Royal Devon University Healthcare NHS Foundation Trust

Title
Extravasation Injuries

Reference Number: RDF1852-23
Date of Response: 27/09/23

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

Please be aware that the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) has existed since 1st April 2022 following the integration of the Northern Devon Healthcare NHS Trust (known as Northern Services) and the Royal Devon and Exeter NHS Foundation Trust (known as Eastern Services).

Extravasation injuries would be defined as follows: the damage caused by the efflux of solutions from a vessel into surrounding tissue spaces during intravenous infusion. This can involve nerves, tendons, and joints.

1. Yearly incidence of extravasation injury in your trust. - for 2018, 2019,2020.2021, 2022 & 2023.
   Please see table below. Please note, the data is Trust wide:

2018	41
2019	23
2020	22
2021	28
2022	15

2. The roles and numbers of staff involved in extravasation management per case in your trust. I refer to incident reporting, staff which take care of the patient for this specific role, specialists e.g. plastic surgeons who have had to review the patient etc.
   As per IV policy – please see attached. Trust staff monitor the site. Trust Doctor's refer to Plastic team for review of Incidents.

   Section 12 (1) of the Freedom of Information Act 2000:

   To provide you with the further information requested would require the manual extraction and manipulation of information from various sources. –

   To try to respond to the question would entail Trust staff undertaking e a deep dive into each case and understand the incident before confirming how many staff and from which profession. To carry out this work would exceed the appropriate cost limit as set out in Section 12 (1) of the Freedom of Information Act 2000 and is therefore exempt.

   Under the Freedom of Information Act 2000 Section 12 (1) and defined in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004, a public authority is not obliged to comply with a request for information if it estimates that the cost of complying would exceed the

appropriate limit. The limit of £450 represents the estimated cost of one person spending two and a half days in determining whether the Trust holds the information, locating, retrieving, and extracting that information.

3. Whether your trust has an extravasation treatment algorithm/protocol and what it entails?
   Yes. Please find attached the following Policies:

- Cytotoxic-Extravasation-Policy -Northern Service.
- Extravasation-and-Infiltration-Injury---Pads-and-Neonates
- Extravasation-injury-management-in-neonates-and-paediatrics-Guideline-V3-0--June19.
- Injectable-medicines-policy-v2.5

Section 40 (2) – Personal Data (Staff

Please note, staff personal information has been redacted when appropriate in the attached documents.

The disclosure of staff names would breach the first data protection principle and fail to meet any of the relevant conditions set out in Schedule 2 of the Data Protection Act (DPA) 2018. The first principle in the DPA requires that disclosure must be fair and lawful, and personal data shall not be processed unless at least one of the conditions in Schedule 2 is satisfied.

The staff concerned would not have expected their names to be disclosed in the public domain and so disclosure would not be 'fair' in the manner contemplated by the DPA. Furthermore, disclosure would not satisfy any of the conditions for data processing set out in Schedule 2 of the DPA.
In particular, we do not consider that there is a legitimate interest in disclosure in this case.
There is no public interest in making information about our staff available in this way contrary to what would have been their legitimate expectation at the time the information was gathered.

4. Whether your trust has compulsory DATIX reporting of extravasation injuries? Yes.

5. If your trust has compulsory DATIX reporting of extravasation injuries, how many incidents have been reported for the last 5 years (1st January 2018 to 1st January 2023)?

Please see response to question 1.

Document Control Report

Title	Cytotoxic Extravasation Policy		
Author		**Author's job title**	Seamoor Unit Manager & Lead Cancer Pharmacist
Directorate	Clinical Support and Specialist Services	**Department**	Cancer Services

Version	Date Issued	Status	Comment / Changes / Approval
1.0		Final	Approved for use by Peninsula Chemotherapy Network group.
2.0	Jan 2016	Final	Review and update of version 1. Approved by Chemotherapy Governance. Updated version including current evidenced based research
3.0	June 2021	Revision	Review and update – Changes to drugs in 2nd line management table
4.0	Sept 2021	Final	Waiting for email approval

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Superseded Documents
Extravasation Policy 2012
Savene Policy 2011

Issue Date	Review Date	Review Cycle
September 2021	September 2024	Three years

Consulted with the following stakeholders: (list all)
- Chemotherapy Governance
- Oncology Consultants
- Haematology Consultants
- Pharmacy

Approval and Review Process
- Cancer Services Governance

Local Archive Reference
G:\CANCER\11. Guidance & SOPS
Local Path
G:\CANCER\11. Guidance & SOPS
Filename
Cytotoxic Extravasation Policy
(right click above text, to update to new filename)

Policy categories for Trust's internal website (Bob)	**Tags for Trust's internal website (Bob)**
Chemotherapy	Intravenous,Chemotherapy, Extravasation,

Contents

1 Purpose

Extravasation is the accidental or inappropriate process of one substance leaking from a vein into the surrounding tissues (Jones & Coe 2004), this term is a generic term for this process however the scope of this guidance is when the substance involved is a cytotoxic agent or a monoclonal antibody used in the treatment of malignant disease.

A broader definition of extravasation includes the resulting injury. Depending on the substance that extravasates into the tissue, the degree of injury can range from a very mild skin reaction to severe necrosis (McCaffrey Boyle & Engelking 1995).

The extent of injury is determined by the following factors:

- the type of drug which extravasates
- the concentration and volume of drug in the tissue
- the location of the extravasation
- the co-morbidities and other patient factors

Although an uncommon event occurring in 0.5-5% of patients receiving chemotherapy, an extravasation injury has the potential for significant impact on the patient's quality of life (Allwood, Stanley, Wright (Ed) 2002).

This guideline has been developed in accordance with the latest scientific understanding and best evidence to date in combination with health professional consensus to ensure the patient receives optimal treatment. However, this is a complex subject where there is limited evidence due to lack of research and low incidence of reporting, which is difficult to ascertain whether this is a true reflection of the incidence of extravasation and subsequently obtaining consensus can be challenging.

The overall goal of this guideline is to help nurses understand and recognise extravasation and improve the prevention and overall management of extravasations in cancer patients.

The specific targets and aims of this guideline are to

- Increase nursing knowledge of specific elements of extravasation
  - Causes and risk factors for extravasation
  - Features and symptoms of extravasation
  - Difference versus flare and other reactions
  - Consequences of extravasation
  - Prevention measures
  - The use of antidotes in treating extravasation
- Encourage successful management of extravasation
- Update and inform nurses of the current standards from different guidelines and protocols
- Encourage adoption of procedures for extravasation that fit with current guidelines.

2 Responsibilities

2.1 Manager – Clinical Areas

The manager of each clinical area must provide opportunity of training to members of staff involved with the ***prevention*****,** ***recognition*** and ***management*** of extravasation and assess competence in line with the agreed SACT training policy.

2.2 Role of Nursing Staff

Nurses are among the best placed professionals to recognise and deal with extravasation in the clinical setting. The nurses who routinely provide cancer therapies intravenously either peripherally or through central venous access devices (CVAD) is particularly important in the on-going management of this possibly serious complication of therapy.

The role of the Chemotherapy Nurse is to ***prevent, recognise*** and ***manage*** extravasations, ensure on-going support for patients and keep accurate and timely documentation.

2.3 Role of Pharmacy

The Pharmacy Department are key in the support of nurses managing an extravasation. Cancer Pharmacists must provide information on the most suitable course of action in the absence of guidance in this document.

The Pharmacy Department are responsible for the prompt replacement of a sealed drug box on receipt of a used box within 48 hours.

2.4 Role of the Clinician

The Clinician is responsible for timely patient review and the prescribing of any drugs that are recommended within this document for the management of extravasation.

In the event of extravasation injury, the Clinician is responsible for the decision and referral of a patient to a Plastic Surgeon based at Royal Devon and Exeter Hospital.

2.5 Role of Joint Chemotherapy Governance

To monitor extravasation incidents and audits, advising action in response to the data.

Data collated to be reported into Northern Devon Healthcare Trust, Drugs and Therapeutics Committee and Quality Assurance Committee.

3 Classification of Cytotoxic Agents

For the purpose of this document as previously stated the classification will relate to cytotoxic agents. However, it is important to note that some non-cancer therapies when extravasated have the potential to cause serious injury.

The classification of cytotoxic agents is based on the potential to cause tissue damage if extravasated:

Vesicants Drugs which are capable of causing pain, inflammation and blistering of the local skin, underlying structures, leading to tissue

death and necrosis

Exfoliants Drugs which are capable of causing inflammation and shedding of the skin**,** but less likely to cause tissue death

Irritants Drugs which are capable of causing inflammation, irritation or pain at site of extravasation but rarely cause tissue breakdown

Inflammitants Drugs which are capable of causing mild to moderate inflammation and flare in local tissues

Neutrals Inert or neutral compounds that do not cause inflammation or damage

However, any chemotherapy drug has the potential to cause significant symptoms or harm if the volume or concentration of the drug that extravasates is high.

4 Identification of Risk Factors

4.1 Patient Factors

- Age: Elderly patients tend to have small mobile veins with friable skin
- Cancer patients may have additional risks due to:
  - Multiple cannulations for chemotherapy; veins maybe hard or sclerosed
  - Impaired circulation (e.g. cannula sited on the side of mastectomy, lymphoedema)
  - Patients with long term side effects from treatment (e.g. peripheral neuropathy)
  - Previous extravasation injury site
  - Multiple investigations (e.g. blood tests)
  - Obstructed vena cava (elevated venous pressure can cause leakage)
- Unconscious, sedated, confused patients, or patients with communication problems who may be unable to report stinging and discomfort around the cannula site or decreased sensation
- Patients suffering from co-morbidities which may lead to decreased sensation or poor circulation (e.g. diabetes, cerebral vascular accidents, Raynaud's syndrome and radiation damage)
- Obesity
- Concurrent medication i.e. analgesics, anticoagulants, anti-fibrinolytics, vasodilators, hormone therapy, steroids, diuretics, anti-histamines, intravenous antibiotics

4.2 Cannulation and infusion procedure factors

- Inferior choice of site for cannulation may increase the risk of a large volume extravasation or may impact on the severity of the injury
- Difficult or multiple attempts at cannulation increase the risk of a subsequent extravasation
- Administration of chemotherapy by untrained or inexperienced staff increases the risk of extravasation
- The size of the cannula
- The utilisation of a pre-existing cannula
- The classification of a chemotherapy drug
- Bolus injection
- High flow pressure

5 Prevention of Extravasation

The following points have been identified in minimising the risk of extravasation

5.1 Training

Only staff who are signed-off as competent can administer chemotherapy, as stipulated within the SACT training policy. All staff who administer chemotherapy must attend a chemotherapy update and have their competence of administration revalidated confirming knowledge and skill annually. Topics for assessment must include the following:

- Assessment of venous access
- Venous Access Devices
- Administration of chemotherapy
- Prevention, recognition and management of extravasation
- Management of hypersensitivity

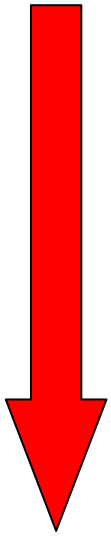
5.2 Selection of site for cannulation

The choice of site is paramount when attempting cannulation for chemotherapy. Cannulating over joints or the anticubital fossa should be avoided as tissue damage due to extravasation may have serious consequences as there is little soft tissue for the protection of underlying nerves and tissues (Allwoood & Stanley 2002; Hayden & Goodman 2005; Weinstein 2007; Dougherty and Lamb 2008; RCN 2010)

When choosing a vein to site the cannula, a large straight, firm, pliable vein which has not been utilised within the previous 24hours would be the ideal choice

However, if the most suitable vein for cannulation has been utilised within the last 24 hours for either cannulation or phlebotomy, any attempts should be higher (closer to the patient’s heart)

If cannulation attempts fail, further cannulation attempts must be above the previous site

Assess veins in both arms and hands, do not use veins veins in compromised limbs or lower extremities		
Criteria for vein selection		**Appropriate choice of venepuncture site**
Most desirable  **Least desirable**	**Ideal vein/best location** Large, soft resilient veins in forearm	Forearm
	Ideal vein/less desirable location Large, soft, resilient veins in hand/antecubital fossa	Hand
	Satisfactory vein/ Best location Small, thin veins in forearm	Forearm
	Satisfactory vein/undesirable location Small, thin veins in hand; veins in forearm not palpable or visible	Hand
	Unsatisfactory vein/ undesirable location Small, fragile veins, which easily rupture in forearm/hand	Connsider central venous line

5.3 Choice of equipment

The choice of equipment/material for administering cancer therapy is important when trying to minimise the risk of extravasation. Important considerations include the size and type of cannula or catheter.

In general, the goal is to choose a needle that is less likely to become dislodged, and on that allows the blood to flow around it. As a rule, it is advisable to use the smallest gauge cannula in the largest vein possible (McCaffrey et al. 1995; Wood et al. 1993; Schrijvers 2003; Hadaway et al, 2005) Specific recommendations include:

- A new cannula ideally should be placed prior to the administration of chemotherapy. There is an increased risk of extravasation if a previously placed cannula is utilised
- Use of a small bore plastic cannula (24g or 22g cannula)
- Steel winged infusion devices are associated with a higher incidence of extravasation therefore in no circumstances should a metal winged butterfly needle be utilised for the administration of chemotherapy
- For peripheral access, short, flexible polyethylene or Teflon
- Use a clear dressing to secure the cannula to allow for constant inspection

- Secure the infusion line, but never cover the line with a bandage (the insertion point must always be visible)

5.4 Patient Education

With regard to extravasation, communication with the patient is vital, since they are being relied upon to report symptoms critical in its recognition.

Using positive language, patients should be told about the nature of the cancer therapy they are receiving and the real possibility of side effect. This should be highlighted at the pre-treatment visit and continuously throughout each cycle of treatment. They should be asked to report any change in sensation, stinging or burning, no matter how insignificant it seems to them.

An informed patient can then help to recognise extravasation early and should always be listened to. For patients with communication difficulties who rely on carers or interpreters, it is important to establish that they understand the significance of reporting symptoms immediately.

5.5 Administration

In addition to careful selection of equipment and veins for administration of intravenous chemotherapy, there are many precautions that can be considered during the infusion to help reduce the risk of extravasation (Schrijvers 2003, Polovich et al 2006). These include:

- Consideration should be given to the use of a Central Venous Access Device (CVAD) in certain situations i.e. regimens with prolonged infusion of vesicant agents, if the patient has previously had an extravasation, or where the Summary of Product Characteristics (SPC) recommends a CVAD.

- Ideally a new peripheral cannula should be sited immediately prior to chemotherapy administration

- Only in exceptional circumstances should a practitioner who is going to administer vesicants or irritants utilise a cannula placed by another practitioner

- If the practitioner has any doubts in relation to the vascular access device the patient should be re-cannulated proximal to first attempt

- Ideally a practitioner will only attempt to cannulate a patient twice before handing over to another practitioner

- Venous access must be assessed and tested immediately prior to and frequently throughout administration of an cytotoxic drugs, checking for backflow, no resistance on syringe plunger on administration and acceptance of free flowing compatible infusion fluid

- If multiple drugs are prescribed within the chemotherapy protocol, ideally vesicants should be administered first, when vein integrity is at its best. However, there are notable exceptions where it is clinically indicated within the protocol that a non-vesicant should be given first

- If a non-vesicant is administered first for clinical reasons the patency of the cannula must be reassessed prior to the administration of vesicants, if there are doubts regarding the integrity if the cannula or the vein the patient should be re-cannulated.

- When administering bolus vesicant agents they must be administered through the side arm of a fast flowing compatible fluid drip continually assessing for signs of extravasation

- The delivery of chemotherapy irrespective of the agent being vesicant or not, is about the individual patient and the clinical assessment any practitioner makes at the time of the administration and will show huge inter and intra patient variability. The administration of chemotherapy needs to be guided by the skill and clinical judgement of the practitioner in the specific and individual circumstances of that administration, with documentation of the practitioner's actions, in line with the professional code of conduct (NMC 2015).

