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INTRODUCTION / PURPOSE OF POLICY

1.1 Background

This document has been reviewed and updated by the Northern Ireland Cancer Network (NICaN). It is intended for use across each of the cancer units and the cancer centre. It is based on a document produced by the North and North East London Cancer networks to which we express our sincere gratitude for granting us permission to adapt their guidelines.

Throughout this guideline the term SACT is used, the majority of which are cytotoxic. This guideline does not include hormonal therapies which are SACT.

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

SACT drug administration for cancer patients throughout the network should be provided by a multidisciplinary team in which doctors, chemotherapy competent nurses and pharmacy staff work to approved written protocols to provide integrated care both within the hospital and the community.

SACT drugs are potentially harmful to both the healthcare professionals involved in their preparation, administration, handling & disposal and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical. It is therefore prudent with the present state of knowledge to take every reasonable precaution to protect staff from unnecessary exposure.

1.2 Purpose

This guideline is intended to safeguard patients and staff by defining best practice for all disciplines involved in the delivery of SACT for malignant disease.

1.3 Objectives

To ensure the responsibilities and actions required by personnel involved in the handling, prescribing and administration of hazardous drugs are clear.
- Staff will be familiar with the appropriate personal protective equipment appropriate for particular tasks.
- Prescribers will be familiar with their responsibilities in relation to prescribing hazardous drugs
Pharmacists will be familiar with their responsibilities in relation prescription verification, preparation, handling, storage and disposal of hazardous drugs.

Nurses will be aware of their responsibilities in relation handling, storage administration and disposal of hazardous drugs.

**SCOPE OF THE POLICY**
This document is primarily aimed at staff delivering SACT drugs for the treatment of patients with malignant disease. It does not deal with SACT specifically for immunosuppressive purposes, or for the treatment of non-malignant disease. Individual Trusts should, where necessary, develop supplementary policies and guidelines to cover these circumstances. In these circumstances it is hoped this document would provide a useful reference source and we would recommend that any policies and guidelines are consistent with this guideline.

Some elements of this document will not apply to SACT drugs used within the context of a clinical trial, for example provision of Out of Hours services. For specific clinical trial recommendations always refer to Standard Operating Procedures and specific clinical trial documentation.

**ROLES/RESPONSIBILITIES**
It is the responsibility of all staff involved in the prescribing, handling and administration of SACT drugs to familiarise themselves with these guidelines.

4.0 **KEY POLICY PRINCIPLES**
The Network is committed to promoting a safe and healthy work place for all staff, and to that end hazardous drugs will be handled in a safe manner, to ensure that the preparation, administration, and disposal of these agents will not pose an undue hazard to the staff or patients involved in their use.

The guideline is also compliant with Manual for Cancer Services Chemotherapy Measures, Version 1.0 (National Peer review programme April 2014) ([http://www.cquins.nhs.uk/?menu=resources](http://www.cquins.nhs.uk/?menu=resources))

5.0 **IMPLEMENTATION OF POLICY**
These guidelines will be implemented by all Health & Social Care Trusts involved in the delivery of SACT to oncology and haematology patients.

6.0 **MONITORING**
Incident reporting
7.0 **EVIDENCE BASE / REFERENCES**
Safe Handling of Hazardous Drugs. HSE Information Sheet MISC615.
COSHH Regulations NI 2003
COSHH (NI): A brief guide to the Regulations. What you need to know about Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 (COSHH (NI)).
For complete of references and bibliography see relevant section in guideline.

8.0 **CONSULTATION PROCESS**
NICaN Pharmacy group
NICaN SACT Clinical Reference group
NICaN SACT Nurses group

9.0 **APPENDICES / ATTACHMENTS**
To be tabulated here and attached below as required.

10.0 **EQUALITY STATEMENT**
In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

- Major impact ☐
- Minor impact ☐
- No impact. √

**SIGNATORIES**
(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

________________________________________________________________________ Date: _____________________________
Author

________________________________________________________________________ Date: _____________________________
Guidelines for the safe prescribing, handling and administration of Systemic Anti-Cancer Therapies (SACT) June 2016
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1. Introduction

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Throughout this guideline the term SACT is used, the majority of which are cytotoxic. This guideline does not include hormonal therapies which are SACT.

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

SACT drug administration for cancer patients throughout the network should be provided by a multidisciplinary team in which doctors, chemotherapy competent nurses and pharmacy staff work to approved written protocols to provide integrated care both within the hospital and the community.

SACT drugs are potentially harmful to both the healthcare professionals involved in their preparation, administration, handling & disposal and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical. It is therefore prudent with the present state of knowledge to take every reasonable precaution to protect staff from unnecessary exposure.

These guidelines aim to minimise these risks by promoting the safe handling of SACT drugs throughout the region. It should be read in conjunction with relevant policies and procedures available in each individual Trust.
We are grateful to the pharmacists, clinicians, nurses and other healthcare professionals who have contributed to the production and review of this document.

**Associated documents**

These guidelines support:

- Standard operating procedures for the safe prescribing, handling and administration of SACT drugs produced by each of the Trusts in Northern Ireland.

2. **Purpose**

This guideline is intended to safeguard patients and staff by defining best practice for all disciplines involved in the delivery of SACT for malignant disease.

3. **Scope of the document**

This document is primarily aimed at staff delivering SACT drugs for the treatment of patients with malignant disease. It does not deal with SACT specifically for immunosuppressive purposes, or for the treatment of non-malignant disease. Individual Trusts should, where necessary, develop supplementary policies and guidelines to cover these circumstances. In these circumstances it is hoped this document would provide a useful reference source and we would recommend that any policies and guidelines are consistent with this guideline.

Some elements of this document will not apply to SACT drugs used within the context of a clinical trial, for example provision of Out of Hours services. For specific clinical trial recommendations always refer to Standard Operating Procedures and specific clinical trial documentation.
4. Health and Safety

SACT drugs interfere with cell division, but as this action is not specific to tumour cells, normal cells may also be damaged. SACT drugs may produce significant side effects in treated patients, or others exposed. This, together with the increasing complexity and usage of anti-cancer therapy, has raised concerns about the risks to health care workers involved in the preparation and administration of chemotherapy and/or the care of patients undergoing treatment. For healthcare personnel the potential for exposure exists during tasks such as drug reconstitution and preparation, administration and disposal of waste equipment or patient waste. Hence, all staff involved in the delivery of services to cancer patients should be aware of all health and safety procedures. This applies to clinicians, nursing, pharmacy and domestic staff in the relevant pharmacy and clinical areas, transport and portering staff carrying SACT or cytotoxic waste.

The more common routes of exposure are contact with skin or mucous membranes (e.g. spillage and splashing), inhalation (over-pressurising vials), and ingestion (e.g. through eating or drinking in contaminated areas or from poor hygiene). Less likely routes of exposure include needle-stick injuries, which can occur during the preparation or administration of these drugs.¹

Some SACT drugs can cause acute or short term health effects including irritation to the skin, eyes and mucous membranes.

Information on chronic, or long-term, health effects of SACT drugs mainly comes from data in animals and from patients given therapeutic doses. It is not certain how relevant this is to workers and any occupational exposures are likely to be at much lower levels.

Health workers preparing cytotoxic doses without adequate precautions have been shown to contaminate themselves and their work environment. Reports of increased foetal loss and birth abnormalities, as well as anecdotal reports of toxicity unrelated to genetic damage have been published. It should be emphasised that these reports relate to exposure occurring prior to the...
introduction of cytotoxic drug handling precautions and guidelines. However, recent studies have shown evidence that contamination of the working environment with cytotoxics may still occur even with current safe handling procedures. Therefore it cannot be guaranteed that such adverse effects will not occur, although the likelihood should be greatly reduced with safer working systems. The adoption of improved handling techniques and the use of isolators has reduced the potential for exposure to SACT drugs significantly.  

4.1 Staff monitoring
All relevant new employees, as outlined above, should receive an orientation to the current ‘Guidelines for the safe prescribing, handling and administration of SACT drugs’ as soon as is feasible after commencement of employment.

There is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to adequately predict the effect of chronic long-term exposure. It is therefore recommended that staff monitoring (e.g. blood or urine testing) is not routinely undertaken until improved methodology and means to interpret the data are available. Hence, the primary focus of safety during the preparation and administration of SACT drugs should be on control of the working environment, minimizing exposure and safe practice.

4.1.1 Personnel records
Records should be kept of all designated posts that require nursing, pharmacy or medical staff to reconstitute or administer SACT drugs. This is the responsibility of the relevant manager. The Health and Safety Executive recommends that the records should contain at least the following: surname, forename, gender, date of birth, permanent address and postcode, National Insurance number, date when present employment started and a historical record of jobs in this employment involving exposure to SACT drugs. Accidental exposure should be documented using Trusts adverse incident reporting process.
4.2 Pregnancy and breastfeeding
EU guidance –
In the long term these drugs cause damage to genetic information in sperm and eggs. Some can cause cancer. Absorption is by inhalation or through the skin. Assessment of the risk should look particularly at preparation of the drug for use (pharmacists, pharmacy technicians, nurses), administration of the drug and disposal of waste (chemical and human).

There is no known threshold limit and exposure must be avoided or reduced. Those trying to conceive a child or who are pregnant or breastfeeding should be fully informed of the reproductive hazard. Pregnant or breast feeding staff will be expected to make an informed choice about working with antineoplastic drugs.

Pregnant worker shall mean a pregnant worker who informs her employer of her condition, in accordance with national legislation and/or national practice

There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to.

As some pregnancies are unplanned, or staff may be unwilling to discuss plans for conception, the emphasis should be on clear guidelines to reduce occupational exposure to all staff at all times.

Most of the published evidence refers to pregnancy however all principles and recommendations should be applied to those staff who are breastfeeding.

Refer to local Trust policy and procedural arrangements relating to new and expectant mothers.

4.2.1. Evidence
There have been some studies suggesting adverse effects on the foetus, as a result of the mother working with cytotoxic drugs. Many of these studies, however, were
carried out, or based on exposure during the 1980’s at a time when the use of personal protective equipment and safety isolators was not well established. Some later studies have failed to find a significant association with foetal adverse effects.

Various studies have demonstrated links between occupational exposure to cytotoxic drugs and menstrual dysfunction\(^6\) infertility\(^7\), miscarriages and stillbirths\(^8\), low birth weight and congenital abnormalities\(^9\). However these studies were mostly carried out either in the 1980s, or based on staff exposure in the 1980s; a time when the use of personal protective equipment and safe handling techniques were not well established. These studies do not on the whole reflect current working practices.

Other studies have failed to find a statistically significant association with spontaneous abortion and congenital malformation\(^10\). This may be due to the increased awareness of the risk, leading to the use of protective clothing and equipment, or the avoidance of cytotoxic handling by staff if they are pregnant.

### 4.2.2 Risk
The time of greatest risk to the unborn child is during the first three months of pregnancy, being the time of most rapid cell division and differentiation. As most staff will not disclose their pregnancy until well into this period any policy for the handling of SACT by pregnant staff should therefore consider the needs of those trying to conceive and indeed those who may not be aware that they are pregnant. Health and Safety Executive advises that a workplace risk assessment must specifically consider any risks to the health and safety of a new or expectant mother, or that of her baby. \(^11,12\).

### 4.2.3 Recommendations
1. A comprehensive method of staff education and assessment in safe handling of SACT drugs should be in place. Regular audit should take place to ensure compliance.
2. Managers should ensure that a risk assessment is carried out in all areas where SACT drugs are handled. This risk assessment should assume that there may be pregnant staff working in the environment at any given time. COSHH (Control of Substances Hazardous to Health) assessment is carried out in all areas where SACT drugs are handled in order to assess the level of risk and the adequacy of control measures in place. The risk assessment should assume that there may be a new or expectant mother working in the environment in the following twelve months.

3. Staff should be encouraged to discuss plans for pregnancy with their manager in confidence, and to inform them as soon as pregnancy is suspected or confirmed. Employees should notify their managers as soon as possible if they are pregnant or are breastfeeding.

4. To comply with HSE guidance, all pregnant staff should be removed from duties involving the preparation of SACT drugs. Under these circumstances, staff should be offered alternative duties.

At the point where an employee discloses pregnancy, a risk assessment specific to the individual should be carried out and any appropriate action taken. All staff should be fully informed of the reproductive risks by:

- Receiving verbal and written information on induction
- Signing to say they have read and understood the relevant risk assessments
- Providing opportunity for discussion of any concerns
- Any risk assessment carried out should follow local policy and be signed and dated by all relevant parties.

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

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

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

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

The preparation of MAbs should be individually risk assessed, taking into account the allergic potential based on the origin of the MAb and toxicities arising from the therapeutic use. Together with the NPSA risk assessment tool for intravenous medicines, an overall risk could then be used to decide whether manipulation should be within an aseptic unit (high risk) or permitted in a clinical area. It is recommended that Trust approval should be obtained for MAbs, if assessed as high risk, being allowed to be manipulated in clinical areas.

