

**492 – GUIDELINES FOR THE MANAGEMENT OF CHEMOBIOLOGICAL SYSTEMIC ANTI-CANCER THERAPY (SACT) EXTRAVASATION IN ADULTS**

**Broad Recommendations / Summary**

These guidelines are to ensure the safe management of adult patients, relevant carers, healthcare professionals and the environment in the event of extravasation in the administration of chemobiological systemic anti-cancer therapy (SACT)

The guidelines have been adapted from the former North East Yorkshire and Humber Clinical Alliance (Cancer) NEYHCA CEG – Guidelines for the Management of Chemotherapy Extravasation in Adults, version 1.5 May (2013) - formally HYCCN. NEYHCA has since ceased to exist as has administration or version control facilitation. Therefore, the adapted, updated guidelines are to rebrand and publish directly onto the local Hull & East Yorkshire (HEY) Trust Intranet Site and linked to the Queens Centre for Oncology and Haematology (QCOH); Cancer Services and Chemotherapy CNS Team Websites to ensure up to date best practice

Relevant evidence based practice consensus and particular acknowledgment to:

Northern Devon Healthcare NHS Trust (NDH) Cytotoxic Extravasation Policy 2016; The Royal Marsden Hospital Handbook of Cancer Chemotherapy (2005) The Royal Marsden Manual (RMM) of Clinical Procedures Ch12 2015; The Department of Health (DOH): The Manual for Cancer Services 2011: Chemotherapy Measures 2013, Hull and East Yorkshire NHS Hospitals Trust (HEY) Administration of Systemic Anti-Cancer Therapy Guidelines V2.0 2016; HEY Extravasation Policy CP246 2014; West of Scotland Cancer Advisory Network (WOSCAN) Chemotherapy Extravasation Guideline 2009; European Oncology Nurses Society (EONS) Extravasation Guidelines Clinical Implementation Toolkit 2007

Previous terminology relating to cytotoxic chemotherapy is now known under the contemporary term of Chemobiological - Systemic Anti-Cancer Therapy, referred to as SACT throughout the text and includes all classifications of intravenous anti-cancer agents including cytotoxic, biological, immunological and hormone therapies in line with up to date evidence and classifications and the term Health Care Professional (HCP) encompasses mainly qualified nurses with training in care of chemotherapy patients and can include appropriate medical and pharmacy staff

**1 PURPOSE / LEGAL REQUIREMENTS / BACKGROUND**

The purpose of these guidelines are to inform all Health Care Professionals (HCP) of their responsibility in the safe practice required during chemobiological systemic anti-cancer therapy (SACT) administration, to minimise the risks involved to avoid, recognise and manage extravasation. EONS (2007) recognise nurses' pivotal role in optimising patient comfort, safety and care, sharing responsibilities and ensuring best possible practice

The potential risk for extravasation exists during intravenous (IV) administration of all classification of chemobiological agents and associated risk of exposure to such drugs regards spillage, absorption and in waste products for patients, carers and staff involved

It remains the responsibility of the practitioners to interpret the application of the guidelines, be aware of best possible practice whilst taking account of local circumstances and the needs and wishes of individual patients. In reviewing the summary guidelines, local clinicians and managers will be required to assess whether the guidance can be met, and if not what service developments need to be undertaken to achieve the ideal service as defined by the available evidence

Although there is extensive scientific studies to support the management of extravasation, controversially, with ever increasing developments in SACT there is not fully conclusive or necessarily proven evidence-based that agrees on all standardised courses of action, particularly for newer classifications and alternative antidotes and techniques. In some cases literature suggests a variety of options rather than a uniformed approach; therefore these guidelines aim to agree a consensus to update current best practice. However, and in agreement with Boulanger et al (2015) recent literature review concludes that further studies and investigation into these issues raised and a more consistent approach nationally is required to agree the most beneficial action and therefore support the continuation and relevance of the new National electronic-Green Card Reporting System to allow further data, evidence collection and practice development (NDH 2016) and acknowledge the need to explore additional strategies and review classifications as more evidence is available

## 2 POLICY / PROCEDURE / GUIDELINE DETAILS

These guidelines will address

- 2.1 DEFINITION of Extravasation
- 2.2 RISK FACTORS of Extravasation
- 2.3 PREVENTION of Extravasation
- 2.4 RECOGNITION of Extravasation
- 2.5 MANAGEMENT & TREATMENT of Extravasation
- 2.6 CONSEQUENCES of Extravasation
- 2.7 DOCUMENTATION in the event of Extravasation

### 2.1 DEFINITION

Extravasation is the process by which fluid/drug accidentally leaks into the surrounding tissues rather than the vascular pathway and in terms of Intravenous (IV) systemic anti-cancer therapy (SACT), extravasation refers to the infiltration of chemobiological agents into the subcutaneous or sub dermal tissues surrounding the intravenous or intra-arterial administration site (Dougherty & Lister 2015; Harrold et al 2013; Perez Fidalgo et al 2012; RCN 2010)

Extravasation is a potentially severe complication that can arise during SACT administration (Boulanger et al 2015) and perceived as a 'dreaded complication' or a 'catastrophe' (Schrijvers 2003) and therefore is acknowledged as an **Oncological Emergency** within the cancer care setting that requires immediate action (NEYHCA 2013)

Extravasations of such drugs are capable of causing pain, necrosis, and/or sloughing of tissue. Tissue damage from extravasation can range from minor erythema, to severe necrosis resulting in loss of function or loss of a limb with the result being more devastating and disabling than the disease itself (Polovich et al 2009; Gault 1993;) therefore reducing risk is fundamental in limiting incidence and then focus on recognition and prompt action

### 2.2 RISK FACTORS

The consensus of risk of extravasation occurrence according to relevant guidelines review can be significantly increased due to one or more of the following factors:

- Small fragile veins
- Cannulation in antecubital fossa or joint spaces
- Hard, sclerosed or corded veins due to previous IV therapy
- Multiple venepuncture or previous cannulation sites
- Predisposition to bleeding or coagulation abnormalities

- Breast or lymph node surgery
- Decreased circulation due to conditions such as peripheral neuropathy, advanced diabetes, vascular disease and lymphodema
- Superior Vena Cava Obstruction (SCVO)
- Inadequate securing of cannula/poor visibility of vein due to dressing
- Topical anaesthetics inhibiting detection and sensation
- Inadequate communication disabling patients to identify or report signs and symptoms

(NDH 2016; RMM 2015; WOSCAN 2009; EONs 2007)

### 2.3 PREVENTION

Majority of extravasations can be prevented with effective risk assessment and standardised, evidence based administration techniques. In order to diminish the risk of extravasation, all practitioners involved in the administration and management of chemobiological agents must be trained and deemed competent including implementation of preventative protocols and minimising risk of SACT (Polovich et al 2009 & Schrijvers 2003)

#### Training and competency

SACT must only be administered by a nurse who has the required or undergoing supervised training, knowledge and skills to assess risk; prevent and recognise the signs and symptoms of extravasation and is competent to perform the management of extravasation (Dougherty & Lamb 2008).

