



Cytotoxic Drug Policy

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Table of Contents

1	Rationale.....	5
2	Aim.....	5
3	Definition.....	5
4	Roles and Responsibilities	6
4.1	Chief Executive.....	6
4.2	Medical Director	6
4.3	Responsibility of Staff	6
5	Clinical Governance	6
5.1	Consent for Treatment.....	6
5.2	Off Protocol Prescribing.....	6
5.3	Requirements for Prescriptions	8
6	Health and Safety	10
6.1	Introduction	10
6.2	Staff monitoring.....	11
6.3	Personnel Records	12
6.4	Pregnancy and Breastfeeding	12
6.5	Monoclonal Antibody (MAbs) (Ref. NHS QA)	14
6.6	Control of Exposure to cytotoxic drugs.....	14
6.7	Disposal and Decontamination of Personal Protective Equipment.....	18
6.8	Needlestick Injuries.....	19
6.9	Personal Contamination Accidents.....	19
7	Prescribing and Administering Chemotherapy.....	20
7.1	Introduction	20
7.2	Prescribers Responsibility (including non-medical prescribers).....	21
7.3	Pharmacists' Responsibility.....	25



7.4	Nurses Responsibility	27
7.5	Facilities and Equipment	28
7.6	Administration of Intravenous Chemotherapy	29
7.7	Peripheral Venous Cannulation	30
7.8	Central Venous Catheters	31
7.9	Sequencing of Drugs	32
7.10	Monitoring Access Sites	32
7.11	General Principles of Intravenous Administration.....	33
7.12	Administration of Vesicant Drugs	35
7.13	Administration of Irritant Drugs.....	35
7.14	Administration of Non-Vesicant Drugs	36
7.15	Extravasation.....	36
8	<i>Prescribing, Dispensing and Administration of Oral anti-Cancer Medicines.....</i>	36
8.1	Principles of Safe Practice	37
8.2	Prescribing.....	37
8.3	Prescription Verification, Dispensing and Labelling.....	37
8.4	General Guidelines for Handling and Administration of Oral Formulations	39
8.5	Spillage	40
8.6	Patient Education and Information.....	40
8.7	Purchasing.....	41
8.8	Pharmacy Cytotoxic Preparation Services	41
8.9	Out of Hours preparation of Chemotherapy Doses.....	42
8.10	Storage in Clinical Areas.....	42
8.11	Transportation	42
8.12	Disposal of Waste.....	43
8.13	Used Disposable Equipment	43



8.14	Contaminated Non-Disposable Equipment/Items.....	43
8.15	Protective Clothing and Wipes.....	44
8.16	Part Used Injectable Doses	Error! Bookmark not defined.
8.17	Unused Oral Doses.....	44
8.18	Patient Waste/Body Fluids.....	44
8.19	Soiled Bedding / Linen	45
8.20	Nappies	45
9	<i>Use of Vinca Alkaloids.....</i>	45
9.1	Rationale	45
9.2	Administration of Injectable Vinca Alkaloids	46



1 Rationale

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

The term “cytotoxic drug” is generally used to refer to any agent that may be genotoxic, oncogenic, mutagenic or teratogenic. The health risk of any procedure involving cytotoxic 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.

Cytotoxic administration must be provided by a multidisciplinary team in which doctors, specialist nurses and pharmacists work to approved written protocols to provide integrated care both within the hospital and the community.

2 Aim

The handling and administration of cytotoxic drugs are hazardous potentially to the Health care 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.

This policy aims to minimise these risks by promoting the safe handling and administration of cytotoxic drugs. It should be read in conjunction with other relevant policies. The policy has been written using best available evidence and practice, and will be reviewed as other guidance and evidence becomes available.

This document is aimed primarily at staff delivering chemotherapy for patients with malignant disease. It does not deal with cytotoxic chemotherapy specifically for any other indication including that for immunosuppression purposes or for the treatment of non-malignant disease, e.g. methotrexate for rheumatoid arthritis. Individual Trusts should, where necessary develop supplementary policies and guidelines to cover these circumstances and it is recommended that the principles outlined in this document should be used to inform those policies.

3 Definition

For the purposes of this document, the term cytotoxic drug is used to refer to all drugs with direct anti-tumour activity including conventional anticancer drugs, monoclonal antibodies and partially targeted treatments (e.g. Imatinib, Sunitinib) and drugs such as Thalidomide. Relevant drugs are listed in the most recent version of the British National Formulary (BNF) Pharmaceutical Press, Section 8.1. Drugs affecting the immune response, including antiproliferative immunosuppressants,



are listed in section 8.2. of the BNF. If in doubt, refer to the Summary of Medical Product Characteristics available at www.medicines.org.uk for the individual drug concerned.

4 Roles and Responsibilities

4.1 Chief Executive

The Chief Executive has responsibility to ensure that the Trust has a policy for the Safe Handling, Prescribing and Administration of Cytotoxic drugs.

4.2 Medical Director

The Medical Director has responsibility for this Policy at Board level.

4.3 Responsibility of Staff

4.3.1 The Trust Drug & Therapeutics Committee has responsibility for this Policy

4.3.2 The Trust Chemotherapy Committee is responsible for the review of this Policy.

4.3.3 For roles and responsibilities of staff following this Policy see Section 7 below, Prescribing & Administration

5 Clinical Governance

5.1 Consent for Treatment

5.1.1 All patients receiving chemotherapy should be fully informed of their treatment and must have given full written consent, See Trust Consent Policy for further details.

5.1.2 Consent should usually be documented on the appropriate form.

5.1.3 If a change in chemotherapy regimen is necessary, patients should be re-consented, after having received regimen specific details. This should be documented as above.

5.1.4 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 the Principal Treatment centre or their relevant Paediatric Oncology Shared Care unit (designated Level 1, 2 or 3 under the review of paediatric oncology services).

5.2 Off Protocol Prescribing

In exceptional circumstances, it may be necessary to treat a patient with a chemotherapy regimen not on the e-prescribing system (MOSAIQ). Protocols on



MOSAIQ (not marked as Off Protocol) form the current list of accepted Chemotherapy regimens. MOSAIQ contains a number of protocols that are marked as Off Protocol. Exceptional circumstances requiring an Off Protocol prescription may arise for instance:

- 5.2.1** Current available regimens do not meet the clinical need of the patient, e.g. toxicity profiles of existing regimens are incompatible with the patients' clinical condition.
- 5.2.2** The route of administration of an existing regimen is inappropriate or inaccessible.
- 5.2.3** Chemotherapy regimens not on MOSAIQ for the particular tumour site are referred to as "Off protocol regimens".
- 5.2.4** If an "Off protocol" regimen is to be used the Consultant must document the intended regimen in the patient's healthcare record this must include the following details:
 - 5.2.4.1** The name of each drug.
 - 5.2.4.2** The intended dose of each drug in milligrams or units per m² or per kilogram. For Carboplatin the desired AUC should be quoted.
 - 5.2.4.3** The schedule on which each drug is given.
 - 5.2.4.4** The route of administration of each drug.
 - 5.2.4.5** The overall length (in days) of each cycle as well as the interval between cycles
 - 5.2.4.6** The total number of cycles to be given.
 - 5.2.4.7** The reason for prescribing a protocol not included on the current Chemotherapy regimens list.
 - 5.2.4.8** It is recommended that monitoring Tests (e.g. Full Blood Counts (FBC), Biochemistry and tumour markers) should be specified for the regimen and intervals also stated dose modifications for out of specification results should also be stated for when results of tests may be outside normal limits.
 - 5.2.4.9** An Off Protocol form must be completed, this can be found at either
<http://ycloud/teams/Pharmacy/civas/SitePages/Home.aspx>
or



<http://www.aswcs.nhs.uk/main.cfm?type=CHEMO&objectid=2725>

- 5.2.4.10** The treatment schedule should be discussed with an Oncology trained pharmacist. Where available, any published protocol details should be provided to pharmacy.
 - 5.2.4.11** For new drugs, five working days should be allowed from the approval of the off protocol regimen to allow pharmacy time to source the drug and arrange worksheets.
 - 5.2.4.12** The Regimen should be discussed with the lead Chemotherapy Nurse to ensure all nursing and administration concerns are addressed.
 - 5.2.4.13** An Off Protocol Form specifies details to enable all healthcare professionals responsible for the patient's care to have appropriate information in order to deliver safe and effective treatment.
 - 5.2.4.14** If there are funding/formulary implications with the use of the Off protocol regimen, the Trust funding/formulary approval processes must be considered and followed, as appropriate, before the Off Protocol Regimen form is completed.
- 5.2.5** A minimum of 2 copies of the completed Off Protocol form should be made.
 - 5.2.6** A copy should be kept in the patient's healthcare record, the second copy should be sent to the Head of the Clinical Chemotherapy service or the Lead Oncology Pharmacist who should then table this for discussion at a future meeting of the local chemotherapy group.
 - 5.2.7** Once approved the Lead Oncology Pharmacist will add the Off protocol form and evidence to the Off Protocol section of the CIVAS YCloud page <http://ycloud/teams/Pharmacy/civas/SitePages/Home.aspx>
 - 5.2.8** Application for regular use of a new chemotherapy regimen must be proposed by the treating consultant, providing evidence to the lead cancer services pharmacist to author the protocol. This should then be ratified by the lead chemotherapy clinician.