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

4.5 Minimising exposure
A full COSHH\textsuperscript{3,4,5} assessment should be undertaken in all areas handling SACT drugs and this is the responsibility of the relevant line manager. The risk assessment should define the controls in place (e.g. isolators) and the specific Personal Protective Equipment (PPE) to use in each activity where SACT drugs are handled.

4.5.1 Control of Exposure to SACT drugs
The following guidance applies to all staff handling SACT drugs during administration of treatment, handling of patient waste and cleaning of spillage.

4.5.2 Recommended Good Practice
- Work should be organised to minimise quantities of drugs used.
- The number of employees potentially exposed and duration of exposure should be kept to a minimum.
- All staff should ensure the safe handling, storage and transport of SACT drugs and cytotoxic waste material containing or contaminated by them.
- Good hygiene practices and suitable welfare facilities should be provided to ensure that staff eating and drinking are prohibited in all areas where SACT drugs are handled.
- Staff working with SACT drugs must be trained on the risks and precautions to take when handling cytotoxic chemotherapy and newer agents, for example monoclonal antibodies.
• Local procedures must always be followed in relation to administration of cytotoxic chemotherapy and monoclonal antibodies.

4.6 Personal protective equipment/clothing to be used when handling SACT drugs
It is important to ensure PPE offers adequate protection and is designed specifically for handling SACT drugs. The correct use of personal protective equipment can shield staff from exposure to SACT and minimise the health risks.

Effective protection will only be obtained if the personal protective equipment chosen is:
• Suitable for the task and fit for purpose
• CE/kite mark and use within expiry date
• Suited to the wearer and the environment
• Compatible with other PPE in use
• In good condition
• Worn correctly.

Pharmacy staff preparing SACT drugs within pharmacy preparation units will wear personal protective clothes as defined by local standard operating procedures.
Employers need to ensure that staff are trained in the use of PPE and that the PPE is adequately maintained and stored.
The following recommendations are considered to be the absolute minimum protective clothing/equipment that should be worn, in clinical areas, for the defined work tasks. Local policy, or specific and individual staff needs, may dictate the use of further supplementary protection.

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

- Permeation of hazardous drugs depends upon glove material, thickness and integrity, the properties of the drug/solvents and the contact time with the drug. Since no material is completely impermeable to SACT drugs and permeability increases with time, users should minimise contact and change their gloves regularly, approximately every hour.

- Gloves should be worn at all times appropriate to the task being undertaken. Powder free, disposable nitrile gloves should be used for the administration of SACT drugs or for handling hazardous waste.

- Gloves should always be changed between patients.

- If the inner surface of a glove becomes contaminated, exposure will occur. Therefore once disposable gloves are removed, they should not be re-applied, but disposed of as detailed in section 14.3.

- Gloves should be changed immediately if damaged or if any contamination occurs.

- Decontaminate hands as per local infection control policy before and after each glove application. Hands must be washed thoroughly with liquid soap/detergent or alcohol gel before and after glove application.

- Individuals suffering from nitrile allergy should be managed with as per local policy and may be referred to Occupational Health.

- Consideration needs to be given as to whether the procedure requires sterile or non-sterile protective gloves.

- They should fit appropriately and be close fitting to ensure dexterity. Individual practitioner’s preferences should be considered with regard to sensation and dexterity.

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

**4.6.2 Eye and face protection**

- Either safety glasses or visors are satisfactory to protect against splashes but goggles are recommended when exposure to vapours or aerosols may occur.
• The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavitary administration and when clearing up cytotoxic spillages.

• Eyewash kits should be readily available in all areas where handling of cytotoxic drugs occurs. For action to be taken in the event of a splash injury see 15.2

Eye protection:
• Should fully enclose the eyes and comply with BS EN166.
• Be disposable, where possible or capable of undergoing decontamination cleaning.

Refer to local Trust Prescription Safety Spectacles Policy for further information.

4.6.3 Armlets (single use only)
• Non absorbent armlets and a plastic apron, or a disposable protective gown should always be worn when administering chemotherapy. Cuffs should be tucked under the gloves.

4.6.4 Torso protection (Plastic aprons):
• Disposable plastic aprons will provide limited protection and prevent absorption into clothing when used where splashing or spraying is possible.

4.6.5 Gowns (single use only) disposable
• Protective disposable gowns should be made of low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs. Cuffs should be tucked under gloves.

4.6.6 Respiratory protection:
Surgical masks do not offer protection against inhalation of fine dust or aerosols. When solid or liquid particles are a risk, an FFP2 or FFP3 filtered face piece respirator should be used. Inhalation is not a significant risk for staff administering prepared SACT drug doses. Therefore, staff are not
required to wear masks during administration. Respiratory protection should be used when dealing with a cytotoxic spillage. Please refer to Trust FFP2/3 mask fitting policy for further information.

All PPE should bear the European CE mark which ensures that the article complies with European regulations. All personal protective equipment should be certified as such according to the European directive 89/686/EEC.

4.6.7 Recommendations for PPE in handling activities:

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<tr>
<th>Activity</th>
<th>Personal Protective Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gloves</td>
</tr>
<tr>
<td>Pharmacy Distribution &amp; Stores activities</td>
<td>Yes</td>
</tr>
<tr>
<td>Setting up &amp; checking</td>
<td>Yes</td>
</tr>
<tr>
<td>Preparation</td>
<td>Yes</td>
</tr>
<tr>
<td>Administration &amp; Disconnection of Parenteral Hazardous drugs</td>
<td>Yes</td>
</tr>
<tr>
<td>Handling contaminated patient waste</td>
<td>Yes</td>
</tr>
<tr>
<td>Handling oral Preparations Of Hazardous drugs</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Spill clean up</td>
<td>‘Berner Cytotoxic Drug Spill kit’ or equivalent is recommended. Cleaning of a hazardous drug spillage should follow local standard operating procedure.</td>
</tr>
</tbody>
</table>

*Eye protection should meet British Standard EN 166 (RCN)
4.6.8 Disposal and Decontamination of Personal Protective Equipment
All aprons, gowns, gloves and disposable personal protective clothing should be disposed of according to the guidelines in section 12 re waste management.
Reusable equipment (e.g. eyewear) may be cleaned thoroughly with mild detergent and water before reuse.

5. Clinical governance

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

5.1 Senior management at individual Trusts should;
- Designate responsibility for the implementation and maintenance of the, “Guidelines for the safe prescribing, handling and administration of SACT drugs”.
- Ensure that all managers and supervisory staff are familiar with, and adhere to, the “Guidelines for the safe prescribing, handling and administration of SACT drugs”.
- Be accountable for clinical and corporate governance.

5.2 Department managers and supervisory staff should
- Ensure that all relevant staff are fully familiar with the NICaN “Guidelines for the safe prescribing, handling and administration of SACT drugs”, the individual Trust intrathecal policy, and that they are properly trained in, and comply with, all policies and procedures.
- Ensure that the health and safety of patients, public and staff are given primary consideration when implementing or altering processes, programmes, or physical facilities related to hazardous drugs.
- Make every effort to ensure that all requests to change work assignments from staff that are pregnant, breastfeeding are accommodated.
- Ensure that appropriate and properly maintained facilities and equipment are available to all staff in employment handling hazardous drugs.
- Ensure personnel records, as outlined in section 3.1.1, are maintained as per Trust policy and training records for three years from the date training occurred.
- Ensure that the service is reviewed against the current COSHH regulations with a trained Trust COSHH assessor.
- Ensure that the training, education and competence assessment of all staff is subject to periodic review.
- Ensure that any member of staff transporting SACT drugs has received training on dealing with a spillage and appropriate access to spillage kit.
- Ensure that standard operating procedures are in place for all likely activities involving SACT drugs describing safe systems of work that meet all current legislative requirements.

5.3 Employees and medical staff should
- Ensure that all safety requirements according to COSHH guidelines and the NICaN “Guidelines for the safe prescribing, handling and administration of SACT drugs” are followed.
- Only carry out potentially hazardous activities when competent or trained to do so.
- Follow departmental standard operating procedures where available.
- Report all unsafe acts and conditions.
- Actively participate in the training programs provided.
- Ensure that equipment and facilities provided to enable safe working are used correctly and any defects are reported promptly to the appropriate person.
- Inform managers/supervisors if they are pregnant or breastfeeding.

6. Staff responsibilities and standards

The recommendations outlined in this document are supplementary to those measures within the Manual of Cancer Standards: Chemotherapy Measures¹⁴
Trusts must maintain a register of clinical staff who are designated to prescribe SACT, the list should be updated at least annually.

6.1 Prescribers responsibility

- The decision to treat a patient with SACT should be made by a Consultant, and the patient should be discussed at an appropriate Multidisciplinary Team Meeting (MDT). The decision and proposed plan of treatment should be documented in writing in the patient’s notes.

- Only appropriately qualified and competent Consultant Medical Oncologists, Clinical Oncologists, Haematologists, Paediatric Oncologists or Paediatric Haematologists may prescribe first courses of SACT. Non-Career Grade Doctors / Specialist Registrars in training who have demonstrated the required level of competency may also prescribe first courses of SACT for the treatment of cancer patients.

- Authorisation of second or subsequent courses may be delegated to Specialist Registrars in training who have demonstrated the required level of competency or supplementary/independent prescribers according to local policy, but only if there are clear written instructions available, in the form of a Trust/ directorate protocol or entry into the patients' medical notes. If modification of a dose is required, the Consultant, Non-Career Grade Doctors or Specialist Registrar should document this in the medical notes. For non-medical prescribers if such modifications are outlined in the patient’s protocol, then the same applies.

- Only appropriately qualified Consultant urologists can prescribe first and subsequent course of intravesical anti-cancer therapies for bladder cancers.

- F1 & F2 doctors are not allowed to prescribe SACT drugs.

- Non-medical prescribers authorised to prescribe medicines within the individual Trust will be included on a Trust register of non-medical prescribers.

- Non-medical prescribers must comply with the Trust medicines policy and related codes of practice.
• Non-medical prescribers may only prescribe medicines for NHS patients under the care of the Trust within the speciality in which they have demonstrated competence.

• Non-medical prescribers will be expected to recognise those situations where it is inappropriate for them to prescribe.

• The non-medical Independent prescriber must obtain the patient’s verbal consent before prescribing any medicine.

• The non-medical Independent Prescriber is responsible and accountable for:
  
  ▪ the assessment of patients with diagnosed or undiagnosed conditions and for decisions about the clinical management required, including prescribing.
  
  ▪ Carrying out reviews of the patient’s progress at regular intervals, including the recording of performance status, investigation results and serious toxicities following a previous cycle of SACT, depending on the nature and stability of the patient’s condition.
  
  ▪ Identifying possible drug related adverse incidents and reporting them within the Trust risk management scheme and where appropriate the Medicines & Healthcare Products Regulatory Agency (MHRA) via the Yellow card scheme.
  
  ▪ Accepting professional accountability and clinical responsibility for their prescribing practice.

• The prescriber is responsible for:
  
  ▪ Checking the allergy status of the patient and for any potential interaction between patient’s current medicines and their SACT or supportive care medicines.
  
  ▪ Checking for a history of specific diseases or conditions affecting fitness for SACT including prior history of SACT, that the minimum physical requirements have been met and current patient medication affecting SACT.
• Documenting performance status.
• Checking response assessment according to the relevant regimen and treatment intention.
• Confirming the appropriate regimen from the agreed list of regimens for the tumour site concerned.
• Ensuring that the body surface area (BSA) calculations are appropriate and have been made using a recent weight. If a patient is 30% over their ideal body weight, or body mass index (BMI) is greater than 30, the need for dose reduction or dose capping should be considered.
• In Trusts where dose banding is approved the prescriber may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels, or indicate on the prescription that ‘dose banding is appropriate for this patient, in accordance with local Trust policies.
• For children, the doses should be calculated according to the relevant protocol, i.e. mg/kg or based on BSA using the UKCCLG (previously the UKCCSG) BSA chart.
• For obese children, guidelines in the individual protocols should be followed, or the weight for the 97th centile for age should be used.
• Ensuring accurate dosing. A maximum of +/-5% variance (according to protocol dosages) in dosage calculation is permitted, or as defined by local policy.
• Prescribing and monitoring all cytotoxic drugs and supportive therapies including antiemetics and hydration. This includes the ongoing monitoring of toxicities and amendment of supportive medicines where required.
• Ensuring the patient is given written information regarding the SACT treatment they will be given.
• Ensuring the patient is fully informed of their treatment and has given consent.
• Ensuring that all relevant safety parameters such as complete blood counts, renal and hepatic function have been checked and that the patient is fit to receive treatment. If doses are modified due to variance of these parameters, the reason for dose modification should be recorded on the prescription and in the patient’s healthcare record.

