University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

Procedure for the Safe Prescribing, Handling and Administration of Cytotoxic and other Chemotherapeutic Agents

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PURPOSE	This document explains the procedures to be taken by clinical staff within University Hospitals Birmingham NHS Foundation Trust for the safe prescribing, handling and administration of cytotoxic and other chemotherapeutic agents
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UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST

Procedure for the Safe Prescribing, Handling and Administration of Cytotoxic and other Chemotherapeutic Agents

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1.0 Introduction and aim of document

Many Cytotoxic and other Chemotherapeutic Agents have been shown to be mutagenic, teratogenic and carcinogenic. Occupational exposure to Cytotoxic and other Chemotherapeutic Agents presents a significant danger to healthcare staff and unwarranted handling of these drugs should be avoided (Meade 2014)

Evidence suggests that safe handling measures are effective in achieving a reduction in exposure levels. In line with the Control of Substances Hazardous to Health (COSHH) regulations, guidance is needed in the safe-handling practices to minimise staff exposure to cytotoxic agents.

In addition, risks to patients from incorrectly prescribed and administered chemotherapy are well documented. Risks to patients are minimised when chemotherapy is delivered by informed staff, adhering to evidence based practice guidelines (COSHH 2002 6th Ed, HSE 2003, NCAT 2011, 2012 & BOPA 2013.)

The aim of this document is to set out the safe procedure for the prescribing, handling and administration of cytotoxic and other chemotherapeutic agents within University Hospitals Birmingham NHS Foundation Trust (UHB).

It is intended to safeguard patients, staff and visitors, by defining acceptable standards of practice for all disciplines involved in cytotoxic and non-cytotoxic chemotherapy.

To ensure the highest standard of safety for patients, staff and visitors within UHB, the Trust should concentrate activities involving chemotherapeutic drugs and cytotoxic agents to appropriately trained, staffed and equipped areas using standardised procedures.

Where relevant, compliance with the Manual of Cancer Measures (2014), which is subject to Peer Review, has been incorporated into this procedure. Although the measures were not intended to apply in the non-cancer setting, the principles should be considered good practice in any arena where cytotoxic drugs or chemotherapeutic agents are used. In addition health and safety and safe handling concerns apply to cytotoxic drugs regardless of the disease for which they are being used, and therefore these procedures should be considered applicable Trust wide.

For clarification on which drugs and which setting require compliance with policy see section 2 – Definitions, and section 3 Risk Management.

2.0 Definitions

2.1 Cytotoxic

The word ‘cytotoxic’ literally means ‘kills cells’. However, the term ‘cytotoxic’ is generally used to denote an agent that may be genotoxic, oncogenic, mutagenic or teratogenic (HSE 2003) by virtue of its effect on DNA production or function.

The drugs or substances listed in Table 1 (Appendix 1) are to be considered as ‘cytotoxic’ within the terms of this document as they require safe handling measures to protect staff and patients from potential hazards caused by the drugs effects on DNA function, regardless of the disease to be treated.

2.2 Chemotherapy and Chemotherapeutic agents

For the purpose of this document, chemotherapy is a collective term used for the treatment of cancer with drugs. A chemotherapeutic agent is one of those drugs used in chemotherapy to treat cancer with the specific action of killing cancer cells or controlling cancerous cell growth.

The term,'chemotherapy' or 'chemotherapeutic agent' includes drugs considered cytotoxic (i.e. those listed in Table 1 Appendix 1) but also includes drugs such as monoclonal antibodies and other relevant agents e.g. signal transduction inhibitors (see Table 2, Appendix 1), when used to treat cancer. In the latter case handling hazards to staff are absent or less clearly defined or evaluated.

Non-cytotoxic chemotherapeutic agents may not require compliance with the safe handling aspects of this document but will require compliance with other aspects relating to safe prescribing and patient care.

See section 3 - Risk Management

2.3 Non - cancer cytotoxic drugs used in other clinical settings

Non-cancer cytotoxic drugs may be identified from time to time and examples include:

- Ganciclovir administered throughout the Trust for cytomegalovirus (CMV) Infections in immuno-compromised individuals.
- Azathioprine a precursor of 6- mercaptoputine used as an immunosuppressant in a wide variety of diseases.

These drugs are considered cytotoxic and potentially teratogenic, and carcinogenic. Therefore they should be handled in accordance with the safe practice guidelines as outlined in this document.

2.4 Monoclonal Antibodies, fusion proteins / and other relevant agents

Reference should be made to the Trust Guidelines for the risk assessment of the Safe Handling and Administration of Monoclonal Antibodies and Related Products (current version) for specific guidance and Pan Birmingham Guidelines for the Preparation or Manipulation of Monoclonal Antibodies Used in the Treatment of Cancer (Current version).

These drugs are administered for a variety of malignant and non-malignant medical conditions. Intravenous administration of monoclonal antibodies, fusion proteins / and other relevant agents can only be administered by intravenous (IV) competent registered practitioners following a formal risk assessment of the individual drug. The risk assessment should be carried out by the most appropriate doctor, nurse and pharmacist with advice when required from appropriate specialists.

The individual registered practitioner must:

- Undertake training and maintain their knowledge on the management of spillage of cytotoxic drugs. **See section 12.**

- Ensure they are aware of the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications and any other patient care issues relating to the treatment.

3.0 Risk Management

3.1 Risk Assessment

Any routine use of cytotoxic drugs or chemotherapeutic agents (see definitions), regardless of route, dose, frequency or clinical setting should be subject to documented risk assessment (to be sent to the Associate Director of Pharmacy for Clinical Governance for submission to the Safe Medicines Practice Committee) by the most appropriate doctor, nurse and pharmacist with advice from appropriate specialists. If appropriate, this could include specific procedures written to supplement this document, identifying any aspects of this document that do not apply and any relevant additional or alternative guidance or practice.

