

Self-administration of low dose cytarabine by subcutaneous injection

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Table of Contents

Introduction	5
Purpose and Scope.....	5
Assessment of Patient / Carer Suitability.....	5
Inclusion Criteria.....	6
Exclusion Criteria.....	6
Assessment of patient / carer	7
Frequency of clinic attendances and blood tests.....	8
Prescribing and Dispensing	9
Prescribing	9
Dispensing.....	9
Collection and carriage of cytarabine by patients / carers to home	9
Courier	10
Storage at Home	10
Administration	11
Prior to administration.....	11
Post administration.....	11
Equipment Required	11
Support for the patient / carer	12
Managing spillage	12
Missed Doses	13
Documentation	13
Scheduling, Monitoring and Recording.....	14
Stopping Self-Administration or Discontinuation of SACT	14
References	15
Appendix 1: SACT Self Administration Patient Assessment and Training and Consent Form	16

Appendix 2: Checklist for initiating patient / carer on self-administration of subcutaneous injections pathway	20
Appendix 3: Subcutaneous Injection Site Record Sheet	22
Appendix 4: Patient Information Guide to Self-Administration	23
Sites for subcutaneous injections	24
Appendix 5: Cytotoxic Spillage Procedure	25
(please print and give a copy to the patient).....	25

Introduction

This standard policy and procedure outlines the safe set up for self / carer administration of subcutaneous cytarabine in the community setting. The community setting denotes the patient's place of residence, i.e. patients own home. Subcutaneous administration of cytarabine in the community is classified as low risk because the treatment selected is:

- Not a vesicant
- Can be given by bolus injection subcutaneously (S/C)
- Not associated with high incidence of allergic reactions

The cytarabine indication this policy covers is for the treatment of acute myeloid leukaemia (AML). Cytarabine is a subcutaneous injection that is administered either daily or twice daily for between 10-14 days every 4-6 weeks. Cytarabine results in multiple patient visits to hospital and the option of self / carer administration has the potential to improve patient experience, increase capacity in the chemotherapy day units and potentially reduce delivery costs.

Purpose and Scope

This policy provides clear guidance for healthcare professionals across South East London Cancer Alliance (SELCA) on the safe provision for self / carer administration of subcutaneous cytarabine in the community setting. This policy should also be read in conjunction with the Trust's Medicines Policy and the associated Codes of Practice and the relevant cytarabine protocol.

Assessment of Patient / Carer Suitability

Prior to commencing a patient on self / carer administration of cytarabine in their own home, appropriate steps must be taken to ensure that they are suitable and safe candidates for this mode of treatment. The patient and/or carers must understand what is expected of them including the risks and benefits, and can consent to self / carer administration of subcutaneous cytarabine at home. The patient and/or carer must be able to comply with and understand the drug regimen and be able to recognise complications and be able to seek emergency assistance/follow advice when given.

Patients who have communication difficulties (e.g. deaf/hard of hearing or for whom English is not their first language) should be supported where possible to ensure they have access to this scheme if appropriate.

Inclusion Criteria

The assessment should include:

- Patient's ability to make informed decisions. A copy of the patients signed consent form (see appendix 1) must be kept in the patients notes
- Patient's willingness to self-administer their treatment at home
- Patient or carer's ability to cope with the practicalities of self-administration including:
 - Does the patient or carer administer their other own medication(s) at home?
 - Does the patient or carer understand the purpose of treatment, dose to take and when to take, possible side effects and how to report these?
 - Can the patient or carer open the packaging and able to self-inject?
 - Can the patient or carer understand and do they have the ability to complete a self-administration record card?
 - Is the patient or carer able come to the hospital to collect their drug when needed?
 - Do they have access to a sink and adequate hand-washing facilities?

If the answer to all the questions is "Yes" then with the patient's consent they should be referred by their clinical team for a specific teaching appointment by a member of the nursing team in the chemotherapy day unit to be shown how to self-administer and to be given all necessary patient information leaflets (See Appendix 1).

If the answer to any of the above questions is "No" then the patient is not suitable for this method of administration and this decision should be documented in the patient's electronic health record. In these cases the patient should be referred to the usual place of treatment in the hospital setting, for administration by trained nursing staff as per standard procedures.