• Ensuring that grade and duration of toxicity from previous cycle is documented using Common Terminology Criteria for Adverse Events (CTCAE)

• Following an episode of neutropenic sepsis the treatment should be modified for subsequent cycles. In potentially curative regimens, granulocyte-colony stimulating factor (GSCF) or prophylactic antibiotics may be considered and in palliative regimens there should be a dose reduction. For other CTCAE grade 3 or 4 toxicities (except alopecia/mucositis/nausea/vomiting) consider reducing dose of all implicated drugs.

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

• Ensuring the patient has appropriate venous access appropriate to the drugs being administered

• Completing the prescription as per section 5.4

• Selecting the appropriate protocol and ensuring correct sequencing for alternating type regimens

• Ensuring that maximum cumulative doses of anthracyclines and bleomycin have not been exceeded.

• If a patient is to be treated with a chemo-radiation protocol, it is essential that the prescriber makes this clear on the prescription, and notifies the relevant nursing, radiotherapy and/or pharmacy staff.

• If a patient is to be treated ‘off protocol’, refer to section 6.6. (Off protocol may be defined as any regimen not included in the relevant
Clinical Management Guideline (CMG) excluding Individual Funding Requests (IFR), ‘cost per case (CPC), clinical trials compassionate use or expanded access programmes).

- After the final cycle is given in a course, the prescriber should ensure that there is a treatment record for each patient that states whether the course was completed or not. If the course was not completed, the reasons for cessation should be documented. For completed courses of non-adjuvant treatment, a reference to the response should be included.

- Wherever possible, SACT should be administered during normal working hours when access to specialist staff is more likely to be available.

6.2 Pharmacists responsibility

- An appropriately trained pharmacist should clinically check all prescriptions for SACT drugs prescribed for the treatment of malignant disease.

- Prior to a SACT dose being released for administration the pharmacist should verify the prescription according to the protocol or treatment regimen, clarify and resolve any discrepancies and check:
  - That the appropriate protocol has been selected.
  - The appropriateness of each element of the prescription as specified in 5.4
  - That all relevant safety parameters such as complete blood counts, renal and hepatic function have been checked.
  - In services where chemotherapy is prescribed and prepared in advance of critical blood results being known it is acceptable for drugs to be released from pharmacy before full blood counts are known, provided the organisation has a policy in place clearly defining the process and identifying who is responsible for checking full blood count results before administration.
  - That dose modifications to previous treatments are maintained if appropriate.
  - There is an appropriate interval between treatment and cycles.
- The patient is not allergic to any prescribed medicines.

- In Trusts where dose banding is approved the pharmacist may amend the dose to the nearest acceptable parameter specified in the Network/Trust approved list of dose banding levels. This endorsement must be made in line with local Trust policies.

- That maximum cumulative doses of anthracyclines and bleomycin have not been exceeded.

- That the volume and medium of infusion is appropriate with respect to the patient, protocol and pharmaceutical stability.

- In the absence of local policy, discrepancies exceeding plus or minus 5% of the dose, calculated according to the patient's treatment plan, should be clarified with the doctor.

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

- The pharmacist should sign the prescription to indicate that it has been verified and validated for the intended patient and that all safety checks have been undertaken.

- If the prescription is for a new SACT protocol, not included on the current relevant CMG and is not covered under ‘Off Protocol prescribing,’ (section 5.6) the prescribing consultant should complete the Trust ‘New SACT protocol request form’ and the ‘New SACT Service Impact Form for Adults & Adolescent.’

6.3 Nurses responsibility

- Registered nurses are responsible for safe administration of SACT drugs prescribed to the correct patient as outlined in the individual Trusts Policy for Administration of Medicines by Nurses/Midwives, the Nursing and Midwifery Council (NMC) Guidelines and the Manual of Cancer Services: Chemotherapy Measures v1.1 (2011). The nurse is also responsible for the
handing over of this information to other nursing staff as required to ensure continuity of care.

- All prescriptions for parenteral SACT drugs should be checked by one chemotherapy competent nurse, another registered nurse or a chemotherapy competent health professional (excluding the prescribing doctor). The chemotherapy competent nurse (as defined in NICaN SACT Administration Competence Framework) is responsible for ensuring that:
  - The correct weight and height have been recorded.
  - The BSA calculations are appropriate.
  - Dose modifications to previous treatments are maintained if appropriate.
  - All SACT drugs and supportive therapies including anti emetics have been prescribed.
  - The route of administration and the duration of infusion have been specified on the prescription.
  - The patient has appropriate venous access prior to administering SACT.
  - There is an appropriate interval between treatments.
  - All relevant safety parameters such as complete blood counts, renal and hepatic function are checked.
  - The patient is not allergic to the prescribed medicines and there are no interactions with any of the patient’s regular medicines.
  - NEWS obtained and recorded pre administration
  - CTC toxicity assessment completed and checked pre administration.
  - The nurse should ensure that monitoring and timely management of patient specific toxicities takes place.
  - The patient is fully informed of their treatment and has given written consent.

- Patients should also have a holistic needs assessment. A nurse should not accept verbal orders for SACT drugs or for adjustments to doses of SACT drugs.
6.4 Prescriptions

- The initial decision to prescribe SACT should be made by a consultant.
- The decision and proposed plan of treatment should be documented in writing in the patient’s notes.
- Prescriptions for SACT drugs should be complete, clear and simple to follow.

Each prescription should contain the following:
- Date prescribed
- Patient name, date of birth, hospital number and address
- Patient’s weight, height, body surface area (BSA) if applicable (NB: Height is not necessary for paediatric prescriptions. Height and weight are not necessary for intrathecal chemotherapy prescriptions or flat doses)
- Allergy status, always declare if ‘No known allergies.’
- Ward / clinic
- Consultant name
- Protocol code, regimen name or clinical trial name and randomisation
- The condition being treated
- The intended number of cycles, where appropriate
- The cycle frequency
- Name of drug(s) - use approved generic drug names; no abbreviations.
- The individual dose in appropriate units (e.g. mg, micrograms or units, and target AUC (area under the curve) for carboplatin etc)
- For children, the doses should be calculated according to the relevant protocol, i.e. in mg/kg or based on BSA using the chart found at the back of the BNFC.
- In the absence of specific instruction in a particular protocol, guidance was issued through the UKALL2003 newsletter (Jane Buckham Paediatric Oncology Pharmacists Group) in Sept 2004 and included again in the UKALL2011 protocol (Details in Appendix 1).
- For carboplatin prescriptions, uncorrected glomerular filtration rate (GFR) should be stated for adult patients and Creatinine ethylenediaminetetraacetic acid (EDTA) half-life should be stated for paediatric patients. (see individual protocol for further guidance).
- The frequency per day and the number of days of treatment.
- The dosing sequence.
- Route of administration (the abbreviations for intrathecal, intraperitoneal or intrapleural are not acceptable and should be written in full).
- For infusions, details of solution and volume.
- Duration of infusion and any other administration instructions.
- Starting dates (and times when appropriate).
- Cycle or course number.
- Antiemetics, hydration and any additional drugs as defined by the protocol.
- Investigations and critical tests required.
- Critical test results such as blood counts, renal and hepatic function, as stated on the prescription should be recorded and endorsed by the prescriber for each treatment.
- All dose reductions, additions or amendments endorsed with prescribers’ signature and date.
- Reason for any dose modifications.
- Signature of the prescriber and the date prescribed.
- Record of drug administration.

- Prescriptions for oral SACT drugs should contain clear directions, including the dose, frequency, and duration including start and stop dates where applicable. This is to avoid patients being treated for longer than intended. For further details, refer to Section 8.1.
- Electronic systems used for prescribing, preparation and administration of SACT drugs should have:
  - Secure mechanisms to guarantee the security of access to those healthcare professionals alone who are competent to take part in the prescribing, clinical screening, preparation and administration of SACT drugs.
  - Clear audit trails for recording who has taken part in the provision of SACT drugs, from the prescriber, to the pharmacy clinical screening and preparation to the administration by nursing staff.
  - Where the whole process of prescribing, clinical screening and administration of SACT drugs is recorded electronically (i.e. there is no
paper based recording of any part of the process), the system should provide all the relevant details listed above, in a manner that does not introduce new risks to the process.

- Where electronic prescribing systems are used, the process for adding and deleting regimens onto the system must be clearly set out in Standard Operating Procedures and each element pertaining to prescribing, clinical screening and administration should be validated by the appropriate clinical discipline involved in that element of the pathway.
- Prescriptions for intrathecal administration must follow the Trust and National Guidance for the administration of Intrathecal chemotherapy.

- Oncology, haematology and paediatric oncology/haematology staff should prescribe SACT drugs for all patients using electronic prescribing systems where these are available.
- In those Trusts where electronic prescribing systems are not currently available, SACT should ideally be prescribed by using appropriate pre-printed prescription proformas.

6.5 Consent for treatment

- All patients receiving SACT drugs regardless of route should be fully informed of their treatment and should have given full written consent.
- It is good practice to ensure that consent is taken following initial pre-treatment consultation and at the point of SACT assessment.
- The name and grade of the doctor taking consent should always be stated on the consent form.
- Consent should only be taken by a clinician sufficiently experienced to judge that the patient's decision has been made after consideration of the potential risks and benefits of the treatment, and that the treatment is in the patient's best interest.
- Consent should be documented on the appropriate form, or a protocol/trial specific consent form. A copy of the completed form should be kept in the
patient's medical notes and a copy given to the patient. The SACT regimen should be documented on the form.

- If a change in SACT regimen is necessary, patients should be re-consented, after having received regimen specific details. This should be documented as before.
- Paediatric patients/carers should be given a copy of the signed consent form to keep in their patient held record.

6.6 SACT ‘Off Protocol’ prescribing

In routine clinical practice there should be no deviation from the relevant network algorithm. In exceptional circumstances, it may be necessary to treat a patient with a protocol not included in the relevant CMG. This situation may arise, for example, in a patient for whom none of the current network approved regimens are appropriate due to pre-existing organ toxicity. See NICaN policy for “Prevention of regular deviation from NICaN approved (Systemic Anti-Cancer Therapy) SACT protocols,” for further information.

7. Preparation, supply and storage of chemotherapy

The purchasing, receipt and storage of SACT in pharmacy are carried out in accordance with agreed procedures by the Pharmacy Department within the Northern Ireland Cancer Network. The pharmacy will ensure the effective control of the quality of these products.

- When purchasing SACT, risk assessments should be carried out as appropriate, to ensure that appropriate products are used. For example, wherever possible blister packed capsules or tablets are preferable to loose preparations, and products in vials would be preferable to ampoule formulations.
7.1 Preparation

- All prescriptions should be received in pharmacy in a timely fashion according to local Trust policy.
- Dispensing and preparation of SACT drugs should take place in Pharmacy (see section 9).
- Preparation of SACT drugs should take place in pharmaceutical isolators situated in a specifically controlled and monitored environment. The equipment should be certified as per manufacturer’s instructions.
- All pharmacy staff preparing SACT drugs will follow the individual Trust pharmacy procedures.
- An appropriately trained pharmacist will clinically check all prescriptions as per section 5.2 and 5.4.
- To facilitate drug preparation, changes to a previously written prescription may be made by an oncology/haematology pharmacist upon verbal confirmation from a doctor. Any changes on the prescriptions should be appropriately annotated by the pharmacist or prescriber, as per local policy.
- The pharmacist performing the clinical checking will document that the prescription is approved for preparation on the appropriate form.
- Appropriately trained pharmacy staff are responsible for the accurate preparation, documentation, labelling, determining and allocating the correct expiry and storage conditions for a SACT drug.
- The pharmacist or accredited technician performing the final product check will ensure correct documentation, computer entry, ensure appropriate preparation, and the pharmacist will release the medication for the patient.
7.2 Supply of SACT drugs

All formulations of SACT drugs must be supplied and labelled in accordance with MHRA and the National Patient Safety Agency (NPSA) guidance and according to Trust Standard Operating Procedures (SOPs).

