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Guidelines for the Safe Handling, Checking and Administration of Cytotoxics.

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Introduction and Aim

Cytotoxic drugs, whether used as part of Systemic Anti-Cancer Therapy (SACT), or in the management of auto-immune disease or an ectopic pregnancy, are potentially harmful to both patients and staff.

The aim of this document is to set out Cardiff and Vale University Health Board (UHB) Guidelines for the safe handling, checking and administration of these drugs.

These Guidelines support, and should be read in conjunction with, the Management of Parenteral Cytotoxic Chemotherapy Procedure and other documents listed below.

Objectives

- To ensure all patients receiving cytotoxic drugs are kept as safe as possible and are fully informed about their treatment
- To promote safe working practices for all staff involved in checking, handling and administering cytotoxics
- To minimise the risk of adverse events

Scope

These Guidelines apply to Cardiff and Vale UHB staff involved in the checking, handling and administration of cytotoxic drugs; regardless of their place of work. They apply specifically to those handling or administering intravenous (IV), subcutaneous (S/C), intramuscular (IM) or oral cytotoxics.

They should be used to support the checking, handling and administration of the following medications: SACT, chemotherapy used in non-cancer settings, immunotherapies and biologics. (They are not intended to be applied to immunosuppressants such as corticosteroids, or inhibitors such as ciclosporin or tacrolimus etc).

They should be used as a practical resource to supplement face to face training; which may be achieved through attendance on the Cardiff and Vale University Health Board's (UHB's) Chemotherapy Study Days.

Equality and Health Impact Assessment	*An Equality and Health Impact Assessment (EHIA) has not been completed because these Guidelines are intended to support the Procedure for Handling Cytotoxics During Pregnancy and the Management of Parenteral Cytotoxic Chemotherapy Policy; both of which have the relevant EHIAs.*
Documents to read alongside this Procedure	• *The Medicines Code: Cardiff and Vale UHB* • *Safe and Secure Handling of Medicines Policy* • *Extravasation Procedure* • *Guidelines for the Administration of Subcutaneous Chemotherapy in the Community*

	• *Handling Spilled Cytotoxic Drugs Procedure* • *Handling Linen Contaminated with Cytotoxic Drugs Procedure* • *Health and Safety Policy* • *Management of Parenteral Cytotoxic Chemotherapy Procedure* • *Procedure for Handling Cytotoxics During Pregnancy* • *Standard Operating Procedure (SOP) for Managing a Chemotherapy Spill at Home (Ambulatory Care)* • *Ambulatory Care SOP (Haematology Directorate)* • *Use of CADD Solis VIP Ambulatory Infusion Pump SOP (Haematology Directorate)* • *Nurse Led Chemotherapy Assessment SOP*

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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	04/06/2020 Medicines Management Group	17/06/2020	New document.

Contents

1.0 Introduction:

1.1 Definitions:
Cytotoxic drugs are defined as drugs which contain chemicals considered toxic to cells. They may be used in the cancer setting to prevent the replication or growth of malignant cells, in auto-immune disease to dampen down the immune response, or as part of the medical management of an ectopic pregnancy.
SACT, however, can be defined as drugs which have direct anti-cancer activity and may include traditional chemotherapies, immunotherapies and targeted biological therapies. Immunotherapies and targeted therapies should be handled, administered and disposed of as cytotoxic drugs with the precautions advocated within this document.

1.2 Risks:
Cytotoxic drugs may present significant risks to those handling or administering them. Occupational exposure can occur through the following: inadvertent contact with skin, absorption, inhalation of aerosols and drug particles, ingestion, or needle stick injury. Common activities performed by Health Care Professionals (HCPs) which may cause exposure to risk include drug preparation, administration, disposal of cytotoxic waste, handling contaminated bodily fluids and cleaning spills. When control measures are insufficient then case reports of abdominal pain, hair loss, nasal sores, vomiting, liver damage, localised allergic reactions, foetal abnormalities or miscarriage have been reported (Health & Safety Executive {HSE} 2014). This guidance aims to minimise those risks.

2.0 Patient and Carer Education:

As a general principle, patients receiving their first cytotoxic treatment should have a face to face information session prior to being asked to consent to that treatment. This will enable the patient, a carer/parent or family member to ask questions or raise concerns. That initial consultation will vary as to who is involved depending on the setting; but it lays the foundations for informed consent. As consent is not a one off process so neither is information giving. Information giving should take into account issues such as age, capacity, language and, as much as it is possible, be tailored to the individual. The overarching aims should be to ensure that the patient/carer or family member:

- understands their treatment
- has disease specific written information
- understands the potential side-effects and has written information about them. (In adults receiving SACT this may be in the form of the

All Wales Patient Chemotherapy Record. Other areas may use different resources that best suit their patients' needs)

- has telephone numbers to contact in case of an adverse reaction or ill health. (In cases of adults being treated with SACT this should be in the form of either the All Wales Chemotherapy or Immunotherapy Alert Card)

Patient and carer education may involve many members of the multi-disciplinary team and will be on-going throughout treatment. Not only will it encompass education on toxicities, and how to manage them, but also any health or safety issues specific to their individual treatment.
N.B. During an initial education session, or consultation, it may also be useful to consider vascular access options (if required) and raise the need for central access if needed.

