

St Luke's Cancer Alliance 

Cytotoxic Policy

**Policy and Guidelines for the Safe Prescribing,
Handling and Administration of Cytotoxic Drugs**

Sixth Edition, August 2016

Acknowledgements

With the kind permission of the authors, this document was originally based around the Policy and Guidelines for the Safe Prescribing and Handling and Administration of Cytotoxic Drugs produced by the North London Cancer Network (November 2002), and built upon by using existing guidelines and policies from across the Surrey, West Sussex and Hampshire Cancer Network (SWSH CN).

The second edition was revised by the SWSH Network Oncology Pharmacist Group and the SWSH Network Chemotherapy Nurses Forum.

The third and fourth editions were revised by Susan Taylor, Oncology Pharmacist, RSCH, with input from SWSH Network Oncology Pharmacist Group, SWSH Network Chemotherapy Nurses Group and SWSH Network Chemotherapy Group.

The 5th and 6th editions were revised after the Cancer Networks were disbanded and the St Luke's Cancer Alliance was formed.

This document is intended for use across the 4 Acute Trusts and 8 CCGs which constitute the St Luke's Cancer Alliance.

The 4 Acute Trusts are:

Royal Surrey County Hospital NHS Foundation Trust (RSCH), including St Luke's Cancer Centre (SLCC)
Ashford and St Peter's Hospitals NHS Trust (ASPH)
Frimley Park Hospital site of Frimley Health NHS Foundation Trust
Surrey and Sussex Healthcare NHS Trust (SASH)

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Version 6 is a minor update of Version 5, with all the web-links updated, plus the addition of an Alliance-wide agreement on the timing of blood tests, in Section 3.8.

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Scope of the Document

This document is aimed at staff delivering chemotherapy for patients with malignant disease, as well as chemotherapy for any other indication, including that for immunosuppression purposes or the treatment of non-malignant disease, e.g. methotrexate or cyclophosphamide for rheumatoid arthritis.

Monoclonal antibodies used for the treatment of malignant disease will also be subject to the guidance within this document.

For the purposes of this document, the term "cytotoxic drug" is used to refer to all drugs with direct anti-tumour activity, including conventional anti-cancer agents, monoclonal antibodies and partially targeted agents (e.g. kinase inhibitors, such as sunitinib, imatinib), and drugs such as thalidomide and lenalidomide.

Relevant drugs are listed in the most recent version of the British National Formulary (BNF) Pharmaceutical Press, section 8.1.

Drugs affecting the immune response, including anti-proliferative immunosuppressants, are listed in section 8.2 of the BNF.

If in doubt, refer to the 'Summary of Medical Product Characteristics' available at www.medicines.org.uk for the individual drug concerned.

The safe handling of gene therapy is outside the scope of this document.

All local policies involving the delivery of chemotherapy drugs must be developed by a multi-professional team and comply with the scope of this document.

Introduction

The St Luke's Cancer Alliance began operating from April 2014. It replaces the Surrey, West Sussex and Hampshire Cancer Network which was established in 2001.

The St Luke's Cancer Alliance comprises of 9 Clinical Commissioning Groups and the Surrey & Sussex Specialised Commissioning Area Team.

Chemotherapy for malignant disease is provided by the following Acute Trusts:

Ashford and St Peter's Hospitals NHS Foundation Trust (ASPH)

Frimley Park Hospital site of Frimley Health NHS Foundation Trust

St Luke's Cancer Centre (SLCC), Royal Surrey County Hospital NHS Foundation Trust (RSCH)

Surrey and Sussex Healthcare NHS Trust (SASH)

Cytotoxic administration throughout the St Luke's Cancer Alliance should be provided by a multidisciplinary team in which doctors, specialist nurses and pharmacists work to approved written protocols to provide integrated care both within the hospital and the community.

The handling and administration of cytotoxic drugs is potentially hazardous to the health care professionals involved in their preparation and administration, as well as to the patients receiving them, and their relatives and carers.

While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely inconclusive. It is therefore prudent, with the present state of knowledge, to take every reasonable precaution to protect staff from unnecessary exposure.

This policy aims to safeguard patients and staff by defining standards of practice for all disciplines involved in the prescribing, handling and administration of cytotoxic drugs. It should be read in conjunction with other relevant policies available for each individual Trust.

It is the responsibility of the individual Trust, via their local Chemotherapy Group, to develop a local Chemotherapy Operational Policy which supports and complies with this document.

The policy should be approved by the head of the Clinical Chemotherapy service for the individual Trust, and then submitted to the St Luke's Cancer Alliance Chemotherapy Group for approval.

The term "cytotoxic" is used to refer to any agent that may be genotoxic, oncogenic, mutagenic or teratogenic. The health risk of any procedure involving cytotoxic drugs stems from the inherent toxicity of the drug and the extent to which workers and patients are exposed. Although in therapeutic doses, some of these drugs are known to produce neoplastic changes in the long term, there is conflicting evidence on the effect of the much lower level of occupational exposure.

The term "Systemic Anti-cancer Therapy" (SACT) is used to encompass biological therapies and cytotoxic chemotherapy used in the treatment of malignant disease. As this policy includes the use of cytotoxics for other indications as well as malignant disease, the term SACT will only be used within this policy when discussing cytotoxics used in malignant disease only.

1. Health and Safety

The potential for cytotoxic exposure to healthcare personnel exists during reconstitution, preparation, administration, transportation, disposal of waste equipment or patient waste, and cleaning spills. Hence all staff involved in the delivery of cytotoxic therapy must be aware of all health and safety procedures. This applies to clinicians, nursing staff, pharmacy staff, domestic staff and portering staff.

The more common routes of exposure are contact with the skin or mucous membranes, inhalation and ingestion. Less likely routes of exposure include needle-stick injuries.

1.1 Staff Monitoring

All relevant new employees should receive an orientation to current "St Luke's Cancer Alliance Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs" as soon as possible after commencement of employment.

Hazards associated with cytotoxic drugs may be short or long term. All relevant legal health and safety measures must be in place to protect staff.

There is currently no form of biological monitoring or health assessment technique which is sensitive enough or specific enough to detect or predict long-term cytotoxic exposure. Therefore staff monitoring via blood or urine testing is not routinely undertaken. The primary focus of safety during the preparation and administration of cytotoxic drugs must be on control of the working environment, minimising exposure and ensuring safe practice.

1.2 Personnel Records

Records of drug exposure should be kept for all personnel who reconstitute, administer or handle cytotoxic drugs.

Details of all incidences involving the handling of cytotoxic drugs (e.g. accidental exposure due to spillage) must be recorded, and occupational health informed.

1.3 Pregnancy and Breast-feeding

There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to. However, as there is no known limit where exposure is thought to be safe, employees must be fully informed of the potential reproductive hazard of cytotoxics. 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 were carried out at a time when the use of isolators was not well established, and some later studies have failed to find a significant association with foetal adverse effects.

If a member of staff working in this area is planning a family or knows they are pregnant, they should notify their manager as soon as possible. This is particularly important as the greatest risk is during the first 3 months of pregnancy.

At the point where the employee discloses pregnancy, a risk assessment specific to the individual and their current roles and responsibilities should be carried out, and appropriate action taken.

Staff who choose not to work with cytotoxic drugs will not be expected to be involved in directly preparing or administering chemotherapy, or handling waste from patients treated with chemotherapy. If appropriate, the line manager and Human Resources, together with the member of staff, will agree new temporary arrangements, and ensure that she is adequately supported during her pregnancy. The Human Resources department will be consulted if no suitable alternative employment is found.

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

1.4 Monoclonal Antibodies

Monoclonal antibodies (MAbs) may affect a wide range of biological functions and staff handling them should be aware of the nature of each product and specific associated problems.

As these agents may contain material of animal origin, they are potentially bio hazardous and so direct handling should be minimised and protective clothing worn to the same level as traditional cytotoxic medicines. There is a theoretical risk of operator sensitisation and staff should be made aware of this.

The preparation of MAbs should be individually risk assessed, taking into account the allergic potential and toxicities of the MAb. Using the NPSA risk assessment tool, an overall risk may be used to decide whether manipulation should be within an aseptic unit (high risk) or permitted in a clinical area (medium and low risk).

1.5 Recommended Good Practice

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

Local procedures must always be followed in relation to administration of cytotoxic chemotherapy and monoclonal antibodies.

Good hygiene practices and suitable welfare facilities should be provided to ensure that staff eating and drinking are prohibited in all areas where cytotoxic drugs are handled.

1.6 Minimising Exposure

A full COSHH risk assessment must be undertaken in all areas handling cytotoxic drugs, irrespective of the route of administration. Directions on how risk assessments can be completed can be found at <http://www.hse.gov.uk/risk/index.htm>

The risk assessment should define the Personal Protective Equipment (PPE) to use in each activity where cytotoxic drugs are handled.

1.7 Personal Protective Equipment (PPE)

It is important to ensure PPE offers adequate protection and is designed specifically for handling cytotoxics. The correct use of PPE can shield staff from exposure to cytotoxic drugs and minimise the health risks only if the PPE is suitable for the task, in good condition, worn correctly, and compatible with other PPE in use.

Employers need to ensure that staff are trained in the use of PPE and that PPE is adequately maintained and stored.

Pharmacy staff preparing cytotoxic drugs within pharmacy aseptic units will wear PPE as defined by local standard operating procedures.

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

1.7.1 Disposable Gloves

- Cuts and scratches 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.
- No glove material is completely impermeable to cytotoxic drugs. Permeation of cytotoxic drugs depends upon glove thickness and integrity, the properties of the drug/solvents and the contact time with the drug. Since no material is completely impermeable to cytotoxic drugs and permeability increases with time, users should minimise contact and change their gloves regularly
- Gloves must be worn at all times when contact with cytotoxic drugs is possible, appropriate to the task being undertaken. (See Table 1 for details on gloves).
- Gloves must always be changed between patients. They must be changed immediately if damaged or if significant contamination occurs.
- Once disposable gloves are removed, they should never be re-applied.
- Non-powdered gloves must be used.
- Following removal of gloves, hands must be washed thoroughly with soap/detergent and water, and dried.
- Staff must adhere to the principles of their local Trust infection control policy.

Table 1 : Recommended Gloves for Use in Handling Cytotoxics

Type of Tasks	Glove Type	
	No Latex Allergy	Latex Allergy
Administration of cytotoxics OR Handling cytotoxic contaminated waste	Powder-free latex, thickness 0.25 - 0.4mm OR Refer to local Trust policy	Refer to local Trust policy
Cleaning up of spillages	Industrial thickness gloves greater than 0.45mm thickness made from latex or neoprene, or nitrile or synthetic rubber OR Refer to local Trust policy	Refer to local Trust policy

1.7.2 Eye and Face Protection

Protective glasses or visors should be considered whenever splashes or sprays of cytotoxic drugs might be generated (e.g. intra-cavitary, intra-arterial or intrathecal administration) and when clearing up cytotoxic spillages. If not disposable, they should be cleaned thoroughly with mild detergent and water before re-use.

Full face protection should be worn when nurses draw up doses of monoclonal antibodies in the clinical area e.g. s/c trastuzumab, rituximab, denosumab.

Eyewash kits must be readily at hand for use in all areas where handling any form of cytotoxic occurs.

In the event of eye contamination, immediate medical advice must be sought, including an ophthalmology opinion, if appropriate (see section 15.2).

1.7.3 Respiratory Protection

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

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

1.7.4 Aprons

Plastic aprons should be worn when administering cytotoxics. These are single-use items, and are to be worn for one episode of patient care and then removed.