SACT drugs are supplied as follows, depending on the form, which is most appropriate:

- **Bolus Intravenous (IV) doses** - in labelled luer-lock syringes
- **Intramuscular (IM) doses** - in labelled luer-lock syringes
- **Subcutaneous (SC) doses** - in labelled luer-lock syringes
- **IV infusions** - in sterile labelled bags of infusion fluid or appropriate infusion device/ambulatory infusion pump
- **Intrathecal doses** - in labelled luer-slip syringes
- **Bladder instillation** - in labelled ‘urotainers’ or 50ml luer-lock syringes, or a commercially available closed system device.
- **Intrapleural** - in labelled luer-lock syringes
- **Intraperitoneal** - in labelled luer-lock syringes or infusion bags
- **Chemoembolisation** - in labelled luer-lock syringes or infusion bags
- **Tablets & capsules** - in clearly labelled bottles or skillets
- **Oral liquids** - in clearly labelled bottles
- **Topical** - in clearly labelled tubes, ointment jars, dropper bottles or original packs
### 7.2.1: Label requirements for dispensed SACT drug preparations

Labels should comply with all statutory and professional requirements, and should include the following information:

<table>
<thead>
<tr>
<th>Category</th>
<th>Parenteral preparation &amp; other aseptically prepared doses</th>
<th>Oral preparation</th>
<th>Topical preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved drug name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Amount of drug in container (micrograms, mg, g, units)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength of preparation or concentration of oral liquid</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Infusion solution (inc volume)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infusion time</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Number of tablets, capsules or volume of oral liquid</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Full directions &amp; indication of length of treatment (e.g., for x days then stop)</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Quantity of preparation (weight for creams or ointments, or volume for topical solutions)</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Preparation date</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s name</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hospital number</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward / Location</td>
<td>✓</td>
<td>✓¹</td>
<td>✓¹</td>
</tr>
<tr>
<td>Batch number</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiry date &amp; time</td>
<td>✓</td>
<td>✓ (date only)</td>
<td>✓¹ (date only)</td>
</tr>
<tr>
<td>Storage conditions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Warning: Cytotoxic Drug (if applicable)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Other drug specific warnings</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eg. for vinca alkaloids</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For External Use Only</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Name &amp; address of Pharmacy dept</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

¹ Where appropriate
7.3 Transportation

- Containers of prepared SACT drugs should be transported in appropriately labelled, sturdy and leak-proof transport boxes or bags.
- All Trust staff involved in the transportation of SACT drugs should be trained to follow their Trust procedure for cytotoxic spillage and have appropriate access to spill kits. The frequency of training will be defined by local Trust policy.
- Intrathecal doses should be transported separately to all other medication. Refer to local Trust Intrathecal Policy.
- Pneumatic tubes should not be used for transporting cytotoxic agents.
- If a product has reached the administration area and a leak has occurred during transport and the product remains within the transport box then contact Pharmacy for advice. The transport box should contain any leak and the spill should be dealt with as per local policy. If the leak and any subsequent spillage occur after removal from the transport box, this should be dealt with promptly following local standard operating procedures. Contact Pharmacy who will log that a leak has occurred and that all waste was disposed of appropriately.
- SACT 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’ as appropriate. 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.\(^\text{15}\)
- A spillage kit should be made available to those involved in transporting the chemotherapy.

7.4 Storage in clinical areas

- Access to SACT drug storage areas on wards or day units should be limited to authorised staff.
- Storage should be designed in a manner that will prevent containers of SACT drugs from falling or being punctured. Such storage areas should be clearly labelled with cytotoxic warning labels.
• A member of nursing staff should receive the SACT drug in the transit bag/box at its destination. Bags/boxes will not be left unattended or with untrained staff on arrival.

• Nurses are responsible for the correct storage of SACT drugs delivered to wards and clinics prior to use. The storage should be in appropriate and designated areas.

• SACT drugs should be stored separately from other drugs.
  - Parenteral doses of SACT drugs should be stored in a designated locked chemotherapy refrigerator or cupboard.
  - Intrathecal doses should be stored in a designated locked intrathecal storage area or refrigerator. Refer to local Trust policy.
  - Oral doses can be stored in a locked drug trolley, cupboard or refrigerator with other medication, as long as they are clearly labelled as cytotoxic, as appropriate.

• Any refrigerators used for the storage of SACT drugs doses should be monitored at least daily to ensure that the temperature is maintained between 2 to 8 degrees Centigrade. Maximum, minimum and current temperature should be recorded. A record of monitoring should be kept.

8 Out of hour’s initiation and administration of SACT

Whenever possible, all SACT regimens should be initiated, and as much as feasible, administered within normal working hours. The risk of accidents is increased when complex SACT regimens are given outside normal working hours, particularly errors of incorrect drug and patient identification, and using the incorrect route of administration of SACT. When SACT continues outside normal working hours, staff skilled in SACT administration and access to expert medical advice must be available.

In a medical emergency, SACT drugs should be prescribed by a Consultant Oncologist/ Haematologist. A record of the number of times that this procedure has taken place outside normal hours should be maintained. Preparation of
SACT drugs out of hours should be in accordance to local arrangements and local policy. (See section 9.2)

8.1 Out of Hours Preparation of SACT Doses
There is no out of hours’ pharmacy preparation services or scheduled on call service at the Cancer Centre or at the Cancer Units however, some units will provide emergency chemotherapy if required, this is by local arrangement.
Whenever possible, all cancer chemotherapy should be initiated, and as much as is feasible, administered, within normal working hours. The risk of accidents is increased when complex SACT drug regimens are given outside normal working hours.
Emergency doses may be required out of hours in some instances e.g. for specific medical emergencies.
A Consultant Oncologist, Haematologist or Paediatric Oncologist or Haematologist should determine that it would be absolutely inappropriate to delay SACT. The decision should be recorded in the medical notes by the responsible Consultant. Refer to local policy for further advice.

8.1.1 Exceptional Circumstances
Patients may only be commenced on a new SACT regimen program beyond normal Monday to Friday working hours in the following circumstances:

- Acute Leukaemia - unanticipated admission of a newly diagnosed patient or a newly diagnosed relapsed patient.
- High grade lymphomas, germ cell tumours, small cell lung and others such as haemophagocytic lymphohistiocytosis.

As far as possible transplant protocols should be scheduled to avoid SACT being initiated out of hours.
A Consultant Oncologist, Haematologist or Paediatric Oncologist must determine that it would be absolutely inappropriate to delay SACT. The decision must be recorded in the medical notes by the responsible Consultant.
In situations such as expired SACT doses or damaged or leaking infusion bags, for patients who are receiving ongoing SACT regimens, contact the on call pharmacist for advice.

There is no preparation of SACT drugs in the cancer centre or cancer units out of hours.

**9 Prescribing, dispensing and administration of oral SACT drug preparations**

**9.1 Prescribing**
- The prescribing of oral SACT should be carried out and monitored to the same standards as those for parenteral SACT.
- Electronic systems, or prescription templates, similar to those for parenteral SACT should be used.
- Prescriptions should state the dose, route, frequency, start date, duration of treatment and the intended schedule for treatment. (The doses of oral mercaptopurine and methotrexate for children treated for acute lymphoblastic leukaemia during the maintenance phases is variable and depends on their blood counts which are checked at least fortnightly. Therefore drugs are labelled “To be taken as directed by the Children’s Haematology Unit”. Original packs of tablets or liquids are supplied.)
- The prescribing and dispensing of oral SACT drugs should remain the sole responsibility of the hospital-based oncologist or haematologist and pharmacist respectively.

**9.2 Prescription verification**
- Prior to dispensing, all prescriptions for oral anti-cancer medicines must be verified and signed* by a pharmacist who has undergone specialist training, demonstrated their competence and is locally authorised for this task. Verification includes assessment that the prescription is appropriate for the patient and that all safety checks have been undertaken, as defined in local policy.
  (* includes auditable electronic authorisation in e-prescribing systems)
9.3 Dispensing and labelling

- Prescriptions should be clinically checked by a pharmacist who has been appropriately trained before dispensing.
- Relevant protocols should be available to all pharmacy staff who may be involved with dispensing oral SACT.
- Specialist oncology/haematology pharmacists should be accessible to advise dispensary staff dealing with oral SACT prescriptions / requisitions.
- Dispensary staff should work to detailed standard operating procedures.
- A dedicated area should be reserved for the dispensing of oral SACT.
- All prescriptions dispensed for oral SACT should be labelled as per section 6.2.1.
- All containers of oral SACT preparations for inpatients should be labelled as an outpatient prescription including full instructions and a ‘Cytotoxic’ warning label should be attached.
- Blister packed tablets should be ordered into the pharmacy department where they are available.
- If a liquid formulation is required, the pharmacy department should try to source a commercially available product.
- Loose tablets or capsules should be counted on designated counting triangles. Triangles should be cleaned with an alcohol wipe after each use which should be disposed of as cytotoxic waste.
- Automated tablet counting machines should NEVER be used to count oral SACT preparations.
- When dispensing tablets or capsules, the complete course of treatment should be supplied.
- Patient information leaflets should be supplied to all patients.
- When dispensing SACT liquid formulations the exact quantity required for the course (plus a small overage) should be supplied. For maintenance therapy it is more appropriate to dispense the drug in its original container.
- During normal working hours all oral SACT quantities should have a second check prior to packaging.
9.4 Administration of oral SACT preparations

- Oral formulations of SACT should not be handled directly.
- Protective gloves should be worn if handling loose tablets or capsules.
- Protective gloves, armlets & apron should be worn if handling liquid formulations.
- Loose tablets / capsules should be dispensed into a medicine cup and given to the patient.
- Where the tablet / capsule is presented in a blister pack the tablet / capsule should be pushed out into a medicine cup using a ‘non touch’ technique.
- Tablets / capsules should be swallowed whole and not chewed.
- Tablets should not be crushed or split. Capsules should not be opened. In exceptional circumstances, if crushing of tablets or capsule opening is deemed essential disposable gloves, apron, mask and protective eye wear must be worn. Crushing should take place in a controlled area, using commercially available devices that are specifically designed for this purpose. Care must be taken in cleaning or disposing of such devices which will contain fine powder. Always contact Pharmacy beforehand for advice.
- For patients with swallowing difficulties an alternative liquid formulation may be available. Contact Pharmacy department for details. If medicine cups are used for the administration of SACT drug tablets or capsules then they should be disposed of as cytotoxic waste. In the community patients should use a designated medicine cup and wash after each use.
- Medicine cups, spoons or oral syringes used to measure doses of liquid oral cytotoxics should be disposed of as cytotoxic waste.

9.5 Spillage

- For all spillages assess the need for using a cytotoxic spillage kit together with the personal protective equipment contained within it (see section 14).
- If an oral dose is dropped, wear nitrile gloves to pick it up and dispose of it into a cytotoxic burn bin. Damp dust the area with a wet paper towel to ensure all fragments are collected. Dispose of the towel as contaminated
waste. Document lost dose in the patient’s healthcare record and on the prescription, as appropriate.

- For oral liquid spills, wear nitrile gloves and gown, soak up the spill and clean the area immediately using soapy water and wipes or paper towels. Dispose of these in a cytotoxic burn bin. It is recommended that a spillage kit is used for volumes greater than 50ml.

- In wards or clinic areas, used administration spoons, medicine pots or oral syringes should be disposed of in cytotoxic waste, see section 14.

9.6 Advice for patients and carers

- Patients and their carers should be given adequate verbal and written information about their SACT regimen, how to take their medication and for how long.

- Education should be given with regards to recognising adverse effects and what to do if these arise.

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

- Nurses/pharmacists skilled in SACT must ensure that the patient understands the following:
  - How and when to take their medicines including ‘gaps’ off treatment
  - Any dose modifications and understands why this is necessary
  - What to do if a dose is missed
  - What to do in the event of vomiting after a dose
  - If a SACT capsule/tablet is dropped return in a resealable plastic bag and inform treatment unit.
  - Common side-effects and what action to take if they occur
  - How to obtain further supplies - if needed
  - To return any unused oral anti-cancer medicines to the hospital pharmacy

- Contact information should be supplied with telephone numbers of the chemotherapy unit and an out of hour’s emergency contact.
10 Preparation of Intravenous SACT

10.1 Pharmacy SACT drug preparation services
The Pharmacy departments at the cancer centre and each of the cancer units operate a SACT preparation service providing parenteral SACT individually dispensed and ready for administration to named patients. The work is carried out within pharmaceutical isolators situated in a specifically controlled and monitored environment. These facilities provide operator protection, as well as ensuring maintenance of the sterility of the products. These units are subject to regular inspection from the Regional Pharmaceutical Quality Assurance Service (RPQAS).

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

During normal working hours, preparation of SACT in a clinical area, outside pharmacy, is unacceptable.

10.2 Out of hour’s preparation of SACT doses in clinical areas
There is no out of hours’ pharmacy preparation services or scheduled on call service at the Cancer Centre or at the Cancer Units. However, some units will provide emergency SACT drugs if required, this is by local arrangement. Whenever possible, all cancer SACT should be initiated, and as much as is feasible, administered, within normal working hours. The risk of accidents is increased when complex SACT regimens are given outside normal working hours.

Emergency doses may be required out of hours in some instances e.g. for specific medical emergencies.

A Consultant Oncologist, Haematologist or Paediatric Haematologist or Oncologist should determine that it would be absolutely inappropriate to delay SACT. The decision should be recorded in the medical notes by the responsible Consultant. Refer to local policy for further advice.
In certain settings however, the preparation/reconstitution of drugs in clinical areas may be carried out if a formal risk assessment has been conducted. A policy and procedure should be written and approved by senior managers. Where possible, such SACT drug preparation should use closed systems.

