Guideline and Procedure Manual for the Safe Use of Systemic Anti-Cancer Therapy (SACT)

Version – 3.0

Approved by the NHS Lanarkshire Systemic Anti-Cancer Therapy Group on 17\textsuperscript{th} January 2019

Revision date : January 2021
## Version History

<table>
<thead>
<tr>
<th>Date</th>
<th>Author</th>
<th>Change</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.07.10.</td>
<td>John Milne, Lead Pharmacist Oncology Services, NHS Lanarkshire</td>
<td>First version</td>
<td>Version 1.0</td>
</tr>
<tr>
<td></td>
<td>Teresa Rennie, Lead Clinical Nurse Specialist Haematology, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gillian Chalmers, Cancer Care Pharmacist, Monklands Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr Vivienne Maclaren, Consultant Oncologist and Acting Lead Clinician for Chemotherapy Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gerry McElhinney, Ward Manager Medical Day Bed Unit, Wishaw General Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Craig Richardson, Senior Cancer Care Pharmacist, Monklands Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mhairi Simpson, Lead Cancer Nurse, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Elaine McAllion, Aseptic Dispensing Services Manager, Hairmyres Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov 2014</td>
<td>Revised by:</td>
<td>General revision of the whole document</td>
<td>Version 2.0</td>
</tr>
<tr>
<td></td>
<td>John Milne, Lead Pharmacist Oncology Services, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Teresa Rennie, Lead Clinical Nurse Specialist Haematology, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr John Murphy Consultant Haematologist and SACT Lead Clinician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>March - Nov 2018</td>
<td>Revised by:</td>
<td>General revision of the whole document. Section added for Acute oncology</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------</td>
<td>---------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>John Milne, Lead Pharmacist Oncology Services, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ann McPhelim, Lead Clinical Nurse Specialist Haematology, NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dr John Murphy, Consultant Haematologist and SACT Lead Clinician</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gillian Chalmers Cancer Care Pharmacist NHS Lanarkshire</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Contents

1. **INTRODUCTION** .............................................................................................................. 6
2. **PURPOSE AND SCOPE** ................................................................................................. 8
3. **STATEMENT OF POLICY** .............................................................................................. 9
4. **PRESCRIBING GUIDELINES** ......................................................................................... 10
   4.1 Definitions of prescribing levels: .................................................................................. 10
   4.2 Initial Treatment Decision and Informed Consent: ...................................................... 12
   4.3 Subsequent patient assessment and prescribing / authorising of treatment: ............. 13
   4.4 Oncology non medical led SACT services: ................................................................. 14
   4.5 Prescription verification: ............................................................................................. 15
   4.6 Off Protocol Prescribing: ............................................................................................ 15
   4.7 Chemocare Prescribing Process ................................................................................. 16
   4.8 Training to support Chemocare prescribing process: ............................................... 18
5. **PHARMACEUTICAL GUIDELINES** .............................................................................. 19
   5.1 Pharmaceutical verification: ......................................................................................... 19
   5.2 Aseptic SACT preparation: .......................................................................................... 22
   5.3 Dispensing of oral SACT: ............................................................................................ 23
6. **ADMINISTRATION** ......................................................................................................... 25
   6.1 General Administration Issues: ................................................................................... 25
   6.2 Nursing SACT Checks Prior to Administration: ......................................................... 26
   6.3 Intravenous (IV) SACT: ............................................................................................... 29
   6.4 Administration of oral SACT ....................................................................................... 33
   6.5 Intrathecal Cytotoxic Chemotherapy ......................................................................... 34
   6.6 Other routes ................................................................................................................. 34
7. **EXTRAVASATION** ......................................................................................................... 40
   7.1 Risk factors .................................................................................................................. 41
   7.2 Patients at risk of extravasation .................................................................................. 41
   7.3 Minimising risk: ......................................................................................................... 42
   7.4 Signs and symptoms of vesicant extravasation: ......................................................... 43
   7.5 Management of extravasation .................................................................................... 44
8. RECEIPT, STORAGE AND TRANSPORT .............................................................. 47
  8.1 Receipt of SACT in Pharmacy ................................................................. 47
  8.2 Storage of SACT in Pharmacy ............................................................... 47
  8.3 Transportation of SACT ......................................................................... 48
9. WASTE DISPOSAL ....................................................................................... 50
   9.1 Disposal of unused SACT, cytotoxic waste and associated equipment .... 50
   9.2 Disposal of Patient Waste .................................................................... 51
10. SPILLAGE ................................................................................................... 54
   10.1 Spillage onto hard surfaces: ................................................................. 55
   10.2 Spillage onto clothing, bed linen etc. .................................................... 56
   10.3 Spillage onto skin or eyes: ................................................................. 56
11. OUT OF HOURS .......................................................................................... 58
12. SACT ADMINISTRATION OUTWITH HOSPITAL SETTING .................. 61
13. EDUCATION AND TRAINING ................................................................. 65
14. QUALITY AND RISK MANAGEMENT ...................................................... 69
   14.1 Clinical Governance ............................................................................ 69
   14.2 General Principles for Handling Cytotoxic Chemotherapy ............... 69
   14.3 Minimising Occupational Exposure ................................................... 70
   Pregnancy, planning pregnancy and breast feeding .................................. 73
   14.4 Quality Assurance and preparation of Cytotoxic Chemotherapy ....... 73
   14.5 Risk Management and Adverse Incident Reporting ......................... 74
15. ACUTE ONCOLOGY ................................................................................... 77
   15.1 Aims .................................................................................................... 77
   15.2 Model .................................................................................................. 77
16. REFERENCES ............................................................................................. 79
1. INTRODUCTION

Systemic anti-cancer therapy medicines (SACT) are generally known to be potentially carcinogenic, mutagenic and teratogenic and are hazardous as defined by the Control of Substances Hazardous to Health (COSSH) Regulations. The risks to patients receiving SACT are well documented and are balanced against clinical benefit. The risk to staff through occupational exposure is less clear however there is sufficient evidence to indicate that all necessary measures should be adopted to prevent exposure.

SACT must be prescribed, dispensed, supplied and administered and disposed of in accordance with the Medicines Act 1968.

Scottish Executive HDL (2001) 13 highlighted the need for health boards to revise systems and policies for the provision of cytotoxic chemotherapy in line with “Guidelines for the Safe Use of Cytotoxic Chemotherapy” which aimed to summarise and augment currently available guidelines. Subsequently, HDL(2005) 29 revised and updated the original guidance and had the same purpose: to promote the safe use of cytotoxic chemotherapy. In recognition of the growing demand for treatment closer to and at home the scope of the guidance has been extended to include this – so called ‘near patient chemotherapy’. It provides a framework for safe practice in the prescribing, preparation, administration and disposal to minimise the risk to patients receiving cytotoxic chemotherapy and protect staff from occupational exposure to these hazardous medicines.

In 2012 HDL(2005)29 was revised in line with the NHS Scotland “Better Cancer Care” strategy published in 2008. CEL30(2012) “Guidance for the Safe Delivery of Systemic Anti-Cancer Therapy” was the result of this review and now supercedes the previous guidance.
CEL22(2009) “Safe Administration of Vinca Alkaloids” has also been superceded as a result of being incorporated into CEL30(2012).

CEL21(2009) “Safe Administration of Intrathecal Cytotoxic Chemotherapy” remains extant.

This NHS Lanarkshire policy and guidance document should be used in conjunction with other relevant clinical guidelines when developing local or regional standards, policies and procedures.

This manual was originally developed for NHS Lanarkshire by a multi-professional sub group of the NHS Lanarkshire Chemotherapy Group within the Cancer Division. A key aim was to identify single Lanarkshire wide policies and procedures for activities supporting the safe use of SACT in Hairmyres, Monklands and Wishaw Hospitals. A significant component of CEL30(2012) is the requirement for clinical management guidelines and treatment protocols for all SACT. This is an ongoing process of creating new protocols and guidelines as new treatments emerge, and reviewing existing protocols. The responsibility for this lies with multidisciplinary specialist groups within the West of Scotland Cancer Network.

Another important area for guidance in this revised CEL is the guidance in relation to quality and risk management. It is worth noting that the Chief Executive or nominated deputy has overall responsibility for the safe use of SACT in NHS Lanarkshire.
2. PURPOSE AND SCOPE

The manual was originally developed on behalf of NHS Lanarkshire Cancer Division by a multi-professional sub group of the NHS Lanarkshire Chemotherapy Group. The manual provides descriptions of the policies and procedures used to meet the standards described in CEL30(2012) “Guidelines on the Safe Use of SACT”.

A key aim of the sub group was to identify single Lanarkshire wide policies and procedures for activities supporting the safe use of SACT in Hairmyres, Monklands and Wishaw Hospitals. By defining a consistency of approach in all areas where chemotherapy services are established the intention is to reduce risk and to provide a foundation for improving quality and safety for staff and patients, e.g., when staff are required to provide support outside their base hospital.

This manual also provides a foundation for the training of all staff working within, or providing support to, SACT services in the cancer division.

The use of cytotoxic medicines for non-cancer indications is out-with the scope of this document but is clearly applicable to all areas of practice where cytotoxic medicines are used.

Specific guidance on the safe use of intrathecal cytotoxic medicines can be found in the NHS Lanarkshire policy written in conjunction with the national guideline CEL21(2009).
3. **STATEMENT OF POLICY**

This policy applies to the prescribing of all SACT for administration by all routes including oral.

3.1 All relevant staff namely medical, pharmacy, nursing, theatre, portering, auxiliary and any other staff group involved in any way with the transporting, prescribing, verification, supply, administration and disposal of cytotoxic chemotherapy for both cancer and non-cancer treatment must be aware of this guidance and understand its impact on practice.

3.2 All staff involved in the transporting, prescribing, verification, supply, administration and disposal of cytotoxic chemotherapy must receive the appropriate training according to their role.

3.3 Patients should only receive cytotoxic chemotherapy in designated areas.

3.4 A copy of the current version of the guidance can be found on FirstPort in the Cancer Services section.

[http://firstport2/staff-support/cancer-services/default.aspx](http://firstport2/staff-support/cancer-services/default.aspx)

3.5 The guidance should be used to support training of staff involved in transporting, prescribing, verification, supply, administration and disposal of SACT.
### 4. PRESCRIBING GUIDELINES

#### 4.1 Definitions of prescribing levels:

<table>
<thead>
<tr>
<th>Competency Level</th>
<th>Examples of Staff Groups</th>
<th>Responsibilities in prescribing process</th>
</tr>
</thead>
</table>
| Level 1          | Consultant grade oncologist / haematologist | ♦ Decision to treat / Initiation of treatment  
♦ Completion of treatment plan  
♦ Assessment of patient before subsequent treatments  
♦ Prescribe chemotherapy for continuation of treatment plan  
♦ Authorise modification of treatment  
♦ Authorise treatment delay  
♦ Authorise discontinuation of treatment  
♦ Request off protocol chemotherapy treatment |
| Level 2          | Specialist Registrar Staff Grade Oncology / Haematology Medical Staff | ♦ Prescribe chemotherapy for continuation of treatment plan  
♦ Assessment of patient before subsequent treatments  
♦ Authorise modification of treatment |
<table>
<thead>
<tr>
<th>Level 3</th>
<th>Authorised non medical prescribers (must have an independent prescribing qualification and recognised by NHS Lanarkshire as a prescriber),</th>
<th>Within approved patient specific groups only. Non medical prescribing protocols for the agreed treatments must be in place and approved by NHS Lanarkshire.</th>
</tr>
</thead>
</table>
|         | ✦ Authorise treatment delay
         | ✦ Continuation of off protocol SACT treatment
         | ✦ Prescribe chemotherapy for continuation of treatment plan in line with approved clinical protocols
         | ✦ Assessment of patient before subsequent treatments
         | ✦ Authorise modification of treatment in line with clinical protocols in consultation with medical staff
         | ✦ Authorise treatment delay in line with clinical protocols in consultation with medical staff

Appropriately trained chemotherapy nurses, specialist nurses and oncology pharmacists who are not qualified as a non medical prescriber may regularly undertake 2nd and subsequent cycle pre-assessment reviews of patients receiving anticancer medicines when the patient does not require medical review. This has increased the flexibility of chemotherapy services and has helped manage increasing workload. However,
prescribing of chemotherapy for each cycle must still be performed by an authorised prescriber on a dedicated chemotherapy prescription form.

