

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Anticancer Medicines Policy including Cytotoxic Chemotherapy for Non-Malignant Conditions

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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.

This policy is designed to be complimentary and used in conjunction with local Trust Policies on Medicines Management, as well as other related policies and guidelines outlined in the document, and those relevant to the individual clinical practice area.

2 Scope

The document provides best practice guidance for all Trust staff involved in the 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 to 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 conventional cytotoxic chemotherapy such as Cyclophosphamide, Hydroxycarbamide, small molecule/ antibody treatments such as Imatinib, Rituximab and other agents such as Interferon, Thalidomide or Lenalidomide, as well as targeted immunotherapies, such as Pembrolizumab.

It **does not** include hormonal or anti-hormonal agents such as Tamoxifen and Anastrozole or Intrathecal cytotoxic chemotherapy (ITC). There is a separate local Trust Policy regarding 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 The Chief Executive has overall accountability for implementation, monitoring and review of this policy on behalf of the Trust Board. This responsibility is delegated to the Trust Lead Clinician for Chemotherapy, supported by the Lead Clinician for Cancer, Lead Clinical Pharmacist (Cancer Services) and the Lead Cancer Nurse; they will be responsible for promoting and supporting the aims and objectives of this policy.
- 4.2 Directorate Managers, Clinical Directors and Heads of Department will support the Chemotherapy Lead Clinician in the application of this policy, by being responsible for ensuring that all staff involved in delivering chemotherapy services are aware of this policy.
- 4.3 The Chemotherapy Lead Clinician will provide leadership to the four designated Clinical Leads responsible for chemotherapy services (adult solid tumour oncology, adult haemato-oncology, Paediatric oncology and Intrathecal Chemotherapy), as well as the Lead Chemotherapy Nurse and designated Lead Pharmacists (adult and paediatric).
- 4.4 The Chemotherapy Lead Nurse will promote and facilitate high quality, patient centred chemotherapy services through the education and development of multi professional staff. They will also support the evaluation and development of chemotherapy services and the Quality Surveillance Team peer review process.
- 4.5 Healthcare professionals involved in the processes of prescribing, manufacturing, dispensing and administration of cytotoxic agents must be aware of their responsibilities, act within their scope of practice, maintain competence to fulfil their role and at all times practice within the guidance of their relevant professional bodies.

5 Process of initiating treatment

The Department of Health 2014 Chemotherapy Standards require that 'Clinical assessments and the decision to initiate the first cycle of a course of chemotherapy should be restricted to consultant medical staff, medical trainee staff (ST 3 and above) and also NCCG (Non-Consultant Career Grade) medical staff who are assessed as competent for this by their approved training programme. This applies to medical oncology, clinical oncology and haemato-oncology only.' In accordance with Chemotherapy Standards, junior medical staff (i.e. F1, F2, ST1 and ST2) CANNOT prescribe anticancer medicines

Non-medical prescribers (NMPs) can only prescribe the first cycle of any chemotherapy regimen/drug after decision to initiate the specific chemotherapy regimen/drug has been made by the patient's doctor. E.g. NMP's cannot make the clinical decision on what course of chemotherapy to prescribe for the patient, but can prescribe first cycle once decision has been made. There is a separate local Trust Policy regarding NMP prescribing.

Prescribers must ensure that they have undertaken all appropriate checks prior to prescribing each cycle of anticancer medicine, including the additional steps taken during initiation of treatments and obtaining informed consent according to local Trust prescribing and consent policies. Written consent must be obtained for all prescribing of anticancer medicines.

The consultation should be recorded in the medical notes and should include the following:

- Indication for and intent of treatment, including individualised risk / benefit analysis
- Past medical history, and comorbidity status.
- 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 non-prescribed medicines bought over the counter.
- Performance status
- Holistic needs assessment
- 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 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).

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.

Written [consent](#) to treatment 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).