All aprons, gloves and disposable PPE should be disposed of according to the guidelines in Section 14.

2. Clinical Governance

The responsibilities of different staff groups in relation to the safe prescribing, administration and handling of cytotoxic drugs is outlined below.

2.1 Heads of Service for Chemotherapy

- Designate responsibility for the implementation and maintenance of the St Luke's Cancer Alliance Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs (the *Cytotoxic Policy*).
- Ensure that all managers and supervisory staff are familiar with and adhere to the *Cytotoxic Policy*.
- Accountable for clinical and corporate governance.

2.2 Departmental Managers and Supervisory Staff

- Ensure that all relevant staff are familiar with the *Cytotoxic Policy* and that they are properly trained in, and comply with, all policies and procedures.
- Ensure that the health and safety of patients and staff are given primary consideration when implementing or altering processes or facilities related to cytotoxic drugs. Risk assessments should be carried out as appropriate.
- Ensure that appropriate and properly maintained facilities and equipment are available to all staff who handle cytotoxic drugs.
- Ensure records of training are maintained, so that current individual competencies can be readily identified.
- Each Trust should maintain lists of named staff who are competent to prescribe, administer or take part in the preparation or transport of cytotoxic drugs, or clinical screening of chemotherapy prescriptions.
- Ensure that any member of staff transporting cytotoxic drugs has received training on dealing with a spillage.
- Make every effort to ensure requests to change work assignments from staff who are pregnant, trying to conceive, or breastfeeding, are accommodated.

2.3 All Staff – Nursing, Pharmacy, Medical and Ancillary

- Follow all safety requirements according to COSHH guidelines and the *Cytotoxic Policy*.
- Follow departmental standard operating procedures where available.
- Report all unsafe acts and conditions, and complete appropriate documentation according to Trust Policy.
- Actively participate in the training programmes provided.
- Inform managers/supervisors if they are pregnant, breastfeeding or trying to conceive.

3. Staff Responsibilities

3.1 Referral Process for Cytotoxic Drugs

Chemotherapy will be chosen as the treatment modality for a patient by their consultant, depending on the known responsiveness of the tumour, stage of spread, history of other diseases or conditions, and performance status of the patient.

The decision to initiate chemotherapy treatment should, unless in exceptional circumstances, be made by a Consultant, with the patient and carer fully involved on an informed choice basis.

Patients may be entered into clinical trials that involve cytotoxic chemotherapy and for these the trial protocol must be read, understood and followed.

Each Trust must have a locally agreed chemotherapy referral process in place.

Before prescribing of the first cycle of treatment, the following information should be recorded: diagnosis; clinical staging; performance status; height and weight; treatment intent.

Essential investigations and tests should be requested, including those specified in the relevant chemotherapy protocol.

3.2 Consent

All patients receiving a new course of chemotherapy should be provided with all the relevant information on the treatment intent, risks and benefits, in order to be able to make an informed consent on treatment.

Information should be given verbally and supported by the use of written patient information (Macmillan patient information should be used where possible; if not yet available for a particular agent, alternative written patient information for that drug should be sourced).

Information must be given initially by the Consultant or SpR responsible for the patient's care, and will be reinforced by an appropriately trained chemotherapy nurse.

Full written consent should be obtained on the appropriate form, as defined by local policy. Patients must receive a copy of the signed consent form.

If a change in chemotherapy regimen, or re-challenge with a previously used chemotherapy regimen, is necessary, patients should be re-consented, after having received regimen-specific details.

3.3 Pre-Chemotherapy Assessment

All patients should receive a holistic nurse assessment before they start a course of chemotherapy. This should be patient-focused rather than disease-centred.

Relevant information should be given to all patients, including 24 hour contact details for the treating Trust's acute oncology service, and an Alert Card regarding neutropenic sepsis.

Nurses should:

- refer to or liaise with any other members of the MDT when appropriate
- ensure all appropriate follow-up appointments are made
- ensure clear documentation of the holistic assessment

3.4 Prescribers Responsibility (including non-medical prescribers)

Only the following staff may prescribe the **first cycle** of chemotherapy for the treatment of cancer patients:

- Consultant Medical and Clinical Oncologists
- Consultant Haematologists
- Oncology and Haematology Specialty Doctors and Associate Specialists
- Oncology and Haematology Specialist Registrars ST4 and above AND with at least 1 year of experience in prescribing anti-cancer chemotherapy.
- Designated paediatricians (Paediatric Oncology Shared Care Unit [POSCU])

The prescriber should inform the patient's GP of the intention to start the course of chemotherapy, including information on planned treatment regimen, approximate start date, planned duration, and treatment intent.

Prescribing of **second and subsequent cycles** of chemotherapy may be delegated to:

- ST3 Specialist Registrars
 - other SpRs with less than 1 year of experience in prescribing anti-cancer chemotherapy
 - non-medical independent or supplementary prescribers who have completed the necessary training, and are authorised by their Trust to prescribe within their competence.
-
- All chemotherapy prescribers should have completed the Trust training programme and be accredited to prescribe chemotherapy as relevant, as well as be on the Trust chemotherapy prescribing register before they may start prescribing chemotherapy.
 - Oncology ST3 SpRs in training, and Oncology SpRs not on the RMH oncology training programme, must have passed an Alliance-agreed assessment of competency before they may prescribe any chemotherapy.
 - Designated Consultants and Specialist Registrars locally registered as holding the relevant competency may also prescribe chemotherapy e.g. named urology surgeons for intravesical instillation of chemotherapy.
 - Only medical and non-medical staff competent in their use may prescribe cytotoxic drugs. Non-medical prescribers will be expected to recognise those situations where it is inappropriate for them to prescribe.
 - FY1, FY2, ST1 & ST2 Grade staff, and all those working outside the speciality, **MUST NOT** prescribe or transcribe chemotherapy for the treatment of malignant disease.
 - Nurses who have passed a locally agreed chemotherapy confirmation competency assessment may confirm chemotherapy prescriptions that have already been prescribed by a doctor / non-medical prescriber as described above.
 - Cytotoxic drugs used as immunosuppressants for the treatment of non-malignant conditions e.g. methotrexate, azathioprine or cyclophosphamide for rheumatic disease (the latter is unlicensed), and methotrexate or azathioprine for ulcerative colitis (both are unlicensed for this indication) may only be prescribed by SHOs (FY2, ST1 and ST2) if under the direct supervision of the Consultant within the speciality.

- GPs should not prescribe systemic *anti-cancer* chemotherapy, nor should clinicians in hospital request GPs to prescribe systemic anti-cancer chemotherapy. The only exception is hydroxycarbamide for the treatment of myeloproliferative diseases, which has been given Amber status by the Trust D&T committee, and a locally agreed shared care protocol has been produced. In this setting the initiation and stabilisation of treatment will always be performed by a consultant haematologist.
- GPs may however prescribe topical cytotoxic agents for the treatment of some skin malignancies or pre-malignant conditions.
- GPs may only prescribe cytotoxic drugs used as immunosuppressants *for the treatment of non-malignant conditions* where the cytotoxic concerned has been given Amber status by the Trust D&T committee and a locally agreed shared care protocol has been produced. In this setting the initiation and stabilisation of treatment will always be performed by a consultant specialist.
- Chemotherapy should be prescribed according to agreed lists of chemotherapy regimens and algorithms, as approved by the individual Tumour Site Specific Groups and the Alliance Chemotherapy Group. All current agreed regimens and algorithms are available at <http://stlukescanceralliance.co.uk/>

3.4.1 All prescribers are responsible for the following:

- Checking the allergy status of the patient.
- Checking for any potential interactions between the patient's current medicines and their chemotherapy or supportive care medicines.
- Selecting the appropriate regimen from the agreed list of regimens for the tumour site concerned.
- Ensuring that the patient is fully informed of their treatment and has given consent as per DOH Guidance.
- Ensuring that the body surface area calculations are appropriate. The patient should be re-weighed prior to each cycle of treatment, and the BSA recalculated, and chemotherapy doses adjusted if necessary.
- Ensuring accurate dosing.
- Prescribing all cytotoxic drugs, and supportive therapies including anti-emetics. This includes the ongoing monitoring of toxicities and amendment of supportive medicines where required.
- Ensuring that maximum cumulative doses of anthracyclines and bleomycin have not been exceeded.
- Specifying the route of administration, and for parenteral doses, the duration of infusion.
- Ensuring, with each subsequent cycle of chemotherapy, that the patient is assessed to determine whether a clinical response is being achieved or whether there is disease progression despite therapy.
- Ensuring an appropriate interval between each cycle.
- Ensuring that all relevant investigations and blood parameters have been checked in accordance with the relevant chemotherapy protocol, and that the patient is fit to receive treatment. If doses are modified due to these parameters, the reason for the dose modification should be documented.

- If a patient is to be treated off-protocol (i.e. with a chemotherapy regimen that is either not on the agreed list of regimens for use within the Trust, or falls outside of an agreed algorithm), the Consultant must document the intended regimen in the patient's notes, and complete an "Off-Protocol Chemotherapy Regimen" form as specified in the "Off-Protocol Chemotherapy Regimen Process" in Section 3.9 below.
- After the final cycle in a given course, the prescriber should ensure there is a record made of whether the course of chemotherapy was completed or not. If the course was stopped before completion, the reason for cessation should be documented. For non-adjuvant chemotherapy, a reference to the response should be documented.
- An end of treatment summary should also be sent to the patient's GP.

Prescriptions for all cytotoxic drugs should be electronic (or pre-printed proforma until electronic prescribing is implemented), not hand-written. Changes to any prescription must be documented electronically or in writing, and not verbal. If a prescription is amended, the changes should be signed and dated by the prescriber before the treatment is administered or dispensed.

There are no arrangements for initiation of chemotherapy outside of normal Monday to Friday working hours. If appropriate, transfer the patient to another treatment centre. (See Section 10.1)

When patients taking oral anticancer chemotherapy are admitted into hospital;

- They should **not** have any further doses of their anti-cancer treatment prescribed by the admitting medical or surgical team, dispensed by pharmacy or administered by the nursing staff. This includes all oral agents in sections 8.1 and 8.2 of the current BNF (see page 7).
- The patient's oncologist / haematologist should be contacted as soon as possible (within 24 hours of admission) to decide whether treatment should continue during the admission.
- If the decision is made to continue treatment, the patient's oncologist / haematologist is then responsible for ensuring that the necessary inpatient chemotherapy prescription, written by a prescriber locally registered as holding the relevant competency, is made. The prescription **must** include the duration of treatment.
- Trust pharmacy and nursing staff should not dispense or administer oral chemotherapy unless it has been prescribed in this way.

3.4.2 All staff who confirm chemotherapy are responsible for checking the following before confirming the prescription:

- patient fit for treatment
- correct regimen selected
- minimum monitoring requirements have been met, including response assessment
- history of toxicities and complications from previous cycles
- dose modifications or delays as per protocol, or in accordance with patient's condition
- supportive drugs prescribed

3.5 Pharmacists Responsibility

An appropriately trained pharmacist on the Trust register must clinically check all prescriptions for cytotoxic agents for the treatment of malignant disease.

Pharmacists who are involved in the clinical checking of chemotherapy prescriptions, and/or provide a clinical pharmacy service to wards where haematology/oncology patients are cared for, should undertake training appropriate to the role. Only once assessed as competent, can prescriptions be checked unsupervised.

