Kent and Medway Cancer Network

Network Guidance Document

Systemic anti-cancer therapy Care Pathway

Preparation & Pharmacy

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Contents

STANDARDS FOR PREPARATION AND PHARMACY

All systemic anti-cancer therapy drugs will be prepared and administered in designated areas. All areas where systemic anti-cancer therapy (SACT) is prepared and administered will have access to the relevant guidelines and protocol documents (covering spillage and waste disposal procedures, administration of systemic anti-cancer therapy guidelines, drug information and SACT protocols).

In addition, clinical areas will require protocols/guidelines for the prevention and management of complications arising from systemic anti-cancer therapy, including emergencies such as anaphylaxis and extravasation.

SACT should only be given during normal working hours (Monday-Friday unless it is part of a multi-day regime) on wards or in outpatient areas which have been designated for the purpose and where it is the whole or part of their allowed activities.

Intravenous SACT should be stored in a designated area that has a suitable storage fridge if required within the ward, outpatient area or pharmacy. If intrathecal systemic anti-cancer therapy is stored after production and before administration, it must be stored in a separate designated fridge within the pharmacy department. (Refer to local Intrathecal policy.)

The identified outpatient area may be used for other aseptic treatments and procedures on cancer patients, but should not be used for general outpatient/day case activity.

1.1 Facilities for Preparation

SACT drugs must be prepared on a named patient basis (for non-licensed aseptic units). Preparation must be centralised in the Pharmacy department and drugs must be reconstituted by appropriately trained staff in a Grade A environment which may be provided by either an appropriate pharmaceutical isolator or a laminar air flow work station according to good manufacturing practice. (Medicines and Healthcare Products Regulatory Agency, Rules and Guidance for Pharmaceutical Manufacturers and Distributors, 2007, the Stationery Office, London). The Pharmacy department must be audited independently by the Medicines Inspector or Regional Quality Controller for at least the aseptic preparation of compounds and the preparation of SACT.

In exceptional circumstances there may be a need to prepare SACT drugs outside of normal pharmacy working hours. These circumstances and the procedures to follow are described in full by the Trusts local policy for out of hours administration and preparation of systemic anti-cancer therapy.

1.2 Authorisation Procedure

i. SACT should be initiated (via an action sheet or referral form) and prescribed by:

- A consultant clinical haematologist/non surgical oncologist
- An associate specialist in clinical haematology/non surgical oncology
- A specialist registrar or equivalent who is undergoing supervised training from one of the above and has been authorised in writing by a consultant oncologist/haematologist or the Director/Deputy Director of the Kent Oncology Centre or the Lead Clinical Haematologist within a Trust, as being competent to prescribe systemic anti-cancer therapy.

ii. The Pharmacy must be supplied (ideally every 6 months) with a list of doctors who are approved to prescribe (intravenous and intrathecal) and administer (intrathecal) SACT. This list should be available within the Pharmacy department and all clinical SACT areas. Pharmacy should also keep a list of pharmacists who are trained and authorised to check SACT prescriptions, as well as a list of trained personnel authorised to prepare SACT. These lists should also be updated at least every 6 months. (For requirements relating to the intrathecal register refer to local intrathecal policy.)

1.3 Prescribing Process

For the purposes of this document the term prescription will also refer to "Patient Specific Directions" as defined by the Department of Health.

Prior to a patient starting a course of SACT, an action sheet/referral form must be completed. This must specify the treatment plan for an individual patient.

i) Prescriptions for SACT drugs must be complete, clear and simple to follow. The Kent and Medway Cancer Network (K&MCN) is working towards producing template prescription proformas for all SACT. Only in exceptional circumstances should a prescription for SACT be handwritten. Each prescription must contain the following:

- Date prescribed.
- Patient name, date of birth and hospital number.
- Patient's weight, height and surface area (where appropriate).
- Ward / clinic.
- Consultant name.
- Regimen name.
- Disease site and indication i.e cancer type
- Therapeutic intent
- Cycle or course number.
- Name of drug – use approved generic drug names; no abbreviations.
- It is advised that each individual dose must be prescribed in the same units as those used within the protocol.
- The number of days of treatment.
- Route of administration (the abbreviation IT is not acceptable, Intrathecal must be written in full.)
- Starting date (and times when appropriate.)
- Antiemetics, hydration and any additional drugs as defined by the protocol.
- Reason for any dose modifications. (It is mandatory for this information to be contained within the action sheet/referral form but it is advisable to also include it on the prescription proforma.)
- Blood counts and biochemical parameters
- Method of drug administration ie. Bolus infusion etc. If the drug is given as infusion, the type and volume of the infusion fluid and its duration should be stated.
- Prescribers' signature.
- It should be signed and dated by the appropriate pharmacist following completion of a clinical screen and final release.