The pregnancy status of the patient, if appropriate, at the time that treatment is discussed and determined. Screening for hepatitis B virus is now recommended in all patients (not only those at risk of this infection) before starting treatment for all indications, and where applicable, the patient's antibody status should be established in relation to chicken pox and measles and they should be provided with vaccination advice.

Written communication to primary and secondary care practitioners involved in the ongoing care of the patient must advise of 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.

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 it must be recorded in the patients' medical notes, whether the course was completed and if not the reasons for cessation – for example; toxicity, sub optimal response, disease recurrence. A copy of this information should be sent to the patient's GP and offered to the patient:

6 Protocols (Oncology specific)

The BNF should **not** be used as a primary source of prescribing information for anticancer medicines. The Trust has agreed the North of England Cancer Network (NECN) approved algorithms it intends to use. Protocols and prescriptions are electronically accessed and available within the ChemoCare® prescribing library and Q-Pulse® quality management system that support adult and paediatric, oncology and haematology prescribing. 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 NECN list of approved protocols and Network Site Specific Groups (NSSG) website pages contain treatment algorithms for anticancer medicines which are an integral part of each NSSG's clinical guidance documents.
<http://www.nescn.nhs.uk/networks/cancer-network/cancer-network-groups/>

The terms 'Off Protocol' / 'Non Approved' Protocols refer to those therapies / regimens that have not been approved for use by NICE or NHS England, the Children's Cancer and Leukaemia group (CCLG) or within the context of a R&D approved clinical trial. These protocols can only be initiated by the Consultant Oncologist / Haemato-oncologist / Paediatric Oncologist responsible for the patient's care and in accordance with NHS England Area Team policy on 'Managing Deviations from Approved Protocols/ Algorithms,' Available at <http://www.nescn.nhs.uk/chemotherapy-documents/>

The Trust Chemotherapy Lead Clinician, Lead Clinical Pharmacist (Cancer Services) and Chair of the Medicines Management Committee must review and monitor the use of 'one-off protocols' and deviations from agreed algorithms with all healthcare professionals responsible for the patient's care and with the appropriate information to safely deliver treatment. The information should include:

- Patient details & diagnosis
- Reason for request (why approved regimen cannot be used)
- Regimen details; dose(s), likely duration, cost, reference/evidence
- Prescriber Name, Signature & Date
- Second clinical opinion/ MDT signature & date (to ensure peer approval)
- Governance / financial authorisation signature(s) (May be same as 2nd opinion)
- Oncology pharmacist approval to ensure availability of the drug

The Trust local chemotherapy group must review and monitor the use of 'one-off protocols' and deviations from agreed algorithms and report this information to the Network Chemotherapy Group (NCG). Patients have the right to ask for funding from commissioners in exceptional circumstances but to do so require the support of their consultant. Patients also have the option of purchasing the medicine(s) privately, either as a private patient or following NHS additional private care guidance.

The patient's 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 an 'Off Protocol' / 'Non Approved' Protocols protocol more than three times a year.

7 Prescribing

7.1 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.

7.2 Oncology and haemato-oncology

The Clinical Lead Clinician is responsible in collaboration with the three Clinical Leads - adult solid tumour oncology, adult haemato-oncology, paediatric oncology) for maintaining a register of anticancer medicine prescribers and this is available within Q-Pulse®.

The first cycle of a course of chemotherapy should be prescribed by consultant medical staff, medical trainee staff (ST 3 and above) and also NCCG (Non Consultant Career Grade) medical staff who are assessed as competent for this by their approved training programme and whose name appears on the Trust's approved list of anticancer medicine prescribers.

Non-medical prescribers (NMPs), whose name appears on the Trust's approved list of anticancer medicine prescribers, can only prescribe the first cycle of any chemotherapy regimen/drug after a decision to initiate the specific chemotherapy regimen/drug has been made by the patient's Multi-Disciplinary Team. This means NMP's cannot make the clinical decision on what course of chemotherapy to prescribe for the patient, but can prescribe the first cycle once a decision has been made. NMPs must not be directly involved in the checking/ administration of prescriptions they have written. Good practice would be for the approval of NMP prescribers to be given by the clinical lead for oral anticancer medicines after discussion at the local chemotherapy group.