- Definition of training is defined within the NHS Manual for Cancer Standards (DOH 2008; Chemotherapy Measures 2013) specifying all clinical chemotherapy services must have policies and procedures in place to ensure staff administering SACT have had competencies assessed in administration, acute oncological emergencies including recognition and treatment of extravasation as identified by that service based on the evidence available (Harrold et al 2013)
- HEY HCPs caring for patients undergoing SACT chemobiological therapy must have received the necessary training and be working through or completed the work-based learning strategy: Chemotherapy Competency Programme (NEYCHA 2013), specifically Topic 5 Health and Safety and Topic 6 Oncological Emergencies related to extravasation
- Administration of SACT needs to be guided by the skill and clinical judgement of the HCP in specific and individual circumstances presented with accurate documentation in line with the Code of Professional Standards (NMC 2015)

#### Patient Education

Full patient awareness and understanding of the risks of SACT administration is vital in order to help prevent and recognise when extravasation occurs, therefore;

- Patients should be informed of the potential risks and possible consequences of an extravasation event (Polovich et al 2009) particularly with malpractice allegations, therefore consent forms will include extravasation risk documented and confirmed
- Positive language and reassuring communication is fundamental to inform patients of signs, symptoms and self-care aspects throughout treatment, reporting any changes in sensation no matter how insignificant and reminded of risk at each subsequent treatment episode
- Patients with communication or capacity issues who may rely on carers or interpreters it is important to establish they understand the risk and significance of extravasation injury and are able to report symptoms immediately, self-care deficits will be identified and managed appropriately
- The importance of patient involvement is underlined by Harold et al (2013) regards informational needs and implied consent as HCP have guidance in using professional judgement on what is in the patients best interest but also advocate shared decision making and choices patients have; citing DOH (2010) paper 'No decision about me, without me' strategy more recently supported by NMC (2015) Code of Professional Standards can only help and enhance patient experience and trust

## Administration

Evidence indicates the position, size and age of the venepuncture site are the factors which have greatest bearing on the likelihood of problems occurring. However, if the following general guidance consensus is borne in mind, the likelihood of extravasation can be significantly reduced;

- For slow infusion of high-risk vesicant drugs, history of previous extravasation or when Summary of Product Characteristics (SPC) (eMC 2016) recommends; use of Central Venous Access Device (CVAD) should be considered
- Cannulation must be performed by a practitioner skilled and competent in venepuncture and cannulation, who is able to assess and select appropriate veins extravasation (Dougherty & Lamb 2008)
- Selection site of cannula site is important; avoiding antecubital fossa and joints due to little soft tissue for the protection of underlying nerves and tissues (RCN 2010; Doherty & Lamb 2008) use firm straight veins, placing above any previous attempts. RMM (2015) support use of large straight vein over dorsum of the hand as a first choice and preferable to smaller veins in the forearm in the administration of SACT
- Utilising a small bore cannula (24g or 22g) enables safer delivery; dependant on amount, rate & viscosity of fluid
- Secure cannula and tubing with a transparent IV dressing applied to ensure a visible insertion site enabling continuous assessment
- Vesicants should be given via a newly established cannula whenever possible (Doherty & Lamb 2008), ensure good blood return, establish free flow with gravity drip and check free from signs of erythema, pain or swelling at the site, consensus should be agreed where appropriate to use existing access (Weinstein 2007)
- The most vesicant drug should be administered first, on the basis that venous integrity reduces over time (Dougherty & Lister 2015; RMM 2015) as vascular integrity decreases over time and vein is most stable and least irritated at the beginning of treatment in addition, the patients awareness of sensation is more acute
- Most vesicants are required to be given as a slow bolus infusion; traditionally manually using a syringe via IV push into the side-arm port of a fast running IV infusion of compatible solution, concluding with sodium chloride 0.9% 10ml flush, whilst checking for intermittent blood return and continuously monitoring the site (Dougherty & Lister 2015).
- Use of smart pumps and mechanical bolus – utilising modern syringe drivers being more commonly used in SACT administration, it is essential that HCP are trained not to rely on infusion pump alarms as extravasation alert and continue to observe and monitor patient throughout infusion (Weinstein 2007)
- HCP administering SACT will have the expertise to recognise other local allergic reactions caused by chemobiological agents, other than extravasation (EONs 2007)
- Patency of the IV site prior to SACT infusion is verified and regularly throughout the procedure; do not let patients leave the clinical area. If there are any doubts, stop and investigate. Re-site the cannula, if the patency of the cannulation is not entirely satisfactory
- When re-siting of the cannula is necessary it must be proximal to the first site or ideally placed in the other limb, assessing exclusions and contra-indications
- Continually reassessing cannula site for signs of redness or swelling
- Carefully document the rate of administration, the location and condition of site, verification of patency, and patient's responses, on giving any potential vesicant/irritant agents

**The veins of patients who have cancer are often fragile and if extravasation occurs following risk assessment and effective communication, after careful cannulation and administration of SACT agents, it is not indicative of negligence and it is the immediate action and reassurance that is imperative and follow up aftercare that is effective (Khan and Holmes 2000)**

## **Infusional Pumps and Syringe Driver Bolus SACT Administration**

New smart technology infusion pumps and syringe drivers include wireless Dose Error Reduction Software (DERS) drug libraries, event memory, data collection, infusion rate calculation, safety and clinical alerts, thus creating efficient, effective and overall a valuable patient safety advancement and shown to be a reliable modern SACT delivery strategy (Garrido et al 2016; ISMP 2016; Upton 2013)

- National Patients Safety Agency (NPSA 2007) recommends a documented double checking strategy for all mechanical infusion device use and software checks and data analysis is encouraged to inform quality improvements
- Although Smart technology offers a safe, efficient delivery solution, it must not distract the practitioner from providing skilled ongoing assessment of the patient, alongside providing appropriate individualised patient education.
- Modern infusion pumps and syringe drivers that incorporate technology to monitor venous pressure during bolus SACT delivery can help to give early warning of impending or actual extravasation. Technology such as venous pressure monitoring must never replace skilled nursing assessment and intervention, which remain at the cornerstone for preventing or managing actual extravasation.
- Patients receiving bolus vesicant SACT with syringe drivers must never be left un-supervised during administration and practitioners need to understand how and when to override the system as necessary
- HCP will receive appropriate supervision and training in the use of infusion pumps and syringe drivers that deliver SACT, particular attention to bolus vesicant agents, and a competency training record retained within the Day Treatment Unit (DTU) and associated in-patient treatment areas competency register (NEYHCA 2013)
- Practitioners administering agents via infusional devices will have a yearly competency update from the identified work based trainers as per Topic 10 and administration of SACT update as per Chemotherapy Competency Programme (NEYHCA 2013)

## **2.4 RECOGNITION**

Early recognition and diagnoses of extravasation is critical to effective management as delay in treatment increases the risk of tissue damage and necrosis (EONs 2007)

IV SACT must include continuous observation and assessment of the administration sites and surrounding tissue for any signs and symptoms of possible extravasation, leakage of drug into the tissues should be suspected if any or more of the recognised following signs and symptoms occur as per evidence consensus

### **Signs**

- Lack of or absence of blood return
- Changes in infusion/flow rate or resistance to administration of drug
- Leakage around the cannula site or CVAD entrance/exit site
- Swelling around cannula or CVAD site and vein pathway

### **Symptoms**

- Any changes in sensation or pain
- Induration (hardening) or leakage is observed from the site
- Erythema or venous discoloration (redness or blanching) is observed at the site
- Burning sensation and/or blistering
- Discolouration alone may not indicate extravasation, as highly coloured drugs such as Doxorubicin, Epirubicin and Mitoxantrone have been reported to do this