5.3 Requirements for Prescriptions

- 5.3.1** For the purposes of this document the term prescription will also refer to "Patient Specific Directions" as defined by the Department of Health



5.3.2 Prescriptions for cytotoxic drugs must be complete, clear and simple to follow. Each Prescription should contain the following:

- 5.3.2.1** Date prescribed
- 5.3.2.2** Patient name, date of birth, hospital number and/or NHS number as appropriate.
- 5.3.2.3** Patient's weight, height (where appropriate) and BSA. (N.B. Height is not necessary for paediatric prescriptions.)
- 5.3.2.4** Allergy status, always declare if "No known allergies"
- 5.3.2.5** Ward / clinic.
- 5.3.2.6** Consultant name
- 5.3.2.7** Protocol code, regimen name or clinical trials name and randomisation arm and randomisation number (where appropriate).
- 5.3.2.8** Disease site and indication
- 5.3.2.9** Cycle or course number
- 5.3.2.10** Name of drug - use approved generic drug names; no abbreviations
- 5.3.2.11** The individual dose must be written in mg or units and target AUC for carboplatin
- 5.3.2.12** The frequency per day and the number of days of treatment
- 5.3.2.13** Route of administration (the abbreviations IT or IP is not acceptable, intrathecal, intraperitoneal or intrapleura must be written in full)
- 5.3.2.14** For Infusions, details of solution and volume
- 5.3.2.15** Duration of infusion and any other administration instructions
- 5.3.2.16** Starting dates (and times when appropriate).
- 5.3.2.17** Antiemetics, hydration and any additional drugs as defined by the protocol
- 5.3.2.18** Reason for any dose modifications



- 5.3.3** Prescriptions for oral chemotherapy must 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 see Oral anti-Cancer medicines (Section 8) of this Policy for recommendations for oral chemotherapy.
- 5.3.4** Oncology, haematology and paediatric haematology and oncology staff should prescribe cytotoxic drugs for patients using the MOSAIQ prescribing system. Unless circumstances permit for alternative arrangements discussed with a cancer services pharmacist and lead Macmillan nurse.
- 5.3.5** Printed copies of prescriptions generated via an electronic prescribing system should comply with all the criteria specified above
- 5.3.6** Electronic systems used for the prescribing, preparation and administration of cytotoxic drugs should have:
- 5.3.6.1** Secure mechanisms to guarantee the security of access to those healthcare professionals alone who are competent to take part in the prescribing, clinical screening, preparation and administration of cytotoxic drugs
 - 5.3.6.2** Clear audit trails for recording who has taken part in the provision of cytotoxic drugs, from the prescriber, to the pharmacy clinical screening and preparation to the administration by nursing staff
 - 5.3.6.3** Where the whole process of prescribing, clinical screening and administration of cytotoxic chemotherapy is recorded electronically (i.e. there is no paper based recording of any part of the process), the system should provide all the relevant details listed above, in a manner that does not introduce new risks to the process.
- 5.3.7** Contingency plans for when the electronic prescribing system is not available are under review. In the event that the electronic prescribing system is not available consult the lead chemotherapy clinician or lead cancer services pharmacist.
- 5.3.8** Prescriptions for intrathecal administration are not to be compounded or administered

6 Health and Safety

6.1 Introduction



- 6.1.1** Cytotoxic drugs interfere with cell division, but as this action is not specific to tumour cells, normal cells may also be damaged. As a result, they can produce significant side effects in treated patients, or others exposed. This, together with the increasing complexity of chemotherapy, has raised concerns about the risks to health care workers involved in the preparation and administration of chemotherapy and/or the caring of patients undergoing treatment.
- 6.1.2** For healthcare personnel the potential of 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 must be aware of all health and safety procedures. This applies to clinicians, nursing staff, pharmacy staff, domestic staff in the relevant pharmacy and clinical areas, and portering staff carrying cytotoxic drugs or cytotoxic waste.
- 6.1.3** 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, drinking or smoking 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 (reference 3).
- 6.1.4** Some cytotoxic drugs can cause acute or short term health effects including irritation to the skin, eyes and mucous membranes.
- 6.1.5** Information on chronic, or long-term, health effects of cytotoxic 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.
- 6.1.6** 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 must be emphasised that these reports relate to exposure occurring prior to the introduction of cytotoxic drug handling precautions and guidelines. The adoption of improved handling techniques and the use of isolators has reduced the potential for exposure to cytotoxic drugs significantly.

6.2 Staff monitoring

- 6.2.1** All relevant new employees, as outlined above, should receive an orientation to the current Cytotoxic Policy as soon as possible after commencement of employment.



6.2.2 COSHH 2002 states that if a risk cannot be eliminated, a staff surveillance programme must be implemented. 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 (reference 6). Hence, the primary focus of safety during the preparation and administration of cytotoxic drugs must be on control of the working environment, minimising exposure and safe practice.

6.3 Personnel Records

6.3.1 Managers responsible for these posts should keep a record of drug exposure for each member of staff in accordance to the Health and Safety Executive (HSE). In the absence of any guidance, it would be good practice to include Monoclonal antibodies (MAb's) and Gene therapy products.

6.3.2 In the absence of defined limit of cytotoxics detected by staff or environmental monitoring, staff record should also be kept detailing all deviation from working standards e.g. accidental exposure due to spillage.

6.4 Pregnancy and Breastfeeding

6.4.1 There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to. As some pregnancies are unplanned, or staff unwilling to discuss plans for conception the emphasis must be on the reduction of exposure to all staff at all times. There have been some studies suggesting adverse effects on the foetus, as a result of the mother working with cytotoxic drugs. Many of these studies, however, were carried out, or based on exposure during the 1980's, at a time when the use of personal protective equipment and safety isolators was not well established. Some later studies have failed to find a significant association with foetal adverse effects.

6.4.2 As the pre-conception period is not included in any health and safety advice, managers must ensure that a COSHH (Control of substances Hazardous to Health) assessment is carried out in all areas where cytotoxic drugs are handled. In order to assess the level of risk and the adequacy of control measures in place. Directions on how risk assessments can be completed can be found at <http://www.hse.gov.uk/risk/index.htm>. The risk assessment should assume that there may be a new or expectant mother working in the environment in the following twelve months. Precautions must be in place at all times to minimise exposure by using protective garments, appropriate equipment as well as safe and validated work practices. This applies to both



male and female staff exposed to both investigational agents and licensed drugs.

- 6.4.3** This policy, along with other Trust policies and procedures aims to reduce the risk of exposure to these drugs as far as possible. However, as there is no known limit where exposure is thought to be safe, employees must be fully informed of the potential reproductive risks.
- 6.4.4** Employees should notify their managers as soon as possible if they are pregnant, trying to conceive or are breastfeeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. This is also to comply with HSE guidance where all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.
- 6.4.5** At the point where an employee discloses pregnancy, a risk assessment specific to the individual should be carried out and any appropriate action taken.
- 6.4.6** All staff should be fully informed of the reproductive risks by:
 - 6.4.6.1** Receiving verbal and written information on induction
 - 6.4.6.2** Signing to say they have read and understood the relevant risk assessments
 - 6.4.6.3** Providing opportunity for discussion of any concerns
 - 6.4.6.4** Any risk assessment carried out should follow local policy and signed and dated by all relevant parties
- 6.4.7** Pregnant or breastfeeding staff will be expected to make an informed choice about working with cytotoxic drugs. Staff who choose not to work with cytotoxic drugs will not be expected to be involved in directly preparing or administering chemotherapeutic agents or handling waste from patients treated with chemotherapy. If appropriate, the line manager and Human Resources Department will agree any new temporary arrangements together with the member of staff and ensure that she is adequately supported during her pregnancy. The Human Resources Department will be consulted if no suitable alternative employment is found.
- 6.4.8** New, expectant and breastfeeding mothers should be specifically advised against any direct involvement in the management of a cytotoxic drug spillage.



