Pan-Birmingham NHS
Cancer Network

Coversheet for Network Site Specific Group Agreed Documentation

This sheet is to accompany all documentation agreed by Pan Birmingham Cancer Network Site Specific Groups. This will assist the Network Governance Committee to endorse the documentation and request implementation.
Green notes to be completed by Network Administrator.

Document Title	West Midlands Children's Cancer Network (WMCCN) "Common Guidelines on Chemotherapy Complications & Safety".
Document Date	To be completed by Network Administrator once guideline is approved by Review Group / CCNCG Chair
Document Purpose	This Guidance has been produced to support the delivery of chemotherapy related supportive care to children 0-16 years across the West Midlands managed care network. It also supports the DH quality measures for children's cancer services 2011 – measure11-7A-133
Authors	Birmingham Children's Hospital NHS Foundation Trust (BCH Principal Treatment Centre) Chemotherapy Working Group – Chair Mr Nigel Ballantine (Specialist Paediatric Oncology Pharmacist) Amalgamation of documents and cover sheet developed by Jeanette Hawkins – Lead Cancer Nurse BCH
References	N.I.C.E. Improving outcomes guidance for children & young people with cancer 2005. Department of Health quality measures for children's cancer services (2009, 2011) See also individual sections within the amalgamated document.
Consultation Process	Consultation was by discussion and email including all BCH Chemotherapy Working Group members & the WMCCNCG meeting, based on 2010 version of the document. Review was by BCH Principal Treatment Centre Chemotherapy Working Group & WMCCNCG in June / July 2011

Review Date (must be within three years)	*To be completed by Network Administrator once guideline is approved by Review Group*
Approval Signatures: Network Site Specific Group Clinical Chair	*To be added by Network Administrator when guideline goes to Review Group*
Date Approved by Network Governance Committee / /	

Pan-Birmingham NHS
Cancer Network

West Midlands Children's Cancer Network Common Guidelines on Chemotherapy Complications

Version History

Version	Date	Summary of change/ process
1	01/07/2010	Initial version of common guidelines for chemotherapy complications prepared for peer review in July 2010 following consultation with the WMCCNCG.
2		Version revised following recommendation by cancer peer review internal validation 2010 that the document would benefit from contents list. User feedback from members of the WMCCNCG also commented that the document was not user friendly. Proposed change takes the approach of adopting BCH policies and providing cover sheet and contents list, which reflects actual practice on policy sharing for previous decade. BCH as the Principal Treatment Centre provides the central guidance with statements to allow for local approved adaptations in Paediatric Oncology Shared Care Units (POSCUs)

1. Scope of the Guideline

This guidance has been produced to support the following:

To meet recommendations in the DH quality measures for children's cancer services 2011 – measure11-7A-133

- The delivery of chemotherapy related supportive care to children 0-16 years across the West Midlands managed care network.
- The safety aspects of chemotherapy administration.
- To meet recommendations in the DH quality measures for children's cancer services 2011 – measure11-7A-133

2. Guideline Background

2.1 The care of children with cancer in the West Midlands has been supported for many years by a cooperative working arrangement between Birmingham Children's Hospital and named district general hospitals who provided shared care for these children under the guidance of the Children's Hospital. This included sharing policies, procedures and guidelines to standardise care.

2.2 This informal cooperative arrangement was formalised in July 2010 with the establishment of the West Midlands Children's Cancer Network Coordinating Group (WMCCNCG) and the DH designation of the hospitals who would be

named as the Principal Treatment Centre (PTC) and the Paediatric Oncology Shared Care Units (POSCUs). The approach is in keeping with guidance from the N.I.C.E. Improving outcomes guidance for children & young people with cancer 2005 and the Department of Health quality measures for children's cancer services (2009, 2011)

2.3 The WMCCNCG worked towards documenting the shared policies, guidelines and procedures during 2010 in one amalgamated document to formalise existing arrangements and to meet the recommended quality measure on common guidelines on chemotherapy complications. The first amalgamated document received feedback that required this revision to make it a more user friendly document.

3. Guideline Statements

3.1 The WMCCN and all POSCUs and PTC's included have agreed to abide by the set of guidelines, policies and procedural documents produced by Birmingham Children's Hospital NHS Foundation Trust in relation to the supportive care of chemotherapy complications and safety issues around chemotherapy administration.

3.2 Where a hospital within the WMCCN has local reasons not to adopt all or part of a policy, guideline or procedural document contained within this Common Guideline Document, they will make the local variation known to the PTC and the WMCCNCG with justification for varying practice. The WMCCNCG will then note and record the variation or recommend that a document is updated to reflect the variation.

The documents contained within these common guidelines have largely been written with the aim of enabling some local variation within a set of common principles and boundaries. For example, the febrile neutropenia policy recommends an antibiotic schedule but states acceptance of antibiotic variations based on local microbiology advice for the microorganisms present. Similarly, individual hospitals are required to have blood administration protocols, but POSCUs may wish to refer to the BCH guidelines for paediatric specific recommendations on blood administration.

3.3 When a member of the WMCCNCG becomes aware of new research or evidence relating to any of the documents contained within these common guidelines they will appraise the PTC Chemotherapy Working Group at BCH and the WMCCNCG of the published information for discussion.

3.4 Section 1 of the Common Guidelines on Chemotherapy Complications include the following paediatric applicable documents;

3.5 Section 2 of the Common Guidelines on Chemotherapy Complications includes policies, guidelines & procedural documents that support health professionals in the delivery of cytotoxic therapy to minimise risks to staff, patients and carers.

6. Patient Information and Counselling

6.1 All patients and their carers will be given access to age appropriate verbal & written information during their investigation and treatment, and will be given the opportunity to discuss their management with a paediatric oncology trained nurse who is a member of the relevant MDT. Some younger patients will not be given written information but will receive regular verbal information or pre–procedural play just before any procedure and with regularly updated information each time the care is delivered. Pots –procedural play with play specialists can also be arranged for traumatic procedures. The patient / cares will have open access to advice about chemotherapy and side effects & complications via the PTC or their local POSCU chemotherapy trained staff. They will be given phone numbers for the 24hr advice lines at the PTC or local POSCU.

All patients / carers will be given the following prior to starting chemotherapy;

- Parent Information Journal (formally known as the “parent held record”) – with specific drug information inserts & specific side effects information inserts applicable to their Child’s treatment
- Going Home Leaflet
- Chemotherapy Leaflet
- Central Line booklet (when applicable)

7. Clinical Trials

7.1 Wherever possible, patients who are eligible should be offered the opportunity to participate in National Institute for Health Research portfolio clinical trials and other well designed studies.

7.2 Where a study is only open at one Trust in the Network, patients should be referred for trial entry. A list of studies available at each Trust is available from Pan Birmingham Cancer Research Network. Email: PBCRN@adf.bham.ac.uk .

7.3 Patients who have been recruited into a clinical trial will be followed up as defined in the protocol.

Monitoring of the Guideline

Implementation of the guidance will be considered as a topic for audit by the NSSG in xxxx/xxxx (3 years from document date).

Authors

Birmingham Children's Hospital NHS Foundation Trust (BCH) Chemotherapy Working Group – Chair Mr Nigel Ballantine (Specialist Paediatric Oncology Pharmacist)

Amalgamation of documents and cover sheet developed by Jeanette Hawkins – Lead Cancer Nurse BCH

References

N.I.C.E. Improving outcomes guidance for children & young people with cancer 2005.

Department of Health quality measures for children's cancer services (2009, 2011)

See also individual sections within the amalgamated document.

Approval Date of Network Site Specific Group Date:

Approval Date of the Governance Committee Date:

Approval Signatures

Pan Birmingham Cancer Network Governance Committee Chair

Name: Doug Wulff

Signature: Date:

Pan Birmingham Cancer Network Manager

Name: Karen Metcalf

Signature: Date:

Network Site Specific Group Clinical Chair
Name:
Signature: Date:

BIRMINGHAM CHILDREN'S HOSPITAL NHS TRUST.
HAEMATOLOGY ONCOLOGY SPECIALTY.

Policy on the prescribing and use of prophylactic and empirical antifungal therapy.

Introduction

Whilst the Specialty has had a policy on the use of empirical antifungal therapy for some years (as part of the management of febrile neutropenia) it has never adopted a policy on the use of prophylactic antifungal therapy.

This document proposes a way forward which is based on evidence presently available in the literature and which it is hoped will meet the needs and concerns of both patients and clinicians.

Background:

Current prescribing practice on the ward and amongst out-patients following bone marrow / peripheral blood stem cell transplantation (BMT/PBSCT), as well as others considered to be at high risk of fungal infection, is to give prophylactic antifungal treatment.

Patients receive either liposomal AmBisome® (L-AmB) or oral Itraconazole (I), but there are problems with the use of both these agents. L-AmB is expensive and its use appears to be based on recommendations originally issued as supplementary to the UKALL R3 protocol. There is no clear evidence base for the thrice weekly dosing regime as recommended in this document, either within patients with relapsed ALL, or more widely. It can only be administered parenterally.

Use of I does not require intravenous administration and is therefore better suited to prolonged administration. However, current practice does not include the use of blood level monitoring. The considerable inter-patient and inter-formulation variability in the biovailability of I makes such monitoring essential if therapeutic blood levels are to be ensured. Even if the cost of blood level monitoring is included, I is considerably cheaper than L-AmB at currently used doses. Bioavailability is generally better and more predictable with the liquid formulation, but many patients find this unpalatable.

Current evidence suggests that the antifungal spectra of L-Amb and Voriconazole (V) are essentially similar. There is increasingly evidence that V is more effective than L-AmB against Aspergillosis, the most life-threatening and difficult to diagnose of the fungal infections seen with any frequency at BCH. Both drugs cover > 95% of Candida species *(Kullberg BJ et al. Voriconazole versus a regimen of amphotericin B followed by fluconazole for candidaemia in non-neutropenic patients: a randomised non-inferiority trial. Lancet, 2005; 366:1435 – 1442)*. Whilst V is not active against mucormycoses, such infections occur only once every 10 years at BCH.

Patient groups:

Three patient groups are proposed, based on current practice. However, there is little evidence that such a classification is based on a true stratification of risk. These are:

- Group 1: In-patients immediately following BMT/PBSCT
- Group 2: In-patients considered to be at higher risk of fungal infection in consequence of profound and/or prolonged neutropenia.
- Group 3: Patients who remain febrile and neutropenic after 96 hours of broad spectrum intravenous antibiotics

Group 1: Patients who are post BMT/PBSCT:

These patients should receive prophylaxis with AmBisome at a dose of 1mg/kg. daily.

When continuing long-term prophylaxis is required following discharge from the HDU, Itraconazole 5mg/kg. daily, in one or two divided doses, should be substituted at the time discharge planning commences, or earlier as indicated.
Due to its relatively greater bioavailability, ALL patients should be strongly encouraged to take the LIQUID formulation.

Group 2a: Patients who are profoundly neutropenic, or likely to become so, and ARE NOT receiving chemotherapy which includes Vincristine:

These patients should receive prophylaxis with **ORAL** Voriconazole, at the appropriate dose obtained from the table below, for a maximum of FOUR weeks.

If continued long-term prophylaxis is required Itraconazole 5mg/kg. daily, in one or two divided doses, should be substituted after four weeks of Voriconazole.
Due to its relatively greater bioavailability, ALL patients should be strongly encouraged to take the LIQUID formulation.

Group 2b: Patients who are profoundly neutropenic, or likely to become so, and ARE receiving chemotherapy which includes Vincristine (e.g. UKALL R3):

These patients should receive prophylaxis with AmBisome 1mg/kg. on THREE days of each week until no further doses of Vincristine (or other Vinca alkaloids) are scheduled.

If continued long-term prophylaxis is required Itraconazole 5mg/kg. daily, in one or two divided doses, should be substituted after the last dose of Vincristine has been given.
Due to its relatively greater bioavailability, ALL patients should be strongly encouraged to take the LIQUID formulation.

Group 3: Patients who remain febrile and neutropenic after 96 hours of intravenous antibiotics and require empirical antifungal treatment:

These patients should receive prophylaxis with **ORAL** Voriconazole, at the appropriate dose obtained from the table below, until they have been apyrexial for 48 hours (according to Specialty policy).

NOTE: Whilst a parenteral preparation of Voriconazole is available its use should be restricted to those patients in whom oral dosing is inappropriate for CLINICAL reasons. Voriconazole at the recommended doses is significantly more expensive than AmBisome.

Dosage of Voriconazole:

The current dosage recommendations in the Summary of Product Characteristics (SmPC) for Voriconazole (April 2007) are set out below:

Route	Age	Dose
Oral, tablets & suspension	2 – 12 years >=12 years, < 40kg. >= 12 years, > 40kg.	200mg. bd 100mg. bd 200mg. bd
Intravenous	2 – 12 years >=12 years	7mg/kg. bd 4mg/kg. bd

Hepatic impairment:

Liposomal amphotericin: No dose modification is required in liver impairment.
Hyperbilirubinaemia has been reported with an incidence of 1% to 10%.

Voriconazole: It is recommended that the standard recommendations be followed but that the maintenance dose be halved in patients with mild to moderate hepatic cirrhosis (Child-Pugh A and B).
Serious hepatic reactions during treatment (including clinical hepatitis, cholestasis and fulminant hepatic failure) have been reported with an incidence of 0.1% to 1%. Hepatic reactions have been noted primarily in patients with serious underlying medical conditions (predominantly haematological malignancy). Transient hepatic reactions, including hepatitis and jaundice, have occurred among patients with no other identifiable risk factors. Liver dysfunction is usually reversible on discontinuation of therapy.

Itraconazole: Itraconazole is predominantly metabolised in the liver and the terminal half-life in cirrhotic patients is prolonged. A decrease in the oral bioavailability of itraconazole from capsules, which can also be expected from the liquid formulation, was also observed in these patients. Dose adjustment should be considered, directed by blood level monitoring due to the contradictory effects.
Very rare cases of serious hepatotoxicity, including some cases of fatal acute liver failure, have occurred with the use of Itraconazole. Most cases of serious hepatotoxicity have involved patients who had pre-existing liver disease, were being treated for systemic indications, had significant other medical conditions and/or were taking other hepatotoxic drugs. Since, however, some reported cases have occurred in patients with no pre-existing liver disease, and within a month of starting treatment, regular liver function monitoring should be considered. In patients with raised liver enzymes or active liver disease, or who have experienced liver toxicity with other drugs, treatment should not be started without consideration of the balance of risks and benefits.

Dosing in renal impairment:

Liposomal Amphotericin: No dose modification is required in renal impairment.
If the renal function deteriorates significantly during AmBisome therapy, consideration should be given to dose reduction or discontinuation until renal function improves. However, this should be done only to prevent further renal impairment - dose modification is not required to avoid accumulation.

Voriconazole: No dose modification is required in renal impairment.
In patients with moderate to severe renal dysfunction accumulation of the intravenous vehicle occurs. Oral voriconazole should be administered to these patients, unless a risk assessment justifies the use of the intravenous preparation. Serum creatinine levels should be closely monitored and consideration given to changing to oral therapy if increases occur.

Itraconazole: A dose increase should be considered in renal impairment due to a decrease in the oral bioavailability of Itraconazole. This has been observed with Itraconazole capsules, and can also be expected with the liquid formulation.

Drug interactions:

	Itraconazole	Voriconazole	Liposomal amphotericin
Aminoglycosides; Vancomycin			Nephrotoxicity is likely to be more common when given concurrently.
Busulfan	Itraconazole may increase the plasma levels of the Busulfan and increase the risk of toxicity.		
Carbamazepine (and phenobarbital)	Avoid due to likelihood of significant reduction in blood levels.	Contra-indicated due to likelihood of significant reduction in blood levels.	
Ciclosporin	Clearance is likely to be significantly reduced due to inhibition of CYP3A4 Cytochrome P450 isoenzyme. When itraconazole is discontinued, Ciclosporin levels must be carefully monitored and the dose increased as necessary.	Clearance is significantly reduced due to inhibition of CYP3A4 Cytochrome P450 isoenzyme. In patients established on Ciclosporin it is recommended that the Ciclosporin dose be halved and drug levels carefully monitored. When voriconazole is discontinued, Ciclosporin levels must be carefully monitored and the dose increased as necessary.	Nephrotoxicity is likely to be more common when given concurrently.
Corticosteroids; Diuretics (loop and thiazide);			Hypokalemia is likely to be more common when given concurrently.
Coumarin anticoagulants (Warfarin)	Itraconazole likely to enhance anticoagulant effects.	Voriconazole likely to enhance anticoagulant effects.	
Histamine H_2-antagonaists (Cimetidine; Ranitidine)	Absorption of Itraconazole impaired.		
Macrolide antibiotics: Azithromycin, Clarithromycin and Erythromycin	Potent inhibitors of CYP3A may increase the bioavailability of itraconazole.		

Omeprazole	Absorption of Itraconazole impaired.	No dosage adjustment of voriconazole is recommended, but manufacturer recommends that the omeprazole dose be halved.	
Phenytoin	Contra-indicated due to likelihood of significant reduction in Itraconazole blood levels.	Avoid combination is possible. Voriconazole plasma levels are reduced whilst phenytoin levels are increased	
	Itraconazole	Voriconazole	Liposomal amphotericin
Rifampicin	Contra-indicated due to likelihood of significant reduction in Itraconazole blood levels.	Contra-indicated due to likelihood of significant reduction in blood levels.	
Tacrolimus	Clearance is likely to be significantly reduced due to inhibition of CYP3A4 Cytochrome P450 isoenzyme. When itraconazole is discontinued, Tacrolimus levels must be carefully monitored and the dose increased as necessary.	Clearance is significantly reduced due to inhibition of CYP3A4 Cytochrome P450 isoenzyme. In patients established on Tacrolimus it is recommended that the Tacrolimus dose be reduced by 66% and drug levels carefully monitored. When voriconazole is discontinued, Tacrolimus levels must be carefully monitored and the dose increased as necessary.	Nephrotoxicity is likely to be more common when given concurrently.
Terfenadine	Increased plasma levels of terfenadine – risk of cardiac arrhythmias	Increased plasma levels of terfenadine – risk of cardiac arrhythmias	
Triazole antifungals (Fluconazole, Itraconazole, Voriconazole)			Effect of amphotericin possibly antagonised.
Vinca alkaloids	Itraconazole may increase the plasma levels of the vinca	Clearance is theoretically reduced due to inhibition of	

	alkaloids and increase the risk of neurotoxicity.	CYP3A4 Cytochrome P450 isoenzyme. Voriconazole may increase the plasma levels of the vinca alkaloids and increase the risk of neurotoxicity.	

Administration of Itraconazole:

The particular issues that need to be addressed in the prescribing and administration of Itraconazole are:

- The need to achieve therapeutic plasma levels.
- Wide inter-patient variability in C_{max} and AUC.
- Patients ability to take the different formulations, whether by reason of taste of the liquid or an in/ability to swallow capsules.
- The effect of food on the bioavailability of the drug.

In order to ensure that the drug is given so as to maximise absorption and the plasma levels achieved the following should be noted:

- Itraconazole should be prescribed at a dose of 5mg/kg/day, either as a single daily dose or in two divided doses.
- Wherever possible the liquid formulation should be administered. Patients should be encouraged to take it in this form because of the better absorption and bioavailability. In order to help mask the taste Itraconazole liquid may be stored in a refrigerator, and administered cold from the 'fridge.
- The liquid formulation should be given on an empty stomach, at least one hour before food.
- Itraconazole liquid should not be taken with orange juice. Grapefruit juice is acceptable.
- Patients concurrently treated with H_2-blockers, proton pump inhibitors or other drugs which raise gastric pH show a reduction of approx. 40% in C_{max} and AUC. To compensate for this effect the dose of Itraconazole should be given with cola (which raises C_{max} and AUC to levels equivalent to those seen when gastric pH is normal).
- If it impossible to get the patient to accept the liquid formulation capsules may be administered. Capsules should be given with food.
- Itraconazole is highly bound to plasma protein (99.8%). It should be given with caution when other highly protein bound drugs are given concurrently since the effect of one or more may be increased.

Drug level monitoring:

- Plasma levels should be obtained in order to confirm that therapeutic levels are achieved.
- The therapeutic plasma level of Itraconazole is > 0.5mcg/ml. in a serum sample taken immediately pre-dose (trough level).
- The first sample should be taken 7 days after starting treatment.

- Levels should be repeated 7 days after any change of dose of Itraconazole, or introduction / cessation of any drug which interacts with Itraconazole.
- Patients receiving long-term prophylaxis, and on stable treatment, should have levels repeated every four weeks.

Dr. Jim Gray, Consultant Microbiologist,
Nigel Ballantine, Lead Cancer Pharmacist
Date of implementation: January, 2006.
Date of next review: January, 2012.

BCH Blood Administration Protocol.

Insert Hyperlink to Pdf on Children's section of PBCN website.

Care of central venous access devices & management of complications

Insert Hyperlink to Pdf on Children's section of PBCN website.

