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Royal Cornwall Hospitals NHS Trust

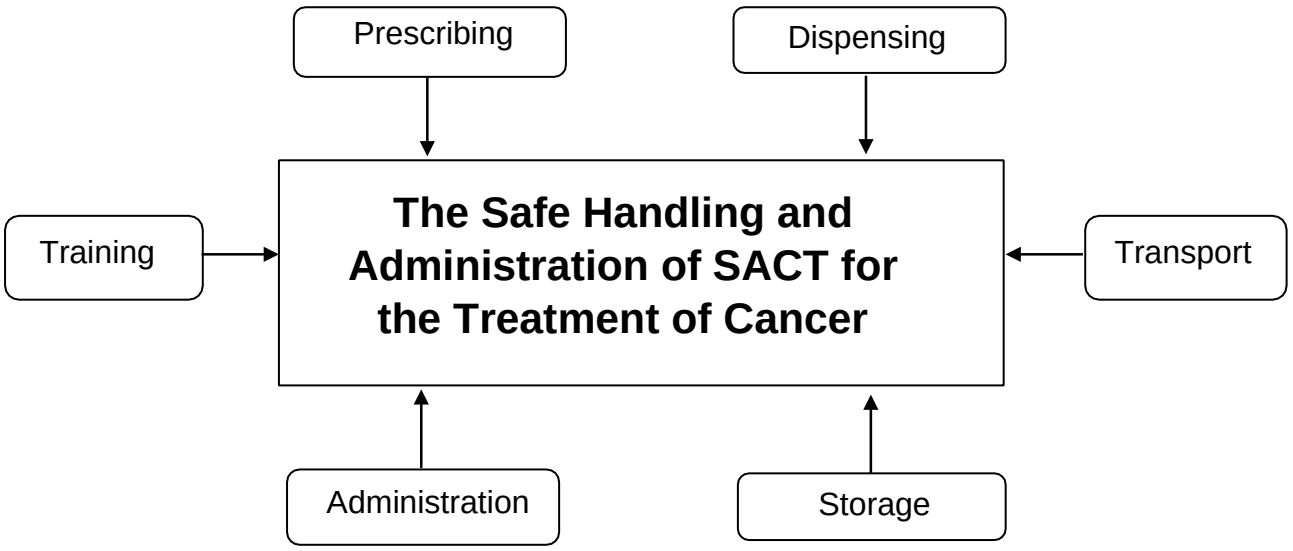
The Safe Handling and Administration of Systemic Anti-Cancer Therapy Policy

V6.0

December 2022

Summary

This policy sets out the way in which Systemic Anti-Cancer Treatments (SACT) are to be used for the treatment of cancer within the Trust with the aim of reducing risks associated with exposure .



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Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

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1. Introduction

1.1. This policy is written in accordance with the requirements of the Trust policy on the use of medicines.

1.2. It must be read in conjunction with:

- Extravasation policy (Adults and Paediatrics)
- Trust Medicines Policy
- Guidelines for Patient Self-Administration of Medication (SAM).
- Clinical Guideline for the use of Intravascular Catheters in Adults at RCHT
- Trust Consent policy
- Non-Medical Prescribing Policy and Strategy
- RCHT Intrathecal policy
- The Nursing and Midwifery Council (NMC) Standards for Medicines Management
- Procedure for the intravesical instillation of drugs (including cytotoxic drugs)
- Guideline for the management of systemic anti-cancer therapy (SACT) related hypersensitivity reactions
- Self-administration of Subcutaneous Systemic anti-cancer therapies (SACT) Policy

1.3. Cytotoxic medicines are potentially hazardous substances which may be mutagenic, teratogenic and/or carcinogenic. There is evidence to suggest that health care personnel exposed to these agents, through preparation and administration of cytotoxic agents, care of patients during SACT and in waste disposal may be at risk if not adequately protected.

1.4. Cancer Treatments

SACT includes steroids, immunosuppressant's, monoclonal antibodies, cytotoxins, target therapy and Immunotherapy. It is the cytotoxic group which has caused concern with regard to possible adverse effects through handling. However, all the groups require this guidance to be followed to ensure the safe and appropriate prescribing, dispensing and administration.

1.5. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

This policy sets out the way in which such products are to be used for treatment of cancer within the Trust with the aim of reducing the risks associated with exposure.

3. Scope

3.1. This policy applies to all personnel involved with cytotoxic medicines for the treatment of cancer, specifically:

- Medical staff
- Pharmacy Staff
- Nursing Staff

4. Definitions / Glossary

4.1. SACT – Systemic Anti-Cancer Therapy.

4.2. For the purpose of this document, the term Oral Anticancer Medicine is used to refer to all drugs with direct anti-tumour activity.

4.3. Oral drugs administered to cancer patients include traditional cytotoxic SACT such as capecitabine, hydroxycarbamide, chlorambucil and small molecule treatments such as imatinib, erlotinib, sunitinib, thalidomide or lenalidomide (this is not an exhaustive list).

4.4. It does not include hormonal or anti-hormonal agents such as tamoxifen, letrozole and anastrozole. This list is constantly evolving and Chapter 8 of the BNF as well as Aria protocols should be consulted for up-to-date information.

5. Ownership and Responsibilities

5.1. Role of the Trust Lead Consultant for SACT

- The Trust Lead consultant for SACT is responsible for ensuring implementation and adherence to this policy.

5.2. Role of the Lead Pharmacist for Cancer Services

- Co-ordinating the education and development for pharmacy staff in the handling, reconstitution, clinical screening and disposal of cytotoxic drugs.
- The maintenance of a register of Pharmacy staff competent to screen cancer SACT prescriptions.

5.3. Role of the Lead Nurse for SACT and SACT CNS

- The education and development of nursing staff in the handling, administration and disposal of cytotoxic drugs.

- The maintenance of a register of nursing staff competent to administer cancer SACT.

5.4. Role of the Occupational Health Department

- The Occupational Health Department will carry out health surveillance as necessary and appropriate for staff exposed to cytotoxic products.

- Advice will be sought from the Occupational Health Department if any adverse occurrence should occur. There is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to predict the effect of chronic long-term exposure. It is therefore extremely important that the working environment is safe and exposure to the medicines minimised.

- Support and guidance will be offered to new, expectant and breastfeeding mothers.

5.5. Role of the Managers

- Managers must ensure that a COSHH (Control of Substances Hazardous to Health) assessment is carried out in all areas where cytotoxic drugs are handled in order to assess the level of risk and the adequacy of control measures in place. The risk assessment should assume that there may be a new or expectant mother working in the environment in the following twelve months. Precautions must be in place at all times to minimise exposure by using protective garments, appropriate equipment, as well as safe and validated work practices.

- There should be no significant exposure to cytotoxic drugs if good handling practices are strictly adhered to.

- At the point where an employee discloses pregnancy, their line manager should conduct and document a work based risk assessment. Pregnant or breastfeeding staff will be expected to make an informed choice about working with cytotoxic drugs.

- Staff who choose not to work with cytotoxic drugs will not be expected to be involved in directly preparing or administering SACT or handling waste from patients treated with SACT.

- New, expectant and breastfeeding mothers should be specifically advised against any direct involvement in the management of a cytotoxic drug spillage.

- There should be no significant exposure to cytotoxic drugs if good handling practices and cleaning are strictly adhered to and personal protective equipment is used.

- Pregnant or breast feeding staff who choose not to work with cytotoxic drugs will agree new working arrangements with their manager in the interim. The Human Resources Department will be consulted if no suitable alternative employment is found.

5.6. Role of Individual Staff

- Any member of staff who suffers an adverse effect as a result of handling a cytotoxic drug, no matter how small, must report this to the Occupational Health Department and DATIX the incident, as soon as possible.

- All incidents that involve the accidental contamination of the skin or eye must be reported to the Occupational Health Department.

- Employees should notify their manager as soon as possible if they are pregnant, trying to conceive or are breastfeeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. This is also to comply with HSE guidance, stating that all pregnant staff, or those trying to conceive, should be removed from duties involving the preparation of cytotoxic drugs.

6. Standards and Practice

6.1. Prescribing of SACT

6.1.1. **Consent**

6.1.1.1. Prior to commencing a course of chemotherapy treatment or participating in a clinical trial with a cytotoxic agent, written consent must be obtained from the patient/guardian on the appropriate consent form in line with the Trust consent policy. Dual stage written consent is mandated other than in emergency situations where treatment is given to prevent rapid patient deterioration and death. Two-stage consent involves an initial agreement in principle and a secondary confirmation of consent, usually on the day of treatment. The patient may withdraw consent at any time.

6.1.1.2. Written and verbal Consent must be obtained for any SACT. This could also include electronic consent, using the trust approved electronic system.

6.1.1.3. Consent will be obtained at the following stages of treatment

- 1st cycle of SACT
- Start of new regimen/line of treatment
- For oral Systemic Anti-Cancer Treatments
- For any trial containing SACT (trial consent form is adequate)
- Chemotherapy-radiotherapy (can be done on one form)

- Initiation of intrathecal treatment (multiple lumbar punctures)

6.1.1.4. Re-consent may not be required if a new drug is prescribed or change of drug is made within one regimen. If it is the same drug classification and has the same side effects and the reason for the change is patient tolerance or poor response, this decision will be the consultants to make. If a drug has been interrupted and the same drug is restarted e.g. Capecitabine/Hydroxycarbamide, re –consent may not be required.

6.1.1.5. The prescriber is responsible for ensuring the appropriate information is documented to enable the treating nurse's access to all relevant information to the patient.

6.1.2. **SACT Information for Patients**

6.1.2.1. Patients / carers will be actively involved in decision making about their treatment. In addition to verbal information given during consultations, patients will be given written information specific to the regimen they will be treated with. Information sheets will include potential side effects, any necessary precautions and 24-hour contact details for use in emergency. This information is reiterated at a pre assessment and should be documented on Aria. Patients will be offered either a face to face, telephone or digital pre-assessment. Digital pre assessments will use links to the MySunrise app, where resources such as written information and videos can be found. Documentation of pre assessments to remain on ARIA.

6.1.2.2. Patients will be provided with a booklet form either Macmillan or Cancer Research UK or specific drug company information that is appropriate for them. Patients with poor literacy and learning disabilities should be facilitated to have appropriate materials for their education, often in partnership with the Learning and Development team. Patients with poor sight should be offered large print copies. Patients with English as their second language should be offered copies of information in their first language if available or needed.

6.1.2.3. Patients receiving cytotoxic therapy at home will be given appropriate written information and equipment. This includes patients receiving oral SACT. Patients must be adequately counselled to ensure their understanding of the regimen details, storage conditions and handing precautions by either a nurse or doctor suitably trained to give this information.

6.1.2.4. Information must be given to parents/guardians on the safe handling required for children receiving chemotherapy.

6.1.2.5. The information given to patients must be from recognised sources.

6.1.2.6. A copy of clinic letters are not routinely sent to oncology patients, but patients can request to receive a copy and should be made aware of this option. Haematology outpatient letters are sent routinely to patients unless they request not to receive this (as per OPD haematology policy).

6.1.3. SACT information for General Practitioners

6.1.3.1. A clinic letter will be sent to the GP prior to the patient's first treatment highlighting the regimen to be administered to their patient. The planned start date and duration of treatment should also be included, along with the treatment intent, expected toxicities and the contact numbers to be used in event of complications. Any role that the GP is expected to play in managing the patient should be made clear.

6.1.3.2. After the patient's final cycle of chemotherapy, a treatment summary should be sent to the patients GP. This should include whether or not the planned course of treatment was completed. If it was not completed the reason why, for example toxicity, sub optimal response, disease recurrence or a combination of these. If the treatment is completed reference to the response to treatment should be included where appropriate.

6.1.3.3. Relevant primary healthcare staff will be informed when a patient is being treated with infusion SACT in the community and they receive training and information from their community practice educator.

6.1.4. Prescribers' Register

6.1.4.1. The list of prescribers who are authorised to prescribe cytotoxic SACT within haematology and oncology shall be maintained via account access to the ARIA prescribing system.

6.1.4.2. Prior to a practitioner being granted with an account an application form must be completed including the category of access required. For prescribers, this must be authorised by a consultant oncologist or haematologist. A SACT framework has been developed to help make these decisions about competency and should be used if there are identified learning needs.