6.4.9 Safe handling procedures must be audited and documented on a regular basis to ensure staff compliance and to reduce risks to as low a level as is reasonably practicable.

6.5 Monoclonal Antibody (MAbs) (Ref. NHS QA)

6.5.1 Monoclonal antibodies affect a wide range of biological functions and staff handling them should be aware of the nature of each product and specific associated problems. As these agents may contain material of animal origin, they are potentially biohazard and direct handling should be minimal and protective clothing worn to the same level as for traditional cytotoxic medicines. There is also a theoretical risk of operator sensitisation as MAbs are proteinaceous in nature and staff should be made aware of this.

6.5.2 The preparation of MAbs should be individually risk assessed, taking into account the allergic potential based on the origin of the MAbs and toxicities arising from the therapeutic use (Ref. Langford S et al. Hospital Pharmacist 2008; 15: 60-64). Together with the NPSA risk assessment tool for intravenous medicines, an overall risk could then be used to decide whether manipulation should be within an aseptic unit (high risk) or permitted in a clinical area. There is a local guideline and procedure in place on the safe handling of MAbs.

6.5.3 Gene therapy or gene transfer therapy is often confused with MAbs and the safe handling of this agent is outside the scope of this document. It generally involves deliberate introduction of genetic material into somatic cells for therapeutic, prophylactic or diagnostic purposes. There are cases of viral vector gene therapy that can be infective and should not be manipulated in clinical areas.

6.6 Control of Exposure to cytotoxic drugs

The following guidance applies for all staff handling cytotoxic drugs during administration of treatment, handling of patient waste and cleaning of spillage.

6.6.1 Recommended Good Practice

Work should be organised to minimise quantities of drugs used.

6.6.1.1 The number of employees potentially exposed and duration of exposure should be kept to a minimum.

6.6.1.2 All staff should ensure the safe handling, storage and transport of cytotoxic drugs and waste material containing or contaminated by them.



6.6.1.3 Good hygiene practices and suitable welfare facilities should be provided to ensure eating, drinking & smoking are prohibited in all areas where cytotoxic drugs are handled

6.6.1.4 Staff working with cytotoxic drugs must be trained on the risks and precautions to take

6.6.2 Minimising Exposure – PPE

6.6.2.1 A full COSHH risk assessment must be undertaken in all areas handling cytotoxic drugs. Directions on how risk assessments can be completed can be found at <http://www.hse.gov.uk/risk/index.htm>. These risk assessments should define the specific PPE to use in each activity where cytotoxic drugs are handled.

6.6.2.2 Personal Protective Equipment (PPE) to be Used When Handling Cytotoxic Drugs

6.6.2.3 It is important to ensure PPE offers adequate protection and is designed specifically for handling cytotoxics. PPE with 'CE' marking (in accordance with Directive 93/68/EEC) satisfies the essential requirements of the relevant European health, safety and environmental protection legislation.

6.6.2.4 The correct use of PPE can shield staff from exposure to cytotoxic drugs and minimise the health risks but only if the following criteria are met, the PPE is:

- Suitable for the task
- Suited to the wearer and the environment
- Compatible with other PPE in use
- In good condition
- Worn correctly

6.6.2.5 Pharmacy staff preparing cytotoxic drugs within pharmacy preparation units will wear personal protective clothes as defined by local standard operating procedures. Employers need to ensure that staff are trained in the use of PPE and that the PPE is adequately maintained and stored.

6.6.2.6 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. Specific and individual staff needs, may dictate the use of further supplementary protection.



6.6.3 Gloves:

- 6.6.3.1** 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.
- 6.6.3.2** Hands must be washed thoroughly with liquid soap/detergent or alcohol gel before and after glove application.
- 6.6.3.3** Gloves must be worn at all times appropriate to the task being undertaken.
- 6.6.3.4** 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 9 below.
- 6.6.3.5** Consideration needs to be given as to whether the procedure requires sterile or non-sterile protective gloves.
- 6.6.3.6** They should fit appropriately, be close fitting to ensure dexterity. Individual practitioner's preferences should be considered with regard to sensation and dexterity.
- 6.6.3.7** Only gloves designed for handling cytotoxic chemotherapy should be used and it should not be assumed that all gloves are impermeable. Nitrile and latex gloves both offer good protection from cytotoxic contamination, but nitrile gloves should not be used when handling Etoposide. Specific gloves to be used will be defined in Trust standard operating procedures (SOPs).
- 6.6.3.8** Gloves should always be disposable and preferably powder free.
- 6.6.3.9** Gloves should be worn at all times when contact with cytotoxic drugs is possible.
- 6.6.3.10** Gloves should be changed regularly, always between patients and immediately after they become damaged or contaminated.



6.6.3.11 For spillages, industrial thickness gloves (> 0.45mm) made of latex or neoprene, nitrile or synthetic rubber is recommended. Alternatively double latex or nitrile gloves can be used.

6.6.4 Eye Protection

6.6.4.1 The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavitary administration and when clearing up cytotoxic spillages.

6.6.4.2 Eyewash kits and spillage kits must be readily at hand for use in all areas where handling of cytotoxic drugs occurs.

6.6.4.3 Eye protection should fully enclose the eyes and comply with BS EN166.

6.6.4.4 Eye protection should be disposable, where possible or capable of undergoing decontamination cleaning.

6.6.5 Plastic Aprons

6.6.5.1 Disposable plastic aprons will provide limited protection and prevent absorption into clothing when used where splashing or spraying is possible.

6.6.5.2 Disposable gowns are preferable, they should:

- Have a closed front, long sleeves and elastic or knitted cuffs
- Be made of low permeability fabric for example saranex/tyvek laminated material or spun bonded polypropylene laminated with polyethylene.
- Laboratory coats must not be used.

6.6.6 Respiratory protection

6.6.6.1 Surgical masks do not offer protection against inhalation of fine dust or aerosols.

6.6.6.2 When solid or liquid particles are a risk, an FFP2 or FFP3 filtered face piece respirator should be used.

6.6.6.3 Inhalation is not a significant risk for staff administering prepared cytotoxic drug doses. Therefore, staff are not required to wear masks during administration.

6.6.6.4 Respiratory protection should be used when dealing with a cytotoxic spillage.



6.6.7 Protective equipment to be used in the event of a cytotoxic spillage: Refer to section 6.10 below regarding spillage.

6.6.8 Recommendations for PPE in handling activities:

Activity/PPE	Gloves	Gown/Apron	Eye Protection	Respiratory
Receipt of Raw Materials	✓	✓		
Setting up/Checking	✓	✓		
Preparation	✓	✓**		
Administration	✓	✓	✓*	
Waste Disposal	✓	✓	✓	✓
Spillage	✓	✓	✓	✓

*Recommended when there is a risk of spraying, splashing or aerosols

**Recommended if preparation is not taking place in closed containment technology

6.7 Disposal and Decontamination of Personal Protective Equipment

6.7.1 All aprons, gowns, gloves and disposable personal protective clothing should be disposed of according to the guidelines in section 9 below.

6.7.2 Reusable equipment (eyewear and respirators) may be cleaned thoroughly with mild detergent and water before reuse.



6.8 Needlestick Injuries

See Trust policy on needlestick injury

6.9 Personal Contamination Accidents

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

6.9.1 Skin

6.9.1.1 Remove any contaminated clothing immediately.

6.9.1.2 The contaminant must be removed as quickly 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.

6.9.1.3 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.

6.9.1.4 In the event of a needlestick injury, encourage the area to bleed. Shower facilities should be used if large areas of skin are contaminated.

6.10 Spillage

6.10.1 Spillage kits are kept on the Macmillan Unit, each kit contains instructions on the use of the kit.

6.10.2 The instructions in the spillage kit should be followed.

6.10.3 All contaminated waste should be placed in a cytotoxic burn bin and disposed of in accordance with the Trusts Waste Disposal Policy.

6.10.4 After clearing the spillage a replacement spillage kit must be ordered through the Integra Finance ordering system.

6.10.5 A Trust Incident form should then be completed.



6.11 COSHH

6.11.1 The lead pharmacist and COSHH advisor for the Trust meet annually to review the service against the current COSHH regulations. Any recommendation as a result of the review will be made known to the Clinical Governance Manager.

7 Prescribing and Administering Chemotherapy

7.1 Introduction

7.1.1 Chemotherapy administration should only be given in named designated clinical area/s where it has been agreed as part of the service level agreement (Department of Health, 2004). An operational policy should indicate what type of clinical activity takes place within the service.

7.1.2 Administration of cytotoxic drugs via all routes must be carried out by nursing or medical staff who have been trained and assessed as competent according to Network agreed competency framework. Competency should be assessed annually. A register should be maintained which details the staff that are authorised to administer chemotherapy intravenously unsupervised (Department of Health, 2004).