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

- That the appropriate regimen/protocol has been selected, with correct sequencing.
- That the body surface area (BSA) calculations are appropriate for the patient. If there is a significant increase or decrease (> 10%) in the patients' weight compared to the baseline, discuss with the prescriber.
- That maximum doses for individual drugs have not been exceeded.
- That the patient is not allergic to any prescribed medicines (and see prescriber's responsibility, 3.4).
- That dose modifications to previous treatments are reviewed.
- That all cytotoxic drugs and supportive therapies including anti-emetics have been prescribed.
- That the date of chemotherapy to be given has been clearly stated.
- That the maximum cumulative doses including previous courses of anthracyclines and bleomycin have not been exceeded. If these drugs have previously been given at another Trust, the referring unit should provide information on cumulative doses already received, as appropriate.
- In Trusts where dose banding is approved, this should be built into any electronic prescribing system. For paper proformas, the pharmacist may amend the dose to the nearest acceptable parameter specified in the latest list of dose banding levels. Changes should be signed and dated by the pharmacist
- The route of administration and the duration of infusion have been specified on the prescription.
- The volume of infusion is correct with respect to the patient, protocol and pharmaceutical stability.
- There is an appropriate interval between the previous cycle and current prescription.
- All relevant investigations and blood parameters should be checked in accordance with the relevant chemotherapy protocol, and drug doses modified where necessary, in discussion with the prescriber.
- The prescription has been signed by an appropriate clinician, either in the electronic or written form.

- If the prescription is prescribed “Off-Protocol” or “Off Algorithm”, the oncology pharmacist must discuss the case with the responsible consultant, as per the Off-Protocol Chemotherapy Regimen process outlined in section 3.9, and in Appendix B. The pharmacist must satisfy themselves that the prescription is appropriate to the individual patient’s circumstances, plus ensure funding is in place, before the prescription can be dispensed.

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

Prior to a cytotoxic dose being prepared or dispensed, the competent oncology pharmacist doing the clinical checking/screening will document that the prescription is approved for preparation.

3.6 Nurses Responsibility

All prescriptions for cytotoxic agents must be checked by a nurse competent in chemotherapy administration, before initiating administration, to ensure that:

- the patient is fully informed and has given written consent for the prescribed treatment
- the correct weight and height have been recorded, and the body surface area calculations are appropriate
- an accurate dose has been prescribed and discrepancies have been clarified with the doctor
- dose modifications to previous treatments are maintained if appropriate
- cumulative doses of cytotoxics have not been exceeded
- all cytotoxic drugs and supportive therapies, including anti-emetics, have been prescribed
- the patient is not allergic to the prescribed medicines (and see prescriber’s responsibility, 3.4)
- the route of administration and the duration of infusion have been specified on the prescription
- the patient has appropriate venous access prior to administering cytotoxic drugs
- there is an appropriate interval between the previous cycle and the current prescription
- all relevant safety parameters such as complete blood counts, renal and hepatic function, toxicities and patient evaluation have been documented
- the prescription has been prescribed by a prescriber on the Trust register, approved by a prescriber or member of staff competent to confirm chemotherapy prescriptions, and checked by a specialist pharmacist on the Trust register

A nurse must not accept verbal orders for cytotoxic agents or for adjustments to doses of cytotoxic agents.

3.7 Prescriptions

Oncology, haematology and paediatric oncology staff should prescribe cytotoxic drugs for patients using an electronic prescribing system, if available.

For Trusts within the Cancer Alliance who have not yet implemented an electronic prescribing system, anti-cancer chemotherapy should be prescribed using pre-printed proformas. Chemotherapy prescriptions should not be hand-written.

Oral anti-cancer chemotherapy must not be prescribed on Hospital FP10s. (The exception to this is hydroxycarbamide for myeloproliferative diseases)

All professions involved in prescribing, checking and administering chemotherapy should always have all the necessary documentation available at the point of the checks. If any information is missing, such as the patient's healthcare records, consent form, or all documented information regarding previous cycles of chemotherapy treatment, then the pathway should be halted until the information becomes available.

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

- Date prescribed
- Patient's name, date of birth, and hospital number
- Patient's weight, height and surface area
- Allergy status, always declare if 'No known allergies'
- Ward / clinic
- Consultant name
- Protocol code or regimen name
- Disease site and indication
- Cycle or course number
- Name of drug – use approved generic drug names; no abbreviations
- It is advised that each individual dose must be written in milligrams, micrograms, units, or target AUC for carboplatin.
- Frequency per day, and number of days of treatment
- Route of administration (the abbreviation IT is not acceptable, intrathecal must be written in full)
- Infusion solution and volume
- Duration of infusion and any other administration instructions
- Starting dates (and times when appropriate)
- Antiemetics, hydration and any additional drugs as defined by the protocol
- Reason for any dose modifications

In order to avoid patients being treated for longer than intended by the prescriber, prescriptions for oral chemotherapy, whether for inpatients or outpatients, must contain clear directions (including the frequency of dosing) and duration of treatment.

Prescriptions for intrathecal administration must follow the Trust and National Guidance for the administration of Intrathecal chemotherapy.

3.8 Essential Investigations and Tests

Essential investigations and tests are specified within each chemotherapy protocol. This includes blood tests, such as FBC, renal and hepatic function, and other investigations, such as blood pressure, urinalysis, EDTA, echo.

It is important to check results and, if abnormal, to confirm whether any dosage modifications are required before initiating treatment.

The acceptable time frame for blood tests before starting a course of treatment, and also before each subsequent dose, has been agreed as below:

- The essential blood tests listed in the chemotherapy protocol are usually performed within 28 days of starting Cycle 1^{**}; and within 72 hours^{*} of Day 1 of subsequent cycles of chemotherapy, provided no other treatment is given within this window.
- ^{*} For continuous anti-cancer therapy (e.g. daily oral dosing, or weekly pulses) with no cyclical nadir, essential blood tests may be performed within 7 days[#] of subsequent cycles ([#]within 14 days for CML patients, and myeloma patients on lenalidomide-, thalidomide- or bortezomib-based treatments).
- ^{**} Care should be taken with patients in an unstable condition; in such patients, investigations may need to be repeated closer to the treatment date than usual, as specified by the prescribing clinician.
- ^{**} For patients switching from one regimen to another with no significant break, then essential blood tests should usually be performed within 72 hours of Cycle 1 of the new course of treatment.
- For doses given within a cycle (e.g. Day 8, Day 15), any essential blood tests required are ideally performed up to 24 hours before the dose is due, but for sites which outsource the chemotherapy, 48 hour bloods are considered acceptable.

The above time frames allow for chemotherapy to be prepared and delivered in time for the administration appointment, and should not normally need to deviate from the specified day in the protocol more than as agreed above.

However, any locally pre-agreed exceptions to these time frames need to be clearly documented in the Trust local operational policy.

3.9 Chemotherapy “Off Protocol” Prescribing Process

- Chemotherapy should be prescribed according to agreed lists of chemotherapy regimens, and chemotherapy algorithms where relevant, as approved by the individual Tumour Site Specific Groups and the St Luke's Cancer Alliance Chemotherapy Group.
- In exceptional circumstances, a chemotherapy regimen not on the approved list may be prescribed for individual patients (See Appendix B for process schematic), e.g. when:
 - current available regimens do not meet the clinical need of the patient, e.g. toxicity profiles of existing regimens are incompatible with the patient's clinical condition
 - the route of administration of an existing regimen is inappropriate or inaccessible.

- Chemotherapy regimens not on the agreed list of chemotherapy regimens for the particular tumour site, or not in an agreed algorithm, are referred to as “Off-Protocol” chemotherapy regimens,
- If there are funding implications with the use of the “Off-Protocol” chemotherapy regimen, funding approval must be obtained before an Off-Protocol Chemotherapy Regimen Form is completed and treatment initiated.
- Off-protocol chemotherapy regimens may only be initiated by the medical/clinical oncology consultant or haematology consultant responsible for the patient's care.
- An Off-Protocol Chemotherapy Regimen Form that specifies details of the off-protocol chemotherapy regimen must be completed so that all healthcare professionals responsible for the patient's care have the appropriate information to deliver safe and effective treatment. (It may also be referred to as a “Green Form”, as it is common practice to print it on green paper for easy identification)
- This form must include the following:
 - Supporting documentation and reference for the regimen. If this is not available, the rationale for its use must be approved by an oncology pharmacist to ensure details are appropriate for the individual patient's circumstances.
 - The name of each drug.
 - The intended dose of each drug in milligrams, micrograms or units per m² or per kilogram. For carboplatin, the desired Area Under The Curve (AUC) should be quoted.
 - The schedule on which each drug is given and the route of administration.
 - The total number of cycles to be given, and the interval between cycles.
 - The reason for prescribing “off protocol”.
 - Monitoring Tests (e.g. Full Blood Counts (FBC), Biochemistry and tumour markers) should be specified for the regimen and intervals also stated; dose modifications for out of specification results should also be stated for when results of tests may be outside normal limits.
- An electronic copy of the Off-Protocol Chemotherapy Regimen form is available at <http://stlukescanceralliance.co.uk/off-protocol-chemotherapy/>
- The Off-Protocol Chemotherapy Regimen Form must be completed IN FULL by the responsible Consultant and supporting documentation/references given to an oncology pharmacist for approval.
 - Failure to provide the appropriate reference or complete the form IN FULL will result in delays for the patient.
 - If dose modifications are not specified on the form, the consultant must be consulted for toxicity management when haematology or biochemistry results are out of range.
 - The pharmacist will provide advice on dose modification information to be added to the Off-Protocol Chemotherapy Regimen Form, as appropriate.
- Since the introduction of chemotherapy algorithms, any deviation from algorithm should also be recorded on an Off-Protocol Chemotherapy Regimen Form, to allow regular review of “Off Algorithm” prescribing at the local chemotherapy group, as well as at the Alliance Chemotherapy Group, as below.

- The Off-Protocol Chemotherapy Regimen Form should be approved by an oncology pharmacist BEFORE the patient is booked into clinic for treatment.
- The original form will be filed in the patient's healthcare record, and one copy sent to the lead oncology pharmacist.
- The lead oncology pharmacist of each Trust will regularly review the use of Off-Protocol regimens and Off Algorithm prescribing via the local Chemotherapy Group.
- The protocol pharmacist will collate Off-Protocol and Off Algorithm usage across the Alliance, and report findings to the St Luke's Cancer Alliance Chemotherapy Group at each Alliance Chemotherapy Group meeting.
- Application for REGULAR USE of a new chemotherapy regimen should be made to the Alliance Chemotherapy Group via the TSSG of the particular tumour site concerned.

4. Purchasing, Preparation, Supply, Transportation and Storage of Chemotherapy

4.1 Purchasing, Receipt and Storage in Pharmacy

- The purchasing, receipt and storage of cytotoxic drugs in a pharmacy are carried out in accordance with agreed procedures by the pharmacy department at each site within the St Luke's Cancer Alliance. The pharmacy will ensure the effective control of the quality of these products.
- Access to cytotoxic agent storage areas must be limited to authorised staff. All such storage areas will be clearly labelled with cytotoxic warnings.
- Main stocks of cytotoxic drugs will be held in the pharmacy department, under appropriate conditions.
- Clinical trial supplies of cytotoxic drugs should be kept separate from main stocks.
- Cytotoxic drugs should not be available as ward stock. They should always be dispensed for individual patients.
- Intrathecal chemotherapy doses must be stored in a separate designated area (see section 9).
- Storage shelves must be designed in such a manner that the risk of breakage of containers of cytotoxic drugs is reduced to a minimum.
- Cytotoxic spillage kits should be available in all areas where cytotoxic drugs are stored.
- Damaged cartons of cytotoxic agents are to be discarded into a rigid sharps box. These should be labelled as cytotoxic waste and dealt with as 'part-used doses' in section 14.4. If there is any contamination of the area or personal exposure to cytotoxic material, refer to the sections on Accidental Contamination and Cytotoxic Spillage, sections 15 and 16.