11 Administration of SACT drugs

11.1 General comments
Pregnant staff should refer to section 3.
SACT should only be given in wards, clinics or theatres where it is agreed as part of, or the whole of, the wards allowed activity.

Double-checking of both oral and parental SACT doses is recommended. All prescriptions for parenteral SACT drugs should be checked by one SACT competent nurse and another registered nurse or a SACT competent health professional (excluding the prescribing doctor). The chemotherapy competent nurse is defined in the NICaN SACT Administration Competence Framework. Staff who are not yet deemed competent to administer SACT may only do so under the direct supervision of a competent staff member. Staff administering SACT should be assessed in their current knowledge of the drugs being given, with respect to:

• The appropriate method of administration, following an agreed protocol.
• The usual dose ranges for each drug.
• Possible immediate, short and long term systemic and local side effects.

11.2 Facilities
SACT should be administered in a dedicated environment with appropriate facilities for safe administration. Areas designated for the administration of SACT drugs should have all relevant policy and protocol documents available. Facilities should include easy access to expert help and all the equipment necessary for the management of emergencies.
11.3 Equipment
All areas in which SACT drugs are administered should have the following equipment:

- Emergency alert system.
- Resuscitation equipment (or access to it as defined by local practice).
- Drugs for the management of emergencies – cardiac arrest and anaphylaxis.
- Access to drugs/ equipment required to treat cytotoxic extravasation.
- Cytotoxic spillage kit. (Berner kit are recommended)
- Eye wash / access to running water.
- Electro-mechanical equipment used to assist administration should be appropriately installed, validated, and have a current maintenance certificate. The practitioner should observe the equipment for consistent performance. They should also be appropriate for the prescribed purpose and used by a competent practitioner only (as defined by local written policy) at all times. Staff should use the MHRA for reporting adverse incidents, and act upon MHRA hazard and safety notices.

11.4 Preparing to give SACT drugs

- Check the patient/carer has been fully informed and has given written consent to receive the proposed treatment.
- Check the prescription is dated correctly, signed, written clearly and unambiguously and is in accordance with the chemotherapy protocol.
- Check pre-SACT investigations have been completed and results reviewed by an Oncology / Haematology doctor, designated SACT trained nurse or an appropriate specialised pharmacist.
- Be aware of the side effects of all the drugs to be administered.
- Check cumulative doses have not been exceeded for anthracyclines and bleomycin.
- Check appropriate antiemetics have been prescribed and given.
- When the protocol contains premedications (e.g. with paclitaxel) or hydration, ensure that these are prescribed and given in line with the protocol.
- For parenteral doses, if the injections or infusions have been stored in a refrigerator they should 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.

- Explain the procedure to the patient/carer and ensure written information has been provided.
- With a second person (as defined earlier), check the following details (if there is a discrepancy contact the Pharmacy):
  - The patient’s name and hospital number correspond with the prescription chart and pharmacy label.
  - Commencement of administration of hazardous drugs should be on the date stated on the prescription.
  - The name of the drug, the dose and for parenteral doses, the infusion fluid: the prescription and pharmacy label should be identical.
  - For parenteral doses the volume of fluid prescribed should correspond to the volume stated on the label or the volume of fluid in a syringe should correspond to the volume stated on the label.
  - Check the name on the patient’s wristband corresponds to the prescription chart. In day chemotherapy areas where patients may not be wearing a wristband, the patient must state their name, home address and date of birth.
  - Check the route of administration is the same on the hazardous drug product label and the prescription.
  - Check the expiry of all drug doses.
  - Check all parenteral doses for particulate contamination e.g. precipitation before administration.
  - Where an infusion pump is required ensure that it is set to the correct rate according to prescription and protocol and checked by two nurses.
  - For intravenous doses, flush well with appropriate compatible solution in between drugs.

11.5 SACT information for general practitioners (GP).
There should be available written guidelines for General Practitioners covering advice to give and action to taken when patients undergoing SACT consult them
with symptoms that may be related to complications. Conditions to be covered include neutropenic sepsis, diarrhoea, mucositis, nausea and vomiting.

These guidelines should be sent to each individual GP each time one of their patients commence a course of cancer chemotherapy. It is the responsibility of the Trust staff member giving the SACT to ensure the appropriate guideline is sent to the GP.

11.6 SACT information for patients
Patients undergoing SACT will be provided with written information related to their treatment. The information should cover advice and action to be taken if and when they develop symptoms that may be related to side effects or complications. Conditions to be covered should include neutropenic sepsis, nausea and vomiting.

It is the responsibility of the Trust staff member giving the SACT to ensure that the patient/guardian has been provided with the appropriate information via the appropriate team member(s).

12 Administration of intravenous SACT

12.1 Venous access
Cannulation of a patient and administration of SACT drugs should be carried out by nursing or medical staff that have been trained and assessed as competent.

12.1.1 The venous access device
- An appropriate venous access device should be selected by a competent practitioner to fulfil the requirements of the proposed treatment plan. A winged infusion set should not be used for the administration of any SACT, except in paediatrics (see section 11.3).
- SACT should NOT be given if there is any doubt regarding the safety of the venous access device.
12.1.2 Peripheral venous cannulation
Small gauge non ported safety cannula, which preserve vein integrity and cause least pain to the patient, are recommended. A closed system with luer-lock attachments should be used. Peripheral cannulae should be changed every 72 hours or more frequently if there is any doubt about the integrity. The care of cannulae should follow local guidelines.

12.1.3 Central Venous Access Devices (CVADs)
- Central venous access should be considered if the drugs or fluids are to be administered over a long duration, are irritant to the peripheral veins, or have the potential to cause tissue necrosis.
- Where the recipient of therapy has insufficient or unsuitable peripheral veins, insertion of a central venous catheter may be indicated.
- Some therapies will justify the placement of a Peripheral Inserted Central Catheter (PICC). However, several months of intensive therapy may indicate the need for tunnelled central catheters or implantable devices. The care and maintenance of central venous catheters should follow local guidelines.

12.1.4 Selection of cannulation site
When choosing a suitable site, both the required cannula size and the size and condition of available veins should be taken into consideration. The following need to be considered:
- The purpose of the cannulation. For example:
  - A large vein required for high flow rate.
  - Irritant solutions or drugs require good flow to assist haemodilution.
- The condition of the accessible vein, the lumen and blood flow.
- Small visible but impalpable superficial veins are rarely suitable for cannulation.
- In the elderly patient particularly, prominent, superficial veins may be sclerosed, tortuous, fibrosed or fragile and therefore may be unsuitable for cannulation.
• The large superficial veins of the forearm are commonly chosen for the cannulation as they are numerous, easily detectable with wide lumens and thick walls and the skin is less sensitive. Most common are: basilic and cephalic veins.

• Veins in the lower limbs must be avoided in adults.

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

• Avoid areas of joint flexion.

• For the administration of SACT use the back of the hand or the antecubital fossa only as a last resort and with senior medical authorisation

• Avoid sites distal to recent cannulation or venepuncture to minimise the risk of fluid extravasation.

• Avoid areas proximal to skin lesions or wounds.

• Avoid areas affected by invading tumour, haematoma, inflamed or sclerosed areas, cardiovascular access etc.

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

• Most difficulties arise when few or no veins in good condition are available. Heat may be used to dilate difficult veins, following local protocol.

• Follow local policy for cannulation.

12.2 Principles of intravenous administration

• Thoroughly wash and dry hands prior to glove application. (Refer to local Infection Prevention & Control Policy).

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

• Ensure appropriate protective clothing is worn (see section 3.4), prior to handling syringes or infusion bags containing SACT drugs.

• SACT drugs should be administered as per protocol, or according to the manufacturers’ instructions.

• Prior to commencing administration check the patency of the cannula or central catheter, by aspirating for blood and flushing with of sodium chloride.
0.9% for injection. **Caution:** remember to check drug compatibility with the fluid used for flushing.

- If there are any doubts regarding cannula patency, recannulate the patient.
- Access of central venous access devices (CVADs) should follow local policy and guidelines.
- If the placement or patency of central access is in doubt, appropriate investigations should be requested prior to commencing treatment.
- Inspect sealed bags before opening to ensure no spillage has occurred within the bag.
- Carefully insert the IV administration set into the SACT infusion at waist height on a supportive surface to minimise the risk of personnel contamination in the event of a spillage.
- Ensure that the infusion solution is covered to protect it from light if the drug is prone to photo degradation (See manufacturers guidelines).
- If a special IV administration set or filter is required, (e.g. paclitaxel, dacarbazin), use only those recommended.
- Checking should follow procedure previously described in section 5.3., immediately prior to administration by the person giving the treatment and the person performing the second check.
- Advise patient to immediately report local or systemic adverse events.
- Use sterile compatible fluid, which is appropriate to the drug being administered, to test and flush the vein and vascular access devices during administration. This should also be done between different drugs, and after SACT drug administration.
- Place a sterile gauze swab under the injection port during administration. Administration should be performed over a protective pad with waterproof backing to protect skin and surfaces from potential SACT leakage.
- Maintain a closed system by using luer-lock syringes. Use IV administration sets and syringes with luer-lock fittings. Intravenous administration sets should be changed every 72 hours. Patients undergoing high dose chemotherapy, bone marrow or stem cell transplant require their set changed every 24 hours.
• Do not expel air from syringes. If air is in a syringe, hold it in such a way that the air is up near the plunger when the entire drug is expelled and the air is reached.

• The administration of a bolus chemotherapy should be commenced and completed by the same member of staff. If this involves multiple syringes that are prescribed sequentially, these should be administered by the same person without interruption.

• To ensure visibility at all times, bandages should not be applied to cannula sites when SACT is in progress.

• On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 14.

• Wash hands thoroughly following the removal of gloves.

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

12.3 Administration of vesicant/exfoliant drugs

Adhere to the following when administering a vesicant/exfoliant drug:

• Use a new cannula if possible, or one that was sited less than 48 hours since insertion. Ensure that it is patent and that there are no obvious signs of extravasation. (Note: Presence or absence of venous return is not an absolute indication of patency.)

• CVADs are recommended for administration of large volume vesicant/exfoliant infusions, but if vesicants/exfoliants are to be administered peripherally, use a pump set to low pressure. A fast running, free flowing infusion of sodium chloride 0.9% must be used for administration of vesicant boluses peripherally.

• For peripheral administration give any vesicant drugs first when administering multiple drugs, as vein integrity is greatest at this time.

• Check for blood return every 2-5mls during peripheral administration and before and after each drug during bolus administration. Doses of vinca alkaloids for all patients treated in teenage, adolescent or adult settings should be administered from 50ml mini bags over 5-10 minutes regardless of the age of the patient (must continually monitor patient/supervise infusion).
12.3.3 Administration of bolus chemotherapy for children.
- In the paediatric setting administration of any SACT peripherally is rare except in long term maintenance therapy for A.L.L in which case Vincristine is given as a single bolus injection via a winged infusion set but only by a consultant.
- For central venous access, ensure patency before administration. A fast running drip is not required for vesicant boluses.

12.4 Patient Monitoring
The patient should be monitored frequently throughout administration for:
- Leakage at the site.
- Swelling.
- Pain.
- Venous irritation.
- Phlebitis.
- Flare reaction.
- Allergic reaction.
- Anaphylaxis.
- Extravasation.
- Known side effects.

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.

13 Administration via specific routes

Other routes of administration include subcutaneous, intramuscular, intravesical and topical and oral. Follow 3.4 (personal protective equipment) 10.4 (preparing
to give hazardous drugs), and local appropriate administration and disposal procedures. (Information also in section 5 & 8).

13.1 **Subcutaneous / Intramuscular SACT**
A subcutaneous injection is given beneath the epidermis into the fat and connective tissue underlying the dermis.

An intramuscular injection is given into the muscle.

13.1.1 **Specific additional equipment**
- Personal Protective Equipment
- Sterile dressing pack or sterile field and gauze
- Clean impermeable tray.
- Appropriate size needle for administration (as per local policy).
- Skin cleanser (as per local policy).
- Cytotoxic waste bin.
- Dressing trolley.

13.1.2 **Procedure**
- Ensure consent is obtained prior to procedure.
- Explain procedure to the patient.
- Ensure the patient is comfortable and has had specific information regarding their treatment.
- Inspect sealed bag before opening to ensure there is no spillage within the bag. Open the bag directly onto the injection tray.
- Thoroughly wash hands prior to glove application.
- Choose a suitable site for the injection, and prepare the skin with 70% isopropyl alcohol & 2% chorhexidine gluconate wipe.
- Carefully remove the connector top from the luer-lock syringe and attach appropriate gauge needle. Ensure needles for administration are secure taking great care to minimise risk of spillage on the skin.
- Using a pinch technique for a subcutaneous injection, administer the injection using a 90° angle.
• 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 minimising reflux.