6.1.4.3. ARIA training must be completed before the live account is activated.

6.1.4.4. Only practitioners who have an ARIA account are authorised to prescribe cytotoxic medicines for haematology and oncology patients.

6.1.4.5. In this policy only, such prescribers are described as "registered prescribers".

6.1.4.6. Within paediatric oncology, the list of authorised prescribers shall be maintained as a separate list by the Paediatric Head of Service/Lead Cancer Pharmacist.

6.1.4.7. Within urology cytotoxic SACT will only be prescribed by Consultants and specialist Registrars within their level of specialism.

6.1.5. **Prescribers**

6.1.5.1. The decision to treat a patient with chemotherapy is the responsibility of the relevant Consultant Oncologist, Consultant Haematologist, Consultant Urologist or Consultant Paediatrician, first courses of SACT may only be prescribed by these Consultants or an authorised Specialist Registrar (see below).

6.1.5.2. Subsequent SACT courses may only be prescribed by registered prescribers.

6.1.5.3. Prescribers in urology are only permitted to prescribe within their own speciality.

6.1.5.4. If oral chemotherapy is to be prescribed by a General Practitioner this should be managed as part of a shared care agreement.

6.1.6. **Authorisation Procedure for Changing the Prescribing role of the Oncology or Haematology SPR and Staff Grade doctors on Aria to allow the Initiation of chemotherapy regimens.**

6.1.6.1. The SPR or Staff Grade doctor must have completed the required training to the satisfaction of his/ her supervisor and completed the local SACT training logbook.

6.1.6.2. The supervisor should write a statement, confirming that the SPR or Staff Grade doctor has completed the training required and is now competent to initiate SACT, to the Cancer Services/E-Prescribing Pharmacist or Lead Cancer Pharmacist.

6.1.6.3. The pharmacist will log a request with the CITS helpdesk requesting that the doctor be changed from the SPR to Consultant User group on Aria.

6.1.6.4. The Cancer Services/E-Prescribing Pharmacist or Lead Cancer Pharmacist will provide upgrade training on Aria for the doctor.

6.1.6.5. Once the access is changed, the SPR or Staff Grade doctor can initiate chemotherapy, but should leave the prescription ‘Pending’ for approval by the supervisor for a minimum of the first five prescriptions until both parties are confident in the

prescribing skills of the doctor on Aria. A log should be kept of these patients for CPD.

6.1.7. Non-Medical Independent or supplementary Prescribers

6.1.7.1. Non-Medical Independent or supplementary Prescribers who have completed the necessary training, are registered with their professional body and are authorised by RCHT to prescribe SACT within their area of competence.

6.1.7.2. Non-Medical prescribers cannot prescribe the first cycle of SACT.

6.1.7.3. Non-medical prescribers who wish to commence prescribing SACT must be approved by the clinical SACT lead after discussion at the SACT MDT.

6.1.7.4. They must work within the Guidance set out in the Non-Medical Prescribing Policy and Strategy.

6.1.8. The Prescription

6.1.8.1. Intrathecal chemotherapy must be prescribed on a separate chart from all other therapies – see RCHT intrathecal policy.

6.1.8.2. All prescriptions must be computer generated using the Aria computer prescribing system in the departments which this is available. Paediatric SACT is prescribed using the Chemocare system. In exceptional circumstances, details of which must be documented on the prescription, handwritten prescriptions on form CHA388 will be accepted.

6.1.8.3. Urology prescriptions for intra-vesical chemotherapy must be produced using the A4 prescription proforma or form CHA388.

6.1.8.4. The prescriber is responsible for ensuring the appropriate relevant support drugs, intravenous fluids and specific instructions pertaining to the individual regimen and patient are prescribed.

6.1.8.5. The following must be documented either on the prescription, in the patient notes or in the patient specific protocol/record prior to the patent commencing SACT:

- Cancer type
- History of specific diseases or conditions affecting fitness for SACT
- Performance status
- Prior history of SACT
- Current patient medication affecting SACT

- That informed consent has been obtained
- Treatment intention e.g., palliative, curative/radical, adjuvant, neo- adjuvant
- Planned regimen and doses
- Number of cycles intended
- Frequency of cycle
- Investigations necessary prior to starting the whole course
- Investigations to be performed serially during the course (to detect and monitor both toxicity and response) and their intended frequency
- For palliative, curative/radical and neo-adjuvant treatments the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course
- That a holistic needs assessment has been carried out

6.1.8.6. SACT regimens should be prescribed in the context of a recognised approved protocol. Adult protocols are available for reference on Aria. In case of Aria unavailability, hard copies are kept as an electronic backup file accessible by the Cancer Pharmacy Team. Please refer to the Aria contingency plan for further details. Paediatric protocols are available on the Chemocare system with hard copies in the CLIC office and electronic copies in the shared paediatric oncology folder.

6.1.8.7. Protocols must have been approved locally by the consultant specialising in that tumour site. or relevant paediatric monitoring forum.

6.1.8.8. New regimens may require confirmation of funding before proceeding.

6.1.8.9. For regimens that are not approved please refer to appendix 11 off protocol prescribing.

6.1.8.10. Prescriptions must be complete, clear and simple to follow. The rules given in the current edition of the Medicines Policy for the Royal Cornwall Hospitals trust must be followed. Prescriptions must include the following information:

- Patient demographic details
- Weight, height, and surface area of the patient where required for the regimen

- Drugs and doses (including all SACT medicines to be used and elective support drugs including anti-emetics)
- Frequency of administration
- Route of administration where the medicine is intended for intrathecal administration the word ‘INTRATHECAL’ should be written in full on the prescription chart. For infusions, details of solution and volume, duration of infusion and any other administration instructions
- Cycle number and date to be given
- The exact duration of treatment or, for continuous treatment, the intended review date
- Reason for any dose modifications

6.1.8.11. All intended deviations from protocol such as dose modifications should be clearly identified as such and recorded in the patient’s notes, on the prescription and communicated to the patient’s GP.

6.1.8.12. The planned course of treatment and arrangements for review/follow up should be recorded in the patient’s notes.

6.1.9. **Clinical Trials**

6.1.9.1. Patients entered into clinical trials will be seen and closely monitored by the clinical trials staff, medical staff and nurses. Any deviation from the trial protocol must be confirmed by the consultant or registrar in charge of the patient's care.

6.1.9.2. Prescriptions for clinical trial patients must be produced using a trial-specific prescription (available on ARIA) and must be clearly annotated with the trial name and patient’s trial number, as relevant. Paediatric trial prescriptions must be completed in the designated space on Chemocare.

6.1.9.3. Written confirmation of patient registration/randomisation in the trial must be sent to pharmacy as soon as possible. This is required before a prescription can be dispensed.

6.1.9.4. Trial specific prescriptions must not be used for non-trial patients.

6.1.9.5. A copy of the trial consent form must be available in clinic areas and should be available on maxims.

6.1.10. **Inpatient Prescribing (on admission)**

6.1.10.1. F1 doctors are not allowed to prescribe SACT for cancer indications. All SACT will not be available for F1 doctors to prescribe via EPMA. In the event of a patient being admitted to

a ward needing routine SACT adding to their EPMA drug chart, contact should be made with a member of the oncology team (CNS, Pharmacist, on call Clinician) to arrange transcription if appropriate, or a more senior level doctor may be able to prescribe if clinically appropriate for the patient and their admission status. Transcription can only occur where a valid ARIA prescription is in place and can be transcribed by registered prescribers or Pharmacist. Where no valid ARIA prescription exists, this would be considered initiation and would need to be prescribed by a haematology/oncology consultant on EPMA as well as ARIA.

6.1.10.2. Patients on oral anticancer medicines admitted to hospital wards are at risk from uncontrolled prescribing. A detailed drug history must be taken on admission including:

- Indication for SACT
- Drug and dose, frequency of administration e.g., daily, weekly, continuous or cyclical.
- Intended start date, duration of treatment, intended stop date for each cycle of treatment and date of next cycle.
- Any supportive medications e.g., anti-emetics.

6.1.10.3. The patient's current medical condition must be assessed to ensure suitability for continued treatment with the medicine.

6.1.10.4. Where possible the patient's own medication should be utilised for the remainder of the cycle, thus minimising the risks associated with prescribing inappropriate/incorrect dose or duration of treatment.

6.1.10.5. All inpatient prescriptions for oral anticancer medicines must be verified by an oncology trained pharmacist. If the patient is not on the designated haematology/oncology ward, the oncology pharmacist will print the protocol information for the patient's notes in order that this information is available to non-specialist staff without Aria access.

6.1.10.6. In situations where the patient is not on the appropriate ward and the patient cannot self-administer, ward staff should also be provided information on the safe handling of oral SACT and be supported by the Clinical Practice Educators in Cancer Services or the Lead SACT nurse.

6.1.10.7. Repeat oral anticancer drug prescribing needs caution and should be prescribed by an authorised prescriber using the appropriate SACT prescription NOT on a discharge prescription.

6.1.11. **Inpatient Prescribing (New Prescriptions)**

6.1.11.1. In- patient prescribing for a new patient must be to the same standards as prescribing for outpatients.

6.1.11.2. Treatment may only be initiated by those prescribers outlined in section 6.1.4.

6.1.11.3. Prescribing must be done using the Aria system (for adults), or Chemocare system for paediatrics.

6.1.11.4. Oral SACT and supportive medicines which are for administration during the inpatient stay will be transcribed to EPMA by the pharmacist or prescriber, with a note attached to indicate that it has been transcribed from the prescription on Aria. Care should be taken not to duplicate administration of drugs on both systems.

6.1.12. **Treatment Review**

6.1.12.1. Before each cycle of SACT is prescribed or administered the patient must be clinically reviewed by an appropriately qualified and competent clinical staff member who will:

- Ensure that the patient's medical condition and blood parameters support ongoing treatment.
- Check results of all investigations, blood parameters and specific drug calculations specified within the treatment protocol and timeframe. Bloods must be within 7 days for most regimes and within 3 days for weekly treatments and as the trial dictates for those individual regimes. Patients on combination treatment (such as chemoraditherapy) may be seen more frequently during treatment by a wider multidisciplinary team.
- Patients who are stable on immunotherapy may be seen formally every 6-9 weeks on treatment.
- Patients on Immunotherapy should have their blood results checked at least every 4-6 weeks during treatment if they are well and without toxicity. Immunotherapy patients with toxicity should have repeat blood tests as outlined in the immuno-oncology guidelines.
- Any toxicities following the previous cycle should be recorded on the Toxicity Assessment form and made available to the treating nurse either on paper or electronically.

6.1.12.2. In the case of in-patients receiving their medications over a period of days, the above checks must be done before the first

dose is given in hospital and then regularly during treatment according to the parameters specified in the written protocol:

- Prior to each cycle and commencing the next the following should be documented, either in the patient's letter or on the prescription/Aria system:
- The results of essential serial investigations applicable to that cycle (and prior to an administration within a cycle if applicable e.g., 'day 8' SACT
- Any dose modifications and whether or not they are intended to be permanent
- Any cycle delays
- Any introduced support drugs not recorded at the initiation of treatment
- Performance status
- Any toxicities following the previous cycle should be recorded on the Toxicity Assessment form and made available to the treating nurse either on paper or electronically.

6.1.13. **High Intensity SACT**

6.1.13.1. Lowen has multiple side rooms equipped with HEPA filtered air Supply for patients receiving High intensity SACT.

6.1.13.2. High Intensity SACT patients may be directly admitted to those beds by Lowen ward Sister or nurse in charge as required. Patients to come in for treatment must be booked through the NIC.

6.1.13.3. High Intensity SACT patients will be given the 24 hour contact number as described above and will also require a pre assessment before starting their treatment and documented on Aria.

6.1.13.4. Consultant Oncologists, Haematologists and Microbiologists will be rostered to provide on call advice and support for High Intensity SACT patients.

