The Safe Handling and Administration of Cytotoxic Products for the Treatment of Cancer

V4.0

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Summary.

This policy sets out the way in which cytotoxic products are to be used for the treatment of cancer within the Trust with the aim of reducing the risks associated with exposure.
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1. **Introduction**

1.1. This policy is written in accordance with the requirements of the Trust policy on the use of medicines.

1.2. It must be read in conjunction with:
- Trust Medicines policy
- Extravasation policy (Adults and Paediatrics)
- Guidelines for Patient Self-Administration of Medication (SAM).
- Clinical Guideline for the use of Intravascular Catheters in Adults at RCHT
- Trust Consent policy
- Non-Medical Prescribing Policy and Strategy
- RCHT Intrathecal policy
- The Nursing and Midwifery Council (NMC) Standards for Medicines Management
- Nursing Guidelines for the Safe Administration of Intraperitoneal Chemotherapy

1.3. Cytotoxic medicines are potentially hazardous substances which may be mutagenic, teratogenic and/or carcinogenic. There is now evidence to conclude that health care personnel exposed to these agents, through preparation and administration of cytotoxic agents, the care of patients during chemotherapy and in waste disposal may be at risk if not adequately protected.

1.4. **Cancer Chemotherapy**

1.4.1. Cancer chemotherapy can be divided into four main groups; steroids, immunosuppressants, monoclonal antibodies and cytotoxics. These guidelines are concerned with the cytotoxic drugs and it is this group which has caused concern with regard to possible adverse effects through handling.

1.4.2. Chemotherapy refers to treatment with drugs, whilst cytotoxic is defined as toxic to cells. Cytotoxic chemotherapy is therefore used largely to treat disease by killing cells. The terms chemotherapy and cytotoxic are used interchangeably in this document.

1.5. This version supersedes any previous versions of this document.

2. **Purpose of this Policy/Procedure**

2.1. This policy sets out the way in which such products are to be used for the treatment of cancer within the Trust with the aim of reducing the risks associated with exposure.

3. **Scope**

3.1. This policy applies to all personnel involved with cytotoxic medicines for the treatment of cancer, specifically:

- Medical staff
- Pharmacy staff
- Nursing staff
- Portering and domestic staff
3.2. This policy is primarily aimed at staff delivering chemotherapy for patients with malignant disease.

3.3. This policy includes oral and intra-vesical chemotherapy as well as parenteral routes.

3.4. Some aspects of the use of cytotoxic medicines in intrathecal chemotherapy are covered in a separate policy: in respect of cytotoxic chemotherapy using the intrathecal route, where there are differences between this document and the intrathecal chemotherapy document, the latter shall apply.

4. Definitions / Glossary

4.1. For the purpose of this document the term Oral Anticancer Medicine is used to refer to all drugs with direct anti-tumour activity, orally administered to cancer patients, including traditional cytotoxic chemotherapy such as capecitabine, hydroxy carbamide, chlorambucil and small molecule treatments such as imatinib, erlotinib, sunitinib and other agents such as thalidomide or lenalidomide. It does not include hormonal or anti-hormonal agents such as tamoxifen, letrozole and anastrazole.

5. Ownership and Responsibilities

5.1. Role of the Trust Lead Consultant for Cancer Chemotherapy
The Trust Lead Consultant for Cancer Chemotherapy is responsible for ensuring implementation and adherence to this policy.

5.2. Role of the Lead Pharmacist for Cancer Services
The Lead Pharmacist for Cancer Services will be responsible for:
- Co-ordinating the education and development of pharmacy staff in the handling, reconstitution, clinical screening and disposal of cytotoxic drugs.
- The maintenance of a register of Pharmacy staff competent to screen cancer chemotherapy prescriptions.

5.3. Role of the Chemotherapy Clinical Nurse Specialist
The Chemotherapy Clinical Nurse Specialist is responsible for:
- The education and development of nursing staff in the handling, administration and disposal of cytotoxic drugs.
- The maintenance of a register of Nursing staff competent to administer cancer chemotherapy.

5.4. Role of the Occupational Health Department
The Occupational Health Department will carry out health surveillance as necessary and appropriate assessment of staff exposed to cytotoxic products.

Advice will be sought from the Occupational Health Department if any adverse occurrence should occur. There is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to predict the effect of chronic long-term exposure. It is therefore extremely important that the working environment is safe and exposure to the medicines minimised.
5.5. **Role of Individual Staff Members**

- Any member of staff who suffers an adverse effect as a result of handling a cytotoxic drug, no matter how small, must report this to the Occupational Health Department and DATIX the incident, as soon as possible.

- All incidents that involve the accidental contamination of the skin or eye must be reported to the Occupational Health Department.

- Employees should notify their manager as soon as possible if they are pregnant, trying to conceive or are breastfeeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. This is also to comply with HSE guidance, stating that all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.

5.6. **Role of Managers**

5.6.1. Managers must ensure that a COSHH (Control of Substances Hazardous to Health) assessment is carried out in all areas where cytotoxic drugs are handled in order to assess the level of risk and the adequacy of control measures in place. The risk assessment should assume that there may be a new or expectant mother working in the environment in the following twelve months. Precautions must be in place at all times to minimise exposure by using protective garments, appropriate equipment, as well as safe and validated work practices.

5.6.2. There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to. There have been some studies suggesting adverse effects on the foetus, as a result of the mother working with cytotoxic drugs. Many of these studies, however, were carried out, or based on exposure during the 1980’s at a time when the use of personal protective equipment and safety isolators was not well established. Some later studies have failed to find a significant association with foetal adverse effects.

5.6.3. At the point where an employee discloses pregnancy, the line manager should conduct and document a work based risk assessment. Pregnant or breastfeeding staff will be expected to make an informed choice about working with cytotoxic drugs.

5.6.4. Staff who choose not to work with cytotoxic drugs will not be expected to be involved in directly preparing or administering chemotherapeutic agents or handling waste from patients treated with chemotherapy.

5.6.5. New, expectant and breastfeeding mothers should be specifically advised against any direct involvement in the management of a cytotoxic drug spillage.

5.6.6. There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to and personal protective equipment is used.
5.6.7. Pregnant or breast feeding staff who choose not to work with cytotoxic drugs will agree new working arrangements with their manager in the interim. The Human Resources Department will be consulted if no suitable alternative employment is found.

6. Standards of Practice

6.1. Prescribing of Chemotherapy

6.1.1. Consent

6.1.1.1. Prior to commencing a course of chemotherapy treatment or participating in a clinical trial with a cytotoxic agent, written consent must be obtained from the patient/guardian on the appropriate consent form in line with the Trust consent policy.

6.1.1.2. Written and verbal Consent must be obtained for any chemotherapy.

6.1.1.3. Consent will be obtained at the following stages of treatment

- 1st Chemo
- Start of new regimen/line of treatment
- For oral chemo/anti cancer treatments
- For any trial containing chemotherapy
- Chemotherapy-radiotherapy (can be done on one form)

6.1.1.4. Re-consent is not required if a new drug is prescribed or change of drug is made within one regimen for reason of patient tolerance or poor response.

6.1.1.5. The prescriber is responsible for ensuring the appropriate information is documented to enable the chemotherapy nurses to give all relevant information to the patient.

6.1.2. Chemotherapy Information for Patients

6.1.2.1. Patients / carers will be actively involved in decision making about their treatment. In addition to verbal information given during consultations, patients will be given written information specific to the regimen they will be treated with. Information sheets will include potential side effects, any necessary precautions and 24 hour contact details for use in emergency.

6.1.2.2. Patients will be provided with a personalised hand held record of their chemotherapy treatment.

6.1.2.3. Patients receiving cytotoxic therapy at home will be given appropriate written information. This includes patients receiving oral chemotherapy. Patients must be adequately counselled to ensure their understanding of the regimen details, storage conditions and handling precautions.

6.1.2.4. Information must be given to parents/guardians on the safe handling required for children receiving chemotherapy.
6.1.2.5. The information given to patients must be from recognised sources.

6.1.2.6. A copy of clinic letters are not routinely sent to patients, but patients can request to receive a copy and should be made aware of this option.

6.1.3. **Chemotherapy Information for General Practitioners**

6.1.3.1. A clinic letter will be sent to the GP prior to the patient’s first chemotherapy highlighting the treatment regimen to be administered to their patient. The planned start date and duration of treatment should also be included, along with the treatment intent, expected toxicities and the contact numbers to be used in event of complications. Any role that the GP is expected to play in managing the patient should be made clear.

6.1.3.2. After the patients final cycle of chemotherapy a treatment summary should be sent to the patients GP. This should include whether or not the planned course of treatment was completed. If it was not completed the reason why, for example toxicity, sub optimal response, disease recurrence or a combination of these. If the treatment is completed reference to the response to treatment should be included where appropriate.

6.1.3.3. Relevant primary healthcare staff will be informed when a patient is being treated with infusional chemotherapy in the community.

6.1.4. **Prescribers’ Register**

6.1.4.1. The list of prescribers who are authorised to prescribe cytotoxic chemotherapy within haematology and oncology shall be maintained via account access to the ARIA prescribing system.

6.1.4.2. Prior to a practitioner being granted with an account an application form must be completed including the category of access required. For prescribers, this must be authorised by a consultant oncologist or haematologist.

6.1.4.3. ARIA training must be completed before the live account is activated.

6.1.4.4. Only practitioners who have an ARIA account are authorised to prescribe cytotoxic medicines for haematology and oncology patients.

6.1.4.5. In this policy only, such prescribers are described as “registered prescribers”

6.1.4.6. Within paediatric oncology, the list of authorised prescribers shall be maintained as a separate list by the Paediatric Head of Service/Lead Cancer Pharmacist.

6.1.4.7. Within urology cytotoxic chemotherapy will only be prescribed by Consultants and specialist Registrars within their level of specialism.
6.1.5. **Prescribers**

6.1.5.1. The decision to treat a patient with chemotherapy is the responsibility of the relevant Consultant Oncologist, Consultant Haematologist, Consultant Urologist or Consultant Paediatrician, first courses of cancer chemotherapy may only be prescribed by these Consultants or an authorised Specialist Registrar (see below).