Birmingham Children's Hospital NHS
NHS Foundation Trust

GUIDELINES FOR THE PREVENTION AND MANAGEMENT OF CHEMOTHERAPY AND RADIOTHERAPY INDUCED DIARRHOEA

Version:	1.0.2
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	May 2010
Name of originator/author:	Nigel Ballantine, Jeanette Hawkins
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Date issued:	8th May 2010
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Nursing, medical, pharmacy and support staff within the Haematology Oncology Specialty

1 Introduction

Diarrhoea is an increase in stool volume and liquidity, resulting in an increase in bowel movements above the patient's baseline frequency.

Chemotherapy-induced diarrhoea is a common side effect of treatment in adult cancer chemotherapy regimes, but is experienced less often in children for reasons that are not established. However, when experienced it can be debilitating and even life threatening due to fluid loss and electrolyte imbalance. The impact of severe diarrhoea should not be underestimated.[1]

Information is limited on the mechanism(s) by which cytotoxic drugs produce diarrhoea in patients, but two mechanisms by which treatment may induce this symptom are proposed. Firstly, through changes in intestinal absorption which may or may not be accompanied by excessive electrolyte and fluid secretion and, secondly, as consequence of a combination of mechanical and biochemical changes caused by chemotherapy. These intestinal functional changes are thought to be a result of direct toxicity of the chemotherapy on the colonic crypt stem cells[8]

2 Purpose

- To assist health care professionals to adequately manage differing grades of diarrhoea.
- To minimise morbidity and maximise patient quality of life while on treatment
- To reduce the need for treatment modification and chemotherapy treatment delays.
- To ensure adequate reporting of high grade toxicity to Multi-Disciplinary Team Meetings and where appropriate to Clinical Trial data managers.
- To advise on assessment tools for grading diarrhoea
- To support staff education & training for managing chemotherapy-induced diarrhoea.

N.B. New agents, monoclonal antibodies or therapies used in Phase I & II clinical trials may have potential side effects and specific monitoring requirements that are not covered in this guidance document. Staff should contact the trial principal investigator, oncology research nurses and or oncology specialist pharmacists in such instances.

3 Duties

3.1 Duties within the Organisation

The BCH Chemotherapy Working Group chaired by Nigel Ballantine (Lead Cancer Pharmacist) is responsible for reviewing this guideline bi-annually in line with the National Cancer Peer Review Programme. Updated versions will be forwarded to the Information and Quality Compliance Manager to present to the Integrated Governance Committee to be ratified.

The BCH ratified document will then be presented to the West Midlands Children's Cancer Supra-Network Group with a Pan Birmingham Cancer Network Cover Sheet for Network approval and dissemination across the West Midlands Paediatric Oncology Managed Care Network.

Nursing staff are responsible for supportive care & patient / parent education outlined in the document. They are responsible for accurate reporting and recording of information given, symptoms, assessments, care given and response to care and treatment.

Medical staff are responsible for assessing reported symptoms, treatment planning and ongoing evaluation of the treatment plan.

3.2 Identification of Stakeholders

BCH Chemotherapy Working Group
BCH Drugs & Therapeutics Committee
BCH Haematology Oncology Programme Meeting
BCH Pharmacy Department
West Midlands Children's Cancer Supra-Regional Network Co-ordinating Group

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy has been developed by the Chemotherapy Working Group after identifying a gap in guidance around this aspect of treatment toxicity while reviewing evidence for National Cancer Peer Review in 2010.

Evidence was gathered following requests for similar policies in the Pan Birmingham Cancer Network for Adult Cancers and from the Royal College of Nursing Children & Young People Cancer Nurses group – see references. A literature search was also conducted with support from the BCH Ben Wood Library

Advice was sought from the Trust Equality & Diversity Leads to establish whether there were any dietary or cleansing practices for any particular ethnic, religious, cultural groups that needed to be taken into account in developing this policy.

The policy was circulated in draft form to Consultants and Senior Nurses within the BCH Cancer Service for comment. Opinion was also sought from the BCH Gastroenterology Service and BCH Infection Control Team. Revisions were made accordingly and a final draft was circulated to the Haematology Oncology Programme Meeting and Cancer Locality Group.

A final version was presented to the BCH Integrated Governance Committee and to the Children's Cancer Network Coordinating Group hosted by Pan Birmingham Cancer Network for acceptance as a West

Midlands Children's Cancer Network Policy.

5 Content

Chemotherapy and radiotherapy-induced diarrhoea may have a dramatic impact on a patient's quality of life, physical and emotional wellbeing, and invariably increases patient costs. There may be associated abdominal pain, cramping, proctitis, and anal or peri-anal skin breakdown. These in turn can lead to weight loss, malnutrition, sleep disturbance & depression.

5.1 Chemotherapy agents associated with diarrhoea in paediatric oncology

In the literature 5-fluorouracil (5-FU), Methotrexate, Irinotecan and Taxanes (Docetaxel, Paclitaxel) are cited as commonly producing diarrhoea, although a wide range of cytotoxic drugs, including monoclonal antibodies and hormonal treatments are reported to produce this effect[3, 8]

Other medicines used in supportive care may also cause diarrhoea, including antibiotics and ciclosporin, although it should be noted that the manufacturer's Summary of Product Characteristics for almost all drugs will include diarrhoea as a potential side effect.

Cancer treatment may also cause diarrhoea indirectly:

- Infections associated with neutropenia
- Graft versus host disease of the gut following stem cell transplantation.
- Radiotherapy

5.2 Common Toxicity Criteria for Grading Diarrhoea

Most clinical trial protocols and national treatment guidelines for children's cancers provide toxicity grading charts, including diarrhoea, within the protocol or guideline. It is essential that any reported diarrhoea is assessed against the trial grading criteria and that Grade 3 - 4 toxicity is reported to the trial coordinators.

Example grading criteria (From MRC UKALL 2003[4])

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
None	2 - 3 stools a day	4 - 6 stools a day or mod. cramps	7 -9 stools a day or severe cramps	≥ 10 stools a day, bloody, parenteral support required

In the absence of a diarrhoea grading chart specific to the clinical trial or national treatment guideline the CTCAE v3.0 grading can be used – See Appendix I.

5.3 Patient / Parent / Carer Information & Education

5.3.1 Patient / carer information is central to the management of chemotherapy-induced diarrhoea, including the possible causes (infection or chemotherapy side effect) and the potential for life threatening dehydration, particularly in babies and young children.

5.3.2 Before starting chemotherapy patients and/or parents should be informed that diarrhoea may occur and what action to take should it do so. Verbal Information is supported by a section in the BCH Oncology Department Parent Held Record.

5.3.3 Patients / carers will require fluid and nutrition advice in order to maintain satisfactory hydration and nutritional status. A low residue diet with high fluid intake may be appropriate.

5.3.4 Patients / carers must be informed that children with poor fluid intake and diarrhoea must be presented to BCH or their designated Paediatric Oncology Shared Care Unit (POSCU) for assessment.

5.4 Patient / Carer advice prior to starting treatment

5.4.1 Their doctor or nurse should be informed of the onset of diarrhoea. If at home telephone BCH or the designated POSCU, on the numbers provided in the Parent Held Record, for advice.

5.4.2 Continue to monitor bowel movements and report immediately if any of the following are present;

- Fever associated with diarrhoea
- Abdominal cramps / pain / bloating (especially if receiving vinca-alkaloids as the diarrhoea may relate to constipation overflow)
- Dizziness
- Blood in faeces
- Inability to drink adequate amounts of fluid
- Low urine output, dry mouth, sunken eyes or sunken fontanel in a baby

5.5 Patient / Carer advice on management of diarrhoea

If patients experience diarrhoea they, or their parent/carer, should:

5.5.1 If at home contact BCH or their designated POSCU on the numbers provided in the Parent Held Record, so that diarrhoea can be documented and further support / information given.

5.5.2 If patient has a fever / suspected neutropenia to attend for urgent FBC, stool specimen and medical review in order to rule out infection prior to starting any anti-diarrhoeal medication.

5.5.3 **Commence dietary & hydration management.**

- Drink plenty of fluids (Clear fluids are best. Avoid milk based drinks).

- Eat small amounts of bland low fibre foods (e.g. Bananas, rice, noodles, white bread, skinned chicken, turkey or white fish) until diarrhoea resolves.
- Avoid greasy / fried foods, raw vegetables, fruit, whole grain breads & cereals, lactose containing products, caffeine, spicy foods, and gas-forming foods including beans, cabbage, broccoli or carbonated drinks until diarrhoea resolves.

5.5.4 Stop all laxatives.

5.5.5 Monitor temperature and report pyrexia.

5.5.6 Monitor diarrhoea and report immediately any increase in stool frequency, or signs of dehydration, low urine output, dry mouth, sunken eyes or, in a baby, sunken fontanel.

5.6 Pre-Chemotherapy Treatment Assessments

Accurate pre-chemotherapy assessment is essential to enable variation from the patient's baseline to be detected. The following should be recorded for all patients:

- Weight in kilograms
- FBC and biochemistry
- Usual bowel habit
- Patient's use of bowel medications, e.g. laxatives

5.7 Toxicity Management

Medical and nursing management of all patients with chemotherapy induced diarrhoea should:

5.7.1 Ensure toxicity assessment prior to each cycle of chemotherapy

5.7.2 Eliminate other potential causes of diarrhoea where possible without delaying treatment, such as:

- infection
- use of laxatives
- constipation overflow
- concurrent drugs, such as antibiotics
- progressive disease.

5.7.3 Explain likely cause of diarrhoea to patient / carer. Explain treatment plan. Provide reassurance and support. Educate regarding personal care.

5.7.4 Ensure optimum hygiene care to anal and peri-anal areas (and / or stoma site). Collaborate with tissue viability service if the patient's skin becomes excoriated particularly for babies still in nappies. Follow the Trust standard care plan for nappy care.

5.7.5 Ensure care givers wear gloves when providing personal care to prevent the risk of cross-infection.

5.7.6 Ensure anti-diarrhoea agents are given as prescribed or that carers who are self medicating understand the medicines and treatment plan.

5.7.7 Monitor and record diarrhoea & associated symptoms (report changes):

- Frequency
- Volume
- Colour
- ConsistencyPresence of fresh blood / melaena
- Change in smell
- Abdominal cramping / pain
- Rectal bleeding
- Nausea / vomiting

5.7.8 Monitor and record effects of anti-diarrhoea agents and other interventions, e.g. skin care, analgesia.

5.7.9 Observe and report signs of dehydration:

- Low urine output
- Dry mucous membranes
- Sunken eyes / fontanel, absence of tears
- Poor tissue turgor
- Negative fluid balance
- Decreased peripheral perfusion
- Deep breathing
- High urea
- Low pH
- Large base deficit

5.7.10 Observe and report signs of low sodium levels:

- Tiredness
- Disorientation
- Headache
- Muscle Cramps
- Nausea

Severely low sodium can lead to seizures or coma.
Severely low potassium can cause cardiac arrhythmias.

5.8 Grade specific management

See patients' clinical trial protocol or national treatment guideline for grading criteria (or Appendix I if no relevant protocol / guideline)

GRADE	MANAGEMENT
1	Commence loperamide (Imodium): Child 4–8 years: 1 mg 3–4 times daily for *up to 3 days only* Child 8–12 years: 2 mg 4 times daily for up to 5 days Child 12–18 years: initially 4 mg, then 2 mg after each loose stool for up to 5 days (usual dose 6–8 mg daily; max. 16 mg daily) • Commence dietary management • Report any changes / unresolved or increase in diarrhoea / pyrexia
2	As Grade 1 • Withhold chemotherapy till settled • If diarrhoea has not resolved after 24 hours, consider adding antibiotics on an individual patient basis following consultant / Microbiology advice • Report any changes / pyrexia / unresolved diarrhoea – medical review of patient – FBC / U&Es / stool culture / vital signs
3	Withhold chemotherapy • Admit – medical review - check FBC / U+Es / stool culture / vital signs • If neutropenic follow neutropenia policy • Start iv fluids (Oncology Handbook – Fluid Prescription[7]), correct electrolyte imbalance • Consider antibiotics
4	Urgent medical review • As Grade 3 + abdominal x-ray • Consider second line treatment (e.g. octreotide) according to specialist advice

5.9 Chemotherapy drug specific management – Irinotecan

5.9.1 Early diarrhoea starts during or within 24hrs of receiving Irinotecan and is cholinergic in nature. It is associated with symptoms of sweating, stomach cramps, watering eyes, blurred vision, dizziness, feeling unwell, and excessive mouth watering.

5.9.2 Experience to date suggests that early diarrhoea is not a major problem. Should treatment be necessary – of diarrhoea, or other cholinergic symptoms – atropine is recommended, and a regime can be found in the ET 2003 04 protocol.

5.9.3 Late onset diarrhoea – starts more than 24hrs after starting an Irinotecan infusion. Loperamide should be given according to the following schedule until a normal pattern of bowel movement returns. Oral rehydration should be given in addition throughout the episode of diarrhoea

>= 43kg: 4mg. after first loose stool. Subsequently 2mg. every 2 hours (2mg. every 4H at night)

30 - 43kg: 2mg. after first loose stool. Subsequently 1mg. every 2 hours (2mg. every 4H at night)

20 - 30kg: 2mg. after first loose stool. Subsequently 1mg. every 3 hours (2mg. every 4H at night)

13 - 20kg: 1mg. after first loose stool. Subsequently 1mg. every 3 hours (1mg. every 4H at night)

< 13kg: 0.5mg. after first loose stool. Subsequently 0.5mg. every 3 hours (0.5mg. every 4H at night)

If a patient needs to take Loperamide they and/or their carers should be counselled to maintain close contact with their treatment centre – BCH or POSCU – and certainly to report if the diarrhoea has not resolved within 48 hours.

5.9.4 Loperamide should not be given prophylactically, even in patients who experienced delayed diarrhoea in previous cycles.

5.9.5. Where the delayed diarrhoea is unresponsive to Loperamide, a trial of Cefixime may be appropriate. Cefixime reduces bowel colonisation by organisms that may reactivate the active metabolite of Irinotecan excreted in the bile, leading to local toxicity. The dose is 8mg/kg/day (Max: 400mg) for five days before Irinotecan and through the course – typically five days per week in two consecutive weeks.

5.10 Stem cell transplant-specific management

5.10.1 All patients presenting with diarrhoea post transplant must be reviewed by medical staff and considered for admission. Admission may require transfer to the transplant / Principal Treatment Centre, depending on severity of symptoms and / or concomitant symptoms.

5.10.2 Management for all patients with chemotherapy-induced diarrhoea in section 5.7.1.to 5.7.10 remains relevant.

5.10.3 Patients with gut GvHD may also experience presence of tissue fragments in the stool, green offensive “mincemeat” diarrhoea, nocturnal diarrhoea and co-existing upper GI symptoms.

5.10.4 Infection screen should include stool specimens for microscopy, culture & sensitivity and virology. If adenovirus is detected, send EDTA blood for adenovirus PCR testing. If *Clostridium difficile* infection is suspected, send two liquid stool specimens 48 hours apart.

Giardia & Cryptosporidium should be considered. Discuss severe cases with a microbiologist.

5.10.5 If diarrhoea is thought to be related to mucositis, Loperamide may be used until engraftment occurs, which usually resolves symptoms.

5.10.6 Patients may require biopsy, but negative biopsies can be a result of “skip” lesions. Positive gut GvHD is managed via a separate policy.

6 References

Sandwell & West Birmingham Hospitals NHS Trust (2007) Management of Chemotherapy Induced Diarrhoea (CID) Guidelines *Chemotherapy Executive Group*

University Hospitals Bristol NHS Foundation Trust (2008) Diagnosis and Management of Patients with Diarrhoea post-transplant *Stem Cell Transplant Programme*

Maloney, A. (2005) Gastrointestinal tract: Diarrhoea Ch.15 pp. 263-266 in *Tomlinson D. & Kline N. (2005) Pediatric Oncology Nursing: Advanced Clinical Handbook* Springer Berlin Heidelberg New York

Medical Research Council (2003) UKALL 2003 UK National randomised trial for children and young adults with acute lymphoblastic leukaemia (A.L.L.) Version 7 August 2009

Cancer Therapy Evaluation Program (2003) Common Terminology Criteria for Adverse Events, Version 3.0, DCTD, NCI, NIH, DHHS March 31, 2003 (http://ctep.cancer.gov), Publish Date: August 9, 2006

Arden Cancer Network (2008) Policy for the Management of Chemotherapy Induced Diarrhoea (Adults) V1

Birmingham Children’s Hospital Oncology Department (2010) Fluid Prescription Oncology Handbook P:\Oncology Department\HANDBOOKS\Specialty Handbook, 3-2010.doc

Gibson R J, Keefe D M K Cancer chemotherapy-induced diarrhoea and constipation: mechanisms of damage and prevention strategies. Support Care Cancer 2006; 14: 890 - 900

7 Equality Impact Assessment

See Appendix

8 Approval, Dissemination and Implementation

8.1 Approval of document

8.2 Dissemination

8.3 Implementation

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

9.2 Standards/Key Performance Indicators

10 Associated Documentation

Procedure for the management of body waste and clinical samples from patients receiving cytotoxic drugs

Appendix I

Common Terminology Criteria for Adverse Events v3.0 (CTCAE) March 31, 2003, Publish Date: August 9, 2006

Toxicity	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Diarrhoea (without stoma)	None	Increase of < 4 stools per day	Increase of < 4 – 6 stools/day or nocturnal stools	Increase of >7 stools/day or incontinence +/- parenteral support	Requires intensive support of haemodynamic collapse	Death
Diarrhoea (with Stoma)	None (normal emptying times)	Mild increase in loose watery output (>1 – 2)	Moderate increase in loose watery output (> 3 – 4)	Severe increase in output, interfering with normal activity	Requires intensive support of haemodynamic collapse	Death

http://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcaev3.pdf

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development	Yes	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	identified?		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Unsure	See para. 9.1.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there a plan to review or audit compliance with the document?	No	See para. 9.1.
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Individual Approval			
If you are happy to approve this document, please sign and date.			
Name		Date	
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name	DTC	Date	15-2-2011
Signature			

Appendix F – Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology Cancer Service	**Assessor: Jeanette Hawkins Lead Cancer Nurse**
Policy/ Service Title: Guidelines for the prevention and management of chemotherapy and radiotherapy-induced diarrhoea	**Date of assessment: 20th. May 2010**
1. Describe the purpose of this policy or function	• To assist health care professionals to adequately manage differing grades of diarrhoea. • To prevent death • To minimise morbidity and maximise patient quality of life while on treatment • To reduce the need for treatment modification and chemotherapy treatment delays. • To ensure adequate reporting of high grade toxicity to Multi-Disciplinary Team Meetings and where appropriate to Clinical Trial data managers. • To implement a standard assessment tool for grading diarrhoea • To support staff education & training for managing CID N.B. New agents, monoclonal antibodies or therapies used in phase 1 & 2 Clinical

	trials may have specific monitoring and potential side effects which are not covered in this Guidance document. Personnel should contact the trial principal investigator, oncology research nurses and or oncology specialist pharmacists in such instances.
2. Who is affected by this policy?	Patients referred to BCH Cancer Service for treatment
3. What are the outcomes or intended outcomes of this policy/ function?	• Safe, effective & equitable management of Chemotherapy Induced Diarrhoea • Adequate reporting mechanism particularly for patients treated within Clinical Trials
4. What consultation has been undertaken during the development of this policy/function?	The policy has been developed by the Chemotherapy Working Group after identifying a gap in guidance around this aspect of treatment toxicity while reviewing evidence for National Cancer Peer Review in 2010. Evidence was drawn from request for similar policies in the Pan Birmingham Cancer Network for Adult Cancers and from the Royal College of Nursing Children & Young People Cancer Nurses group. Two policies which are referenced provided a starting point. A literature search was also conducted with support from the BCH Ben Wood Library. Advice was sought from the Trust Equality & Diversity Leads to establish whether there were any dietary or cleansing practices for any particular ethnic, religious, cultural groups that needed to be taken into account in developing this policy. The policy was circulated in draft form to Consultants and Senior Nurses within the BCH Cancer Service for comment. Opinion was also sought from the BCH Gastroenterology Service and BCH Infection Control Team. Revisions were made accordingly and a final draft was circulated to the Haematology Oncology Programme Meeting and Cancer Locality Group. A final version was presented to the BCH Integrated Governance Committee and to the Children's Cancer Network Coordinating Group hosted by Pan Birmingham Cancer Network for acceptance as a West Midlands Children's cancer network Policy.
5. What information or evidence has been used to assess the potential impact across the equality strands?	Advice was sought from the Trust Equality & Diversity Leads to establish whether there were any dietary or cleansing practices for any particular ethnic, religious, cultural groups that needed to be taken into account in developing this policy.

