Haematology and Oncology Clinical Chemotherapy/Systemic Anti-Cancer Therapy Service Operations Policy

Date | Version
---|---
October 2016 | 5

Purpose
To describe the policies and procedures governing the provision of chemotherapy to patients with neoplastic disease treated at Plymouth Hospitals NHS trust

Who should read this document?
All members of staff with involvement in the clinical chemotherapy service

Key messages
Multidisciplinary team delivery of chemotherapy.

Accountabilities
Production: Sarah Wellington, Kirsty Jenkins
Review and approval: Chemotherapy Operations Group/Medicine Governance Committee and Drugs and Therapeutics Committee
Ratification: Dr Philip Hughes
Dissemination: Via Trust Documents. Hard copies in all clinical areas with responsibility for chemotherapy provision
Compliance: Dr Patrick Medd

Links to other policies and procedures
PHNT Intrathecal Chemotherapy Policy
Pharmacy Documents:
PHNT Procedures for Administering Injectable Drugs
PHNT Standard Operating Procedures for the Safe Handling and Administration of Injectable Cytotoxic Drugs
PHNT Standard Operating Procedures for the Management of Phlebitis, Infiltration, Air Embolism, Speedshock and Extravasation
PHNT Standard Operating Procedures (SOPs) for Preparing and Administering Intravenous Medicines and Fluids
PHNT Research and Development Policy

Version History
1.0  December 2012  Document created
2  June 2013  Document update to include new wards
3  Nov 2014  Document Updated
4  May 2015  Document Update
5  October 2016  Document Updated

Last Approval | Due for Review
---|---
October 2016 | October 2020
PHNT is committed to creating a fully inclusive and accessible service.

Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff.

We will treat people with dignity and respect, actively promote equality and diversity, and eliminate all forms of discrimination regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/ maternity.

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Introduction

1. Systemic anticancer therapy (SACT) is also known as cancer chemotherapy or antineoplastic drugs. These names refer to drugs which have the ability to kill or arrest the growth of living cells and include conventional cytotoxic drugs (for example Cyclophosphamide and Methotrexate), monoclonal antibodies (for example Anti-thymocyte Globulin (ATG), Alemtuzumab, Rituximab) and small molecules (for example Imatinib and Erlotinib). Monoclonal antibodies and small molecules are often called targeted therapies because they target specific parts of the tumour genesis.

2. SACT should only be used within agreed protocols for the treatment of malignant diseases or for the management of haematological immune conditions such as Aplastic Anaemia. Prescribing should be undertaken using our electronic prescribing program.

3. Anticancer therapy should be provided by a multidisciplinary team in which doctors, nurses and pharmacy staff work together with approved written protocols providing integrated and safe care.

4. Cytotoxic drugs and their bi-products found in body fluids are potentially hazardous to the patients receiving them, their carers, health care professionals and other visitors to the clinical environment where cytotoxic drugs are used. These risks can be reduced if treatment is delivered:
   - by trained and competent staff
   - in an unhurried atmosphere
   - in normal working hours and
   - with adequate checks on patient safety at every stage.

5. This Policy has been written using the best available current evidence and practice and aims to minimise risk to both health care professionals and patients.

6. This Document refers to some areas of the administration of Intrathecal Chemotherapy. For details please refer to National and Trust Intrathecal Chemotherapy Guidelines.

7. Intrahepatic administration of chemotherapy (chemo-embolisation) is covered in Appendix 8 attached to this policy.
Definitions

Chemotherapy is the treatment of cancer with one or more cytotoxic drugs.

Cytotoxic refers to any agent or process that kills cells

SACT – Systemic Anti-Cancer Therapy

Extravasation is an inadvertent infiltration of a vesicant solution or medication into surrounding tissues instead of into the intended vascular pathway.

Haematology is the study of blood, the blood-forming organs, and blood diseases

Intrahepatic chemotherapy is the process of injecting drugs through a catheter into the artery that supplies blood to the tumor in the liver.

Intrathecal chemotherapy refers to drugs which are administered into the space under the arachnoid membrane of the brain or spinal cord

Oncology is the branch of medicine that deals with cancer.

Radiotherapy sometimes abbreviated to XRT or DXT, is the medical use of ionizing radiation, generally as part of cancer treatment to control or kill malignant cells.

Vesicant drug is a solution or medication that can cause tissue damage

MUAC – Medicines Utilisation and Assurance Committee

CCS – Clinical Chemotherapy Service

COG – Chemotherapy Operations Group

NCCS – Network Clinical Chemotherapy Service
### Duties of the Multi-Professional Team

**Head of Service / Lead Clinician for Chemotherapy**

Dr Patrick Medd - This is agreed with the Trust Lead clinician for Cancer

NB When the Head of service is a Haematologist the deputy will be an Oncologist clinician – Currently Dr Geoff Cogill.

When the lead Clinician post is held by an Oncologist consultant then the deputy will be a Haematology consultant.

Responsibilities of Head of Service

- To agree the following list of duties with the lead cancer clinician
- To agree the list of responsibilities for the lead chemotherapy nurse with the nurse’s line manager
- To agree and define those areas, both wards and day case areas where chemotherapy may be delivered
- To chair the chemotherapy operations group and agree membership, and to be a regular attendee of the Network Chemotherapy group.
- To agree the list of acceptable regimens for this service and ensure that this list is compatible with the list produced by the cancer network
- To agree a written policy with the chair of the network chemotherapy group for preventing regular use of regimens not on the accepted list.
- To agree the patient verification procedures prior to chemotherapy delivery
- To agree the safe chemotherapy work load
- To agree the policy and arrangements for administration of chemotherapy outside working hours
- To agree the arrangements for the 24 hours telephone advice service
- To agree the named chemotherapy nurse with responsibility for training and the list of staff trained for chemotherapy administration
- To agree a policy relating to those staff not authorised on the list of trained staff for chemotherapy administration who should only give chemotherapy while supervised by trained staff.
- To represent COG on the Medicines Utilisation and Assurance Committee and the Medicines Governance and Operations committee.
Lead Chemotherapy Nurse

Lead Chemotherapy Nurses are Sarah Wellington and Kirsty Jenkins as a shared role – this is agreed by the Lead Clinician for Cancer.

The lead chemotherapy nurses have an agreed set of responsibilities including completion of advanced study and advanced communications skill

Responsibilities of CCS Lead Chemotherapy Nurse

- The nurse must have regular personal involvement with the administration of chemotherapy as part of their timetable, besides their duties as lead chemotherapy nurse.

- They will be an active member of the Trust COG and Network Chemotherapy Nurses Group.

- They will work in collaboration with the head of service to promote, lead and coordinate the nursing contributions to the CCS.

- They will be responsible in collaboration with members of the cancer management team for co-ordinating the chemotherapy element of the peer review process

- They will promote the effective achievement of the chemotherapy specific national quality measures

- In collaboration with head of service and local chemotherapy nurses they will contribute to the development and implementation of necessary clinical algorithms, guidelines and policies.

- They will ensure the necessary nursing protocols, policies and guidelines are authorised by the relevant heads of service and in place and adhered to.

- In collaboration with the head of service they will ensure that patient’s chemotherapy records and verification process prior to administration of chemotherapy comply with the Manual for Cancer Standards.

- They are responsible together with the matron for monitoring the chemotherapy workload to ensure safe working levels at all times

- In collaboration with matron and the chemotherapy nurses and clinical nurse specialists they are responsible for ensuring patients have 24 hour support, advice and relevant support materials and information.

- They are responsible for the training and assessment of all nursing staff according to the Directorate’s agreed training programme implementing a robust system that review’s nurses competencies in accordance with agreed Network training programme.

- They will maintain a list for all staff that are competent to administer chemotherapy (list agreed with Head of service).
• Together with the directorate education staff they will facilitate the professional development of chemotherapy staff

• They will be responsible for ensuring that service improvement is integrated into the service by being involved with service developments supported by the relevant service managers and modernization leads as appropriate, supporting the implementation of action plans for continuous quality improvement.

• Leadership is a core competency for senior chemotherapy nurses and the lead chemotherapy nurse will act as role model / mentor to other chemotherapy nurses.

**Intrathecal Chemotherapy (ITC) Service**

• The Trust has a paediatric and adult ITC with Dr David Lewis as the ITC Lead and ITC Training lead.

**Pharmacy**

• The Lead Pharmacist for Chemotherapy services is the Director of Pharmacy – Simon Mynes
• The Designated Pharmacist role is shared between Birgit Cloos and Phillip Dunn.

*Responsibilities of their role:*

• They shall agree the following list with the head of service.
• They have overall responsibility of oncology services to the named wards above.
• They have overall responsibilities for oncology services to the outpatient areas listed above.
• They have overall responsibility for cytotoxic chemotherapy/ SACT – verifying prescriptions, and overseeing delivery where appropriate.
• They have overall responsibility for SACT given within a trial setting.
• They must attend and be an active member of the Network Group for Chemotherapy Pharmacists.
• They are an active member of the COG, with particular duties including compiling the list of adverse events.
• In collaboration with the Head of Service are responsible for the investigation and outcomes following adverse events.
• In collaboration with the Head of service responsible for verifying prescriptions and identifying prescribing outside recognised policies and regimens to the head of service/ Oncology deputy.
• Responsible in collaboration with pharmacy managers for the coordination of activities towards Peer review inspection, and the annual regional QA audits.
Technical Services

The overall responsibility for the aseptic chemotherapy preparation facilities of the pharmacy service is held by Amanda Horton – Technical Services and QC Pharmacist.

Chemotherapy Operations Group - COG

These important meetings are held 8.15-9.15 am on the second Tuesday of each month.

Terms of Reference for COG

- The committee will be chaired by the Head of service for chemotherapy or deputy who is also a member of the drugs and therapeutics committee.

- The Committee will be comprised of, Directorate Manager, Quality Manager, Cancer Services Manager, Consultant Haematologists, Consultant Oncologists, Director of Pharmacy, Specialist Pharmacists for Haematology/Oncology, Pharmacy Technical Services Manager, Matron, Lead Chemotherapy Nurses, Ward Managers – Bracken, Brent and Chemotherapy Day Case Unit (level 2) and Birch Day Case.

- Quorate:
  The meeting shall be deemed quorate with 4 members present, including 1 consultant, 1 nurse and 1 pharmacist

- Aim:
  To ensure the effective, safe, and efficient use of SACT within the Trust, including prescribing, dispensing, and administration practice.

- Objectives:
  1. To enhance communication across the CCS
  2. To review and approve new and/or amended protocols, agreeing what can be prescribed without recourse to separate funding. Any funding issues identified will be escalated to the appropriate body for approval before any changes in practice are ratified.
  3. To review the clinical evidence and safety of new anticancer therapies prior to their use at Derriford Hospital and to consider options for funding. This information is fed back to the monthly MUAC meetings for final ratification of new therapies) (see Appendix 3)
  4. To maintain up to date protocols for all chemotherapy regimens
  5. To explore new ways of working within individual departments and therefore improving patient care, reducing wastage and unnecessary costs
  6. To implement systems and process for monitoring and improving services including consultation and staff/patient involvement
  7. To review and update the current cytotoxic drug policy and intrathecal policy on an annual basis
  8. To ensure a safe and effective service to all patients receiving chemotherapy
  9. To review clinical incidents in respect to chemotherapy which will be graded according to the NPSA classification.
  10. To ensure maintenance of training and competency and matching staff function to competency
  11. Ensure compliance with National and Local Cancer service standards.
12. Reports to clinical governance committee of the trust.
13. The minutes from the COG meetings are presented and discussed if required at the monthly Trust Medicines Governance and Operation (MGOC) and the Medicines Utilisation and Assurance Committee.

The CCS MDT is a multi-professional group responsible for the safe delivery of SACT within PHNT. It meets monthly at the Chemotherapy Operations Group (COG) meeting (see below) under the chair of either the Lead Clinician for Chemotherapy service, or the Lead Oncology Clinician for chemotherapy (see below).

Core Members

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
<th>DEPUTY / COVER</th>
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<tbody>
<tr>
<td>Dr Patrick Medd</td>
<td>Consultant Haematologist / Head of service for CCS/</td>
<td>Dr Geoff Cogill</td>
</tr>
<tr>
<td>Dr Geoff Cogill</td>
<td>Consultant Clinical Oncologist / Trust Chemotherapy Lead.</td>
<td>Dr Patrick Medd</td>
</tr>
<tr>
<td>Simon Mynes</td>
<td>Lead Pharmacist Haematology and Oncology service Line</td>
<td>Birgit Cloos/Phillip Dunn</td>
</tr>
<tr>
<td>Rob Wosley</td>
<td>Deputy Service Line Manager Haematology and Immunology</td>
<td>Victoria Isaacs</td>
</tr>
<tr>
<td>Sarah Wellington</td>
<td>CNS Chemotherapy Lead Nurse CCS</td>
<td>Kirsty Jenkins</td>
</tr>
<tr>
<td>Kirsty Jenkins</td>
<td>CNS Chemotherapy Lead Nurse CCS</td>
<td>Sarah Wellington</td>
</tr>
<tr>
<td>Birgit Cloos</td>
<td>Oncology/Haematology Pharmacist</td>
<td>Phillip Dunn</td>
</tr>
<tr>
<td>Phillip Dunn</td>
<td>Oncology/Haematology Pharmacist</td>
<td>Birgit Cloos</td>
</tr>
<tr>
<td>Amanda Horton</td>
<td>Technical Services Manager</td>
<td>Ann Mason</td>
</tr>
<tr>
<td>Sharon Raymond</td>
<td>Matron For Haematology and Oncology Service Line</td>
<td>Kelly Allmett, Jane Ransome, Heather Christie, Samantha Rowe</td>
</tr>
<tr>
<td>Jane Ransome</td>
<td>Unit Manager Oncology Day Case</td>
<td>Jenny White, Jess Reed, Faye Dudfield &amp; Tracy Taylor</td>
</tr>
<tr>
<td>Kelly Allmett</td>
<td>Unit Manager Birch Day Case</td>
<td>Vanessa Davies and Liz Drysdale</td>
</tr>
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</table>
Core members of the MDT are expected to attend at least 2/3rd of the COG meetings.
Clinical Chemotherapy Service

The CCS covers a population of 480,000 spanning East Devon, West Cornwall, and the City of Plymouth. Systemic anti-cancer treatment (SACT) is delivered largely within the acute Hospital Trust setting, either on an inpatient basis on Brent and Bracken ward, or in the chemotherapy day case units on levels 8 (Birch Outpatients) or level 5 (Lyd). In addition an outreach service is provided in 3 community settings – Tavistock Clinic, Liskeard Hospital and South Hams Hospital. Please see Outreach Chemotherapy policy document – Appendix 10

Currently some patients receive Herceptin in their own homes given by Healthcare at Home.

Departments and Hours of Operation

- Adult in-patient chemotherapy is given on Brent and Bracken wards, which are now fully integrated and under the management of one modern matron.
- Adult Oncology and Haematology in-patients are accommodated on Brent ward, a 31 bedded unit.
- Adult haematology patients are also accommodated on Bracken ward a 10 bedded stem cell transplant unit.
- Paediatric in-patients will be cared for on level 12 – Wildgoose ward. Paediatric outpatient chemotherapy is delivered on Children and Young Adults Out Patients (CYPOD).
- Adult oncology patients are treated within Lyd, level 5 which operates Monday to Friday 0800-1900. They can be treated in the outreach service (for intravenous chemotherapy) offered at Kingsbridge, Liskeard and Tavistock.
- Adult haematology patients are treated within Birch Day Case Unit (intravenous and intrathecal chemotherapy). This service operates Monday – Friday 08.00 – 19.00hrs.
- Adult oncology patients receiving oral chemotherapy are treated within the level 2 Oncology Outpatient Unit.
- Adult haematology patients receiving oral chemotherapy are treated within out-patient clinics either in Main Outpatients on level 6, or on Birch Day Case Unit.

Out of hours Chemotherapy

All vesicant chemotherapy treatments must be commenced between 08.30 and 17.00. Other than long infusions which are given as an inpatient, other routine chemotherapy will only be given outside 08.00 – 19.00 as an emergency measure, or if demanded by specific protocols (inpatients only) - see administration of chemotherapy section below.

Rarely Chemotherapy is given in other areas in the Trust – e.g. Intensive Care. In this scenario – the chemotherapy is administered by chemotherapy trained staff from Bracken/Brent wards, under the care of a Haematologist/Oncologist.
**5. Education and Training**

It is a requirement that nursing, medical, and pharmacy staff who are likely to be involved in the delivery of SACT should undergo a recognised training programme.