4.2 Preparation of Cytotoxics

The pharmacy departments within the St Luke's Cancer Alliance provide parenteral cytotoxic agents individually dispensed and ready for administration to named patients.

The only remaining aseptic unit within the St Luke's Cancer Alliance is based at the Royal Surrey County Hospital, opening hours Monday to Friday, 8am – 4pm.

Trusts without their own cytotoxic reconstitution facility must purchase supplies from a licensed unit. These units must be subject to regular inspection from local and regional Pharmacy Quality Assurance Departments. Licensed units are also subject to inspection by the Medicines and Healthcare products Regulatory Authority (MHRA).

- All prescriptions should be received into pharmacy in a timely fashion according to local Trust policy.

- Cytotoxic chemotherapy must be prepared in a pharmacy aseptic unit by trained and competency-assessed staff.
- Reconstitution of cytotoxic drugs or drawing up into a syringe in a clinical area is unacceptable. Under no circumstances should cytotoxic reconstitution take place by untrained staff, or outside of a controlled environment.
- The Trusts within the Alliance do not offer a cytotoxic reconstitution service outside of normal Monday to Friday working hours.
- Professional and technical staff who are expected to participate in the reconstitution of cytotoxic drugs and dispensing of non-injectable dosage forms must have a record of competence.
- The appropriate pharmacy manager will maintain a register of staff holding a certificate of competence and will ensure their training is updated at appropriate intervals. The training programme should include:
 - Reading the St Luke's Cancer Alliance *Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs*.
 - Reading the local Trust's Chemotherapy Operational Policy.
- Appropriately trained pharmacy staff are responsible for the accurate preparation, documentation, labelling, determining and allocating the correct expiry, and storage conditions for a cytotoxic dose.
- The pharmacist or accredited technician performing the final product check in the aseptics department will ensure correct documentation, appropriate preparation of dose, dispense and release the medication for the patient.

4.3 Transport

- Containers of prepared cytotoxic agents must be transported in designated transport bags or boxes. The bags or boxes should be clearly labelled: **"CYTOTOXIC DRUGS – HANDLE WITH CARE"**
- Additional precautionary labels should be added to the containers and the transport bags or boxes as appropriate, for example room temperature or refrigerated storage required.
- Chemotherapy drugs should be delivered to a registered nurse on the ward who takes responsibility for the appropriate storage, as defined on the additive label attached to the cytotoxic agent.
- Pneumatic tubes should not routinely be used for transporting cytotoxic agents, unless a full risk assessment has been undertaken and measures put into place to reduce the risk of spillage or contamination by cytotoxic drugs to negligible levels.
- Staff involved in the transportation of cytotoxic drugs must be trained to follow the "Cytotoxic Spill" procedure. Records of training should be maintained in the relevant areas.

- Intrathecal doses must be transported separately to all other medication (See local Trust Intrathecal Policy and National Guidance)
- Any cytotoxic drugs received, but not administered, must be safely returned to the pharmacy department in a designated transport bag or box as soon as possible.
- Cytotoxic drugs that are to be transported outside of the hospital should be placed in sturdy, leak-proof transport bags or boxes. They should be clearly labelled as "Cytotoxic – Handle with Care". Details of the recipient and delivery address should be clear. The label should also contain the name and address of the originating hospital and a direct contact in pharmacy, in case of an emergency.
- Managers must ensure that insurance companies are made aware that cytotoxic drugs are transported within the relevant vehicles.

4.4 Storage in Clinical Areas

- Pharmacy staff are responsible for correct storage of drugs prior to delivery to wards.
- Nurses are responsible for the correct storage of cytotoxic drugs delivered to wards and clinics prior to use. They are also responsible for appropriate monitoring of storage facilities.
- Chemotherapy drugs must be delivered to a qualified nurse on the ward, who takes responsibility for the appropriate storage, as defined on the label attached to the cytotoxic agent.
- Bags or boxes will not be left unattended, or with untrained staff, on arrival in a clinical area.
- Cytotoxic drugs must be stored on wards separately from other drugs, in locked medicine cupboards or refrigerators as appropriate.
 - parenteral doses of chemotherapy should be stored in a designated locked chemotherapy fridge or cupboard
 - intrathecal doses must be stored in a designated intrathecal refrigerator or box. Refer to Trust intrathecal policy.
 - oral doses may be stored in a locked trolley, fridge or cupboard, as long as they are clearly labelled as cytotoxic.
- Access to cytotoxic agent storage areas on wards or day units must be limited to authorised staff.
- Cytotoxic drugs should be stored in a manner that will prevent containers of cytotoxic drugs from falling. Such storage areas should be labelled with cytotoxic warning labels.

5. Dispensing and Administration of Oral Cytotoxic Preparations

The use of oral anti-cancer medicines is increasing in scope and complexity. Prescribing, dispensing and administration of oral anti-cancer medicines must be carried out to the same standard as injected anti-cancer therapy.

- All staff involved must have access to protocols which include guidance on monitoring and treatment of toxicity.
- Patients must be fully informed, and must receive verbal and written information about the oral treatment, including 24 hour contact details for specialist advice.
- Written consent must be obtained before treatment starts.
- Prescribing of oral anti-cancer therapy must be initiated by a cancer specialist, and carried out to the standards described in this policy.
- An appropriately trained pharmacist on the Trust register must check all oral cytotoxic prescriptions before they are dispensed.

5.1 Dispensing and Labelling

- Staff checking or dispensing oral anti-cancer prescriptions must have access to the protocol.
- All dispensed containers of oral cytotoxics should be labelled with a "Cytotoxic" warning label, such as "Cytotoxic, to be handled with care by the patient or carer only".
- Automated dispensing systems should only include oral anti-cancer medicines which are available as unit doses. A local risk assessment should be carried out before inclusion in an automated dispensing system.
- Tablets or capsules should not be handled directly. All staff should use a "no touch" technique or wear gloves, to minimise the risks of exposure.
- Wherever possible pharmacy will purchase blister or foil packed tablets or capsules of oral cytotoxic drugs.
- Any packing that comes in cytotoxic tablet containers (e.g. cotton wool etc.) should be disposed of in a cytotoxic waste bin.
- Designated counting triangles, which are only used for cytotoxic drugs should be used. These must be cleaned after use with an IMS wipe. Wipes should be disposed of in a cytotoxic waste bin.
- Automated tablet counting machines should NEVER be used for oral cytotoxic preparations.
- When dispensing liquid formulations, work over a leak-proof tray to contain any spillage.
- All quantities of oral anti-cancer medicines should have a physical double check (count) prior to release to the patient.
- Oral cytotoxics should not be routinely dispensed in compliance aids or monitored dose systems, unless a full risk assessment has been carried out.

- The exact quantity for the complete cycle of treatment should be supplied. It is not appropriate to supply original packs of anti-cancer medicine if this means that the patient will receive more doses than required for their intended course.
- Oral anti-cancer medicines should not be supplied to a patient unless they have received education relating specifically to the medicines and the likely side effects. It is important that the patient understands and accepts their roles and responsibilities relating to the treatment.
This statement applies to ALL patients, including those receiving their oral chemotherapy via a non-NHS pharmacy, or via a home delivery company.

5.2 General Guidelines for Handling and Administration

- Accidental exposure which may arise from handling uncoated tablets, loose capsules or oral liquids should be minimised.
- All staff and carers should use a “no touch” technique or wear gloves, to minimise the risks of exposure.
- Patients and carers should be warned to keep handling of cytotoxics to a minimum and that, as far as possible, the cytotoxic drugs should only be handled by the patient for whom they are prescribed.
- Hands should be washed thoroughly after handling any oral cytotoxic medicine.
- Patients should be advised to swallow tablets or capsules whole and not chew them.
- Ideally, tablets should never be crushed or halved, and capsules should never be opened.
- If the patient is unable to tolerate capsules or tablets, contact the pharmacy about the possibility of an alternative liquid preparation.
- Where a commercial liquid preparation is not available, there is sometimes information from the manufacturer regarding dispersal of the tablet in water (e.g. capecitabine). Written information regarding dispersing the tablets and handling procedures must be provided to these patients, in a locally agreed information leaflet.
- Patients and carers should be advised to wash their hands after taking or administering any cytotoxic medication.
- Staff/carers or patients must **not** use any tablets or capsules if loose powder or liquid is present in the container, where this would not be expected. Seek advice from the pharmacy.
- On wards or in clinics, oral doses should be dispensed into a medicine pot prior to administration. Blister or foil packed medicines should not be removed from their wrapper, but dispensed with the wrapping intact. Patients with poor manual dexterity or impaired vision can have the dose unwrapped at the bedside by a nurse.
- In wards or clinic areas, used medicine pots, oral syringes and administration spoons should be disposed of in cytotoxic waste.
- If a tablet or capsule is dropped in any clinical area, wear gloves to pick it up and dispose of it into a cytotoxic waste bin. Damp dust the area with a wet paper towel, to ensure all fragments are collected. Dispose of the paper towel in cytotoxic waste. Document the lost dose in the patient's healthcare record and on the prescription.

- When patients taking oral anticancer chemotherapy are admitted into hospital, nursing staff should **not** administer any further doses of the anti-cancer treatment unless continuation of treatment has been approved by the patient's oncologist / haematologist, and a prescription has been written by an oncology / haematology SpR or Consultant locally registered as holding the relevant competency.
- Trust pharmacy and nursing staff should not dispense or administer oral chemotherapy for in-patients unless it has been prescribed in this way. See Section 3.4.1 for details.

5.3 Patient Education and Information

- The use of oral chemotherapy patient diaries is recommended.
- Before every cycle, all patients should be seen by an oncologist, haematologist, specialist oncology nurse or trained oncology pharmacist.
- Patients should be asked about any problems or side effects that have occurred since their previous cycle of treatment.
- Patients must be adequately counselled to ensure their understanding of the regimen, storage conditions and handling precautions. Handling precautions are particularly important during long maintenance courses.
- Medicine spoons, cups and oral syringes used for administration in the home should be reserved for chemotherapy treatment only, washed thoroughly between doses and safely disposed of at the end of treatment.
- Designated members of the team must ensure that the patient understands the following:
 - How and when to take their medicine, including "gaps" off treatment
 - What to do if a dose is missed
 - What to do in the event of vomiting after a dose
 - Any dose modifications and why this is necessary
 - Common side effects and what action to take
 - To return any unused oral cytotoxic medicine to the hospital pharmacy
 - The role of their GP with regards to the treatment
 - How to deal with a spillage, accident or improper storage in the home
 - To use the 24 hour contact details for specialist advice

6. Administration of Cytotoxic Agents

All practitioners administering cytotoxic agents must follow procedures in the St Luke's Cancer Alliance *Cytotoxic Policy*, and relevant Trust Policies.

Chemotherapy should only be given in named designated clinical areas within a Trust, as determined by local policy.

Administration of cytotoxic drugs via all routes must be carried out by nursing or medical staff who have been trained and assessed as competent, according to the Trust's competency standards. Competency should be assessed annually. A register should be maintained which details the staff who are authorised to administer chemotherapy unsupervised.

Staff administering cytotoxic drugs must have current general knowledge of the drugs being given. They should be aware of the correct administration procedure, following an agreed protocol. They should be aware of possible immediate, short and long term side effects, and the actions to be taken if these occur.

