Cancer Policy Unit
Planning & Quality Division

Scottish Government
Riaghaltas na h-Alba
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Dear Colleague

[REVISED] GUIDANCE FOR THE SAFE DELIVERY OF SYSTEMIC ANTI-CANCER THERAPY

CEL 30 (2012)

Revised 2023

DL (2023) 15

For implementation 5th June 2023

For action
Chief Executives
Medical Directors
Directors of Nursing
Directors of Pharmacy

For information
National Cancer Recovery Group
Clinical Leads, Network Managers, Network Pharmacists – Regional Cancer Networks

Background

Systemic anti-cancer therapy (SACT) includes but is not limited to cytotoxic chemotherapy, biological therapies, targeted therapy, immunotherapy, and advanced therapy medicinal products. Cytotoxic chemotherapy is known to be potentially carcinogenic, mutagenic and is hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH).

Treatment involving such medicines is required to be prescribed, dispensed, supplied and administered in accordance with the Medicines Act, 1968.

Purpose

The attached guidance, endorsed by the National SACT Programme Board, has been updated to reflect new knowledge, national guidelines and legislation on the safe delivery of SACT and covers all care settings including the patient's home.

This CEL supersedes Guidance for the Safe Use of Cytotoxic Chemotherapy CEL 30 (2012), published July 2012.

Safe Administration of Intrathecal Cytotoxic Chemotherapy CEL 21 (2009) remains extant.

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Action

NHS Boards are:

- required to be able to demonstrate compliance in discharging their clinical governance responsibility by ensuring implementation and monitoring of this guidance
- required to participate in Healthcare Improvement Scotland SACT Governance Framework to support quality assurance and demonstrate compliance
- required to work with their Regional Cancer Networks to develop action plans to address areas of non-compliance and share good practice
- advised that the National Cancer Recovery Group will oversee progress against implementation of the guidance.
- It is expected that NHS Boards, Regional Cancer Networks, the Managed Service Network for Children & Young People with Cancer, and Healthcare Improvement Scotland will work together to agree how best to take this guidance forward.

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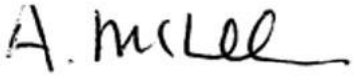
Yours sincerely,

Professor Sir Gregor Smith
Chief Medical Officer for Scotland



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Chief Nursing Officer for Scotland

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Introduction

Better Cancer Care, published in 2008, set out a commitment to review the previous guidance for the safe use of cytotoxic chemotherapy, HDL (2005) 29. Since the publication of HDL (2005) 29 there has been a significant change in the cancer service landscape in NHS Scotland, and also the publication of an audit, the NCEPOD Report – care of patients in England and Wales who died within 30 days of receiving systemic anti-cancer therapy (SACT).

The initial work to update this guidance was undertaken accounting for the quality ambitions set out in Scotland's Quality Strategy (2010) that care will be safe, effective and person-centred, and CEL 30 (2012) was published in July 2012. A refresh of the guidance has now been undertaken, however the revised and updated CEL 30 has the same purpose: to promote the safe delivery of SACT.

SACT is required to be prescribed, dispensed, supplied, administered and disposed of in accordance with the Medicines Act 1968. This CEL provides NHS Boards with a framework for safe practice in the prescribing, preparation, administration and disposal of SACT which will minimise the risk to patients receiving SACT and protect staff from occupational exposure to cytotoxic SACT.

Implementation of the guidance will be monitored by the NHS Board Lead Clinician for SACT who will report compliance with the CEL to the NHS Board Chief Executive as part of their clinical governance procedures. NHS Boards are required to demonstrate compliance with the standards contained within this guidance document.

In 2021 the Scottish Cancer Network was established by Scottish Government, with one of the primary objectives being to explore the option for a 'Once for Scotland' approach in the development of Clinical Management Pathways. Clinical Management Pathways aim to build on existing regional Clinical Management Guidelines, bringing clinicians and Regional Cancer Networks together from across Scotland to agree national consensus on all elements of the patient pathway, from initial diagnosis through to recovery, living with cancer or end of life care. It is recognised that if this programme is rolled out across all cancer services and tumour groups, there will be a period of transition in which some tumour groups will still be utilising existing Clinical Management Guidelines whilst they await the development and roll out of a Clinical Management Pathway. Therefore, the standards refer to Clinical Management Guidelines/Pathways interchangeably to allow for this transition period. Once a Clinical Management Pathway has been developed and approved for use by the regional networks across Scotland, any existing regional Clinical Management Guideline for that tumour group would become superseded.

Scope

The scope of this document includes the use of any systemic therapy in the treatment of cancer, this may include, but is not limited to, cytotoxic chemotherapy, biological therapies, targeted therapy, immunotherapy, and advanced therapy medicinal products. It covers patients of all age groups receiving

SACT, including clinical trials and any route of administration except intrathecal which is covered by the extant CEL 21 (2009).

It is recognised that radiopharmaceuticals are also used in the treatment of some cancers. These are highly specialised medicines and should be used under the control of healthcare professionals who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals. Radiopharmaceuticals are out with the scope of this guidance, and are also covered by The Ionising Radiation (Medical Exposure) Regulations 2017, but the principles within the guideline should be considered in the development of local policies and procedures for these agents when used to treat cancer, based on risk assessment. Health Board SACT leadership must be aware of, and comfortable with, the governance of their use in cancer.

It excludes hormonal therapies.

This guidance is intended to promote the safe use of medicines to treat cancer.

Process

The work to update the previous guidance was requested by the Scottish Government Health Department and undertaken under the auspices of the SACT Programme Board which reports directly to the National Cancer Recovery Group. A Review Short Life Working Group (membership at annex A) was established to revise and update the previous version of the CEL 30 published in July 2012. This working group comprised multi-professional stakeholders from the three Regional Cancer Networks, the Scottish Government Cancer Policy Team, and involved other relevant health professionals when needed. The updated guidance has also been peer reviewed within NHS Scotland via the Regional Cancer Networks.