• Remove the syringe and needle, covering the site with low lint gauze and ensuring there is no leakage from the site.

• If further injections are required, rotate the site of administration.

• Dispose of all cytotoxic contaminated waste immediately as described in section 14.

13.2 Administration of chemoembolisation

• Prescriptions for chemoembolisation should only be written by designated Consultants experienced in its administration.

• Chemoembolisation can only be carried out by, or under the direct supervision of, a designated consultant radiologist who has expertise in the technique and who has received training in the safe handling of hazardous drugs.

• The SACT drug used in the procedure is doxorubicin which is loaded onto the DC bead delivery system. Planning and co-ordination with the Pharmacy department is essential.

13.3 Intravesical Instillation

Intravesical instillation is the administration of cytotoxic drugs directly into the bladder, via a urinary catheter.

13.3.1 Specific additional equipment

* Disposable catheter
* Urinary drainage bag or catheter valve for catheter already in place
* Disposable incontinence pads.
* Cytotoxic waste bin.
* Dressing trolley x2.
* Personal Protective Equipment
* Catheter packs.
13.3.2 Procedure
This may be done with a disposable catheter or with a catheter already in situ.

- Ensure that written consent has been obtained. Explain the procedure to the patient.
- The cytotoxic drug should be instilled by an appropriately trained and accredited doctor or chemotherapy competent nurse.
- Ensure patient privacy. Ensure the patient is comfortable and has had any specific information regarding their treatment.
- Clean dressing trolley with locally approved cleaning solution.
- Thoroughly wash hands.
- If required, catheter insertion and management of existing catheters should follow local policy and principles of best practice.
- Ensure the patient’s bladder is empty prior to the administration of the SACT.
- Connect the bladder syringe/Urotainer securely to the catheter, release the clamp and instil the drug slowly into the bladder. Rapid instillation can be painful, especially if the bladder wall is scarred from previous surgery.
- Carefully check that there are no signs of leakage of drug around the catheter site.
- Reclamp the catheter if the catheter is to remain in. Disconnect the syringe / Urotainer from the valve using a cotton swab to absorb any drops left on the end of the valve.
- Remove temporary catheter with syringe / urotainer attached and dispose of as cytotoxic waste (section 12)
- If a drainage bag is being used, connect this to the valve but do not open the valve, to allow retention of the drug within the bladder for at least one hour.
- Ensure patient’s skin is protected around the catheter.
- Clear away all contaminated disposables. (See section 12).
• Ensure the comfort of the patient, assisting him/her to reposition themselves and ensure they have easy access to a call bell.

• Advise the patient of the need to retain the drug for one to two hours if possible. If the patient has an urge to void or if the catheter is bypassing, it will be necessary to open the valve before the allotted time.

• If catheter in situ after one to two hours: Wash hands thoroughly before putting on disposable gloves.

• Attach a urine drainage bag. Unclamp the catheter and allow drainage of the bladder contents into the drainage bag for 15 minutes.

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

• The contents of the drainage bag (drug and urine) should be emptied down the toilet followed by a strong bleach based detergent & left for 15 minutes prior to flushing twice. The bag should then be disposed of as cytotoxic waste.

• If a temporary catheter was used the patient should void directly into the toilet. Men should sit down to avoid splashing.

• Advise patients to wash genitalia thoroughly to minimise potential skin irritation problems following contact with cytotoxic drugs.

• Dispose of all cytotoxic contaminated waste immediately as described in section 14.

14 Extravasation

14.1 Definition
Extravasation is defined as the unintended administration of a pharmaceutical into the tissue spaces surrounding a vein during intravenous injection. The consequences are often pain, erythema, inflammation and discomfort. Damage can continue for months and involve nerves, tendons and joints. If left undiagnosed, or if treatment is delayed, surgical debridement, skin grafting, and even amputation may result, depending on drug classification.
14.2 Prevention of extravasation
The most important issue in managing extravasation injury is prevention. When administering intravenous drugs precautions should be taken to minimise the risk.

(See section 11 Administration of intravenous chemotherapy).

- Some patient groups are at increased risk of extravasation. These include elderly and paediatric patients, patients with fragile veins, thrombocytopenic patients, and unconscious or sedated patients, patients with superior vena cava obstruction and diabetics with peripheral neuropathy. Extra care should be taken with these patient groups.

- Vesicant drugs should routinely be given as an intravenous bolus when given peripherally. There may be exceptions to this e.g. amsacrine, dacarbazine, carmustine, vinca alkaloids and streptozocin. This list is not exhaustive; refer to local policy and procedure. Intravenous infusions administered peripherally should be infused under gravity control or a pump set to low pressure.

14.3 Treatment of Chemotherapy Extravasation
Refer to local Trust policy.

15 Disposal of cytotoxic waste

Biological agents (including monoclonal antibodies) used in cancer treatment should be treated in the same way as cytotoxic drugs for the purposes of waste disposal since it is not yet clear how hazardous it is if there is inadvertent exposure to these agents.

The recommendations in this section act as a guide, and are supplementary to those detailed in individual trust waste disposal policies.

Information aimed at patients, carers and community staff regarding disposal of cytotoxic waste in the home or community environment is outlined in Appendix 2.
The recommendations in this section act as a guide, and are supplementary to those detailed in individual trust waste disposal policies.

15.1 Used disposable equipment
While wearing gloves and plastic apron/gown place any equipment used into a rigid cytotoxic burn bin (A yellow burn bin with a purple lid designated for cytotoxic waste). Used oral administration spoons, medicine pots or oral syringes should be placed in a rigid cytotoxic burn bin. Giving sets should be closed off and not be removed from infusion bags prior to disposal. Sharps boxes for cytotoxic waste are yellow in colour with purple lids. The method of disposal shall be in accordance with the requirements for the disposal of hazardous drugs by high temperature incineration to ensure degradation of the cytotoxic agents. Sharps disposal boxes/burn bins containing cytotoxic waste should be regularly collected.

15.2 Contaminated non-disposable equipment/items
Re-usable plastic or metal trays should be cleaned with a large wipe containing 70% isopropyl alcohol between patients and then cleaned with a detergent disinfection solution or 70% isopropyl alcohol wipe at the end of each shift. Wear eye protection, gloves and gown, or disposal apron and armlets. If non-disposable equipment or items are sent to another department for terminal cleaning, they should be transported in sealed leak-proof bags or containers. These should be clearly labelled indicating that they are potentially contaminated by hazardous drugs.

15.3 Protective clothing and wipes
Contaminated protective clothing, wipes, plastic aprons and gloves worn during the administration of SACT should be placed in a yellow burn bin with a purple lid. No bin should be filled more than two thirds full and no burn bin or sharps box should weigh more than 9kg.
After a cytotoxic spillage, (dealt with according to the cytotoxic spillage procedure), arrangements must be made for collection of the rigid cytotoxic sharps/burn bin for incineration as per local Trust policy. (See Section 16 for further details).

15.4 Part used doses
While still wearing protective clothing, attach a luer-lock cap to the syringe or to the end of an infusion line. If disposing of an infusion bag leave the IV administration set in place and clamp it off. Place the syringe/bag in an orange clinical waste bag and place into a rigid cytotoxic sharps box (purple lid). It should be clearly documented how much of the dose was administered and the reasons for discontinuation of treatment. Medical staff should also be notified. Contact the Pharmacy who will log that the product has been partially used and disposed of appropriately. Community staff can contact the helpline for further advice.

15.4.1 A damaged or leaking parenteral dose
See section 6.3
If a leak occurs at commencement or during administration of an infusion, discontinue administration and deal with as per cytotoxic spillage procedure. (See section 16 for further details). Do not return leaking or contaminated equipment to pharmacy as transporting this may increase the risk of further contamination.

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

- Loose tablets/capsules: Put into a sealable plastic bag or a medicine bottle / sample pot securing the lid, before placing in a cytotoxic burn bin.
• Oral liquids: Pour into a medicine bottle / sample pot securing the lid, before placing in a cytotoxic burn bin with a purple lid.

15.6 Patient waste/body fluids
Patient waste e.g. urine, faeces, vomit may contain high concentrations of hazardous 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 SACT or intravesical treatment.

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

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

• Wear disposable gloves and disposable protective aprons or gowns.
• Double flushing of sluices after emptying potentially SACT contaminated matter from bedpans, catheter bags, dialysis bags etc is recommended. Bedpans should be put through a bedpan washer twice at high temperature.
• Staff are advised to follow the precautions described in individual Trust Control of Infection Policy Manuals.
• Ideally patients should use separate toilet 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 (again to minimise splashing). A strong bleach based detergent should be poured into the toilet after voiding, for patients who have received intravesical BCG therapy. The bleach and urine should be left to stand in the toilet for 15 minutes before flushing twice.

If there is accidental spillage of bodily fluids (for example through incontinence or vomiting) which are potentially cytotoxic contaminated, the waste, gloves, disposable protective apron/gown and disposable wipes may be double bagged
and disposed of as clinical waste. Surfaces should subsequently be cleaned with a locally approved detergent.

15.7 Soiled bedding / linen
A risk assessment should be undertaken of soiled bedding and linen to determine the level of soiling and therefore the appropriate action to be taken. If there is only a small amount of soiling the bedding/linen should be treated as infected linen and handled as such, placed in a dissolvable laundry bag and then in red laundry bag and sent to the hospital laundry according to the procedures described in the individual Trusts Control of Infection Policy and Procedures.
If there is heavy soiling of the bedding/linen it should be handled as contaminated waste, double bagged in an orange clinical waste bag, placed in a rigid cytotoxic burn bin and sent for incineration.

15.8 Nappies and stoma bags
Non-disposable nappies should be treated as infected linen and handled according to the procedures described in the individual Trusts Control of Infection Policy Manual. Disposable nappies and stoma bags should be double bagged. They should be placed in an orange clinical waste disposal bag, placed in a cytotoxic burn bin and sent for incineration.

15.9 Disposal of waste in primary care/ community care
See appendix 2 for further information.

16 Personal accidents
If a patient, member of staff or visitor is involved in a spillage of SACT drugs or potentially contaminated patient waste the following procedures should be followed. All such events/accidents should be reported to a senior member of staff and fully documented on the local Trust Incident Report form.
16.1 Skin
- Remove any contaminated clothing immediately using disposable gloves.
- The contaminant should be removed as rapidly as possible by flushing the affected area with a large volume of cold water. If running water is not immediately available, bottles or bags of sterile water or normal saline should be kept as an alternative.
- 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.
- Medical attention should be sought from the nearest Emergency Department.
- A Trust Incident report form should be completed, and the Head of Department & Occupational Health informed.

16.2 Eyes
- In the case of contact with eye(s), hold back the eye lid and flush the affected eye(s) with copious amounts of water or sodium chloride 0.9%. Use Emergency Eye Wash Equipment available or alternatively cold tap water can be used if necessary. When anthracycline contamination occurs, flush eye(s) for at least 15 minutes. Refer to relevant Summary of Product Characteristics and Product Safety data sheet for further details.
- Medical attention should be sought immediately from the nearest Eye Clinic or Emergency Department.
- A Trust incident report form should be completed and the Head of Department & Occupational Health informed.

16.3 Needlestick injuries
- When a needlestick injury results in contamination, first squeeze the area until it bleeds.
• Wash the puncture site/wound thoroughly with copious amounts of cold water and cover with a waterproof dressing.
• If the needle contained any SACT drug contaminant, check the vesicant status of the drug by referring to, ‘The Management of Extravasation’ policy, or by seeking advice from a senior oncology or haematology pharmacist.
• Report the incident immediately to a senior member of staff.
• Follow the Trust’s Sharps Care Pathway and consider seeking advice from the Emergency Department or Occupational Health, especially if the needle had been in contact with a patient.
• A Trust incident report form from should be completed.

16.4 Clothing
• Any contaminated clothing should be removed immediately. Put on gloves and an apron. Rinse the clothing under running tap water. Squeeze dry and place in a plastic bag.
• Hospital linen should be double bagged in the appropriate laundry bags and sent to the hospital laundry according to the procedures described in the individual Trusts Control of Infection Policy Manual.
• Uniforms and personal clothing should be taken home for laundering. Such items should be laundered twice where possible. The first wash should be separate from other clothing. They may be laundered with other items for the second wash.
• Dispose of gloves and apron into a double orange clinical waste bag.
• If there is a likelihood that the drug has soaked through the outer clothing, underwear should be removed and treated as above, and the area of skin treated as in section 15.1 above.

17 Cytotoxic spillages

A cytotoxic spillage kit should be available, at all times, in all clinical areas where hazardous drugs are administered, and in all pharmacy areas where SACT drugs
are handled or stored. All staff should know how to use it and where it is stored. If a kit is used it should be replaced immediately. Cytotoxic spillage kits are available from Pharmacy or Supplies Departments, depending on local practice. Commercially available spillage kits are used in all hospitals providing a chemotherapy service to Oncology and Haematology patients in Northern Ireland. Information aimed at patients and carers regarding cytotoxic spillages in the home or community environment is outlined in Appendix 2.