### **Central Venous Access Devices (CVADs) – additional related signs**

- Aching or discomfort in shoulder or neck area
- Pain, burning or swelling in upper arm or chest area
- Fluid leakage at or around entrance/exit site and along subcutaneous canal

### **Types of CVADs:**

- Skin Tunnelled Catheter (STC) – chest

- Split Cath – chest
- Implantable Port (Port-a-Cath) – chest
- Implantable Port (P.A.S-Port) – Peripheral
- Peripheral Inserted Central Catheters (PICC) – upper arms

It is uncommon for an extravasation to occur with CVAD's, although instances may occur due to the following factors as identified by RMM (2015): -

- Needle dislodgement causing perforation of the vein or misplacement in subcutaneous implanted ports.
- Catheter fractures or ruptures, causing leakage either near the insertion site, at the port attachment under the skin, or along the line in STC, Ports and PICCs
- Fibrin sheath formation forcing pressure to allow drug to leak out of the line at connections or causing backflow along catheter from insertion site

Some symptoms may not occur immediately, induration (local tissue hardening) and blistering can present later stages in the extravasation process, therefore monitoring of the site should continue during and sometime following infusion and this should be reinforced with patients to report any symptoms that may occur later, at home (EONS 2007)

### **Differential Diagnosis**

Some agents, even when correctly administered can cause local reactions which can resemble extravasation (Doherty & Lister 2015; Perez Fidalgo et al 2012)

**Flare Reaction** - A local reaction to an agent manifested by red tracking along the vein caused by a venous inflammatory response to histamine release resulting in urticaria (itchy hives), raised red streaks tracking up arm, unlikely to cause pain, dissipating within 30-90 mins and can be resolved by application of topical steroids and slowing infusion rates

**Chemical Phlebitis/Vessel Irritation** – vein inflammation often followed by thrombosis or sclerosis of the vein, causing aching and tightness sensation at the cannula site and cramping along the vein proximal to the site minutes after administration, unlikely to swell can result in erythema or dark discoloration, blood return is usual but not always intact

**Venous Shock** – can occur when drugs administered are too cold causing the muscle wall of the vein to go into spasm, usually appears immediately on or after administration, blood return can be absent

WHERE ONE OR MORE OF THE SIGNS AND SYMPTOMS OF EXTRAVASATION MAY BE PRESENT AND EXTRAVASATION IS SUSPECTED: **ASSUME EXTRAVASATION**

**EXTRAVASATION OCCURRENCE AND TREATMENT MUST BE CONSIDERED AN ONCOLOGICAL EMERGENCY AND REQUIRES IMMEDIATE ACTION**

In all areas where chemobiological SACT is being administered, practitioners will be competent in risk assessment, prevention and appropriate management of extravasation. Written guidelines for handling and administering chemobiological agents and associated procedures; including; in case of an extravasation, spillage and waste disposal must be present (Chemotherapy Measures 2013; Manual of Cancer Standards 2008; Dougherty & Lamb 2008, Schrijvers 2003). In addition, an extravasation kit, with all the necessary materials and drugs to treat extravasation, must be present (Perez Fidalgo et al 2012)

## **2.5 MANAGEMENT**

Specific course of action depend on:

- Classification of drug
- Amount of extravasation
- Location of extravasation

Intravenous SACT agents can be classified into 5 categories according to their damage potential, ranging from skin erythema to soft tissue necrosis (HSE 2016). It is also important to note that non-cancer therapies when extravasated can also have the potential to cause injury (CP246 2014). Though some classifications are well established for their injury potential, scarcity of up to date evidence makes it difficult to develop an optimal management scheme (Boulanger et al 2015)

as some pharmacological properties are still not fully understood resulting in some conflicting classifications dependent on evidence read (Harrold et al 2013), a number of antidotes are available but lack of evidence to demonstrate their value and role is not yet clear (Polovich et al 2009) and therefore the National Reporting electronic Green Card System must be used for each episode to gain further knowledge and data (Appendix i)

1. **Neutrals:** Drugs that neither cause inflammation nor damage on extravasation. Monoclonal Antibodies (MABs) can also be generally listed amongst this category
2. **Inflammitants:** Drugs that cause mild to moderate inflammation, painless skin erythema and flare reaction at the extravasation site
3. **Irritants:** Drugs that can cause inflammation, pain or irritation at the extravasation site without blister formation. These drugs can also cause a burning sensation in the vein whilst being administered
4. **Exfoliants:** Drugs that can cause inflammation and shedding (peeling off) of skin without causing underlying tissue death. Drugs may cause superficial tissue injury, blistering and desquamation
5. **Vesicants:** Drugs that can result in tissue necrosis or formation of blisters, vesicants are sub classified into the mechanisms by which they cause tissue damage; DNA-binding or non-DNA binding agents

Tissue damage following extravasation occurs for a number of reasons; whether a drug binds to DNA or not. DNA binding vesicants bind to nucleic acids in the DNA of healthy cells, resulting in cell death by apoptosis that in turn can cause progressive and permanent tissue damage (Boulanger et al 2105), due to the cellular uptake of extracellular substances sets up a continual cycle of tissue damage as the DNA binding drug is retained and recirculated in the tissue. Whereas non-DNA binding drugs have an indirect affect and are eventually metabolised in the tissue and neutralised more easily than DNA binding drugs (RMM 2015) therefore damage is generally more mild to moderate, injury is localised and the condition will usually improve over time (Boulanger et al 2015).

Therefore it is advised regards use of specific antidotes are utilised to localise and neutralise or disperse and dilute agents from the tissue (Perez Fidalgo et al 2012; Polovich et al 2009)

Below is table to demonstrate current drug group classification in increasing order of damage potential from neutral drugs which are expected to cause the least damage to vesicant drugs which may cause tissue necrosis and ulceration based on consensus evidence

Group 1	Group 2	Group 3	Group 4	Group 5
Neutrals	Inflammitants	Irritants	Exfoliants	Vesicants
<b>Alemtuzumab</b> <b>Aflibercept</b> <b>Asparaginase</b> <b>Azacitidine</b> <b>Bevacizumab</b> <b>Brentuximab</b> <b>Bortezomib</b> <b>Bleomycin</b> <b>Cladribine</b> <b>Clofarabine</b> <b>Cyclophosphamide</b> <b>Cytarabine</b> <b>Edroclomab</b> <b>Eribulin</b> <b>Fludarabine</b> <b>Gemcitabine</b> <b>Ifosfamide</b> <b>Ipilimumab</b> <b>Melphalan</b> <b>Novolumab</b> <b>Ofatumumab</b> <b>Pembrolizumab</b> <b>Pentostatin</b> <b>Pertuzumab</b> <b>Rituximab</b> <b>Thiotepa</b> <b>β-Interferons</b> <b>Aldesleukin (IL-2)</b> <b>Trastuzemab</b>	<b>Cetuximab</b> <b>Etoposide</b> <b>Fluorouracil</b> <b>Methotrexate</b> <b>Phosphate</b> <b>Pemitrexed</b> <b>Raltitrexed</b>	<b>Arsenic</b> <b>Carboplatin</b> <b>Etoposide</b> <b>Ganciclovir</b> <b>Irinotecan</b> <b>Teniposide</b> <b>Temsirolimus</b>	<b>Aclarubicin</b> <b>Cabazitaxel*</b> <b>Cisplatin</b> <b>Lipsomal-</b> <b>Daunorubicin</b> <b>Liposomal-</b> <b>Doxorubicin –</b> <b>Floxuridine</b> <b>Mitozantrone</b> <b>Oxaliplatin*</b> <b>Topotecan</b>	<b>Amsacrine</b> <b>Bendamustine</b> <b>Carmustine</b> <b>Dacarbazine</b> <b>Dactinomycin</b> <b>Daunorubicin</b> <b>Docetaxel*</b> <b>Doxorubicin</b> <b>Epirubicin</b> <b>Idarubicin</b> <b>Mitomycin C</b> <b>Mustine</b> <b>Paclitaxel*</b> <b>Streptozocin</b> <b>Trabectedin*</b> <b>Treosulfan</b>  <b>Vinca</b> <b>Alkaloids</b> <b>Vinblastine</b> <b>Vincristine</b> <b>Vindesine</b> <b>Vinorelbine</b>