This would apply to the following:

- Non-malignant conditions e.g.
- Methotrexate (cytotoxic) oral, intra-muscular (IM) or sub-cutaneous (SC) for inflammatory arthritis, bowel and skin disease
- Rituximab (non-cytotoxic) infusion for inflammatory arthritis, connective tissue disease and vasculitis
- Methotrexate (cytotoxic) IM for ectopic pregnancy
- Azathioprine (cytotoxic) oral for vasculitis, inflammatory arthritis, bowel and skin disease
- Ganciclovir (cytotoxic) for cytomegalo-virus (CMV)

Or

- Malignant conditions which do not require Oncologist or Haemato-oncologist Supervision e.g.
- Mitomycin (cytotoxic) bladder instillation for bladder cancer
- Isolated limb perfusion for melanoma

3.2 Liability

The employing authority accepts vicarious liability in situations where staff have undertaken activities for which they have received appropriate training and have been deemed competent to undertake such activities. The activity must lie within the scope of their role and job description and must follow local policy, and appropriate professional code of conduct and ethics. (NMC 2008, General Medical Council Good Medical Practice 2006, the Royal Pharmaceutical Society of Great Britain 2009).

3.3 Errors, incidents and near misses

Medication related incidents (actual events or near misses) must be reported through the Trust incident reporting scheme in accordance with the Trust policy and procedure for prevention and management of incidents including Serious Incidents Requiring Investigation (SIRI). Reporting is in addition to, and not a substitute for, timely and appropriate action to manage the incident.

4.0 Consent

Consent for treatment must be obtained in accordance with the Trust consent policy and associated procedural documents, the Trust's Consent to Examination or Treatment policy (current version) and Procedure for Consent to Examination or Treatment (current version).

In addition, informed written consent must always be obtained from patients receiving systemic anti-cancer treatment (SACT) i.e. chemotherapeutic agents for malignant conditions administered via the following routes:

- Oral
- Intravenous
- Intrathecal
- Intrapleural or intraperitoneal.
- Topical

Consent must only be obtained by a Consultant or Registrar in charge of the patients care. Before signing the consent form, patients must be allowed sufficient time to read:

- Specific patient information leaflets relating to the relevant regimen and side effects www.macmillancancersupport.co.uk

All patients of child bearing age and are over the age of 16 years, will be asked to provide verbal consent to undertake a pregnancy test prior to commencing any form of cytotoxic treatment. Any pregnancy testing requires verbal informed consent and documentation in the patient's medical record, including test results or patient refusal, (refer to the UHB Policy for Consent to Examination or Treatment (024 V6)). The reasons for any refusal by a patient to consent to testing should be clearly documented in the patient's medical notes and/or Clinical Portal. It should also be stated exactly what risks have been explained to the patient.

If treatment with an alternative chemotherapy regimen is subsequently proposed, patients must be provided with the relevant information and written informed consent must be obtained again from the patient.

If consent is taken 21 days or more prior to the start of treatment, the patient must re-sign the consent form on the day of treatment. Confirmation of consent can be taken by the treating registered nurse as per Trust Procedure for consent to examination or treatment (current version).

All health professionals involved with the administration of chemotherapy should be aware of any guidance on consent issued by their own regulatory bodies and those put in place by the Trust.

If the patient is unable to give their consent, the registered practitioner must act in accordance with the *Mental Capacity Act (2005)* and document in the patient's notes why they believe the administration of chemotherapeutic agents to be in the patient's best interests, including any involvement from other health professionals, family, or carers in reaching that decision.

4.1 Patient information and education

Information given to patients, their families and carers should be tailored to the needs of each individual patient, the disease to be treated and the specific treatment they are to receive. Patients should receive written (where suitable materials exist) and verbal information in a format and language suitable to their needs. Details regarding the information given to patients must be documented in the patient's notes.

Each patient must be provided with information concerning each chemotherapy protocol to be used. This information should include:

- Treatment intention
- Expected response rates
- Anticipated side effects including incidence of morbidity and mortality from neutropenia
- Duration of treatment – numbers of cycles of chemotherapy and length of time in hospital for each course
- Possible late effects of chemotherapy such as infertility, organ dysfunction and second malignancies
- Necessity for blood product transfusion, administration of antibiotics and antifungal agents (BCSH 2005)
- The potential harmful effects of the treatment upon a pregnancy conceived during cytotoxic treatment.

Patient information should also include, where appropriate, advice on action to take, and whom to contact with regard to dealing with:

- Neutropenic sepsis including temperature taking
- Signs of infection and preventing infections
- The process to follow in the event of adverse reactions to treatment
- 24 hour contact details
- Extravasation
- Nausea and vomiting
- Stomatitis, other mucositis and diarrhoea
- 7day rule (patients body waste)
- Fertility advice
- Pregnancy, contraception, sperm banking and ovarian preservation

The above list is not an inclusive list and any patient information should be tailored to the individual patient circumstances.

