The Quality Unit
Planning & Quality Division

The Scottish Government

DELIVERING
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Dear Colleague

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

Background

Systemic anti-cancer therapy (SACT) encompasses biological therapies and cytotoxic chemotherapy. 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 must be prescribed, dispensed, supplied and administered in accordance with the Medicines Act, 1968.

Purpose

The attached guidance, endorsed by the Scottish Cancer Taskforce, 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 HDL (2005) 29 and Safe Administration of Vinca Alkaloids CEL 22 (2009).

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

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.
- Advised that a framework setting out governance and escalation routes is being developed by Healthcare Improvement Scotland to support quality assurance. This is likely to include self-assessment and peer review.

CEL 30 (2012)

July 2012

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

For information
Scottish Cancer Taskforce
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- advised that national quality performance indicators (QPIs)
- are being developed to support quality improvement of chemotherapy services (in line with CEL 6 (2012)).

- note that reporting of performance against QPIs is a mandatory requirement of the national cancer quality programme
- 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 Scottish Cancer Taskforce will oversee progress against implementation of the guidance.

It is anticipated that NHS Boards, Regional Cancer Networks and Healthcare Improvement Scotland will work together to agree how best to take this guidance forward.

Yours sincerely,

Sir Harry Burns (CMO) Ros Moore (CNO) Bill Scott (CPO)

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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 NHSScotland, 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 work to update this guidance has now been undertaken and takes account of the quality ambitions set out in Scotland's Quality Strategy (2010), that care will be safe, effective and person-centred.

This CEL replaces HDL (2005) 29 and CEL 22 (2009). The revised and updated guidance however, has the same purpose: to promote the safe delivery of SACT.

SACT must 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 wh

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.

Scope

The scope of this document includes biological therapies and cytotoxic chemotherapy. 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 does not include hormonal therapies.

This guidance is primarily intended to promote the safe use of medicines to treat cancer. The clinical governance and risk management arrangements for these medicines in non-cancer indications should be consistent with best practice as detailed in this guidance.

Process

The work to update the previous guidance was undertaken under the auspices of the Chemotherapy Advisory Group (CAG) which reports directly to the Scottish Cancer Taskforce. An Executive Steering Committee (membership at annex A) was established to revise and update the previous guidelines (HDL (2005) 29) to be published in the form of a Chief Executive Letter (CEL). This committee comprised multiprofessional stakeholders from the three Regional Cancer Networks and also oversaw the work of a number of virtual short life working groups drawn from the membership of CAG, but also involving other relevant health professionals when needed. The guidance has also been peer reviewed within NHS Scotland via the

Regional Cancer Networks and externally 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 The NHS Board Chief Executive demonstrates compliance and ensures 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. They are supported by a senior pharmacist and a senior nurse.

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 for SACT services establishes systems to ensure compliance 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 for the safe delivery of SACT across all care settings in the NHS Board
- a cross regional audit programme, with external peer review from another cancer network, is in place to provide assurance on the safe delivery of SACT services in all NHS Board areas. Non-conformance remediation plans, with priorities and timescales assigned, are in place to achieve full compliance with the standards
- an education and training programme for all staff involved in the delivery of SACT services is in place
- systems are in place for the development, approval and review of Clinical Management Guidelines (CMGs), SACT protocols and associated supportive treatment guidelines, including document control. These are prepared by a professional group representative of each of the professions likely to contribute to care.

1.1.8 A co-ordinated regional approach to the development of CMGs and SACT protocols is in place to support a consistent approach to care delivery.

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

1.1.10 Nationally agreed Quality Performance Indicators for SACT are regularly measured and reported to the appropriate clinical governance group.

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 for SACT services ensures the development of a programme of education and training, including competencies and methods of assessment, 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 and SACT protocols relevant to area of clinical practice
- consent and information giving
- holistic assessment of patients receiving SACT
- prevention and management of adverse effects
- selection and use of equipment
- safe handling of cytotoxic chemotherapy.

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

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 competencies.

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 establishes systems for the risk management of the NHS Board SACT services.

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 action plan/register 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.

1.4 Clinical Management Guidelines

1.4.1 A Clinical Management Guideline (CMG), as defined in the glossary, is in place for all common cancers. In paediatric cancer care, an approved clinical trial protocol may replace a CMG.

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

1.4.3 All CMGs or SACT protocols are approved by the appropriate, disease specific Managed Clinical Network (MCN) and local or regional governance arrangements.

1.4.4 An approved clinical trial protocol may be used in the absence of a SACT protocol.

1.4.5 Policies and procedures are in place to manage off-protocol requests for SACT, ensuring compliance with CEL (17) 2010.