17.1 Immediate action

- Restrict access to the spillage area.
- Alert other members of staff in the vicinity and inform a senior member of staff.
- If you have been injured or contaminated, another member of staff should deal with the spillage while you receive attention for the injury or contamination following the procedure detailed in Section 15.
- Untrained and new and expectant mothers should not have direct involvement in the management of a cytotoxic spillage.
- Turn off all fans and reduce any draughts.
- Open a Cytotoxic Spillage Kit (refer to local policy).
- If protective clothing has been contaminated during the spillage, remove the contaminated items and put on fresh protective clothing from the spillage kit. Place all contaminated items in a cytotoxic burn bin.

- Before dealing with the spillage ensure you have put on:
  - a disposable protective gown
  - a pair of protective plastic armlets
  - a pair of gloves (Tuck the armlet sleeves inside the glove cuffs)
  - a mask (preferably a respirator)
  - protective eye wear
  - put on a pair of plastic overshoes (only if spillage is on the floor).
  - For dry powder spills also refer to local procedures.
17.2 Subsequent action
The procedure as outlined in the spillage kit or the local standard operating procedure should be followed. Such procedures should also be accessible in all relevant ward, clinic and pharmacy areas. A Trust incident report form should be completed.

18 Ambulatory and Community SACT

SACT is usually given in an appropriate hospital based facility, either on the wards as an in-patient or on a day care unit. However, current practice of SACT and cancer management means that many patients now receive SACT in settings outside of conventional hospital facilities. The hospital-based team, regardless of the place of SACT drug delivery retains the overall responsibility for the patient. It is essential however that the patient’s GP and involved community staff are informed of the method and place of SACT delivery and the support package available, including 24-hour contact numbers. Moving care out of hospital and into the community is more than just a change of location. Transforming patient treatment in this way presents challenges in terms of managing clinical risk, maintaining clinical standards and ensuring adequate communication as patients’ progress along their care pathway.

18.1 Delivering SACT closer to home
The provision of SACT administration and care outside the acute hospital setting requires careful planning to ensure continuity of care and mitigate clinical risk. Community services need to be safe, of high quality, equitable and offer the maximum benefit to patients and the NHS.

- The criteria for selecting patients to be offered SACT in a community setting should be agreed locally.
- The location and nature of community SACT services needs to be agreed locally.
SACT delivery in the home is usually by commercial companies specialising in home treatment. It is essential that the prescribing, dispensing and administration of home chemotherapy should be carried out and monitored to the same standards as those for hospital based parenteral chemotherapy.

Certain SACT administration procedures are not suitable for home delivery. These include intrathecal, intrapleural and intraperitoneal administration. At any point during a treatment plan, the patient should be able to opt out of home treatment, and continue with hospital based treatment, if they wish to do so.

18.1.1 Assessment of suitability for community SACT
All patients need to be referred to the community team for a formal assessment. Although the actual assessments tools used in practice may vary, the following factors should be considered as a minimum requirement.

Patients should be assessed to ensure that:
- They have consented to SACT
- The SACT regimen is appropriate for community administration.
- The routes of SACT administration are appropriate.
- They wish to receive treatment in the community.
- They have a good understanding of their disease and the treatment side effects.
- They are able to manage treatment administration devices (where appropriate).
- They understand when to contact the hospital if unwell.
- The family and carer are aware of the community based treatment.
- They have a permanent address and have a working phone.
- There is a clear management plan for the patient, detailing the laboratory tests and assessment that needed to be carried out, when and acceptable clinical parameters.
- Readmission pathways are clearly identified at the time of referral.
18.2 Support for patients
Patients should be presented with the alternatives about the location of care clearly and coherently at the appropriate point in their patient journey. Community SACT should be presented as a choice and patients should be reassured that they will still receive the full range of acute hospital services.

As a minimum requirement all providers should:

- Provide written information about their SACT treatment, likely side effects, and who they should contact if they feel unwell.
- Ensure copies of this information are sent to the patient’s GP.
- Comply with local policies regarding 24 hour telephone advice service.
- Provide patients with written information on the main aspects of community treatment, key information about their treatment and contact details.

18.3 Delivering SACT in a community setting
The minimum requirements are:

- There is a clear statement detailing responsibilities and accountability.
- There is a clear procedure covering the selection and referral of patients to the community service.
- The prescribing, dispensing, handling, managing spillages and waste disposal of SACT should be to the same standards as per acute hospital, refer to relevant sections in this guidance.
- If reviewing the patient’s laboratory results and patient assessment for the SACT cycle is to be carried out by the community service, the person carrying out this role must be trained and assessed as competent to do so.
- SACT should only be administered by nurses who have been trained and assessed as competent.
- Each patient should have a management plan, detailing when tests and assessments should be carried out and acceptable clinical parameters.
- There should be clinical treatment policies, procedures and protocols including the management of anaphylaxis, allergic reactions and extravasation, including access to emergency services.
- Patient clinical data should be recorded and the acute hospital should be able to access this.
• Arrangements should be in place for the manufacture and supply of cytotoxic drugs and supportive care medications.
• Policies and procedure should be in place for carrying out laboratory tests.
• Arrangements should be in place for referring patients back to hospital who feel unwell or wish to be repatriated back to the acute setting for their treatment.
• Patients should understand when and how to contact the hospital and the 24-hour telephone advice service if unwell.

18.3.1 Assessment of suitability for home SACT
If the patient is to be treated in their own home the environment should be assessed to ensure that:
• There is a working telephone.
• There is running water.
• There is a safe area clear of obstacles and hazards for the nurse and patient.
• There is place for the patient to be comfortable whilst receiving treatment.
• The patient is happy for treatment to be administered in this environment.
• The safety of the visiting nurse is not compromised.

18.4 Commercial home chemotherapy providers
There are a number of companies that provide home chemotherapy services. This may be on an individual patient basis or as part of a hospital home care policy. Before embarking on a home SACT programme, it is essential that any service provider be formally assessed. When assessing a commercial company the following factors should be taken into account and considered as a minimum requirement:

• The company should be experienced in home SACT administration.
• Company facilities and services should be open to inspection by hospital based staff if felt necessary.
• There should be a patient assessment that is used to check that the patient is fit for treatment prior to administration.
• Policies and procedures for the management of anaphylaxis, allergic reactions and extravasation should be the same as that of the requesting Trust.
• There should be a policy relating to patient data, and who can access individual patient details.
• The recruitment and training of nursing staff administering the SACT doses should be of a similar standard to Trust staff.
• The company should hold indemnity insurance.
• Emergency contact nos. for patients/carers

Once a tender from a commercial company is agreed, a number of processes and pathways need to be agreed upon before a home SACT programme can commence. These include:

• A procedure for the initial referral of the patient to the company homecare team.
• The referral policy for an unwell patient. This should usually state that the patient is referred back to the medical team as per local arrangements, and not to the GP.
• Appropriate pathways for feedback and handover of documentation to the hospital based team. A reasonable time frame would need to be agreed with the Trust involved.
• An agreement should be in place concerning the supply of medications. This should include the dispensing of the hazardous drugs as well as the dispensing of any supportive drugs such as anti-emetics. Pharmacy verification of the prescription (see section 5.4) must be performed before SACT is made for homecare patients. If the company is supplying the medication, it is essential that there is a process for a prescription to be available in advance for the preparation and dispensing of the doses.
• A pathway should exist for the prescription to be available in advance for the nursing staff to administer from.
18.5 Administration of home SACT
The procedure for the actual administration of any SACT drug in the home setting should be as outlined in sections 11.

18.6 Disposal of home and ambulatory SACT
Patients on fluorouracil ambulatory infusors should be provided with the following equipment to be used in the event of a spillage;
- 1 x copy of Nurses Guide to Care of an Infusor
- 1x copy of Patients Guide to Care of an Infusor
- 1 x Cytotoxic burn bin
- 1 x luer (red) cap
- 2 x Nitrile gloves
- 1 x Absorbent pad
The cytotoxic burn bin and luer (red) cap should be supplied on first and subsequent visits.
Refer to Appendix 2 and local arrangements for further information on disposal.

18.7 Management of side effects and complications
- All patients and health care providers involved in the administration of home chemotherapy should be aware that any side effects and complications should be managed by referral to the base hospital.
- Guidelines for the management of infusion related reactions and hypersensitivity should be agreed between the commercial chemotherapy provider and the individual Trust.
- In the event of an extravasation, refer to section 13.

18.8 Hospital based SACT with intermittent administration in the home or community setting
Some patients within Northern Ireland may be treated with regimens in which most of the SACT doses are administered within the hospital setting, but may involve some part of their treatment also being managed or delivered at home or in the community setting.
Such patients should be regularly reviewed by the hospital based medical or nursing team to ensure that they are still fit for treatment. The frequency of review will be dependent on local practice and the SACT regimen.

Patients should be provided with all appropriate supplementary equipment

It is essential that for all these settings the patients and carers have received full information and advice concerning their SACT treatment. They should also have been given adequate training and support regarding safe handling, storage and disposal of the drug doses and management of spillages. (Refer to Appendix 2).

Patients, carers or community nurses will not be expected to prepare or reconstitute any hazardous drugs at home. All hazardous drugs for administration will be in a ready to administer form such as pre-filled syringes, infusion bags or prepared infusor devices. Disconnection and disposal of SACT infusor systems will be undertaken by appropriately trained personnel.

18.8.1 Continuous intravenous infusions
The hospital based nursing or medical staff will undertake an assessment of patient suitability for continuous infusional SACT before a patient is allocated to receive treatment. All patients need to be referred to the to the respective Trust District Nursing teams.

Disposable elastomeric infusors are the device of choice for delivery of continuous infusions in the home setting.

Patients, carers or community nursing staff should be provided with information regarding their treatment as well as how to care for the central venous access device.

The following information should be given to the patient, carer, GP and/or community nurse:

I. The name of the drugs(s), dose(s) and duration of infusion.
II. The name of the pump or infusion device and how it operates.
III. Care of the central venous access device.
IV. Potential problems and management.
V. Safe handling, storage and disposal.
VI. Spillage procedure and spillage kit.
VII. 24-hour contact telephone numbers.

The patients or carers understanding of the above will be assessed. Additional supplementary written information will also be provided.

18.8.2 Intravenous, subcutaneous or intramuscular cytotoxic boluses
The hospital based nursing or medical staff will undertake an assessment of patient suitability for treatment in the home or community setting. All patients need to be referred to the community team for a formal assessment. The actual administration of intravenous cytotoxic boluses in this setting will be by an appropriately trained nurse.

The following information should be given to the patient, carer and/or community nurse:
- The name of the drug(s) and dose(s)
- Potential problems and management
- As per (IV-VII) in 17.2.1

The patients understanding of the above will be assessed using a teaching checklist. Additional supplementary written information will also be provided.

19 Education and training

Mandatory training in SACT is required for all healthcare professionals involved in the prescribing, reconstitution, dispensing and administration of SACT drugs. These staff should have explicit knowledge of SACT, including the potential hazards to personnel, the environment as well as the effects on patients and the care they require. Knowledge of regulatory frameworks to support safety
with SACT is essential to the employee’s area of work. Education and training should focus on the “whole patient” experience. Practical training is essential and should be assessed through a competency based framework as stated in the Manual of Cancer Services Chemotherapy Measures Version 1.0 (National Peer Review Programme April 2014) and Chemotherapy Services in England: Ensuring Quality and Safety; a report from the National Chemotherapy Advisory Group (NCAG 2009).

Training and information should also be provided for ancillary staff and the wider allied health professionals who come into contact with SACT or with patients who have received SACT e.g. community staff, health care assistants and porters.