IMPACT
1. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? The aim of the policy is to ensure equitable, safe and effective care is provided to all patients referred to BCH Cancer Services who experience this side effect of treatment regardless of race, ethnicity, colour, nationality or national origin.
2. Please complete the following list and identify if there is, or likely to be, an impact on a group

a) Grounds of race, ethnicity, colour, nationality or national origins.	Yes ☐ No ☐	Adverse? ☐ Provide further details:
b) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
c) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
d) Grounds of religion or belief	Yes ☐ No ☐	Adverse? ☐ Provide further details:
e) Grounds of disability	Yes ☐ ~~No~~ ☐	Adverse? N☐ Provide further details: Special consideration is given in the policy to patients with disability who may need additional support in managing chemotherapy-induced diarrhoea
f) Grounds of age	Yes ☐ ~~No~~ ☐	Adverse? N☐ Provide further details: Special consideration is given in the policy in regard to age as babies and children will require additional support in managing chemotherapy-induced diarrhoea, and children and teenagers may feel embarrassed discussing symptoms or requesting support with personal care.
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Appendix G - Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)
1.0.2	15.02.2011	Jeanette Hawkins – Lead Cancer Nurse	Changes to section 5.10 SCT infection screen section on Page 11 following recommendations by Ursula Nusgen after policy sent to D&TC for ratification.

Appendix H - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Procedure for the management of spillage of cytotoxic drugs		
Date finalised:		**Dissemination lead: Print name and contact details:** Nigel Ballantine (NB)	BCH email Ext: 8673
Previous document already being used?	**Yes / ~~No~~** (Please delete as appropriate)		
If yes, in what format and where?	Paper copies in policy files in key clinical areas within the Specialty		
Proposed action to retrieve out-of-date copies of the document:	Review of all policy files		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
HaemOnc Policy files	NB	P/E	
Trust policies	NB	E	

Extravasation Policy

Insert hyperlink to pdf in Children's section of PBCN website

Birmingham Children's Hospital NHS
NHS Foundation Trust

GUIDELINE FOR THE PREVENTION, RECOGNITION & MANAGEMENT OF CHILDREN & YOUNG PEOPLE WITH CANCER & FEVER.

Version:	3.0.3
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC)
Date ratified:	9th. September, 2010
Name of originator/author:	Dr. Jayashree Motwani/ Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Date issued:	3rd March 2011
Review date:	Document to be reviewed not less than every two years – first review not later than September, 2012
Target audience:	Medical, nursing and pharmacy staff within the Haematology Oncology Specialty

1 Introduction

Febrile neutropenia and neutropenic sepsis is a significant clinical risk for patients receiving immunosuppressive treatment, whether such treatment is treatment of their malignant disease or immunosuppression following stem cell, or other, transplantation.

A structured approach to the assessment of the patient and prompt and effective treatment are essential, and this guideline is intended to provide the basis for such an approach.

2 Purpose

These guidelines provide a basis for the prevention, prompt recognition and effective treatment and management of patients presenting with a febrile neutropenic illness.

However, in common with other such clinical guidelines they are no substitute for the regular clinical assessment of patients - a vital part of the effective management of febrile neutropenia in children & young people – and appropriate response to such assessment. In all cases, advice from senior colleagues should be sought sooner rather than later if there is any uncertainty. POSCUs must contact the patient's PTC consultant or PTC on-call consultant for advice.

This guideline covers children & young people with cancer and other non-malignant haematological disorders treated with immunosuppressive therapies. The majority of patients will have neutropenia related fever. However these guidelines are also appropriate for non-neutropenic patients where a course of parenteral antibiotics is considered necessary. It should also be noted that some patients (particularly those who are post stem cell transplant or with non-malignant immunodeficiency conditions) may have an adequate neutrophil count but still have an inefficient immune system and high risk of sepsis.

3 Duties

3.1 Duties within the Organisation

This guideline covers a range of health professionals across the haematology / oncology service and staff and departments working in partnership with the service.

Managers have a duty to ensure the guidelines are being followed.

Employees have a duty to undertake care as described in the guideline, or to consult with the consultant responsible for the patient to discuss individual variations, or with managers where practice is regularly not meeting the required standard, so that variations can be monitored.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; medical, nursing and support staff within the Haematology Oncology specialty; the Birmingham Children's Hospital Antimicrobial Prescribing Committee.

Outside BCH: The West Midlands Children's Cancer Network Group.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The guideline was drafted by Nigel Ballantine (Chair, PTC Chemotherapy Working Group and PTC Lead Cancer Pharmacist) and Dr. Jayashree Motwani (Consultant Paediatric Haematologist) following a number of discussions with consultant and other staff within both the Haematology Oncology specialty and the Microbiology department. The content was agreed at the Specialty programme meeting on 9th. September, 2010.

5 Content

5.1 Introduction

Children receiving cytotoxic drugs are at risk from infection, particularly bacterial. This risk is greatest in those children undergoing intensive treatment such as bone marrow transplantation, high dose chemotherapy with stem cell support or during leukaemia induction treatment. Where leukaemia is concerned the problems tend to be more severe in children with A.M.L than A.L.L.

5.2 Prophylactic antibiotics

- Prophylactic Cotrimoxazole (Septrin), for PCP is given to all children receiving treatment for A.L.L.

- Cotrimoxazole and antifungal agents (AmBisome/ voriconazole/ fluconazole/ itraconazole) are given to children who are expected to have a prolonged period of neutropenia. This includes patients with AML and those undergoing transplantation procedures.

- Children with Down's syndrome and A.L.L. are given prophylactic ciprofloxacin at various stages in their treatment. (see Down's Syndrome amendment of U.K.A.L.L. 2003 protocol).

- Other children are not routinely given prophylactic antibiotics, but may occasionally be prescribed these on an individual basis.

- Children with solid tumours can also become severely pancytopenic, although in general this is for a shorter period. In the majority of these

children the blood count nadir usually occurs 10 to 14 days after a course of treatment, and recovery has occurred by day 21.

ANY SUGGESTION OF INFECTION IN CHILDREN AT RISK MUST BE URGENTLY INVESTIGATED AND TREATED.

5.3 Definitions

Fever - a temperature of ≥ 38^{o}C)

Neutropenia - an absolute neutrophil count of ≤1 x 10^{9}/L.

Unwell child: Any child receiving chemotherapy who appears unwell but is not febrile or neutropenic may still need treating with antibiotics. Children with Down's syndrome are at particular risk of sepsis; they may present with non-specific symptoms and may be afebrile even when septic.

Discuss with more senior colleague or the PTC if you are not sure.

5.4 Referral

If and when a child at home becomes febrile or unwell a parent will have been advised to phone the PTC or POSCU for advice. On-Call Medical Staff must not ask parents to contact their GP without first discussing with a more senior colleague whether this is appropriate advice. All children on cancer treatment with fever must be assessed at their local POSCU or the PTC. Children with brain tumours on concurrent chemotherapy and radiotherapy must be treated at the PTC only.

Children attending the PTC at Birmingham Children's Hospital should be advised to attend the Oncology Clinic in working hours or the Emergency Department out-of-hours. Notify the department of the patients expected arrival.

Children attending one of the designated West Midlands POSCUs have direct access to assessment within the POSCU Children's ward(s). Notify the department of the patients expected arrival.

5.5 Initial review

The child will come to a POSCU ward or the PTC oncology day care unit (during working hours) or the PTC Emergency Department (out-of-hours) and be triaged as RED. Haem/Onc SHOs, called to review, should prioritise this child. Liaise with the Clinical Co-ordinators out-of-hours if they are unable to do so.

The child needs to have been assessed and receive parenteral antibiotics if appropriate within 1 hour of arrival. (NCAG National Standard)

When a child suspected of having an infection attends, take a history and do a full examination, specifically to document any history of symptoms such as diarrhoea or cough, or the presence of focal signs of infection such as skin sepsis.

Document all observations and calculate PEWS (Paediatric Early Warning Score). N.B. Although fever is not scored in PEWS it is a significant finding in immunocompromised patients. There may be rapid progression from fever to sudden deterioration in PEWS. Increase frequency of observations as necessary.

Assessment must be undertaken by a Doctor or appropriately trained Advanced Nurse Practitioner. In BCH Emergency Department and oncology clinic there are ready prepared Febrile Neutropenia admission packs containing assessment documents, blood forms etc.

If the child has any signs of haemodynamic compromise, e.g. delayed capillary refill time, tachycardia (not explained by fever), or hypotension:

i. Inform the registrar or consultant immediately.
ii. Oxygen should be administered to maintain adequate oxygen saturation.
iii. Give a fluid bolus – 20 mls/kg of 0.9% sodium chloride IV and reassess.
iv. Inform ICU (if not already aware) as soon as the first bolus has been given, using the local "Observation & Monitoring policy." Utilise PEWS information and SBAR reporting structure. (SBAR = Situation, Background, Assessment, Recommendations)
v. Review the patient with a haematology/oncology registrar grade or above and discuss subsequent management with ICU staff as appropriate.
vi. Monitor vital signs and urine output closely (half hourly to hourly depending on patient status). Urinary catheterisation may be necessary if no urine output, despite improvement in haemodynamic status. Any patient this unwell MUST be discussed with the local consultant and the first on call consultant at BCH if admitted to a shared care centre.
vii. If child **presents** with haemodynamic compromise – commence Meropenem and Gentamicin. See flowchart
viii. If child **develops** haemodynamic compromise after initial assessment and whilst receiving Piperacillin/Tazobactam and Gentamicin, change to Meropenem without waiting for cultures. This should be done as soon as the haemodynamic compromise occurs.

Intravenous antibiotics should be commenced after appropriate cultures and blood tests are taken as below:

- FBC
- Coagulation (especially if child septic and unwell)
- Group and Save if appropriate
- Chemistry, with CRP
- Blood cultures from all lumens of central lines, urine and stool cultures.

There is no need to wait for neutrophil count before starting antibiotics if the child is unwell or if blood results are taking longer than 1 hour to obtain.

If the central line will not bleed back and it appears that the child's condition warrants immediate antibiotics – DO NOT delay giving antibiotics whilst waiting for the line to be cleared with urokinase. In this situation take a blood culture from a peripheral vein and start antibiotics via cannula. If it then becomes possible to sample from the central line, send a further blood culture from the central line.

- Clearly distinguish on bottles and forms if more than one set of cultures is taken.
- Throat swab, line site swab- as appropriate.

A chest X-ray is not required on admission of all febrile neutropenic children, but should be done in any child with respiratory symptoms, e.g. cough, tachypnoea, or if the fever persists for >24 hours after admission without any obvious focus.

Lumbar punctures are not part of routine screening for febrile neutropenia. However, if you think one is indicated, e.g. if the child has neck stiffness, discuss with a consultant oncologist or haematologist and neurosurgeon for children with brain tumours. Children with neutropenia are also likely to be thrombocytopenic which increases the risks from lumbar puncture.

If a child has respiratory symptoms (upper or lower) consider whether a nasopharyngeal aspirate (NPA) should be taken.

Oral chemotherapy should be discontinued on admission. In rare circumstances e.g. during intensification blocks for leukaemia or T-cell lymphoma a consultant at the PTC may authorise the continuation of oral chemotherapy. This decision must be taken at consultant level.

If a child is clinically well and stable with no haemodynamic compromise, has no central line and has neutrophils >0.5-normal, discharge on oral antibiotics after discussion with PTC consultant may be considered.

This approach is not appropriate for children in the following categories:

- AML
- ALL not on maintainence treatment.
- Relapsed ALL
- Downs
- Transplant patients
- Patients with focal signs of infection
- Patients with previous admissions for serious bacterial or fungal infection
- Patients unwilling or unable to take oral antibiotics
- Low confidence in carer response to changes
- Challenging social circumstances

If in any doubt – admit and give parenteral antibiotics.

Isolation of *Candida* or *Staph. aureus* from a central line necessitates prompt discussion with the consultant about the need for line removal.

6 Patient / Parent Education

Patients / parents must be educated about the risks of neutropenic sepsis and how to detect and respond to signs & symptoms of fever and infection, as per page 4. Their understanding should be checked by asking them to re-iterate information. The “Going Home Chat” should be delivered by nurses who have been trained to deliver accurate information. Suitable training would be the BCH Practical Oncology Programme foundation supportive care module or similar.

Verbal information should be backed up with written information with consideration to the need for interpreters for non-English speaking / reading families.

The medical “Alert Card” for risk of neutropenic sepsis should be provided with an explanation of how to use the card, particularly if using an emergency department while on holiday / visiting other regions.

A digital thermometer is provided for use at home to assist families with monitoring for fever. A normal home life should be encouraged and parents should be counselled about not needing to do routine monitoring at home but to use the thermometer if they suspect the child is unwell or hot. Families who do not find reading the thermometer easy can be taught to put their face against the child’s to see if the child feels a lot hotter than their own skin. Families should be counselled to call the PTC or POSCU if the child has fever or is unwell and present for review even if this is during the night. Modes of transport should be discussed, along with the need to use the 999 emergency ambulance service if their child is very unwell or if the cannot get to hospital by their own means.

When discussing the prevention of infection parents should be advised about the need to balance avoiding obvious sources of infection (e.g. relatives with D&V, colds, flu) and the need to maintain normal routines (e.g. attending school when well). Refer to the West Midlands Children’s Cancer Network Schools Policy.

7 Medical “Alert Card” for risk of neutropenic sepsis

The West Midlands Children’s Cancer Network is keen to implement the NCAG recommendations on a 1hour ‘door to needle’ time for cancer patients presenting with fever and suspected neutropenia. Patients are issued with an “Alert Card” to show to Emergency Departments or Assessment units when they present with symptoms. This includes the contact details of the PTC and local POSCU and basic guidelines on initial care.

The PTC and POSCUs should implement local actions to ensure the NCAG recommendations are followed.

8 References

CCLG – PONF (2008) Treatment of low risk febrile neutropenia in paediatric oncology: a framework document *Accessed September 20, 2010* http://www.cclg.org.uk/members/wg/files/SC_FebrileNeutropeniaFrameworkGuid

BNF for children, 2010-2011:
Piperacillin with tazobactam ('Tazocin'): p.324
Meropenem: p.334
Gentamicin: p.341
Vancomycin: p.349 Vancomycin is dosed qds rather tds (as recommended in the BNFc) based on local audits, showing that tds dosing does not provide a therapeutic level of 5mg/L. in the majority of patients.

National Chemotherapy Advisory Group (August 2009) Chemotherapy services in England: Ensuring quality & safety DH Best Practice Guidance *Gateway no: 12208*

9 Equality Impact Assessment

See Appendix F

10 Approval, Dissemination and Implementation

10.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

10.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

10.3 Implementation

The guideline is currently in use within the Haematology Specialty. This document updates the current version and brings the guideline into Trust-approved format.

11 Monitoring Compliance With and the Effectiveness of the policy

11.1 Process for Monitoring Compliance and Effectiveness

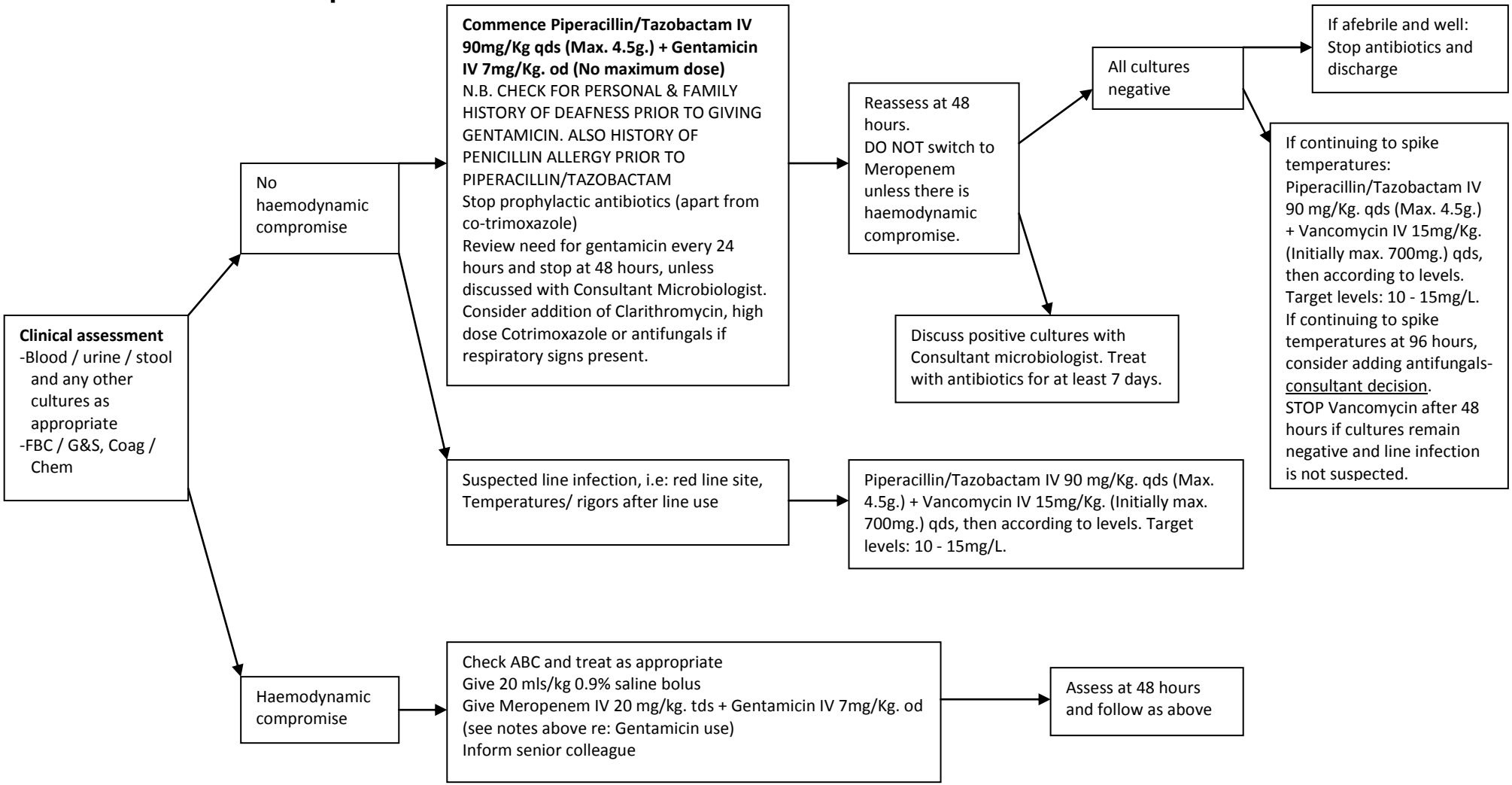
Routine audit.

11.2 Standards/Key Performance Indicators

12 Associated Documentation

Appendix I

Fever in an immunocompromised child



Appendix D - Checklist for the Review and Approval of Procedural Document
To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	N/A	
	Are key references cited?	N/A	
	Are the references cited in full?	N/A	
	Are supporting documents referenced?	N/A	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	No	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Guideline for the management of patients with malignant solid tumours / leukaemia and fever.	**Date of Assessment:** 15-9-2010

6. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and has been reviewed and brought to Trust standard as part of the peer view process for cancer services.
7. Who is affected by this policy?	Medical, nursing and pharmacy staff within the Haematology Oncology specialty at BCH.
8. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff managing patients presenting with febrile neutropenia have available a clinical guideline for effectively managing such patients. Secondarily, compliance with Children's Cancer Measures 2009.
9. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
10. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have no implications with respect to Equality Impact

IMPACT		
3. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
4. Please complete the following list and identify if there is, or likely to be, an impact on a group		
g) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
h) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
i) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
j) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
k) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
l) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Appendix G - Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)
3.0.2	3-3-2011	J. Hawkins	Minor amendment only.

Appendix H - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Guideline for the management of patients with malignant solid tumours / leukaemia and fever.		
Date finalised:		**Dissemination lead: Print name and contact details:** Nigel Ballantine (NB)	BCH email Ext: 8673
Previous document already being used?	**Yes / ~~No~~** (Please delete as appropriate)		
If yes, in what format and where?	Paper copies in Specialty handbook and policy files in key clinical areas within the Specialty. Electronic copies on the Trust intranet.		
Proposed action to retrieve out-of-date copies of the document:	Review of all policy files		

To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
HaemOnc Policy files	NB	P/E	
Trust policies	NB	E	

Birmingham Children's Hospital NHS
NHS Foundation Trust

HAEMATOLOGY AND ONCOLOGY

Guidelines for immunisation of children following treatment with

I Chemotherapy
II Stem Cell Transplant

Version:	4
Ratified by:	Chemotherapy Working Group
Date ratified:	June 2010
Name of originator/author:	Dr Sarah Lawson and Dr Helen Jenkinson
Name of responsible committee/individual:	Dr Sarah Lawson and Dr Helen Jenkinson
Date issued:	March 2009
Review date:	March 2012
Target audience:	Children's cancer Services

Method for development

Consultation and Communication with Stakeholders

Adapted from RCPCH Best Practice Statement, February 2002 and Green Book 2006 and with input from Dr Paul Carter, Immunisation Advisor Walsall PCT and Dr Mary Ramsey, Consultant Epidemiologist at Health Protection Agency, Co-editor of the Green Book

Content

Immunisation of children treated with standard chemotherapy

General Principles

Avoid **all live vaccines** in patients on active treatment and for six months following cessation of treatment. This includes MMR, BCG, oral typhoid and yellow fever vaccines.

Recommendations for Immunisation

1. During treatment and up to six months after completion of treatment

- Administration of non-live vaccines may be considered during treatment, following the universal childhood immunisation schedule as closely as possible. This depends on the child's general condition being stable and expected to stay so for approximately three weeks from immunisation.

