NHS England

East Midlands Cancer Alliance

East Midlands Expert Clinical Advisory Group
Systemic Anti-Cancer Therapy (SACT) Policy

(Formerly known as The Cytotoxic Policy)

Date of Original: Replacing Cytotoxic Policy originally July 2007
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Document Location

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Revision History

Acknowledgement: Versions 1 to 8 were written by Colin Ward and Chris Clarke. V9 has been adapted from these earlier versions.

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Date of next revision: Jul 2022

Revision date	Summary of Changes	Changes marked
July 2007	First issue	
17.11.10	Include revised extravasation Guidelines	No
17.11.10	Further revision to extravasation Guidelines	No
21.09.11	Revision to extravasation Guidelines and content	No
26.01.12	Encompasses requirements of Peer Review Measures, amended terminology inline with Chemo mandatory dataset and revision of profession roles. Extravasation Guidelines review date amended to September 2013	Yes
24.09.13	Revision to extravasation Guidelines and content and SCN Header added.	
May 18	Revised links and references to electronic prescribing and immunotherapy. Renamed as SACT Policy	No
Jul 20	Revised links	Yes

1. INTRODUCTION

This policy is designed to support the delivery of Systemic Anti-Cancer Therapy (SACT) used to treat cancer in East Midlands. The standards relate to all cancer patients, both adult and paediatric, in acute in-patient, daycase, outpatient settings and delivery in the community. It covers chemotherapy treatment for all solid tumour and haematological malignancies, including those in clinical trials.
Systemic Anti-Cancer Therapy refers to all drugs, irrespective of their route of administration, with direct anti-tumour activity, including:

- Traditional cytotoxic chemotherapy such as cyclophosphamide.
- Small molecule targeted therapy such as imatinib,
- Antibody treatments including those with cytotoxic potential e.g. rituximab and Trastuzumab-emtansine (Kadcyla®)
- Immunotherapy such as nivolumab, ipilimumab, interferon and lenalidomide
- Other agents which must be prescribed by oncologists for malignant disease such as enzalutamide, abiraterone and bexarotene.

Intrathecal chemotherapy is covered by separate trust policies although the principles below also apply.

This Policy is not intended to cover the prescribing and administration of SACT such as hormones (excluding abiraterone/enzalutamide) or other non hazardous molecules which are often prescribed by General Practitioners. With the diversity of treatments now available for the treatment of cancer this policy aims to ensure the safe delivery of SACT and support the development of outreach services and decentralised clinics.

Chemotherapy medicines may be used for two purposes:
- Treating cancer and
- Managing non-malignant conditions

This policy is applicable to all personnel involved in handling these medicines for the treatment of cancer:
- Medical Staff
- Pharmacy Staff
- Nursing Staff in Hospitals
- Community Nursing Staff
- Independent Sector Treatment Providers

It is anticipated that Trusts will use this policy not only to improve the quality of cancer chemotherapy services, but also to inform the development of chemotherapy services for patients with non-malignant conditions.

Separate policies and procedures exist for pharmacy areas dispensing cytotoxics.

Cytotoxic Drugs should be considered potentially harmful to all personnel handling them unless a risk assessment demonstrates they are safe to be handled as standard medicines.

Many Cytotoxic Drugs act as an extreme irritant to the eyes, skin, mucous membranes and other tissues. They may also be sensitisers and some are potentially carcinogenic and teratogenic. Therefore, it is of the utmost importance that staff are warned of the risks and protected accordingly against the acute effects of accidental contamination and trained in the proper use of protective equipment. Cytotoxic Drug substances are potentially hazardous to health and as such fall into the COSHH Regulations 1988.

The Policy refers to all SACT administered by the following routes:

- Oral
- Parenteral including:
    - Intravenous
    - Intramuscular
    - Subcutaneous

Specialist areas may also administer using the following routes:

- Intraarterial
- Intraperitoneal
- Intravesical (e.g. bladder instillation).
- Intraurethral
- Intralesional/ Intratumour (e.g. T-VEC)
- Topically
- Intradermal
- Intrathecal (see separate Trust policy)

2. PRESCRIBING

Routine Prescribing

2.1.1. **Written informed consent must be obtained for SACT administration by whichever route. This may be the national CRUKconsent forms or trust approved locally developed forms.** See section 9 patient information

2.1.2. It is essential that systems be in place to ensure SACT treatment is performed with adequate safety and quality control procedures.