Prescribers of first and subsequent treatments must ensure they have undertaken all appropriate checks prior to prescribing each cycle of anticancer medicines, including the additional steps taken during initiation of treatments

and obtaining informed consent prior to all prescribing according to local Trust prescribing and consent policies.

In accordance with cancer standards, junior medical staff (i.e. F1, F2, ST1 and ST2) CANNOT prescribe anticancer medicines.

7.3 Prescriptions (Systemic Therapies)

All systemic cytotoxic chemotherapy and anticancer medications, barring exceptional circumstances, must be prescribed on a named patient basis and using designated documentation. Prescriptions must be computer system generated, controlled documents, which have been developed in accordance with Network or National guidance, such as the ChemoCare® system.

Systemic medication must **not** be hand written on a patient's fluid balance / intravenous therapy chart or within a standard hospital in patient medication chart. The prescription must be clear 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.

For repeat cycles details of the previous cycle should be available for reference Prescribers who write oral anticancer medicine prescriptions for patients who will have their medicines administered in external organisations to acute Trusts, e.g. nursing homes, prisons, and children's homes **MUST** provide the external organisation with details of the specified regimen and protocol.

7.4 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 CCLG BSA chart which can be found at the back of the BNF for children).

- 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), and oedema.
- Chemotherapy dose-intensity is a critical determinant of cancer outcomes and should be maintained in all patients, irrespective of obesity, full weight– based chemotherapy doses should be used in the treatment of the obese patient with cancer, particularly when the goal of treatment is cure. Clinicians should respond to all treatment-related toxicities in obese patients with cancer in the same ways they do for non-obese patients.
- If a dose reduction is employed in response to toxicity, consideration should be given to the resumption of full weight– based doses for subsequent cycles, especially if a possible cause of toxicity (e.g., impaired renal, hepatic function) has been resolved; there is no evidence to support the need for greater dose reductions for obese patients compared with non-obese patients.
- The use of fixed-dose cytotoxic chemotherapy is rarely justified (except for a few select agents).e.g. anthracycline has a lifetime cumulative dose and cardiac toxicity. 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.
- Protocol guidelines should always be followed for obese patients who are within a clinical trial.
- 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 health care professional (doctor, nurse, pharmacist) 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. 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.
- 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 Common Toxicity Criteria (CTC) grade 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 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. anti-emetics, pre-medication, topical applications, etc.

The following verification process must be performed together with those defined within the 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.

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 / ST3 or above) 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.

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.

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.

9.3 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°C – 8°C).

10 Administration Standards (Systemic Therapies)

Administration of these medicines should, barring 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.

Freeman Hospital <ul style="list-style-type: none">• Ward 33 NCCC• Ward 34 NCCC• Ward 35 NCCC• Ward 36 NCCC• Bobby Robson Clinical Trials Unit• Out Patients NCCC (Oral chemotherapy)• Radiology Department (Chemo-embolisation)	Royal Victoria Infirmary Children's Hospital <ul style="list-style-type: none">• Ward 4• Ward 14 Day Unit• Teenage Cancer Unit• Paediatric theatres
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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.

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 and liaise with 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.

Anticancer medicines must be 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 both adult and paediatric oncology this individual will invariably be a nurse. Oncology chemotherapy nurse administrators must have undertaken the Trust training and have, or be working towards, acquiring academic accreditation to support their practice. They 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 undertake an annual review of competence to support their practice.

10.1 Administered during normal working hours:

For the purpose of this document, 'normal working hours' refers to the usual 'day time hours', that are flexible to the needs of service provision, when medical, nursing and support services are available to support the delivery of anticancer medications on the 'named ward / area'. Administration outside of these normal working hours is to be discussed with the units senior Nurse and Matron before treatment delivery is agreed.

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 patient's 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'.

10.2 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.

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.

10.3 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'](#).