In addition, every patient receiving myelosupressive drugs should be given clear instructions on what to do if they feel unwell or have a temperature, and should be encouraged to monitor their temperature on a daily basis. Patients having oral chemotherapy must be given additional information to ensure concordance with taking medication at home e.g. timings of drugs relative to meals and bedtime, drug interactions, cycle length, when to stop treatment, safe handling of oral medication and should also receive advice on sources of further information e.g. cancer information centres

4.2 Pre chemotherapy holistic assessment for cancer patients

- All patients receiving their first cycle of anti-cancer chemotherapy regardless of the route of administration should have a comprehensive assessment completed by an appropriately trained registered practitioner
- Assessments will also be carried out prior to subsequent cycles as appropriate to review severity of toxicities and effectiveness of interventions to counteract side effects
- The purpose of each assessment is to ensure all patients and their families are fully informed about their chemotherapy, to provide a baseline of patient specific information relating to health, fitness, social and psychological, emotional and spiritual needs and to monitor symptoms and toxicity.
- During the Pre-Chemotherapy Assessment a pregnancy test will be performed for those patients who are of child bearing age and under the age of 16 years and who have provided verbal consent for the test to be undertaken.

4.3 General practitioner and district nurse information

General practitioners (GPs) need appropriate information covering the advice they should give and any action they should take when contacted by chemotherapy patients.
GPs should be informed as soon as possible after a patient has commenced chemotherapy of potential common side effects and regimen specific complications.
The route by which the GP is informed will be determined by the clinical area / department within which the patient is receiving treatment.
Community nurses will rarely need to administer cytotoxic or other chemotherapeutic drugs but may visit patients in the community who have received them or are receiving oral agents.
Specific information must be given by the appropriate registered practitioner to the community nurses on an individual patient basis regarding side effects and management as required.

5.0 Staff training

All personnel who prescribe handle and administer cytotoxic or other chemotherapeutic agents must receive education and training appropriate to the drug/regimen, the disease being treated and their level of involvement.

5.1 Medical staff

All new medical staff working within Oncology and Haematology must attend an induction which will include orientation to, and education around:

- Trust Procedure for Safe Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of Medicines
- Trust Procedures for Safe Prescribing, Handling and Administration of Cytotoxic and Chemotherapeutic agents
- Trust Policy for Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy
- Prescribing chemotherapy to include rotas and appropriate clinical checks
- Assessment of patients receiving chemotherapy
- Management of symptoms, side effects and complications associated with chemotherapy
- Health and safety and extravasation, updated annually

Medical staff prescribing chemotherapeutic agents for non-malignant conditions will have training and supervision as agreed by the consultant responsible for the patient group.

5.2 Nursing staff

Training must be delivered in line with the Expanded Practice Protocol for the Administration of Systemic Anti Cancer Treatment by Registered Nurses (controlled document number 249 (formerly CP 19) and Trust Procedures for Safe Prescribing, Handling and Administration of Cytotoxic and Chemotherapeutic Agents.

5.2.1 Registered nurses

5.2.1.1 Administering Intravenous Chemotherapy

All registered practitioners administering intravenous chemotherapy must:

- Have completed a course as per the Expanded Practice Protocol for the Administration of Systemic Anti Cancer Treatment by Registered Practitioners (controlled document number 232 (formerly CP 03) and understand the wider implications of undertaking this practice. They must have demonstrated clinical competence in the administration of IV medications before progressing to the administration of IV chemotherapy (RCN 1998).
- Have completed a period of training, the content of which should be agreed by the Lead Nurse responsible for chemotherapy training and education, and the Pan Birmingham Cancer Network (Manual of Cancer Services 2014).

Training must include as a minimum:

- Attendance at the Trust Approved Chemotherapy Study Days
- Supervision of practice
- Assessment of competence using a competency framework
- Assessment of underpinning knowledge
- Provide evidence of competence reviewed annually (Manual of Cancer Services 2014).
- A record of trained and competent staff must be maintained within the clinical chemotherapy service (Manual of Cancer Services 2014).
- Cease administering chemotherapy unsupervised if their competency has expired.
- Whilst undergoing their period of training only administer chemotherapy under the supervision of a registered practitioner who is fully trained and competent in administration of chemotherapy.
- Attend a Trust Chemotherapy Study Day within 3 - 6 months of start date if new to the Trust.

5.2.1.2 Checking Intravenous chemotherapy

Registered nurses acting as the second checker for chemotherapy must be a competent practitioner as outlined in the Procedure for Safe Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of Medicines (UHB 2008).

5.2.1.3 Administering oral chemotherapy

Oral chemotherapy can only be administered by registered nurses who:

- Have successfully completed the Trust approved oral drug assessment and attained competence
- Have a working knowledge of the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications and any other patient care issues relating to the treatment

5.2.1.4 Intrathecal chemotherapy:

Refer to Trust Policy for Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy (current version), and HSC 2008/001: Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy (2008).

5.2.2 Non-registered nursing staff

All non-registered nursing staff working in clinical areas where cytotoxic drugs are regularly administered must receive training in safe handling, spillage, storage and disposal of cytotoxic and waste products annually either on the in-house chemotherapy study day held monthly or by attending the Oncology / Haematology Band 2 Training day which is run quarterly.

5.2.3 Community nurses

Community nurses will rarely need to administer cytotoxic drugs other than subcutaneous cytarabine, intramuscular or subcutaneous methotrexate, or disconnection of pumps that have contained cytotoxic drugs. In all cases, registered community nurses will be given written authorisation for administration from the hospital doctor for each patient. The authorisation will give instructions for the administration of the drugs, safe handling, spillage advice and extravasation instructions. Specific training will be offered to community nurses involved on a 'when necessary' basis by the Lead Chemotherapy Nurse. PCT's are responsible for the producing and maintenance of necessary guidelines, policies and protocol.

5.3 Pharmacy staff

Pharmacists must only provide an accuracy check on aseptically prepared chemotherapeutic agents following successful completion of an in-house training and assessment programme.
Pharmacy technicians and pharmacy support staff must undergo an in-house training programme appropriate to their level of involvement.
All staff working in Pharmacy Departments where cytotoxics are prepared must receive training in safe handling, spillage, storage and disposal of cytotoxic and waste products.