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

Medical staff administering cytotoxic doses must undergo the same training and competency assessment as nursing staff (see separate Trust Policy for Intrathecal chemotherapy).

Drugs administered by routes other than the intravenous route, e.g. intrapleural and intrathecal (see separate Trust Policy for intrathecal drugs) must also be administered by appropriately trained and competent personnel.

6.1 Facilities

Cytotoxic drugs should be administered in a designated dedicated environment with appropriate facilities for safe administration and within safe working staffing levels.

Areas designated for the administration of cytotoxic drugs should have all the relevant policy and protocol documents available.

Facilities should include easy access to expert help and all the equipment necessary for the management of emergencies.

6.2 Equipment

The following MUST be available in ALL designated clinical areas where chemotherapy is administered.

- All agreed chemotherapy protocols (ideally in electronic format)
- Protective clothing – gloves, aprons, eye protection

- Emergency drugs for anaphylaxis
- Cytotoxic waste bins
- Extravasation kit, including hot and cold packs (*if designated area for intravenous chemotherapy*)
- Spillage kit
- Eye wash/access to running water
- Emergency bell/telephone
- Resuscitation equipment

For chemotherapy administration in the patient's home, a risk assessment should be carried out and the equipment identified as necessary from the assessment must be available.

Electronic pumps used to assist administration must be appropriately installed, validated and have a current maintenance certificate. They should be appropriate for the prescribed purpose and used by a competent practitioner only at all times.

Staff should use the Trust governance process to report adverse incidents, as well as act upon any MHRA hazard and safety notices and NPSA alerts.

7. Administration of Intravenous Cytotoxics

All chemotherapy will be administered either by a nurse or doctor trained and assessed as competent in the administration of cytotoxic drugs.

The selection of the appropriate route for venous access should be based on the patient's short- and long-term best interests.

A practitioner skilled in cannulation and the administration of IV chemotherapy is key to preventing infiltration and extravasation.

When administering cytotoxics intravenously via a peripheral cannula or a central venous access device (CVAD), the professional must be knowledgeable about:

- Which patients are at risk of extravasation
- Sequence of the cytotoxics
- How to prevent extravasation
- How the rate of administration and route can affect the risk
- How to recognize and manage extravasation should it occur

See St Luke's Cancer Alliance Guidelines for Prevention and Management of Chemotherapy Extravasation, available at <http://stlukescanceralliance.co.uk/guidelines/>, for further information on extravasation.

No cytotoxic drug should be given if there is any doubt regarding the patency of the venous access device.

7.1 Selection of Venous Access Device

7.1.1 Peripheral Venous Cannulation

Small-gauge Teflon® or silicone cannulae which preserve vein integrity and cause least pain to the patient are recommended.

When inserting the cannula, the professional must be knowledgeable about where to site the cannula, which gauge cannula to use, and general good practice.

The most appropriate location is considered to be the forearm (although a large straight vein over the dorsum of the hand is preferable to a small vein in the forearm). The numerous superficial veins of the arm are most commonly chosen for cannulation because they are easily detectable and the skin is less sensitive. Most common are cubital, basilic and cephalic veins, and accessory veins that drain off these.

When choosing a suitable site, consider the purpose of the cannulation.

For example:

- a large vein is required for a high flow rate
- irritant solutions or drugs require good flow to assist haemodilution.

Avoid use in the following:

- Siting a cannula over a joint, particularly the antecubital fossa, as tissue damage following extravasation in this area has very serious consequences. Therefore the antecubital fossa should never be used for the administration of chemotherapy.
- Sites directly below a venipuncture site or failed cannulation attempt when administering vesicants, as there can be a leak via the old site.
- Superficial veins in the region of the back of the wrist, as extravasation injury may cause significant tissue damage.
- Areas proximal to skin lesions or wounds.
- Veins close to arteries or deep lying vessels such as nerves, as accidental puncture can cause painful spasm or prolonged bleeding.
- Areas affected by invading tumour, haematoma, and inflamed or sclerosed areas.
- Limbs where there is lymphatic impairment following surgery, chemical occlusion or radiotherapy even if there is no obvious lymphoedema.
- The dominant arm, in order to maintain patient mobility and independence whenever possible.
- Veins in the lower limbs (legs or feet) should never be used
- Prominent, superficial veins may be sclerosed, tortuous, fibrosed or fragile and therefore unsuitable for cannulation.
- Small visible but impalpable superficial veins are rarely suitable for cannulation.

Most difficulties arise when few or no veins in good condition are available (at which point a central venous access device should be considered).

The following patients are at increased risk of extravasation and extra caution should be taken: elderly, paediatric patients, thrombocytopenic patients, patients with fragile veins, obese, diabetics with peripheral neuropathy. Non-English speaking patients and those with communication difficulties are also at risk. Extra care should be taken with all these patient groups.

If there are any doubts regarding cannula patency, re-cannulate the patient.

To help dilate difficult veins:

- Soak the arm in hot water for about two minutes. Alternatively, a heat pad may be applied, although this will only dilate the veins directly under it, rather than all the veins in the forearm.
- Position the patient in a comfortable and appropriate position, 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 prior to the procedure (45 minutes prior for Ametop; at least 1 hour prior for EMLA cream). In certain severe circumstances, oral lorazepam (0.5 – 2mg) may be considered. These should be prescribed on the patient's drug chart. Again, the insertion of a central venous access device should be considered for future doses.

Site of cannula placement and date should be documented in patient's records as per local policy. Number and sites of attempted cannulation should also be documented.

7.1.2 Central Venous Catheters

- Where the recipient of therapy has insufficient or unsuitable peripheral veins, infusions are prolonged, or venous access becomes difficult, insertion of a central venous catheter may be indicated. Types of CVAD include: peripherally inserted central catheter, skin-tunnelled catheters (e.g. Hickman, Groshong), and totally implanted vascular access devices (e.g. Portacath)
- Central venous access is the route of choice if drugs or fluids are to be administered over a long period of time, if they are irritant to the peripheral veins, or have the potential to cause tissue necrosis.
- For paediatric oncology patients, refer to local policies for guidance on central or peripheral administration.
- Care and maintenance, and access of CVADs should be in accordance with Trust guidelines and local policies.
- If placement or patency of the CVAD is in doubt, an x-ray and venogram should be undertaken prior to commencing treatment.
- It is often assumed that extravasation will not be a problem with CVADs. However, although the incidence of extravasation is lower with CVADs, detection may be delayed and hence the severity of injury may be greater.

7.2 Preparing to give Cytotoxic Drugs

- Check the prescription details are all satisfactory, as specified in section 3.6
- Be aware of the use and side effects of all the drugs to be administered. Further information and advice should be sought if necessary.
- If the injections or infusions have been stored in a fridge they must be allowed to reach room temperature before administration to a patient. This is to reduce the risk of infusion bags splitting during insertion of the giving set, and to reduce venous spasm.
- Check the patient has given written consent to receive the proposed cytotoxic regimen.
- Explain the procedure to the patient, and ensure that written information has been provided and understood.
- With another chemotherapy trained nurse, oncology doctor or oncology pharmacist, check the chemotherapy syringes and bags against the prescription as follows:
(If there is a discrepancy, contact the Pharmacy Cytotoxic Reconstitution Unit or, out of hours, the on-call pharmacist).
 - The patient's name and hospital number must correspond with prescription chart and pharmacy label.
 - Check the name and date of birth with the patient (or their wristband) to ensure that it corresponds to the prescription chart.
 - Cytotoxics must be administered on the date stated on the prescription.
 - The name of the drug and infusion fluid on the prescription and the pharmacy label must be identical.
 - The volume of fluid prescribed must correspond to the volume stated on the label OR the volume of fluid in a syringe must correspond to the volume stated on the label.
 - If multiple syringes are used to make up one cytotoxic dose, the total dose contained in the syringes must be added up to check that it corresponds with the prescribed dose.
 - Check the route of administration is the same on the cytotoxic label and the prescription.
 - As the chemotherapy doses are checked against the prescription, they should be placed directly in to an individual patient tray.
 - The tray should not be left unattended once checked.
 - If the checking process is interrupted at any point, staff should be vigilant for this, and the whole process should be restarted.
 - There should be a final check of the details on each syringe/bag of chemotherapy against the prescription and the patient immediately prior to administration.
 - Check all doses for particulate contamination, e.g. precipitation, before administration.

7.2.1 Sequencing of Drugs

- Vesicant cytotoxics should always be given before non-vesicant cytotoxic and non-cytotoxic drugs.
- The exception to this is where patients require supportive therapy e.g. pre-hydration or anti-emetic therapy prior to vesicant therapy.
- If there is any uncertainty about the sequencing, advice should be sought from an experienced chemotherapy nurse or pharmacist.

7.2.2 Monitoring

This is the key to early detection of 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 or rash
- anaphylaxis
- extravasation
- known side effects

The nurse must always confirm patency by ensuring there is blood return and by flushing with at least 5-10ml sodium chloride 0.9% before administering any intravenous medication.

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.

Since one of the first symptoms of 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 cytotoxic is administered, what symptoms to look out for, and to report them immediately. It may be particularly important to ensure children are able to raise these issues. It may be local irritation or venous spasm, but an early warning provides the opportunity to stop and investigate.

To ensure visibility at all times, an appropriate clear dressing should be fixed over the cannula or CVAD as local policy. It is important to secure cannulae and giving sets efficiently, to ensure that the cannula does not become dislodged. Opaque bandages should not be applied to cannula sites while chemotherapy is in progress.

With a CVAD, 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 local policy.

Stop administration if:

- there is any doubt about the checks that have been carried out.
- the patient requests the treatment to stop
- the patient demonstrates side effects or complications, particularly signs of anaphylaxis or extravasation
- the equipment fails to function effectively.
-

7.2.3 General Principles of Intravenous Administration

- Use of aseptic technique should be maintained throughout intravenous administration (as local policy)
- Systematic site management (including dressings and cleaning of needle free access devices) should follow local policy
- Ensure appropriate protective clothing is worn, see section 1.7.
- Checking should follow procedures previously described (see section 3.6 and section 7.2). Patient details should be confirmed verbally by patient, or with wristband for in-patients, immediately prior to administration by the person giving the treatment.
- Maintain a closed system by using Luer-lock fittings. Designated needle-free systems are recommended.
- Inspect sealed bags before opening to ensure no spillage has occurred within the bag.
- Open cytotoxic doses directly onto the tray, or dressing pack.
- 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 leakages.
- A fast running infusion of sodium chloride 0.9% or compatible solution should be used in adults, for the administration of all bolus doses of vesicant and irritant drugs, and also with peripheral infusions of vinorelbine.
- Ensure correct rate of administration.
- Flush well with appropriate compatible intravenous diluent prior to, in between, and after drugs have been administered.
- When disconnecting intravenous fluids, infusion bags should be held over a clean tray with gauze placed under the point where giving set is to be disconnected, so as to contain any leakages or spillages.
- On completion of dose administration, clear away all equipment, waste and sharps, as outlined in section 14.
- Record the administration on the electronic prescribing system (or pre-printed proforma), and in the medical or nursing notes.
- 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 reason for discontinuation of treatment. Medical staff should also be notified. For disposal of part-used doses, see section 14.4.

7.2.4 Administration of Bolus Chemotherapy

- Disinfect latex injection port or obturator with cleaning solution (as per local policy) and allow to dry. **Do not use the 'flip-cap port' of the cannula where present.**
- Do not expel air from syringes. If air is in a syringe, hold it so that the air is up near the plunger, so that the entire drug is expelled once the air is reached.
- Ideally, peripheral bolus doses of vesicants should be given via a newly sited cannula.
- Where vesicant or irritant drugs are to be given to adults, administer the bolus vesicant via the side arm of a giving set via a fast running drip of sodium chloride 0.9% or a compatible infusion. For children, follow local policy.

