GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number:** UHB 039 **Version Number:** 4 **Date of Next Review:** *07 Dec 2023* **Previous Trust/LHB Reference Number:**

Handling of Cytotoxics During Pregnancy Procedure.

Introduction and Aim

The aims of this Procedure are to:

- ensure exposure to cytotoxic drugs is minimised for staff who are pregnant, trying to conceive or breast feeding
- provide principles for the safe handling of cytotoxic drugs, and cytotoxic waste, which are supported by risk assessments

This document supports the Parenteral Cytotoxic Chemotherapy Policy.

Objectives

- To ensure the safety of new/pregnant mothers, or staff who are trying to conceive
- To provide managers with guidance to ensure the risks to new and expectant mothers who may handle cytotoxic agents, or waste, are assessed and necessary measures taken to reduce them to as low as reasonably practical
- To provide staff with information on the options available to them

Scope

This procedure applies to any area in Cardiff and Vale University Health Board (UHB) where cytotoxic drugs are reconstituted or administered. Administration may be through any of the following routes: intravenous, oral, subcutaneous, intramuscular, intrathecal, intravesical, intraarterial, intravitreal, subconjunctival and topical. It also applies to any waste products related to the reconstitution or administration of such drugs.

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a positive impact. Key actions have been identified and these can be found in the EHIA incorporated within this document.
Documents to read alongside this Procedure	• Management of Parenteral Cytotoxic Chemotherapy Procedure • Risk Assessment for New and Expectant Mothers Procedure • Extravasation Procedure • Waste Management Policy • Health and Safety Policy • Control of Substances Hazardous to Health (COSHH) Procedure

	• Guidelines for the Safe Handling, Checking and Administration of Cytotoxics • Maternity risk assessment procedure • Health and safety risk assessment procedure
Approved by	*Committee/ Group*

Accountable Executive or Clinical Board Director	*Title of post holder*
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Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	March 2011	8th April, 2011.	New document
2	July 2014	17th September, 2015.	Up-dated in line with current evidence and recommendations and summary of these recommendations added under Implementation/Summary.
			References up-dated.
			Risk assessments reviewed and minor changes made. Tool up-dated.
			Equality impact assessment up-dated.
			Re-formatted as per requirements for all Cardiff & Vale written control documents.
3	18th January 2018		Up-dated in line with current evidence and recommendations. Information added on the use of Closed System Devices.
			References up-dated.
			Risk assessments reviewed and changes made to reflect the implementation of the Closed System Devices and the introduction of Ambulatory Care.

			Equality and Health Impact Assessment up-dated.
			Re-formatted as per requirements for all Cardiff & Vale UHB written control documents.
4	07/12/2021	14/01/2022	Up-dated in line with current evidence and recommendations. Additional advice added regarding administration during the second and third trimesters.
			References reviewed and up-dated.
			Equality and Health Impact Assessment reviewed and up-dated where required.
			Risk assessments reviewed and up-dated.

HANDLING OF CYTOTOXICS DURING PREGNANCY PROCEDURE

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Appendices

1.0 INTRODUCTION

Various studies have demonstrated links between occupational exposure to cytotoxic drugs and the following: menstrual dysfunction, sub-optimal fertility, miscarriages, stillbirths, low birth-rate and congenital abnormalities. However, these studies were mostly carried out either in the 1980s, or based on staff exposure in the 1980s; when the use of personal protective equipment and safe-handling techniques were not as well established as they are now. These studies do not on the whole reflect current working practices; which now include the use of Closed System Devices during the administration process. Defined as devices which 'do not exchange unfiltered air or contaminants with the adjacent environment' (NIOSH 2004/2016), these are in use throughout Cardiff and Vale UHB wherever intravenous (IV) chemotherapy is administered; their aim being to reduce the risks associated with exposure to cytotoxic agents.

Other more recent studies have failed to find a statistically significant association with spontaneous abortion and congenital malformation. This might be due to increased awareness of the risk and the use of protective clothing and equipment, or alternatively, the avoidance of cytotoxic handling by staff if they are pregnant.

A further review of 447 patients who received chemotherapy whilst pregnant concluded that the use of chemotherapy in the second and third trimesters would appear to be safe (http://www.breastcancer.org/research-news/20120821-2 {2012}).

The period of greatest risk to the developing foetus is considered to be during the first trimester; which is the time of most rapid cell division and differentiation.(https://ecancer.org/en/journal/article/418-is-it-safe-for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations. 2014).
Guidance from the Health and Safety Executive (HSE 2021), for new and expectant mothers, states that because a safe level of exposure can-not be determined, everything possible should be done either to avoid exposure, or reduce it to as low a level as is reasonably practicable.

2.0 POLICY STATEMENT

Cardiff & Vale UHB is committed to ensuring that parenteral cytotoxic chemotherapy is administered safely and that the organisation is compliant with national guidance. This Procedure will ensure that new and expectant mothers' exposure to cytotoxic agents is either eliminated or significantly reduced. This document defines 'new and expectant mother' as a woman who is pregnant, has given birth within the last six months or who is still breastfeeding her infant (**www.hse.gov.uk** 2014).