6.1.5.2. Subsequent cancer chemotherapy courses may only be prescribed by registered prescribers.

6.1.5.3. Prescribers in urology are only permitted to prescribe within their own speciality.

6.1.5.4. If oral chemotherapy is to be prescribed by a General Practitioner this should be managed as part of a shared care agreement.

6.1.6. **Authorisation Procedure for Changing the Prescribing role of the Oncology or Haematology SPR and Staff Grade doctors on Aria to allow the Initiation of chemotherapy regimens.**

6.1.6.1. The SPR or Staff Grade doctor must have completed the required training to the satisfaction of his/her supervisor.

6.1.6.2. The supervisor should write a statement, confirming that the SPR or Staff Grade doctor has completed the training required and is now competent to initiate chemotherapy, to the Cancer Services/E-Prescribing Pharmacist or Lead Cancer Pharmacist.

6.1.6.3. The pharmacist will send a copy of this letter to the CITS Business Support team, at the same time requesting that the doctor be changed from the SPR to Consultant User group on Aria.

6.1.6.4. The Cancer Services/E-Prescribing Pharmacist or Lead Cancer Pharmacist will provide upgrade training on Aria for the doctor.

6.1.6.5. Once the access is changed, the SPR or Staff Grade doctor can initiate chemotherapy, but should leave the prescription ‘Pending’ for approval by the supervisor for a minimum of the first five prescriptions until both parties are confident in the prescribing skills of the doctor on Aria. A log should be kept of these patients for CPD.

6.1.7. **Non Medical Independent or supplementary Prescribers**

6.1.7.1. Non Medical Independent or supplementary Prescribers who have completed the necessary training, are registered with their professional body and are authorised by RCHT to prescribe can prescribe chemotherapy within their area of competence.

6.1.7.2. Non Medical prescribers cannot prescribe the first cycle of chemotherapy.
6.1.7.3. Non-medical prescribers who wish to be added to the register of authorised chemotherapy prescribers must be approved by the clinical chemotherapy lead after discussion at the chemotherapy MDT.

6.1.7.4. They must work within the Guidance set out in the Non-Medical Prescribing Policy and Strategy.

6.1.8. **The Prescription**

6.1.8.1. Intrathecal chemotherapy must be prescribed on a separate chart from all other therapies – see the separate policy.

6.1.8.2. All prescriptions must be computer generated using the Aria computer prescribing system in the departments which this is available. In exceptional circumstances, details of which must be documented on the prescription, handwritten prescriptions on form CHA388 will be accepted.

6.1.8.3. Urology prescriptions for intra-vesical chemotherapy must be produced using the A4 prescription proforma or form CHA388.

6.1.8.4. The prescriber is responsible for ensuring the appropriate relevant support drugs, IV fluids and specific instructions pertaining to the individual regimen and patient are prescribed.

6.1.8.5. The following must be documented either on the prescription, in the patient notes or in the patient specific protocol/record prior to the patient commencing chemotherapy treatment:

- Cancer type
- History of specific diseases or conditions affecting fitness for chemotherapy
- Performance status
- Prior history of chemotherapy
- Current patient medication affecting chemotherapy
- That informed consent has been obtained
- Treatment intention-e.g. palliative, curative/radical, adjuvant, neo-adjuvant.
- Planned regimen and doses
- Number of cycles intended
- Frequency of cycle
- Investigations necessary prior to starting the whole course.
- Investigations to be performed serially during the course (to detect and monitor both toxicity and response) and their intended frequency.
- For palliative, curative/radical and neo-adjuvant treatments the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course
- That a holistic needs assessment has been carried out.

6.1.8.6. Chemotherapy regimens should be prescribed in the context of a recognised approved protocol. Adult protocols are available for reference on Aria. In case of Aria unavailability, hard copies are kept in the Cancer Pharmacy Office. Please refer to the Aria contingency plan for further details. Paediatric protocols are stored on the Paediatric oncology shared drive with hard copies in the CLIC office.
6.1.8.7. Protocols must have been approved locally by the Chemotherapy MDT, or relevant paediatric monitoring forum.

6.1.8.8. New regimens may require confirmation of funding before proceeding.

6.1.8.9. For regimens that are not approved please refer to appendix 11 off protocol prescribing.

6.1.8.10. Prescriptions must be complete, clear and simple to follow. The rules given in the current edition of the Medicines Policy - in the Royal Cornwall Hospitals trust must be followed. Prescriptions must include the following information:
- Patient demographic details
- Weight, height and surface area of the patient where required for the regimen.
- Drugs and doses (including all cytotoxic chemotherapy medicines to be used and elective support drugs including anti-emetics)
- Frequency of administration
- Route of administration where the medicine is intended for intrathecal administration the word ‘INTRATHecal’ should be written in full on the prescription chart. For infusions, details of solution and volume, duration of infusion and any other administration instructions.
- Cycle number and date to be given
- The exact duration of treatment or, for continuous treatment, the intended review date.
- Reason for any dose modifications.

6.1.8.11. All intended deviations from protocol such as dose modifications should be clearly identified as such and recorded in the patient’s notes, on the prescription and communicated to the patient’s GP.

6.1.8.12. The planned course of treatment and arrangements for review/follow up should be recorded in the patient’s notes.

6.1.9. **Clinical Trials**

6.1.9.1. Patients entered into clinical trials will be seen and closely monitored by the clinical trials staff, consultants and chemotherapy nurses. Any deviation from the trial protocol must be confirmed by the consultant or registrar in charge of the patient's care.

6.1.9.2. Prescriptions for clinical trial patients must be produced using a trial-specific prescription (available on ARIA) and must be clearly annotated with the trial name and patient’s trial number, as relevant. Paediatric trial prescriptions must be stamped with the ‘On Trial’ stamp.

6.1.9.3. Written confirmation of patient registration/randomisation in the trial must be sent to pharmacy as soon as possible. This is required before a prescription can be dispensed.

6.1.9.4.
6.1.9.5. Trial specific prescriptions must not be used for non-trial patients.

6.1.9.6. A copy of the trial consent form must be available in clinic areas

6.1.10. **Inpatient prescribing (on admission)**

6.1.10.1. F1 doctors are not allowed to prescribe chemotherapy drugs for cancer indications. All chemotherapy will not be available for F1 doctors to prescribe via EPMA. In the event of a patient being admitted to a ward needing routine chemotherapy adding to their EPMA drug chart, contact should be made with a member of the oncology team (CNS, Pharmacist, on call Clinician) to arrange transcription if appropriate, or, get a F2 to add. Transcription can only occur where a valid ARIA prescription is in place and can be transcribed by registered prescribers or Pharmacist. Where no valid ARIA prescription exists, this would be considered initiation and would need to be prescribed by a haematology/oncology consultant on EPMA as well as ARIA.

6.1.10.2. Patients on oral anticancer medicines admitted to hospital wards are at risk from uncontrolled prescribing. A detailed drug history must be taken on admission including:
- Indication for anti-cancer therapy
- Drug and dose, frequency of administration e.g. daily, weekly, continuous or cyclical.
- Intended start date, duration of treatment, intended stop date for each cycle of treatment and date of next cycle.
- Any supportive medications e.g. anti-emetics.

6.1.10.3. The patient’s current medical condition must be assessed to ensure suitability for continued treatment with the medicine.

6.1.10.4. Where possible the patient’s own medication should be utilised for the remainder of the cycle, thus minimising the risks associated with prescribing inappropriate/incorrect dose or duration of treatment.

6.1.10.5. All inpatient prescriptions for oral anticancer medicines must be verified by an oncology trained pharmacist. If the patient is not on a cancer ward, the oncology pharmacist will print the protocol information for the patient’s notes in order that this information is available to non-specialist staff without Aria access.

6.1.10.6. In situations where the patient is not on the cancer ward and the patient cannot self-administer, ward staff should also be provided information on the safe handling of oral chemotherapy.

6.1.10.7. Repeat oral anticancer drug prescribing needs caution and should be prescribed by an authorised prescriber using the appropriate chemotherapy prescription NOT on a discharge prescription.
6.1.11. **Inpatient prescribing (new prescriptions)**
6.1.11.1. In-patient prescribing for new patient must be to the same standards as prescribing for outpatients.

6.1.11.2. Treatment may only be initiated by those prescribers outlined in section 6.1.4

6.1.11.3. Prescribing must be done using the Aria system (for adults), or for paediatrics using form CHA38.

6.1.11.4. The EPMA chart should be annotated to indicate that the patient has been prescribed cytotoxic medication on Aria or that it is handwritten, using the drug file ‘Chemotherapy-see Aria’. If prescriptions need to be transcribed onto EPMA, they must be deleted from the Aria prescription.

6.1.12. **Treatment Review**
6.1.12.1. Before repeat cycles of chemotherapy are prescribed or administered the patient must be clinically reviewed by an appropriately qualified and competent clinical staff member who will:
  - Ensure that the patient’s medical condition and blood parameters support ongoing treatment.
  - Check results of all investigations, blood parameters and specific drug calculations specified within the treatment protocol.

6.1.12.2. In the case of in-patients receiving their medications over a period of days, the above checks must be done before the first dose is given in hospital and then regularly during treatment according to the parameters specified in the written protocol

6.1.12.3. Prior to each cycle commencing the following should be documented, either in the patient’s notes or on the prescription/Aria system:
  - The results of essential serial investigations applicable to that cycle (and prior to an administration within a cycle if applicable e.g. ‘day 8’ chemotherapy
  - Any dose modifications and whether or not they are intended to be permanent
  - Any cycle delays
  - Any introduced support drugs not recorded at the initiation of treatment
  - Performance status
  - Any toxicities following the previous cycle

6.1.13. **High Intensity Chemotherapy**
6.1.13.1. The 18 beds on Lowen ward are designated for High Intensity Chemotherapy patients. 7 of these beds are side rooms, 5 with HEPA filtered air supply.

6.1.13.2. High Intensity Chemotherapy patients may be directly admitted to those beds by Lowen ward staff as required.
6.1.13.3. High Intensity Chemotherapy patients will be given the 24 hour contact number as described above.

6.1.13.4. Consultant Oncologists, Haematologists and Microbiologists will be rota’d to provide on call advice and support for High Intensity Chemotherapy patients.