The Chemotherapy service at PHNT is divided into several areas of competence. Individual staff groups are responsible for differing parts of the pathway of Prescribing, Verification, Production, Checking and Administration.

The following table summarises these processes, the staff responsible, and the assessment of the skills required.

<table>
<thead>
<tr>
<th>COMPETENCY</th>
<th>STAFF</th>
<th>SKILLS / TRAINING REQUIRED</th>
<th>ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of a chemotherapy regimen</td>
<td>Consultant medical staff and Oncology Specialist Registrars with the FRCR part II</td>
<td>Completed specialist training in Oncology or Haematology</td>
<td>Attainment of CCST</td>
</tr>
<tr>
<td>Prescribing chemotherapy</td>
<td>Consultants and Specialist Registrars Haem-onc trained Pharmacist</td>
<td>Completed or undergoing specialist training in haematology or oncology</td>
<td>CCST/Completion of training process *</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-medical prescriber course</td>
<td>Non-medical prescriber course*</td>
</tr>
<tr>
<td>Verification of Prescription</td>
<td>Haematology oncology specialist pharmacist Registered Pharmacists (applicable for oral chemotherapy)</td>
<td>In house departmental training</td>
<td>Competency assessment*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In-house departmental training</td>
<td>Competency assessment*</td>
</tr>
<tr>
<td>Production of Chemotherapy</td>
<td>Technicians, pharmacists and ATOs</td>
<td>In house departmental training</td>
<td>Competency assessment *</td>
</tr>
<tr>
<td>Dispensing chemotherapy</td>
<td>Pharmacy staff, Pharmacists, Technicians, ATOs</td>
<td>In house departmental training</td>
<td>Competency assessment *</td>
</tr>
<tr>
<td>Administration of Chemotherapy</td>
<td>Nursing staff Oral, subcutaneous Intravenous, topical Medical staff Intrathecal</td>
<td>Registration with NMC Undergone Network agreed Administration of chemotherapy training Completed or undergoing specialist training in haematology / paediatric oncology</td>
<td>Competency assessment*</td>
</tr>
</tbody>
</table>

**Intrathecal Training procedure**
5.1 Medical staff

The decision to treat a patient with chemotherapy should be made at a multidisciplinary team meeting; if this is not possible the Consultant Oncologist/ Haematologist responsible for the patient should initiate the first cycle of chemotherapy. Oncology Specialist Registrars who have passed the FRCR part II examination are also permitted to prescribe 1st cycles of chemotherapy if they have assessed the patient.

Authorised prescribers include Consultants, Specialist Registrars and Associated Specialists in Oncology and Haematology.

Consultant medical staff are responsible for Initiation of chemotherapy regimens and supervision of prescribing of chemotherapy, and administration of chemotherapy by the Intrathecal, or Intrahepatic routes. Oncology Specialist Registrars who have passed the FRCR part II examination are also permitted to prescribe 1st cycles of chemotherapy if they have assessed the patient.

A consultant physician is consider competent to Initiate and prescribe Chemotherapy by the attainment of a CCST (Certificate Of Completed Specialist Training) and membership of the Royal College of Pathology in the case of Haematology and of the Royal college of Radiologists for Oncologists (or having passed FRCR part II for SpRs).

Annual competency is assured by the participation in the CPD – Continuing Professional Development) schemes of the Royal Colleges, and by the Annual PHNT Appraisal process.

Trainee Medical Staff

Specialist Trainee medical staff at grade ST3 and above may prescribe Chemotherapy or administer Intrathecal Chemotherapy

A Specialist trainee is considered competent to prescribe chemotherapy having:

- Undergone the Peninsula Cancer Network Chemotherapy prescribing training day including:
  - Classification of chemotherapy agents, and modes of action
  - Routes of administration
  - Toxicities and side effects and WHO toxicity scoring system
  - Dose modification and reduction
  - Extravasation
- Good clinical practice in research (NB to be formally involved in clinical research trials involved formal Trust GCP training)
• Received Local training on the use of the PHNT e prescribing system given by the Haematology/oncology pharmacists.

Assessment of Competency is by the consultant for whom the Trainee is working for, or by their Consultant educational supervisor.

Consultants are responsible for any Prescribing done by their trainees for their patients.

Annual competency does not often apply to Trainees as they rotate around the region on an annual basis, however for those trainees remaining at PHNT for greater than one year at a time annual competency is assessed at their annual training assessments, and with regular educational supervision meetings.

To be involved in the prescribing and administration of Intrathecal Chemotherapy Specialist Trainees must undergo the PHNT’s IT chemotherapy training package, successfully complete the questionnaire, and be witnessed performing a procedure – please refer to IT chemo policy

5.2 Nurses

In order to administer chemotherapy, a nurse must:

• Be a registered general nurse with the NMC (Nursing and Midwifery Council) and be employed to act in the capacity by PHNT.
• Have a thorough understanding of local drug policy, cytotoxic policy and COSHH regulations
• Have experience in Oncology/Haematology nursing of 6 months or more and demonstrate a good understanding of the diseases, treatment plans and rationale for treatment for individuals

Training

This will include:

• A study period including both theoretical and practical teaching.
• A period of observation of chemotherapy trained nurses delivering chemotherapy to patients
• A period of supervised practice in administering chemotherapy via infusion and bolus injection
• Completing the Chemotherapy skills work book and demonstrating sound knowledge in:
  • The health and safety issues related to handling and administering chemotherapy.
  • The classifications of chemotherapy agents
  • The toxicities and side effects associated with each agent and a thorough understanding of the WHO toxicity scoring system.
  • Cannulation skills and management of venous access devices, eg Hickman lines
  • The actions required in the event of adverse incidents such as extravasation and cytotoxic spillage
  • Good clinical practice in research (NB to be formally involved in clinical research trials involved formal Trust GCP training)
Chemotherapy Nurse Trainers/Assessors

These nurses will have current registration with the NMC. They will have at least two years experience in chemotherapy management and administration. The nurses are band 7 or above, or lead chemotherapy nurses, or directorate nurse education sisters who have current competence to deliver chemotherapy. Band 6 staff can assist in the training of chemotherapy administration but not assess competence.

Assessment by the Nominated Chemotherapy assessor

The chemotherapy nurse trainers will provide practical training to allow the practitioner to meet the required competencies. Band 6 staff will assist.

Competency is mutually agreed by the nurse and the assessor following which the lead chemotherapy nurse can deem a nurse competent.

Nurses who have received training, have had supervised practice and who have been declared competent may then perform the administration of chemotherapy and the care of patients receiving chemotherapy unsupervised.

A certificate of attainment of competency to administer chemotherapy will be given

A register is held by the lead chemotherapy nurse of those nurses who are authorised to administer chemotherapy unsupervised

Annual assessment of competency

Chemotherapy trained nursing staff undertake an annual network agreed written assessment of their knowledge, skills and fitness for practice to administer chemotherapy. On completion of this assessment staff will receive a certificate to confirm competence has been reassessed annually.

Further Training

NURB diploma / degree level chemotherapy courses

The University of Plymouth (in partnership with South Devon Healthcare Trust) provide a 20 credit module at level 5 or 6 for staff expected to deliver chemotherapy as part of their nursing role. This course is recognised by the Peninsula Cancer Network as the educational gold standard. This course should be undertaken by staff taking a lead in chemotherapy services and for Chemotherapy nurse trainers/assessors.
Network Chemotherapy training course

Chemotherapy nurses across the Peninsula cancer network have developed a competency framework for nurses who are expected to administer chemotherapy and or look after patients who have received chemotherapy. This has 3 levels:

Level 1: Health and Safety awareness – collection of chemotherapy/support workers

Level 2: Practitioners who are expected to care for patients who have received chemotherapy treatment.

Level 3 Practitioners who are expected to administer chemotherapy unsupervised as part of their role.

The PHNT chemotherapy key skills training is level 3. Levels 1 and 2 training are encompassed in the ward staff induction training programmes.

5.3 Pharmacy Staff

Several staff groups within pharmacy are involved in the delivery of chemotherapy which includes the clinical verification of prescriptions, manufacture and dispensing of SACT.

In 2011 PHNT started outsourcing some of the out-patient services. The Lloyds Pharmacy based at Derriford Hospital is responsible for the clinical verification of oral chemotherapy prescriptions and their dispensing. All staff grades at Lloyds follow SOPs from the hospital pharmacy and have to screen ten test prescriptions.

Dispensary

Pharmacists clinically verifying oral chemotherapy prescriptions

Every prescription is clinically verified prior to dispensing. Authorised pharmacists follow the SOP on clinical verification of chemotherapy prescriptions. An annually updated oral chemotherapy handbook is available within pharmacy referring to the prescribed protocols.

Training record/Assessment of competency:

Attend teaching session about chemotherapy and clinical verification of prescriptions

Assessment - clinical verification of 10 prescriptions

Pharmacists and accredited checking pharmacy technicians final check of dispensing

All dispensed medication is checked either by an accredited checking technician or by a pharmacist prior to handing the medication to a patient. Accreditation is not specific to chemotherapy items however during the competency assessment some chemotherapy prescriptions are checked.

Training record/Assessment of competency

Technicians – competency assessment 1000 items (National framework)

Pharmacists – competency assessment 500 items
Pharmacy Technicians and ATOs dispensing oral anti-cancer medication
Training record
Competency assessment of 500 items including chemotherapy

Technical Services
The Pharmacy department has designated staff working within technical services. Every pharmacy technician and ATO has a personal portfolio containing their competency assessments. There is an error reporting system for all items made in technical services which is audited monthly.

Pharmacists clinically verifying intravenous chemotherapy prescription
Training record: regular self-directed learning, CPD
Annual assessment – Mandatory appraisal process

Pharmacists releasing chemotherapy products in technical services
Training record: Competency assessment of 50 items

Pharmacy technicians and ATOs who manufacture intravenous, intrathecal, intrahepatic chemotherapy
Training record: competency assessment

Pharmacist Independent prescribers
Training record: Accredited prescribing course, regular CPD
Annual assessment – Mandatory appraisal process

5.4 Authorised Assessors of Competency
Consultant Medical Staff
Oncology – Dr G Cogill, Dr A Roy, Dr S Pascoe, Dr S Dubey, Dr U Panwar, Dr D Sherriff
Haematology – Dr H Hunter, Dr D Lewis, Dr W Thomas, Dr T Nokes, Dr P Medd, Dr S Rule, Dr C Hutchinson
Chemotherapy Nurse Assessors
Lead Chemotherapy Nurses/ Band 7 Sisters
Sarah Wellington, Kirsty Jenkins, Rachel Bryce, Jane Ransome, Kelly Allmett
Pharmacists

Haematology oncology specialist pharmacists – responsible for assessment of other pharmacists involved in verification and dispensing oral chemotherapy

Birgit Cloos
Phil Dunn

Responsibility for assessment of haematology oncology specialist pharmacy staff

Simon Mynes

Dispensing – Pharmacists and technicians

Neil Carvell

Technical services – pharmacists and technicians

Amanda Horton and Ann Mason

Pharmacist Independent Prescribers

Simon Mynes

5.5 Intrathecal chemotherapy

The Initiation, prescription, verification, dispensing and administration of Intrathecal chemotherapy is covered in detail within the separate PHNT Intrathecal chemotherapy policy.

To be involved in any aspect of the provision of IT chemotherapy a healthcare professional must be named on the IT chemotherapy register, have undergone the training package, have been assessed by written questions, and witnessed practice. Annual competency requires attendance at an update session, written questionnaire and documented involvement in the procedure at least once in the year preceding.

The Lead Assessor/lead trainer for IT chemotherapy is the Intrathecal Chemotherapy lead.

Other departments – eg Child health, Nursing, and Pharmacy have local named assessors – please ref IT chemotherapy list of named assessors for an up to date list. This is held in the intrathecal chemotherapy lead’s office within the master IT Chemotherapy folder.

5.6 Training and use of mechanical drug delivery devices MDDDs

Mechanical drug delivery devices MDDDs must only be used by registered nursing staff that have had the necessary PHNT training and have been assessed as competent in their use. Following training and assessment staff will record and maintain details of their training within their personal training folders kept in each ward area. In addition each clinical area has a link nurse/train the trainer responsible for cascading the training for the use of MDDDs to staff.
Please refer to PHNT policies available on the PHNT intranet via Plymouth healthnet/staff training and development/ PHNT medical devices training/MDT policies.

- Medical Equipment Management Service MEMS: Medical Equipment User’s Guide.
- Policy and procedure for the training of PHNT staff in the use of medical devices.
- Diagnostic and therapeutic equipment training and competency assessment
6 Health and Safety

1. For healthcare personnel, the risk of exposure to potentially hazardous substances exists during drug reconstitution, preparation, administration and when dealing with the disposal of contaminated equipment or patient waste.

2. Staff working with cytotoxic drugs must be made aware and kept aware of these potential risks and how to avoid exposure and environmental contamination of these drugs (Control of substances hazardous to health COSHH). For further information refer to PHNT COSHH policy. This applies to clinicians, nursing staff, pharmacy staff, domestic staff in the relevant clinical areas, and hospital porter’s carrying cytotoxic drugs or cytotoxic waste.

3. All staff must wear personal protective equipment when handling or administering cytotoxic drugs. It is essential that staff use nitrile gloves and a chemo protect gown.

4. The chemo protect gown may be worn by an individual nurse for the duration of a shift to administer chemotherapy unless there is evidence of contamination.

5. Staff should be aware that PPE does not guarantee total protection and must be used in conjunction with safe handling techniques in an appropriate clinical setting.

6. Face protection is not used as part of the standard PPE. There are goggles and a face shield available for staff to use if they perceive the risk warrants face protection.

8. In line with the Health and Safety at work legislation all staff must use a totally enclosed system where reasonably practicable.

7. Staff must be instructed and assessed as competent to handle cytotoxic drugs. This is a key element of the chemotherapy key skills pack. Trained staff will undertake the chemotherapy key skills following successful completion of the intravenous drugs administration training. Training and assessment will be led by the Lead Chemotherapy Nurses and Education Co-ordinators for Haematology and Oncology.

Related policies

Staff should read the following associated procedural documents produced by Pharmacy and located in Trust Folders and on Plymouth Healthnet:

- PHNT Procedures for Administering Injectable Drugs
- PHNT Standard Operating Procedures for the Safe Handling and Administration of Injectable Cytotoxic Drugs
- PHNT Standard Operating Procedures for the Management of Phlebitis, Infiltration, Air Embolism, Speedshock and Extravasation
- PHNT Standard Operating Procedures (SOPs) for Preparing and Administering Intravenous Medicines and Fluids
Administration of oral cytotoxic drugs

- Wear nitrile gloves
- Wherever possible use a non-touch technique
- Never crush or break tablets.

6.1. Guidelines for use of Personal Protective Equipment

1. Under the Personal Protective Equipment at Work Regulations 1992, personal protective equipment (PPE) should be provided and used wherever there are risks to health and safety that cannot be adequately controlled in other ways.

2. It is recommended that:
   - Current, local COSHH risk assessment has been carried out for the activity that might result in exposure.
   - Staff should not handle cytotoxic drugs or waste unless they understand the risks and appropriate techniques for avoiding exposure.
   - A no touch approach should be adopted when handling cytotoxics products or wastes i.e. wear appropriate disposable gloves and other PPE suitable for the task.
   - Recommendations for PPE should be adapted appropriately for people receiving cytotoxic drugs and their carers.
   - Personal Protective equipment should be available to all staff and appropriate for purpose. This consists of:
     - Gloves
     - Gowns
     - Eye protection
     - Respiratory Protection

Recommendations for PPE in handling activities

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Disposable gloves

1. Wear disposable gloves at all times when contact with cytotoxic drugs is made e.g. preparing, handling, administering.
2. However ‘no glove material will provide unlimited protection from cytotoxic drugs’. Health and Safety Executive (HSE) Information Sheet.
3. Change gloves regularly and always between patients.
4. Damaged gloves should be changed immediately.
5. Wash hands properly before and after use of gloves.
6. Powder-free gloves are preferred since the powder may absorb cytotoxic contamination.
7. Use of latex (or nitrile gloves) must be risk assessed due to potential for latex allergy in staff and patients.
8. There is evidence that nitrile and latex gloves offer good operator protection against cytotoxic contamination.
9. The individual practitioner’s preferences should be considered with regard to sensation and dexterity.
10. For spillages, industrial thickness gloves (0.45mm) made of latex and neoprene, nitrile or synthetic rubber is recommended. Alternatively double latex or nitrile gloves can be used.