7.1.3 Staff administering cytotoxic drugs must have current general knowledge of the drugs being given. They should be aware of the correct administration procedure, following an agreed protocol. They should be aware of possible immediate, short and long term systemic and local side effects and the actions to be taken if these occur. They should also be aware of patients educational, psychological, supportive care needs and overall treatment plan.

7.1.4 Staff who are undergoing their chemotherapy training may only give chemotherapy under the direct supervision of authorised staff.

7.1.5 Double-checking of chemotherapy doses is recommended as best practice (Nursing and Midwifery Council, 2008). Prior to administration the nurse or doctor who will be administering the chemotherapy should check the chemotherapy with a registered IV competent nurse, doctor or pharmacist familiar with chemotherapy administration. Neither professional should have been involved in the dispensing process. Likewise cannulation of a patient for intravenous chemotherapy should be carried out by a staff member who has been trained and assessed as competent.



7.2 Prescribers Responsibility (including non-medical prescribers)

- 7.2.1** The decision to initiate chemotherapy treatment should be made by a consultant and the patient's treatment should be discussed at an appropriate Multidisciplinary team meeting (MDT).
- 7.2.2** Only appropriately qualified and competent Consultant Medical Oncologists, Clinical Oncologists, Haematologists, Paediatric Oncologists, Staff Grades, Associate Specialists may initiate the first course and prescribe the first cycle of chemotherapy for the treatment of cancer patients.
- 7.2.3** The prescriber should inform the patient's general practitioner of the intention to start the course of chemotherapy and provide sufficient information for action to be taken in the event of the patient experiencing side effects.
- 7.2.4** Prescribing of second or subsequent cycles may be delegated to Specialist registrars in training (ST3 or above), non-medical independent or supplementary prescribers who have completed the necessary training and are registered with their professional body and are authorised by their Trust to prescribe within their competence. Delegation of this responsibility is only permitted if the relevant consultant has given clear written details of the patients' treatment plan, documented in the patient's healthcare record and that the regimen being prescribed is included in the Network/Trust agreed list of regimens. If modifications of doses are required, the Consultant or the Specialist Registrar in training (ST3 or above) must document this in the healthcare record.
- 7.2.5** It is recommended that cytotoxic medicines should only be prescribed by medical staff, or non-medical independent or supplementary prescribers who have completed the necessary training and are registered with their professional body and are authorised by their Trust to prescribe within their competence. All these prescribers should have completed the Trust/Network training programme and be accredited to prescribe chemotherapy.
- 7.2.6** Medical doctors who are provisionally registered with the GMC (FY1) MUST NOT prescribe chemotherapy, for the treatment of malignant disease.
- 7.2.7** For patients admitted to YDH on cytotoxic medicines for a cancer diagnosis, prescribing on an in-patient prescription card should only be done by a consultant haematologist or oncologist. If a consultant haematologist or oncologist is unavailable cytotoxic medicines can be prescribed after verbal confirmation that treatment is appropriate for the patient. A record of this verbal confirmation should be made in the patients' medical notes.



- 7.2.8** Non-medical prescribers authorised to prescribe medicines within the individual Trust will be included on a Trust register of non-medical prescribers
- 7.2.9** Non-medical prescribers must comply with the Trust medicines policy and related codes of practice.
- 7.2.10** Non-medical prescribers may only prescribe medicines for NHS patients under the care of the Trust within the speciality in which they have demonstrated competence.
- 7.2.11** Non-medical prescribers will be expected to recognize those situations where it is inappropriate for them to prescribe.
- 7.2.12** The independent prescriber must obtain the patient's verbal consent before prescribing any medicine.
- 7.2.13** The non-medical Independent Prescriber is responsible and accountable for:-
- The assessment of patients with diagnosed or undiagnosed conditions and for decisions about the clinical management required, including prescribing.
 - Accepting professional accountability and clinical responsibility for their prescribing practice
- 7.2.14** Non-medical independent prescribers can prescribe within their competence, any licensed medicine for any medical condition. They can also prescribe medicines for "off-label" use where this is part of accepted clinical practice. The "off-label" uses should be listed either within the BNF or the Trust formularies and not be specifically restricted. Independent prescribers cannot prescribe unlicensed medicines.
- 7.2.15** Nurse independent prescribers can prescribe controlled drugs within their scope of practice
- 7.2.16** Pharmacist independent prescribers can prescribe controlled drugs within their scope of practice
- 7.2.17** In the case of supplementary prescribing written consent is obtained by the patient signing the clinical management plan before any prescribing activity takes place.
- 7.2.18** The supplementary prescriber is accountable and responsible for:
- Prescribing within the limits of the Clinical Management Plan (CMP)



- Ensuring that patients are aware of the scope and limits of supplementary prescribing and how the patient can obtain other items necessary for their care. 210 Altering the medicines prescribed, within the limits set out in the CMP, if monitoring of the patient's progress indicates that this is clinically appropriate.
- Monitoring and assessment of the patient's progress as appropriate to the patient's condition and the medicines prescribed.
- Consulting the independent medical prescriber as necessary.
- Accepting professional accountability and clinical responsibility for their prescribing practice.
- Recording prescribing and monitoring activity contemporaneously in the common patient record.

7.2.19 Supplementary prescribing must be supported by regular clinical review of the patient's progress by the independent medical prescriber, at pre-determined intervals appropriate to the patient's condition and the medicines to be prescribed

7.2.20 A supplementary prescriber can prescribe within their competence, any medicines stated in the CMP including controlled drugs, and unlicensed ("off-label") uses of licensed medicines.

7.2.21 The Clinical Management Plan (CMP) is a legal requirement of supplementary prescribing.

7.2.22 A clinical management plan (CMP) must be prepared and agreed with the patient and the independent medical prescriber before prescribing is undertaken by supplementary prescriber

7.2.23 Checking the allergy status of the patient

7.2.24 Selecting the appropriate regimen from the agreed list of regimens for the tumour site concerned and ensuring correct sequencing for alternating type regimens.

7.2.25 Ensuring that the body surface area (BSA) calculations are appropriate and have been made using a recent weight. If a patient is 30% over their ideal body weight, or body mass index (BMI) is greater than 30, the need for dose reduction or dose capping should be considered.

7.2.26 Where dose banding is approved the prescriber may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels, or indicate on the prescription that dose banding is appropriate for this patient in accordance with local Trust policies.



- 7.2.27** For children, the doses should be calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the UKCCLG (previously the UKCCSG) BSA chart.
- 7.2.28** For obese children, guidelines in the individual protocols should be followed, or the weight for the 97th centile for age should be used.
- 7.2.29** To ensure accurate dosing a maximum of 5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local policy.
- 7.2.30** Prescribing all cytotoxic drugs and supportive therapies including antiemetics and hydration.
- 7.2.31** Ensuring that maximum cumulative doses of anthracyclines and bleomycin have not been exceeded. If these drugs have been given to the patient at other Trusts e.g. tertiary referral to a Cancer Centre from a District General Hospital, the referring unit should provide information on cumulative doses already received, as appropriate.
- 7.2.32** Specifying the route of administration and for parenteral doses, the duration of infusion on the prescription, if necessary.
- 7.2.33** Ensuring the patient has appropriate venous access prior to prescribing infusions of vesicants.
- 7.2.34** Ensuring there is an appropriate interval between each treatment and cycle, as defined by the protocol.
- 7.2.35** Ensuring the patient is fully informed of their treatment and has given consent.
- 7.2.36** Ensuring the patient is given written information regarding the chemotherapy treatment they will be given.
- 7.2.37** Ensuring that all relevant safety parameters such as complete blood counts, renal and hepatic function have been checked and that the patient is fit to receive treatment. If doses are modified due to variance of these parameters, the reason for dose modification should be recorded on the prescription and in the patient's healthcare record.
- 7.2.38** 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 and/or pharmacy staff.
- 7.2.39** If a patient is to be treated off-protocol, refer to section 5.2 above of this Policy



7.2.40 Wherever possible, chemotherapy should be initiated during normal working hours when access to specialist staff is more likely to be available. Only in exceptional circumstances can chemotherapy be initiated outside of normal working hours. An example of this would be administration on the childrens ward (ward10- Dillington) of cytarabine over the weekend as part of the UKALL2003 or UKALL2011 protocol.

7.2.41 Prescriptions for all cytotoxic drugs should be electronic (or written), not verbal, and changes to any of these prescriptions must be documented electronically or in writing as per local policy. If a prescription is amended, the changes should be signed and dated by the doctor or the pharmacist before the treatment is administered or dispensed.

