West Midlands Systemic Anti-Cancer Therapy (SACT) Management Policy for Adult Patients
v4.0

West Midlands Cancer Alliance
Expert Advisory Group for SACT

West Midlands Cancer Alliance

This sheet is to accompany all documentation agreed by the West Midlands Clinical Network Expert Advisory Groups. This will assist the Clinical Network to endorse the documentation and request implementation.

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Key Amendments to Document

Version	Date	Amendment	By
v.01	19/07/2017	Review of draft	EAG
v.02	11/11/2017	Formatting changes accepted and wording changes around closed systems made	Rachel Powell
v3.0	17/04/2018	Agreed changes and signed off	EAG
V4.0	02/11/ 2021	General review of policy on renewal	EAG

Contents

1.0 SCOPE

This policy was developed and clinically verified by the West Midlands Expert Advisory Group for Systemic Anti-Cancer Therapies (SACT). This guideline has been developed to support the handling, prescribing and administration of SACT agents for adult patients within the West Midlands Network.

Note: Please refer to separate individual trust policy for guidance on intrathecal drug administration.

2.0 INTRODUCTION

SACT are potentially hazardous substances, which are administered for two purposes:

- Treating cancers
- Managing non-malignant conditions.

SACT have the potential to cause serious toxicity; therefore, there must be appropriate assessment of clinical and non-clinical risks. Local toxicity due to accidental contamination includes dermatitis, inflammation of mucous membranes, allergic reactions, blistering and in extreme cases tissue necrosis. Long-term hazards are less well defined too but some drugs can be teratogenic, mutagenic or carcinogenic and thus pose a potential hazard to staff involved in their preparation and administration. The risks are minimised however, if treatment is delivered:

- By trained expert staff working within agreed policies, procedures and guidelines
- In an unhurried atmosphere
- In a ready to administer form in order to minimise exposure to administering staff.
- Utilising all available protective measures
- With adequate checks on patient safety at every stage

3.0 STATEMENT OF INTENT

This policy is intended to maximise safety for both adult patients and practitioners involved in the process of SACT administration. **It must be applied to all administration routes** (except intrathecal); oral, parenteral, (subcutaneous, intramuscular and intravenous), topical, intracavity (pleural and peritoneal) and intravesical. Local procedures and guidelines must be developed for all routes of administration to support this document.

4.0 DEFINITIONS

For the purpose of this policy SACT refers to cytotoxic drugs, monoclonal antibodies, cancer immunotherapy and enzyme therapy.

5.0 CHEMOTHERAPY PRESCRIBING

5.1 Holistic Assessment

Prior to a course of SACT an individual holistic assessment of the patient's and carers (if applicable) needs must take place. It must be undertaken by a Registered health professional and occur separately from and after any consultations at which the treatment plan is agreed with the patient. For each patient, this must occur, prior to starting a new course of SACT (whether it is their first course or they have previously undergone a course or courses of SACT). This should incorporate a review of the patient and carers physical, social, psychological, emotional and spiritual needs (NHS England 2014).

5.2 Prescription Writing

SACT regimens should routinely be prescribed on the basis of a written recognised treatment algorithm, protocol and treatment plan (NPSA 2008, NHS England 2014). The protocol must be readily available and should have taken into account the toxic effects of medicines used. In the rare instance that drugs do not fulfil the above criteria, then refer to network deviation policy (to be written).

SACT prescriptions must be, where available prescribed electronically using an electronic prescribing system. In the rare event that this is not available they must be

- Written or typed in indelible black ink.
- Legible.
- Unambiguous.
- Dated.
- Signed in full (not initials), With prescriber's printed name (and GMC/PIN number if Trust policy states this is a requirement of prescribers)
- Prescribed on the designated chemotherapy prescription form or prescribed on the correct pre-printed prescription forms (where available).
- Written by authorised Consultants, senior medical staff authorised to do so and Nurse/Pharmacist Non-Medical Prescribers who have completed the agreed training programme.