Gowns

1. Disposable gowns are preferred and should have:
   • Closed front
   • Long sleeves
   • Elastic or knit cuffs
2. Disposable gowns should be made of Saranex coated Tyvek™, polyethylene – coated Tyvek™ or another suitable composite material which has been shown to be impermeable to cytotoxic drugs
3. Disposable plastic aprons provide limited immediate protection and prevent absorption into clothing when used where splashing or spraying is possible.

Eye Protection

1. Eye protection should fully enclose the eyes, meeting British Standard EN 116.
2. The most suitable form of eye protection for clinical use is safety goggles, giving the eyes protection from dust and splashes.
3. Goggles should be disposable or capable of undergoing decontamination cleaning.
6.2 Guideline for the safe handling, administering and disposal of cytotoxic drugs

- Use nitrile gloves and a chemoprotect®.
- Prepare the equipment for administering chemotherapy on a clean large white tray, lined with a white paper dressing towel to contain and absorb any spills.
- Place the prepared tray on the top shelf of the trolley and a cytobin on the bottom shelf.
- Ensure a chemotherapy spillage kit is available in all clinical areas.
- Take the tray / trolley to the patient’s bedside.
- When spiking bags, use a closed administration system and do so horizontally over the white tray. This will minimise risk in the event of a spillage. **Do not** spike bags hanging on a drip stand.
- Bolus chemotherapy should be administered using gauze underneath the port site to absorb any small drops that leak from the port site. **Closed system administration bungs** should be used with bolus chemotherapy syringes.
- When the administration of chemotherapy is complete sharps must be disposed of immediately in a cytobin. **Do not** separate needles from syringes.
- All disposable waste is to be wrapped in the white towel within the white tray. Waste is then to be disposed of in an orange-bagged bin designated for cytotoxic waste.
- Nitrile gloves and plastic aprons **must** be worn when emptying bedpans, urinals and vomit bowls belonging to patients who are receiving or have had chemotherapy in the last seven days.
- Clean tray with detergent wipes wearing nitrile gloves.
- Gloves and aprons are to be disposed of in a designated orange bagged bin designated for cytotoxic waste.
- **Wash hands before and after all procedures.**

6.3. Pregnancy

1. All staff involved in the handling, transportation or administration of chemotherapy should be informed of the potential reproductive hazards by:-
   - Information provided at induction.
   - Having access to relevant up-to-date literature.
   - Signing to say they have read and understood the relevant COSHH assessments.
   - Providing opportunities for discussion of concerns.

2. The time of greatest risk to the unborn child is during the first three months of pregnancy; the time of most rapid cell division and differentiation.

3. It is important that female employees inform their manager that they are pregnant, have given birth in the previous six months or are breast feeding. Those trying to conceive are encouraged to discuss their plans for pregnancy with their manager.

4. When managers receive notification they must review COSHH risk assessments. This assessment must take into account any advice provided by the pregnant staff member’s GP or Midwife, however it is assumed that no pregnant member of staff will handle, or administer Chemotherapy.
5. Managers should have consideration for their staffs’ perception of the risk and offer alternative duties if they choose not to work with cytotoxics at this time.

6. As some pregnancies are unplanned, or staff may be unwilling to discuss plans for conception; the emphasis is to reduce exposure to all staff at all times.

7. A comprehensive method of staff education and assessment in safe handling of cytotoxics aims to reduce the risk for all staff.

8. Safe handling procedures must be audited and documented on a regular basis to ensure staff compliance and to reduce risks to as low as reasonable practicable.

6.4. Breastfeeding

1. There is currently no evidence to suggest that children who are being breastfed are at any greater risk of harm if their mother is involved in handling and manipulating cytotoxic chemotherapy, or if she isn’t.

2. However, expert opinion suggests that the same recommendations for pregnancy should be followed, and those breast feeding should not handle or administer chemotherapy.
1. All chemotherapy should be prescribed according to the approved protocol for the site specific disease using the agreed Aria Computerised prescribing system.

2. The decision to treat a patient with chemotherapy should be made at a multidisciplinary team meeting; if this is not possible the Consultant Oncologist/ Haematologist responsible for the patient should initiate the first cycle of chemotherapy. Authorised prescribers include Consultants, Specialist Registrars and Associated Specialists in Oncology and Haematology.

3. The benefits and risks associated with chemotherapy need to be carefully discussed with the patient who should also be provided with high quality written information to supplement face to face communication. Consent should then be obtained and recorded in detail in terms of the aims of treatment and both the common and serious side effects of treatment.

4. A separate chemotherapy talk will be delivered by a competent nurse.

5. Check that a holistic assessment has been carried out.

6. Careful reassessment is needed before the start of any subsequent cycle of treatment. This should include reassessment of performance status,
documentation of any serious toxicity (e.g. grade 3 or 4 toxicities) and appropriate blood tests. Dose modifications should be made where necessary. Response to treatment should be documented at appropriate intervals. This reassessment may be carried out by appropriately qualified medical or nursing staff.

7. Specialist Registrars (ST3, ST4, ST5) and Consultants in Oncology and Haematology are the only authorised prescribers for chemotherapy in their field of specialty (signatures of approved prescribers are kept in pharmacy and clinical areas and require regular updates) – the exception is hydroxycarbamide for which a shared care guideline allows GPs to continue prescribing in agreed patients. Patients continue to be monitored in secondary care by the Haematology Team.

8. All patients require a treatment plan for each line of chemotherapy they undergo. This treatment plan must be authorised and signed by a consultant oncologist or haematologist.

This treatment plan should include the following information as a minimum:-

- Diagnosis and staging according to an internationally recognised staging system
- Performance status and co-morbidities
- Treatment Intent
- Tests required pre-chemotherapy
- Planned numbers of cycles
- Frequency and method of assessment if appropriate
- Any deviation from protocol and why.
- History of current medication
- Previous history of Chemotherapy
- This must be communicated to the GP – usually in the form of a letter which may be copied to the patient as is appropriate.

9. The electronic prescribing program Aria should be used for approved protocols which will also provide the information for the SACT data set

10. All prescriptions need to be verified by chemotherapy trained pharmacists

11. Intravenous chemotherapy has to be administered by chemotherapy trained nurses

12. The prescribing and administration of intrathecal chemotherapy is explained and defined in the designated policy

7.1 Consent

1. All patients planned to receive chemotherapy by any route must give informed consent as per Trust guidelines.

2. For patients who are deemed not to have capacity to consent as defined by the Mental Capacity Act trust policy must be carried out, either using the specific designed PHNT trust consent for, signed by two doctors, and involvement of independent assessors eg the IMCA service.

Please refer to the updated Trust consent policy held on StaffNet.
3. The vast majority of patient will be able to give informed consent – this undertaken on the PHNT generic chemotherapy consent form. This form enables patient to confirm that they have received written and verbal information on toxicities.

4. The consent form is generic and is supplemented by regimen specific information – which is documented on the consent form.

5. The consent form is printed in duplicate – allowing all patients to be offered/given their own

7.2. The prescriber’s responsibility

1. Following the correct treatment protocol to ensure the correct sequencing for alternating type regimens.

2. Ensuring that SACT is prescribed on a standard chemotherapy prescription form giving clear and concise details of the drug administration requirements. Standard chemotherapy prescription forms include computer generated Aria prescriptions when available, hand written chemotherapy prescriptions and green chemotherapy outpatient prescriptions for oral chemotherapy.

3. Ensuring that the body surface area calculations are correct, and have been made using a recent weight unless otherwise specified by the patient’s protocol

4. Any dosage modification required due to toxicity, patient weight or age are clearly documented on the prescription chart and the patient’s individual protocol.

5. Prescribing all supportive therapies including antiemetic, mesna and appropriate hydration fluids on current in-patient prescription chart.

6. Obtain consent as documented above.

7. Documentation of the SACT minimum dataset on the Aria system will be required prior to administration of chemotherapy.

7.3. Pharmacist’s Responsibility

1. A Pharmacist trained in checking chemotherapy should clinically screen all prescriptions for SACT for the treatment of malignant disease in adherence with the SOP on screening chemotherapy prescriptions.

2. Prior to a SACT being prepared the pharmacist should verify the prescription according to the protocol or treatment regimen, clarify and resolve any discrepancies and check that:-
   - The appropriate protocol has been selected, with correct sequencing.
   - The protocol / treatment regime is supported by NICE or local / NHS England commissioning decision
   - Appropriate funding is in place for the duration of the treatment course, either via NHS England or Cancer Drug Fund (CDF)
   - The body surface area calculations are appropriate, and have been made using a recent weight (applicable for high dose chemotherapy).
   - Dose modifications to previous treatments are maintained if appropriate.
All cytotoxic drugs and supportive therapies including anti-emetics have been prescribed.

Dose calculations are correct

The route of administration and duration of infusion have been specified on the prescription.

The infusion volume and diluent as well as its infusion time are appropriate with respect to the patient, protocol and pharmaceutical stability.

Ensuring that all relevant safety parameters such as complete blood counts, renal and hepatic function are reviewed and drug doses modified where necessary.

The prescription has been signed and countersigned.

The prescription has the patient’s name, date of birth and hospital number documented clearly on the prescription.

Allergies have been documented on the drug chart.

7.4 Pre Treatment consultation

The NCAG has set a requirement that patients undergo a course of chemotherapy should be able to have a separate further consultation with a health professional before starting a course of chemotherapy, whether first or subsequent, and after any consultation where the chemotherapy treatment plan is first agreed with them and they receive the associated patient information.

The aim is to try to ensure that they have had time to fully understand the implications of undertaking the course of treatment and to provide an opportunity to ask questions.

It is recognised that this is not applicable to all patients, some will need urgent treatment, others will decline this opportunity – however it must be offered to all patients.

It is also recognised that the patient pathways leading up to chemotherapy are complex and varied and chemotherapy is delivered in different settings and by differing staff.

Examples of how a further pre-treatment consultation opportunity works in practice within the CCS are given below.

- Further outpatient appointment with consultant on another day; eg Haematology oral chemotherapy
- Further outpatient appointment with chemotherapy specialist nurse; eg Some solid tumour sites
- Consultation with chemotherapy nurse/clinical nurse specialist after consultation with consultant; eg when rapid therapy needed
- Time spent with chemotherapy/ward nurse after consultation with Consultant; eg those in patients requiring urgent in-patient initiation of therapy.

The documentation of this pre-treatment consultation will form part of the Chemotherapy care plan. For those treated purely with oral chemotherapy as an outpatient documentation of a further pre-treatment consultation will be in the clinical record.
8 Chemotherapy Ordering and Preparation

1. All SACT must be prepared in the Technical Services Department located on Level 5 PHNT, prepares and dispenses Intravenous (IV), Intrathecal (IT), Subcutaneous (SC), Intramuscular (IM) SACT for PHNT. Any exception to this must only be after completing and recording full risk assessment by the Quality Assurance pharmacy Lead.

2. Monoclonal Antibodies (MABs) are highly active biological agents which affect wide range of biological functions. MABs are not conventional cytotoxic agents and do not damage DNA or RNA but they still cause cell death and may be potentially hazardous to staff. Those staff involved in handling them must be aware of potential risks of each individual product. MABs assessed as medium to low risk may be prepared at ward level. Any staff involved in such manipulation must be aware of potential risks of individual drugs and must use personal protection equipment of gloves and gowns the use of a closed system.

3. The dispensary located on Level 5 PHNT (clinical trial prescriptions or inpatient supply only) and the Lloyds Pharmacy level 6 (outpatient prescriptions) supply oral SACT and supportive medication.

4. All prescriptions for SACT have to be verified (screened) by a cancer trained pharmacist.

5. Prescriptions for intravenous SACT should ideally be prescribed in advance to allow more effective capacity planning in technical services and a timely delivery of the SACT to the clinical area. (Refer to the Service Level Agreement between Pharmacy and the Oncology and Blood Service Directorate).

6. See Section Initiation and Administration of Chemotherapy Out of Hours.
9 Transportation and storage

9.1 Transportation

1. All staff involved in the transportation of cytotoxic drugs must be trained to follow the cytotoxic spillage procedure and must know what to do in the event of a spillage.

2. Cytotoxic agents must be transported in appropriately labelled, sturdy and leak proof transport bags or boxes. These must be suitable for the product and robust enough to withstand normal transport and handling conditions. They should also be able to be clearly distinguishable from other containers used for transporting non-chemotherapy agents.

3. If damaged or leaking cytotoxic products are received on the Ward or Outpatient Unit, follow cytotoxic spillage procedure.

4. If the products require refrigeration, the cold-chain should be maintained.

5. Intrathecal chemotherapy must be transported separately to all other SACT medication. Only designated and approved pharmacy staff are allowed to deliver intrathecal chemotherapy. (Refer to PHNT policy for Safe Administration of Intrathecal Chemotherapy).

9.2. Storage in Clinical Areas

1. Intravenous chemotherapy and oral SACT should be received on the clinical area by a trained staff member who is responsible for ensuring that the contents are stored safely and appropriately. All intravenous chemotherapy must be stored separately from other drugs in the designated locked chemotherapy refrigerator or cupboard that is present in all areas where chemotherapy is to be delivered.

2. Storage must be designed in a manner that will prevent containers of cytotoxic drugs from falling; such storage areas should be clearly labelled with cytotoxic warning labels.

3. Ensure that the temperature of all refrigerators storing chemotherapy is maintained between 2 - 8°C. Inform technical services during normal working hours or contact the on-call pharmacist for advice out of hours if there are any concerns.

4. All cytotoxic chemotherapy prepared by a pharmacy department will have an expiry date assigned to it.
10 Administration of SACT

10.1 Patient, Family and Carers

1. The safe administration of medicines is a collaborative process which involves the nurse, doctor and pharmacist and includes making sure that the patient (and family or carer where appropriate) understand what medicines they are taking and why, including the likely side effects.

2. The patient should be informed of -
   - The possible side effects of the SACT
   - How to manage any side effects
   - The types of supportive therapy they may receive
   - Where, when and how they are to receive the drugs

3. Patients should receive written information, which should be used to reinforce verbal explanation and enable patients and carers to spend time reading and formulating any questions about treatment. Information in other formats will be made available if requested.

4. Written consent must be obtained and documented at the start of treatment and at any time when the patient’s treatment protocol is changed.

10.2 Fit for Chemotherapy Assessment

1. Prior to chemotherapy being administered a competent doctor must assess the patient to be fit for chemotherapy. Chemotherapy trained nurses may take part in this process within the Chemotherapy Outpatient Department and Birch Day Case Unit on the day of treatment and refer the patient back to the Consultant/SpR if there are any concerns regarding the fitness of the patient.

2. This should include review and documentation within the Aria medical record of the following:
   - Past Medical History, performance status, prior chemotherapy, current medication
   - Full Blood Count results taken within 2 - 3 days of the planned chemotherapy administration. Results must be within acceptable limits documented in individual protocols. If chemotherapy administration is scheduled for Monday, blood levels taken on the preceding Friday are acceptable.
   - Relevant pre-treatment test results (as per patient treatment protocol) such as GFR, lung function, cardiac function and audiology tests.
   - Whether the patient has been assessed and is medically fit to receive the prescribed chemotherapy.
   - New Patient Assessment - on Aria completed prior to first cycle of chemotherapy to ensure the patient has had all the correct information including written Macmillan information sheets, Derriford Patient information booklet and a yellow alert card, consent form has been signed and the patient has had a nutritional assessment.
Holistic assessment – As well as physical needs and condition, a patient's social needs must also be assessed prior to commencement of chemotherapy. Additionally they will be offered an opportunity for review of their spiritual needs. This assessment is undertaken by the trained nursing staff using the Chemotherapy Symptom Assessment Scale found on the Aria prescribing system.

10.3 Safe Administration of Cytotoxic Drugs

1. Chemotherapy should only be given in specialist clinical areas where it is an agreed part of the ward or clinic activity and where appropriate support and expert advice is available. The following clinical areas may administer chemotherapy to adult oncology and haematology patients:-

   - Brent Ward, Lyd, Bracken Ward and Birch Day Case Unit.
   - In exceptional circumstances chemotherapy may require administration in other clinical areas e.g. Intensive Care, in which case it is always be administered by a chemotherapy trained nurse from the Oncology and Blood Services Directorate

2. Safe administration of cytotoxic drugs is a priority for all members of the clinical team. If any member of the team recognises factors which may contribute to an unsafe environment or workload the Lead Clinician and Matron must be informed and an action plan instigated.