**Oxaliplatin\*** has been classified as an irritant but more recent reports suggest the agent possesses vesicant characteristics (Herrington & Figueroa 2012). Oxaliplatin extravasation has been associated with increased risk of pain, oedema and neurological symptoms and delayed erythematous and necrosis (Barbee et al 2014) and therefore has been relocated to the classification spectrum to a group 4 risk category and recognised as responsive to heat management (RMM 2015). These symptoms can develop more slowly than with other agents and although classified as an irritant is a non-DNA binding drug therefore suggests can be safely treated with heat to avoid risk of paraesthesia which can be precipitated by cold and localise and neutralise process (NDH 2016Boulanger et al 2015; NECN 2014)

**Trabectedin\*** combines to DNA and is implied as having potential to cause vesicant type toxicity that when extravasated can result in symptoms of pain, erythema and blistering, inflammation and necrosis and may necessitate surgical intervention (Todd et al 2016). There is no published antidote currently and it is recommended that the drug is administered via CVAD to avoid contact with the vein wall (SPC 2016)

### Taxanes

Literature surrounding taxanes is limited and controversial there is little evidence to support extravasation treatment as there are several factors make classification challenging; pre-clinical data describing potential mechanisms of tissue damage or vesicant like properties are lacking and therefore appropriate management poorly defined (Barbee et al 2014) thus clinical intervention is varied and inconsistent. Existing Guidelines fail to categorise specifically chemotherapeutic



agents as either vesicants or irritants and so should be based on known physicochemical properties, currently accepted definitions and data available and currently management strategy recognised as a localise and neutralise strategy (Polovich et al 2009)

**Paclitaxel\*** available evidence suggests the potential for conventional tissue damage is dependent on the concentration and infusion duration of the drug, which is not yet established (Barbee et al 2014), though considered a local irritant, recent reports suggest vesicant properties (Herrington & Figueroa 2012) classification pre standard definitions is therefore recognised currently as a vesicant as evidence remains contradictory (Boulanger et al 2015; Polovich et al 2009; Stanford & Hardwick 2003)

**Docetaxel\*** has also been suggested as a vesicant agent in some studies it is noted that extravasation site reactions are usually mild where no blistering has occurred and therefore maybe falsely labelled as a vesicant type reaction (Ho et al 2003; Ascherman et al 2000) however classification pre standard definition remains as a vesicant (Polovich et al 2009)

**Cabazitaxel\*** experience is limited compared to other taxane extravasation injury and currently standard definition as indeterminate but classified as an irritant (Polovich et al 2009)

**Monoclonal Antibodies** (MABs) and other biologically active non-cytotoxic agents are generally classified as neutrals and irritants though guidance on handling during preparation and administration of MABs is not well established (Mead 2015) and research has not identified any specific cases of skin irritation

Non-licensed, trial drugs or drugs not listed on this guidelines the practitioner should contact the on call pharmacist to establish the classification and appropriate management.

*The current list is not comprehensive to all chemobiological SACT agents as new treatments are approved or removed on frequent basis therefore it is the responsibility of the HCP managing patient SACT administration to ensure awareness of any new agent and classification it will belong to and liaise with pharmacy*

## IMMEDIATE TREATMENT

**If extravasation is suspected treatment must begin as soon as possible. Early detection and starting treatment within 24 hours can significantly reduce tissue damage. However in some cases extravasation may only become apparent 1-4 weeks after administration. Therefore extravasation kits are required to assist urgent action**

### Extravasation Box

Extravasation kits are recommended to enable immediate management and assembles according to the needs of the particular service, kits should be simple to avoid confusion but comprehensive enough to meet all reasonable needs (RMM 2015). Extravasation box(s) will be provided in each clinical area where chemobiological SACT is administered and will contain all necessary equipment and antidotes required to treat extravasation quickly and safely. The Extravasation box will be easily accessible within the clinical area with classification list attached for ease of agent category identification with clear instruction algorithm to enable HCP to follow procedure in understandable steps (Appendix ii). Extravasation box(s) will be checked at least weekly by clinical staff, including expiry dates of drugs and equipment. Boxes will be checked and renewed by pharmacy following each extravasation incident as soon as possible following use.

### Extravasation Kit Contents List

<b>Extravasation Kit - Box Contents</b>	<b>Number</b>
Hydrocortisone Sodium Succinate 100mg Vial	1 Box
Hydrocortisone Cream 1% 15g Tube	1
Cold Pack	1
Hyaluronidase 1500units Vial	1 Box
Heat Pad	1
Water for injection 5ml Miniplasco	1 Box
Normasol Sachet	1
Chloraprep Sterets	6
1ml Syringes	2
5ml Syringes	2
Orange 25g Needles	4
Blunt Needles	4
Sterile Gallipot	1
Gauze Square Pack	1
Micropore Tape 1" Roll	1
Cotton Bandage	1
Sling	1
Sterile Skin Marker	1
Patient Information Leaflet	1
Extravasation Record	1
Patient Consent for Clinical Photography Form	1
Extravasation Record	1
<b>PLEASE RETURN TO PHARMACY ONCE SEAL BROKEN</b>	

It is advised to outline the extravasation area with the sterile pen provided to monitor the evolution of the injury and also recommended to have an image of the injury, particularly with vesicant involved regarding volume of fluid infiltrated and severity of reaction (EMSO-EONS 2012; WOSCAN 2009)

It is advised to obtain a picture of the injury and file for comparison and reassessment for follow up &/or referral to plastic surgery. The HCP will ensure a digital image taken with a coded tablet in DTU and is uploaded to the shared hard-drive to enable those with codes to access the images as required. Patient consent for clinical photography is required prior to taking the image (Appendix iii) and will be filed in the medical records along with the Extravasation Record (Appendix iv)

Effective treatment of extravasation is dependent on whether the drug leakage into the tissue is classified as a **NON-VESICANT** (Group 1&2) or VESICANT agents

VESICANT agents can then be further sub classified into:

- **VESICANTS/EXFOLIANTS/IRRITANTS** (Groups 3,4&5) For DNA-Binding agents a **Localise and Neutralise** strategy is utilised; encompassing the use of intermittent cold compresses act to encourage vasoconstriction, reducing the spread of extravasated agent, allowing time for the vascular and lymphatic system to disperse the drug locally. Hydrocortisone is also administered as an anti-inflammatory to further neutralise the effects.
- **VESICANT/VINCA ALKALOIDS** (Group 4&5) For Non-DNA Binding agents a **Disperse and Dilute** strategy is utilised; encompassing the use of continuous warm compresses to promote vasodilation, thereby increasing blood flow and distribution and absorption of the drug and thus

disperse it out of the affected area. Hyaluronidase, an enzyme, is also administered to further promoting drug diffusion and enhancing drug absorption to further dilute the effects.