The original 2012 publication was externally peer reviewed through the National Cancer Action Team in England and Cancer Policy colleagues in the Welsh Assembly.

GUIDANCE

1. CLINICAL GOVERNANCE, QUALITY AND RISK MANAGEMENT

1.1 Clinical Governance

1.1.1 It is the responsibility of the NHS Board and the NHS Board Chief Executive to demonstrate compliance and ensure implementation of this guidance through discharging their clinical governance responsibilities.

1.1.2 Effective clinical governance arrangements are in place for SACT services including the safe delivery of intrathecal SACT in line with CEL 21 (2009).

1.1.3 The NHS Board identifies a named Lead Clinician for SACT services who will be a consultant oncologist or haematologist, supported by nominated pharmacy and nursing leads. Adequate time is required to be assigned to fulfil the lead and supportive roles, NHS Boards will agree locally sufficient time for job planning purposes. In Boards where children and young people receive SACT in the cancer centre, there is a nominated Lead Clinician for Paediatric SACT Services, again supported by nominated pharmacy and nursing leads, to provide support to the NHS Board Lead Clinician for SACT services.

1.1.4 The Lead Clinician's accountability for the safe delivery of SACT services is clearly defined in the NHS Board's clinical governance structures.

1.1.5 The Lead Clinician provides an annual report to the appropriate clinical governance group on the safe delivery of SACT in the NHS Board.

1.1.6 The Lead Clinician ensures that systems are compliant with current legislation, national standards and guidelines.

1.1.7 The roles and responsibilities of the Lead Clinician include ensuring that:

- systems are in place to develop, approve, implement, and regularly review policies and guidelines for the safe delivery of SACT across all care settings in the NHS Board, including SACT protocols and associated supportive treatment guidelines
- quality assurance processes are in place including demonstration of compliance with these standards through participation in Healthcare Improvement Scotland's (HIS) SACT Governance Framework
- an education and training programme for all staff involved in the delivery of SACT services is in place; and
- systems are in place for implementation of Clinical Management Guidelines/Clinical Management Pathways (CMGs/CMPs).

1.1.8 A co-ordinated regional or national approach to the development of CMG/CMPs and SACT protocols is in place to support a consistent approach to care delivery.

1.1.9 CMGs/CMPs and SACT protocols are readily available to all clinical staff involved in the delivery of SACT.

1.1.10 As part of the SACT Governance Framework, Healthcare Improvement Scotland (HIS) hosts a national external review group to conduct a review of board-level exception reports and action / improvement plans generated by the internal and external peer review audit cycle. This will generate a report for the Scottish Government.

1.2 Education and Training

1.2.1 All staff involved in SACT have appropriate skills, knowledge and training in their field of practice.

1.2.2 The Lead Clinician ensures the implementation of a programme of education and training, including competencies and methods of assessment as appropriate, for all staff involved in the delivery of SACT services.

1.2.3 The education and training programme includes:

- principles of safe use and relevant national guidance
- local policy and procedures on safe use
- principles of SACT
- CMGs/CMPs and SACT protocols relevant to area of clinical practice
- process for the education and training of the MDT involved in prescribing, verification, administration, and management of adverse events for new SACT, at the point of introduction into practice
- consent and information giving
- toxicity assessment
- holistic assessment of patients receiving SACT
- prevention and management of adverse effects
- explicit training on selection and use of equipment
- safe handling

1.2.4 Evidence of this training is documented in each staff member's training record as relevant.

1.2.5 A system is in place for the quality assurance of education and training for all staff involved in the safe delivery of SACT which includes maintaining skills and competency assessment.

1.2.6 Guidance is provided for clinical staff working in non-cancer specialities who may have to care for patients receiving SACT.

1.3 Risk Management

1.3.1 The Lead Clinician ensures systems are in place to maintain adequate risk management of the SACT service in the NHS Board.

1.3.2 Capacity and workforce plans for SACT services are available and are reviewed and reported to senior managers and the appropriate NHS Board clinical

governance group on a regular basis.

1.3.3 All clinical incidents of avoidable harm, such as adverse events and near misses involving SACT are documented, reviewed and learning shared to prevent future actual/potential harm.

1.3.4 All deaths occurring within 30 days of administration of SACT are reported and reviewed as part of the NHS Board clinical governance arrangements.

1.3.5 Risk assessments are regularly undertaken to identify potential risks in the SACT service to enable steps to be taken to minimise avoidable harm. A risk register and action plan is reviewed at regular intervals and reported to the appropriate NHS Board clinical governance group.

1.3.6 The initiation of SACT outside routine working hours is avoided except in exceptional clinical circumstances. In exceptional clinical circumstances, a policy is in place to ensure the safe delivery of SACT.

1.3.7 In addition to NHS board clinical governance arrangements clinical incidents of avoidable harm involving children and young people's services are reported to, and reviewed by, the Managed Service Network for Children and Young People with Cancer (MSNCYPC).

1.4 Clinical Management Guidelines/Clinical Management Pathways

1.4.1 A CMG/CMP, as defined in the glossary, is in place for all common cancers. In paediatric cancer care, an approved clinical trial protocol or approved national Children's Cancer Leukaemia Group (CCLG) guideline may replace a CMG/CMP.

1.4.2 In rarer cancers, where there is no CMG/CMP, a SACT protocol is in place.

1.4.3 Development of CMGs/CMPs is be led by appropriate regional or national tumour specific Managed Clinical Networks (MCNs) or Pathway Boards and approved via local and regional governance arrangements.