1.5 SACT protocols

1.5.1 SACT protocols are in place for all SACT approved for use. These can be web based, within an electronic prescribing and administration system or paper-based.

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 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.

1.5.5 When a SACT protocol is regularly altered a new protocol and prescription is prepared and approved.

2. DECISION TO TREAT, CONSENT AND INFORMATION FOR PATIENTS

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 after discussion at a multi-disciplinary team (MDT) meeting, if appropriate. This is done in consultation with the patient or carer, where appropriate.

2.1.2 Selection of the SACT protocol is the responsibility of the consultant oncologist/haematologist, taking into account the patient's wishes, co-morbidities and life expectancy.

2.1.3 The consultant oncologist/haematologist or delegated deputy obtains written informed consent to treatment.

2.1.4 Consent is taken at an appropriate period of time after the patient has been provided with verbal and written information which includes the potential risks and anticipated benefits.

2.1.5 The treatment decision, treatment intent and the proposed patient specific management plan are documented in the patient's record and communicated to the GP within 14 days.

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

2.1.7 For poor performance status patients 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.

2.1.8 The patient specific management plan contains clear information on when and how response will be assessed before further treatment is given.

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

2.2 Information for Patients

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

- SACT protocol specific toxicities
- signs and symptoms of extravasation
- 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 Additional information is provided to support safe self management for patients self administering SACT outwith a healthcare setting, for example, oral treatment.

2.2.3 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 required to support safe and appropriate prescribing.

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

3.1.4 When a protocol is modified in response to individual patient circumstances the alterations must be explicit and recorded in the patient specific treatment plan and prescription.

3.1.5 The patient is assessed for adverse effects at appropriate intervals, as determined by local protocols, and graded using a recognised toxicity grading system, such as CTCAE criteria. Reasons for any dose adjustments are clearly documented.

3.1.6 Performance status is assessed prior to each prescription and recorded on the prescription.

3.2 Prescriptions and Documentation

3.2.1 SACT is prescribed using an electronic prescribing and administration system or a standardised SACT prescription and complies with current legal requirements and local prescribing policy.

3.2.2 All prescriptions are written in a clear and unambiguous manner and include the information contained in Appendix 2.

3.2.3 There is a single SACT prescription for all medicines including supportive care and hydration.

3.2.4 SACT prescriptions are readily accessible in patient's records for audit purposes.

3.2.5 SACT is not prescribed by repeat prescription.

3.2.6 The planned course of treatment and follow up arrangements are recorded in the patient's record and a review date set.

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 pharmacist in accordance with legislative requirements, national standards and local policy prior to dispensing and release from pharmacy. Key checks are outlined in Appendix 3.

4.1.2 If any discrepancies are found appropriate procedures are followed to address these prior to verification.

4.1.3 The prescription is signed and dated as a record of verification according to local policy.

4.2 Aseptic Preparation and Dispensing

4.2.1 All SACT is supplied from a pharmacy controlled facility.

4.2.2 All SACT is dispensed for the individual patient in a ready to administer form.

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 pharmacist verification has taken place prior to release from pharmacy.

4.2.5 Systems are in place to independently audit the aseptic service every two years. The audit will be carried out by the MHRA for licensed facilities, or as part of the NHS Scotland pharmacy services aseptic audit programme for unlicensed facilities.

4.2.6 Non-conformance remediation plans, with priorities and timescales assigned, are 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 and adolescent unit the prescribed dose is dispensed and supplied from the pharmacy controlled facility ready to administer in a 50ml minibag.

4.3.2 When vinca alkaloids are prescribed for children or adolescents treated in a childrens unit the prescribed dose is dispensed in a syringe. The vinca alkaloids can be given undiluted however it is considered good practice, wherever possible, to dilute all vinca alkaloids and dispense in a 10ml or greater syringe size.

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

4.4 Oral dispensing

4.4.1 Oral SACT is dispensed in accordance with local policy and procedures that incorporate legal requirements, national standards and guidelines. As a minimum local dispensing procedures must encompass information contained in Appendix 4.

4.4.2 Compliance aids are not routinely recommended when dispensing oral SACT. If it is necessary to use a compliance aid, a risk assessment must be performed to ensure that any risk to patients, carers and other health care professionals is managed appropriately.

4.4.3 Oral liquid preparations of cytotoxic SACT which do not have an EU or UK marketing authorisation are purchased from a licensed specials manufacturer unless the pharmacy has specialised facilities for compounding such liquid preparations.

4.5 Issuing Oral SACT

4.5.1 Staff issuing oral SACT ensure that the patient (and/or carer) understands how and when to take their medicines and are able to confirm that the patient is made aware of any required monitoring arrangements. If the patient has had their dose adjusted from the previous dispensing episode, the patient is made aware of the changes to treatment.

