

<b>Reference Number:</b> UHB 329 <b>Version Number:</b> 2	<b>Date of Next Review:</b> November 2022 <b>Previous Trust/LHB Reference Number:</b> N/A
<b>MANAGEMENT OF PARENTERAL CYTOTOXIC CHEMOTHERAPY PROCEDURE</b>	
<b>Introduction and Aim</b> This Procedure supports the Policy for the Management of Parenteral Cytotoxic Chemotherapy and describes the facilities required, staff training, prescribing, preparation, administration, and waste management of parenteral cytotoxic chemotherapy.	
<b>Objectives</b> <ul style="list-style-type: none"> <li>• To ensure that the interests of the patient, the staff and the UHB are fully protected.</li> <li>• To ensure the safe administration of parenteral cytotoxic chemotherapy to patients in the UHB.</li> <li>• To ensure compliance with national guidelines on prescribing, supply and administration of parenteral cytotoxic chemotherapy.</li> <li>• To provide guidance to UHB staff on the safe administration of parenteral cytotoxic chemotherapy.</li> </ul>	
<b>Scope</b> This Policy applies to all staff involved with intravenous, intraarterial, intramuscular, subcutaneous, intrathecal, intraventricular, intravesical, intravitreal and subconjunctival cytotoxic drugs administered to all patients.	
<b>Equality Health Impact Assessment</b>	There was no evidence of any impact in the EqIA undertaken in 2016 A Health Impact Assessment (HIA) has / has not been completed
<b>Documents to read alongside this Procedure</b>	The Management of Parenteral Cytotoxic Chemotherapy Policy and the Procedure for Safe Handling and Administration of Intrathecal Chemotherapy
<b>Approved by</b>	Quality, Safety and Experience Committee in the first instance thereafter this can be delegated to the Medicines Management Group and/or UHB Cytotoxic Chemotherapy Group

<b>Accountable Executive or Clinical Board Director</b>	Medical Director
<b>Author(s)</b>	Lead Pharmacist Paediatric Oncology