Agreed limits on the capacity of the SACT service and the notification for planned therapy should be in place locally and form part of a local capacity plan. There should be an agreed arrangement whereby the Head of the Cancer Service, in consultation with the pharmacy service and lead chemotherapy nurse, is able to limit the number of chemotherapy patients being treated when they judge the workload to have reached unsafe levels. This should take into account all elements of the service.

2.1.3. Consultant medical staff must refer patients who require SACT to an oncologist or haematologist specialising in the treatment of these patients.

2.1.4. All SACT must be electronically prescribed
Local Governance documents covering the implementation, access and use of the electronic prescribing system must be adhered to.

2.1.5. Medical Staff and other non-medical practitioners must not be allowed to initiate SACT until they have undergone appropriate training and competency assessment, with documentary proof of this training. It is the responsibility of the supervising Consultant to arrange this training and assessment. The first cycle of a course of SACT must be prescribed and approved by a Consultant Haematologist/Oncologist. An Associate Specialist, post FRCR trainee /Senior Haematology SpR (years 4 or 5) or non-medical practitioner, following documented discussion with the named Consultant or deputising Consultant may also prescribe and approve the first cycle of treatment, if they have received appropriate training. It is their responsibility to ensure that all SACT and any 'regime specific' treatments required for individual patients to be correctly prescribed. The details of the local process must clearly show the required stages and staff permitted to undertake them.
Prescribers must be deemed competent to prescribe (allocate) first prescriptions and feel confident to do so before proceeding.

2.1.6. The Consultant responsible for the overall care of the patient must ensure that any healthcare professional who prescribes SACT has adequate experience and specific instructions concerning dosage, route of administration and common toxicity of all medicines prescribed.
SACT irrespective of the route of administration must be prescribed by an oncologist/haematologist of registrar grade (SpR/ST3 or equivalent) or above or a competent non-medical prescriber. The only exceptions to this are intravesical SACT administered into the bladder which may be prescribed by a urologist and administered under their care, carmustine wafers prescribed for use in theatre and radiologists administering intraarterial chemotherapy. Other specialist SACT e.g. intraperitoneal, intradermal should be managed under the care of an oncologist.

2.1.7. SACT regimens must be prescribed electronically using an approved protocol (including those used as part of a clinical trial). The validation of local protocols should where possible reflect regional/national algorithms/regimen details or nationally developed algorithms where available. There should be a process in place to ensure regular review and timely resolution of differences and issues identified through the use of the prescribing system.

2.1.8. Local Chemotherapy Governance systems must be in place to ensure access to the electronic prescribing system at an appropriate level is controlled. The roles of staff in using the system should be clearly defined in the local Governance framework.

2.1.9. The first cycle of a regimen of SACT should only be prescribed (i.e. allocated/confirmed as defined locally) following a documented plan e.g. MDT, entry in medical notes, referral form etc. Where the first cycle is not prescribed by a consultant solid tumour oncologist or haemato-oncologist, the details of the local process must clearly show the required stages and staff permitted to undertake this task. A staff grade/SpR/ST3/independent prescriber must be deemed competent to prescribe (allocate) first prescriptions and feel confident to do so before proceeding.

2.1.10. Prior to the first cycle of SACT; details of specific diseases or conditions affecting fitness for treatment (including that the minimum physical and investigational requirements have been met), performance status, allergies, prior history of SACT and current patient medication affecting SACT must be checked and documented. Informed consent must have been obtained and the regimen is in accordance with departmental protocols. Consideration should be given to making this information available to other members of the multi-disciplinary team to allow a double check of the appropriateness of the regimen proposed. A Holistic Needs Assessment (HNA) should have been carried out or scheduled.

2.1.11. Specialty doctors, registrars (SpR/ST3) and non-medical prescribers who prescribe SACT must seek advice from the relevant Consultant if a change of dosage becomes necessary that is not covered by local treatment guidelines or Specification of Product Characteristics (SPC).

Intrathecal Chemotherapy

See the Department of Health national guidance on the safe administration of intrathecal chemotherapy and any specific Trust intrathecal chemotherapy policy

Prescribing – Off Protocol Chemotherapy

2.1.12. Requests for "one off" SACT not included in an approved protocol may only be prescribed under the direction of Consultant medical staff approved to prescribe SACT.

