Lincolnshire Community Health Services NHS
NHS Trust

Standard Operating Procedure for the administration of Apomorphine via the APO-go Pump using Pre-filled Syringes

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Name of originator/author:	Sally-Ann Bradley/Jackie Shaw
Name of approving committee/responsible individual:	Drugs and Therapeutic Committee
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Standard Operating Procedure (SOP) for Administration of Apomorphine via the Apo-Go pump using Pre-filled Syringes

Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/Amended by
1		New Document	Nov 16	Sally-Ann Bradley/Jackie Shaw

Standard Operating Procedure (SOP) for
Administration of Apomorphine via the Apo-Go pump using Pre-filled Syringes

Contents

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Statement

Background	To promote safe and effective administration of subcutaneous apomorhpine via the Apo-go pump to adults with complex Parkinson's Disease.
Statement	This standard operating procedure provides advice and guidance on safely administering subcutaneous apomorhpine via the Apo-go pump.
Responsibilities	Managers and service leads are responsible for ensuring that Standard Operating Procedures are in place for all clinical situations involving the handling of medicines. Standard Operating Procedures must be reviewed and updated at least once every 12 months and whenever procedures are amended.
Training	Managers and service leads are responsible for ensuring that any staff training needs are met to ensure implementation of this policy. Training should be provided to ensure that all staff working to Standard Operating Procedures are competent to do so.
Dissemination	Website Intranet /Email
Resource implication	This policy has been developed in line with national and local guidance documents supporting the production of Standard Operating Procedures and for the subcutaneous administration of apomorhpine via the Apo-go pump.

STANDARD OPERATING PROCEDURE FOR
Preparation of elixirs and topical solutions by the addition of water for reconstitution.

SOP comes into effect	
SOP Review date	
Purpose	To promote safe and effective administration of subcutaneous apomorhpine via the Apo-go pump to adults with complex Parkinson's Disease
Scope	The SOP covers training requirements, prescription requirements, equipment needed, preparation of apomorhpine, setting up of pump, site selection and taking down the pump.

Author Signature: Date:	Name: Position:
Approval Signature: Date:	Name: Position: Service manager **Has responsibility for authorising the use of the SOP and ensuring it complies with any relevant legislation that may cover the procedures detailed within.**

Responsibilities Staff	**All staff working within the standard operating procedure is responsible for identifying any deficiencies in the SOP and notifying their line manager accordingly.** **All staff have a duty of care under the Health and Safety at Work Act 1974. Staff should also be familiar with the Trusts Whistle- Blowing Policy and should be able to share concerns without fear of recrimination.** **All staff have a responsibility to access, be familiar with and complies with all policies relating to this SOP.** **Staff must always practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct if applicable.** **All staff have a responsibility to report near misses, adverse incidents and serious untoward incidents as detailed in the NHS Lincolnshire Incident Reporting Policy.**
Responsibilities Manager	**It is the responsibility of the manager to inform their staff of the implementation of the SOP and to ensure that the necessary training has been undertaken to enable staff to carry out safely the procedures detailed in the SOP.** **It is the responsibility of the manager to ensure all staff have access to all LCHS policies that relate to their place of work and role within the LCHS.**

All staff who will be working to this SOP should sign below to say they have read and understood the SOP and agree to act in accordance with its requirements.

Name	Job Title	Signature	Date

STANDARD OPERATING PROCEDURE FOR
The Administration of Apomorphine via the Apo-go Pump using Pre-filled Syringes

PROCEDURE		
Activity	**Rationale**	**Responsibility**
1. Patient Selection For LCHST nursing staff to administer subcutaneous apomorhpine via the Apo-Go Pump, the following criteria have to be fully met: • The use of the Apo-go pump has been deemed necessary by a consultant. • The apomorhpine has been prescribed by the patient's GP. • The apomorhpine has been prescribed on the appropriate medication administration documentation for either the community or community hospital setting. • The patient has already been receiving the apomorhpine prior to community nursing or community hospital involvement.	To meet the patients clinical needs	The prescriber
2. Maintenance and Decontamination • If any problems are encountered with a pump or it malfunctions, contact Britannia Pharmaceuticals Ltd via the Apo-Go Helpline on 0844 880 1327 (open 24 hours a day, 365 days a year) and complete a Datix. This should be reported to the medical devices agency (MDA). • A new pump should be delivered within 3 working days or the next day in the case of an emergency. Delivery is by courier service and advice should be sought from the patient's GP and/or the patient's consultant or Parkinson's Specialist nurse. • Clean pump in line with Infection Control Policy and manufacturers instructions.	Britannia Pharmaceuticals are responsible for the maintenance and repair of the pumps. Reporting the incident to the MDA complies with the Trust Incident Reporting and Medical Devices policies.	Nursing Staff