3.0 Consent:

Standard practice in Cardiff and Vale UHB is for consent for cytotoxic treatment to be obtained in writing; using either specific trials consent forms, the Cardiff and Vale generic consent forms (dependent on age and capacity), or the Cancer Research UK SACT consent forms. (Copies of the consent form will be available in both English and Welsh). Time should be given, wherever possible, for patients or carers to digest and consider any information given before being asked to consent in writing.
Written consent will need to be obtained again should the treatment change.
Confirmation of consent should be checked by the nurse administering the drug(s) and verbal assent to proceed obtained from the patient/parent/carer prior to beginning treatment.

4.0 Approved Areas for Administration:

SACT and other chemotherapies should generally only be administered in approved areas throughout the health board. A list of those approved areas is available in pharmacy and on clinical portal; attached to the Management of Parenteral Cytotoxic Chemotherapy Procedure. This Procedure also details the correct action to be taken in exceptional circumstances; where, for example treatment must be given in a non-approved area, or out of hours.
Other medicines, such as monoclonal antibodies, may be administered in areas that are not approved for chemotherapy administration.
However, all areas where cytotoxics are given will require trained and experienced staff; as well as appropriate equipment to manage anaphylaxis, extravasation and a cytotoxic spillage.

In some cases, patients may receive their SACT via an ambulatory infusion device; which allows the treatment to be initiated in hospital, (in an approved area), then continued at home. In this instance patients and carers will receive information regarding the safety of chemotherapy delivery as per the Ambulatory Care and Ambulatory CADD Solis Infusion Pump SOPs.

5.0 Storage of Cytotoxic Drugs in Clinical Areas:

Cytotoxics must be clearly labelled and sealed in polyseal bags, then placed in a zipped yellow padded bag to be transported between departments. They may only be transported by pharmacy staff, or nurses, who have received training in the safe handling of cytotoxics and what to do in the event of a spillage or leak.
IV, S/C and IM chemotherapy may only be accepted in the clinical area by a chemotherapy trained nurse or pharmacist.
The nurse/pharmacist should don an apron and gloves to receive the drug(s).
Cytotoxics must be clearly labelled as to whether to store in a refrigerator or at room temperature. If refrigerated, SACT drugs must be kept in a refrigerator solely for that purpose, or if that is not possible then on the lower shelves of a refrigerator in the treatment room and in rigid plastic trays to minimise the risk of contamination.
Cytotoxic drugs stored at room temperature should be placed in a rigid plastic tray lined with an absorbent towel in a designated locked cupboard; or kept in the padded yellow bag.
It may also help ensure appropriate storage if deliveries are documented on arrival. After the drug is received, the expiry date and time should be checked and the nurse caring for that patient notified that the drug has arrived. Some drugs have a short expiry period so this is particularly important.

6.0 Training and Competency

6.1 Chemotherapy Awareness Study Day:
Health care professionals involved in caring for patients receiving cytotoxics should receive training during their induction and, if working in areas where SACT or other chemotherapies are administered, must also attend the Cardiff and Vale UHB Chemotherapy Awareness Study Day. This is a generic study day suitable for all (non-medical) members of the multi-disciplinary team, to raise awareness of the issues involved in caring for patients on chemotherapy.

6.2 Chemotherapy Administration Training and Competency:

SACT, and intravenous chemotherapy for autoimmune disease, must be checked and administered (however) by registered nurses who have attended both the Cardiff and Vale UHB Chemotherapy Awareness Study Day and the two day Chemotherapy Administration Workshop. Prior to this they must have undertaken UHB approved training in Medicines Management and Intravenous (IV) Therapy, have been trained in Aseptic Non Touch Technique (ANTT), have attended Infusion Device Training and be fully competent in all of the aforementioned. Nurses administering SACT, or chemotherapy used in other areas, must also only administer via the route for which they have been trained/assessed.

Training will be followed by a period of supervised practice, completion of the United Kingdom Oncology Nurses Society SACT Passport or other relevant workbook, and final assessment. (The person supervising should be experienced and fully competent in administration). Final assessment will be carried out by the Chemotherapy CNS for adults, the Paediatrc Chemotherapy CNS, or a designated assessor. Details of the assessment will be held electronically by the relevant CNS and made available to all managers as required. Assessment thereafter is annual.

Additional training and competency assessments will be required for nurses caring for Ambulatory Care patients, in line with the Ambulatory Care SOP.

Nurses who administer only subcutaneous chemotherapy (S/C) may attend the Chemotherapy Awareness Study Day and an abbreviated training session, specific to the drug and route of administration. (i.e. dermatology or rheumatology nurses administering only s/c methotrexate).

6.3 Training for the Administration of other Cytotoxics:

Immunotherapies, or biologics administered for autoimmune disease, are not classed as traditional chemotherapies. Therefore they may be administered by any registered nurse who is competent in medicines management and pump usage. There is no requirement to attend the above training.

Education may be available from individual pharmaceutical companies on specific drugs.