2.1.13. Any off protocol SACT prescribing must be done in accordance with the EM Non Protocol Chemotherapy Policy. Sufficient time must be allowed for electronic prescriptions to be completed and validated prior to prescribing.

2.1.14. The Expert Advisory Group must review all adult off protocol prescribing annually

2.1.15. The children's cancer network (CCN) and the co-ordinating group (CCNCG) must review off protocol prescribing for children annually.

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Oral Chemotherapy

2.1.16. Oral SACT used for treating cancer should only be prescribed (initiated) by an authorised Consultant, staff grade, registrar (ST3) or non-medical prescriber; all cycles should be prescribed by the Acute Trust. Primary care colleagues must not be asked to prescribe SACT for patients unless a robust governance framework is in place. Hydroxycarbamide may be prescribed in primary care as part of a Shared Care Agreement ensuring patients are under the care of a consultant haematologist. GPs may also prescribe topical cytotoxic agents for some skin malignancies or pre-malignant conditions.

2.1.17. All oral SACT prescriptions must be electronic and on the same system as parenteral therapy. If inpatient administration is required, they may be transcribed to the relevant electronic/paper prescription but the supply of drug must be initiated and recorded on the standard electronic prescribing system.

2.1.18. Patients admitted to hospital on oral SACT **must** be referred to the relevant oncology/haematology team with 24 hours for review of oral

SACT drugs. The drug should not be prescribed until a suitable review has occurred.

Electronic prescribing

2.1.19. All trusts administering SACT should be using an electronic prescribing system which:

Enables electronic prescribing using approved protocols,

Provides an auditable record of SACT, encompassing the national SACT dataset requirements

Allows interfacing between and integration of: patient demographics, laboratory test results, and dispensing, and there should be a procedure for exceptional manual patient registration onto the system.

2.1.20. There should be guidance for the use of the system which includes: 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

3. VERIFICATION AND DISPENSING

General Principles

3.1. All SACT prescriptions must be clinically verified by a Pharmacist who then signs / electronically authorises the prescription

3.2. 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

3.3. SACT (irrespective of the route of administration) should only be routinely dispensed during normal working hours (as per local Operational Policy). Procedures should be in place to cover out of hours requirements.

3.4. The Pharmacist / appropriately trained technician must release the medication for administration using the appropriate electronic prescription.

3.5. Staff dispensing SACT should be aware of safe handling requirements

Oral Chemotherapy

3.6. Staff dispensing oral SACT must do so using the appropriate electronic prescription unless a separate inpatient order is requested by a pharmacist. Systems should be in place to ensure duplicate/continuation of supply is managed appropriately. They must ensure when giving out that the patient is aware of the required monitoring arrangements.

Parenteral Chemotherapy

3.7. Parenteral cytotoxic chemotherapy dispensing must be carried out in clean rooms compliant with current MHRA advice. Where alternative arrangements exist e.g. immunotherapies/other biological therapies, a risk assessment must be undertaken.

3.8. Where outsourced chemotherapy is dispensed this must be from an accredited supplier ideally following regional contracting processes.

3.9. Only authorized staff should prepare parenteral chemotherapy. Staff must not be allowed to dispense parenteral chemotherapy until they have undergone appropriate training and competency assessment.

3.10. The aseptic dispensing of chemotherapy must be under the supervision of a specialist Pharmacist or suitably qualified technician in accordance with pharmacy procedures. The number and experience of the technical staff must be adequate for the work undertaken and this must proceed in an ordered, systematic and unhurried fashion.

3.11. Pharmacy should receive adequate advance notice of intended parenteral SACT, even where this is provisional and the final decision to prepare and administer the medicines depends, for example, on the patient's blood count. Where the final decision to treat is delayed account of the impact on other dispensing activity must be considered by the full clinical team.

4. TRANSPORTATION

Hospital

4.1.1. Ready made parenteral SACT drugs must be transported from the pharmacy in containers able to contain leaks, appropriately labelled to ensure staff are aware of the contents.