6.2. Dispensing of Chemotherapy

6.2.1. Reconstituting Cytotoxic Drugs
6.2.1.1. The Director of Pharmacy is responsible for ensuring that cytotoxic reconstitution services are provided in appropriate audited facilities or otherwise that products are purchased from licensed cytotoxic facilities. Handling procedures for manufacturing staff in the Directorate of Pharmacy are documented in standard operating procedures.

6.2.1.2. No cytotoxic drugs should be reconstituted in clinical areas, with the exception of:
   - Savene when used for Extravasation, see RCHT Extravasation policy.
   - Mitomycin for intravesical administration, prepared using the mito-in device in the urology clinic, urology theatres and at West Cornwall day case unit.

6.2.2. Pharmacy Preparation
6.2.2.1. Preparation of aseptically prepared cytotoxic medicines in Pharmacy will commence after prescription verification by a suitably trained oncology pharmacist.

6.2.2.2. To enable efficient organisation of workload and to minimise delays in administration, chemotherapy prescriptions should be generated on ARIA good time, preferably 72 hours before the patient’s appointment time. This allows documentation and assembly to be completed before preparation.

6.2.2.3. Each dispensed product shall be labelled with the following details:
   - patient's name or Trial number
   - ward/clinic
   - drug
   - dose
   - diluent and volume
   - route of administration
   - cytotoxic preparation batch number (if appropriate)
   - expiry date and time
   - storage requirements
   - relevant additional cautionary or advisory labels as per local policy
6.2.3. Vinca Alkaloids (Vincristine, Vinblastine, Vindesine, Vinflunine and Vinorelbine)

6.2.3.1. A syringe, bag, or infuser containing a vinca alkaloid must be labelled with:

| FOR IV USE ONLY - POTENTIALLY FATAL IF GIVEN BY ANY OTHER ROUTE |

6.2.3.2. Adult and teenage patients treated in the headland unit will only receive vinca alkaloids from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9% (for some brands of Vinorelbine glucose 5% solution for injection may be used instead of sodium chloride 0.9%).

6.2.3.3. Vinca alkaloids must be supplied in volumes of greater than 10ml. Paediatric doses of 1mgm or less will be diluted to at least 10ml.

6.2.3.4. Paediatric wards are the only area where vinca alkaloids may be administered via a syringe.

6.2.3.5. All doses of vinca alkaloids for children greater than 1.0 milligram must be diluted to 20ml to alert practitioners that the intravenous route is the only route of administration and volumes of this size CANNOT be administered by the intrathecal route.

6.2.3.6. All Vinca alkaloid preparations will be individually wrapped in outer tamper evident bags which must be labelled:

| WARNING |
| DO NOT REMOVE THIS OUTER CONTAINER UNTIL THE MOMENT OF INJECTION. FOR INTRAVENOUS USE ONLY. POTENTIALLY FATAL IF GIVEN BY ANY OTHER ROUTE. |

6.2.3.7. The vinca minibag should be infused intravenously over 5 – 10 minutes and the patient closely monitored for signs of extravasation. Incidents of extravasation should be reported and shared via the National Extravasation Information Service.

6.2.4. Issue From Pharmacy
All chemotherapy preparations will be wrapped in sealable outer bags. The final product is checked by a Pharmacist before release to the ward or clinic.

6.2.5. Dispensing and Labelling Of Oral CytotoxicChemotherapy

6.2.5.1. All prescriptions for oral chemotherapy must be validated by an authorised pharmacist.

6.2.5.2. The prescription will be dispensed by the hospital pharmacy or the hospital outpatients pharmacy (Lloyds pharmacy at time of writing) in accordance with pharmacy standard operating procedures. Currently it is not recommended that oral anticancer medicines are dispensed by community pharmacies.
6.2.5.3. For courses of chemotherapy the exact number of tablets needed will be supplied. The quantity supplied must be subject to a second independent check during the dispensing process.

6.2.5.4. Label directions must be clear and unambiguous and include, where relevant, the intended period of treatment, start and stop dates or the number of days expressed as ‘for X days ONLY’.

6.2.5.5. The member of pharmacy staff handing the drugs to the patient should ensure the patient understands the dose they should take, what to do if any side effects/problems arise and who to contact including out-of-hours. In addition the following should be covered:
- Principles of safe handling, storage and disposal
- That, if used, spoons and measures should be used once only and then disposed of safely
- Any drug specific advice regarding safe crushing of tablets or opening of capsules

6.2.5.6. If, after counselling the patient on their medication it becomes apparent that the patient does not understand how to take the medicines or will have difficulty in compliance, the member of pharmacy staff should refer to one of the cancer pharmacists or to the clinic.

6.2.6. Supply of oral cytotoxic chemotherapy to inpatients
6.2.6.1. Where possible, patients own medicines must be used. Temporary stocks must not be used.

6.2.6.2. All anticancer medicines must be dispensed and labelled to include the following information:
- 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 conditions
- ‘Cytotoxic’ warning label
- Name and address of pharmacy department

6.2.6.3. Patients should be advised to return any unused oral anticancer medication that they may have at home.

6.2.7. Access to oncology pharmacy advice
6.2.7.1. There will always be available a trained cancer services pharmacist and paediatric pharmacist who are able to provide cancer drug advice to General pharmacy staff, Lloyds pharmacy staff and ward/clinic staff. They may be contacted via bleep.

6.2.7.2. In the absence of a cancer services pharmacist, a technical services pharmacist may be contacted and, out of hours, the technical services on call pharmacist.
6.3. **Transport**

6.3.1. Manufactured syringes, infusion devices and bags should be placed in a snap top plastic bag and transported in a designated leak proof container to provide adequate protection for the handler.

6.3.2. Oral cytotoxic drugs should be transported in the same way as non-cytotoxic medication and labelled as cytotoxic, in addition to the normal prescription label.

6.3.3. Staff involved in the transportation of cytotoxic agents must be trained and have access to the correct protective equipment to deal with spillage.

6.4. **Storage of Chemotherapy**

6.4.1. Cytotoxic Drugs that are to be stored at room temperature should be kept in a designated locked cupboard in an approved clinical area.

6.4.2. Cytotoxic drugs that are to be refrigerated should be kept in a designated dedicated locked drug refrigerator in an approved clinical area. The refrigerator temperature should be monitored daily.

6.4.3. Oral chemotherapy may be stored with but segregated from other oral preparations:

- Ward stock oral chemotherapy will be stored in the locked room temperature chemotherapy cupboard or chemotherapy fridge as applicable.
- Patient named room temperature oral chemotherapy can be stored in their individual drug lockers if they are deemed competent in line with the RCHT Trust Guidelines for Patient Self-Administration of Medication (SAM).

6.4.4. For storage of intrathecal chemotherapy see the separate policy.

6.4.5. **Storage within Pharmacy**

6.4.5.1. If cytotoxic drugs, including reconstituted drugs, partially filled vials, filled syringes and infusion solutions containing cytotoxic drugs are to be stored, this must be in a dedicated refrigerator or in a section of the cold room reserved solely for this purpose.

6.4.5.2. Cytotoxic drugs that are to be stored at room temperature, will be stored in the same area as, but segregated from other room temperature drugs

6.4.6. **Storage at Home – Advice to the Patient**

Cytotoxic medicines must be stored at the appropriate temperature in a safe place out of the reach of children. This aspect must be stressed to the patient and their family by hospital and community staff. Carers of patients should be advised to use safe handling procedures.
6.5. Administration of Chemotherapy

6.5.1. Checking
The requirements set out below are in addition to those given in the Trust Medicine’s policy.

6.5.1.1. Checks Prior to Administration
The patient’s fitness for treatment must be assessed in addition to all blood tests and relevant results and investigations, as identified by the specific regimen must be reviewed by the doctor/nurse prior to administration.

6.5.1.2. Checking of the Chemotherapy
- The Trust requires double checking for all injectable medicines administered intravenously e.g. IV boluses and IV infusions, by registered doctors, nursing and ODP staff.

- Therefore, double-checking of chemotherapy is required as best practice. Immediately prior to administration the nurse who will be administering the chemotherapy should check the chemotherapy with a registered IV competent nurse who has been assessed and deemed competent in the checking of chemotherapy administration. Both staff should then sign that it has been administered.

- It is the responsibility of the competent chemotherapy giver to ensure that they have appropriate current knowledge of the drugs being given. They should following the agreed protocol, be aware of possible immediate, short and long term side effects and the actions to be taken if these occur. They should also be aware of patients educational, psychological, supportive care needs and overall treatment plan.

- Staff undergoing chemotherapy training may only give chemotherapy under the direct supervision of authorised staff and must be in the process of completing their Chemotherapy workbook.

6.5.1.3. Paediatric Oncology Chemotherapy Verification Procedure:
6.5.1.3.1. Check patient’s identification. Confirm the patient’s details correspond with the prescription chart and all labelled chemotherapy. Patients who have been admitted must wear a name band with the correct identification.

6.5.1.3.2. Check that the patient has been assessed as ‘fit for chemotherapy’ by a competent doctor or senior nurse.

6.5.1.3.3. Check that spillage kit and extravasation kit are available (if pegasparaginase is to be administered check that the Asparaginase Rescue Kit is available)

6.5.1.3.4. Check that patient and family have consented to chemotherapy protocol
6.5.1.3.5. Check that the treatment protocol and cycle of treatment (treatment record at front of patient’s notes) correspond with what is documented on the chemotherapy prescription (current and previous)

6.5.1.3.6. Cycle number/week

6.5.1.3.7. Administration as the schedule within the cycle
- Check that the chemotherapy prescription and chemotherapy drugs have: The correct patient name and hospital number
- Check administration date is correct (confirm with date of last cycle)
- The correct drug (regimen and individual drug identification) and diluents with dilution volumes and any hydration and mesna
- The correct drug/dose (check this with the most recent patient’s weight and calculated surface area), route and rate
- Check expiry date has not expired

6.5.1.3.8. Check that critical tests have been carried out and that the results fall within the agreed protocol parameters eg FBC

6.5.1.3.9. Check that supportive drugs have been prescribed and given (RCHT Guideline for antiemetics in Paediatric Oncology)

6.5.1.3.10. Check that the prescription has been signed and countersigned

6.5.1.3.11. If the answer to any of these questions is no do not proceed. Refer to doctor/nurse in charge.

6.5.1.4. Adult verification procedure: check the following for each cycle before administration of chemotherapy:

6.5.1.4.1. Check for written and verbal consent before start of regimen. The individual administering the drug/s should revalidate consent prior to each cycle of treatment.