7.0 Patient Assessment:

All patients will need to be reviewed prior to starting treatment or in between cycles. The person reviewing may be a consultant, a registrar competent in prescribing chemotherapy, a non-Medical prescriber, or a nurse competent in toxicity assessment. The development of senior nursing roles, such as Advanced Nurse Practitioners (ANPs), means it may not always be a doctor who consents the patient or decides he/she is fit for treatment. Fitness for treatment should either be documented in the patient's notes, be part of the

authorisation process on the prescription, or documented as part of the nurse-led toxicity assessment process.

7.1 Treatment Day:

Nurses administering the drug(s) should carry out the following checks prior to administration as a minimum:

- In women of child-bearing age, confirm the patient is not pregnant
- Baseline observations; including blood pressure, temperature, oxygen saturation level, pulse and respiratory rate. (A NEWS score should be obtained and any abnormalities discussed with an appropriate medic or ANP)
- Review any annotations from last clinic entry, medic/ANP review and electronic prescription and confirm the patient is well enough to proceed; with no new toxicities
- Confirm patient/parent/carer understands the treatment, has consented in writing, has no further questions and is clear on when to take action. (This also acts as re-confirmation of consent if the patient was consented in advance)
- Ensure written information (specific to your patient cohort) has been provided e.g. alert cards, patient chemotherapy records, information leaflets etc
- If administering SACT in the adult setting complete the pre-chemotherapy checklist in the Core Risk Assessment Booklet, or other pre-chemotherapy assessment tool. (Some areas may have nurses who are trained in nurse-led assessments. Full guidance on nurse-led assessments may be found in the Nurse Led Chemotherapy Assessment SOP)
- Confirm bloods within range – depending on the individual protocol - and all pre-investigations completed. (Although this is not strictly a nurse's responsibility it is considered good practice). If the patient is on steroids as part of their treatment ensure a base-line blood glucose is performed and repeated before each cycle. (For nurses conducting a nurse-led chemotherapy assessment all of these checks, however, would form an essential part of the assessment process)
- Confirm no variations in weight from weight on the prescription. A 10% variation must be reported to the prescriber or patient's medic and to pharmacy
- If having intravenous chemotherapy/cytotoxics confirm vascular access device is patent and has a visual infusion phlebitis (VIP) score of 0; addressing any issues highlighted
- If the patient is receiving SACT, or chemotherapy for auto-immune disease, confirm that he/she (or the /parent/carer) has a thermometer, is able to use it and knows the process to follow if they have an abnormal reading

- Ensure the patient/parent/carer understands how and when supportive medication or any oral cytotoxic drugs should be taken

8.0 Prescription and Drug Administration Checks:

8.1 Who?

- Parenteral SACT prescriptions, and chemotherapy prescriptions used in auto-immune conditions, must be checked by two registered chemotherapy trained nurses; at least one of whom must have been assessed as competent in the required method of administration. (The other may be under-going chemotherapy training). If given by infusion, both nurses must also be competent in the use of the required pump. The two nurse check will continue until the infusion is commenced and the pump rate set
- Non-SACT cytotoxics, such as monoclonal antibodies, may be checked by two registered nurses who are fully competent in medicines management. (As above – they are not required to undego chemotherapy training just to check or administer monoclonals or other immunotherapies)

8.2 Where?

- In adults the checking of SACT and cytotoxics against the prescription will occur at the patient's bed (or chair side) at the time of administration
- In paediatrics patient and drug details will be checked against the prescription in the treatment room and patient details confirmed again at the bed/chair side

8.3 What?

- Check patient's allergy status, prophylactic medication given, hydration, fluid compatibility, any special instructions or regimen specific nursing assessments
- Check the prescription to ensure it has the correct patient details; including name, address, date of birth and hospital or NHS number
- Confirm correct date, time, dose, drug, route of administration
- Ensure prescriber's signature, pharmacy check and authorisation. If using electronic prescribing the paper copy of the prescription must match the signatures on the electronic one and the nurse should also check any previous entries on the treatment notes section
- Confirm sequence of drug administration

- The patient should positively identify themselves stating their name, address and date of birth; which should be checked against both their wristband and the prescription, along with their hospital or NHS number
- Patients who are unable to confirm these details should have them verified with a next of kin, guardian or legal representative
- The administering nurse will read out the batch number, expiry date and time and the nurse checker will document both on the prescription
- Both nurses must sign the prescription and the nurse administering will also document date and time of administration

8.4 Checking of Oral Cytotoxics:

- In-patient oral Cytotoxics may be prescribed on a general in-patient prescription chart. A yellow sticker with 'Cytotoxic' may be added to the prescription chart to promote safe practice. They should be prescribed by a prescriber who is competent to prescribe cytotoxic drugs. All care should be taken to ensure that the medication is not continued unnecessarily without review
- Out-patient oral cytotoxics will be prescribed on out-patient prescriptions. They should be prescribed by a prescriber who is also competent to prescribe cytotoxic drugs and may be checked (and given to the patient) by a suitable pharmacist, medic or non-medical prescriber
- In-patient oral SACT should preferably be checked by 2 nurses; at least one of whom has been assessed as competent in the administration of oral chemotherapy. Nursing students should not check oral SACT
- If oral SACT is being administered in an area without chemotherapy trained nurses, advice should be given regarding safe handling, storage and the use of personal protective equipment (PPE). Wherever possible the patient should be encouraged to self-administer to minimise the risks to staff. With paediatric patients parents/guardians will be taught to administer the oral SACT