3. Chemotherapy should be prescribed to coincide with times when chemotherapy trained staff are available to check and administer the medicines. This should generally be during normal working hours (between 09:00-17:30 hours). Chemotherapy may be administered out of hours when the protocol schedule clearly defines administration times to be outside the scope of normal working hours and when the continuation of the treatment is in the best interest of the patient. This is only done in the in-patient setting and requires the presence of on call medical staff, and authorised nursing staff present to administer chemotherapy. Infusions which have to be given over up to 24 hours should preferably be started within working hours.

In exceptional circumstances chemotherapy administration may need to be initiated outside of normal working hours, for example:-

   - When a patient's condition or prognosis will be compromised if treatment is delayed, such as at diagnosis, relapse or treatment regimens with proven "on time benefit".
   - There should be discussion and agreement between the Matron and Lead Clinician when chemotherapy is initiated outside of normal working hours.
   - Plans must be in place to ensure that there are trained staff available to administer and check the chemotherapy and the on call doctor SpR/Consultant is aware and can offer support as required.
   - For all such patients, the Lead Clinician must discuss treatment with the on-call pharmacist at the earliest opportunity.
4. Chemotherapy will be checked and administered by a registered nurse or doctor trained and assessed as competent in the administration of SACT.

5. Staff undergoing chemotherapy training may only give chemotherapy under direct supervision of appropriately trained staff.

10.4 Emergency Equipment

All areas in which SACT are administered must have access to the following equipment:-

- Emergency bell
- Resuscitation equipment
- Drugs for the management of emergencies including cardiac arrest and anaphylaxis
- Extravasation kit
- Cytotoxic spillage kit
- Eye wash and access to running water
- Cytotoxic waste container (purple lid sharps bin).

10.5 Prevention, recognition and management of allergic reactions including anaphylaxis

All drugs used within chemotherapy treatment protocols have the potential to cause allergic or hypersensitivity reactions, these may vary from mild to life threatening. Key principles of care to prevent or recognise and manage drug reactions include:-

- Chemotherapy prescribers and givers must check the patient's drug allergy history.
- The givers must be aware of the potential reaction profile of each drug and administer any drug with a high risk of reaction with caution (e.g. Asparaginase, Rituximab, Taxanes, re-exposure to Carboplatin)
- Ensure emergency equipment is readily available.
- Ensure emergency medications are prescribed and available.
- Base line observations should be taken and recorded prior to administration.
- Ensure any pre-medication is given as per patient's protocol.

Patient and carer should be informed of the potential for drug reactions or allergies and asked to report any unusual symptoms during the infusion such as; uneasiness or agitation, abdominal cramping, itching, chest tightness, light-headedness, dizziness, confusion, chills, rash, urticaria, severe nausea or vomiting. If patient experiences any of the above symptoms:-

- Stop the infusion and notify the doctor urgently
- Assess the patient as per PHNT resuscitation guidelines and monitor and record patient's observations.

If patient is collapsed or has the following symptoms; stridor, wheeze, respiratory distress or clinical signs of shock **DIAL 2222**
10.6. The Nursing Role in Chemotherapy Administration.

1. Responsibilities of the Ward/Outpatient nurse:-

- Check that the patient has been consented for the treatment prior starting the first cycle.
- Check patient’s weight on admission against the weight on prescription chart. Discuss with medical staff if there is a significant change in the current weight and the prescription weight.
- Liaise with Technical Services to ensure SACT are prepared and delivered at the appropriate time.
- Ensure trained chemotherapy staff are available to check and administer the prescribed drugs.
- Ensure patient has been assessed as “fit for chemotherapy” by the designated doctor and that this has been documented in the patient’s notes.
- Provide information, ongoing monitoring and supportive care for the patient before, during and after chemotherapy administration.

2. The chemotherapy administrator must only proceed to administer chemotherapy if it is safe to do so. This includes confirming:-

- Emergency equipment is available.
- The patient is fit and willing to proceed, bloods have been checked and are within safe parameters and the patient has had no previous reactions to the prescribed drugs.
- IV access is available and patent.
- The correct chemotherapy is available in the clinical area in accordance with the patient’s named protocol and prescription.
- All supportive medications are prescribed on a current in-patient prescription chart and are available.

10.7 Procedure for verification of prescribed chemotherapy prior to administration by the chemotherapy giver and checker.

1. On initial admission/attendance to the ward/outpatients for chemotherapy, a registered nurse must confirm the patients’ name and date of birth with the patient, and attach a name band on them.

2. Ensure that the patient has been assessed as ‘fit for chemotherapy’.

3. Confirm the patient details (name, hospital number, date of birth) correspond with the prescription chart.

4. Confirm the patient has consented to treatment protocol.
5. Two competent practitioners to check the chemotherapy prescription and chemotherapy drugs to include:

- patient name and hospital number
- any previous allergic reactions to the prescribed drugs
- drug dose, route and rate
- check expiry date has not passed

A full check must then be undertaken at the patient’s bedside/chair to confirm the patient’s details with the patient themselves, their name band, prescription and cytotoxic drug, including that correct rate is set.

IF ANY ERROR OR PROBLEM WITH IDENTIFICATION IS IDENTIFIED DO NOT PROCEED – CHECK WITH MEDICAL STAFF AND REPORT AS PER TRUST INCIDENT REPORTING PROCESSES.

10.8 Route of Administration for Chemotherapy

1. Cytotoxic drugs can be administered by a variety of routes.

2. The correct administration route and schedule is vital to the safety and efficacy of the drug and also in toxicity management.

10.8.1. Intravenous (IV)

Cytotoxic drug administration via a peripheral or central vein is the most commonly used route. IV administration allows rapid and reliable delivery of the cytotoxic drug to the tumour site and rapid drug dilution thus reducing local irritation and tissue damage.

1. Selection of the most appropriate intravenous access for the patient should be made by the treating consultant prior to prescribing chemotherapy.

2. A Central Venous Catheter (CVC) should normally be used if cytotoxic drugs are:

- to be administered over an extended period of time
- highly irritant/vesicant drugs
- to be given to a patient who has limited peripheral access sites or is needle phobic.

Please refer to PHNT Injectable Drug Administration policy V.5 2011

10.8.2. Administration of Peripheral Vesicant Cytotoxic Drugs

1. Vesicant cytotoxic drugs should only be administered in hospital during normal working hours (Mon – Fri 09:00 – 17:30); exceptions require the notification and agreement of the Consultant on-call for the designated area.
2. Only medical staff trained and assessed as competent in the administration of peripheral vesicant chemotherapy can cannulate and then administer peripheral vesicant chemotherapy.

3. Vesicant cytotoxic drugs must only be administered using a newly established and patent cannula.

4. Any patient receiving an infusion of vesicant chemotherapy via peripheral access must have continuous monitoring to check for any signs or symptoms of extravasation.

5. In the event of a suspected or actual extravasation injury, refer to the Extravasation Guideline.

10.8.3. Administration of Non-Vesicant Cytotoxic Drugs

1. Non-vesicant cytotoxic drugs can be administered using an established peripheral cannula providing the IV access has been assessed as patent.

2. Bolus or short infusions of non-vesicant cytotoxic drugs can be administered via peripheral access either by a registered nurse or doctor trained and assessed as competent in the administration of cytotoxic drugs.

10.8.4. Principles for the safe administration of Chemotherapy Infusions

1. Connect the chemotherapy bag to the giving set using a closed system connection device. This should be done using a horizontal technique over a white tray with an absorbent towel in place.

2. Always prime lines prior to administration of chemotherapy with 0.9% sodium chloride flush. Flush in between chemotherapy infusions and at the completion of chemotherapy administration lines must be flushed with either 0.9% sodium chloride or 5% glucose depending on the prescription.

10.8.5. Oral administration of cytotoxic drugs

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

2. Clinical staff administering oral anticancer medicines on non oncology/haematology wards to in-patients should contact members of the patient’s specialist team for information and advice about the oral anticancer medicine.

3. Two practitioners are required to check and administer oral anticancer medicines.

4. Patients, parents or carers who are required to administer oral chemotherapy must be trained in safe practice. This includes storage, administration and waste disposal measures.

5. Appropriate personal protective equipment must be worn. As a minimum requirement gloves must be worn when checking and administering oral chemotherapy. An apron and goggles may also be worn where appropriate.
6. Before oral anticancer medicines are administered in a healthcare organization premises the patient must be clinically reviewed by an appropriately qualified and competent clinical staff member who:

- 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/local guidelines
- Document the administration of the medicine in the patient’s medical notes

Please note that tablets and capsules must **NOT** be crushed or broken

7. Tablets should not be cut. If the dose prescribed for the patient is not able to be given using whole tablets then a review of the prescription should be made in consultation with the pharmacist. Consider whether the drug is available in liquid form. If not it may be possible to adjust the prescription to give different doses in a split schedule.

8. Any spillage should be dealt with as per spillage procedure.

9. Any equipment used during the checking, preparation and administration of oral chemotherapy must be disposed of in a cytotoxic waste container.

**10.8.6. Procedure for dispersing oral chemotherapy safely**

If tablets need to be taken and patient cannot swallow the dose, the following procedure is recommended as safe practice to disperse chemotherapy tablets such as methotrexate.

The appropriateness of dispersing oral chemotherapy should be checked with a Cancer Services Pharmacist.

1. Only nurses’ administering and checking the dose are present.
2. Wear appropriate protective clothing
3. Working over a large tray:
   - Count correct number of tablets into a disposable tablet cup
   - Remove plunger from a 10ml oral syringe
   - Place tablets inside the syringe
   - Reinsert syringe plunger
   - Draw up a small amount of sterile water into the syringe.
   - Attach a cap onto syringe end
   - Allow time for dispersing to occur
4. Following the appropriate patient checks with a second nurse, administer the dissolved solution to the patient in the agreed manner (via mouth or NG tubing).

**10.8.7. Intramuscular (IM) and subcutaneous (SC) injection**

1. Only staff who are trained and assessed as competent in the administration of chemotherapy should administer IM or SC chemotherapy.
2. Appropriate personal protective equipment must be worn (gloves, goggles, apron).
3. Ensure age appropriate preparation and support provided to patient and family.
4. Administer using standard IM or SC practice.

5. Dispose of all equipment into a cytotoxic waste container.

**10.8 Guidelines for chemotherapy administration outside of designated oncology/haematology wards**

Chemotherapy should only be administered to adult oncology and haematology patients on Brent Ward, Bracken Ward, Lyd and Birch Day Case Unit.

In exceptional circumstances chemotherapy may be administered in areas not designated for chemotherapy administration (e.g. Intensive Care Unit, Emergency Department). In these cases the Matron must ensure that the Ward Manager is informed to ensure the availability of appropriately trained staff. This must be approved by Lead Clinician and documented in the patient’s notes.

**10.9 24 hour telephone contact for patients**

1. All patients receiving cancer therapy are given 24 hour telephone contact numbers which they are advised to phone should they become unwell, or suffer severe or unexpected side effects.

2. It is the responsibility of the nurse administering chemotherapy, or the doctor prescribing oral chemotherapy in out-patients to make sure that the patient has the pre-printed yellow Alert cards documenting phone numbers.

3. For calls during working hours patients are instructed to use the phone numbers for Lyd or Birch Day Case.

4. For calls outside working hours, patients are instructed to phone Brent or Bracken Ward as appropriate.

5. At all hours patients are able to speak to a registered nurse who is skilled and knowledgeable in the management of patients receiving chemotherapy who has appropriate support e.g. Specialist registrar and Consultant on call. Alternatively the Medical staff may speak to a patient directly as appropriate.

6. A record is kept of all telephone advice given to patients using the UKON telephone triage system. This records patient details, contact numbers, reason for call, symptom assessment, staff member details and advice or action taken.

7. The original copy of the advice sheet is placed in the patient’s notes and the copy kept in file for review and audit by the ward manager and the chemotherapy operations group.
10.11 Recording of chemotherapy treatment

1. The electronic Aria prescription (or in rare cases hand written chemotherapy prescription) together with the patient medical record forms the basis of the record of chemotherapy administration. A full record of chemotherapy prescriptions can be viewed electronically.

2. Oral chemotherapy green prescriptions are filed in pharmacy (Lloyds Pharmacy or Hospital Pharmacy as applicable) as a permanent record of what has been prescribed and dispensed.

3. At the end of a treatment course the patient’s notes should be annotated with a summary of treatment received, side effects and response. This shall be communicated by letter to the patient GP.

4. It is envisaged that this will be further supplemented by the generation of an end of treatment summary by the updated Aria system.
Intrathecal Chemotherapy

The prescribing, ordering and administration of intrathecal chemotherapy are strictly controlled and only undertaken by approved trained staff.

Intrathecal chemotherapy is to be administered within normal working hours (9-5) and in a specially designated room on Birch Day Case and Children’s and Young People’s Outpatient Department (CYPOD). In emergency situations intrathecal chemotherapy can be administered out of hours and in x-ray, theatres, ITU and ED at the discretion of the Intrathecal Lead, Consultant Haematologist or Consultant Haematologist paediatrician. Please refer to the current intrathecal policy for information on the prescribing, supply and administration of intrathecal chemotherapy.

The Intrathecal Lead is Dr David Lewis and the Intrathecal Nurse Lead for adults is Kelly Allmatt. All trained members of staff are listed on the intrathecal register. Copies of the trust intrathecal chemotherapy policy can be found on Birch Day Case, Bracken ward, Brent ward, Chemotherapy day unit, Wildgoose ward, Plym Theatres, CYPOD, Pharmacy, and Dr David Lewis’s office.
Disposal of cytotoxic waste

The recommendations in this section act as a guide, and are supplementary to those detailed in PHNT Waste Disposal policies.

Equipment
1. While wearing gloves and plastic apron place any needles, syringes, giving sets, empty ampoules/vials or infusion bags into an appropriate rigid sharps disposal box with purple lids.
2. Giving sets should not be removed from infusion bags prior to disposal.
3. The sharps disposal box with purple lid should be clearly labelled as cytotoxic waste so it can be incinerated at 1000ºC to ensure degradation of the cytotoxic agent.
4. Sharps disposal boxes containing cytotoxic waste must be regularly collected.
5. After a cytotoxic spillage, arrangements must be made for immediate collection and the incineration of the rigid sharps bin containing all material used for cleaning the contaminated area.
6. Re-usable plastic trays should be wiped down with detergent wipes.
7. Protective clothing, wipes, aprons and gloves worn during the administration of chemotherapy should be placed in an orange clinical waste bag.

Unused Oral Doses
1. Any unused oral doses (e.g. tablets that have been dropped or oral liquids that have been refused etc) should be disposed of in a cytotoxic sharps box.
2. Patients should be encouraged to return any unused medicines to the hospital pharmacy for destruction. This is essential for investigational medicinal products (IMP’s) where an audit trail of medication is required.

Patient Waste/Body Fluids
1. Personal protective clothing (i.e. plastic apron and gloves) must be worn when dealing with blood, vomit or excreta from all patients.
2. Patient waste/body fluids e.g. urine, faeces, vomit may contain high concentrations of cytotoxic drugs or active metabolites both during administration and up to seven days after treatment has ceased. Particular care should be taken with patients receiving high dose chemotherapy.
3. It has been shown that these unchanged cytotoxic drugs or active metabolites can be irritant to the skin, eyes and mucous membranes. Although evidence of long-term toxicity is inconclusive and conflicting, all staff and family members handling patient waste should take reasonable precautions to limit exposure and ensure absorption does not occur.
4. Carers should be advised to wear gloves and a plastic apron when managing body waste from a patient treated with chemotherapy in the last 7 days.
5. All body fluids (urine, faeces, vomit) should be disposed of as soon as possible.
6. Any spillage of body fluids should be managed according to the
Chemotherapy Spillage Guidelines.

7. Disposable items, (e.g. bedpans, urinals, vomit bowls, incontinence pads and
nappies) are recommended over re-useable ones.

8. Staff and carers should utilise different toilet facilities from patients. Male
patients should be encouraged to urinate whilst sitting on the toilet, to
minimise splashing. The toilet lid should be replaced before flushing to
minimise aerosol and patients should be encouraged to double-flush the toilet.
This procedure should be followed for at least 48 hours after any cytotoxic
chemotherapy administration.

9. Other users of the patient’s toilet at home should be reassured that there is
minimal risk under normal circumstances. No other precautions should be
needed.

10. Soiled bedding and linen should be treated and handled as infected linen,
double bagged and sent to the hospital laundry according to the procedures
described in the PHNT Infection Control Policy.

Personal Accidents Involving Cytotoxic Drugs & Contaminated Patient Waste

1. If a patient, member of staff or visitor is involved in a spillage of cytotoxic
drugs or potentially contaminated patient waste the following procedures must
be followed.