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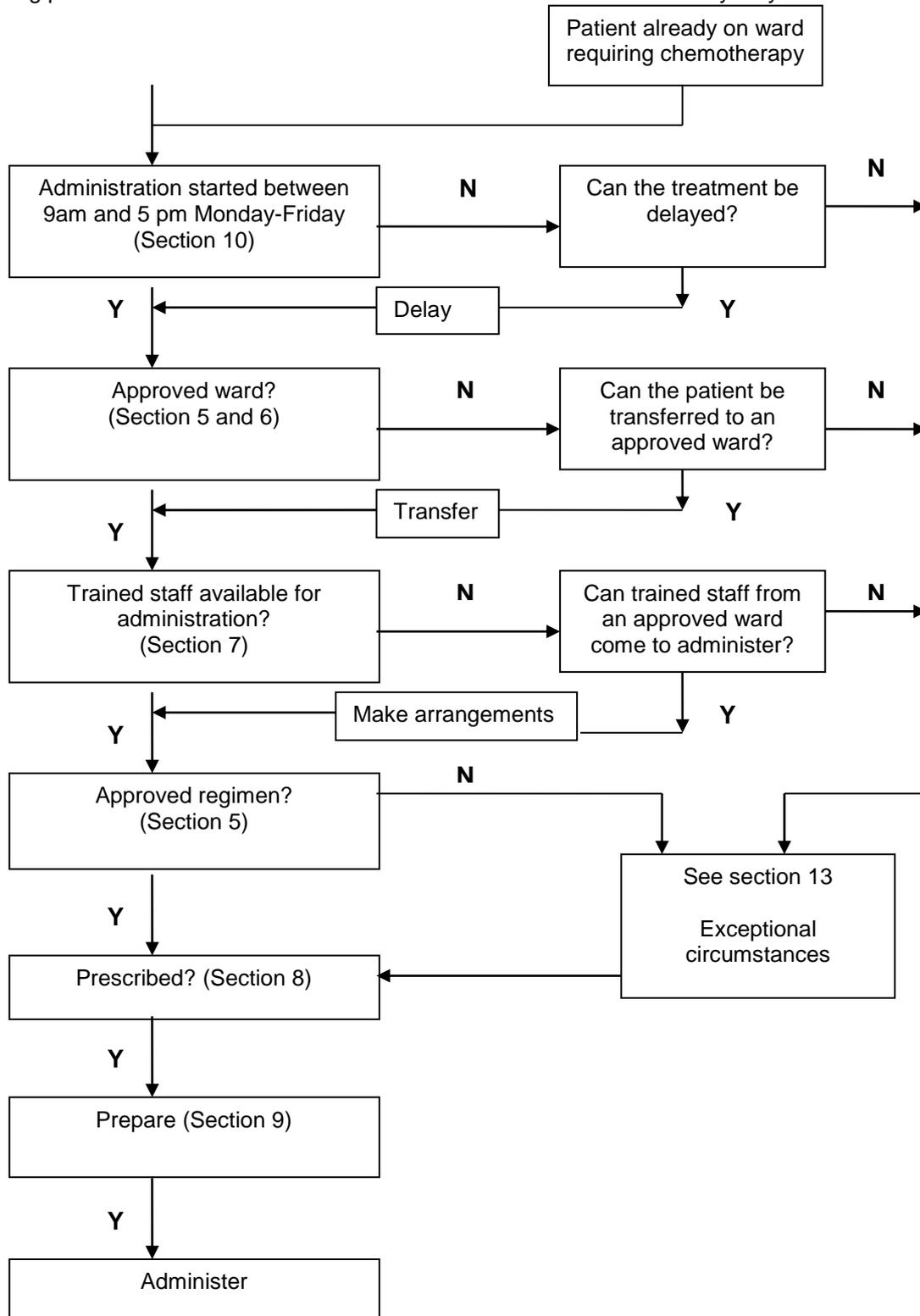
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<b>Summary of reviews/amendments</b>			
<b>Version Number</b>	<b>Date of Review Approved</b>	<b>Date Published</b>	<b>Summary of Amendments</b>
1	28/06/2016	02/11/2016	This is a new Procedure that has been extracted from the UHB's previous Policy. During the process, minor amendments were made. The need to read the Procedure for Safe Handling and Administration of Intrathecal Chemotherapy has been included within the Procedure.
2	07/11/2019	15/11/2019	Updating Procedure UHB 329.

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## Flow diagram for administration of cytotoxic chemotherapy

The flow diagram below provides an aid to the decision making process and is designed to support safe administration of cytotoxic chemotherapy. The patient's consultant is responsible for carrying out the decision making process. The order in which the activities below are undertaken may vary within cancer specialities.



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## MANAGEMENT OF PARENTERAL CYTOTOXIC CHEMOTHERAPY PROCEDURE

### 1. INTRODUCTION

This Procedure is based on the recommendations of a report by the Joint Council for Clinical Oncology (1994) and is compliant with Department of Health Standards for Cancer Services (2001), National Guidance on the Safe Administration of Intrathecal Chemotherapy (2001), the Health & Safety at Work Act (1974), Health and Safety Executive guidance on the safe Handling of cytotoxic drugs (2003), Environmental Protection Act (1990), Hazardous Waste Regulation 2005, (Special Waste Regulations (1996)) and Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations (1996) and the UHB's Policy on the Management of Parenteral Cytotoxic Chemotherapy.

### 2. POLICY STATEMENT

Cardiff and Vale University Health Board (UHB) is committed to ensuring that parenteral cytotoxic chemotherapy is administered safely and that the organisation is compliant with national guidance. The policy will clearly identify the key elements of parenteral cytotoxic chemotherapy.

### 3. SCOPE

This Procedure applies to intravenous, intraarterial, intramuscular, subcutaneous, intrathecal, intraventricular, intravesical, intravitreal and subconjunctival cytotoxic drugs administered to all patients.