9.0 General principles for Handling and Administration:

Cytotoxic chemotherapy drugs are known to be potentially hazardous to staff due to their carcinogenic, mutagenic and teratogenic properties (Sessink et al 2015, HSE 2014). Immunotherapies and biological targeted therapies may pose additional risks because their long-term impact has not been established (Meade 2015). The following principles should therefore be applied to minimise any risk, not only to staff but to patients also:

- Checking process to be completed as above. (See 'Prescription and Drug Administration Checks). If any discrepancies in the process,

clarification and confirmation must be sought from pharmacy, the prescriber, or a senior healthcare professional prior to commencing the administration

- Prior to administration the nurse administering, (if they have not been responsible for storing the drug), is to ensure storage requirements have been met. If the drug has been incorrectly stored please check for discolouration or precipitation and seek advice from pharmacy
- Administer before the drug is due to expire. If there are any doubts as to whether the drug will expire before it has been completely administered seek advice from pharmacy
- Personal protective equipment (PPE) comprising gloves, apron and goggles, (or glasses if worn), should be used for IV administration. As a minimum gloves and an apron are required for S/C, IM and oral administrations
- Ensure availability of a Cytotoxic Spill Kit, Extravasation Kit and Extravasation Treatment Summary in your area. Check expiry dates of kits regularly and do not administer cytotoxics without having in date kits
- Patients receiving Ambulatory SACT should be provided with a specific spill kit for use at home, educated on the management of a spill at home and given the corresponding patient information leaflet (What to do now… you have had a chemotherapy spill at home)
- Cytotoxic sharps bins and floor bins are also a requirement for safe and appropriate disposal of waste. In areas where administration is infrequent a purple sharps bin will suffice
- Rigid plastic trays lined with an inco. pad or absorbent paper towel should be used for administering IV, S/C and IM cytotoxics. The tray should be taken to the patient on a trolley along with a cytotoxic sharps bin
- National guidelines advocate the use of closed systems to minimise the hazards associated with cytotoxic administration (Sessink et al 2015, HSE 2014, International Society of Oncology Pharmacy Practitioners {ISOPP} 2007). In Cardiff and Vale UHB closed systems are used for most in-patient and day case IV SACT administrations and for chemotherapy used to treat auto-immune disease; the exception being patients receiving ambulatory SACT where closed systems are not considered feasible. Closed systems are not used for stand-alone immunotherapies given for the management of autoimmune disease because of the lack of evidence about the risks of exposure. Nor are they used for small volume S/C administration; although they may be used for large volume S/C injections such as Rituximab

10.0 Procedure for the Administration of Cytotoxic Infusions

10.1 Using Closed Systems:

- Having carried out all the confirmatory assessments, apply PPE as above
- Select either a saline or glucose flush, depending on fluid compatibility, and label with the patient's details and date and start time of the infusion. This flush may be used to prime the giving set and flush between, and after, all cytotoxic infusions. (Providing closed systems are used, the port cleaned thoroughly and allowed to dry, and the flush is correctly labelled, then each flush may be used for up to 24 hours)
- Pierce the flush bag with a bag spike, using a line connector to connect the giving set to the spiked flush (**see images below**). Prime the giving set and access the patient's Vascular Access Device (VAD). A VAD is defined as patent if it bleeds back and flushes without resistance. Ensure patency of the device, connect the giving set and hang the flush on a drip-stand
- Using PPE retrieve the cytotoxic drug from storage and place in the lined plastic tray with a spare bag spike and gauze
- 2 nurses to check the drug: ask the patient's name, address, date of birth and confirm against the wrist band. Check the correct dose, drug, time, route and expiry. Document the expiry, batch number and date and time of administration
- If all correct, nurse administering to spike the infusion bag with the bag spike; holding within the tray. Gauze may be used to ensure no drips when spiking the bag
- Disconnect the giving set from the flush leaving the flush (with bag spike) hanging on the drip-stand
- Attach the spiked cytotoxic bag to the giving set using the line connector to attach
- Place the infusion bag on the drip stand
- Dispose of all waste as cytotoxic waste, then remove contaminated gloves before programming the infusion pump. (As a general rule: sharps and infusion bags or syringes to be disposed of in a purple lidded sharps bin and all other waste, including absorbent towel, gauze and PPE to be disposed of in a cytotoxic floor bin)
- Both the checker and the nurse administering should check the rate and volume to be infused
- Ensure VAD is secure and the patient is left comfortable and aware of the importance of reporting any signs of extravasation or hypersensitivity reactions

- Both nurses to sign the paper prescription and, if electronic prescribing is being used, one to document the administration on the electronic prescribing system

Bag spike

Line connector

Line connector: attached

10.2 Without Closed Systems:

- The same safeguards should be applied in terms of checking, handling and disposal of waste as above. But additional care should be taken when administering cytotoxics without closed systems, especially when spiking or de-spiking an infusion. All manipulations and connections should be done over a lined rigid plastic tray as above and all connections wiped with gauze.
- As Ambulatory chemotherapy cassettes will not be able to use closed systems, extra diligence must be taken to minimise the potential for exposure to cytotoxics. Every effort has been made to ensure both patient and staff safety, but particular care should be taken when needing to prime the giving set with the drug. For safety advice on administering SACT via an ambulatory pump please refer to the SOP