4.1.2. Intrathecal therapy is delivered/collected in accordance with the relevant Trust Intrathecal Chemotherapy Policy.

4.1.3. SACT must only be transported in appropriate containers by members of staff aware of the risks or patients taking SACT home for administration by district nurses.

4.1.4. Additional checks should be performed at the time of delivery to ensure the drug is stored appropriately.

Hospital Outreach Services / Community

4.1.5. Parenteral SACT medication for the use in the community will be given to the appropriate member of nursing staff / patient in an appropriate container appropriately labelled to ensure staff are aware of the contents

4.1.6. The prescribing of parenteral SACT provided by a Homecare company remains the responsibility of the provider organisation and must be managed via guidelines and contracts. Appropriate provision for the management of side effects documentation and records of administration must be made.

5. STORAGE

Hospital

On receipt in the clinical area, the nurse must check the expiry date and storage conditions and ensure that the drug is not administered outside of this period without further reference to a pharmacist.

5.1. Dispensing and storage of Intrathecal chemotherapy must be in line with the relevant local Trust Policy for the management of Intrathecal chemotherapy.

5.2. There must be dedicated areas for the storage of SACT at ward level, for items stored at both room temperature and in the refrigerator. Sufficient space and separation of patient/drug supplies must be ensured to avoid confusion, administration of products in the wrong order (expiry) or increase clinical risk. The temperature of all storage areas must be monitored and recorded in accordance with local procedures.

5.3. If a regimen is to run over more than one nursing shift, it is the responsibility of the nurse in charge of the clinical area to ensure that a suitably trained professional is available throughout the proposed period of treatment.

5.4. Unused and unopened syringes/infusions containing SACT should be retained in the clinical area and/or returned to pharmacy in accordance with locally agreed procedures. Evidence of appropriate storage must be available for drugs to be reused.

5.5. SACT infusions, which have been partly used or damaged and require disposal must be disposed of on the ward following locally agreed procedures.

Hospital Outreach Services / Community

Appropriate storage for parenteral SACT should be available in outreach or home settings.

5.6. There should be arrangements in place to monitor the temperature within the storage area (in particular refrigeration) with defined maximum and minimum temperature thresholds. Patients should be advised who to contact should storage temperatures deviate from permissible ranges.

6. ADMINSTRATION and CHECKING OF SACT

Parenteral SACT (IV SC and IM)

6.1.1. All staff who administer parenteral cytotoxic SACT must have successfully completed an agreed competency based training course. Peripheral vesicants must always be given by medical practitioners (paediatrics) or nurses who have successfully completed an agreed competency based training course specific to peripheral vesicants.
Adult haematologists and oncologists do not administer traditional chemotherapy including vesicants.
Nursing staff are able to administer monoclonal antibodies with immunotherapy or cytotoxic potential e.g. nivolumab, rituximab providing they adhere to the requirements in this policy and have been assessed as competent to administer IV therapy. See Location/Immunotherapy below)

6.1.2. A list of staff authorised to administer parenteral SACT must be maintained by each service provider. Only staff whose names are on the list are authorised to administer SACT. This should be in conjunction with the electronic prescribing system governance.

6.1.3. Nursing staff of any grade may only administer SACT under the supervision of an appropriately trained nurse until they have completed the necessary training and achieved competency.

6.1.4. SACT must only be administered to a patient when:

- There is an electronically generated prescription which meets all the requirements of the local governance policy.
- The drugs have been checked against the prescription with another suitably trained member of staff.
- The prescription must always be available when any SACT is administered.
- If this is the first cycle of treatment, check that the consent form has been signed and appropriate patient information has already been received.

In the event of a discrepancy at any of the stages of verification, the SACT must not be given until the problem is resolved to the satisfaction of the prescriber, pharmacist and the nursing staff. If the discrepancy cannot readily be resolved, Consultant advice must be sought.

- **If in doubt, do not proceed.**

6.1.5. The following must be checked with another designated practitioner against the prescription sheet:

- Height, weight, look appropriate for the patient being treated (at the point of administration)
- Patient Identification (using Trust policy for positive patient identification, or equivalent)
- Laboratory results (if appropriate) are within accepted limits
- Toxicity results are within accepted limits
- Correct drug
- Correct dose of drug
- Correct dilution of drug (infusion fluid and volume)
- Correct route and method of administration
- Expiry date is sufficient to permit the completion of planned therapy.
- Confirm Informed consent has been obtained for the planned therapy

6.1.6. The rate of infusion if applicable should be checked by both members of staff on the infusion pump against the prescription.