6.5.1.4.2. Check the required blood results and any other required monitoring tests are within range at the start of treatment or have been approved by the prescriber.

6.5.1.4.3. Assess toxicities and complications from previous cycles.

6.5.1.4.4. If any toxicities or complications are noted, ensure dose modifications or delays in treatment have occurred as per protocol.

6.5.1.4.5. Check that the patient has been prescribed anti-emetic drugs & supportive measures and where appropriate, these have been administered e.g. pre hydration.

6.5.1.4.6. Check that the name of the regimen and cycle number are correct.

6.5.1.4.7. Check that the drug and dose match exactly that prescribed on the drug chart or ARIA prescription.

6.5.1.4.8. Check that the correct diluents and dilution volumes are correct.
6.5.1.4.9. The patient's name must be on the chemotherapy packaging or container as appropriate. In the case of clinical trials, it may be the patient trial number or the patient’s initials only.

6.5.1.4.10. The route the drug is to be administered by and the duration intended.

6.5.1.4.11. The drug is to be administered in the correct sequence.

6.5.1.4.12. The drug will not expire before the infusion is completed.

6.5.1.4.13. Check that the drug has been appropriately stored.

6.5.1.4.14. If there are any discrepancies do not proceed, seek advice from the patient’s consultant.

6.5.2. Verification of the Patient Identity

6.5.2.1. Prior to administration of chemotherapy the chemotherapy nurse and checker should confirm patient identification as follows:

- Ask the patient to provide their name, address and date of birth.
- Check the hospital/NHS number on the patient’s wristband.
- Check that this corresponds with the prescription.

6.5.2.2. If there are any discrepancies identified refer to the patient’s consultant or a senior cancer pharmacist before proceeding.

6.5.3. Administration

6.5.3.1. Within the Royal Cornwall Hospital Trust, cytotoxic drugs may only be administered in designated areas approved for the purpose by the Head of Cancer Services, as shown in Appendix 3.

6.5.3.2. Cytotoxic chemotherapy for cancer must be administered by a suitably trained member of staff. Wherever possible the patient should be brought to one of the designated areas. If this is not possible appropriately trained staff will administer the chemotherapy in the clinical area where the patient is based. (e.g. ITU) The administering staff must ensure the team caring for the patient are fully aware of the safety precautions necessary in caring for the patient including waste handling (including bodily waste).

6.5.3.3. A register of those staff trained and permitted to administer adult cytotoxic chemotherapy will be maintained by the Chemotherapy Clinical Nurse Specialist. The register of those staff trained and permitted to administer paediatric cytotoxic chemotherapy to children will be maintained by the Ward Manager for Sennen ward.

6.5.3.4. An Extravasation kit, as defined in the Trust Extravasation Policy, must be available in all clinical areas where parenteral cytotoxic drugs are administered. There are separate kits for use in adult and paediatric areas. Kits are ordered from pharmacy when required.
6.5.3.5. Appropriate protective clothing is available and must be used when administering cytotoxic drug by any route.

6.5.4. **Gloves**
6.5.4.1. Gloves must always be worn when any cytotoxic drugs are handled.

6.5.4.2. Cuts and scratches on the skin should be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged. Staff with dermatological conditions (e.g. eczema) should be referred to occupational health for assessment of fitness to operate in their role.

6.5.4.3. Hands must be washed thoroughly with liquid soap/detergent or alcohol gel before and after glove application.

6.5.4.4. Gloves must be worn at all times appropriate to the task being undertaken and consideration needs to be given as to whether the procedure requires sterile or non-sterile protective gloves.

6.5.4.5. Gloves must always be disposable and preferably powder free, they must never be reapplied.

6.5.4.6. They must be changed regularly, always between patients and immediately after they become damaged or contaminated.

6.5.4.7. Individual practitioner's preferences should be considered with regard to sensation and dexterity, but they should fit appropriately and be close fitting.

6.5.4.8. Only gloves designed for handling cytotoxic chemotherapy should be used and it should not be assumed that all gloves are impermeable. Nitrile and latex gloves both offer good protection from cytotoxic contamination. Specific gloves to be used will be defined in Trust standard operating procedures (SOPs).

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

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

6.5.6. **Respiratory protection:**
6.5.6.1. Surgical masks do not offer protection against inhalation of fine dust or aerosols.

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

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

6.5.7. **Eye protection**
6.5.7.1. The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavity administration and when clearing up cytotoxic spillages.

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

6.5.7.3. Eye protection:
- Should fully enclose the eyes
- Be disposable where possible, or capable of undergoing decontamination cleaning.

6.5.8. All aprons, gowns, gloves and disposable personal protective clothing should be disposed of according to RCHT guidelines.

6.5.9. **Administration of oral chemotherapy**
6.5.9.1. Administration of oral anticancer medicines on oncology/haematology wards must be undertaken by appropriately qualified clinical staff who are competent to follow the same safeguards and checks as when administering IV anticancer medicines.

6.5.9.2. Clinical staff administering oral anticancer medicines on non oncology/haematology wards to inpatients must contact members of the patient’s specialist team for information and advice about the oral anticancer medicine if there are any uncertainties and be aware of safe handling procedures.

6.5.9.3. It is best practice for two practitioners to check and administer oral anticancer medicines. The trusts Administration of Medicines policies must be complied with.

6.5.9.4. Staff administering oral anticancer medicines must have access to the specified regimens/protocols. In areas where staff do not have access to Aria this will be provided as written protocol information, printed from the Aria system.

6.5.9.5. When patients are self-administering their oral anticancer medicines, the trust policy for Patient Self Administration of Medicines (SAM) should be followed.
6.5.10. **Administering Intravenous Chemotherapy**

6.5.10.1. **Selection of Device**

6.5.10.1.1. An appropriate vascular access device should be selected by a competent practitioner to fulfil the requirements of the proposed treatment plan.

6.5.10.1.2. Devices should be cared for following trust Guidelines:

6.5.10.1.3. Prior to chemotherapy administration it is important to establish that there is a free flowing rapid and consistent drip rate on gravity with a compatible infusion.

6.5.10.1.4. The administering practitioner must ensure appropriate venous access with regards to:

- Site
- Position
- Patency
- Integrity
- Visibility

6.5.10.1.5. For vein selection advice see Appendix 10.

6.5.10.1.6. With a CVC it should be possible to obtain blood return. If no blood return is obtained, there must be further verification of the patency of the device, as per trust policy.

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

6.5.10.1.8. See appendix 12 for further information.

6.5.10.2. **Sequencing of drugs**

6.5.10.2.1. Vesicant cytotoxics should always be given before non-vesicant cytotoxic/non cytotoxic drugs, unless the protocol specifies otherwise.

6.5.10.2.2. The exception to this is where patients require supportive therapy e.g. pre-hydration and anti-emetics prior to vesicant therapy.

6.5.10.2.3. If there is any uncertainty around the sequencing of the drugs then advice should be sought from an experienced chemotherapy nurse, pharmacist or doctor.
6.5.10.3. Monitoring

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

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

6.5.10.3.2. Since one of the first symptoms of infiltration or extravasation is discomfort at the site of cannulation or a burning stinging pain, it is important that the nurse explains to the patient, before the first drug is administered, what kind of symptoms to look out for and to report them immediately. Any change in sensation should be verbalised by the patient and checked by the nurse.

6.5.10.3.3. To ensure visibility at all times, an appropriate clear dressing should be fixed over the cannula or CVC as per Trust policy.

6.5.10.3.4. Opaque bandages should not routinely be applied to cannula sites when chemotherapy is in progress. If it is necessary to bandage the site, then the cannula should be observed frequently.

6.5.10.4. General Principles of Intravenous Administration

6.5.10.4.1. Use of aseptic non-touch technique should be maintained throughout intravenous administration

6.5.10.4.2. Ensure appropriate protective clothing is worn, as outlined above.

6.5.10.4.3. Checking of the patient and drug should follow procedure previously described in section 10.

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

6.5.10.4.5. Open the cytotoxic doses directly into a blue tray on a chemotherapy trolley

6.5.10.4.6. Ensure that the giving set is primed with a suitable flushing solution.

6.5.10.4.7. Always insert the adder line of the giving set into the cytotoxic infusion at waist height and over the trolley or tray. This is to minimise the risk of personal contamination in the event of a spillage.
6.5.10.8. When connecting the adder line to the infusion set check the connections on the giving set for leakage or cracking.

6.5.10.9. Ensure correct rate of administration.

6.5.10.10. Flush well between drugs using either 0.9% sodium chloride 0.9% or 5% glucose, depending on drug compatibility.

6.5.10.11. If the drug is prone to photo degradation, ensure that the infusion solution is covered to protect it from light, including the IV line, or use an appropriate giving set.

6.5.10.12. If a special giving set or filter is required, (e.g. paclitaxel), use only those recommended.

6.5.10.13. On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 19.

6.5.10.14. Giving sets should be changed every 24 hours.

6.5.10.15. A few vesicants (e.g. dacarbazine) can be administered as infusions through a peripheral line with care and close supervision.

6.5.10.16. Doses of vinca alkaloids should be administered from 50ml minibags, over 5-10 minutes with compatible fluid running simultaneously.

6.5.10.17. Record the completed administration of chemotherapy on Aria.

6.5.10.18. In the event of an adverse event necessitating an incomplete administration, it should be clearly documented how much of the dose was administered and the reasons for discontinuation of treatment. Medical staff and pharmacy should also be notified.

### 6.5.10.5. Administration of bolus chemotherapy for adults

6.5.10.5.1. Where bolus chemotherapy drugs are to be given they are administered, without exception, via the side arm of a giving set with a fast running drip of sodium chloride 0.9% or compatible solution.