5.4 Patients, parents and carers

Patients, parents and carers of any patient receiving chemotherapy will be provided with training appropriate to their level of involvement in the treatment by specialist personnel involved in the administration of the chemotherapy.

5.5 Porters and domestic staff

Consideration must be given to staff that could be indirectly exposed to cytotoxic drugs (COSHH 2002) and therefore relevant portering and domestic staff must receive training in transportation and dealing with cytotoxic drug spillage where appropriate, this will be provided by the lead chemotherapy nurse / chemotherapy nurse trainer.

6.0 Staff responsibilities

6.1 Medical staff

6.1.1 Prescribing

- The decision to initiate chemotherapy must be made by consultant responsible for the patient's care.
- The first cycle of a course of systemic chemotherapy must be prescribed by a consultant or specialist registrar (SpR).
- Subsequent cycles of chemotherapy may be prescribed by junior medical staff if authorised by consultant in charge of patients care.
- FY1 doctors must NOT be involved in the prescribing or administration of oral, intravenous, intramuscular or intravesical chemotherapy.
- Any alterations to treatment must be authorised by consultant or SpR.
- Cessation of treatment must be authorised and documented in medical notes by consultant or SpR.
- Chemotherapeutic agents must only be prescribed by specialists experienced in the treatment of the condition for which the drug is being used.
- Chemotherapeutic agents must only be prescribed by registered medical staff that have a working knowledge of the Trust Procedure for Safe Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of Medicines.

The prescriber is responsible for all aspects of the prescription i.e. treatment protocol choice, compliance with NICE guidance, network formulary and local policies as well as dosing, appropriate intervals between treatments; proceed rules, administration details and supportive drugs therapies.

6.2 Nursing staff

6.2.1 Registered nurses

Registered nurses are responsible for:

- Correct storage of drugs before use
- Checking the dose is correct
- Checking of blood results to see if they are satisfactory
- Checking that the patient has signed a consent form
- Checking the prescription matches the treatment described in the consultant / SPR's annotation
- Checking the patient identification details against the prescription to ensure they both correspond.
- Checking that the patient has been assessed as fit for treatment.

In addition chemotherapy trained nurses are responsible for:

- Ensuring all chemotherapeutic agents and associated treatments of a chemotherapy protocol are administered to the correct patient in the correct manner
- Providing the patient with information regarding treatment
- Monitoring the patient during their treatment
- Liaising with the community nursing team or other professionals as appropriate to ensure ongoing support.

6.2.2 Non-registered nursing staff

Non-registered nursing staff are responsible for ensuring that they only undertake tasks that they have received appropriate training for e.g. disposal of the clinical waste.

6.3 Pharmacy Staff

Appropriately trained pharmacists are responsible for:

6.3.1 Prescription safety

All prescriptions must be clinically screened by a pharmacist who has read and understood the departmental Standard Operation Procedures for clinical screening.

All prescriptions for chemotherapeutic agents (see definitions) regardless of route, dose, frequency or clinical setting must be clinically screened by an appropriately trained pharmacist with reference to section 8 of this policy. Where information about the usual dosage of an agent in the relevant setting is readily available from the pre-printed prescription, PICS, the British National Formulary or from information sheets generated by the relevant specialist pharmacist no additional training, aside from local induction, is necessary. For example:

- Methotrexate oral, Intramuscular (IM), or sub-cutaneous (SC) for inflammatory arthritis, bowel and skin disease.
- Azathioprine oral for vasculitis, inflammatory arthritis, bowel and skin disease.
- Mitomycin bladder instillation for bladder cancer

For intravenous and oral chemotherapeutic agents associated with a particular treatment regimen where knowledge of that specific regimen is required or where aseptic manipulation in pharmacy is required, a more detailed prescription screening process is necessary in accordance with departmental standard operating procedures. Pharmacists involved in this process must complete an in house training programme and be assessed as competent by the Lead Pharmacist for Cancer Services. Training provided includes how to access the relevant regimens, monitoring relevant blood results, calculating surface area and adjusting doses in renal and hepatic failure. A list of pharmacists deemed competent in this area is available in the department. In addition pharmacists who are involved in clinically screening prescriptions for intrathecal chemotherapeutic agents will undergo additional training as detailed in the Trust Intrathecal Policy.

When a new cytotoxic or chemotherapeutic agent becomes available or an existing agent is to be used in a non cancer setting a risk assessment will be undertaken (see section 3 Risk management). This risk assessment must include a determination of the restrictions (if any) on

the pharmaceutical clinical screening of that agent.

6.3.2 Safe and accurate compounding of cytotoxic drugs

Refer to departmental Standard Operating Procedures.

6.3.3. Safe and accurate dispensing of all cytotoxic and chemotherapeutic agents.

Refer to departmental Standard Operating Procedures

7.0 Pharmacy services

7.1 Purchasing, receipt and storage

- The purchasing, receipt and storage of chemotherapeutic drugs are carried out by pharmacy staff in accordance with agreed pharmacy procedures and the Trust's Standing Financial Instructions.
- All free samples, 'compassionate use' supplies, named patient supplies, trial material, home care supply and/or administration services etc, must be ordered, received and managed via the pharmacy department. Medical and nursing staff are NOT permitted to order or take receipt of drugs or services from drug companies, home care suppliers or wholesalers.
- Pharmacy will store drugs in designated areas under appropriate secure conditions with temperature monitoring.
- Chemotherapeutic drugs will be supplied to wards and departments on a named patient basis. Wards and departments must not keep 'stock' of chemotherapeutic agents.