10.3 During the Infusion:

Observe VAD for signs of infiltration or extravasation. (Please refer to the Extravasation Procedure for guidance on how to identify and manage an infiltration or extravasation)

- Patients receiving drugs with a known high hypersensitivity risk should be nursed in an area where they can be observed throughout; with appropriate cover and anaphylaxis equipment readily available

10.4 On Completion:

- Take a cytotoxic sharps bin to the patient
- Wearing PPE turn the pump off and ensure the roller clamp is closed. If using the flush which has been pierced with a bag spike, thoroughly wipe the port on the bag spike and allow to dry. Disconnect the cytotoxic infusion from the giving set making sure not to de-spike the

bag. Immediately dispose of both the infusion (and attached bag spike if used) in a cytotoxic sharps bin
- If not using closed systems a new flush will be required after every cytotoxic infusion
- Attach the flush and hang on the drip-stand, then remove gloves and give sufficient fluid to clear the giving set of the drug. This will be a minimum of 25mls and should be administered at the same rate as the preceding cytotoxic drug (to reduce the risk of a sudden bolus)

10.5 Vinca Alkaloids:
- Vinca Alkaloids, in the adult setting, are administered over 5-10 minutes in minibags of saline. (A longer infusion time increases the risk of chemical phlebitis). A short infusion using a minibag also avoids the risk of inadvertent intrathecal administration historically associated with boluses of these drugs
- In paediatrics, Vinca alkaloids are normally administered as minibags, but may, on occasion, be given as a bolus (via a syringe) in doses of less than 0.3mgs.
- Vinca alkaloids are vesicants and should be administered under constant observation; monitoring for signs of extravasation. If administering as an infusion please free flow and do not use a pump

11.0 Procedure for the Administration of Bolus Cytotoxics:

Please note that practice may vary slightly between the adult and paediatric setting. In adults, bolus cytotoxics are generally given through the side port of a free flowing infusion. In some circumstances in paediatrics they may be bolused directly into the VAD. In that case please see section 10.0 for administration as an infusion.

- PPE, checking and assessment processes as above (See section 8.0)
- Using a giving set with a port, establish a fast flowing infusion of 0.9% saline or 5% dextrose; depending on fluid compatibility.
- Thoroughly clean the injection port with a clinell wipe and allow to dry
- If using closed systems attach a smartsite (see below) to the port
- Once the drug is checked attach a syringe connector (see below) to the syringe
- Securely attach the syringe to the injection port; ensuring the injection port is positioned over your rigid plastic tray. A gauze swab should be positioned below the connection point to absorb any inadvertent spillage
- Administer the bolus at a steady rate allowing the drug to be diluted in the infusion fluid. Check regularly to make sure the infusion is still free

flowing, that the chamber is not filling up and that the patient is not experiencing any discomfort, swelling or leakage at the site of the VAD

- The process will be the same if not using closed systems but the syringe connector will not be required
- On completion disconnect and dispose of the syringe immediately into your cytotoxic sharps bin. Gauze, absorbent pad and PPE should be disposed of in the cytotoxic floor bin
- Allow 25mls of infusion fluid to clear the giving set and dispose of the giving set in the cytotoxic sharps bin

Smartsite

Syringe connector

12.0 Procedure for the Administration of S/C and IM Cytotoxics:

- PPE, checking the drug, patient assessment and disposal of waste as above (See section 8)
- A full blood count should be conducted prior to administering an IM drug; with particular attention paid to the patient's platelet count. Please ensure the platelet count is within a medically acceptable range prior to giving medication into the muscle
- Administration techniques as per standard administration for S/C or IM medicines. Routine cleansing of the skin is not required for S/C or IM injections if the patient is 'socially clean,' but may be done if requested (World Health Organisation). Please rotate the sites of administration; using the abdomen, upper arms and thighs
- Closed systems are not routinely used for administering small volume S/C or IM cytotoxic drugs; but may be used for reconstituting larger volume S/C drugs such as S/C Rituximab for example. (0.1 mls may remain in the syringe connector and not be received by the patient. This would be undesirable where only a low dose/volume was being administered)

12.1 Patient/Carer/District Nurse Administration of S/C Cytotoxics:

- 'Guidelines for the Administration of Subcutaneous Chemotherapy in the Community' are available to cover patient/carer administration and district or practice nurse administration. Education is available for district nurses from the Chemotherapy Nurse Specialist for adults. Patients/carers must be trained and assessed as to suitability to administer and provided with all necessary equipment; including PPE and a cytotoxic sharps bin. Disposal of waste may be arranged in the community, if the service is available, or the full and sealed sharps bin may be returned to day unit for safe disposal. Written, and pictorial, step by step guidelines and information sheets are available for patients who wish to self administer, or for their carer

13.0 Procedure for the Administration of Oral Cytotoxics:

- Oral cytotoxics should not be administered if a patient has been admitted acutely unwell, until it has been confirmed by an appropriate registrar or consultant that they should continue
- Checking as per section 8.4 using a 2 nurse check
- Hands should be washed both before and after administration
- Nurse to wear gloves and use a non-touch technique to administer
- Do not divide, break or crush. Please administer whole
- If a patient is unable to tolerate tablet or capsule form please liaise with the appropriate pharmacist and patient's consultant to discuss suitable alternatives