ii) Oncology, haematology and paediatric oncology staff should prescribe SACT drugs for patients using an electronic prescribing system, if available. The action sheet/referral form must be signed and dated by an approved prescriber. This may involve the use of electronic password mediated signatures, and electronically recorded dates if using an electronic action sheet system.

iii) The action sheet/referral form must be filed with the patient's SACT notes.

iv) Any variance in treatment from the standard SACT protocol must be documented on the action sheet/referral form and the amendment, for example, reduced dose due to toxicity, signed and dated (where a SACT prescription is not in accordance with an agreed protocol, the Treatment Algorithm Deviation Policy should be followed.)

v) A prescription must be written for each course of treatment. For inpatients the SACT prescription must be attached to the ward drug chart before the chart is sent to Pharmacy for dispensing. It is the prescriber's responsibility to ensure that all drug charts relating to a patient are sent to Pharmacy. For inpatients, Pharmacy should not dispense SACT until both the SACT and the ward drug chart are received, or reviewed and signed by the oncology pharmacist.

vi) Standardised pre-printed proformas are available for most approved SACT regimes within the K&MCN and these must be used where available. When using prescription proformas:

- The treatment schedule, ie. course number, cycle number or week number and treatment date should be stated
- Dosage of all drugs requested (IV or supportive care medicines) must be completed
- Drugs which are not required should clearly be run through and initialled.
- Any instructions on the form to delete as appropriate or delete if not required should be carried out at all times
- Any additional requests must be prescribed (IV or supportive care medicines) using generic drug names
- Any changes in drugs and/or dosage regimes should be clearly stated on the prescription along with the reasons for the change. Such changes should be initialled
- All supportive care medication requests should be written out in full to include name, form, dose, frequency and duration.

vii) Where an authorised nurse or pharmacist has completed dosage details, he/she must initial those details and countersign the prescription. Non-medical prescribers should be authorised and work within local Trust policies.

1.4 Dispensing

i) All parenteral SACT drugs will be dispensed within the Pharmacy aseptic unit within normal working hours following good manufacturing and good dispensing practice. In exceptional circumstances SACT may need to be dispensed out of hours. See separate Trust policy for Out of Hours.

ii) All SACT prescriptions should be checked by a pharmacist who has undergone specialist training, demonstrated their competence and are locally authorised/accredited for the task. The oncology pharmacist should sign the chemotherapy prescription to indicate that it has been verified and validated for the intended patient and that all safety checks have been undertaken. The pharmacists clinical screen signature must be visible on the prescription that is used for SACT delivery or administration. This includes prescriptions for oral SACT (Refer to the Kent & Medway Cancer Network Guidance on the Safe use of Oral anti-cancer medicines).

iii) All Pharmacy departments must have Standard Operating Procedures describing the dispensing process from receipt of a prescription to final release. These Standard Operating Procedures should describe the training and competencies required for oncology and/or aseptic services pharmacists. These should be reviewed periodically (at least annually).

iv) A record of the batch numbers and expiry for all drugs used must be documented on the worksheet for each regimen/systemic anti-cancer therapy drug.

v) Special arrangements are required for the dispensing of intrathecal preparations of Cytarabine, Methotrexate and Hydrocortisone (refer to local intrathecal policy) as well as intravenous preparations of Vinca Alkaloids.

vi) When Vinca Alkaloids are prescribed, dispensed or administered in adult SACT units doses in syringes should no longer be used. The prescribed dose should be supplied from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9% (for some brands of Vinorelbine glucose 5% infusion may be used.) The following warning should be prominently displayed on the label of ALL vinca alkaloid doses- **"For Intravenous Use Only – Fatal if Administered by Other Routes "** There should be judicious use of colour and design on the label, outer packaging and delivery bags to further differentiate minibags containing Vinca Alkaloids from other minibag infusions.(Ref: National Patient Safety Agency Rapid Response Report on using minibags to administer Vinca-Alkaloids-NPSA/2008/RRR004)

vii) When Vinca Alkaloids are prescribed, dispensed or administered in paediatric SACT units the guidance is as follows:

a) For patients over the age of 10 years, the pharmacy should dilute the volume of Vincristine to a maximum concentration of 0.1mg/ml. The drugs should be dispensed in a 10ml syringe **as a minimum**.
b) For children under the age of 10 years the Vincristine can be given undiluted at a concentration of 1.0mg/ml.(Ref: National Guidance on the Safe Administration of Intrathecal Chemotherapy-HSC2003/010 with update from HSC2008/001)

viii) Where facilities for preparation are compromised SACT may be purchased pre-prepared from an independent company licensed to do so. If this is the case then the ordering, receipt and subsequent release of such SACT will be conducted by the appropriate, trained pharmacy personnel at each local acute Trust.