6.5.10.5.2. Do not expel air from syringes. If air is in a syringe, hold it in such a way that the air is up near the plunger when the entire drug is expelled and the air is reached.

6.5.10.5.3. Place a sterile gauze swab under the injection port during administration. Administration should be performed over a sterile towel with waterproof backing to protect skin and surfaces from potential cytotoxic leakage.

6.5.10.5.4. Check for blood return every 2-5 ml during administration and before and after each drug during bolus administration.
6.5.10.6. **Administration Via Specific Routes**

6.5.10.6.1. Subcutaneous / Intramuscular
6.5.10.6.2. Intrapleural - into the pleural cavity
6.5.10.6.3. Intravesical - administration directly into the bladder, via a urinary catheter.
6.5.10.6.4. Intrapertitoneal – administration into the peritoneal cavity
6.5.10.6.5. Topical Cytotoxic Chemotherapy - Cytotoxic drugs for topical administration may come in a number of different formulations, including creams, ointments, gels and solutions. Topical cytotoxic drugs may be applied either directly to the skin or as ear or eye drops.

6.5.11. **Subcutaneous / Intramuscular Chemotherapy**

6.5.11.1. A subcutaneous injection is given beneath the epidermis into the fat and connective tissue underlying the dermis
6.5.11.2. An intramuscular injection is given into the muscle.
6.5.11.3. Wear appropriate protective clothing as outlined above
6.5.11.4. A maximum diluted volume of 2-3 mls per injection be should adhere to where possible for patient comfort. Volumes greater than this should be split into two or more separate syringes and administered into different sites.
6.5.11.5. Inspect sealed bag before opening to ensure there is no spillage within the bag. Open the bag directly onto the injection tray.
6.5.11.6. Choose a suitable site for the injection, and prepare the skin
6.5.11.7. Carefully remove the connector top from the Luer-lock syringe and attach appropriate gauge needle. Ensure needles for administration are secure taking great care to minimise risk of spillage on the skin.
6.5.11.8. Administer injection using the Z track technique. This involves displacing the skin and the subcutaneous layer in relation to the underlying muscle so that the needle track is sealed off before the needle is withdrawn minimising reflux.
6.5.11.9. Remove the syringe and needle, covering the site with low lint gauze and ensuring there is no leakage from the site.
6.5.11.10. If further injections are required, rotate the site of administration.
6.5.11.11. Dispose of all cytotoxic contaminated waste immediately as described below
6.5.12. **Others**

6.5.12.1. Please see individual policies for Intraperitoneal, Intrathecal and Intravesical administration of Chemotherapy.

6.5.12.2. Other routes of administration do not generally occur at RCHT. If such incidences did occur the procedure guidelines in the Royal Marsden Hospital Manual of Clinical Nursing Procedures 17th Ed, would be followed. If such incidences became routine then research would be carried out and a Guideline for RCHT produced.

6.5.13. **Administration of Chemotherapy Out Of Hours**

6.5.13.1. Where possible all chemotherapy must be administered during normal working hours that is between the hours of 08.00 and 1900 Monday to Friday. This allows for access to experienced haematology or oncology medical staff, pharmacy staff and the referral to plastic surgery medical team in the event of extravasation of a vesicant drug.

6.5.13.2. Some regimens will mean that weekend or over night administration of chemotherapy is require and can not be deferred. In these cases this must be carried out in a designated chemotherapy area, see exceptions below.

6.5.13.3. No bolus doses of anthracyclines should be administered after 8pm, and infusional anthracyclines MUST be given via central line.

6.5.14. **Exceptions**

6.5.14.1. Chemotherapy may be routinely administered outside these hours (extended hours clinics) following a risk assessment of the regimen/drug. Other exceptions include:

- Continuous Infusions
- Timed chemotherapy
- Chemotherapy given more than once a day

6.5.14.2. In cases where there is a clinical need for chemotherapy to be given urgently out of hours, the following criteria should apply:

- The patient's consultant or the consultant on call will identify the clinical urgency to give chemotherapy out of hours.

- the nurse will be familiar with the treatment and agreeable to giving the treatment as prescribed.

- An experienced member of the medical staff (minimum SpR level) must be available whilst vesicant treatment is being given.

- The on call pharmacist will be consulted regarding the feasibility of preparing the drugs if not already available.
6.6. Standards for Oral chemotherapy

6.6.1. In January 2008, the National Patient Safety Agency (NPSA) issued a Rapid Response Report - ‘Risks of incorrect dosing of oral anti-cancer medicines’ which outlines good practice standards relating to the prescribing, dispensing or administration of oral chemotherapy and also standards for counselling and information provision to patients.

6.6.2. The Clinical Lead for oral chemotherapy is the Head of Chemotherapy Services.

6.6.3. Prescribing, dispensing and administration of oral anti-cancer medicines must be carried out to the same standard as injected therapy.

6.6.4. All staff involved with prescribing, dispensing and administration of oral anticancer medicines must have ready access to regimen protocols and treatment plans including guidance on monitoring and treatment of toxicity. This is most readily available in the form of Aria regimens.

6.6.5. Prescribers initiating treatment with oral anticancer medicines must assess the patient’s suitability for oral treatment including ability to swallow tablets or capsules and ability to comply with the proposed drug regimen.

6.6.6. A suitably qualified healthcare professional will ensure that the patient understands the following:
- How and when to take their medicines including ‘gaps’ off treatment
- Any dose modifications and understands why this is necessary
- What to do if a dose is missed
- What to do in the event of vomiting after a dose
- Common side-effects and what action to take if they occur
- How to obtain further supplies - if needed
- To return any unused oral anti-cancer medicines to the hospital pharmacy
- The role their GP is expected to play in treatment
- Who to contact in case of problems including out-of-hours.

6.6.7. A patient-held record can be produced using Aria which contains information on the regimen prescribed. There is also space to document that the patient has been counselled on the above points. This record should be presented to the dispensing pharmacy and to any other health professionals who may be involved with caring for that patient e.g the GP or A&E staff.

6.6.8. Pharmacists should be able to verify that the prescribed dose is appropriate for the patient. They can do this by referring to the written protocol available on Aria, the written protocols stored in the paediatric department or by referring to the specialist pharmacist.

6.6.9. An Oral Chemotherapy Handbook is available for General Pharmacy and Lloyds Pharmacy. This contains information to support that available within the regimens particularly in relation to the counselling of patients.
6.7. **Capacity and Scenario Planning**

6.7.1. The Head of Service, in consultation with the Chemotherapy Pharmacy team and the Lead Chemotherapy Nurse may agree that the number of chemotherapy patients treated each day can be capped if they deem excess numbers have been reached across any of the chemotherapy production or delivery units.

6.7.2. This limit may be reviewed daily or weekly depending on staffing levels across pharmacy production, Lowen or the Headland Unit.

6.7.3. In the event of safe limits being exceeded, patients may be re-assigned to alternative treatment areas if acceptable.

6.7.4. In the event of a major incident or staffing crisis, the clinical need of individual patients would be assessed in consultation with their own consultant and chemotherapy treatments may be cancelled and rebooked as appropriate.

6.7.5. Capacity planning across the cancer service will be undertaken yearly using local audit tools and ARIA data.

6.8. **Primary Care**

6.8.1. All prescriptions for parenteral Cytotoxic Drugs for administration in the community must be dispensed by pharmacy or supplied by a licensed manufacturer in a reconstituted ready to administer form.

6.8.2. All parenteral drugs dispensed from the hospital for administration in the community must have a prescription supplied with them to allow administration to be documented.

6.8.3. These medicines must be stored at the appropriate temperature in a safe place out of the reach of children. This aspect must be stressed to the patient and their family by hospital and community staff. Suitably trained primary care nurses may administer cytotoxic drugs in accordance with the policies of the Trust for which they work.

6.8.4. Patients discharged into the community on a continuous cytotoxic chemotherapy Infusion may be overseen by the community staff. The pump may be disconnected and disposed of by appropriately trained community staff.

6.9. **Advice to patients post-treatment**

Patients should be provided with the chemotherapy hand held record and emergency contact number.

6.10. **Waste**

6.10.1. All waste that has come into contact with cytotoxic drugs is treated as cytotoxic clinical waste.

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

6.10.4. Potentially hazardous equipment includes:
- Sharps
- Syringes and needles
- Infusion sets and bags
- Protective clothing
- Gauze swabs
- Vials Urinary catheters and drainage bags from patients undergoing cytotoxic therapy

6.10.5. Gloves and Aprons should be placed in a yellow cytotoxic clinical waste bag.

6.10.6. Non-Disposable Items that have been in contact with chemotherapy
Eye protection, trolleys, trays, etc. must be washed using hot soapy water and dried thoroughly whilst wearing protective gloves and apron.

6.10.7. Unused Injection or Infusions should be returned to pharmacy via the Technical Services transport.

6.10.8. Completed Infusions, Syringes and Any Item in Direct Contact With Cytotoxic Drugs Close the roller clamp of infusion tubing. Place all items in a cytotoxic sharps bin or yellow bag marked chemotherapy and dispose of as per local waste policy.

6.10.9. Incomplete Infusions, Punctured Infusion Bags with Leakage Close the roller clamp and place in a yellow plastic bag, and place in an unused cytotoxic sharps bin which should be sealed and disposed of as per local waste policy. Any spillage should be dealt as described below. Complete a clinical incident form.

6.11. Handling Body Fluids, Vomit and Excreta

6.11.1. In addition to the risk of carrying bacteria or viruses, the vomit and excreta of patients receiving chemotherapy may contain measurable levels of cytotoxic drugs and their metabolites during and for up to 7 days after completion of treatment.

6.11.2. Staff should wear appropriate gloves and waterproof aprons when dealing with blood, vomit, urine, stools or any other body fluid. Hands should be washed thoroughly afterwards.

6.11.3. Disposable bedpans, urinals and vomit bowls should be used.

6.11.4. Incontinence pads and nappies from patients receiving cytotoxic chemotherapy should be placed in a yellow cytotoxic waste bag.