7.2.5 Administration of Infusional Chemotherapy

- Ensure that the giving set is primed with a suitable flushing solution.
- Check connections on the giving set for leakage or cracking.
- Always insert the giving set into the cytotoxic infusion at waist height, working over a clean tray, to minimize the risk of contamination in the event of a spillage. It is recommended that the bag is in a horizontal position and the port through which the giving set is placed is not kinked. This reduces the risk of the giving set piercing through the port.
- If the drug is prone to photo-degradation, ensure that the infusion solution is covered to protect it from light, including the IV line.
- Maintain regular observation of IV cannula sites for signs of swelling or inflammation, the patient for adverse signs and symptoms, and observe and check the rate of infusion. The frequency of observation will depend on the drug and the patient, and should be agreed locally. For some drugs, the frequency and requirements for patient monitoring are specified within the protocol.
- A few vesicants, as specified in the Alliance Extravasation Guidelines, may be administered as infusions through a peripheral line with care and close supervision. These infusions should be of short duration, less than three hours. However, remember that the central venous route minimises the extravasation risk, and should be considered on an individual patient basis.
- Vinca alkaloids are to be administered as mini-bag infusions to adults, and teenage patients being treated on an adolescent unit, according to local Trust "Policy for Prescribing, Dispensing and Administration of IV Vinca Alkaloids" and the NPSA alert RRR04 (2008).
- Non-vesicant infusions should be administered via an infusional pump.
- Infusions of vesicants should usually be administered under gravity control. If an electronic device is used, it should be a low-pressure device.

7.2.6 Giving Sets and Infusional Pumps

- Giving sets should be changed in accordance with local policy.
- If a special giving set or filter is required (e.g. paclitaxel), use only those recommended. Failure to use the correct giving set or filter may result in:
 - chemical leaching from the plastic, causing patient contamination
 - inadvertent under-treatment due to large drug molecules not being able to pass through a fine filter
 - not removing fine particulate contaminant due to lack of appropriate filter, leading to risk of embolus
- It is recommended that each Trust minimizes the different types of devices and pumps used, to minimize the potential for error.

8. Administration Via Specific Routes

8.1 Subcutaneous or Intramuscular Injection

A subcutaneous injection is given beneath the epidermis into the fat and connective tissue underlying the dermis. Several cytotoxic drugs can be given subcutaneously, according to St Luke's Cancer Alliance chemotherapy protocols (e.g. bortezomib, cladribine, cytarabine, trastuzumab, rituximab), as well as methotrexate for non-malignant conditions.

An intramuscular injection is given into the muscle.

- Choose a suitable site for injection and prepare the skin as per local policy.
- Ensure the appropriate gauge needle is attached securely to the syringe, and take care to minimise risk of spillage on the skin.
- For subcutaneous injection, use a pinch technique, and administer the injection using a 90° angle. Aspiration is not required prior to injection.
- Administer an intramuscular 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, so minimizing reflux.
- After administration, remove the needle and syringe, and cover the site with a plaster, or gauze, ensuring there is no leakage from the site.
- If further injections are required, rotate the site of administration.

8.2 Intravesical Instillation

Intravesical treatment refers to the administration of chemotherapy or immunotherapy directly into the bladder, via a urinary catheter.

Intravesical chemotherapies are used to treat residual transitional cell carcinoma (TCC) after resection and reduce tumor cell 're-implantation', and as a prophylaxis following resection. They also aim to increase the disease free interval.

The European Association of Urology (EAU) guidelines recommend a single dose of intravesical chemotherapy be given within six hours of bladder tumour resection.

Common chemotherapy agents include mitomycin C and epirubicin which may be given as a single dose or course of treatment.

Intravesical immunotherapy, Bacillus Calmette-Guerin (BCG), is used to treat high risk superficial bladder cancer, including carcinoma in situ. BCG may prevent progression of superficial bladder cancer to muscle invasive disease and increases the disease free interval.

Only competent trained nurses or doctors can administer intravesical chemotherapy.

For details of specific procedure, refer to guidelines produced at Trust level.

8.3 Intrapleural Instillation

Following drainage of a pleural effusion caused by malignant cells, the doctor may wish to instill a cytotoxic drug (usually bleomycin) into the pleural cavity via the pleural drain.

Only competent trained doctors can administer intrapleural chemotherapy.

For details of specific procedure, refer to guidelines produced at Trust level.

8.4 Intraperitoneal Instillation

Following drainage of the peritoneum, the doctor may wish to instill a cytotoxic drug into the peritoneal cavity, via the mechanism used for drainage.

Individual drugs used for administration by this route should be fully investigated for the appropriateness to do so. Management of a patient receiving drugs via this route must be understood by nursing staff caring for the patient.

Only competent trained doctors can administer intraperitoneal chemotherapy.

For details of specific procedure, refer to guidelines produced at Trust level.

8.5 Administration of Chemo-embolisation

Chemo-embolisation is a combination of local delivery of chemotherapy and a procedure called embolisation. It is used to treat cancer, most often of the liver.

Only competent trained radiologists can administer chemotherapy using this technique.

For details of a specific procedure, refer to guidelines produced at Trust level.

8.6 Administration of Topical Cytotoxic Chemotherapy

Cutaneous lesions can be treated with topical application of chemotherapy. e.g. cutaneous T-cell lymphoma, basal cell carcinoma and squamous cell carcinoma.

Cytotoxic drugs for topical administration may come in a number of different formulations including creams, ointments and gels.

- Apply the topical cytotoxic therapy as prescribed until the lesions become necrotic (may be up to 4 weeks).
- Ensure regular application of the drug using safe handling technique. Gloves must be worn by the carer or patient.
- Ensure accurate application to tumour site only, avoiding eyes, mouth, or areas close to mucous membranes.
- Systemic side effects are rare unless the majority of the skin is being treated; hydrocortisone is often used topically as supportive therapy to alleviate local discomfort.
- If the treatment is to be continued in the home, ensure that the patient is provided with appropriate information regarding application of the preparation, handling and disposal instructions.

8.7 Intra-ocular Chemotherapy

This is a specialist procedure, used during trabeculectomy surgery for glaucoma. Intra-ocular 5FU or mitomycin C may be administered into the eye, according to local surgical practice.

All theatre staff must be aware of the relevant health and safety procedures around safe handling and disposal of cytotoxic waste.

9. Intrathecal / Intraventricular Chemotherapy

Individual Trusts within the St Luke's Cancer Alliance each have a separate policy for the administration of intrathecal chemotherapy within that Trust to cover the individual operational aspects of the supply, prescribing and administration of intrathecal chemotherapy. Local policy must be in place to ensure compliance with the latest National Guidance.

Each Trust within the Cancer Alliance will assess annually the number of intrathecal administrations which have been undertaken over the previous 12 months. If the number falls below 10 per year, a risk assessment for all those involved in the process of administration of intrathecal chemotherapy will be undertaken.

Under no circumstances should any Trust within the Cancer Alliance administer intrathecal chemotherapy to children under the age of 16 years. All intrathecal chemotherapy for children and adolescents will be administered at the paediatric oncology centre.

Intrathecal / intraventricular chemotherapy is used for patients with active central nervous system (CNS) involvement of disease, or who are at high risk of developing CNS disease. Not many chemotherapy agents cross the blood brain barrier, therefore therapy needs to be injected directly into the cerebral spinal fluid (CSF).

The only drugs routinely administered by this route are:

- Methotrexate
- Cytarabine
- Hydrocortisone

Other intrathecal drug(s) may only be initiated by a Consultant included on the Trust ITC register after discussion with the Trust ITC Lead and completion of the St Luke's Cancer Alliance Off-Protocol Chemotherapy Regimen ("green") form. This form must include reference(s) to published evidence demonstrating safety and efficacy of the planned intrathecal treatment.

The two ways to inject are as follows.

- Intrathecal, which is performed by doing a standard lumbar puncture and injecting into the cerebro-spinal fluid.
- Intraventricular administration is achieved through an Ommaya reservoir. This is surgically implanted and is a procedure likely to happen at a specialist centre. Chemotherapy is administered via the port.

9.1 Roles and Responsibilities

- The chief executive of each Acute Trust within the St Luke's Cancer Alliance will identify a 'Designated Lead' for intrathecal chemotherapy. This may be a consultant, senior cancer nurse or oncology pharmacist. The person who assumes this responsibility must be given protected time to carry out this responsibility. The designated lead is accountable to the chief executive of the Trust for ensuring compliance with National Guidance on Intrathecal Chemotherapy.

- Only individuals on an appropriate register of competent individuals are permitted to take part in any part of the process of prescribing, dispensing, administering or checking intrathecal chemotherapy.
- Training requirements for all staff groups can be identified within local policy.
- If the patient requires intravenous and intrathecal chemotherapy, the intravenous chemotherapy must be prescribed, supplied and administered before the intrathecal chemotherapy is supplied. Evidence of intravenous administration MUST be received in pharmacy before intrathecal chemotherapy will be released for supply.

10. Exceptional Circumstances

10.1 Out-of-Hours Chemotherapy

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

The exception would be cancer chemotherapy initiated during normal working hours, but which requires subsequent administration out of hours due to scheduling of the regimen e.g. twice daily dosing that falls into the evening, or doses on subsequent days which fall over a weekend.

A record of all out-of-hours chemotherapy should be maintained within each Trust.

The Trusts within the Cancer Alliance do not offer a cytotoxic reconstitution service outside of normal Monday to Friday working hours, and there are no exceptional circumstances whereby it may be arranged to reconstitute chemotherapy outside of these working hours. If appropriate, transfer the patient to another treatment centre.

At St Peter's Hospital and Frimley Park Hospital, pre-filled, ready-to-use doses of cyclophosphamide, doxorubicin and vincristine are available for out-of-hours use. The Trust must ensure that these doses are only used within strict criteria which minimise the increased risk involved.

10.2 Capacity Planning

Chemotherapy should only be administered if there is adequate staffing provision in all areas, to ensure the service is delivered in a safe manner.

Each Trust should prepare a capacity plan for activity in each clinical area, including pharmacy services. Capacity planning should be routinely carried out in advance of critical times such as bank holidays. There should be an escalation process for if planned activity is approaching maximum capacity.

A contingency plan for unexpected events, e.g. staff shortages, must be in place at each Trust. It may be necessary to include contingency plans for transporting chemotherapy drugs from licensed aseptic facilities to individual acute Trusts across the Cancer Alliance.

10.3 Administration in a Non-Designated Site

All efforts should be made to ensure that parenteral chemotherapy is administered in a designated area, only then may chemotherapy be given in a non-designated area.

The criteria for chemotherapy administration in a non-designated site are as follows.

- In the opinion of the patient's consultant, the patient is too ill to be moved to a designated area. A full risk assessment by all members of the team involved in giving chemotherapy should be undertaken. Full documentation of this assessment must appear in the patient's records.

- That the chemotherapy administration is urgent and needs to be commenced before a bed can be found in a designated site, therefore making it unsafe to move the patient with chemotherapy in progress.
- The patient requires intrathecal chemotherapy under general anaesthetic, or lumbar puncture requires spinal needle placement under imaging guidance

In the event that chemotherapy may have to be administered in an area that is not a designated site, it is the responsibility of the nurse/doctor administering the drugs, to ensure that the necessary safety equipment is available (see checklist, 6.2) and the required safety precautions are maintained. The nursing staff caring for the patient should be given instructions of any special observations and precautions that are required, and these instructions should be documented in the patient's healthcare record.