7.2 Reconstitution

Cytotoxic drugs:

- MUST NOT be reconstituted or drawn up in ward areas, clinics or departments. Trained pharmacy staff using appropriate facilities in accordance with relevant national, regional and local legislation, recommendations, guidelines and policies will undertake manipulation of cytotoxic drugs.
- Exceptions to this are permitted only where a risk assessment deems them necessary and appropriate. Examples of exceptions include :
- Mitomycin and BCG for bladder instillation where pharmacy approved closed system reconstitution and administration kits are used. (Refer to expanded practice protocol for the Preparation and Instillation of Intravesical Drugs for the Prophylaxis or Treatment of Recurring Bladder Tumours: controlled document number 245 (formerly CP 12).
- Isolated Limb Infusion where melphalan is mixed with non cytotoxic drugs in an infusion bag immediately before infusion in theatre.

Non-cytotoxic chemotherapeutic drugs:

For example, some monoclonal antibodies may be reconstituted or prepared by registered nursing staff in clinical areas if appropriate. Each drug should be individually risk assessed for potential handling hazards. Refer to Guidelines for the Management of safe prescribing, handling and administration of Monoclonal Antibodies.

7.3 Dispensing

- Cytotoxic drugs and other chemotherapeutic agents reconstituted in the pharmacy must be supplied in a 'ready to use' form.
- Prescriptions must be sent to the pharmacy as soon as possible after they have been written and within published cut off times. If the drugs are required urgently, or the cut off time has been exceeded, the pharmacy chemotherapy aseptic unit must be contacted prior to sending the chart to ensure capacity is available to prepare the doses.
- Preparation should be carried out daily during published opening hours. Preparation outside of these hours or at weekends or bank holidays may only be carried out with prior arrangement with the pharmacist responsible for the unit.
- Prescriptions should not be accepted by pharmacy unless they comply with the prescribing requirements in section 8 (Prescribing). An appropriately trained pharmacist must screen the prescription in accordance with departmental standard operating procedures. Doses may be rounded to allow measurable doses or the use of pre-filled syringes or bags within 5% of the calculated dose (with the exception of individual trials).
- Aseptic preparation of chemotherapy and final release must be carried out following departmental standard operating procedures in accordance with relevant national, regional and local legislation, policies, guidelines and recommendations.
- Chemotherapeutic drugs should be supplied to the wards frequently to minimise the need for ward storage. The drugs must be transported to wards in designated cytotoxic bags. The ward/department nurse in charge may designate a suitably trained member of hospital staff to collect the bags. For intrathecal chemotherapy refer to Trust Policy for Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy.
- Infusion bags for in-patients must be weighed in pharmacy and labelled with the approximate volume of the contents to enable accurate setting of flow rates.
- All items must be labelled clearly with contents, route, expiry, storage conditions and patient details. Labels should, where practical, be positioned so as not to obscure the volume of a syringe or the printed detail on an infusion bag.
- All items must be sealed into a plastic wrap to protect from leakage. Light sensitive products must be provided wrapped in light protective plastic film. Vinca alkaloids must be supplied wrapped in blue plastic film.
- If leakage is suspected the wrapping MUST NOT be opened, the item must be sealed in a secure container and pharmacy contacted immediately.
- The registered nurse receiving the items on the ward / department must ensure that all items required have been supplied and are correct before administration commences. If any chemotherapy is missing or incorrect the Pharmacy must be contacted immediately.

- As soon as the drugs arrive on the ward they must be stored according to the instructions on the label in a lockable area or fridge designated for storage of chemotherapy. Note: not all chemotherapeutic drugs should be stored in the fridge and will be clearly labelled 'STORE AT ROOM TEMPERATURE' if appropriate.
- Oral chemotherapy will be dispensed using designated triangles if blister packed products are not available.
- Oral chemotherapy prescriptions will be given the same level of screening as other forms of chemotherapy.

8.0 Prescribing of Chemotherapy

The Procedure for Safe Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of medicines must be adhered to.
In addition:

8.1 Intrathecal prescribing

Refer to Trust Policy for Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy (current version)

8.2 Computer Generated Prescriptions

All Chemotherapy will be prescribed via the Prescribing Information and Communication System (PICS). If a regimen is not available on PICS then a pre-printed prescription must be used.

8.3 Prescription details

Prescriptions must be legible, written in black ink and unambiguous and must include:

- Disease site
- Title or acronym of regimen
- Frequency and intended number of cycles
- Approved drug names written in full in capital letters
- Route and method of administration
- Dose calculation
- Number of doses and relative timing of different drugs if important
- Durations of infusions and type and volume of infusion fluid
- Date of prescribing and start date of prescription
- Prescribers signature, name and title clearly stated

The prescription chart must carry:

- The patient's name, date of birth, hospital number, NHS number, and the patient's most recently determined height and weight measurements and surface area calculation
- Any test results relevant to the dose calculation (dated)
- Cycle number

- The date of intended administration
- Dose of each drug
- If patient is entered into a trial, the name of the trial and the patient's trial number.
- Prescriptions must include any standard regimen specific prophylaxis or treatment for potential side effects e.g. hydration, anti-emetics, mesna, folinic acid etc.

8.4 Authorised regimens

Only chemotherapy regimens that have been approved by the Trust's Divisional Medicines Management Expert Panels (MMEP) should be prescribed.

In general, only regimens approved as above should be prescribed. However, there may be occasions when an individual patient requires further chemotherapy options, where there is a level of evidence to support this. In this case a Chairman's Action must be instigated to the Chair of the MMEP in addition to the new drug approval process of the Trust (see trust intranet site).