4.5.2 The patient and/or carer is instructed on safe handling and storage of oral SACT and advised to return any unused oral SACT to the pharmacy.

5. ADMINISTRATION

5.1 General Administration Issues

5.1.1 Policies and procedures are in place for SACT administration. This includes the oral route and all other routes of administration used within the NHS Board.

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

5.1.3 Staff who administer SACT are aware of immediate potential side effects, administration related risks and their management.

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

5.1.5 SACT protocol administration is commenced during normal working hours, wherever possible, when support services and expert advice are available.

5.1.6 The patient's condition and clinical parameters are assessed using a recognised toxicity grading system immediately prior to administration.

5.2 Pre-Administration Verification

5.2.1 Procedures exist for two 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.

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.

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 families 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 minibag, 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 and their GP are kept fully informed of ongoing management.

6.2.4 All SACT extravasation injuries are documented in the patient’s record and a clinical incident report completed.

6.2.5 The patient is followed up and reviewed at regular intervals and the final outcome of management and degree of injury, if present, is recorded.

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:

- patient/carer information on what they should 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, 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. DELIVERY OF SACT OUTWITH CANCER CENTRES/UNITS

It may be appropriate to deliver SACT or other supportive therapies outwith the Cancer Centre/Unit in, for example, the rural general hospital, GP surgery, community hospital, or in the patient's home. This may allow patients to remain at home or nearer to home while receiving treatment.

8.1 SACT service delivery, regardless of location and/or provider, is compliant with the standards in this guidance.

8.2 The Lead Clinician for SACT services is accountable for the safe delivery of all SACT in their NHS Board area, regardless of location.

8.3 A shared care framework for the delivery of SACT outwith the Cancer Centre/Unit is agreed regionally and approved by individual NHS Board clinical governance groups.

8.4 The shared care framework includes information on the systems of care for patients receiving treatment outwith the Cancer Centre/Unit including:

- clear definitions of the roles and responsibilities of each healthcare professional involved in the delivery of the SACT
- education and training requirements for each healthcare professional involved in delivery of SACT
- patient and carer responsibilities and education and training requirements
- patient selection and assessment arrangements
- premises, facilities and equipment assessment arrangements
- specific procedures to support safe delivery of SACT outwith the Cancer Centre/Unit including:
  - prescribing, verification, preparation, dispensing and administration of treatment
  - prevention and management of extravasation and other adverse effects
  - safe handling of cytotoxic SACT
- systems for patient assessment, monitoring, communication and referral criteria
- supportive care pathways
- systems for monitoring and auditing compliance with the shared care framework and monitoring of patient outcomes.

8.5 The selection of the SACT for delivery via the shared care framework occurs following risk assessment and agreement between the Cancer Centre/Unit SACT team and primary care representatives/clinicians based in the areas where the SACT is to be delivered. The SACT for delivery via the shared care framework is approved by the individual NHS Board clinical governance groups.

8.6 Only SACT from approved SACT protocols and CMGs can be included in shared care frameworks. SACT with a high risk of immediate adverse effects requiring specialist care must be excluded from the shared care framework e.g. risk of anaphylaxis to first course of SACT.

9. SAFE HANDLING OF CYTOTOXIC SACT

SACT encompasses biological therapies and cytotoxic chemotherapy. Cytotoxic medicines are hazardous as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). Biological therapies may have a different level of risk and should be handled in line with COSHH definitions. 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 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 tampered with in any way and 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 Receipt, transport and storage

9.2.1 Systems and procedures are in place for the receipt of cytotoxic SACT into the pharmacy according to safe handling procedures.

9.2.2 Cytotoxic SACT must be stored securely and safely in locations separate from other medicines and clearly marked for the storage of cytotoxic SACT only.

9.2.3 Systems and procedures are in place to ensure cytotoxic SACT is transported in a safe and secure manner.

9.2.4 Reconciliation records are in place for the receipt of cytotoxic SACT in patient areas.

9.3 Disposal

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

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

9.4 Spillages

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

9.4.2 Cytotoxic spill kits are available and prominently displayed in all areas where cytotoxic SACT is stored or handled.