- It is known that certain pharmacological and formulation issues such as pH make a difference; volume and temperature are also important, larger volumes will require slow administration and the greater the temperature difference between the administered drug and physiological 36.8 the greater the degree of 'venous shock' and consequential shutdown and risk of extravasation

- Between each individual intravenous drug administration and on the completion of treatment the cannula must be flushed with at least 30ml of compatible fluid

- A number of regimens may now require patients to receive infusional vesicant agents. Patients receiving agents in this way must be closely monitored for signs of extravasation as there may be a theoretical increased risk of a larger volume extravasation

- Chemotherapy drugs must be infused over the prescribed time and as stipulated in the SPC

- Patients receiving peripheral intravenous infusions of vesicant drugs must not be allowed to leave the clinical area and **MUST** be observed at all times

6 Recognition (14-3S-118 & 14-3S-119)

6.1 Early Recognition

The early recognition and diagnosis of extravasation is critical as delays in recognition and management of a vesicant extravasation increases the likelihood of tissue damage and necrosis (McCaffery et al 1995, EONS 2007). The awareness and responsiveness to signs and symptoms is the most effective way to recognise and detect extravasation. If an extravasation is suspected it is important that a correct diagnosis is established seeking a second opinion is always warranted if in any doubt.

6.2 Patient Reporting

Patient must be informed of the potential risk of extravasation and the importance of reporting any symptoms below, irrespective of how insignificant they may be:

- Pain

- Change in sensation

- Burning

- Stinging

- Discomfort

Patients must be informed that these symptoms may not be an extravasation, however that a definitive diagnosis will need to be established.

6.3 Visual Assessment

Visual signs, while by no means exclusive to extravasation, do provide useful confirmation for patient reporting of symptoms in suspected extravasation. The common signs, occurring at or around the site of the cannula – or, in the case of the central line around the CVAD and the surrounding area – include:

- **Early Symptoms**
  - Swelling/Oedema
  - Redness/Erythema
- **Later Symptoms**
  - Inflammation
  - Induration (Localised tissue hardening)
  - Blistering

Importantly, many of these symptoms do not occur immediately upon infusion, induration and blistering, in particular, tend to appear later in the extravasation process. Therefore, careful monitoring of the site must continue during the infusion time and for some time following an infusion. Patients must be informed of the importance of reporting any pain, swelling, inflammation, blistering around the infusion site that occurs when at home (EONS 2007).

6.4 Warning Signs related to the Vascular Access Device

In addition to the patient reporting of symptoms and visual assessment, the following may support a diagnosis of extravasation

Signs of extravasation in relation to the cannula include:

- Increased resistance when administering intravenous drugs
- Slow or sluggish infusion
- Change in infusion flow
- Lack/loss of blood return from the cannula
- Leakage from around the cannula site

Inclusive of the above list, signs of extravasation in relation to CVAD:

- Aching discomfort in the shoulder/neck
- Pain, burning, aching/discomfort, swelling of chest wall
- Fluid leakage at or around exit site and along subcutaneous canal

It is important to note that all signs and symptoms may not occur instantaneously and if the practitioner has any concerns, then the administration must be stopped immediately until extravasation is excluded. If a definitive diagnosis cannot be established however other potential diagnoses have been excluded then the extravasation procedure must be instigated.

6.5 Distinguishing between Extravasation and other conditions

A definitive diagnosis can be difficult to establish and requires expert clinical judgement. However a definitive diagnosis enables the imitation of appropriate interventions and management strategies at the earliest possibility opportunity.

The following table distinguishes between other possible conditions that resemble extravasation.

	Presenting Symptoms	**Colouration**	**Timing**	**Swelling**	**Blood Return**
Flare Reaction	Itchy blotches or hives; Pain & burning uncommon	Raised red streak, blotches or 'hive-like' erythema along the vessel; Diffuse or irregular pattern	Usually appears suddenly and dissipates within 30-90 minutes	Unlikely	Usually but not always
Vessel Irritation	Aching and tightness	Erythema or dark discolouration along the vessel	Usually appears within minutes of injection. Colouration may only appear later in the process	Unlikely	Usually but not always
Venous Shock	Muscular wall of the blood vessel in spasm	n/a	Usually appears straight after the injection	n/a	Often absent
Extravasation	Pain and burning are common at injection; Stinging may occur during the infusion	Erythema around area of needle or around the venepuncture site	Some symptoms start to appear straight after the injection; symptoms endure	Occurs often does not dissipate for several days	Usually absent or sluggish

7 Management of Extravasation (14-3S-118 & 14-3S-119)

The management of an extravasation is dependent upon a number of contributing factors:

- The drug involved
- The volume extravasated
- The site of extravasation

The early initiation of treatment reduces the potential for tissue damage and necrosis and therefore is a critical part in the management of extravasation. However, in some cases an extravasation injury may not become apparent until a number of days or weeks later.

Extravasation is a Chemotherapy emergency and treatment should be initiated as soon as extravasation is suspected (*See appendix 1, Extravasation kit*). It is now acknowledge there are three tiers of management of an extravasation

- Basic management of extravasation (1st line)
- Decide on appropriate treatment based on cytotoxic involved (2nd line)
- Specific management instructions (3rd line)

If an extravasation is suspected the most senior nurse must coordinate the management of the extravasation by initiating 1st line treatment and a doctor must be informed of the incident immediately.

Pathway for 1st line management is as follows:

Irrespective of the nature of the drug the initial response to a suspected extravasation is the same. The initial aim is to minimise the volume extravasated cytotoxic agent into surrounding tissues

Step 1
- Stop the infusion immediately
- Do not remove the cannula/central venous access device (CVAD)

Step 2
- Inform and reassure the patient what is happening
- Request a member of staff to collect extravasation kit and bring to patient

Step 3
- Disconnect the infusion from the cannula/CVAD (ensuring the end of the giving set is securely placed in a tray to avoid spillage)

Step 4
- Try to aspirate as much as possible from the cannula/CVAD with a 10ml syringe
- Do NOT apply direct pressure to the suspected extravasation site

Step 5
- Mark the affected area with an indelible ink pen
- With patient consent, if possible take digital image

Step 6
- Remove the cannula; Do NOT remove CVAD

Step 7
- Elevate limb
- **Inform haematology/oncology medical team**

Step 8
- Administer pain relief if required

Step 9
- Follow the 2nd line management pathway
- Consider 3rd line management

Pathway for 2nd line management is as follows:

The subsequent management of a suspected extravasation is determined by the cytotoxic drug involved. There are two specific pathways for the second line management of extravasation, localise and neutralise (cold packs) and disperse and dilute (warm pack). For some cytotoxic drugs there is currently no further specific action other than the basic management required, however the patient must be given a follow up appointment and informed of the importance of contacting the Acute Oncology Service/Site Co-ordinator (out of hours) if further concerns arise.

The following table indicates the pathway required for individual cytotoxic agents

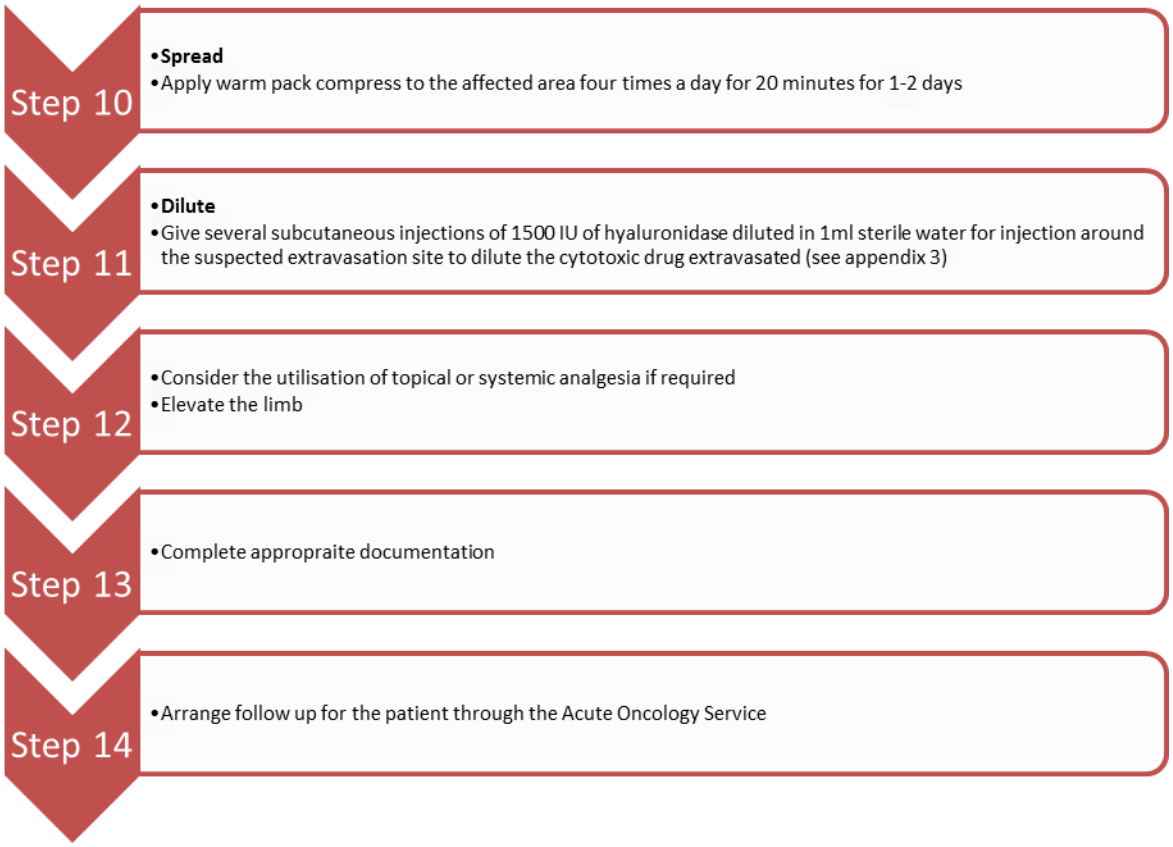
Vesicants (Non-DNA-Binding) Carbazitaxel Nab-paclitaxel (Abraxane) Vinblastine Vincristine Vinorelbine **Irritants** Oxaliplatin	**Aim: Spread and Dilute** Reconstitute 1500IU of Hyaluronidase with 1ml of water for injection Give this Hyaluronidase solution as 5 seperate 0.2ml subcutaneous injections around the circumference of the extravasated area **(NB. Administration within 1 hour for best results)** (Appendix 3) Apply a HOT pack to the affected area for 30 minutes 4 times daily for 1-2 days Then, apply hydrocortisone cream 1% four times per day for as long as erythema persists Elevate limb above the heart
Vesicants (DNA Binding) Amsacrine Dacarbazine Dactinomycin Daunorubicin Doxorubicin Epirubicin Idarubicin Mitomycin C Trabectidin **If >3ml do not apply DMSO & see appendix 5**	**Aim: Localise and Neutralise** Apply a thin layer of DMSO 50% cream to the marked area only, immediately, using a cotton bud **(NB. DO NOT use DMSO if blistering is present)** (Appendix 4) Once DMSO has dried, cover area with gauze, using only micropore to secure at two opposite ends within 10-25 minutes Apply cold pack for 30 minutes, repeat every four hours for 24 hours 3 hours after DMSO appliaction, apply hydrocortisone 1% cream, repeat every 6 hours for 7 days Elevate limb above the heart
Irritants Carboplatin Cisplatin Liposomal Daunorubicin Lipisomal Doxorubicin Cyclophosphamide Docetaxel Etoposide Fluorouracil Ifosfamide Irinotecan Melphalan Mitoxantrone Topetecan Trastuzumab emtansine (Kadcyla) Streptozocin **Vesicant (Non-DNA Binding)** Paclitaxel **Vesicant (DNA Binding)** Bendamustine Carmustine Chlormethine (Mustine) Treosulfan	**Aim: Localise** Apply cold pack for 30 minutes every 4 hours for 24 hours Apply Hydrocortisone cream 1% every 6 hours for 7 days or as long as erythema persists
Neutral Azacitidine Bleomycin Bortezomib Brentuximab Carfilzomib Cladribine Clofarabine Cytarabine Eribulin Fludarabine Gemcitabine Immunotherapy Methotrexate Moniclonal Antibodies Pemetrexed Pixantrone	**Aim: Symptomatic Relief** Elevate limb above the heart Apply Hydrocortisone Cream 1% 4 times each day if erythema is present Consider applying cold pack if local symptoms occur

IF AN EXTRAVASATION OCCURS WITH A DRUG NOT LISTED IN THE ABOVE TABLE PLEASE CONTACT PHARMACY ASEPTIC SUITE FOR ADVICE

Spread and Dilute Pathway (continues from Step 9 of initial management)

The "spread and dilute" 2nd line pathway utilises warm compresses to promote vasodilation and encourage blood flow in the tissues therefore spreading the extravasated agent.

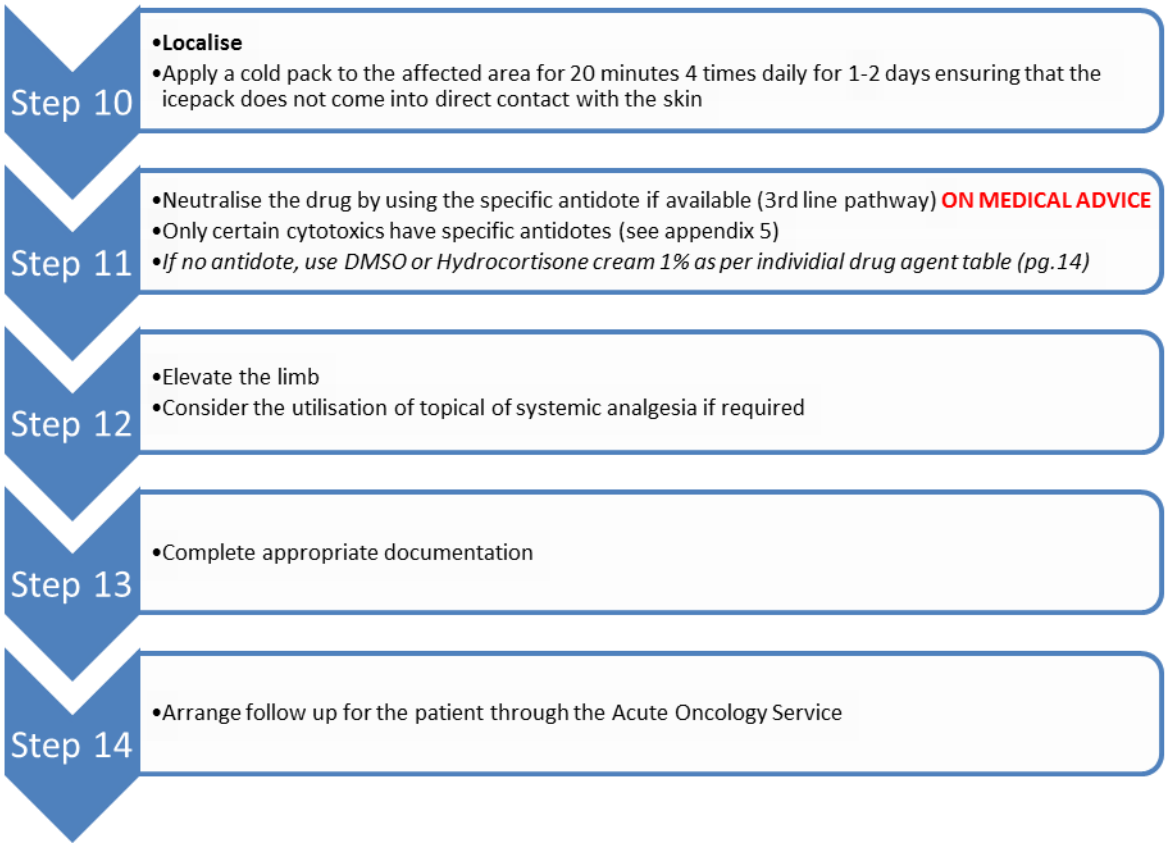
Hyaluronidase may be utilised with the aim of promoting drug diffusion and enhancing drug absorption.