2. All such events/accidents should be reported to a senior member of staff and
fully documented on a PHNT Clinical Incident Form.

Skin

1. Remove any contaminated clothing immediately.

2. The contaminant must be removed as rapidly as possible by flushing the affected
area with a large volume of cold water. If running water is not immediately
available, bottles or bags of sterile water or normal saline should be kept as an
alternative.

3. After initial copious 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.

4. Shower facilities should be used if large areas of skin are contaminated.

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

6. Medical attention must be sought from the nearest Emergency Department and
treated accordingly following details listed in COSHH monographs.

7. A PHNT Clinical Incident Report form must be completed, and the Head of
Department & Occupational Health informed.

8. Generally, systemic absorption from such an injury will be negligible, although
local irritation may occur.
Eyes
1. The contaminant must be removed as rapidly as possible by flushing the eyes and surrounding areas with a large volume of sterile normal saline. Alternatively cold tap water can be used if necessary.
2. Medical attention must be sought immediately from the nearest Emergency Department or Royal Eye Infirmary on Level 3.
3. A PHNT Clinical Incident Report form must be completed and the Head of Department & Occupational Health informed.

Clothing
1. Disposable gloves and appropriate PPE should be worn when handling any cytotoxic spillage. Any contaminated clothing must be removed immediately.
2. Uniforms or hospital linen should be double bagged in an appropriate, leak-proof polythene laundry bag and sent to the hospital laundry according to the procedures described in the PHNT Control of Infection Policy Manual.
3. Patient clothing if excessively wet with chemotherapy should be disposed of. Other items of clothing only mildly contaminated with chemotherapy should be placed in an alginate bag and a green plastic hospital carrier bag for the patient to take home. The patient should be informed to wash this item of clothing separately at 60C in the alginate bag.
4. If the spillage is excessive, dispose of the garments in a cytotoxic sharps bin.

Inoculation injuries
Follow PHNT Needle Stick Injury procedure.

Cytotoxic Spillage Procedure (includes drug and body fluids spills)
1. Ensure safe prompt action, clear and isolate spillage area.
2. Prevent other personnel entering the area.
3. Collect spill kit.
4. Place warning sign near spill area.
5. Put on apron, gloves, mask, goggles and overshoes and get another member of staff to assist.
6. Absorb spillage using toweling and dispose of in the bags provided in spillage kit. If dry powder spillage, use toweling dampened with water.
7. Wash contaminated area with copious amounts of water and use toweling to absorb the water. Dispose of in bags provided in spillage kit.
8. Clean area thoroughly.
9. Place all waste and protective clothing in the spillage kit bags.
10. Place bags in PHNT orange cytotoxic labeled waste bags and contact the hospital porter to collect bags for destruction.
11. Wash hands thoroughly.
13. Replace all used equipment. Spill kits can be provided by Technical Services. If spillage is on skin or clothing, remove clothing immediately and wash area with soap and water.

**Spill Kit Contents**

- Full protective suit with hood
- Mask, goggles, overshoes and 2 pairs of gloves
- Disposable towels, Instructions, warning sign
- Plastic waste bags
- Wooden tongs, dustpan and scraper
- Bottle of water for cleaning
Guidance for the management of anaphylaxis is taken from the national guidance issued by the resuscitation council. For further guidance refer to the monograph for adrenaline in PHNT Procedures for Administering Injectable Drugs and/or the Peninsula Hypersensitivity and Anaphylaxis Guidance. Copies are available in all clinical areas.

See PHNT Resuscitation Policy on Staff Net, Trust Documents, Resuscitation Policy.
Clinical trials in Oncology and Haematology

The Haematology and Oncology Service Line is very active and motivated to set up clinical trials and to recruit appropriate patients. Research teams across both specialities are well developed including clinicians, specialist research nurses and administration staff.

Patients who are taking part in clinical trials should be treated according to the trial protocol; this includes disease monitoring and toxicity assessment. If dose reductions or treatment delays are required then these should be according to the trial protocol.

Clinical trial protocols are available in the designated research offices; for haematology in the Birch Research Office Level 8 and for oncology in the Research Office Level 3.

The pharmacy department keeps copies of protocols for all approved clinical trials in the pharmacy research office Level 5. All clinical trial pharmacy medicines (IMP and non IMP) must be stored and issued from pharmacy and must not be stored in clinical areas – exceptions to this must be with the approval of the Director of Pharmacy following a full risk assessment of the reasons and storage are

For any chemotherapy related questions the relevant Specialist Research Nurses or Specialist Pharmacists (oncology/ haematology/ clinical trials) should be contacted initially.
Supportive care and side effect protocols and guidelines

The CCS has access to protocols and guidelines covering the administration of chemotherapy, the management of side effects, prevention of side effects etc.

Those pertaining solely to chemotherapy are contained within this operation policy, or its attachments – the others are held in other clinical areas, and are referenced below.

**Cytotoxic administration techniques:** See also PHNT Standard Operating Procedures for the Safe Handling and Administration of Injectable Cytotoxic Drugs. See also general procedures for administering drugs by IV bolus, intermittent IV infusion or continuous IV infusion in the PHNT Procedures for Administering Injectable Drugs.

**Care of venous access devices including central lines:** Guidelines for the management of central venous devices, policy for the management of peripheral intravenous devices,

**Mechanical drug delivery devices:** the Management and use of medical devices,

**Haematopoietic growth factors and patient support using blood and blood products:** Oncology and blood services guidelines and protocol folder (on wards), GCSF guidelines, Administration of Blood and blood products guideline – Trust net – under clinical guidelines. (This guideline is under review pending new NICE guidelines on the management of neutropenic sepsis)

**Recognition and treatment of Cytotoxic Extravasation** – see also PHNT Standard Operating Procedures for the Management of Phlebitis, Infiltration, Air Embolism, Speedshock and Extravasation

**Recognition and treatment of Allergic reactions including Anaphylaxis** – see also the monograph for adrenaline in PHNT Procedures for Administering Injectable Drugs

**Neutropenic sepsis:** see also PHNT Oncology and Blood Services Acute Oncology & Cancer of Unknown Primary Service Treatment Protocols Page 10. Refer to NICE guidance CG151. PHNT Clinical Guidelines - Antibiotic policy for Empirical treatment of Neutropenic fever. GCSF use in the Management of Chemotherapy Induced Neutropenia (This document is awaiting updated guidance on financing from NHS England)

**Anaemia:** Use of Erythropoietin Stimulating Agents (ESAs) in Anaemia in Patients with Cancer who receive chemotherapy (This guideline is awaiting publication on Trust Documents)

This local guidance is in response to the November 2014 NICE guidance (TA323): Erythropoiesis-stimulating agents (epoetins and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142)

**Prevention and treatment of cytotoxic induced emesis:** See PHNT Management of Chemotherapy related nausea and vomiting.

**Prevention and treatment of stomatitis and Mucositis:** See PHNT Management of Chemotherapy related Stomatitis and Mucositis.
Management of diarrhoea: See PHNT Management of chemotherapy related Diarrhoea.

Additionally please refer to individual protocols for regimen specific complications and their management.
16  Error reporting

The Clinical chemotherapy service is committed to reducing error and to continual service improvement.

Any adverse event occurring in either in or out-patient setting involving chemotherapy must be reported through the trust’s Datix System.

The Lead clinician for chemotherapy, the Lead chemotherapy nurse and the lead pharmacist must be informed as soon as is possible of any severe adverse events resulting in harm or death.

Otherwise any events are captured by the lead pharmacist and brought to the monthly COG for discussion and development of an action plan as necessary.

The Investigation and closure of each Datix report is the responsibility of the lead manager for the area in which the event took place.

An annual report of all incidents is produced and reported to the Network chemotherapy group and the Directorate management group.

The minutes of the COG are discussed at the Trust Medicines Operations and Governance Group (MGOC) which in turn feeds into the Trust Governance Board. All serious incidents are discussed at the MGO.

17  Overall Responsibility for the Document

The Chemotherapy Operations Group and the Medical Governance Committee are responsible for the review and approval of this document. The Medical Director has ratified this document.

18  Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of two years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Chemotherapy Operations Group/Medicines Governance Committee and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the approving group or committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.
19 | Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust’s formal documents library and all staff will be notified through the Trust’s normal notification process, currently the ‘Vital Signs’ electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the named Executive Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

20 | Monitoring Compliance and Effectiveness

Datix incidents will be inspected by Peer Review at the Chemotherapy Operations Group Monthly and onwards to the Medical Governance Committee if appropriate. Systemic Anti-cancer Treatment (SACT) dataset is collected using the eprescribing system.

21 | References and Associated Documentation

ISO9001 British Standards Institute

NMC Standards of conduct, performance and ethics for nurses and midwives

NMC Standards for medicines management

RCN Standards for Infusion Therapy. Royal College of Nursing, London.

The Cancer Reform Strategy DOH

The Manual for Cancer Services published, Department of Health, London

The Royal Marsden Hospital Manual of Clinical Nursing Procedures Wiley - Blackwell Publishing Ltd.
Appendix 1

Service Level Agreement (SLA) for the Service between Pharmacy and Haematology and Oncology Service Line

In order that chemotherapy is delivered to all patients in a timely, efficient and cost effective way the following working practices have been discussed and agreed by all stakeholders. It is the responsibility of the managers of these areas to ensure that these agreements are adhered to wherever possible.

Monitoring of SLA

The SLA will be monitored on a monthly basis via the Chemotherapy Operational Group (COG).

- % of prescriptions received in pharmacy, from each clinical area, within the defined time period.
  Standard = 90%

- % of chemotherapy available in each clinical area, at the desired time.
  Standard = 90%

Data will be collated by technical services on receipt of prescriptions. The wards/departments within Oncology/Haematology will record any late treatments due to chemotherapy not being available. Discussions regarding service improvement are part of the monthly COG meetings.

Planned scheduled chemotherapy

Most chemotherapy treatments are planned in advance and patients receive further treatments in a regular interval depending on their chemotherapy protocol.

For those patients, treatment should be prescribed 72h prior to the next appointment to allow the Cancer Services Pharmacist and the chemotherapy coordinator sufficient time for clinical verification of prescriptions.

In cases when the clinician is not able/considers it to be not appropriate to prescribe chemotherapy prescriptions in advance (e.g. patient has not been reviewed in clinic yet), a copy of the generated prescription may be used to place an order with the outsource company (currently Hospira); however the prescription must verified by a pharmacist prior to the release of the chemotherapy item from technical services. On agreement with the responsible Consultant the Cancer Services Pharmacist may pre-prescribe treatments to ensure a timely order of the chemotherapy. It is the responsibility of the clinician to review prescriptions and authorise them prior to the release of the chemotherapy from pharmacy.
Table 1 illustrates when treatments have to be prescribed by to guarantee delivery of the item within the clinical area by 9am on the day of treatment.

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<thead>
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<th>Treatment due:</th>
<th>Prescribed by 2pm:</th>
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Table 1: Prescribing deadlines

Table 2 illustrates the process schedule for technical services regarding chemotherapy agents which are outsourced.

(The following drugs are being outsourced: paclitaxel, carboplatin, cisplatin, irinotecan, oxaliplatin, etolposide, daunorubicin, mitoxantrone, docetaxel, 5-fluorouracil, gemcitabine, vinorelbine, dacarbazine, vinblastine, bleomycin, cytarabine, cyclophosphamide.)

<table>
<thead>
<tr>
<th>TREATMENT DUE</th>
<th>PRESCRIPTION TO BE PRESCRIBED &amp; SCREENED</th>
<th>PRESCRIPTION TO ARRIVE IN PHARMACY (BY 9.30)</th>
<th>PLACE ORDER BY (12.00)</th>
<th>IF ORDER ON HOLD TO BE CONFIRMED BY (12.00)</th>
<th>DAY TREATMENT ARRIVES (BEFORE 8.30)</th>
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<td>MONDAY</td>
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Table 2: working schedule for chemotherapy which is outsourced
For high cost drugs a ‘wait for confirmation’ service aims to reduce waste in case patients are not well on the day of treatment or require further review by a clinician. It is the responsibility either of the Cancer Services Pharmacist, chemotherapy nurse or chemotherapy co-ordinator to highlight relevant prescriptions appropriately with ‘wait for confirmation’. Technical services are aiming to deliver the chemotherapy within 90 minutes of confirmation of those patients; however this will depend on the workload within the unit. Technical services will inform the clinical area if a delay in treatment is likely.

Patients requiring short shelf life treatments will not be booked in before 12 noon on Mondays at any treatment area. If patients are booked into earlier times the scheduled appointment time cannot be guaranteed. (Short shelf life drugs include rituximab, trastuzumab, cetuximab, bevacizumab, bortezomib, actinomycin D, intrathecal chemotherapy, asparaginase, bendamustine, melphalan, carmustine, liposomal doxorubicin, azacitidine, pemetrexed, amsacrine, arsenic trioxide, dacarbazine, trabectedin.)

**Clinical Trials**

Prescriptions for patients who are treated within clinical trials should preferably also be prescribed 72 hours prior to the scheduled treatment. Prescriptions have to be indicated clearly that the patient is taking part in a clinical trial; including the clinical trial name and patient clinical trial number.

**Prescriptions for patients who are treated within Outreach Service**

Treatments have to be prescribed at least 72 hours in advance of the appointment day.

All outreach prescriptions will be identified with an outreach label.

Treatments will be delivered to Chemotherapy Outpatients either the day before treatment or at 09.00 on the day of treatment.

A refrigerator will be provided at each outreach site for storage of medication awaiting patient treatment. Medication will be delivered to each site in an appropriately labelled cool box.

**Emergency treatments**

There may be situations when urgent chemotherapy is required. This most likely applies to newly diagnosed patients who have an aggressive, fast progressing cancer. Every effort has to be made to ensure patients receive their treatment in a timely manner; if necessary within 2 hours from arrival of the prescription in technical services. It is the responsibility of the Cancer Services Pharmacist to confirm the urgency of the treatment with a Consultant Oncologist or Haematologist. Technical Services is auditing the amount of emergency treatment requests; presenting results at the monthly COG Meetings.
Urgent requests (e.g. dose or treatment modifications to planned treatments)

Prescribing treatment in advance may require additional dose modifications after the clinical review of the patient or their blood results. In these circumstances the prescribing clinician should alert the Cancer Services Pharmacist at the earliest possible about a new prescription. The prescription should be endorsed with ‘dose change. Technical services are aiming to deliver the product within 90 minutes from arrival of the prescription in technical services; however this will depend on the workload within the unit. Technical services will inform the clinical area if a delay in treatment is likely. Technical Services is auditing the amount of urgent treatment requests due to dose modifications; results are to be presented at the monthly COG Meetings.

Out of hours treatment

Out of hours is defined as overnight (19.00 to 08.00) and weekend (Saturday, Sunday and Bank Holidays – 09.00 to 17.30)

In the rare case that chemotherapy has to continue throughout the weekend and it is not possible to make the chemotherapy in advance then the Cancer Services Pharmacist has to liaise with the clinical area, the on-call pharmacist and the on-call technician about the practicalities of production and delivery at the weekend. This must be agreed at the latest by Friday afternoon.

Emergency treatment at weekends is only to be made at the request of a consultant. The consultant will liaise directly with the on-call pharmacist. This will include any requests for intrathecal chemotherapy.

If overnight treatments are required due to leaking bags, precipitation, expired or missing products then the final decision lies with the consultant on-call. The on-call pharmacist has to contact by the on-call consultant to confirm that the chemotherapy is required overnight and that a delay until the next morning is not in the best interest of the patient. The consultant on-call should use their long standing expertise and experience to make the final decision. If possible the production of outstanding chemotherapy items should be resolved as a priority the following morning.

Workload Agreement between Technical Services and all clinical areas

There is an ever increasing demand for chemotherapy due to the earlier diagnosis of patients with cancer, patients receiving multiple lines of chemotherapy and the increase in the incidence of certain cancers

There may be times when technical services is working above its usual capacity; contributing factors may be low staffing levels due to sickness or annual leave or high workload in one or more clinical areas

It may be challenging to plan ahead for those scenarios of extreme capacity pressures; equally it is unrealistic to define a maximum daily number of chemotherapy items which can be made in technical services. Outsourcing chemotherapy is one method to free up capacity within technical services.

When acute capacity pressures occur, the technical services manager or deputy should be informed at the earliest possible via a senior member of staff in technical services. It is the responsibility of the technical services manager or deputy to liaise
urgently with the clinical areas regarding the number of patients to be treated during this day or time period. It is the responsibility of senior staff within the clinical area (in agreement with Consultants and SpRs) to decide which patients can be deferred to a later day.

