1 Introduction

Handling and administration of cytotoxic chemotherapy, and a variety of other anticancer medicines, are potentially hazardous to Health Care Professionals and patients / carers. Although the risks to patients are generally well documented, and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical.

2 Scope

The document provides best practice guidance for all Trust staff involved in prescribing, dispensing, supplying, administering and monitoring of patients, of any age, who are receiving these medications for any clinical indication. In order to support the implementation of national standards (DoH 2004 / NPSA 2007 / NCAG 2009 / NCAT 2008), specific guidance relating the care / management of oncology patients is identified within the document as ‘Oncology Specific’.

For the purposes of this document the term ‘Anticancer Medicine’ is used to refer to all medications, irrespective of their route of administration, with direct anti-tumour activity including traditional cytotoxic chemotherapy such as cyclophosphamide, hydroxy carbamide, small molecule/ antibody treatments such as imatinib, rituximab and other agents such as interferon, thalidomide or lenalidomide. It does not include hormonal or anti-hormonal agents such as tamoxifen and anastrazole or Intrathecal cytotoxic chemotherapy (ITC).

For the purposes of this document adult patients are those individuals over the age of 18 years.

3 Aims

This document aims to support the delivery of high quality evidence based care and minimise the risks associated with the delivery of cytotoxic chemotherapy, and other anticancer medicines, to patients within the Trust.
4 Duties - Roles and responsibilities

4.1 Multi-Professional Management and Leadership

The supply and administration of anticancer medications is facilitated across the Trust by multidisciplinary teams of doctors, nurses and pharmacy staff. These Health Care Professionals have received additional training pertaining to the disease speciality, and the use of these medications. They also work in accordance with approved written protocols and guidelines to provide integrated care for patients within the hospital and community.

4.2 Trust Chemotherapy Lead

Within oncology, the Trust Chemotherapy Lead is the nominated Clinical Lead for all anticancer medicines within the Trust. The Chemotherapy Lead Clinician is supported by the Nurse Consultant for Cancer Services, four designated Clinical Leads who are responsible for specific aspects of the service (adult solid tumour oncology, adult haemato-oncology, Paediatric oncology and Intrathecal Chemotherapy) and a designated Lead Pharmacists (adult and paediatric).

5 Process

The consultation, at which the decision to initiate treatment is made, must be undertaken by a Consultant, Specialist Staff Grade or SpR. (The decision to initiate treatment must be made at Consultant level). Discussion, assessment and documentation, within the patient’s medical notes (and where appropriate their prescription) should be made of the following:

- Indication for treatment and treatment intent
- History of specific disease or condition affecting fitness for treatment, thus confirm minimum physical and investigational requirements have been met. (Where appropriate including details of investigations necessary prior to starting the whole course, serially during the course and the maximum number of cycles after which response to treatment is to be reviewed prior to continuing the course)
- Suitability for treatment (including compliance, route of administration) e.g. prior history of chemotherapy, drugs affecting chemotherapy, ability to swallow tablets, pregnancy / lactation / fertility etc)
- Complementary or OTC medicines
- Performance status - Within oncology the decision to initiate treatment in patients with poor performance status (WHO 3 or 4), must be made at Consultant level and should follow discussion at a Multi disciplinary team meeting which includes representatives from palliative care.
- Holistic needs assessment
- Individualised risk / benefit analysis
- Proposed regime / protocol (Oncology - see section 6)
• Deviations from protocol and rationale e.g. dose modifications
• Treatment plan, monitoring and follow-up arrangements (including dates as appropriate) in accordance with local and national guidance.

The Clinician will also:

• Provide the patient (and carers / parent / significant others as agreed with the patient) with verbal and written information / advice, in an appropriate form, to include any potential complications associated with their treatment. (This might include: - neutropenic sepsis, extravasation, nausea and vomiting, stomatitis / mucositis, diarrhoea, care of venous access devices etc). (Oncology written information).

Best practice would support that all of the following written information, some of which in oncology will be taken from the original protocol, should be given to patients (N.B. This is a mandatory requirement for all patients who are prescribed oral anticancer medicines):

• Treatment intent
• Intended regime
• Treatment plan
• Administration process
• Arrangements for monitoring
• Review / Follow up
• 24 hour contact details for information / advice.

• Acquire consent to treatment. (Written consent is required in oncology for a course / episode of treatment and is recommended as best practice when using cytotoxic drugs for non malignant conditions. The consent form should enable the patient (or individual with parental responsibility) to acknowledge that they have received generic and if applicable regimen specific information).

• Determine the pregnancy status of the patient, if appropriate, at the time that treatment is discussed.

• Where applicable, establish the patient’s antibody status in relation to chicken pox and measles and provide vaccination advice.

• Provide written communication to significant primary and secondary care practitioners involved in the ongoing care of the patient. These practitioners must be advised regarding any role they are to have in the ongoing management of the patient. GP communication should include details of the treatment regimen, start date, planned duration and treatment intent.

**N.B.** Within oncology; GPs must **not** be issued with a copy of an oral ‘chemotherapy’ prescription due to the risk of inappropriate continuation of medicine.
When the final cycle in the course is given the following information must be documented in the patient’s medical notes, and a copy of this information sent to the patient’s GP and offered to the patient:

- Whether the course was completed or not and if not the reasons for cessation - toxicity, sub optimal response (non-adjuvant treatment), disease recurrence (adjuvant treatment), other.

6 Protocols (Oncology specific)

All Health Care Professionals within the Trust have access to written, adult, regimen protocols for all anticancer medicines and details of the Trust’s list of approved regimens. Hard copy of approved protocols specific to that area can be found in the following locations:

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<td>Ward 35 NCCC</td>
<td>Ward 14 Day Unit</td>
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<td>Ward 36 NCCC</td>
<td>Teenage Cancer Unit</td>
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<td>Out Patients NCCC</td>
<td>Main Pharmacy</td>
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<td>Cytotoxic Pharmacy</td>
<td>Clinical Trials office</td>
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<td>R&amp;D Department</td>
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N.B. The BNF should not be used as a primary source of prescribing information for anticancer medicines.

All protocols contain the following information:

- Definition of the clinical condition being treated
- Names (approved) of all medicines to be given
- Dosing schedule for each medicine
- Maximum individual dose where applicable
- Maximum cumulative doses where applicable
- Supportive therapy
- Pre-treatment and ongoing investigations
- Special precautions, expected toxicities and contraindications
- Potential interactions and medications to be avoided
- Recommendations for dose modifications.

6.1 Use of ‘Off Protocol’ or ‘Non Approved’ Protocols / Regimens (Oncology specific)

- The terms ‘Off Protocol’ or ‘Non Approved’ Protocols refer to those therapies / regimens that have not been approved for use by the North of
England Cancer Network or within the context of a R&D approved clinical trial. In addition, for children and adolescents, an approved regimen can be a Children’s Cancer and Leukaemia Group (CCLG) approved treatment guideline or a published, peer reviewed best standard therapy for rare diseases. Although the Trust needs to monitor and prevent the regular use of ‘Off Protocol’ or ‘Non Approved’ protocols / regimens, it is acknowledged that there are exceptional circumstances for which these may be indicated, i.e.:

- Current regimens do not meet the clinical need of the patient, e.g. toxicity profiles of existing regimens being incompatible with the patient’s clinical condition.
- The route of administration of an existing regimen is inappropriate or impracticable.

For the purpose of this document, regimens which are not within the Network or CCLG agreed list of regimens or R&D approved trials are referred to as ‘One-off protocols’. These protocols can only be initiated by the Consultant Oncologist / Haemato-oncologist / Paediatric Oncologist responsible for the patient’s care. A request for a ‘One-Off’ medication for a named patient should contain the following information:

- Patient details including diagnosis
- Reason for request
- Why an approved regimen cannot be used
- Rational for using a non approved regimen (including evidence base)
- Cost
- Regimen Details; Medication/s, Dose/s, likely duration
- Prescribers Name, Signature and Date.
- Person giving clinical and corporate governance approval.