5.3 Initiation of SACT

The first cycle of a course of SACT must only be prescribed and approved by a Consultant Haematologist/Oncologist. An Associate Specialist or post FRCR trainee /Senior Haematology SpR (years 4 or 5) following documented discussion with the named Consultant or deputising Consultant may also prescribe and approve the first cycle of treatment. It is their responsibility to ensure that all SACT and any 'regime specific' treatments required for individual patients to be correctly prescribed.

5.4 Checks prior to the Prescription of the First Cycle

The prescribing doctor must ensure that the following information has been checked prior to prescribing the first cycle of SACT:

- History of specific diseases or conditions affecting fitness for anti-cancer treatment. This includes that the minimum physical and investigational requirements have been met;
- Performance status;
- Prior history of SACT;
- Current patient medication affecting SACT;
- That informed consent has been obtained.
- Regimen is in accordance with departmental protocols;

- That a holistic assessment has been carried out or is scheduled (NHS England 2014).

5.5 Subsequent Cycles/Dose Changes or Discontinuation of Treatment

Medical Staff above foundation/ Nurse/Pharmacist Non-Medical Prescribers that have completed a training programme may prescribe subsequent cycles. Changes of dose or cessation of therapy may only be undertaken after discussion with the named prescriber and a record of discussion documented in the patient's health care records.

5.6 For patients who are admitted to hospital mid-way through a cycle of oral SACT

Treatment must not continue to be prescribed or administered until they have been reviewed by the Haematology/Oncology Consultant or relevant team member.

5.7 Route of Administration

The prescription must clearly and unambiguously state the intended route of administration for all drugs.

5.8 Verification by a Pharmacist

- All SACT prescriptions must be clinically verified by a Pharmacist who then signs / electronically authorises the prescription.
- SACT will only be released on receipt of an authorised electronic or written, signed prescription.
- Dose changes within 6% of the prescribed dose i.e. due changes in body surface area/ weight/ accurate measurement may be changed at the discretion of the clinical pharmacist. This must be documented within the clinical records.

- Staff verifying SACT must have access to information in the written protocol and treatment plan from the hospital where treatment is initiated and advice from a pharmacist with experience in cancer in that hospital.

- Where appropriate the pharmacist must ensure that the patient is aware of the required monitoring arrangements (NPSA 2008)

5.9 Dispensing

Staff dispensing SACT should be aware of safe handling requirements – see section on safe handling of SACT below.

5.10 Storage of SACT

- All SACT must be stored in a locked designated cupboard/fridge in the designated anticancer treatment areas. This must be stored separated from other medications.

- Some intravenous products require protection from light and must be stored in the light protective wrapper supplied by pharmacy. This must also be kept over the infusion bag during administration.

- Labels must be checked carefully to see if the drug needs to be stored in the fridge or at

room temperature.
- Staff food or drink **must not** be consumed or stored in areas of SACT preparation or administration.

5.11 Electronic Prescribing

All trusts administering SACT should be using an electronic prescribing system which:
- Enables electronic prescribing using approved protocols
- Should have replaced manual prescriptions as the default method for SACT prescribing
- Provides an auditable record of SACT, encompassing the national SACT dataset requirements
- Enables data extraction using Business Objects / Data Warehousing
- Allows interfacing between and integration of: patient demographics, laboratory test results, and dispensing, and there should be a procedure for exceptional manual entry of laboratory test results, and manual patient registration onto the system.

There should be an SOP for the use of the system which includes:
- Selection of suggested new variations to the system's use, including new regimens and/or modifications of regimens.
- The validation of the system's use with regard to individual regimens or modifications of regimens or protocol variations prior to their being first released for prescribing to patients including
- validation of the system protocol against the local, agreed treatment protocol;
- Validation of any drugs new to the system, included in the protocol.

6.0 ADMINISTRATION OF SACT

6.1 Designated Areas

Intravenous SACT must only be administered in designated areas unless it is not possible to transfer the patient to a designated area, this must be in agreement with the Lead Chemotherapy Nurse and Head of Department.

A list of designated areas must be kept and maintained by the lead chemotherapy nurse.Initiation and administration of day or inpatient cytotoxic chemotherapy must whenever possible be undertaken within the departments normal working hours since the danger of error multiplies outside this period. The exceptions are:

- Continuous infusions.