- Influenza vaccination is recommended annually in the autumn for all patients receiving chemotherapy, and for those within six months of completion of chemotherapy. Patients require 2 doses 6 weeks apart for the first year and then one dose each Autumn thereafter.

2. *S*ix months and later after completion of treatment

- **At six months** following completion of treatment booster doses of the following immunisations are required: Diphtheria, Tetanus, Acellular pertussis, IPV, Hib (these 5 vaccines are contained within Pediacel), Men C, MMR and Pneumococcal vaccine

  It is recommended that these are administered according to the following regimen:

  1. **a) Pediacel**
     b) Pneumococcal Conjugate Vaccine (PCV, Prevenar) and
     c) MMR

  2. **Two months later:**
     a) PCV (if not already completed age appropriate PCV schedule prior to chemo) and
     b) Men C (if not given 2 months earlier)

3. **Two months later (and after second birthday)**
   Pneumovax (pneumococcal polysaccharide vaccine)

4. **Continue normal age appropriate immunisation schedule**
   (subsequent routine booster doses will not be necessary if they are due within one year of these additional immunisations)

- If the patient has previously had BCG and is considered to be in a high risk group (see Green Book for definitions of high risk groups), check tuberculin test and if negative revaccinate. If a patient has not previously had BCG, immunisation need only be given if indicated according to local policy.

3. Other specific vaccines

- Varicella Zoster – routine administration is not practiced currently in the UK. Its use however may be considered appropriate in individual patients after careful assessment of potential benefits and disadvantages. There are now two fully licensed live attenuated vaccines available in the UK. Current Green book recommendations are that two doses are needed two months apart age 13 year and over, but it is suggested current USA guidelines be followed and a second dose given to all ages. Prior to administration please ensure that a) the lymphocyte count is greater than 0.7×10^9/l, b) immunosuppressive therapy is withheld for one week prior to and one week after each dose and c) no steroids are given for the following two weeks. Cases of varicella zoster are reported after immunisation and may be treated with aciclovir.

4. Passive Immunisation

- This is applicable to all patients on active treatment or within six months of completion of therapy.

a) Passive immunisation following measles contact

Contact requires action regardless of antibody status.

Children who have significant contact (play or direct contact for more than 15 minutes) with an individual with virologically confirmed measles during the infectious period from up to five days prior to, to four days after, the onset of the rash require passive immunisation. Every effort should be made to confirm the diagnosis of measles in the index case, but this may not always be possible.

If less than 14 days from contact give either intramuscular human normal immunoglobulin (HNIG) or intravenous immunoglobulin. Protection lasts approximately four weeks.

IVIg dose: 0.4g/kg

Intramuscular human normal immunoglobulin dose:

Under one year of age	250mg
1-2 years of age	500mg
Over 2 years	750mg

NB This preparation is in limited supply and only available as detailed in the BNF (Volume 52, p. 636)

The benefit of HNIG is likely to be limited in individuals with detectable antibody and so, where an individual is known or likely to have pre-existing measles antibody, HNIG may not be required particularly where the degree of immunosuppression is less severe.

b) Passive immunisation after varicella zoster contact

For varicella antibody positive patients no action is necessary.

For varicella antibody negative patients treatment is necessary following significant contact with an individual with chicken pox or disseminated zoster (play or direct contact for more than 15 minutes) during the infectious period from two days prior to the onset of the rash, until crusting of all vesicles, or with herpes zoster* (direct contact with exposed lesions only). Treatment required includes either:

1. Oral aciclovir from 7-21 days following the initial contact.

Aciclovir dose:

Under 2 years	200mg 4 times daily
2-6 years	400mg 4 times daily
> 6 years	800mg 4 times daily

or,

2. If less than 72 hours from contact, give intramuscular zoster immunoglobulin (ZIG) or intravenous immunoglobulin. Protection lasts approximately 4 weeks.

ZIG dose:

Under 5 years	250mg
5-10 years	500mg
Over 10 years	750mg

IVIg dose: 0.4g/kg

NB ZIG is NOT available unless the contact is proven to be antibody negative

* Immunosuppressed patients with localised zoster on any part of their body should be managed as exposed zoster (as viral shedding may be greater)

II. Immunisation Schedule following Stem Cell Transplantation

All patients following stem cell transplantation will require a full re-immunisation schedule.

All Stem Cell Transplants (SCT) recipients must:

- be off all immunosuppression for 6 months (12 months for live vaccines)
- be off intravenous immunoglobulin (IVIg) for 3 months
- have no evidence of active Graft versus Host Disease (GvHD)
- have had immune reconstitution documented
- be 12 months post SCT for autografts and sibling grafts
- be 18 months post SCT for all other grafts

before re-immunisation schedule is commenced.

For patients with chronic GvHD and not on IVIg, consider non-live vaccines.

No live vaccines until:

- off all immunosuppression for at least 12 months and
- no evidence of chronic cGvHD

- **Avoid BCG** unless clear case of need and good evidence of immune recovery

- Significant **contact with measles or with VZV infection** requires passive immunisation (IVIg or aciclovir). This recommendation is applicable until 12 months post sibling/auto SCT and 18 months post other SCT and 12 months off all immunosuppression.

- **Recommendations for wounds likely to engender a risk of tetanus in children after HSCT**

  Patients suffering wounds likely to engender a risk of tetanus, and who have not been re-immunised yet, should be considered non-immune and should receive a first dose of tetanus vaccine.

  Tetanus immunoglobulin (250 – 500 units intramuscularly) should also be given, along with wound toilet and prophylactic antibiotics (intravenous benzylpenicillin or co-amoxiclav).

NB. In some patients/transplant groups immune reconstitution may be slower and

a) response to non live vaccines may be suboptimal and responses may need to be checked;
b) live vaccines should be deferred until know that there is good immune reconstitution

Table 1 details which vaccinations need to be given and when.

Table 2 details the schedule and vaccine preparations.

Table 1

Vaccine	**Sibling donor and auto SCT recipients (time from SCT)**	**Other SCT recipients (time from SCT)**	**Number of doses recommended**
1. Tetanus toxoid	12 months	18 months	3 *at monthly intervals*
2. Diphtheria toxoid	12 months	18 months	3 *at monthly intervals*
3. Pertussis ***(acellular)***	12 months	18 months	3 *at monthly intervals*
4. **Inactivated** poliovirus *(Salk)*	12 months	18 months	3 *at monthly intervals*
5. Haemophilus influenzae B	12 months	18 months	3 *at monthly intervals*
6. Meningitis C vaccine (conjugate)	12 months	18 months	2 *at monthly intervals*
7. Pneumococcus *a. Prevenar (conjugate vaccine)* *b. Pneumovax (polysaccharide vaccine)*	12 months *(conjugate vaccine (Prevenar) and then polysaccharide (Pneumovax) when* 26 months *post*	18 months *(conjugate vaccine (Prevenar) and then polysaccharide (Pneumovax) when* 32 months *post*	*3 doses of conjugate (at 0, 2 and 12 month intervals) Pneumovax – 1 dose only, not less than 2 months after last PCV*
8. MMR *(live attenuated)*	18 + 19 months	24 + 25 months	2 *(as MMR)* *NB 12 months off all immunosuppressive therapy Usually one month apart unless outbreak*
9. Influenza A	12 months	12 months	1 *(annually in winter months if recommended. Two does 6 weeks apart for first year)*

Table 2 Immunisation schedule (regardless of age)

Vaccine type	Recommended immunisation	Timing of each immunisation after SCT	
		Sib/auto SCT	Other SCT
DTaP/IPV/Hib Pneumococcal conjugate	Pediacel Prevenar	12 months	18 months
DTaP/IPV/Hib Meningitis C	#Pediacel #Meningitec, Neisvac or Menjugate	13 months	19 months
DTaP/IPV/Hib Meningitis C Pneumococcal conjugate	#Pediacel #Meningitec, Neisvac or Menjugate Prevenar	14 months	20 months
MMR	MMR II or Priorix	18 months	24 months
MMR	MMR II or Priorix	19 months	25 months
Pneumococcal conjugate*	Prevenar *	24 months	30 months
Meningitis C/Hib booster*	Menitorix*	25 months	31 months
*probably acceptable to give Menitorix one month earlier with Prevenar, though effectiveness of giving these two vaccines at same time still being researched (07/2007)			
dTaP/IPV or DtaP/IPV booster Pneumococcal polysaccharide	Repevax or Infanrix-IPV Pneumovax	26 months	32 months
Influenza A		12 months: Two doses 6 weeks apart first year then one dose each Autumn	

#Note: Pediacel is the optimum priming immunisation but if the larger diphtheria content of the first dose causes an unacceptable reaction, the second and third doses should be given as Repevax and Menitorix in place of Pediacel and MenC

6. References

Adapted from RCPCH Immunisation of the Immunocompromised Child, February 2002; The Green Book 2006

For further information please contact, BMT Unit, Dr Sarah Lawson (sarah.lawson@bch.nhs.uk) or Dr Helen Jenkinson (helen.jenkinson@bch.nhs.uk)

Birmingham Children's Hospital NHS
NHS Foundation Trust

MOUTHCARE FOR CHILDREN AND YOUNG PEOPLE WITH CANCER: EVIDENCE BASED GUIDELINES.

BCH NHS Trust from PONF CCLG guidelines

DENTAL CARE / TREATMENT

AT DIAGNOSIS: Oral & dental assessment	• Ideally by a dentist or dental hygienist linked to the cancer centre. • Any treatment required should be undertaken by a consultant or specialist paediatric dentist. • If there is not a paediatric dental unit liaising with the cancer centre there should be clear communication between the cancer centre and the routine dental provider.
DURING ONCOLOGY TREATMENT: Dental assessment every 3 – 4 months	• Ideally by a dentist linked to the cancer centre (retain registration and communication with usual dental provider). • Any treatment required should be undertaken ideally by dentist linked to the cancer centre. • If not available, then by usual dental provider with clear communication & guidance from the cancer centre.
POST TREATMENT	• By usual dental provider with clear communication & guidance from the cancer centre.

BASIC ORAL CARE

AT DIAGNOSIS & DURING TREATMENT	• Brush teeth well twice a day using fluoride toothpaste and soft toothbrush. • Whilst in-patient, oral assessment using OAG and score recorded. Frequency of assessment determined by individual need. • **OAG score >8 means increased risk of oral complications.** • Use of additional aids e.g. floss, fluoride tablets and electric toothbrushes – by recommendation of dental team only. Chlorhexidine is not recommended unless – see below. (If unable to brush teeth, clean mouth with oral sponges moistened with water or diluted chlorhexidine)

ORAL COMPLICATIONS

	PREVENTION	TREATMENT
MUCOSITIS	• Basic oral care (as above).	• Basic oral care (as above). • Appropriate pain control.
CANDIDIASIS	• Basic oral care. *Clinical decision required. If antifungal agent to be used, choose one absorbed from GI tract e.g. fluconazole, itraconazole or ketoconazole.* • Check treatment protocols. • Nystatin is not recommended.	• Basic oral care, plus *Clinical decision required about which antifungal agent to use, choose one that is absorbed from the GI tract eg fluconazole, itraconazole or ketoconazole.* • Check treatment protocols. • Nystatin is not recommended.
XEROSTOMIA	• Basic oral care	• Basic oral care. • Consider saliva stimulants/artificial saliva.

HERPES	• Basic oral care • Aciclovir is only recommended as a preventative strategy for herpes simplex in patients undergoing high dose chemotherapy with stem cell transplant / BMT	• Basic oral care, plus Mild and/or non progressive lip lesions: topical aciclovir. Moderate/severe and/or progressive lip lesions & for Mild/Moderate oral lesions: oral aciclovir. Severe oral lesions or if oral cannot be tolerated: IV aciclovir. (*for doses see BNF – Children*)

Guideline for the management of chemotherapy induced nausea & vomiting

Insert hyperlink to pdf in children's section of PBCN website.

Birmingham Children's Hospital NHS
NHS Foundation Trust

GUIDELINE FOR THE ADMINISTRATION OF NEBULISED PENTAMIDINE WITHIN THE HAEMATOLOGY ONCOLOGY SPECIALTY

Version:	1.0.2
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Date issued:	June 2010
Review date:	Document to be reviewed every three years – first review not later than March, 2013
Target audience:	Medical, nursing and pharmacy staff within the Haematology Oncology Specialty

1 Introduction

This guideline provides information, particularly to nursing staff, on the administration of Pentamidine by nebuliser.
It should not be considered prescriptive. A number of issues will need to considered and addressed when administering Pentamidine by nebuliser and nursing and other staff will need to apply the information within this guideline to the individual clinical situation in order to provide the most appropriate and effective care to the patient and support to parents, carers and other staff.

2 Purpose

This guideline addresses key issues with respect to the administration of Pentamidine by nebuliser. It seeks to provide information that avoids some of the myths that are prevalent with respect to the administration of this drug, and provides the basis for a balanced appraisal of risk in the individual clinical situation whilst ensuring the best quality of care for the patient.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

5.1. Teratogenicity:

Concern with regard to teratogenicity arises from the fact that many anti-infective agents interfere with the duplication or expression of genetic material within the infecting organism, and may also do so in the host.

Pentamidine has been available for many years and was first marketed at a time when carcinogenicity, mutagenicity and teratogenicity were not systematically studied prior to marketing. However, in this respect pentamidine is no different from many other drugs. Whilst it is known that Pentamidine is able to inhibit the enzyme dihydrofolate reductase – with consequent effects on purine and pyrimidine synthesis - there is presently no evidence of adverse effects on the foetus in pregnancy, and this is supported by in vitro studies which similarly show a lack of, or only a very weak, positive response to the tests carried out. Whilst the manufacturer notes a single case of a miscarriage during the first trimester of pregnancy in the SmPC there are a number of documented cases of patients with AIDS who have been given prophylactic nebulised pentadimidine and have given birth to normal, healthy babies.

However, it should be acknowledged that there is some evidence of miscarriage and bone defects in rabbits.

Conclusion: There is presently no evidence that nebulised pentamidine has adverse effects on the foetus during pregnancy in the clinical situation, either in respect to the treated patient, or staff who experience occupational exposure.

5.2. Acute occupational exposure:

Cough, bronchospasm, a metallic taste and nausea are well-recognised acute effects of nebulised pentamidine. There are reports in the literature of nursing staff experiencing ocular irritation, peri-oral and peri-nasal paraesthesiae and numbness, and bronchospasm. All such effects resolved on avoiding further exposure.

It is impossible to prevent contamination of the surrounding environment when drugs are nebulised. However, calculations of occupational exposure suggest that nurses and carers are likely to receive a dose 10,000 times less than that administered to patients. Nevertheless, strategies need to be adopted which will minimise the occupational exposure of nurses and carers.

These will include:

- Pre-medication of the patient with salbutamol, either from a metered-dose inhaler or by nebuliser, to minimise the risk of coughing.

- Use of the most appropriate mouthpiece or mask according to the age of the child and their ability to comply with treatment.

- The solution containing the required dosage should be administered by inhalation using a suitable nebuliser such as a

Respirgard II (trade mark of Marquest Medical Products inc.), modified Acorn system 22 (trade mark of Medic-Aid) or an equivalent device with either a compressor or piped oxygen at a flow rate of 6 to 10 litres/minute. The optimal particle size for alveolar deposition is between 1 and 2 microns and any alternative nebuliser should be capable of delivering a droplet size of < 2µm.

- Wherever possible a well fitted one way system should be employed such that the nebuliser stores the aerosolised drug during exhalations and disperses exhaled pentamidine into a reservoir. A filter should be fitted to the exhaust line to reduce atmospheric pollution. However, it is appreciated that the treatment of young children who are not familiar with a nebuliser will commonly make it impossible to prevent loss of nebulised solution into the room air.

- Whenever possible it is advisable to administer Pentamidine in a well-ventilated room and use a suitable exhaust tube which vents directly through a window to the external atmosphere. A suitable system has been described by Montgomery et al (Lancet 1987;August 29:480-483). However, it is appreciated that this will not always be possible given the constraints on the type of rooms available.

- Staff and carers should minimise the amount of time spent with the patient while drug is being nebulised. Those with a history of asthma or upper airway disease should avoid being in the room whilst Pentamidine is administered.

Conclusion: Acute reactions may occur in health workers and carers exposed to atmospheric pentamidine during nebulised treatment. The risk can be minimised using the strategies above. Systemic toxicity is extremely unlikely.

5.3. Transmission of pulmonary infection:

Concern in this respect has arisen because most patients treated with nebulised pentamidine are suffering from AIDS, and may be infected with organisms in addition to *Pneumocystis jirovecii (*formerly *Pneumocystis carinii)*. The coughing induced by nebulised Pentamidine may cause infected sputum to be expelled into the atmosphere. Particular concern has been raised with regard to risk of transmission of TB.

Given the nature of our patients, multiple pulmonary infections will be very uncommon. There may be a risk of transmission of Pneumocystis pneumonia (PCP) where patients are receiving active treatment.

Recommendation: In cases when it is necessary for staff and/or carers to remain with the patient whilst Pentamidine is being nebulised advice should be sought from Infection Control. They will advise as to the protective measures that are most appropriate to the patient's clinical status. This is NOT necessary if the Pentamidine treatment is prophylactic.

6 References

Beach JR, Campbell M and Andrews DJ. Exposure of health care workers to Pentamidine isethionate. Occup. Med. 1999; 48(4): 243 – 245

Montgomery AB, Corkery KJ, Brunette ER et al. Occupational exposure to aerosolized Pentamidine. Chest 1990; 98: 386 - 388

Pentamidine. COSHH guidance for managers in the NHS. British Occupational Hygiene Society. June 2006.

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Records kept by nursing and medical managers.

9.2 Standards/Key Performance Indicators

- All staff feel that their concerns have been addressed
- No staff feel pressured into making a particular decision
- All staff feel comfortable with the decision arrived at

10 Associated Documentation None

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	N/A	
	Are key references cited?	N/A	
	Are the references cited in full?	N/A	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	No	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Individual Approval			
If you are happy to approve this document, please sign and date.			
Name		Date	
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name		Date	
Signature			

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Guideline for the administration of nebulised Pentamidine within the Haematology Oncology specialty	**Date of Assessment:** 10-5-2010

11. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.
12. Who is affected by this policy?	Medical, nursing and pharmacy staff within the Haematology Oncology specialty at BCH.
13. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff who have concerns about handling chemotherapy whilst pregnant or breastfeeding are supported in their decision as to whether or not to continue doing so, and that such decisions are reached with due consideration of the needs of both the staff concerned and the service. Secondarily, Compliance with Children's Cancer Measures 2009.
14. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
15. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have no implications with respect to Equality Impact

IMPACT		
5. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
6. Please complete the following list and identify if there is, or likely to be, an impact on a group		
m) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
n) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
o) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
p) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
q) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
r) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Appendix G - Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)

Appendix H - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Guideline for the administration of nebulised Pentamidine within the Haematology Oncology specialty		
Date finalised:		**Dissemination lead: Print name and contact details:** Nigel Ballantine (NB)	BCH email Ext: 8673
Previous document already being used?	**Yes / ~~No~~** (Please delete as appropriate)		
If yes, in what format and where?	Paper copies in policy files in key clinical areas within the Specialty		
Proposed action to retrieve out-of-date copies of the document:	Review of all policy files		

To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
HaemOnc Policy files	NB	P/E	
Trust policies	NB	E	

Anaphylaxis Guidelines

Guidelines for the management of anaphylaxis. http://www.resus.org.uk/pages/reaction.pdf

1. Telephone enquiry from parent of child / Y.P. with malignancy or similar haematological condition e.g. Aplastic Anaemia, post Stem Cell Transplant

2. Record (On a case notes continuation sheet);
- **Date & Time**
- **Name of person making the call and relationship to patient**
- **Patients Name & Hospital Number if Known or Date of Birth**
- **Contact Number in case you need to call back**

3. Enquiry not related to a current health concern, e.g. not sure when next appointment is – provide advice if you are able or ask caller to call back to Oncology Clinic on 9282 during working hours

4. Problem relates to a current health concern – establish the following;
What is caller's main concern? Ask questions about the following
- Need for emergency care. ABC Airway, Breathing, Circulation, Disability (AVPU)
  - Alert
  - Responds to Voice
  - Responds to Pain
  - Unconscious (or Fitting)
- Diagnosis
- Last Chemotherapy / Radiotherapy / Transplant date
- Neutrophil Count if known or other known immune dysfunction
- Fever – does child have a central line or port. When was it last flushed – recent flush & fever linked to infection incidence
- Bleeding
- Pain
- Diarrhoea or vomiting
- Last passed urine or wet nappy
- Able to eat & drink
- How does patient look / feel / level of interaction & play compared to normal

5. Advise carer to call for an ambulance if problems with ABC or AVPU
If carer states they only want to come to BCH, tell carer they can ask ambulance crew but crew have rules to take patient to nearest E.D. for their immediate safety. They can request transfer later once child is stable.

6. Fever of >38°C. Child must be reviewed.

7.
BCH Patient (does not have established POSCU arrangement)– Advise carer to take child to **BCH E.D.** Notify Hospital @ Night Team Coordinator & E.D.