6.2. Dispensing of SACT

6.2.1. **Reconstituting Cytotoxic Drugs**

6.2.1.1. The Chief Pharmacist and Head of Technical Services Pharmacist are responsible for ensuring that cytotoxic reconstitution services are provided in appropriate audited facilities or otherwise that products are purchased from licensed cytotoxic facilities. Handling procedures for

manufacturing staff in the Pharmacy Technical Services Unit are documented in their standard operating procedures.

6.2.1.2. No cytotoxic drugs should be reconstituted in clinical areas, with the exception of:

- Savene when used for Extravasation, see RCHT Extravasation policy.
- Mitomycin for intravesical administration, prepared using the myto-in device in the urology clinic, urology theatres and at West Cornwall day case unit (closed system).
- Rituximab (IV or SC) Trastuzumab (SC), Daratumumab (SC) and Phesgo (SC) vials may be prepared for administration in a designated area on the Headland Unit or relevant ward area.

6.2.2. **Pharmacy Preparation**

6.2.2.1. Preparation of aseptically prepared cytotoxic medicines in Pharmacy will commence after prescription verification by a suitably trained oncology pharmacist.

6.2.2.2. To enable efficient organisation of workload and to minimise delays in administration, SACT prescriptions should be generated on ARIA in good time, preferably 72 hours before the patient's appointment time. This allows documentation and assembly to be completed before preparation, if the recommended prescription time is not met there is a risk that the patient will not receive their treatment on the required day and their treatment will be deferred. Patients who do not have a SACT prescription completed on the day will be automatically have their treatment deferred.

6.2.2.3. Each dispensed product shall be labelled with the following details:

- Patient's name or Trial number
- Ward/clinic
- Drug
- Dose
- Diluent and volume
- Route of administration
- Cytotoxic preparation batch number (if appropriate)
- Expiry date and time

- Storage requirements
- Relevant additional cautionary or advisory labels as per local policy

6.2.3. **Vinca Alkaloids (Vincristine, Vinblastine, Vindesine, Vinflunine and Vinorelbine).**

6.2.3.1. A syringe, bag, or infuser containing a vinca alkaloid must be labelled with:

FOR IV USE ONLY - POTENTIALLY FATAL IF GIVEN BY ANY OTHER ROUTE

6.2.3.2. Adult and teenage patients treated in the headland unit will only receive vinca alkaloids from the hospital pharmacy ready to administer in a 50ml mini bag of sodium chloride 0.9% (for some brands of Vinorelbine glucose 5% solution for injection may be used instead of sodium chloride 0.9%).

6.2.3.3. Vinca alkaloids must be supplied in volumes of greater than 10ml. Paediatric doses of 1mg or less will be diluted to at least 10ml.

6.2.3.4. Paediatric wards are the only area where vinca alkaloids may be administered via a syringe.

6.2.3.5. All doses of vinca alkaloids for children greater than 1.0 milligram must be diluted to 20mI to alert practitioners that the intravenous route is the only route of administration and volumes of this size CANNOT be administered by the intrathecal route.

6.2.3.6. All Vinca alkaloid preparations will be individually wrapped in outer tamper evident bags which must be labelled:

WARNING DO NOT REMOVE THIS OUTER CONTAINER UNTIL THE MOMENT OF INJECTION. FOR INTRAVENOUS USE ONLY. POTENTIALLY FATAL IF GIVEN BY ANY OTHER ROUTE.

6.2.3.7. The vinca mini bag should be infused intravenously over 5 – 10 minutes and the patient closely monitored for signs of extravasation.

6.2.4. **Issue From Pharmacy**

All SACT preparations will be wrapped in sealable outer bags. The final product is checked by a Pharmacist or Suitably qualified Pharmacy Technician before release to the ward or clinic.

6.2.5. **Dispensing and Labelling of Oral Cytotoxic SACT**

6.2.5.1. All prescriptions for Oral SACT must be validated by an authorised pharmacist.

6.2.5.2. The prescription will be dispensed by the hospital pharmacy or the hospital outpatient pharmacy (Lloyds pharmacy at time of writing) in accordance with pharmacy standard operating procedures. Currently it is not recommended that oral anticancer medicines are dispensed by community pharmacies.

6.2.5.3. For courses of SACT the exact number of tablets needed will be supplied. The quantity supplied must be subject to a second independent check during the dispensing process.

6.2.5.4. Label directions must be clear and unambiguous and include, where relevant, the intended period of treatment, start and stop dates or the number of days expressed as 'for X days ONLY'.

6.2.5.5. The member of pharmacy staff handing the drugs to the patient should ensure the patient understands the dose they should take, what to do if any side effects/problems arise and who to contact including out-of- hours. In addition, the following should be covered:

- Principles of safe handling, storage and disposal
- That, if used, spoons and measures should be used once only and then disposed of safely
- Any drug specific advice regarding safe crushing of tablets or opening of capsules

6.2.5.6. If, after counselling the patient on their medication it becomes apparent that the patient does not understand how to take the medicines or will have difficulty in compliance, the member of pharmacy staff should refer to one of the cancer pharmacists or to the clinic.

6.2.6. **Supply of oral cytotoxic SACT to inpatients**

6.2.6.1. Where possible, patients own medicines must be used. Temporary stocks must not be used.

6.2.6.2. All anticancer medicines must be dispensed and labelled to include the following information:

- Patient name
- Generic drug name
- Strength of tablets or capsules, or concentration of oral liquid

- The number of tablets/capsules in the container or volume of liquid
- Administration instructions
- Length of treatment, including stop date as appropriate
- Storage conditions
- ‘Cytotoxic’ warning label
- Name and address of pharmacy department

6.2.6.3. Patients should be advised to return any unused oral anticancer medication that they may have at home.

6.2.6.4. Oral SACT stored on Lowen will be placed in a light sensitive bag, labelled, and stored away from other patient medications in the designated room temperature SACT cupboard or SACT refrigerator.

6.2.7. **Access to Oncology Pharmacy Advise**

6.2.7.1. There will always be available a trained cancer services pharmacist and paediatric pharmacist who are able to provide cancer drug advice to General pharmacy staff, Lloyds pharmacy staff and ward/clinic staff. They may be contacted via a shared mobile phone (Pharmacy Cancer Team) or bleep (Paediatric Pharmacists).

6.2.7.2. In the absence of a cancer services pharmacist, a technical services pharmacist may be contacted and, out of hours, the technical services on call pharmacist.

6.3. Transport

6.3.1. Manufactured syringes, infusion devices and bags should be placed in a snap top plastic bag and transported in a designated leak proof container to provide adequate protection for the handler.

6.3.2. Items of SACT to be collected from the General Pharmacy (e.g., rituximab bags) should be collected in the designated yellow SACT transport bag.

6.3.3. Oral cytotoxic drugs should be transported in the same way as non-cytotoxic medication and labelled as cytotoxic, in addition to the normal prescription label.

6.3.4. Staff involved in the transportation of cytotoxic agents must be trained and have access to the correct protective equipment to deal with spillage.

6.4. Storage of SACT

6.4.1. Cytotoxic Drugs that are to be stored at room temperature should be kept in a designated locked cupboard in an approved clinical area.

6.4.2. Cytotoxic drugs that are to be refrigerated should be kept in a designated dedicated locked drug refrigerator in an approved clinical area. The refrigerator temperature is continually monitored by a digital system maintained by the Pharmacy QA department.

6.4.3. Oral SACT may be stored with but segregated from other oral preparations:

- Ward stock oral cytotoxics will be stored in a locked room SACT designated cupboard or refrigerator as applicable.
- Patients own Oral SACT stored on Lowen will be placed in a light sensitive bag, labelled, and stored away from other patient medications in the designated room temperature SACT cupboard or SACT refrigerator.

6.4.4. For storage of intrathecal chemotherapy see the separate policy.

6.4.5. **Storage within Pharmacy**

6.4.5.1. If cytotoxic drugs, including reconstituted drugs, partially filled vials, filled syringes and infusion solutions containing cytotoxic drugs are to be stored, this must be in a dedicated refrigerator or in a section of the cold room reserved solely for this purpose.

6.4.5.2. Cytotoxic drugs that are to be stored at room temperature, will be stored in the same area as, but segregated from other room temperature drugs.

6.4.6. **Storage at Home – Advice to the Patient**

Cytotoxic medicines must be stored at the appropriate temperature in a safe place out of the reach of children. This aspect must be stressed to the patient and their family by hospital and community staff. Carers of patients should be advised to use safe handling procedures.

6.5. Administration of SACT

6.5.1. **Checking**

The requirements set out below are in addition to those given in the Trust Medicine's policy.

6.5.1.1. Checks prior to Administration

The patient's fitness for treatment must be assessed in addition to all blood tests and relevant results and investigations (see appendix 13) as identified by the specific

regimen must be reviewed by the doctor/nurse prior to administration. It is advised that an up to date toxicity assessment should been completed with a suitably trained doctor or CNS in clinic. Any discrepancies should be discussed and actioned before the patient is due to receive their SACT. All patients attending the Haematology clinic will receive a thorough face to face toxicity assessment and any concerns documented on Aria.

6.5.1.2. Checking of SACT

- The Trust requires double checking for all injectable medicines administered intravenously (IV) e.g. IV boluses and IV infusions, by registered doctors, nursing and ODP staff.

- Therefore, double-checking of SACT is required as best practice. Immediately prior to administration, the nurse who will be administering SACT should check the SACT with a registered IV competent nurse who has been assessed and deemed competent in the checking of SACT administration. Both staff should then sign that it has been administered.

- It is the responsibility of the competent SACT administrator to ensure that they have appropriate current knowledge of the drugs being given. They should follow the agreed protocol, be aware of possible immediate, short and long term side effects and the actions to be taken if these occur. They should also be aware of patients educational, psychological, supportive care needs and overall treatment plan.

- Staff undergoing SACT training may only give SACT under the direct supervision of authorised staff and must be in the process of completing their UKONS passport supported by the clinical practice educators and Lead Nurse for SACT.

- Paediatric Oncology Chemotherapy Verification Procedure:

  - Check patient's identification. Confirm the patient's details correspond with the prescription chart and all labelled chemotherapy. Patients who have been admitted must wear a name band with the correct identification

  - Check that the patient has been assessed as 'fit for chemotherapy' by a competent doctor or senior nurse

- Check that spillage kit and extravasation kit are available (if peg-asparaginase is to be administered (check that the Anaphylaxis Kit is available)

- Check that patient and family have consented to SACT protocol

- Check that the treatment protocol and cycle of treatment (treatment record at front of patient's notes) correspond with what is documented on the chemotherapy prescription (current and previous)

- Cycle number/week

- Administration as the schedule within the cycle

  - Check that the SACT prescription and SACT drugs have: The correct patient name and hospital number

  - Check administration date is correct (confirm with date of last cycle)

  - The correct drug (regimen and individual drug identification) and diluents with dilution volumes and any hydration and Mesna

  - The correct drug/dose (check this with the most recent patient's weight and calculated surface area), route and rate

  - Check expiry date has not expired

- Check that critical tests have been carried out and that the results fall within the agreed protocol parameters e.g., FBC

- Check that supportive drugs have been prescribed and given (Bristol antiemetic guideline is used, link on the RCHT clinical shelf)

- Check that the prescription has been signed and countersigned

- If the answer to any of these questions is NO do not proceed. Refer to doctor/nurse in charge

6.5.1.3. Adult verification procedure: check the following for each cycle before administration of SACT:

- Check for written and verbal consent before start of regimen. The individual administering the drug/s should revalidate consent prior to each cycle of treatment

- Check the required blood results and any other required monitoring tests are within range at the start of treatment or have been approved by the prescriber

- It is advised that an up-to-date toxicity assessment should been completed with a suitably trained doctor or CNS in clinic. Any discrepancies should be discussed and actioned before the patient is due to receive their SACT. All patients attending the Haematology clinic will receive a thorough face to face toxicity assessment and any concerns documented on Aria

- If any toxicities or complications are noted, ensure dose modifications or delays in treatment have occurred as per protocol

- Check that the patient has been prescribed anti-emetic drugs and supportive measures and where appropriate, these have been administered e.g., pre hydration

- Check that the name of the regimen and cycle number is correct

- Check that the drug and dose match exactly that prescribed on the drug chart or ARIA prescription

- Check that the correct diluents and dilution volumes are correct

- Check the 'Administration Instructions' box on the Aria prescription for any specific requirements e.g., relating to special giving sets/filters to be used or any post-treatment observation period required. The patient's name must be on the SACT packaging or container as appropriate. In the case of clinical trials, it may be the patient trial number or the patient's initials only

- The route the drug is to be administered by and the duration intended

- The drug is to be administered in the correct sequence

- The drug will not expire before the infusion is completed

- Check that the drug has been appropriately stored

- If there are any discrepancies do not proceed, seek advice from the patient's consultant or pharmacy

6.5.2. **Verification of the Patient Identity**

6.5.2.1. Prior to administration of SACT the nurse and checker should confirm patient identification as follows:

- Ask the patient to provide their name, first line of address and date of birth.
- Check the hospital/NHS number on the patient's wristband.
- Check that this corresponds with the prescription.