- Regimens where SACT is administered for more than 5 consecutive days.
- Timed SACT.
- SACT administered more than once a day.
- Intravesical chemotherapy that needs to be administered within six hours post-surgery.
- Emergency SACT.

Each designated area must have a process in place to deal with an unexpected event that may delay the completion of treatment beyond normal working hours to ensure that treatment can continue in a safe manner.

Designated areas should always have available:
- Regimen details as per list of treatment protocols for regimens in use
- Equipment for the management of emergencies of: anaphylactic shock, extravasation of

cytotoxics, cardiac arrest, spillage of cytotoxics
- A separate and identified area for tasks involved in preparation and delivery of treatment and locked temporary storage as specified above.

(NHS England 2014)

6.2 Checks Prior to Administration

The patient's fitness for treatment as well as all blood tests and relevant results/investigations/appropriate venous access for the treatment being administered as identified by the specific regimen must be reviewed by the doctor/nurse/pharmacist before administration occurs (RCN 2010).

6.3 Verification of the Patient

Active patient identification is essential at all stages of the checking procedure. Prior to administration of SACT, the patient must be asked to identify him/herself and to provide their date of birth and hospital number or address must be checked against their systemic anti-cancer prescription chart and their identity bracelet. This must be an active not a passive response unless the patient does not have the capacity to identify themselves (see local Trust guidance for identification of patients without capacity.)

6.4 Verification of a Patient's SACT

To verify a patient's SACT, for each drug:

- The name of the drug and dose must match exactly with that prescribed on the drug chart or prescription.
- The name of the drug must correspond exactly with the regimen recorded within the patient's health care records.
- The dose corresponds with the dose calculation
- Correct diluent and diluent volumes have been used
- The drug is to be administered via the route intended.
- The drug is to be administered in the correct sequence as prescribed.
- The drug will not expire before administration is completed. Note: Pharmacy must be consulted in individual cases where there is a possibility that the drug may expire before administration is complete.

- The details on the prescription chart match with the patient's identification bracelet.
- Any dose or schedule modification must be documented clearly, with reasons for changes, in the patient's health care records.
- Supportive drugs have been given as per prescription
- Critical test results have been have been checked
- Minimum monitoring requirements as per protocol have been met
- Response assessment has been performed as per regimen and treatment intention
- Patient's most recent weight must be checked against the prescription and height verified.

(NHS England, 2014)

Note: If there are any discrepancies do not proceed and seek advice from a senior colleague or pharmacist.

6.5 The Use of Drug Delivery Devices

Drug delivery devices used in the administration of SACT are infusion pumps and elastomeric

devices.

The manager of each clinical area is responsible for ensuring that:

- All chemotherapy nurses are trained and assessed as competent to operate any devices used to deliver SACT in an accurate and safe manner and that staff who have not undertaken specific training are aware that they must not use that item of equipment. The manager is also responsible for ensuring that records of staff training are maintained.

- The correct drug delivery device is used for the correct purpose/regimen of treatment/task.
- Reporting any deterioration or change in the drug delivery device performance or condition, which leads them to suspect that the accuracy or precision of the device may be in question,

- Ensuring that the device is used in a suitable way, under proper operating conditions to make sure that accuracy is maintained.
- Ensuring that it is reported as a clinical adverse event in the event that the device is found to be out of calibration or not working as per manufacturer instructions if in use.
- All drug delivery devices are suitably controlled, maintained and calibrated, and that records of maintenance are kept.

7. INTRAVENOUS SACT

7.1 Administration of treatment MUST be stopped if:

- There is any doubt about the checks that have taken place
- The patient requests the treatment to stop
- The patient demonstrates side effects or complications, particularly signs of anaphylaxis or extravasation,
- The equipment fails to function properly

7.2 Using a peripheral cannula:

- Select an appropriate sized none ported cannula
- Select an appropriate vein (avoiding use of the ante-cubital fossa) and place a waterproof and absorbent towel under the chosen limb.

