Network Guidance for Ensuring Safety and Quality of Chemotherapy Services
August 2012

incorporating
Network Guidance for
Safe Prescribing, Handling and Administration of Cytotoxic Drugs
June 2006

STOP! – Have you got the most up to date version of this policy?
Always check www.mccn.nhs.uk before reading further

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Note that only substantive changes are listed- changes of para number have not been listed

| Jan 10     | Title       | Changed to emphasise quality and safety                                                                                                  |
| Jan 10     | 1.0         | Complications added, additional reports added                                                                                             |
| Jan 10     | 3.0         | Pre-prescribing, prescribing divided into first and subsequent, addition of treatment plan, consent, change of NMP to allow first cycle prescribing |
| Jan 10     | 3.7         | First cycle prescribing allowed for NMP provided treatment plan in place                                                                |
| Jan 10     | 3.8         |                                                                                                                                 |
| Jan 10     | 3.9         | New standards for prescription verification and verification of electronic prescriptions                                                 |
| Jan 10     | 9.1         | Section on capacity added                                                                                                                |
| Jan 10     | 10          | New section managing complications and triage, patient carer support and advice                                                          |
| Jan 10     | 11          | New section on end of treatment care                                                                                                |
| June 10    | 3.4         | Criteria for consent forms added                                                                                                          |
| June 10    | 3.5         | Safety wording for first cycle prescribing strengthened to include competence                                                           |
| July 12    | 1           | Additional documents                                                                                                                     |
| July 12    | 3.3         | Treatment plan to GP added                                                                                                               |
| July 12    | 3.5         | GP prescribing policy / protocols and algorithms                                                                                           |
| July 12    | 3.8a        | New section on dosing of obese patients                                                                                                   |
| July 12    | 3.8b        | Renamed from 3.8 Cancer type, toxicities and performance status added to treatment records                                                |
| July 12    | 3.9         | Algorithm substituted for protocols                                                                                                       |
| July 12    | 4.0         | Addition of third party providers                                                                                                          |
| July 12    | 9.3         | Or equivalent added to third bullet point                                                                                                |
| July 12    | Appendix 1  | Approval and renewal date updated                                                                                                         |
1 Introduction

The purpose of this document is to set out the Guidelines for the Safe Prescribing, Handling, Administration and management of complications of Cytotoxic Chemotherapy for the Merseyside and Cheshire Network (MCCN) Trusts. National and regional standards that this document adheres to and should be read in conjunction with include:

- Manual for Cancer Service Standards 2004
- National Intrathecal Guidance HSC 2003/010
- MCCN Guide to Care and Maintenance of Venous access devices incorporating the Collaborative Intravenous Nursing Service guidelines for venous access devices for Cheshire and Merseyside NHS Northwest
- MCCN 24 hour telephone advice specification (September 2010)
- Reference Guide to Consent for Examination or Treatment, DH 2001
- National Chemotherapy Advisory Group Report (NCAG), August 2009
- Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines, BOPA January 2010
- PCT Chemotherapy Policies
- MCCN Chemotherapy competency framework (July 2012)

Additionally, local chemotherapy operational policies, protocols and guidelines that support and comply with this document have been developed, these include:

- Network and local Extravasation Policies
- Local cytotoxic spillage / disposal policies
- Network and local Anaphylaxis policies
- Local consent policies

This policy is intended to safeguard patients and staff, by defining best practice for all disciplines involved in cytotoxic chemotherapy. This policy is not intended to be prescriptive but to provide a framework of principles upon which local policies must
be based. However, any deviations from network guidance must be specified and justified in any local policy.

The handling and administration of cytotoxic drugs is potentially hazardous to both the health care professionals involved in their preparation and administration, and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to health care staff are largely theoretical. It is therefore prudent with the present state of knowledge to take every reasonable precaution to protect staff from unnecessary exposure.

This policy aims to minimise these risks by promoting the safe handling of cytotoxic drugs. It should be read in conjunction with other relevant policies. The policy has been written using best available current evidence and practice, and will be reviewed as other guidance and evidence becomes available.

2 Scope of Policy

This document is primarily aimed at staff delivering chemotherapy for patients with malignant disease, in in-patient and out-patient settings. It includes topical and intravesical chemotherapy but does not deal with cytotoxic chemotherapy specifically for immunosuppressive purposes, or for the treatment of non-malignant disease.

For the purposes of this document, the term cytotoxic drug is used to refer to all drugs with direct anti-tumour activity including conventional anti-cancer drugs, monoclonal antibodies, partially targeted treatments (such as imatinib, gefitinib) and drugs such as thalidomide. Purely, hormonal treatments are excluded.

This document does not cover the practice of intrathecal chemotherapy. National guidance and local policy should be referred to.

3 Prescribing Chemotherapy

Each clinical chemotherapy service must have a policy for the prescribing of chemotherapy. The following are the principles upon which a prescribing policy
3.1 Pre-prescribing

Pre-prescribing should be introduced for the large majority of elective chemotherapy treatments. The minimum time that a prescription should be available in the pharmacy before the patient arrives for treatment is a matter for local decision but should be at least 24 hours to be considered pre-prescribing.