Localise and Neutralise Pathway **(continues from Step 9 of initial management)**

The "localise and neutralise" pathway utilises cold compresses to limit the spread of the extravasated agent. It is proposed that the cellular uptake of the agent into the tissues is reduced when cold compresses are utilised. The cold compresses also may reduce local discomfort.

There are a number of antidotes available for certain cytotoxic agents and these are drug/group specific, these must be considered for 3rd line management to reduce the potential for severe tissue damage or injury.



3rd Line Pathway for specific cytotoxic agents

Following commencement of the 2nd line management pathways, clinicians should consider the utilisation of antidotes where available. These antidotes when utilised appropriately may help to prevent progression to ulceration and severe tissue damage.

The decision will be based on a holistic assessment of the individual patient, their treatment protocol, the suspected extravasated drug, their co-morbidities and concurrent medications. The evidence to support the utilisation of antidotes is often inconclusive and any decision to utilise these antibodies should be carefully considered.

Referral to plastic surgeons should be made by a clinician for all vesicants, DNA binding or non-binding cytotoxic extravasations. For other cytotoxic extravasations it is the responsibility of the treating clinician if a referral to plastic surgeons is necessary.

Extravasated Drug	Suggested antidote	Level of evidence	Advice
THE DECISION TO UTILISE EITHER SAVENE OR DSMO FOR AN ANTHRACYCLINE EXTRAVASATION MUST BE UNDERTAKEN BY A HAEMATOLOGY/ONCOLOGY DOCOTR BASED ON AN ASSESSMENT OF THE INDIVIDUAL'S CO-MORBIDITIES AND CONCURENT MEDICATIONS			
Anthracyclines	Savene (Dexrazoxane) the only licensed antidote. Savene neutralises anthracyclines	Efficacy in biopsy confirmed anthracycline extravasation has been confirmed in clinical trials	3 day course of treatment Day 1 (within 6 hours of extravasation), 1000mg/m^2; Day 2, 1000mg/m^2; Day 3, 500mg/m^2
Anthracyclines	Topical DMSO (99%) It is proposed this prevents ulceration by its property of scavenging free radicals	Suggested as a possible antidote in many literature sources	Apply locally as soon as possible. Repeat every 8 hours for 7 days stop if blistering occurs
Mitomycin C	Topical DMSO (99%) It is proposed this prevents ulceration by its property of scavenging free radicals	Suggested as a possible antidote in many literature sources	Apply locally as soon as possible. Repeat every 8 hours for 7 days stop if blistering occurs
Vinca alkaloids	Hyaluronidase breaks down hyaluronic acid ("cement") in connective/soft tissue, allowing for dispersion of the extravasated drug, thereby reducing the local concentration of the damaging agent and increasing its rate of absorption	Suggested as a possible antidote in many literature sources	1,500 IU subcutaneously around the area of extravasation
Taxanes	Hyaluronidase breaks down hyaluronic acid ("cement") in connective/soft tissue, allowing for dispersion of the extravasated drug, thereby reducing the local concentration of the damaging agent and increasing its rate of absorption	Suggested as a possible antidote in many literature sources	1,500 IU subcutaneously around the area of extravasation

8 Follow Up

All patients must have a review of their extravasation injury within 1 week; this appointment must be arranged prior to the patient leaving the Unit.

Advise the patient of the importance of contacting the 24 hour helpline if there is any deterioration in the affected limb.

All patients must be referred to the Acute Oncology Service (AOS) to ensure the patient is added to the active AOS patient follow up list. This referral can be made by providing a *copy* of the completed green card alongside verbal handover from the practitioner managing the extravasation and an AOS Triage Log Sheet must be completed by the AOS nurse at the time of referral.

9 Documentation

Each incident of extravasation must be thoroughly documented and reported. The practitioner managing the extravasation must complete the following:

- DATIX report via the Trust Intranet
- Green Card via the http://www.northdevonhealth.nhs.uk/extravasation/
- Extravasation self-adhesive label and inserted in the patient's notes

Documentation serves several purposes:

- To provide an accurate account of what has happened (in the event that there is litigation)
- To protect practitioners involved (showing they have followed procedure)
- To gather information on extravasations (auditing)
- Highlight any possible deficits in practice which require review

Please refer to appendix 6 for details mandatory for documentation following an extravasation.

10 Equality Impact Assessment

Group	Positive Impact	Negative Impact	No Impact	Comment
Age			**x**	
Disability			**X**	
Gender			**X**	
Gender Reassignment			**X**	
Human Rights (rights to privacy, dignity, liberty and non-degrading treatment), marriage and civil partnership			**X**	
Pregnancy			**X**	
Maternity and Breastfeeding			**X**	
Race (ethnic origin)			**X**	
Religion (or belief)			**X**	
Sexual Orientation			**X**	

11 References

Allwood, M., Stanley, A. and Wright, P, (2002) Cytotoxic Handbook. (4th ed.). Oxford: Radcliffe Medical Press Limited.

Dougherty, L. and Lamb, J. (2008) Intravenous Therapy in Nursing Practice, (2nd ed.) Blackwell Oxford.

European Oncology Nursing Society (2007) Extravasation Guidelines 2007 – Guidelines Implementation Toolkit.

Hadaway, L.C. and Millam, D.A. (2005) On the Road to Successful IV starts. Nursing **35** pp.1-14.

Hayden, M.K. and Goodman, M. (2005) Chemotherapy: Principles of Administration Cancer Nursing – Principles and Practice, Edited by Henke Yarbo.

Jones, L. and Coe, P. (2004) Extravasation. European Journal of Oncology Nursing **8** pp.355-358.

McCaffrey Boyle, D. and Engelking, C. Vesicant (1995) Extravasation: myths and realitites. Oncology Nurses Forum **22**(1) pp.57-67.

Nursing and Midwifery Council (2015) The Code – Professional Standards of Practice and Behaviour for Nurses and Midwives. London: Nursing and Midwifery Council.

Polovich, M., White, J. and Kelleher, L. (2006) Chemotherapy and Biotherapy Guidelines and Recommendations for Practice (2nd ed.). Oncology Nursing Society.

Royal College of Nursing (2010) Standards for Infusion Therapy, London

Schrijvers, D.L. (2003) Extravasation a dreaded complication of chemotherapy. Annals of Oncology **14** (Suppl3):pp.iii26-iii30.

Weinstein, S. (2007) Antineoplastic therapy, Plumers Principles and Practices of Intravenous Therapy, (8th ed). Lippincott: Philadelphia.

Wood, L.S. and Gullo, S.M. (1993) IV vesicants: How to avoid extravasation. American Journal of Nursing **93**(4) pp.42-46.

12 Associated Documentation

- SACT Training Policy/SOP

Appendix 1
Extravasation Kit

Location

The Extravasation Kit must be kept in an easy accessible area by medical professionals in the event of an extravasation injury; this area must be clearly identified with the use of signage and conveyed to medical professionals during training and staff induction.

Contents of the extravasation kit:

The contents of extravasation kit must be stored within an easy to carry container, sealed with a tamper tag.

- ✓ 2 x 2ml Syringe
- ✓ 2 x 10ml Syringe
- ✓ 2 x Filter Needle
- ✓ 8 x 25g needles (orange)
- ✓ 1 x Sterile Cotton Swabs
- ✓ 2 x Non-Woven Swab (gauze)
- ✓ 1 x Micropore tape
- ✓ 1 x Dressing Towel
- ✓ 1 x Apron
- ✓ 2 x Pair of gloves
- ✓ Indelible pen for marking the affected area
- ✓ Instant Cold Pack
- ✓ Extravasation Policy
- ✓ Drug Box including:
  - ☑ 1 x Hydrocortisone 1% Cream
  - ☑ 1 x Hyaluronidase 1500IU
  - ☑ 1 x Dimethylsulfoxide (DMSO 99%)
  - ☑ 1 x Water for Injection 10ml
  - ☒ Savene **NOT** included

The expiry date of the extravasation kit is determined by the expiry dates of the equipment/drug box enclosed. This must be written on the box with indelible ink

Monitoring

The contents and expiry date of the extravasation kit must be monitored by healthcare professionals within the area the extravasation kit is stored using the monitoring document illustrated in appendix 2.

The following must be inspected and recorded daily:

- Tamper tag
- Expiry Date of the box

NB. In the event the tamper tag is damaged, there are signs of entry or the expiry date is illegible. The entire contents of the kit must be checked and missing equipment replaced where appropriate, sealing the kit with a new tamper tag. If the "drug box" is missing from the kit, the incident must be reported to the manager immediately and recorded via the online incident reporting system; by the individual who has detected the incident.

In the event the extravasation kit is used, the individual who has managed the extravasation must

- Return the used "drug box" within the extravasation kit to the Pharmacy Aseptic Suite immediately to be replaced.
- Replenish the extravasation kit in line with the contents list and seal the kit using a new tamper tag, returning the kit to its named area for storage.

Complete the extravasation monitoring document

Appendix 2

Extravasation Kit Monitoring Document

Extravasation Kit Number:					Month:		
Date	Time	Tag #	Expiry Date	Comments		Name	Signature
1							
2							
3							
4							
5							
6							
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11							
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30							
31							

This document must be retained for auditing purposes

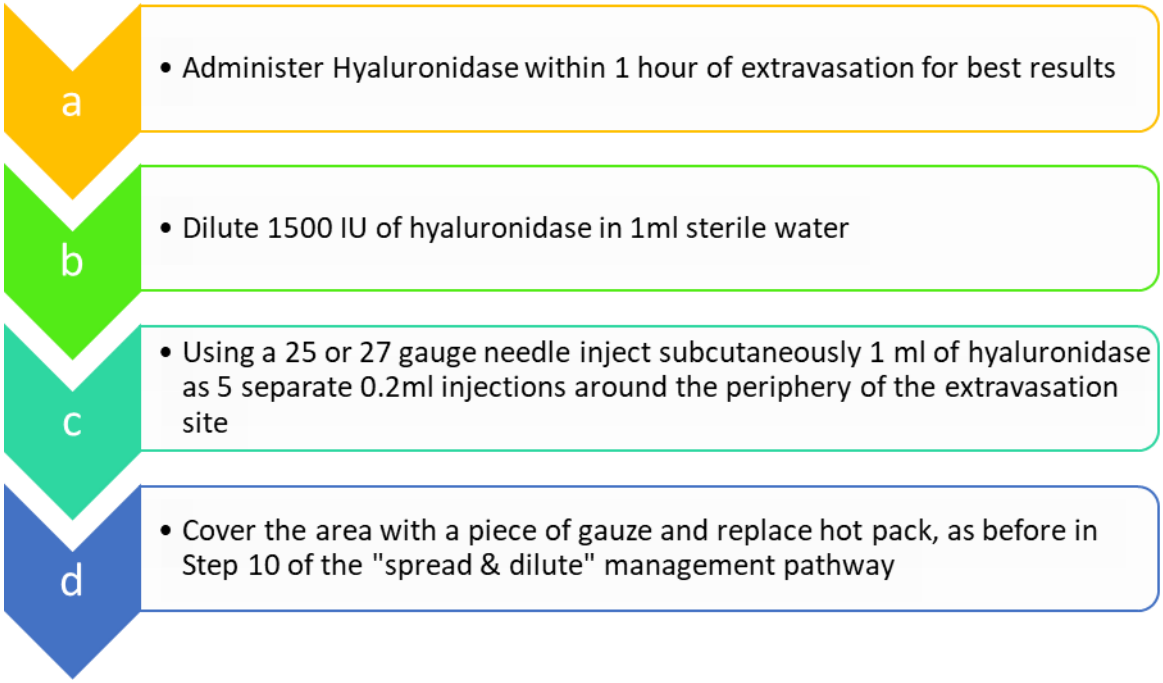
Appendix 3
Administering Hyaluronidase

Hyaluronidase may be indicated for suspected or known extravasation of:

- Dextrose in concentration of >10%;
- Parenteral alimentation solution (glucose or protein);
- Solutions containing calcium or potassium;
- Aminophylline;
- Antibiotics.

In addition, there are recommendations for hyaluronidase in response to vinca alkaloid extravasation.

Steps for administration of Hyaluronidase



Appendix 4

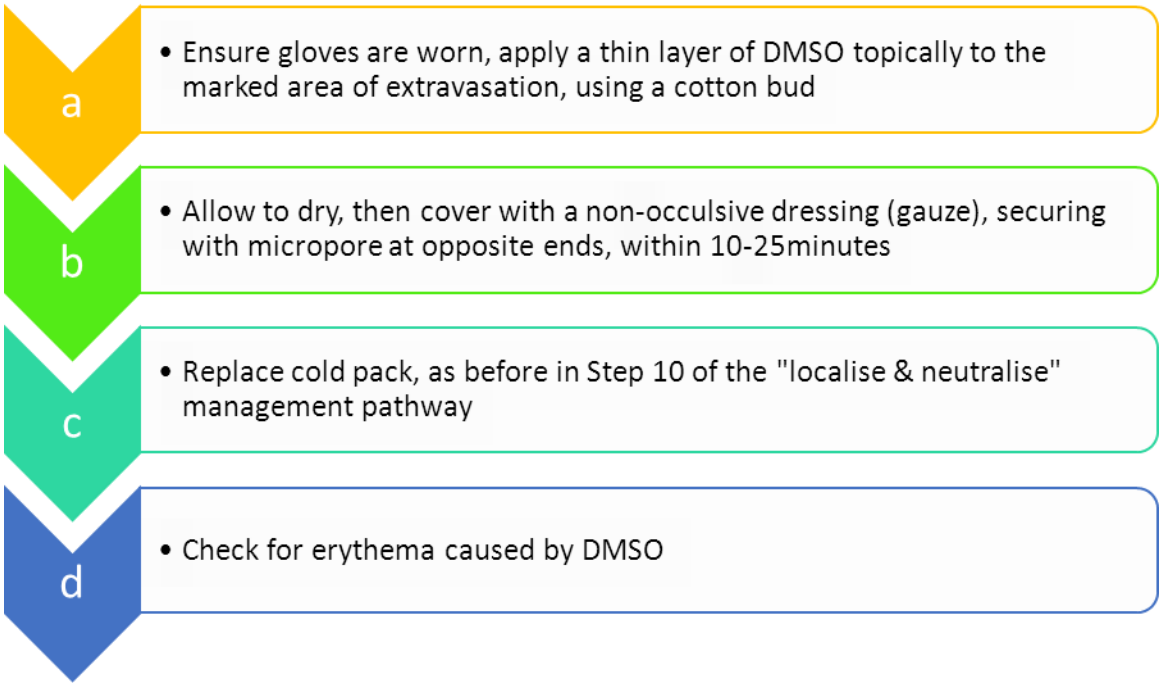
Use of Dimethylsulfoxide (DMSO 99%)

Dimethylsulfoxide (DMSO 99%) is an option for the treatment of extravasation with anthracyclines, where an antidote is not available.

For Mitomycin C, Doxorubicin, Idarubicin, Epirubicin and Actinomycin D; DMSO/corticosteroids should **not** be used.

Steps for administration of Dimethylsulfoxide (DMSO 99%)

DO NOT USE DMSO IF BLISTERING IS PRESENT



Appendix 5

Prescribing, Reconstituting and Administering Savene™ (Dexrazoxane)

Savene™ is a DNA topoisomerase II drug that protects against tissue damage with specific anthracycline drugs. Savene™ is the only licensed treatment for anthracycline extravasation (doxorubicin, epirubicin, daunorubicin, idarubicin). Savene™ is a cytotoxic drug; and must be prescribed by a specialist doctor, reconstituted within the Aseptic Suite by competent professionals within the department and administered by a Chemotherapy competent nurse within the specified areas for the administration of cytotoxic drugs as per the Chemotherapy Operational Policy.