Thus enabling safe and effective management (Boulanger et al 2015; RMM 2015; Perez Fidalgo et al 2012; EONS 2007). If in doubt, the HCP will consult the classification list on the extravasation box lid, check with the drug data sheets SPC (eMC) or contact the oncology pharmacists for further information

Where administration of a combination of classifications, consideration must be given to which is the most appropriate antidote and management; regards which group of drugs are more likely to cause the most harm, therefore where vinca alkaloids are used, this would be the correct action to be taken to reduce the potential tissue damage (RMM 2015)

### **WHEN EXTRAVASATION HAS OCCURRED AND CLASSIFICATION OF DRUG IS NOT IDENTIFIED AS **NON-VESICANT** BUT A **VESICANT AGENT**, A '**LOCALISE & NEUTRALISE**' OR '**DISPERSE & DILUTE**' METHOD WILL BE UTILISED AS FOLLOWS:**

Steps to be taken in event of peripheral extravasation as management algorithm adapted from EMSO-EONS guidance 2012 (Appendix ii)

#### **MANAGEMENT OF NEUTRAL/INFLAMMITANT AGENTS (NON-VESICANTS)**

1. Stop the infusion immediately. Do not remove cannula or winged infusion device Do not flush cannula
2. Obtain extravasation box & mark the extravasated area with marker pen provided and take digital image (gain patient consent)
3. Alert experienced member of nursing staff and inform senior member of medical staff
4. Aspirate 2-5ml blood back through cannula to remove as much of the drug as possible
5. Remove cannula clean skin with sterile saline \*

#### **MANAGEMENT OF IRRITANTS-EXFOLIANTS-VESICANT AGENTS**

##### **Localise & Neutralise**

Follow steps 1 – 5 as for non-vesicant agent management, then:

- a) Using 1ml syringe consider aspirating subcutaneous infiltrate (blisters)
- b) Dissolve 100mg Hydrocortisone in 2ml sterile water for injection. Inject sub-cutaneous in portions of 0.2mls around the circumference of portions of the extravasated area to dilute the infusate
- c) Clean with sterile saline and apply sterile dressing
- d) Apply **cold** pack for 30 minute periods every 2 hours for 24 hours avoiding direct skin contact
- e) Hydrocortisone cream 1% can be applied to reduce erythema

##### **MANAGEMENT OF VESICANT- VINCA ALKALOID AGENTS Disperse & Dilute**

Follow steps 1 – 5 as for non-vesicant agent management – \*consider injecting through cannula delivering the enzyme antidote to reach the damaged tissue prior to removal

- a) Using 1ml syringe consider aspirating subcutaneous infiltrate (blisters)
- b) Dissolve 1500u Hyaluronidase in sterile water for injection. Inject sub-cutaneous in portions of 0.2mls around the circumference of portions of the extravasated area
- c) Clean with sterile saline and apply sterile dressing
- d) Apply **heat** pad continuously for period of 24 hours, each pad lasting 8 hours
- e) Do **NOT** apply topical cream with vinca alkaloid extravasation

### **Then follow steps 6 – 12 for all extravasations**

6. Elevate arm in sling to shoulder height and encourage finger movements
7. Provide analgesia and advice for pain management, reassure and inform patient
8. Consult medical staff to assess if SACT to continue and assess other arm if possible. Do not use vein pathway of extravasation site and always re-site proximal to original site if safe to do so
9. Ensure extravasation site is reassessed 24 hours after occurrence and continued relevant follow up as required
10. Consider referral to plastic surgeon for assessment of debridement and/or skin grafting may be necessary if necrosis/ulceration occurs or is suspected
11. Provide patient with information leaflets, additional medications as required and follow up appointments confirming 24 hour contact
12. Document, Datix and e-Green card report incident (Appendix i)

Elevation of the affected limb is recommended to minimise swelling when extravasation has occurred in the hand using a sling provided in the extravasation kit. Gentle movement of the limb should be encouraged to prevent adhesion of damaged areas to the underlying tissue (RMM 2015)

### **Plastic Surgery Team Referral**

**Consider immediate referral to Plastic Surgery for all significant vesicant extravasation events.**

#### **Refer to On Call Plastic Surgery registrar via switchboard for immediate review**

Surgical washout (Gault technique 1993) can reduce local tissue necrosis. A saline irrigation flushing-out technique can be considered and carried out by plastic surgeon in order to 'wash out' any of the DNA-binding drug out of the tissue with saline before it can affect the cell DNA to reduce or omit potential necrosis and surgical intervention (Harrold et al 2013). Referral should be immediate and the procedure performed as soon as or within 6 hours of the incident (Schulmeister 2011) although some evidence suggests some benefit up to 24 hours post injury but with reduced efficacy (Schrijvers 2003; Giunta 2004; Gault 1993)

The surgeon will perform the procedure under local anaesthetic involving small incisions made around the injury providing sufficient access to affected subcutaneous tissue and flushed through using an infiltration cannula with saline, injecting 20-30mls at a time through each incision, allowing it to drain out of the other incisions, up to an average of approx. 500mls. A dressing will be applied, limb wrapped in padded bandage and elevated for 24hrs. Under the plastic surgeons advice, prophylactic antibiotics may be prescribed for poor risk/potentially neutropenic patients (Gault Technique 2003)

### **Further Surgical Management**

As vesicant extravasation can progress to ulceration, blistering and deep tissue necrosis may require consideration of debridement and subsequent skin grafts. Optimal timing and referral criteria still remain controversial (Wickham et al 2006; Boulanger 2015)

**Contact On-Call Plastic Surgery registrar via switchboard as soon as tissue damage is suspected. The service operates a 7 day consultant clinic which can facilitate review of urgent (non-emergency) referrals**

### **Continuation of Treatment Option**

Following treatment of extravasation incident, after discussion and reassurance, reassess the patient and consider re-cannulation in unaffected arm to continue SACT unless reason to delay eg: breast cancer patients who have undergone axillary node clearance or patient preference (Harrold et al 2013; Cole 2006) and/or consider referral for CVAD as appropriate for subsequent treatment

### **Extravasation from Central Venous Catheters (CVCs)**

With the increasing use of Central Venous Catheters (CVCs), it is essential that all practitioners are able to identify and assess any problems that may occur with their use. Prior to the administration of SACT, practitioners must be competent in Topic 7 Care of Central Venous Access Devices - Chemotherapy Competency Programme (NEYHCA 2013) and follow Guidelines for the management of Central Venous Catheters (CVC) in Oncology and Haematology Adults (HEY 2016).

Central line extravasation may be rare but can be devastating as the agent administered may accumulate in the mediastinum, pleura or subcutaneous tissue space in the chest or neck, around the catheter (Boulanger et al 2015). Indicator of CVC extravasation most frequently experienced with CVCs is patient reporting chest pain or neck pain (EMSO-EONS 2012) and practitioner administration issues including 'frothy' or poor blood return.