### 4. INTRATHECAL CYTOTOXIC CHEMOTHERAPY

Intrathecal or intraventricular cytotoxic chemotherapy is used only as a part of approved treatment regimens within the specialities of Clinical Haematology and Paediatric Oncology/Haematology, at the UHW site. Intrathecal cytotoxic chemotherapy is not normally administered at the Llandough site. Please refer to the Procedure for safe handling and administration of intrathecal chemotherapy Ref UHB209.

### 5. DEFINITIONS

Management of cytotoxic chemotherapy includes prescribing, preparation, storage, administration, safe handling and disposal.

**Approved wards** or departments are equipped for the administration of cytotoxic chemotherapy. These may be either specialist wards or those on which cytotoxic drugs are an essential part of the treatment of patients, but used less frequently. In approved areas where the drugs are used less frequently, it may not be possible to ensure that appropriately trained staff are available to administer cytotoxic drugs.

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[APPROVED WARD AREAS FOR THE ADMINISTRATION OF CYTOTOXIC CHEMOTHERAPY2.PDF](#)

**Ward area** is a room on a ward containing one or more beds. For example a cubicle containing one bed or an eight bedded ward area.

**Specialist wards** or departments are those in which cytotoxic chemotherapy are administered as a part of everyday practice. For example Paediatric Oncology, Respiratory Oncology or Clinical Haematology wards. These wards are equipped for the purpose and have staff trained to administer the drugs and to care for patients who have received chemotherapy.

**Approved regimens.** Cytotoxic chemotherapy regimens are often complex, involving a number of drugs, given by a variety of routes, over a number of days. At present individual consultants or clinical directorates approve regimens.

- Treatment regimens designed by external organisations for example the MRC trial protocols, must be approved locally by the directorate using the trials or the SE Wales Cancer Network Clinical Group
- Other treatment regimens must be approved by the consultant using the protocol and the clinical director or lead consultant for the speciality.

**CNST.** Clinical Nurse Specialist Trainer for cytotoxic drug administration.

## 6. FACILITIES

6.1 In-patient cytotoxic chemotherapy is administered only on approved wards or departments where it is an agreed part of or whole of the activity of that ward or department's activity.

6.2 Outpatient cytotoxic chemotherapy is administered in approved outpatient areas where it is an agreed part of or whole of the activity of that ward or department. In the session in which chemotherapy is being given, the area is only used for the administration of chemotherapy and other aseptic treatments and procedures on cancer patients.

6.3 Intrathecal/intraventricular cytotoxic chemotherapy must be administered in an area where no other cytotoxic drugs are administered or stored. If it is not possible to designate an area to be used only for administration of intrathecal/intraventricular drugs, intrathecal/intraventricular doses may be administered in a ward area (see definitions), provided the ward area is not used for intravenous bolus drug administration, to any of the patients, at the same time.

All the intravenous bolus drug doses for all of the patients within the ward area (see definitions) must be removed from the ward area prior to the intrathecal/intraventricular drugs being transferred to the area. Intravenous infusions which have already been started should be continued. The removal of intravenous drug doses from the ward area must be documented on the intrathecal

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chemotherapy prescription, before the intrathecal/intraventricular doses are transferred into the area. When there is a need for different patients within the same ward area to be treated with intravenous and intrathecal/intraventricular cytotoxic chemotherapy, the intrathecal/intraventricular therapy should normally be given priority.

If it is necessary to store intrathecal/intraventricular cytotoxic chemotherapy doses on approved wards or departments, before administration, they must be stored in dedicated lockable refrigerators, see document, wards and departments approved for the administration of cytotoxic chemotherapy.

- 6.4 The Medical Director maintains a list of the approved wards and departments. The Medical Director will ensure that an up to date list of approved wards is available on all wards and in the pharmacies.
- 6.5 All of these wards and departments must have copies of treatment protocols for the drug regimens used by the directorate and copies of the procedures and equipment necessary for the management of emergencies such as cardiac arrest, anaphylaxis, extravasation and spillage of cytotoxic drugs.
- 6.6 All of these wards and departments must have an area within them for the storage and for the organisation of chemotherapy before administration.