Prescribing Guidelines:

- Savene™ is **NOT** recommended for use in children or in patients with hepatic or renal impairment
- Savene™ is **NOT** generally recommended in combination with live attenuated vaccines (contraindicated with Yellow Fever Vaccine)
- Savene™ is **NOT** generally recommended in combination with Phenytoin
- Cytotoxic agents may interact with oral anticoagulants.
- Savene™ must be administered as soon as possible and within **6 hours** of the anthracycline extravasation
- Most common side effects related to Savene™ therapy are nausea and haematological toxicities; including neutropenia and raised LFT's
- Cooling and **DMSO** should **NOT** be used during treatment with Savene™
- Give Savene™ as an intravenous infusion once daily for 3 consecutive days according to body surface area:

    a. Day 1: 1000 mg/m^2 (within 6 hours)

    b. Day 2: 1000 mg/m^2 (24 hours after initial dose +/- 3 hours)

    c. Day 3: 500 mg/m^2 (24 hours after 2nd dose +/- 3 hours from initial dose)

- Please contact Pharmacy Aseptic Suite (Internal 3787) for further advice, prescribing information; including full list of contraindications, precautions and warnings

For patients with a body surface area of more than $2m^2$ the single dose should not exceed 2000mg

Fontaine et al. (2011)

Guidelines for administration:

Post administration of Savene™

- Injury examination and haematological monitoring should be performed on a regular basis after treatment until resolution via the Acute Oncology Service following appropriate referral.

- Patients at risk of hyperkalaemia should be monitored for plasma potassium levels.

- Savene™ also contains sodium which may be harmful to patients who have raised sodium levels

- Patients treated with anti-coagulants should be monitored more frequently (daily whilst receiving Savene™)

Chemotherapy cycles following extravasation

- As Savene™ is an antidote to anthracyclines and blocks its action, therefore the Haematologist or Oncologist managing the patient's chemotherapy treatment must decide if the cycle is repeated.

- It is not advised to repeat treatment during the 3 day Savene™ treatment. However, final decision regarding subsequent chemotherapy treatment will be made on a case-by-case basis.

- If the extravasation has occurred at the beginning of a chemotherapy cycle, it can be assumed that the patient did not receive the cycle. Chemotherapy could be restarted relatively quickly, the soonest would be the day following the completion of Savene™ therapy. However, it is advisable to wait 7-10days and carry out haematological monitoring.

- If the extravasation has occurred at a late stage of the cycle, the quantity of anthracycline already infused on previous days will have had its full effect. Therefore, it may be sufficient to justify waiting until the next scheduled cycle. In addition, patients receiving chemotherapy other than anthracycline will still benefit from the efficacy of the other treatments administered.

Appendix 6
Documentation

In the event of extravasation, documentation is vital for several reasons

There are three places the nurse managing the extravasation must document

Extravasation Sticker

The extravasation sticker must be ***fully*** completed and placed within the patient's notes for record of the injury

Extravasation Details Date…… Time……..

Name of drug extravasated:..……..……

Regimen:..……

(Delete as appropriate)
Bolus / Bag CVAD/Peripheral cannula Gauge…….

Approximate volume of extravasation…….ml

Patient's Signs/Symptoms

Burning ☐	**Stinging** ☐	**Pain** ☐
Discomfort ☐	**Inflammation** ☐	**Swelling** ☐

Other:……

Initial Treatment Detail
Cold Pack ☐ Heat Pack ☐
Amount aspirated from cannula**……ml**

Name of Doctor Informed:……..……

Signature of Nurse:……..

Name of Nurse:……..…

Incident Report

An incident report must be completed via the Trust Intranet and include the following details:

- Patient name & unit number
- Date & time of injury
- Regimen patient was receiving
- Location of injury
- Drug extravasated
- How much drug had been administered
- Estimated amount of drug extravasated
- Type of device extravasated
- How extravasation was identified (patient or staff identified); including signs & symptoms
- Action taken at time of extravasation
- Follow up action in place

Green Card

A Green Card must be completed via http://www.northdevonhealth.nhs.uk/extravasation/

Royal Devon and Exeter NHS
NHS Foundation Trust

Clinical Guideline for:
Neonatal and Paediatric Extravasation and Infiltration Injuries

SUMMARY

This guideline outlines the process of managing neonatal and paediatric extravasation and infiltration injuries.

KEY POINTS

The essential elements of this guideline are:

- Early identification and management of extravasation/infiltration injuries is essential to prevent long-term tissue damage.
- Extravasation injury is a medical emergency and requires immediate attention and management.
- Neonates are at high risk of extravasation and infiltration injury.
- Consider liaising with tissue viability and/or plastic surgeons when there are concerns over wound healing or necrosis

CONTENTS

1. INTRODUCTION

1.1 This clinical guideline is designed to provide advice, guidance and direction to staff whilst leaving room for professional judgement, and adaptation, to fit individual circumstances.

1.2 Infiltration or Extravasation occurs when IV fluid or medication leaks into the surrounding tissues instead of flowing along the intended venous pathway. This can be caused by misplacement, dislodgement, or leakage from a peripheral cannula, short long line, central venous catheter (CVC) or intraosseous (IO) needle.

1.3 Neonates undergoing intensive care are at particularly high risk because of their poorly developed skin and subcutaneous supporting tissue, prolonged use of IV infusions and difficulties with venous access resulting in peripheral infusion of potentially hazardous fluids. However there is no initial difference in the recognition or management of neonatal and paediatric injuries.

1.4 Early recognition and intervention of extravasation, can substantially reduce the impact of injury.

1.5 This guideline does not cover the management of extravasation injuries secondary to chemotherapy agents, which are directly damaging to surrounding cells and require specific antidotes. Please see local 'extravasation policy for cytotoxic agents' guideline.

Extravasation is a medical emergency any time of the day or night and requires immediate attention and management.

2. DEFINITIONS

2.1 Extravasation

The inadvertent administration of a vesicant, acidic or alkaline medication/solution going into the surrounding tissue instead of the intended vessel. This can lead to pain, marking of the skin, necrosis and in severe cases, surgical intervention.

See Appendix 1 (section 6) for examples of drugs known to cause extravasation injuries.

2.2 Infiltration

The inadvertent administration of a non–vesicant, non-acidic, or non-alkaline medication/solution going into the surrounding tissue instead of the intended vessel. Leading to pain, oedema, and in severe cases compartment syndrome.

2.3 **Vesicant Drugs**

Solutions or medications that cause the formation of blisters with subsequent tissue necrosis and require management to limit tissue damage.

2.4 **Phlebitis**

Inflammation of the vein.

3. RECOGNITION OF INJURY

3.1 The table below displays signs of injury which can be suggestive of infiltration or extravasation injury. Infiltration injuries are typically stage 1 or 2 and do not require extensive management to prevent long-term skin and tissue damage. Stage 3 or 4 injuries have greater potential for skin necrosis and may need pharmacological treatment.

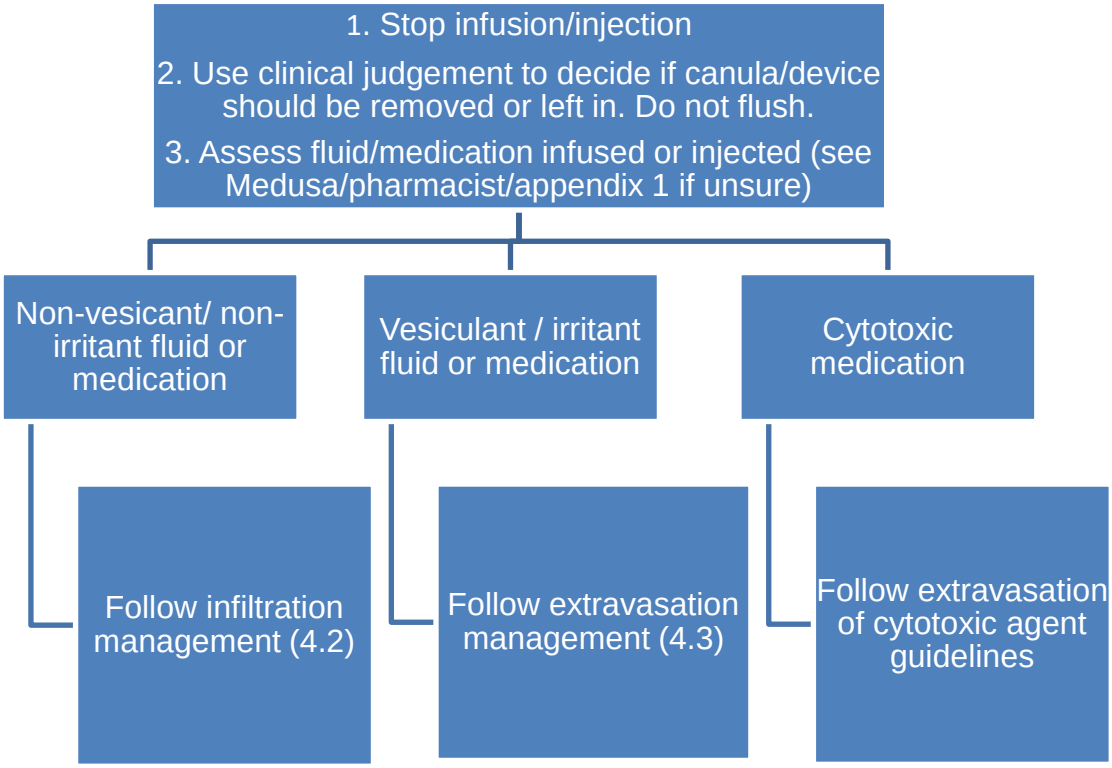
Table 1. Grading of tissue damage

Stage 1	Stage 2	Stage 3	Stage 4
Painful IV site	Painful IV site	Painful IV site	Painful IV site
No erythema	Erythema present	Blanching	Blanching
No swelling	Slight swelling	Marked swelling	Very marked swelling
Flushes with difficulty	No blanching	Cool to touch	Cool to touch
	Brisk capillary refill distal to infiltration site	Brisk capillary refill distal to infiltration site	*Cap refill >4sec
	Good pulse distal to infiltration site	Good pulse distal to infiltration site	*Decreased or absent pulse
			*Skin breakdown or necrosis

* the presence of any of these signs constitutes a grade 4 injury.

4. MANAGEMENT

4.1 The initial management can be classified as below.



4.2 Management of Infiltration injury

- If infusion running, stop immediately.
- Use clinical judgement to decide whether cannula/device should be removed or left in. Do not flush.
- Elevate limb and observe.
- Inform Doctor caring for the child and the need for a medical review.
- Perform regular observations until the area returns to its usual colour and size.
- For significant infiltration injuries consider photographs from medical illustration.
- Consider liaising with tissue viability team about possible use of an absorbent silicone dressing.
- Document which fluids/drugs infused, record date and time of event, site and area affected in the patient's notes.
- Complete datix form for moderate and significant injuries.
- Ensure parents/ carers are informed and are aware of planned care.
- Administer analgesia as required/prescribed.

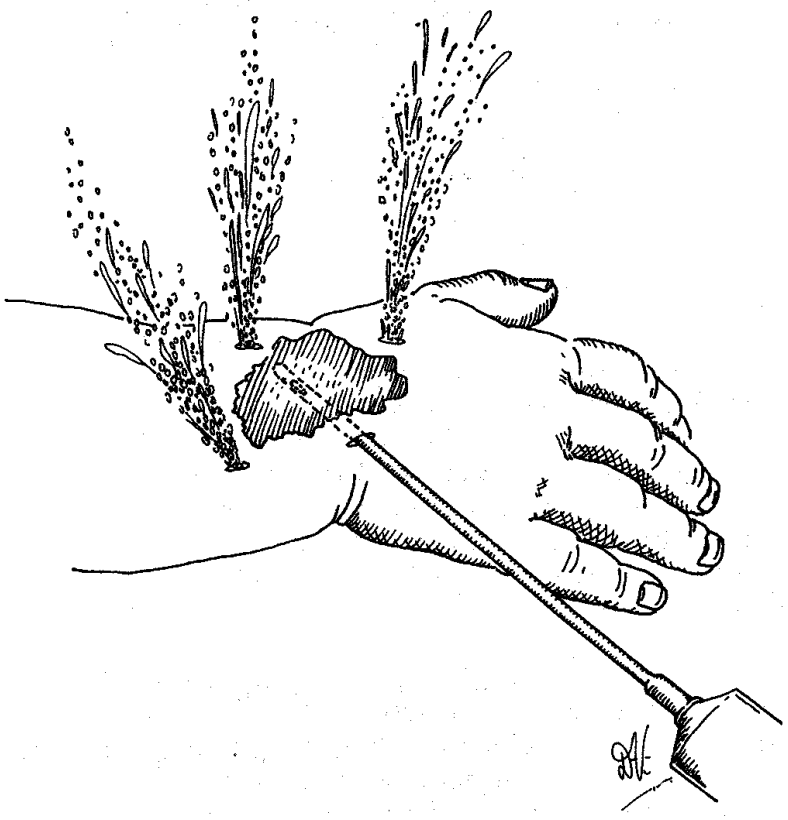
4.3 Management of Extravasation injury

- Stop injection/infusion
- Confirm identity of drug/infusate and consult the IV drug guide on HUB https://injmed.wales.nhs.uk/IVGuideDisplaySelectP.asp or ward pharmacist for advice on how to deal with extravasation
- Assess site
- Aspirate as much of the infusate as possible
- Use clinical judgement to decide whether cannula/device should be removed or left in for treatment purposes. Do not flush.
- Arrange medical photography and get parental consent
- Administer analgesia as required/prescribed
- Irrigate as below or use specific antidote/neutralising agent (see below, section 4.4 and 5)
- Refer to tissue viability if any skin damage
- Complete a datix
- Inform and explain incident to parents
- Document which fluids/drugs infused, record date and time of event, site and area affected in the patient's notes. Include extent and full management of injury required.
- Following irrigation treatment, all injuries should be reviewed at least 6 hourly for the first 24 hours of the extravasation occurring.
- Refer to the local plastics team if there are concerns about skin necrosis or poor wound healing after initial treatment.

4.4 Irrigation technique

- This should be performed by the medical team or ANNP
- Give morphine bolus as analgesia (For neonates: ventilated infants 100mg/kg, self-ventilating 50 – 75mg/kg but watch for respiratory depression. See BNFC for all other age doses)
- Full aseptic technique
- Infiltrate affected area and a small margin of surrounding skin with 1% lignocaine (maximum of 0.3ml/kg in neonates to 11yrs) for analgesia.
- Infiltrate hyaluronidase (1500 units) into affected area. Make four small puncture holes over the area using a lancet or large bore needle
- Flush with 3 – 5ml aliquots of normal saline using a blunt ended cannula, if cannula left in-situ then use this (to avoid damage to underlying structures). Fluid should extrude through the puncture holes. Gentle massage may be used to aid drainage through puncture sites.
- Continue until there is a visible difference in the affected area. The maximum flush volume is 50ml.

- Seek advice from tissue viability on most suitable dressing, usually Hydrocolloid.



- Elevate the limb until swelling has reduced

Saline washout technique

5. ANTIDOTES

Agent	Dose and administration	Caution	Mechanism of action
Hyaluronidase	1500unit solution – given as four subcutaneous injections into extravasation site. One injection may be given via cannula if in-situ	Most effective if administered within 2hrs, reports of efficacy up to 12hrs post injury. Effect lasts 24-48 hrs. Only to be used in conjunction with saline irrigation	Breaks down connective tissue hyaluronic acid increasing the distribution and absorption of locally injected substances.
Phentolamine	5mg made up to 10ml with 0.9% Saline solution - given as subcutaneous injections into extravasation site and/or via cannula if	Effective up to 12 hrs post injury. Systemic absorption may result in tachycardia and hypotension.	Competitive α-adrenergic blockade. Reverses the alpha mediated vasoconstriction properties of **vasopressors**.

	remains in-situ Dose: 0.1-0.2mg/kg max dose 5mg.		

6. APPENDIX 1

Drugs known to cause extravasation injuries (not an exhaustive list).