7.2.42 After the final cycle, within a given course, the prescriber should ensure that there is a treatment record for each patient, stating 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 documented.

7.3 Pharmacists' Responsibility

7.3.1 An appropriately trained pharmacist must clinically screen all prescriptions for cytotoxic drugs prescribed for the treatment of malignant disease.

7.3.2 Prior to a cytotoxic dose being prepared the pharmacist must verify the prescription according to the protocol or treatment regimen, clarify and resolve any discrepancy and check that:

7.3.3 The appropriate regimen/protocol/proforma has been selected, with correct sequencing.

7.3.4 The patient name, date of birth, unit number and NHS number are indicated

7.3.5 The BSA calculations are appropriate for the patient taking into consideration the patient's age and other factors. If a patient is 30% over their ideal body weight, or BMI is greater than 30, the pharmacist will contact the prescriber and discuss possible implications and the need for dose reduction or dose capping.

7.3.6 For children, the doses should be calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the Dubois formula that can be found on the BNF online: <http://www.medicinescomplete.com/mc/bnf/current/PHP18585-body-surface-area.htm>.



- 7.3.7** For obese children, guidelines in the individual protocols should be followed, or the weight for the 97th centile for age should be used.
- 7.3.8** An accurate dose has been prescribed A maximum of 5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local policy.
- 7.3.9** Dose modifications to previous treatments are maintained if appropriate.
- 7.3.10** All cytotoxic drugs and supportive therapies including antiemetics and hydration have been prescribed.
- 7.3.11** Ensuring that maximum cumulative doses for anthracyclines and bleomycin have not been exceeded. If these drugs have been given to the patient at other Trusts e.g. tertiary referral to a Cancer Centre from a District General Hospital, the referring unit should provide information on cumulative doses already received, as appropriate.
- 7.3.12** The route of administration and the duration of infusion have been specified on the prescription.
- 7.3.13** The volume and medium of infusion is appropriate with respect to the patient, protocol and pharmaceutical stability.
- 7.3.14** There is an appropriate interval between treatment and cycles.
- 7.3.15** All relevant safety parameters such as complete blood counts, renal and hepatic function are reviewed and drug doses modified where necessary.
- 7.3.16** The patient is not allergic to any prescribed medicines.
- 7.3.17** The dates for administration of chemotherapy are clearly stated.
- 7.3.18** The prescription has been signed by an appropriate clinician, either in the electronic or written form.
- 7.3.19** Where dose banding is approved the pharmacist may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies.
- 7.3.20** If the prescription is for a new chemotherapy regimen, not included on the current Chemotherapy regimens list, or is prescribed "off protocol" the oncology/haematology pharmacist must discuss the case with the responsible consultant. A copy of an original paper 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. If in any doubt see Section 5.2 for Off Protocol prescribing.

- 7.3.21** Discrepancies exceeding plus or minus 5% of the dose, calculated according to the patient's treatment plan, must be clarified with the doctor unless the protocol specifies otherwise.
- 7.3.22** 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 as per local policy, and any changes will be communicated to other team members as appropriate. The pharmacist will complete a deviation report on the YDH Technical Services database detailing the discrepancy and the resolution

7.4 Nurses Responsibility

- 7.4.1** 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 and the Nursing and Midwifery council (NMC) Guidelines. The nurse is also responsible for handing over of this information to other nursing staff as required to ensure continuity of care.
- 7.4.2** All prescriptions for cytotoxic agents must be checked by a chemotherapy certified nurse. The chemotherapy nurse is responsible for ensuring that:
- 7.4.3** The correct weight and height have been recorded.
- 7.4.4** The BSA calculations are appropriate.
- 7.4.5** An accurate dose has been prescribed. A maximum of 5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local policy. In the absence of a local policy, discrepancies exceeding plus or minus 5% of the dose, calculated according to the patient's treatment plan, must be clarified with the doctor.
- 7.4.6** The appropriate dose banded dose has been selected. Where dose banding is approved the pharmacist may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies. The nurse will administer the dose banded dose and check that the variance is a maximum of 5% from the calculated dose.
- 7.4.7** Dose modifications to previous treatments are maintained if appropriate.



- 7.4.8** All cytotoxic drugs and supportive therapies including antiemetics and hydration have been prescribed.
- 7.4.9** The patient is not allergic to the prescribed medicines.
- 7.4.10** The route of administration and the duration of infusion have been specified on the prescription.
- 7.4.11** Ensuring the patient has appropriate venous access prior to administering cytotoxic drugs.
- 7.4.12** There is an appropriate interval between treatments and cycles.
- 7.4.13** All relevant safety parameters such as complete blood counts, renal and hepatic function, toxicities and patient evaluation are in line with the patient's treatment plan and protocol guidelines.
- 7.4.14** Ensuring that the patient is fully informed of their treatment and has given written consent.
- 7.4.15** Patients should also be assessed for the need of any additional psychological, social or spiritual support.
- 7.4.16** A nurse may NOT accept verbal orders for cytotoxic drugs or for adjustments to doses of cytotoxic drugs.

7.5 Facilities and Equipment

- 7.5.1** Cytotoxic drugs should be administered in a dedicated therapeutic environment with appropriate facilities for safe administration and within safe working levels. The area should also have a regular annual risk assessment undertaken to ensure fit for purpose. This assessment should encompass "Equality Impact Assessments". Annual checks of medical equipment used within the area must be undertaken on an annual basis.
- 7.5.2** Areas designated for the administration of cytotoxic drugs should have all relevant policy and protocol documents available. At Yeovil District Hospital the areas designated for the administration of cytotoxic drugs for the treatment of cancer are:
- Douglas Macmillan Cancer Care Unit (DMCCU)
 - Castleton Day Unit Rooms at the Yeatman Hospital
 - Ward 10 (Dillington) Childrens ward
- 7.5.3** The availability (hours of opening) of the chemotherapy unit is listed in the MacMillan Operational Policy



- 7.5.4** Facilities should include easy access to expert help and all the equipment necessary for the management of emergencies.
- 7.5.5** For storage of cytotoxic drugs within clinical areas see section 8.10.
- 7.5.6** All areas in which cytotoxic drugs are administered must have the following equipment and staff trained to use them:
- Emergency bell
 - Resuscitation equipment (or access to it as defined by local practice).
 - Drugs for the management of emergencies – cardiac arrest and anaphylaxis.
 - Extravasation kit.
 - Cytotoxic spillage kit.
 - Eye wash / access to running water.
 - For the equipment required within a community setting Appendix 2
- 7.5.7** Electronic pumps used to assist administration must 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.
- 7.5.8** Staff should use the Trust governance process and the MHRA for reporting adverse incidents, and act upon MHRA hazard and safety notices.

7.6 Administration of Intravenous Chemotherapy

- 7.6.1** An appropriate vascular access device should be selected by a competent practitioner to fulfil the requirements of the proposed treatment plan and in consultation with the patient.
- 7.6.2** The selection of the appropriate route for venous access should be based on the patient's short – and long-term best interests
- 7.6.3** A practitioner skilled in cannulation and the administration of IV chemotherapy is the key to preventing infiltration and extravasation.
- 7.6.4** When administering drugs intravenously via a peripheral cannula or CVAD, the professional must be knowledgeable about:
- Which patients are at risk of infiltration and extravasation
 - Sequence of the drugs
 - How the rate of administration and route can impact on the risk
 - How to prevent extravasation
 - How to recognize and manage extravasation should it occur



7.6.5 Cytotoxic drugs should NOT be given if there is any doubt regarding the safety of the venous access device.

7.7 Peripheral Venous Cannulation

7.7.1 When inserting the cannula, the professional must be knowledgeable about where to site the cannula, which gauge cannula to use (the smallest possible to accommodate the therapy) and general good practice, such as not cannulating directly below a venepuncture site or failed cannulation attempt when administering vesicants (as there can be a leak from the old site) and 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.

7.7.2 The most appropriate location for a peripheral cannula is considered to be the forearm, although a large straight vein over the dorsum of the hand is preferable to a small vein in the forearm. The superficial veins of the arm 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.

7.7.3 Siting a cannula over a joint, particularly the antecubital fossa, should be avoided as tissue damage following extravasation in this area has very serious consequences. Therefore, the recommendation is that the antecubital fossa should never be used for the administration of vesicants.

7.7.4 Avoid:



- Veins in the lower limbs in adults due to high risk of DVT and increase risk of injury.
- veins close to arteries or deep lying vessels as accidental puncture can cause painful spasm or prolonged bleeding.
- areas affected by invading tumour, haematoma, inflamed or sclerosed areas.
- limbs where there is lymphatic impairment following surgery, chemical occlusion or radiotherapy even if there is no obvious lymphoedema.
- areas proximal to skin lesions or wounds.
- use of dominant arm if possible in order to maintain patient mobility and independence.