3.0 ROLES AND RESPONSIBILITIES

The prescribing, preparation, supply, checking and administration of cytotoxic chemotherapy must be undertaken by staff trained, assessed and accredited to do so. The following identifies who will be accountable for ensuring implementation of this procedure:

3.1 **Chief Executive/Operational Health & Safety Committee**

The Chief Executive/Operational Health & Safety Committee should: Ensure arrangements are in place to implement the Handling of Cytotoxics During Pregnancy Procedure

3.2 **Line Manager**

Line Managers are responsible for:

- Reviewing existing risk assessments when informed that an employee is pregnant. Please see the following:
  - Table 1 for specific activity risk guidance
  - Appendix 1: Risk assessment Checklist for Assessment of New and Expectant Mothers
  -Appendix 2: Example of generic risk assessment for handling cytotoxics during pregnancy)

- Informing members of staff about the potential risks and the measures taken to prevent exposure to these risks

- Regularly reviewing the risk assessment

- Liaising with Occupational Health regarding any individual problems or concerns

Advice to Line Managers:

The emphasis is to reduce occupational exposure to all staff at all times to as low as reasonably practicable. The Activity Risk Assessment in Table 1 should be used as guidance. Any activities not listed should be risk assessed using the same criteria. Assistance can be provided by the authors of this document.

Certain activities where open systems are used have been assessed as higher risk for pregnant staff and therefore pregnant staff must not undertake the activities in the higher risk category (Table 1: Activity Risk Assessment). In addition, pregnant carers whose relative/friend is receiving ambulatory chemotherapy should also be advised not to handle a chemotherapy spillage and to avoid contact with bodily fluids.

Medium risk activities, where closed systems and PPE are used to reduce the risk of direct exposure, may be undertaken by expectant mothers; but only during their second and third trimester and if the staff

member is willing to do so. Employees should not feel pressurised to administer due to staff shortages. Where employees are keen to continue to administer the following are required beforehand:
- risk assessment of the specific activity
- provision of relevant information
- identification and implementation of the necessary control(s)
-discussion and agreement between the member of staff and their line manager
This should be initiated by the member of staff and not based on clinical need or perceived pressure to administer. (If an area finds they are short of nurses who are able to administer cytotoxic drugs please approach the Chemotherapy Nurse Specialists for support meeting their training needs).
Low risk activities, where there is deemed to be no risk of direct exposure to cytotoxic drugs, may be undertaken by new or expectant mothers.
If, after safety measures have been implemented, there is still deemed to be a significant risk to the new or expectant mother, which goes beyond the level of risk expected outside the workplace, then the following HSE (2014) guidance should be followed (in conjunction with Occupational health and /or Human Resources).

Step 1: temporarily adjust her working conditions and/or hours of work; or, if it is not reasonable to do so, or would not avoid the risk…

Step 2: offer suitable alternative work if any is available. In line with current guidance, (RCN 2016, HSE 2016), pregnant staff and those trying to conceive should always be offered alternative duties if they choose not to work with cytotoxics at this time.) If that is not feasible, you must proceed to Step 3…

Step 3: offer leave from work (on full pay) for as long as is necessary to protect her health and wellbeing, or that of the developing foetus.

3.3 **Employee**

Employees who are pregnant, or planning a pregnancy, are advised to:

- Inform their manager as soon as a pregnancy is planned, confirmed, or suspected (HSE 2021). When the Health Board receives notification, a risk assessment will be carried out by the line manager

- Comply with the risk assessment undertaken and follow the advice given

3.4 **Occupational Health Service**

It is the role of the Occupational Health Service to:

- Provide advice to both new and expectant mothers regarding their health and their occupational hazards and risks
- Advise managers regarding their responsibilities

3.5 **Human Resources Staff**

Human Resources staff may be required to:

- Assist managers and offer guidance if working conditions and / or hours of work have to be temporarily adjusted
- Support line managers who are looking for suitable alternative work for their staff
- Advise on the implications of suspending new or expectant mothers from work for the time necessary to protect the health and safety of the staff member or the un-born child

3.6 **Consultants**

Consultants who use cytotoxic chemotherapy are responsible for:

- Training and assessing all medical staff involved in the administration of these agents
- Raising awareness of the existence of this Procedure and its contents

3.7 **Chemotherapy CNS**

The Chemotherapy CNSs are responsible for:

- Training and assessing nurses who administer and check chemotherapy, and also training those staff involved in the care of patients who have received chemotherapy. Education regarding these guidelines will be incorporated into induction, the Chemotherapy Awareness Study Day and the Chemotherapy Administration Workshop
- Advising senior nurses/managers whose staff are involved in the handling of cytotoxics

3.8 **Chief Pharmacist**

The Chief Pharmacist is responsible for:

- Ensuring that pharmacy staff who prepare, check or supply cytotoxic agents are trained and assessed on the risks
- Incorporating training on this Procedure into that training

4.0 Guidelines

4.1 Staff should be encouraged to inform their manager as soon as a pregnancy is confirmed, or suspected (HSE 2021). A risk assessment will then be conducted as per the UHB's procedure for maternity risk assessment. (See Appendix 1)

4.2 Staff who are pregnant, or planning a pregnancy, should be able to discuss in confidence any concerns with their manager and/or chemotherapy CNS; and ensure they receive sufficient information to be able to make an informed decision about their options

4.3 As some pregnancies are un-planned, all staff should be made aware of the potential risks as part of their induction programme and advised of the need to follow local policies and procedures at all times. (e.g. Nursing staff will receive both verbal and written information during induction and on the 'Chemotherapy Awareness' training days)

4.4 In line with HSE guidance, pregnant staff should be removed from those duties that have been assessed as being higher risk. (Please refer to those activities listed in red in Table 1)

4.5 Managers will need to be aware of staffs' concerns regarding the handling of cytotoxics during pregnancy. Alternative duties may be offered to those who work with cytotoxics at this time

4.6 Finally, a comprehensive method of staff education and risk assessment should be in place (Dougherty and Lister 2015) and safe handling procedures assessed regularly to reduce the risks to as low a level as possible for all staff.

Stage 1 Initial Assessment

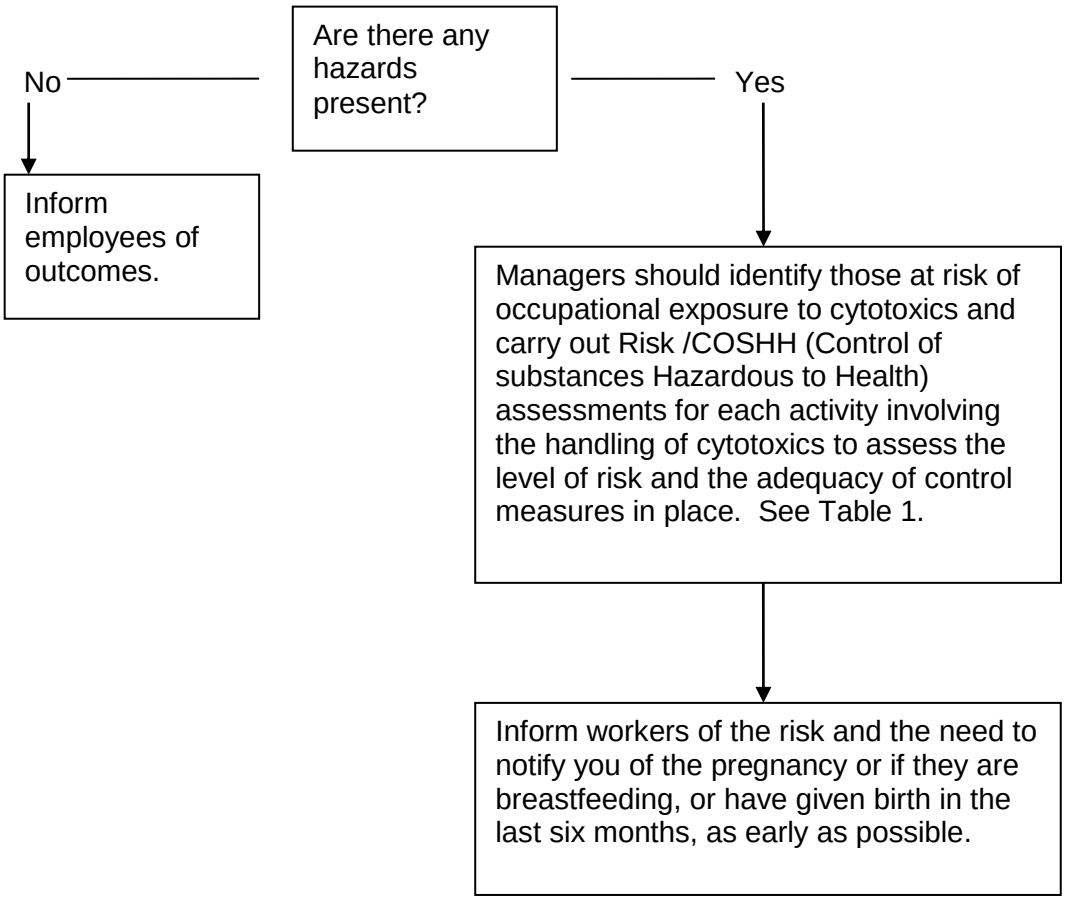


Table 1 Activity Risk Assessment

Low	No risk of direct exposure to cytotoxic drugs	Can be undertaken by pregnant staff
Medium	Use of closed systems eliminating direct exposure. PPE used.	May be undertaken by pregnant staff following: • risk assessment specific activity • provision of relevant information • identification and implementation of necessary controls • discussion and agreement between the member of staff and the line manager
Higher risk	Open systems, higher risk of direct exposure. PPE used	Pregnant staff must not undertake this activity