3.2 Who can prescribe

All chemotherapy services should keep lists of clinicians who are designated to prescribe chemotherapy. These should be maintained and reassessed at least annually. These should make clear which staff can prescribe a first cycle of chemotherapy and who can prescribe subsequent cycles. It is recommended that GPs do not prescribe any cancer chemotherapy nor should clinicians in hospital request GPs to prescribe cancer chemotherapy.

3.3 Decision to treat and treatment plan

The decision to treat a patient with chemotherapy should be made by a Consultant, and the patient should be discussed at an appropriate Multidisciplinary Team Meeting (MDT).

All patients should have a treatment plan for each course of chemotherapy they undergo. This treatment plan must be authorised and signed by a consultant oncologist or haematologist.

Inpatient delivery of chemotherapy should be kept to a minimum. This can be achieved by maximising the use of oral treatments and central lines and day case units for delivering prolonged infusions.

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.

A copy of the treatment plan should be sent to the patient's GP. At a minimum this should contain:
- Treatment regimen
- Treatment start date
- Planned duration
- Treatment intent – palliative, curative, adjuvant, neo-adjuvant, other

### 3.4 Consent

A standardised consent form is used which includes as minimum best practice:
- Regimen details
- Treatment intent (curative, palliative etc)
- Details of the toxicities discussed – this may be a tick box format where relevant toxicities are ticked from a standard list or each form may list all the toxicities expected for that specific regimen
- Confirmation of delivery of standardised written information. The written information should include details of key worker contact if needed.

The consent form may be used alongside the MCCN chemotherapy protocol. A copy of the consent form should be given to the patient as well as one being filed in the patient’s case record.

Standardised written information is given to patients which is relevant to a particular chemotherapy regimen.

### 3.5 First cycle prescribing

Who can prescribe a first cycle of chemotherapy should be determined and agreed by each local chemotherapy service.
MCCN recognises the contribution that restricting first cycle prescribing to consultant level has played in maintaining patient safety. Chemotherapy services must not change any practise in first cycle prescribing until they are confident that policies and procedures are in place to ensure that every patient has a recognised and accessible treatment plan as described by the NCAG report and that all relevant staff have access to this plan. Until trusts have such policies and procedures in place then the prescribing of first cycle chemotherapy must remain with the consultant.

However, provided a recognised treatment plan is in place which fulfils the NCAG requirements a first cycle of chemotherapy may be prescribed by:

- A solid tumour oncologist at consultant /specialist staff grade / specialist registrar level
- A Haemato-oncologist at consultant /specialist staff grade / specialist registrar level
- A Non Medical prescriber who is competent and accredited as described in section 3.7

Familiarity with chemotherapy regimens and the drugs therein plays a vital role in the safe prescribing of chemotherapy. The above should only prescribe first cycle chemotherapy if they have experience and are competent to prescribe in the therapeutic area that pertaining to the prescription.

Lists of clinicians who are designated to prescribe chemotherapy should be maintained and reassessed at least annually. These should make clear which staff can prescribe a first cycle of chemotherapy and who can prescribe subsequent cycles. General practitioners must not prescribe any systemic anti cancer chemotherapy including oral, or intracavitary when acting under direct contract or SLA with the PCT. The only exceptions to this are oral hydroxycarbamide where the overall care remains under a secondary care haematologist and topical cytotoxic agents used for some skin malignancies or pre malignant conditions. Secondary care clinicians should never request GPs to prescribe cancer chemotherapy.

Handwritten prescriptions for parenteral chemotherapy should be replaced as soon
as possible by pre-printed forms or, preferably, by electronic prescribing systems.

Protocols and algorithms should be agreed across a network and up to date lists of protocols and algorithms should be available in all locations where chemotherapy is prescribed or delivered. Protocols should also be available to all relevant emergency departments.

For children and young people there should be an agreed regimens list and protocols must be available on the Principle Treatment centre.

### 3.6 Prescribing subsequent cycles

Subsequent cycles should ideally be prescribed by an oncologist / haematologist, specialist registrars, staff grades or a non medical prescriber as described below. But if not, then medical staff should ask advice of one of the above for changes of dose or cessation of therapy and document advice given and by whom.

Chemotherapy services need to ensure that standardised processes are established for recording performance status, investigation results and all toxicities following a previous cycle of chemotherapy.

### 3.7 Non Medical Prescribing

Non medical prescribers are nurses, pharmacists or other allied health professionals who have undertaken an accredited prescribing qualification.

Non medical prescribers may prescribe first and subsequent cycles of chemotherapy regimens according to their sphere of competence /local guidelines and the approved treatment plan.

Specialist registrars and non medical prescribers will only be allowed to prescribe chemotherapy within their sphere of competence after accreditation according to local guidelines.

MCCN fully supports maximising the use of non medical prescribers and nurse and
pharmacist led clinics. All chemotherapy services should assess the potential for nurse or pharmacist-led clinics and agree appropriate working protocols.