The Consultant will be notified in writing if their application is approved. The Consultant must document approval within the patient’s medical notes and inform the appropriate oncology pharmacist in a timely manner. Patients requiring ‘One-off’ medications should not be consented and scheduled for treatment until written approval has been received. (In some instances approval may need to be documented by the Consultant on / within the inpatient / day case referral proforma). The three designated Clinical Leads (adult solid tumour oncology, adult haemato-oncology, Paediatric oncology), in consultation with the appropriate oncology lead pharmacists, are required to record the use of regimens which are not on the agreed list and report these to the Trust Chemotherapy Committee. The Oncology pharmacists are responsible for providing a summary of the use of ‘one-off protocols’ to the Network Lead Pharmacist. N.B. Within adult oncology and haemato-oncology, Clinicians should liaise with the
appropriate Network Tumour Specific Group to submit an application to
the Network if they propose to use a ‘Off Protocol’ / ‘Non Approved’
Protocols protocol more than three times a year.

7 Prescribing

7.1 Personnel

- Non malignant conditions

The first cycle / dose of chemotherapy should be prescribed by a specialist at
Consultant, Specialist Staff Grade or SpR level. These individuals should
receive training and be deemed competent in prescribing the medication for
patients with the specified medical condition / disease. Subsequent cycles of
treatment should only be prescribed by competent practitioners who have
experience in managing patients with the specified medical condition /
disease and have acquired specific training and local approval.

- Oncology

The first, and subsequent, cycles of all anticancer medicines must be
prescribed by an adult or paediatric oncology or haemato-oncology specialist
at Consultant, Specialist Staff Grade or SpR level who have been assessed
as competent and whose name appears on the Trust’s approved list of
anticancer medicine prescribers (This list is maintained by the Clinical Lead
Clinician in collaboration with the three Clinical Leads - adult solid tumour
oncology, adult haemato-oncology, paediatric oncology). (In the future, non-
medical prescribers may be able to prescribe the second and subsequent
course of anticancer medicines provided they acquired Trust approval and
are working within agreed Trust and patient specific protocols / guidelines.
Although approval will be acquired using existing Trust processes this will
also be in consultation with the Cancer Lead Clinician). **N.B.** In accordance
with cancer standards, junior medical staff (i.e. F1, F2, ST1 and ST2)
CANNOT prescribe anticancer medicines.

7.2 Prescriptions (Systemic Therapies)

- All systemic cytotoxic chemotherapy and anticancer medications must be
  ordered on a named patient basis and using designated documentation.
  Systemic medication should not be hand written on a patient’s fluid balance /
  intravenous therapy chart or within a standard hospital drug Kardex. The
  prescription or order must be clearly written and contain the following
  information:

  - Patient details (including height, weight, surface area as appropriate)
  - Protocol or regimen name
• Medication names (generic), and doses (as mg/m², AUC or per kg and the actual / final calculated dose)
• Frequency of administration
• Start date
• Number of days or doses to be dispensed (expressed in words and figures e.g. for three (3) days – abbreviations must not be used)
• If treatment is continuous or cyclical with duration of cycle
• Review date.

N.B. Prescribers who write oral anticancer medicine prescriptions for patients who will have their medicines administered in organisations external to the Trust, e.g. nursing homes, prisons, and children’s homes must provide the external organisation with details of the specified regimen and protocol.

(Oncology specific)

• Prescriptions for all anticancer medicines should, baring exceptional circumstances and those identified below*, be computer or electronically generated, controlled, documents which have been developed in accordance with Network or National guidance.
• (*Presently, within paediatric oncology and haemato-oncology this is not always the case but it is anticipated that this will be addressed once electronic prescribing via ChemoCare is implemented. It is also acknowledged that some oral anticancer medicines may not have a computer or electronically generated prescription. In these instances, oral anticancer medicines must always be prescribed using a Trust approved designated ‘chemotherapy’ prescription and they must not be prescribed by repeat prescription. (Handwritten prescriptions for oral anticancer medicines will not be dispensed except in the exceptional circumstances outlined above)).
• For repeat cycles details of the previous cycle should be available for reference.

7.3 Dosage (Systemic Therapies - Oncology specific)

• The initial and subsequent dose of systemic treatment may be modified on the grounds of medical history, performance status, pre-treatment investigation results (e.g. renal, hepatic, pulmonary function) rational for treatment (curative, palliative intent) treatment toxicity etc. (Dose modifications and whether or not they are intended to be permanent must be recorded in the patients medical notes)

• Body surface area (BSA)

Commonly used for the calculation of chemotherapy doses in adult patients and in most instances this is calculated using the DuBois formula.
Doses for patients treated within a clinical trial should be calculated in accordance with the protocol. (In paediatric oncology the dose may be based on mg/kg or based on body surface area using the UKCCSG BSA chart which can be found at the back of the BNF for children).

- **Weight.**

A patient’s weight should be assessed when establishing their BSA and potential causes for large BSA evaluated e.g. excess body fat, lean muscle mass, ascites (which is important for methotrexate therapy), oedema. If a patient is significantly overweight, doses of chemotherapy can be 25-35% higher than if ideal bodyweight is used to calculate the BSA. There is concern that this increase in dose may cause excess toxicity to the patient.

For obese adult patients (BMI ≥ 30) there is no evidence to support routine dose reduction but consideration should be given to capping the surface area at 2-2.2m², or recalculating BSA using ideal weight. This may be more important for some therapies e.g. anthracycline has a lifetime cumulative dose and cardiac toxicity, than for other medications. Each patient should be considered individually with regard to chemotherapy agent, treatment intent (curative / palliative), response to, and toxicity from, previous therapies and any co-existing medical conditions.

For obese paediatric patients who are not being treated within a clinical trial, the weight on the 98th centile for age should be used to calculate the dose of treatment.

**N.B.** Protocol guidelines should always be followed for obese patients who are within a clinical trial.

- **Height.**

For adult patients less than 140cm tall or less than 44kg, the BSA estimation chart cannot be used and the following equation (Mosetallar) should be used instead;

\[ \text{BSA (m}^2) = \sqrt{\frac{\text{weight (kg) x height (cm)}}{3600}} \]

**N.B.** The dosage of some medications may be calculated in accordance with a patient’s renal function and may be adjusted or modified to reflect a patient’s renal or hepatic function. The height and weight of each patient must be re-measured prior to their first cycle of treatment to confirm that the dose calculation has been performed using the correct data.
8 Pre Treatment Verification Process

- The speciality specific nominated doctor / chemotherapy nurse administrator must holistically assess and review the patient prior to each cycle of treatment, and at designated times within the patient’s pathway, as defined within the protocol. This individual must also:
  
  - Ensure that the patient’s medical condition supports the proposed administration of their treatment
  - **N.B.** An active mode of enquiry should be adopted when questioning patients to assess their performance status and complications / toxicities.
  - For systemic treatment, check results of all critical tests / investigations, blood parameters and specific drug calculations specified within the treatment protocol / local guidance
  - **N.B.** The results of all critical tests / investigations, (including response assessment where appropriate), blood parameters, specific drug calculations (and any data required to support this e.g. height, weight) complications from previous cycles, dose modifications or delays consequent on complications / toxicities must be documented in the patient’s medical notes)
  - A patient’s performance status must also be assessed prior to every cycle of treatment. Any patient whose performance status has worsened to WHO 3 or 4 must not be given treatment without being reviewed by a Consultant (Ongoing treatment decisions should be made in collaboration with the patient / carer and appropriate health care professionals e.g. palliative care)
  - History of complications and / or toxicity (**CTC**) must also be assessed prior to every cycle of treatment and treatment must not be administered to patients with a CTC >2 without a medically led and agreed treatment plan e.g. prevention (e.g. dose reduction / growth factor support) or modified toxicity management plan (e.g. antiemetic ladder)
  - Check that any supportive medications have been administered in accordance with the patient’s prescription e.g. antiemetics, pre-medication, topical applications, etc.