## **7. PERSONNEL AND TRAINING**

- 7.1 The prescribing, preparation, supply and checking of cytotoxic chemotherapy must be undertaken by staff trained, assessed and accredited to do so. Consultants using cytotoxic chemotherapy must ensure that arrangements are made for the training and assessment of medical staff, to which the responsibility for prescribing or administration of these drugs is delegated. The CNST will train and assess nurses involved in administration and checking of cytotoxic chemotherapy, and also staff involved in the care of patients who have received chemotherapy. The Service Director for Pharmacy and Medicines Management will ensure that pharmacy staff who prepare, check or supply cytotoxic chemotherapy are trained and assessed. The Medical Director, Nurse Director and Service Director for Pharmacy and Medicines Management are responsible for ensuring lists of accredited medical, nursing, and pharmacy staff, respectively, are maintained. The list will include details of the role the individual is accredited to undertake.
- 7.2 The administration of correctly and clearly prescribed intramuscular, intravenous, intravesical and topical cytotoxic chemotherapy is normally the responsibility of appropriately trained and accredited nurses.

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7.3 Intrathecal cytotoxic chemotherapy must be administered only by consultants, staff grade doctors and specialist registrars, who are UHB accredited in the administration of cytotoxic drugs by this route. Specialist registrars, in training, may undertake the procedure under supervision of a UHB accredited consultant. The Medical Director will maintain a register of medical staff accredited to undertake this procedure. The checking procedure for administration of intrathecal cytotoxic chemotherapy must involve a nurse accredited in the administration of intrathecal cytotoxic drugs. Patients or their relatives or carers may choose to check the name of the drug, route and dose of the drug prescribed with those on the label of the syringe. They should be enabled to do this if they wish and if it is practically possible. [REGISTER OF AUTHORISED PERSONNEL - INTRATHECAL CHEMOTHERAPY.PDF](#)

7.4 Intravitreal, subconjunctival and topical ophthalmic cytotoxic chemotherapy must be administered by consultant ophthalmologists or specialist registrars accredited in the administration of cytotoxic drugs by this route. Specialist registrars and senior house officers, in training, may undertake the procedure under supervision of an accredited consultant or specialist registrar.

7.5 Nurses who administer parenteral cytotoxic chemotherapy must

- Be registered by the Nursing and Midwifery Council (NMC)
- Have completed a training programme recognised by the UHB on the administration of cytotoxic chemotherapy
- Administer chemotherapy at least monthly, to maintain competency
- Have had their competence in the parenteral administration of cytotoxic chemotherapy assessed by the designated assessor for the ward or directorate annually.
- Where administration involves the use of electronic volumetric, syringe or ambulatory infusion pumps, the nurse must be trained and accredited to use the pump, in accordance with the UHB Infusion Pumps Policy.

7.6 The CNST should inform the Clinical Board Nurse when a nurse is accredited.

7.7 Doctors who administer parenteral cytotoxic chemotherapy must:

- Have completed a training programme recognised by UHB on the administration of cytotoxic chemotherapy. This must include training specific to the route of administration to be used.
- Have had their competence in the administration of cytotoxic chemotherapy, by the route of administration to be used, assessed by the designated assessor for the ward or directorate.

The clinical director or lead consultant for the specialty must inform the Medical Director when a doctor is accredited.