Patient has an established arrangement with a Paediatric Oncology Shared Care Unit (POSCU) – Advise carer to take child to POSCU for review & notify POSCU. Patients have a right to "choice" & can request to come to BCH if bed available.

8. Mild Fever <38°C

9. Monitor temperature & general condition. Call back at anytime if the child's condition worsens or if any of the problems in box 4 & 6 arise. Consider a follow-up call back to family.

10. Bleeding / bruising

11. Advise carer to apply pressure to try to stop bleeding. May require a follow up phone call to monitor outcome.
Establish location of bleeding & severity.
Is blood count known (look if recent FBC available on ICE).
Recent chemo, dose increases & date of Transplant considered.

Bleeding won't stop after applied pressure - Attend BCH or POSCU as per box 7.
Thrombocytopenia known or presumed to be low – Attend BCH or POSCU as per box 7.
Haematemesis, rectal bleeding or blood in urine needs review – Attend BCH or POSCU as per box 7.
If bleeding stops but took a while, e.g. prolongued nose bleed suggest getting FBC done next day, either in Oncology clinic, POSCU or community Nurse
New bruising / petechiae – Can be dealt with in working hours

Brain Tumour Patients – keep platelets above 30

12. Pain

13. If possible establish cause / characteristics of pain – OLDCART

i. Onset
ii. Location
iii. Duration
iv. Characteristics – Stabbing, aching, pulsating, throbbing
v. Aggressiveness – How bad is it?
vi. Relieving Factors – have they tried anything, does it help?
vii. Temporal – Timing, chronology, sequence, timing patterns?

Is the pain in isolation of anything else or are there other symptoms. **Some pain needs to be reviewed at a hospital as per box 7 if unsure refer to medical staff in Hospital @ Night Team**

Common causes of pain in oncology;
Palliative Care / Symptom Control related – Refer to Macmillan On-Call Team via switchboard

Headache – in the absence of any other symptoms advise paracetamol 4-6 hourly maximum 4 doses in 24hrs, but consider possibility of masking fever – refer to Dr. if unsure. Advise carers to call again at any time if the child's condition worsens & any of the problems in box 4 arise. If other symptoms present consider need for review. Establish if patient has had a lumbar puncture in last 48hrs. **Refer to Consultant on-call if patient has Brain Tumour and you are unsure. For post Transplant patients, do not advise paracetamol until patient has been reviewed and platelet count known.**

Chemo induced Sore Mouth – Use OLDCART system to establish severity. Most can be managed over night with paracetamol and review in working hours next day by phone or visit. Question carer about fever. **Needs review during night if patient not drinking for significant period of time (consider age of child) or if patient not swallowing own saliva.**

Worsening episode of a chronic or established pain problem – In the absence of new symptoms other than increased pain – refer call to Hospital @ Night Medical Team for medicine review. If other symptoms present consider need for hospital review either during night or next day via Oncology Clinic / Ward 15 weekends or POSCU

14. Diarrhoea, Vomiting, Nausea

15. Establish details (Use OLDCART to guide). Consider degree of fluid loss and age of child, signs of dehydration & low urine output, and presence or absence of other symptoms. Do other family members have symptoms? **Decision on need for review out-of-hours based on severity, presence of other symptoms, age, possible cause** (Common 'tummy bugs' can be managed at home if no compounding problems)

Post Chemo related nausea – discuss usual antiemetic regime and what carer has available at home. Use antiemetic policy to advise on re-starting or stepping up anti-emetics.
Children with Brain Tumours – assess for signs of cerebral irritation. Review platelet count if vomiting severe – risk of cerebral bleed.
Post Transplant – consider Gastro-intestinal Graft versus Host Disease & severity of symptoms when deciding whether to review during night or next day.

16. Other concerns

17.
Medication queries – Refer non-urgent queries to working hours. Urgent queries, e.g. possible overdose of medication at home – take details, discuss with consultant on-call and act on their advice. Discuss need to contact pharmacist on-call with Consultant on-call.

Carers of newly diagnosed or recently transplanted children / Y.P. wanting to know if something is normal – refer to Nurse in Charge on ward 15 if you are unable to answer query.

Carer just concerned about child but can't articulate it – Give carer option of bringing child for review

Contact with infectious diseases / rash – Contact with CPox / measles issues can be dealt with next working day. Leave message and patient details for day staff. Rash is difficult to manage over the phone and should be considered alongside other signs and symptoms. Discuss with medical staff if unsure.

Naso-gastric tube problems – refer to nurse in charge on ward 15 if you are unable to answer query. Tubes can always be removed and re-passed in normal working hours.

Central Line problems:
Clamp found undone – re-clamp, no need to attend for line flush.
Line fallen out – apply pressure (exit site rarely bleeds much). If removal happened in a traumatic way and carers think that line may have snapped off – child should attend for X-Ray to check no section of line remains in situ.
Line split or has hole – apply clamps above the trauma (supplied by hospital when line inserted). If no clamp available use string or strong thread. Attend for line repair first thing next morning.

18. Request for advice from Local Paediatric Oncology Shared Care Unit, Community Nurse or GP

19. Utilise this algorithm to provide advice on any items covered so far.

Condition of BCH Oncology / Leukaemia patient deteriorating in a Shared Care Unit → Refer to Consultant on-call & inform Clinical Co-ordinator of outcome of discussions.

RECORD ALL INFORMATION & DECISIONS TAKEN – amalgamate record with case notes at earliest opportunity – ward clerk folder for filing

If child is attending for review the call record should be taken / 'podded' to the receiving area for continuation of record.

Who can give advice – details in the Cancer Service Operational Policy

*Chemo trained nurse – Nurse who has completed the Practical Paediatric Oncology Programme – supportive care & cytotoxic therapy modules or approved equivalent.
A Doctor working within Haematology Oncology, or who is on the Hospital at Night rota and will have received Haem Onc induction training.

Birmingham Children's Hospital NHS
NHS Foundation Trust

GUIDELINE FOR THE MANAGEMENT OF TUMOUR LYSIS SYNDROME.

Version:	1.0.1
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC)
Date ratified:	Chemotherapy Working Group Approved June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Medical, nursing and pharmacy staff within the Haematology Oncology Specialty

1 Introduction

Tumour Lysis Syndrome is the triad of hyperuricaemia, hyperkalaemia, and hyperphosphataemia, that occurs when dying malignant cells release purines, potassium and phosphate into the circulation faster than they can be excreted by the kidney. Unless precautions are taken uric acid or phosphate salts will deposit in the renal tubules resulting in reduced renal function. A domino effect occurs in the remaining nephrons and patients may rapidly enter established anuric renal failure.

Tumour lysis syndrome is common in the haematological malignancies of childhood. Around one in five children with acute leukaemia or non-Hodgkin's lymphoma will develop the condition. Fortunately most can be managed medically without the need for dialysis. The condition also rarely occurs in small children with bulky stage 4S neuroblastoma or hepatoblastoma. The risk of tumour lysis syndrome depends mainly on the extent of the tumour burden, and to a lesser extent the rapidity with which the malignant cells both divide and respond to treatment.

2 Purpose

This guideline provides an outline for the management of patients at risk of tumour lysis syndrome. As with all such guidelines the recommendations below are no substitute for appropriate assessment of the patient, and response to that assessment. In all cases, advice from senior colleagues should be sought sooner rather than later if there is any uncertainty.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy

(HoC) and Lead Cancer Clinician (LCC).

5 Content

Three risk groups can be identified from the following pre-treatment factors:

	Low	Medium	High
Renal function	Normal renal function	High 'normal' serum creatinine	Pre-existing renal impairment
WCC (X 10^9/l)	<50	50 to 100	> 100
Lymphadenopathy	Minimal lymphadenopathy	Significant lymphadenopathy	Massive lymphadenopathy or malignant effusions
Hepatosplenomegaly	None	Mild (2-3 cm)	Major
Serum Urate	low	<0.45 mmol/l	> 0.45 mmol/l
Other			L3 ALL (Burkitt's leukaemia) Rising creatinine and or phosphate

The consultant on-call will advise on the most appropriate risk group for a particular patient

Low Risk

- Give Allopurinol 100 mg/m^2 three times per day by mouth (Round up to nearest 50 mg, maximum single dose 200 mg). Continue for 5 days.

- Dextrose Saline (usually Sodium chloride 0.45% / Dextrose 5% Dextrose) by IV infusion at not less than 2,000 ml/m^2/24 hours for at least 48 hours. **No added potassium unless specifically directed by consultant.**

- Monitor fluid balance - weight patient twice daily.

- Monitor U&Es, creatinine, Ca & PO_4 12 hourly for at least the first 24 hours after treatment starts, then daily until IV hydration stops.

Medium Risk

- Give Allopurinol 100 mg/m^2 three times per day by mouth (Round up to nearest 50 mg, maximum single dose 200 mg). Continue for 5 days.

- If risk status increases (see above) then change to Rasburicase (Fasturtec® – urate oxidase) – see below for dose.

- Dextrose Saline (usually Sodium chloride 0.45% / Dextrose 5% Dextrose) by IV infusion at not less than 3,000 ml/m^2/24 hours for at least 48 hours. **No added potassium unless specifically directed by consultant.**

- Observe strict fluid balance. Allow insensible losses of 300 - 500 ml /m^2 /24 hours depending on presence or absence of pyrexia. If urine output falls give furosemide - inform consultant if there is no response within 1 hour. Fluid challenge and / or higher dose may be required. Weigh patient twice daily.

- Monitor U&Es, creatinine, Ca & PO_4 6 hourly for at least 48 hours. Reduce to 8 hourly, then 12 hourly and then daily in consultation with the consultant in charge.

High Risk

- Inform on-call consultant paediatric nephrologist and consultant paediatric intensivist.

- Rasburicase (Fasturtec® – urate oxidase) 0.2mg/kg. IV once daily. Infuse in 50ml. Sodium chloride 0.9% over 30 min.

- **Caution: Risk of anaphylaxis, draw up adrenaline prior to first dose, administer with doctor present. Risk increased with history of atopy.**

- **Caution: Risk of red cell lysis in G6-P deficiency. Exclude in patients of Asian, Mediterranean or Afro-Caribbean ethnic origin.**

- Dextrose Saline (usually Sodium chloride 0.45% / Dextrose 5% Dextrose) by IV infusion at not less than 3,000 – 4,000ml/m^2/24 hours until directed to stop by consultant. **No added potassium unless specifically directed by consultant.**

- Observe strict fluid balance. Allow insensible losses of 300 - 500 ml /m^2 /24 hours depending on presence or absence of pyrexia. If urine output falls then give furosemide. If necessary this can be by infusion using a sliding scale. Inform consultant if there is no response within 1 hour. Fluid challenge and / or higher dose may be required. Weigh patient twice daily.

- Monitor U&Es, creatinine, Ca & PO_4 6 hourly for at least 48 hours. Reduce to 8 hourly, then 12 hourly and then daily in consultation with the consultant in charge.
- A rising creatinine and phosphate together with a falling calcium and urine output are indications that dialysis or haemofiltration may be required. Inform consultant **immediately** if this occurs.

- The tables – see Appendix I – should be completed for all patients with a medium or high risk of tumour lysis syndrome. Once renal function has returned to normal they should be filed in chronological order in the narrative section of the case notes.

6 References

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Routine audit of clinical areas.

9.2 Standards/Key Performance Indicators

10 Associated Documentation

Appendix I

Surname:_____ Forename:_____ D.O.B. _ _ / _ _ / _ _

Hosp No:_____ Weight: _ _ _._ Kg Surface area: _ _._ m^2

Date/ Time	Sampling frequency (hours)	Weight	Minimum hourly IV rate	Minimum hourly urine volume*	Signature

- Minimum hourly urine volume equals hourly infusion rate – (13 X S.A.)

Surname:_____Forename:_____D.O.B. _ _ / _ _ / _ _

Hosp No:_____Weight: _ _ _._ Kg Surface area: _ _._ m^2
Uric acid at diagnosis: _ _ _ mmol/l

Date	Time	Hb	WCC	Plat	Na	K	Creat	Ca corrected	PO_4	Urate

Note on the measurement of uric acid: Measurement may be affected by both allopurinol and rasburicase (urate oxidase). Repeat measurement is only necessary if requested by consultant.

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	No	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Guideline for the management of tumour lysis syndrome.	**Date of Assessment:** 10-5-2010
16. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.

17. Who is affected by this policy?	Medical, nursing and pharmacy staff within the Haematology Oncology specialty at BCH.
18. What are the outcomes or intended outcomes of this policy/ function?	This guideline will ensure that patients who are at risk of developing tumour lysis syndrome and/or who develop tumour lysis syndrome are appropriately managed. Secondarily, compliance with Children's Cancer Measures 2009.
19. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
20. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have no implications with respect to Equality Impact

IMPACT		
7. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
8. Please complete the following list and identify if there is, or likely to be, an impact on a group		
s) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
t) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
u) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
v) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
w) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
x) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Appendix G - Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)

Appendix H - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Guideline for the management of tumour lysis syndrome.		
Date finalised:		**Dissemination lead: Print name and contact details:** Nigel Ballantine (NB)	BCH email Ext: 8673
Previous document already being used?	**Yes / ~~No~~** (Please delete as appropriate)		
If yes, in what format and where?	Paper copies in policy files in key clinical areas within the Specialty		
Proposed action to retrieve out-of-date copies of the document:	Review of all policy files		

To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
HaemOnc Policy files	NB	P/E	
Trust policies	NB	E	

Birmingham Children's Hospital NHS
NHS Foundation Trust

GUIDELINES FOR THE ADMINISTRATION OF CHEMOTHERAPY FOR MALIGNANT DISEASE

Version:	1.1.1
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than July, 2012
Target audience:	Nursing, medical and support staff within the Haematology Oncology Specialty The document may also be used as a Good Practice Guideline for all BCH staff involved in the administration of cytotoxic therapies to children & young people with non-malignant conditions

1 Introduction

This Policy outlines the staff who are authorised to administer chemotherapy and other anti-cancer treatments, the area's designated for the administration of anti-cancer treatments and training required. Pre-treatment checks and potential reasons for not proceeding with treatment are also covered. The policy covers administration via a variety of routes.

2 Purpose

- To support safe and effective practice with the administration of anti-cancer drugs
- To outline a consistent approach to care.
- To fulfil criteria for Chemotherapy related policies in DH Quality Measures for Children's Cancer Services (2009).

3 Duties

3.1 Duties within the Organisation

The BCH Chemotherapy Working Group Chaired by Nigel Ballantine is responsible for reviewing this guideline annually in line with the National Cancer Peer Review Programme. Updated versions will be forwarded to the Information and Quality Compliance Manager to present to the Integrated Governance Committee to be ratified.

The BCH ratified document will then be presented to the West Midlands Children's Cancer Supra-Network Group with a Pan Birmingham Cancer Network Cover Sheet for Network approval and dissemination across the West Midlands Paediatric Oncology Managed Care Network.

3.2 Identification of Stakeholders

BCH Chemotherapy Working Group
BCH Drugs & Therapeutics Committee
BCH Haematology Oncology Programme Meeting
BCH Pharmacy Department
West Midlands Children's Cancer Supra-Regional Network Co-ordinating Group

4 Method for development

4.1 Consultation and Communication with Stakeholders

This policy has been adapted from the Pan Birmingham Cancer Network Policy on the Administration of Anti-cancer Treatment (Adults) by the BCH Chemotherapy Working Group for application to practice in Paediatrics.

Consultation is with the groups identified in 3.2. Any necessary amendments will be identified in the Version log.

5. Guideline Statements

5.1 Staff Authorised to Administer Cytotoxic Drugs

Only specialist Haematology-Oncology nurses who have been assessed as competent by completing the Children's Cancer Network

Co-ordinating Group approved training programme (as per DH Quality Measure 09-7B-149 & 09-7A-134) may administer cytotoxic drugs orally, or by the subcutaneous, intravenous (bolus and infusion) and intramuscular routes.

There are three exceptions to this requirement:

- There is a list of exemptions in the DH Quality Measures for Children's Cancer Services (2009) which cover staff who were trained prior to the publication of the Measures.
- Staff who are not authorised on the list above, as defined in DH quality measure 09-7B-147, may administer chemotherapy but only as part of their training according to the Children's Cancer Network Co-ordinating Group approved training programme, and in the presence of authorised staff.
- Administration of intra-arterial Melphalan in the treatment of retinoblastoma by an appropriately trained consultant paediatric oncologist.

The names of staff who have completed competency based training are kept on a current register of competent staff by the BCH Lead Chemotherapy Trainer.

Medical staff are not routinely required to administer intravenous chemotherapy (with the exception noted above), but may do so having received the same training and competency assessment as nursing staff, or be covered by the exemptions in the DH Quality Measures (2009). This may be covered by the "Low Risk" Chemotherapy Training for one specific drug group e.g. the administration of intravenous bolus vinca-alkaloids.

Only medical staff assessed as competent to do so according to the relevant Trust policy, and whose names appear in the current register of competent staff, may administer intrathecal chemotherapy (see separate policy).

5.2 Designated areas for administration of chemotherapeutic agents

In-patient chemotherapy is delivered on Ward 15 (incorporating the Haematology Oncology HDU and the Teenage Cancer Trust Unit (TCT)).

In addition chemotherapy may be administered on:
Ward 10 for patients whose neurosurgical care dictates this is their best place of care, or
PICU for patients requiring ICU care. or
Operating theatres for patients:

- receiving intrathecal methotrexate (where the administration cannot be carried out in the out-patient clinic theatre without the need for an additional anaesthetic), or

- patients receiving intra-arterial Melphalan. For these patients the interventional radiology suite may also be used.

If there is a clinical need to administer chemotherapy in any other area due to exceptional circumstances (e.g. surgical needs for care on a surgical specialist ward) there must be a discussion with the appropriate clinical teams which should include the Chemotherapy Lead Clinician or Pharmacist & IV / Chemotherapy Nursing Team. Consideration should be given to whether the patient could be transferred temporarily to Oncology Day Care for their treatment.

For treatment that would normally be delivered in Oncology Day Care, e.g. in-patients with febrile neutropenia who are deemed fit for routine Vincristine, patients should be temporarily transferred to Oncology Day Care for treatment unless there are exceptional circumstances as set out above.

Intrathecal chemotherapy will only be given in areas specified in the current version of the BCH Intrathecal Chemotherapy Policy.

Out-Patient Chemotherapy is administered in the Oncology Clinic in the following specified rooms;

- Treatment Rooms
- Day Care Beds
- Isolation Cubicle
- Consulting Rooms that have been allocated as over-flow isolation rooms due to demand on the day by the nurse in charge
- Clinic Theatre (N.B. Intrathecal Drugs only as per the Intrathecal Chemotherapy Policy)

Out-patient Chemotherapy for patients in Phase I,II or III clinical trials may also be administered in the Wellcome Clinical Research Facility in the following rooms;

- Treatment Rooms
- Isolation / Consulting Rooms designated on the day by the nurse-in-charge
- Day Care Beds
- Ward 15 (for out-patient treatment out-of-hours, e.g. patients due out-patient treatment at the weekend)

Whenever possible, administration should occur during standard working hours, which are defined as 8.00am to 5.30pm, Monday to Friday, excluding Bank and Statutory holidays.

Chemotherapy items to be administered in non-designated locations, with the exception or oral chemotherapy, will be delivered and stored

on Ward 15 until required. Note: The requirements for the storage of items for intrathecal administration are set out in the relevant policy.

Designated areas will have all relevant policy and protocol documents available

All areas in which chemotherapy drugs are administered must have the following equipment available and routinely checked, where appropriate, to ensure suitability (e.g. within expiry date) and function. Where administration is to take place in a non-designated area any items on the list below that are not routinely available must be provided before administration may proceed:

- Emergency bell/telephone
- Resuscitation equipment
- Drugs for the management of emergencies – cardiac arrest and anaphylaxis
- Extravasation kit
- Cytotoxic spillage kit
- Access to running water
- Disposal equipment e.g. appropriate sharps bins
- Copies of relevant policies and procedures

5.3 Staff training in checking and administering of anticancer drugs

Staff administering anti-cancer treatment must have completed the West Midlands Children's Cancer Network Coordinating Group approved competency based training programme (as per 5.2 above) or be covered by the exceptions for the administration of anti-cancer drugs and work within professional and local guidelines and protocols for the checking and administration of both the prescription and the drugs.

As per the DH Quality Measure for Children's Cancer Services (2009) (09-7B-141) treatment records should be held for each individual patient fulfilling the following minimum criteria including:

- Patient's identification
- Weight, height, surface area
- Cancer type
- Regimen and doses (including all cytotoxic chemotherapy drugs to be used and elective essential supportive drugs other than antiemetics); trial name or number if applicable
- Route of administration (oral, IV, IV Infusion, IM, SC)
- Number of cycles intended
- Frequency of cycles and of administration within a cycle
- Investigation necessary prior to starting the whole course
- Investigation to be performed serially during the course (to detect / monitor both toxicity & response) and their intended frequency
- Planned attendances managed by agreed non-medical staff, for example, nurse-led attendances

- Site of administration (PTC, POSCU, Community)

N.B. The DH Quality Measures for Children's Cancer Services provides the following definitions of treatment duration:

> A course – a complete period of treatment. E.g. UKALL 2003 would be described as a course of treatment.
> A cycle – Drugs, either singly or in combination, given as in a repeated pattern. E.g. 12 week maintenance cycles within UKALL 2003
> An administration – the separate occasions when drugs are given within a cycle

In paediatric practice the term "Block" may also be used. It denotes a discrete episode of administrations within a course that are not part of a repeated pattern, or which form a section of a cycle, e.g. Delayed Intensification in UKALL 2003.