6.5.2.2. If there are any discrepancies identified refer to the patient's consultant or a senior cancer pharmacist before proceeding.

6.5.3. **Administration**

6.5.3.1. Within the Royal Cornwall Hospital Trust, cytotoxic drugs may only be administered in designated areas approved for this purpose by the Lead for SACT, as shown in Appendix 3.

6.5.3.2. SACT must be administered by a suitably trained member of staff. Wherever possible the patient should be brought to one of the designated areas. If this is not possible appropriately trained staff will administer the SACT in the clinical area where the patient is based. (e.g., ITU) The administering staff must ensure the team caring for the patient are fully aware of the safety precautions necessary in caring for the patient including waste handling (including bodily waste).

6.5.3.3. A register of those staff trained and permitted to administer adult cytotoxic SACT will be maintained by the SACT CNS's and the Lead Nurse for SACT. The register of those staff trained and permitted to administer paediatric cytotoxic SACT to children will be maintained by the Ward Manager for CLIC.

6.5.3.4. An Extravasation kit, as defined in the Trust Extravasation Policy, must be available in all clinical areas where parenteral cytotoxic drugs are administered. There are separate kits for use in adult and paediatric areas. Kits are ordered from pharmacy when required.

6.5.4. **Closed Systems**

6.5.4.1. Closed system for administration has been incorporated on the Headland unit and Lowen ward following UKONS guidance and must be used when reconstituting Rituximab, Daratumumab, Herceptin and Phesgo.

6.5.4.2. Training will be supported by the SACT CNS's and Lead Nurse for SACT.

6.5.5. **Gloves**

6.5.5.1. Gloves specifically for cytotoxics must always be worn when any cytotoxic drugs are handled.

6.5.5.2. Cuts and scratches on the skin should be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged. Staff with dermatological conditions (e.g., eczema) should be referred to occupational health for assessment of fitness to operate in their role.

6.5.5.3. Hands must be washed thoroughly with liquid soap/detergent or alcohol gel before and after glove application.

6.5.5.4. Gloves must be worn at all times appropriate to the task being undertaken and consideration needs to be given as to whether the procedure requires sterile or non-sterile protective gloves.

6.5.5.5. Gloves must always be disposable and preferably powder free, they must never be reapplied.

6.5.5.6. They must be changed regularly, always between patients and immediately after they become damaged or contaminated.

6.5.5.7. Individual practitioner's preferences should be considered with regard to sensation and dexterity, but they should fit appropriately and be close fitting.

6.5.5.8. Only gloves designed for handling cytotoxic SACT should be used and it should not be assumed that all gloves are impermeable. Nitrile and latex gloves both offer good protection from cytotoxic contamination.

6.5.5.9. For spillages, industrial thickness gloves (> 0.45mm) made of latex or neoprene, nitrile or synthetic rubber is recommended. Alternatively double latex or nitrile gloves can be used. Available in the spillage kit.

6.5.6. **Plastic Aprons**

Disposable plastic aprons will provide limited protection and not prevent absorption into clothing when used where splashing or spraying is possible; urgently a barrier protective apron is used.

6.5.7. **Respiratory Protection:**

6.5.7.1. Surgical masks do not offer protection against inhalation of fine dust or aerosols. The closed system device should be used for making up any aerosol treatments on the unit. Staff have the option to wear appropriate respiratory protection at their discretion.

6.5.7.2. Inhalation is not a significant risk for staff administering prepared cytotoxic drug doses, therefore, staff are not required to wear masks during administration.

6.5.7.3. Respiratory protection should be used when dealing with a cytotoxic spillage (inside spillage kit).

6.5.8. **Eye Protection**

6.5.8.1. The use of eye protection should be considered whenever splashes or sprays of cytotoxic drugs might be generated, for example during intracavity administration and when clearing up cytotoxic spillages.

6.5.8.2. Eyewash kits and spillage kits must be readily at hand for use in all areas where handling of cytotoxic drugs occurs.

6.5.8.3. Eye protection:

- Should fully enclose the eyes
- Be disposable where possible or capable of undergoing decontamination cleaning.

6.5.9. All aprons, gowns, gloves and disposable personal protective clothing should be disposed of according to RCHT guidelines.

6.5.10. **Administration of oral SACT**

6.5.10.1. Administration of oral anticancer medicines on oncology/haematology wards must be undertaken by appropriately qualified clinical staff who are competent and follow the same safeguards and checks as when administering IV anticancer medicines.

6.5.10.2. Clinical staff administering oral anticancer medicines on non oncology/haematology wards to inpatients must contact members of the patient's specialist team for information and advice about the oral anticancer medicine if there are any uncertainties and be aware of safe handling procedures.

6.5.10.3. It is best practice for two practitioners to check and administer oral anticancer medicines. The trusts Administration of Medicines policies must be complied with.

6.5.10.4. Staff administering oral anticancer medicines must have access to the specified regimens/protocols. In areas where staff do not have access to Aria this will be provided as written protocol information, printed from the Aria system.

6.5.10.5. When patients are self-administering their oral anticancer medicines, the trust policy for Patient Self Administration of Medicines (SAM) should be followed.

6.5.11. **Administering Intravenous SACT**

6.5.11.1. Selection of Device

- An appropriate vascular access device should be selected by a competent practitioner to fulfil the requirements of the proposed treatment plan.

- Devices should be cared for following trust Guidelines:
- Prior to SACT administration it is important to establish that there is a free flowing rapid and consistent drip rate on gravity with a compatible infusion.
- The administering practitioner must ensure appropriate venous access with regards to:
  - Site
  - Position
  - Patency
  - Integrity
  - Visibility
- For vein selection advice see Appendix 10.
- With a central venous catheter (CVC) it should be possible to obtain blood return. If no blood return is obtained, there must be further verification of the patency of the device, as per trust policy.
- Cytotoxic drugs should NOT be given if there is any doubt regarding the safety of the venous access device.
- See appendix 12 for further information.

6.5.11.2. Sequencing of drugs

- Vesicant cytotoxics should always be given before non-vesicant cytotoxic/non cytotoxic drugs, unless the protocol specifies otherwise (see ARIA notes section for advice).
- The exception to this is where patients require supportive therapy e.g., pre-hydration, rasburicase, anti-emetics, monoclonal antibodies, immunotherapy and prior to vesicant therapy.
- If there is any uncertainty around the sequencing of the drugs then advice should be sought from an experienced SACT nurse, pharmacist or doctor.

6.5.11.3. Monitoring

- This is the key to early detection of infiltration or extravasation and allergic reaction. The patient and the vascular access device should be monitored frequently before, during, and after administration for:

- Leakage at the site
- Venous irritation
- Phlebitis
- Flare reaction
- Allergic reaction
- Anaphylaxis
- Extravasation
- Known side effects

- Since one of the first symptoms of infiltration or extravasation is discomfort at the site of cannulation or a burning stinging pain. It is important that the nurse explains to the patient, before the first drug is administered, what kind of symptoms to look out for and to report them immediately. Any change in sensation should be verbalised by the patient and checked by the nurse.

- To ensure visibility at all times, an appropriate clear dressing should be fixed over the cannula or CVC as per Trust policy.

- Opaque bandages should not routinely be applied to cannula sites when chemotherapy is in progress. If it is necessary to bandage the site, then the cannula should be observed frequently.

6.5.11.4. General Principles of Intravenous Administration

- Use of aseptic non-touch technique should be maintained throughout intravenous administration

- Ensure appropriate protective clothing is worn, as outlined above.

- Checking of the patient and drug should follow procedure previously described in section 10.

- Inspect sealed bags before opening to ensure no spillage has occurred within the bag.

- Open the cytotoxic drugs directly into a blue tray on a chemotherapy trolley using gloves. Inspect both the front and back of the bag to check even distribution of the drug.

- Ensure that the giving set is primed with a suitable flushing solution using the closed system devices.

- Always spike or screw in SACT bags/syringes at waist height and over a tray that is securely placed on the surface of a trolley. This is to minimise the risk of personal contamination in the event of a spillage.

- If an adder line is required to add onto the infusion administration set, check the connections on the administration set for leakage or cracking.

- Ensure correct rate of administration.

- Flush well between drugs using either 0.9% sodium chloride 0.9% or 5% glucose, depending on drug compatibility.

- If the drug is prone to photo degradation, ensure that the infusion solution is covered to protect it from light, including the IV line, or use an appropriate giving set.

- If a special administration set or filter is required, (e.g., paclitaxel), use only those recommended.

- On completion of dose administration clear away and dispose of all equipment, waste and sharps as outlined in section 19

- Administration sets should be changed every 24 hours.

- Doses of vinca alkaloids should be administered from 50ml mini bags, over 5-10 minutes with compatible fluid running simultaneously if directed.

- Record the completed administration of SACT on Aria.

- In the event of an adverse event necessitating an incomplete administration, it should be clearly documented how much of the dose was administered and the reasons for discontinuation of treatment. Medical staff and pharmacy should also be notified.

6.5.11.5. Administration of bolus SACT for adults

- Where bolus chemotherapy drugs are to be given, they are administered, without exception, via the side arm of a giving set with a fast-running drip of sodium chloride 0.9% or compatible solution using the closed system connectors.

- Do not expel air from syringes, use a closed system connecter on the end of the syringe. If air is in a syringe,

hold it in such a way that the air is up near the plunger when the entire drug is expelled, and the air is reached.

- Place a thick pad of gauze swabs under the injection port during administration.

- Check for blood return every 3-5 ml during administration and before and after each drug during bolus administration.

6.5.11.6. Administration Via Specific Routes

- Subcutaneous / Intramuscular

- Intravesical - administration directly into the bladder, via a urinary catheter.

- Intraperitoneal – administration into the peritoneal cavity

- Topical Cytotoxic Chemotherapy - Cytotoxic drugs for topical administration may come in a number of different formulations, including creams, ointments, gels and solutions. Topical cytotoxic drugs may be applied either directly to the skin or as ear or eye drops.

6.5.12. **Subcutaneous/Intramuscular SACT**

6.5.12.1. A subcutaneous injection is given beneath the epidermis into the fat and connective tissue underlying the dermis.

6.5.12.2. An intramuscular injection is given into the muscle.

6.5.12.3. Wear appropriate protective clothing as outlined above.

6.5.12.4. A maximum diluted volume of 2-3 mls per injection should usually be adhered to where possible for patient comfort. Volumes greater than this should be split into two or more separate syringes and administered into different sites. Rituximab, Daratumumab, Herceptin and Phesgo subcutaneous and given in larger volumes as they are formulated using hyaluronidase which facilitates dispersal into the tissues.

6.5.12.5. Inspect sealed bag before opening to ensure there is no spillage within the bag. Open the bag directly onto the injection tray.

6.5.12.6. Choose a suitable site for the injection, and prepare the skin.

6.5.12.7. Carefully remove the connector top from the Luer-lock syringe and attach appropriate gauge needle. Ensure needles for administration are secure taking great care to minimise risk of spillage on the skin.

6.5.12.8. Administer injection using the Z track technique. This involves displacing the skin and the subcutaneous layer in relation to the underlying muscle so that the needle track is sealed off before the needle is withdrawn minimising reflux. Leave needle in place for a minimum of 5 seconds prior to removing the needle.

6.5.12.9. Remove the syringe and needle, covering the site with low lint gauze and ensuring there is no leakage from the site.