Exclusion Criteria

- Patients with concerning mental health problems/capacity issues that would preclude their ability to comply with treatment safely. Any concerns should be assessed using the Mental Capacity and Best Interest Checklist or similar
- Patients with a recent history of addiction or substance misuse
- Patients who do not have access to the required facilities at home including a secure fridge that permits safe storage of SACT and hand washing facilities

- Patients who are unable to competently perform tasks required for self-administration and have no carer to help
- Patients who have any concerns about the people who they live with interfering with their medication or treatment administration
- Patients who are unable to self-care
- Patients who are unable to, or have access to, use a phone to contact the hospital or come back to the hospital in the event of a problem
- Patients who have had previous reactions or adverse effects to cytarabine (greater than grade 2 or any grade that has warranted withholding treatment) not including haematological toxicity, which is expected
- Patients who have any contraindications to cytarabine as outlined in the cytarabine SPC
- Patients / patient carer who have failed to understand and meet the criteria, assessment and training outlined in Appendix 1.

If **any** exclusion criteria are present, the patient should be referred to the usual place of treatment in the hospital setting for administration by appropriately trained nursing staff as per standard procedures. (This is not an exhaustive list of exclusion criteria and each patient will need to be assessed individually by their medical team to ensure suitability for self / carer-administration of cytarabine).

Assessment of patient / carer (Refer to Appendix 1)

If a patient has met the inclusion criteria for self-administration and has been identified by his/her consultant as appropriate for self-administration then the patient can be referred for an **assessment and education appointment** by a trained nurse. The patient and/or carer must be willing to receive training **and** be assessed as capable of manipulating all the required equipment in order to ensure safe administration of the drug (see Appendix 1).

When considering a patient's eligibility for carer / self-administration of subcutaneous cytarabine, at least the *first cycle of treatment should be administered in the usual setting (i.e. chemotherapy day unit) and at least one dose be administered by the patient / carer under direct healthcare professional supervision. Any deviation from this, where clinical need or individual patient circumstances warrant it, must be agreed with the patient and their medical consultant in advance and clearly documented in their health records. For example, *in some instances where patients cannot attend the hospital twice daily for 10-14 days, then the patient's consultant may decide that the patient can have one dose administered in the usual setting and then the rest of the first cycle at home.

The patient or named designated carer may only self-administer after successful completion of assessment and education by a trained nurse during this appointment.

(Note: The chemotherapy nurse consultant or equivalent will be responsible for maintaining a register of staff that are permitted to fulfil this role).

The following actions must be completed after a patient has successfully passed their self / carer administration assessment during the assessment and education appointment:

- The nurse should also complete Appendix 2 prior to the first cycle of self / care administration: Patient information and checklist with the patient +/- carer and provide them a copy of this. This should also be scanned onto the patient's electronic healthcare record.
- The standard consent form for the patient to start this therapy will also be completed with the patient by the prescribing doctor and scanned onto the patient's electronic health record.
- The dates for self-administration must be agreed with the patient / carer and the nurse on chemotherapy day unit when the patient attends clinic/is collecting their medication and prior to the patient going home. The nurse must then book the patient into the relevant nurse led toxicity assessment clinics on the first day of administration and as applicable thereafter but at least weekly which administering treatment
- A self-administration pack (which includes all equipment and printed information for patient/carers) must be supplied to the patient/carers

Frequency of clinic attendances and blood tests

Frequency of clinic attendance will be at the discretion of the treating clinician and will be dependent on the stability of the patient's disease. The clinician reviewing the patient in clinic will have the responsibility of prescribing and approving the relevant number of cytarabine prescriptions until the patient's next clinic appointment and indicating the number of cycles confirmed for self-administration.

Blood tests will be done prior to each cycle of treatment and must be reviewed by either pharmacy or nursing staff prior to release to patients.

Patients must be informed by their treating team that they cannot collect their cytarabine for self / carer administration until their bloods have been taken and reviewed. If any essential levels are below the required threshold the prescribing clinician will be contacted to advise on supplementation if appropriate and continued dosing as per protocol.