In paediatric practice this information will be provided by the clinical trial protocol according to which the patient is being treated (whether or not the patient is formally entered into the trial). For patients with rare or refractory tumours following an individualised regime the information should be provided in the case notes in the form of a flow chart or other appropriate format.

5.4 Patient and treatment identification (DH Quality Measure 09-7B-144)

Prior to the administration of any dose of chemotherapy, whether on the first day, or any subsequent day, of a treatment cycle the nurse preparing to administer the dose(s) should ensure:

- That the patient's identification is confirmed according to Trust policy and that the details on any and all prescription charts and prepared drug doses are consistent and without ambiguity. If there is any doubt over the patient's identify and/or whether the drugs doses supplied are intended for a particular patient administration should not proceed until all uncertainties or ambiguities have been addressed and removed.
- All critical test results have been documented and the patient is fit for treatment to proceed.
- The treatment course, cycle, including cycle number, and individual administration(s) within the cycle are identified and the individual drug doses provided are consistent with them and the prescription.
- That any supportive drugs, including hyper-hydration, have been prescribed as appropriate for the treatment cycle/administration and given according to the prescription.
- That the administration route and duration are clearly stated on the prescription
- That any and all diluents and dilution volumes are clearly stated on both the prescription and the individual drug doses supplied, and correspond.

5.5 Clinical assessment criteria prior to administering chemotherapy
(DH Quality Measure 09-7B-136)

Before a course of chemotherapy to be given by any route the patient must be clinically assessed to ensure:

- Haematology parameters, particularly neutrophil and platelet counts, are sufficient for treatment to proceed.
- Clinical chemistry parameters, appropriate to the treatment and as set out in the treatment protocol, are sufficient for the treatment to proceed.
- Any other investigations e.g. renal function, audiology or cardiology, that impact on whether the treatment can be given and/or at what dose, have been performed, reported and reviewed.
- Investigations listed on the front of ChemoCare prescriptions or as detailed in the clinical trial protocol or national guideline. These investigations should be listed in the case notes for patients following individualised treatment plans.
- The patient is clinically well.

The administering practitioner must ensure appropriate venous access with regards to:

- site
- position
- patency
- integrity
- visibility

Use of aseptic non-touch technique, observation of universal precautions and product sterility are required in all intravenous procedures [1]

5.6 Reasons not to start administration of cytotoxic drugs:

Cytotoxic drugs can be administered via a variety of routes. Regardless of the route of administration DO NOT START administration if:

- The environment in which treatment is being administered is deemed unsafe
- There is any doubt regarding the stability of the drug, route and method of administration, expiry, drug dosage, pre-treatment investigations or the prescription is in any way unclear as to what is required
- There is any doubt regarding the integrity of the venous access device being used

5.7 Reasons to stop administration of cytotoxic drugs:

Cytotoxic drugs can be administered via a variety of routes. Regardless of the route of administration STOP if:

- The patient or their parent/carer requests the treatment to stop. In the case of a child too young to be competent to give consent the nurse must assess the reasons for the child requesting the treatment

to stop, e.g. painful cannula. If after thorough assessment there is no obvious reason to stop treatment should be continued with appropriate reassurance to the child and ongoing vigilance for a problem developing.

- The patient demonstrates unexpected side effects or complications which are not routinely managed with planned supportive care, particularly signs of hypersensitivity reaction or anaphylaxis.
- The equipment fails to function effectively or as expected.

5.8 Routes of administration for anticancer drugs

5.8.1 Intravenous chemotherapy delivered as a bolus (vesicant and non-vesicant)

Treatment should be administered according to the sequence set out in the prescription.

However if treatment is to be administered through a cannula consideration should be given to giving the most irritant or vesicant drug first. Vesicant drugs should be given via a newly established cannula wherever possible. The practitioner should sit with the patient and deliver a slow bolus manually using a regular flashback technique.

Consideration should be given to changing the cannula site after 24 hours. However, if the fluid runs freely, there is good blood return and there are no signs of erythema, pain or swelling at the site the existing cannula may be used, with careful monitoring of the treatment site, particularly immediately after treatment is commenced.

Patency of central venous access devices (CVADs) should be confirmed prior to use using blood return. Patency should be re-checked during administration of every few millilitres during the administration of a vesicant using the flashback technique.

Intravenous bolus injections should be given SLOWLY, over approximately 5 minutes

Luer-lock syringes must be used for the bolus administration of all intravenous chemotherapy

Prior to administration the patient should be advised of possible local or systemic adverse events and asked to immediately report any that occur.

Observation of a peripheral administration site should be maintained at regular intervals throughout administration and a Trust extravasation / phlebitis scoring chart used to record observations of the site. Signs of infiltration, extravasation must be addressed immediately according to the Trust extravasation policy, which can be found at:

5.8.2 Intravenous chemotherapy delivered by infusion

Chemotherapy drugs should be regarded as high risk infusions. Infusion pumps used should be specifically designed for this purpose.

Giving sets should be primed (and flushed on completion of infusion) with a suitable compatible intravenous solution. Intravenous administration sets should have luer lock fittings.

Using a non-touch aseptic technique and wearing personal protective equipment, carefully insert the giving set into the cytotoxic infusion at waist height to minimise the risk of personal contamination in the event of a spillage

Patency of the line should be confirmed (see points above).

Prior to administration the patient should be advised of possible local or systemic adverse events and asked to immediately report any that occur.

The infusion site should be checked according to the Trust extravasation policy and the patient monitored for systemic adverse reactions.

5.8.3 Oral Chemotherapy

The prescribing, dispensing and administration of oral chemotherapy should be carried out and monitored to the same standards as those for administration by other routes.

Patients should be reviewed prior to every cycle or block of oral chemotherapy either by an oncologist / haematologist, specialist nurse or pharmacist.

5.8.4 Dispensing

All pharmacy staff involved with dispensing oral chemotherapy should have access to copies of the relevant protocols.
Requests for information and/or clarification should be made to the Lead Cancer Pharmacist in the first instance.
Wherever possible oral chemotherapy will be supplied in blister or foil packed tablets or capsules.
Tablets or capsules should not be handled directly, all staff should use a ‘no touch’ technique to minimise the risks of exposure.
Liquid medicines should be handled in such a way as to minimise contamination of the outside of the bottle. Any evidence of contamination should be removed using a damp

paper towel whilst wearing gloves. The paper towel must be disposed of as for contaminated waste.

5.8.5 Administration to in- and day-patients

Tablets or capsules should not be handled directly, all staff should use a 'no touch' technique to minimise the risks of exposure.
On wards or clinics oral doses of chemotherapy should be dispensed into a disposable medicine pot or cup prior to administration to a patient. Dispose of pots as clinical waste.
All oral chemotherapy should be taken with plenty of water and swallowed whole not chewed to avoid local irritation to the oral mucosa.
Tablets should preferably not be crushed or capsules opened. However, when dealing with children absence of suitable liquid formulations may make this impossible to avoid. See Patient Information Leaflet.

Liquid medicines should be handled in such a way as to minimise contamination of the outside of the bottle. Any evidence of contamination should be removed using a damp paper towel whilst wearing gloves. The paper towel must be disposed of as for contaminated waste.
Tablet crushers and splitters should be rinsed with water after use to remove any residue from the tablet. Avoid splashing that might contaminate surrounding surfaces. Leave to dry.
N.B. TAKE CARE: The tablet splitter contains a sharp blade.

5.8.6 Administration at home.

Responsibility for the administration of oral chemotherapy at home lies with the patient, their parents or carers. It is therefore necessary that they are adequately prepared and have been given appropriate information, both verbal and written, and telephone numbers should they need help and support out-of-hours.

Tablets should preferably not be crushed or capsules opened. However, when dealing with children absence of suitable liquid formulations may make this impossible to avoid.

Liquid medicines should be handled in such a way as to minimise contamination of the outside of the bottle. Any evidence of contamination should be removed using a damp paper towel whilst wearing gloves. The paper towel must be disposed of as for contaminated waste.

All oral chemotherapy should be taken with a drink of water or squash (avoid fruit juice). Using a drink in this way will not only

take the taste away but rinse the oral mucosa to minimise local irritation.

Patients must be adequately counselled about drug storage and handling precautions whilst at home and keeping drugs out of reach of children and animals.

Patients should be advised that medicine spoons, oral syringes or cups should be reserved for chemotherapy treatment only and not used for the administration of other drug doses. They should be washed thoroughly between doses and safely disposed of after the treatment course

Tablet crushers and splitters should be rinsed with water after use to remove any residue from the tablet. Avoid splashing that might contaminate surrounding surfaces. Leave to dry.
N.B. TAKE CARE: The tablet splitter contains a sharp blade.

Dropped medicines should be picked up wearing gloves, put in a plastic bag and disposed of into a sharps bin. The area should be damp dusted with wet towel and dispose of towel as clinical waste. See Spillage Policy.
Patients / Parents / Carers should be informed about:

- How and when to take medicines
- What to do in the event of missing one or more doses
- What to do in the event of vomiting after a dose
- Likely adverse effects and what to do about them
- When and how to obtain further supplies

5.8.7 Intrathecal Chemotherapy

Only staff who have been appropriately trained and accredited, and whose names appear in the appropriate Trust register are permitted to have involvement in the prescribing, dispensing, issue, checking and/or administration of intrathecal chemotherapy appropriate to their role and training.

All staff involved in the administration of intrathecal chemotherapy must comply at all times with the Trust's integrated policy for the prescription, preparation, supply and administration of intrathecal chemotherapy, and thereby with the current National Guidance. The Trust policy can be found at
P:\Oncology Department\CHEMOTHERAPY\INTRATHECAL CHEMOTHERAPY\

5.8.8 Intramuscular injection

The most appropriate needle should be selected based on consideration of the length of needle required to access the muscle (but no further) and the bore (which should be as large

as possible to minimise the pressure at which the injection is delivered).

The 'Z' track technique should be used to avoid leakage into the skin.

Ensure no leakage from the site – cover with a cotton wool ball / plaster if necessary injection sites should be rotated to minimise irritation

5.8.9 Subcutaneous Injection

Care should be taken to ensure the smallest appropriate needle is used and positioned correctly when giving drugs by this route.

Use a pinch technique to administer the injection at 45^{o} to the skin surface

Injection sites should be rotated to minimise irritation. Insufflon needles should be considered if the patient required multiple injections over a short period of time e.g. four day blocks of Cytarabine

Ensure no leakage from the site – cover with a cotton wool ball / plaster if necessary

5.8.10 Intravesical and Intracavitary chemotherapy

This is rarely, if ever, administered at the Children's Hospital.

Should the need arise to administer chemotherapy by this route all staff involved must ensure that they are completely satisfied that they understand what is required and have the necessary skills to prescribe and administer chemotherapy for administration by this route.

5.8.11 Topical

Topical cytotoxic drugs may be applied either directly to the skin, or as ear or eye drops. Bleomycin, mitomycin C and 5-fluorouracil solutions are administered topically in the Operating department outside of the cancer service and are not covered in detail in this document.

However, as guidance the principles in this policy around training, safe handling, documentation, assessment, patient information, monitoring etc. may be utilised. Eye or ear drops are rarely, if ever, administered at the Children's Hospital.

Gloves should be worn while handling or applying the product and using cotton buds rather than fingers is also advisable where the site makes this appropriate. It is important to protect

the normal skin and avoid the eyes and other mucous membranes during administration.

The affected area should not be washed vigorously during the treatment. Although risks may be small, patients should be counselled regarding the toxicity to normal skin and the risks of contamination via direct contact or clothing to other areas of skin or to the skin of other people.

Patients should receive information and instructions regarding their treatment to ensure they are aware of the potential hazards to their family and environment.

5.8.12 Intra-Ocular

Cytotoxic drugs for intraocular (subconjunctival or intravitreal) administration e.g. Carboplatin, will be prepared by the pharmacy department. Intraocular chemotherapy will be administered by the consultant ophthalmic surgeon.

5.8.13. Intra-arterial

Cytotoxic drugs for intra-arterial administration, which at the present time are limited to Melphalan, but which may in future include Carboplatin and Topotecan, will be prepared by the pharmacy department. Intra-arterial chemotherapy will be administered by the retinoblastoma specialist consultant paediatric oncologist. A protocol is available and will be further developed as experience increases.

5.8.14 Miscellaneous Routes of Administration

Other routes of administration of cytotoxic drugs include:

- Intrahepatic
- Intracranial
- Regional infusion (e.g. isolated limb infusion)

None of these are routinely used at Birmingham Children's Hospital.

Should the need arise appropriate policies and procedures will be created to support the administration of cytotoxic drugs by these routes.

5.8.14 Non-cytotoxic drugs handled as cytotoxics.

Certain drugs have similar properties to the cytotoxic drugs with respect to the risk of carcinogenicity, mutagenicity and/or teratogenicity. These should be handled in all respects as if they were cytotoxic drugs.

Currently at BCH the following drugs should be treated in this way:

- Ganciclovir (intravenous)

- Cidofovir (intravenous and topical)
- Gemtuzumab ozogamicin (Mylotarg) (intravenous)

5.9 Administration Equipment – Peripheral Devices

Should be placed in the peripheral veins in the arm but may also be placed in the veins of the hand or foot.

The smallest, shortest gauge cannula should be used; it has been shown that the incidence of vascular complications increases as the ratio of cannula external diameter to vessel lumen increases [3]

Metal needles / “butterfly needles” should never be used for administration of chemotherapy

Prior to inserting a peripheral cannula consider the site, condition of the vein, purpose of the infusion (that is the rate of flow required and the solution to be infused) and the duration of therapy.

Veins should feel bouncy and refill when depressed and should be straight and free of valves to ensure easy advancement of the cannula.

Cannulae should ideally not be sited over a joint. However, in paediatrics particular babies & toddlers the combination of small veins and subcutaneous fat with prolonged treatment and multiple cannulations over time, may mean that less than ideal sites have to be utilised at times. This location should only be considered for vesicant drugs when the practitioner can sit with the patient during the bolus injection or short infusion and the site can be constantly monitored.

Site selection should be initiated in the distal areas of the upper extremities; subsequent cannulation should be made proximal to the previously cannulated site [5]

Shaving of the arm prior to cannulation should not be performed because of potential for causing micro-abrasions which increase risk of infection [1]

If unsuccessful after third attempt at cannulation, then help from another experienced practitioner should be sought. In paediatrics it is common to have children with very poor venous access, but who do not have the option of a CVAD, for whatever reason. In such cases repeated attempts at cannulation – always by an experienced practitioner, and with play specialists and sometimes psychology support – may be appropriate. There should be continual negotiation with the child and carers as to how many attempts are made in one session before the child has a break (this will usually be 3, but may be more if all concerned, particularly the patient, are in agreement to continue).

Current recommendations indicate that peripheral cannula should be re-sited every 48 – 72 hours [3]. Again in paediatrics this has to be

balanced against the continuous trauma of re-cannulation in fragile veins and patient psychological factors. The Trust Extravasation policy and IV Therapy Policy contain supporting documentation – standard cannula care plan & extravasation / phlebitis score chart.

Cannula size, position, number of attempts, contraindications, time and date of cannulation and that flashback will be obtained periodically throughout the administration should be documented in the patients' records.

There is a Haematology Oncology Standard Operating Procedure in the Specialty Handbook providing instruction on the correct technique for bolus vinka-alkaloids via peripheral cannula

5.9.2 Administration Equipment – Central Venous Access Devices

Please refer to the Trust IV Therapy guidelines for the use of CVADS

5.9.3 Administration Equipment – Giving sets

Standard solution giving sets should be used for the majority of drugs.Some drugs e.g. dacarbazine require special light protection for the giving set during the infusion.

Proper integrity must be ascertained prior to use of the administration set [3]

5.9.4 Administration Equipment – Medical Devices

Cytotoxic drugs should be infused using pumps designed for high-risk infusions. Positive pressure pumps should be avoided (with the exception of syringe drivers) unless specifically designed for the administration of cytotoxic drugs.

Staff using rate controlling devices will have received training and understand their use and limitations as per Trust Medical Devices Policy.

If elastomeric infusion devices are required, pharmacy should be consulted regarding availability and suitability.

5.10 Related policies

This guideline should be read, and its recommendations followed, in conjunction with:

- Policy for the management of spillage of cytotoxic drugs.
- Policy on the handling of chemotherapy by staff who are pregnant or breast-feeding.
- Policy for the management of body waste and clinical samples from patients receiving cytotoxic drugs.
- Policy on nurse re-scheduling of chemotherapy.
- Policy on protective clothing for the handling of chemotherapy.

- Procedure for the prescribing of injectable chemotherapy
- Extravasation policy – BCH
- Medical Devices Policy
- IV Therapy Policy
- Intrathecal Chemotherapy Policy

5.11 Related information

- Parent Held record
- Advice for parents caring for children receiving cytotoxic chemotherapy.

6. References (from the original Network document)

1. RCN (2005) Standards for Infusion Therapy. Royal College of Nursing, London
2. The Royal Marsden Hospital Manual of Clinical Nursing Procedures. 6th Edition (2004) Blackwell Publishing Ltd
3. Allwood M et al (2002) The Chemotherapies Handbook. 4th Ed. Oxford. Radcliffe Medical Press
4. INS (2000) Standards for Infusion Therapy. Infusion Nurses Society, Massachusetts
5. Dougherty, L. et al (2004) 'Vascular Access Devices' in Dougherty, L and Lister, S (eds) The Royal Marsden Manual of Clinical Nursing Procedure. 6th ed, Oxford. Blackwell Publishing.
6. Dougherty, L. (1999) Obtaining peripheral vascular access. In: Intravenous Therapy in Nursing Practice (eds L.Dougherty & J.Lamb). Churchill Livingstone, Edinburgh.
7. Weinstein, SM, 2001. Plumer's principles and practice of infusion therapy. 7th ed. Philadelphia: Lippincott Williams and Wilkins
8. Goodman, M. (2000) Chemotherapy: principles of administration. In: Cancer Nursing (eds C.Henke Yarbro et al.). Jones & Bartlett, Boston
9. Macrae, K. (1998) Hand held Dopplers in central catheter insertion. *Prof Nurse*, **14**(**2**), 99-102
10. Springhouse Corporation (2002) Intravenous Therapy Made Incredibly Easy. Springhouse, Lippincott, Williams & Wilkins, Philadelphia.
11. The Royal Marsden Hospital Manual of Clinical Nursing Procedures. 6th Edition (2004) Blackwell Publishing Ltd

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC, LCC and LCN.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

9.2 Standards/Key Performance Indicators

10 Associated Documentation

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	No	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Chemotherapy Working Group**
Policy/ Service Title: Guidelines for the administration of chemotherapy for malignant disease	**Date of Assessment: 20th May 2010**

1. Describe the purpose of this policy or function	• To support safe and effective practice with the administration of anti-cancer drugs • To outline a consistent approach to care. • To fulfil criteria for Chemotherapy related policies in DH Quality Measures for Children's Cancer Services (2009).
2. Who is affected by this policy?	Patients Admitted to BCH for Anti-Cancer Treatment
3. What are the outcomes or intended outcomes of this policy/ function?	Safe and efficient practice Minimise risk Compliance with DH Quality Measures for Children's cancer services
4. What consultation has been undertaken during the development of this policy/function?	BCH Chemotherapy Working Group Haem Onc Programme Meeting – senior nurses , medical staf, pharmacy staff Cancer Locality Group
5. What information or evidence has been used to assess the potential impact across the equality strands?	Pan Birmingham Cancer Network Policy for the administration of Anti-Cnacer Treatment (Adults) Previous practice & staff experience

IMPACT
1. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? Potential positive impact in the reduction of risks associated with the administration of anti-cancer treatment
2. Please complete the following list and identify if there is, or likely to be, an impact on a group

a) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
b) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
c) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
d) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
e) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
f) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details: Positive impact on all groups
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Appendix G – Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)
1.0.1	17-5-10	Chemotherapy Working Group	Based on Pan Birmingham Cancer Network Policy on the Administration of Anti-Cancer treatment (Adults) – revised for application to paediatrics.

Birmingham Children's Hospital NHS
NHS Foundation Trust

PROCEDURE FOR THE MANAGEMENT OF BODY WASTE AND CLINICAL SAMPLES FROM PATIENTS RECEIVING CYTOTOXIC DRUGS

Version:	1.0.1
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Nursing and support staff within the Haematology Oncology Specialty

1 Introduction

Much attention has been paid over the years to the potential hazards associated with contact with chemotherapy drugs during administration. Little attention has been paid to the issues surrounding the management of body waste from patients receiving chemotherapy treatment.