6.5.12.10. If further injections are required, rotate the site of administration.

6.5.12.11. Dispose of all cytotoxic contaminated waste immediately as described below.

6.5.13. **Others**

6.5.13.1. Please see individual guideline for Intravesical administration of cytotoxics.

6.5.13.2. Other routes of administration do not generally occur at RCHT. If such incidences did occur guidance would be taken from the SACT MDT in haematology and oncology.

6.5.14. Administration of SACT Out Of Hours

6.5.14.1. Where possible all SACT must be administered during normal working hours that are between the hours of 09.00 and 1900 in the Headland (0900-1700 for vesicants- see extravasation policy) Monday to Friday. This allows for access to experienced haematology or oncology medical staff, pharmacy staff and the referral to plastic surgery medical team in the event of extravasation of a vesicant drug.

6.5.14.2. Some regimens on Lowen and due to capacity issues will mean that weekend or overnight administration of SACT is required and cannot be deferred. In these cases this must be carried out in a designated SACT area, see exceptions below.

6.5.14.3. No bolus doses of anthracyclines should be administered after 5pm, and infusional anthracyclines MUST be given via central line.

6.5.15. Exceptions

6.5.15.1. SACT may be administered outside these hours following a risk assessment of the regimen/drug. Other exceptions include:

- Continuous Infusions
- Timed SACT

- SACT given more than once a day e.g., AML regimes

6.5.15.2. In cases where there is a clinical need for SACT to be given urgently out of hours, the following criteria should apply:

- The patient's consultant or the consultant on call will identify the clinical urgency to give chemotherapy out of hours.
- The nurse will be familiar with the treatment and agreeable to giving the treatment as prescribed.
- An experienced member of the medical staff (minimum SpR level) must be contactable whilst vesicant treatment is being given.
- The on-call pharmacist will be consulted regarding the feasibility of preparing the drugs if not already available.

6.6. Standards for Oral SACT

6.6.1. In January 2008, the National Patient Safety Agency (NPSA) issued a rapid Response Report - 'Risks of incorrect dosing of oral anti-cancer medicines' which outline good practice standards relating to the prescribing, dispensing or administration of oral SACT and also standards for counselling and information provision to patients.

6.6.2. The Clinical Lead for oral SACT is the Lead Clinician for SACT.

6.6.3. Consenting, prescribing, dispensing and administration of oral anti-cancer medicines must be carried out to the same standard as injected therapy.

6.6.4. All staff involved with prescribing, dispensing and administration of oral anticancer medicines must have ready access to regimen protocols and treatment plans including guidance on monitoring and treatment of toxicity. This is most readily available in the form of Aria regimens.

6.6.5. Prescribers initiating treatment with oral anticancer medicines must assess the patient's suitability for oral treatment including ability to swallow tablets or capsules and ability to comply with the proposed drug regimen.

6.6.6. A suitably qualified healthcare professional will ensure that the patient understands the following:

- How and when to take their medicines including 'gaps' off treatment
- Any dose modifications and understands why this is necessary
- What to do if a dose is missed
- What to do in the event of vomiting after a dose

- Common side-effects and what action to take if they occur
- How to obtain further supplies - if needed
- To return any unused oral anti-cancer medicines to the hospital pharmacy
- The role their GP is expected to play in treatment
- Who to contact in case of problems including out-of-hours.

6.6.7. A patient-held record can be produced using Aria if requested which contains information on the regimen prescribed. There is also space to document that the patient has been counselled on the above points. Currently Macmillan, Cancer research UK or drug specific booklets are handed out to patients with the addition of a neutropenic or immunotherapy card.

6.6.8. Pharmacists should be able to verify that the prescribed dose is appropriate for the patient. They can do this by referring to the written protocol available on Aria or Chemocare, or by referring to the specialist pharmacist.

6.7. Capacity and Scenario Planning

6.7.1. The SACT Lead in consultation with the Cancer Services Pharmacy team and the Lead Nurse for SACT / SACT CNS may agree that the number of SACT patients treated each day can be capped if they deem excess numbers have been reached across any of the SACT production or delivery units.

6.7.2. This limit may be reviewed daily or weekly depending on staffing levels across pharmacy production, Lowen or the Headland Unit.

6.7.3. In the event of safe limits being exceeded, patients may be re-assigned to alternative treatment areas if acceptable.

6.7.4. In the event of a major incident or staffing crisis, the clinical need of individual patients would be assessed in consultation with their own consultant and SACT treatments may be cancelled and rebooked as appropriate.

6.7.5. Capacity planning across Cancer Services will be monitored in conjunction with the cancer services manager and lead cancer pharmacist, using local audit tools and ARIA data.

6.8. Primary Care

6.8.1. All prescriptions for parenteral cytotoxic drugs for administration in the community must be dispensed by pharmacy or supplied by a licensed manufacturer in a reconstituted ready to administer form.

6.8.2. All parenteral drugs dispensed from the hospital for administration in the community must have a prescription supplied with them to allow administration to be documented.

6.8.3. These medicines must be stored at the appropriate temperature in a safe place out of the reach of children. This aspect must be stressed to the patient and their family by hospital and community staff.

6.8.4. Suitably trained primary care nurses may administer cytotoxic drugs in accordance with the policies of the Trust for which they work.

6.8.5. Patients discharged into the community on a continuous SACT Infusion may be overseen by the community staff. The pump may be disconnected and disposed of by appropriately trained community staff. The equipment necessary to do this must be provided by the discharging.

6.8.6. Haematology patients currently self-administer subcutaneous Velcade and Cytarabine, this is generally initiated in the outpatient clinic by the haematology CNS team and the appropriate paperwork completed. These patients will have all relevant contact numbers in case of complications. Guidance is available in the Self Administration of SACT therapies Policy, including patient information leaflets.

6.9. Advice to patients' post-treatment

Patients should be provided with the SACT information, emergency contact numbers, Relevant patient RCHT published information and a neutropenic and/or Immunotherapy alert card.

6.10. Waste

6.10.1. All waste that has come into contact with cytotoxic drugs is treated as cytotoxic clinical waste.

6.10.2. The sharps disposal box must have purple colour coding to denote cytotoxic waste as well as a purple lid so it can be incinerated at 1000ºC to ensure degradation of the cytotoxic agent.

6.10.3. Sharps disposal boxes containing cytotoxic waste must be regularly collected.

6.10.4. Potentially hazardous equipment includes:

- Sharps
- Syringes and needles
- Infusion sets and bags
- Protective clothing Gauze swabs
- Vials

- Urinary catheters, drainage bags, continence supplies such as stoma bags and pads from patients undergoing cytotoxic therapy

6.10.5. Gloves and Aprons should be placed in a designated cytotoxic clinical waste bag.

6.10.6. Non-Disposable Items that have been in contact with SACT Eye protection, trolleys, trays, etc. must be washed using hot soapy water and dried thoroughly whilst wearing protective gloves and apron.

6.10.7. Unused Injection or Infusions should be returned to pharmacy via the Technical Services transport.

6.10.8. Completed Infusions, Syringes and Any Item in Direct Contact with Cytotoxic Drugs close the roller clamp of infusion tubing. Place all items in a cytotoxic sharps bin or a designated cytotoxic waste bag and dispose of as per local waste policy.

6.10.9. Incomplete Infusions, punctured infusion bags with leakage close the roller clamp and place in a designated plastic bag, place in an unused cytotoxic sharps bin which should be sealed and disposed of as per local waste policy. Any spillage should be dealt as described below. Complete a clinical incident form.

6.11. Handling Body Fluids, Vomit and Excreta

6.11.1. In addition to the risk of carrying bacteria or viruses, the vomit and excreta of patients receiving SACT may contain measurable levels of cytotoxic drugs and their metabolites during and for up to 7 days after completion of treatment.

6.11.2. Staff should wear appropriate gloves and waterproof aprons when dealing with blood, vomit, urine, faeces, or any other body fluid. Hands should be washed thoroughly afterwards.

6.11.3. Disposable bedpans, urinals and vomit bowls should be used.

6.11.4. Continence pads and nappies from patients receiving cytotoxic SACT should be placed in a designated cytotoxic waste bag.

6.11.5. Catheters and drains (bottle/bags) can be emptied and then be placed into a designated cytotoxic waste bag. If the drain is a sealed unit it can be disposed straight into a designated cytotoxic waste bag.

6.12. Spillage

6.12.1. A sealed spillage kit containing protective clothing must be available at all times in all clinical areas where cytotoxic drugs are administered. If a kit is used it must be replaced immediately, by ordering a new kit from pharmacy. All appropriate staff must know how to use the kit and where it is stored (training documents held by the CPE / SACT CNS).

6.12.2. Spillage must be dealt with by staff aware of the hazards immediately by an appropriate member of staff in accordance with the procedure contained within the spillage kit.

6.12.3. Other members of staff and patients should be asked to leave the immediate vicinity whilst the spill is dealt with.

6.12.4. The spillage kit should be used to clean up the spillage and a replacement arranged once the spillage has been contained.

6.12.5. Wet spills should be wiped up from the outside to the middle. Dry spills should be wiped up using a damp cloth.

6.12.6. The equipment used to clear the spill and any broken item should be disposed of appropriately and sealed immediately in a cytotoxic sharps bin.

6.13. Accidental Contact with Cytotoxic Drugs

6.13.1. Medical and pharmacy advice should be sought immediately

6.13.2. Report the incident to occupational health if it involves a member of staff.

6.13.3. A Datix incident form must be completed

6.14. Skin Contact

6.14.1. Wash the contaminated area immediately using copious amount of running water for at least 10 minutes.

6.14.2. After initial flushing with water, the contaminated skin should be thoroughly washed with liquid soap or antiseptic scrub and water. After rinsing, the process should be repeated.

6.14.3. Shower facilities should be available for use if large areas of skin are contaminated.

6.14.4. Do not use hand creams and emollients as these may aid absorption of the drug.

6.14.5. A Datix incident form must be completed.

6.15. Eye Contact

6.15.1. An eye-wash kit should be available in all areas where SACT is administered.

6.15.2. The contaminant must be removed as rapidly as possible by flushing the eyes and surrounding areas with a large volume of sterile normal saline using an eye wash station where available. Alternatively cold tap water can be used if necessary.

6.15.3. Rinse the affected eye(s) immediately with sterile sodium chloride 0.9% for at least 10 minutes and refer direct to Emergency Eye Clinic or Occupational Health.

6.15.4. A Datix incident form must be completed.

6.16. Needle stick injury

6.16.1. Allow the wound to bleed freely.

6.16.2. Wash the puncture site/wound thoroughly with copious amounts of cold water.

6.16.3. If the needle contained any cytotoxic drug contaminant, check the vesicant status of the drug by referring to the extravasation policy, or by seeking advice from a senior oncology or haematology pharmacist.

6.16.4. Follow the Trust's Needle stick injury procedure and consider seeking advice from the Accident and Emergency Department or Occupational Health, especially if the needle had been in contact with a patient.

6.16.5. A Datix incident form must be completed.

6.17. Contamination of Clothing, Staff Uniforms and Linen

6.17.1. Any contaminated clothing should be removed immediately and placed in a sealed plastic bag until it can be washed. It should then be washed at maximum possible temperature on a full cycle in a washing machine separately from other clothing. Gloves should be worn when handling contaminated clothing.

6.17.2. Contaminated bed linen should be placed in a designated cytotoxic waste bag and disposed of as clinical waste. If contamination occurs in the home, then the procedure for contamination of clothing should be used. Gloves should be worn when handling contaminated bed linen.

7. Dissemination and Implementation

7.1. Training – General

7.1.1. Training in SACT is required for all healthcare professionals involved in the prescribing, reconstitution, dispensing and administration of SACT.

7.1.2. Individuals should have essential SACT knowledge, including the potential hazards to personnel and the environment as well as the effects on patients and the care they require. They should have knowledge of the regulatory frameworks and policies that support working safety with cytotoxic drugs.

7.1.3. Practical training is essential and should be assessed using a competency-based framework such as the UKONS SACT Passport. Training and support will be provided by Trust Approved Assessors, and annual re-assessments will take place following guidance from

UKONS.