7.7.5 The following patients are at increased risk of extravasation and extra caution should be taken with:

- Elderly patients
- Patients with fragile veins
- Patients with thrombocytopenia
- Paediatric patients who do not have a Hickman line or portacath

7.7.6 If there are any doubts regarding cannula patency, recannulate the patient

7.7.7 The use of ported cannulas are not recommended due to their increased infection risk

7.7.8 Site of cannula placement and date should be documented in patients records as per local policy.

7.8 Central Venous Catheters

7.8.1 Where the recipient of therapy has insufficient or unsuitable peripheral veins, infusions are prolonged or venous access becomes difficult, insertion of a central venous catheter may be indicated. Types of CVADs include: peripherally inserted central catheters, skin tunnelled catheters e.g. Hickman and Groshong lines and totally implanted vascular access devices e.g. Bard Port and portacath

7.8.2 Central venous access is the route of choice 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.

7.8.3 It is often assumed that once a patient has a CVAD in place, extravasation will not be a problem. However, the number of CVAD extravasations is estimated at 3-6% (Dougherty 2008). Although the incidence of extravasation is lower with CVADs, detection may be delayed and hence the severity of injury may be greater (Stanley 2002; Polovich et al 2005).



7.8.4 The routine care and maintenance of CVAD should follow local guidelines.

7.9 Sequencing of Drugs

7.9.1 Subject to any sequencing specified on proforma, vesicant cytotoxics should then be given before non-vesicant cytotoxic/non cytotoxic drugs. The exception to this is where patients require supportive therapy e.g. pre-hydration prior to vesicant therapy. If vesicant drugs are given after non-vesicants, the vascular access device site must be monitored more frequently.

7.10 Monitoring Access Sites

7.10.1 This is the key to early detection of infiltration or extravasation. The patient and the vascular access device should be monitored frequently before, during, and after administration for:

- Leakage at the site.
- Venous irritation.
- Phlebitis.
- Flare reaction.
- Allergic reaction.
- Anaphylaxis.
- Extravasation.
- Known side effects.

7.10.2 The nurse must always confirm patency by ensuring there is blood return and by flushing with at least 5-10 mls of 0.9% sodium chloride before administering any vesicant solution or medication.

7.10.3 Since one of the first symptoms of infiltration or extravasation is discomfort at the site of cannulation or burning stinging pain, it is important that the nurse explains to the patient what kind of symptoms to look out for and to report them immediately. Any change in sensation should be verbalized by the patient and checked by the nurse. It may be local irritation and venous spasm, but the early warning provides the opportunity to stop and investigate, and prevent any further leakage of drug into the tissues (Hyde and Dougherty 2008).

7.10.4 To ensure visibility at all times, the appropriate clear dressing should be fixed over the cannula or CVAD as per local policy.

7.10.5 Bandages should not be applied to cannula sites when chemotherapy is in progress.



7.10.6 With a CVAD it should be possible to obtain blood return. If no blood return is obtained from a CVAD, there must be further verification of the patency of the device, as per local policy.

7.10.7 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

7.11 General Principles of Intravenous Administration

7.11.1 Use of aseptic non-touch technique should be maintained throughout intravenous administration (as per local policy).

7.11.2 Systematic site management (including dressings and cleaning of needle free access devices) should follow local policy.

7.11.3 Ensure appropriate protective clothing is worn as per local policy (see section 6.6.8).

7.11.4 Checking should follow procedure previously described in section 5.3. Patient details should be confirmed verbally with the patient/carer, or with their wristband, immediately prior to administration by the person giving the treatment.

7.11.5 Maintain a closed system by using Luer-lock syringes/connections e.g. bionector hubs, for the administration of all cytotoxic drugs.

7.11.6 Check the connections on the giving set for leakage or cracking.

7.11.7 Inspect sealed bags before opening to ensure no spillage has occurred within the bag.

7.11.8 Open the cytotoxic doses directly onto the tray or dressing pack.

7.11.9 Place a sterile gauze swab under the injection port during administration.

7.11.10 Administration should be performed over a sterile towel with waterproof backing to protect skin and surfaces from potential cytotoxic leakage.



- 7.11.11** Do not expel air from syringes. If air is in a syringe, hold it in such a way that the air is up near the plunger when the entire drug is expelled and the air is reached.
- 7.11.12** Ensure blood return is present
- 7.11.13** Where vesicant or irritant drugs are to be given, connect the venous access device to sodium chloride 0.9% or compatible infusion. Maintain fast running infusion throughout administration.
- 7.11.14** Infuse the first 20mls of the flushing solution and ask the patient to report any discomfort.
- 7.11.15** Always insert the giving set into the cytotoxic infusion at waist height to minimise the risk of personnel contamination in the event of a spillage. This should be carried out over a clean tray or yellow clinical waste bag. It is recommended that the bag is in a horizontal position and the port through which the set is placed is not kinked. This reduces the risk of the giving set piercing through the port and causing a leakage.
- 7.11.16** Ensure correct rate of administration. Refer to the protocol, manufacturers guidelines or seek advice from the Haematology/Oncology Pharmacist.
- 7.11.17** Drugs should not be reconstituted to give solutions of higher concentrations than the manufacturers recommendations. Further information may be obtained from the Summary of Product Characteristics or Pharmacy Department.
- 7.11.18** Flush well with appropriate solution in between drugs using either sodium chloride 0.9% or 5% glucose, depending on drug compatibility. If in doubt please contact pharmacy.
- 7.11.19** If the drug is prone to photodegradation, ensure that the infusion solution is covered to protect it from light (See manufacturers guidelines).
- 7.11.20** Maintain regular observation of IV catheter sites for signs of swelling or inflammation, the patient for adverse signs and symptoms and the rate of infusion. The frequency of observation will depend on the drug, duration of infusion and clinical condition of patient, and should be agreed locally.
- 7.11.21** If a special giving set or filter is required, (e.g. paclitaxel), use only those recommended. Failure to use the correct infusion set and/or filter may risk personnel contamination, dose reduction, adverse clinical event for patient and/or litigation.



7.11.22 It is recommended that units minimise the different types of devices used, to minimise confusion and potential for error (see MHRA guidance).

7.11.23 Giving sets should be changed every 48 hours, except for patients undergoing high dose chemotherapy, bone marrow or stem cell transplant when giving sets should be changed every 24 hours.

7.11.24 On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 9.

7.11.25 Record the administration on the prescription sheet, in the medical, nursing notes, and electronic prescribing system if available.

7.12 Administration of Vesicant Drugs

For examples of vesicant drugs see ASWCS website

7.12.1 Ideally vesicants should be given via a newly sited cannula. Ensure that it is patent and bleeds back.

7.12.2 Observe and educate the patient regarding the risks.

7.12.3 Doses of vinca alkaloids for all patients treated in dedicated paediatric settings should be administered from syringes as a bolus, regardless of the age of the patient. Lines should be flushed with at least 10mls of 0.9% sodium chloride after administration.

7.12.4 Check for patency of vein at regular intervals

7.12.5 Doses of vinca alkaloids for all patients treated in teenage, adolescent or adult settings should be administered from 50ml minibags, over 5-10 minutes, regardless of the age of the patient. (Ref NPSA Alert)

7.12.6 Infusion pumps are not generally recommended for the administration of peripheral vesicant drugs, however new infusion devices (eg category A pumps) are now available in some clinical areas. When an electronic infusion device is used to administer a vesicant medication, a low-pressure device should be the instrument of choice (Reference 13).

7.12.7 A few vesicants (e.g. Paclitaxel, Amsacrine, Carmustine, Decarbazine, Mannitol and Streptozocin) can be administered as an infusion through a peripheral line with care and close supervision, under gravity control only. These infusions should be of short duration of usually less than one hour.

7.13 Administration of Irritant Drugs

7.13.1 Use a new cannula if possible. Ensure that it is patent and bleeds back.



7.13.2 Ensure that the drug is reconstituted with the correct solution and dilution.

7.13.3 Observe and educate the patient regarding the risks.

7.13.4 Infusions are usually administered under gravity control, however an electronic infusion device (e.g. hospira Plum A+ pump) can be used, providing the correct pressure readings are set.