Appendix 1

SACT Protocol Framework

- the sole use of an acronym to identify a protocol is minimised
- definition of the clinical condition being treated including line of therapy
- treatment intent
- 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
- hydration schedules (if required)
- supportive therapy including, where appropriate, prophylaxis for the prevention of neutropenic sepsis
- concomitant radiotherapy & scheduling where relevant
- relevant haematology and biochemistry parameters
- any other tests that need to be performed before SACT starts and during treatment
- special precautions and contraindications to treatment
- potential medicines and food interactions
- expected toxicities
- extravasation risk
- recommendations for treatment delays or dose reductions based on relevant toxicities and/or haematology and biochemistry parameters
- where relevant, reference should be made to policies for the management of toxicities
- decision points including response assessment and advice on when patients should be 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 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 oral SACT, 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.

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.

- prescriber details and signature are present and confirm they are authorised to prescribe SACT
- ensure protocol has been through local approval processes
- for the first cycle, the protocol is the intended treatment as documented in the patient specific treatment plan and is appropriate for the indication
- the protocol is appropriate for the patient's diagnosis, medical history, performance status and SACT history
- 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
- body surface area (BSA) is correctly calculated, 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
- cumulative dose and maximum individual dose 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 essential tests have been undertaken where appropriate
- 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.

Appendix 4

Oral Dispensing

Policies and procedures which incorporate legal requirements, national standards and guidelines are in place for:

- **Dispensing oral SACT**

    - staff dispensing oral 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 must be performed to address any risks to patient safety
    - the quantity of tablets/capsules 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 oral SACT**

    - 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
    - labels contain the warning “Cytotoxic Medicine” where this is appropriate.

Appendix 5

Supportive Treatments

Protocols for the following conditions are developed locally and endorsed by local or regional governance groups. The detail of the content will reflect local practice.

- neutropenic sepsis in line with the Best Practise statement for management of neutropenic sepsis
- nausea and vomiting
- diarrhoea and constipation
- mucositis
- skin toxicity
- tumour lysis syndrome
- hypersensitivity reactions.

Annex A

MEMBERSHIP OF WORKING GROUPS

CEL EXECUTIVE GROUP MEMBERS

- David Dunlop, Clinical Director, Beatson, West of Scotland Cancer Centre (Chair)
- Gail Caldwell, Pharmacy Director, NHS Forth Valley
- Jane Tighe, Head of Service for Clinical Haematology, NHS Grampian
- Jennifer Armstrong, Senior Medical Officer, Scottish Government
- Steven Leadbetter, Aseptic Services Manager, NHS Greater Glasgow and Clyde
- Lynn Adams, Consultant Cancer Nurse, NHS Grampian
- Gill Chadwick, Macmillan Lead Cancer Nurse, NHS Western Isles
- Mark Parsons, Macmillan Regional Lead Cancer Pharmacist, North of Scotland Regional Cancer Network
- Jacqui Davie, Head of Nursing Oncology and Haematology, NHS Tayside
- Angela Bowman, Consultant Medical Oncologist, NHS Lothian
- Mary Maclean, Regional Cancer Care Pharmacist, West of Scotland Regional Cancer Network
- Rachael Dunk, Head of Cancer Strategies, Scottish Government
- Patrick McAuley, Cancer and End of Life Policy Manager, Scottish Government
- Pamela Warrington, Deputy Chief Pharmaceutical Officer, Scottish Government
- John Milne, Lead Cancer Care Pharmacist, NHS Lanarkshire

Additional Members of Short Life or virtual working groups

- Elaine Barr, Clinical Educator, NHS Greater Glasgow and Clyde
- Carol Stevenson, Senior Nurse Chemotherapy, NHS Greater Glasgow and Clyde
- Fiona Galbraith, Chemotherapy Charge Nurse, NHS Forth Valley
- Alison Inglis, Senior Charge Nurse, Oncology Unit, NHS Tayside
- Fiona Campbell, Macmillan Chemotherapy Clinical Nurse Specialist, NHS Highland
- Maggie Grundy, Programme Director, NHS Education for Scotland
- Maxine Henderson, Staff Nurse, NHS Greater Glasgow and Clyde
- Susan Healy, Principal Pharmacist, NHS Grampian
- Heather Dalrymple, Lead Cancer Care Pharmacist, NHS Lothian

GLOSSARY

ADVERSE EVENT – Is any unfavourable, and unintended (including an abnormal laboratory finding), symptom, sign or disease temporally 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.

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 MANAGEMENT GUIDELINE - Clinical Management Guideline (CMG) 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.

INTRAVENOUS – Given into a vein by injection or infusion.

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

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.

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

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 on the basis of individual patient need delineated by exceptional circumstances.

PHARMACEUTICAL CARE – A systematic approach applied by a pharmacist 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 pharmacist 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 treatment plan that includes one or more SACT medicine. It is also often described as a SACT regimen.

SYSTEMIC ANTI-CANCER THERAPIES (SACT) - Encompasses biological therapies and cytotoxic chemotherapy.

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