Bloods may be taken locally in some instances and in this case it is still a requirement for the treating clinician or pharmacist to review the bloods prior to release of cytarabine and supportive care.

Prescribing and Dispensing

Prescribing

Local Trust processes for prescribing SACT should be followed, and the prescriber must be on the SACT prescribing register. All cytarabine prescriptions must be prescribed on Mosaik and supportive medication will be prescribed and dispensed as per local policy. All prescriptions must be prescribed a minimum of 72 hours in advance.

The prescriber must outline on the QCL to the screening pharmacist that the patient is now on the self / carer administration pathway. The prescriber should inform the patient which pharmacy or day unit to collect their medication from.

Dispensing

Local Trust processes for dispensing SACT should be followed. Cytarabine syringes will be dispensed from aseptic unit pharmacy and transferred to the chemotherapy day unit for handing out the patient/carer.

Nursing staff must document on the electronic prescribing system, if any medication has been administered on the chemotherapy day unit and how many doses have been supplied to the patient, if any. If the cytarabine has been supplied directly to the patient by pharmacy then they must document that the cytarabine has been handed out.

Collection and carriage of cytarabine by patients / carers to home

During the initial assessment and training session delivered by a chemotherapy day unit nurse, the patient / carer should be informed about the appropriate transportation of cytarabine. Cytarabine requires storage at room temperature. Patients will be advised to bring a suitable plastic storage container with them upon collecting their medication.

When transporting cytarabine home, the effects of temperature fluctuations should be minimized by:

- Not exposing the syringes or container to direct sunlight
- Not leaving syringes/containers in a parked car where the temperature may rise significantly for an extended period
- Not exposing the syringes/containers to hot air blowers in cars/transport
- Not placing syringes/containers in direct contact with heaters
- Placing the medicine in a safe room temperature place as soon as the patient returns home

The patient should be made aware of the expiry date of the medications and how and where to check this. If there are any outstanding doses there needs to be clear arrangement and documentation between nursing or pharmacy staff and the patient / carer as to when and where these will be collected and the quantity of the outstanding doses to be collected if there are outstanding doses.

Courier

In certain circumstances the pharmacy may agree to courier medicines wherever possible to the patient's residence to prevent hospital attendance. The pharmacy team will organise the appropriate courier for transportation of subcutaneous SACT medicines. An appropriate courier must be able to transport medicines via a trackable service, the courier must be authorised to take injectable cytotoxic and non-cytotoxic medicines, and if necessary will be supplied with appropriate cytotoxic spill kits for transportation. The courier must be able to maintain the safe transfer of medicines and maintain any storage requirements regarding temperature e.g. maintaining a cold chain if required and actively preventing any extreme fluctuations in temperature.

Storage at Home

Cytarabine syringes should be kept in the sealed bag/container supplied by the pharmacy and within a plastic container provided by the patient / carer.

Cytarabine syringes should be placed out of reach of children and pets. If for any reason the syringes have been damaged, have expired or any other reason that they become unsuitable for use, the patient should contact either their CNS or an appropriate healthcare professional
Sub-cutaneous Cytarabine self-administration policy

on the chemotherapy day unit to arrange a replacement dose. Any unused cytarabine syringes should be returned to pharmacy via the day unit/clinic at the patient's next hospital appointment for safe disposal.

Administration

Prior to administration

The patient / carer must ensure that they have all of the relevant equipment and information to support self-administration which is supplied to the patient when they attend the hospital for either a clinic appointment or for bloods etc.

Post administration

The patient / carer will record the date and time that they have administered their medication and record the site of injection in order to allow for rotation of injection site. See Appendix 3.

On the day of self-administration, a nurse from the chemotherapy day unit will call the patient (via the nurse led toxicity assessment clinic) to check that administration was uneventful and that the patient is well in themselves. This telephone consultation should be documented in the patient's electronic health record.

Equipment Required

The patient and/or carer **must** be supplied by the hospital with adequate quantities of equipment. This should include:

- **Syringes containing cytarabine**

Unused syringes must be returned to the appropriate specialist unit and transported as above in a suitable plastic container.

- **Needles**

The patient will require a minimum of 1 orange safety needle for each dose to be administered.