6.11.5. Catheters and drains (bottle/bags) can be emptied and then be placed into a yellow cytotoxic waste bag. If the drain is a sealed unit it can be disposed straight into a yellow cytotoxic waste bag.
6.12. **Spillage**

6.12.1. An unused spillage kit containing protective clothing must be available at all times in all clinical areas where cytotoxic drugs are administered. If a kit is used it must be replaced immediately, by ordering a new kit from pharmacy. All appropriate staff must know how to use the kit and where it is stored.

6.12.2. Spillage must be dealt with by staff aware of the hazards immediately by an appropriate member of staff in accordance with the procedure contained within the spillage kit.

6.12.3. Other members of staff and patients should be asked to leave the immediate vicinity whilst the spill is dealt with.

6.12.4. The spillage kit should be used to clean up the spillage and a replacement arranged once the spillage has been contained.

6.12.5. Wet spills should be wiped up from the outside to the middle. Dry spills should be wiped up using a damp cloth.

6.12.6. The equipment used to clear the spill & any broken item should be disposed of appropriately & sealed immediately in a cytotoxic sharps bin.

6.13. **Accidental Contact with Cytotoxic Drugs**

6.13.1. Medical and pharmacy advice should be sought immediately.

6.13.2. Report the incident to occupational health if it involves a member of staff.

6.13.3. A Datix incident form must be completed.

6.14. **Skin Contact**

6.14.1. Wash the contaminated area immediately using copious amount of soap and running water for at least 10 minutes.

6.14.2. After initial flushing with water, the contaminated skin should be thoroughly washed with liquid soap or antiseptic scrub and water. After rinsing, the process should be repeated.

6.14.3. Shower facilities should be available for use if large areas of skin are contaminated.

6.14.4. Do not use hand creams and emollients as these may aid absorption of the drug.

6.14.5. A Datix incident form must be completed.

6.15. **Eye Contact**

6.15.1. An eye-wash kit should be available in all areas where chemotherapy is administered.

6.15.2. The contaminant must be removed as rapidly as possible by flushing the eyes and surrounding areas with a large volume of sterile normal saline.
using an eye wash station where available. Alternatively cold tap water can be used if necessary.

6.15.3. Rinse the affected eye(s) immediately with sterile sodium chloride 0.9% for at least 10 minutes & refer to eye casualty or occupational health.

6.15.4. A Datix incident form must be completed

6.16. **Needle stick injury**
6.16.1. Allow the wound to bleed freely.

6.16.2. Wash the puncture site/wound thoroughly with copious amounts of cold water.

6.16.3. If the needle contained any cytotoxic drug contaminant, check the vesicant status of the drug by referring to the extravasation policy, or by seeking advice from a senior oncology or haematology pharmacist.

6.16.4. Follow the Trust’s Needle stick injury procedure, and consider seeking advice from the Accident & Emergency Department or Occupational Health, especially if the needle had been in contact with a patient.

6.16.5. A Datix incident form must be completed

6.17. **Contamination of Clothing, Staff Uniforms and Linen**
6.17.1. Any contaminated clothing should be removed immediately and placed in a sealed plastic bag until it can be washed. It should then be washed at maximum possible temperature on a full cycle in a washing machine. Gloves should be worn when handling contaminated clothing.

6.17.2. Contaminated bed linen should be placed in a yellow cytotoxic waste bag and disposed of as clinical waste. If contamination occurs in the home, then the procedure for contamination of clothing should be used. Gloves should be worn when handling contaminated bed linen.

7. **Dissemination and Implementation**

7.1. **Training - General**
7.1.1. Training in chemotherapy is required for all healthcare professionals involved in the prescribing, reconstitution, dispensing and administration of chemotherapy.

7.1.2. These staff should have knowledge of cytotoxic therapy, including the potential hazards to personnel and the environment as well as the effects on patients and the care they require. They should have knowledge of the regulatory frameworks and policies that support working safety with cytotoxic drugs.

7.1.3. Practical training is essential and should be assessed through a competency based framework as stated in the Manual of Cancer Services (2008) and Chemotherapy Services in England: Ensuring Quality and Safety; a report from the National Chemotherapy Advisory Group (NCAG 2009).
7.1.4. Training and information should also be provided for all staff, including the wider allied health professionals who come into contact with cytotoxic chemotherapy.

7.1.5. Training of all medical, nursing, pharmacy, portering and domestic staff who handle cytotoxic drugs or cytotoxic waste is essential. Such staff should understand the potential hazards associated with cytotoxic drugs and be familiar with relevant procedures.

7.1.6. Nursing and pharmacy staff are encouraged to access the available chemotherapy courses and study days as required. Wherever possible such training should be financially supported by the Trust.

7.2. **Training - Medical Staff**

7.2.1. Medical staff in RCHT are not trained to administer IV chemotherapy for adult cancer therapy. Where treatment by other routes requires medical staff to administer, training around safe handling and waste disposal must be undertaken.

7.2.2. Medical staff prescribing chemotherapy and working in the Haematology/oncology units within RCHT must have the knowledge of the principles of chemotherapy and be familiar with related protocols, policies and ways to treat chemotherapy emergencies.

7.2.3. All Medical staff undergo ARIA training and are therefore deemed competent in the prescribing of chemotherapy. An up to date list of trained medical personal can be obtained from ARIA.

7.3. **Training - Nurses**

7.3.1. Nurses are required to undertake additional training and competency assessment before administering cytotoxic medicines to patients. Details of competent practitioners will be held on a central register and staff competency will be reassessed on an annual basis.

7.3.2. The register of those staff trained and permitted to administer adult cytotoxic chemotherapy will be maintained by the Chemotherapy Clinical Nurse Specialist. The register of those staff trained and permitted to administer paediatric cytotoxic chemotherapy to children will be maintained by the Ward manager for Harlyn ward.

7.3.3. Newly appointed nursing staff of whatever grade may not administer cytotoxic chemotherapy until they have completed the necessary training and achieved competency in the following manner:

- Nursing staff previously involved in chemotherapy giving will provide evidence of their training, become familiar with all RCHT’s policies relating to chemotherapy and its side effects and complete the RCHT’s annual assessment for that year.
- Nursing staff who have no previous experience in chemotherapy administration will complete RCHT’s Chemotherapy work book 1 & 2
and be supervised until deemed competent by the chemotherapy CNS or unit Managers

- Nurses working in Oncology/Haematology (adult and paediatric) are encouraged to be in possession of recognised accredited Oncology/Haematology qualifications.

- All agency and bank nursing staff will be instructed on their arrival within the Ward/outpatient area where chemotherapy drugs are administered that they will be excluded from any involvement with those drugs and procedures. The exception to this is where an agency or bank nursing staff has had previous experience in the administration of chemotherapy, can provide evidence of this and has been deemed competent by the Chemotherapy CNS.

7.4. **Nurses maintaining skill and knowledge**

7.4.1. Nurses regularly administering chemotherapy across cancer services will be assessed annually to maintain their competence in administration of chemotherapy by completing a short assessment book and being practically assessed.

7.4.2. For chemotherapy competent nurses that have left the clinical area, but return to do agency and wish to administer chemotherapy or for those that work in clinical trials and wish to administer chemotherapy they must complete their annual update as above.

7.4.3. Nurses must demonstrate a commitment to keeping their chemotherapy skills up to date and deliver a service that is safe. Each individual nurse must decide how to maintain their competence in administering chemotherapy, there is no set amount of chemotherapy they need to administer per year.

7.5. **Training - Pharmacy Staff**

7.5.1. Training of pharmacy staff must be undertaken in accordance with the pharmacy standard operating procedures. Pharmacists responsible for validating parenteral and oral cytotoxic prescriptions must be authorised to do so by the Lead Cancer Pharmacist, who will maintain a Register of these pharmacists (‘Registered Pharmacists’).

7.5.2. Pharmacists will complete a period of supervised training and collect evidence of prescriptions they have verified. They will also complete assessment questions based on the British Oncology Pharmacy Association competencies and undergo final assessment with the Lead Cancer Pharmacist before being deemed competent.

7.5.3. Registered pharmacists will demonstrate ongoing competence by providing evidence of prescriptions they have verified every two years, and for the dedicated cancer pharmacists, will collect evidence of clinical interventions and Continuing Professional Development.

---

1 Pharmacy procedures are not available on the document library at present. They may be seen and read on application to the Director of Pharmacy.
7.5.4. Training on the safety aspects of anticancer medicines for pharmacy staff involved in dispensing and supply of these medicines will be provided as part of the induction process for new staff and repeated every 2 years.

7.6. **Training - Supplies and Domestic Staff**
All supplies and domestic staff working in areas where cytotoxic drugs are used should have received training and education on the safe handling and disposal of waste related to cytotoxic drugs, as per their own departmental procedures.

7.7. **Training - Portering Staff**
All portering staff involved in transporting cytotoxic drugs should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste. They should be familiar with the procedures for handling cytotoxic spillages.