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- 7.8 Nurses caring for patients who have received cytotoxic chemotherapy will be trained to provide a supporting role in cytotoxic chemotherapy.
- 7.9 Every professional (medical or nursing) who administers chemotherapy must be assessed annually to ensure ongoing competency. A written record of this assessment must be maintained at both a personal and ward level.
- 7.10 Any professional assessed as no longer competent to practise unsupervised ***must*** undergo further training as deemed necessary by their assessor or line manager. They must then be reassessed and deemed competent before being permitted to administer further chemotherapy unsupervised. The Medical Director or Chief Nurse/Executive Nurse Director must be informed if accreditation is removed from a doctor or nurse, respectively.
- 7.11 Every professional who administers chemotherapy must keep up to date with current evidence and knowledge regarding chemotherapy administration.
- 7.12 Having been deemed competent, the onus is then on each individual to give only the chemotherapy that they feel competent to administer.
- 7.13 All staff involved in the care of patients receiving cytotoxic chemotherapy must challenge colleagues, if in their judgement, either protocols are not being observed or the actions of an individual may cause a potential risk to a patient. Challenging a colleague should not be seen as adversarial, but as an additional check to improve patient safety.
- 7.14 The responsibility for individual action cannot be delegated. If a senior colleague advises or directs a particular course of action, which in the judgement of the member of staff receiving the advice or direction, may cause risk to a patient, the senior colleague must be challenged.
- 7.15 Nursing staff who undertake administration of cytotoxic chemotherapy who become pregnant may choose to either be redeployed to other duties or to continue in their cytotoxic administration role. The decision will be made following a risk assessment, discussion and agreement between the nurse and line manager. Refer to procedure for handling cytotoxic drugs in pregnancy.

## **8. PRESCRIBING**

- 8.1 Parenteral cytotoxic chemotherapy must be prescribed by an appropriately accredited consultant, specialist registrar, staff grade or non-medical prescriber.
- 8.2 Only specialty approved chemotherapy regimens are used.

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- 8.3 Due to the risks associated with prescribing and administering chemotherapy, electronic prescribing should be used in all settings to reduce risk. Where this is not possible, pre-printed, consultant authorised prescription charts should be provided.
- 8.4 The clinical director or lead consultant for the specialty must ensure that:
- A list of approved chemotherapy regimens used in the directorate is maintained. The list must indicate a version number for each regimen and the date it was approved.
  - Ensure that copies of the list and the regimens are provided to pharmacy and to each clinical area.
  - Inform the haematology/oncology pharmacist and the ward managers of each clinical area if an amendment is made to a treatment protocol or approved regimen.
- 8.5 The ward sister/charge nurse or data manager in paediatric oncology and the Lead Pharmacist for cancer speciality must ensure that only the most up to date version of approved treatment regimens are stored in the clinical area or pharmacy department, respectively.
- 8.6 Written Consent, using the appropriate approved consent form, to treat, should be obtained from the patient, person with parental responsibility for a non Gillick competent child, court appointed deputy or attorney of a personal welfare lasting power of attorney, prior to administration of chemotherapy. If there is reason to doubt the patient's mental capacity, the Mental Capacity Act 2005 must be followed. This may be in the form of a treatment plan which is discussed and a copy given to the patient or representative mentioned above.
- 8.7 Nursing staff who undertake administration of cytotoxic chemotherapy should ensure that the patient/parent/attorney/deputy has received both verbal and written information regarding the side effects of chemotherapy and other implications of treatment prior to its administration.

## **9. PREPARATION**

- 9.1 All of the parenteral and topical cytotoxic drug doses must be prepared in the pharmacies at either University Hospital Llandough or St Mary's Pharmaceutical Unit. Some prepared doses are purchased from outside manufacturers, to be stored and dispensed from the pharmacy UHW.
- 9.2 The pharmacies at St Mary's Pharmaceutical Unit and University Hospital Llandough have a Specials Manufacturing Licence and are audited biennially by the Medicines and Healthcare Products Regulatory Agency (MHRA).
- 9.3 Preparation and supply are carried out under the supervision of pharmacists with expertise in both aseptic services and oncology/haematology.

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9.4 The preparation of cytotoxic chemotherapy is undertaken by assistant technical officers, pharmacy technicians or pharmacists who have received the appropriate training and been assessed as competent.

- A written record of the assessment is maintained at a personal and departmental level.
- The Service Director for Pharmacy and Medicines Management is informed when pharmacy staff are accredited

## 10. TIMING

10.1 In order to ensure availability of experienced and senior medical and nursing staff and supporting services, wherever possible cytotoxic drug administration is undertaken during normal working hours (9am-5pm Monday-Friday).

10.2 Some chemotherapy regimens will require administration of drugs to continue over night or over the weekend. These regimens must be planned and started within normal hours.