7.1.4. Training and information should also be provided for all staff, including the wider allied health professionals who come into contact with cytotoxic SACT.

7.1.5. Training of all medical, nursing, pharmacy, portering and domestic staff who handle cytotoxic drugs or cytotoxic waste is essential. Such staff should understand the potential hazards associated with cytotoxic drugs and be familiar with relevant procedures.

7.1.6. Nursing and pharmacy staff are encouraged to access the available SACT courses and study days as required. Cancer Services supports CPD requirements.

7.2. Training – Medical Staff

7.2.1. Medical staff in RCHT are not trained to administer IV SACT for adult cancer therapy. Where treatment by other routes requires medical staff to administer, training around safe handling and waste disposal must be undertaken.

7.2.2. Medical staff prescribing SACT and working in the haematology/oncology units within RCHT must have the knowledge of the principles of SACT and be familiar with related protocols, policies and ways to treat SACT emergencies.

7.2.3. All Medical staff who are required to undergo ARIA training are deemed competent in the prescribing of SACT. An up to date list of trained medical personal can be obtained from ARIA.

7.3. Training – Nurses

7.3.1. Nurses are required to undertake additional training and competency assessment before administering cytotoxic medicines to patients. Nurses on average start the UKONS Passport (or equivalent) approximately a year after starting in cancer services, however this will depend on previous experience and skills. Details of competent practitioners will be held on a central register and staff competency will be reassessed on an annual basis by completing the SWAG and Peninsula Cancer Alliance refresher workbook and a practical assessment.

7.3.2. Newly appointed nursing staff regardless of grade may not administer SACT until they have completed the necessary training and achieved competency in the following manner:

- Nursing staff previously involved in SACT administration will provide evidence of their training, become familiar with all RCHT’s policies relating to SACT and its side effects and complete the RCHT’s annual assessment for that year unless already completed.

- Nursing staff who have no previous experience in SACT administration will complete the UKONS passport and be supervised until deemed competent by Lead Nurse for SACT and/or Clinical Practice Educators.

- Nurses working in Oncology/Haematology (adult and paediatric) are encouraged to be in possession of recognised accredited Oncology/ Haematology qualifications.

- All agency and bank nursing staff will be instructed on their arrival within the Ward/outpatient area where SACT drugs are administered and that they will be excluded from any involvement with those drugs and procedures until adequately assessed and evidence provided. The exception to this is where agency staff have been specifically booked for this purpose and their agency has conducted all SACT assessments. Agency staff will still undertake a form of assessment by CPE or Lead Nurse for SACT and have completed the relevant paperwork.

7.4. Nurses maintaining skill and knowledge

7.4.1. For SACT competent nurses to continue to administer SACT, they must complete their annual SACT workbook and practical assessments and must be administering SACT throughout the year (suggested minimum 8 days). The SACT nurse must also 'demonstrate continued professional development in relation to SACT handling and administration' (UKONS SACT Competency Passport v.4 2019).

7.4.2. Nurses must demonstrate a commitment to keeping their SACT skills up to date and ensure safe service.

7.5. Training - Pharmacy Staff

7.5.1. Training of pharmacy staff must be undertaken in accordance with the pharmacy standard operating procedures, held on the QPulse documents system. Pharmacists responsible for validating parenteral and oral cytotoxic prescriptions must be authorised to do so by the Lead Cancer Pharmacist, who will maintain a Register of these pharmacists ('Registered Pharmacists').

7.5.2. Pharmacists will complete a period of supervised training and collect evidence of prescriptions they have verified. They will also complete assessment questions based on the British Oncology Pharmacy Association competencies and undergo final assessment with the Lead Cancer Pharmacist before being deemed competent.

7.5.3. Registered pharmacists will demonstrate ongoing competence by providing evidence of prescriptions they have verified every two years, and for the dedicated cancer pharmacists, will collect evidence of clinical interventions and Continuing Professional Development. Training on the safety aspects of anticancer medicines for pharmacy staff involved in dispensing and supply of these medicines will be

provided as part of the induction process for new staff and repeated every 2 years.

7.6. Training – Supplies and Domestic Staff

All supplies and domestic staff working in areas where cytotoxic drugs are used should have received training and education on the safe handling and disposal of waste related to cytotoxic drugs, as per their own departmental procedures.

7.7. Training – PTSU transport staff

All PTSU staff involved in transporting cytotoxic drugs should have received training and education on the health risks associated with cytotoxic drugs and cytotoxic waste. They should be familiar with the procedures for handling cytotoxic spillages.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	• Accurate list of SACT prescribers, administrators and others handling SACT. • DATIX relating to SACT • Audits of: services provided, Patient Held record, National Patient satisfaction surveys, consent audits.
Lead	SACT leads as outline in policy
Tool	Audit and review tool on a word or excel spreadsheet
Frequency	As required
Reporting arrangements	Reporting will be done to the Medicines Practice Committee via the MDT
Acting on recommendations and Lead(s)	Recommendations made by the MDT will be implemented by Haematology and Oncology Cancer leads
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 4 weeks or as agreed in the action plan. A lead member of the team will be identified to take each change forward where appropriate

9. Updating and Review

9.1. This policy will be reviewed every two years, in line with Chemotherapy Peer Review

9.2. Revisions can be made ahead of the review date if required. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

9.3. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	The Safe Handling and Administration of Systemic Anti-Cancer Therapy Policy V6.0
This document replaces (exact title of previous version):	The Safe Handling and Administration of Cytotoxic Products for the Treatment of Cancer V5.2
Date Issued/Approved:	November 2022
Date Valid From:	December 2022
Date Valid To:	December 2025
Directorate / Department responsible (author/owner):	Emma Nicholls, Lead Pharmacist Cancer Services and Juliet Rickard Lead SACT Nurse
Contact details:	01872 25 8347 / 07825 124975
Brief summary of contents:	Defines the policy for safe handling and administration of cytotoxic SACT for the treatment of cancer.
Suggested Keywords:	SACT, Cytotoxic, Immunotherapy, Administration, Capacity, Spillage, Waste, Chemotherapy Information, Teaching, Education, Chemotherapy Consent, Prescribing
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Haematology and Oncology SACT Quarterly MDT
General Manager confirming approval processes:	Ian McGowan
Name of Governance Lead confirming approval by specialty and care group management meetings:	Suzanne Atkinson
Links to key external standards:	See below

Related Documents:	**RCHT:** • Prevention and management of the Extravasation of Systemic Anti-Cancer Therapy in Adults Clinical Guideline • Extravasation of Cytotoxic Drugs in Children Clinical Guideline • Self-Administration of Medicines (SAM) by Competent Patients Policy • Use of Intravascular Catheters in Adults Clinical Guidelines • Oral Chemotherapy procedure • Consent to Examination or Treatment • Self-Administration of Subcutaneous Systemic Anti-Cancer Therapies (SACT) Policy • The Safe Administration of Intrathecal Chemotherapy Clinical Guideline • Guideline for the management of systemic anti-cancer therapy (SACT) related hypersensitivity reactions - Adults • Delivery of SACT via CADD Pump: Solis VIP Ambulatory Standard Operating Procedure • Non Medical Prescribing Policy • IT policy **Other:** • The Nursing and Midwifery Council (NMC) Standards for Medicines Management • Department of Health (2011) The Manual Cancer Service Standards (2011) Topic 3C-Chemotherapy. • West Midlands Expert Advisory Group for Systemic Anti-Cancer Therapy (SACT)(2018) Network Guidance – SACT and Management Policy for Adult Patients. • Dougherty. L., Lister. S. (2020) The Royal Marsden Hospital Manual of Clinical Nursing Procedures (10th ed), Oxford, Blackwell Publishing. • Barton-Burke. M., Wilkes. G., Ingwerson, K. (2001) Cancer Chemotherapy A Nursing Process Approach (3rd ed), Boston, Jones and Bartlett Publishers. • Allwood. M., Stanley. A., Wright., P. (2002) The Cytotoxic Handbook (4th ed) CRC Press

Information Category	Detailed Information
	• National Patient Safety Agency (2014) NPSA/2008/RRR001: Risk of incorrect dosing of oral anti-cancer medicines • NHSPQA Committee (2018) Guidance on Handling of Injectable Cytotoxic Drugs in Clinical Areas in NHS Hospitals in the UK. • SACT training logbook (Dr G Stewart)
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Cancer Services

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
June 2009	V0.0	Created by Paul Evans	Paul Evans
June 2009	V1.0	Edited to comply with the Trust "Policy on Policies" for submission to MPC for final approval before signature	John Pickup
June 2009	V1.1	Introductory paragraph to s5.2 added.	John Pickup
July 2010	V1.2	Revised to take account of location changes	Paul Evans
July 2010	V1.3	Revised to take into account procedural changes	Paul Evans
November 2011	V1.4	Revised to take into account new Peer Review Chemotherapy Measures. Merger of document: Intravenous administration of Cytotoxic drugs. Put into new trust format	Lisa Nicholls
July 2012	V2.0	Merger and update of document: Standards for the safe use of oral chemotherapy. Revised to take into account other procedural changes. Update to trust format. Removal of references to non-cancer indications	Emma Nicholls

Date	Version Number	Summary of Changes	Changes Made by
August 2013	V3.0	Review and update – Recommenced Peer review changes: Nurse checking and doctors training records. And : F1 prescribing, changes in booing rules, consent, the checking of chemotherapy, update to staff training, update in waste disposal of drain/catheters.	Lisa Nicholls
June 2015	V4.0	Review and update	Lisa Nicholls Emma Nicholls
Sep 2019	V5.0	Review, update addition of GDPR information. Flow chart re-done and added to, new SACT terminology added.	Rachel Hopper Emma Nicholls
June 2020	V5.1	Update to terminology and updated Appendix 1 and 2	Rachel Hopper Emma Nicholls
August 2020	V5.2	Additional of Appendix 15	Emma Nicholls, Lead Pharmacist Cancer Services and Rachel Hopper, Lead Nurse SACT
November 2022	V5.3	Review and update. Addition of appendix 16 SACT spillage guidance for patients	Emma Nicholls, Lead Pharmacist Cancer Services and Rachel Hopper, Lead Nurse SACT

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	The Safe Handling and Administration of Systemic Anti-Cancer Therapy Policy V6.0
Directorate and service area:	Cancer Services
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Emma Nicholls, Lead Pharmacist Cancer Services and Juliet Rickard, Lead SACT Nurse
Contact details:	01872 253842 / 07825 124975

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To ensure safe handling and administration of cytotoxic SACT for cancer treatment.
2. Policy Objectives	To ensure safe handling and administration of cytotoxic SACT for cancer treatment and provide guidance.
3. Policy Intended Outcomes	To ensure safe handling and administration of cytotoxic SACT for cancer treatment.
4. How will you measure each outcome?	By checking documents meet the above objectives and outcomes.
5. Who is intended to benefit from the policy?	Users of the Trust Services and staff. The Trusts reputation

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** MDT Medication Practice Committee
6c. What was the outcome of the consultation?	Agreed
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:
Emma Nicholls, Lead Pharmacist Cancer Services and Juliet Rickard, Lead SACT Nurse

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Locations

1. Areas within the Royal Cornwall Hospitals Trust in which Intravenous Cytotoxic Therapy may be administered for malignant disease:

    - Child Health Directorate – CLIC ward
    - Lowen Ward – SACT inpatient ward / RCHT
    - The Headland - SACT Outpatient Unit / RCHT
    - Clinical Trials areas in oncology and haematology
    - Urology – (including Urology clinic RCHT, General Theatres RCHT and West Cornwall)
    - Haematology and Oncology RCHT Clinics (oral)

2. If SACT is to be given outside of these clinical areas, it must be first discussed with the lead SACT pharmacist or lead SACT Nurse / SACT CNS and will only occur if the patient is too unwell to be transferred to an allocated SACT treatment area, e.g., Critical Care patients or when SACT needs to be given under general anaesthetic in theatre.

3. In such cases the SACT competent nurse administering the treatment will take the required safety equipment with them i.e., extravasation and spillage kits, personal protective clothing, and waste disposal. It is also recommended that the relevant guidance and safety information is taken to the administrating area for staff support , including SACT prescription access.