7.14 Administration of Non-Vesicant Drugs

7.14.1 Use a new cannula if possible. Ensure that it is patent and bleeds back.

7.14.2 Ensure the drug is reconstituted with the correct solution and dilution.

7.14.3 Observe and educate the patient regarding the risks.

7.14.4 Non-vesicant infusions should be administered via an infusion pump.

7.15 Extravasation

7.15.1 During transition from ASWCS website to the South West Network Chemotherapy group, the ASWCS website guidance on extravasation remains valid until superseded by a copy from the South West Network Chemotherapy group. There is also a copy of the guidance in the extravasation kit available everywhere where intravenous cytotoxic chemotherapy is administered.

8 Prescribing, Dispensing and Administration of Oral anti-Cancer Medicines

The use of oral anti-cancer medicines is increasing in scope and complexity. Benefits to patients include treatment at home and ability to feel empowered to be more in control of their disease. However, oral chemotherapy can be associated with similar toxicity to intravenous (IV) chemotherapy.

In January 2008, the National Patient Safety Agency (NPSA) issued a Rapid Response Report – “Risks of incorrect dosing of oral anti-cancer medicines” which outlines good practice standards relating to the prescribing, dispensing or administration of oral chemotherapy and also standards for counselling and information provision to patients. The draft report of the National Chemotherapy Advisory Group (NCAG) also made recommendations to improve the quality and safety of chemotherapy services that are relevant to oral chemotherapy.

The guidance outlined below incorporates key recommendations from the above reports.



8.1 Principles of Safe Practice

- 8.1.1** Each Healthcare organisation must ensure that it has in place policies and procedures which define and describe safe use of oral anti-cancer medicines in accordance with the guidance outlined in the NPSA Rapid Response Report.
- 8.1.2** Prescribing, dispensing and administration of oral anti-cancer medicines must be carried out to the same standard as injected therapy
- 8.1.3** All staff involved must have ready access to regimen protocols and treatment plans including guidance on monitoring and treatment of toxicity
- 8.1.4** Patients must be fully informed and receive verbal and up to date written information about their medicines including 24 hour contact details for specialist advice
- 8.1.5** Effective communication between primary and secondary care and with patients is central to safe and effective treatment

8.2 Prescribing

- 8.2.1** Treatment must be initiated by a cancer specialist
- 8.2.2** Prescribing must be by authorised prescribers and be within the context of a written protocol and treatment plan
- 8.2.3** Prescribing of oral anti-cancer medicines must always be done via an electronic prescribing system or on pre-printed pro-forma prescriptions. Hand-written prescriptions are no longer acceptable
- 8.2.4** All deviations from protocol such as dose modifications must be clearly described on the prescription.
- 8.2.5** Prescribing of oral anti-cancer medicines in primary care should be considered exceptional and must only be undertaken within agreed shared care guidelines. A register of such guidelines must be kept.

8.3 Prescription Verification, Dispensing and Labelling

- 8.3.1** Prior to dispensing, all prescriptions for oral anti-cancer medicines must be verified and signed* by a pharmacist who has undergone specialist training, demonstrated their competence and is locally authorised for this task. Verification includes assessment that the prescription is appropriate for the patient and that all safety checks have been undertaken, as defined in local



policy. (* includes auditable electronic authorisation in e-prescribing systems).

- 8.3.2** Staff verifying or dispensing prescriptions must have access to the protocol and treatment plan from the hospital that initiated treatment and to advice of an oncology specialist pharmacist in that hospital – such that they can confirm that the prescribed dose is appropriate for the patient and that the patient is aware of the required monitoring arrangements
- 8.3.3** Dispensary staff should work to detailed standard operating procedures
- 8.3.4** Label details should comply with NPSA recommendations as defined in local policy
- 8.3.5** All dispensed containers should be labelled with a Cytotoxic warning label
- 8.3.6** Automated dispensing systems should only include oral anti-cancer medicines that are available as unit doses (e.g. Temozolomide and Idarubicin). A local risk assessment should be carried out prior to inclusion.
- 8.3.7** Tablets or capsules should not be handled directly. All staff should use a “no touch” technique or wear gloves to minimise risks of exposure
- 8.3.8** Counting triangles designated only for use for cytotoxic drugs should be used. These should be cleaned after use with IMS (Industrial Methylated Spirit 70%), or an alternative locally approved agent, and a wipe. Wipes should be disposed of as cytotoxic waste.
- 8.3.9** Automated counting machines should NEVER be used for oral anti-cancer medicines.
- 8.3.10** During normal working hours, all quantities of oral anti-cancer medicines should have a physical double check (count) prior to release to patient.
- 8.3.11** Ideally, tablets should never be crushed or halved and capsules should never be opened. Where a commercial liquid preparation is not available and Pharmacy is able to extemporaneously prepare a formulation this must be done in an appropriate controlled environment.
- 8.3.12** Oral anti-cancer medicines should not be dispensed in compliance aids or monitored dose systems.
- 8.3.13** When dispensing tablets or capsules, sufficient quantity for the complete cycle of treatment should be supplied.



- 8.3.14** When dispensing short courses of oral anti-cancer drugs in liquid formulations, the exact quantity required (plus an overage of approximately 10mls) should be supplied.
- 8.3.15** Work over a leak-proof tray to contain any spillage. For patients on maintenance treatment (for example, mercaptopurine for paediatric leukaemic patients), it is more appropriate to dispense a complete original container.
- 8.3.16** All patients must receive appropriate written information in accordance with NPSA guidance. This should either be in the form of manufacturer's PIL or a locally approved information leaflet.
- 8.3.17** For external hospital requests for supply of oral anti-cancer medicines, confirmation of the patients dose and consultants intention for them to continue treatment needs to be sought, before making any supplies.

8.4 General Guidelines for Handling and Administration of Oral Formulations

- 8.4.1** Oral anti-cancer medicines can be potentially hazardous if handled carelessly.
- 8.4.2** Accidental exposure which may arise from handling uncoated tablets, loose capsules or oral liquids should be minimised.
- 8.4.3** Hands should be washed thoroughly after handling any oral anti-cancer medicine.
- 8.4.4** In exceptional circumstances, if crushing of tablets or capsule opening is deemed essential disposable gloves, apron, mask and protective eye wear must be worn. Crushing should take place in a controlled area, using commercially available devices that are specifically designed for this purpose. Care must be taken in cleaning or disposing of such devices which will contain fine powder.
- 8.4.5** Patients should be advised to swallow tablets or capsules whole and not to chew them. Patients and carers should wash their hands thoroughly after taking/administering oral anti-cancer medicines.
- 8.4.6** Do NOT use any tablets or capsules if loose powder or liquid is present in the container. Request a replacement from the Pharmacy department.
- 8.4.7** On wards or in clinics, oral doses should be dispensed into a medicine pot prior to administration to the patient. Blister/foil packed oral medicines should not be removed from their wrapper but dispensed into a medicine pot with the blister intact.



8.4.8 Patients with poor manual dexterity or impaired vision can have the dose unwrapped at the bedside by a nurse. This reduces the number of manipulations and prevents exposure from opened blisters within the original container.

8.5 Spillage of oral doses

8.5.1 If an oral dose is dropped, wear gloves to pick it up and dispose of it into a cytotoxic waste bin. Damp dust the area with a wet paper towel to ensure all fragments are collected. Dispose of the towel as contaminated waste.

8.5.2 For oral liquid spills, wear gloves, soak up the spill and clean the area immediately using soapy water and wipes or paper towels. Dispose of these in a Cytotoxic waste bin. Consider using a spillage kit for volumes greater than 50ml.

8.5.3 In wards or clinic areas, used administration spoons, medicine pots or oral syringes should be disposed of in a yellow waste bag.

8.6 Patient Education and Information

8.6.1 Written information including regimen details, treatment plan and arrangements for monitoring should be given to the patient

8.6.2 Before every treatment cycle, all patients should be seen by an oncologist, haematologist, specialist nurse or pharmacist

8.6.3 Patients must be adequately counselled to ensure their understanding of the regimen details, storage conditions and handling precautions. Handling precautions are particularly important during long maintenance courses such as for childhood leukaemia.

8.6.4 Medicine spoons, oral syringes and cups used for administration in the home should be reserved for chemotherapy treatment, washed thoroughly between doses and safely disposed of at the end of treatment.

8.6.5 The multi-disciplinary team should ensure that the patient is given appropriate information at each stage of their “chemotherapy journey”. The use of “information prescriptions” should be encouraged to standardise this process. Ideally, most information should be given at a pre-treatment visit and reinforced at subsequent visits.

8.6.6 Patients should be asked about any problems or side-effects that have occurred since their previous cycle of treatment.