3.8a Prescribing for Obese Patients (Adults)
In line with recent guidelines from ASCO, chemotherapy doses for obese adult patients should no longer be capped at 2m² unless there are compelling clinical reasons to do so. Weight or surface area alone is not sufficient reason to cap doses. Existing trust dose banding policies should continue. Capping or flat dosing should continue in the following circumstances:

- Flat or fixed dosing for carboplatin or bleomycin as directed by network protocols
- Vincristine should be capped at 2mg when used as part of the CHOP+/−R or CVP+/−R regimens

Dose reductions for obese patients should follow the same pattern as those for non obese patients. Most of the evidence for full dosing in obese patients is in early stage disease. Clinicians should be mindful of adverse event in obese and non obese patients especially in late stage disease. (NCEPOD 2009)

Body surface area for obese patients should be calculated using standard formulas as for non obese patients.

Clinicians should also be mindful that the evidence for this policy is very much based upon data from patients with adjuvant and early stage disease. Clinicians should exercise care and judgement in chemotherapy dosing in late stage disease.

The above should be agreed by local Clinical chemotherapy services and if necessary trust drug and therapeutic committees before implementation.


Dosing for children and young people must be in accordance with the chemotherapy protocol and advice from the Principle Treatment Centre.

3.8b Prescription requirements
All prescriptions for cytotoxic drugs must contain the following information:
- Full name
- Hospital ID number/ unique patient identifier
- Date of birth
- Name of consultant
- Ward/area where drugs are to be given
- Height, weight and surface area where appropriate
- Prescribed regimen and patient diagnosis where appropriate
- Stage and status of the disease where appropriate
- Cycle/course number
- Number of cycles and intended frequency of cycles
- Approved drug name and dose
- Clear intent of the formulation of the drug to be delivered where there is more than one available formulation eg liposomal preparations
- Allergies
- Route of administration
- Volume, diluent and rate of administration
- Date and time dose to be given
- Signature of prescribing doctor and date

In addition treatment records should contain the following

- Cancer type
- Regimen and doses (including all cytotoxic chemotherapy drugs to be used and elective essential support drugs).
- Investigations necessary prior to starting the whole course.
- Investigations to be performed serially during the course (to detect/monitor both toxicity and response) and their intended frequency.
- Frequency and total number of cycles or duration of treatment.
- For palliative, curative and neo adjuvant treatments, i.e. any treatment other than adjuvant; the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course.
- Attendances managed by agreed non-medical staff e.g. nurse led attendances.
• Any dose modifications and whether or not they are intended to be permanent.
• Any cycle (or administration) delays.
• Any introduced support drugs.
• Any toxicities from the previous cycle
• Performance status prior to each cycle

3.9 Chemotherapy ‘Off Protocol / algorithm’ Prescribing

• In exceptional circumstances, it may be necessary to treat a patient with a protocol not included on the current list of accepted Network Chemotherapy Algorithms.
• See appendix 1 for Network off algorithm policy.
• If an ‘Off Algorithm’ treatment is to be used, the Consultant must complete an ‘Off Protocol’ Proforma as outlined in appendix 2.

A record should be kept of all instances where patients are treated off-protocol and regular audits conducted to examine the reasons why such off-protocol treatments were necessary.

Off protocol or non network approved regimens should be reported to the network pharmacist.

• The network chemotherapy group will annually review all off algorithm chemotherapy prescribing.

4 Prescription verification

All chemotherapy prescriptions should be checked by an oncology / haematology pharmacist, who has undergone specialist training, demonstrated their appropriate competence and is locally authorised/accredited for the task. This applies to oral as well as parenteral treatments. A list of designated pharmacists should be kept in each hospital where chemotherapy is prescribed/delivered.

Clinical pharmacy and chemotherapy services should operate to at least the standards described in Standards for Clinical Pharmacy Verification of Prescriptions
Where pharmacists are not directly performing the required check, clinical chemotherapy services should ensure that the check is being performed by an approved person. This includes prescription verification by third party contractors, eg homecare companies.

Prescription verification processes must encompass pre-prescribing, oral chemotherapy and methods of prescription transfer such as faxing.

### 4.1 Checking Standards

- Check prescriber’s details and signature are present and confirm they are authorised to prescribe Systemic Anti Cancer Therapy (SACT)
- Ensure regimen has been through local approval processes e.g. clinical governance and financial approval and/or is included on a list of locally approved regimens
- On the first cycle check the regimen is the intended treatment as documented in a treatment plan, in the clinical notes or in the electronic record
- Check regimen is appropriate for patient’s diagnosis, medical history, performance status and chemotherapy history (using the treatment plan, clinical notes or electronic record)
- Check there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s)
- Check that the timing of administration is appropriate i.e. interval since last treatment
- Check patient demographics (age, height and weight) have been correctly recorded on prescription
- Check body surface area (BSA) is correctly calculated, taking into account recent weight. Note there should be local agreement for frequency of monitoring and checking patients weight.
- Check all dose calculations and dose units are correct and have been
calculated correctly according to the protocol and any other relevant local guidance, e.g. dose rounding / banding