- Cannulate the patient according to Trust guidance.
- Check the patency of the cannula in the following ways:
    - Acceptance of free flowing compatible infusion fluid
    - Gently applying negative pressure by pinching the infusion set and ensuring that a back flow of blood is observed
    - Lowering the bag of infusion fluid and ensuring that a back flow of blood is observed
- Ensuring that the site is not painful for the patient and that there is no evidence of redness or swelling at the infusion site. Document gauge, position and number of attempts to cannulate.

7.3 Using a central venous access device (Port-a-Cath, PICC Line, Hickman Line):

Access central venous access device (CVAD) ensuring that guidelines for insertion, care and

management of CVADs and guidelines for administration of intravenous drugs are followed – refer to Network Guidelines for the care of Central Venous Access Devices.

7.4 Bolus intravenous SACT:

Either by using the injection port of an infusion set or secondary infusion line of an infusion pump:

- Administer each syringe of drugs in the correct sequence as prescribed,

- Ensure that the treatment is administered at the correct rate ensuring the intravenous route is patent throughout the administration period by either using the methods as described above as a minimum every 5mls or by monitoring the pressure setting on the infusion pump and ensure that the cannula site is checked on a regular basis.

- Ensure the patient is aware to tell the administering nurse if they feel any pain or discomfort at the cannula site or distant to the cannula site throughout the administration period.

- After the administration of each drug ensure that the line is flushed with at least 20mls of a compatible infusion fluid.

7.5 Infusional intravenous SACT:

- Ensure correct administration equipment and filter is selected for therapy
- Always change infusion bags at waist height unless a closed system is being used using a plastic tray and/or a trolley to avoid contamination if the intravenous bag is accidentally punctured.
- Ensure the intravenous route is patent using the methods as described above throughout the infusion period.
- Ensure the drug is running to correct prescribed flow rate. If using an infusion pump, the rate, volume and pressure must be set and checked as per Trust Policy.
- Ensure the patient is aware to tell you if they feel pain or discomfort at the cannula site or distant to the cannula site throughout the administration period. If at any time redness, swelling or pain occurs around the infusion site whilst drugs are being administered, the administration/infusion should be stopped and the Network Guidelines for the Management of Extravasation be initiated.

- After the administration of each drug ensure that the line is flushed with at least 20mls of a compatible infusion fluid.

7.6 Continuous infusional anti-cancer treatment:

- Patient should have Central Venous Access Device in situ.

- Ensure that the correct Infusion Device is used as per the prescription.
- Ensure the drug is running to correct prescribed flow rate. If using an infusion pump, the rate, volume and pressure must be set and checked by the 2 health care professionals who have checked the drugs.

- All staff using infusion devices must be trained and assessed as competent to do so.
- Ensure that patient has been given instructions on the use of the infusion device and the action to be taken should any alarm or fault occur, including telephone contact information After the administration of each drug ensure that the line is flushed with at

least 20mls of a compatible infusion fluid.

- At the end of treatment, remove the intravenous device, and cover with sterile gauze and apply digital pressure until bleeding stops, or flush central venous access device as per guidelines. Apply an appropriate sterile dressing. If patient is receiving treatment by an ambulatory pump, they should be advised on how to observe that the pump is infusing and to use contact numbers in case of any leakage or spillage.

7.7 Vesicant Drugs

Vesicant drugs should be administered first if giving drugs in combination and it is ideal to administer vesicant drugs into a newly sited cannula, if this is not possible the member of staff must be confident that the cannula is patent before proceeding with any infusion of treatment.

If there is any concern that the drug has extravasated, please refer to the Network guideline for management of extravasation.

For Adults only - VINCA ALKALOID DRUGS MUST BE administered in a 50ml mini infusion bag of Sodium Chloride 0.9% via a free flowing infusion over 5 -10 minutes as prescribed. The nurse MUST stay with the patient and observe the infusion site throughout the infusion (NPSA/2008/RRR04).

7.8 Administration of Intramuscular Anti-cancer Treatment

(Vesicant drugs must never be administered via this route)

- Platelets must be checked prior to administration and should usually be >50x10^{9}/L for an intramuscular injection.
- Attach a 21-23 gauge needle to the syringe containing the anti-cancer treatment.
- Clean injection site using an appropriate skin cleansing agent.
- Administer drug using a z-track technique.
- Rotate sites of administration to prevent local irritation.