10.3 If a patient is to be treated with a regimen which includes both intrathecal and intravenous cytotoxic drugs:

- The drugs must not be supplied at the same time. Wherever possible regimens must be adjusted so that intrathecal drugs and intravenous drugs are given on different days.
- If this is not possible, for example in out-patient or day case cytotoxic chemotherapy
  - The intravenous drugs must be administered first.
  - The intrathecal drugs will be supplied only once the intravenous drugs have been administered, and the administration has been documented on the prescription.
- The sequencing of intravenous drugs before intrathecal drugs may not be possible in children receiving intrathecal drugs under general anaesthesia in an operating theatre. In this situation, only the intrathecal drugs are supplied to the theatre where the intrathecal administration takes place.

## 11. CYTOTOXIC WASTE

11.1 Legislation requires the UHB to segregate cytotoxic waste from clinical waste and all hazardous and non-hazardous waste.

11.2 The ward sister/charge nurse is responsible for the cytotoxic waste generated during the administration of cytotoxic drugs, until it is collected from the ward or department by the authorised waste collector.

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11.3 The ward sister/charge nurse must ensure:

- That adequate secure storage is provided for cytotoxic waste.
- That cytotoxic waste is appropriately packaged, sealed, identified and labelled as cytotoxic waste using the appropriate label i.e. (large red lettering on white background).
- That cytotoxic waste is segregated from other clinical and special waste at point of production.
- That cytotoxic waste is collected by an authorised waste collector who is notified of its production for collection to occur as required.

11.4 The authorised waste collector is responsible for the delivery of cytotoxic waste to a secure central storage facility on site.

11.5 The UHB Waste Manager must ensure that:

- UHB waste collection staff and external contractors, who collect waste from wards and departments within the UHB, are trained in the operation of this policy and in the safe handling of cytotoxic waste.
- A secure storage area is made available for the on site storage of cytotoxic waste, following collections from wards and departments within the UHB, prior to consignment to external contractors for transport and disposal.
- Completion and archiving of documentation relating to the transport and disposal of cytotoxic waste is maintained in line with current legislation.
- During the selection and monitoring of external contractors for the transport and disposal of cytotoxic waste, those contractors undertaking this activity are licensed by the Environment Agency to undertake these activities.

11.6 Bed linen from patients who have received cytotoxic chemotherapy does not need to be treated differently to other patients' linen unless the patient is incontinent or cytotoxic drugs are spilled onto the linen.

- If cytotoxic chemotherapy itself is spilled onto bed linen the recommendation is that the linen should be disposed of as cytotoxic waste.
- There is a risk that very small amounts of cytotoxics may be present in the urine and to a lesser extent other body fluids such as faeces and vomit for up to 7 days following chemotherapy administration. Therefore if a patient is incontinent during this period, the linen should be treated as infected linen to protect hospital and laundry staff from exposure.
- If a patient is receiving cytotoxic chemotherapy and is not incontinent then bed linen is treated as normal (i.e. to be sent to the laundry).

## 12. AUDIT AND EXTERNAL ASSESSMENT

12.1 Cytotoxic drug administration throughout the UHB is audited against the Department of Health Standards for Cancer Services and the Welsh

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Association of Chemotherapy Nurses Audit Tool, every two years. A report of the audit is presented to the Medication Safety Executive.

12.2 The designated assessors participate in a programme of external assessment every two years.

12.3 The UHB Waste Manager audits the handling of cytotoxic waste within the UHB using the Waste Department's audit tool. Visits to external contractor's premises are conducted annually to ensure compliance with the UHB Duty of Care.

12.4 An auditor appointed by the Welsh Government will undertake an annual external audit of the intrathecal chemotherapy within the UHB.

### 13. EXCEPTIONAL CIRCUMSTANCES

13.1 Occasionally, in emergency situations, it is necessary to start cytotoxic chemotherapy outside normal hours.

- Decision to do so must be made by the patient's consultant.
- A risk assessment must be undertaken and documented by the patient's consultant in the medical notes.
- A Datix Incident Form must be completed, so that the frequency of these events can be monitored.