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

19.1 Training programmes for nurses administering SACT

At a minimum the training programme should include the following:

- Knowledge of the principles of SACT
- Safe handling of SACT drugs.
- The various routes of administration of SACT with focus on intravenous and oral routes, to include warning of the dangers of incorrect administration of vinca alkaloids.
- Knowledge and demonstrated competence in intrathecal chemotherapy as instructed by Department of Health HSC 2008/001 policy. NPSA and national guidance relating to the safe use of vinca alkaloids and NPSA Rapid Response Alert (NPSA/2008/RRR004) relating to the safe use of oral anti-cancer medicines.
- Consent and information giving.
- Holistic assessment of patients receiving chemotherapy.
- Supportive care.
- Selection and use of equipment:
  - Peripheral and CVADs, including line complications.
• Recognition of complications associated with SACT including myelosuppression and its appropriate management.
• Common SACT side effects including nausea, vomiting, stomatitis, diarrhoea, infertility, phlebitis and alopecia.
• SACT 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.
• Containment and exposure, including the procedure for handling cytotoxic spillage.
• Health and safety associated with SACT administration, including protective clothing, safe handling and correct waste disposal.
• Knowledge of the principles of clinical trials and good clinical practice (GCP).
• Knowledge of local treatment protocols/regimens.
• Patient education, information and resources
• Applied knowledge of the contents of the “NICaN Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti-Cancer Drugs” (2013)

19.1.1 Nurses administering SACT
• All registered nurses administering intravenous SACT must have successfully completed the Administration of Intravenous Drugs course.
• All registered nurses involved in the administration of SACT must demonstrate their competence in chemotherapy administration and be deemed competent by a designated assessor on an annual basis.
• Competence in chemotherapy administration is defined as having successfully completed a clinical assessment of competence and a theoretical test of knowledge (multiple choice test scoring a minimum of 70%) within this time frame.
• The clinical supervised practice and summative assessment must be documented using the NICaN chemotherapy clinical competence framework.
• In the unlikely event of staff not obtaining the agreed pass mark of 70% a support strategy will be implemented.
• Nurses should undertake a clinical assessment to the level of competence that equates to their area of practice.
• Subsequent annual clinical assessments will take the format of assessing the practitioner at their highest level of practice.
• Only registered nurses who have successfully demonstrated their competence in the administration of SACT may administer cytotoxic drugs unsupervised.
• SACT may be administered by any registered nurse under the direct supervision of a registered nurse who has successfully demonstrated their competence in the administration of chemotherapy.
• All newly appointed nurses should undertake the validated Queen’s University Belfast (QUB) course ‘Administration of Systemic Anti-cancer Therapies’, where possible within a year of their appointment.
• Once competent, the individual is responsible for maintaining and updating his/her knowledge and skills in relation to the administration of SACT.
• See appendix 3: IV SACT Administration Minimum Competency Process Flowchart

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

19.2 Prescribing SACT
Medical and non medical prescribers who are involved in prescribing SACT should receive training and competency assessments in order to be accredited to prescribe. Non medical staff prescribing SACT should be educated on an accredited non medical prescribing course and assessed in that area of practice. Each Trust should maintain a register of named medical
and non medical staff who have been reviewed as competent to prescribe chemotherapy.

19.2.1 Intrathecal chemotherapy
Each Trust should maintain a register of medical staff trained to administer intrathecal chemotherapy unsupervised. A register of checkers for intrathecal administration should also be available. Please refer to local Trust policy.

19.3 Pharmacy Staff
19.3.1 Handling
Pharmacy staff involved in the handling of SACT drugs e.g. purchasing and receipt of goods, packaging, storage, transportation etc., must adhere to the Trust policies - General Health & Safety, COSHH, Adverse Incident Reporting.

Staff should satisfactorily complete the following initial training programme relating to their role in handling SACT drugs. These training records should be retained by Trust managers.

- Read the sections in the ‘Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti Cancer Drugs’ that are relevant to their work.
- Have received training and education on the health risks associated with handling SACT drugs.
- Be familiar with the national guidance and local policy on intrathecal chemotherapy.
- Be familiar with information on the specific hazards associated with the drugs used.
- Read local pharmacy procedures and receive a practical demonstration of the relevant activities (such as dealing with a cytotoxic spillage), provided by the designated officer or the pharmacist acting under his / her authority.
19.3.2 Preparation
Professional and technical staff expected to participate in the aseptic preparation of SACT drugs must be trained and assessed as competent with respect to their role. The training should underpin knowledge. It should be practical and documented. An appropriate pharmacy manager will ensure that training is updated and reassessed at appropriate intervals and that training records are maintained. The manager may maintain a register of staff accredited to prepare SACT.

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

- Explicit knowledge of the ‘Guidelines for the Safe Prescribing, Handling & Administration of Systemic Anti Cancer Drugs’.
- Explicit knowledge of the national guidance and local policy on intrathecal chemotherapy.
- Practical training in aseptic technique where applicable, and local procedures on SACT reconstitution from a designated officer or pharmacist acting under his / her authority.

19.3.3 Clinical Screening of SACT Prescriptions (including oral SACT)
It is recommended that pharmacists who are involved in the clinical screening of SACT prescriptions and/or provide a clinical pharmacy service to wards where Haematology/Oncology patients are cared for should undertake an additional Trust specific training program. At a minimum, the training programme should include: the principles of SACT; national guidance on intrathecal chemotherapy, the safe use of vinca alkaloids and oral SACT; holistic assessment, consent and information and supportive care; equipment and devices; recognition and management of SACT - related complications, adverse effects and oncological emergencies; health and safety and COSHH; the principles of clinical trials and GCP; knowledge of local policies and procedures.
Only once assessed as competent can prescriptions for SACT be checked unsupervised. BOPA “Standards for Pharmacy Verification of Prescriptions for Cancer Medicines” should be followed.

Each Trust should maintain a register of named pharmacy staff who have been assessed as competent to clinically screen chemotherapy prescriptions.

19.4 Domestic Staff
All domestic staff (including agency staff) involved in cleaning duties in clinical areas should have received appropriate training and education on the health risks associated with cytotoxic drugs and cytotoxic waste, and the consequences of ineffective cleaning.

19.5 Portering Staff
All portering staff involved in transporting SACT 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.

19.6 Other staff in clinical areas
All other staff in clinical areas involved in assisting with the administration or, preparation of SACT, or transporting SACT (including volunteers) should undergo an induction to ensure they are aware of the risks associated with cytotoxic chemotherapy.

19.7 Multidisciplinary education and training
Where possible staff should attend multidisciplinary training and education programmes.
APPENDIX 1

Guidance on Dosing in Children

In most cases children’s SACT doses are calculated using their surface area. However in some instances particularly in those children less than 1 year or those less than 12 kg the dose can be based on the child’s weight rather than the surface area. Also doses eg Carboplatin dose may be determined from the GFR or EDTA t1/2 (refer to individual protocols)

Information provided previously from UKALL2003 newsletter (Jane Buckham Paediatric Oncology Pharmacists Group) Sept 2004 and also provided as an Appendix to UKALL 2011 protocol provides advice on dosing at the extremes of childhood obesity and underweight.

Children should be weighed in light clothes and on scales that are regularly calibrated. To ensure that children are treated effectively, without overdosing due to treatment related fat deposition, the Body Mass Index (BMI) should be checked at diagnosis and at approximately 3 monthly intervals and compared to standard Child Growth foundation BMI charts for their respective sex.

Calculate using the formula:

\[
\text{BMI} = \frac{\text{weight (kg)}}{\text{height}^2 (\text{m} \times \text{m})}
\]

Use the BSA charts in children to determine the surface area for dose calculation. These can be found at the back of the BNFC

For children with a BMI that falls within the 2\text{nd} to 98\text{th} percentile – dose by actual weight using the BSA area charts to determine the surface area for dose calculation.

For children who have a BMI > 98\text{th} percentile read off the BMI at 98\text{th} percentile for their age.

Calculate the dose weight using the formula:

\[
\text{Dosing weight (kg)} = \text{BMI at 98\text{th} percentile} \times \text{height}^2 (\text{m} \times \text{m})
\]

Use the BSA charts to determine the SA for dose calculation.
For children < 2nd percentile, repeat as above reading the BMI at the 2nd percentile for calculation.”

For children who have a greater than 10% weight loss due to illness during treatment it may be necessary to re-assess their BMI and dosing weight prior to recommencing treatment.

APPENDIX 2

Advice for patients and carers for the disposal of cytotoxic waste and management of cytotoxic spillages in the home

This leaflet contains the answers to some questions patients and carers may have about the disposal of cytotoxic waste and the management of a cytotoxic spillage in the home.

General information

• Keep all cytotoxic medication in a safe place according to the storage instructions on the product label (refrigerator or at room temperature).
• Ensure that all medicines, administration equipment and sharps or burn bins are out of the reach of children or pets & temporary locking mechanisms are activated.
• If you are the carer, and are pregnant, think you may be pregnant or are breast feeding, it is preferable that you do not handle cytotoxic drugs, or waste, unless absolutely necessary.
• Always wash your hands thoroughly after handling cytotoxic drugs or waste & upon removing personal protective equipment.

Disposal of cytotoxic waste

How should I dispose of empty medicine containers/bottles?

• Empty chemotherapy medicine bottles and cartons can be disposed of in household waste. Liquids, tubes or ointment jars should be returned to the treatment unit for disposal. Put lids / caps on the containers before discarding or returning.
• Medicine spoons, syringes and cups used to give oral chemotherapy should be washed and discarded in household waste after the course of treatment has been completed.
How should I dispose of intravenous infusion devices/bags and/or syringes?

• Empty infusion devices, bags or syringes that are used for the administration of cytotoxic drugs should be disposed of in a purple top burn bin. These bins will be provided by the hospital.
• Once the purple top burn bin is ‘three-quarters’ full, it should be sealed and returned to the hospital ward/clinic on your next visit.

What should I do with unused cytotoxic medicines?
• All unused cytotoxic medication (tablets, capsules, oral liquids, ointments, infusors, and syringes for intravenous administration) should be returned to the hospital pharmacy department, or ward/clinic. They should NOT be flushed down the toilet or thrown away in household waste.

How should body fluids be disposed of?
• Urine, stools and vomit can contain cytotoxic drugs, or their breakdown products, for as long as seven days after a patient has received treatment.
• Therefore, it is important that patients/carers wear gloves when handling urine, stools, vomit, contaminated bed linen and nappies for seven days following treatment. You should either use the gloves provided by the hospital, or a pair of rubber household gloves kept especially for this purpose.
• Gloves should be changed immediately if torn or contaminated.
• The contents of vomit bowls/bedpan/urinals should be flushed down the toilet with the lid down, and the toilet should be double flushed. Any disposable containers should then be double bagged and disposed of in the household waste. Non-disposable containers should be washed thoroughly in warm soapy water.
• Nappies and gloves should be double bagged and disposed of in the household waste.
• Contaminated bed linen and clothes should be washed separately to other items. Contaminated bed linen should be washed twice where possible. The first wash should be separate from other clothing. The bed linen may then be washed with other items for the second wash.
Management of liquid cytotoxic spillages

General Information

• Any liquid spillages of cytotoxic drugs onto the floor, or on your clothes or skin should be dealt with immediately to minimise potential harm to yourself or other people.
• You must wear gloves when dealing with a chemotherapy spillage. Make sure that they are not damaged, torn or split. Keep a separate pair of gloves for dealing with a spillage and an extra pair in case the other ones get damaged. If you have been provided with equipment to deal with a spillage use this equipment.
• You should contact your treatment unit to report the spillage and seek further advice.

What should I do if there is a cytotoxic spillage on work surfaces, furniture or floors?

• Cover the spillage using absorbent paper towels or absorbent pad provided, and ensure that all the liquid has been mopped up. The work surface, furniture or floor should then be wiped clean using warm soapy water (i.e. washing up detergent) as soon as possible using gloves & equipment provided by your treatment unit. This washing process should be repeated.
• All used absorbent towels should be disposed of in cytotoxic burn bin provided.
• For soft furnishing i.e. mattress an individual assessment should be made regarding the appropriateness of cleansing or disposal.

How should I deal with a cytotoxic spillage onto the skin?

• Wash the area with plenty of tap water. This should then be repeated using warm soapy water, and the area gently dried.
• Do not apply any moisturising cream or hand cream on the affected area.
• If redness or irritation lasts for longer than a few hours, contact your GP or ward/clinic/patient helpline.
How should I deal with a cytotoxic spillage in the eyes?

• Immediately flush the eyes and the surrounding areas with large volumes of cool tap water. This should be done for at least ten minutes.
• Go to your nearest Emergency Department as it is important that you seek medical attention for any spillages into the eye.

How should I deal with a cytotoxic spillage onto clothing/bed linen etc?

• Wearing a pair of gloves, blot dry with a paper towel or absorbent pad and remove the contaminated clothing immediately.
• The clothes/linen should be washed separately from other clothing as soon as possible. Where possible, repeat the wash cycle to ensure all drugs are completely removed.
• If the drug has soaked through the clothes to the skin, this should be dealt with as outlined above.

If you are in any doubt, please contact the clinical area where you are receiving treatment.

24 hour contact number……………………………………………………………………..
Appendix 3: IV SACT Administration Minimum Competency Process Flowchart

IV SACT Administration Minimum Competency Process Flow Chart

Venepuncture
   → IV drug Administration
   → Cannulation
   → Competent in the Care and Management of CVADs
   → Attend 2 Day In House Introduction to SACT Course
   → Given the SACT Competency Framework booklet
   → Engages in supervised SACT admin practice
   → Completes NICaN competency framework*
   → Annual review to include completion of exam with score of ≥70% and practical competence sign off.

* ICAN competency framework
References
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