(Oncology specific)

- The following verification process must be performed together with those defined within the organisations medicines management procedures prior to administration:
  
  - Patient identification as agreed / checked with the patient on that occasion, on the prescription chart and labelled medications
  - Critical test results (as defined by the protocol and outlined above)
  - Regimen and individual medication identification
  - Diluents, dilution volumes and any hydration
• Administration route and duration
• Cycle number
• The administration, as per schedule, within the cycle
• The minimum monitoring requirements by physical examination and by investigation are met
• Response assessment according to the relevant regimen and treatment intention.

• **N.B.** In the absence of a defined written protocol which would support the administration, variances identified within the verification process must be discussed with the patient’s treating clinician (Consultant / SpR) before proceeding with the administration of treatment.

**9 Dispensary Standards**

• All prescriptions must be checked and authorised by an appropriately trained and accredited pharmacist who has received additional training within their speciality. Pharmacy staff should follow Standard Operating Procedures available within the pharmacy department.

• Trust approved prescriptions / proformas must be used when ordering anticancer medicines (section 5.2).

• The pharmacist will resolve any discrepancies identified with the prescriber prior to dispensing medication(s).

**9.1 Oral Cytotoxic Medicines**

• When dispensing oral medication the pharmacy should supply the complete course of treatment and provide the exact quantity of tablets / capsules required.

• When dispensing short distinct courses of cytotoxic medications in liquid formulations, the exact quantity required (plus an overage of approximately 10mls) should be supplied. For patients who are on maintenance treatment (for example, Mercaptopurine for paediatric leukaemic patients) the medication should be dispensed in its original container.

• All oral anticancer medications dispensed for all prescriptions, including inpatients, must be labelled as a TTA and include the following details:
  • Patient name
  • Generic drug name
  • Strength of tablets or capsules, or concentration of oral liquid
• The number of tablets / capsules in the container, or volume of liquid
• Administration instructions
• Length of treatment, including stop date as appropriate
• Storage instructions / conditions
• Caution: Cytotoxic Drug (as appropriate)
• Name and address of pharmacy department.

• **N.B.** Oral anticancer tablets or capsules **must not** be dispensed in multi-compartment compliance aids or monitored dose systems. Dispensing of all anticancer medicines should take place within the pharmacy department and must be dispensed to an individual patient.

9.2 **Parenteral (intravenous) subcutaneous, intramuscular and intravesical cytotoxic Medicines**

• Items should be heat-sealed in a strong bag that is clearly labelled with a copy label of each item inside, to allow easy identification.

10 **Transportation of cytotoxics for administration within the organisation (Parenteral (intravenous) subcutaneous, intramuscular and intravesical)**

• All medicines should be delivered to the clinical areas in a ready to use form or a suitable safe transfer device.

• Medicines should be transported in a rigid, sealed, leak proof container to prevent or contain any spillage. Containers are available for transportation from the pharmacy. (Pharmacy staff will not release the product unless an appropriate container is available for use).

• The containers should be marked “cytotoxic drugs” and should only be used for that purpose.

• Yellow containers are used exclusively for the transportation of intrathecal chemotherapy which **must** always be transported separately from intravenous anticancer medications.

• The container should be labelled with the appropriate ward / destination and sealed using cytotoxic tape. It should also be labelled with information regarding what to do in case of a spill. (Staff may contact the Cytotoxic Dispensing Suite, NCCC or the Pharmacy Production Unit, RVI for further information).

• Once on the ward / department, it is the responsibility of the individual who has transported the anticancer medicines to hand over the container to a qualified member of the nursing team. This nurse is then responsible for emptying the container and storing syringes and infusion bags immediately and appropriately.
The label will provide details of how to store each item (i.e. in a fridge or at room temperature). Failure to store the items promptly and correctly may compromise the expiry date of the product and may induce degradation or precipitation of some products.

- Designated treatment areas must have within them, or adjacent to them, separate identified area/s for the temporary storage of chemotherapy agents.

- Items stored at room temperature, e.g. Etoposide should be placed in plastic containers and stored in a designated lockable cupboard used only for the storage of these items. This cupboard should be appropriately labelled.

- Items requiring storage in a fridge - Ideally a separate lockable fridge should be available for the storage of these medicines. Dedicated shelves within a lockable ward fridge can be used, in some circumstances, providing they are labelled appropriately. Within the fridge, anticancer items must be placed in plastic containers, in case of spillage. Fridge temperatures must be recorded daily and where appropriate, fridges must be alarmed. Pharmacy should be contacted for advice when fridge temperatures fall outside normal parameters ($2^\circ C – 8^\circ C$).

11 Administration Standards (Systemic Therapies)

- Administration of these medicines should, baring exceptional circumstances, be undertaken on named wards / departments where it is agreed as part of the wards regular activity and to which patients are admitted in preference to other wards (See table below for designated oncology areas). Within non oncology areas directorates should work towards consolidating and defining areas in which cytotoxic chemotherapy can be administered to optimise care and minimise risks.

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<tr>
<td>Ward 36 NCCC</td>
<td>• Paediatric theatres</td>
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<tr>
<td>Bobby Robson Clinical Trials Unit</td>
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<td>Out Patients NCCC (Oral chemotherapy)</td>
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<tr>
<td>Radiology Department (Chemo-embolisation)</td>
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- These areas must, depending on the type of medication / route of administration, have appropriate protocol (regimen) documents and equipment for the management of anaphylactic shock, cardiac arrest, spillage and where appropriate extravasation e.g. areas only administering cytotoxic medications via
a subcutaneous route will not need equipment for the management of extravasation.

- The designated Clinical Lead who is responsible for the appropriate aspect of the service, can, in consultation with the designated Lead Pharmacist, Clinical Director and Matron, limit the number of chemotherapy patients being treated when the workload has been judged to have reached unsafe levels. Workload is primarily depended on the availability of skilled staff and therefore relies on ongoing communication between all clinical teams. It is acknowledged that in some circumstances chemotherapy / anticancer medication may need to be administered outside the usual ‘named ward / area’. This would apply to situations where the patient’s requirement for specialist or intensive care, provided within a non-designated area, outweighs any potential risks associated with administering these medicines outside the ‘named ward / area’ or when patients who are having anticancer medication / chemotherapy are admitted to non-designated area for additional interventions e.g. elective surgery. In these instances it is imperative that the non-designated area is supported by medical, nursing and pharmaceutical staff from the ‘named ward / area’ where the patient’s treatment would usually be managed / administered. Clinical staff in these areas must contact members of the patient’s specialist team for specific information and advice regarding the prescribing (treatment plan / protocol), administration, safe handling and management / observation of the patient during treatment.

- Administered by a chemotherapy administrator (i.e. a doctor / qualified nurse who is competent in the appropriate medication administration route, has received specific training and is deemed competent in chemotherapy administration). Within adult oncology this individual will invariably be a nurse, or within paediatric oncology a medical registrar or above. Oncology chemotherapy nurse administrators must have undertaken the Trust training and have, or be working towards, acquiring accreditation to support their practice e.g. AC0310 Chemotherapy: Enhancing Practice. These individual must also have been assessed by an accredited assessor, undertake an annual review of competence and their name must also appear on the Trust’s approved list of chemotherapy administrators. Nurses who administer cytotoxic medications in non oncology areas must have undertaken the Trust training and should endeavour to acquire accreditation to support their practice.

- Administered during normal working hours: For the purpose of this document ‘normal working hours’ refers to the usual ‘day time hours’ when medical, nursing and support services are available to support the deliver of anticancer medications on the ‘named ward / area’. Although it is practicable, in most cases, to commence treatment and administer ‘bolus’ / short infusions during ‘normal working hours’, it is acknowledged that for some groups of patients this may not be possible. These may include patients who require emergency treatment, continuous infusion therapy, regimens which require
intermittent therapy and hydration or regimens where bolus infusions are integrated with infusion therapy. In these instances the risks associated with administering anticancer medicines outside ‘normal working hours’ would be outweighed by the clinical benefits associated with the patient having their treatment administered as per their regimen or protocol and this risk assessment should be clearly documented in the patients medical notes. Appropriately qualified Health Care Professionals’ e.g. chemotherapy administrators, oncology trained pharmacists and doctors should be available (or on call) for areas administering anticancer medicines, especially chemotherapy, outside ‘normal working hours’.