1.4.4 For children and young people, CMGs/CMPs or SACT protocols are approved via the MSNCYPC.

1.4.5 Policies and procedures are in place to manage individual requests for treatments not routinely available in line with NHS Board medicine governance processes and Scottish Government Health Department policy.

1.5 SACT protocols

1.5.1 SACT protocols are in place for all SACT regimens in use. These can be digital or within an electronic prescribing and administration system, but are readily available to all relevant healthcare professionals involved in patient's care.

1.5.2 SACT protocols are evidence based and, where appropriate, in line with national guidelines.

1.5.3 SACT protocols are written in a clear and unambiguous manner and comply with the framework outlined in Appendix 1.

1.5.4 An approved clinical trial protocol or national paediatric guideline may be used in the absence of a SACT protocol.

1.5.5 Robust clinical governance systems are in place for the construction of protocols and associated prescriptions on electronic prescribing and administration systems. This includes:

- assigned responsibilities
- procedures for validation, double checking of entries, and the use of test prescriptions.

2. DECISION TO TREAT, CONSENT, AND INFORMATION FOR PATIENTS/ CARERS

2.1 Decision to Treat and Consent

2.1.1 The decision to initiate a new course of SACT is taken by a consultant oncologist/haematologist[1]. For *initial* treatment this will be after discussion at a multi-disciplinary team (MDT) meeting, and in consultation with the patient or carer, where appropriate. It is advised that more than one haematologist or oncologist is present at an MDT to ensure consensus treatment decision. In cases where initial treatment with SACT is prescribed in an emergency situation, prior to MDT discussion, the treatment plan is subsequently discussed and documented in the relevant MDT.

2.1.2 Selection of a SACT regimen, is the responsibility of the consultant oncologist/haematologist[1], taking into account the patient's wishes, co-morbidities and life expectancy, the CMG/CMP and SACT formulary choices available.

2.1.3 If patient specific circumstances require an alteration to the MDT plan (e.g. co-morbidities), or if there is a reason to vary from the CMG/CMP, this is explained and discussed with the patient and is clearly documented in the patient central records, letter to GP and on the SACT electronic prescribing record (consent form and treatment plan). Local/regional governance processes are followed to request access to non-approved SACT where appropriate.

2.1.4 The consultant oncologist/haematologist or appropriate deputy obtains written informed consent to treatment in accordance with national guidance and local policy.

2.1.5 Consent process is in line with HIS Guidance on consent for SACT.

2.1.6 The treatment decision, treatment intent (curative vs. non curative) and the proposed patient specific management plan, including planned assessment of treatment response, are documented in the patient's record and communicated to

[1] or other consultant physician specifically approved and defined by their Board's governance structures to make the decision to initiate treatment with SACT for specific oncological conditions, e.g. Consultant Dermatologists in some skin cancer cases.

the GP within 14 days. This may be within 14 days of discharge following prolonged admission.

2.1.7 Relevant information summarising anticipated SACT toxicities, such as a copy of the consent form, are readily available to Emergency Departments and other providers of Unscheduled Care, ideally in the patient's Electronic Patient Record (EPR).

2.1.8 The performance status of the patient and any co-morbidities are documented in the patient's record.

2.1.9 For patients with poor performance status (ECOG PS 3 and 4) the rationale for treatment is clearly documented in the patient specific management plan and additional monitoring arrangements are in place including escalation to consultant level.

2.1.10 If patient's performance status is out with that recommended by the protocol the decision making process is clearly documented.

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

2.2 Information for Patients and Carers

2.2.1 There is provision of written and verbal information to patients receiving SACT and as a minimum the patient and/or carer receiving treatment is made aware of the following:

- SACT protocol specific toxicities
- signs and symptoms of extravasation for intravenous SACT
- safe handling of SACT
- information on what to do in the event of developing a toxicity including when, who, and how to contact the appropriate services
- safe handling and disposal of patient waste.

2.2.2 A record of the information given to patients is documented.

3. PRESCRIBING SACT

3.1 Prescribing

3.1.1 Only an appropriately qualified, competent practitioner, as defined by local policy, prescribes SACT.

3.1.2 SACT prescribers have access to all relevant clinical data, from electronic prescribing systems and other supporting clinical systems, to support safe and appropriate prescribing as defined by local or regional policy.

3.1.3 Clinical data used to support prescribing is collected within an appropriate timescale as defined by local or regional policy.

3.1.4 Where there are significant alteration options within a protocol, prescribing systems have separate regimens set up for these options.

3.1.5 The patient is assessed for any adverse effects prior to each prescribing episode of SACT. These are graded using a recognised toxicity grading system, such as CTCAE or WHO criteria, and recorded in the patient record. Reasons for any dose adjustments or protocol amendments are also clearly documented within the patient's electronic record. In addition, systems are in place to ensure the patient is made aware of changes and any monitoring requirements.

3.1.6 Performance status is assessed prior to each prescribing episode of SACT and recorded in the patient's electronic prescribing record.

3.2 Prescriptions and Documentation

3.2.1 SACT is prescribed using an electronic prescribing and administration system and complies with current legal requirements and local, regional, or national prescribing policy. Prescribing using a paper system is only undertaken in very limited circumstances, as defined by local policy, and needs to be readily accessible in the patient's record.

3.2.2 All prescriptions are written in a clear and unambiguous manner and include the information contained in Appendix 2 and in accordance with local or regional prescribing policies.

3.2.3 Where possible, there is a single SACT prescription for all medicines including all appropriate supportive care and hydration. Where additional supportive therapies are to be prescribed separately, this will be clearly indicated within the protocol, additional prescribing note on prescription or local/regional guidelines.

