent in English.

26 Sources of advice in relation to this document
The Policy Author, responsible Assistant Director or Director as detailed on the policy title page should be contacted with regard to any queries on the content of the policy.
Appendix 1
Guidance on Dosing in Children
UKALL2003 newsletter (Jane Buckham Paediatric Oncology Pharmacists Group)
Sept 2004

“The BMI should be checked at diagnosis and compared to standard Child Growth foundation BMI charts for their respective sex.
For children with a BMI that falls within the 2nd to 98th percentile – dose by actual weight using the UKCCSG weight/surface area charts to determine the surface area for dose calculation.
For children who have a BMI > 98th percentile read off the BMI at 98th percentile for their age. Calculate the dose weight using the formula:
Dosing weight (kg) = BMI xHt^2 (m x m)
Use the UKCCSG Wt/SA charts to determine the SA for dose calculation.
For children < 2nd percentile, repeat as above reading the BMI at the 2nd percentile for calculation.”
Appendix 2
Advice for patients and carers for the disposal of cytotoxic waste and management of cytotoxic spillages in the home

This leaflet contains the answers to some questions patients and carers may have about the disposal of cytotoxic waste and the management of a cytotoxic spillage in the home.

General information

• Keep all cytotoxic medication in a safe place according to the storage instructions on the product label (refrigerator or at room temperature).
• Ensure that all medicines, administration equipment and sharps or burn bins are out of the reach of children or pets & temporary locking mechanisms are activated.
• If you are the carer, and are pregnant, think you may be pregnant or are breast feeding, it is preferable that you do not handle cytotoxic drugs, or waste, unless absolutely necessary.
• Always wash your hands thoroughly after handling cytotoxic drugs or waste & upon removing personal protective equipment.

Disposal of cytotoxic waste

How should I dispose of empty medicine containers/bottles?

• Empty chemotherapy medicine bottles and cartons can be disposed of in household waste. Liquids, tubes or ointment jars should be returned to the treatment unit for disposal. Put lids / caps on the containers before discarding or returning.
• Medicine spoons, syringes and cups used to give oral chemotherapy should be washed and discarded in household waste after the course of treatment has been completed.

How should I dispose of intravenous infusion devices/bags and/or syringes?

• Empty infusion devices, bags or syringes that are used for the administration of cytotoxic drugs should be disposed of in a purple top burn bin. These bins will provided by the hospital.
• Once the purple top burn bin is ‘three-quarters’ full, it should be sealed and returned to the hospital ward/clinic on your next visit.
What should I do with unused cytotoxic medicines?

• All unused cytotoxic medication (tablets, capsules, oral liquids, ointments, infusors, and syringes for intravenous administration) should be returned to the hospital pharmacy department, or ward/clinic. They should NOT be flushed down the toilet or thrown away in household waste.

How should body fluids be disposed of?

• Urine, stools and vomit can contain cytotoxic drugs, or their breakdown products, for as long as seven days after a patient has received treatment.
• Therefore, it is important that patients/carers wear gloves when handling urine, stools, vomit, contaminated bed linen and nappies for seven days following treatment. You should either use the gloves provided by the hospital, or a pair of rubber household gloves kept especially for this purpose.
• Gloves should be changed immediately if torn or contaminated.
• The contents of vomit bowls/bedpan/urinals should be flushed down the toilet with the lid down, and the toilet should be double flushed. Any disposable containers should then be double bagged and disposed of in the household waste. Non-disposable containers should be washed thoroughly in warm soapy water.
• Nappies and gloves should be double bagged and disposed of in the household waste.
• Contaminated bed linen and clothes should be washed separately to other items. Contaminated bed linen should be washed twice where possible. The first wash should be separate from other clothing. The bed linen may then be washed with other items for the second wash.

Management of liquid cytotoxic spillages

General Information

• Any liquid spillages of cytotoxic drugs onto the floor, or on your clothes or skin should be dealt with immediately to minimise potential harm to yourself or other people.
• You must wear gloves when dealing with a chemotherapy spillage. Make sure that they are not damaged, torn or split. Keep a separate pair of gloves for dealing with a spillage and an extra pair in case the other ones get damaged. If you have been provided with a spillage kit, use the contents of the kit for spillage.
• You should contact your treatment unit to report the spillage and seek further advice.
What should I do if there is a cytotoxic spillage on work surfaces, furniture or floors?

• Cover the spillage using absorbent paper towels or absorbent pad provided in spillage kit, and ensure that all the liquid has been mopped up. The work surface, furniture or floor should then be wiped clean using warm soapy water (i.e. washing up detergent) as soon as possible using gloves & equipment provided in your home spillage kit. This washing process should be repeated.
• All used absorbent towels should be disposed of in cytotoxic burn bin provided.
• Follow the instructions you have been given in your home spillage kit.
• For soft furnishing i.e. mattress an individual assessment should be made regarding the appropriateness of cleansing or disposal.

How should I deal with a cytotoxic spillage onto the skin?

• Wash the area with plenty of tap water. This should then be repeated using warm soapy water, and the area gently dried.
• Do not apply any moisturising cream or hand cream on the affected area.
• If redness or irritation lasts for longer than a few hours, contact your GP or ward/clinic/patient helpline.

How should I deal with a cytotoxic spillage in the eyes?

• Immediately flush the eyes and the surrounding areas with large volumes of cool tap water. This should be done for at least ten minutes.
• Go to your nearest Accident & Emergency Department as it is important that you seek medical attention for any spillages into the eye.

How should I deal with a cytotoxic spillage onto clothing/bed linen etc?

• Wearing a pair of gloves, blot dry with a paper towel or absorbent pad from spillage kit and remove the contaminated clothing immediately.
• The clothes/linen should be washed separately from other clothing as soon as possible. Where possible, repeat the wash cycle to ensure all drugs are completely removed.
• If the drug has soaked through the clothes to the skin, this should be dealt with as outlined above.
If you are in any doubt, please contact your treatment unit or the patient helpline where you are receiving treatment.

24 hour contact number _______________________________

(Individual areas to complete)