Steps to be taken in event of peripheral extravasation as management algorithm adapted from EMSO-EONS guidance 2012 (see appendix ii)

- Treat visible extravasation as per guidelines
- Urgent CXR or thoracic CT
- Refer to plastic surgeon for further opinion to drain remaining solution
- Use of steroids, antibiotics, analgesia to reduce risk of secondary pleuritic
- Consider removal of CVAD and contralateral device or peripheral cannulation

## 2.6 CONSEQUENCES

Pain at the intravenous site may be moderate or severe, usually burning or stinging. There may be erythema (redness), swelling and tenderness, blanching (whitening) of the skin due to lack of capillary filling and poor blood return from the cannula but not all these symptoms may be necessarily present (Vandeweyer et al 2000) and therefore careful assessment, identification and prompt, effective treatment is essential. All evidence considered:

### Late effects

Consequences of untreated or poorly managed extravasation can include:

- Blistering; indicative partial thickness skin injury (typically 1-2 weeks post extravasation)
- Induration (hardening) of the skin is a reliable sign of eventual ulceration
- Ulceration; yellow fibrotic base with surrounding rim of persistent erythema (1-2 weeks post extravasation)
- Peeling and sloughing of the skin (approximately 2 weeks post extravasation)
- Tissue necrosis; mottled, darkened skin, associated with pain (2-3 weeks post extravasation)

Leading to:

- Increased infection risk
- Damage to nerves, tendons and joints
- Functional and sensory impairment of affected area and limb disfigurement/loss

Resulting in:

- Delay in treatment plans or treatment being stopped
- Hospitalization due to complications, serious injury or required surgery
- Increases hospital attendance for ongoing assessment and treatment
- Psychological distress – fear re treatment outcomes and worried may occur again
- Loss of income due to physical effects or anxiety
- Impact on family and carers'
- Impact on HCP – guilt, blame, fear and loss of confidence
- Legal aspects, liability and lawsuits

## 2.8 DOCUMENTATION

### SCOPE

All trained and competent HCP caring for patients in the event of an extravasation of chemobiological SACT agents.

## OBJECTIVE

In the event of extravasation the patient will receive prompt effective management, reassurance, information and follow up with accurate documentation and reporting

## RESPONSIBILITIES

Due to the potential risk and possible event of extravasation of SACT it is the responsibility of the nurse in charge to ensure all trained HCP working in the clinical area possesses the required knowledge and skills to recognise, treat and document the incident effectively

## DOCUMENTATION

- Nursing Documentation/medical notes
- Chemotherapy Prescription Chart
- Extravasation Report (Appendix ii)
- Consent for Clinical Photography (Appendix iii)
- Patient Information Leaflet – Management of SACT Extravasation  
(<https://www.hey.nhs.uk/patient-leaflet/management-systemic-anti-cancer-therapy-chemotherapy-extravasation/>)
- Incident Form (DATIX)
- National Extravasation Reporting System – electronic Green Card (Appendix i)

## METHOD

1. The nurse responsible will recognise extravasation has occurred and will follow extravasation procedure and document the following.
  - Patient details and clinical area
  - Date and time of extravasation
  - Venous access device, gauge and site
  - Sequence and name of SACT agents involved
  - Approximate amount of drug extravasated
  - Symptoms experienced by the patient.
  - Assessment of the site, the extent of extravasation, if swelling/redness present mark with sterile disposable marker pen and image obtained
  - Nursing action and immediate treatment
  - Physician notification and action requested
  - Follow-up measures to be taken and patient information provided
  - Pharmacy informed and extravasation box re-issued
2. An extravasation intervention report form will be completed and placed with chemotherapy documentation and event sticker placed in medical records
3. An incident report form will be completed (DATIX) – access via intranet
4. An electronic Green Card National Reporting System (NDH 2106) <http://www.northdevonhealth.nhs.uk/extravasation/> will be completed (will be applied to identified desk tops in relevant clinical areas)
5. Ongoing observation and follow up assessment of the injury arranged

## 3 PROCESS FOR MONITORING COMPLIANCE.

Qualified staff new to the service will be expected to attend the 3 day Chemotherapy Competency Induction Workshop to be entered into the work based learning Chemotherapy Competency Programme (NEYHCA 2013). The monitoring of compliance with and clinical competency of staff regarding the administration and management of all aspects of SACT will be undertaken by the ward/department managers with support from the Chemotherapy Nurse Specialist Team. All nursing staff will complete required competency and will reviewed yearly, with specific regard to

health and safety (Topic 5) and Oncological Emergencies (Topic 6) Chemotherapy Competency Programme.

Guidelines will be monitored and reviewed as per the cancer standards and Peer Review process with advice and support from the Trust Chemotherapy Committee Meeting (CCM) members.

All extravasation incidents must be documented accordingly as per guidelines and reported via HEY Trust DATIX to be reviewed by the CCM and National electronic Green Card Reporting system

Audit of extravasation incidence will be carried out every 2 years and report findings via the Chemotherapy Committee Meeting and disseminated to the wider team.

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## **5 APPENDICES**

- i) electronic-Green Card National Reporting System
- ii) Algorithm 1 & 2 – Management of Extravasation (Peripheral & CVC)
- iii) Consent for Clinical Photography
- iv) Management of Extravasation Record
- v) Patient Information Leaflet - Management of Chemotherapy Extravasation

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<b>Document Managed by Title:</b>	Chemotherapy CNS Team	<b>Date EIA Completed:</b>	
<b>Consultation Process</b>			
Chemotherapy CNS Team Chemotherapy Committee Members DTU representatives S. Renn – Pharmacy Technical Services Manager S. Scargill – Senior Principle Pharmacist Dr R. Patmore – Medical Director for Clinical Support Dr R. Roy – Divisional Clinical Lead Dr A. Dhadda – Head of Clinical Chemotherapy Services Clinical Effectiveness Policies & Practice Committee			
<b>Key words (to aid intranet searching)</b>			
Extravasation, chemotherapy, chemobiological therapy; systemic anti-cancer therapy SACT			
<b>Target Audience</b>			
<b>All staff</b>	Clinical Staff	Non-Clinical Staff	
Managers	Nursing Staff	Medical Staff	
<b>Version Control</b>			
<b>Date</b>	<b>Version</b>	<b>Author</b>	<b>Revision description</b>
December 2016	1	Mandi Elliott	New Guideline

## Appendix 1

## Extravasation National Data Collection

An extravasation injury has the potential for significant impact on the patients' quality of life, therefore it is imperative that data is collected via a reporting system to analyse trends, risk factors, incidence and management, providing evidence for future practice

This is the current electronic green card National Reporting System and can be accessed via internet

<http://www.northdevonhealth.nhs.uk/extravasation/> and completed for each episode

### Extravasation details

#### 1. Extravasation Date

Date / Time DD / MM / YYYY hh : mm AM/PM

#### 2. Name of Chemotherapy Regimen

#### 3. Name of drug extravasated

#### 4. Was this a bolus or a bag

#### 5. Approximate volume of extravasation (ml)

#### 6. What Trust did this occur in? (this information will remain confidential)

#### 7. Type of device extravasated

Other (please specify)

#### 8. What size cannula (please select if you chose peripheral cannula above)

- 24g
- 22g
- 20g
- 18g

**9. Manufacturer of cannula? (please complete if you chose peripheral cannula in question 7)**

**10. Where is the device placed?**

**11. Where has the extravasation occurred on the body?**

**12. Patient's Signs and Symptoms**

- Burning
- Stinging
- Pain
- Discomfort
- Inflammation
- Swelling
- Redness
- Other (please specify below)