6.1.7. Both practitioners should ensure the correct giving set has been selected (eg correct filter etc)

6.1.8. Practitioners should be fully trained to use the volumetric devices used to deliver the treatment

6.1.9. A nurse who has completed an agreed competency based training course must always be one of the two practitioners responsible for checking, "signing" and administering SACT. One of the two people checking any SACT must be the administering person.
The following details must be documented in line with Trust policy for medicines administration:

- Date of administration
- Time of administration

Timing

Where possible parenteral SACT should be commenced and completed during the working day, as defined locally, unless medically indicated. This is in order to ensure the ready availability of appropriate sources for advice.

Exceptions:

- Continuous Infusions

- Timed SACT
- SACT given more than once a day
- Urgent need to administer out of hours as agreed locally.

Location

Cytotoxic SACT administration should be undertaken in designated clinical areas that are regularly used for the purpose and equipped to deal with any emergencies that might arise from the treatment. These areas must comply with the relevant national guidance.

In exceptional circumstances, appropriately trained staff will administer SACT in the clinical area where the patient is based. The administering staff must ensure the team caring for the patient are aware of the safety precautions necessary in caring for the patient.

Immunotherapy

Immunotherapy and antibody therapy and potentially other types of SACT do not require specialist cannulation or have notable risks of extravasation (neither vesicant nor irritant). Following local risk assessment, it is permissible for such drugs to be administered by staff not specifically trained in cytotoxic SACT administration. They may also be given in an area other than one dedicated to the administration of SACT. A local risk assessment must be undertaken to assess the suitability of an area/service to ensure patients receive a safe and effective service with suitable assessment of side effects relevant to therapy previously administered.

The development of specialist immunotherapy clinics is likely to increase and capacity plans should take account of all SACT therapies.

Specialist SACT administration by other routes

Administration of SACT to specific sites (e.g. bladder, intraarterial, intralesional) will occur in areas designed to deliver such therapy. Agreed prescribing, reconstitution, dispensing and delivery procedures must be adhered to.

Checking procedures should follow the principles above and local trust policies. Administration and checking will be undertaken by appropriately trained staff.

Intrathecal Chemotherapy

This must be carried out according to Department of Health national guidance on the safe administration of intrathecal chemotherapy and the relevant Trust Intrathecal Chemotherapy Policy

Hospital Outreach Services / Community *Administration*

6.1.10. Prior to any parenteral SACT being administered outside of the acute trust setting, this must be discussed with the patient and relevant staff. This should take account of:

- Staff safety (in conjunction with any organisational policies on lone working)
- Patient (and contacts if appropriate) safety
- Environment for drug administration
- Risk of spillage and potential consequences
- Access to medical support
- Access to emergency medicines and equipment

6.1.11. If the above risks are deemed unacceptable, steps must be taken to mitigate the risks to an acceptable level at the proposed location. Where this is not feasible an alternative location must be sought

6.1.1. Patients discharged into the community on continuous cytotoxic chemotherapy infusions may be overseen by appropriately trained community nursing staff. The device may be disconnected and disposed of by these staff under local agreement. Waste management is in accordance with local policies.

Oral SACT Administration

6.1.2. Prior to commencing administration, there must be confirmation that the relevant oncologist/haematologist or relevant medical specialist has reviewed the patient since admission. Systems must be in place to ensure prescribing of oral SACT agents is undertaken by suitably trained prescribers or following consultation with such prescribers.

6.1.3. However oral SACT may be administered in any clinical area.

6.1.4. Tablets should not be handled and must **not** be crushed or capsules opened prior to administration without consulting pharmacy. Advice should be sought from the pharmacy team if patients experience swallowing problems.

Prescriptions and labelling should clearly indicate the therapy as Cytotoxic, the dose and duration to ensure staff administering oral therapy have sufficient information.

If in doubt, do not proceed.

Minimising Wastage

6.1.5. Unused prepared treatment that is no longer required must be returned to the Pharmacy as soon as possible to maximise the potential for re-issue by the Pharmacy. Treatment must be stored correctly, and 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.