11. Ambulatory Infusion Devices / Home Chemotherapy

An assessment of patient suitability for home chemotherapy will be undertaken by medical and nursing staff before a patient is allocated to receive it.

A number of infusion devices are available for use in patients receiving infusional chemotherapy. The type of device used will be determined by the chemotherapy regimen.

If electronic devices are used, sufficient teaching/training should be offered to patients and carers before treatment starts.

A number of St Luke's Cancer Alliance patients may be discharged on continuous infusional chemotherapy to be administered at home.

The patient's general practitioner or community nursing staff must be contacted before any arrangements are made concerning administration of bolus doses by community nursing staff. (e.g. s/c cytarabine)

The following information should be given to the patient and community nurse.

- The name of the drug(s) and duration of infusion.
- Care of the central venous access device (CVAD).
- Storage and disposal arrangements.
- Potential problems and management.
- 24-hour on-call telephone numbers.
- Written information on how to deal with a chemotherapy spillage in the home.

Additional support for the community nurse must be offered, e.g. training in pump and line management.

However, it is the responsibility of the community nurse manager to ensure that community nurses are trained to the appropriate level for this patient group.

11.1 Complications during Home Chemotherapy

The patient, carer or district nurse must seek expert advice from referring centre if:

- the equipment fails to function effectively.
- the patient demonstrates complications associated with a CVAD, particularly infection, bleeding along the catheter, swelling in the arm or neck, or sudden onset pain in the shoulder.
- the patient demonstrates unexpected or severe side effects associated with the drugs.

12. Extravasation

Extravasation is the inadvertent administration of drugs into the surrounding tissues, rather than into the intended intravenous compartment.

Extravasation of vesicants is a medical emergency. Early detection and prompt appropriate action is required to prevent necrosis and functional loss of the tissue or limb involved.

The master copy of the current version of the St Luke's Cancer Alliance "Guidelines for Prevention and Management of Chemotherapy Extravasation" is available at <http://stlukescanceralliance.co.uk/guidelines/>

All chemotherapy trained nursing staff should ensure that they are familiar with this document.

13. Anaphylaxis

Anaphylaxis is a severe, life threatening reaction, but is reversible if treated promptly.

The master copy of the current version of the St Luke's Cancer Alliance "Guidelines for the Management of Intravenous Chemotherapy-Related Allergic Reactions, including Anaphylaxis, in Adults" is available at <http://stlukescanceralliance.co.uk/guidelines/>

All chemotherapy trained nursing staff should ensure that they are familiar with this document.

14. Disposal of Cytotoxic Waste

The recommendations in this section act as a guide; disposal must be in line with local waste disposal policy.

All staff, including portering and ancillary staff must be trained with regard to the risks of handling cytotoxic drugs and cytotoxic waste. All members of staff must be aware of what to do in the event of a spillage. Documentation of the training of staff must be completed and records kept by the relevant heads of department.

Biological agents, including monoclonal antibodies, used in cancer should be treated in the same way as cytotoxic drugs for the purpose of waste disposal.

14.1 Used Disposable Equipment

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

Used oral administration spoons, oral syringes and medicine pots should be placed in a sharps box with a purple lid.

The sharps disposal box should be clearly labelled as cytotoxic waste, and must have a purple lid, so it can be incinerated at 1000°C to ensure degradation of the cytotoxic agent.

Sharps disposal boxes containing cytotoxic waste must be regularly collected.

14.2 Contaminated Non-disposable Equipment / Items

Re-usable plastic or metal trays should be cleaned after every use. They may be rinsed with cold water (removes traces of cytotoxic agents), then washed with detergent OR cleaned with disinfectant / detergent wipes e.g. Clinell universal sanitising wipes. Wear gloves and an apron.

If non-disposable equipment/items are sent to another department for terminal cleaning, they must be transported in sealed leak-proof bags or containers. These should be clearly labelled that they are potentially contaminated by cytotoxics.

14.3 Protective Clothing and Wipes

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

After a cytotoxic spillage (dealt with according to the cytotoxic spillage procedure, section 16), arrangements must be made for immediate collection of the rigid sharps bin for incineration.

14.4 Part-Used Doses

While still wearing protective clothing, cap any syringes. If disposing of an intact bag, leave the giving set in place and clamp off. Place in a cytotoxic sharps bin. If pierced or damaged, place the syringe / bag in a yellow bag and place into a rigid sharps box. These should be labelled as cytotoxic waste for disposal.

14.5 Patient Waste / Body Fluids

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

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

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

- Wear gloves and protective aprons.
- Any spilt patient waste should be treated as cytotoxic spillage.
- Staff are advised to follow the precautions described in individual Trust's Control of Infection Policy Manuals.
- Double flushing of sluices after emptying potentially cytotoxic contaminated matter from bedpans, catheter bags and dialysis bags is recommended. Bedpans should be put through a bedpan washer twice at high temperature.
- Ideally, patients should use separate toilets facilities to staff. Men should be advised to void sitting down to minimise splashing. Following voiding, toilets should be flushed twice, with the lid down.
- Soiled bedding, linen and non-disposable nappies should be treated as infected linen and handled according to the procedures described in the individual Trust's Control of Infection Policy Manual.
- For patients who have received intravesical BCG therapy, a strong bleach based detergent should be poured into the toilet after voiding.
- Disposable nappies should be double-bagged; placed in a tied plastic bag, then in a cytotoxic clinical waste disposal bag, and sent for incineration.

14.6 Disposal of Chemotherapy in Community

Used chemotherapy infusors should have a new 'blind end' bung attached to the end. They must be placed in a cytotoxic waste bin, along with all other potentially contaminated equipment, and which is then sealed.

These bins are then transported by the nurse in the boot of their car to the nearest designated cytotoxic waste disposal point. Ensure insurance companies are aware that such activity takes place within the relevant vehicles.

Use designated cytotoxic bins for this purpose.

Do not allow the patient to return the box to the hospital themselves. It is the responsibility of the nurse to remove contaminated/cytotoxic waste from the patient's home. Disposal should then take place according to local policy, in line with the recommendations of the Environment Agency.

15. Accidental Contaminations/Exposure

If a patient, member of staff or visitor is involved in a spillage of cytotoxic drugs or potentially contaminated patient waste, the procedures listed below must be followed:

It may be appropriate to seek medical attention from the nearest Accident and Emergency Department. Ensure appropriate incident forms are completed, as per Trust policy.

15.1 Skin

- Remove any contaminated clothing immediately.
- The contaminant must be removed as rapidly as possible by flushing the affected area with a large volume of water. If running water is not immediately available, bottles or bags of sterile water or normal saline should be available as an alternative.
- After initial copious flushing with water, the contaminated skin should be thoroughly washed with liquid soap or antiseptic scrub and water. After rinsing, the process should be repeated.
- Shower facilities should be available for use if large areas of skin are contaminated.
- Do not use hand creams and emollients as these may aid absorption of the drug.
- An adverse incident report form must be completed and the head of department and Occupational Health must be informed.

15.2 Eyes

- An eye-wash kit should be available in all areas where chemotherapy is administered.
- The contaminant must be removed as rapidly as possible by flushing the eyes and surrounding area with at least 1 litre of sterile normal saline.
- The optimum method is to use a bag of saline 0.9% for IV infusion with giving set attached, as this allows easy flushing of the eye, including under the eye lids.
- Alternatively tap water can be used if necessary. Remove contact lenses if worn and wash thoroughly.
- Medical attention must be sought immediately from the nearest Eye Clinic or Accident and Emergency Department.
- An adverse incident report form must be completed and the head of department and Occupational Health must be informed.

15.3 Needlestick Injuries

- Allow the wound to bleed freely
- Wash the puncture site with copious amounts of cold water.
- Check status of drug. If the drug is a vesicant or irritant, seek expert advice.
- Report the incident immediately to a senior member of staff.
- Then follow the Trust's needlestick injury procedure and complete an Adverse Incident Form.

15.4 Clothing

- Any contaminated clothing must be removed immediately. Put on gloves and an apron prior to handling contaminated clothing.
- Linen or personal clothing contaminated with cytotoxic drugs, blood, vomit or excreta from a patient who has received these drugs within 48 hours, should be placed in a red alginate bag (water soluble, so take care if item very wet), which should be clearly labelled 'cytotoxic hazard' and with area of origin. This bag and its contents should be pre-washed on its own. This linen may then be added to other linen for an additional wash.
- If there is a likelihood that the drug has soaked through the outer clothing, underwear must be removed and treated as above, and the area of skin treated as in section 15.1 above.

16. Cytotoxic Spillages

A cytotoxic spillage kit must be available, at all times, in all clinical areas where cytotoxic drugs are administered, and in all pharmacy areas where cytotoxic drugs are handled or stored.

All staff must know how to use it and where it is stored. If a kit is used, it must be replaced immediately.

16.1 Contents of Spillage Kit

- One white plastic apron and pair of protective armlets or a three-quarter length disposable gown with absorbent surface and impermeable backing.
- Two pairs of latex gloves.
- Mask and pair of eye goggles or Visimask.
- Plastic overshoes.
- Spillage towels or Chemosorb pads/granules.
- Tray and forceps, or scoop, for clearing up spillage.
- Disposal bags/bin.

16.2 Management of Spillage

- Restrict access to the spillage area.
- Call for assistance and warn others. Do not leave the spill site unguarded. If a 'Warning cytotoxic spill' sign is available, this should be placed at the site of the spillage.
- If you have been injured or contaminated, another member of staff must deal with the spillage while you receive attention for the injury or contamination.
- New and expectant mothers should not have direct involvement in the management of a cytotoxic spillage.
- Turn off all fans and reduce any draughts.
- Assess the spill for size, type (dry or liquid), drug involved and danger to others.
- Collect spillage kit and lay it out carefully away from the spill area.
- Wear overshoes, gown or apron and armlets and latex gloves.
- Put on mask and goggles, or Visimask.
 - If using particle-filtering P3 protective half mask, ensure it is fitted tightly by pulling it tight at the two ends of the rubber band. When fitted correctly you will hear the flaps of the valve when breathing.

- Put on second pair of gloves. If latex gloves are of two thicknesses, put the thinner pair on first.
- Gently cover and absorb liquid spills with dry towels or Chemosorb pads/granules and towels, avoid splashing.
- For large spills (greater than 5ml or 5g) work from the outside in.
- Chemosorb pads/granules absorb the liquid and transform the liquid into a gel. Gather up the gel.
- Place cleared spillage waste in a plastic bag and seal, then dispose of in cytotoxic waste bin.
- Repeat previous four steps as necessary.
- Pick up solids (powder) by covering the spillage with a layer of paper towels, then wet the towels with water until moist but NOT dripping. This prevents mobilization of powder particles.
- Carefully pick up the wetted powder with the moist towels and place into a plastic bag and seal, then dispose of in cytotoxic waste bin.
-
- Pick up sharp/broken material with forceps or scoop.
- Place sharps in sharps bin labelled cytotoxic waste and dispose of as per waste policy.
- After removal of cytotoxic agent, clean spill area at least three times using mild detergent followed by large amounts of clean water.
- Discard all contaminated material in disposal bag, including gloves and shoe coverings, seal and dispose of as cytotoxic waste.
- Record incident as per Trust policy.
- Order new cytotoxic spillage kit from pharmacy or Supplies department, depending on local practice.
- Arrange for immediate collection of cytotoxic sharps bin.
- Inform Occupational Health.