The deferral of patients due to capacity pressures should be recorded and discussed at the next COG Meeting.
Appendix 2
Agreement for limiting chemotherapy workload within the clinical areas

In accordance with the National Manual for Cancer Standard for chemotherapy the following guideline is agreed by the Directorate for Oncology and Blood Services and is to be used alongside the capacity planning too.

**Lyd/ Birch Day Case Unit**

To assist with calculation of safe limits for the number of patients treated per day the following is a breakdown of average time it takes to treat a patient. This includes the completion of documentation and full holistic support for the patient in accordance with the measures. The times shown are approximate and based on a patient who is coping well with treatment. However, many patients have complications that need addressing before or during treatment. These complications increase the treatment time. The time needed for administering different regimens or drugs also varies.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Task Description</th>
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<tr>
<td>15 mins</td>
<td>Prep time</td>
</tr>
<tr>
<td></td>
<td>Review prescription; assess necessary blood results; prepare anti-emetics and additional fluids as prescribed. For dose-banded chemotherapy assemble and record chemotherapy syringes as per agreed dose banding protocol file.</td>
</tr>
<tr>
<td>10 mins</td>
<td>Assess the patient</td>
</tr>
<tr>
<td>30 mins</td>
<td>Administration</td>
</tr>
<tr>
<td></td>
<td>Cannulation; administration of anti-emetics, premedication (if indicated) and cytotoxic drugs; Perform necessary observations</td>
</tr>
<tr>
<td></td>
<td>(The time for the treatment administration depends largely on the complexity of the chemotherapy protocol and the number of administered chemotherapy agents and may take up 8 hours including hydration fluids).</td>
</tr>
<tr>
<td>15 mins</td>
<td>Supportive care</td>
</tr>
<tr>
<td></td>
<td>MDT referrals; medical advice; collection of TTAs or administration of TTA pre-packs</td>
</tr>
<tr>
<td></td>
<td>TTA advice to patients. Complete Aria documentation; signing for administration.</td>
</tr>
<tr>
<td>15 mins</td>
<td>Ongoing care / Supplementary care</td>
</tr>
<tr>
<td></td>
<td>Monitoring of infusions; observation of infusion site; vital signs and fluid balance. Blood tests as required. Follow-up arrangements; disconnection of infusions; patient discharge</td>
</tr>
<tr>
<td>Total</td>
<td>85 mins per patient</td>
</tr>
</tbody>
</table>
Therefore each nurse can safely treat up to a maximum of 5-6 patients per day if not responsible for any other duties. Adhering to this limit will minimise risk and maximise patient care. It will also ensure a safe and practicable workload for the pharmacy chemotherapy service.

Please note 45 min is added to treatment time for all patients receiving their first cycles if new patient talks are given at the time of chemotherapy administration. This is to account for the time taken to discuss the chemotherapy, confirm consent and answer any questions the patients may have.

Furthermore, it should be noted that throughout the nurses’ working day, they will be taking several calls from patients and relatives needing advice (average 3-4 per day). This requires them to complete documentation and follow the case in accordance with standard (see section below on telephone advice).

**Brent Ward**

Chemotherapy patients are admitted and their treatment commenced by one of the chemotherapy trained Registered Nurses. Due to the nature of the chemotherapy treatments given on an inpatient basis they are often more time-consuming and the patients can be more complex. Furthermore, the nurse will still be managing chemotherapy for patients who commenced their treatment on previous days. Therefore it is agreed that the following limit is appropriate:

Monday to Friday - 3 new patients per day up to a total of 5 patients with 2 having ongoing treatment.

**Birch Day Case Unit**

The number of patients that can be treated on the unit each day will vary according to type of treatment, patient performance status and number of staff on duty. Therefore, the Nurse in Charge will monitor bookings and will prevent any further bookings when they deem the workload for the day to have reached its safe limit. Chemotherapy is to be treated as above on Chemotherapy Day Case.

**Bracken Ward**

Bracken Ward is treating in addition to elective patients often several newly diagnosed patients with emergency chemotherapy. The Nurse in Charge should monitor the amount of inpatients on chemotherapy on a daily basis and discuss staff requirements with the Bracken Ward Sister or Matron as necessary.

If there are any concerns regarding workload that cannot be resolved with the Ward/Department Sister, then these should be referred to the Matron and or the Chemotherapy lead clinician/ Head of service and oncology pharmacy for advice.
Appendix 3

Standard Operating Procedure for the prescribing of anticancer therapies (safety, governance and financial implications)

Purpose

To provide guidance on the safe prescribing of anticancer therapy within Plymouth Hospitals NHS Trust including processes for additional funding requests.

It is aimed to meet the governance requirements of Plymouth Hospitals NHS Trust and the Commissioning Primary Care Trusts.

Scope

This procedure covers all anticancer medicines i.e. cytotoxic agents, monoclonal antibodies, small drug molecules/TKIs and anti-hormonal therapies when given for the treatment of cancer.

Further unlicensed anticancer drugs prescribed according to a compassionate use programme are covered.

Cytotoxic drugs prescribed for non-malignant disease are outside the remit of this policy.

There is ongoing development by the South West Chemotherapy Network Group of the network agreed protocols and treatment algorithms. Approved chemotherapy regimens according to cancer site are found on Aria in the Regimen Library and the protocols are based on the network agreed protocols wherever possible.

Cytotoxic Drugs that have undergone a NICE Technology Appraisal

The prescribing of anticancer therapy that is NICE approved, proceeds according to the guidance, and is audited periodically.

Prior to introduction of new NICE guidance there must be an assessment of the governance arrangements in place to ensure that the clinical service and pharmacy technical services have sufficient capacity and appropriate safety arrangements in place to ensure the drug is handled safely.

Applying for CDF or IFR funding

CDF / IFR applications must be completed by the prescribing clinician themselves and “peer reviewed” before submitting to NHSE.

The pharmacy department has a centralised record of all applications and support the process of all applications. Please contact Kerry Edmundson or Gemma Tamblyn.
Chemotherapy Agents/ regimens used off protocol (available on Drug Formulary)

The prescribing of chemotherapy regimens has to follow approved protocols which are available in the Chemotherapy Protocol Book/downloaded onto the Aria electronic prescribing system.

Prescribing of regimens which are not included in the protocols according to cancer site, need to be discussed with CD or deputies.

- One off regimen changes for individual patients e.g. for toxicity purposes can be discussed with the Trust Lead for Chemotherapy, or their nominated deputy and approval by chairman’s action will be given. A list of such approvals is kept and discussed at the Monthly Chemotherapy Operation Group, and in turn reported annually to the Cancer Network Chemotherapy Group.

- High cost regimens (>£1000 in total excluding supportive care medications) prescribed for indications not included in the protocol book will require IFR, or CDF requests. The regimen must not be prescribed / administered prior to financial approval being granted by the appropriate commissioner.

- Chemotherapy regimens prescribed ‘off indication’ particularly in the palliative setting with a total cost of less than £1000 (excluding supportive care meds) can be expected to be sanctioned in advance of a ETP/IFR/CDF but this must still be applied for. In these circumstances the “Service Line” has to accept the financial risk.

- To incorporate a new regimen within the recognised protocol list, or extend the use of a recognised regimen to a new tumour site an application must be made to the Chemotherapy Operations Group by filling out the appropriate form (Request for Addition of new Cytotoxic Regimen to PHNT list of recognised Protocols)

A ‘cost neutral ‘ change in protocol can be approved by the COG, as a sub committee of the MUAC, however an application with significant cost implication either in drug costs or in increased support cost may need to be forwarded to the PCT/Commissioner for final approval.

NB to add a completely new agent to the PHNT formulary will still require a formal Drug and Therapeutics Committee submission – see below.
Emergency treatment requiring off-protocol prescribing

It is expected that funding via an Individual Funding Request (IFR), or an application to the Cancer Drugs Fund (CDF) will occur in advance of the prescribing of high cost drugs or drugs outside NICE guidance, however it is recognised that there are circumstances where patient's care and wellbeing are not best served by the inevitable delay.

In these cases the proposed treatment must be discussed with the Care Group Director for Oncology and Blood Services.

If the total cost of the whole regimen (conventional number of cycles) is less than £1000 then it is expected that the CD will sanction the prescription in advance of the ETP/IFR/CDF, with the directorate going ‘at risk’ for this prescription. The ETP/IFR/CDF must still be completed.

Regimens which cost in excess of £1000 will require prior funding approval except in very exceptional circumstances.

In the absence of the Care group Director – either the Trust Chemotherapy Lead (Chair of the Chemotherapy Operations Group) or the Lead Oncologist for Chemotherapy will deputise.

Addition of New anticancer therapies to the PHNT formulary

The addition of a new anticancer therapy to the PHNT formulary requires formal submission to the DTC, using DTC submission paper work – available form Jeremy Morris (Formulary Pharmacist).

However it is recognised that the COG has the multidisciplinary expertise required to assess new anticancer agents and therefore all new anticancer drugs will be discussed at the COG and then passed through to the DTC for formal ratification. It is the responsibility of members of the COG to review clinical evidence, safety, monitoring requirements, scope of administering the drug and financial implications and potential sources of funding.
New anticancer therapies will have either:

A) Gone through a NICE appraisal process, in which case a shortened version of The DTC application form is completed or

B) Will have not gone through NICE – in which case a full submission process including further discussion at the monthly CCG / SCG commissioning meeting (as will be a pass through drug excluded from tariff) will be required.

Drugs prescribed under a compassionate use scheme

Rarely anticancer therapies may be acquired for individual named patients on a compassionate use basis.

These medications are generally unlicensed and require specific patient consent. (Please refer to PHNT Use of Unlicensed Medication Policy) As part of the consent process the patient must be made aware of the fact that the drug may cease to be available at any time. Should the company withdraw the free drug and there are no continued funding arrangements in place from NHSE (i.e. NICE approval / NHSE policy) then the drug will have to be withdrawn.

An “unlicensed drug application form” must be submitted to and approved by the chair of the Drug and Therapeutics Committee and the Chair of the COG/Lead clinician for chemotherapy BEFORE use. The indication, preparation, administration, supportive care needs, major side effects and toxicities must be reviewed in advance.

The prescriber is responsible for ensuring that all information regarding 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.

The specialist oncology / haematology pharmacists will notify NHSE of any drug used as part of a compassionate use scheme.

A drug acquired on a Named patient basis cannot be used for any other patient.

The prescriber is responsible for reporting any suspected adverse effects to the manufacturer on the day the adverse effect is identified and also to the MHRA (yellow card).
Chemotherapy drugs prescribed in the Trial setting

Pharmaceutical industry sponsored clinical trials

Chemotherapy regimens for clinical trials sponsored by the pharmaceutical industry are covered by additional controls within the Trusts Research & Development control and policy.

NCRI / clinical trials not sponsored by the pharmaceutical industry

Chemotherapy regimens containing NICE drugs in e.g. NCRI trials where the NHS is meeting some or all of the cost of the drugs must also have a Treatment Initiation Form completed at the start of treatment.

New anticancer regimens or drugs

<table>
<thead>
<tr>
<th>NICE</th>
<th>COG</th>
<th>DTC</th>
<th>Funding</th>
<th>LICENSING</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ONE OFF</strong> alterations of a regimen for toxicity, or use of an existing regimen for different indication</td>
<td>Chairman’s action by e-mail from chair, deputy, (or CD)</td>
<td>N/A</td>
<td>Usually from directorate, may need CDF if &gt; £1000</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>New regimen consisting of existing drug/drugs currently on formulary for &gt; 1 patient, requesting place in approved protocol list</strong></td>
<td>Fill in 'Request for new protocol' form</td>
<td>N/A</td>
<td>Will need commissioning approval, CDF, IFR, ETP</td>
<td>N/A</td>
</tr>
<tr>
<td>(chairman’s action for first patient if urgent)</td>
<td>To discuss at COG, Clinician to attend if possible</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### New drug, Non-Formulary

<table>
<thead>
<tr>
<th>New NICE approved drug/protocol, not on formulary/protocol book</th>
<th>Shortened DTC form discussed at COG</th>
<th>Shortened DTC form send to appropriate consultant - to fill in; then return to pharmacy</th>
<th>N/A (NICE approved)</th>
<th>N/A</th>
</tr>
</thead>
</table>

### Not NICE approved, not looked at by NICE

<p>|</p>
<table>
<thead>
<tr>
<th>One Off or Compassionate Use</th>
</tr>
</thead>
</table>

Chairman’s action by e-mail from chair, deputy, (or CD)

SEND E-MAIL

<p>|</p>
<table>
<thead>
<tr>
<th>CDF</th>
</tr>
</thead>
</table>

Compassionate use programme

IFR

ETP

If not licensed please fill in Trust ‘request form for use of an unlicensed medicine’ – (see trust unlicensed medicines policy)

### Not NICE approved/ not looked at by NICE

<table>
<thead>
<tr>
<th>&gt;1 Patient – Requesting Place on Formulary</th>
</tr>
</thead>
</table>

Please complete full DTC form (available from Jeremy Morris)

To discuss at COG, Clinician to attend if possible

Ratified by DTC after COG – attendance not necessary

Will need commissioning decision

In meantime IFR/CDF

If not licensed please fill in Trust ‘request form for use of an unlicensed medicine’ – (see trust unlicensed medicines policy)
Appendix 4

Guidelines for Assessment and Management of Patients with Chemotherapy Induced Hand-Foot Syndrome

Introduction

Hand-foot syndrome (HFS) or Palmar-Plantar Erythrodysesthesia (PPE) is a side effect of some chemotherapy drugs.

The exact cause is not proven.

One theory is that the amount of the drug in the capillaries of the hands and feet is increased due to the blood supply to the area increasing, as a result of heat and/or friction. With an increase in blood supply, small amounts of the drug can ‘leak’ out of the smallest blood vessels in the palms of the hands and soles of the feet. Once the drugs are out of the blood vessel, the surrounding tissues become damaged.

Another theory is that the keratinocytes in the skin may have upgraded levels of Thymidine Phosphorylase (the enzyme linked to Capecitabine activation) which may cause accumulation of metabolites within the specialised skin cells.

Although HFS is commonly seen at grades one or two in patients receiving Capecitabine and intravenous 5FU, more severe reactions at grade three and four are more likely to occur with Liposomal Doxorubicin (Caelyx).

Chemotherapy drugs known to cause hand-foot syndrome include:

- 5-Fluorouracil
- Capecitabine
- Continuous infusion Doxorubicin
- Liposomal Doxorubicin
- Cytarabine

The patient can experience anything from mild discomfort to the inability to carry out normal activities. All patients receiving chemotherapy should be informed about the risks of developing hand-foot syndrome and encouraged to contact the Chemotherapy nursing team for advice, using the numbers provided in the chemotherapy information booklet and alert card. This information should be provided at their ‘New Patient Talk’.

Assessment of patients

Chemotherapy induced hand and foot syndrome are assessed using the NCIC CTC toxicity grading system and criteria established by Roche protocol for patients receiving Capecitabine
<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand and foot syndrome (clinical domain)</td>
<td>None</td>
<td>Numbness, tingling, painless erythema and swelling</td>
<td>Painful erythema and swelling.</td>
<td>Moist desquamation, ulceration, blistering and severe pain</td>
<td>Bedridden or hospitalised</td>
</tr>
<tr>
<td>Hand and foot syndrome (functional domain)</td>
<td>None</td>
<td>Discomfort that does not disrupt normal activities</td>
<td>Discomfort that affects activities of daily living</td>
<td>Severe discomfort, unable to work or perform activities of daily living</td>
<td>Bedridden or hospitalised</td>
</tr>
</tbody>
</table>

If there is a discrepancy of grading between the clinical and functional domains, assess and document as the higher grade.

Observe for Symptoms of Hand-Foot Syndrome

- Tingling or burning or numbness
- Redness
- Flaking skin or dry and cracked skin
- Swelling
- Small blisters
- Small sores on the palms of the hands or soles of the feet
- Evidence of infection.

Prevention

Prevention is very important in trying to reduce the development of hand-foot syndrome. Encourage patients

- To reduce exposure of hands and feet to friction and heat.
- To avoid hot water (Washing dishes, long showers or hot baths).
- To avoid dishwashing gloves (exposure to rubber will hold the heat)
- To avoid jogging, aerobics, power walking, jumping and long days of walking.
- To avoid using tools that requires squeezing hands against a hard surface (eg, garden tools, household tools, kitchen knives).
- To take short showers in tepid water which will reduce exposure of the soles of the feet to the drug
- To keep hands and feet moisturised to prevent cracking.