7. INFORMATION

SACT Information for General Practitioners

7.1.1. General Practitioners should be informed about the planned treatment including regimen, start date, duration and intent from the initiating hospital. A treatment summary after the final cycle should provide information on whether treatment was completed or reasons for stopping treatment and response.
NB. caution must be taken if trusts issue a copy of 'prescriptions' to GPs as there is a risk of inappropriate continuation of medicine. Any written communication must clearly show that the medication is NOT for continuation by primary care.

SACT Information for Patients

7.1.2. Patients should be fully informed and receive verbal and up-to-date written information about their anticancer therapy from the initiating hospital including copies of correspondence to GP's if they wish. Information should include contact details for specialist advice, which can be shared with non-specialist practitioners. Written information, including details of the intended anti-cancer regimen treatment plan and possible side effects should be given to the patient.

7.1.3. There should be written guidelines for patients undergoing SACT covering advice and action to be taken if and when they develop symptoms that may be related to side effects or complications. Conditions to be covered should include side effects relevant to the proposed SACT e.g. neutropenic sepsis, immunotherapy reactions, nausea and vomiting, diarrhoea, infertility, hair loss and the potential option for scalp cooling.

7.1.4. Where possible peer reviewed SACT information (e.g. Macmillan, CRUK etc.) should be used and supplemented with local information about accessing advice and services.

7.1.5. It is the responsibility of the SACT prescriber to ensure the patient/guardian has an opportunity to receive the appropriate written information.

8. PROTECTION OF PERSONNEL

Pregnant Staff & Nursing Mothers

8.1.1. An individual risk assessment must be undertaken at the first opportunity. Where other risks cannot be mitigated to an acceptable level consideration should be given to redeploying the member of staff within the organisation

9. PROTECTION OF THE ENVIRONMENT

Spillage

9.1.1. The main priorities are to contain and prevent further contamination or operator exposure.

9.1.2. The responsibility for clearing up a spillage lies with the member of staff involved with the incident, unless it is felt by a senior member of staff that this person is not sufficiently trained to deal with the spillage or is pregnant. In this event, the senior staff member or deputy will decide upon who will deal with the spillage.

10.1.3. In the event of a spillage staff must follow the local chemotherapy spillage policy

Contact with Eyes

9.1.3. Eye wash facilities must be available for the use in the event of contamination of the eyes.

9.1.4. The relevant local policy must be followed at all times.

Contact with Skin

9.1.5. For **ALL** cytotoxic agents **rinse the skin well** with copious amounts of water unless otherwise stated below or refer to the manufacturer's guidelines. If necessary, seek medical advice.

9.1.6. Contaminated clothing or linen should be changed immediately and treated according to the local policy for soiled linen. (See spillage policy)

9.1.7. The relevant local policy must be followed at all times

Needlestick injuries

9.1.8. Refer to hospital policy

Disposal of Cytotoxic Waste

9.1.9. Local waste disposal policies must be followed at all times

Disposal of Excreta

9.1.10. Significant amounts of cytotoxic substances may be excreted in urine, vomit and faeces for up to three weeks after administration of these drugs.

9.1.11. The local policy must be followed at all times

Bed Linen

9.1.12. When contaminated by excreta, bed linen should be dealt with in the same way as spillage of the drug during preparation (See spillage policy)

9.1.13. In the **community** contaminated bed linen should be bagged separately until it can be washed in the normal way – **separate to other washing**.

Surfaces

9.1.14. Surfaces contaminated by spillage after cleaning must be decontaminated chlor clean or equivalent as per local policy.

Cleaning up Materials

9.1.15. Aprons, gowns and gloves – **all disposable** – should be double bagged in heavy duty clinical waste bags, sealed and labelled:

"DANGER CYTOTOXIC HAZARD FOR INCINERATION"

as should any paper towels used to assist in the washing process

10. MANAGEMENT OF CYTOTOXIC EXTRAVASATION

The Expert Advisory Group (EAG) Extravasation or *Medusa Extravasation Guide* guideline must be followed at all times (See appendix 2) The East Midlands EAG aims to work with Medusa to ensure a sustainable national extravasation guideline going forwards.