N.B. Specific oncology guidance can be found in section 9.12

11.1 Procedural Guidance for Administration via any route

- Medication must be checked in accordance with:
  - The patient’s prescription and protocol
  - Trust’s procedures / guidelines pertaining to the administration of medicines including those pertaining to the route of administration (including all Trust medicines management policies, purple book etc)
  - Professional guidelines.

- Prior to administering the patient’s treatment the administrator (oncology specific – whose name is recorded within the Trust register of authorised chemotherapy administrators) must check the identity of the patient and ensure that:
  - The prescription has been written in accordance with their protocol and guidelines identified above and authorised by appropriate personnel (section 5.1).
  - The patient is able to proceed with their treatment as outlined in the pre-treatment verification process (section 6).
  - Confirm that the patient has received all the information they require to provide informed consent to treatment.
  - Two qualified practitioners, one of whom should be a qualified chemotherapy administrator (who will take responsibility for the administration of the patient’s medicine), are required to check and administer the patient’s medicines. The following additional checks should be made:

    - Details on the medication (container and contents) **must** correspond with the patient’s prescription and this must reflect the treatment protocol.
    - Medication containers / packaging must be inspected to ensure there is no leakage or spillage.
N.B. Any variances identified within the pre-administration process must be actioned accordingly involving appropriate senior multi-professional colleagues as required e.g. Consultant / SpR, pharmacist.

Patients requiring Emergency ‘Out of Hours’ Treatment

- Directorates should discuss and agree, in which patient’s, emergency ‘out of hours’ treatment may be required. Cancer related information can be found within ‘Policy and Procedure for Essential Out-of Hours Cancer Chemotherapy’.

11.2 Parenteral (intravenous) Administration (Including information pertaining to vesicants)

- The following guidance should be read in conjunction with existing Trust procedures (section 9.1).

- To protect the patient and practitioner from untoward contact with the medications use Luer-Lok fittings on all syringes / intravenous giving sets and where practicable, use a needle-free system (Integral / Luer-Lok).

- Commence an infusion of a compatible solution as prescribed. (In most cases this will be Sodium Chloride 0.9% which could be prescribed within the protocol or under a Patient Group Direction (PGD)).

- Prepare any supplementary medications / specific equipment for administration in accordance with the patient’s prescription / treatment protocol, e.g. antiemetics, ultraviolet protection / non PVC intravenous giving set etc.

- Two qualified practitioners, one of whom must be a qualified chemotherapy administrator (i.e. a doctor or qualified nurse who is competent in intravenous medication administration, has received specific training and is deemed competent in chemotherapy administration and who will take responsibility for the administration of the patient’s medicine), are required to check and administer the patient’s medicines in accordance with section 9.1.(Nurses undergoing training can administer chemotherapy provided they are being supervised by a qualified chemotherapy administrator).

- Wash hands and don Nitrile gloves, eye protection and a plastic apron.

- Consult the patient regarding sensation around the vascular access insertion area and inspect the cannula / central line site / port for signs of displacement, swelling and local inflammation.
• (All information pertaining to vascular access, including the location and condition of the cannula / central line / port, must be documented in the patient’s notes)

N.B. Specific guidance regarding the care of Central Venous Catheters are defined within local guidelines and the Royal Marsden Manual. Intravenous peripheral cannulation is governed by best practice, which supports the use of the shortest cannula with the smallest bore i.e. 22 or 24 gauge, non-ported plastic cannula. Distal veins of the hand and arm should be used and the median cubital veins should be avoided.

• Establish patency of the vascular access devices. This is usually confirmed by:
  • Confirming the vascular access device facilitates the free flow of intravenous fluids
  • Acquiring blood return either via aspiration or by stopping the infusion and via gravity acquiring blood return.

N.B. Uninterrupted observation of a patient, by a competent chemotherapy administrator must be maintained when a patient is having a vesicant administered peripherally in order to reduce the risks associated with a potential extravasation, even if a medical device is being used. The administrator must stay with the patient throughout the infusion of their medication and if appropriate the defined flush volume of the intravenous giving set / appropriate section of the intravenous giving set.

Infusion:

• Change infusion bags at waist height over a plastic tray. (Infusion bags should never be changed while hanging from a drip stand).

• Electronic devices should always be used to administer infusions and these should be set with low occlusion setting (section 9.21)

• Regularly consult the patient about sensation around the venous access insertion site and observe / record the condition of the site before commencing an infusion bag and hourly during infusions.

Bolus injection (including vesicants):

• Administer bolus injections via the port / connector, which is situated approximately 4 inches from the end of the administration set.

• Clean port / connector / rubber injection cap of the intravenous giving set using 2% Chlorhexidine in 70% Isopropyl Alcohol spray or impregnated
swab / wipe (cleaning for 1 minute) and allowed to air dry just prior to accessing.

- When needle-free systems are not in use, immediately prior to administration, remove the blind hub from the syringe and place a short, small gauge needle on the Luer-Lok syringe. Place a gauze / waterproof pad or tray under the connector / rubber injection cap of the intravenous giving set, taking care not to touch the cleaned injection cap.

- The speed of administration of a bolus injection will be influenced by a number of factors including the medication and the volume of the bolus to be infused, the route of administration (i.e. peripheral or central, adult or paediatric) and patient characteristics. All bolus injections should be administered slowly, usually over a period of approximately 3-30 minutes, via a fast running infusion of a prescribed compatible fluid (in most cases this will be Sodium Chloride 0.9%). A fast running infusion of a compatible fluid may not be required when administering specific medications to paediatric patients who have a central venous access device.

- Specific information pertaining to the administration of vesicant medications:
  - Where there are concerns regarding venous access consideration should be given to delivering intravenous medications via a central venous catheter.
  - Due to the risks associated with extravasation when administered peripherally these medications are usually administered by bolus injection. When administered peripherally and / or as a bolus injection they require uninterrupted observation of the patient and their administration site by a competent chemotherapy administrator throughout the infusion of the medication and the flush volume of the specific section of the intravenous giving set (i.e. the administrator must stay with the patient throughout the infusion of their medication and the associated flush).
  - Patency of the vascular access devices should be assessed immediately before, during and after administering a vesicant medication.
  - Electronic devices can be used to administer bolus injections and these should be set with low occlusion setting (section 9.21).
  - An intravenous ‘flush’ of a prescribed compatible solution should be administered between each medication and on completion of the patient’s regimen. (In most cases this will be Sodium Chloride 0.9% which could be prescribed within the protocol or administered under a Patient Group Direction (PGD)). The ‘flush’ volume should equate to the number of
millilitres required to prime the intravenous giving set (if administering consecutive intravenous infusions), or to prime the specific section of the intravenous giving set (when administering consecutive bolus injections).

- Observe and instruct the patient to inform staff of signs of local and systemic problems which can occur during, or immediately after, medication administration e.g. medication specific side effects, venous irritation, phlebitis, flare reaction, extravasation, hypersensitivity / anaphylaxis. These should be managed in accordance with local, regional and national procedures / guidelines.

- Dispose of all cytotoxic contaminated waste immediately (section 11).

- Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.

- Provide post procedural information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  - Home care instructions – toxicity management / health education
  - Review / Follow up arrangements
  - Pathway for self-referral including ‘out of hours’ contact information (Appendix 2).

**Electronic Medical Devices**

- Vigilance must be maintained when administering cytotoxic chemotherapy via an electronic infusion device and a low-pressure device being the instrument of choice. (Within adults devices should usually be set to 200mmhg. Within paediatrics, maximum pressures are usually pre-set on devices prior to commencing the infusion).

11.3 Subcutaneous and Intramuscular Administration

**Additional Procedural guidance:**

- Open the bag directly onto the injection tray.

- Wash hands; don Nitrile gloves and a plastic apron.

- Choose a suitable site for the injection and prepare the skin as per Trust policy.

- Where appropriate carefully remove the connector top from the Luer-lock syringe and securely attach sterile needle to minimise risk of spillage on
the skin. Administer in accordance with Trust and national guidance (RCN2004). (Subcutaneous 26 or 30 gauge needle / ≤12mm length, Intramuscular needle 23g/30mm or 21g/40mm).