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

- The following guidance should be read in conjunction with existing Trust procedures and Network Adult Venous Access Policy which included care and management of CVADs. Available at <http://www.nescn.nhs.uk/chemotherapy-documents/>
- 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. antiemetic's, 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

Specific guidance regarding the care of Central Venous Catheters are defined within local Trust 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.

10.4.1 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.

10.4.2 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.

10.4.3 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, other than vesicants, and these should be set with low occlusion setting.
- 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.
- 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).

10.4.4 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).

10.5 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 / ≤ 12 mm length, Intramuscular needle 23g/30mm or 21g/40mm).

10.5.1 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.

10.5.2 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.

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.

10.1 Intravesical Instillation

The administration of Intravesical chemotherapy should, barring exceptional circumstances, be undertaken on Ward 1 or within the Urology Assessment Suite Freeman Hospital, where it is agreed as part of the ward's regular activity and to which patients are admitted in preference to other wards. Intravesical treatments are administered by urology nursing or medical staff who have undertaken a schedule of training and competency based assessments before being entered on the Trust chemotherapy register available within Q-Pulse®.

All intravesical chemotherapy barring exceptional circumstances must be prescribed on a named patient basis. Prescriptions must be controlled documents generated via the ChemoCare® system to facilitate safe prescribing practice and capture of SACT data.

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 sought from the patient's Consultant or Uro-oncology Clinical Nurse Specialist.

10.1.1 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 instil the medication slowly into the bladder. Rapid instillation can cause bladder spasm and 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.

10.1.2 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.

10.1.3 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.

10.2 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 (section 13), 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

10.3 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.

10.4 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.

10.5 Oral Medication

10.10.1 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.

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.

Information/advice should be provided 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.

10.10.2 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. antiemetic's.
- The patient's prescription must reflect their protocol and the details on the patient's medication box / bottle.
- Where possible, the patient's 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 patient's 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 administering 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.
- 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 ChemoCare® record 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.

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

11.1 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 ChemoCare® system.
- Identify and initiate an assessment / review pathway during admission and for discharge (including any requirement for discharge medication).

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 ChemoCare® record and within their medical notes.

11.2 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 rationale 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
- Confirm arrangements for the cytotoxic chemotherapy / anticancer medicines review of the patient

12 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.

13 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.

14 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.

15 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.

16 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.

17 Monitoring Compliance

Standard/process/issue	Monitoring and audit			
	Method	By	Committee	Frequency
All staff will have annual assessments in the administration of cytotoxic medications.	Records of assessments	Clinical Educators for Paediatric Oncology and NCCC.	Trust Chemotherapy Group	Annual
All nurses administering intravesical chemotherapy will have annual assessment of competency in that route only.	Records of assessments	Lead Uro-Oncology Specialist Nurse	Trust Chemotherapy Group	Annual

18 Consultation and review

This Guidance document was developed in consultation with senior oncology medical, nursing and pharmacy staff members of the Trust Chemotherapy Committee. Comments on content / implementation should be directed to Dr Andrew Hughes Chemotherapy Lead Clinician, Alison East Nurse Consultant, Cancer

Services, and Denise Blake Senior Lead Clinical Pharmacist Cancer Services. The document has been reviewed and ratified by the Trust Chemotherapy Committee

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Appendix 1

Out-of-hours Patient Self-referral Service

Scope and Objective

The Acute Oncology Service provides Oncology and Haematology patients with a single 24 hour point of contact (0191 2139302) for use when they have any issues regarding their health during their treatment, whilst outside of the hospital environment. This document defines the processes supporting the availability and use of this service

Definitions and abbreviations

- Standard hours: Monday to Friday, 0900-1700
- Out of hours: Monday to Friday, 1700-0900, Saturday & Sunday, 24 hours
- NSAO: Nurse Specialist (Acute Oncology)
- TP: Triage Practitioner - designated senior nurse in charge on each shift