13.1 Patient or Carer Administration:

- Inpatients will need to be assessed as competent to administer oral cytotoxics in line with the Patient Orientated Medication System (POMS). The nurse looking after the patient will be responsible for carrying out this assessment. Outpatients or their carers will also be trained and assessed by the chemotherapy trained nurse (or key worker) as to their suitability to administer
- Patients who self-administer their oral cytotoxics should be fully informed as to the potential toxicities, indications and contra-indications
- Advice should be given on storage at home – away from children and vulnerable adults - and according to the requirements of the individual drug
- Both patients and carers should be advised to wash their hands before and after administration and carers should be supplied with gloves to administer
- Any excess medication should be returned to pharmacy for disposal

- If the patient vomits after taking a dose advice should be sought from his/her treatment centre; using the emergency telephone numbers provided. The patient's anti-emetic control should also be reviewed

14.0 Management of a Clinical Incident:

Cardiff and Vale UHB have a policy of openness with regards to any clinical incident and all staff are encouraged to report any issues, in the first instance, to their line manager. (Ambulatory Care incidents should also be reported to the pharmacist and Ambulatory Care Manager). In addition all clinical incidents should be reported using DATIX and will then be investigated. Incidents should also be fed back to the Cytotoxic Board for consideration, monitoring and audit.
For further information or advice on managing a spillage, (including a spillage at home), extravasation, or handling contaminated linen please see the appropriate document listed above under 'procedures to be read alongside this document'.
Spillage and Extravasation kits should be available in all areas where cytotoxics are administered, along with the Management of Extravasation Treatment Summary. Extravasations should be reported to the adult or paediatric Chemotherapy CNS for on-going monitoring. Accidental contact (e.g. skin, eyes) is covered in the 'Procedure for Handling Spilled Cytotoxic Drugs'. For needlestick injury encourage bleeding, wash with copious amounts of warm soapy water and follow the health board's needlestick guidance.

15.0 Pregnant Staff:

It is recognised that chemotherapies and some cytotoxic drugs are potentially teratogenic and mutagenic and therefore staff who are pregnant, or trying to conceive, may be at greater risk from occupational exposure to these drugs (Sessink et al 2015, HSE 2014). The first three months of pregnancy is the time of greatest risk; being a time of rapid cell division in the developing foetus.
Staff who are planning a pregnancy or who are pregnant should be able to discuss in confidence any concerns with their manager and be offered alternative duties if that is what they would prefer. Nursing staff may choose to move to an area where cytotoxics and other SACT drugs are not administered.
However, as some pregnancies are unplanned, all staff should be made aware of the potential hazards and the need to follow the procedures designed to minimise exposure to cytotoxics at all times.

Further information, advice and risk assessments are available in the 'Procedure for Handling Cytotoxics During Pregnancy.'

16.0 Handling of Excreta and Bodily Fluids:

Traces of cytotoxic drugs can be excreted as unchanged drugs, or active metabolites, in urine or faeces for up to 7 days after treatment, and small traces may also be present in other body fluids.
Gloves and a plastic apron should always be worn when handling patient's bodily fluids or excreta and hands washed thoroughly after removing PPE.
Disposable containers must be used for patient excreta and vomit. These should be placed carefully into the sluice to avoid splashing. Bed pans / urinals used to collect excreta for patients receiving cytotoxics must be disposed of as soon as possible. Ambulatory Care patients required to monitor urine output at home will be given plastic jugs, cytotoxic waste bags and gloves.
Patients/carers should be advised that, although the risk of harm is low, it is important to protect others from contact with cytotoxics. Therefore they should flush the toilet immediately after use, wash hands thoroughly and carers should wear rubber gloves if body fluids are spilled or handled.

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Equality & Health Impact Assessment for

{insert title of strategy/ policy/ plan/ procedure/ service}

Please read the Guidance Notes in Appendix 1 prior to commencing this Assessment

Please note:

- The completed Equality & Health Impact Assessment (EHIA) must be
  - Included as an appendix with the cover report when the strategy, policy, plan, procedure and/or service change is submitted for approval
  - Published on the UHB intranet and internet pages as part of the consultation (if applicable) and once agreed.
- Formal consultation must be undertaken, as required[1]
- Appendices 1-3 must be deleted prior to submission for approval

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	
3.	Objectives of strategy/ policy/ plan/ procedure/ service	
4.	Evidence and background information considered. For example • population data • staff and service users data, as applicable • needs assessment • engagement and	

[1] http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,73860407,253_73860411&_dad=portal&_schema=PORTAL

	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[2] and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need[3].	
5.	Who will be affected by the strategy/ policy/ plan/ procedure/ service	

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

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

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			
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			
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			

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
going through any medical procedures. Sometimes referred to as Trans or Transgender			
6.4 People who are married or who have a civil partner.			
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.			
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers			

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
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief			
6.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual)			
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			
6.10 People according to their income related group: Consider people on low income,			

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
economically inactive, 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			
6.12 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service			

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 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 (e.g. immunisation and vaccination, falls			

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
prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc Well-being Goal – A healthier Wales			
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 prosperous Wales			
7.4 People in terms of their use of the physical environment: Consider the impact on the			

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
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			
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			

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
and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos Well-being Goal – A Wales of cohesive communities			
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			

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	

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?				
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required? This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?				