4.2 **Initial Treatment Decision and Informed Consent:**

4.2.1 The initial decision to prescribe chemotherapy must be made by a consultant oncologist or haematologist after discussion at a multi-disciplinary team meeting if appropriate, taking into account patient wishes, co-morbidities and life expectancy.

4.2.2 The NHS Lanarkshire chemotherapy referral form / treatment plan must be completed by the consultant oncologist or haematologist. A copy must be filed in the patient’s case notes.

4.2.3 Informed consent must be obtained from the patient and the consent form signed by the patient and the consultant oncologist or haematologist, specialist registrar or staff grade (reverse page of NHS Lanarkshire treatment plan / consent form) in advance of patient receiving first cycle of chemotherapy. Consent is taken at an appropriate time after the patient has been provided with verbal and written information which includes the potential risks and anticipated benefits. Consent forms must be completed in full by medical staff responsible for consenting the patient.

4.2.4 The decision to treat and treatment plan must be documented in the patient’s case record. The treatment plan must include all relevant patient demographic details, treatment intent, specific regimen, number of treatment cycles, duration of treatment, disease evaluation parameters and review arrangements. This information must be communicated to the patient’s G.P. within 14 days.

4.2.5 The performance status and co-morbidities are documented in the patient record. For poor performance status patients the rationale for treatment is clearly documented in the patient specific management plan and additional monitoring is in place including escalation to consultant level.
4.2.6. The patient specific management plan contains clear information on when and how response will be assessed before further treatment is given.

4.2.7 The outcome of treatment and the decision to stop or change treatment is clearly documented in the patient record.

4.2.8 Where an electronic prescribing system is in use the patient should be allocated the appropriate SACT course by the consultant oncologist or haematologist, specialist registrar or staff grade. If the patient is to receive their first cycle of SACT the consultant oncologist or haematologist, specialist registrar or staff grade should authorise the treatment.

4.3 **Subsequent patient assessment and prescribing / authorising of treatment:**

**Patient Assessment**

4.3.1 Before each course of chemotherapy the patient should be reassessed as being fit to receive the prescribed treatment as specified within the chemotherapy protocol.

4.3.2 This assessment may be undertaken by the following practitioners

- Consultant oncologist or haematologist (level 1)
- Specialist registrar / Staff Grade (level 2)
- Authorised Non medical prescribers (level 3) within limitations

4.3.3 Other staff within patient specific groups, who have acquired the recognised competencies, may be authorised to undertake this assessment. This practice must be clearly defined in a protocol which must be approved by the Lead Clinician for SACT.

**Prescribing SACT treatment**

4.3.4 Prescribing SACT beyond the initial treatment may be performed by:

- Consultant oncologist or haematologist (level 1)
4.3.5. If the patient deviates from the treatment parameters as defined in the SACT protocol, the patient must be referred to a consultant oncologist or haematologist, specialist registrar or discussed within the tumour specific multi-disciplinary team before decisions regarding modification or discontinuation of SACT can be made.

4.3.6 Modification to the SACT prescription with an explanation must be clearly documented within the SACT treatment plan. This must be filed within the patient’s case record.

4.4 **Oncology non medical led SACT services:**

4.4.1 Regulations allowing independent prescribing by pharmacists and nurses came into effect in 2006. Given the increasing workload in SACT treatments and limited specialist oncologist time, the new legislation means that there is scope to improve the quality of the service offered to patients by introducing more flexible team working and making it easier for patients to access prescription medicines, eg, SACT, premedication, intravenous fluids and take home medicines.

4.4.2 Planning of new non medical led services must comply with the agreed WoSCAN framework for provision of non medical prescribing services.

4.4.3 Staff involved with non medical prescribing must have an independent prescribing qualification, be an authorised NHS Lanarkshire non medical prescriber and have the appropriate competencies as described in specific tumour group NMP protocols.

4.4.4 NMP Nurses must only work between two tumour groups to ensure their knowledge and skills competencies remain current to the tumour group they are prescribing for.
4.4.5. Nursing and pharmacy staff with appropriate training and competencies may perform patient toxicity assessments and blood result reviews against established clinical protocols. (See 4.3.3.).

4.4.6 Additional cycles of SACT may be allocated on Chemocare by non medical prescribers where necessary. Initial allocation should be performed by medical staff responsible for initiating treatment or consenting patient for treatment.

4.4.7 A current list of authorised SACT prescribers can be found in the Cancer Services section or FirstPort (http://firstport2/staff-support/cancer-services/default.aspx)

4.5 **Prescription verification:**

4.5.1 All SACT prescriptions (including oral) must be verified according to agreed standard operating procedures by an appropriately qualified oncology pharmacist to ensure the clinical appropriateness of the prescription and that drug calculations, drug dose, route, timing and scheduling are correct. (see section 5 for more details)

4.5.2 The pharmacist must indicate on the prescription and via the electronic prescribing system where in use that the prescription has been verified.

4.5.3 Where the pharmacist has been involved in the prescribing process as a supplementary or independent prescriber the prescription verification must be undertaken by another appropriately qualified oncology pharmacist.

4.6 **Off Protocol Prescribing:**

4.6.1 Prescribing outwith the agreed SACT protocols must be requested by a consultant oncologist or haematologist. Treatments should be evidence based and authorised by the associate medical director according to the NHS Lanarkshire policy for approving unfunded medicines. For oncology treatments,
the Clinical Director of the Beatson may be asked to support the decision making process on an individual patient basis.

4.6.2 If treatments are “off label” or unlicensed, the consultant should follow the procedure for use of unlicensed medicines by completing an unlicensed medicines form. Patients must also sign an unlicensed informed consent form.

4.6.3 For licensed medicines for licensed indications that have not been approved by the Scottish Medicines Consortium, the NHS Lanarkshire procedure for Individual Patient Treatment Requests (IPTR) must be followed. For oncology treatments, the regional IPTR form must be used and submitted via the regional cancer network IPTR process

4.6.4 The reason for using the treatment must be clearly documented in the patient’s case records.

4.6.5 The treatment must be requested on Chemocare or agreed local standardised SACT prescription.

4.6.6 The prescription must be signed (confirmed / authorised) by the consultant oncologist or haematologist.

4.6.7 Non medical prescribers should not prescribe “off protocol” SACT treatments because there is no written support or clinical protocol in place for these treatments.

4.7 **Chemocare Prescribing Process**

4.7.1 Chemocare forms part of the patient’s health record and as such all care episodes must accurately reflect the patient’s diagnosis and treatment delivered. This will also ensure meaningful reports are generated from the system.

4.7.2 Patients must only be allocated a regimen in Chemocare that reflects their agreed management plan.

4.7.3 If a new diagnosis, a new chemotherapy regimen, or access to an existing regimen from a new diagnosis is required please notify your local NHS board
Clinical Superuser (CS). Refer to SOP on the WoSCAN intranet website: CEPAS ‘Adding/Amending a Regimen/Drug/Diagnosis within Chemocare Version 5.2bi’ for further information on process.

4.7.4 When allocating a treatment regimen to a patient on Chemocare all the planned treatments should be allocated to the patient prior to the patient being scheduled for their treatments.

4.7.5 To prescribe on Chemocare each treatment episode should be confirmed and authorised on the system by the prescriber. The prescription should then be printed and wet signed before passing on to pharmacy for verification. The wet signature acts to identify the final prescription (there is a risk that incorrect or multiple copies may have been printed).

4.7.6 If blood results are awaited and the patient is assessed as fit for treatment, prescribers may use the “confirm only” procedure. This requires the prescriber to confirm, but not authorise the prescription on the system. The prescription must be printed and wet signed as in 4.7.5 and passed on to pharmacy for verification. Pharmacy will authorise the prescription if the critical tests report within the acceptable levels to proceed with treatment. If the tests report outwith the acceptable levels pharmacy will discuss next steps with the prescriber.

4.7.7 If the prescriber has no access to a printer or if the prescriber is off site, then the “e-signature” procedure may be used. This requires the prescriber to confirm and authorise the prescription as in 4.7.5. Pharmacy must be notified when the treatment is prescribed to allow verification to be performed. Once verified, the pharmacist will print the prescription which will contain the electronic signature of both the prescriber and the pharmacist verifier. The pharmacist will annotate the printed prescription with “e-signature Rx” and will sign. This ensures that the correct prescription is identified (there is a risk that incorrect or multiple copies may have been printed).
4.8 Training to support Chemocare prescribing process:

4.8.1 Only staff that have completed local Chemocare training for the SACT prescribing process will be issued with a Chemocare password with prescriber security level, ie, authorised to prescribe chemotherapy.

4.8.2 Chemocare training for prescribers will be performed by a senior cancer care pharmacist.

4.8.3 The regional Chemocare request form must be completed and signed by the new prescriber, their line manager and pharmacist Chemocare trainer. The completed form should be returned to the local system administrator for Chemocare who will arrange for the change to be made.
5. PHARMACEUTICAL GUIDELINES

5.1 Pharmaceutical verification:

All SACT prescriptions (including oral) must be verified according to an agreed standard operating procedure (SOP) by an appropriately qualified pharmacist to ensure the clinical appropriateness of the prescription and that drug calculations, drug dose, route, timing and scheduling are correct.

5.1.1 Verification process:

The verifying pharmacist should annotate and sign the prescription or indicate as per local SOP once satisfied that the chemotherapy is appropriate for the patient. Where electronic prescribing is in use the verifying pharmacist should record the verification electronically and by signing the original prescription.

Where a pharmacist has been involved in the prescribing process as a non medical prescriber the prescription verification MUST be undertaken by another appropriately trained oncology pharmacist.

5.1.2 Check – prescription content

The prescription is written in full. Each prescription must contain the patient’s name, date of birth, patient identification number, CHI number and relevant ward/clinical area.

The prescription must also include:

- the patient’s diagnosis
- chemotherapy protocol
- cycle/treatment day number
- all chemotherapy medicines to be given including protocol doses
- interval between cycles
- All appropriate diluents, hydration schedules, pre-medications and appropriate supportive therapy should be included as described in the chemotherapy protocol including duration of therapy.
- The route, method and duration of administration should be clearly stated including infusion volumes.

- Where appropriate, reference should be made to any concomitant radiotherapy treatment.

- The prescription must include the patients height, weight, BSA where appropriate, haematology, biochemistry, any other relevant tests and calculated doses to be administered as indicated in the chemotherapy protocol.

- Any dose modifications or substitutions should be indicated.