17. Cytotoxic-Related Error Reporting

Errors can arise in the prescribing, dispensing and administration of cytotoxics. These errors are invariably preventable. It is important that the St Luke's Cancer Alliance reports and learns from medication-related errors, in order to reduce future risk.

The local Chemotherapy Group of the individual Trusts across the Alliance will regularly review cytotoxic-related errors and incidents at their Trust.

A designated representative from each Trust will bring a summary of errors to the St Luke's Cancer Alliance Chemotherapy Group at each meeting of that group.

The Alliance Chemotherapy Group will review the reported errors and resulting actions, and feed back to the local Chemotherapy Groups accordingly.

18. Education and Training

Mandatory training in chemotherapy is required for all healthcare professionals involved in the prescribing, reconstitution, dispensing and administration of chemotherapy. These staff should have explicit knowledge of cytotoxic therapy, including the potential hazards to personnel, the environment, as well as the effects on patients.

An agreed training programme should include theory that underpins practice, practical supervision, and testing of agreed competencies.

Practical training is essential and should be provided through a competency based framework.

Training and information should also be provided for ancillary staff, such as health care assistants, porters, community staff, who come into contact with cytotoxic chemotherapy or with patients who have received chemotherapy.

18.1 Prescribing chemotherapy

Medical and non-medical prescribers who are involved in prescribing chemotherapy should receive training and competency assessments in order to be accredited to prescribe, as detailed in section 3.4.

Non-medical staff prescribing chemotherapy should be educated on an accredited non-medical prescribing course and assessed in that area of practice.

All prescribers should read the relevant sections in the St Luke's Cancer Alliance *Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs*.

Each Trust should maintain a register of named medical and non-medical staff who are competent to prescribe chemotherapy.

18.2 Training programmes for nurses

An agreed training programme should include theory that underpins practice, practical supervision, and testing of agreed competencies.

At a minimum the training programme should include:

- Knowledge of the principles of chemotherapy
- Safe handling of cytotoxic drugs, including PPE and correct waste disposal
- The various routes of administration, with focus on intravenous and oral routes
- Consent and information giving
- Holistic assessment of patients receiving chemotherapy
- Supportive care
- Selection and use of equipment:
 - Peripheral and central venous access devices
 - Infusion control devices
 - Scalp cooling
- Common chemotherapy side effects including nausea and vomiting, stomatitis, diarrhea, infertility, phlebitis and alopecia.

- Recognition of complications associated with chemotherapy, including myelosuppression and its management.
- Chemotherapy-related oncological emergencies:
 - Management and treatment of anaphylaxis
 - Management and treatment of extravasation
 - Management and treatment of neutropenic sepsis
 - Management and treatment of tumour lysis syndrome
- Procedure for cytotoxic spillage
- Knowledge of St Luke's Cancer Alliance chemotherapy protocols, and supportive care guidelines
- Knowledge of information and resources for chemotherapy patients

18.3 Nursing staff administering chemotherapy

Nurses who are to administer chemotherapy must have completed an accredited course along with local assessment of competence, OR the certificate can be obtained following satisfactory completion of a theoretical and practical local assessment of the nurse's competence in cytotoxic drug administration. Senior nursing staff will assess competencies.

All nurses involved with administering chemotherapy must attend an annual chemotherapy update and have their clinical skills assessed annually prior to renewal of certificate of competence being issued.

All staff should also read and comply with St Luke's Cancer Alliance *Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs*.

Each Trust will maintain a register of named nursing staff who have been reviewed as competent to administer chemotherapy.

18.4 Pharmacy Staff

18.4.1 Aseptics Staff

Handling

All staff involved in the handling of cytotoxic drugs must adhere to COSHH and health and safety at work regulations.

All staff should complete the following training programme related to their role in handling cytotoxic drugs:

- Read the sections of the St Luke's Cancer Alliance *Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs* that are relevant to their work.
- Have received training and education on the health risks associated with handling cytotoxic drugs
- Be familiar with the national guidance and local policy on intrathecal chemotherapy
- Read local pharmacy procedures, and receive a practical demonstration on dealing with a cytotoxic spillage.

Preparation

All staff expected to participate in the aseptic preparation of cytotoxic drugs must be trained and assessed as competent with respect to specific Trust SOPs and competency frameworks.

An appropriate pharmacy manager will ensure that training is updated and assessed at appropriate intervals, and that training records are maintained.

Pharmacy staff assessed as competent to aseptically prepare and dispense chemotherapy must have:

- Explicit knowledge of the *St Luke's Cancer Alliance Policy and Guidelines for the Safe Prescribing, Handling and Administration of Cytotoxic Drugs*
- Explicit knowledge of the national guidance and local policy on intrathecal chemotherapy
- Practical training in aseptic technique and local procedures for cytotoxic reconstitution

18.4.2 Clinical Screening of Chemotherapy Prescriptions (including oral chemotherapy)

Pharmacists who are involved in the clinical screening of chemotherapy prescriptions, or provide a clinical pharmacy service to wards where chemotherapy patients are cared for, should undertake an additional specific training programme. Only once assessed as competent, can prescriptions for chemotherapy be checked unsupervised.

The BOPA standards for chemotherapy prescription verification should be followed.

18.5 Portering Staff

All portering staff and drivers 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.

18.6 Domestic Staff

All domestic staff involved in cleaning duties in clinical areas should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste, and the consequences of ineffective cleaning.

18.7 Other Staff in Clinical Areas

All other staff in clinical areas, including volunteers, involved in assisting with the administration, preparation or transport of cytotoxic drugs, should undergo an induction to ensure they are aware of the risks associated with chemotherapy.

18.8 Criteria for Assessors of Competence

All Trusts should follow the Alliance-wide guidance document "Criteria for acting as an Assessor of Competence", which details the on-going criteria for a staff member to be considered capable of assessing the competency of other staff to practice in chemotherapy services

Completion of a local Trust's training and assessment programme for a certain competency does not automatically make the individual an assessor of competence for other staff.

Designated assessors of chemotherapy-related tasks must be agreed at each Trust. Responsibility for training records is held by the designated assessors within each professional group.

Appendix A Useful Names and Addresses

ASHFORD AND ST. PETERS HOSPITALS NHS TRUST

Lead Oncology / Haematology Pharmacist	01932 722886
St Peter's Haematology Nurse Specialist, Haematology/Oncology Day Unit	01932 722347, pager 8341
Lead Chemotherapy Nurse	01932 872000 ext 6494
Ashford Chemotherapy Day Unit	01932 723697

FRIMLEY PARK HOSPITAL NHS FOUNDATION TRUST

Haematology Pharmacist	01276 604604 bleep 561
Haematology Day Unit Manager	01276 604604 ext 4248 / bleep 277
Matron, G1 Ward	01276 604604 ext 6364

ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST

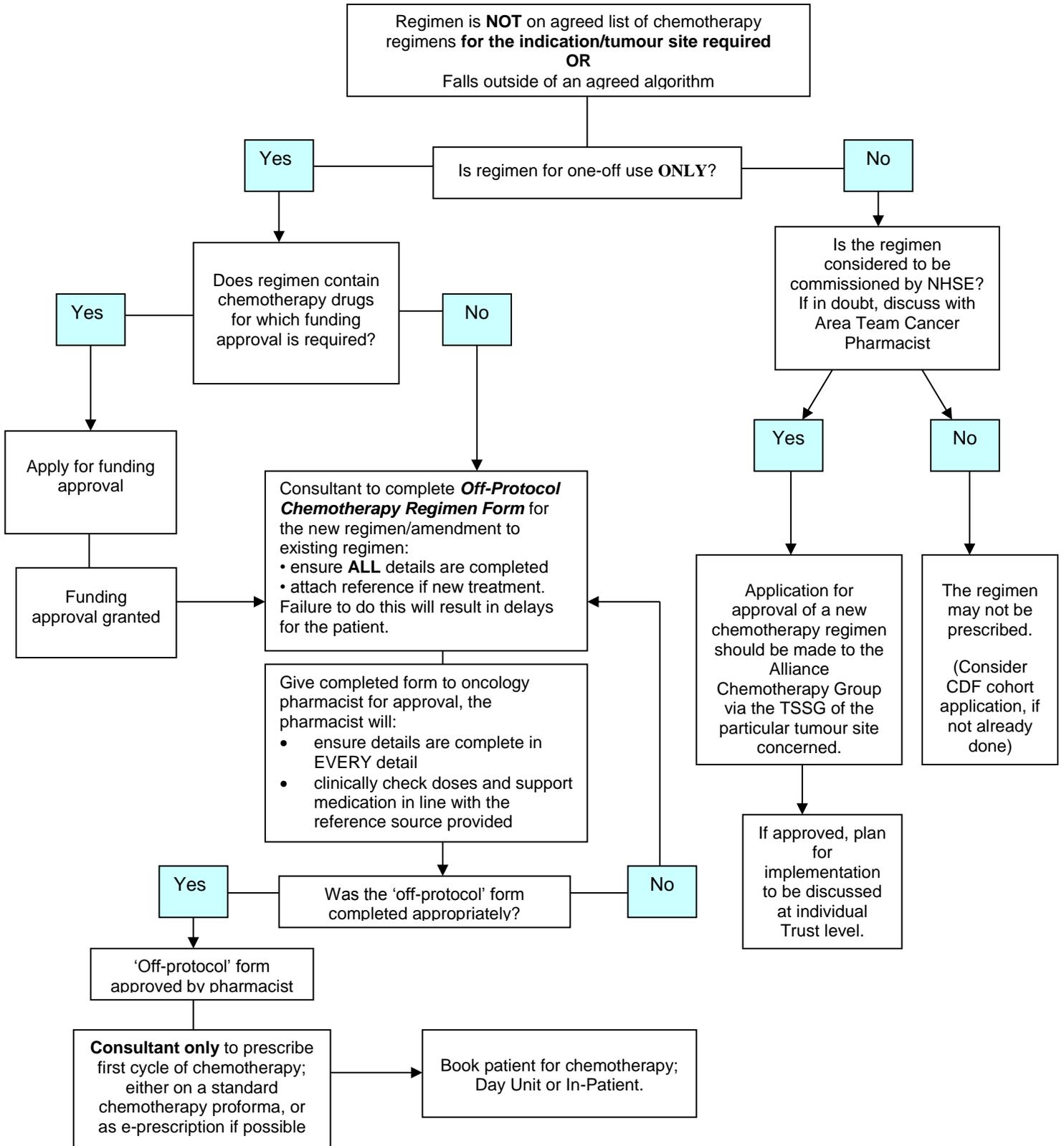
Lead Oncology Pharmacist	01483 571122 bleep 71-0990
Aseptic Services Manager	01483 571122 ext 4588
Oncology Pharmacist (Onslow Ward)	01483 571122 bleep 71-4330
Lead Chemotherapy Nurse	01483 571122 bleep 76-6515
Sister Onslow Ward	01483 571122 ext 6858
Sister Chilworth Day Unit	01483 571122 ext 6772
Nurse Led Clinic	01483 571122 ext 2037

SURREY AND SUSSEX HEALTHCARE NHS TRUST

Cancer Services Pharmacist	01737 768511 ext 6249
Lead Cancer Nurse	01737 768511 ext 6689
Lead Chemotherapy Nurse	01737 768511 Ex 6889/6446
Chemotherapy Day Unit, East Surrey	01737 768511 ext 6889
Godstone Ward, East Surrey	01737 768511 ext 6366 or 1664
Comet Chemotherapy Day Unit, Crawley	01293 600300 ext 3201

Appendix B

Off-Protocol Chemotherapy Regimen Process within St Luke's Cancer Alliance



Appendix C

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