- Aciclovir
- Adrenaline
- Aminophylline
- Amiodarone
- Amphotericin
- Calcium Chloride
- Calcium gluconate
- Cefotaxime
- Ciprofloxacin
- Clarithromycin
- Co-trimoxazole
- Diazepam
- Dobutamine
- Dopamine
- Epoprostenol
- Erythromycin
- Ganciclovir
- Gentamicin
- Hypertonic glucose (10% or greater)
- Hypertonic saline (1.8% or greater)
- Mannitol
- Noradrenaline
- Parenteral nutrition
- Phenytoin
- Potassium chloride
- Prostaglandins
- Sodium bicarbonate
- Vancomycin
- Contrast media

7. MONITORING COMPLIANCE WITH THIS GUIDELINE

7.1.1 Any concern or non-compliance with this guideline that is identified through the investigation of clinical incidents, complaints or claims will be reviewed as per Trust policy and may result in an audit and / or amendment to the guideline.

8. REFERENCES

Beaulieu MJ.(2012) Hyaluronidase for extravasation management. *Neonatal Network*; 31(6):413-418.

Beall V, Hall B, Mulholland JT, Gephart SM. (2013)Neonatal Extravasation: An Overview and Algorithm for Evidence-based Treatment. *Newborn & Infant Nursing Reviews*; 13(4):189-195.

Gopalakrishnan PN.(2017) **Saline irrigation for the management of skin extravasation injury in neonates** *Cochrane Database of Systematic Reviews*.

Kostogloudis N, Demiri E, Tsimponis A, Dionyssiou D, Ioannidis S, Chatziioannidis(2015) I et al. Severe Extravasation Injuries in Neonates: A Report of 34 Cases. *Pediatric dermatology*; 32(6):830-835.

McSharry B. (2016) Extravasation and Infiltration Injuries – management in PICU. https://www.starship.org.nz/guidelines/extravasation-and-infiltration-injuries-management-in-picu/ Accessed 26th May 2020.

Peripheral intravenous extravasation: nursing procedure for initial treatment.Thigpen JL. Neonatal Network 2007; 26(6): 379-84.

Preventing the scars of neonatal intensive care. Davies J, Gault D, Buch

Restieaux M, Maw A, Broadbent R, Jackson P, Barker D, Wheeler B. (2013) **Neonatal extravasation injury: prevention and management in Australia and New Zealand-a survey of current practice** *BMC Pediatr*; 13:34.

University Hospitals Bristol and Western. Clinical Guideline: Extravasation and Infiltration: Identification and management in neonates and paediatric patients. March 2020.

9. PUBLICATION DETAILS

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Document Control

Title

Extravasation injury management in neonates and paediatrics Guideline

Author	Author's job title
	Senior Neonatal Nurse and Educator Senior Paediatric Nurse and Educator Paediatric Consultant
Directorate Unplanned care	**Department** Paediatric and Neonatal Services

Version	Date Issued	Status	Comment / Changes / Approval
0.1	2012	Draft	Initial version for consultation
1.0	May 2013	Final	Approved by Paediatric Specialty Team on 31/5/2013
1.1	Jun 2013	Revision	Converted to Trust template.
1.2	Aug 2013	Revision	Minor amendments by Corporate Governance.
1.3	Nov 2014	Revision	Additions by Migs Luckie to create joint neonatal & paediatric guideline. Sent out for comments
2.0	May 2016	Final	Approved by Paediatric Specialty Team 27/5/16
3.0	June 2019	Final	Approved by Paediatric Speciality Team 19/7/19

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Superseded Documents
Extravasation injury guideline v1.2 22Aug13.doc
Extravasation injury management in neonates and paediatrics Guideline-V2.0-May16

Issue Date	Review Date	Review Cycle
June 2019	June 2022	Three years

Consulted with the following stakeholders: (list all)

- Clinical staff SCBU
- Paediatric department
- Paediatric Pharmacist
- Clinical Nurse Specialist Intravascular Fluid Management

Approval and Review Process

- Paediatric Specialty Team

Local Archive Reference
G:\Paediatric Resources\Neonates\Neonatal guidelines\previous versions of guidelines
Local Path
G:\Paediatric Resources\Neonates\Neonatal guidelines

Filename	
extravasation injury guideline v3.0	
Policy categories for Trust's internal website (Bob) Neonatal medical, Neonatal nursing, Paediatrics	**Tags for Trust's internal website (Bob)** Hyaluronidase, phlebitis, infiltration, VIP Score, vesicant, necrosis, extravasation

CONTENTS

1. Purpose

This document sets out Northern Devon Healthcare NHS Trust's best practice guidelines for the management of extravasation injuries.

2. Purpose

The aim of this guideline is to define and outline the grading and management of extravasation injuries to reduce the risk and morbidity of these injuries in the Neonatal and Paediatric Service.

Neonates undergoing intensive care are at particularly high risk of extravasation injury because of their poorly developed skin and subcutaneous supporting tissue, prolonged use of IV infusions and difficulties with venous access resulting in peripheral infusion of potentially hazardous fluids. In regional neonatal NICUs in UK the prevalence of extravasation is 38/1000 (Wilkins and Emmerson, 2004). About 4 % of neonates leave Neonatal units with functionally or cosmetically significant scars. 70% of the injuries occur in neonates < 26 weeks of gestation. Preterm babies are at the highest risk as they have the most immature skin which can be easily damaged, require more intravenous therapy and have difficult venous access. Extravasation can occur both in central and peripheral lines. Intravenous pumps do not always alert staff to an extravasation injury in progress.

The following general principles can be applied in order to improve:

- Patient care
- Identification and treatment of extravasation injury in neonates and children

In accordance with best practice guidance for extravasation injury management in neonates and children

This guideline applies to all clinical staff working in the Neonatal and Paediatric wards and must be adhered to. Non-compliance with this guideline may be for valid clinical reasons only. The reason for non-compliance must be documented clearly in the patient's notes.

3. Definitions / Abbreviations

Infiltration - The inadvertent leakage of a non-vesicant solution from its intended vascular pathway (vein) into the surrounding tissue.

Extravasation - The non- intentional leakage of a vesicant solution or medication from the vein into the surrounding tissue which may cause tissue damage.

Vesicant Drugs - Solutions or medications that cause the formation of blisters with subsequent tissue necrosis and require management to limit tissue damage.

Phlebitis - Inflammation of the vein.

(Dougherty 2008)

4. General principles of Extravasation injury management

4.1 Factors and drugs affecting extravasation injury

The degree of tissue damage due to infiltration is dependent upon:

- The volume of the infusate
- The infusate's pH & osmolarity
- The pharmacological action of any drug(s) being infused

4.2 Examples of vesicant drugs, this list is not exhaustive

Alkali / Acidic solutions	Vascular regulators	Hyperosmolar solutions
Thiopentone	Adrenaline	Calcium chloride
Phenytoin	Noradrenaline	Potassium chloride
Methyleneblue	Dopamine	Sodium bicarbonate
Amphotericin B	Dubutamine	TPN
Vancomycin	Vasopressin	X-Ray contrast medium
Acyclovir		Dextrose
Gentamicin		Mannitol 15%
Cefotaxime		

4.3 Prevention

- Percutaneous long lines for the administration of total parenteral nutrition and glucose concentrations greater than 12.5%.
- Ensure central line position is confirmed by medical staff by X-ray before commencement of fluid infusions.
- Avoid giving vasoactive and inotropic drugs like dopamine and dobutamine in a peripheral vein if possible.
- Avoid scalp vein cannula where possible
- Line insertion sites should be covered with an appropriate transparent dressing to ensure visibility of insertion site.
- Line insertion sites must allow inspection of the line and should not compromise venous flow.
- Hourly recording of observation of cannula site whilst in use for oedema, firmness, swelling, redness, blanching, discolouration or leaking using the appropriate VIP Score (see Appendix A and B)

- If the pressure alarm sounds check site for the above.

(There is currently no evidence that monitoring infusion pump pressures reduces the incidence of extravasation injuries).

4.4 Recognition of extravasation

IV sites are assessed hourly and documented using Visual Infusion Phlebitis (VIP) Score whilst in use:

- Increasing pressure readings on infusion pumps.
- Erythema, swelling and tenderness.
- Induration with mottling and blistering (partial thickness skin damage).
- Cold, white area without capillary filling (full thickness damage). If untreated this will progress to a black eschar with underlying ulceration on separation.

4.5 Stages of infiltration/ extravasation injury

Use this grid when scores are rising on the VIP Score.

Stage 1	Stage 2	Stage 3	Stage 4
No erythema or swelling, Flushes with difficulty.	Mild Swelling Redness No skin blanching Normal capillary refill and peripheral pulsation 1-2 seconds capillary refill below site Pain	Moderate Swelling Skin blanching and cool to touch Cool blanched area Normal capillary refill and peripheral pulsation Pain Blister	Marked Swelling Skin blanching Cool blanched area Reduced capillary refill +/- Absent pulse +/- Skin breakdown or necrosis Pain Blister
Check cannula and splints/tapes and observe hourly	Stop infusion Review cannula and splints/tapes Consider resiting Elevate limb Observe circulation Document	Stop infusion Leave cannula in situ until review by Doctor Consider irrigation of affected area Remove constricting tapes	Stop infusion Leave cannula in situ until review by Doctor (Photograph lesion - providing no delay in further treatment)

Stage 1	Stage 2	Stage 3	Stage 4
	findings	Elevate limb Observation circulation Document findings/Incident form	Irrigate affected area Elevate limb Inform Consultant +/- plastic surgery Observe circulation Document findings/Incident form

Adapted from Massey Luanne (2010)

Note - Neonates may not exhibit pain in the same way as older children.

Most infiltration injuries are of Grades 1 & 2 and do not require extensive intervention to prevent long-term skin and soft tissue damage. Elevate limb, observe circulation and document findings

Grade 3 & 4 injuries have a greater potential for skin necrosis, compartment syndrome and need for future plastic surgery, depending on the type of solution infiltrated

5. Management

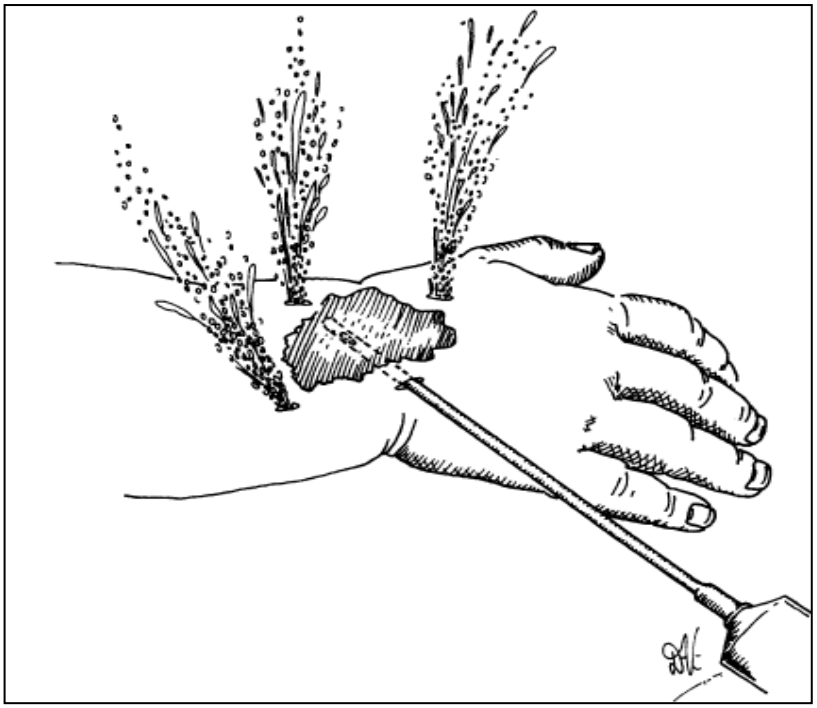
Steps	Management for all IV infusions
1	Check site hourly and document using VIP score, (see appendix A and B)
2	If pressure alarm on pump rings always check site
3	Stop injection/infusion according to VIP Score and Stages of Extravasation grid (4.4) Document findings.
4	Inform Medical Staff
5	If the site is only mildly inflamed elevate limb and observe (grade 1-2).
	If extravasation is confirmed:
6	DO NOT remove cannula
7	Aspirate as much of the infusate as possible.
8	Assess damage – take photograph (after written consent of parents). Documentation for consent can be found on the Trust's intranet site.
9	Confirm identity of drug / infusate and document batch number and expiry

	date.
10	Irrigate as below or use specific neutralising agent if grade 3-4 (see irrigation technique point 6)
11	Refer to local tissue viability team and Plastics Surgeons, if necessary seek advice from Paediatrics plastic surgery team in Bristol.
12	Use tissue viability assessment forms (see Trust intranet site) to document wound care, treatment and progression.
13	Complete incident report, document in patients records and inform the parents.

6. Irrigation technique

	Irrigation Equipment Required
	Dressing pack Cleaning fluid according to age of baby/child Sterile gloves Dressing towels Sterile bowl Lignocaine for local analgesia Hyaluronidase Syringes/needles 19 gauge cannula 3 way tap 20 ml syringe Jelonet or duo derm dressings
	Irrigation Technique
1	Give pain relief (bolus morphine as analgesia in ventilated infants 100 mcg/kg, in self-ventilating babies 50mcg /kg but watch for respiratory depression)
2	Use aseptic technique.
	Put a sterile towel and a sterile bowl beneath the area to be irrigated.
3	Infiltrate affected area and a small margin of surrounding skin with 1% lignocaine (maximum of 0.3ml/kg) for analgesia.
4	Make four small puncture holes over the area using a lancet or large bore. Cannula 19 gauge
5	Infiltrate hyaluronidase (1, 000 units) into affected area through existing cannula and the four holes
6	Flush with 3 – 5ml aliquots of normal saline using existing cannula or a blunt ended 19 gauge cannula (to avoid damage to underlying structures)

	connected to a three way tap on a 20 ml syringe. Fluid should extrude through the puncture holes. Gentle massage may be used to aid drainage through puncture sites. Continue until there is a visible difference in the affected area. The maximum flush volume is 50ml.
7	Repeat photograph at end of irrigation
8	Dress with Jelonet or Duoderm and elevate limb.



7. Documentation

- Hourly observations of cannula site prior to injury
- Detailed account of action taken where there is concern about the patency of the cannula and/ or any swelling around the site before injury
- Documentation of the infused fluid, the site and size of the injury, an assessment of the wound and documentation of the chosen dressing used.
- Care plan for the treatment of the wound
- Photograph of the wound with scale included
- Parents informed and documented

- Complete DATIX
- Observe and document change in colour and decrease in swelling hourly for 6 hours then every 6 hours then at the start of each shift at handover as appropriate
- With each dressing change document the assessment of the wound bed, change in size, detailes of replacement dressing and planned date of review.
- Documentation of any liaison with other specialities including tissue viability.

8. Investigations

No specific investigations are required. However, if the wound appears infected, a wound swab, full blood count, CRP and blood culture should be taken and the infant commenced on IV Antibiotics.

9. Further Information

National extravasations information service
St Chad's Unit,
Dudley Road Hospital,
Birmingham B18 7QH
Tel: 0121 554 3801
Fax: 0121 507 5724

10. Education and Training

Responsibility for education and training lies with the Lead Clinician for neonates. It will be provided through informal training on the ward as required

11. Consultation, Approval, Review and Archiving Process

The author consulted with all relevant stakeholders. Please refer to the Document Control Report.

Final approval was given by Paediatric Specialty Team on 27/5/16

The guidelines will be reviewed every 3 years. The author will be responsible for ensuring the guidelines are reviewed and revisions approved in accordance with the Document Control Report.

All versions of these guidelines will be archived in electronic format by the author within the Neonatal Team policy archive.

Any revisions to the final document will be recorded on the Document Control Report.

To obtain a copy of the archived guidelines, contact should be made with the team.

12. Monitoring Compliance with and the Effectiveness of the Guideline

Staff are informed of revised documentation. There is an expectation that staff are responsible to keep updated on any improvements to practice and deliver care accordingly.

Extravasation incidents are reported by the Datix system and South West Neonatal Network incident reporting process. These incidents are monitored by the Neonatal and Paediatric governance team and the neonatal network.

Non-adherence is reviewed and action plans made if required. Discussion and reviews occur at South West Neonatal Network governance meetings, Trust Directorate meetings, Paediatric Governance meetings and Ward meetings. Learning and action plans are cascaded at these meetings and improvements implemented. Key findings and learning points will be disseminated across network and to relevant staff.