1.5 Purchasing, Receipt and Storage

The purchasing, receipt and storage of SACT drugs in Pharmacy are carried out in accordance with agreed procedures by the Pharmacy Department at each site within the K&MCN. The Pharmacy will ensure the effective control of the quality of these products.

i) Access to SACT drug storage areas must be limited to authorised staff.

ii) Main stocks of SACT drugs will be held in the Pharmacy Department under appropriate conditions.

iii) Clinical trial supplies of SACT drugs should be kept separate from main stocks.

iv) SACT drugs should not be available as ward stock. They should always be dispensed for individual patients.

v) SACT drugs must be stored separately from other drugs in locked medicine cupboards or refrigerators as appropriate or within pharmacy.

vi) Intrathecal SACT doses must be stored in a separate designated fridge within the pharmacy department (Refer to local intrathecal policy.)

vii) Storage shelves must be designed in such a manner that the risk of breakage of containers of SACT drugs is reduced to a minimum.

viii) Containers of prepared SACT agents, cytotoxic or otherwise, must be transported in designated transport bags or boxes deemed fit for purpose. The bags or boxes should be clearly labelled:

"CYTOTOXIC DRUGS – HANDLE WITH CARE"
Additional precautionary labels should be added to the containers and the transport bags or boxes as appropriate.

ix) SACT drugs should be delivered to a registered chemotherapy nurse on the ward who takes responsibility for the appropriate storage, as defined on the attached additive label.

x) Pneumatic tubes (capsule pipelines powered by compressed air or vacuum) should not routinely be used for transporting cytotoxic agents, unless a full risk assessment has been undertaken and measures put into place to reduce the risk of spillage or contamination by cytotoxic drugs to negligible levels.

xi) Staff involved in the transportation of cytotoxic drugs **must** be trained to follow the “Cytotoxic Spill” procedure. Records of training should be maintained in the relevant areas.

xii) Damaged containers of SACT agents are to be discarded into a rigid sharps box fit for cytotoxic waste. These should be labelled as cytotoxic waste. If there is any contamination of the area or personal exposure to cytotoxic material, refer to the SACT Care pathway section on Health and Safety, section 1.8.

xiii) Any SACT drugs received, but not administered, must be safely returned to the Pharmacy Department in a designated transport bag or box for disposal or re-issue as soon as possible. A senior member of the Pharmacy aseptics team or the Oncology Pharmacist should be informed of the return.

Document Administration

Approval Record

Approval		
Date	**Name / Title**	**Signature**
07/05/09	Circulated for comments and feedback to Network Chemotherapy Group and Network Nursing and Pharmacy Group	
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Enquiries

All enquiries relating to this document should be addressed to:

Addressee: Name Caroline Waters

Address Macmillan Network Pharmacist
Kent and Medway Cancer Network,
Preston Hall,
Aylesford
Kent, ME20 7NJ

Telephone: 01622 713050

Email: Caroline.waters@nhs.net

Addressee: Name Sarah Wade

Address Macmillan Pharmacy Technician
Kent and Medway Cancer Network,
Preston Hall,
Aylesford
Kent, ME20 7NJ

Telephone: 01622

Email:

Document Location

The document is located in the Kent and Medway Cancer Network office, in hardcopy and in electronic format on the Kent & Medway Cancer Network website at www.kentmedwaycancernetwork.nhs.uk

DATE OF NEXT REVIEW

This item is next to be reviewed **July 2013** by Network Macmillan Senior Systemic anti-cancer therapy Nurse Specialist

Revision History

Date	Version	Status	Author	Summary of Changes
07/04/09	V0.1	Draft	Sarah Wade	Words 'chemotherapy, cytotoxic, monoclonal' etc. changed to 'systemic anti-cancer therapy' to reflect NCEPOD report
11/05/09	V0.2	Draft	Bryony Neame	Grammar changes as suggested by Dr. Waters – no operational changes
01/06/09	V0.3	Draft	Sarah Wade	Changes incorporated as suggested by M.Plant-no operational changes.
21/06/11	V1.1		Kate Miller	SACT abbreviation used throughout document. Updated name of off protocol policy to Treatment Algorithm Deviation Policy General review – no operational changes
28/07/11	V2	Final	Kate Miller	