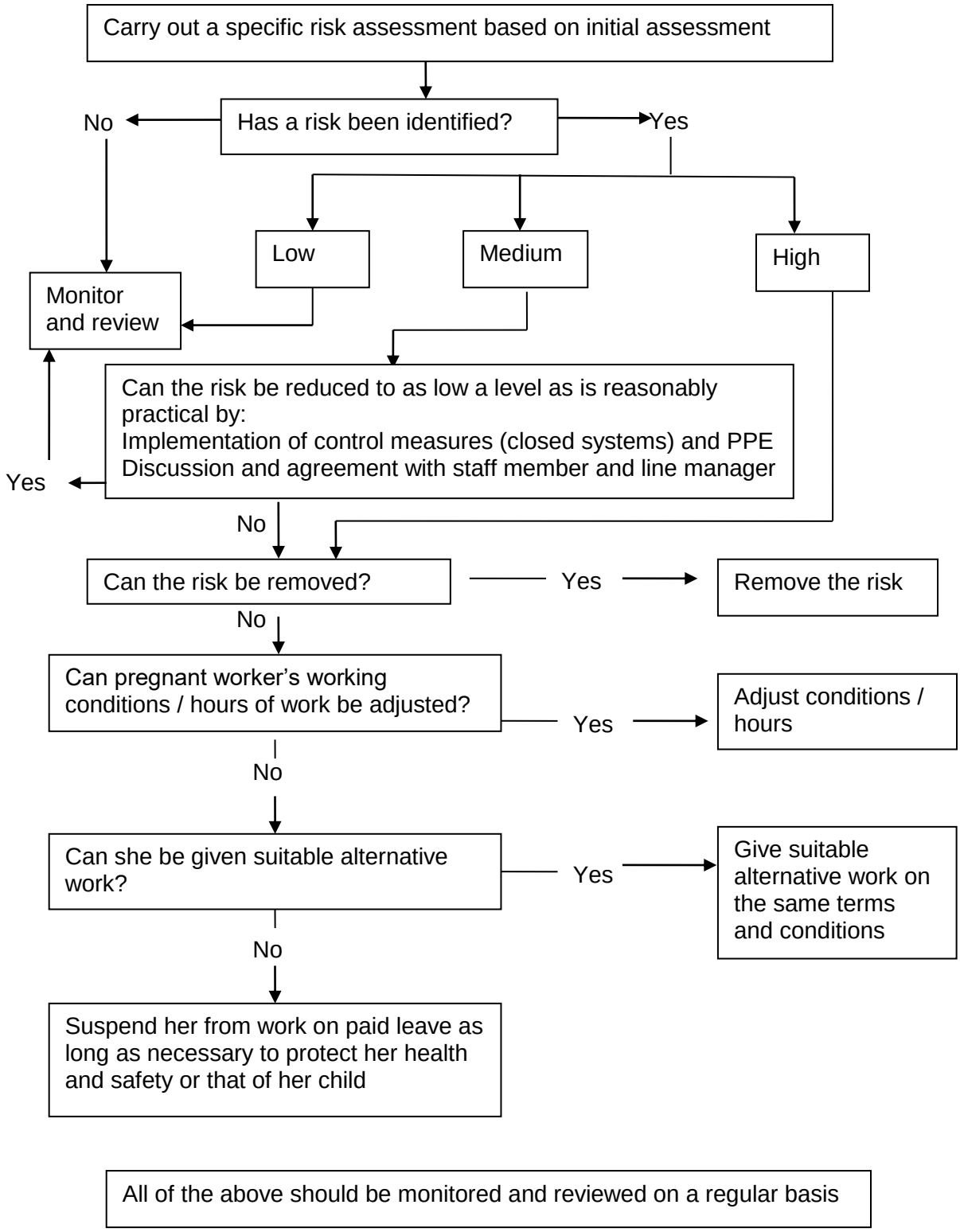
Activity	**Site**	**Professional group**	**Hazard**	**Risk**	**Control**
Prescribing	Clinic, Day Unit or Ward	Medical or non-medical prescriber	n/a	low	n/a
Checking prescriptions	Ward, Pharmacy	Pharmacist	n/a	low	n/a
Preparing manufacturing documentation	Pharmacy	ATO	n/a	low	n/a
Maintaining clinical trial records	Pharmacy	Pharmacist, Pharmacy Technician	n/a	low	n/a