- The prescription must contain the printed name of the prescriber, their signature, designation and the date. The prescriber must be authorised to prescribe SACT.

The SACT regimen should be checked against the standard SACT protocols available in pharmacy, clinical area or via the WoSCAN intranet website (link available on Chemocare and on Firstport). Any deviation from the standard protocols must be discussed with the prescriber before dispensing can proceed. If the prescriber is contacted regarding any aspect of the prescription, the issue and outcome of the discussion must be clearly documented on the prescription and recorded as an intervention in the patients pharmaceutical care plan. If alterations are made to the prescription, the prescriber must amend the patient’s case notes and ward copy of the prescription or fluid chart if different from pharmacy copy.

Where an electronic prescribing system is in use, changes to the patient’s chemotherapy must be made electronically. Other healthcare professionals in pharmacy and the ward/clinical area must also be informed of the change.

5.1.3 **Check - Appropriate time between cycles has lapsed**

Any uncertainty regarding time between cycles must be discussed with the prescriber before dispensing can proceed. Subsequent courses should be checked against the SACT protocol and the patient’s previous cycle. Any deviations must be discussed with the prescriber. Reasons for deviations from protocol must be recorded in the patient treatment plan.
5.1.4 Check - Patients’ haematology results

Patient’s white cell count should be greater than or equal to \(3.0 \times 10^9\)/L unless the SACT protocol states otherwise. The patient’s neutrophil count should be, in general, greater than \(1.0 \times 10^9\)/L for curative chemotherapy or greater than \(1.5 \times 10^9\)/L for palliative therapy unless SACT protocol states otherwise. If counts are lower than the limits set out in the chemotherapy protocol, the verifying pharmacist must contact the prescriber to confirm if chemotherapy is to proceed.

NB - For certain chemotherapy regimens e.g. those used in haematological malignancies, sarcomas and teratomas, lower white cell and neutrophil counts may be acceptable due to the chemotherapy intention or nature of the disease. Such values should always be discussed with the prescriber.

Ensure patient’s platelet count is greater than or equal to \(100 \times 10^9\)/L unless chemotherapy protocol states otherwise before proceeding with chemotherapy dispensing.

5.1.5 Check – Renal function

For some SACT regimens, the creatinine clearance value is required as a critical test on the prescription. Reference should be made to individual SACT protocols for specific information and recommended actions, such as dose modifications. BOPA Guidance for Cytotoxics and Renal Impairment is also a useful reference.

Creatinine clearance may be calculated using the calculator in Chemocare, but limitations of the Cockroft and Gault formula using actual body weight should be taken into consideration. The pharmacist verifying the SACT prescription must raise any issues regarding dose modification with the prescribing doctor. Changes and amendments must be recorded clearly on the prescription and also documented as an intervention in the pharmaceutical care plan.

5.1.6 Check - Liver function

All patients should have liver function tests (LFTs) checked prior to first cycle of SACT. Depending on the treatment regimen, it may be necessary to monitor LFTs every cycle. This should include as a minimum ALT, AST, ALP and Bilirubin. This is of particular
importance with the taxanes, anthracyclines and irinotecan where hepatic impairment may result in a drug omission or dose reduction. Any abnormal LFT results should be discussed with the prescriber. Reference should be made to individual SACT protocols for specific information and recommended actions. BOPA Guidance for Cytotoxics and Hepatic Impairment is also a useful reference. The pharmacist verifying the SACT prescription must raise any issues regarding dose modification with the prescribing doctor. Changes and amendments must be recorded clearly on the prescription and also documented as an intervention in the pharmaceutical care plan.

5.1.7. Check – other critical tests
Depending on the regimen these tests may include magnesium levels, thyroid function tests, blood pressure, urinalysis, ECHO/ECG results, mid treatment scans, etc.

5.1.8 Check - Anti-emetics and supportive medicines
The emetogenic risk of the SACT regimen should be assessed i.e. high, moderate, low or minimal risk. Ensure the appropriate anti-emetics, as per local antiemetic policy are prescribed. WoSCAN protocols should be checked to identify the emetogenic risk.

Appropriate toxicity limiting medicines/hydration schedules are prescribed as per SACT protocol e.g. folinic acid rescue and pre/post hydration for high dose methotrexate, mesna and pre/post hydration with ifosfamide and pre and post hydration with cisplatin.

5.2 Aseptic SACT preparation:
5.2.1 Premises in which SACT is prepared must meet the standards for aseptic dispensing as required by the report on Aseptic dispensing for NHS Patients and MEL (1996) 95.

5.2.2 SACT must be prepared to the same standard out of hours as within normal working hours.

5.2.3 All SACT prepared by the pharmacy department will have a shelf life assigned to it based on the known physical stability of the product.
5.2.4 Only pharmacy staff trained and validated in aseptic dispensing of cytotoxic chemotherapy can prepare SACT.

5.2.5 A negative pressure ducted isolator must be used for preparing SACT.

5.2.6 All staff involved in the preparation of SACT must wear suitable protective clothing and aseptic garments according to local procedure.

5.3 **Dispensing of oral SACT:**

5.3.1 Dispensing of oral SACT should be carried out and monitored to the same standards as those for aseptic dispensing of parenteral SACT.

5.3.2 All prescriptions for oral cytotoxic chemotherapy must be verified by an appropriately trained pharmacist according to the verification procedure described above before the prescription is dispensed.

5.3.3 Cytotoxic chemotherapy should not be touched directly or be allowed to come into contact with the skin.

5.3.4 Tablets or capsules present a lower risk than solutions while blister or foil packaging provides further protection.

5.3.5 Final containers should be labeled with a warning that persons other than the patient should avoid touching the cytotoxic chemotherapy directly. A patient information leaflet should be issued with oral chemotherapy.

**Dispensing procedure:**

5.3.6 All dispensing must be carried out in a designated dispensing area within a pharmacy.

5.3.7 All pharmacy staff involved with dispensing oral SACT should have access to relevant chemotherapy protocols and specialist oncology pharmacist advice.

5.3.8 Disposable gloves must be worn.

5.3.9 Equipment used for dispensing must be dedicated for chemotherapy, clearly marked e.g. with cytotoxic tape, and never used for any other type of medicine. The equipment must be thoroughly cleaned after each use. Contaminated
disposable items must be placed in appropriately labeled, puncture-proof designated incinerator containers.

5.3.10 Whole tablets should be prescribed. This may involve dose rounding or prescribing different doses each day. The prescriber must be contacted to alter the prescription.

5.3.11 The exact amount of treatment required is dispensed for the designated treatment / cycle duration. Where there is deviation from this requirement, ie, if packs cannot be split or if a clinical trial, then a risk assessment should be conducted to ensure risk to the patient is minimized

5.3.12 The quantity of oral medication dispensed should be double checked as part of the final check of the prescription.

5.3.13 Cytotoxic chemotherapy tablets must not be crushed; capsules must not be opened or tampered with in any way. If a patient is unable to take the prescribed medication the prescriber should be contacted to discuss possible alternatives.

5.3.14 The label directions must be clear and unambiguous and should state that the medicine is cytotoxic and should be handled with care.

5.3.15 The label must clearly state the start date and time limit on treatment, e.g., starting on 20th August for 5 days then stop.

5.3.16 Oral SACT should not be labeled “as directed” unless the patient or carer has been given explicit written and verbal instructions regarding dose, frequency of administration and duration.
6. ADMINISTRATION

6.1 General Administration Issues:

This section is to provide good practice guidance that will optimise quality of care and safety for both patients and staff. (see Section 14.2 Occupational Exposure)

6.1.1 SACT administration should be carried out by staff who have successfully completed a competency-based locally agreed training programme. (See Section 13)

6.1.2 Prior to commencing treatment ensure valid informed consent is obtained from the patient. If no valid consent form is available treatment will not go ahead until a valid consent form is made available. Provide written information with regards to potential side effects.

6.1.3 Protocols are available which will provide access to up to date information on the nature of the SACT being administered, which will include common toxicity profiles, treatment of acute exposure and a COSHH risk assessment for each individual drug. Pharmacy will be able to provide any additional information required.

6.1.4 SACT administration should be prescribed to coincide with times where there is appropriately trained staff available to administer the drugs. Wherever practical SACT should be administered during normal working hours or in specialised areas where support services and expert advice are available.

6.1.5 In the event of an emergency where SACT requires to be administered out with normal working hours the unit must have at least one nurse competent in chemotherapy administration infusional and vesicant bolus on duty (Section 11 - Out of Hours).

6.1.6 SACT should only be administered in clinical areas which are equipped to deal with emergencies that may arise.
6.1.7 Prior to administration of any SACT the patient’s full blood count and any other relevant parameters must be checked by prescriber, pharmacy and staff who are administering the chemotherapy.

6.1.8 SACT will only be given in designated areas and wards where there are appropriate facilities for safe administration. (See Section 10.)

6.1.9 All of these designated areas will have the following:

- Emergency buzzer equipment
- Access to resuscitation equipment
- Extravasations kits (see Section 7)
- Cytotoxic spillage kits
- Access to running water

6.1.10 In the case of near patient chemotherapy, a risk assessment requires to be undertaken. (see section 12).

6.2 **Nursing SACT Checks Prior to Administration:**

6.2.1 Explain the procedure of cannulation, chemotherapy administration and potential side effects to the patient. Provide written information to reiterate what has been discussed verbally. Apply patient identity bracelet.

6.2.2 Teach the patient and their relatives how to record their temperature and give instructions on what action to take should a fever develop. Provide patient with a Cancer Treatment Helpline red card.

6.2.3 Check the patient’s height and weight at the start of each cycle. This will establish the dose of SACT to be prescribed. Check the patient’s blood results
before administering chemotherapy to ensure they meet the parameters required for treatment (See section 5)

6.2.4 Ensure patient privacy and comfort and that they have received any specific information.

6.2.5 Prior to SACT administration all patients must have baseline temperature, pulse and blood pressure recorded.

6.2.6 Thoroughly wash hands prior to putting on gloves and apron (Section 14)

6.2.7 Intravenous cannulation should only be carried out by nursing staff that have completed recognized training and are proficient in this procedure. The dorsum of the hand is the most appropriate site for chemotherapy administration.

6.2.8 Once cannulation has been carried out, establish patency of the vein by flushing with 5mls Normal Saline 0.9%.

6.2.9 Ensure the prescribed anti-emetics are delivered 30 minutes before commencing intravenous SACT.

6.2.10 Intravenous administration of SACT must only be delivered by a nurse who has successfully completed a competency based locally agreed training programme

6.2.11 Intravenous SACT should be administered whenever possible during normal working hours. Nursing staff must be familiar with potential side effects of all drugs, and the necessary interventions should a problem arise.

6.2.12 Prepare equipment for aseptic administration. Check integrity of the administration set and connections. All bolus SACT must be administered with luer lock syringes.

6.2.13 Inspect sealed bag of chemotherapy before opening to ensure no spillage within the bag.

6.2.14 Check SACT protocol and follow stipulated guidelines.
6.2.15 Two registered nurses (at least one must be trained in SACT administration and
the other must be trained and competent in IV drug administration) must check
the patient’s identification and cytotoxic prescriptions against the labels on the
drugs supplied by pharmacy. Check expiry date and time and both nurses must
sign the prescription form.