13.2 Administration of chemotherapy on non-specialist areas. Occasionally it may be necessary to administer cytotoxic drugs to patients on approved, but non-specialist wards, where there is no suitably trained nursing staff.

- It is the patient's consultant's responsibility to manage clinical risk.
- This may include negotiating for the transfer of the patient to an area in which the drugs can be administered by suitably trained staff or for suitably trained staff to come to the approved area to administer the drugs. In these circumstances, the responsibility for the arrangements for prescribing and administering chemotherapy remains with the patient's consultant.
- If transfer of patients or staff is necessary, a datix incident form must be completed by the patient's consultant, so that the frequency of these events can be monitored.

13.3 Some directorates use single agent cytotoxic chemotherapy regularly but infrequently. In this circumstance it may not be possible to maintain a group of nurses who are trained, assessed and accredited to administer cytotoxic chemotherapy as described in section 7.5. An alternative is for the directorate to identify a nurse who can administer the single agent. The following conditions must apply:

- the nurse is an experienced member of staff
- the nurse is trained by the UHB Cytotoxic Chemotherapy Nurse Trainers in administration of the named single agent.

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- the nurse is assessed as competent by the UHB Cytotoxic Chemotherapy Nurse Trainers.
- only the named single agent can be administered
- the indication must be either licensed or the UHB Medicines Management
- Group and Clinical Director must approve the indication and protocol.

13.4 Occasionally patients are diagnosed with conditions, for which there are no appropriate current national clinical trial or recognised treatment protocols, but nevertheless require urgent treatment. In these circumstances the patients' consultant may decide to use a treatment protocol which is not formally recognised or approved but is based on the best evidence available and previous experience. The patient must be made fully aware of this during the consent process.

13.5 In exceptional circumstances if two chemotherapy trained nurses are not available to administer chemotherapy, then the chemo administration may be undertaken by a trained nurse and the consultant.

## **14. RESOURCES**

No additional resources were identified as a result of approval of this procedure.

## **15. EQUALITY IMPACT AND ASSESSMENT**

Cardiff and Vale UHB is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff, patients and others reflects their individual needs and that we will not does not discriminate, harass or victimise individuals or groups unfairly on the basis of sex, pregnancy and maternity, gender reassignment, disability, race, age, sexual orientation, disfigurement, religion and belief, family circumstances including marriage and civil partnership. These principles run throughout our work and are reflected in our core values, our staff employment policies, our service delivery standards and our Strategic Equality Plan and Equality Objectives. We believe that all staff should have fair and equal access to training as highlighted in both the Equality Act 2010 and the 1998 Human Rights Act. The responsibility for implementing the Plan falls to all employees and UHB Board members, volunteers, agents or contractors delivering services or undertaking work on behalf of the UHB.

## **16. DISTRIBUTION**

This Procedure will be available for viewing via the UHB Intranet.

A copy will also be provided to all Clinical Board Directors, Clinical Board Directors of Operations and Directorate Managers for onward distribution and circulation to staff as necessary.

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<http://howis.wales.nhs.uk/doclib/2005-3-e.pdf>
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10. Safe Handling of Cytotoxic Drugs (2003) HSE Information Sheet MISC615, Health and Safety Executive
11. Handling of Cytotoxic During Pregnancy Procedure. Cardiff and Vale UHB  
<http://www.cardiffandvaleuhb.wales.nhs.uk/sitesplus/documents/864/Handling%20Cytotoxics%20during%20Pregnancy%20Procedure.pdf>

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## **18. CYTOTOXIC CHEMOTHERAPY GROUP**

This procedure was updated by the Cardiff and Vale University Health Board Cytotoxic Chemotherapy Group:

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Jordan Morris, Macmillan Lung Cancer Pharmacist  
Eurig Jenkins, Lead Pharmacist Paediatric Oncology  
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Claire Lawson Chemotherapy Nurse Specialist  
Caroline Bates, Specialist Urology Sister  
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Faye Blackborrow, CNS, TYA unit  
Awen Proctor, Aseptic Senior Pharmacist, UHL