3.2.4 SACT is not prescribed by repeat prescription.

4. PHARMACEUTICAL VERIFICATION, PREPARATION AND DISPENSING OF SACT

4.1 Pharmaceutical Verification

4.1.1 All prescriptions for SACT are verified by a suitably trained registered pharmacy professional in accordance with legislative requirements, national standards and local or national policy prior to dispensing and release from pharmacy. Key checks are outlined in Appendix 3.

4.1.2 If any discrepancies are found during verification, appropriate procedures are followed to address these prior to sign-off, as defined within local policy.

4.1.3 Verification of each prescription is recorded within the electronic prescribing and administration record according to local policy. In the exceptional circumstances in which a paper prescription is used, it is signed and dated manually (wet signature) as a record of verification.

4.2 Aseptic Preparation and Dispensing

4.2.1 All SACT is supplied from a pharmacy controlled facility.

4.2.2 SACT is either, dispensed and labelled for the individual patient in a ready to administer form or, where appropriate after risk assessment, supplied as ward stock e.g. subcutaneous preparations.

4.2.3 The preparation and dispensing of SACT complies with relevant legislative standards, national standards and guidelines.

4.2.4 Staff preparing and dispensing SACT are able to confirm that pharmacy verification has taken place prior to release from pharmacy. Where SACT is supplied from ward stock, staff administering the treatment must check that pharmacy verification has taken place prior to administration

4.2.5 Systems are in place to independently audit the aseptic service in line with NHS Scotland pharmacy aseptic audit programme for unlicensed facilities. The audit will be carried out by the MHRA (Medicines Healthcare products Regulatory Authority) for licensed facilities.

4.2.6 Non-conformance remediation plans, with priorities and timescales assigned, have to be agreed by the local Board and be in place to achieve full compliance with the audit standards.

4.3 Preparation and Labelling of Intravenous Vinca Alkaloids

4.3.1 When a vinca alkaloid is prescribed for administration in an adult or young people's unit, the prescribed dose is dispensed and supplied from the pharmacy controlled facility ready to administer in a 50ml mini-bag.

4.3.2 When vinca alkaloids are prescribed for children or young people treated in a children's unit the prescribed dose is dispensed diluted and presented in a minimum 10ml syringe size.

4.3.3 For all vinca alkaloids dispensing labels are required to state, in addition to the standard information: **"*FOR INTRAVENOUS USE ONLY - FATAL IF GIVEN BY OTHER ROUTES".***

4.4 Dispensing

4.4.1 Ready to administer SACT is dispensed in accordance with local policy and procedures that incorporate legal requirements, national standards and guidelines.

As a minimum, local dispensing procedures have to encompass information contained in Appendix 4.

4.4.2 When an oral suspension or liquid is dispensed the dose is measured using a suitable oral/enteral syringe.

4.4.3 Monitored dosage systems (MDS) are not routinely recommended when dispensing oral SACT. If it is necessary to use an MDS compliance aid, a risk assessment is performed to ensure that any risk to patients, carers and other health care professionals is managed appropriately.

4.4.4 Oral liquid preparations of cytotoxic SACT which do not have an EU or UK marketing authorisation are purchased from a MHRA licensed special manufacturer.

4.5 Issuing SACT for Self-Administration

4.5.1 Staff issuing SACT directly to patients/carers ensure that the patient/carer understands how and when to take their medicines and have been appropriately counselled.

4.5.2 If SACT for self-administration is being delivered directly to a patient's address local processes are in place to ensure all relevant information in relation to SACT is provided to the patient/carer as defined in section 2.2, and any changes made to dosing have been discussed (see 3.1.5).

4.5.3 Parenteral subcutaneous pre-filled syringes are supplied to patient with appropriate storage containers, safe-handling and waste disposal equipment, and training in correct usage provided.

4.5.4 The patient and/or carer is instructed on safe handling, storage, administration, spillage and disposal of SACT for self-administration, and is advised to return any unused SACT to pharmacy.

5. ADMINISTRATION

5.1 General Administration Issues

5.1.1 Policies and procedures are in place for SACT administration and key checks are undertaken. This includes all routes of administration used within the NHS Board.

5.1.2 SACT is administered in areas which are risk assessed as safe and appropriate for the treatment being administered.

5.1.3 Staff who administer SACT have demonstrated an approved level of skill, expertise and experience as defined by local policy. They will be aware of potential side effects, administration related risks and their management.

5.1.4 Resuscitation equipment is available in clinical areas where SACT is administered.

5.1.5 SACT administration is commenced during normal working hours, wherever possible. If administration of SACT is required to continue outside of normal working hours then appropriately trained staff are in attendance to monitor delivery of the treatment.

5.1.6 The patient's condition and clinical parameters are assessed using a recognised toxicity grading system immediately prior to administration to ensure it reflects the most recent clinical assessment. The toxicity assessment undertaken and any significant differences highlighted to the prescriber prior to administration uses the same tool as prior to prescription (3.1.5), and is compared with this. Any clinically significant differences are highlighted to the prescriber prior to administration.

5.1.7 The presence of a signed consent form must be verified before cycle 1 of a new SACT regimen is administered.

5.2 Pre-Administration Verification

5.2.1 Procedures exist for two person pre-administration checks, one of which is undertaken by the practitioner administering the SACT. The second checker is determined by local policy.

5.2.2 The pre-administration checks independently confirm:

- patient identity in line with local policy
- patient name and CHI number match SACT prescription
- correct date and time of administration
- correct drug name, dose, volume bolus/infusion, diluent, route of administration and administration rate in relation to the prescription
- expiry date and time will not pass before administration is complete
- appearance and physical integrity of SACT
- appropriate pre-medication and/or supportive therapies have been administered.
- prescriber's signature and additional signature to indicate that pharmacy verification has been carried out.
- checklist order reflects the order in which the SACT to be checked.
- check for allergies
- confirm venous access device patency.