Appendix 4. Agreement Responsibilities for Head of Service for SACT at RCHT

The Lead Cancer Clinician agrees that the Lead SACT Clinician will be responsible for the ensuring the provision of a safe and effective chemotherapy service at the RCHT. Individual responsibilities and targets are specified by the National Cancer Action Team and listed in the SACT Measures in the Manual for Cancer Services. The Head of SACT Services will also be the designated Clinical Lead for oral anticancer medicines.

Date

Head of SACT Services

Date

Director of Cancer Services

Appendix 5. Agreement Responsibilities for Lead SACT Nurse at RCHT

1. The Lead SACT Clinician and the Lead SACT Nurse's Line Manager agree that the Lead SACT Nurse will be responsible for assisting with the safe delivery of the SACT service at RCHT.

2. The duties include those outlined in the Lead Nurse for SACT job description, and the individual responsibilities and targets that are specified by the National Cancer Action Team, which are listed in the SACT Measures in the Manual for Cancer Services

Date

Head of SACT Services

Date

Divisional Nurse, Cancer Services and General Surgery, Lead Cancer Nurse

---

Date

SACT Lead Nurse

Appendix 6. Agreement Responsibilities for Lead Pharmacist at RCHT

1. Overall responsibility for Oncology pharmacy services to Lowen ward, the Headland Unit, Clinical Oncology (Sunrise), and Haematology.

2. Overall responsibility for the provision of cytotoxic SACT.

3. Overall responsibility for ensuring compliance with pharmacy related standards of the SACT Measures and other relevant guidance e.g. NPSA alerts.

4. Involvement with the development and implementation of policies and procedures relating to the use of SACT.

5. Attendance at the SACT/Governance MDT.

6. To be a representative at the regional pharmacy Cancer groups as necessary.

7. Involvement with the set up and administration of Clinical Trials involving Oncology or Haematology. This includes liaison with the Senior Pharmacist for clinical Trials where oral drugs are involved and with the Pharmacy Technical Services Unit for the parenteral therapies.

Date

Head of SACT Services

Date

Lead Pharmacist for SACT

Date

Chief Pharmacist

Appendix 7. Agreement of the responsibilities of the Lead Pharmacist for Paediatric Oncology at the Royal Cornwall Hospital NHS Trust

- To ensure that the Lead and Designated pharmacists engaged in Paediatric Oncology work effectively together.
- To ensure that all paediatric oncology prescriptions are clinically checked and signed by a pharmacist appropriately trained in oncology.
- To ensure that decisions regarding the operational policies are ratified, documented and made available to all areas involved with administering paediatric SACT.
- To take overall responsibility for ensuring that the Pharmacy Department meet Peer Review Quality Measures
- To provide a link with the Network NSSG, and Regional Paediatric Oncology Pharmacists group, either by attending in person or by nominating another to attend and to liaise with the Lead Paediatric Oncology Pharmacist for the Primary Treatment Centre.
- To lead for service improvement and audit in relation to safe and effective usage of SACT.
- To ensure the organisation of any activities, such as training pharmacists and other healthcare professionals, to ensure the best functioning of the team.
- Overall responsibility for the pharmacy service to inpatient and outpatient SACT services on, Fistral Ward, Polkerris Ward, and the CLIC unit.
- To take overall responsibility for the pharmacy department for cytotoxic SACT.
- To liaise over pharmaceutical matters with investigators carrying out clinical trials and/or other clinical research involving the drug treatment of malignant diseases
- To lead on COSHH reviews of current regulations.
- To lead on investigations into drug incidents involving SACT.

Signature…… **Date……**	**Lead Paediatric Pharmacist RCHT**
Signature…… **Date……**	**Lead Clinician for Cancer (Paediatric)** **RCHT**
Signature…… **Date……**	**Chief Pharmacist**

Appendix 8. Agreement of the responsibilities of the Designated Cancer Pharmacists for Paediatric Oncology at the Royal Cornwall Hospital NHS Trust

- To act as the Designated Pharmacist on behalf of the Lead Pharmacist.
- To be responsible for inpatient and outpatient SACT services to Sennen Ward, Fistral Ward, Polkerris Ward, and the Gwithian unit.
- To ensure all paediatric oncology prescriptions are clinically checked and signed by a pharmacist appropriately trained in oncology.
- To ensure the timely provision, of prescriptions to the Pharmacy dispensary and Technical Services Unit, and liaise with them over any production/clinical interface issues.
- To liaise with and provide information on pharmaceutical matters to paediatric medical, nursing and other ward staff.
- To participate in such training as to ensure the best functioning of the team.
- To support the Lead Pharmacist for Cancer Services in their role.
- Liaison with PTC pharmacist in relation to paediatrics
- Overall responsibility for cytotoxic SACT in the paediatrics speciality
- Liaison over pharmaceutical matters with investigators carrying out clinical trials and other clinical research involving the drug treatment of malignant diseases in the paediatrics speciality

Signature……	**(Designated Pharmacist) Specialist Pharmacist – Paediatrics RCHT**
Date……	
Signature……	**(Designated Pharmacist) Directorate Pharmacist – Paediatrics RCHT**
Date……	
Signature……	**(Lead Pharmacist) Lead Paediatric Pharmacist Cancer Services RCHT**
Date……	
Signature……	
Date……	**Chief Pharmacist RCHT**

Appendix 9. Agreement of the Aseptic SACT Preparation facilities at the Royal Cornwall Hospital NHS Trust

Responsibilities as the designated Pharmacist for aseptic SACT preparation facilities:

- Overall responsibility for the clean SACT preparation facilities of the pharmacy service.
- Responsible for the management and leadership of Technical Service activities within the Trust. Activities include: aseptic preparation of radiopharmaceuticals, cytotoxics, parenteral nutrition, specialist intravenous injections, intrathecal and epidural injections and medical devices, and also pre-packing and overlabelling of medicines.
- Named as Production Manager on the Medicines & Healthcare products Regulatory Agency (MHRA) Specials Licence held by the Trust for the preparation of radiopharmaceuticals and non-sterile prepacking/overlabelling activities.
- Responsible for ensuring all medicinal products manufactured under licence are prepared in line with Good Manufacturing Practice (GMP). All other aseptic work is carried out under a Section 10 exemption of the Medicines Act 1968. Responsible for ensuring that these activities are performed in accordance with both the Act and GMP.
- In conjunction with the Quality Assurance Manager, responsible operation of the Technical Service facility.
- To provide specialist information on all Technical Service issues.

Signature……	
Date……	**Head Pharmacist Technical Services RCHT**
Signature……	
Date……	**Lead Pharmacist Cancer Services RCHT**
Signature……	
Date……..	**Chief Pharmacist RCHT**

Appendix 10. Selection of Cannulation Site.

When choosing a suitable site, both the required cannula size and the size and condition of available veins must be taken into consideration, ideally the smallest cannula placed in the largest most suitable vein.

The following needs to be considered:

- The purpose of the cannulation. For example:
    - A large vein required for high flow rate.
    - Irritant solutions or drugs require good flow to assist haemodilution.
- The condition of the accessible vein, the lumen and blood flow.
- Small visible but impalpable superficial veins are rarely suitable for cannulation.
- In the elderly patient particularly, prominent, superficial veins may be sclerosed, tortuous, fibrosed or fragile and therefore unsuitable for cannulation.
- The superficial veins of the arm are commonly chosen for the cannulation as they are numerous, easily detectable with wide lumens and thick walls and the skin is less sensitive. Most common are median cubital, basilic and cephalic veins.
- In children, cannulas may be sited in the feet.
- Veins in the lower limbs should not be used in adults for SACT.
- Avoid use of dominant arm to maintain patient mobility and independence whenever possible.
- Avoid areas of joint flexion.
- Avoid use of cubital fossa, especially for vesicants.
- Avoid sites distal to recent cannulation or venepuncture to minimise the risk of fluid extravasation.
- Avoid areas proximal to skin lesions or wounds.
- Avoid veins close to arteries or deep lying vessels as accidental puncture can cause painful spasm or prolonged bleeding.
- Avoid areas affected by invading tumour, haematoma, inflamed or sclerosed areas.
- Avoid limbs where there is lymphatic impairment following surgery, chemical occlusion or radiotherapy even if there is no obvious lymphoedema.
- Most difficulties arise when few or no veins in good condition are available. To help dilate difficult veins:

- Utilise warming techniques such as the Air glove.
- If the patient is very nervous or needle phobic, try applying local anaesthetic cream to the proposed site at least 30 minutes prior to the procedure. In severe circumstances in adults, oral or sublingual lorazepam (at doses of 0.5 to 1mg) may be considered.

Appendix 11. Off protocol Prescribing of SACT

For a SACT regimen to be ON PROTOCOL, it must be specified in the Trust approved list of SACT regimens (TALCR) for the same disease and stage of disease.

The TALCR is available on the computerised prescribing systems (ARIA or Chemocare). 'Off-protocol' SACT is defined as:

- Any anticancer agent or combination of agents not on the TALCR
- Use of a regimen on the TALCR, but for an indication or stage of disease other than that specified
- Addition of a new anti-cancer agent to an existing regimen on the TALCR
- Removal or change in dose of an anti-cancer medicine listed in the TALCR other than for toxicity, poor performance status or tolerance

Where a drug/regimen is being used outside of NICE or NHS England approved indications, the appropriate funding source must be obtained e.g., exceptional cases application or Cancer Drug Fund.

The first cycle 'Off-protocol' SACT can only be prescribed by an oncologist or haematologist experienced in the site-specialty, at consultant level, subsequent cycle can be prescribed by registered prescribers. The first cycle must be prescribed by the patient's own consultant or, with their agreement, by another consultant familiar with the regimen.

Details required in an Off-Protocol SACT prescription include:

- Treatment intention,
- Protocol choice,
- Dose selection,
- Appropriate interval between treatments,
- Correct administration details including number of cycles intended,
- The decision to treat on the grounds of haematological and biochemical parameters.

In the event of an off-protocol regimen needing to be prescribed the consultant must contact one of the specialist cancer pharmacists to discuss writing an ad hoc prescription on ARIA

The off-protocol prescription should contain all relevant supporting medication e.g., anti-emetics, hydration details.

Information for Professionals and Patients

All patients should receive written and verbal information pertaining to their specific treatment indicating details of the regimen and anticipated side effects.

Medicines Information (particularly regarding toxicity profile) should be readily available for healthcare professionals involved in prescribing, dispensing and administering the drug or delivering emergency care where a drug is unlicensed e.g. compassionate use.

Patients must specifically be made aware if the proposed treatment is unlicensed.

COMPASSIONATE USE PROGRAMME ANTICANCER MEDICINES

Requests to use an unlicensed compassionate use medicine must be discussed with the Cancer Pharmacist and NHS England before an initial request is made. The prescriber must request patient specific access to the unlicensed medicine through the company who manufacture the medicine and provide the necessary clinical detail.

Any new 'free drugs' available under an expanded access scheme must be discussed at the Expanded Access Sub-Group and ratified at relevant governance groups such as the SACT quarterly meeting.