- **Subcutaneous** - Using a pinch technique, administer the injection (in adults a bolus injection up to the volume of 1.5mls could be administered via this route depending on patient comfort). Although the needle angle will be dependent on the needle length, manufacturer’s instructions and the age of the patient, in the majority of instances this will be 90° angle.
- **Intramuscular** - Administer the intramuscular injection, (in adults a bolus injection up to the volume of 3mls could be administered via this route depending on patient comfort), using the Z track technique which involves displacing the skin and the subcutaneous layer in relation to the underlying so that the needle track is sealed off before the needle is withdrawn, therefore minimising reflux.

**N.B.** The small amount of air that may be present in a Luer Lok pre-filled system does not need to be expelled and aspiration, to support the absence of blood return, is not required prior to the injection.

- Remove the syringe and needle, covering the site with sterile gauze and ensuring there is no leakage from the site.
- Wash hands thoroughly after the procedure.
- Observe and instruct the patient to inform staff of signs of local and systemic problems which can occur during, or immediately after, medication administration e.g. medication specific side effects, hypersensitivity / anaphylaxis. These should be managed in accordance with local procedures / guidelines.
- If further injections are required, rotate the site of administration.
- Dispose of all cytotoxic contaminated waste immediately (section 11).
- Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.
- Provide post procedural information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  - Home care instructions – toxicity management / health education
  - Review / Follow up arrangements
  - Pathway for self-referral including ‘out of hours’ contact information.
11.4 Intravesical Instillation

- Mitomycin, BCG and Epirubicin can be given by the intravesicular route. Treatment should not be administered to a patient with heavy haematuria, a urinary tract infection or if there is any risk of them being immunosuppressed e.g. steroids. In these instances advice should be sough from the patient’s Consultant or Uro-oncology Clinical Nurse Specialist.

Additional Procedural guidance:

- Where appropriate catheterise the patient in accordance with Trust procedures. Treatment must not be administered if there is trauma associated with the catheterisation.

- Provide the patient with a gown and assist the patient to assume a recumbent or semi-recumbent position and expose the catheter.

- Lay an incontinence pad under the catheter and over the thighs.

- Wash hands and don plastic apron. Open and assemble the sterile products and don one pair of sterile Nitrile gloves.

- If an irrigation bag is in use, disconnect the fluid and spigot the catheter inlet. Clamp the catheter.

- If necessary, disconnect the drainage bag from the catheter. Document the volume of urine to ensure an accurate fluid balance is recorded. Put the catheter valve in a closed position to provide a means of blocking the catheter and to facilitate drainage after the recommended time.

- Connect the bladder syringe or Mito-in connector / Urotainer securely to the catheter, release the clamp and instill the medication slowly into the bladder. Rapid instillation can be painful, especially if the bladder wall is scarred from previous surgery.

- Carefully check that there are no signs of leakage of medication around the catheter site.

- Reclamp the catheter. Disconnect the syringe or Mito-in connector / Urotainer from the valve using a sterile gauze swab to absorb any drops left on the end of the valve.

- Wash hands thoroughly after the procedure.
• Dispose of all waste, including cytotoxic contaminated waste immediately (section 11).

• Observe and instruct the patient to inform staff of signs of local and systemic problems which can occur during, or immediately after, medication administration e.g. medication specific side effects, hypersensitivity / anaphylaxis. These should be managed in accordance with local procedures / guidelines.

If catheter is to remain in situ

• If a drainage bag is being used, connect this to the flip flow valve but do not open the valve, to allow retention of the medication within the bladder for at least one hour.

• Ensure the comfort of the patient, assisting him/her to reposition themselves and ensure they have easy access to a call bell.

• Reinforce to the patient the need to retain the medication for one hour if possible. If the patient has an urge to void, or if the catheter is bypassing, it will be necessary to open the valve before the allotted time.

• After one hour: Wash hands and don Nitrile gloves and a plastic apron.

• Attach a urine drainage bag. Release the flip flow valve and allow drainage of the bladder contents into the drainage bag for 15 minutes.

• Remove the drainage bag and connect a new one if the catheter is to remain in situ, as per local policy.

• If the catheter is to be removed attach a syringe to the balloon inlet of catheter. Once correct balloon inflation volume has been removed with syringe, gently remove the catheter completely, ensuring disposable sheet under meatus of urethra.

• The contents of the drainage bag (medication and urine) should be emptied into a sluice followed by two flushes. Urine from patients who have received BCG treatment should be emptied into the sluice, bleach based detergent applied and then left for 15 minutes with appropriate safety signage in position, prior to flushing.

• The bag should then be disposed of as cytotoxic waste (section 11) and hands washed thoroughly after the procedure.
If catheter is to be removed

- Remove the catheter and attached Urotainer / or syringe.
- Advise the patient of the need to retain the medication for one hour if possible.
- After one hour: Advise the patient to go to the bathroom to void urine into toilet. Men must void sitting down to minimise splashing. The toilet should be flushed twice, with the lid down (again to minimise splashing).
- Advise the patient to wash their genitalia thoroughly with copious amounts of soap and water and wash their hands afterwards, to minimise potential skin problems following contact with cytotoxic medications.
- Maintain hygiene as normal after the initial emptying of their bladder.
- Pour strong bleach based detergent into the toilet after voiding if they have received BCG treatment, and leave for 15 minutes prior to flushing.
- If any cytotoxic medication comes in contact with the patient’s skin, refer to section 12.
- Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.
- Provide post procedural information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  - Home care instructions – toxicity management / health education
  - Review / Follow up arrangements
  - Pathway for self-referral including ‘out of hours’ contact information.

11.5 Chemo-embolisation

- Chemo-embolisation can only be prescribed by a designated Consultant interventional radiologist who is experienced in its administration. Chemo-embolisation 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 cytotoxic medications. The cytotoxic chemotherapy that is usually used in the procedure is Doxorubicin, usually combined with drug eluting beads. As the shelf life of the cytotoxic preparation can be relatively short, planning and co-ordination with the pharmacy department is essential.
Additional Procedural guidance:

- Before the procedure on imaging, assess the anatomy of the tumour and the portal vein.
- Appropriate equipment should be collated and prepared.
- Observe and instruct the patient to inform staff of signs of local and systemic problems which can occur during, or immediately after, medication administration e.g. medication specific side effects, hypersensitivity / anaphylaxis. These should be managed in accordance with local procedures / guidelines.
- Don plastic apron and protective glasses. Wash hands and don Nitrile gloves.
- Inspect sealed bag and open the bag.
- Attach the syringe containing the cytotoxic and drug eluting bead material to a sterile 3 way tap. Hold the assembled 3 way tap and syringe so that the scrub nurse, also wearing appropriate personal protective equipment (section13), can attach a syringe from the sterile angio trolley, which is compatible with a micro catheter, to the 3 way tap and aspirate the cytotoxic beads. The 3 way tap and original syringe are then discarded carefully into the clinical waste bin.
- The cytotoxic beads are mixed with sterile water soluble contrast medium via a second 3 way tap and the mixture is then gently rotated for a few minutes to ensure an easily injectable suspension.
- Under local anaesthesia and analgesia, preliminary transfemoral hepatic angiography is carried out to map out the anatomy of the hepatic arteries and to confirm patency.
- Selective cannulation of the main vessel supplying the tumour is performed. Usually this requires insertion of a very fine microcatheter through the (larger) outer catheter.
- Avoiding any spillages, inject the cytotoxic preparation into the hepatic arterial microcatheter, using full aseptic precautions,. The injection is performed in 0.5ml aliquots, carefully flushing the microcatheter with prescribed sodium chloride 0.9% after each injection of beads.
- As the sodium chloride is injected the contrast in the bead mixture shows whether forward flow is still occurring. As soon as it is evident that there is
a significant embolic effect and that contrast is starting to reflux back around the microcatheter, the treatment is stopped.

- On removal of the microcatheter further angiography through the parent catheter will confirm the adequacy of the embolisation procedure. Additional embolic material may, on rare occasions when the tumour is large and very hypervascular, need to be injected to produce an adequate local embolic effect. The decision whether or not to inject additional embolic material in an individual patient lies with the Consultant radiologist carrying out the procedure.