6.2.16 Nursing staff should wear nitrile gloves, and a waterproof apron as a minimum.

6.2.17 **Administer vesicant drugs first.** This is when the vein integrity is greatest.
Normal Saline 0.9% infusion should be allowed to free flow during the
administration of a vesicant drug. The vesicant should be administered via the
side arm of the infusion set. Flush the line between each SACT drug with Normal
Saline 0.9%, and at the end of the infusion, this will prevent possible drug
interaction. Ensure a sharps bin is kept near for safe disposal of equipment.
(Refer to separate guidelines for vinca-alkaloids administration).

6.2.18 If an infusion is required, administration must be through a volumetric pump and
set alarms. Two nurses must check the patient’s identity, drug prescription, dose,
and administration rate and record the time commenced.

6.2.19 Observe the infusion site for signs of extravasation, ask the individual to inform
you if there is any pain, burning, swelling or leakage. If there is, act immediately:
- (Refer to the extravasation guidelines).

6.2.20 Record nursing activity in the SACT Nursing Document. Written details should
include the SACT regime, toxicities, date of commencement, blood results, vital
functions, any side effects experienced during treatment delivery and nursing /
medical interventions. Discuss this with staff.

6.2.21 Once treatment has been administered, remove cannula and cover with a
dressing.

6.2.22 Ensure the individual has been given a chemotherapy diary with contact details,
and alert card. This will enable them to seek advice or discuss any concerns with
regards to their chemotherapy treatment following discharge.
6.2.23 Ensure the individual has the correct take home medications, e.g. anti-emetics prior to discharge.

6.2.24 Ensure appropriate follow up appointment is arranged.

6.3 Intravenous (IV) SACT:

6.3.1 Venous Access

An appropriate vascular access device should be selected for IV SACT by a competent practitioner to fulfill the requirements of the proposed treatment plan. Cytotoxic drug administration should NOT be given if there is any doubt regarding the safety of the venous access device.

6.3.2 Peripheral Vein Administration – choice of cannula

A small gauge device, which preserves vein integrity and causes least pain to the patient, is recommended. The selected device should be fastened and secured using a transparent dressing to allow visual inspection during administration. Peripheral cannulas should be changed every 48 hours unless indicated prior to this time. The patency of the cannula should be verified prior to use and replaced if in doubt.

6.3.3 Selection of Cannulation Site

The choice of vein is very important. Anticubital fossa and lower limb veins should NOT be used to administer SACT drugs. When choosing a suitable site, both the required cannula size and the size and condition of available veins must be taken into consideration. The following need to be considered:

- The vein should be firm and bouncy and if possible previously unused. **If a vein has been accessed within the last two hours, vesicant agents must not be administered into a more distal vein.** This allows the first vein to heal adequately and reduces risk of fluid extravasation at this site (see Section 7 - Extravasation)

- The vein should always be palpated and skin cleansed with an alcohol wipe before cannulation is attempted
• Bruised or inflamed areas should be avoided

• Any limb with compromised circulation should be avoided e.g. lymphoedema, post auxiliary surgery, thrombophlebitis, trauma, immobilised fracture, invading neoplasm

• If there is no alternative than to use a limb at risk of lymphoedema, permission to use this limb should be sought from the patient’s consultant. Consultant approval and the patient’s verbal consent should be clearly documented in the patient’s case notes. Strict aseptic technique must be enforced and the patient must be assessed for early signs of infection/cellulits/lymphoedema in order for appropriate management to be commenced. Consideration of a central venous access device should be discussed with medical staff and patient at this point, depending on the aim of treatment for example adjuvant or palliative.

• It is advised that no more than two attempts at cannulation be made unless patient requests further attempts by that particular individual. Most difficulties arise when few or no veins in good condition are available. To help dilate difficult veins soak the patients arm in warm water or apply a heat pad

• Once the patient has been cannulated successfully the patency of the cannula must be checked using a fast, free flowing IV Infusion of 0.9% sodium chloride, or other compatible infusion fluid. If there are any doubts regarding cannula patency, re-cannulate the patient

• For the slow infusion of vesicant drugs, a central venous line or PICC line or other long line must used wherever possible. Access and maintenance of these lines should follow policy.

6.3.4 Administration of Vesicant cytotoxic drugs via a peripheral cannula

The competent nurse or practitioner administering the vesicant drug should preferably cannulate the patient themselves just prior to the administration to have confidence in full vein integrity.

• The patency of the cannula should always be checked throughout the procedure of administering the vesicant drug. This is done by stopping the procedure and
checking for backflow of blood into the cannula. However, it should be noted that the absence of blood return is not conclusive evidence of non-patency.

- Prior to and during administration of the vesicant drug, patients are asked to report any pain or change in sensation at or distal to the venous access device during the administration. Patients are advised of the importance of reporting any changes.

- Vesicants should be administered slowly via the IV access port within the administration set whilst the saline infusion is running rapidly and freely.

  VOLUMETRIC PUMPS SHOULD NOT BE USED WHILST THE VESICANT DRUG IS BEING ADMINISTERED

- A pulsed stop-start action should be employed to prevent the drug from travelling up the infusion tube.

- With the exception of a specific procedure for vinca alkaloids (with reference to directive CEL 22 2009), vesicant drugs must not be administered as an infusion directly into a peripheral vein via a cannula.

- If the vesicant drug is part of a regime containing more than one chemotherapy then it must be administered first as vein integrity is greatest at this time.

- At the end of the drug administration the vein must be flushed through with sufficient volume of compatible fluid to ensure that all of the drug is cleared from the cannula. The volume infused will depend on the patient and the drug administered.

6.3.5 Administration of Non-Vesicant Drugs via a peripheral cannula.

- On commencing an infusional SACT regime, a new cannula should be inserted where possible or one used that has been sited less than 48 hours since insertion. The patency of the cannula must be observed/checked by flushing the device with 0.9% normal saline and checking that the cannula can bleed back.

- If more than one non-vesicant bolus is to be administered by bolus injection or infusion, an amount of 0.9% sodium chloride or compatible fluid must be given
between each drug to prevent any interaction. The suggested volume should be that which is equivalent to the volume of the injection/infusion tubing

- Throughout an IV infusion, the cannula should be checked frequently for signs of inflammation, infiltration and or infection. The patient will be advised to report any signs of pain or change in sensation at or distal to the venous access site during the administration of the SACT.

- It is recommended that a bandage is not applied over the access device to allow for visual inspection.

6.3.6 Central Venous Administration

For the slow infusion of vesicant drugs, a central venous line or PICC line or other long line should be used. Access and maintenance of these lines should follow local policy.

- Prior to accessing any central venous access device that has been newly inserted, (eg. Hickman or PICC line), the patient’s case record sheet must be checked to ensure it is documented that the line has been correctly positioned. If this information is not available SACT will not be administered until either a chest x-ray is carried out or a radiologist contacted to confirm this.

- The patency of the central line must be checked before any SACT is administered. Any existing anticoagulant that has been instilled into the central line must be cleared before administration of any drug

- Vesicant and non-vesicant drugs may be infused/injected directly into a central line. It is preferred that wherever possible the SACT drugs are given as an infusion

- Care should be given when injecting bolus cytotoxic drugs via a central line as the patient may experience unpleasant sensations if drugs are administered too quickly, (eg., dizziness, palpitations). It is recommended that bolus cytotoxic drugs should be given via a fast flowing compatible infusion to prevent any unwanted side effects.
• At the end of any infusion/injection into a central venous access device the line must be flushed with an adequate amount of compatible infusion fluid prior to heparin locking the line or maintaining the line as defined in relevant local policy.

6.4 **Administration of oral SACT**

6.4.1 Disposable gloves must be worn by any person (nurse, patient, or carer) handling cytotoxic containers and SACT. Skin contact with oral cytotoxic preparations must be avoided wherever possible.

6.4.2 Whole tablets must be prescribed.

6.4.3 If the patient is unable to take the SACT in the form prescribed, the cancer care pharmacist or Medicines Information department should be contacted. The pharmacy may be able to supply the medicine in another form, or dispense a modified form in a safer environment. Information about the hazards of modifying the formulation should be given to everyone concerned with the patient’s care. If the formulation of the medicine requires to be altered, the prescriber must provide a new prescription in line with the agreed change.

6.4.4 Dispense loose tablets directly from their container or packaging into a measuring cup. Do not touch loose tablets.

6.4.5 Medicine cups/spoons used for the administration of oral SACT must be disposed of after single use into appropriately labeled, puncture proof purple lidded cytotoxic incinerator container.

6.4.6 For spillage of oral SACT preparations, including liquids see Section 10.

6.4.7 Patients and their carers should be given the advice outlined in “Chemotherapy Safety At Home Leaflet”.
6.5 Intrathecal Cytotoxic Chemotherapy

NHS Lanarkshire has a separate local policy for the safe administration of intrathecal chemotherapy that is compliant with national guidance CEL 21 (2009). Only trained and certified competent individuals whose name is held on the local intrathecal register can prescribe, verify, prepare, check, supply or administer intrathecal chemotherapy.

Inadvertent intrathecal administration of vinca alkaloids intended for the intravenous route may be fatal. Vinca alkaloids must be prepared as a 50ml infusion, in line with additional national guidance CEL 30 (2012).

In the interests of patient safety this policy must be adhered to at all times.

6.6 Other routes

6.6.1 Intramuscular

- Ensure patient privacy and comfort and if they have received any specific information
- Confirm correct patient details.
- Explain the procedure to the patient.
- Ensure bloods are monitored as per protocol.
- Verify that the appropriate prescription forms have been signed prior to administration.
- Wash hands, put on disposable apron, and nitrile gloves, (Individuals with a known allergy to latex should use an alternative type of glove).
- Inspect sealed bag before opening to ensure no spillage within the bag
- Read the label on the syringe, ensuring details match with the patient’s details.
- Check drug name, dose and expiry date.
Attach appropriate sized needle to the luer lock syringe for intramuscular administration, making sure the needle for administration is secure to minimise risk of spillage on the skin.

Choose a suitable site for injection and clean the skin with appropriate alcohol wipe.

Once needle inserted into the site aspirate to ensure correct site. Administer the injection into the selected site.

Hold cotton wool ball over site for 1 minute following removal of needle, then cover with an appropriate dressing.

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

Dispose of syringes and needles in cytotoxic sharps container.

Remove gloves and discard in sharps container.

Wash hands.

Document delivery of SACT/ interventions in the patient’s case notes.

6.6.2 Subcutaneous

Ensure patient privacy and comfort and if they have received any specific information.

Confirm correct patient details.

Explain the procedure to the patient.

Ensure bloods are monitored as per protocol.

Verify that the appropriate prescription forms have been signed prior to administration.

Wash hands, put on disposable apron, and nitrile gloves, (Individuals with a known allergy to latex should use an alternative type of glove).

Inspect sealed bag before opening to ensure no spillage within the bag.
Read the label on the syringe, ensuring details match with the patient's details.

- Check drug name, dose and expiry date.

- Attach appropriate sized needle to the luer lock syringe for subcutaneous administration, making sure the needle for administration is secure to minimise risk of spillage on the skin.

- Choose a suitable site for injection and clean the skin with appropriate alcohol wipe.

- Using a pinch technique, administer the injection using a 90 degree angle. Aspiration not required prior to injection.

- Hold cotton wool ball over site for 1 minute following removal of needle, then cover with an appropriate dressing.

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

- Dispose of syringes and needles in cytotoxic sharps container.

- Remove gloves and discard in sharps container.

- Wash hands.

- Document delivery of chemotherapy / interventions in the patient’s case notes.

- If injections are given at home, the patient / carer must return sharps box to the hospital unit for appropriate disposal. (see “Chemotherapy Safety At Home Leaflet”.