Responsibilities

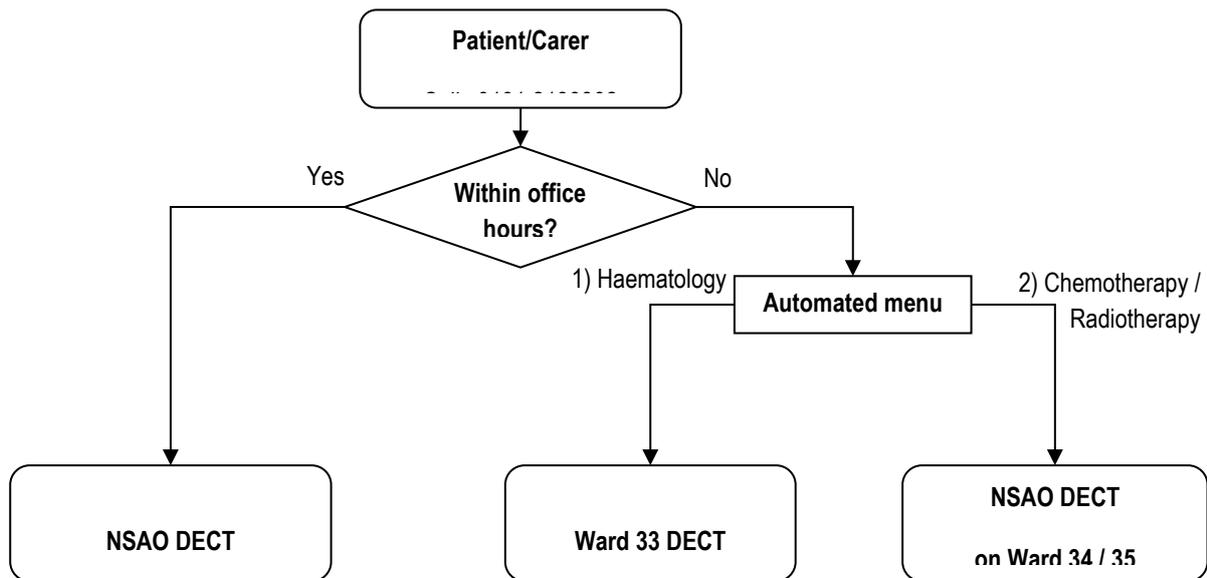
- Clinical Director - Approves the service.
- Matron - Escalates bed availability issues.
- NSAO - coordination of service, handover of telephone system, data collection.
- Ward 33, 34 & 35 Sisters - assigning TP for each shift, assigning telephone rota.
- Ward 33, 34 & 35 TPs – acknowledging receipt of telephone, triaging patient using UKONS toolkit, recording assessments and communicating outcomes/required actions.

Documentation

- UKONS Toolkit ([EXT_034](#))
- Alert Card ([AOS_005](#))
- Telephone handover sheet ([AOS_006](#))

Overview

The service is coordinated by the NSAO who acts as the single contact during standard hours. Outside of these hours, calls are handled by an automated system which gives the patient the option of “Haematology” or “Chemotherapy/Radiotherapy” and diverts the call accordingly (Ward 33 for Haematology or Wards 34/35 for Oncology/Radiotherapy patients) as shown below;



Answering calls

Calls should be answered in a calm professional manner. The NSAO/TP must state their **name**, **designation** and **ward** and proceed to assess the caller's problem using the UKONS rapid assessment toolkit. All call details, actions and outcomes must be recorded on the Log Sheet.

Service handover

The **NSAO** is responsible for the handover of service and management of the automated call handling facility as follows;

Starting out of hours service:

- Alert Helpline DECT Phone
 - NSAO hands phone to the TP/NIC on ward 34/35
 - NSAO communicates any outstanding or potential issues
 - TP/NIC on ward 34/35 signs handover sheet to acknowledge receipt of telephone
- Ward 33 nurses station phone
 - Calls automatically diverted from 2139302
 - NSAO Communicates any outstanding or potential issues

Resume standard service:

- Alert Helpline DECT Phone
 - NSAO recovers phone from the TP/NIC on ward 34/35
 - NSAO discusses any issues raised and collects completed Log Sheets
 - NSAO signs handover sheet to acknowledge receipt of telephone
- Ward 33 nurses station phone

- Calls automatically diverted back to 2139302
- NSAO discusses any issues raised and collects completed Log Sheets

Reporting

Any issues that have been raised during a call must be communicated to the relevant staff (i.e. Consultants, Radiographers etc) as soon as practicable.