- Check cumulative dose, if appropriate
- Check reason for any dose adjustments, e.g. reduction(s) and ensure reason is documented
- Check method of administration is appropriate
- Check laboratory values, FBC, U&E’s and LFT’s are within accepted limits if appropriate (see 3.2 above)
- Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities
- Check other essential tests have been undertaken if appropriate
- Check supportive care is prescribed and it is appropriate for the patient and regimen
- Sign and date prescription as a record of verification

Trusts using electronic prescribing systems should ensure that these systems are fully validated and that as for paper based prescribing, a clinical pharmacy check is required to authorise the prescription. This needs to be auditable. In addition there should be clear medical, pharmacy, nursing checks of the e-prescribing template for each chemotherapy regimen.

Pharmacists should ensure that regimens prescribed are network approved and if not then the “off protocol / algorithm” process described above should be followed

Network-wide treatment algorithms should be developed with approved and agreed treatment regimens. The up to date protocols and algorithms should be available at all sites of chemotherapy prescribing, dispensing, delivery and where patients may be admitted with acute complications of treatment.

5 Safe handling of cytotoxic drugs

Each clinical chemotherapy service must have a policy detailing the safe handling of cytotoxic drugs. The following are the principles and guidelines upon which the local
Cytotoxic drugs interfere with cell division, but as this action is not specific to tumour cells, normal cells may also be damaged. As a result, they can produce significant side effects in treated patients, or others exposed. This, together with the increasing complexity of chemotherapy, has raised concerns about the risks to health care workers involved in the preparation and administration of chemotherapy and/or the caring of patients undergoing treatment.

For healthcare personnel the potential of exposure exists during tasks such as drug reconstitution and preparation, administration and disposal of waste equipment or patient waste. Hence, all staff involved in the delivery of services to cancer patients must be aware of all health and safety procedures.

The more common routes of exposure are contact with skin or mucous membranes (e.g. spillage and splashing), inhalation (over-pressurising vials), and ingestion (e.g. through eating, drinking or smoking in contaminated areas or from poor hygiene). Less likely routes of exposure include needle-stick injuries, which can occur during the preparation or administration of these drugs.

Some cytotoxic drugs can cause acute or short-term health effects including irritation to the skin, eyes and mucous membranes. Information on chronic, or long-term, health effects of cytotoxic drugs mainly comes from data in animals and from patients given therapeutic doses.

It is not certain how relevant this is to workers and any occupational exposures are likely to be at much lower levels. The adoption of safe handling techniques reduces the potential for exposure to cytotoxic drugs significantly.

5.1 Staff Monitoring

All relevant new employees, as outlined above, should receive an orientation to the Cytotoxic Policy as soon as possible after commencement of employment. The primary focus of safety during the preparation and administration of cytotoxic drugs
must be on control of the working environment, minimising exposure and safe practice.

5.2 Pregnancy and Breastfeeding

As the pre-conception period is not included in any health and safety advice, managers must ensure that a risk assessment is carried out in all areas where cytotoxic drugs are handled. This risk assessment should assume that there might be a new or expectant mother working in the environment in the following twelve months.

Precautions must be in place at all times to minimise exposure this policy, along with Trust policies and procedures aims to reduce the risk of exposure to these drugs as far as possible. However, as there is no known limit where exposure is thought to be safe, employees must be fully informed of the potential reproductive hazards.

Employees should notify their managers as soon as possible if they are pregnant, trying to conceive or are breastfeeding.

This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs. At the point where an employee discloses pregnancy, a risk assessment specific to the individual should be carried out and any appropriate action taken.

Staff must not administer cytotoxics during the first trimester of pregnancy (when the pregnancy is confirmed) and must never reconstitute cytotoxics whilst pregnant. This policy recommends that staff do not administer bolus cytotoxics throughout pregnancy. Individuals wishing to continue to give cytotoxics throughout pregnancy should seek advice from their local occupational health department. Pregnant staff should also be aware of the risks of handling body fluids from patients receiving cytotoxic drugs. Staff have the right to be moved away from chemotherapy areas whilst pregnant.

If appropriate, the line manager and Human Resources Department, together with the member of staff, will agree any new temporary arrangements. The Human
Resources Department will be consulted if no suitable alternative employment is found. New, expectant and breastfeeding mothers should be specifically advised against any direct involvement in the management of a cytotoxic drug spillage.

### 5.3 Minimising Exposure

A full COSHH (Control of Substances Hazardous to Health, 2002) assessment must be undertaken in all areas handling cytotoxic drugs. The following guidance applies for all staff handling cytotoxic drugs during administration of treatment, handling of patient waste and cleaning of spillage.

#### 5.3.1 Personal Protective Equipment/Clothing

The correct use of personal protective equipment can shield staff from exposure to cytotoxic drugs and minimise the health risks.

Pharmacy staff preparing cytotoxic drugs within pharmacy preparation units will wear personal protective clothes as defined by local standard operating procedures.