- For specialist or high volume subcutaneous injections please refer to the manufacturer's instructions.

6.6.3 Intravesical Mitomycin Administration

Preparation of patient

1. Ensure restricted fluids for 6 hours prior to treatment.
2. Record baseline Temperature, pulse and blood pressure. If the patient is pyrexial, treatment should not be given until the cause is found and any infection has subsided.

3. If the patient has proven UTI or symptoms suggesting infection treatment should not be given until this has been treated and symptoms have subsided.

4. If blood and protein show up in urinalysis give treatment, but if leucocytes and nitrates show do not give. (As per Consultants wishes).

5. Ensure patient dignity at all times.

6. Ensure full information is given and full explanation of treatment given.

7. Respect confidentiality at all times.

8. Ensure patient aware of all side effects and possible reactions of treatment. Contact hospital for any information or concerns.

9. Instruct patient to remove clothing waist downwards and lie on bed. Cover patient with appropriate sheet or blanket.

Preparation of Equipment

1. Clean dressing trolley with aseptic solution to standards of trust protocol.

2. Items required will be – dressing pack, chlorhexidine 0.02% sachet, size 12 lofric catheter, 40mls of sterile water or saline, scissors clamp, two aprons, mask, double gloves, double clinical waste bag, bed pad.

3. Always have a litre of sterile saline and drip stand to flush bladder in case of reaction.
Procedure for instillation of mitomycin

1. Lie patient on their back and preserve dignity at all times.

2. Open dressing pack and lie mitomycin on dressing trolley along with syringe of water for flushing.

3. Make sure clamp is to hand and all equipment is within reach.

4. Fill hydrophilic catheter and tape to dressing trolley.

5. Put on double apron and gloves.

6. Put on mask.

7. Insert lofric catheter as per guidelines of Trust.

8. Place connection on end of catheter.

9. Attach mitomycin to end of connection and instil slowly, ensuring no pain felt by patient.

10. Clamp catheter with blue scissors clamp to ensure no backflow of mitomycin and no spillage.

11. Remove mitomycin syringe and insert syringe to flush.

12. Remove clamp.

13. Flush with water.

14. Remove lofric catheter.

15. Instruct patient to lie on alternate sides, front and back, for 15 mins consecutively.

16. Observe for pain or leakage.

17. Patient must try to hold mitomycin for one hour.

18. If pain or discomfort occurs allow patient to pass mitomycin into a designated toilet immediately.

19. When passing into toilet male patients should sit to avoid splashes.

20. Flush toilet twice in hospital.
21. Allow patient to go home once treatment finished, with following appointment.
22. At home the patient should use bleach down the toilet after passing urine for the first 24 hours after treatment.
23. If splashes occur on patient’s skin wash the affected area immediately with soap and water.
24. If rashes or swelling of extremities occur at home, instruct patient to phone hospital for advice or attend their GP.
25. Inform patient that blood in urine is a likely side effect of treatment and that they may develop symptoms of a UTI. If this occurs contact GP.

Mitomycin therapy lasts for six consecutive weeks, providing there are no reactions or problems. If reactions occur treatment must be stopped immediately and patient referred back to the consultant. Once all six treatments have been given the patient then awaits a date for check cystoscopy to check effectiveness of treatment.

(SOP courtesy of Hairmyres Urology Service)
7. EXTRAVASATION

Extravasation is an unintentional injection or leakage of a vesicant agent into the extravascular tissue that can lead to severe inflammation and necrosis, which if left untreated, may cause permanent damage requiring plastic surgery (Allwood, M., Stanley, A., Wright, P. (1997)). The management and treatment of extravasation is a complex and controversial one but comprehensive treatment and expert advice must be available as early as possible following an extravasation. Ideally this should occur within ten minutes of the event, certainly within one hour and definitely within twenty-four hours (Cancer Chemotherapy 2005, Royal Marsden Hospital). The incidence of cytotoxic extravasation should be relatively low, affecting less than one percent of patients receiving IV cytotoxic chemotherapy (How and Brown (1998)).

The West of Scotland Cancer Advisory Network (WoSCAN) issued guidelines on the management and prevention of extravasation in 2010 and a revision of this guidance in 2015. These guidelines are available in all wards and departments that administer cytotoxic chemotherapy and in pharmacy departments that prepare treatments. It is intended that the WoSCAN guidelines and individual drug algorithms for first aid management are used as reference where there is a suspected extravasation.

Extravasation Drug Classifications:

- **Vesicant**
  
  Capable of causing pain, inflammation and blistering of the skin, underlying flesh and structures, leading to tissue death and necrosis.

- **Exfoliants**
  
  Capable of causing inflammation and shedding of the skin, but less likely to cause tissue death.

- **Irritants**
  
  Capable of causing inflammation and irritation, rarely proceeding to breakdown of the tissue.

- **Inflammatory Agents**
Capable of causing inflammation and irritation and flare in local tissue.

- Neutral agents

## 7.1 Risk factors

When administering intravenous SACT the aims are:

- To minimise the risk of extravasation occurring and
- Early detection and prompt management of extravasation.

Risk factors associated with extravasation are:

- Error associated with administration technique
- Error associated with administration device
- Factors associated with the patient
- The inherently physical properties of the drugs concerned (Allwood, 2002).

## 7.2 Patients at risk of extravasation

(Shulman et al 1998; CP Pharmaceuticals 1999, Goodman 2000)

- Infants and young children
- Elderly patients
- Those who are unable to communicate e.g. sedated, unconscious, confused, language issues
- Those with chronic diseases e.g. cancer, peripheral vascular disease, SVC syndrome, lymphoedema
- Those on medications – anti-coagulants, steroids
- Those who have undergone repeated IV cannulatory venepuncture
• Those with fragile veins or who are thrombocytopenic
• Those with disease parameters e.g. lymphoedema in breast cancer.

### 7.3 Minimising risk:

Risk minimisation is also covered in Section 6 - Administration.

The position, size of the venepuncture site and the length of time cannula has been in situ are the factors which have the greatest bearing on the likelihood of problems occurring.

Checklist for inserting a cannula safely cytotoxic drug administration

• Avoid small and fragile veins
• Never attempt to insert a cannula into a limb that is affected by lymphoedema or has a neurological weakness. Wherever possible, the cannula should be placed in the patient’s dominant limb
• Avoid veins adjacent to tendons, nerves or arteries
• Avoid sites distal to recent venepuncture and areas of recent irradiation.
• Areas of high venous pressure should also be avoided. Starting near the hand is advisable when administering vesicant drugs
• Use plastic cannulas rather than steel needles because their flexibility reduces the chance of vein penetration while they are in use. In addition, the use of steel cannulas is contraindicated with certain drugs, namely platinum compounds
• Ensure a good blood flow before use and inject a compatible diluting agent before cytotoxic drugs are infused. Similarly, the vein should be flushed after each drug is given if multiple cytotoxic drugs are to be infused.
• Ensure the cannula is secured in position but that the venepuncture site is visible
• Administer bolus chemotherapy slowly into a fast-running compatible infusion
• Check the cannula site at regular intervals while in use
• Vesicant drugs should be given first. For practical reasons, drugs given by infusion should be given last. The integrity of the vein is also greater at this time (RCN 1998)
• It is important not to obscure the cannula site. The use of transparent occlusive dressings is advised as this makes viewing easier
• Always flush the cannula with a compatible solution after cytotoxic drugs have been given. Remember that saline is not compatible with all cytotoxic drugs
• Ask the patient to report any discomfort, stinging or burning sensation at the cannula site during and immediately after chemotherapy
• When removing the cannula, apply pressure to the venepuncture site for several minutes to prevent leak back and minimise bruising. Future use of the site will be compromised if leak back or bruising have occurred.

7.4 Signs and symptoms of vesicant extravasation:
• Burning or stinging pain at cannulation site
• There is evidence of swelling, induration, leakage, erythema at the site
• There is resistance on the plunger of the syringe
• There is absence or slowing down of free flowing infusion
• There is no blood return (if found in isolation should not necessarily be regarded as indication of a non-patent vein). NB, Drug solutions stored in the refrigerator may cause venospasm and pain if not allowed to reach room temperature before administration
Doxorubicin, epirubicin and mitozantrone have been reported to cause a venous flare reaction, sometimes accompanied by a local itch. Dacarbazine bolus and melphalan are known to cause local myalgia.

### 7.5 Management of extravasation

Several strategies for the treatment of extravasation injuries are described in the literature (including administration of antidotes and flushing out techniques). The evidence to support these strategies is inconclusive, the body of evidence being individual case reports.

The West of Scotland Cancer Network recently issued policy, guidance and tools to facilitate the management of chemotherapy extravasation in practice. This is available as a ring binder in all chemotherapy treatment locations and pharmacy departments where chemotherapy is prepared. This package contains all the information and individual drug management guidelines to manage an extravasation and should be used as a reference in practice.

Extravasation kits must be available and clearly visible in all areas where cytotoxic chemotherapy is administered.


**Immediate management of extravasation**

- Stop the infusion immediately but leave the cannula in situ
- Act promptly explaining to the patient what may have happened and call for assistance
- Withdraw as much of the drug from the cannula as possible
- Remove cannula
• Collect extravasation kit from clinical area (extravasation policy included within kit)
• Apply 1% hydrocortisone cream to the whole area
• Follow extravasation procedure for the specific extravasated drug (see Table 1). There are two main treatment methods for vesicant cytotoxic drug extravasations.
  o Spread and dilute (non-DNA binding vesicant drugs) use hot pack
  o Localise and neutralise (DNA binding vesicant drugs) use cold pack
• Mark circumference with an indelible pen (included in extravasation kit)
• Elevate the area
• For all suspected VESICANT extravasations arrange for the area to be photographed
• Inform medical team and arrange for a medical review
• Review the extravasation site hourly for 3-6 hours then as per medical instruction
• Complete the following documentation
  o Nursing records
  o Medical records
  o DATIX clinical incident report form
  o Extravasation report form
  o National extravasation audit form (complete on-line at www.extravasation.org.uk)
• Inform the Senior Nurse if the incident involves a vinca alkaloid. NHS Lanarkshire is required to report any extravasations involving vinca alkaloids to the West of Scotland Cancer Network.
• All vesicant extravasations of approximately 5 ml should be urgently discussed with the plastic surgery team at the Glasgow Royal Infirmary (Page plastic surgeon on call via GRI switchboard).

**Mixed Extravasations**

In the event of a mixed extravasation of agents from different classifications the following policy applies:

- The order of precedence for the different classification is Vesicant > Exfoliant > Irritant > Inflammatory
- For drugs of the same classification those requiring a cold compress take precedence over applying a hot compress – apply a cold compress.
- For mixed extravasations from drugs in different classifications, apply the temperature compression of the drug that takes precedence.
8. RECEIPT, STORAGE AND TRANSPORT

8.1 Receipt of SACT in Pharmacy

8.1.1 Pharmacy stores staff must be aware that a medicine delivered is cytotoxic and therefore the need for the safe handling and transportation of that medicine within the pharmacy department.

8.1.2 Pharmacy stores staff must receive training in the handling and transportation of cytotoxic SACT appropriate to their role.

8.1.3 Pharmacy stores staff must wear gloves when unpacking cytotoxic SACT from the medicine orders.

8.2 Storage of SACT in Pharmacy

8.2.1 SACT must be segregated from other products when the order is received. The outer containers should be clearly marked to identify the contents are cytotoxic. The outer containers must be robust and provide protection for the handler. No other medicines should be placed in these containers.