- **Alcohol and gauze swabs**

- **Gloves**

- **Apron** (only required if administration by a carer)

Sub-cutaneous Cytarabine self-administration policy

- **Sharp bins.**

This should be a purple lid cytotoxic sharps disposal bin when supplying cytotoxics.

Instructions should be given that the bin should not be over-filled, the lid must be closed when full and the patient must return it to the hospital when it is full or at the end of each cycle, whichever happens first.

Patients must also be supplied with the information outlined in support for patient / carer section below.

Support for the patient / carer

The patient should be informed of possible complications, how to problem solve and when and who to telephone for help and advice – this should be given verbally and supported by written information including:

- Patient information leaflet for the drug supplied printed off from the following website: www.medicines.org.uk
- A treatment diary if applicable
- A copy of appendix 3, 4 & 5
- A video explaining how to self-administer a subcutaneous injection via the following link: <https://info.guyscanceracademy.co.uk/giving-yourself-an-injection/>

Support will be provided for patients through the nurse led toxicity assessment clinic which will be on the day of every administration for at least the first 3 cycles of self-administration. The frequency of these clinics may be reduced for patients who are stable on treatment and who have had and continue to have no issues with self / carer administration.

Managing spillage

Pre-filled syringes/vials with small volumes of liquid reduce the risk of spillage. Spillage guidelines (Appendix 5) will be supplied to all patients receiving cytarabine at home.

The key points regarding a cytotoxic spill (including needle stick injury) are:

- If the carer is managing a spillage, and they are pregnant, or think that they may be pregnant or are breastfeeding, it is preferable that they do not handle cytotoxic drugs, or waste, unless absolutely necessary.
- If the medication comes into contact with the skin, or following a needle-stick incident, the area should be thoroughly washed with water.
- If the medicine enters the eyes, they should be thoroughly irrigated with water and medical advice sought.
- Always wear double gloves when dealing with spillages.
- Wipe up any spillage with paper/kitchen towel, place in a bag and dispose of directly into the cytotoxic sharps bin.

Any spillage incidents should be reported to the chemotherapy day unit.

Missed Doses

If a patient misses a dose for any reason they should contact their Clinical Nurse Specialist or the chemotherapy day unit for advice. Any reasons for the missed dose and advice given to the patient or action taken should be documented clearly in the patient's electronic notes.

Documentation

Documentation should be completed and filed in the patient's notes/EPR as a record of training, consent, patient acknowledgement, and confirmation that the appropriate patient specific information and training have been provided and supplies and deliveries have been arranged. This should also be documented as completed on the patient's SACT electronic navigator.

The patient must record administration of injections on the copy of the proforma supplied (See Appendix 3). This must be uploaded / scanned into the patient's electronic record on completion of the cycle, or at their next hospital attendance.

Each nurse led toxicity assessment clinic should be documented on the patient's electronic health record.

Scheduling, Monitoring and Recording

The scheduling of SACT treatments should not change. Patients should have administrations scheduled on EPR and booked on PiMs; however day unit appointments should be annotated as “self-administration”.

Patients should be regularly monitored whilst on self-administration of injectable SACT through continued clinic appointments with clinical team and through the nurse led toxicity assessment clinics. The clinical teams should use the scheduled appointment times to liaise with the patient on the day of administration. Any issues or deviations to treatment must be appropriately escalated.

Specific clinical monitoring requirements for each drug are outlined in the patient information leaflets and in the cytarabine protocol available on the intranet. Monitoring practices should not change from routine practice.

Stopping Self-Administration or Discontinuation of SACT

If at any time the patient who is self-administering cytarabine has a change of mental capacity, changes their mind about self-administration or there are any reasons why self-administration becomes unsafe (e.g. clinical deterioration) then home self-administration must be stopped and the patient will restart having treatment on the appropriate day unit via nurse administration. This must be clearly documented on the patient’s electronic health record.

Any unused cytarabine syringes must be returned to pharmacy, in a suitable plastic storage container, for reconciliation and safe disposal. Doctors are reminded to notify nursing/scheduling team and pharmacy if a patient’s treatment is being amended or discontinued for any reason via a QCL or email.