7.9 Administration of Sub-Cutaneous Anti-cancer Treatment:

(Vesicant drugs must never be administered via this route)

- Attach a 23-27 gauge needle to the syringe containing the anti-cancer treatment.
- Clean injection site using an appropriate skin cleansing agent
- Administer drug into the subcutaneous tissue as per manufacturer's instructions.
- Rotate sites of administration to prevent local irritation.

7.10 Administration of Oral SACT

- The health professional dispensing tablets must use a no-touch technique. Gloves must be worn if touching is unavoidable. Hands must be washed thoroughly before and after administration.
- Patient must swallow tablets or capsules whole do not crush tablets or break open capsules. If crushing/breaking open tablets/capsules are essential, advice must be sought from pharmacy. Do not use any tablets or capsules if there is any loose powder or liquid present in the container – inform pharmacy and request a replacement.

- If a tablet is dropped it should be placed in a bag and returned in original box to hospital at their next visit along with any unused medication
- Patient receiving oral SACT must be given advice of safe storage, handling and disposal of their SACT.

7.11 Extravasation of SACT

Many systemic anti-cancer agents have an irritant, vesicant or allergenic action and cause local damage to skin and mucous membranes. For many anti-cancer drugs, extravasation (injection into extra- vascular tissue) can have serious consequences with permanent tissue damage, regardless of the efforts made to rescue the situation. Every effort must be made to prevent this occurring during the administration of SACTs. Please refer to the Network Guideline for management of Extravasation

7.12 Minimising Wastage

In order to minimise wastage, unused prepared treatment that is no longer required must be returned to the Pharmacy as soon as possible.

- To ensure safe and proper storage conditions.

- To maximise the potential for re-issue by the Pharmacy
- The Pharmacy must be informed of the reason(s) for return.

It must be returned to pharmacy in the identified containers designated for the safe transport of SACT and labelled "Cytotoxic" following the same procedure for transporting SACT from pharmacy.

8.0 RISK ASSESSMENT AND MANAGEMENT

8.1 Risk Assessment

Risk assessments must be carried out in conjunction with local Trust policies and procedures and updated annually. A designated person in each Trust who has been trained in risk assessment techniques must, in areas where SACTs are used, assess the risks and take suitable precautions necessary (Health and Safety Executive (HSE), 2014)

8.2 Risk Management

An incident/adverse event form / Datix must be completed in the event of any near miss, error or extravasation injury. Where appropriate, this must include an agreed action plan which is implemented and evaluated. Information relating to these must be collated by a designated individual within each Trust and discussed/minuted at the local SACT group.

8.3 Safe handling of SACT

The toxicity of cytotoxic drugs means that they can present significant risks to those who handle them. Occupational exposure can occur when control measures are inadequate. Exposure may be through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and needle stick injuries resulting from the following activities:

- drug preparation
- drug administration
- handling patient waste
- transport and waste disposal, or
- Cleaning spills

Inadequate control measures could lead to;

- Abdominal pain, hair loss, nasal sores, vomiting, and liver damage
- Contact dermatitis and local allergic reactions.
- Foetal loss in pregnant women and malformations in the children of pregnant women
- Alterations to normal blood cell count
- Abnormal formation of cells and mutagenic activity or mutations forming

(HSE 2014)

8.4 Minimising Exposure

Cytotoxic drugs are hazardous substances, as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). Each Trust must undertake a COSHH assessment. This assessment will detail how to minimise exposure. This includes:

- Use of totally enclosed systems where reasonably practicable
- Adopting safe handling techniques
- Wearing protective equipment when dealing with SACT particularly in the handling of syringes, infusion bags, infusion devices and infusion tubing containing SACTs
- Ensuring staff are appropriately trained on the risks and precautions to take

8.5 Handling Vomit and Excreta

In addition to the risk of carrying bacteria or viruses, blood, vomit and excreta of patients receiving SACT may contain measurable levels of cytotoxic drugs and their metabolites. Staff must wear appropriate Personal Protective Equipment (PPE), when dealing with vomit, urine or stools. Hands must be washed thoroughly afterwards. Disposable bedpans, urinals and vomit bowls should be used or these items be double sluiced.
Patients must be advised on the safe handling and disposal of vomit and excreta