Treatment and Actions

Toxicity Grade 1-2

- Keep hands and feet moisturized with Emollients such as E-45 cream.
- Cooling procedures for 15 minutes at a time may provide relief for pain and tenderness. Placing palms of hands and soles of feet in cool water may help. Extremes of temperature, such as ice should be avoided.
- Avoid restrictive clothing.
- Elevate hands and feet.
- For patients receiving Capecitabine with toxicity grade 2, discontinue treatment until resolved to grade 0-1, restart at recommended dose reduction (see guidelines)
- Consider Vitamin B6 (Pyridoxine) 50mg TDS.
- Consider topical steroid, eg. Hydrocortisone 1%
- Systemic anti-inflammatory, eg steroid / ibuprofen

Toxicity Grade 3-4

- Follow comfort and treatment measures as Grade 1-2.
- Take FBC to assess for neutropenia.
- Delay treatment for one week
- For patients receiving Capecitabine with toxicity grade 3 and 4, discontinue treatment until resolved to grade 0-1, restart at recommended dose reduction or consider no further Capecitabine treatment (see guidelines)
- Consider Vitamin B6 (Pyridoxine) 50mg TDS.

References;


## Appendix 5

### Safe prescribing of oral anticancer medicines

<table>
<thead>
<tr>
<th>1.</th>
<th>General Prescribing Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.</td>
<td>The prescribing of oral anticancer medicines should be carried out and monitored to the same standards as IV chemotherapy.</td>
</tr>
<tr>
<td>1.2.</td>
<td>This document is applicable for adult patients who receive oral anticancer medicines for conditions which require treatment either in oncology or haematology. It is noticed that other clinical areas may use oral cytotoxic therapies; similar safety standards should be apply however this is outside the scope of this document.</td>
</tr>
<tr>
<td>1.3.</td>
<td>The Lead for Chemotherapy is responsible for the implementation of safe practice for oral anticancer medicines within the Oncology and Blood Service Directorate.</td>
</tr>
<tr>
<td>1.4.</td>
<td>With the exemption of Hydroxycarbamide all other oral anticancer medicines which include cytotoxic chemotherapy, targeted therapies, Thalidomide and Lenalidomide are to be prescribed by authorised prescribers at the Oncology and Blood Service Department. The first cycle of a course of oral chemotherapy should ideally be prescribed by a Consultant Oncologist/Haematologist. If this is not possible the specialist registrar may initiate treatment based on the agreed treatment plan via the MDT.</td>
</tr>
<tr>
<td>1.5.</td>
<td>All oral chemotherapy should only be prescribed within the context of a written protocol and treatment plan.</td>
</tr>
<tr>
<td>1.6.</td>
<td>The Consultant Oncologist/Haematologist is responsible for specifying the oral chemotherapy prescription for an individual patient and has to document that the treatment plan has been explained and accepted by the patient and a consent form signed.</td>
</tr>
<tr>
<td>1.7.</td>
<td>The only authorised prescribers for oral anticancer medicines are Consultants and SpRs/ ST3s and appropriately trained Associate Specialist/Trust Grade Doctors in oncology or haematology. Junior doctors (F1, F2, ST1 or equivalent) must not prescribe any anticancer medicines. Preferably the 1st cycle of treatment should be prescribed at Consultant level. New Specialist Registrars working in oncology or haematology have to be assessed for their competency prior prescribing and their names have to be entered on the list of authorised prescribers after successful assessment.</td>
</tr>
<tr>
<td>1.8.</td>
<td>Hydroxycarbamide may be prescribed by the general practitioner. However this requires treatment initiation by the Haematology Consultant and continuous monitoring via the haematology department. GPs have to agree to the shared care guideline prior to taking over the prescribing. (See Shared care Guideline for Hydroxycarbamide). The monitoring remains for all patients within secondary care.</td>
</tr>
<tr>
<td>1.9.</td>
<td>Patients admitted to hospital wards on oral anticancer medicines are at risk from uncontrolled prescribing. The patient’s current medical condition must be assessed to ensure suitability for continued treatment with the medicine and a</td>
</tr>
</tbody>
</table>
detailed medication history must be taken to ensure all information on the dosage of the oral anticancer medicine is known. If it is possible a copy of the original prescription for the oral anticancer medicine should be obtained and the patient's original prescriber contacted to prescribe the medicine on the inpatient drug chart. The Cancer Services Pharmacist should be informed to review the patient’s drug history and validate the drug chart at the earliest possible time. This is of particular importance in patients who are on oral anticancer medicines but are not initially under the care of the oncology or haematology team and are admitted to general medical or surgical wards. Junior doctors and any doctors from other medical or surgical teams are not authorised to prescribe oral anticancer medicines for patients who have received these medicines as part of their treatment by the Oncology and Blood Service. Oral chemotherapy for inpatients must only be prescribed by either a Specialised Registrar working within oncology/haematology or by a Consultant Oncologist/ Haematologist.

1.10. For patients who start oral chemotherapy on the ward, the same information about their treatment has to be available as for patients attending outpatient clinics. It is the responsibility of the prescriber to provide the required information or delegate this task to the specialist nurse or Cancer Services Pharmacist.

1.11. Patients discharged from hospital with oral chemotherapy need to be made aware about their next clinic appointment. Junior doctors should mention the oral chemotherapy on the discharge letter as part of the medical management. However the oral chemotherapy should be supplied prior to discharge from a valid chemotherapy prescription prescribed by an authorised prescriber and not from the discharge letter.

1.12. All prescribers initiating treatment for oral anticancer medicines must:-

- Assess the patient’s suitability for oral treatment including ability to swallow tablets or capsules.
- Assess the patient’s ability to comply with the proposed drug/ regimen.
- Obtain written consent from the patient as per Trust policy.
- Provide verbal and written information about their oral anticancer therapy (this information has to include contact details for specialist advice).
- Ensure appropriate communication to patient’s GP and referring consultant about their medicines, ensure the GP is clear on the role they play in managing the patient.
- Ensure patients are appropriately counselled on the use of their medicines, this information may be provided/ reinforced by the pharmacist or nurse.
- Record the planned course of treatment and arrangements for review/ follow up in the patient’s notes and set a review date.

1.13. In-patient prescribing must be done to the same standards as prescribing for day case and out-patients.

1.14. All authorised prescribers who write prescriptions for oral anticancer medicines for patients who will have the medicines administered in organisations external to Derriford Hospital; e.g. nursing homes, prisons and community hospitals
must ensure that the external organisation has access to the written protocols and treatment plans.

1.15. The patient and the patient’s GP should be provided with written information about the regimen and likely toxicities using the patient information leaflets of the medication and the Cancer Backup printouts on their condition and its treatment. The patients should be given the cytotoxic chemotherapy alert cards.

1.16. Staff dispensing oral chemotherapy should be able to confirm that the prescribed dose is appropriate for the patient, and that the patient is aware of the required monitoring arrangements. They should have access to the written protocol and a pharmacist with experience in cancer treatment.

1.17. The counselling of patients should be a multi-disciplinary process with an increased input of pharmacy staff.

2. Prescribing in the context of a written protocol or treatment plan

2.1. Authorised prescribers must have access to agreed drug protocols for the regimens in use. The British National Formulary (BNF) is not recommended as a primary source of anticancer drug prescribing information as it currently does not contain detailed regimen information.

2.2. Pharmacy departments dispensing and nursing staff administering oral anticancer medicines must have access to the agreed regimen protocols.

2.3. Electronic regimen protocols are available for all oral anticancer medicines on Aria. The protocols must be consistent with the Cancer Network agreed regimens where applicable.

2.4. Written protocols must contain:

- Definition of the clinical condition being treated
- Names of all medicines to be given
- Dosing schedule for each medicine
- Maximum individual dose where applicable
- Maximum cumulative doses where applicable
- Supportive therapy
- Tests needed before chemotherapy starts
- Monitoring required during treatment
- Special precautions, expected toxicities and contraindications
- Potential interactions and medications to be avoided
- Recommendations for dose modifications
- Review periods
- Reference sources

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

2.6. Oral anticancer medicines must not be prescribed by repeat prescriptions.
2.7. Patients should be fully informed and receive verbal and up-to-date written information about their oral anticancer therapy from the initiating hospital. The information should include contact details for specialist advice, which can be shared with non-specialist practitioners. Written information, including details of the intended oral anticancer regimen, treatment plan and arrangements for monitoring, taken from the original protocol should be given to the patient.

3. **Good Practice Standards for Prescription Forms**

4.1. All prescriptions for oral anticancer medicines should be computer-generated using regimens from the agreed list of approved protocols. Aria should be used to generate prescriptions for oral anticancer medicines.

4.2. Prescriptions must contain the following details:

- Patient details including height, weight and body surface area.
- Protocol or regimen name.
- Drug names (generic), and doses (according to protocol as mg/m² or per kg and the final calculated dose).
- Frequency of administration.
- Number of days or doses to be dispensed.
- The intended start date.
- Avoid using abbreviations.
Appendix 6

Intrahepatic chemotherapy policy and procedure

Standard Operating Procedure for TACE (Trans-arterial chemoembolisation)

Decision at MDT

Discuss with patient and information sheet provided

Consultant to vet IR procedure and prescribe on Aria
Admin staff to schedule patient on Aria and advise pharmacist of correct day of treatment

Day of Procedure

1. Preassessment bloods
   a. Childs A/B
   b. Neutrophil count >1
   c. Platelets >50

2. Clinical assessment
   a. Absence of significant ascites
   b. Absence of encephalopathy
Consent form signed, NBM from midnight (am procedures), cannula sited

Radiology
   a. Chemotherapy agents* requested on drug chart by consultant radiologist 24hrs prior to procedure.
   b. Drugs prepared in pharmacy and pre-mixed with lipiodol within 1 hour of procedure (normally 10ml volume)
   c. Standard hepatic venography with superselective cannulation of branch hepatic arteries
   d. 10mls of lipiodol chemotherapy mix delivered to feeding vessel
   e. Extravasation protocols in department

Aftercare
   a. Overnight stay
   b. Regular post procedure obs, bed rest 4 hrs
   c. Blood tests on D5, D10 approx
   d. See attached info sheets
Appendix 7 | Scalp Cooling

**Guidelines for Achieving Best Results with the Paxman Scalp Cooler**

When not in use, the scalp cooler should be left switched on, but with the pump switched off. The couplings should be unattached to the machine. The machine should only be switched off when it will not be used on a daily basis e.g. weekends.

Check scalp cooler regularly to ensure that the coolant level is correct and that all couplings and lines are in good working order.

**When using the scalp cooler:**

- Ensure that the patient’s hair has not thinned to a point where scalp cooling would be inappropriate. (If hair is too thin, there is a risk of causing permanent damage to the scalp.)

- Determine cap size to be used. Cap should have close contact with the scalp in all places, without being uncomfortably tight. Record colour used in the patient’s nursing documentation.

- Cannulate the patient prior to commencing cooling, as venous access will deteriorate once cooling commences.

- Dampen the patient’s hair and comb through a small amount of conditioner. This improves contact between the scalp and cap.

- Attach cap to cooler, attach spare couplings to side of cooler not in use. Switch pump on.

- Assist patient to put the cap on, ensuring that the cap covers the hairline but not the forehead. Adjust the chinstrap and velcro fastening until comfortable.

- Allow 30 minutes for the scalp to cool prior to infusing alopecia-inducing drugs.

- Refer to manufacturer’s recommended scalp cooling times for specific drugs. These recommendations are contained in the Paxman scalp cooling reference manual available in Chemotherapy Day case Unit and Brent Ward.

- The cap can be disconnected from the cooler for up to 5 minutes during the cooling time if required, but the cap must not be removed from the head.

- When cooling is complete, the pump should be switched off and the cap left in situ for a few minutes to prevent pulling hair that has frozen to the inside of the cap.

- Patients should be advised not to wash their hair for 24 hours following cooling, leaving the conditioner in their hair. The manufacturers believe this will improve the efficacy of scalp cooling. Wash the cap in warm soapy water after every use.
Procedure for the safe management of chemotherapy in an outreach clinic

1) Patient referral

The nurse in charge of outreach will take the patient referral from a number of sources. Often these referrals come from other chemotherapy nurses or the treating consultant and are based on patient preference, their treatment and their geographical location. Their chemotherapy regime has to be suitable to fit in the time frame of an outreach clinic and further details of these regimes are found below.

2) Outreach patient criteria and chemotherapy regimes

**Patient inclusion criteria:**
- Reasonable performance status (WHO grade 0, 1 or 2).
- Must have given written consent to outreach chemotherapy.
- To receive chemotherapy suitable for day-case administration (see appendix three)

**Exclusion criteria**
- Concurrent uncontrolled medical illness likely to cause complications in an outreach setting.
- To receive chemotherapy cycles likely to precipitate hypersensitive reactions.
- Poor peripheral venous access unless patient has functioning central venous access device.

Chemotherapy regimes

Numerous chemotherapy regimens and treatments are suitable for administration in an outreach location. Regimens particularly suitable for outreach will include:

- bolus injections via fast infusions
- shorter infusions
- ambulatory chemotherapy
- sub-cutaneous injections
- Central line care

However, when a chemotherapy cycle is likely to have a high risk of hypersensitive or anaphylactic reaction then it must be conducted within the oncology / haematology wards at Derriford Hospital. Examples of such high-risk cycles are:

- first and second exposure to taxanes
- carboplatin (re treatment),
- caelyx
- first cycles of biotherapies.
Additionally, outreach treatment with vesicant drugs should be agreed on an individual patient basis by the named clinic nurse in consultation with the appropriate medical team. Where peripheral venous access is poor then risk of extravasation is considerably increased. Patients will be warned of this risk. In such patients insertion of a central venous access device should be considered.

3) Clinical trial patients

Currently patients participating in intravenous chemotherapy trials will be precluded unless outreach therapy is specifically detailed in the ethical approval for the relevant trial. All future chemotherapy trials will be screened by the PHNT trust pharmacist to assess potential for outreach chemotherapy; if suitable then ethical approval will be requested from the trial organisers.

4) Allocated Outreach Nurse

The Band 6 nurses from chemotherapy outpatients currently rotate every 6 months to be in charge of the outreach service. This allocated nurse will be responsible for organising a system of work consisting of the following:

- Ensure the patient medical notes are available for the outreach clinic
- Maintain patient outreach clinic packs with chemotherapy prescription, blood form, wrist band and latest blood results recorded
- Liaise with each Consultant that refers patients to the clinic to ensure patients are reviewed regularly.
- Liaise with other members of the MDT to ensure coordination of the service (outpatient chemotherapy pathway: appendix two).
- Retrieve blood results and other necessary tests; inform the relevant medical team if results are outside normal parameters.
- Liaise with pharmacy technical services regarding provision of outreach chemotherapy and other medicines.
- Arrange final appointment times with the individual patients
- Maintain a clinic file to include:
  - Emergency and hospital telephone numbers and local policies
  - Stores at each clinic that need topping up
  - Patient appointments for each clinic
- Maintaining a clear system of work ensures that in the case of a sudden absence of the named nurse another chemotherapy outreach nurse can take over.

5) Staff Training

- All staff to be registered with the NMC and must meet appropriate requirements to maintain their registration.
- The registered general nurse is required to have experience in chemotherapy administration, cannulation and caring for central venous access devices. Exceptionally, where the second nurse attending the outreach clinic is proficient in intravenous administration and is currently undertaking the chemotherapy key skills training he / she may administer chemotherapy under the supervision of chemotherapy-trained nurse.
- The nurse must have received training in the management of anaphylaxis, intermediate life support, and extravasation.
- Continuing professional development will include:
  - Anaphylaxis training every 12 months
  - Intermediate life support training every 12 months
  - Chemotherapy key skills review and assessment every 12 months
- A record of the key skills review and other training will be kept by each nurse in their portfolio of professional practice and also by the Chemotherapy Sister.

6) Sudden absence

In the event of sudden absence from a clinic the Outreach Manager or senior nurse in charge of day case chemotherapy will be contacted. The manager will explore all possible options to cover the absence. Where no appropriately trained nurse is available to cover the absence then the outreach chemotherapy clinic will be cancelled. All affected patients will be immediately informed and alternative arrangements made to administer chemotherapy at Derriford Hospital or one of the alternative outreach locations. Cancellation of an outreach chemotherapy clinic must be recorded on a PHNT incident form. Where chemotherapy is delayed more than 24hrs the relevant Oncologist or registrar must be informed.