	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 proposa 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				

Appendix 1

Equality & Health Impact Assessment

Developing strategies, policies, plans and services that reflect our Mission of 'Caring for People, Keeping People Well'

Guidance

The University Health Board's (the UHB's) Strategy 'Shaping Our Future Wellbeing' (2015-2025) outlines how we will meet the health and care needs of our population, working with key partner organisations to deliver services that reflect the UHB's values. Our population has varied and diverse needs with some of our communities and population groups requiring additional consideration and support. With this in mind, when developing or reviewing any strategies, policies, plans, procedures or services it will be required that the following issues are explicitly included and addressed from the outset:-

- Equitable access to services
- Service delivery that addresses health inequalities
- Sustainability and how the UHB is meeting the requirements of the Well-being of Future Generations (Wales) Act (2015)[4]

This explicit consideration of the above will apply to strategies (e.g. Shaping Our Future Strategy, Estates Strategy), policies (e.g. catering policies, procurement policies), plans (e.g. Clinical Board operational plans, Diabetes Delivery Plan), procedures (for example Varicella Zoster - chickenpox/shingles - Infection Control Procedure) and services /activity (e.g. developing new clinical services, setting up a weight management service).

Considering and completing the Equality & Health Impact Assessment (EHIA) in parallel with development stages will ensure that all UHB strategies, policies, plans, procedures or services comply with relevant statutory obligations and responsibilities and at the same time takes forward the UHB's Vision, 'a person's chance of leading a healthy life is the same wherever they live and whoever they are'. This process should be proportionate but still provide helpful and robust information to support decision making. Where a more detailed consideration of an issue is required, the EHIA will identify if there is a need for a full impact assessment.

Some key statutory/mandatory requirements that strategies, policies, plans, procedures and services must reflect include:

- All Wales Standards for Communication and Information for People with Sensory Loss (2014)[5]
- Equality Act 2010[6]

[4] http://thewaleswewant.co.uk/about/well-being-future-generations-wales-act-2015
[5] http://gov.wales/topics/health/publications/health/guidance/standards/?lang=en

- Well-being of Future Generations (Wales) Act 2015[7]
- Social Services and Well-being (Wales) Act 2015[8]
- Health Impact Assessment (non statutory but good practice)[9]
- The Human Rights Act 1998[10]
- United Nations Convention on the Rights of the Child 1989[11]
- United Nations Convention on Rights of Persons with Disabilities 2009[12]
- United Nations Principles for Older Persons 1991[13]
- Welsh Health Circular (2015) NHS Wales Infrastructure Investment Guidance[14]
- Welsh Government Health & Care Standards 2015[15]
- Welsh Language (Wales) Measure 2011[16]

This EHIA allows us to meet the requirements of the above as part of an integrated impact assessment method that brings together Equality Impact Assessment (EQIA) and Health Impact Assessment (HIA). A number of statutory /mandatory requirements will need to be included and failure to comply with these requirements, or demonstrate due regard, can expose the UHB to legal challenge or other forms of reproach. This means showing due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation;
- advance equality of opportunity between different groups; and
- foster good relations between different groups.

EQIAs assess whether a proposed policy, procedure, service change or plan will affect people differently on the basis of their 'protected characteristics' (i.e. their age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion, sex or sexual orientation) and if it will affect their human rights. It also takes account of caring responsibilities and Welsh Language issues.
They provide a systematic way of ensuring that legal obligations are met and are a practical means of examining new and existing policies and practices to determine what impact they may have on equality for those affected by the outcomes.

HIAs assess the potential impact of any change or amendment to a policy, service, plan, procedure or programme on the health of the population and on the distribution of those effects within the population, particularly within vulnerable groups. HIAs help identify how people may be affected differently on the basis of where they live and potential impacts on health inequalities and health equity. HIA increases understanding of potential health impacts on those living in the most deprived communities, improves service delivery to

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[6] https://www.gov.uk/guidance/equality-act-2010-guidance
[7] http://gov.wales/topics/people-and-communities/people/future-generations-act/?lang=en
[8] http://gov.wales/topics/health/socialcare/act/?lang=en
[9] http://www.wales.nhs.uk/sites3/page.cfm?orgid=522&pid=63782
[10] https://www.equalityhumanrights.com/en/human-rights/human-rights-act
[11] http://www.unicef.org.uk/UNICEFs-Work/UN-Convention
[12] http://www.un.org/disabilities/convention/conventionfull.shtml
[13] http://www.ohchr.org/EN/ProfessionalInterest/Pages/OlderPersons.aspx
[14] http://www.wales.nhs.uk/sites3/Documents/254/WHC-2015-012%20-%20English%20Version.pdf
[15] http://gov.wales/topics/health/publications/health/guidance/care-standards/?lang=en
[16] http://www.legislation.gov.uk/mwa/2011/1/contents/enacted

ensure that those with the greatest health needs receive a larger proportion of attention and highlights gaps and barriers in services.