Local policies should detail any necessary personal protective equipment and clothing for the dispensing, administration and disposal of cytotoxic agents. These should include advice on the use of:

- Gloves
- Eye and Face protection including eyewash kits
- Respiratory protection
- Aprons
- Gowns

Policies should also include advice on cuts or abrasions to hands as well as hand washing before and after glove application.

For advice on cytotoxic spillage including the recommended contents of a spillage kit see section 7.0
In line with the Department of Health and the National Patient Safety Agency, the network supports the move toward a latex free working environment.

**5.3.2 Disposal and Decontamination of Personal Protective Equipment**

All aprons, gowns, gloves and disposable personal protective clothing should be disposed of as cytotoxic waste according to the Hazardous Waste Regulatory Guidelines 2005, (see bibliography). For advice on reusable equipment, refer to local trust infection control policy.

**6 Reconstitution**

Each Clinical chemotherapy service must have a policy detailing the safe reconstitution of cytotoxic drugs. The following are the principles and guidelines upon which the local policy should be based.

Manipulating and reconstituting cytotoxics poses the greatest risk. For this reason, cytotoxics should only be reconstituted in an accredited and regulated/audited pharmacy aseptic unit by appropriately trained and experienced staff. Any staff responsible for reconstituting cytotoxic drugs must have undergone training in line with the 1988 Health and Safety Commission approved Code of Practice entitled “The Control of Substance Hazardous to Health” (COSHH). This training is to include safe handling and disposal of substances hazardous to health. Cytotoxic drugs are only to be reconstituted within agreed times for each local chemotherapy service.

Contact the on call pharmacist for advice in emergency circumstances, such as:

- Any out of hours chemotherapy request
- Expired or unusable chemotherapy

Ideally all chemotherapy should be reconstituted after receipt of a prescription. The local policy should detail procedures for faxed or prescriptions transmitted in other formats. No chemotherapy should be released from pharmacy without authorisation. Likewise local arrangements should be in place to ensure that as far as practicable high cost items are only reconstituted after patient’s blood results are known.
All cytotoxic drugs should be reconstituted in accordance with the summary of product characteristics and produced in a ready to use form.

Where possible all syringes should have luer lock devices unless this is clinically impracticable. Local policies should detail when a luer lock device is not used eg for intrathecal, intrahepatic, or bladder washouts.

‘ONLY TRAINED PHARMACY STAFF MAY RECONSTITUTE CYTOTOXIC DRUGS’

7 Storage and transportation

Each Clinical chemotherapy service must have a policy detailing the safe storage and transport of cytotoxic drugs. The following are the principles and guidelines upon which the local policy should be based.

- Cytotoxic drugs should be stored in a pharmacy department wherever possible within a dedicated area of a refrigerator that is continually monitored for temperature.
- Any cytotoxic drugs stored within a chemotherapy department must be clearly labelled and stored in a dedicated area of a refrigerator. This refrigerator must be continually monitored for correct temperature.
- Cytotoxic drugs that must be kept refrigerated can be stored for a short period of time at room temperature. This is built into the expiry date/time of the drug.
- Cytotoxic products must be sealed within a leak proof plastic bag prior to use. This outer bag should only be removed immediately prior to administration of the drug. Once removed from the bag handling should be kept to a minimum and gloves should be worn.
- The transportation of all cytotoxics must be in a robust and leak proof container marked “cytotoxic drugs”
- Each service must decide locally if a specific policy or part policy is needed to deal with cytotoxic spillage during transport

8 Cytotoxic Spillage and safe disposal of waste

Each clinical chemotherapy service must have a policy or part policy on cytotoxic spillage including spillage kits. Policies must include advice on:

Network Guidance for Ensuring Safety and Quality of Chemotherapy Services Version 4.0 June 2010
Personnel

- Priority given to personnel contamination
- Contamination of personnel or patients including skin and eye decontamination.
- When occupational health referral is needed
- Needlestick (if not covered elsewhere)

Kits

- Location, use and content of spillage kits
  - Kits may be purchased commercially or made up locally. All kits should contain as a minimum
    - Gloves
    - Goggles
    - Scoop/forceps
    - Face mask
    - Gown
    - Overshoes
    - Absorbent towels/roll
    - Eye wash
    - Disinfection agent
    - Instructions on how to use the kit
    - Chemotherapy spill hazard sign
- How to restock a used spillage kit
- Who is responsible for updating the contents

Form of the spillage

- Liquids
- Powders
- Broken Glass
- Method of disinfection
- Number of times disinfection is to be performed
- Excreta
Environment

- Carpets, hard surface, clothing, soft furnishings (may need to consider disposal)
- Isolators
- Public areas
- Warning sign to indicate spill has occurred
- Who to inform that cleaning is required

Disposal of contaminated items

- Follow The hazardous waste (England and Wales) regulations 2005 (see bibliography)

Records

- Incident forms
- What to detail
- When a form is to be filled in e.g. all spillages or just those involving personnel contamination

9 Administration

Each Clinical chemotherapy service must have a policy detailing the safe administration of cytotoxic drugs. The following are the principles and guidelines upon which the local policy should be based.