8.2.2 SACT must be transported directly to the appropriate aseptic department, dispensary or other storage area within the pharmacy.

8.2.3 SACT must be assigned a separate storage location in the pharmacy department. These locations must be clearly marked as being for cytotoxic medicines only.

8.2.4 If a spillage or breakage involving SACT occurs during goods receipt or distribution of products from the store, pharmacy stores staff should isolate the area and alert a pharmacist or technician immediately. The spillage must be dealt with as outlined in Section 10.
8.3  Transportation of SACT

8.3.1  From the Pharmacy Department to Wards/Clinical Areas

8.3.1.1 SACT prepared by the pharmacy department must be packaged to ensure no escape, leak or spillage during handling or transportation.

8.3.1.2 The packaging must be suitable for the product;
   o robust;
   o tamper evident where possible;
   o provides protection for the handler;
   o contains any leakage;
   o labeled to state the name and address of the pharmacy department and recipient ward/clinical area;
   o labeled with contact name, telephone number and written guidelines in the event of a spillage. The spillage guidelines should be in a sealed, waterproof cover in order that the information is still legible in the event of a spillage.
   o The container must also be labeled to identify the nature of the contents along with a cytotoxic symbol.

8.3.1.3 Individuals transporting SACT must be trained in the actions to be taken in the event of a spillage appropriate to their role, and the reporting of such an incident.

8.3.1.4 SACT must be received on the ward/clinical area by a member of staff. They must sign the reconciliation record to confirm receipt.

8.3.1.5 SACT must be stored in original packaging in a safe and secure area in the ward/clinical area if not for immediate use, following storage instructions on label. These storage areas for SACT must be separate from the storage of other medicines and must be clearly marked as being for SACT.
8.3.1.6 Where SACT is received from pharmacy marked ‘items to be refrigerated’ – these items must be stored in the ward refrigerator. The cold chain for these products must be maintained at all times.

8.3.2 Out with the hospital

8.3.2.1 SACT is classified as restricted material by the Royal Mail and must not therefore be sent by routine post. In exceptional circumstances, special arrangements may be made with the Royal Mail by contacting the Customer Service Centre.

8.3.2.2 Transportation of SACT between hospital sites must be undertaken by hospital trained drivers. Drivers must receive training in the handling and transportation of SACT appropriate to their role, including what they should do in the event of identifying a spillage or leaking package containing SACT medicines.

8.3.2.3 Packaging must be suitable for the product and robust enough to withstand normal conditions of handling and transport. SACT must be double bagged and sealed to minimize the risk of a damaged product leaking from the packaging. Protective bubble wrapping or polystyrene chips should also be used to minimize potential damage to the product by restricting movement within the final packaging. The cold chain must be maintained if appropriate.

8.3.2.4 Spillage kits must be available in the vehicles routinely used for the transportation of cytotoxic chemotherapy.

8.3.2.5 In exceptional circumstances SACT may be transported via taxis. The SACT must be appropriately packaged (see 8.3.2.2) and clear instructions given to the taxi driver on what to do if there is leakage or spillage.
9. WASTE DISPOSAL

9.1 Disposal of unused SACT, cytotoxic waste and associated equipment

9.1.1 Cytotoxic waste must be placed in dedicated rigid yellow sharps bins with purple lids, and must be identified with a ‘Cytotoxic Waste’ hazard warning.

9.1.2 NHS Lanarkshire clinical waste management policy should be referred to and local procedures followed for segregation and uplift of waste.

9.1.3 Pharmacy must be contacted directly if there are any unused cytotoxic drugs to be returned from the ward area. Cytotoxic drugs or contaminated equipment must not be returned to pharmacy in routine drug delivery containers.

9.1.4 Unused injections or infusions.
  • Contact the ward pharmacist who will arrange disposal.

9.1.5 Partly used preparations.
  • Double wrap in plastic disposal bags to ensure no leakage, then contact the ward pharmacist who will arrange disposal.

9.1.6 Punctured Infusion bags.
  • Where there is significant leakage it is recommended that staff deal with this as for a spillage as outlined in Section 10
  • Double wrap the infusion bag in plastic disposal bags and dispose of it in a cytotoxic waste container.

9.1.7 Completed infusions and injections.
  • Do not disconnect the giving set from the infusion bag.
  • Double wrap the drip tubing and empty infusion bag and place in a cytotoxic waste container.
• Syringes and needles should be put directly into a cytotoxic waste container and not left lying on any surface before disposal.

• To avoid the risk of aerosol formation contaminated needles, giving sets and tubing should be disposed of intact and not clipped or cut.

9.1.8 **Gloves.**

• Gloves and any other items that have been in contact with SACT should be put into a cytotoxic waste container.

9.1.9 **Re-usable equipment**

• Trays and other equipment should be washed with copious amounts of cold water followed by the usual procedure for disinfection.

**WASTE MUST NOT BE ALLOWED TO ACCUMULATE IN EITHER CLINICAL OR STORAGE AREAS**

9.2 **Disposal of Patient Waste**

9.2.1 Examination of the pharmacokinetics of cytotoxic agents indicates that the risk of occupational exposure does not end with drug administration. Excreta from patients receiving chemotherapy may contain residues of cytotoxic agents and should therefore be treated as a biohazard.

9.2.2 The period over which staff handling patient waste is at risk depends on:

• the particular drug involved.

• pharmacodynamic factors: dose, route of administration, and duration of therapy, renal and/or hepatic function.

• concomitant drug therapy, which may influence elimination rates.

9.2.3. As a general rule, the excreta from patients receiving cytotoxic drugs should be assumed to be hazardous for 7 days after the completion of treatment. Such patients should be clearly identified to ward staff.
9.2.4 It should be assumed that there will be a significant concentration of oral cytotoxic chemotherapy present in patients’ vomit for up to 2 hours after administration.

9.2.5 **Recommended precautions for staff / relatives caring for patients:**

- Wear appropriate protective clothing (aprons and nitrile gloves) when handling the faeces, urine or vomit of patients.
- All protective clothing should be treated as hazardous waste and disposed of in hazardous waste bags.
- If contamination of the skin, eyes or mucous membranes is suspected, the area should be rinsed thoroughly with copious amounts of water and then washed with soap and water.
- Scales should be used for urine measurement to avoid having to pour urine into a measuring jug. This avoids aerosol formation.
- Double sluicing of bedpans, vomit bowls and other items contaminated with waste materials should be carried out. Disposable items should be used where available. These should be treated as contaminated waste and disposed of appropriately.
- Contaminated linen / uniforms may pose a threat to laundry staff and should be bagged as hazardous. Heavily contaminated items may need to be incinerated.
- Male patients should be encouraged to urinate while sitting on the toilet to minimise splashing.
- The toilet lid should be replaced before flushing to minimise aerosol formation and patients should be encouraged to double-flush the toilet. This procedure should be followed for at least 48 hours after any cytotoxic chemotherapy administration.
- On discharge patients should be supplied with written information about what precautions should be taken at home. (see “Chemotherapy Safety At Home Leaflet”).
10. SPILLAGE

The risk of spillage should be minimised by having appropriate training for all staff involved in the preparation, transportation and administration of SACT. All cytotoxic spillages must be dealt with immediately and reported on a DATIX clinical incident form. A cytotoxic spillage kit must be used and protective clothing worn.

Spillage Kits

The location of cytotoxic spillage kits should be prominently displayed in all areas where SACT is administered and prepared. Patients receiving a slow infusion of SACT via a central line at home must also be supplied with some basic consumables and written instructions for managing spillage in the home environment.

MANAGEMENT OF SACT SPILLAGE

Spillage kits are located in each Ward and Day Unit where SACT is administered, and in each pharmacy where SACT is prepared.

Spillage box - .
(Cytotoxic Drug Spills Kit, Guest Medical Ltd, ORDER CODE H9612)

- Visimasks
- Aprons
- Chemotherapy gloves
- CT-Zorb Granules x 2
- Scoop & scrapers
- Surface wipes
- Yellow Disposal Bag
- Cytotoxic waste tape
- Instruction card / procedure
10.1 Spillage onto hard surfaces:

10.1.1 Act immediately.

10.1.2 Call for assistance and warn others about the area affected by spill to avoid them being contaminated.

10.1.3 Ask a colleague to bring you a spillage kit and disposable white absorbent towelling roll.

10.1.4 Put on appropriate protective clothing as per kit. Ensure two pairs of gloves are worn.

10.1.5 Pick up any sharp or broken material with scoop / scraper or forceps.

10.1.6 If the spill is liquid:

- Contain spillage by laying CT-Zorb granules over substance.
- Allow granules one to two minutes to absorb the fluid then use the scoop and scraper to collect the contaminated granules.
- Use absorbent toweling or surface wipes to mop up residual fluid by working from the outside of the spillage inwards.

10.1.7 If the spill consists of powder (pharmacy only):

- Contain spillage by carefully laying gauze swab over powder.
- Dampen gauze swab with water.
- Wipe up spillage. Use scoop / scraper if necessary.

10.1.8 Wash contaminated surfaces with copious amounts of lukewarm water.

10.1.9 Double bag all cleaning materials, then place in bag provided, ensure bag is sealed and dispose of in a cytotoxic waste container.

10.1.10 Wash hands thoroughly.

10.1.11 Alert the ward pharmacist.
10.1.12 Follow accident-reporting procedures by completing DATIX.

10.1.13 Order new spillage kits from pharmacy.

10.2 **Spillage onto clothing, bed linen etc.**

10.2.1 Wear protective clothing i.e. gloves, apron etc.

10.2.2 **Spillage in hospital:**

10.2.2.1 For smaller spillage (<10ml), treat as infected linen;

10.2.2.2 For larger spillage (>10ml), seal in yellow bag and send for disposal according to NHS Lanarkshire clinical waste management policy.

10.2.3 **Spillage in the home:**

10.2.3.1 For patients going home with an ambulatory chemotherapy pump, a member of the cancer care team will explain how to manage a spillage and provide the patient with a sharp safe bin and written information leaflet. For spillage at home, instructions in the Chemotherapy Safety at Home patient information leaflet should be followed.

10.2.3.1 For smaller spillage or leakage from infusion device, contaminated items should be laundered as usual, but as a separate load from other items;

10.2.3.2 For larger spillage, contaminated items should be packed in a leak-proof polythene bag or yellow bag out of spillage kit and brought to the hospital for disposal.

10.2.3.3 Patients should inform the centre that is treating them of the spillage as soon as possible to enable replacement medication arrangements to be made, if required.

10.3 **Spillage onto skin or eyes:**

10.3.1 Contamination of eyes:
10.3.1.1 Hold eyelids apart and flush for five minutes with eye wash solution e.g sterile water or 0.9% saline;

10.3.1.2 Seek medical attention and/or refer to Eye Clinic, if possible.

**10.3.2 Contamination of intact skin:**

10.3.2.1 Remove any contaminated clothing and wash skin with copious amounts of soap and water for five minutes.

**10.3.3 Contamination of broken skin or from a needlestick injury:**

Systematic absorption from such an injury will be negligible but local irritation may occur.