11. REFERENCES

- Control of Substances Hazardous to Health Regulations 1988.
- Health and Safety at Work Act 1974.
- Clinical Practice Guidelines. The Administration of Cytotoxic Chemotherapy. Recommendations Royal College of Nursing 1998.
- National Guidance on the Safe Administration of Intrathecal Chemotherapy 2001.
- NPSA Rapid Response Alert – Risks of Incorrect Dosing of Oral Anti-cancer Medicines (NPSA/2008/RRR001), January 2008
- Chemotherapy Services in England: Ensuring quality and safety - A report from the National Chemotherapy Advisory Group; August 2009
- National Cancer Peer Review Programme, Manual for Cancer Services: Chemotherapy Measures, Version 1.0, April 2014. Gateway 16104
- Medusa Extravasation Guide. NHS Wales

Appendix 1 – Staff Definitions

Throughout this document, certain specialist titles describe healthcare staff who have defined responsibilities regarding the management of medicines. Only staff with contracts (or honorary contracts of employment) to work in the relevant Trust are recognised as having any involvement with medicines.

Medical Practitioner
A doctor registered with the GMC

Nurse
A nurse registered with the NMC.

Pharmacist
A Pharmacist registered with the General Pharmaceutical Council

Pharmacy Technician
A Medical Technical Officer who has completed a nationally recognised qualification in pharmacy, and may perform authorised roles under the supervision of a pharmacist or other qualified practitioner. They are registered with the General Pharmaceutical Council

Designated Practitioner
A practitioner from a Health Care Group (approved by the Trust) identified by the Appointed Practitioner in Charge as competent and appropriate to perform a specific function and the designation as such has been communicated to and accepted by the practitioner.

Independent Prescriber
-A UK registered doctor,
-A dentist prescribing from the Dental Formulary,
-A nurse prescriber prescribing within their area of competence.
-A pharmacist prescriber prescribing within their area of competence.

Appendix 2 see [eastmidlandscanceralliance.nhs.uk-Extravasation]

Your nearest extravasation kit is located:

GUIDELINE FOR MANAGEMENT OF EXTRAVASATION

NHS England
East Midlands Cancer Alliance

Extravasation is a severe complication in the administration of cytotoxic chemotherapy. It causes pain, erythema, inflammation, discomfort and if left undiagnosed or inappropriately treated can lead to necrosis, secondary infection and functional loss of the tissue and/or limb concerned.
This may also hinder future treatments in some cases. If treatment is delayed, surgical debridement, skin grafting and even amputation may be the consequence

1. STOP the injection immediately, but leave the cannula in place
2. Classify the agent using the tables below and treat as directed (if not listed below consult Pharmacy)
3. Collect extravasation kit
4. Apply COLD pack immediately (WARM if non DNA binding Vesicant)
5. Aspirate as much fluid as possible through the cannula, try to draw back about 3 to 5ml of blood
6. Mark the extravasation area with a permanent marker pen
7. Contact the patient's doctor
8. Remove the cannula only after appropriate treatment

Vesicants DNA-binding

Amsacrine
Dacarbazine
Dactinomycin
Daunorubicin
Doxorubicin
Epirubicin
Idarubicin
Mitomycin C
Mrabectidin

AIM: LOCALISE & NEUTRALISE

- Neutralise the infusate by applying a thin layer topical DMSO to the marked area using a cotton bud. Do not use DMSO If blistering present.
- Allow the DMSO to dry, and then cover with a non-occlusive gauze dressing, this should be applied within 10-25 minutes
- Apply a cold pack for 30 minutes. Repeat every 4 hours for 24 hours to help localise the infusate
- 3 hours after first DMSO application apply hydrocortisone 1% cream. Repeat every 6 hours for 7 days
- Elevate the limb

Consider referral to Hand/Plastic Surgeon

Vesicants Non-DNA-binding

Cabazitaxel
Nab-paclitaxel
Vinblastine
Vincristine
Vindesine
Vinflunine
Vinorelbine