13. References

- Davies J et al, Preventing the scars of neonatal intensive care. *Arch Dis Child* 1994;70: F50-1 (source of diagram)
- Dougherty L . IV Therapy: recognizing the differences between infiltration and extravasation. *British Journal of Nursing*.2008 Vol 17, No 14
- Subhani et al, Phentolamine use in a neonate for the prevention of dermal necrosis caused by dopamine. *J Perinatol* 2001 21(5):324-6
- Gault DT. Extravasation Injuries. *Br J of Plastic Surgery* 1993; 46; 91-96.
- Gopalakrishnan PN, Goel N, Banerjee S. Saline irrigation for the management of skin extravasation injury in neonates.*Cochrane Database of Systematic Reviews* Feb 2012
- Massey Luanne (2010), Intravenous cannulation recognition and management of infiltration injuries (including clysis), New born services clinical guidelines. Available at. http://www.adhb.govt.nz/newborn/guidelines/vascularcatheters/IVInfiltrationInjuries.htm. Accessed 20/12/2011
- Extravasation injury in neonates treatment and prevention, University Hospital Bristol, local NICU guideline 2011
- Guideline for extravasation injury in North Trent Neonatal network Aug 2009
- GOSH. (2014) [0n-line]. Extravasation and infiltration clinical guideline. http://www.gosh.nhs.uk/health-professionals/clinical-guidelines/extravasation-and-infiltration/ (accessed 7/11/14)

- Wilkins, C.E., and Emmerson, A.J. (2004). Extravasation injuries on regional neonatal units. Arch Dis Child Fetal Neonatal Ed. 2004; 89(3), p274-5.

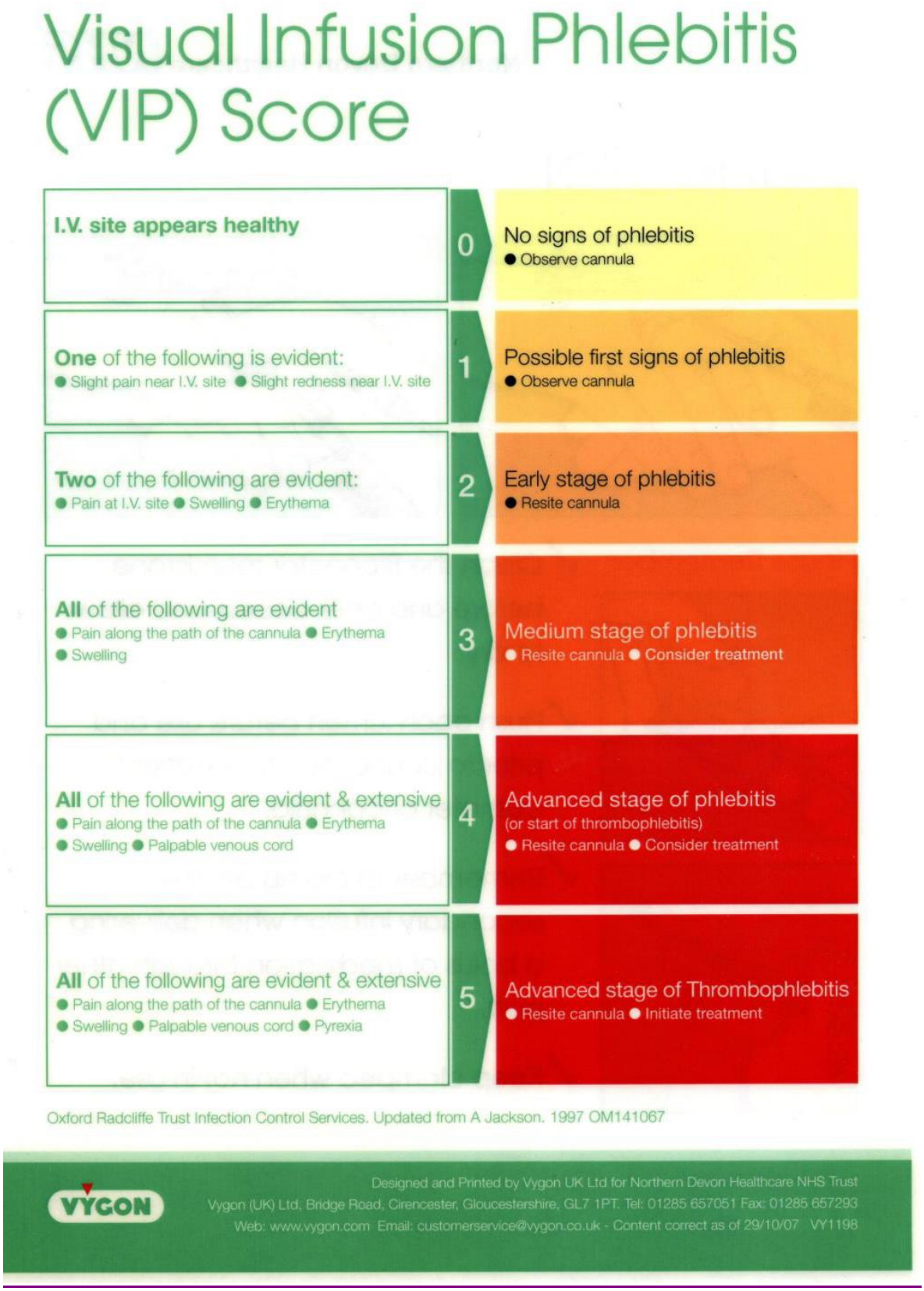
14. Associated Documentation

- Injectable Medicines Policy.
- Paediatric Infusions Policy.
- Intravenous Device Policy.

Appendix A - Neonatal Visual Infusion Phlebitis (NVIP)Score

IV site appears healthy	0	Observe site/cannula hourly
Slight redness, and, or, pressure rising	1	Observe site/cannula hourly
Redness, slight swelling and, or, pressure rising	2	Observe site/cannula hourly. Consider resiting cannula
Redness, moderate swelling/blanching and, or leaking	3	Resite cannula
Rednes/blanching/gross swelling and, or, leaking	4	Resite cannula – consider actions for extravasation
Extravasation	5	Leave cannula for irrigation, consider treatment, follow extravasation guideline. Resite new cannula.

Appendix B. Visual Infusion Phlebitis (VIP) Score



Injectable Medicines Policy

Post holder responsible for Procedural Document	[redacted] Head of Safety Risk & Patient Experience. [redacted] Acting Lead Nurse for Safety & Patient Experience.
Author of Policy	[redacted] Head of Safety, Risk & Patient Experience. [redacted], Acting Lead Nurse for Safety & Patient Experience.
Division/ Department responsible for Procedural Document	Safety, Risk & Patient Experience
Contact details	x[redacted]
Date of original document	October 2011
Impact Assessment performed	**Yes** / No
Ratifying body and date ratified	Clinical Effectiveness Committee: 3rd May 2018 version 2.2-Chair's approval- 10 Dec 19
Review date (and frequency of further reviews)	July 2019 (every 2½ years)
Expiry date	January 2020
Date document becomes live	8 October 2018 version 2.5: 14 April 2020

Please specify standard/criterion numbers and tick ✓ other boxes as appropriate

Monitoring Information		Strategic Directions – Key Milestones	
Patient Experience		Maintain Operational Service Delivery	
Assurance Framework		Integrated Community Pathways	
Monitor/Finance/Performance		Develop Acute services	
CQC Fundamental Standards - **Regulation: 10**		Infection Control	
Other (*please specify):*			
Note: This document has been assessed for any equality, diversity or human rights implications			

Full History		Status: Final	
Version	**Date**	**Author**	**Reason**
1.1	17/11/2011	Chief Pharmacist, Deputy Chief Pharmacist	Original document
2.0	07/12/2017	Head of Safety, Risk & Patient Experience	Policy title change (from Intravenous Therapy Policy). 2 associated SOPs created
2.1	01/10/2018	Acting Lead Nurse for Safety & Patient Experience	Addition of point 10.1.11 in policy
2.2	17/12/2019	Acting Lead Nurse for Safety & Patient Experience (minor revision by Medication Safety Pharmacist)	Risk mitigations (5.7. + 5.8 + appendix 2) Minor revisions to NPSA risk assessment form in Appendix 1.
2.3	13/01/2020	Medication Safety Pharmacist	Section 10.7.1-0.11% changed to 0.9%
2.4	28/01/2020	Medication Safety Pharmacist	Sections 4.6 & 8.5: 0.10% changed to 0.9%
2.5	April 2020	Medication Safety Pharmacist	Appendix 3 updated: Injectable Risk Assessment Flowchart (Community)

Associated Trust Policies/ Procedural documents:	Medicines Management Policy Standard Operating Procedure for Preparing Injectable Medicines Standard Operating Procedure for Administering Injectable Medicines Venous Access Device Policy & Procedures Policy for Safe Practice with Intrathecal Cytotoxic Drugs Safe Use of Systemic Anti-Cancer Therapies (SACT) in the Treatment of Cancer Policy Clinical Guideline for: Administration of Non-Obstetric Epidural Analgesia Clinical Guideline for: Epidural/(PCEA) Patient Controlled Epidural Analgesic Infusion in Children Extravasation Policy for Cytotoxic Agents Clinical Guideline for: Neonatal Extravasation Injuries Hand Hygiene Policy Aseptic Technique Guidance
Key Words	Intravenous, intramuscular, subcutaneous, inject, fluid, extravasation, infiltration, infusion, infuse, pump, device, giving set, IV policy, IV

In consultation with and date:

- Governance Managers, Divisional Directors, General Managers, Associate Medical Directors, Assistant Directors of Nursing, Senior Nurses, Matrons (Dec 2017)
- Medicines Management Group 110/04/2018
- Quality Assurance Stage: 26/04/18
- Clinical Effectiveness Committee: 03/05/18
- Chairs approval to addition of 10.1.11: 02/10/18

• Chairs approval of version 2.2: 10/12/19	
Contact for Review:	Head of Safety, Risk & Patient Experience
Executive Lead Signature:	 Medical Director

CONTENTS

1. INTRODUCTION

1.1 This policy gives guidance on the safe preparing, prescribing and administration of injectable medicines. Injectable therapy is a high-risk intervention and this policy sets out required standards that all staff must adhere to.

1.2 The policy sets out the responsibilities of prescribers and those administering injectable medicines including intravenous therapy.

1.3 This policy must be read in conjunction with the medicines management policy, which can be found on the Trust intranet. In addition to this, reference is made to the Nursing and l Midwifery Council Standards for Medicine Management (2007)

1.4 This policy must also be read in conjunction with relevant infection control policies, including Aseptic Technique Guidance, Venous Access Device (VAD) Policy and Procedures, Hand Hygiene and other relevant Trust policies.

1.5 Staff must also be aware of further guidance covering other elements of safe intravenous therapy, such as guidance provided by the Vascular Access Team, Medusa and infusion device guidance provided by the Medical Equipment Management team.

1.6 This policy relates to drug administration by injection by the routes specified in section 3 below.

1.7 Administration of intrathecal and epidural (adult and paediatric) injections is covered by other Trust policies and guidelines.

1.8 **Failure to comply with this policy could result in disciplinary action.**

2. PURPOSE AND OUTCOMES

2.1 The intended outcomes of this policy are evidence that:

- Principles of safe injectable medicine practice are adhered to all staff across the Trust.
- Appropriate risk assessments are carried out and risk mitigation is in place

3. DEFINITIONS

- **Intra-articular** - Administration of an injection into the cavity of a joint
- **Intracardiac** - Administration of an injection into the heart muscles or ventricles
- **Intradermal** - Administration of an injection into the skin
- **Intralesional** - Administration of an injection into a lesion
- **Intramuscular (IM)** - Administration of an injection into the muscle
- **Intraocular** - Administration of an injection into the eyeball
- **Intraosseou**s - Administration into the bone
- **Intravenous (IV)** - Administration of an injection into the vein
- **Intrapleural** - Administration of an injection into the pleural space
- **Intravitreal** - Administration of an injection inside the vitreous cavity (eye)
- **Patient Controlled Analgesia (PCA)** - Infusion of analgesia controlled by patient
- **Subconjunctival** - Administration of an injection beneath the conjunctiva
- **Subcutaneous (SC)** - Administration of an injection or an infusion under the skin

4. DUTIES AND RESPONSIBILITIES OF STAFF (AUTHORISED PROFESSIONALS)

4.1 The **Medical Director** has overall responsibility for compliance with this policy. This responsibility is exercised via delegation to the matrons and clinical staff.

4.2 **Senior Nurses/Matrons** are responsible for: ensuring all staff within their sphere of responsibility are aware of this policy and the procedure which are to be adhered to.

4.3 Role of **Registered Nurses and Midwives.**

4.4 **Registered nurses** and **midwives** may give injectable medicines once they have undergone additional post–registration training and can demonstrate competence. Registered practitioners administering injectable therapy within the Trust must have completed the Trust recognised current injectable training provision, or completed the 'Fast Track' assessments and knowledge components. The appropriate injectable competences must also have been completed and recorded centrally via Professional Development.

4.5 In addition, **midwives** may administer without a prescription, drugs as listed in the standard operating procedure for midwives exemptions.

4.6 In exceptional circumstances a registered nurse may delegate this task to an unregistered nurse who has been assessed as competent to do so. The accountability for the delegation remains with the registrant. These will be approved areas of practice, and approved via the Clinical Effectiveness Committee. The only exception to this is the administration of sodium chloride 0.9% IV flushes after cannulation by non- registered staff who have completed the course and competencies and have been signed-off as competent.

4.7 **Registered Radiographers** Registered radiographers may administer injections as part of radiological procedures once they have undergone additional post–registration training, and can demonstrate competence.

4.8 **Operating Department Practitioners** Operating Department Practitioners may administer drugs involved in anaesthetic, scrub and recovery areas once they have undergone additional post–registration training and can demonstrate competence.

4.10 **Registered Physiotherapists and Chiropodists m**ay administer injectable medicines as part of their practice following training ratified by their professional bodies and completing the specific training and competency programmes.

4.10 **Student Nurses and Student Midwives** may administer subcutaneous and intra-muscular injections under direct supervision of a registered nurse or midwife.

4.11 Student nurses and midwives in their final placement that meet the pre-course requirements may administer injectable medicines under direct supervision of a registered nurse or midwife following attendance at the Trust's Student Venous Access Skills Course.

4.12 **All staff prescribing, preparing and administering injectable medicines,** must practice within the guidelines laid down by their regulatory bodies. All staff must be aware of the drugs which have administration restrictions and work according to their competencies and job descriptions.

4.13 It is the responsibility of the prescriber to specify drug, dose, route, infusion rate, volume of diluent and frequency (if applicable).

4.14 The following areas have separate governance arrangements in place:

- Blood products are governed by separate policies, competencies and training requirements
- Cytotoxic drugs (see separate policy)
- Immunoglobulins (see guidance on Trust intranet)
- Parenteral Nutrition must only be prescribed by member of the Nutrition Support Team (except out of hours and paediatric/neonatal patients - further guidance see Nutrition Support team intranet pages).

4.15 For intravenous fluids, patients should have an IV fluid management plan and fluids should be prescribed in line with NICE (2013) guidance (CG174) for one of the following reasons:

- Resuscitation
- Routine maintenance
- Replacement
- Redistribution

4.16 Fluids and electrolytes should be prescribed for a 24 hour period, and assessed daily.

5. ADMINISTRATION

5.1 All medicines should be prepared and administered following:

- Preparing Injectable Medicines Standard Operating Procedure
- Administering Injectable Medicines Standard Operating Procedure

5.2 **Administration of Injectable Medicines in the Community (non-hospital setting)**

5.2.1 It is accepted that healthcare professionals will be required to administer injectable medicines in a variety of settings including the patient's home environment as part of their practice.

5.2.2 In exceptional circumstances in the community setting, a registered nurse may delegate this task to an unregistered nurse who has been assessed as competent to do so. The accountability for the delegation remains with registrant.