8.6.7 Designated members of the multi-disciplinary team must ensure that the patient understands the following:



- 8.6.7.1** How and when to take their medicines including “gaps” off treatment
- 8.6.7.2** Patient has been told about any dose modifications and understands why this is necessary
- 8.6.7.3** What to do if a dose is missed
- 8.6.7.4** What to do in the event of vomiting after a dose
- 8.6.7.5** Common side-effects and what action to take if they occur
- 8.6.7.6** How to obtain further supplies - if needed
- 8.6.7.7** To return any unused oral anti-cancer medicines to the hospital pharmacy
- 8.6.7.8** The role their GP is expected to play in treatment

8.6.8 Patients should be told who their “key worker” is and given details of appropriate and readily accessible 24 hour points of contact if further advice is needed. Ideally this information should be contained in a personal chemotherapy handbook given to the patient at the start of their treatment.

8.7 Purchasing

8.7.1 The Pharmacy Guidelines on Purchasing for Safety are followed at all times and are available from the Pharmacy Department.

8.8 Pharmacy Cytotoxic Preparation Services

8.8.1 The Pharmacy Department operates a centralised cytotoxic preparation service providing parenteral cytotoxics individually dispensed and ready for administration to named patients. Some cytotoxics are outsourced from commercial suppliers. Regardless of the source, the reconstitution is carried out within HEPA filtered vertical laminar flow air cabinets or isolators situated in a specifically controlled and monitored environment. These facilities provide operator protection, as well as ensuring maintenance of the sterility of the products. The unit is subject to regular inspection from local Pharmacy Quality Control Departments.

8.8.2 Trained technicians, whose aseptic techniques are regularly validated, carry out all the preparation operations following standard operating procedures. Accredited pharmacists carry out clinical checks of all chemotherapy prescriptions.



8.8.3 In most situations during normal working hours, preparation of cytotoxic drugs in a clinical area, outside pharmacy, is unacceptable.

8.8.4 In certain settings however, the preparation/reconstitution of drugs in clinical areas may be carried out if a formal risk assessment has been conducted. A policy and procedure should be written and approved by senior managers. Where possible, such cytotoxic drug preparation should use closed systems. An example of this is the preparation, by trained urology staff, of Mitomycin-C as a bladder instillation using the commercially available Mito-In device.

8.8.5 Pharmacy CIVAS is available from 8.30 a.m. to 5.00 pm Monday to Thursday and 8.30 to noon on Friday.

8.9 Out of Hours preparation of Chemotherapy Doses

8.9.1 All cancer chemotherapy must be initiated within normal working hours. The risk of accidents is increased when complex cytotoxic regimens are given outside normal working hours, when support services, clinical expertise and back up are at a minimum.

8.10 Storage in Clinical Areas

8.10.1 The product should be received on the ward/unit by a staff member who will be responsible for ensuring that the contents are stored safely and appropriately until required for use.

8.10.2 Storage must be designed in a manner that will prevent containers of chemotherapy drugs from falling; such storage areas should be clearly labelled with cytotoxic warning labels.

8.10.3 Chemotherapy drugs must be stored separately from other drugs, in a designated section of a locked chemotherapy refrigerator or cupboard.

8.10.4 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 (2-8°C).

8.11 Transportation

8.11.1 Containers of prepared chemotherapy drugs must be transported in appropriately labelled, sturdy and leak-proof transport bags or boxes. These must be suitable for the product and robust enough to withstand normal transport and handling conditions. They should also be clearly distinguishable from other containers used for transporting non-chemotherapy agents. All transportation containers are yellow. Yellow metal



containers are used for the Macmillan Unit. All other cytotoxics are delivered in designated tamper-proof yellow bags. All injectables are double-wrapped in layflat plastic tubing before leaving the Pharmacy

8.11.2 All Trust staff involved in the transportation of chemotherapy drugs must be trained to follow the “cytotoxic spillage” procedure and must know what to do in the event of a spillage.

8.11.3 Pneumatic tubes must not be used for transporting chemotherapy drugs.

8.11.4 If damaged or leaking chemotherapy drugs are received on the wards or day units, follow spillage procedure (section 6.10 of this Policy).

8.11.5 If the product(s) requires refrigeration, the cold-chain should be maintained.

9 Disposal of Waste

9.1 Introduction

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

9.1.2 Information aimed at patients and carers regarding disposal of cytotoxic waste in the home or community environment must be provided if required

9.2 Used Disposable Equipment

9.2.1 While wearing gloves and plastic apron place any needles, syringes, giving sets, empty ampoules/vials or infusion bags into a rigid sharps disposal box. Giving sets should not be removed from infusion bags prior to disposal.

9.2.2 The sharps disposal box must have purple colour coding to denote cytotoxic waste as well as a purple lid so it can be incinerated at 1000°C to ensure degradation of the cytotoxic agent.

9.2.3 Sharps disposal boxes containing cytotoxic waste must be regularly collected

9.3 Contaminated Non-Disposable Equipment/Items

9.3.1 Re-usable plastic or metal trays should be rinsed with cold water into a sluice (to remove traces of cytotoxic agents) and then washed with detergent and hot water (to prevent cross- infection). Wear gloves and apron.

9.3.2 If non-disposable equipment or items are sent to another department for terminal cleaning, they must be transported in sealed leak-proof bags or



containers. These should be clearly labelled with a purple stripe indicating that they are potentially contaminated by cytotoxic drugs.

9.4 Protective Clothing and Wipes

9.4.1 Contaminated protective clothing, wipes, plastic aprons and gloves worn during the administration of chemotherapy should be placed in a double clinical waste disposal bag with a purple stripe or sharps box with a purple lid, marked as cytotoxic waste to be sent for incineration.

9.4.2 After a cytotoxic spillage (dealt with according to the cytotoxic spillage procedure), arrangements must be made for immediate collection of the rigid cytotoxic sharps bin with purple lid for incineration (see Section 9 for further details).

9.5 Unused Oral Doses

9.5.1 Any unused oral doses (e.g. tablets that have been dropped or oral liquids that have been refused etc) should be disposed of in a cytotoxic sharps box with a purple lid. To minimise the risk of damage and potential contamination, they should be discarded as follows:

9.5.2 Loose tablets/capsules: Put into a sealable plastic bag or a medicine bottle / sample pot securing the lid, before placing in a cytotoxic sharps box with a purple lid.

9.5.3 Oral liquids: Pour into a medicine bottle / sample pot securing the lid, before placing in a cytotoxic sharps box with a purple lid.

9.6 Patient Waste/Body Fluids

9.6.1 Patient waste e.g. urine, faeces, vomit may contain high concentrations of cytotoxic 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.

9.6.2 It has been shown that these unchanged cytotoxic 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, as below.

9.6.3 The use of universal precautions applies here as with all body fluids

9.6.4 Wear gloves and protective aprons.



9.6.5 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.

9.6.6 Staff are advised to follow the precautions described in Control of Infection Policy Manuals.

9.6.7 Ideally patients should use separate toilet facilities to staff. Men should be advised to avoid 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.

9.7 Soiled Bedding / Linen

9.7.1 A risk assessment should be under taken of soiled bedding and linen to determine the level of soiling and therefore the appropriate action to be taken.

9.7.2 If there is only a small amount of soiling the bedding/ linen should be treated as infected linen and handled as such, placed in a red bag and sent to the hospital laundry according to the procedures described in the individual Trusts Control of Infection Policy Manual.

9.7.3 If there is heavy soiling of the bedding/linen it should be handled as contaminated waste, double bagged in a yellow bag with purple stripe and sent for incineration.

9.8 Nappies

9.8.1 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.

10 Use of Vinca Alkaloids

10.1 Rationale

10.1.1 The National Patient Safety Agency (NPSA) issued a Rapid Response Alert in August 2008 that required the NHS and independent sector to comply with the guidance on the using Vinca Alkaloid minibags in Adult and Adolescent Units.



10.1.2 This was in response to reports of fatal and serious incidents outside the UK where injectable vinca alkaloids had been administered by a route other than intravenously.

10.1.3 This Policy conforms to the requirements of this rapid response alert NPSA/2008/RRR004.

10.2 Administration of Injectable Vinca Alkaloids

10.2.1 Doses in syringes will not be used

10.2.2 The prescribed dose will be supplied ready to administer from the Pharmacy in a 50mls minibag of sodium chloride 0.9%

10.2.3 Some brands of vinorelbine will require 50mls of glucose 5%

10.2.4 The warning “For Intravenous Use Only - Fatal if Administered by Other Routes”

10.2.5 The vinca alkaloid minibag will be infused over 5 to 10 minutes and the patient closely monitored for extravasation. Incidents of extravasation must be reported and shared with the National Extravasation Information Service (www.extravasation.org.uk)

10.2.6 Chemotherapy procedures will reflect these requirements

10.2.7 Staff will follow these guidelines