AIM: DISPERSE & DILUTE

- Give several subcutaneous (or intradermal) injections of 150 – 1500 IU of hyaluronidase diluted in 1 mL sterile water as 5 separate 0.2ml injections around the periphery extravasated area to dilute the infusate (*for **paclitaxel** only – treat using a cold compress applied for 30 minutes and apply hydrocortisone cream 1% every 6 hours for 7 days or as long as erythema persists).
- Use 25 to 27 gauge needle and change after each injection
- If there is no blood return in the affected IV catheter, consider infusing 0.4ml of hyaluronidase mixture directly through the affected IV catheter before removing the catheter and administering the remainder of the dose subcutaneously around the periphery extravastion
- Apply hydrocortisone 1% cream every 6 hours for as long as erythema persists.
- Elevate the limb
- Apply a warm pack to the affected area for 30 minutes 4 times daily for 1 to 2 days

NB. Administration of hyaluronidase should begin within 1 hour of extravasation for best results

Consider referral to Hand/Plastic Surgeon

Irritants[1]
Arsenic Trioxide
Cyclophosphamide
Liposomal Daunorubicin
Liposomal Doxorubicin
Etoposide
Fluorouracil
Ganetespib
Ifosfamide
Mephalan
Mitoxantrone
Streptozocin

Possible irritants[2]
Carboplatin
Cisplatin
Docetaxel
Gemtuzumab Ozogamicin
Irinotecan
Oxaliplatin*
Topotecan

Vesicants Non-DNA binding
Paclitaxel

Vesicants DNA binding
Bendamustine
Busulfan
Carmustine
Chlormethine (Mustine)
Treosulfan

AIM: LOCALISE

- Apply cold pack for 30 minutes every 4 hours for 24 hours (*for **oxaliplatin** only – treat using a warm compress to avoid the risk of paraesthesia which can be precipitated by cold)
- Apply hydrocortisone cream 1% every 6 hours for 7 days or as long as erythema persists

For VESICANTS consider referral to Hand/Plastic Surgeon

Non-vesicants[1]
Aflibercept
Asparaginase
Bleomycin
Bortezomib
Brentuximab vedotin
Carfilzomib
Cladribine
Clofarabine
Cytarabine
Eribulin
Etoposide phosphate
Fludarabine
Gemcitabine
Immunotherapy
Inotuzumab ozogamicin
Interferons
Interleukin-2
Methotrexate
Mifamurtide
Monoclonal antibodies
Nelarabine
Pemetrexed
Pentostatin
Pixantrone
Raltitrexed
Temsirolimus
Thiotepa
Trastuzumab emtansine
Vosaroxin

AIM: SYMPTOMATIC RELIEF

- Elevate the limb
- Consider applying a cold pack if local symptoms occur
- Apply hydrocortisone cream 1% four times each day if erythema is present

[1] Any agent extravasated in high enough concentration may be an irritant

[2] There have been few reports of these agents acting as irritants, but there is no clear evidence for this

NOTE: For those medications that are not considered a vesicant but cause prolonged patient discomfort at the infusion site, it is strongly recommended that a central line be placed

NB. Causes which may commonly lead to misdiagnosis include: Allergic reaction / flare reaction / vessel reaction / venous shock / phlebitis etc

- Complete documentation and send to nominated person:
  - Nursing +/- Medical notes / records
  - Drug chart
  - Incident form (DATIX form)
  - Patient information leaflet
- Give analgesia if necessary
- Arrange a follow-up appointment. The extravasation should be reviewed after it has occurred at:
  - 24 hours
  - 1 week
  - 3-4 weeks and then subsequently until resolution of erythema if present
- Contact pharmacy for replacement drugs

The treatment proposed above is "first aid" only. Seek further advice – early review by plastic surgeon is advisable, consider medical photography

For latest version see

www.eastmidlandscanceralliance.nhs.uk/cancer/chemotherapy

Last updated: May 2018
Review date: May 2020

Large prints are available in treatment areas detailing location of Extravasation kit

Appendix 3

EXTRAVASATION KIT CONTENTS

Antidotes/Medication/Diluents	**Items available in clinic area**
1 x DMSO topical solution 2 x Hyaluronidase 1500 units injection 2 x Hydrocortisone 100mg injection 1 x Hydrocortisone 1% Cream 4 x Water for injection amps 2 x Sodium Chloride 0.9% amps	Injection swabs Gloves Apron Dressings Sterile gauze dressing Drug chart Tape measure/ruler (disposable)
Equipment	**Documentation**
Syringes 25-27 Gauge Needles 1 x Black permanent marker pen 1 x Hot pack 1 x Cold pack	Drug Chart Patient information leaflet