This is probably due to the fact that most patients with cancer are adults who will usually be continent and able to anticipate vomiting. In the case of young children who are not potty trained and do not recognise that nausea may precede vomiting, parents and/or nursing staff will dispose of body waste. In doing so, it is important to recognise that chemo-therapeutic drugs and their metabolites may be excreted in urine and faeces both during treatment and for some days after the administration of treatment is completes (See Appendix I). Drug may also be present in vomit, saliva and tears.

2 Purpose

Recognising the duty of all staff under the Health & Safety at Work Act 1974 to ensure the safety of other staff and the public, the following offers what is hopefully a ‘common-sense’ approach to the issues in the absence of any published guidelines.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children’s Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

5.1 Identification:

All in-patients who are receiving chemotherapy, or who have received chemotherapy within the previous seven days, should be identified with a label above, or at the foot of, their bed.

5.2 Clinical samples:

5.2.1. Any clinical sample consisting of fluid (e.g. blood, urine, ascitic or pleuritic fluid, CSF, saliva, BAL) or faeces taken from a patient identified as in 5.1. above, should be considered as being potentially contaminated with chemotherapy drugs and/or their metabolites.

5.2.2. The risk from tissue samples is probably less, but unquantified.

5.2.3. Since the volumes of clinical samples will generally be small (less than 10ml.) the amount of cytotoxic drug present will also be small.

5.2.4. Standard techniques for taking samples, which aim to avoid or reduce the risk of contamination of the sample or contact by healthcare staff, will also protect against contact with cytotoxic drugs or metabolites.

5.2.5. All staff taking or handling clinical samples from patients should wear gloves.

5.2.6. ALL clinical samples obtained should be placed and sealed into the appropriate container AT ONCE. If for practical purposes this is impossible, the samples should be transferred and sealed at the earliest opportunity.

5.2.7. Advice has been received from the laboratories regarding the identification of clinical samples from patients who are currently, or have recently, received chemotherapy. That advice is that such clinical samples sent to the hospital or an external laboratory would not be handled differently from routine samples, even if identified. It is therefore not proposed to identify such samples.

5.2.8. Any spillage of clinical samples should be managed according the appropriate policy. REMEMBER: Other policies may also apply such as those relating to blood or infected samples.

5.3 Body waste:

5.3.1. All staff handling body waste from patients identified as in 5.1. above should wear gloves and a plastic apron.

5.3.2. All body waste, including but not limited to urine, faeces and vomit, should be disposed of as soon as possible to avoid the risk of any spillage.

5.3.3. Where this is not possible, for example if there is a need to retain the sample for clinical testing, the sample should stored in an appropriate area away from the routine 'traffic' of the ward.

5.3.4. When a sample from a patient identified as in 5.1. above is stored, the sample should be labelled as potentially containing cytotoxic drug and/or metabolites.

5.3.5. Any testing required should be done as soon as possible to minimise the period of storage and the sample disposed of in the correct manner once testing has been done.

5.3.6. Any spillage during storage or disposal should be managed according the appropriate policy. REMEMBER: Other policies may also apply such as those relating to blood or infected samples.

5.4 Parents on the ward:

5.4.1 In caring for their child on the ward parents should be required, as a responsibility under the Health & Safety at Work Act 1974, to follow the same procedures as set out for staff in 3. above when handling bedpans, vomit or wet and/or soiled nappies or clothing.

5.5 Parents and carers at home:

5.5.1 Parents and carers should be advised to wear gloves and a plastic apron when managing body waste from a treated child. This will include nappy changing, managing 'accidents' and clearing up after a child has been sick. The gloves and apron can be normal household items that should be washed and dried after each use.

5.5.2 All body waste should be disposed of as soon as possible to avoid the risk of any spillage.

5.5.3 Any spillage during cleaning up or disposal should be managed according the 'Spillage' policy.

5.5.4 Depending on the circumstances the body waste and any materials used to clean up should be disposed of:

- **Either** down the toilet,

- **Or** in the household waste bin making sure that a double layer of plastic bags (for example, a kitchen bin liner within a dustbin liner) is used. These should be put in the dustbin or other receptacle kept outside the home.

5.5.5 If any clothing, bed-linen or other fabric material becomes contaminated it should be washed as soon as possible on a cycle appropriate to the fabric being washed. The washing machine should NOT be run on a 'half-load' setting since this reduces the amount of water used.

6 References

The Cytotoxics Handbook, 4th edition, 2002, Edited by Michael Allwood, Andrew Stanley and Patricia Wright

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC, LCC and LCN.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Routine audit of clinical areas.

9.2 Standards/Key Performance Indicators

- Appropriate use of personal protective equipment (PPE) by both staff and carers.
- Appropriate storage and labelling of retained samples.

10 Associated Documentation

Procedure for the management of spillage of cytotoxic drugs

Policy for the use of personal protective equipment when handling chemotherapy, spillage of chemotherapy and body waste from patients receiving chemotherapy.

Appendix I

Excretion of cytotoxic drugs and metabolites.

		Duration (days) after completion of therapy for which precautions are necessary when handling	
Drug	Route	Urine	Faeces
Bleomycin	IV	3	
Cisplatin	IV	7	
Cyclophosphamide	Any	3	5
Cytarabine	Any	3	3
Dactinomycin	IV	5	7
Daunorubicin	**IV**	2	7
Doxorubicin	IV	6	7
Epirubicin	IV	7	5
Etoposide	Any	4	7
Melphalan	Oral	2	7
Mercaptopurine	Oral	3	
Methotrexate	Any	3	7
Mitoxantrone	IV	6	7
Thiotepa	IV	3	
Vinca alkaloids	IV	4	7

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Procedure for the management of body waste and clinical samples from patients receiving cytotoxic drugs	**Date of Assessment:** 10-5-2010

6. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.

7. Who is affected by this policy?	Medical, nursing and support staff within the Haematology Oncology specialty at BCH.
8. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff who handle body waste and/or clinical samples are clear as to how such samples should be managed in order to minimise the risk of personal or environmental contamination as required by the Health & Safety at Work Act 1974 Secondarily, compliance with Children's Cancer Measures 2009.
9. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
10. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have minor implications with respect to Equality Impact

IMPACT		
3. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
4. Please complete the following list and identify if there is, or likely to be, an impact on a group		
g) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
h) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
i) Grounds of gender	Yes ☐ ~~No~~ ☐	Adverse? ☐ Provide further details: Female staff who are pregnant may not wish to deal with such situations but this is dealt with separately in the policy on the handling of chemotherapy by staff who are pregnant or breastfeeding.
j) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
k) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
l) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:

Birmingham Children's Hospital NHS
NHS Foundation Trust

POLICY FOR THE USE OF PERSONAL PROTECTIVE EQUIPMENT WHEN HANDLING CHEMOTHERAPY, SPILLAGE OF CHEMOTHERAPY, BODY WASTE AND/OR CLINICAL SAMPLES FROM PATIENTS RECEIVING CHEMOTHERAPY.

Version:	1.0.1
Ratified by:	Head of Chemotherapy (HoC)/ Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Medical, nursing and support staff within the Haematology Oncology Specialty

1 Introduction

For many years it has been well understood that certain cancer chemotherapeutic agents may be carcinogenic (cancer-producing), mutagenic (DNA-damaging) and/or teratogenic (producing malformation of the foetus). However, it should be appreciated that not all cancer chemo-therapeutic agents (chemotherapy) have such properties and those that do may exhibit combinations of the above without producing all three.

Because cancer chemo-therapeutic agents may have the effects listed above, and others, it is appropriate that staff exposure to such drugs should be the minimum achievable.

2 Purpose

This policy sets out the personal protective equipment (PPE) that should be worn by all staff handling or administering chemotherapy, dealing with body waste or clinical samples from patients receiving chemotherapy or dealing with a spillage of a cytotoxic drug within the Haematology Oncology specialty.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

5.1 Issues

In deciding on the PPE that is appropriate a balance needs to be found between:

- The need to protect staff from drugs which are potentially hazardous by contact with skin, eye and/or mucous membrane and ingestion, whether by swallowing, inhalation or needle-stick.

- The need for staff wearing PPE to be able to carry out the duties required of them. As such the PPE worn should not restrict free movement and should not impair, to any significant degree, manual dexterity or vision.

- The need to avoid frightening young children and their extended family who may not understand the need for such precautions, particularly during the early phase of treatment.

5.2 Policy

5.2.1 At all times staff must handle cytotoxic drugs, in whatever form, in a manner which minimises the risk of contamination of themselves, other staff, patients and visitors, and the ward environment (Health & Safety at Work Act 1974).

5.2.2 ALL staff should wear PPE at all times when chemotherapy is being handled or administered. This should include both the person handling the chemotherapy and the assistant or checker. BOTH must wear the PPE appropriate to the task being performed – see below.

5.2.3 The PPE worn should be appropriate to the risk, as follows:

5.2.3.1 When handling prepared injectable chemotherapy or closed bottles of oral formulations – tablets, capsules or suspensions – gloves should be worn (See Appendix I).

The situations included under this heading will include, but not be limited to:

- putting away prepared injectable chemotherapy delivered to the ward
- removing prepared injectable chemotherapy from the refrigerator or cupboard
- obtaining or replacing bottles containing oral formulations from the cupboard or drug trolley.

While this may seem restrictive staff should be aware that it has been demonstrated that vials of injectable chemotherapy as supplied by the manufacturer are contaminated with drug on the outside of the vial. This makes it impossible to be sure that such contamination is not transmitted down through the whole process by which treatment is delivered to the patient. Staff will also be aware that bottles of tablets commonly contain dust, which may also contaminate the outside of the container, and that crusts, potentially containing cytotoxic drug, are often found around the neck of bottles of liquid formulations.

5.2.3.2 When preparing chemotherapy for administration to the patient gloves, armlets, safety glasses (See Appendix II) and a plastic apron should be worn.

The situations included under this heading will include, but not be limited to:

- administration of bolus doses of cytotoxic drug
- setting up of infusions of cytotoxic drug and their connection to the patient
- handling of oral solid dosage form of cytotoxic drugs which are to be given to the patient without opening the capsule or crushing the tablet. (Only gloves are required in this situation).
- handling liquid formulations of cytotoxic drugs.

5.2.3.3 When preparing oral chemotherapy which requires a capsule to be opened or a tablet to be crushed gloves, armlets, safety glasses, a face mask (See Appendix III) and a plastic apron should be worn.

The potential risk arising from the inhalation of dry powder containing cytotoxic drug makes it appropriate for additional measures to be taken in this situation in addition to those appropriate to a lower level of risk.

In addition to the contents of this policy staff should be aware of the following related policies which set out how other situations should be managed.

5.2.3.4 When dealing with body waste from patients receiving chemotherapy, or within seven days of the last dose of chemotherapy.

PPE as for the preparation of chemotherapy (5.2.3.2) should be worn

5.2.3.4 Managing a spillage of chemotherapy.

PPE as for the preparation of chemotherapy (5.2.3.3) should be worn

See also associated policies (Section 10)

6 References

MARC Guidelines www.marcguidelines.com

The Cytotoxics Handbook, 4th. edition Ed. Allwood, Stanley & Wright (2002)

ASHP Technical Assistance Bulletin on handling Cytotoxic and Hazardous Drugs, 1990.

Manual of clinical nursing procedures, Royal Marsden Hospital.

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Routine audit of clinical areas.

10.2 Standards/Key Performance Indicators

All staff handling cytotoxic drugs wearing/using PPE appropriate to the task being undertaken.

Appendix I

Gloves.

There is no consensus as to the type and quality of glove most appropriate for use when handling cytotoxic chemotherapy.

In making decisions about the purchasing of gloves for use when handling cytotoxic chemotherapy the following considerations should be addressed:

No glove is completely impermeable to all cytotoxic agents (so don't waste time trying to find one that is!)

- Is the glove of a suitable thickness and integrity to maximise protection?
- Industrial thickness gloves (> 0.45mm. thick) made from latex and neoprene, nitrile or synthetic rubber should be available to clean up large scale spills.
- Can manual dexterity be maintained whilst wearing the glove?
- Latex gloves should be avoided because of the increasing awareness of sensitivity to latex.
- Powder-free gloves should always be used since it is now recognised that the powder may act as a carrier of protein residue from the glove and permit surface or airborne transmission of latex.
- Individuals who are latex sensitive should stop using latex gloves, be provided with alternatives and avoid areas where latex glove powder may be airborne.
- Recognise that airborne carriage of latex residues from gloves has the potential to affect individuals, other staff, patients and/or visitors, who are latex sensitive even if they are not in direct contact with latex gloves.

See guidance issued by the Health & Safety Executive (HSC 1999/186) and the Medical Devices Agency (MDA DB 9601 and MDA SN 9825)

Appendix II.

Eye protection:

- **Eye protection that conforms to BS EN 166:2002 is required for handling cytotoxic chemotherapy in an 'uncontrolled' environment such as a ward or clinic.**

- The most suitable form of eye protection is safety glasses in which the entire periphery of the goggle is in contact with the face. For protection against liquid chemicals the frame should be marked 'C' and the glass '3'.

- The difficulty in providing a range of safety glasses such that this can be achieved for all staff working in a particular clinical area is recognised.

- The issue of raising concerns amongst patients and parents/visitors through the wearing of safety glasses is recognised. If a unit makes a policy decision not to wear eye protection this decision, and the reasons for it, should be fully documented.

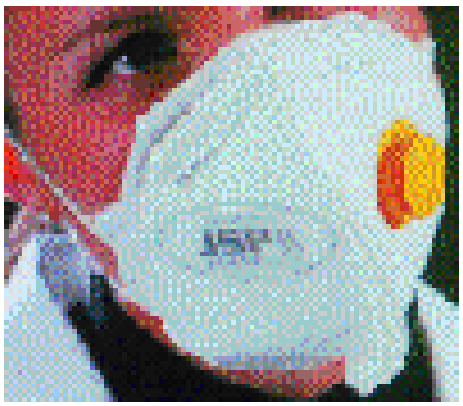
Appendix III.

Respiratory protection.

- Respiratory protection which conforms to BS EN 149 should be used whenever there is a risk from inhalation of cytotoxic drug. This is defined as a spill estimated to be in excess of 10ml. of fluid or any preparation, handling or spillage of powder, such as a crushed tablet or capsule contents.

- It is essential that any respiratory protection fits correctly so that it is sealed tightly to the wearer's face. The size and shape of the face, facial hair, spectacles and jewellery may all affect the fit.

- The type of mask which conforms to BS EN 149 is illustrated below:



Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment
To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Policy for the use of personal protective equipment when handling chemotherapy, spillage of chemotherapy and body waste from patients receiving chemotherapy.	**Date of Assessment:** 10-5-2010

11. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.

12. Who is affected by this policy?	Medical, nursing and support staff within the Haematology Oncology specialty at BCH.
13. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff handling chemotherapy, disposing of body waste and/or handling clinical samples from patients receiving chemotherapy or managing spills of chemotherapy are appropriately protected as required by the Health & Safety at Work Act 1974. Secondarily, compliance with Children's Cancer Measures 2009.
14. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
15. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have minor implications with respect to Equality Impact

IMPACT

5. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large?

   None

6. Please complete the following list and identify if there is, or likely to be, an impact on a group

m) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
n) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
o) Grounds of gender	Yes ☐ ~~No~~ ☐	Adverse? ☐ Provide further details: Female staff who are pregnant or breastfeeding may not wish to deal with such situations but this is dealt with separately in the policy on the handling of chemotherapy by staff who are pregnant or breastfeeding.

p) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
q) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
r) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Birmingham Children's Hospital NHS
NHS Foundation Trust

POLICY ON THE HANDLING OF CHEMOTHERAPY BY STAFF WHO ARE PREGNANT OR BREASTFEEDING

Version:	1.0.1
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician / Lead cancer nurse (LCN)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Medical, nursing and support staff within the Haematology Oncology Specialty

1 Introduction

For many years it has been well understood that certain cancer chemotherapeutic agents may be carcinogenic (cancer-producing), mutagenic (DNA-damaging) and/or teratogenic (producing malformation of the foetus). However, it should be appreciated that not all cancer chemo-therapeutic agents (chemotherapy) have such properties and those that do may exhibit combinations of the above without producing all three.

Because cancer chemo-therapeutic agents may have the effects noted above, it has long been established practice that female staff who are pregnant are not required to handle these drugs.

This policy seeks to build on such established good practice whilst recognising some limitations of a blanket policy and seeking to support the individual member of staff in taking the action they feel most comfortable with.

2 Purpose

To provide a framework for staff and managers that is both supportive of the individual member of staff and cognisant of the potential impact on the care of patients when addressing the issues arising when a members of staff who handles chemotherapy and/or body waste from patients receiving chemotherapy as part of their routine duties becomes pregnant and/or returns to work whilst continuing to breast feed.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

The following issues may be used against the concept of a blanket ban on the handling of cancer chemotherapy by pregnant staff or those who have returned to work whilst continuing to breast-feed their child:

- **It is likely that the greatest damage to the developing foetus will be caused by exposure to cancer chemo-therapeutic drugs during the earliest phases of the pregnancy. At this time, many women will not be aware that they are pregnant, or may not have had the pregnancy confirmed. If they handle cancer chemotherapy as part of their routine duties it is likely that will continue to do so during this time. Therefore, it may not be logical to stop handling such drugs after the time at which the greatest damage will have occurred, if it is going to.**

- **All chemotherapy for *parenteral* administration is supplied ready for administration or for addition to a drip chamber. As such, potential for exposure of staff to the contents of the syringes or infusion bags is minimal, although it is recognised that accidents do happen and equipment does fail.**

- **Personal protective equipment will protect staff from all but the most idiosyncratic spillage or leakage from syringes and infusion bags supplied to the ward.**

- **Provision of care to patients may be compromised if the number of staff available to administer chemotherapy, or care for children receiving chemotherapy, is reduced.**

Policy:

Any member of staff who believes she is, or may be, pregnant or who is planning to return to work whilst continuing to breast-feed should seek a meeting with a senior member of staff at the earliest opportunity.

At that meeting, the issues around the risks of continuing to handle chemotherapy should be discussed leading to a decision as to whether or not the member of staff will continue to handle chemotherapy during her pregnancy/breastfeeding.

If the member of staff does not wish to continue to handle chemotherapy, no pressure will be brought to encourage the member of staff to do so.

If the member of staff does **not** wish to continue to handle chemotherapy she should not:

- Handle or administer chemotherapy supplied for oral or parenteral administration.

- Dispose of body waste or soiled bed linen from patients receiving chemotherapy, and for seven days after chemotherapy is completed.

- Dip stick urine or handle any samples of body fluids to be sent for laboratory analysis during the period chemotherapy is being administered, and for seven days afterwards.

If the member of staff **does** wish to continue to handle chemotherapy they will be given the option of opting out of any of the three categories above, recognising that in practice the potential risk from uncontained body fluids and/or waste is probably the greatest.

In either case the member of staff will be asked sign a form confirming the choice that they have made.

6 References

None

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Records kept by nursing and medical managers.

9.2 Standards/Key Performance Indicators

- All staff feel that their concerns have been addressed
- No staff feel pressured into making a particular decision
- All staff feel comfortable with the decision arrived at

10 Associated Documentation

None

Appendix I

Confirmation of decision regarding the continued handling of cancer chemotherapy during pregnancy or breast-feeding

I, ……., confirm that:

I believe I am pregnant/have had a pregnancy confirmed* on ……

I wish to continue to breast-feed on my return to work* on …… …..

I have had a meeting with ……. (senior nurse) to discuss whether or not I will continue to handle chemotherapy during my pregnancy/whilst I am breast-feeding*.

I have reached my decision of my own free will and without feeling under any pressure to make one decision or another.

I have decided not* to continue to handle chemotherapy during my pregnancy.

I have decided not* to continue to handle chemotherapy whilst breast-feeding.

Having decided to continue to handle chemotherapy during my pregnancy/whilst breast-feeding*, I have agreed to:

- Handle or administer chemotherapy supplied for oral or parenteral administration*
- Dispose of body waste or soiled bed linen from patients receiving chemotherapy, and for seven days after chemotherapy is completed*
- Dip stick urine or handle any samples of body fluids to be sent for laboratory analysis during the period chemotherapy is being administered, and for seven days afterwards*

Signed: ……

Print name: …….