8.5 Advance Prescribing

Refer to Pre-Prescribing Flowchart for chemotherapy outpatient treatment (1st treatment and subsequent treatment) this is kept in chemotherapy outpatients.

9.0 Safe Handling of Cytotoxic Materials

Healthcare professionals may be exposed to cytotoxic agents during:

- Preparation
- Administration
- Transportation
- The disposal of waste following the preparation and administration
- The handling of patients waste products

(Allwood et al 2002)

A full Control of Substances Hazardous to Health Regulations assessment must be undertaken yearly in all areas handling cytotoxic drugs. (Refer to COSHH 1994).

9.1 Personal Protective Equipment (PPE)

The correct use of PPE can shield staff from exposure to cytotoxic drugs and minimise the health risks (HSE 2003).

Pharmacy staff handling chemotherapy within the aseptic unit must comply with departmental standard operating procedures for the choice and use of protective clothing and equipment (See Table 3, Appendix 2).

9.1.1 Disposable Nitrile Gloves

No glove material is completely impermeable to cytotoxic drugs. Permeation of cytotoxic drugs depends upon glove thickness and integrity, the properties of the drug / solvents and the contact time with the drug. Nitrile and neoprene gloves have been shown to offer better

protection than latex. Since no material is completely impermeable to cytotoxic drugs and permeability increases with time, users should minimise contact and change the gloves as a minimum between every patient (HSE 1992).

The following guidelines must be followed:

- Non-powdered Nitrile Gloves to be used since the powder may absorb cytotoxic contamination
- A new pair of gloves when attending each patient
- Gloves must be worn at all times when handling cytotoxic drugs and patient waste. A double gloving technique is required for reconstitution and decontamination of cytotoxic spills.
- Gloves must be changed immediately if damaged or contaminated.
- Cuts and scratches must be covered with a waterproof dressing to prevent infiltration of the skin if gloves are damaged.
- Hands must be washed thoroughly with soap / detergent, before and after glove application.

Staff with dermatological conditions e.g. eczema should be referred to Occupational Health for assessment of fitness to operate in this role.

9.1.2 Eye and face protection

Protective glasses must be worn if undertaking a procedure where there is a high risk of cytotoxic drug splashes e.g. disconnecting an intravenous giving set containing cytotoxic drugs from a cannula or central venous catheter.
If involved with cleaning up a spillage of cytotoxic drugs protective glasses must be worn as supplied in the spillage kit.
Equipment appropriate to facilitate eye washing such as bags of sterile saline or a running tap must be readily available in all areas where handling of cytotoxics or waste occurs.

9.1.3 Respiratory protection

There is no research evidence to demonstrate that staff administering cytotoxics are at risk from inhalation. Therefore, staff are not required to wear masks during administration of cytotoxic drugs.
If involved with decontamination a mask must be worn and is supplied within the cytotoxic spillage kit.
Reconstitution of cytotoxic drugs will be carried out in a negative pressure containment cabinet (isolator) which will protect the staff from inhalation risks.

9.1.4 Aprons and armlets

Plastic aprons must be worn when handling cytotoxic drugs and patient waste.
If involved with cleaning up a spillage of cytotoxic drugs a full gown, overshoes must be worn and are supplied within spillage kits.
Pharmacy personnel involved with reconstitution of cytotoxics must wear clothing appropriate for aseptic units which also protect from exposure to cytotoxic material.

9.2 Oral dosage forms of cytotoxic drugs

Wherever possible oral dosage forms will be purchased and supplied as strip-pack or blister pack presentations which minimise the handling of the tablets or capsules. Handling of loose tablets and capsules must be avoided unless nitrile gloves are worn. Tablets should not be crushed and capsules should not be opened unless specific advice has been sought. Gloves must always be worn when measuring and administering oral liquids. Medicine tots, spoons or oral syringes must be discarded after use and treated as cytotoxic waste.

9.3 Staff

9.3.1 Pregnant staff

Refer to separate Pan Birmingham Cancer Network (PBCN) Policy (chemotherapy information folder on all oncology / haematology wards) or www.birminghamcancer.nhs.uk.
Note: In the absence of clear evidence for the safety of monoclonal antibodies in pregnancy, the PBCN policy for pregnant staff recommends that monoclonal antibodies should be treated in the same way as cytotoxic drugs in terms of pregnant staff involvement in handling and administration.

9.3.2 Students

Mentors must inform their students of the hazards of cytotoxic agents and the appropriate use of PPE in dealing with patient waste and bed linen. Students MUST NOT be involved in the administration of chemotherapy or dealing with the spillage of cytotoxic drugs.

9.3.3 Health screening

At present monitoring staff for biological evidence of enhanced exposure to cytotoxic drugs is unreliable and therefore considered inappropriate at the present time (COSHH 2002). However, reliance must be placed on a robust training program, which periodically evaluates and verifies staff adherence to and performance of safe handling practices and procedures
The Occupational Health Department must keep information regarding the handling of cytotoxic drugs in staff files (HSE 2003).
Staff handling Bacillus Calmette-Guérin (BCG) should be offered Purified Protein Derivative (PPD) skin testing. PPD negative staff should have yearly documented PPD skin testing.

9.4 Pathological samples and body waste

All staff working in areas where patients have received chemotherapy require appropriate education in relation to contaminated body fluids.
Excreta from treated patients may contain unchanged cytotoxic drugs or active metabolites (HSE 2003).

All body fluids of patients who have received cytotoxic chemotherapy drugs within the previous seven days should be treated as contaminated and appropriate PPE must be worn when handling body fluids.