Other (please specify)

**13. How many millimetres were aspirated from the cannula?**

**14. Initial treatment details**

- Cold pack
- Warm pack
- None

**15. Antidote administered**

- Savene  
 DMSO  
 Hydrocortisone  
 Hyaluronidase (hyalase)  
 Other (please specify below)

Other (please specify)

**16. Other intervention**

- Plastics referral  
 Photography  
 Other (please specify below)

Other (please specify)

**17. Other medication administered, including pain relief****18. Has the patient been referred for follow up?**

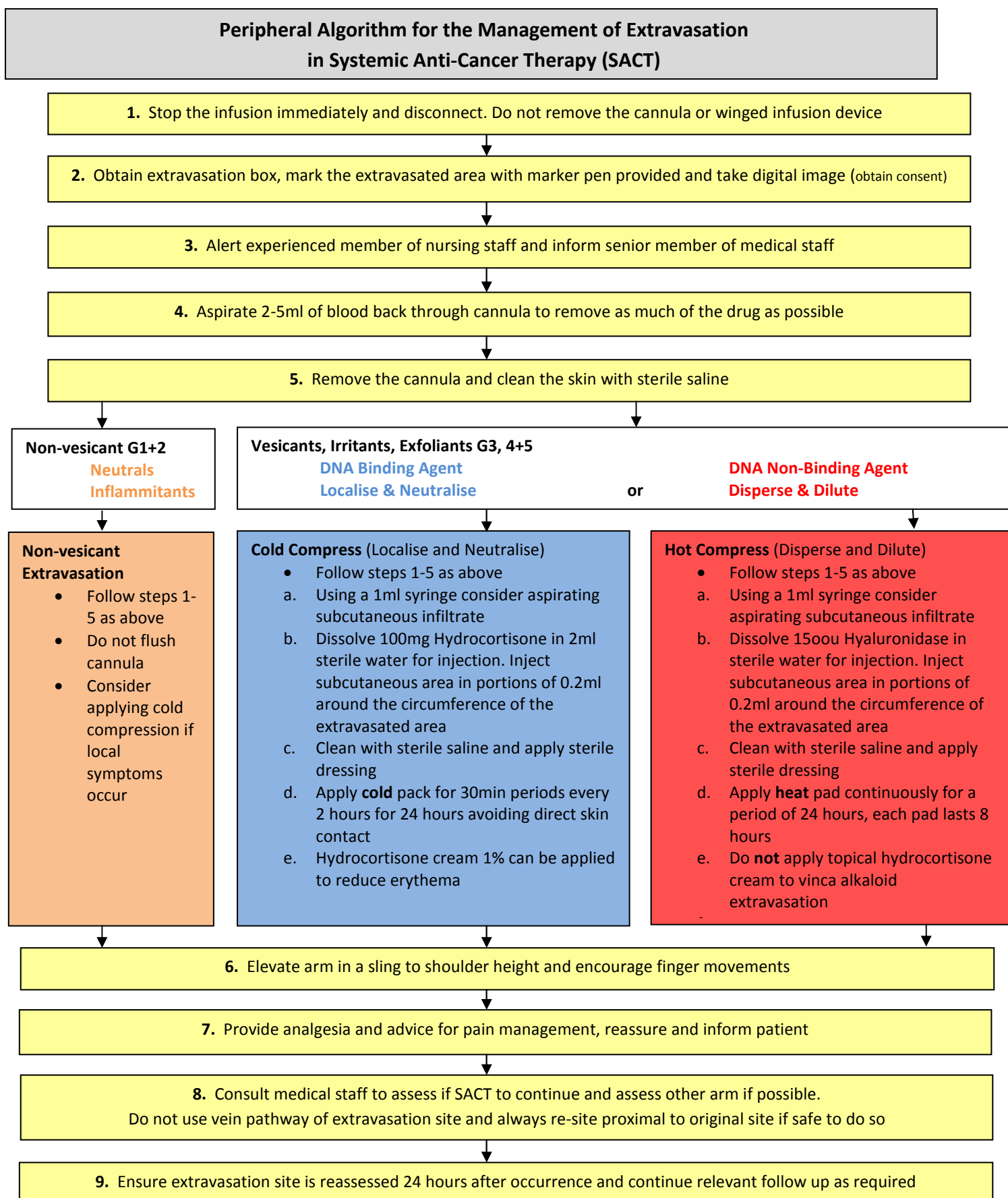
- Yes  
 No

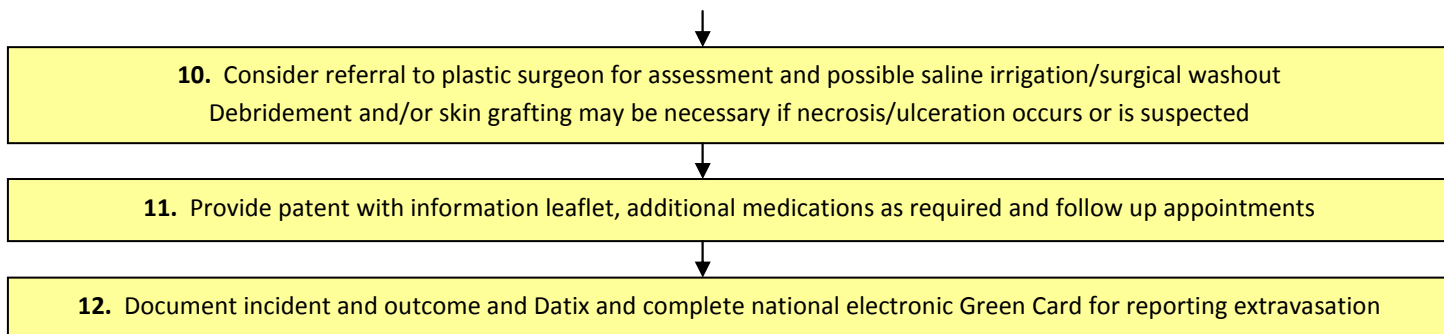
Done (processed via survey monkey on internet page)