8.6 Management of Accidental Anti-Cancer Treatment Contamination and/or Spillage

In the case of spillage, accidental contact with SACT or needle stick injury please refer to the SACT EAG Spillage Policy

8.7 Health Surveillance

At present, health surveillance for health care workers involved in handling SACT in the UK is controversial as there are no set limits of exposure. However, it is recommended that employers keep a health record on all staff potentially exposed to SACT. The health record should contain at least the following: surname, forenames, gender, date of birth, permanent address and post code, National Insurance Number, date when present employment started and a historical record of jobs in this employment involving exposure to SACT (HSE 2014). Individual Occupational Health Departments may provide health surveillance programmes, but this is variable between different trusts.

8.8 Pregnant Staff and Nursing Mothers

Women who are planning to become pregnant or are pregnant and/or breastfeeding should avoid direct contact with cytotoxic drugs, such as connecting, disconnecting cytotoxic drugs from a patient, handling of bodily fluids or dealing with a cytotoxic spillage.
(European Oncology Nurses' Society (EONS) Safety Manifesto (2019)).

Employers must identify hazards within each clinical area where systemic anti- cancer treatment administration occurs as there is a potential health and safety risk to new and expectant mothers (HSE 2014).
Many systemic anti-cancer treatments have mutagenic, teratogenic and carcinogenic properties. As pregnancies are often unplanned or unknown for several weeks the emphasis must therefore be to ensure safe practice at all times for all staff. Pregnant women or women breast feeding should be advised of potential risks associated with handling SACT, particularly in the first 84 days of pregnancy (Gilani and Girdharan, 2014). Recommendations include:

- All staff involved in the handling and administration of SACT should be familiar with and adhere to local and national policies, and follow safe practice and standard operating procedures.
- It is the responsibility of the employee (pregnant member of staff) to inform the employer regarding their decision to conceive, when they become pregnant, or when they lactate in writing. A log of all discussions should be maintained.

- The line manager must undertake an individual risk assessment.
- Pregnant staff /lactating mothers should be given the opportunity to refrain from working within the clinical area.
- All staff involved in handling and administering chemotherapy must undergo appropriate training and education for safe handling of systemic anti-cancer drugs.
- Employers should take responsibility to facilitate avoiding exposure and provide local guidelines.

(American Society of Hospital Pharmacists, 2006; Gilani S, Girdharan S, 2014).

Note: Staff are encouraged to discuss any issues relating to pregnancy or breastfeeding with their line manager and Occupational Health.

8.9 Completed Infusions

Upon completion of the infusion, the roller clamp must be closed and the administration set should remain attached to the empty infusion bag and be disposed within the designated cytotoxic container.

8.10 Incomplete Infusions

All part-used infusions should be placed in a designated cytotoxic sharps bin. The bin should be sealed, labelled and disposed of in the same manner as all SACT waste.

8.11 Protective Equipment, Syringes or Other Items in Contact with Anti-cancer Treatment

All disposable equipment associated with SACT should be treated as cytotoxic waste. All anti-

cancer treatment waste should be separated from other clinical waste (HSE 2014) and disposed of according to individual Trust policies. All sharp items must be placed in 'Designated Cytotoxic Sharps' boxes and disposed of according to individual Trust 'sharp' policies.

8.12 Non-disposable Items

All non-disposable items – eye protection, trolleys etc. must be washed using hot soapy water and dried thoroughly whilst wearing protective gloves and apron. If linens/disposable items are contaminated with a cytotoxic drug (not the excreta of a patient receiving the drug), handle as cytotoxic waste and place in a Cytotoxic Waste Receptacle.

9.0 STAFF COMPLIANCE STATEMENT

Clinical Guidelines assist in decision making; they do not replace clinical judgement. Regardless of the strength of evidence, it remains the responsibility of the clinician to interpret the application of the clinical guidance to local circumstances and the needs and wishes of the individual patient. Where variations of any kind do occur, it is important to document the variations and the reason for them in the patient's health record.

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