10.0 Disposal of cytotoxic materials

10.1 Disposal of equipment that contains NO visible residual chemotherapy

Needles, empty syringes, empty vials and ampoules, must be disposed of in a purple lidded cytotoxic sharps bin. The bin must be labelled with the ward area, date assembled, date of disposal, and signed by the member of staff assembling/disposing of the bin.
Empty infusion bags must be disposed of in a yellow with purple stripe cytotoxic plastic clinical waste bag.

All other disposable equipment i.e. paper towels, absorbent pads, disposable gloves, masks, aprons must be discarded in a yellow plastic clinical waste bag.

10.2 Disposal of equipment that contains ANY visible residual chemotherapy

Any needles, syringes, vials, ampoules, giving sets or chemotherapy bags that contain any trace of residual cytotoxic drug must be disposed of in an empty purple lidded cytotoxic sharps bin. The bin must be labelled with the ward area, date assembled, and signed by the member of staff, a chemotherapy return form must be completed and the bin and returns form returned to Pharmacy for disposal.

All other disposable equipment contaminated with cytotoxic drugs i.e. paper towels, absorbent pads, disposable gloves, masks, aprons, linen must be put in a yellow with purple stripe cytotoxic plastic clinical waste bag, swan neck tied and put into ward waste disposal areas for collection by porters.

10.3 Non-disposable equipment

This includes scissors and trolley tops. These should be decontaminated by washing with soap or detergent and water, rinsing well. Protective clothing must be worn during the decontamination procedure.

10.4 Pathological samples/ body waste

Bedpans and vomit bowls must be disposed of in a sluice. Continence products etc. must be placed in a yellow bag, labelled ‘Clinical Waste’.
Spillage of these materials must be treated according to the spillage instructions see section 12.

10.5 Unused or out of date drugs

These must be returned as soon as possible to the Aseptic Unit using a designated Cytotoxic Bag. The sealed Cytotoxic Bag must be returned to pharmacy with a chemotherapy returns form indicating which drugs and doses are being sent back, and why

the drugs have been sent back, and must be signed by the member of staff disposing of the drugs.

10.6 Collection of waste

Waste labelled 'CYTOTOXIC WASTE' must be segregated from all other waste. It is only collected from the pharmacy department so all Cytotoxic waste must be delivered to pharmacies aseptic lab for collection. All bags and sharps bins labelled as cytotoxic waste must be ultimately disposed of by incineration at temperatures of at least 1000^{o}c. Failure to appropriately label and document hazardous waste could result in legal action taken against the Trust.

11.0 Extravasation

This is a medical emergency.
Refer to Pan Birmingham Cancer Network Extravasation Policy
http://www.uhb.nhs.uk/chemotherapy.htm

12.0 Spillage / contamination of skin / mucous membranes

Refer to Pan Birmingham Cancer Network Guidelines for Management of Spillage of Cytotoxic Drugs http://www.uhb.nhs.uk/chemotherapy.htm

NOTE: In the absence of clear evidence for the safety of monoclonal antibodies the PBCN spillage policy recommends that monoclonal antibodies should be treated in the same way as cytotoxic drugs in terms of spillage management.

13.0 Administration

Refer to Pan Birmingham Cancer Network Guidelines for the administration of Anti Cancer Treatment http://www.uhb.nhs.uk/chemotherapy.htm

14.0 Administration equipment

Peripheral Cannula
Refer to Trust Guidelines for the insertion, care and removal of peripheral venous cannula (Controlled Document Number 225, current version).

Central Venous Access Devices
Refer to Trust Guidelines for the care of central venous access devices (Controlled Document Number 224, current version).

15.0 Audit

A programme of annual audits will be carried out to establish the effectiveness, implementation of and extent of compliance with this procedure to provide assurance that the appropriate and effective systems are in place. The lead chemotherapy nurse and lead

cancer services pharmacist through divisional Medicines Management Expert Panel, (MMEP) will lead the audit with support from the Practice Development Team.

16. 0 Associated Documents

This document must be read in conjunction with Trust:

- Expanded Practice Protocol for the administration of Intravenous Drugs (Controlled Document number 232)
- Expanded Practice Protocol for the Administration of Systemic Anti Cancer Therapy by Registered Nurses (Controlled Document number 249)
- Guidelines for the insertion, care and removal of peripheral venous cannula (Controlled Document Number 225)
- Guidelines for the care of central venous access devices (Controlled Document Number 224)
- Guidelines for the Management of safe prescribing, handling and administration of Monoclonal Antibodies (awaiting Trust release date)
- Procedure for Consent to examination or treatment
- Procedure for safe Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of medicines
- Policy for Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy
- Control of Substances Hazardous to Health Regulations 1994 Policy)
- Waste Disposal Policy
- Manual Of Cancer Measures section 3C (DH 2014)
- Department of Health (2008) Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy (HSC 2008/001)
- Royal Marsden Manual of Clinical Nursing Procedures (current edition)
- The administration of cytotoxic chemotherapy – Clinical Practice Guidelines: Royal College of Nursing (1998)
- Standards for Infusion Therapy. RCN IV Therapy Forum: Royal College of Nursing (2005)
- National Patient Safety Agency (2007) Patient Safety Alert (PSA 20) – Promoting safer use of injectable medicines
- National Patient Safety Agency (2008) Rapid Response Report (RRR2008/001) - Risk of Incorrect dosing of oral anti-cancer medicines
- National Patient Safety Agency (2008) Rapid Response Report (RRR2008/004)– Using Vinca Alkaloid Mini bags (Adult / Adolescent Units)
- National Patient Safety Agency (2004) Patient Safety Alert (PSA 03): Reducing the Harm Caused by Oral Methotrexate

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Pan Birmingham Cancer Network (current version) Guidelines for Safe Handling and Management of cytotoxic spillage.