The **EHIA** brings together both impact assessments in to a single tool and helps to assess the impact of the strategy, policy, plan, procedure and/or service. Using the EHIA from the outset and during development stages will help identify those most affected by the proposed revisions or changes and inform plans for engagement and co-production. Engaging with those most affected and co-producing any changes or revisions will result in a set of recommendations to mitigate negative, and enhance positive impacts. Throughout the assessment, 'health' is not restricted to medical conditions but includes the wide range of influences on people's well-being including, but not limited to, experience of discrimination, access to transport, education, housing quality and employment.

Throughout the development of the strategy, policy, plan, procedure or service, in addition to the questions in the EHIA, you are required to remember our values of *care, trust, respect, personal responsibility, integrity and kindness* and to take the Human Rights Act 1998 into account. All NHS organisations have a duty to act compatibly with and to respect, protect and fulfil the rights set out in the Human Rights Act. Further detail on the Act is available in Appendix 2.

Completion of the EHIA should be an iterative process and commenced as soon as you begin to develop a strategy, policy, plan, procedure and/or service proposal and used again as the work progresses to keep informing you of those most affected and to inform mitigating actions. It should be led by the individual responsible for the strategy, policy, plan, procedure and/or service and be completed with relevant others or as part of a facilitated session. Some useful tips are included in Appendix 3.

For further information or if you require support to facilitate a session, please contact Susan Toner, Principal Health Promotion Specialist (susan.toner@wales.nh.uk) or Keithley Wilkinson, Equality Manager (Keithley.wilkinson@wales.nhs.uk)

Based on

- Cardiff Council (2013) Statutory Screening Tool Guidance
- NHS Scotland (2011) Health Inequalities Impact Assessment: An approach to fair and effective policy making. Guidance, tools and templates[17]
- Wales Health Impact Assessment Support Unit (2012) Health Impact Assessment: A Practical Guide[18]

[17] http://www.healthscotland.com/uploads/documents/5563-HIIA%20-%20An%20approach%20to%20fair%20and%20effective%20policy%20making.pdf (accessed 4 January 2016)

[18] http://www.wales.nhs.uk/sites3/page.cfm?orgid=522&pid=63782 (accessed on 4 January 2016)

Appendix 2 – The Human Rights Act 1998[19]

The Act sets out our human rights in a series of 'Articles'. Each Article deals with a different right. These are all taken from the European Convention on Human Rights and are commonly known as 'the Convention Rights':

1. Article 2 Right to life. NHS examples: the protection and promotion of the safety and welfare of patients and staff
2. Article 3 Freedom from torture and inhuman or degrading treatment. NHS examples: issues of dignity and privacy, the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travellers, issues of patient restraint and control
3. Article 4 Freedom from slavery and forced labour
4. Article 5 Right to liberty and security. NHS examples: issues of patient choice, control, empowerment and independence, issues of patient restraint and control
5. Article 6 Right to a fair trial
6. Article 7 No punishment without law
7. Article 8 Respect for your private and family life, home and correspondence. NHS examples: issues of dignity and privacy, the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travellers, the right of a patient or employee to enjoy their family and/or private life
8. Article 9 Freedom of thought, belief and religion. NHS examples: the protection and promotion of the safety and welfare of patients and staff, the treatment of vulnerable groups or groups that may experience social exclusion, for example, gypsies and travellers
9. Article 10 Freedom of expression. NHS examples: the right to hold and express opinions and to receive and impart information and ideas to others, procedures around whistle-blowing when informing on improper practices of employers where it is a protected disclosure
10. Article 11 Freedom of assembly and association
11. Article 12 Right to marry and start a family
12. Article 14 Protection from discrimination in respect of these rights and freedoms. NHS examples: refusal of medical treatment to an older person
13. solely because of their age, patients presented with health options without the use of an interpreter to meet need, discrimination against UHB staff on the basis of their caring responsibilities at home
14. Protocol 1, Article 1 Right to peaceful enjoyment of your property
15. Protocol 1, Article 2 Right to education
16. Protocol 1, Article 3 Right to participate in free elections
17. Protocol 13, Article 1 Abolition of the death penalty

[19] https://www.equalityhumanrights.com/en/human-rights/human-rights-act

Appendix 3

Tips

- Be clear about the policy or decision's rationale, objectives, delivery method and stakeholders.
- Work through the Toolkit early in the design and development stages and make use of it as the work progresses to inform you of those most affected and inform mitigating actions
- Allow adequate time to complete the Equality Health Impact Assessment
- Identify what data you already have and what are the gaps.
- Engage with stakeholders and those most affected early. View them as active partners rather than passive recipients of your services.
- Remember to consider the impact of your decisions on your staff as well as the public.
- Record which organisations and protected characteristic groups you engaged with, when you engaged with them and how you did so (for example, workshop, public meeting, written submission).
- Produce a summary table describing the issues affecting each protected group and what the potential mitigations are.
- Report on positive impacts as well as negative ones.
- Remember what the Equality Act says – how can this policy or decision help foster good relations between different groups?
- Do it with other people! Talk to colleagues, bounce ideas, seeks views and opinions.