Activity	Site	Professional group	Hazard	Risk	Control
Assembling components for manufacture	Pharmacy	ATO	Skin contact	medium	PPE: Nitrile gloves
Checking documentation and assembly of raw materials	Pharmacy	ACT	Skin contact	medium	PPE: Nitrile gloves
Dispensing solid oral doses	Pharmacy	ATO, technician, pharmacist	Skin contact	medium	Blister packs Film coated tablets PPE: Nitrile gloves
Aseptic processing using closed systems and isolator work-stations	Pharmacy clean room	ATO, technician, Pharmacist	Skin contact Inhalation of aerosol	higher	Closed systems Negative pressure isolator work station Full PPE:
Checking finished products	Pharmacy	Pharmacist, technician	Skin contact with material on outside of final container	medium	PPE: Nitrile gloves
Delivery to clinical area	Transfer	Porter	n/a	low	n/a
Receipt and storing finished product	Clinic, Day Unit, Ward	Nurse	n/a	low	n/a
Checking dose against prescription	Clinic, Day Unit, Ward	Nurse	n/a	low	n/a
Intravenous administration using closed systems, subcutaneous, intrathecal and intramuscular administration	Clinic, Day Unit, Ward	Nurse, Doctor	Skin contact. Risk of ingestion.	medium	PPE: latex free gloves, apron, goggles. Closed system devices added to intravenous giving set.

Activity	Site	Professional group	Hazard	Risk	Control
Oral administration	Clinic, Day Unit, Ward	Nurse	Skin contact	medium	PPE: latex free gloves and apron
Intravesical administration including withdrawal of solution	Clinic, Day Unit, Ward	Nurse	Skin contact – open system	higher	PPE: latex free gloves, visor, apron
Intra arterial administration for liver chemoembolisation	Radiology	Radiologist	Skin contact – open system	higher	PPE: latex free gloves and lead apron
Topical administration of cytotoxic drugs	Clinic, Day Unit, Ward	Nurse or surgeon	Skin contact – open system	higher	PPE: latex free gloves and apron
Monitoring progress of infusion	Clinic, Day Unit, Ward	Nurse	n/a	low	n/a
Monitoring patient for toxicity	Clinic, Day Unit, Ward	Nurse, Doctor	n/a	low	n/a
Handling bodily fluids	Clinic, Day Unit, Ward	Nurse, Doctor	Skin contact – open system	medium	PPE: latex free gloves and apron
Managing spilled body waste and contaminated linen	Clinic, Day Unit, Ward	Nurse	Skin contact – open system	higher	PPE: latex free gloves and apron
Acute management of extravasation	Clinic, Day Unit, Ward	Nurse, Doctor	Skin contact – open system	higher	PPE: latex free gloves and apron
Handling spillage	Pharmacy, Clinic, Day Unit, Ward	Pharmacy staff or nursing staff	Skin contact – open system	higher	PPE: nitrile gloves, mask, eye protection, apron, shoe covering
Handling waste administration equipment	Clinic, Day Unit, Ward	Nurse	Skin contact	medium	PPE; latex free gloves and apron, use of closed systems

Activity	Site	Professional group	Hazard	Risk	Control
Transfer of contained cytotoxic waste	Transfer	Operational services staff	Skin contact – open system	low	n/a
Handling of urine from 24 hour collection for calculation of creatinine clearance	Laboratory	Medical Laboratory assistants or Biomedical scientists	Skin contact – open system (decanting of urine)	higher	White lab coat, gloves, if labelled High Risk Biomedical scientist would handle rather than Lab assistant (extra precautions taken)

Stage 2 On Notification of Pregnancy or Breast Feeding



All of the above should be monitored and reviewed on a regular basis

5.0 RESOURCES

Additional training of senior staff/managers may be required as a result of this procedure.

6.0 TRAINING

6.1 All training must be carried out in compliance with Cardiff & Vale UHB's Parenteral Cytotoxic Chemotherapy Policy. Staff at risk of exposure to cytotoxics will receive formal training concerning management of these risks on induction and/or on the Chemotherapy Awareness Study Day and the Chemotherapy Administration Workshop; as well as on-going training as per the above policy

6.2 Training for senior nurses on the implementation of this procedure will be the responsibility of the Chemotherapy CNSs

6.3 Consultants using cytotoxic chemotherapy will take responsibility for ensuring that medical staff who administer these agents are fully aware of this procedure.

6.4 The Chief Pharmacist will ensure training of the appropriate pharmacy staff.

7.0 IMPLEMENTATION / SUMMARY

Managers / senior nurses whose staff are involved in the handling of cytotoxics will be advised of the implementation of this procedure and offered training as required. Below is a summary of the most up to date recommendations based on current evidence.