5.2.3 If any discrepancies are found local procedures are followed to address these prior to administration.

5.2.4 Both the practitioner administering and the checker will sign the appropriate sections of the administration document as soon as is practical following the start of administration (this may be a digital signature). If intravenous SACT, administering practitioner is required to be SACT trained.

6. EXTRAVASATION

6.1 Minimising Risk of Extravasation

6.1.1 Policies and procedures for the administration of intravenous SACT include techniques which aim to minimise the risk of extravasation.

6.1.2 Patients and carers are made aware of the potential risk, signs and symptoms of extravasation and action they need to take if symptoms develop.

6.1.3 When a vinca alkaloid is administered in a 50ml mini-bag, a full risk assessment is undertaken locally to determine the most suitable method for intravenous infusion. The patient is closely monitored for signs of extravasation.

6.2 Treatment of Extravasation

6.2.1 A local extravasation procedure is in place to allow for the management of the suspected or actual extravasation and includes criteria for referral to specialist plastic surgical services.

6.2.2 Extravasation treatment kits and a copy of the extravasation procedures are readily available in areas where SACT is administered.

6.2.3 In the event of an extravasation, the patient, their consultant, and their GP are kept fully informed of ongoing management. The procedure requires to state the means by which the GP is informed e.g. standard template letter or via electronic record.

6.2.4 All SACT extravasation injuries are documented in the patient's record and an adverse event report completed in accordance with local policy.

6.2.5 The patient is followed up and reviewed at regular intervals as appropriate to local guidance and level of injury.

7. SUPPORTIVE CARE DURING TREATMENT

7.1 Services delivering SACT have guidelines and protocols available for supportive treatment. These guidelines and protocols are readily available to all healthcare professionals and services who may be involved in the acute care of SACT complications, in particular neutropenic sepsis. A minimum list of the guidelines required is contained in Appendix 5.

7.2 Patient/care pathways for the management of complications of SACT are approved by local clinical governance groups and are accessible to all relevant staff across the NHS Board area. This may include staff in NHS 24 Centres, NHS Board

Out of Hours Centres, Emergency Care Centres and Acute Admission Units. The pathways include:

- optimum self-care prevention and management strategies for minor toxicities
- patient/carer information on what they are required to do in the event of developing a complication including when, who and how to contact relevant services
- signposts to guidelines and protocols for supportive treatment including Alert Cards advising of the signs and symptoms of neutropenic sepsis, and immunotherapy toxicities with details on how to access timely advice, 24 hours a day, every day, from an appropriate specialist and details of treat and transfer arrangements, if appropriate
- arrangements for communication with, and timely review by, appropriate specialist.

8. ALTERNATIVE MODELS OF SACT DELIVERY

If a location is being used on a regular basis for SACT delivery then that location has to comply fully with the requirements for an outpatient SACT delivery area.

The remainder of this section applies only to delivery of SACT out with the Cancer Centre/Unit in, for example, the rural general hospital, GP surgery, community hospital, or in the patient's home on an individual named patient basis or via dispensing services provided by community pharmacy or homecare suppliers, which may allow patients to remain at home or nearer to home while receiving treatment.

It is necessary for the prescription, pharmacy verification and clinical management of the patient to be managed within the structure of an established Cancer centre/unit.

Different models may be developed or utilised in the delivery of SACT out with the cancer centre/unit. This could involve, but is not limited to; patient, carer or district nurse administration in the patient’s home or setting of their choice; centralised prescribing, verification and preparation at the cancer centre/unit with administration in a facility closer to home but under the supervision and management of the cancer centre/unit; a shared care framework with other services that may include any of the following:

- Prescribing of SACT
- Pharmaceutical verification of SACT
- Monitoring and follow up of SACT
- Dispensing of SACT
- Administration of SACT

9. SAFE HANDLING OF CYTOTOXIC SACT

Cytotoxic medicines are hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). In relation to services delivering cytotoxic SACT the overriding health and safety principle is to minimise exposure and to prevent or minimise environmental contamination.

9.1 Minimising occupational exposure

9.1.1 Systems and procedures are in place to minimise occupational exposure in line with COSHH and establish safe handling as routine practice.

9.1.2 Personal protective wear and equipment, appropriate to the level of handling of cytotoxic SACT, is available to staff.

9.1.3 Parenteral cytotoxic SACT is issued from a pharmacy controlled facility in a 'ready to administer' form.

9.1.4 Local procedures specify that the cytotoxic SACT is not manipulated any way outside of a pharmacy situation. Policy outlines the action to be taken if the patient is unable to take the cytotoxic SACT in the form presented.

9.1.5 Systems are in place for the reporting of incidents involving accidental spillage and potential exposure to cytotoxic SACT.

9.2 Disposal

9.2.1 Systems and procedures are in place for the safe disposal of unused doses and all items contaminated with cytotoxic SACT.

9.2.2 Systems and procedures are in place for safe handling and disposal of patient waste potentially contaminated with cytotoxic SACT.

9.3 Spillages

9.3.1 Systems and procedures, including COSHH risk assessments, are in place to minimise the risk of spillage.

9.3.2 Cytotoxic spill kits are available and prominently displayed in all areas where cytotoxic SACT is stored or handled. Spillage kits are provided to patients self-administering liquid/injectable SACT.

10. RECEIPT, TRANSPORT AND STORAGE OF SACT

10.1 Systems and procedures are in place for the receipt of SACT into the pharmacy according to safe handling procedures, including product integrity checks and maintenance of temperature during transportation, where appropriate.