8. **Monitoring compliance and effectiveness**

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accurate list of chemotherapy prescribers, administrators and others handling chemotherapy.</td>
<td>Chemotherapy leads as outlined in policy</td>
</tr>
<tr>
<td>DATIX relating to cancer chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Audits of: services provided, Patient Held record, National Patient satisfaction surveys, consent audits.</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Tool</th>
<th>Reporting arrangements</th>
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<tbody>
<tr>
<td>Various, depending on which apart of service being reviewed</td>
<td>Reporting will be done to the Medicines Practice Committee via the Chemotherapy MDT</td>
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</table>

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Acting on recommendations and Lead(s)</th>
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</thead>
<tbody>
<tr>
<td>As required</td>
<td>Recommendations made by the Chemotherapy MDT will be implemented by Hematology and Oncology Cancer leads</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Change in practice and lessons to be shared</th>
<th>Change in practice and lessons to be shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required changes to practice will be identified and actioned within 4 weeks or as agreed in the action plan. A lead member of the team will be identified to take each change forward where appropriate.</td>
<td></td>
</tr>
</tbody>
</table>

9. **Updating and Review**

9.1. This policy will be reviewed every two years, in line with Chemotherapy Peer Review.

9.2. Revisions can be made ahead of the review date if required. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

10. **Equality and Diversity**

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

10.2. The Initial Equality Impact Assessment Screening Form is at Appendix 2.
### Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>The Safe handling and administration of cytotoxic products for the treatment of cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>August 2015</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>August 2015</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>August 2018</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Emma Nicholls, Lead Pharmacist Cancer Services and Lisa Nicholls, Chemotherapy CNS</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252984/8347</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Defines the policy for safe handling and administration of cytotoxic chemotherapy for the treatment of cancer.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Chemotherapy, Cytotoxic, Administration, Capacity, Spillage, Waste, Chemotherapy Information, Teaching, Education, Chemotherapy Consent, Prescribing</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>June 2015</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>The Safe handling and administration of cytotoxic products for the treatment of cancer v3.0</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Chemotherapy MDT (01.07.15) Medication Practice Committee CSSC Governance DMB</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Sally Kennedy, Divisional Director CSSC</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not required</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>{Original Copy Signed} Name: Janet Gardner, Governance Lead CSSC</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
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## Links to key external standards

See below:

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<th>Related Documents:</th>
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<tr>
<td>RCHT:</td>
</tr>
<tr>
<td>- Management of Extravasation of Cytotoxic Drugs in Adults</td>
</tr>
<tr>
<td>- Management of Extravasation of Cytotoxic Drugs in Children</td>
</tr>
<tr>
<td>- Guidelines for Patient Self-Administration of Medication (SAM).</td>
</tr>
<tr>
<td>- Clinical Guideline for the use of Intravascular Catheters in Adults at RCHT</td>
</tr>
<tr>
<td>- Oral Chemotherapy procedure</td>
</tr>
<tr>
<td>- Trust Consent policy</td>
</tr>
<tr>
<td>- Non-Medical Prescribing Policy and Strategy</td>
</tr>
<tr>
<td>- RCHT IT policy</td>
</tr>
<tr>
<td>Other:</td>
</tr>
<tr>
<td>- The Nursing and Midwifery Council (NMC) Standards for Medicines Management</td>
</tr>
<tr>
<td>- Nursing Guidelines for the Safe Administration of Intraperitoneal Chemotherapy</td>
</tr>
<tr>
<td>- The Manual Cancer Service Standards (2011) DOH Topic 3C-Chemotherapy</td>
</tr>
<tr>
<td>- Bromley Hospitals Intravenous Therapy Guidelines 2001</td>
</tr>
<tr>
<td>- NPSA/2008/RRR001 Risk of incorrect dosing of oral anti-cancer medicines NPSA Alert 03 Reducing the harm caused by oral methotrexate</td>
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## Training Need Identified?

No
## Version Control Table

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<td>Paul Evans</td>
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<td>Jun 09</td>
<td>1.0</td>
<td>Edited to comply with the Trust “Policy on Policies” for submission to MPC for final approval before signature</td>
<td>John Pickup</td>
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<td>Jul 10</td>
<td>1.2</td>
<td>Revised to take account of location changes</td>
<td>Paul Evans</td>
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<tr>
<td>Jul 10</td>
<td>1.3</td>
<td>Revised to take into account procedural changes</td>
<td>Paul Evans</td>
</tr>
<tr>
<td>Nov 11</td>
<td>1.4</td>
<td>Revised to take into account new Peer Review Chemotherapy Measures. Merger of document: Intravenous administration of Cytotoxic drugs. Put into new trust format</td>
<td>Lisa Nicholls</td>
</tr>
<tr>
<td>July 2012</td>
<td>2.0</td>
<td>Merger and update of document: Standards for the safe use of oral chemotherapy. Revised to take into account other procedural changes. Update to trust format. Removal of references to non-cancer indications</td>
<td>Emma Nicholls</td>
</tr>
<tr>
<td>August 2013</td>
<td>3.0</td>
<td>Review and update – Recommended Peer review changes: Nurse checking and doctors training records And : F1 prescribing, changes in booing rules, consent, the checking of chemotherapy, update to staff training, update in waste disposal of drain/catheters</td>
<td>Lisa Nicholls</td>
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<tr>
<td>June 2015</td>
<td>4.0</td>
<td>Review and update</td>
<td>Lisa Nicholls and Emma Nicholls</td>
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**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Form

| Name of the strategy / policy / proposal / service function to be assessed (hereafter referred to as policy) (Provide brief description):
The Safe handling and administration of cytotoxic products for the treatment of cancer |
| Directorate and service area: CSSC, Pharmacy & Cancer Services | Is this a new or existing Policy? Existing |
| Name of individual completing assessment: Lisa Nicholls / Emma Nicholls | Telephone: 01872 252984 |

1. Policy Aim*
   Who is the strategy / policy / proposal / service function aimed at?
   To ensure safe handling and administration of cytotoxic chemotherapy for cancer treatment.

2. Policy Objectives*
   To ensure safe handling and administration of cytotoxic chemotherapy for cancer treatment.

3. Policy – intended Outcomes*
   To ensure safe handling and administration of cytotoxic chemotherapy for cancer treatment.

4. *How will you measure the outcome?
   By checking documents meet the above objectives and outcomes

5. Who is intended to benefit from the policy?
   Users of the Trust Services & staff.
   The Trusts reputation

6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?
   No

   b) If yes, have these *groups been consulted?
   N/A

   C). Please list any groups who have been consulted about this procedure.
   Chemotherapy MDT
   Medication Practice Committee

7. The Impact
   Please complete the following table.

   Are there concerns that the policy could have differential impact on:
   Equality Strands: Yes No Rationale for Assessment / Existing Evidence
   Age No

The Safe Handling and Administration of Cytotoxic Products for the Treatment of Cancer
Page 39 of 52
<table>
<thead>
<tr>
<th>Category</th>
<th>Yes/No</th>
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</thead>
<tbody>
<tr>
<td>Sex (male, female, transgender / gender reassignment)</td>
<td>No</td>
</tr>
<tr>
<td>Race / Ethnic communities / groups</td>
<td>No</td>
</tr>
<tr>
<td>Disability - learning disability, physical disability, sensory impairment and mental health problems</td>
<td>no</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
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</tr>
<tr>
<td>Marriage and civil partnership</td>
<td>no</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>no</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>no</td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
  - No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation.  or
  - Major service redesign or development

8. Please indicate if a full equality analysis is recommended. No

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director

Date of completion and submission

Names and signatures of members carrying out the Screening Assessment
1. Lisa Nicholls
2. Emma Nicholls

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ______________________

Date ______________________
Appendix 3 - Locations

1. Areas within the Royal Cornwall Hospitals Trust in which Intravenous Cytotoxic Therapy may be administered for malignant disease:

   - Child Health Directorate - Sennen and Gwithian units
   - Lowen Ward
   - The Headland - Chemotherapy Daycare Unit
   - Mobile Chemotherapy Unit
   - Clinical Trials areas in Oncology and Haematology
   - Urology – (including Urology clinic Treliske, General Theatres Treliske and West Cornwall) – Intravesical chemotherapy

2. If chemotherapy is to be given outside of these clinical areas, it must be first discussed with the lead chemotherapy pharmacist or lead chemotherapy nurse and will only occur if the patient is too unwell to be transferred to an allocated chemotherapy area, e.g. ITU patients or when chemotherapy needs to be given under general anaesthetic in theatre.

3. In such cases the chemotherapy competent nurse administering the chemotherapy will take the required safety equipment with them i.e. extravasation and spillage kits, personal protective clothing, and chemotherapy waste disposal. It is also recommended that the required policies are taken to the administrating area.
Appendix 4. Agreement Responsibilities for Head of Service for Chemotherapy at RCHT

The Lead Cancer Clinician agrees that the Lead Chemotherapy Clinician will be responsible for the ensuring the provision of a safe and effective chemotherapy service at the RCHT. Individual responsibilities and targets are specified by the National Cancer Action Team and listed in the Chemotherapy Measures in the Manual for Cancer Services. The Head of Chemotherapy Services will also be the designated Clinical Lead for oral anticancer medicines.

__________________________________________
Head of Chemotherapy Services

Date

__________________________________________
Director of Cancer Services

Date
Appendix 5. Agreement Responsibilities for Lead Chemotherapy Nurse at RCHT

1. The Lead Chemotherapy Clinician and the Lead Chemotherapy Nurses Line Manager agree that the Lead Chemotherapy Nurse will be responsible for assisting with the safe delivery of the chemotherapy service at RCHT.

2. The duties include those outlined in the Chemotherapy Clinical Nurse Specialist’s job description, see attached, and the individual responsibilities and targets that are specified by the National Cancer Action Team, which are listed in the Chemotherapy Measures in the Manual for Cancer Services.

__________________________________________________________________________

Head of Chemotherapy Services

__________________________________________________________________________

Divisional Nurse, Clinical Support Services & Cancer Division, Lead Cancer Nurse

__________________________________________________________________________

Chemotherapy Lead Nurse
Appendix 6. Agreement Responsibilities for Lead Pharmacist at RCHT

1. Overall responsibility for Oncology pharmacy services to Lowen ward, the Headland Unit, Clinical Oncology (Sunrise), Haematology and Sennen Ward.

2. Overall responsibility for the provision of cytotoxic chemotherapy.

3. Overall responsibility for ensuring compliance with pharmacy related standards of the chemotherapy Measures and other relevant guidance e.g. NPSA alerts.

4. Involvement with the development and implementation of policies and procedures relating to the use of chemotherapy.

5. Attendance at the Chemotherapy Multidisciplinary Group and reporting from this group to the Medication Practice Committee.

6. To be a representative at the Network Oncology Pharmacy Group and the Network Acute Oncology Chemotherapy Group.

7. Involvement with the set up and administration of Clinical Trials involving Oncology or Haematology. This includes liaison with the Senior Pharmacist for clinical Trials where oral drugs are involved and with the Pharmacy Technical Services Unit for the parenteral therapies.