3. Training • The pump should only be used by registered nursing staff that have completed the training provided by Britannia Pharmaceuticals Ltd, which specifies the use of pre-filled syringes. • Staff will need to update their competency every 2 years or earlier if the competency has not been maintained i.e. longer than 6 months. • Additional training may be arranged via Britannia Pharmaceuticals and their Parkinson's disease nurse specialists as teams require.	All teams will be provided with a resource pack from Britannia Pharmaceuticals.	Nursing Staff
4. Essential information to be included on the Patient Medicines Administration Chart: ✓ Name of patient, date of birth and NHS number ✓ Name and signature of authorised prescriber ✓ Date prescribed ✓ Number of milligrams of apomorhpine to be infused **per hour** and length of infusion e.g. 12 or 15 hours. ✓ Name and strength of medicine (e.g. apomorhpine 50mg in 10ml prefilled syringe) ✓ Route (subcutaneous infusion) ✓ Frequency of infusion e.g. daily **For example:** ✓ Apomorphine 2mg **per hour** infused over 12 hours via subcutaneous infusion daily ✓ The setting on the pumps is in mls per hour therefore 0.4mls on the pump. See Chart below Apo-go 50mg in 10ml Solution for Infusion in pre-filled Syringe (PFS)	To comply with legal requirements and NPSA Alert No 20 and to ensure the information is clear and unambiguous.	Authorised prescriber.

5. Equipment The following equipment is required before setting up the grey Apo-go pump: ▪ Apo-Go infusion pump ▪ 1 Penta Ferte Apo-Go plastic syringe ▪ 1 Rigid Connector ▪ Battery (lithium 3 volt CR 123A Photo lithium Battery ▪ Spacer (for a 10ml setting) Blue key to open battery compartment ▪ New pumps do not have Spacers ▪ Syringe pump holder/elastic belt ▪ Preparation tray and towel. *(can be obtained from Britannia Pharmaceuticals Ltd)* The pump comes with a battery and spare battery in the box, batteries last approximately six months. Patients need to purchase their own spare batteries. Instructions for use: ▪ Apo-Go Pump User Guide provided by Britannia Pharmaceuticals Ltd with Apo-Go infusion pump abbreviated user guide for apomorhpine 50mg/10ml prefilled syringes. **Additional equipment required:** ▪ Sphygmomanometer ▪ Patient Medicines Administration Chart/Prescription chart signed by General Practitioner/authorised prescriber. ▪ Record of treatment ▪ Prescribed medicine (Apomorphine 50mg/10mls in prefilled syringes) ▪ Single use sterile dressing pack ▪ Additional pair of single use disposable non-sterile gloves ▪ Alcohol swab ▪ Sharps container ▪ Suitable transparent occlusive dressing ▪ Adhesive label specifying drug, dose, date and time ▪ Suitable infusion set	To ensure all equipment is available To support appropriate usage of equipment.	Trained nurses
6. Check Patient Details • Verbally check the identity of the patient against the current Patient Medicines Administration Chart and the pharmacy label on the medicine with the patient, confirming patient's name and date of birth. If not possible check details with family or carers. • On Community Hospital wards check details against patient wristband as well. • Establish if the patient has any known allergies.	To confirm that the patient is the correct recipient of the medication. To ensure the patient is not allergic	Trained Nurses

• Establish the patient has given appropriate consent: refer to the Trust consent policy for further details if required. **7. Check Patient Medicines Administration Chart** • Check the Patient Medicines Administration Chart is clear and unambiguous and contains all essential information. • Check the pharmacy label on the box of apomorhpine, issued by the supplying pharmacist against the Medicines Administration Chart, checking the name of the patient, that the pharmacist has supplied apomorhpine 50mg in 10ml prefilled syringes, the number of milligrams of apomorhpine to be administered **per hour** and the length of infusion. • Check the name and strength of the medicines on the manufacturer's packaging corresponds to the Patient Medicines Administration Chart and the pharmacy label.	to apomorhpine and to ensure appropriate selection of giving set and occlusive dressing, To ensure the pharmacy has dispensed the correct medication	Trained Nurses.
8. Blood Pressure Monitoring The patient's blood pressure should be recorded regularly. Be aware that low blood pressure and postural hypotension can be a side effect of apomorhpine. Parkinson's Disease (PD) patients can often have very low blood pressure, but are usually asymptomatic. However, if the patient becomes symptomatic, then blood pressure should be recorded on a daily basis sitting and standing and reported to the GP in the same span of duty and the Parkinson's Disease Specialist Nurse (if involved) as soon as possible. (typical symptoms include feeling faint or dizzy, falls, fainting/blackouts)	Apomorphine is known to reduce blood pressure.	Trained Nurses.
9. Setting up of Pump Please refer to the visual display cards 'setting up the APO-go infusion and PUMP' provided by Britannia Pharmaceuticals Ltd. Alternatively please refer to http://leedsformulary.nhs.uk/docs/ApoGo%20setup.pdf	To ensure the pump is set at the appropriate setting and correct rate.	Trained Nurses or delegated to patient/carer.