10.2 SACT is required to be stored securely and safely at appropriate temperatures in locations separate from other medicines and clearly marked for the storage of SACT only.

10.3 Systems and procedures are in place to ensure SACT is transported in a safe and secure manner. Transported products are required to be maintained within the cold chain for the duration of the transported period, where relevant, and sensitive products are not subject to any conditions which may affect product stability e.g. agitation/rough handling of monoclonal antibody products.

10.4 Reconciliation records are in place for the receipt of SACT in clinical areas.

Appendix 1

SACT Protocol Framework

- the protocol name in full - sole use of an acronym to identify a protocol is minimised
- definition of the clinical condition(s) being treated including indication, line of therapy and any restrictions to eligibility (e.g SMC restrictions)
- treatment intent – restricted to either ‘curable’ or ‘non-curable’
- usual baseline performance status required for treatment
- all SACT medicines by full generic name and, if appropriate by formulation and proprietary name
- dosing schedule for each medicine
- route, method and duration of administration
- maximum cumulative doses where applicable
- any pre-medication required
- diluents and appropriate infusion volumes
- ensure appropriate infusion line in use (when relevant)
- hydration schedules (when relevant)
- supportive therapy including, where appropriate, prophylaxis for the prevention of neutropenic sepsis
- concomitant radiotherapy & scheduling where relevant
- relevant critical tests – including haematology and biochemistry parameters and any other tests that need to be performed before SACT starts and during treatment
- special precautions and contraindications to treatment
- clinically significant medicines and food interactions
- expected toxicities / adverse effects
- extravasation risk
- recommendations for treatment delays or dose reductions based on relevant toxicities and/or haematology and biochemistry parameters
- where relevant, reference is made to policies for the management of toxicities
- decision points, including response assessment and advice on when patients are referred for review
- reference source(s)

Appendix 2

SACT Prescriptions

The following patient specific information is documented:

- name, date of birth, CHI number
- height, weight and body surface area where relevant
- diagnosis
- performance status
- relevant haematology and biochemistry results
- any other relevant critical tests
- calculated doses to be administered
- indication of any dose modifications made

Prescriptions are clear and unambiguous and include:

- the name of the SACT protocol
- all SACT medicines to be given including protocol doses
- the full generic name of each medicine and, where appropriate, the specific formulation and its proprietary name
- intervals between cycles
- maximum cumulative doses where applicable
- route, method and duration of administration
- where appropriate, diluents and infusion volumes
- hydration schedules if required
- pre-medication if required
- appropriate supportive therapy
- indication of concomitant radiotherapy where applicable
- cycle number and date of administration
- for SACT for self-administration - the start date and duration of each treatment cycle
- name of prescriber, signature* and date prescribed
- pharmaceutical verification signature* and date
- administration signatures*, date and time where relevant.

*within electronic prescribing and administration systems these details will be recorded electronically

Appendix 3

Key Pharmaceutical Checks

This list of pharmaceutical checks is not exhaustive but forms the basis of local policy and practice. For specific SACT regimens additional checks may be necessary or, conversely, some checks may not be relevant. In both these scenarios a risk assessment is completed and documented to determine which checks are required to maintain patient safety and quality of care.

Prior to the first cycle of a new course of treatment, ensure that:

- the protocol has been through local approval processes
- the protocol is the intended treatment as documented in the patient's clinical record and is appropriate for the indication
- the appropriate regimen selection for a patient in accordance with CMGs/CMPs, local, regional and national guidance or as per individual patient treatment request.
- the protocol is appropriate for the patient's diagnosis, medical history, performance status and SACT history. The diagnosis includes pathology, staging, tumour markers and other relevant factors, as applicable, that determine eligibility for prescribed treatment.
- the patient has signed a SACT consent form for the new course of treatment

Prior to all cycles of treatment, ensure that:

- there are no known medicine or food interactions or conflicts with patient allergies or previous adverse reactions
- the timing of administration is appropriate in relation to interval since last treatment
- patient demographics including age, height and weight are correctly recorded on prescription
- an appropriate body surface area (BSA) is correctly calculated where relevant, taking into account recent weight
- all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance
- maximum cumulative dose and maximum individual dose is not exceeded, as appropriate
- reason for any dose adjustment is documented and the dose adjustment is appropriate
- method of administration is appropriate
- relevant laboratory values are within accepted limits as defined in the SACT protocol
- other critical tests, including toxicity assessment, have been undertaken and recorded as defined in the SACT protocol
- doses are appropriate with respect to renal and hepatic function, performance status and co-morbidities and any experienced toxicities
- supportive care is prescribed and it is appropriate for the patient and SACT protocol
- requirement for dose adjustment and/or prophylaxis, to minimise risk of neutropenic sepsis, as specified in the SACT protocol

- prescriber details and signature (written or digital) are present and confirm they are authorised to prescribe SACT

Appendix 4

Dispensing Standards for SACT[2]
Policies and procedures which incorporate legal requirements, national standards and guidelines are in place for:

- **Dispensing**
  - staff dispensing SACT are able to confirm that the pharmacist verification has taken place prior to release from the pharmacy
  - the exact amount of the treatment required is dispensed for the designated treatment/cycle duration, where there is deviation from this requirement, for clinical trials or if packs cannot be split, a risk assessment has to be performed to address any risks to patient safety
  - the quantity of tablets/capsules/ sc syringes is double checked as part of the final check of the prescription
  - the prescription is endorsed with the amount supplied for all strengths of products dispensed
  - the dispensed items are checked by an appropriately trained member of staff to ensure:
    - the correct medicine has been dispensed
    - the correct dose, frequency, duration and dates of treatment as appropriate are detailed on the label
    - the correct patient name is on the label
    - the correct quantity of medicine to be dispensed has been calculated
    - the correct quantity of medicine has been dispensed.