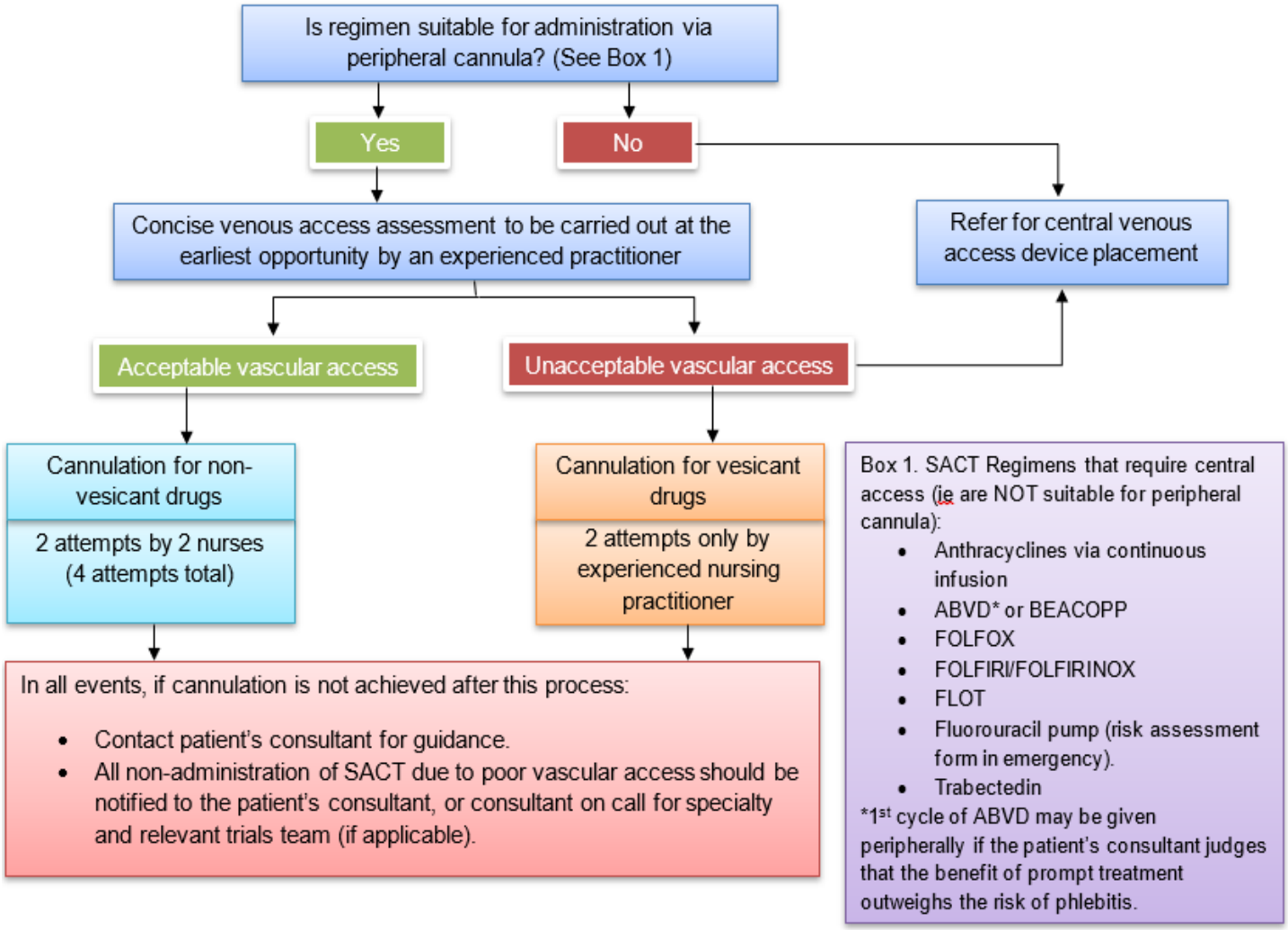
Once the use of the medicine has been agreed, the order must be set up through the pharmacy. If there are forms to be completed and signed by the consultant, these must be passed on to the specialist pharmacist to proceed with placing the order.

The prescriber is responsible for ensuring that all information pertaining to the safe administration and monitoring of the unlicensed medicine are accessible to all staff caring for the patient, including staff involved in out of hours emergency care. New SACT drugs are summarised in a safety brief drug profile that is shared with all SACT nurses, both via ward and outpatient safety briefings and via electronic email. The specialist pharmacist who has dealt with the request for the new drug will place the relevant information e.g., SPC into these files.

The prescriber is responsible for providing appropriate information to the patient on the unlicensed nature of the treatment and possible side-effects of the treatment. This information should also be available to the patients GP.

The prescriber is responsible for reporting any suspected adverse effects to the manufacturer on the day the adverse effect is identified and to the MHRA (yellow card).

Appendix 12. Cannulation on Headland Unit and Lowen Ward.



Appendix 13. Management of blood results on Headland

It is the responsibility of the prescribing clinical team and the dispensing pharmacist to check that the core parameters for safe delivery of SACT are satisfied.

Haematology patients proceeding with treatment will either be confirmed via treatment day clinic review or ARIA notes entry.

If treatment is to be given outside of these stipulated parameters, a clear note must be made on ARIA.

In order to aid patient flow/prevent delay it may be necessary for pharmacy to prepare and send SACT before blood results are available. In this instance a sticker to notify nursing staff will be attached to the outer bag, as well as a note on Aria, and responsibility for checking bloods will fall to the administering nurse(s).

Patients on single agent immunotherapy without toxicity can have blood results within 6 weeks of treatment (within 3 weeks of first dose). To reduce attendance, blood tests in clinically stable patients may be done on cannulation and treatment can proceed. Details of these patients should be emailed to rcht.oncologyregistrars@nhs.net so that they can be checked retrospectively.

The following guide should be followed for other bloods test results

Electrolytes	
Potassium	Refer to Trust guidelines and flow chart in Headland. If potassium >5.3 but under 6.4, consider repeating and a baseline ECG. This may not be needed if the level is chronic. If potassium >6.4 or ECG abnormal, escalate to FY2. If repeat potassium remains above 5.3, escalate to doctor
Magnesium	Refer to Trust guidelines and flow chart in Headland.
Sodium	If new abnormality > 150mmol/l or <130mmol/l, escalate to FY2 but see in context of clinical situation and other results.
Calcium	If new value or corrected calcium <2.0mmol/l or >2.7mmol/l, escalate to FY2. Exercise special care in patients on bisphosphonates / denosumab or calcium supplements.
Phosphate	Only actionable if <0.6mmol/l. Refer to Trust guidelines and flow chart in Headland.
Renal Function	
If new or worsening AKI flagged on results, escalate to doctor	

Liver Function	
Bilirubin	If newly > 1.5x ULN, flag to Clinical Oncology Team (SpR or Consultant)
ALT / AST	If newly >2.5x ULN (137u/l), flag to Clinical Oncology Team (SpR or Consultant)
ALP / Albumin	No intervention required on Headland if bilirubin is stable
Miscellaneous	
LDH	No intervention required
Tumour markers	Reviewed in clinic

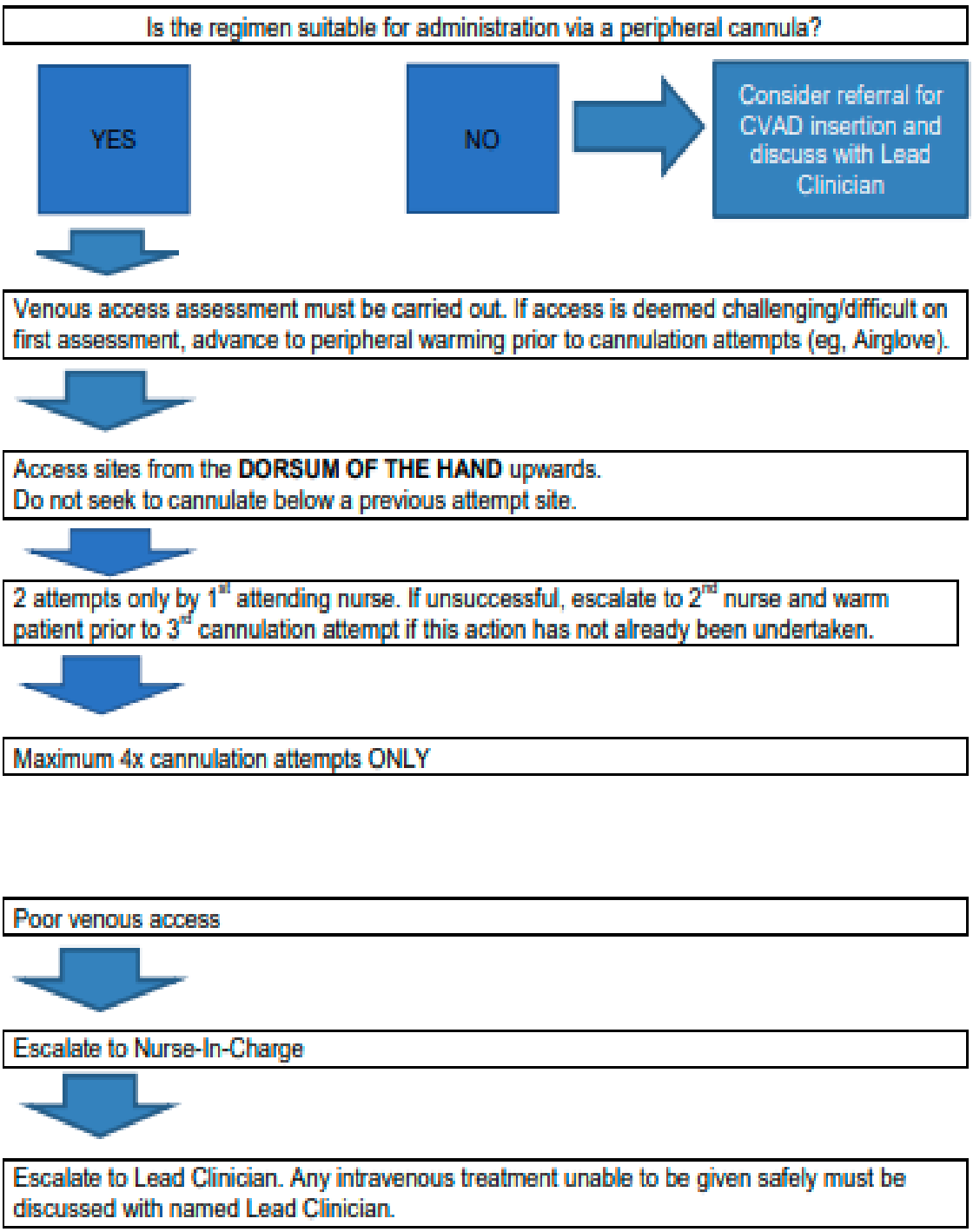
Appendix 14. Telephone / Digital SACT Pre-Assessment

Due to covid 19 and the impact this has and will continue to have on capacity and social distancing telephone / digital SACT pre-assessments will become part of the Headland unit practice. This has been agreed with clinical leads and Lead SACT pharmacist and nurse. The following will ensure a similar process for patients to follow and will be completed by the assessing nurse.

- Appointment time agreed with patients prior to call, patient must be able to hear conversation and have agreed to the pre assessment over the phone or via 'attend anywhere' video call.
- Questionnaire on aria completed for pre-assessment.
- Side effects discussed and explained as per Aria questionnaire
- 24hr helpline number explained and advised patient of how and when to use it (Emergency symptoms discussed) Confirmation that the patient already has the card must be obtained, if not the assessing nurse will arrange for a card to be posted out to the patient.
- Confirm patient has a thermometer or will get one before treatment commences
- Neutropenic sepsis card explained and discussed, as above ensure the patient has this if they are receiving chemotherapy (check expiry date and allergy status are correct)
- Check with patient that they either have or have an appointment to get pre-treatment bloods, height and weight done in order for treatment to be prescribed (arrange this if not).
- Condition of veins to be checked in person by; specialist nurses, Headland unit or Acute Oncology prior to 1st treatment, if this has not been completed and felt necessary before treatment the patient will need to attend the Headland unit
- Discuss the use of GP / practice/ district nurses for pre-treatment bloods prior to every treatment throughout duration, unless bloods agreed not required with consultant prior for treatments such as immunotherapy, Herceptin and Pertuzumab
- Contact Headland unit to arrange wig referrals if required
- Advise patients about the use of parking permits and how to obtain them
- Advise patients that relatives / friends are not allowed on the unit during present circumstances
- Document all information on Aria same day including any notes about relevant information discussed

Appendix 15. Cannulation/Peripheral access guidance for patients receiving immunotherapy ONLY

This guidance is to be used for patients receiving immunotherapy ONLY. Immunotherapy patients are often receiving palliative treatment and due to poor health and receiving previous intravenous SACT treatments, venous health can be affected. Efforts are being made to reduce the number of venepuncture and cannulation attempts for this patient group, therefore the guidance below has been issued. In some situations, central venous access devices (CVAD) are not appropriate given infrequent infusions (6 weekly regimens).



Appendix 16. Managing a spill from your ambulatory infusion pump. Patient information leaflet.

Available at: http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/PatientInformation/CancerServices/RCHT1978ManagingSpillageFromAmbulatoryInfusionPump.pdf