10. Site Selection. • Explain and discuss the procedure with the patient. • Choose an appropriate site for infusion to be placed in consultation with the patient. • See appropriate cards • Site the subcutaneous infusion in line with Procedure Guideline 16.19 Medication: Subcutaneous infusion of fluids, The Royal Marsden Hospital Manual of Clinical Nursing Procedures 8th Edition. • Document procedure; ensure batch numbers, expiry date, dose site of infusion are recorded, including name, signature and designation of nurse. • **Record all patients' medication on Medication Administration chart at the end of the process and ensure S1 notes are completed.**	To comply with Healthcare Record Keeping policy.	
11. Observation of site and Apo-go Pump. • Observe for any moisture underneath transparent dressing (for any leakage) • Observe the pump, ensuring infusion time is decreasing (a whirring sound from the pump can be heard if the pump is infusing). • Observation of the syringe can also be made to ensure it is infusing. Patients and carers should also be advised to observe the syringe during the course of the day. (see where to find help, appendix 2) • The patient or carer should also observe for any swelling or redness or leaking from the needle site. • Nodule formation is a common side effect of Apomorphine treatment. These can be felt easily under the skin and is sometimes associated with skin discolouration and scarring. This should be reported to the patient's GP at the earliest opportunity.	To ensure safe delivery of infusion contents. To highlight early signs of inflammation.	
12. Taking pump down. • Decontaminate hands prior to procedure. • Put on single use apron. • Apply single use disposable non sterile gloves. • See instruction manual. • On completion of procedure remove and dispose of PPE to comply with waste management policy. • Document the volume of Apomorphine solution left in the pump after the infusion period. • Following the procedure hands should be decontaminated.		

13. Common Problems

- All patients will initially require domperidone taken orally when first commencing treatment. Domperidone 10mg three times a day is to be used for the shortest period of time possible. Generally 48 to 72 hours prior to commencing apomorphine and then stopping if at all possible; unless residual nausea and vomiting do no respond to any other control.
- Domperidone has been the subject of an MHRA alert (May 2014) due to its QT interval prolongation and potential interaction with other drugs with this adverse effect.
- Patients should be observed for anything that may indicate altered heart rate.
- Apomorphine reduces blood pressure (see section 8 on blood pressure monitoring).
- Nodule formation at the needle site.

A reassessment of the patient's condition is required by both the nursing and medical staff in order to determine the clinical nature and change in the patient's condition.

To comply with MHRA alert May 2014

Trained staff

14. Advice to Patients and Carers

- Apomorphine should be stored at room temperature, below 25°C and protected from light and kept in the box issued by the supplying pharmacist.
- Store ampoules in a safe place away from children
- Observe syringe to monitor contents are infusing.
- Observe for redness, pain, swelling or leaking from needle site.
- Give contact details in the event of queries or problems.
- The Apo-go pump remains the property of Britannia Pharmaceuticals Ltd and should be returned if no longer required.

15. Advice re: position and care of an Apo-Go Pump.

- Do not get wet.
- Do not expose to direct sunlight
- Avoid extremes of temperatures
- Do not open
- Do not clean with strong household detergents or solvents
- Recommend suitable means of carrying to try to prevent pump being dropped.

16. Adverse Events.

All adverse events should be reported . Reporting form and information can be found at www.mhra.gov.uk/yellowcard . Also report to Medical information on 0870 851 0207 or dso@britannia-pharm.com .

Training
The pump should only be used by registered nurses who have successfully undertaken training provided by Britannia Pharmaceuticals Ltd in the use of the Apo-Go pump, using prefilled syringes, or those who have been shown how to use the pump by referring hospitals on discharge of patients. (Training will still need to be undertaken from Britannia Pharmaceuticals Ltd within one month of the patient being admitted to a community caseload).