A copy of each Log Sheet must be placed in the patient notes when next available. Original Log Sheets must be retained for audit purposes.

Reports on helpline usage may be generated from the automated system for subsequent analysis.

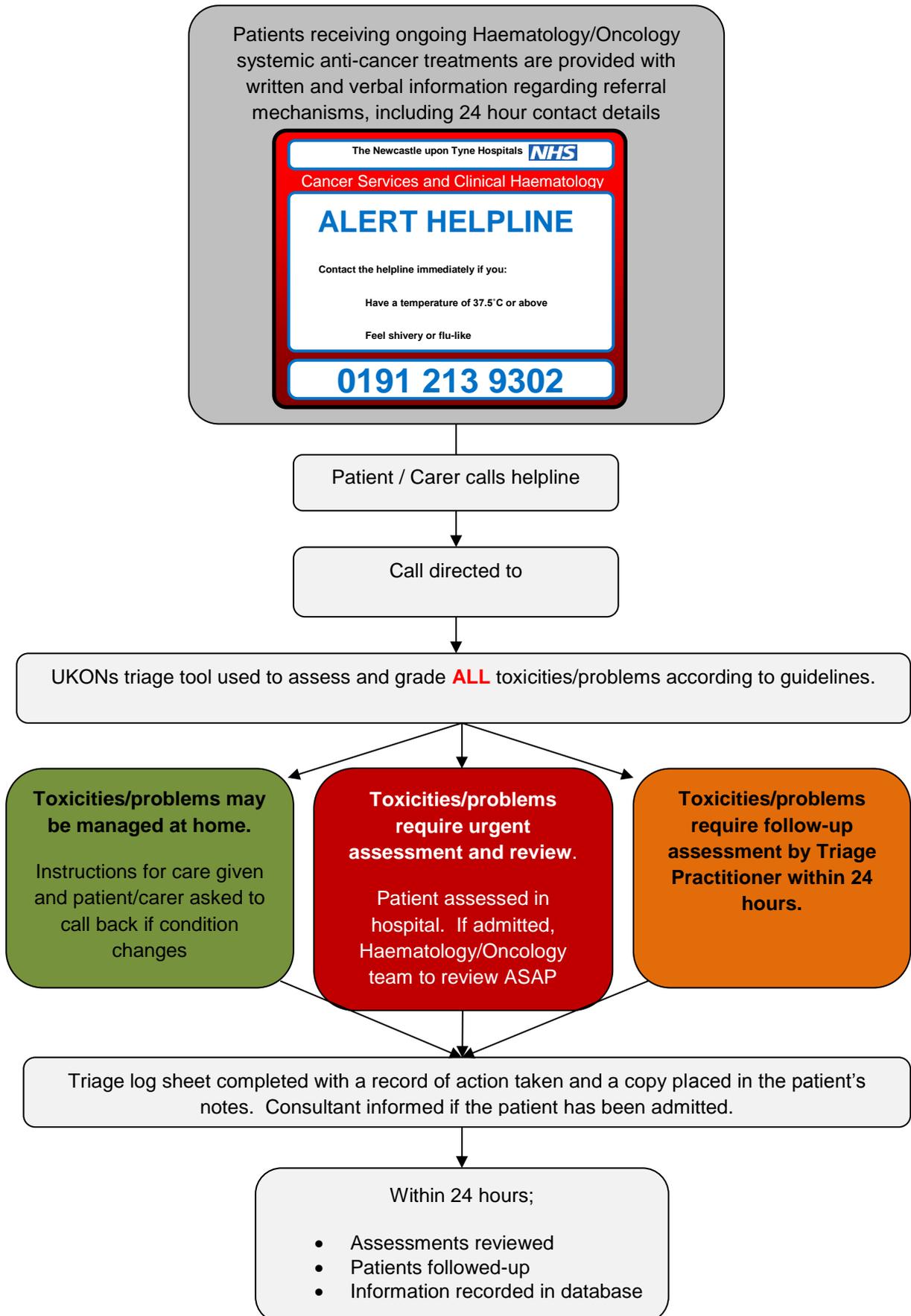
Radiotherapy Issues

If any Radiotherapy issues have been raised, the NSAO contacts Radiotherapy Scheduling on 38777 as soon as practicable. Scheduling staff are responsible for arranging collection of the log sheet from the NSAO (receipt of the log sheet is recorded in Mosaiq). Scheduling are responsible for forwarding the log sheet to the relevant treatment room.

Contingency Plan

In the event that AOS staff are not available due to unforeseen circumstances, NCCC Matron will allocate responsibilities to other staff to cover the service.

Out-of-hours Haematology/Oncology Patient Self-referral Service



Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. **Assessment Date:**
2. **Name of policy / strategy / service:**
3. **Name and designation of Author:**
4. **Names & designations of those involved in the impact analysis screening process:**
5. **Is this a:** Policy Strategy Service
Is this: New Revised
Who is affected Employees Service Users Wider Community
6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*
7. **Does this policy, strategy, or service have any equality implications?** Yes No
- If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:**

8. Summary of evidence related to protected characteristics

Protected Characteristic	Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups	Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address <i>(by whom, completion date and review date)</i>	Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? <i>(by whom, completion date and review date)</i>
Race / Ethnic origin (including gypsies and travellers)	Provision of Interprets Information available in other formats on request Mandatory EDHR Training Health Improvement Service for Ethnic Minorities available for advice and support Trust partnership work with 3 rd sector organisations BAME Staff Network	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Sex (male/ female)	Single Sex accommodation policy Mandatory EDHR Training Women's Health and Sexual Health Services available for advice and support Trust partnership work with 3 rd sector organisations	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Religion and Belief	Chaplaincy Team available for advice and support. Religion, Belief and Cultural Practices Policy and Guidance	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Sexual orientation including lesbian, gay and bisexual people	Mandatory EDHR Training Trust partnership work with 3 rd sector organisations Trust support of Northern Pride LBGBT Staff Network	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this