9.1 Capacity

All cancer networks and the providers of chemotherapy services should undertake rigorous capacity planning.

Inconvenience to patients attending day case units should be minimised by streamlining care. Capacity and demand at different times of day should be carefully examined to make best use of available resources, including the use of extended opening hours. The CPORT chemotherapy planning tool can help in this regard.

9.2 Training

Each trust must have a nominated chemotherapy nurse trainer who will maintain a
register of staff who are competent to administer chemotherapy unsupervised. (Appendix 3)

Only trained nurses are to administer chemotherapy. Nurses in training may administer chemotherapy under the supervision of an authorised member of staff.

Competence should be reviewed and reconfirmed annually.

9.3 General Principles

Local administration policies should include the following general principles. All staff involved in the administration of cytotoxic drugs should:

- Adhere to NMC guidelines on the administration of medicines.
- Be familiar with local and network policies on safe prescribing, handling, and administration of cytotoxic drugs and the Strategic Health Authority policy on vascular access devices.
- Have undergone the Mersey and Cheshire Cancer Network chemotherapy training programme or equivalent
- Be familiar with MCCN treatment protocols and information on the specific hazards associated with the drugs used.
- Know what action to take if haematological or biochemical parameters fall outside accepted limits.
- Be familiar with the procedures for intravenous, oral and other routes of chemotherapy administration.
- Be familiar with peripheral and central venous access devices, including line complications.
- Be familiar with mechanical pumps and other devices used for chemotherapy service delivery.
- Able to recognise signs and complications of myelosuppression.
- Be familiar with common chemotherapy side effects including nausea, vomiting, stomatitis, diarrhoea, phlebitis and alopecia.
- Have knowledge of the extravasation, anaphylaxis and neutropenia policies
and be able to deal with these oncological emergencies by knowing where to find extravasation kits and sources of information.

- Be familiar with the precautions and techniques regarding the safe handling of cytotoxic drugs, storage, disposal and spillage and where the spillage kits are located.
- Ensure that appropriate support drugs are prescribed and available.
- Ensure that all new and existing patients receiving chemotherapy by any route including oral are given the fully completed MCCN chemotherapy alert card and instructed to carry it with them and present it to all health professionals including primary care practitioners when needed.
- Other written and verbal information as detailed under section 8.5 is given to all patients receiving oral chemotherapy this would normally include a printed copy of the chemotherapy protocol or access to an electronic version.

9.4 Patient Identification and prescription checking procedures

It is essential that the patient is fully informed about what is planned and why. The nurse administering the chemotherapy has the responsibility of assessing, expanding and reinforcing the patient’s understanding.

Local policies must include patient identification and checking procedures prior to chemotherapy administration including:

- Informed, written consent for the drugs that they are about to receive. In cases where the patient is under 16 or is unable to give consent due to incapacity, please refer to local consent policies and the department of health publication *Reference Guide to Consent for Examination or Treatment* (2001)
- The positive identification of the patient by asking them to verbally tell you their full name, address and date of birth
- Procedure to ensure that the patient identifiers are checked against the prescription
- Haematological and biochemical parameters are checked when necessary
- Prescription and drug checks including confirmation of:
o Cycle number, regimen and individual drug identification.
o The expiry date of drugs
o The date on the prescription and due date of chemotherapy
o Product batch numbers if used
o The route of administration
o Anti-emetics and other support drugs are prescribed when needed
o The formulation of preparation intended by the prescriber where more than one formulation exists eg liposomal preparations

9.5 General guidelines on administration of cytotoxic drugs

In line with the National Patient Safety Agency Rapid Response Report 004 Using Vinca Alkaloid Minibags (Adult/Adolescent Units) all vinca alkaloids (vincristine, vinblastine, vindesine, vinorelbine) must be supplied and administered in 50ml infusion bags of Sodium Chloride 0.9%.

Additionally:
When vinca alkaloids are prescribed, dispensed or administered in adult and adolescent units:

- Doses in syringes should no longer be used.
- The prescribed dose should be supplied from the hospital pharmacy ready to administer in a 50ml minibag of sodium chloride 0.9% (for some brands of vinorelbine glucose 5% solution for injection may be used instead of sodium chloride 0.9%).
- The following warning should be prominently displayed on the label of ALL vinca alkaloid doses ‘For Intravenous Use Only – Fatal if Administrated by Other Routes’.
- There should be judicious use of colour and design on the label, outer packaging and delivery bags to further differentiate minibags containing vinca alkaloids from other minibag infusions.
- The vinca minibag should be infused intravenously over 5 - 10 minutes and the patient closely monitored for signs of extravasation. Incidents of extravasation should be reported and shared via the National Extravasation Information Service (www.extravasation.org.uk).
• Chemotherapy policies and procedures should be amended to reflect these requirements.
• Staff should be alerted and trained to follow the new practice.
• Practice should be audited to ensure compliance with the revised safety procedure.

Note that the above does not apply to paediatric units where vinka alkaloids may continue to be given via the bolus route.