- **Labelling**
  - comprehensive directions for use are provided to patients supplied with SACT for self-administration
  - SACT is never supplied and labelled 'Take as directed' unless the patient or carer is given additional explicit verbal and written information regarding dose, frequency of administration and duration
  - A yellow label is attached to SACT to highlight type of medicine and that cancer specialist advice should be sought if patient is admitted to hospital. For example, "This is an anti-cancer medicine. In the event of hospital admission/surgical procedure, discontinue this medicine until advice is sought from a cancer specialist".

[2] SACT not prepared in an aseptic dispensing facility – including oral SACT, licensed pre-filled sc injections.

Appendix 5

Supportive Treatments

Protocols for the following treatment related toxicities are developed locally or regionally/nationally and endorsed by local or regional governance groups. The detail of the content will reflect local practice.

- neutropenic sepsis in line with the Best Practice statement for management of neutropenic sepsis[3]
- nausea and vomiting
- diarrhoea and constipation
- mucositis
- skin toxicity
- tumour lysis syndrome
- hypersensitivity reactions
- immunotherapy related toxicity
- vaccination advice (updated annually)
- pandemic management strategy
- bone modifying agents
- use of G-CSF

[3] Scottish Government (2011) Best Practice Statement for management of neutropenic sepsis.

Appendix 6

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Clinical Governance Overview

Clinical governance is the process by which accountability for the quality of health care is monitored and assured. It should be supported through a culture where delivery of the highest quality of care and support is understood to be the responsibility of everyone working in the organisation – built upon partnership and collaboration within teams and between healthcare professionals and managers.

Clinical governance structures and processes assure Health Boards that this is happening – whilst at the same time empowering clinical and care staff to contribute to the improvement of quality as well as making sure that there is a strong voice of the people who use services.

Quality of care should be given the highest priority at every level within services. Delivery of effective clinical governance provides assurance to patients, clinical staff, managers, Directors and the Board that:

- Quality of care, effectiveness and efficiency drives decision making about the planning, provision, organisation and management of services;
- The planning and delivery of services take full account of the perspective of patients and service users;
- Unacceptable clinical and care practice will be detected and addressed.

Effective clinical governance is not the sum of all these activities; rather it is the means by which these activities are brought together into a structured framework and linked to strategic commitments to deliver safe, effective and person-centred care.

Clinical governance structures and processes should support staff in continuously improving the quality and safety of care. It will also ensure that wherever possible poor performance is identified and addressed. All health professionals are professionally accountable for their individual clinical and care decisions.

This CEL is underpinned by the preceding clinical governance arrangements outlined through:

NHS HDL (2001) 74 Clinical Governance Arrangements.
Scottish Executive
http://www.sehd.scot.nhs.uk/mels/HDL2001_74.htm

NHS MEL (2000) 29 Clinical Governance.
Scottish Executive
http://www.sehd.scot.nhs.uk/mels/2000_29final.htm

NHS MEL (1998)75 Clinical Governance.
Scottish Executive
http://www.sehd.scot.nhs.uk/mels/1998_75.htm

Annex A

REVIEW GROUPS MEMBERSHIP

Review Short Life Working Group Membership	
Azmat Sadozye	Chair, SMO Cancer
John Murphy (retired)	Chair of SACT Programme Board, NHS Lanarkshire
Keith Willcock	SG Pharmacy & Medicines Division
Ewan Brown	SCAN SACT Lead, NHS Lothian
Sophie Barrett	WoSCAN SACT Lead & Consultant Oncologist, NHS Greater Glasgow & Clyde
Caroline McKinnel / Gillian Wilson	Joint Chairs & SCAN SACT Nurse Leads NHS Lothian and NHS Fife respectively
Ann McKenna	WoSCAN Nurse Lead, Senior Specialist Nurse (Haematology & Oncology), NHS Lanarkshire
Fiona Campbell	NCA Nurse Lead, Nurse Consultant (SACT), NHS Highland
Heather Dalrymple	National Clinical Lead Cancer Medicines, HIS
Seonaid McLachlan	WoSCAN Pharmacy Representative, Principal Pharmacist Cancer Services, NHS Ayrshire & Arran
Mary Maclean (retired)	Lead Cancer Pharmacist, WoSCAN & National Clinical Lead – Cancer Medicines, HIS
Judith Jordan	NCA Pharmacy Representative, Lead Pharmacist North Cancer Alliance
Jane Tighe (retired)	Head of Service for Clinical Haematology, NHS Grampian
Peter MacLean	Head of Service for Clinical Haematology, NHS Ayrshire & Arran
Scott Nicol	Aseptic Pharmacy Representative, NHS Greater Glasgow & Clyde
Lesley Symington	Haematology ANP, NHS Lothian
Seona Carnegie	Secretariat, SG Cancer Policy Team
Rae Thomson	SG Cancer Policy Team
Gregor McNie	SG Cancer Policy Team

Additional SACT Programme Board Review Group Members	
David Cameron	Chair, SACT PB, NHS Lothian
Angela Russell	Lead Nurse, MSNCYPC, NHS Lothian
Dermot Murphy	National Clinical Director, MSNCYPC, NHS Greater Glasgow & Clyde
Karon McDowall	Lead Pharmacist, MSNCYPC, NHS Greater Glasgow & Clyde
Tracey Cole	Projects & Planning Manager, WoSCAN

GLOSSARY

ADVANCED THERAPY MEDICINAL PRODUCTS - a novel class of medicines that are based on genes, tissues or cells. They can be classified into 3 main types: 1) gene therapy medicines, 2) somatic-cell therapy medicines, 3) tissue-engineered medicines

ADVERSE EVENT – any unfavourable, and unintended (including an abnormal laboratory finding), symptom, sign or disease temporarily associated with the administered treatment.