7) Patient information

It will be ensured that all patients will receive the same information accessed by patients being treated at Derriford Hospital

New Patients:
- Will have attended a new patient talk on an earlier date at Derriford Hospital
- Be given a green chemotherapy information booklet
- Additional Macmillan information specific to their treatment regime or procedure
- A yellow alert card detailing emergency treatment advice and contact numbers

Following treatment the patient will be given the following:
- Their next appointment time
- Take home medication and the nurse has ensured the patient understands when to take the medicines
- Blood form

8) Consent to treatment

All patients must have a signed consent form for their specific chemotherapy before commencing treatment. This must be checked in the patient notes prior to treatment at outreach and documented on Aria.
9) Patient safety

- The chemotherapy outreach nurse must follow PHNT policies for: administration of medicines, IV therapy manual, and the relevant sections of the Royal Marsden Manual of Nursing Policies (Dougherty and Lister 2004).
- The nurse will also adhere to all other relevant policies e.g., COSHH, Health and Safety, local fire and other emergency policies.
- The nurse must have access to the patient information on Aria and take the patient medical notes to the outreach clinics. In cases where the medical notes are not available then the outreach chemotherapy cannot proceed. The patient will be informed, chemotherapy deferred until the notes are available or a temporary duplicate set of medical notes are constructed. An untoward incident form will be completed and sent for review at the next clinical incident meeting. All notes will be transported in the boot of the car and delivered back to the Cancer Centre, Derriford at the end of the clinic. Patient confidentiality is of vital importance and a key responsibility of all staff. In the event that the notes are not returned the same day, the nurse must take them in to their own house for safekeeping overnight. All staff need to be familiar with the following trust policies:
  - Caldicott Implementation Management Audit & Improvement Plan
  - Corporate information security and control policy
  - Data leaving PHNT: data protection requirements and agreement.

10) Documentation of patient assessment and treatment

- All new patients will have a pre assessment of their physical, mental and social well-being and this will be recorded on ‘New Patient Form’ on Aria.
- A ‘Chemotherapy Symptom Assessment Scale’ will be completed on Aria prior to subsequent treatments and changes recorded as necessary.
- All details concerning treatment given will be clearly documented electronically on ‘Chemotherapy Progress Sheet’.
- Hospital notes/Aria records are used for clinical coding of activity.

11) Pharmacy

The outreach chemotherapy pathway (appendix two) illustrates the process for ordering chemotherapy from Pharmacy Technical Services department. It is agreed that:

- All prescriptions are ideally ready 24 hours in advance i.e. Drs must prescribe in clinic.
- The Oncology Pharmacist will need to complete screening the day before.
- All bloods results checked and chemotherapy confirmed by 2pm.
- Pharmacy will aim to deliver chemo for outreach by 5pm on evening before the outreach clinic.
- Late delivery of chemotherapy after 0930 on the morning of the clinic will need to be taxied out to the clinic. Pharmacy should be made aware of these charges for these taxis so outsourced chemotherapy supply companies will potentially be fined for late delivery.
- TTAs from Lloyds will need considered. These are the GCSF prescriptions and unusual doses of dexamethasone.
12) Transportation of chemotherapy and cytotoxic waste

Currently the transportation of chemotherapy and cytotoxic waste will be necessary for all outreach clinics. The Directorate of Oncology and Blood Services leases a 3 door van specifically for the outreach service. This vehicle will be based at the Oncology Centre. PHNT vehicle insurance will be provided to cover all risks. Risk assessments must be completed to assess the risk of transporting hazardous materials to each outreach site.

Refer to the PHNT Standard Operating Procedures for the Safe Handling and Administration of Injectable Cytotoxic Drugs.

Directorate lease vehicle

- A vehicle log will be used to record all journeys. This log will show date, name of driver, destination, return and mileage.
- This log will be used to reconcile all journeys against recorded mileage.
- The driver of the vehicle will use a directorate fuel card to purchase petrol from an approved retailer.

Cytotoxic drugs

- All cytotoxic drugs to be carried in closed rigid containers: ‘cool boxes’ and transported in the boot of the car.
- Drugs requiring to be kept cool will be transported in a separate cool box to those drugs that are to be kept at room temperature
- Spill kits must be routinely carried in the car separate from the chemotherapy or waste.
- The car must display UN1851 alert sign with toxic diamond 6 symbol warning of the hazardous contents of the vehicle. This alert notice can be removed whilst the hazard is not in transit.

Cytotoxic waste

- Full cytotoxic waste sharps bins must be stored securely in the van when being transported to prevent the cytotoxic bin tipping up.
- Disposal of cytotoxic waste will be back at Plymouth Cancer Centre, Derriford Hospital.

13) Safe driving

- Each team member must ensure that they are safe and professional when driving to an outreach clinic
- A copy of their driving licence will be given to the Chemotherapy Day Case Manager.
- They must inform the manager if their driving licence is revoked by the DVLA
- They must not use mobile phones whilst driving unless they are using a hands free mobile kit.
- Each team member must take all reasonable care of the base vehicle. They must ensure that the vehicle has fuel, windscreen fluids, tyres are inflated and all lights and indicators are functioning. Any problems to be reported to Day Case Manager.
14) Emergencies at a clinic

The named nurse must ensure that the following details and policies are available in the event of an emergency at the clinic.

- Cardiac arrest number and local policy must be in the clinic file
- Fire number and the local policy must in the clinic file
- Spillage – the spillage procedure will be followed, a copy of this policy will be kept in the clinic file.
- Extravasation will be dealt with according to the PHNT policy; a copy of this document must be available in the file. Additionally, the patient will need to immediately attend the Plymouth Cancer Centre to be assessed by the relevant oncology team.
- Anaphylaxis will be dealt with according to the PHNT policy; a copy of this document must be available in the file. Additionally, the nurse may administer adrenaline in accordance with the Directorate of Oncology Patient Group Direction for emergency use of adrenaline. A copy of this PGD must be kept in the clinic file.

In event of anaphylaxis, cardiac arrest or oncological emergency, life support will be given as per above protocols. Additionally, the nurse will immediately dial 999 requesting an ambulance urgently. The patient will then be transported to Derriford Accident and Emergency Department for further acute management. The nurse will inform the relevant oncology medical team of the emergency. The oncology medical team will liaise with the duty Consultant for Derriford Accident and Emergency Department.

15) Medical cover and informing GP

Liskeard, Tavistock and Kingsbridge Community Hospitals are all GP lead units. These GPs regularly visit the wards of these hospitals and at other times as required. Medical cover is not routinely available. Consequently, any questions regarding the non-emergency medical management of oncology patients must be referred to the relevant Oncology team at Derriford.

The consultant will inform the patient’s GP via the normal GP letter that the patient is receiving chemotherapy and at which outreach hospital they are being treated.

16) Audit / Service evaluation

The chemotherapy treatments are recorded electronically so any audits required can be accessed from the Aria system. The outreach manager will complete the outreach audit report on an annual basis or more often as required.

Patient satisfaction with chemotherapy outreach will be assessed using the Chemotherapy Patient Satisfaction Questionnaire on an annual basis in line with the rest of the chemotherapy service provided by Derriford Hospital. (CPSQ) (Sitzia and Wood 1999).
17) Adverse weather conditions

In the event of the clinic being cancelled due to adverse weather, each patient will be telephoned by their named clinic nurse and a new treatment date organised. Where treatment is delayed more than 24hrs then the appropriate oncologist will be informed.

18) Policies

When referring to any PHNT policy then such policies will be the latest version of such policies available via public folders of PHNT intranet email system. Local hospital policies will be available in the site files for each clinic.

References:


Contact Numbers

Clinical Director: Dr Ian Higginson (Consultant in Emergency Medicine)
Directorate Manager: Denise Roddy
Matron: Sharon Raymond
Lead for Chemotherapy: Dr P Medd (Consultant Haematologist)

Haematology

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Bracken Ward</td>
<td>Ext 55080 or 52677</td>
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<tr>
<td>Birch DCU</td>
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<td>Haematology Research</td>
<td>Ext 31043</td>
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Consultant Haematologists

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<tbody>
<tr>
<td>Dr David Lewis</td>
<td>Lymphoma, Transplants and CLL</td>
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<tr>
<td>Dr Hannah Hunter</td>
<td>Transplants, Myeloma, Acute leukaemia, Paediatric malignant Haematology</td>
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<td>Dr Tim Nokes</td>
<td>Haemostasis, Myeloma, Paediatric non-malignant Haematology</td>
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<td>Dr Simon Rule</td>
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<td>Dr Wayne Thomas</td>
<td>Haemostasis, Lymphoma, Blood Transfusions</td>
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<tr>
<td>Dr Patrick Medd</td>
<td>Transplants, Lymphoma, Acute leukaemia</td>
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<td>Dr C Hutchings</td>
<td>Research, CLL and Lymphoma</td>
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Senior Haematology Nurses

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<tr>
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<tbody>
<tr>
<td>Bracken Unit Sister</td>
<td>Sam Rowe</td>
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<tr>
<td>Bracken Unit Junior Sisters</td>
<td>Stuart Green and Anna Gardiner</td>
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<tr>
<td>Birch Day Case - Sister</td>
<td>Kelly Allmett</td>
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<td>Birch Day Case – Junior Sisters</td>
<td>Vanessa Davies and Elizabeth Drysdale</td>
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<td>Birch Research Nurses</td>
<td>Nicky Crosbie &amp; Becky Reddell-Denton, Monica Grant, Ruth Geffens and Kelly Morgan, Rachel Penrose</td>
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<td>Transplant Co-ordinators</td>
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<tr>
<td>Lymphoma Specialist Nurse</td>
<td>Kelly Morgan</td>
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<tr>
<td>Bleeding Disorders</td>
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### Myeloma Specialist Nurse and TYAC Specialist Nurse
Kerry McKay

### Oncology

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### Consultant Oncologists

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<tr>
<td>Dr Pete Sankey</td>
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<tr>
<td>Dr Sidharth Dubey</td>
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</tr>
<tr>
<td>Dr Martin Highley</td>
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<td>Dr Sarah Pascoe</td>
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<td>Dr Amy Roy</td>
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<td>Dr David Sherriff</td>
<td>Hepato-Biliary, Neuro-endocrine, Colorectal</td>
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<td>Dr Geoff Cogill</td>
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<tr>
<td>Dr Uda Panwar</td>
<td>Breast, Sarcoma</td>
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<tr>
<td>Dr Liz Lim</td>
<td>Brain</td>
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<tr>
<td>Dr R Goranova</td>
<td>Breast, Head and Neck</td>
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<td>Dr B Goranov</td>
<td>Lung and Lower GI</td>
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<td>Dr S Hussain</td>
<td>Urology, testicular, bladder &amp; renal</td>
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<tr>
<td>Brent Ward Sister</td>
<td>Heather Christie</td>
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<td>Brent Ward Junior Sisters</td>
<td>Nick Anderson, Isabel Williams, Kathryn Joll, Tess Losbanes, Ria McConnachie</td>
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<tr>
<td>Chemotherapy/Oncology Outpatients Sister</td>
<td>Jane Ransome</td>
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<tr>
<td>Chemotherapy Outreach Team Leaders</td>
<td>Jenny White, Faye Dudfield, Jess Clarke and Tracy Taylor</td>
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<tr>
<td>Matron for Research</td>
<td>Nicola Donlin</td>
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<tr>
<td>Chemotherapy Nurse Specialist/Lead</td>
<td>Sarah Wellington and Kirsty Jenkins</td>
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<td>Fran Hampton</td>
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<td>Education Sister Haematology</td>
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<td>Chemotherapy Co-ordinator</td>
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## Pharmacy

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<tr>
<td>Director of Pharmacy</td>
<td>Simon Mynes</td>
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<tr>
<td>Assistant Director for Pharmacy</td>
<td>Andrew Prowse</td>
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<tr>
<td>Specialist Pharmacists Oncology / Haematology</td>
<td>Birgit Cloos &amp; Phil Dunn</td>
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<tr>
<td>Clinical Trial Pharmacist</td>
<td>Maggie Kalita</td>
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<td>Technical Services and QC Pharmacist</td>
<td>Jonathan Turton</td>
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<td>Clinical Trials Senior Technicians</td>
<td>Mike Marner &amp; Chimene Morgan</td>
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<tr>
<td>Technical Services and Quality Assurance</td>
<td>Amanda Horton</td>
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<td>Dispensary Manager</td>
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## Phone Numbers

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<td>Technical Services</td>
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<tr>
<td>Clinical Trials Pharmacy Office</td>
<td>Ext 53423</td>
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<tr>
<td>Birgit Cloos</td>
<td>Pager 89337</td>
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<td>Phil Dunn</td>
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## Dissemination Plan

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<td><strong>Date Finalised</strong></td>
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- **Appendix 10**


Review Date October 2020
## Review and Approval Checklist

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### Core Information

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<th>Dr Patrick Medd</th>
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<tbody>
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<td>Directorate</td>
<td>Haematology and Oncology Service Line</td>
</tr>
<tr>
<td>Date</td>
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<td>Title</td>
<td>Haematology and Oncology Service Line Clinical Chemotherapy Service Operations Policy</td>
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### What are the aims, objectives & projected outcomes?

Aims – to inform and facilitate the safe delivery of anticancer agents to patients form PHNT.

Outcome – safe delivery of anticancer agents, measured by recorded clinical incidents.

### Scope of the assessment

### Collecting data

#### Race

Consideration will be made for patients whose first language isn’t English through the Chemotherapy process.

Consideration will be made if information provided to patients/carers is required in a different language.

Data collected from Datix incident reporting and complaints will ensure this is monitored.

#### Religion

There is no evidence to suggest that there is an impact on religion or belief and non-belief regarding this policy.

Data collected from Datix incident reporting and complaints will ensure this is monitored.

#### Disability

Consideration will be made if information about chemotherapy is required in different formats for people with disabilities/learning disabilities.

Consideration is made for those patients lacking capacity to give consent.

Data collected from Datix incident reporting and complaints will ensure this is monitored.
| **Sex** | There is no evidence to suggest that there is an impact on sex regarding this policy for patients.  
Consideration is made about the risks for staff working with cytotoxic drugs that are pregnant or returning to work and continuing to breastfeed.  
Data collected from Datix incident reporting and complaints will ensure this is monitored. |
| --- | --- |
| **Gender Identity** | There is no evidence to suggest that there is an impact on gender identity regarding this policy.  
Data collected from Datix incident reporting and complaints will ensure this is monitored. |
| **Sexual Orientation** | There is no evidence to suggest that there is an impact on sexual orientation regarding this policy.  
Data collected from Datix incident reporting and complaints will ensure this is monitored. |
| **Age** | There is no evidence to suggest that there is an impact on age regarding this policy.  
Data collected from Datix incident reporting and complaints will ensure this is monitored. |
| **Socio-Economic** | There is no evidence to suggest that there is an impact on socio-economic regarding this policy. |
| **Human Rights** | Consideration is made for those patients lacking capacity to give consent. |
| **What are the overall trends/patterns in the above data?** | No comparative data has been used to date which means that no trends or patterns have been identified. |
| **Specific issues and data gaps that may need to be addressed through consultation or further research** | No gaps have been identified at this stage but this will be monitored via data collected from Datix incident reporting and complaints. |

**Involving and consulting stakeholders**

**Internal involvement and consultation**
Chemotherapy Operations Group  
Chemotherapy Lead Nurse  
Pharmacy (cancer services)

**External involvement and consultation**
No external consultation has been undertaken.
**Impact Assessment**

**Overall assessment and analysis of the evidence**

- Consideration will be made for patients whose first language isn’t English through the Chemotherapy process.
- Consideration will be made if information provided to patients/carers is required in a different language.
- Consideration will be made if information about chemotherapy is required in different formats for people with disabilities/learning disabilities.
- Consideration is made for those patients lacking capacity to give consent.
- Consideration is made about the risks for staff working with cytotoxic drugs that are pregnant or returning to work and continuing to breastfeed.

**Action Plan**

<table>
<thead>
<tr>
<th>Action</th>
<th>Owner</th>
<th>Risks</th>
<th>Completion Date</th>
<th>Progress update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collect and monitor data collected from Datix on incidents and complaints</td>
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</table>

**Links to other PHNT Policies and Protocols**

- PHNT Procedures for Administering Injectable Drugs
- PHNT Standard Operating Procedures for the Safe Handling and Administration of Injectable Cytotoxic Drugs
- PHNT Standard Operating Procedures for the Management of Phlebitis, Infiltration, Air Embolism, Speedshock and Extravasation
- PHNT Standard Operating Procedures (SOPs) for Preparing and Administering Intravenous Medicines and Fluids