- Particulate embolic material should not be added to the cytotoxic bead formulation but should be injected separately after this has been administered.

- Dispose of all cytotoxic contaminated waste immediately (section 11).

- Record details of administration in the patient’s medical notes in accordance with the Trust and professional procedures / guidelines.

- Following administration, the patient must be provided with access to a call bell and appropriate equipment made available for the management of potential emesis.

- Provide post procedural information / advice to the patient / clinical staff

### 11.6 Topical Chemotherapy

- Cytotoxic medications for topical administration may come in a number of different formulations, including creams, ointments, gels and solutions e.g. Efudix (Fluorouracil) cream for actinic keratosis, and Imiquimod cream for actinic keratosis, Bowen’s disease and superficial spreading Basal Cell Carcinoma.

- The preparation should be checked by an appropriately qualified and experienced registered nurse and medical practitioner (the former will take responsibility for the administration of the patient’s medicine).

- Wash the affected area on the skin with mild soap and dry thoroughly before the application.

- Wash hands; don Nitrile gloves and a plastic apron.

- Apply the preparation (cream, ointment or gel) using gloved fingertips, cotton wool or cotton tipped applicators. Solutions should be gently, but generously, using cotton wool or cotton tipped applicators.
• Unless directed otherwise, apply the cytotoxic preparation to the affected area only.

• Avoid contact with the eyes, nose, mouth or areas close to mucous membranes. If the preparation comes into contact with unaffected skin, wipe the area with gauze and warm soapy water.

• If the preparation is to be applied to the entire body, use gauze. Apply the preparation more lightly to the groin, armpits, inside bends of elbows, and backs of knees because of the increased risk of dermatitis.

• Do not cover the skin with a dressing, unless specifically advised to do so.

• If necessary, after the required contact time, the preparation should be rinsed off the area carefully. If the preparation has been applied to a large area, the patient should be advised to have a shower, rather than a bath, to ensure that they do not sit in bath water that contains medication residue. Once the medication has been showered off, the patient can have a bath if desired.

• Once the application is completed, dispose of all cytotoxic contaminated waste immediately (section 11).

• Observe and instruct the patient to inform staff of signs of local acute skin reactions (i.e. severe burning or rashes) or systemic problems (which are unlikely unless the majority of the body is being treated) that can occur during, or immediately after, medication administration e.g. medication specific side effects, hypersensitivity / anaphylaxis. These should be managed in accordance with local procedures / guidelines. If acute skin reactions occur the prescriber must be notified as the medication dose or frequency, may need to be reduced on subsequent applications. Some cytotoxic medications (e.g. fluorouracil) may cause redness, soreness, scaling and peeling of the affected skin after one or two weeks of use. This effect may last for several weeks after the treatment is stopped.

• Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.

• Provide post procedural information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  • Home care instructions – toxicity management / health education
  • Review / Follow up arrangements
  • Pathway for self-referral including ‘out of hours’ contact information.
N.B. If treatment is to be continued at home, appropriate information concerning the application of the preparation, handling, disposal instructions and details of obtaining further medicine supplies if needed.

11.7 Eye Treatment

- Solutions of cytotoxic medications (such as Fluorouracil (5-FU) and Mitomycin) may be administered postoperatively as subconjunctival 5-FU injections in eyes that had undergone prior cataract surgery or failed filtering surgery. Cytotoxic medications may also be used intraoperatively using a cellulose sponge soaked in the cytotoxic solution or as subconjunctival injection.

- The preparation should be checked by an appropriately qualified and experienced registered nurse and medical practitioner (the former will take responsibility for the administration of the patient’s medicine).

- Consider applying a prescribed lubricating eye ointment on the inferior eyelid to minimise skin contact with the cytotoxic medication.

- Wash hands and don Nitrile gloves.

- Tilt the patient’s head back, and gently pull the lower eyelid down.

- Hold the dropper above the eye and squeeze one drop inside the lower eyelid. Ensure that the dropper tip does not come into contact with the eye, eyelashes or any other surface. Let go of the eyelid and instruct the patient to blink a few times to spread the drop over the whole eye surface. If more than one drop is prescribed, wait for at least two minutes before putting the second drop into the eye. Repeat the procedure for the other eye, if the medication is prescribed for both eyes.

- If the preparation comes into contact with unaffected skin, gently blot any liquid and then wipe the area with gauze and warm soapy water.

- If applied intraoperatively using a cellulose sponge soaked in the cytotoxic solution or as subconjunctival injection, once the application is complete rinse eyes copiously.

- Once the application is completed, dispose of all cytotoxic contaminated waste immediately (section 11).

- Wash hands thoroughly after the procedure.
• Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.

• Provide post procedural information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  
  • Home care instructions – toxicity management / health education
  • Review / Follow up arrangements
  • Pathway for self-referral including ‘out of hours’ contact information.

N.B. If treatment is to be continued at home, appropriate information concerning the administration of the eye drops, handling, disposal instructions and details of obtaining further medicine supplies if needed.

11.8 Oral Medication

11.8.1 Oral Medication – ‘Outpatient’ Administration within designated / defined areas’

• Prior to giving the patient a supply of their medicine to take home the administrator must check all information defined within section 9.1 and that compliance can be achieved.

N.B. Patients and staff must not break, halve or crush tablets and capsules must not be opened. Queries about difficulties in taking oral medicines should be directed to the appropriately qualified pharmacist. If an oral liquid formulation is not commercially available, the Pharmacy Department may be able to prepare an alternative liquid form. In such cases, doses may be extemporaneously prepared in an appropriate controlled environment to give a suitable form ready for administration to the patient.

• The use of multi-compartment compliance aids or monitored dose systems are not recommended. If the patient requires this type of aid then a full risk assessment must be undertaken and documented in the patient’s medical notes.

• Oral medication must be administered in accordance with Trust procedures with specific attention given to checking the medication labelling to ensure the following information is noted on the box / bottle:
  
  • Patient name
  • Generic drug name
  • Strength of tablets or capsules, or concentration of oral liquid
• The number of tablets / capsules in the container, or volume of liquid
• Administration instructions
• Length of treatment, including stop date as appropriate
• Storage instructions /conditions
• Caution: Cytotoxic Drug (as appropriate)
• Name and address of pharmacy department.

• Provide information / advice to the patient and carer / significant others (with the patient’s agreement) including:
  • How and when to take their medication
  • Administration details to include:
    - What to do in the event of missing one or more doses
    - What to do in case of vomiting after taking a dose
    - Likely adverse effects and what to do about them (i.e. toxicity management / health education)
    - Any need for and how to obtain further supplies
    - The role their GP is expected to play in their treatment
    - The need to inform their health care team if they are taking any over the counter medications/ supplements.
    - Principles of safe handling, storage and disposal
    - Written information
    - Manufacturers patient information leaflet
    - Within oncology - Medication specific information AND the Trust Generic Patient Information – Oral Anticancer Medication
    - Review / follow up arrangements
    - Pathway for self-referral including ‘out of hours’ contact information (Appendix 1).

• Record details of administration in the patient’s medical notes and patient held records (if used) in accordance with the Trust and professional procedures / guidelines.

11.8.2 Oral Medication - Administration to ‘In-patients’ within designated / defined areas’

• It is acknowledged that in some instances oral anticancer medication or oral chemotherapy for non oncology conditions may need to be administered to patients who are admitted to the Trust. A detailed medical / medication history and holistic assessment of the patient must be undertaken on admission and medication must only be prescribed and administered when it is confirmed that it is clinically appropriate and safe to do so.
- Any supplementary medications should be administered in accordance with the patient's prescription / treatment protocol e.g. antiemetics.

- The patient’s prescription (section 5.2) must reflect their protocol and the details on the patient’s medication box / bottle.

- Where possible, the patients own medication should be utilised for the remainder of the cycle to minimise the risks associated with prescribing inappropriate / incorrect dose or duration of treatment. If the patients own medication is not available, ‘patient only’ stock should be ordered.