5.2.3 Where a patient or their carer is able to administer injectable medicines and are visited by the community nursing team, the community nursing team will need to assure themselves of the patients or carers competence to undertake the delegated administration.

5.2.4 If another provider is undertaking medication administration as a delegated task via the injectable route, the community nursing team may ask for assurance on the competence of the staff undertaking the delegated administration.

5.2.5 **Clinical Effectiveness Committee** are responsible for the ratification of the Policy to ensure it meets the standards required.

5.2.6 **Medicines Management Group** is responsible for ensuring the content of the policy meet the standards required.

5.2.7 **Medication Safety Group** is responsible monitoring incidents related to injectable medicines via the group on a quarterly basis.

6. RISK ASSESSMENT

6.1 Injectable medicines and injectable therapy is a common but high-risk intervention used in the Trust. It is good practice to risk assess all injectable medicine processes to identify those where the risk of patient harm is significant, and to identify ways of reducing that risk. (National Patient Safety Agency, 2007)

6.2 The NPSA devised a risk assessment process and proforma (Appendix 1) for injectable medicines covering the following eight factors to consider when risk assessing products:

- Therapeutic risk
- Use of concentrate
- Complex calculation
- Complex method of preparation
- Reconstitution of powder
- Use of part of an ampoule or vial or use of more than one ampoule or vial
- Use of infusion device e.g. pump or syringe driver
- Use of non-standard giving set e.g. light protected, in-line filter, low adsorption etc.

6.3 Detailed risk assessments should be used in clinical areas for all injectable medicine products which can normally be found ready prepared in the Trust injectable drug guide on the Trust's intranet.

6.4 On occasions where an injectable medicinal product does not have a pre-prepared risk assessment available, one should be carried out by a pharmacist and preferably with a senior clinical practitioner from the area. An injectable medicine product risk assessment proforma can be found in Appendix 1. Please see Appendix 2 for Community Services Injectable Medication Risk Assessment Flowchart.

6.5 The risk assessment once completed should be retained in the area/speciality of use and a copy retained by Medicines Information in Pharmacy who will ensure a dated copy is also available on the Trust intranet.

6.6 The risk assessment stratifies the injectable medicine product into one of three levels depending on the number of risk factors (as per 5.2):

6 or more factors	3-5 factors	1-2 factors
High Risk (red)	Moderate Risk (amber)	Low Risk (green)

6.7 High-risk injectable medicines should be reviewed in order to consider whether there are mitigations or measures that can be introduced in order to reduce the risk. This review must involve a pharmacist and should consider high risk aspects of both the product and practice. Examples suggested by NPSA can be found in appendix 2.

6.8 A Trust wide generic risk assessment is kept on the Risk Register and a specific list of high risk injectable medicines (where no risk mitigations are in place) can be found on the Trust Intranet here.

7. APPROVED DOCUMENTATION

7.1 Injectable medicines must be administered against either a written prescription or given under an approved and current Patient Group Direction (PGD).

7.2 As with all medicines, only Trust approved documentation/systems are permitted to be used for the purpose of prescribing injectable medicines and recording their administration. Unapproved or out of date documentation must not be used.

7.3 The batch number must be recorded for all IV medicines that have been added to IV fluids where the original container is not retained during the infusion.

7.4 For in-patients, most injectable drugs are either prescribed on **Prescription Medication and Administration Records (PMAR)** (e.g. bolus injections, short infusions) or the fluid chart (e.g. longer infusions, electrolytes).

7.5 **Intravenous insulin** must only be prescribed on the Trust approved 'Variable rate intravenous insulin infusion in adults (VRIII)' or other specialist diabetes charts (e.g. DKA chart). For the treatment of hyperkalaemia, intravenous insulin should be prescribed using the Trust approved 'Emergency Treatment of severe hyperkalaemia - prescription and monitoring chart'.

7.6 For certain specialist drugs, custom charts have been designed to support the safe prescribing and administration (e.g. rituximab).

7.7 The prescribing and administration of parenteral SACT (systemic anti-cancer therapy) is governed by separate guidelines and procedures. Parenteral SACT must only be prescribed or administered in accordance with the rules that are set out by Cancer Services.

8. TRAINING AND COMPETENCE ASSESSMENT

8.1 There is no specific injectable therapy training available for prescribers. Prescribers must ensure that they receive induction training on injectable medication prescribing in the speciality that they are working in, and that they familiarise themselves with locally used guidelines or charts for prescribing injectable medication. Prescribers should familiarize themselves with NICE Clinical Guideline 174 (2013) with regards the prescribing of intravenous fluids and electrolytes.

8.2 Registered practitioners are authorised to administer injectable medicines, providing that they have been signed-off as competent. Other staff are permitted to administer injectable therapy in line with a Patient Group Direction (PGD) but only where the PGD specifically permits the registered professional to administer or supply the therapy or medicine.

8.3 Competence can be achieved in two ways:

- Successful completion of the Trust approved injectable training provision, including theoretical element and work-based assessment.
- Successful completion of the Trust fast-track process (for those staff returning to injectable practice or those who were trained in another organisation).

8.4 Further information can be obtained by contacting Professional Development.

8.5 Non-registered staff who have completed the Trust cannulation course and competencies will have completed the competency to administer sodium chloride 0.9% flushes after cannulation. They are not permitted to flush on any other occasions, or with any other drugs. They are not required to complete the Trust injectable training.

8.6 All staff are required to maintain their competence in line with their professional obligations and any essential learning requirements defined by the Trust. Updates for clinical skills are provided by Professional Development if required, however, these are not mandatory and staff will update their knowledge and skills as part of their own professional development.

9. CLINICAL REFERENCE SOURCES

9.1 All staff involved in the process of prescribing and administering injectable therapies, including fluids and electrolytes, must ensure they understand the therapeutic details, risks, benefits and monitoring requirements.

9.2 The main injectable therapy reference source available in the Trust is Medusa. The monographs give an overview on the safe use of the medicine (e.g. diluent, flushing, rate of administration, monitoring requirements, usual dosing). Many monographs also give guidance on the level of risk involved in using the medicines, and display a risk rating in accordance with the risk assessment in Appendix 1.

9.3 The Medusa guide can be accessed by all staff via the intranet, on both PCs and mobile devices.

9.4 Clinical areas should ensure that staff can access online Medusa monographs efficiently in key locations where such as where drugs are prepared e.g. treatment rooms. This could be achieved by the installation of electronic devices local to these areas e.g. a PC or tablet.

9.5 Printed hard copies of monographs are considered not a robust solution and should not be used, as information could become out of date and inaccurate at any time.

9.6 The information in the Medusa guide provides generic information about a medicine. It does not constitute a clinical guideline for the use of the medicines at the Trust. The use of all medium and high risk injectable medicines should be supported by local clinical guidelines and procedures.

9.7 The neonatal unit also has specific reference sources for injectable medicines.

9.8 All staff should be aware of the NICE clinical guideline 174 (2013) with regards the prescribing, administration and monitoring of IV fluids and electrolytes.

10. ADMINISTRATION OF INJECTABLE/INTRAVENOUS THERAPY

10.1 General principles

10.1.1 All preparation of therapy must be carried out in an environment that is suitable for aseptic and high risk preparation in acute and community hospitals. The only exception to this is outside of the hospital setting e.g. a patient's home. Interruption of staff preparing injectable therapy should be kept to a minimum and ideally should be avoided.

10.1.2 Staff should seek advice if any of the prescription is unclear or incorrect, or there are any concerns in relation to administration of the drug. Advice should be sought from the prescriber, pharmacist or senior colleagues.

10.1.3 Injectable therapy for one patient should be prepared and then administered immediately. It is not good practice for one practitioner to prepare injectable therapy for more than one patient at a time. Prepared medicines must not be left unattended.

10.1.4 Infusions containing a medicine should ideally be infused separately. If it is absolutely necessary to administer two infusions via the same vascular access device, mixing should occur as close to the vascular access device as possible.

10.1.5 Where IV therapy is given concurrently though the same access device, the compatibility of all components must be ascertained before infusing or injecting through the same device. Compatibility information can be found in the Medusa guide or by contacting Pharmacy (usually the clinical pharmacist for the area, or Medicines Information, by email, or extension 2450).

10.1.6 Note that Medusa's compatibility information has some important caveats such as assuming medicines mix close to the vascular device and that *standard* concentrations are used. These caveats can be reviewed by clicking on the 'i' symbol. If unsure, please contact Pharmacy.

10.1.7 Infusion bags must never be re-used (i.e. used to withdraw fluid several times). Infusion bags are designed to be accessed only once for the purpose of adding or withdrawing fluid.

10.1.10 When drawing up fluid from glass ampoules it is recommended that filter or fine bore needles (23g) to minimise the risk of injecting glass particles.

10.1.11 Prior to administration of injectable medicines, the staff involved in the administration must ensure that they are familiar with the drugs to be administered, and that the route and site in which they are to be administered is appropriate.

10.1.12 Patients being transferred between clinical settings for continued treatments using injectable medications must be appropriately handed over prior to transfer to ensure appropriateness of treatment and availability of all consumables including the PMAR.

10.1.13 The port on the top of peripheral cannulae should not be used if at all possible. This is due to their wide aperture and the difficulty in cleaning the cavity, both of which significantly increase the risk of microbial contamination and particle infusion. In addition, it is difficult to regulate the rate at which the drug is injected, due to the one-way valve in the port.

Exceptions to this include induction of anaesthesia and emergency access for resuscitation.

10.2 Restricted medicines

10.2.1 High strength potassium ampoules are only permitted to be used in certain areas, due to the risk of death if undiluted or inappropriately prepared infusions are used. This is covered by a separate policy on the intranet.

10.3 Second Checking

10.3.1 For adult patients, a second check for injectable therapy that has been risk assessed as 'low risk' is not mandatory. Staff can request a second check, but this is not a Trust requirement.

10.3.2 This level of risk of any injectable drug or procedure should be assessed in line with the risk assessment in Appendix 1.

10.3.3 In Paediatrics, and the Neonatal Unit (NNU), all injectable therapy must be fully second checked, with the exception of saline flushes.

10.3.4 In acute and community hospitals for patient safety, second checks are required for medium and high risk products (e.g. where complex calculations are required or the medicine has been identified as having a high therapeutic risk).

10.3.5 For community settings e.g. patient home registrants will follow the NMC Standard for Medicine Management: 'Wherever possible, two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication'.

10.3.6 Calculations should be checked by independently carrying out the calculation for a second time.

10.3.7 In addition, all injectable drug therapy that is given using an infusion pump or syringe driver requires a second check. This requirement does not apply to IV or SC fluids that do not contain medication.

10.3.8 The principles for second checking of controlled drugs in accordance with the Medicines Management Policy must be adhered to in the acute and community hospital settings.

10.3.9 The following table summarises the type of checks required for adult patients:

Aspect to Check	Controlled Drug Injectable	High Risk Injectable	Infusion Device	Complex Calculation
Prescription/Dose/Timing	Yes	Yes		
Drug/Strength/Expiry	Yes	Yes		
Diluent		Yes		
Calculation	Yes	Yes		Yes
Volumes Drawn Up And Transferred	Yes	Yes		Yes
Connection To Infusion Device	Yes (where using)	Yes (where using)	Yes (not for fluid infusions without added medication)	
Set-Up Of Infusion Device	Yes (where using)	Yes (where using)	Yes (not for fluid infusions without added medication)	
Disposal Of Any Drug	Yes			

10.3.11 The second checking rules for chemotherapy and blood products are covered in the respective policies.

10.4 Reconstituting Injectable Medicines From Powder

10.4.1 Many injectable medicines are presented as sterile powders. They must first be reconstituted with a suitable type and volume of diluent. The correct diluent and volume can be either found in the Medusa Guide or the manufacturer's literature (e.g. summary of product characteristics –SPC).

10.4.2 Preparing Injectable Medicines Standard Operating Procedure shows the procedure for the reconstitution of medicines from powder.

10.5 Bolus Administration Via a Peripheral Cannula

10.5.1 Administering Injectable Medicines Standard Operating Procedure shows the procedure for administering medicines by bolus.

10.5.2 See Venous Access Device Policy & Procedures for other lines.

10.6 Adding Medicines to an Infusion

10.6.1 **Note:** medicines must never be added to blood products or parenteral nutrition.

10.6.2 Administering Injectable Medicines Standard Operating Procedure shows the procedure for adding medicines to an infusion.

10.7 Flushing Peripheral IV Cannula

10.7.1 Usually Sodium Chloride 0.9% is used to flush cannula prior to IV medication administration, however there may be occasions when another solution is prescribed depending on the medicine being infused or the condition of the patient.

10.7.2 Flush volumes (before and after IV administration) are as follows:

Neonates and children aged 0 – 2 years:	0.5 - 2mLs
Children aged 2 – 12 years:	3 - 5mLs
Children aged over 12 years:	5mLs
Adults:	5mLs or as specified in Medusa

10.8 IV Fluids & Electrolytes

10.8.1 IV fluids should be prescribed as part of a protocol and a documented IV fluid management plan.

10.8.2 All patients receiving IV fluids need regular monitoring to include:

- Daily blood tests
- Accurate Fluid balance charts
- Twice weekly weight

10.8.3 Those on longer term therapy need less frequent monitoring (which should be documented as part of their management plan).

10.8.4 Clear incidents of IV fluid mismanagement (for example prolonged dehydration or inadvertent overload due to IV fluids) must be incident reported.

10.9 Setting up an IV infusion

10.9.1 Administering Injectable Medicines Standard Operating Procedure shows the procedure for priming, setting up and discontinuing a gravity infusion.

11. EXTRAVASATION

11.1 Extravasation

11.1.1 Extravasation is the inadvertent administration of vesicant medicines into the surrounding tissue, rather than into the intended intravenous vein. The extravasation of chemotherapy is managed according to separate guidance provided by Cancer Services.

11.1.2 Extravasation is a medical emergency and early detection and prompt action is required to prevent necrosis and functional loss of tissue or limb involved.

11.2 Prevention of extravasation

11.2.1 Forethought, planning and improved prevention measures can minimise the risk of extravasation.

11.2.2 Careful assessment of the most appropriate cannulation site should be undertaken before insertion. Avoid inserting cannula over joints, as tissue damage in these areas has serious consequences.

11.2.3 Extravasation can occur in central venous access devices (CVAD), often with delayed onset and can be recognised by the patient complaining of discomfort, inflammation and swelling around the site.

11.2.4 Staff should refer to the Venous Access Device Guidance about choice and siting of devices.

11.2.5 Some patient groups are at increased risk of extravasation. These include elderly and paediatric patients, thrombocytopenic patients, diabetics with peripheral neuropathy and patients who had previously chemotherapy/radiotherapy.

11.3 Signs and symptoms

11.3.1 Extravasation should be suspected if one or more of the following symptoms have occurred:

- The patient complains of burning, stinging or any discomfort/pain at the injection site. This should be distinguished from a feeling of cold that may occur with some medicines.
- Observation of swelling, redness or blistering at the injection site.
- A resistance is felt on the plunger of the syringe of a bolus medicine. There is absence of free flow of infusion.

11.4 Management of extravasation (adult and paediatric patient)

11.4.1 Extravasation in neonatal patients is covered by a separate guideline, (Neonatal Extravasation Injuries.

11.4.2 Early detection and urgent initiation of treatment is vital for the prevention of complications associated with the extravasation of non-cytotoxic agent.

11.4.3 The following actions should be taken:

- Stop the injection, but leave the cannula
- Aspirate as much fluid as possible through the cannula, try to draw back about 3-5ml of blood. Contact the patient's doctor
- Remove the cannula after review by doctor
- Mark the extravasation with a pen, consider whether a photograph maybe appropriate.
- Urgent assessment by medical staff, consider referral to plastic surgeon
- Document the incident by completing Trust Incident Report Form and make a full record in the patient's medical notes.

11.4.4 If the medicine is not listed in the Medusa Guide and further advice about extravasation is required, contact Pharmacy.

12. INFILTRATION

12.1 Infiltration

Is the inadvertent administration of fluids or non-vesicant medicines into the surrounding tissue, rather than into the intended intravenous vein.