7.1 All staff who are involved in the preparation, handling and administration of cytotoxics should familiarise themselves with, and abide by, both local and national policies (https://ecancer.org/en/journal/article/418-is-it-safe- for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations. 2014). Staff should follow standard operating procedures and use appropriate PPE to ensure safe practice (https://ecancer.org/en/journal/article/418-is-it-safe-for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations 2014)

7.2 Pregnant staff should, wherever possible, be given the choice to avoid working in direct contact with cytotoxics (HSE 2021)

7.3 Staff are responsible for informing their employer of their pregnancy or if they are lactating (https://ecancer.org/en/journal/article/418-is-it-safe-for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations. 2014, HSE 2021)

7.4 The 1st 12 weeks of a pregnancy have been identified as being when staff handling cytotoxics may be at the greatest risk of potentially harmful exposure. Staff should avoid handling cytotoxics during this time, or indeed when they are lactating. After this time staff must use PPE and adhere to standard safety procedures if they are to continue handling cytotoxics (https://ecancer.org/en/journal/article/418-is-it-safe-for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations. 2014)

7.5 Staff involved in handling and administration of cytotoxics must receive appropriate training and education

8.0 FURTHER INFORMATION

Health and Safety Executive (2017)
Royal College of Nursing (2016)

9.0 RECOMMENDED READING

Breast.Cancer.org (2012).
Available at:
http://www.breastcancer.org/research-news/20120821-2 {2012}).
Accessed 28.09.17

Dougherty L, Lister S (2015). The Royal Marsden Hospital Manual of Clinical Nursing Procedures 9th edit. Oxford. Wiley-Blackwell.

Gilane S, Giridharan S (2014). Is it safe for pregnant health-care professionals to handle cytotoxix drugs? A review of the literature and recommendations. (8) 418-420.
Available from:
https://ecancer.org/en/journal/article/418-is-it-safe-for-pregnant-health-care-professionals-to-handle-cytotoxic-drugs-a-review-of-the-literature-and-recommendations.
Accessed 26.05.21

Health and Safety Executive (2013) *New and Expectant Mothers who Work: a brief guide to your health and safety.*
Available at:
https://www.hse.gov.uk/pubns/indg373.pdf
Accessed 17.06.21

Health and Safety Executive (2021). Protecting New and Expectant Mothers at Work.
Available at:
https://www.hse.gov.uk/mothers/employer/index.htm
Accessed 17.06.21

Health and Safety Executive 2021. Safe handling of cytotoxic drugs in the workplace.
Available from:
https://www.hse.gov.uk/healthservices/safe-use-cytotoxic-drugs.htm
Accessed 15.04.21

National Institute for Occupational Safety and Health (NIOSH), (2004 –up-dated 2016). Preventing Exposure to Antineoplastic and Other Hazardous Drugs in Healthcare Settings.
https://www.cdc.gov/niosh/docs/2016-161/
Accessed 28.09.17

RCN (2016) Standards for Infusion Therapy: The RCN IV Therapy Forum. 4th edit. (Pending review)

10.0 EQUALITY

An equality impact assessment has been undertaken to assess the relevance of these guidelines on different groups specifically with regards to race, disability, gender, sexual orientation, religion/belief and Welsh language.

The assessment identifies understandable gender bias, as the guidelines are largely aimed at pregnant or breast-feeding women. However, everything possible has been done to address the concerns of both sexes who are trying to conceive and thus redress the balance.

11.0 AUDIT

Cytotoxic drug administration throughout the UHB can be measured against the Department of Health Standards for Cancer Services and via Systemic Anti-Cancer Therapy (SACT) peer review. Any audits are then presented to the Cytotoxic Board and the Clinical Standards Committee.

12.0 REVIEW

Review date every 3 years in conjunction with the Policy on the Management of Parenteral Cytotoxic Chemotherapy.

13.0 DISTRIBUTION

This document will be distributed in accordance with the Cardiff and Vale University Health Board Policy for the Management of Policies, Procedures and all other written Control Documents.

APPENDICES

Appendix 1: Risk Assessment checklist for new and expectant mothers

RISK ASSESSMENT CHECKLISTS FOR NEW AND EXPECTANT MOTHERS	
Name of member of staff:	
Department:	
Occupation:	
Pregnancy or new mother details, date of commencing maternity leave/medical certificate from GP:	
Expected/Actual date of delivery:	
Has a risk assessment of the workplace been undertaken? (MHSW1A – available on public folders, COSHH, Manual Handling) If *NO*, complete risk assessment as required – *date completed:*	*YES / NO* ……..
Has a risk been identified?	*YES / NO*
Has the employee been informed of the potential risk?	*YES / NO*
Do special precautions need to be considered?	*YES / NO*
Do you need to adjust her working conditions?	*YES / NO*
Are you able to offer her suitable alternative work (if applicable)?	*YES / NO*
Is there still a potential risk to the new or expectant mother?	*YES / NO*
If *YES,* does medical suspension apply?	*YES / NO*
Date:	……..
Is referral to Occupational Health required? Date referred to Occupational Health: Response received: Action required:	*YES / NO* ……..
Name of person completing form: Designation:	…… …… ……

General Risk Assessment Form – Part 2

Reference Numbers		
UHB	Clinical Board	Directorate
UHB wide		

Premises/ Location (if applicable)	UHW/LLandough/Chemotherapy Mobile Unit	**Clinical Board/ Department**		**Exact Location (if applicable)**	

Description of Activity/Risk Area: Handling Cytotoxics During Pregnancy.