- In some instances patients, and or carers, can self administer their medicines in accordance with Trust procedures. In this situation the responsibility for administration lies with the patient with the Health Care Professional’s role being one of assessment, monitoring and support. Patients must remember to wash their hands thoroughly before and after handling their medication and carers should wear gloves.

- If the patient / carer are not self medicating then two qualified practitioners are required to check and administer oral anticancer medicines in accordance with Trust policies. The administering nurse is responsible for assessing (section 9.1) and monitoring the patient’s condition and promptly reporting any treatment related toxicities to the patient’s specialist team. (In oncology areas the administrating nurse must be a chemotherapy administrator whose name is included within the Trust register of authorised chemotherapy administrators - Nurses undergoing training can administer medication providing they are being supervised by a qualified chemotherapy administrator. If a child is to continue taking an oral anticancer medicine when admitted to a non oncology area at the RVI their oral anticancer medication must be administered by a paediatric oncology chemotherapy administrator. These nurses are responsible for ensuring that the patient is able to proceed with their treatment as outlined in the pre-treatment verification process (section 6).

- Nurses who administer oral anticancer medications should avoid direct contact with these medications. If the tablet or capsule are within a blister or foil packed, the required number of dose units should be cut from the dispensed strip and put in a medicine pot. The medication can then be taken to the patient’s bedside where it can be pushed through the blister / foil wrapping by the patient or
nurse, either onto the patient’s hand or into their medicine pot / cup for administration.

**N.B.** If a patient’s oral medication is suspended on admission and then restarted by the patient’s specialist team, during their admission or on discharge, specific details regarding the revision in the duration / timing of cyclical treatment must be recorded within the patient’s inpatient drug Kardex and within their medical notes. The specialist pharmacist should be consulted prior to the patients discharge to ensure that they are discharged with the correct amount of appropriately labelled medications.

12 **Admission of a patient who is receiving Systemic Cytotoxic Chemotherapy or Anticancer Medication**

12.1 **Unplanned / Emergency Admission of patients to a non-designated area**

- All patients who are receiving chemotherapy are at risk of neutropenia and the risk of this complication should be assessed and managed immediately in accordance with local guidance.
- A member of the patient’s cytotoxic chemotherapy / anticancer medication team must be contacted within 24 hours of an emergency admission to undertake a detailed medical / medication history and holistic assessment of the patient:
  - Indication for therapy
  - Medication(s) and dose(s), route and frequency of administration, e.g. daily, weekly, continuous or cyclical
  - Intended start date, duration of treatment, intended stop
  - If appropriate date for each cycle of treatment and date of next cycle
  - Any supportive medications, e.g. anti-emetics
  - Toxicity assessment
  - Where possible a copy of the original prescription should be obtained.

- A senior doctor (Consultant/ Specialist Staff Grade / SpR) from the patient’s oncology / chemotherapy team (or a designated senior deputy identified by one of these individual) **must** be contacted to:
  - Confirm the patient’s medication history
  - Assess the patient’s suitability for continued treatment
  - Acquire specific regime / protocol details
  - Prescribe the patients treatment in the patient’s inpatient drug Kardex (Paediatric oncology and adult haemato-oncology) OR confirm and countersign (in the case of adult solid tumour oncology patients), the patient’s inpatient prescription / drug Kardex.
• Identify and initiate an assessment / review pathway during admission and for discharge (including any requirement for discharge medication).

**N.B.** Oral anticancer medicine must not be prescribed or administered until it is confirmed that it is clinically appropriate and safe to do so. The patient’s medications should only be prescribed by appropriate personnel (section 5.1). If a patient’s oral medication is suspended on admission and then restarted by the patient’s specialist team, during their admission or on discharge, specific details regarding the revision in the duration / timing of cyclical treatment must be recorded within the patient’s inpatient drug Kardex and within their medical notes.

12.2 Planned Admission of a patient to a non-designated area OR a patient requiring treatment in a non designated area

• The Consultant responsible for the cytotoxic chemotherapy / anticancer medicine management of the patient should be contacted by the treating Clinician / ward / department and, having undertaken a risk assessment, decide if administering these medicines outside of the ‘named ward / area’ would be appropriate. The Consultant must:

  • Provide the treating Clinician and the ward with details pertaining to the patient treatment protocol.
  • In advance, inform the treating ward of the patient’s pending admission in order to enable them to consult with the patient’s treating team as outlined below.
  • In the case of parenteral administration, document in the patient’s medical notes the rational for administering chemotherapy outside the usual ‘named ward / area’.

• The sister / designated deputy of the treating ward / department should contact a senior member of the patient’s cytotoxic chemotherapy / anticancer medicines nursing team (e.g. ward sister, named nurse, CNS, matron) to acquire specific information and support: This individual will, where appropriate:

  • Provide verbal and written information regarding the nursing management / observation of the patient during / post treatment focusing on minimising side effects, maintaining safety and 24-hour contact numbers for information / support (Appendix 1).
  • Ensure that the non-designated area has the relevant equipment for the management of anaphylactic shock, cardiac arrest, spillage and extravasation. (The chemotherapy administrator may be required to collect and transport the extravasation pack, spillage kit, cytotoxic sharps bin and personal protective equipment to the non-designated area).
• Establish transport arrangements for the patient’s therapy. (A chemotherapy administrator may be required to transport intravenous therapy from the Cytotoxic Pharmacy Dispensing Unit to the non-designated area).

• Facilitate the appropriate verification and pre treatment assessment to be completed (section 6 and where appropriate elements within section 9)

• Confirm arrangements for the cytotoxic chemotherapy / anticancer medicines review of the patient.

13 Disposal of Cytotoxic Waste

• A Trust segregation chart should be displayed in each area handling cytotoxic chemotherapy.

• All sharps, syringes and unused / unwanted / expired cytotoxic medication (including un-emptied infusion bags) should be placed in a ridged yellow sharps container with a purple lid and identified as containing ‘cytotoxic’ waste. Sharps boxes must only be filled to two thirds of their capacity and all three locks engaged.

• All other items used in the preparation, administration and handling of these medicines e.g. intravenous administration sets (together with waste contaminated with cytotoxic medicines which is of a disposable nature e.g. nappies, incontinence pads) must be placed in a ‘cytotoxic’ waste bag which is a yellow bag with a purple stripe. Once two-thirds full the bag, the top of the bag should be pulled together, taped, twisted firmly, fold over to form a swan neck taped again and secured with a yellow cable tie.

• When in use the bag should be kept in yellow sack holders which have foot operated lids. Cytotoxic magnetic labels are available to attach to the lid.

• “Weaver” rigid containers (25 or 50 litre) are available if one bag is not suitable. They can be obtained from supplies.

• Cytotoxic waste bags and sharps boxes must be labelled using a general waste label which includes details of the hospital, ward or department, time, date and initials of the member of staff. An additional label stating ‘Contaminated – For disposal by incineration – Cytotoxics’ must also be added.

• All cytotoxic waste must be stored in a designated area or a large four wheeled yellow cart fitted which will be fitted by the porters with a purple Bio-track label. The lids of these carts must be kept locked at all times. The porter must be contacted when the bin / area is almost full to enable them to remove waste to the cytotoxic waste collection point for the contractor.
• Contaminated linen should be treated as infected waste and disposed of in a soluble red ‘sunlight’ bag, tied and secured with a yellow cable tie before being sent to the laundry. Bags awaiting transportation to the laundry should be stored in a designated locked storage area. If linen is too heavily contaminated then it should be treated as dry cytotoxic waste and disposed of as identified in the second bullet point above.

14 Management of Cytotoxic Spillage

• Clear the contaminated area of all people, other than those cleaning the spill, and restrict access. Do not leave the area unattended. Display the safety sign near the spill area.

• If the spillage is >5 mls and / or over an area greater than 30 cm's, locate the cytotoxic spillage kit, which must be available on each ward where cytotoxic chemotherapy is administered and follow the instructions on or within it. (The spillage kit contains instructions on handling spillage, using and replacing the kit and cleaning the area).