Other vesicant drugs should continue to be given via the bolus route or by infusion bag through a central venous catheter as local policy dictates.

Local administration policies should also include guidance on:

- The requirement to follow local regimen protocols or work instructions for the regimen prescribed including haematological and biochemical parameters
- Patient information before and after treatment including drug side effects, contact information and emergency 24-hour access arrangements.
- Holistic care including physical, psychological and spiritual assessment
- Protective clothing
- Infection control and aseptic technique
- Administering refrigerated iv drugs at room temperature
- Any additional fluid requirements for administration of bolus vesicants
- Vascular access device selection
- Cannulation and vein selection and equipment needs
- Poor venous access
- Needle phobic patients
- Vein and access device patency
- Priming of lines and giving sets
- Checks during administration
- Flushing between drugs and order of administration if more than one drug
- When to stop administration
- Physical environment
- Post administration treatment advice and documentation
- Records to be made at the end of a course of chemotherapy.
- Details of all routes of administration: intravenous, subcutaneous, oral, intravesical and intramuscular. Any specialist routes eg intra-arterial or intra-hepatic should be included.
- Administration by community nurses including safe disposal of waste
- Advice to primary care practitioners
- Procedures for the safe use of oral anti-cancer agents as described in 9.6.1 below

9.6 Routes of administration other than intravenous

Local policies must include details of the administration of chemotherapy by all routes which may be used in the chemotherapy service. These may include subcutaneous, oral, intravesical, intrathecal and intramuscular. Any specialist routes eg intrahepatic or intra-arterial must also be included.

The standards of intravenous administration must be applied to other routes. In particular patients receiving oral chemotherapy should have access to specialist pharmaceutical and nursing counselling and advice.

9.6.1 Oral Anti Cancer Medicines (Chemotherapy)

In January 2008 the NPSA issued NPSA/2008/RRR001 Risks of incorrect dosing of oral anti-cancer medicines. This report specifies actions that must be undertaken by all trusts and cancer networks in order to comply. These actions must have been in place since 22nd July 2008.

Oral anti-cancer medicines include any medicine which has a direct anit-tumour activity including but not limited to: bexarotene, buslulphan, capecitabine, chlorambucil, cyclophosphamide, estramustine, etoposide, fludarabine, hyddroxycarbamide, idarubicin, lomustine, melphalan, mercaptopurine, methotrexate, mitotane, procarbazine, tegafur/uracil, temozolamide, tioguanine, topotecan, treosulphan and vinorelbine. Targeted therapies such as the kinase inhibitors dasatinib, erlotinib, imatinib, sorafenib, and sunitinib are also included. It does not include hormonal or anti-hormonal therapies.
It primarily applied to the safe use of these medicines in the treatment of cancer. Where these medicines are used for non-cancer treatment local organisations should undertake a risk assessment and apply the guidance as appropriate.

**Doctors, nurses, pharmacists and their staff must be made aware that the prescribing, dispensing and administering or oral anti-cancer medicines must be carried out and monitored to the same standard as injected therapy.**

**Risks are increased if non specialist practitioners prescribe, dispense or administer oral chemotherapy and bypass the normal safeguards used for injected anti-cancer medicines**


### 9.6.2 Local Policies and Procedures

All trusts should prepare local policies and procedures that describe the safe use of oral anti-cancer medicines including:

- Treatment must be initiated by a cancer specialist
- All oral chemotherapy must be prescribed in the context of a written protocol and treatment plan
- Non specialists who prescribe or administer on-going oral anticancer medicines should have ready access to appropriate written protocols and treatment plans including guidance on monitoring and treatment of toxicity
- Staff dispensing oral anti-cancer medicines 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 by having access to the written protocol and treatment plan from the hospital where the treatment was initiated and advice from a pharmacist with experience in cancer treatment in that hospital
- Patients should be fully informed and receive verbal and up-to-date written information about their oral anti-cancer therapy from the initiating hospital including:
  - Contact details for specialist advice
  - Intended oral anti cancer regimen
9.6.3 Network responsibilities

MCCN will make available via the network website all network approved protocols containing oral chemotherapy or an oral chemotherapy component:

- These will be updated on a regular basis

10  Management of Complications

Effective management of complications requires good education, advice and information to patients and carers, clear pathways and protocols for patient care, effective 24 hour triage and telephone advice. It will also require close links between the chemotherapy service, the acute oncology service and the emergency medicine service.

Policies and protocols including a neutropenic sepsis protocol must be agreed between all these services. This applies especially when the services are not operating on the same site.

10.1 Patient Carer Information Support and Advice

The provision of clear consistent written and verbal information and advice is essential for the safe and effective delivery of chemotherapy. All chemotherapy services should ensure that:

- They provide written information to patients about the chemotherapy they will be receiving, the likely side effects and who they should contact if problems arise (including out of hours). Delivery of such information should be documented. Language and literature support should be provided for those for
whom English is not their first language.

- They ensure that copies of this information are sent to the patient's GP
- They provide face to face education either on a one to one basis or to groups of patients if appropriate.