References

Royal Marsden NHS Foundation Trust Policy. 2020. Policy and procedures for patient/carer administration of subcutaneous SACT in the community.

Leukaemia Care (2020) Low dose cytarabine for Acute Myeloid Leukaemia (AML) Available at: <https://media.leukaemiacare.org.uk/wp-content/uploads/Low-dose-Cytarabine-for-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf> [Accessed 20 February 2022]

Appendix 1: SACT Self Administration Patient Assessment and Training and Consent Form

PATIENTS NAME: **Hosp No:**

Date of Birth:

AIM: The patient and/or carer will acquire the knowledge and skills necessary to safely and effectively administer subcutaneous injections. If at anytime there is concern the patient/carer will not be able to administer the medication safely at home, please refer back to the appropriate day unit for treatment and document reasons on the EPR. Any nurse supporting patients or their carers to administer a subcutaneous injection must have the relevant skills and knowledge to undertake this, acting within their competency at all times (<https://www.nmc.org.uk/standards/code>)

Assessment of ability to self-administer (to be completed by nurse and patient/carer)

Learning outcome to be achieved (delete as appropriate)	Instructed (date/sign) Mark where not applicable	Observed (date/ sign) if applicable	Achieved (Patient and/or Nurse to date/sign)
Able to understand principles of asepsis, non touch technique and good hand washing techniques			
Able to select appropriate site for injection			
Understands how to clean site prior to injection			
Denosumab and trastuzumab only: Can follow the instructions for drawing up of the injection			
Understands how to handle a pre-filled syringe and needle without contaminating it prior to injection (where required			

management of a vial & how to draw up contents into a syringe)			
Understands how to and is competent to inject contents of syringe correctly			
Knows how to correctly store medications (ensure patient has access to a domestic fridge if required for medication storage)			
Knows how to dispose of sharps and syringe safely			
Knows what to do if there is a problem and who to contact			
Knows how to access educational information			

Additional criteria to be met

	YES	NO	Name & Signature of Nurse	Date
Does the patient have the ability to understand the treatment and patient/carer able to safely self-administer SACT				
Does the patient/carer have sufficient manual dexterity to self-administer a subcutaneous injection?				
Has the patient signed a SACT consent form for this treatment?				

Has the patient received education on self-administration in both written and verbal format?				
If required, the relevant specialist pharmacist has been informed that equipment pack will be need to be sent with medication				
Has the patient been scheduled for nurse led toxicity assessment for ongoing treatment as per this policy?				
Ensure the patient / carer is aware how to document that they have administered their injection and the site of their injection				
Ensure the patient / carer is aware of the need to return cool boxes to the hospital if applicable				

Nurse & Patient / Carer Confirmation (complete whichever section applies):

Nurse assessing patient for self/carers administration SACT treatment

I (print name) deem patient/carers is competent to administer subcutaneous and confirm I have provided all of the relevant equipment and documentation.

Signed..... Date.....

If patient is to self-administer SACT treatment

I (print name) am competent to administer subcutaneous and confirm I am willing to self-administer this treatment in the community.

Signed..... Date.....

If carer is to administer SACT treatment

I (print name) consent my carer (print name) to administer this treatment in the community.

I, the carer (print name) am competent to administer subcutaneous and confirm I am willing to administer this treatment in the community.

Patient: Signed..... Date.....

Carer: Signed..... Date.....

Please file the completed copy of this form in the patient's electronic notes

Appendix 2: Checklist for initiating patient / carer on self-administration of subcutaneous injections pathway

PATIENTS NAME: **Hosp No:**

Date of birth:

	Tick when complete	Instructions	Nurse Name & Signature	Date
Explain dose to patient/carer				
Demonstration of injection technique provided and understood		Refer to appendix 1		
Explain the frequency to patient/carer		Weekly or twice weekly/ every 3 weeks or daily (complete days/dates on the Subcutaneous injection Site Record Sheet)		
Explain all possible sites of administration		Rotation of injection site is necessary to minimise local irritation. Injection site choices: R & L abdomen or R & L thigh (refer to Subcutaneous injection Site Record Sheet)		
Safe storage + expiry check		Store injections in the fridge/ room temperature Allow to come to room temp before injecting to reduce discomfort of injection if the medication is stored in the fridge. Check expiry date on pharmacy label – do not use after this date		