Source: National Extravasation Electronic Green Card Reporting System 2016

North Devon Health NHS Hospitals Trust

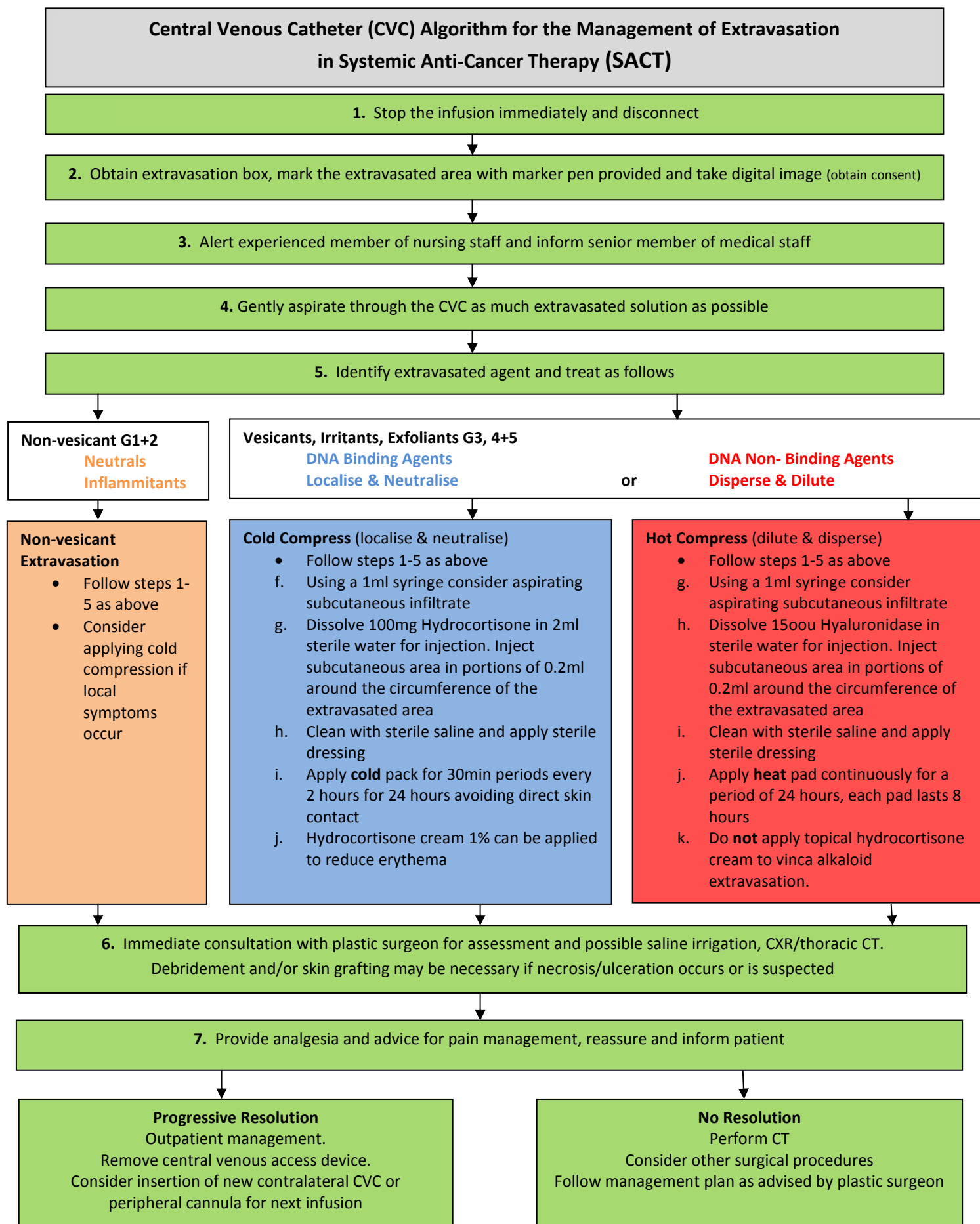
## Appendix 2



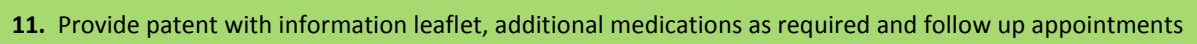


Chemotherapy CNS Team 2016 as per Extravasation Guidelines V2.0

## Appendix 3

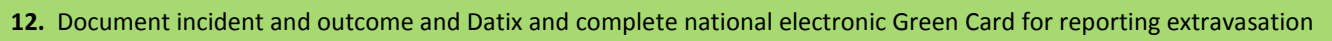






↓ ↓

**11.** Provide patient with information leaflet, additional medications as required and follow up appointments



↓

**12.** Document incident and outcome and Datix and complete national electronic Green Card for reporting extravasation

Chemotherapy CNS Team 2016 as per Extravasation Guidelines V2.0

**Appendix 4**

**Patient Name:**

**Hospital ID No:**

In the event of an extravasation there are three places the incident must be documented



**Extravasation Record**

The extravasation form must be **fully** completed by the HCP managing the incident and placed within the patients’ notes for an accurate record of the injury

**Extravasation Details**      Date ..... Time .....

Name of drug extravasated: .....

Regimen: .....


Bolus/Bag    CVAD/Peripheral cannula-Gauge: ..... Pump .....

(Delete as appropriate)

Approximate volume of extravasation.....ml

**Patient’s signs/symptoms**

<b>Pain</b> <input type="checkbox"/>	<b>Burning</b> <input type="checkbox"/>	<b>Erythema</b> <input type="checkbox"/>
<b>Induration</b> <input type="checkbox"/>	<b>Blistering</b> <input type="checkbox"/>	<b>Swelling</b> <input type="checkbox"/>



**Initial Treatment Detail**      **Reported to:** .....

Cold Pack     Heat Pack       Hydrocortisone     Hyalase

Amount aspirated from      Digital Image     Follow up

Cannula.....ml      **Actioned by:** .....

**Digital Image**

The HCP managing the incident will gain consent for a clinical photograph to be taken and kept as part of their health records and must read and sign form as attached over the page

Patient Sticker

**CONSENT FOR CLINICAL PHOTOGRAPHY / VIDEO RECORDINGS**

The health professional caring for you is proposing to take photographs or video recordings of your treatment or condition. He or she has explained the reason for this. The photos or videos will be kept as part of your health records for future reference and with your permission used (without identifying you) for teaching, training and publication.

**Please read the statements below and tick the level of your consent**

**I agree that the images or video taken of me may be:**

- Level 1: Held with my health records for future reference and / or treatment
  - Level 2: Used by a health professional(s) for teaching and/or training purposes
  - Level 3: Used for future reference and/or treatment, teaching, training and publication
- (if your images are used in a publication you will be notified beforehand)**

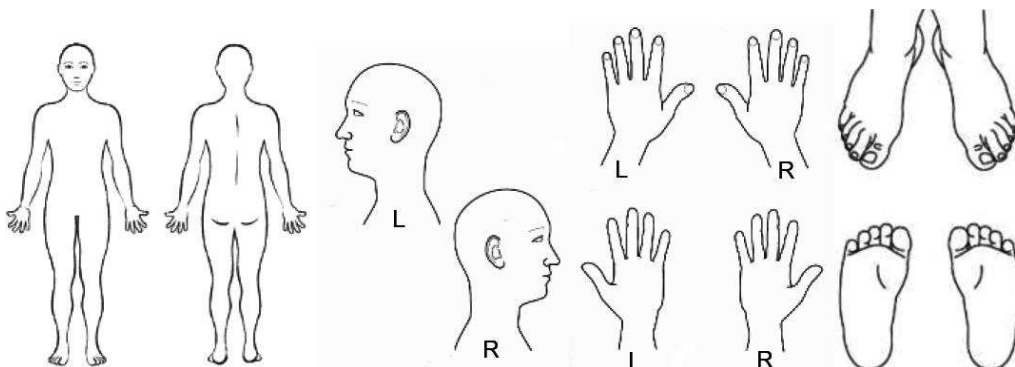
\_\_\_\_\_ Patient  
 t Signature                      Print Name                      Date

\_\_\_\_\_ Witness  
 Signature                      Print Name                      Date

**Indicate areas to be photographed and clearly complete the diagnosis (including any post-operative/biopsy results)**

**Diagnosis** \_\_\_\_\_

**Date Image Taken** \_\_\_\_\_ **Signed** \_\_\_\_\_ **Print Name** \_\_\_\_\_



## Appendix 5

Follow up appointment Leaflet can be found at :-

<https://www.hey.nhs.uk/patient-leaflet/management-systemic-anti-cancer-therapy-chemotherapy-extravasation/>