10.3.3.1 Remove any contaminated clothing

10.3.3.2 Encourage the area to bleed;

10.3.3.3 Wash skin with copious amounts of soap and water for five minutes;

10.3.3.4 Apply a dressing if required;

10.3.3.5 Contact Occupational Health Department.

10.3.3.6 Seek medical attention and/or refer to Dermatology Clinic if possible;

**10.4** In all cases of personal contamination by SACT, a DATIX accident/incident reporting form must be completed.

**10.5** Occupational Health Department must be informed of all DATIX incidents of this nature..
11. OUT OF HOURS

11.1 Prescribing and administration of SACT outwith normal daily working hours (9 am to 5 pm) is to be avoided. Prescribing and administration of bolus or infusional SACT outwith normal working hours is rarely indicated. It is appreciated that some oncological emergencies may require that SACT treatment is initiated immediately, or the chance of that treatment benefiting the patient would be significantly compromised.

11.2 The requirement for out-of-hours treatment should be reviewed by a consultant. “Emergency” SACT may be indicated for the treatment of a malignant condition known to be sensitive to chemotherapy which has presented as an emergency outwith the normal daily working hours.

Examples of such situations would include:

- Spinal cord compression by an exquisitely chemo-sensitive malignancy such as non-Hodgkin’s lymphoma, small cell lung cancer or germ cell malignancy;
- Significant life threatening organ compromise in a patient with a chemo-sensitive malignancy;

11.3 In these situations, the on-call pharmacist must be contacted in the first instance. The on call pharmacist will contact a senior cancer care pharmacist who will assess the situation and co-ordinate pharmaceutical verification and supply of treatment.

11.4 Cytotoxic chemotherapy must be verified, prepared and dispensed to the same standard out of hours as within normal working hours.

11.5 Administration of treatment must be carried out by a SACT trained nurse competent at administering vesicant cytotoxic agents.
11.6 It may be necessary to refer patients to the regional cancer centre for emergency treatment if local resources or expertise is unavailable to treat patients safely in line with CEL30 (2012).

11.7 The following SACT products are available in pre-filled, dose banded ready to use presentations.

- Cyclophosphamide injections
- Doxorubicin injections
- Epirubicin injections
- Fluorouracil injections
- Gemcitabine infusions
- Methotrexate injections
- Oxaliplatin infusions
- Vincristine infusions

11.8 SACT for emergency use must be prescribed by a level 1 prescriber, ie, a consultant haematologist or oncologist. They must document in the clinical notes that the chemotherapy was prescribed outside of normal working hours and was a necessary emergency treatment.

11.9 SACT may be required to be given as part of a planned treatment regimen outside normal working hours, eg, weekends. Pharmacy may be able to prepare doses in advance (stability permitting) for storage on the ward. Alternatively, it may be necessary to make arrangements to prepare chemotherapy during a weekend if the stability of the drug is too short.

11.10 If additional doses of SACT are required outside normal working hours for a non emergency planned in-patient treatment, (eg, leaking infusion or expired drug), it is usually acceptable to defer further treatment until pharmacy services are open. If the prescribing consultant considers that this delay would compromise the
patient’s condition then this would be managed as an emergency as detailed from 11.3 to 11.7.
12. **SACT ADMINISTRATION OUTWITH HOSPITAL SETTING**

12.1 It may be appropriate to provide some intravenous ambulatory SACT outwith the day units and wards. This can allow patients to remain at home or near to home whilst receiving treatment.

12.2 Specialist Oncology Services centre/units offering outreach or Near Patient Cytotoxic Chemotherapy (NPCC) have a team responsible for the care of patients receiving NPCC. This team includes consultant oncologist/haematologist, oncology nursing, oncology pharmacy and primary care representatives.

12.3 Patients may be treated within a regimen which has been approved through SACT management guidelines/clinical governance (Section 14) that can involve having part of their treatment at, or near to home. Such patients will be reviewed and supported within the hospital by suitably qualified nursing, pharmacy and medical staff, prior to discharge home.

12.4 SACT regimens with a high risk of adverse effects are excluded from NPCC.

**Continuous Infusional 5FU via Central Venous Catheter**

12.5 Patients who are on a continuous infusion of 5fluorouracil via a Central Venous Access device (mainly a PICC line - Peripherally Inserted Cannula) can have part of their treatment at home. Depending on their treatment regimen the 5FU pump may be required to change 48 or 96 hours after discharge from hospital by primary care staff. Alternatively, patients may return to the ward or day unit after the infusion period to have their pump disconnected or changed.

12.6 There are guidelines and procedures in place to support the Near Patient Cytotoxic Chemotherapy, ie.,

- Spillage and disposal
- Education and training
- Patient information
12.7 Patients will be discharged home with the appropriate supplementary equipment. This would include cytotoxic spillage kit, sharps bins, and equipment for primary care staff or competent patient/carer to disconnect, flush and re-dress the line.

12.8 Patients will receive full information in the form of verbal and written information regarding their ambulatory pump and dealing with any spillages that may occur (Section 10).

12.9 Patients, carers or community nurses will not be expected to prepare, reconstitute or administer any intravenous cytotoxic SACT drugs at home.

12.10 All ambulatory pumps will be connected to the patient’s PICC/CVC line within the hospital by a competent nurse.

12.11 Primary care staff or competent patient/carer who have attended the appropriate training and education from the hospital cancer unit will disconnect the SACT pump within the patient’s home.

12.12 Sharps bins will be returned to day unit or ward of issue for disposal.

**Continuous Intravenous Infusions**

12.13 Prior to insertion of their PICC line the patient will be informed of the procedure and complications that can be encountered with a PICC line.

12.14 The appropriately trained nurse will gain written consent from the patient.

12.15 It is not current practice to visit patients homes prior to PICC insertion, but there are specific questions that should be asked and documented prior to gaining consent:

- Do they have a telephone?
- Do they have running water?

12.16 If a patient does not have one of the above then it is the responsibility of the nurse that is consenting the patient to make arrangements to have their treatment as an in-patient. This would involve liaising with the bed manager and medical staff.
12.17 The following information is made available to the patient/carer and or community nurses:

- The name of the drug/dose/ and duration of the infusion will be labeled on the infusor pump
- Care of the PICC/Hickman Line and maintenance – leaflet available
- Potential problems with PICC line and troubleshooting guide
- Checking mechanism when in place
- Procedure if pump infuses too quickly or too slowly

12.18 The patient will be discharged home with the following:

- Spillage kit
- Cytotoxic disposal bins
- Dressings and flushing equipment
- Written information with emergency contact details on it

12.19 Guidelines and procedures are in place to support NPCC

12.20 Patients and Premises

Prior to discharge, nurse will ensure:

- Checklist on back of consent form is complete
- Spillage kit and cytotoxic disposal bins given to patient
- SACT/PICC referral form system in place with patients WHO status on this.
- Treatment choice – written information given to patient re PICC line and consent procedures prior to treatment and placing of line.
- Information on handling and wearing the pump is issued
- Information on managing spillage and pump malfunctions is issued

12.21 Administration - See Section 6
12.22 Support Staff

Hospital based nursing staff connecting a 5FU infusional pump to a PICC line will have received in-house training in the format of a competency programme and will have undertaken supervised practice. Evidence of training for each nurse must be kept by the cancer unit ward manager.
13. **EDUCATION AND TRAINING**

13.1 Training of all medical, nursing, pharmacy, portering, domestic and any other staff who handle cytotoxic drugs or cytotoxic waste is essential. Such staff should understand the potential hazards associated with cytotoxic drugs and be familiar with relevant procedures before being allowed to practice.

13.2 It is mandatory for all staff involved in the prescribing, verifying, preparing, issuing and administration of SACT to receive education and training appropriate to their roles.

13.3 All staff should be familiar with the NHS Lanarkshire ‘Guideline and Procedure manual for the Safe Use of SACT.

13.4 Staff prescribing, verifying, preparing, issuing, administering and witnessing administration of intrathecal SACT should be familiar with national guidance and local policy on intrathecal SACT and receive appropriate training (CEL 21 (2009) and CEL 30 (2012). Personnel involved in activities relating to the administration of intrathecal chemotherapy must be on the register of approved staff and must attend compulsory training every 2 years to remain on the register.

13.5 Although the training of staff will be the responsibility of the Heads of Professions, they may delegate the training to named medical, pharmacy and nursing trainers.

13.6 The nominated trainers should keep a record of the training needs and training delivered to their staff group. They must ensure training and education is reviewed in line with current evidence, eg, annual update training for nursing staff..

13.7 Up to date individual training records are required for all staff involved in the handling, prescribing, supply and administration of SACT with competency reviews. Training and/or competency records are held by individual department managers.
13.8 Staff must complete a local in-house training programme or a recognised accredited course.

13.9 Following training, all staff administering chemotherapy should be assessed and reviewed for competence according to local training programmes. Competence should be re-assessed and reconfirmed annually.

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

13.12 All portering staff involved in transporting cytotoxic drugs should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste. They should be familiar with the procedures for handling cytotoxic spillage.

13.13 Individual departments for portering and domestic staff should maintain a list or register of those staff attending training.

13.14 Each Division/Department should maintain a list or register of named nursing and medical staff who have been reviewed as competent to administer chemotherapy unsupervised and who may be able to act as an assessor/supervisor.

13.15 Staff will be deemed competent by the clinical educator, chemotherapy team leader or a named assessor/supervisor.

13.16 For education, training and competencies related to oncology nurse/pharmacy led SACT services please refer to Section 4 Prescribing Guidelines.
NHS Lanarkshire Training Programmes

Nursing

- Nursing staff should complete an accredited course prior to the handling and administration of SACT.
- Safe handling practices included in orientation package for nurses in the unit.
- The Safe Handling Policy advertised and main points laminated and displayed at ward level in treatment and staff rooms.
- Lead SACT Nurse should list the names of staff who will administer SACT and record the dates of attendance at the mandatory updates. The list should be kept as part of the Health and Safety.
- Formal presentation of the Safe Handling Policy on a yearly basis with certification. This is open to all disciplines.
- Compulsory attendance at an annual Mandatory SACT Update for all nursing staff involved in the administration and handling of SACT.

Pharmacy

- Pharmacy staff involved in handling of SACT must complete the in-house vocational safe handling training schedule.
- Pre-registration pharmacists must complete basic aseptic and safe handling training as part of their nationally agreed training programme.
- Pharmacy technicians preparing SACT under aseptic conditions must complete the local aseptic training programme for preparation of non cytotoxic drugs before training is started training for the preparation of cytotoxic medicines
- Cancer care pharmacists must complete the national vocational stage 3 pharmacist training developed by the Scottish Oncology Pharmacy Practice Group. The training programme consists of a core module to be completed by all pharmacists and a selection of optional tumour specific modules to be completed where relevant to current practice. The pharmacist must be deemed competent by a senior oncology
pharmacist mentor before being allowed to verify prescriptions for SACT unsupervised.

**All staff groups**

- Compulsory biennial assessment and demonstration of competency for all staff groups involved in any part of the administration of intrathecal chemotherapy as laid out in CEL 21 (2009) and CEL 30 (2012).

- An annual audit of practice against the guidelines set out in CEL 30 (2012).
14. QUALITY AND RISK MANAGEMENT

14.1 Clinical Governance

14.1.1 NHS Lanarkshire Board and Chief Executive has explicit corporate responsibility for clinical performance across the Health Board. The Chief Operating Officer of the Acute Division has responsibility for the safe use of SACT within the acute settings and this has been delegated to a Lead Clinician for SACT Services.

14.1.2 In collaboration with a multi-disciplinary sub group of the NHS Lanarkshire SACT Group, the Lead Clinician for SACT Services has developed clear policy guidance for the safe use of cytotoxic chemotherapy.