Safe disposal		All sharps, needles and syringes must be disposed of in the sharps bin provided (purple lid). Once full – seal and return to clinic/chemotherapy day unit at your next hospital visit.		
Obtaining further supplies / new prescriptions / blood tests		Sharps bin to be supplied by pharmacy/chemotherapy day unit Blood tests to be done at date / time required by prescriber Medication and other ancillaries collected from chemotherapy day unit (during Mon-Fri).		
Contact details		Patient has contact details for the ward/unit and clinical nurse specialist		
Patient information provided		Patient information Leaflet Patient advised of where to access leaflets & film on s/c injections on the Trust website (see policy for details) Appendix 2 & 3 of this policy		
Consent signed				
Appendix 1 completed				

Please file the completed copy of this form in the patient's electronic notes within 24 hours of completing

Appendix 4: Patient Information Guide to Self-Administration

A nurse will have either shown you how to give yourself a subcutaneous (under the skin) injection or will have talked the process through with you over the telephone. The following steps will remind you how to do it.

You will need:

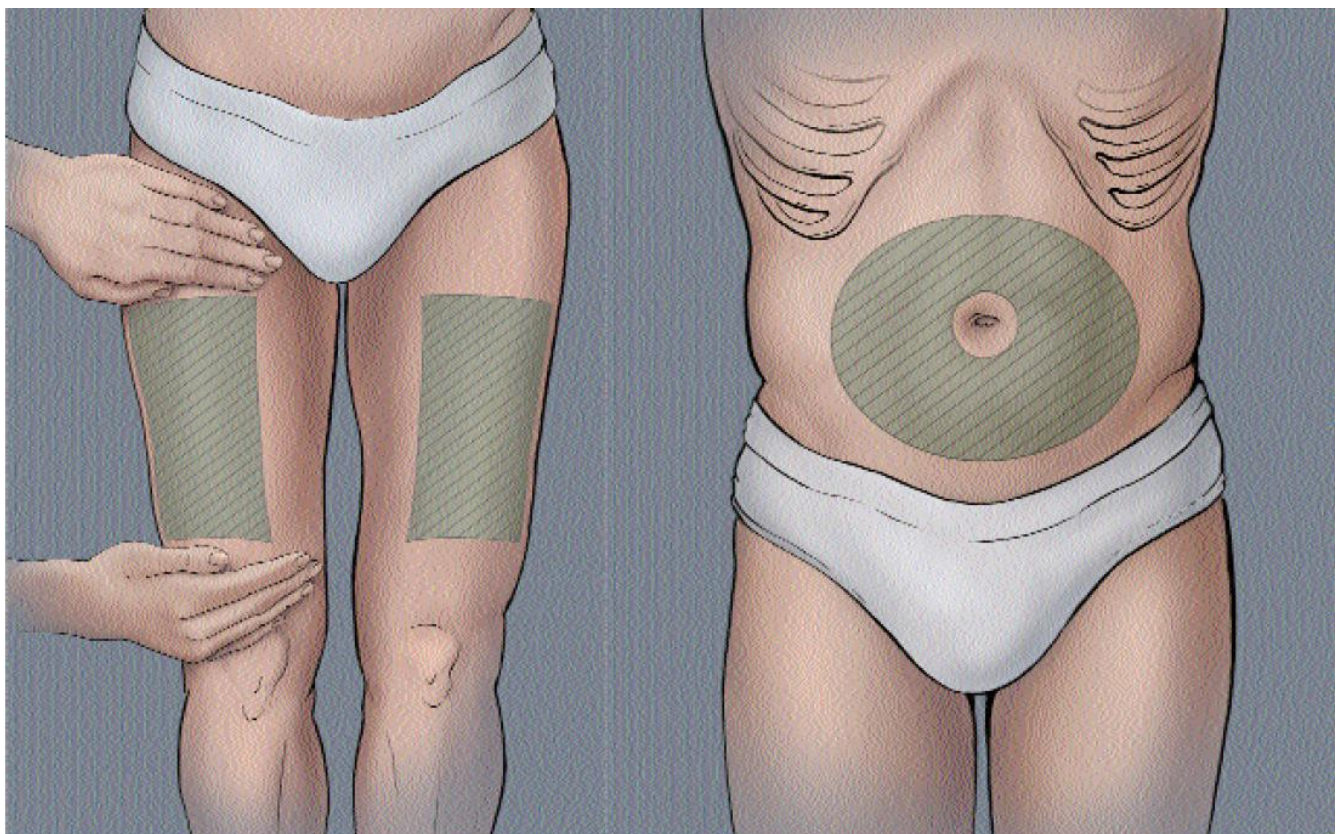
- 70% Alcohol swabs in packet
- Gauze swab
- Syringe containing cytarabine
- Injection needle
- Sharps bin
- Apron and gloves if applicable.