AUDIT - A method by which those involved in providing services assess the quality of care. Results of a process or intervention are assessed, compared with a pre-existing standard, changed where necessary then reassessed.

BIOLOGICAL THERAPIES - agents derived from biological sources designed to stimulate or restore the ability of the body's immune system to fight infection and disease. Examples used in cancer treatment include monoclonal antibodies, immunotherapy agents, and targeted therapies.

CARCINOGEN - A substance that causes or can help to cause cancer.

CHI NUMBER - The Community Health Index (CHI) number is the unique patient identifier for NHS Scotland. Everyone who is registered with a GP practice in Scotland has a CHI number.

CLINICAL GOVERNANCE GROUP - clinical governance is the framework through which NHS organisations are accountable for continuously improving the quality of their services and safe-guarding high standards of care. SACT clinical governance groups within NHS Boards ensure that this true for SACT services.

CLINICAL MANAGEMENT GUIDELINE/CLINICAL MANAGEMENT PATHWAY – A Clinical Management Guideline (CMG)/Clinical Management Pathway (CMP) (see introduction) is a multi-professional document which promotes multi-professional provision of high quality care by detailing appropriate management through all stages of the patient's journey – screening, diagnosis, staging, histopathology, investigations, radiotherapy, SACT, supportive treatment and follow up.

COSHH – Control of Substances Hazardous to Health Regulations 2002.

COURSE - In the context of this document, this is the total number of SACT treatments planned for one patient at a given stage in the clinical management plan. It is often spread over a number of weeks or months e.g. 6 cycles of SACT at monthly intervals will make up one course.

CTCAE - Common Terminology Criteria for Adverse Events.

CYCLE - In the context of this document, each individual SACT treatment for a patient, the sum of which make up the course, e.g. 6 cycles of SACT make up one course.

CYTOTOXIC – Chemicals that are directly toxic to cells preventing their replication or growth.

CYTOTOXIC SACT - A group of medicines active against cancer, but can also be used for non-malignant conditions. Also often referred to as cytotoxic chemotherapy.

They are commonly classified according to their mode of action e.g. alkylating agents.

DISPENSING - The activity of supplying a product in the appropriate form for a specific patient according to a prescription.

EPISODE - In the context of this document, each time a patient attends for treatment within a cycle.

EXTRAVASATION – Leakage of an intravenous medicine from the vein into surrounding tissues.

GUIDELINE – A document containing best practice advice. May be used to develop specific local policies and procedures.

IMMUNOTHERAPY – a type of cancer therapy that treats disease by activating or suppressing the immune system.

INTRAVENOUS – Given into a vein by injection or infusion.

INTRATHECAL – Injection into the cerebrospinal fluid bathing the spinal cord and brain.

LEAD CLINICIAN – for the purposes of this document the term lead clinician is used to indicate the named clinician within an NHS Board who has responsibility for SACT services and governance

LICENSED FACILITY – A site is in possession of a Manufacturer's Specials Licence granted by the MHRA which allows the site to manufacture unlicensed medicines (specials).

MANAGED CLINICAL NETWORK (MCN) - A linked group of health professionals from primary, secondary and tertiary care, working in a co-ordinated manner, unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality, clinically effective, and patient centred services.

MANAGED SERVICE NETWORK (MSN) – network of healthcare specialists from different NHS Boards working together in a co-ordinated manner unconstrained by existing professional and NHS Board boundaries, to ensure equitable provision of high quality, clinically effective, and patient centred services

MHRA - Medicines and Healthcare products Regulatory Agency; the UK medicines licensing regulatory authority.

MONITORED DOSAGE SYSTEMS - a simple storage device for a patient's medication. The dosage system is made up of multiple compartments, divided into the days of week and times of the day common for medicine taking.

MUTAGEN – A substance that can cause or increase the rate of genetic mutation.

NEAR MISS – An incident where the people involved came to no actual harm, but which could have had serious consequences.

OCCUPATIONAL EXPOSURE – Risks encountered from exposure to potentially or actually hazardous substances in the workplace.

OFF-PROTOCOL - A treatment or protocol choice made based on individual patient need delineated by exceptional circumstances.

PHARMACEUTICAL CARE – A systematic approach applied by a registered pharmacy professional to ensure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons.

PHARMACEUTICAL VERIFICATION - A process by which a registered pharmacy professional ensures a prescription is clinically appropriate by reviewing relevant clinical parameters and all medicines being taken by the patient. The purpose is to identify, resolve and prevent medicine-related problems.

POLICY- A plan of action adopted by a group or organisation.

PREPARATION - The manipulation of raw materials and components within the pharmacy to make a final product for dispensing or in anticipation of dispensing in accordance with a prescription.

PROCEDURE - A document giving detailed instructions on how to carry out a task, based on good practice.

QUALITY PERFORMANCE INDICATOR (QPI) - a proxy measure of quality care.

RECORDS - A permanent written account of a process undertaken.

SACT PRESCRIPTION - The prescription is used to order SACT medicines, authorise treatment and record their administration.

SACT PROTOCOL – a written summary of all relevant safety and medicines governance guidance for use of a specific SACT regimen, including: indication/place in treatment pathway(s), SACT regimen details (as specified below), required critical tests, side effects and monitoring criteria, etc. (see Appendix 1)

SACT REGIMEN – the specific treatment course including all SACT drugs, doses, days of administration, treatment intervals and duration of treatment.

SYSTEMIC ANTI-CANCER THERAPIES (SACT) - Encompasses biological therapies, immunotherapies, advanced therapy medicinal products and cytotoxic chemotherapy.

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