The individual pre-chemotherapy assessment (including holistic assessment) by oncology nurses/pharmacists at the start of a programme of chemotherapy should be separated from the imminent administration of chemotherapy. This should preferably be on different days, but could be at very different times on the same day so as to allow the patient and carers time to assimilate the information and come back with questions before treatment is administered.

They provide each patient with a card containing key information about the treatment and contact details. This card must meet network and national standards for content.

Rehearse with patients what they should do in the event of developing a complication (see step 6). This should include consideration of which hospital they would go to and how they would get there both during and out of working hours.

Consider the use of a pro-active telephone follow-up service where this is appropriate.

Trusts should ensure that chemotherapy patients have easy access to support and rehabilitation services eg social workers, advice on nutrition, wig suppliers and psychological support.

**10.2 Telephone advice and Triage**

All chemotherapy services should ensure that a 24 hour telephone advice service is available. Refer to the MCCN 24 hour telephone advice specification. Those giving the advice should have access at least to basic information about a patients condition and treatment. They should also actively manage the the pathway of care if an acute assessment is required. Processes and algorithms should be put in place to track / follow up any actions that occur following the call.
Telephone advice and triage services should operate at least to the standards described in the UKONS NHS 24 hour helpline brochure.

11 Post Treatment Care

All chemotherapy services should ensure that patients are provided with adequate post treatment care and support. Work on this is ongoing with the national survivorship initiative however all services should:

- Complete a summary record after the completion of chemotherapy and copy this to the patient and GP.

- Draw up a care plan for each patient after the completion of treatment. The format of these care plans is a matter for local decision, but will be informed by work emanating form the National Cancer Survivorship Initiative.

12 Further reading


Safe Handling of Cytotoxic Drugs. HSE Information Sheet MISC615.


A Guide to Risk Assessment Requirements. HSE.

COSHH Regulations 2002. HSE.

Marc guidelines (www.marcguidelines.com).

Department of Health Consent Forms.


Appendix 1

11-1E–103s: CHEMOTHERAPY CNG NETWORK POLICY FOR PREVENTING regular deviation from Local and CNG agreed treatment Algorithms

This policy should be read in conjunction with the MCCN algorithm specification.

The Manual for Cancer Services 2008, defines a chemotherapy algorithm. MCCN chemotherapy CNG has also agreed an algorithm specification detailing the minimum information to be included in an algorithm. There is no requirement for a network approved list of algorithms but the chemotherapy CNG must agree all the network site specific group (CNG’s) agreed algorithms and additionally all local chemotherapy services must have agreed algorithms compatible with the network.
The network is also required to log and discuss deviations from the approved list.

In exceptional circumstances, it may be necessary to treat a patient with a regimen not included in the current treatment algorithm.

This situation may arise, for example:

- in a patient for whom none of the regimens listed in the current network approved algorithm are appropriate due to pre-existing organ toxicity
- the cancer being treated is rare, and there isn't an existing treatment algorithm
- a patient has responded to several previous courses of treatment and for whom further chemotherapy is justified but no specific regimens are included in the existing algorithm
- a new drug has become licensed within year and is not included within any algorithm, but named patient funding has been agreed with the PCT or the cancer drug fund.

In the circumstance where a protocol or algorithm is to be used which is not included within the Network approved list of chemotherapy algorithms, the requesting clinician should seek authorisation from the Clinical Director for the clinical chemotherapy service using a locally agreed non-protocol or algorithm chemotherapy treatment request form.

Approved chemotherapy CNG 14th July 2011
Review July 2014

Appendix 2

Off-Protocol Chemotherapy Treatment Request Form

<table>
<thead>
<tr>
<th>Addressograph / Patient’s details</th>
<th>Date</th>
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<tbody>
<tr>
<td>Name</td>
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<td>Hospital No.</td>
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<td>D.O.B.</td>
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<th>Diagnosis</th>
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<th>Previous Treatment</th>
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<tr>
<th>Non-protocol Treatment Requested</th>
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Network Guidance for Ensuring Safety and Quality of Chemotherapy Services Version 4.0 June 2010
Reason for Request

Provide relevant reference/publication if possible. Continue on back of form if necessary.

Requesting Consultant

Signed by Name (print)

Request Approval (Please circle): YES NO

Reason for non-approval

Approved requests will be reviewed by the Trust Chemotherapy Sub-Committee quarterly.

Signed by __________________________ Date ____________

Name (print) __________________________
Consultant Haematologist or Chemotherapy Head of Service

Appendix 3

Register of Staff Authorised to Administer Chemotherapy

<table>
<thead>
<tr>
<th>Name</th>
<th>Competency Assessed</th>
<th>Competency Review Date</th>
</tr>
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Competency Assessed: Not required for staff that have two or more years experience of chemotherapy training. All staff identified have completed specialist study i.e. Care of the Patient requiring Chemotherapy (formerly N59) or Oncology Nursing Course (formerly ENB 237).

However all staff will be re-assessed and reconfirmed annually, with effect from 04/2006, as per Merseyside & Cheshire Cancer Network Training Programme.