			policy should highlight risk
Age	Children and Young People's Services and Elderly Medicine Services Trust work in relation to Dementia Care Your'e Welcome Accreditation for Children and Young People's Services Services for teenagers for example Cancer Services Mandatory EDHR Training Trust partnership work with 3 rd sector organisations	No	This policy has been developed with input from the specialist paediatric oncology team at the Great North Childrens hospital. Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section	Psychological and Mental Health Services Rehabilitation Services Professions Allied to Medicine services Accessible Information Standard Provision of BSL Signers and Deaf Blind Guides LD Liaison Nurse, flagging of learning disability and patient passport. Trust work to support Carers Mandatory EDHR Training Trust partnership work with 3 rd sector organisations Disability Staff Network	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Gender Re-assignment	Trust Gender Identity Working Group Mandatory EDHR Training Trust partnership work with 3 rd sector organisations	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this

			policy should highlight risk
Marriage and Civil Partnership	Mandatory EDHR Training	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk
Maternity / Pregnancy	Staff involved in handling and administration of Maternity Services available for advice and support. Breast Feeding Policy and signage Mandatory EDHR Training Trust partnership work with 3 rd sector organisations	No	Staff should be aware of how protective characteristics can influence risk management and vulnerability of individuals Any training associated with this policy should highlight risk Staff who are pregnant are excluded from the administration of cytotoxic chemotherapy and this is outlined in this anti-cancer medicines policy.

9. Are there any gaps in the evidence outlined above? If 'yes' how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement? Yes No

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)

No

PART 2

Name:

Dr Andrew Hughes Medical Oncologist and Lead Clinician for Chemotherapy

Date of completion:

05 12 16

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)