Risk/Issued (Including Impact) to UHB due to shortfalls:
Handling Cytotoxics During Pregnancy:
It is well recognised that chemotherapy has the potential to be teratogenic; meaning to cause harm to the developing foetus. The potential for exposure for the mother (to be) may occur during handling of packaging, inadvertent leakage during administration, skin contact if administering oral chemotherapy, cytotoxic spillage, contact with the drug whilst managing an extravasation and contact with bodily fluids containing metabolites of the drug.

Risk Domain (See Table 1 – Risk Matrix)

Impact on the Safety of Patients, staff or Public.	Y	Quality/Complaints/Audit.	Y
Human Resources/Organisational Development etc…	N	Statutory Duty/Inspections.	Y
Adverse Publicity/ Reputation.	Y	Business Objectives/Projects.	N
Finance Including Claims.	Y	Service Business Interruption.	Y
Environmental Impact	N		

Number of people exposed to the Hazard/Risk during the work activity (if applicable)

Staff / Students / Contractors – list job roles	Service / Patient Users
• Registered nurses trained in administering chemotherapy • HCSWs • Physios • Occupational therapists • Intrathecally accredited consultants and registrars	Whilst chemotherapy may be administered to patients who are pregnant in extreme circumstances it is not within the remit of this risk assessment to assess risk v benefit for the individual patient.

Frequency of Exposure (if applicable)

Infrequently ☐ Annually ☐ Monthly ☐ Weekly ☐ Daily Y Hourly ☐ Constantly

Control Measures already taken to reduce risk:

1. Policies and Procedures

- Management of Parenteral Cytotoxic Chemotherapy
- Procedure for Handling Cytotoxics During pregnancy (Use for guidance on administration via different routes)
- HSE New and Expectant Mothers at Work: A Guide for Employers
- Procedure for Handling a Spillage
- Procedure for Managing an Extravasation
- Waste Management Policy
- Health and Safety Policy
- Guidelines for the Safe Handling, Checking and Administration of Cytotoxics

2. Use of closed systems delivery devices for intravenous administration

3. Education and Training

- Induction training – Haematology and TCT only
- Chemotherapy Awareness Study day
- Chemotherapy Administration Workshop

- Annual assessment
- Staff are advised to notify their manager of any pregnancy plans and offered removal from said duties
- Chemotherapy nurse trainers as an expert resource

4. COSHH and risk assessments

5. Use of personal protective equipment to minimise the risk of exposure

- Gloves
- Apron
- Goggles

6. Staff may choose not to administer whilst pregnant

7. Pregnant carers whose friend/family member is having ambulatory chemotherapy are to be advised not to handle a chemotherapy spillage

Adequacy of existing control measures:

No Controls in Place	Inadequate Controls in Place	Adequate but more action required	Optimum Controls No further action required Y
☐	☐	☐	

Current Risk Rating	Consequence (score from Table 1)	3	X	Likelihood (score from Table 2)	2	=	Risk Rating (see Table 3)	**6**

Risk Grading (see Table 4) Moderate ☐ High ☐ Extreme ☐

Additional control measures required: None

With the above action implemented the risk rating figure would be reduced to:

Target Risk Rating	Consequence (score from Table 1)	3	X	Likelihood (score from Table 2)	2	=	Risk Rating (see Table 3)	**6**

Risk Grading (see Table 4) Moderate Y High ☐ Extreme ☐

Assessors Name(s) S. Rowland	Signature(s)	Position(s) Chemotherapy and IV Access CNS

Date of Assessment 26.09.17

Review Period Every 2 years

Dates of Review

26.09.19	17.06.21			

Progress Report:	**Date:**	**Signature:**

Appendix 1

Equality & Health Impact Assessment for: Cardiff and Vale University Health Board (UHB) Guidelines on Handling of Cytotoxics during Pregnancy.

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	Handling of Cytotoxics During Pregnancy Procedure.
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Cardiff and Vale University Health Board The Chief Executive has ultimate responsibility for Health & Safety issues within the UHB; however, responsibility for many aspects of the management of these guidelines has been devolved down as follows: • Executive Lead • Head of Health and Safety • Occupational Health • Pharmacy • Chemotherapy Nurse Specialists (Adult & Paediatrics) • Health and Safety Advisers • Senior Nurses/Clinical Managers
3.	Objectives of strategy/ policy/ plan/ procedure/ service	• To ensure the health, safety and welfare of staff, whose role includes handling of cytotoxic drugs, who are pregnant, breastfeeding mothers, or staff who are trying to conceive. • To provide managers with appropriate information and guidance to ensure the risks to staff who may handle cytotoxic agents, or waste, are assessed and necessary risk assessments are completed in order to minimise exposure. • To ensure measures taken to reduce risks to as low as reasonably practical. • To provide staff with information on the options available.
4.	Evidence and background information considered. For example • population data • staff and service users data, as	Since the 1980s various historical studies have demonstrated the potential occupational risks to staff when handling cytotoxic drugs (Wick et al. 2003). It is well documented that exposure to these drugs can present a significant risk to staff involved in handling them due to the

	applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory[1] and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need[2].	risk of exposure during the process (Connor et al. 2014; Mead 2014; Graeve et al. 2016). The most common routes of exposure to health care workers include: skin absorption, inhalation and ingestion (HSE 2017). There are numerous studies documenting the potential health risks to staff exposed to cytotoxic drugs which include adverse reproductive outcomes (Skov et al. 1990; Rekhadevi et al. 2007; Ratner et al. 2010; HSE 2017). Occupational exposure often occurs when control measures are inadequate (HSE 2017). Current safety standards include rigorous training and the use of personal protective equipment (PPE) in order to protect staff (HSE 2017). This includes aprons, gloves and eye protection. Cardiff and Vale UHB now also provide closed system devices (CSDs) for use in the cytotoxic chemotherapy administration process in accordance with the UK Health and Safety Executive (HSE - 2015) recommendations to use them where reasonably practical. Contributory background factors include: • Staff training to ensure all staff are aware of the risks and options. • Training and increased awareness amongst senior nurses and clinical managers. • Completion of appropriate risk assessments • Adequate staffing levels so that risks are minimised and staff are safe and supported. • An atmosphere of openness to ensure staff are encouraged to discuss any plans/, issues or concerns. The outcome of these guidelines may be adversely affected by any of the above factors not being in place.
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service	CV UHB is committed to ensuring that staff work in a safe environment. These guidelines will affect: • Staff who are pregnant, breast-feeding or trying to conceive. Implementation of these guidelines will involve the following: • Health and Safety Department • Occupational Health Department • Pharmacy/Sterile Production Services

[1] http://nww2.nphs.wales.nhs.uk:8080/PubHObservatoryProjDocs.nsf
[2] http://www.cardiffandvaleuhb.wales.nhs.uk/the-challenges-we-face

		• Chemotherapy Nurse Specialists (Adult & Paediatrics) • Senior nurses/Clinical Managers

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate.** Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	No impact		
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	No impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.3 People of different genders: Consider men, women, people undergoing gender reassignment **NB** Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	This policy is mainly aimed at women who are pregnant or trying to conceive and therefore has a positive impact for them. However, it is acknowledged that there are concerns of all sexes and genders in relation to conception. This document aims to address all aspects to ensure equality.	To use closed system devices in line with the UK Health and Safety Executive (HSE - 2015) guidance.	Closed system devices used in administration of cytotoxic chemotherapy to further reduce staff exposure.
6.4 People who are married or who have a civil partner.	No impact		
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Positive impact.	Individual risk assessments must be completed for all pregnant women who handle cytotoxic drugs as part of their role.	Managers must complete risk assessments for all pregnant staff on their unit.
6.6 People of a different race, nationality, colour, culture or ethnic origin	No Impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
including non-English speakers, gypsies/travellers, migrant workers			
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief	No impact		
6.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual)	No impact		
6.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design Well-being Goal – A Wales of vibrant culture and thriving Welsh language	Policy can be made available in Welsh if requested.		
6.10 People according to their income related group: Consider people on low income, economically inactive,	No impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
unemployed/workless, people who are unable to work due to ill-health			
6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	No impact		
6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	None		

7. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.1 People being able to access the service offered: Consider access for those	No impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
living in areas of deprivation and/or those experiencing health inequalities Well-being Goal - A more equal Wales			
7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc Well-being Goal – A healthier Wales	No impact		
7.3 People in terms of their income and employment status: Consider the impact on the availability and accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions Well-being Goal – A	No impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
prosperous Wales			
7.4 People in terms of their use of the physical environment: Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces Well-being Goal – A resilient Wales	No impact		
7.5 People in terms of social and community influences on their health: Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos Well-being Goal – A Wales of cohesive communities	No impact		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate Well-being Goal – A globally responsible Wales	No impact		

Please answer question 8.1 following the completion of the EHIA and complete the action plan

8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service	The Equality and Health Impact Assessment undertaken identifies understandable gender bias, due to the fact that the guidelines are predominantly aimed at pregnant or breast feeding women. However it is acknowledged that there are concerns of both sexes have been addressed in relation to conception. Thus ensuring equality.

Action Plan for Mitigation / Improvement and Implementation

	Action	**Lead**	**Timescale**	**Action taken by Clinical Board / Corporate Directorate**
8.2 What are the key actions identified as a result of completing the EHIA?	No changes identified			
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required?	No			

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.4 What are the next steps? Some suggestions:- • Decide whether the strategy, policy, plan, procedure and/or service proposal: o continues unchanged as there are no significant negative impacts o adjusts to account for the negative impacts o continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so) o stops. • Have your strategy, policy, plan, procedure and/or service proposal approved • Publish your report of this impact assessment • Monitor and review	Policy continues unchanged as there are no significant negative impacts			