Pan Birmingham Cancer Network (current version) Guidelines for the management of extravasation.

Pan Birmingham Cancer Network (current version) Guidelines for the Administration of Anti-cancer Treatment

Pan Birmingham Cancer Network (current version) Guideline for the preparation or manipulation of Monoclonal Antibodies (MABs) used in the Treatment of Cancer. http://www.uhb.nhs.uk/chemotherapy.htm

Pan Birmingham Cancer Network (current version) Guidelines for expectant mothers and those trying to conceive involved in the administration of and/or the care of patients receiving Chemotherapy/Monoclonal Antibodies. http://www.uhb.nhs.uk/chemotherapy.htm

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University Hospital Birmingham NHS Foundation Trust (current version) Expanded Practice Protocol for the administration of intravenous chemotherapy by registered nurses (Controlled Document number 249)

University Hospital Birmingham NHS Foundation Trust (current version) Guidelines for the care of Central Venous Access Devices (CVADs). (Controlled Document Number 224)

University Hospital Birmingham NHS Foundation Trust (current version) Guidelines for the insertion, care and removal of peripheral venous cannula (Controlled Document Number 225)

University Hospital Birmingham NHS Foundation Trust (current version) Medicines Policy

University Hospital Birmingham NHS Foundation Trust (current version) Policy for consent to examination or treatment,

University Hospital Birmingham NHS Foundation Trust (current version) Procedure for the Prescribing, Supply, Dispensing, Handling, Storage, Administration and Disposal of Medicines including Controlled drugs

University Hospital Birmingham NHS Foundation Trust (current version) Guidelines for Pregnancy Assessment/Pregnancy Testing Prior to Administration of Systemic Anti Cancer Treatment

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Appendix 1

Table 1: Cytotoxic drugs and substances

ACLARUBICIN	IDARUBICIN
AMSACRINE (m – AMSA)	IRINOTECAN
ARSENIC TRIOXIDE	IFOSFAMIDE
ASPARAGINASE	LOMUSTINE (CCNU)
AZATHIOPRINE	MELPHALAN
BCG	MERCAPTOPURINE
BLEOMYCIN	METHOTREXATE
BUSULFAN	MITOMYCIN C
CAPECITABINE	MITOTANE
CARBOPLATIN	MITOXANTRONE
CARMUSTINE (BCNU)	MITOBRONITOL
2-CHLORODEOXYADENOSINE	CHLORMETHINE (Mustine, Nitrogen mustard mechlorethamine
CHLORAMBUCIL	OXALIPLATIN
CISPLATIN	PEMETREXED
CIDOFOVIR	PENTAMIDINE
CLADRIBINE	PENTOSTATIN(Deoxycoformycin)
CLOFARABINE	PLICAMYCIN (Mithramycin)
CYCLOPHOSPHAMIDE	PROCARBAZINE
CYTARABINE (Ara C or Cytosine Arabinoside)	RALTITREXED
DACARBAZINE (DTIC)	RAZOXANE
DACTINOMYCIN (Actinomycin C)	STREPTOZOCIN
DAUNORUBICIN	THIOTEPA
DOCETAXEL	TIOGUANINE (Thioguanine)
DOXORUBICIN (Adriamycin)	TEGAFUR
EDATREXATE	TEMOZOLAMIDE
EPIRUBICIN	TENIPOSIDE
ESTRAMUSTINE	TEMSIROLIMUS
ETOPOSIDE (VP-16)	TOPOTECAN
5-FLUOROURACIL	TREOSULFAN
FLUDARABINE	VIDARABINE
GANCICLOVIR	VINDESINE
GEMCITABINE	VINCRISTINE
GEMTUZUMAB OZOGAMICIN	VINBLASTINE
HYROXYCARBAMIDE (Hydroxyurea)	VINORELBINE

PACLITAXEL	

Note: The list is not exhaustive and may be added to as new drugs become available. The presence of a drug on this list does not imply the drug is approved for general use within the Trust or Pan Birmingham Cancer Network.

Table 2: Monoclonal Antibodies, fusion proteins and other relevant agents (safe handling aspects of these drugs should be determined through risk assessment)

MONOCLONAL ANTIBODIES/FUSION PROTEINS	**Signal transduction inhibitors and other relevant agents**
ALEMTUZUMAB	ABATACEPT
CETUXIMAB	BORTEZEMIB
BEVACIZUMAB	DASATINIB
RITUXIMAB	ERLOTINIB
TRASTUZUMAB	IMATINIB
INFLIXIMAB	LAPATINIB
ADALIMUMAB	NILOTINIB
CERTOLIZUMAB	PAZOTINIB
TOCILIZUMAB	PEGAPTANIB
GOLIMUMAB	SORAFENIB
NATALIZUMAB	SUNITINIB
	LENOLIDOMIDE
	THALIDOMIDE

Note: The list is not exhaustive and may be added to as new drugs become available. The presence of a drug on this list does not imply the drug is approved for general use within the Trust or Pan Birmingham Cancer Network.

Appendix 2

Table 3: PPE to be used when handling cytotoxics

	GLOVES	**APRONS**	**GOWNS**	**OVER SHOES**	**MASK**	**GLASSES**
Reconstitution of cytotoxics	YES DOUBLE		YES	YES		
Administration of cytotoxics	YES	YES				
Spillage of cytotoxics	YES DOUBLE		YES	YES	YES	YES
Handling patient waste / soiled linen	YES	YES				
Reconstitution of Monoclonal Antibodies, fusion proteins / signal transduction inhibitors	YES	YES			Optional – if deemed necessary	