14.1.3 This policy guidance has been developed in line with the requirements set out in the Scottish Executive letter CEL 30 (2012).

14.1.4 The guidance includes SACT clinical protocols, training arrangements, prescribing, dispensing and administration guidance and all other aspects of service delivery relating to the safe use of cytotoxic SACT.

14.1.5 All clinical management guidelines and SACT protocols must be approved by the West of Scotland Cancer Network Prescribing Advisory Group and the NHS Lanarkshire Area Drug and Therapeutics Committee and funding approved before they become an established authorised treatment.

14.2 General Principles for Handling Cytotoxic Chemotherapy

14.2.1 Cytotoxic medicines are hazardous as defined by the Control of Substances Hazardous to Health Regulation 2002 (COSHH).

14.2.2 In line with COSHH regulations and the health and Safety control book, staff working with carcinogenic substances are made aware of the risks and circumstances under which they may be exposed to the carcinogen.
14.2.3 All staff must handle cytotoxic medicines in accordance with local safe handling procedures as to minimise exposure since little is known about the consequences of repeated exposure to small quantities of cytotoxic drugs.

14.3 Minimising Occupational Exposure

The following guidance applies for all staff handling cytotoxic drugs during administration of treatment, handling of patient waste and cleaning of spillage.

14.3.1 Exposure to cytotoxic drugs can cause local irritant reactions and the effects of exposure may be cumulative. It is therefore important that health care professionals take every precaution to protect themselves and others from exposure to drugs.

14.3.2 The correct use of personal protective equipment can shield staff from exposure to cytotoxic drugs and minimise the health risks.

Potential Routes of Exposure

14.3.3 Clinical and non clinical workers may be exposed to cytotoxic drugs by performing a variety of activities, eg, when they create aerosols, generate dust, clean up spills or touch contaminated surfaces during the preparation, administration or disposal of drugs.,eg,

- Expelling air from syringes filled with hazardous drugs (creation of aerosols – exposure to skin, airways, eyes)

- Administering hazardous drugs by intramuscular, intraperitoneal, intra-cavity, subcutaneous or intravenous routes (contaminated syringe surface/ leaking syringes)

- Priming IV giving sets with cytotoxic solution at the patient’s bedside

- Handling body fluids or body-fluid contaminated clothing, dressings, linens and other materials
• Handling contaminated wastes generated at any step of the preparation or administration process
• Decontaminating and cleaning drug preparation or clinical areas
• Transporting chemical or hazardous waste containers
• Removing and disposing of personal protective equipment after handling hazardous drugs or waste

14.3.4 Protective Equipment recommended for Administration of Cytotoxic Drugs:
• NHS Lanarkshire uniform policy must be adhered to
• Nitrile gloves
• Plastic Apron
• Eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavity administration.

14.3.5 Protective Equipment for handling waste from patients receiving chemotherapy:
• Nitrile gloves
• Plastic Apron

14.3.6 Cuts and scratches on the skin should be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged.

14.3.7 No glove material is completely impermeable to cytotoxic drugs. Permeation of cytotoxic drugs depends upon glove material, thickness and integrity, the properties of the drug/solvents and the contact time with the drug. Since no glove material will provide unlimited protection from cytotoxic drugs and permeability increases with time, users should minimise contact with contaminated and potentially contaminated objects and change their gloves regularly.
There are no definitive guidelines of the type of gloves that should be used for administration or handling cytotoxic waste, however, latex or nitrile gloves are recommended. Staff who have a latex allergy must wear hypoallergenic or nitrile gloves.

Nitrile gloves must be worn at all times when contact with cytotoxic drugs or waste products is possible.

Change gloves regularly and always change between patients.

Gloves should be changed immediately if damage or contamination occurs.

Non-powdered gloves must be used as the powder may absorb cytotoxic contamination.

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

**Eye and face protection**

Protective eye wear such as goggles, safety glasses or visors is relevant and may be worn when administering chemotherapy via specific routes particularly intracavity administration and when cleaning up cytotoxic spillage.

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

**Respiratory Protection**

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

However, masks should be worn when dealing with a cytotoxic spillage.

Surgical masks only act as a physical barrier and do not offer protection against aerosol inhalation.

**Disposal of Personal Protective Equipment**

All personal protective clothing should be treated as contaminated and disposed of by placing it in bag for incineration. See NHS Lanarkshire waste management policy.
Pregnancy, planning pregnancy and breast feeding

The reconstitution and administration of cytotoxic agents in pregnancy is a large and complex issue. Nevertheless, despite conflicting results reported throughout the biomedical literature, it is generally agreed that there is some evidence to raise concern that there is an occupational risk to staff exposed to cytotoxic drugs. Therefore recognised steps should be taken to reduce or minimise exposure to these substances in a working environment. This guidance and the policies contained in it are designed to reduce this risk of exposure.

While the Royal College of Nursing suggests that pregnant women should not be exposed to cytotoxic agents in the first trimester of pregnancy, there is no conclusive proof that foetal damage occurs when pregnant staff handle cytotoxic agents. Much of the data is based on studies carried out in the 1980’s when the use of personal protective clothing and safe handling techniques was not well established.

However because of the uncertainty and emotive nature of this issue, these concerns should be recognised. Therefore pregnant women, staff planning pregnancy or women who are breast-feeding should be entitled to transfer to duties that do not involve handling cytotoxic drugs or waste products. Individuals should have full access to information and counselling through Occupational Health. A medical certificate should support this concern. It may not be possible to follow this recommendation rigorously because many women are not aware of pregnancy until well into the first trimester.

14.4 Quality Assurance and preparation of Cytotoxic Chemotherapy

14.4.1 The Pharmacy Aseptic Preparation Service provides ready to administer unlicensed injectable formulations prepared in line with NHS quality guidelines. The basis for NHS quality guidelines governing pharmacy unlicensed preparation is “Aseptic Dispensing for NHS Patients: A guidance
Document for Pharmacists in the UK” (Farwell Report). The recommendations of the Farwell report have led to the development of more detailed guidance in the form of “The Quality Assurance of Aseptic Preparation Services”. This provides further guidance on the standards expected and how to achieve them. As with all quality systems it is also necessary to validate compliance with the standards. Compliance is checked by external audit using the nationally agreed audit tool developed by the Scottish Aseptic Service Specialist Interest Group and Quality Assurance Specialist Interest Group.

14.5 Risk Management and Adverse Incident Reporting

14.5.1 In accordance with the requirements of the Health and Safety Control Book for Managers, control of substances hazardous to health (COSHH) assessments must be completed at departmental/ward level for all cytotoxic chemotherapy used within the area.

14.5.2 This information will be readily accessible to staff and will be subject to audit as part of the annual Health and Safety Control Book audit process.

Adverse Incident and Near Miss Reporting

14.5.3 The DATIX clinical adverse incident reporting policy must be adhered to for the reporting of all adverse incidents and/or near misses relating to cytotoxic chemotherapy.

14.5.4 Staff are required to report any incidents or circumstances where events arising during clinical care could have or did lead to unexpected or unintended harm, loss or damage.

14.5.5 A key objective of the adverse incident reporting system is to learn from events and minimise the risk of re-occurrence.

14.5.6 DATIX reporting forms must be used to report all incidents of this type.

14.5.7 All reports must be forwarded to the appropriate line manager for review and grading.
14.5.8 Significant incidents should be brought to the attention of the Cancer Divisional Management team.

14.5.9 Where an incident adversely affects the quality or safety of a patient’s care, discussions should take place with the Consultant in charge of the patient’s care and the Associate Medical Director for Cancer Services regarding communication of the incident to the patient and, with the patient’s consent, any relatives.

14.5.10 All incidents must be subject to an appropriate level of local investigation and causal analysis and, where relevant, an improvement plan should be agreed.

14.5.11 Consideration should be given to applying the NHS Lanarkshire Critical Incident Review using Root Cause Analysis Guidance to any clinical, non-clinical near miss or adverse incident, complaint or claim rated high/very high using the QIS Risk Assessment Matrix.

14.5.12 In all such cases, investigations should be led by nominated staff with status and knowledge (appointed by the GM) to make authoritative recommendations which should be carried out as soon after the event as is practical. Incident investigations should:

- Identify root causes
- Identify underlying contributory factors
- Learn from incidents and make recommendations
- Implement improvement plans to help prevent or minimise recurrences, thus reducing future risk of harm
- Satisfy mandatory and reporting requirements.

14.5.13 Investigative reports should include as a minimum a reporting template providing:

- Context (statement of problem(s); patient details, including co-mobility, stage of care etc.)
• How did the incident happen (immediate cause(s))?
• Why did it happen (underlying/root cause(s))
• What preventative action was taken or proposed?
• What impact did the incident have (on the patient(s) and the organisations, including medical attention, increased length of stay and level of care, impact or key objectives (e.g. Waiting lists) and financial costs)?
• What factors did or could have been minimised the impact of the incident?
• What were the recommendations for action?

14.5.14. In all instances, further guidance on the reporting of adverse incidents can be obtained from the NHS Lanarkshire Clinical Incident. Reporting Policy.
15. **ACUTE ONCOLOGY**

To deliver safe stratification of care to the most appropriate area of requirement for each individual patient who is experiencing an unscheduled event, related to treatment toxicities or symptoms suggestive of disease burden and/or progression.

15.1 **Aims**

- Accelerated care of cancer patients with complications of disease and/or treatment – early recognition, improved treatment, rapid referral back to specialist teams, early involvement of palliative care teams, early discharge.

- Appropriate investigation of patients with cancer of unknown primary (CUP) in line with the Regional Guideline for Investigation, Diagnosis and Management of Patients with Malignancy of Undefined Primary Origin.

15.2 **Model**

- National Cancer Treatment Helpline (CTH) referrals will be directed to the cancer nurse ‘On call’ for Unscheduled care. The nurse will call the patient back to further assess ensuring the area of review is more refined and stratified to meet the patient’s needs.

- Medical Oncology ANP will work in partnership with Emergency Care Department, Medical Assessment and Ambulatory Care Units, GP Assessment Bays, Oncology Day Units, Oncology Outpatient Clinics and the ‘On Call’ Cancer Nurse for the CTH to assess and manage treatment toxicities. This will also enable advice and recommendations to ensure all emergency reviews are managed in an efficient manner allowing early commencement of appropriate treatment using the correct treatment pathway.

- Input from the ANP will ensure the advice is appropriate to the patient’s “level of risk.”

- Improved access for standardised advice.
• Improved education through reflective practice, continuous measures/audit and collaborative working through partnership working.

• Enhance communication between teams of all unscheduled events providing documented evidence of actions and outcomes with clear recommendations pertinent to each individual patient care needs.

• Improve ‘follow up’ of patients following an unscheduled event thus giving the opportunity to move unscheduled events into a planned care event.
16. REFERENCES

3. West of Scotland Cancer Network Framework for delivering nurse/pharmacy led chemotherapy
4. NHS Lanarkshire Guideline for the Management of Healthcare Waste
5. BOPA Standards for Clinical Pharmacy Verification of SACT, January 2010
7. CEL 21 – Safe Administration of Cytotoxic Chemotherapy – Scottish Government (June 2009)
8. CEL 22 – Safe Administration of Vinca Alkaloids – Scottish Government (June 2009)


23. Health and Safety Executive. Safe handling of cytotoxic drugs. *Information sheet MISC615 HSE 09/03*.