• Put on protective clothing, safety glasses, gown and, if the spillage kit is required, both pairs of gloves, mask and overshoes / shoe coverings (if the spillage is on the floor).

• If a cytotoxic agent or anticancer medicine comes into contact with the eyes irrigate thoroughly, for approximately 20 minutes, with either Sodium Chloride 0.9% eyewash or cold water taken from the tap. The Ophthalmology department must then be contacted for additional advice and information.

• Broken skin areas should be irrigated with water and bleeding controlled.

• Deal with spillage on people first:
  
  • **Patient** - Explain the procedure to the patient. Remove any clothing and wash contaminated skin with copious amounts of soap and water while maintaining the patient’s privacy and dignity. Document the spill in the patient’s medical notes. Review COSHH data summary for individual medication requirements.
  
  • **Staff** - Remove any clothing and wash contaminated skin with copious amounts of soap and water while maintaining privacy and dignity. Inform occupational health, or if out of hours Casualty or Admissions Suite. Review COSHH data summary, located within the ward / department, for individual medication requirements.

• Spillage area
  
  **Liquid Spillage** - Cover a liquid spill with absorbent swabs or pads. Use swabs to mop up the spill, starting at the outer edge of the spill area and working in a
circular motion inwards, towards the centre. If the pads supplied within the spillage kit transform liquid into a gel, use the scoop to place the contaminated gel into the cytotoxic waste bag supplied within the spillage kit.

- **Dry Spillage** - Dampen and pick up powders / solids using moistened absorbent swabs or the scoop supplied within the spillage kit. Using absorbent swabs, start at the outer edge of the spill area and working in a circular motion inwards, towards the centre.

- The scoop from the cytotoxic spillage kit should be used to place any broken glass into the ‘cytotoxic’ sharps container.

- Left over infusion fluid should be placed in a sharps box with absorbent wipes, sealed and labelled appropriately as per procedure for the disposal of waste (section 13).

- When the spillage has been removed, the area should be thoroughly cleaned using spill towels, mild detergent and water. Rinse the area well with clean water and dry the area completely using paper towels.

- When finished using the spillage kit, remove mask, safety glasses, gown, overshoes and outer pair of gloves and place them in the cytotoxic waste bag supplied. Wearing the inner gloves close the bag with a cable tie and place it inside the second cytotoxic waste bag. Remove inner gloves, close bag and secure with a cable tie.

- When the spillage kit is not required, remove protective clothing and place in a cytotoxic waste bag.

- Contaminated linen should be treated as infected waste and disposed of in a soluble red ‘sunlight’ bag, tied and secured with a yellow cable tie before being sent to the laundry. Bags awaiting transportation to the laundry should be stored in a designated locked storage area. If linen is too heavily contaminated then it should be treated as dry cytotoxic waste and disposed of in accordance with section 13.

- Wash hands thoroughly with soap and water and complete a Trust incident / accident form.

15 **Occupational Health**

- All staff are responsible for minimising their occupational exposure to anticancer medicines and waste products from patients receiving anticancer medicines by:
  
  - Ensuring that their working practices are in accordance with best practice defined within local, national and professional guidelines.
• Using appropriate personal protective equipment e.g. Nitrile gloves, plastic apron and eye protection if there is a risk that medication could spray into the administrator's eyes.

• Staff who are pregnant or who are breast-feeding should not be involved in administering anticancer medicines or managing spillage or waste products from patients who are receiving anticancer medicines. Although individuals who are trying to conceive should also minimise their exposure to cytotoxic agents, providing they maintain safe practice the potential risks are negligible. Pharmacy staff should refer to local Standard Operating Procedures for specific guidance.

16 Training

Specific training for the administration for anti-cancer medications exists for nursing, pharmacy and medical staff. All staff administering cytotoxic medications undergo annual assessments.

17 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.

18 Monitoring Compliance

<table>
<thead>
<tr>
<th>Standard/process/issue</th>
<th>Monitoring and audit</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>All staff will have annual assessments in the administration of cytotoxic medications</td>
<td>Records of assessments</td>
<td>Clinical educators for children’s and NCCC</td>
<td>Trust Chemotherapy Group</td>
</tr>
</tbody>
</table>

19 Consultation and review

This Guidance document was developed in consultation with senior oncology medical, nursing and pharmacy staff within the Trust. Comments on content / implementation should be directed to M. Vincent, Nurse Consultant, Cancer Services, D. Blake Senior Lead Clinical Pharmacist Paediatric Oncology or E Reay Lead Clinical Pharmacist Adult Cancer Services. The document has been reviewed and ratified by the Trust Chemotherapy Committee.
20 Implementation (including raising awareness)

All staff affected by this policy should be made aware of its contents. Staff will be informed via Line managers across NCCC and Systemic Therapies Group.

21 References


34. Royal College of Nursing (RCN) (2004) Administering subcutaneous Methotrexate for Inflammatory Arthritis


37. UK Children’s Cancer and Luekaemia Group


22 Bibliography


Pathway for ‘Out of Hours’ Self–Referral for oncology patients receiving systemic anti cancer medicines

Patients receiving ongoing haematological / oncology treatments and care have been provided with written and verbal information regarding referral mechanisms, including 24-hour contact details.

Patient / relative contacts the following areas within the Trust ‘Out of Hours’
- **NCCC Adult Oncology** – Ward 34 & 35 (0191 2137034/ 0191 2137035)
- **Adult Haemato- Oncology patients** – Ward 33 (0191 2137033) or as NCCC if previously received treatment in that area
- **RVI Paediatric Haemato-oncology patients** - Ward 4 (0191 2826004)
- **RVI Paediatric Oncology patients** – Ward 4 (0191 2826004)
- **RVI Paediatric BMT patients** – Ward 3 (0191 2826003)

Patient contacts the ward with the following:
- **High Temperature**: 
  - **Adults**: 2 separate readings, 1 hour apart, above 37.5°C OR 1 reading above 38°C
  - **Paediatrics**: 2 separate readings, 1 hour apart, above 38°C OR 1 reading above 38.5°C
- nausea / vomiting, pain / discomfort, diarrhoea, chesty cough, urinary symptoms, confusion, oral problems, generally unwell or requires advice

A senior qualified nurse completes the out of hour’s patient proforma

Patients advised to attend the ward

Patient attends the ward for assessment and has appropriate investigations:
- **Baseline Observations** (TPR, BP, Oxygen Saturation) & **Physical Assessment** - including venous access line / wounds / mouth
- **If pyrexial**: MSU / blood cultures / sputum / nose & throat swabs / stool specimen / chest X-ray - line / wound swab
- **Bloods** – FBC, U&E, Bone Chemistry, LFT’s, C Reactive Protein (CRP), X match, clotting

Patient’s condition is reviewed by a member of the medical team

Patient remains in hospital for treatment

Patient discharged home

Communication: Health Care Professionals are advised / informed, in writing using the out of hour’s patient Proforma or GP letter, regarding the outcome of the patient’s visit / telephone triage.
This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>Policy Title:</th>
<th>Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)</th>
</tr>
</thead>
</table>
| 1. | - Race * N  
- Ethnic origins (including gypsies and travellers) N  
- Nationality N  
- Gender * N  
- Culture N  
- Religion or belief * N  
- Sexual orientation including lesbian, gay and bisexual people * N  
- Age * N  
- Disability – learning difficulties, physical disability, sensory impairment and mental health problems * N  
- Gender reassignment * N  
- Marriage and civil partnership * N |
| 2. | Is there any evidence that some groups are affected differently? N |
| 3. | If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable? N/A |
| 4(a). | Is the impact of the policy/guidance likely to be negative? (If “yes”, please answer sections 4(b) to 4(d)). N |
| 4(b). | If so can the impact be avoided? |
| 4(c). | What alternatives are there to achieving the policy/guidance without the impact? |
| 4(d). | Can we reduce the impact by taking different action? |

**Comments:**

Name and Designation of Person responsible for completion of this form: DR A HUGHES Medical Oncologist/Trust Cancer Lead Date: MAY 2014

Names & Designations of those involved in the impact assessment screening process: DR A HUGHES Medical Oncologist/Trust Cancer Lead

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact, both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.