* Delete as applicable

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	N/A	
	Are key references cited?	N/A	
	Are the references cited in full?	N/A	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology		**Assessor: Nigel Ballantine**	
Policy/ Service Title: Policy on the handling of chemotherapy by staff who are pregnant or breastfeeding		**Date of Assessment:** 10-5-2010	
16. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.		
17. Who is affected by this policy?	Medical, nursing and support staff within the Haematology Oncology specialty at BCH.		
18. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff who have concerns about handling chemotherapy whilst pregnant or breastfeeding are supported in their decision as to whether or not to continue doing so, and that such decisions are reached with due consideration of the needs of both the staff concerned and the service. Secondarily, compliance with Children's Cancer Measures 2009.		
19. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy		
20. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have minor implications with respect to Equality Impact		
IMPACT			
7. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None			
8. Please complete the following list and identify if there is, or likely to be, an impact on a group			
s) Grounds of race, ethnicity, colour, nationality	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:	

or national origins.		
t) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
u) Grounds of gender	Yes ☐ ~~No~~ ☐	Adverse? ☐ Provide further details: This policy impacts specifically on female staff but is designed to ensure that staff feel supported and do not feel pressured when making decisions about handling chemotherapy whilst pregnant or breastfeeding.
v) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
w) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
x) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Birmingham Children's Hospital NHS
NHS Foundation Trust

PROCEDURE FOR THE AUTHORISATION OF A CHEMOTHERAPY REGIMEN NOT INCLUDED IN THE ACCEPTED LIST OF REGIMENS

Version:	1.0.2
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than May, 2012
Target audience:	Consultant staff and/or clinical trial Chief or Principal Investigators

1 Introduction

This policy has been written and implemented in order to address Measure 09-7B-134 (DH Manual for Cancer Services 2008: Children's Cancer Measures 2009) which requires that *'the PTC chemotherapy group should agree a written policy with the CCNCG (CCNCG – Children's Cancer Network Coordinating Group) for preventing regular use of regimens not on the accepted list'.*

2 Purpose

- To ensure that consultant staff and/or clinical trial Chief or Principal Investigators are aware of the procedure for the inclusion into the 'accepted list' of a new chemotherapy regimen not previously used at BCH.

- To ensure that when chemotherapy is prescribed using a regimen not included in the 'accepted list' that an appropriate process is followed to ensure that the intended regime is clinically appropriate, that nursing and pharmacy staff have all the information they require in order to obtain and administer the regimen and that all funding issues have been addressed.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; consultant staff and senior/specialist nursing staff within the Haematology Oncology specialty.
Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

The following procedure should be followed whenever it is proposed to use a chemotherapy regimen that is not included in the current 'accepted list' of chemotherapy regimes:

- **The Chair of the CWG should receive a request for use of the proposed regimen from the appropriate Diagnostic and Therapeutic Multidisciplinary Team (D+T MDT). The request should provide clear and explicit details of:**
  - **The patient, including BCH registration number, date of birth, a recent body weight and consultant.**
  - **The clinical reasons for considering a treatment regimen not on the current 'accepted list'.**
  - **The chemotherapy regimen, including but not limited to:**
    - **The doses of the individual drugs comprising the chemotherapy regimen**
    - **Dose reductions appropriate for young patients on the basis of age and/or body weight**
    - **The method of administration**
    - **The duration of any intravenous infusion(s)**
    - **Any regimen-specific timing of administration of chemotherapy drugs with respect to other chemotherapy drugs and/or supportive treatment**
    - **The frequency with which individual cycles will be given**

  - **An outline treatment plan with respect to number of cycles to be given and the criteria for dose modification and stopping treatment.**

  - **laboratory blood tests and other investigational parameters to be fulfilled prior to starting the chemotherapy course (intended number of cycles) and before individual cycles**

  - **The treatment and/or prevention of regimen-specific complications, including but not limited to**
    - **intravenous pre- and post-hydration**
    - **folinic acid rescue**
    - **the use of MESNA**
    - **the prevention of serious hypersensitivity reactions.**

- **The Chair will forward copies of the request to members of the Working Group and seek confirmation that the necessary information is available to permit the safe and effective delivery of the proposed treatment.**

- **If a scheduled meeting of the CWG is not imminent this should not preclude communication within the group via phone and email in order to provide a prompt response to the requesting clinician/D+T MDT.**

- **Should members of the group not have the necessary information available it is anticipated that that they will take responsibility, as appropriate to their professional duties and**

expertise, for finding the information required, communicating it to the group and making recommendations based upon it.

- **Should it be necessary to seek further information or clarification from the patient's consultant this should be done through the Chair of the CWG.**

- **The Chair will also liaise with the Interface team in pharmacy to identify any funding issues related to the use of high cost drugs and, whenever necessary, assist the requesting consultant to complete a request for PCT funding.**

- **If any of the drugs in use in the regimen are not on the BCH hospital formulary the Chair or Head of chemotherapy will assist the requesting consultant to complete an application form for the BCH Drug and Therapeutics Committee**

- **Once the CWG is satisfied that all clinical issues relevant to the safe and effective preparation and administration of the regimen have been addressed, and funding secured, the Chair will inform the HoC and LCC of their recommendation that use of the regimen should be approved.**

- **The HoC and LCC, if satisfied with the recommendation, ratify the decision and inform both the Chair of the appropriate D+T MDT and the patient's consultant.**

- **In situations where a delay in agreeing the proposed regimen would have adverse clinical implications for the patient, provided all the information in the checklist in Appendix I is available treatment may be initiated with Chair's approval provided that the members of the CWG, the HoC and the LCC are informed the following day.**

- **The provisions in the paragraph immediately above do not remove the need to ensure before prescribing the regimen that funding is secured whenever the drug(s) to be administered will have a significant cost consequence to BCH.**

  Nor should they be used to avoid informing the CWG of the intention to use a regimen not included in the 'accepted list' in a timely manner such that a decision can be made following proper consideration of all the issues and circumstances.

The procedure above should be followed for the first three patients it is intended to treat with the individual regimen. Following approval of the third use, or sooner if it is anticipated at the outset that three or more patients will be eligible to receive the regimen each year, it is expected that the appropriate D+T MDT will make a formal application to the CWG for the regimen to be included in the 'accepted list'.

6 References

Not applicable

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

An electronic copy will be provided for all consultant staff within the Specialty and to pharmacy.

It will be available electronically via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

Compliance with the policy will be monitored by the Pharmacy department who will identify any prescription for a regimen that is not included on the 'accepted list' and ensure that the CWG is informed of any such situation.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

It is intended that the CWG will receive a report on the use of regimens not included in the 'accepted list' at six monthly intervals. Such reports will inform an assessment as to whether the procedure set out above is appropriate to the needs of patients, staff and the service and suggest regimens that should be considered for inclusion in the 'accepted list'.

9.2 Standards/Key Performance Indicators

- All proposed use of regimens not at the time included in the 'accepted list' to have been notified to the CWG in a timely manner.
- All issues regarding high-cost drugs to have been addressed to ensure financial risk and implications for the Trust are minimised.
- All required information to enable the regime to be safely and effectively prescribed, prepared and administered is available at the outset.
- The accepted list is maintained and updated to ensure it reflects current practice with respect to the delivery of chemotherapy to patients in the care of the Trust.

10 Associated Documentation

The 'accepted list' of chemotherapy regimens at BCH

Appendix I

Check list for use of a non-approved regimen

Has the request come from a Diagnostic & Therapeutic MDT?	
Is the patient appropriately identified?	
Is the clinical rationale clearly stated?	
Is the chemotherapy regimen explicit with respect to:	
Laboratory and other investigations required prior to each treatment course?	
Drugs required?	
Dose(s), and any dose reduction for young age / low body weight?	
Route(s) of administration?	
Method(s) of administration – dilution, infusion time etc?	
Supportive treatment(s) required e.g. rescue medication, supportive care?	
Number of intended cycles, and cycle frequency?	

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	N/A	
	Are key references cited?	N/A	
	Are the references cited in full?	N/A	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	N/A	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	Yes, use of regimens not included on the list
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology		**Assessor: Nigel Ballantine**
Policy/ Service Title: Procedure for the authorisation of a chemotherapy regimen not included in the list of accepted regimens		**Date of Assessment:** 10-5-2010
21. Describe the purpose of this policy or function	The Children's Cancer Measures 2008 (7B-134) require that the *'PTC (principal treatment centre) chemotherapy group should agree a written policy with the CCNCG (Children's Cancer Network Co-ordinating Group) for preventing regular use of regimens not on the accepted list. The policy should state:* *• the exceptional circumstances under which such a regimen could be used;* *• the procedure which is then required to authorise it'.* This policy has been created to address this requirement.	

22. Who is affected by this policy?	Medical, nursing and pharmacy staff at BCH.
23. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that when unusual or previously unused regimens are used staff will have the information necessary to ensure that, if approved, the treatment can be prescribed, prepared and administered safely and effectively. Secondarily, compliance with Children's Cancer Measure 7B-134.
24. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
25. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have no implications with respect to Equality Impact

IMPACT		
9. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
10. Please complete the following list and identify if there is, or likely to be, an impact on a group		
y) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
z) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
aa) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:

bb) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
cc) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
dd) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

Birmingham Children's Hospital NHS
NHS Foundation Trust

PROCEDURE FOR THE MANAGEMENT OF SPILLAGE OF CYTOTOXIC DRUGS

Version:	1.0.1
Ratified by:	Head of Chemotherapy (HoC) / Lead cancer clinician (LCC) / Lead cancer nurse (LCN)
Date ratified:	Approved by Chemotherapy Working Group June 2010
Name of originator/author:	Nigel Ballantine
Name of responsible committee/individual:	Chemotherapy Working Group (CWG)
Review date:	Document to be reviewed not less than every two years – first review not later than April, 2012
Target audience:	Nursing and support staff within the Haematology Oncology Specialty

1 Introduction

Chemotherapy drugs are potentially carcinogenic, mutagenic and/or teratogenic and as such pose a potential risk to any person coming into contact with them.

Since all chemotherapy drugs for parenteral administration are provided in the syringe or infusion bag from which they are administered, and the majority of oral dosage forms are presented in blister packaging, the most likely scenario for such inadvertent contact and/or ingestion is through spillage. This may occur through misuse of the syringe or infusion bag, damage to either of these, or the necessary crushing or opening of various oral dosage forms to facilitate administration to younger patients.

This procedure sets out the steps that should be taken in the event of spillage of a cytotoxic drug to ensure that the spillage is dealt with efficiently and effectively, and thereby risk any to staff, carers and visitors is minimised.

2 Purpose

Recognising the duty of all staff under the Health & Safety at Work Act 1974 to ensure the safety of other staff and the public, the following defines the actions to be taken should spillage of cytotoxic drugs, in liquid or other forms, occur within the clinical areas of the Haematology Oncology Specialty.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; nursing and support staff within the Haematology Oncology specialty.

Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

5.1 General Guidelines

All staff involved in the handling of cytotoxic drugs, or who work in areas where such drugs are handled, must be aware of the policies and procedures for managing spillage or contamination of individuals or surfaces with cytotoxic drugs.

All staff must take reasonable precautions to avoid spillage, recognising the duties of staff under the Health & Safety at Work Act 1974.

Protective clothing must be worn at all times when handling cytotoxic drugs.

Any spill, however small, must be dealt with as a matter of urgency.

Any spill, however small, must be 'cordoned off' in a way that prevents other staff, parents, visitors and patients coming into contact with the spillage. If any spill occurs around or onto the patient's bed, patient(s) and visitors should be removed from the vicinity at once. The notice included within the spillage kit (See Appendix II) should be displayed in such a way as to be clearly visible to both staff and visitors. **No spill should be left unattended.**

ALL spills of cytotoxic drugs must be reported as a clinical incident.

5.2 Protective clothing

All staff should be aware that personal protective equipment (PPE), including clothing, only offers protection to those areas covered and only then if the equipment is worn correctly. At all times staff must handle cytotoxic chemotherapy in a responsible manner that minimises the possibility of personal contamination, the contamination of others and/or the environment.

For dealing with spills: The spillage kit provides two sets of PPE each containing the items listed in Appendix I.

5.3. Spillage kits

Spillage kits are located in:

- Treatment room on Ward 15
- Treatment room on Ward 15 HDU
- Treatment room in Teenage Cancer Trust (TCT) unit, Ward 15
- Treatment room in Oncology OPD
- Treatment room on Ward 10

5.4 Procedure for liquid spills

Obtain the spillage kit from the treatment room. See Appendices I & II for the contents of the spillage kit. The kit itself also contains a list.

Put on **ALL** the PPE provided. Use the kneeling mat provided in the spillage kit if it will be necessary to kneel down to wipe up a significant spill at floor level.

Isolate any continuing source of contamination such as a leaking infusion bag or 'Sharps' bin by enclosing it in the large blue plastic waste sack provided in the spillage kit.

Assess the presence of 'sharps' e.g. broken glass, needles etc. Use the tweezers provided in the spillage kit to remove as many such items as possible and place them into the large blue plastic waste sack. Do not spend too much time on this in order to avoid delaying management of the spill.

Use the SLIPPA pack laid on top of the spill to absorb the majority of the liquid. If the liquid covers a wide area the pack can be moved around so as to wipe up all of the spillage.

Once as much of the spill as possible has been absorbed into the SLIPPA pack transfer this into the blue plastic waste sack. Use great care to avoid further contamination of the area and take particular care if 'sharps' are present.

Once the SLIPPA pack has been removed, empty one or both of the ampoules of eye wash into the 20ml. spray bottle provided and use this to spray the contaminated area. Do not over-wet.

Wipe up this wetting with the lint-free wipes provided and repeat until you are satisfied that the entire area of contamination has been cleaned. Use particular care if there are small particles of broken glass in the contaminated area. Place each wipe as used into the blue plastic waste sack.

Ensure the area is left dry by using further lint-free wipes as necessary.

Dispose of the blue plastic waste sack according to the Trust waste disposal policy for contaminated waste. NOTE: If the blue plastic sack contains 'Sharps' it MUST be disposed of in a 'Sharps' bin.

Complete Trust clinical incident form and inform pharmacy.

5.5 Procedure for spillages of powder

Obtain the spillage kit from the treatment room. See Appendices I & II for the contents of the spillage kit. The kit itself also contains a list.

Put on ALL the PPE provided.

Isolate the container by enclosing it in the large blue plastic waste sack provided in the spillage kit. Use the tweezers in the spillage kit as necessary.

Assess the presence of ‘sharps’ e.g. broken glass, needles etc. Use the tweezers to remove as many such items as possible and place them into the large blue plastic waste sack. Do not spend too much time on this in order to avoid delaying management of the spill.

Fill the 20ml. spray bottle with one or both of the ampoules of eye wash supplied in the spillage kit and use this to wet the powder spill and the immediately surrounding area.

Take a lint-free wipe from the spillage kit and place over the spillage. Work the towels to wipe up as much of the spill as possible. Use particular care if there are small particles of broken glass in the contaminated area.

As each wipe is used carefully place into the blue plastic waste sack.

Repeat the above until all visible powder has been removed.

Dry the area with further lint-free wipes, discarding as above.

Dispose of the blue plastic waste sack according to the Trust waste disposal policy for contaminated waste. NOTE: If the blue plastic sack contains ‘Sharps’ it MUST be disposed of in a ‘Sharps’ bin.

Complete Trust clinical incident form and inform pharmacy.

5.6 Procedure for contamination of clothing or bed linen

Any clothing which becomes contaminated should be removed from the patient, visitor or member of staff as quickly as possible and treated as soiled linen.

Any person whose clothing becomes contaminated should be bathed or showered at the earliest opportunity paying particular attention to the area below where the contamination occurred, unless it is CERTAIN that the contamination did not penetrate the clothing and contact the patient’s skin.

Any clothing (e.g. theatre gown), bed-linen or other fabric material belonging to the **Trust** that becomes contaminated should be removed as soon as possible and treated as soiled linen.

If any clothing, bed-linen or other fabric material belonging to the **patient** or their family becomes contaminated the material should be treated as soiled linen until it can be washed in the washing machine on the ward. A cycle appropriate to the fabric being washed should be used but the washing machine should NOT be run on a 'half-load' setting since this reduces the amount of water used. While the washing machine is running it should be labelled as containing cytotoxic-contaminated materials and once the patient's materials have been removed it should be run through a complete cycle empty as a flushing procedure.

5.7 Procedure for contamination of other materials

If a cytotoxic spillage occur in the patient's bed area it is possible that other materials will be contaminated.

If these are of a non-porous nature e.g. a plastic toy, gross spillage should be dealt with as above (see para. 5.3). The item should then be placed in a plastic bag and washed at the earliest opportunity. This should be done away from other staff and visitors ensuring that the appropriate protective clothing is used (see para. 5.2).

If the contaminated items are porous, for example a soft toy, gross spillage should be dealt with as above (see para. 5.3). Parents/carers should then be informed that it is impossible to ensure that all contamination has been removed and that the safest thing to do would be to destroy the item.

If parents/carers are agreeable to the destruction of the contaminated item it should be dealt with as contaminated waste according to Trust policy.

If parents/carers are unwilling to allow the item to be destroyed it should be placed in a plastic bag and returned to them. They should be asked to remove the item from the ward at the earliest opportunity and also to sign a statement that they have been advised to destroy the item (see Appendix III.)

5.8 Procedure for spills occurring in the home

In general the procedures outlined in paras. 5.3 and 5.4 should be followed according to the nature of the spill. Para. 5.3 will be appropriate for spills of liquid medicines and injectable chemotherapy administered in the home. Para. 5.4 will be appropriate for crushed tablets or the contents of capsules.

Whenever possible medicines should be prepared and administered in areas such as the kitchen where the medicines can be handled on non-porous surfaces. This makes cleaning easier if spillage should occur.

Should soft furnishings such as fabric covered chairs and carpets become contaminated paper towels or other absorbent material should be placed on the spill IMMEDIATELY to minimise penetration of the spill into the fabric.

All materials used to clean up after a spill should be disposed of as soon as possible by placing in a double layer of plastic bags (for example, a kitchen bin liner within a dustbin liner) which should then be put in the dustbin or other receptacle kept outside the home. DO NOT put in a waste bin in the kitchen or other living area.

The contaminated area should then be sponged with as much water as possible on two or three occasions. As far as possible, avoid allowing the area to dry out between applications.

6 References

MARC Guidelines www.marcguidelines.com

The Cytotoxics Handbook, 4th. edition Ed. Allwood, Stanley & Wright (2002)

ASHP Technical Assistance Bulletin on handling Cytotoxic and Hazardous Drugs, 1990.

Manual of clinical nursing procedures, Royal Marsden Hospital.

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC, LCC and LCN.

8.2 Dissemination

A paper copy will be placed in the policy files within the Haematology Oncology Specialty.

Electronic copies will be provided via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

The policy is currently in use within the Haematology Specialty. This document brings the policy into Trust-approved format.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

Given the rarity of spillage incidents planned audit is not possible.

However, such instances as do occur provide an opportunity for review of the management of the incident in order to learn lessons and refine practice.

10.3 Standards/Key Performance Indicators

Spillage managed according to procedure

10 Associated Documentation

Personal protective equipment (PPE)

Appendix I

Personal Protective Equipment Included in the Spillage Kit

Two packs of PPE are included, each containing: 1	Microguard 2500 white laboratory coat.
1 pair	Microguard 2500 white overshoes
1 pair	Eye shields with side protection against splashes and aerosols
2 pairs	Specialist cyto-gloves for double gloving.
1	Moldex 2435 facepiece to protect against splashes and aerosols (not intended to protect against fumes or vapour).

Appendix II

Further items included in the spillage kit:

Clean up equipment

1	Blue / white SLIPPA super-absorbing polymer which can absorb up to 1 litre of liquid.
1	Protective floor / kneeling mat.
3	Ampoules of eye wash containing 20ml. each.
12	Lint-free wipes
3	Grey absorbent pads

Waste disposal equipment	
1	Waste bag and tie.
1	Disposable labels.
3	Laminated warning signs.

Appendix III
Statement regarding patients own property which is contaminated by cytotoxic chemotherapy:

Dear Parent,
Following the recent incident that resulted in the following items being contaminated with cytotoxic drugs, we have advised you that in the circumstances the safest thing to do would be to allow us to destroy these items.

You have told us that you are unwilling to allow us to destroy them. We are returning them to you in a sealed bag to prevent any further immediate contamination and request that you remove the bag from the ward within 24 hours. The bag will be stored in the sluice, and will be disposed of if it is not removed within 24 hours.
We ask you to sign this paper to agree that you have been advised to destroy the contaminated items.

Signature of parent	Signature of member of staff (state grade)

Date:

Appendix D - Checklist for the Review and Approval of Procedural Document
To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Unsure	See para. 9.1.
	Is there a plan to review or audit compliance with the document?	No	See para. 9.1.
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Procedure of the management of spillage of cytotoxic drugs	**Date of Assessment:** 10-5-2010

1. Describe the purpose of this policy or function	The Children's Cancer Measures 2009 requires the PTC (principal treatment centre) to have a range of policies in place to support the safe and effective delivery of chemotherapy from the perspective of patients, carers and staff. This policy has been in place for a number of years and is being brought to Trust standard as part of the peer view process for cancer services.

2. Who is affected by this policy?	Nursing, support staff and parents/carers within the Haematology Oncology specialty at BCH.
3. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that staff who manage spills of cytotoxic drugs are clear as to how such situations should be managed in order to minimise the risk of personal or environmental contamination as required by the Health & Safety at Work Act 1974 Secondarily, compliance with Children's Cancer Measures 2009.
4. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
5. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have minor implications with respect to Equality Impact

IMPACT		
11. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
12. Please complete the following list and identify if there is, or likely to be, an impact on a group		
ee) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
ff) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
gg) Grounds of gender	Yes ☐ ~~No~~ ☐	Adverse? ☐ Provide further details: Female staff who are pregnant may not wish to deal with such situations but this is dealt with separately in the policy on the handling of chemotherapy by staff who are pregnant or breastfeeding.
hh) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
ii) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
jj) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		