How to administer:

1. Remove the cytarabine syringe from its safe storage container
2. Check the details on the label of the medication to ensure it has your name on it.
3. Check the syringe contents is clear and not discoloured and the volume matches the label.
4. Check the injection has not passed the expiry date
5. Gather all your equipment and place on a clean surface
6. Wash your hands thoroughly and dry them.
7. Remove and open the packets containing the syringe and the gauze swabs.
8. Remove appropriate clothing to expose the area you will be using for the injection (e.g. your abdomen or thigh, see the diagram below). Remember to alternate between your left and right and abdomen and your right and left thigh (refer to Subcutaneous injection site record sheet).
9. If a carer is administering the medication then they should put on an apron and gloves
10. Open an alcohol swab packet and take out the swab
11. Use the alcohol swab to clean the skin where you are going to inject yourself and allow to dry for 15-30 seconds
12. Take the plastic cover off the needle and hold the syringe between the thumb and forefinger of your dominant hand as if holding a dart.

13. With your free hand gently pinch the skin of the area chosen for injection to elevate the subcutaneous tissue and if you can grasp 2 inches then inject at 90 degrees. If you can only pinch 1 inch then insert the needle at an angle (45 degrees).
14. When the needle is completely inserted, slowly push the plunger down as far as it will go. The entire contents of the vial should be injected.
15. Withdraw the needle and apply gentle pressure on the injection site with a gauze swab. Do not massage the area.
16. Cover the injection site with a plaster if necessary.
17. Do not put the needle back into the needle cover.
18. Put the used needle and syringe into the sharps container. When this is filled to the line on the bin, close the lid and bring it back to hospital at your next visit or contact your local council to arrange collection

Sites for subcutaneous injections



Appendix 5: Cytotoxic Spillage Procedure

(please print and give a copy to the patient)

If you are the carer, and are pregnant, think you may be pregnant or are breast feeding, it is preferable that you do not handle cytotoxic drugs, or waste, unless absolutely necessary.

PROCEDURES TO FOLLOW IN THE EVENT OF A SPILLAGE

1. Put on two pairs of disposable gloves
2. Soak up the spill using kitchen towel for small spills by working from the outside of the spill inwards, placing the kitchen towel gently over the spill to avoid splashing
3. Place the kitchen towel and any sharp material into a bag and then into the cytotoxic sharps bin
4. Take off the top pair of gloves and clean the floor or work surface with warm soapy water (i.e. washing up liquid) and kitchen towel
5. After cleaning put the kitchen towel and gloves into a bag and then into the cytotoxic sharps bin
6. Wash hands thoroughly
7. Contact the Nurse in Charge (NiC) on the chemotherapy day unit to inform them of the spillage and to arrange replacement medication if required

PROCEDURES TO FOLLOW IN THE EVENT OF A CYTOTOXIC SPILL ONTO SKIN OR MUCOUS MEMBRANES*

(* For example, at the nostrils, mouth, lips, eyelids or ears)

In the event of accidental contact with cytotoxic medication, the following procedures should be adopted immediately:

1. Wash the area thoroughly with soapy water as soon as possible. For large spillages/splashes, remove contaminated clothing (and wash separately from other clothes), shower and put on a clean set of clothes
2. In the event of a cytotoxic splash to the eye, irrigate thoroughly with tap water for approximately 20 minutes
3. Immediately report the incident to your clinical nurse specialist or the nurse in charge at the chemotherapy day unit