12.2 Prevention of infiltration

12.2.1 Careful assessment of the most appropriate cannulation site should be undertaken before insertion. Avoid inserting cannula over joints.

12.2.2 Staff should refer to the Venous Access Device Policy about choice and siting of devices.

12.2.3 Some patient groups are at increased risk of infiltration. These include elderly patients, diabetics with peripheral neuropathy and patients who are unable to communicate.

12.3 Signs and symptoms of infiltration

12.3.1 Infiltration should be suspected if one or more of the following symptoms have occurred:

- The patient complains of burning, stinging or any discomfort/pain at the injection site. This should be distinguished from a feeling of cold that may occur with some medicines.
- Observation of swelling, coolness and blanching at the injection site. This should be distinguished from the redness and mottling of extravasation.
- A resistance is felt on the plunger of the syringe of a bolus medicine and there is absence of free flow of infusion.

12.4 Management of infiltration

12.4.1 Note: staff must be aware of the differences between infiltration and extravasation to ensure correct management – if unsure, stop the infusion and contact Pharmacy and discuss further management.

12.4.2 If confirmed infiltration:

- Stop the injection and aspirate as much fluid as possible through the cannula
- Remove the cannula
- Mark the infiltration with a pen
- Elevate the limb and treat symptoms of pain / discomfort
- Document in the patient's medical notes.

13. GUIDANCE FOR GRAVITY INFUSIONS / INFUSION DEVICES

13.1 All staff must be trained and deemed competent to use the infusion device required. Competency assessments can be found on the trust intranet and staff must be aware of the Medical Equipment and Devices Management and Training Policy.

13.2 All drugs that have been risk assessed as medium or high risk must be administered through a Trust approved infusion device to ensure patient safety and reduce the risk of harm to the patient.

13.3 The following groups of patients are deemed to be in medium or high risk categories and therefore should only receive an infusion via an infusion device:

- Paediatric / Neonatal
- Cardiac conditions
- Renal conditions
- Liver conditions
- History of pulmonary and / or peripheral oedema
- Multiple co-morbidities

13.4 Staff may choose to use an infusion device in other circumstances if they feel patient safety may be an issue i.e. non-concurrence with IV therapy.

13.5 Staff must be aware of the risks associated with gravity infusions and be able to reduce those risks.

14. ARCHIVING ARRANGEMENTS

The original of this policy will remain with the Head of Safety, Risk & Patient Experience. An electronic copy will be maintained on the Trust Intranet (A-Z), P – Policies – I – Injectable Medicines. Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 11 years.

15. PROCESS FOR MONITORING COMPLIANCE WITH AND EFFECTIVENESS OF THE POLICY

15.1 To evidence compliance with this policy, the following elements will be monitored:

What areas need to be monitored?	How will this be evidenced?	Where will this be reported and by whom?
Incidents relating to injectable medicines	Reported through Datix, reviewed on a quarterly basis.	Medication Safety Group, by the Head of Safety, Risk and Patient Experience and the Deputy Chief Pharmacist.

16. REFERENCES

H.P. Loveday, J. W. (2014). epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. *Journal of Hospital Infection, S1-S70.*

Available at: http://www.his.org.uk/files/3113/116113/411011/epic3_National_Evidence-Based_Guidelines_for_Preventing_HCAI_in_NHSE.pdf [Accessed 25-04-111]

National Institute for Health and Care Excellence. (2013). *CG174: Intravenous Fluid Therapy in Adults in Hospital (Dec 2013, updated May 2017).* Available at: https://www.nice.org.uk/guidance/CG174 [Accessed 25-04-111]

Nursing and Midwifery Council (2007). *Standards for Medicines Management.* (Updated 2015) London: NMC. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf [Accessed 25-04-111]

National Patient Safety Agency. (2007). *Patient Safety Alert 20: Promoting Safer Use of Injectable Medicines*. London: NPSA.
Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=5111112
[Accessed 25-04-111]

World Health Organization (20011). Guidelines on Hand Hygiene in Health Care. Geneva: WHO. Available at: http://www.who.int/infection-prevention/publications/hand-hygiene-20011/en/ [Accessed 25-04-111]

UK Medicines Information. Medusa – The Injectable Medicines Guide. (online)
Available at: http://www.injguide.nhs.uk/
[Accessed 25-04-111, requires login]

APPENDIX 1: RISK ASSESSMENT FOR INJECTABLES MEDICINES

Risk assessment for Injectable Medicines (discrete form available on the intranet)

	Name	Diluent / Final Volume	Infusion/injection method
Medicine			

	Clinical Area	Site
Location		

	Pharmacist	Senior Practitioner (e.g. nurse or other)	Date
Assessors	Name:	Name:	
	Sign:	Sign:	

	Risk factor	Description	Tick if yes
1	**Therapeutic risk**	Where there is a significant risk of patient harm if the injectable medicine is not used as intended. Where loading doses are used	☐
2	**Use of a concentrate**	Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate.	☐
3	**Complex calculation**	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/kg/hour, dose unit conversion such as mg to mmol or % to mg.	☐
4	**Complex method**	More than five non-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.	☐
5	**Reconstitution of powder in a vial**	Where a dry powder has to be reconstituted with a liquid.	☐
6	**Use of a part vial or ampoule, or use of more than one vial or ampoule**	Examples: 5ml required from a 11ml vial or four x 5ml ampoules required for a single dose.	☐
7	**Use of a pump or syringe driver**	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.	☐
11	**Use of non-standard giving set/device required**	Examples: light protected, low adsorption, in-line filter or air inlet.	☐
		Total number of product risk factors:	

≥ 6 = high-risk product	3-5 = moderate-risk product	1-2 = lower-risk product
→ Risk reduction strategies are required to minimise these risks.	→ Risk reduction strategiesare recommended.	→ Risk reductionstrategies should be considered

Refer to *Injectable Medicines Policy* and related *SOP* or *Syringe Pump Policy for Adult Supportive & Palliative Care* for guidance.

For further advice on completing this form and implementing risk reduction strategies (refer to appendix 2) contact Pharmacy

APPENDIX 2: RISK MITIGATION STRATEGIES FOR HIGH RISK INJECTABLES

The NPSA recommends that a pharmacist and a senior practitioner(s) from the relevant clinical area carry out a risk assessment of injectable medicine products and procedures. This should be done again before new injectable products or procedures are introduced.

Measures that can improve patient safety are outlined below.

For high-risk injectable *practices*:

- Provide written essential technical information and procedures.
- Use injections that are prepared or used in closed, not open, systems.
- Reinforce and audit policy to ensure all syringes and infusions containing injectable medicines that leave the hands of practitioners during use, are labelled.
- Prepare all cytotoxic and total parenteral nutrition (TPN) products, and make all additions to TPN, in the pharmacy department.
- Reinforce a 24-hour expiry date (or less if pharmaceutically required) for infusion products prepared in clinical areas.
- Ensure there are adequate numbers and types of infusion pumps and syringe drivers available.
- Ensure that single-use products are only used to prepare single doses.
- Have an organisation-wide therapeutic protocol that clarifies unlicensed or 'off-label' use of injectable medicines.

For high-risk injectable *products*:

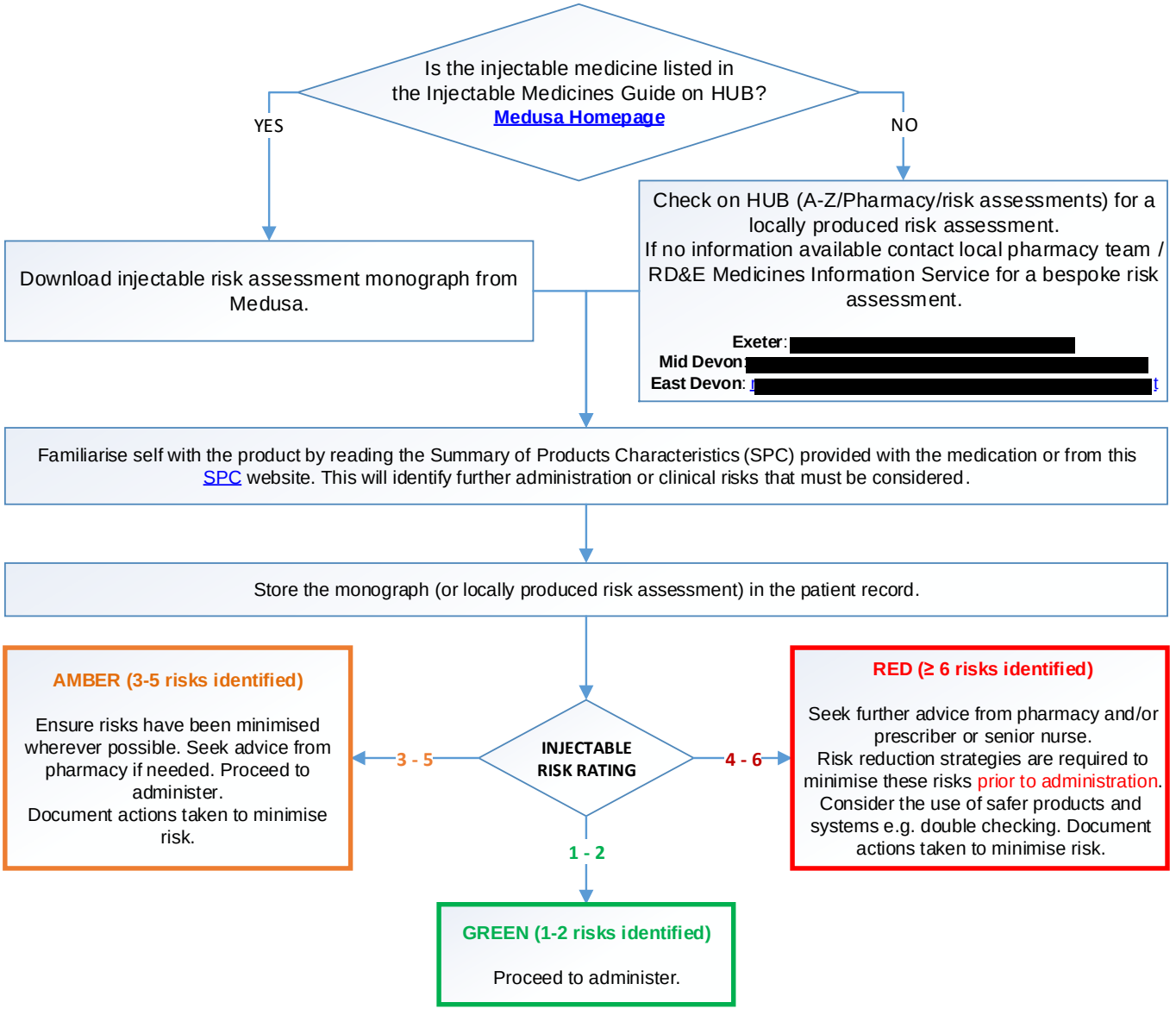
- Simplify and rationalise the range and presentation of injectable medicines and provide the most appropriate vial or ampoule sizes.
- Provide ready-to-administer or ready-to-use injectable products of standard strength. This will minimise risks when preparing and administering injectable medicines.
- Provide dose calculation tools. For example, dosage charts for a range of body weights that eliminate the need for calculating doses.
- Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines that clarifies how to safely prepare and administer them.
- Consider providing pre-printed prescriptions or stickers that makes the prescribing, preparing and administering of high-risk products clearer.
- Use double checking systems such as an independent check by another practitioner, and dose checking software in 'Smart' infusion pumps and syringe drivers.
- Use infusion monitoring forms and check lists for the duration of the administration.

APPENDIX 3: INJECTABLE RISK ASSESSMENT FLOW CHART (COMMUNITY SERVICES)

It is good practice to risk assess the use of an injectable medicine to identify potential causes of patient harm and minimise these risks prior to administration. Risk factors associated with a specific medicine administration process can be identified by obtaining a risk assessment for the specific route and method of administration intended. The Trust organisation and the individual administering the medication must practice risk reduction strategies to minimise these risks. Refer to the Injectable Medicines Policy for information.

Use the flow chart to identify steps to take when a direction to administer by a prescriber or a patient group direction authorises the administration of an injectable medicine to a patient in community services.

Injectable Risk assessments are available from the injectable medicines guide website, Medusa, via HUB (A-Z/pharmacy). If using an internally produced risk assessment it must be up to date and reflect the intended method of administration.



Process outlined by National Patient Safety Alert 20

APPENDIX 4: COMMUNICATION PLAN

The following action plan will be enacted once the document has gone live.

Staff groups that need to have knowledge of the policy	All staff that administer injectable medications.
The key changes if a revised policy	The updated Policy has been renamed 'Injectable Medicines Policy' There are now two associated supporting standard operating procedures to support the updated policy. 'Preparing Injectable Medicines Standard Operating Procedure' and 'Administering Injectable Medicines Standard Operating Procedure'. Version 2.2: Risk mitigations (5.7. + 5.8 + Appendix 2). Minor revisions to NPSA risk assessment form in Appendix 1 Version 2.3-Section 10.7.1 0.11% changed to 0.9%.
The key objectives	This policy gives guidance on the safe preparing, prescribing and administration of injectable medicines. Injectable therapy is a high-risk intervention and this policy sets out required standards that all staff must adhere to.
How new staff will be made aware of the policy and manager action	Cascade from Managers
Specific Issues to be raised with staff	• To ensure the principles of the Injectable Medicine policy and associated SOPs are adhered to. • Direct staff to the SOPs for clear guidance.
Training available to staff	Support from managers.
Any other requirements	None
Issues following Equality Impact Assessment (if any)	None
Location of hard / electronic copy of the document etc.	Document available on the Trust intranet

APPENDIX 5: EQUALITY IMPACT ASSESSMENT TOOL

Name of document	Injectable Medicines Policy
Division/Directorate and service area	Nursing, Quality and Professional Development.
Name, job title and contact details of person completing the assessment	[redacted], Senior Nurse for Patient Experience & Practice Education. [redacted]
Date completed:	22/12/2017

The purpose of this tool is to:

- **identify** the equality issues related to a policy, procedure or strategy
- **summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. What is the main purpose of this document?

To ensure the identification of all patients is a pre-requisite for the delivery of consistently safe and effective patient care. The purpose of this policy is to ensure that each patient is correctly identified at each point of contact and prior to undergoing every consultation, investigation or treatment.

2. Who does it mainly affect? *(Please insert an "x" as appropriate:)*

Carers ☐ Staff X Patients Other (please specify)

3. Who might the policy have a 'differential' effect on, considering the "protected characteristics" below? (By *differential* we mean, for example that a policy may have a noticeably more positive or negative impact on a particular group e.g. it may be more beneficial for women than for men)

Protected characteristic	Relevant	Not relevant
Age	☐	X
Disability	☐	X
Sex - *including: Transgender, and Pregnancy / Maternity*	☐	X
Race	☐	X
Religion / belief	☐	X
Sexual orientation – *including: Marriage / Civil Partnership*	☐	X

4. A teristics, which other groups in society might this documen

4. A teristics, which other groups in society might this documen

None

5. Do you think the document meets our human rights obligations? X

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:
• ***Fairness –*** *how have you made sure it treat everyone justly?* • ***Respect –*** *how have you made sure it respects everyone as a person?* • ***Equality –*** *how does it give everyone an equal chance to get whatever it is offering?* • ***Dignity –*** *have you made sure it treats everyone with dignity?* • ***Autonomy –*** *Does it enable people to make decisions for themselves?*

6. Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?

During the revision of this policy appropriate individuals have been involved to ensure that the Policy has been updated to reflect current guidance and practice. The following people and groups have been involved to ensure a varied representative.

- Governance Managers, Divisional Directors, General Managers, Associate Medical Directors, Assistant Directors of Nursing, Senior Nurses, Matrons (Dec 2017)
- Medicines Management Group: 111/04/20111
- Quality Assurance Process: 24/04/20111
- Clinical Effectiveness Committee 03/05/111

7. If you have noted any 'missed opportunities', or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.

"Protected characteristic":	
Issue:	
How is this going to be monitored/ addressed in the future:	
Group that will be responsible for ensuring this carried out:	