Head of Chemotherapy Services

Date

Lead Pharmacist for Chemotherapy

Date

Chief Pharmacist

Date
Appendix 7. Agreement of the responsibilities of the Lead Cancer Pharmacist for Paediatric Oncology at the Royal Cornwall Hospital NHS Trust

- To ensure that the Lead and Designated pharmacists engaged in Paediatric Oncology work effectively together.
- To ensure that all paediatric oncology prescriptions are clinically checked and signed by a pharmacist appropriately trained in oncology.
- To ensure that decisions regarding the operational policies are ratified, documented and made available to all areas involved with administering paediatric chemotherapy.
- To take overall responsibility for ensuring that the Pharmacy Department meet Peer Review Quality Measures.
- To provide a link with the Network NSSG, and Regional Paediatric Oncology Pharmacists group, either by attending in person or by nominating another to attend and to liaise with the Lead Paediatric Oncology Pharmacist for the Primary Treatment Centre.
- To lead for service improvement and audit in relation to safe and effective usage of chemotherapy.
- To ensure the organisation of any activities, such as training pharmacists and other healthcare professionals, to ensure the best functioning of the team.
- Overall responsibility for the pharmacy service to inpatient and outpatient chemotherapy services on Sennen Ward, Fistral Ward, Polkerris Ward, and the Gwithian unit.
- To take overall responsibility for the pharmacy department for cytotoxic chemotherapy.
- To liaise over pharmaceutical matters with investigators carrying out clinical trials and/or other clinical research involving the drug treatment of malignant diseases.
- To lead on COSHH reviews of current regulations.
- To lead on investigations into drug incidents involving chemotherapy.

Signature……………………………………
Date……………………………………

Lead Pharmacist Cancer Services
RCHT

Signature……………………………………
Date……………………………………

Lead Clinician for Cancer (Paediatric)
RCHT

Signature……………………………………
Date……………………………………

Chief Pharmacist
Appendix 8. Agreement of the responsibilities of the Designated Cancer Pharmacists for Paediatric Oncology at the Royal Cornwall Hospital NHS Trust

- To act as the Designated Pharmacist on behalf of the Lead Pharmacist.
- To be responsible for inpatient and outpatient chemotherapy services to Sennen Ward, Fistral Ward, Polkerris Ward, and the Gwithian unit.
- To ensure all paediatric oncology prescriptions are clinically checked and signed by a pharmacist appropriately trained in oncology.
- To ensure the timely provision of prescriptions to the Pharmacy dispensary and Technical Services Unit, and liaise with them over any production/clinical interface issues.
- To liaise with and provide information on pharmaceutical matters to paediatric medical, nursing and other ward staff.
- To participate in such training as to ensure the best functioning of the team.
- To support the Lead Pharmacist for Cancer Services in their role.
- Liaison with PTC pharmacist in relation to paediatrics
- Overall responsibility for cytotoxic chemotherapy in the paediatrics speciality
- Liaison over pharmaceutical matters with investigators carrying out clinical trials and other clinical research involving the drug treatment of malignant diseases in the paediatrics speciality

**Signature**…………………………………… (Designated Pharmacist)
**Date**…………………………………… RCHT

**Signature**…………………………………… (Designated Pharmacist)
**Date**…………………………………… RCHT

**Signature**…………………………………… (Lead Pharmacist)
**Date**…………………………………… RCHT

**Signature**……………………………………
**Date**……………………………………

Chief Pharmacist
**Date**……………………………………

RCHT
Appendix 9. Agreement of the Aseptic Chemotherapy Preparation facilities at the Royal Cornwall Hospital NHS Trust

Responsibilities as the designated Pharmacist for aseptic chemotherapy preparation facilities:

- Overall responsibility for the clean chemotherapy preparation facilities of the pharmacy service.

- Responsible for the management and leadership of Technical Service activities within the Trust. Activities include: aseptic preparation of radiopharmaceuticals, cytotoxics, parenteral nutrition, specialist intravenous injections, intrathecal and epidural injections and medical devices, and also pre-packing and overlabelling of medicines.

- Named as Production Manager on the Medicines & Healthcare products Regulatory Agency (MHRA) Specials Licence held by the Trust for the preparation of radiopharmaceuticals and non-sterile pre-packing/overlabelling activities.

- Responsible for ensuring all medicinal products manufactured under licence are prepared in line with Good Manufacturing Practice (GMP). All other aseptic work is carried out under a Section 10 exemption of the Medicines Act 1968. Responsible for ensuring that these activities are performed in accordance with both the Act and GMP.

- In conjunction with the Quality Assurance Manager, responsible operation of the Technical Service facility.

- To provide specialist information on all Technical Service issues.

Signature……………………………………
Date……………………………………
Head Pharmacist Technical Services
RCHT

Signature……………………………………
Date……………………………………
Lead Pharmacist Cancer Services
RCHT

Signature……………………………………
Date……………………………………
Chief Pharmacist
RCHT
Appendix 10. Selection of Cannulation Site.

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

- The purpose of the cannulation. For example:
  - A large vein required for high flow rate.
  - Irritant solutions or drugs require good flow to assist haemodilution.

- The condition of the accessible vein, the lumen and blood flow.

- Small visible but impalpable superficial veins are rarely suitable for cannulation.

- In the elderly patient particularly, prominent, superficial veins may be sclerosed, tortuous, fibrosed or fragile and therefore unsuitable for cannulation.

- The superficial veins of the arm are commonly chosen for the cannulation as they are numerous, easily detectable with wide lumens and thick walls and the skin is less sensitive. Most common are: median cubital, basilic and cephalic veins.

- In children, cannulas may be sited in the feet.

- Veins in the lower limbs should be avoided in adults.

- Avoid use of dominant arm in order to maintain patient mobility and independence whenever possible.

- Avoid areas of joint flexion.

- Avoid use of cubital fossa, especially for vesicants.

- Avoid sites distal to recent cannulation or venopuncture to minimise the risk of fluid extravasation.

- Avoid areas proximal to skin lesions or wounds.

- Avoid veins close to arteries or deep lying vessels as accidental puncture can cause painful spasm or prolonged bleeding.

- Avoid areas affected by invading tumour, haematoma, inflamed or sclerosed areas.

- Avoid limbs where there is lymphatic impairment following surgery, chemical occlusion or radiotherapy even if there is no obvious lymphoedema.

- Most difficulties arise when few or no veins in good condition are available. To help dilate difficult veins:
  - Soak the arm in hot water for about 2 minutes or apply a heat pad.
- Lie the patient supine with a tourniquet applied to the arm and place the forearm on a level below the heart.

- If the patient is very nervous or needle phobic, try applying local anaesthetic cream to the proposed site at least 30 minutes prior to the procedure. In severe circumstances in adults, oral or sublingual lorazepam (at doses of 0.5 to 1mg) may be considered.
Appendix 11. Off protocol Prescribing of Chemotherapy

For a chemotherapy regimen to be ON PROTOCOL, it must be specified in the Trust approved list of chemotherapy regimens (TALCR) for the same disease and stage of disease.

The TALCR is available on the computerised prescribing systems (ARIA).

‘Off-protocol’ chemotherapy is defined as:

- Any anticancer agent or combination of agents not on the TALCR
- Use of a regimen on the TALCR, but for an indication or stage of disease other than that specified
- Addition of a new anti-cancer agent to an existing regimen on the TALCR
- Removal or change in dose of an anti-cancer medicine listed in the TALCR other than for toxicity, poor performance status or tolerance

Where a drug/regimen is being used outside of NICE or NHS England approved indications, the appropriate funding source must be obtained e.g. exceptional cases application or Cancer Drug Fund.

The first cycle ‘Off-protocol’ chemotherapy can only be prescribed by an oncologist or haematologist experienced in the site-specialty, at consultant level, subsequent cycle can be prescribed by registered prescribers. The first cycle must be prescribed by the patient’s own consultant or, with their agreement, by another consultant familiar with the regimen.

Details required in an Off-Protocol chemotherapy prescription include:

- treatment intention,
- protocol choice,
- dose selection,
- appropriate interval between treatments,
- correct administration details including number of cycles intended,
- the decision to treat on the grounds of haematological and biochemical parameters.

It is not permissible to prescribe electronically a regimen already available on the electronic prescribing systems for an off-protocol indication.

In the event of an off protocol regimen needing to be prescribed the consultant must contact one of the specialist cancer pharmacists to discuss writing an ad hoc prescription on ARIA.

The off-protocol prescription should contain all relevant supporting medication e.g. anti-emetics, hydration details.
Information for Professionals and Patients

All patients should receive written and verbal information pertaining to their specific treatment indicating details of the regimen and anticipated side effects.

Medicines Information (particularly regarding toxicity profile) should be readily available for healthcare professionals involved in prescribing, dispensing and administering the drug or delivering emergency care where a drug is unlicensed e.g. compassionate use.

Patients must specifically be made aware if the proposed treatment is unlicensed.

COMPASSIONATE USE PROGRAMME ANTICANCER MEDICINES

Permission to use an unlicensed medicine must be granted by NHS England before it can be requested. Where a request is urgent, this can be fast-tracked as an exceptional request, signed off by the Chief Pharmacist and Divisional Manager/Medical Director.

The prescriber must request patient specific access to the unlicensed medicine through the company who manufacture the medicine, and provide the necessary clinical detail.

Once the use of the medicine has been agreed, the order must be set up through the pharmacy. If there are forms to be completed and signed by the consultant, these must be passed on to the specialist pharmacist to proceed with placing the order. The prescriber is responsible for ensuring that all information pertaining to the safe administration and monitoring of the unlicensed medicine are accessible to all staff caring for the patient, including staff involved in out of hours emergency care. A Drug information file is based both on Headland and Lowen for this purpose. The specialist pharmacist who has dealt with the request for the new drug will place the relevant information e.g. SPC into these files.

The prescriber is responsible for providing appropriate information to the patient on the unlicensed nature of the treatment and possible side-effects of the treatment. This information should also be available to the patients GP.

The prescriber is responsible for reporting any suspected adverse effects to the manufacturer on the day the adverse effect is identified and also to the MHRA (yellow card).
Appendix 12. Cannulation on the Headland Unit.

Concise venous access assessment to be carried out at pre-assessment

- **GOOD**
  - **Non vesicant drugs**
    - 2 attempts by 2 nurses (4 overall)
  - **Vesicant drugs**
    - x2 Nursing attempts only

- **POOR**
  - Refer for permanent line

If cannulation is not achievable after this process – contact patients consultant for referral for permanent central venous line

Regimens that should be referred for a permanent line:
- ABVD
- Oxaliplatin MDG
- Irinotecan MDG
- MDG Pumps