Appendix 1

Milligrams per hour	Flow rate value to set on pump Mls per hour	Number of milligrams of apomorhpine over 12 hours infusion
1.0	0.2	12
1.5	0.3	18
2.0	0.4	24
2.5	0.5	30
3.0	0.6	36
3.5	0.7	42
4.0	0.8	48
4.5	0.9	54
5.0	1.0	60
5.5	1.1	66
6.0	1.2	72

APPENDIX 2
Where to find help:

Briatannia Pharmaceuticals Ltd have a helpline available 24 hours per day telephone:
0844 880 1327
200 Longwater Avenue, Green Park, Reading, Berkshire RG2 6G
www.britannia-pharm.com

Liz Carter Parkinson Nurse Specialist Genus Pharmaceuticals **07503 230128**

References:

1. Britannia Pharmaceuticals Ltd (2015) Setting up the APO-go Infusion and PUMP Britannia Pharmaceuticals Ltd .
2. National Patient Safety Agency (NPSA) Alert no 20 Promoting Safer Use of Injectables (March 2007)
3. NMC (2008) Code of Professional conduct: standards for conduct, performance and ethics.
4. NMC (2010) Standards for Medicine Management
5. The Royal Marsden Hospital Manual of Clinical Nursing Procedures (8th edition) (2011) Dougherty and Lister (Eds)
6. www.gov.uk/drug-safety-update/domperidone-risks-of-cardiac-side-effects @ 11.00 hours on 7/7/16.

1 Appendix One: Equality Analysis

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The aim of this service operating procedure is unified approach to the administration and care of Parkinson's patients who require the delivery of apomorphine via a Apo-go pump.		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	The policy defines how nursing staff will deliver the prescribed apomorphine via the Apo-go pump.		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	No		
D.	Will/Does the implementation of the policy\service result in different impacts for protected characteristics?	No		
		Yes	No	
	Disability		X	
	Sexual Orientation		X	
	Sex		X	
	Gender Reassignment		X	
	Race		X	
	Marriage/Civil Partnership		X	
	Maternity/Pregnancy		X	
	Age		X	
	Religion or Belief		X	
	Carers		X	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Sally-Ann Bradley		
Date:		9th May 2016.		

APPENDIX TWO

NHSLA Monitoring Template

Minimum requirement to be monitored	**Process for monitoring e.g. audit**	**Responsible individuals/ group/ committee**	**Frequency of monitoring/audit**	**Responsible individuals/ group/ committee (multidisciplinary) for review of results**	**Responsible individuals/ group/ committee for development of action plan**	**Responsible individuals/ group/ committee for monitoring of action plan**

Setting up the APO-go Infusion and Pump

Equipment required

Make sure you have a **Sharps bin** (or equivalent) and these 5 items on your preparation tray before you begin:

- **A** **1 x APO-go Pump** (with Spacer if setting up the Pump on a 10ml fill)
- **B** **1 x APO-go Prefilled Syringe** (x 1 for 10ml fill or x 2 for 20ml fill)
- **C** **1 x Empty plastic syringe** (from plastic syringe packaging: keep blue cap, throw away needle in sharps bin)
- **D** **1 x Connector**
- **E** **1 x Infusion Line**

Settings:
(Not to be altered unless discussed with HCP)

Bolus (d)

Flow rate (f)

Time

1 Check that **APO-go** Pump is set to OFF. Place upright in tray compartment.

2 Ensure plunger in plastic syringe moves freely, push the black bung as far into the barrel as possible. Unscrew plunger anti-clockwise, leaving the black bung at the top of the empty plastic syringe.

3 Attach empty plastic syringe to **APO-go** pump. Ensure wings click into place.

4 Attach connector to empty plastic syringe.

5 Attach **APO-go** PFS to other end of connector. Push fluid slowly into empty syringe.

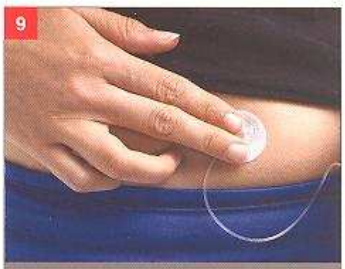
6 Unscrew **APO-go** PFS and connector and screw blue cap onto plastic syringe, throw empty **APO-go** PFS and connector in sharps bin.

7

Unscrew blue cap and attach infusion line to plastic syringe on the Pump.

8

Press and hold the Red (+) button to switch Pump ON. Press and hold blue (d) button to prime the infusion line.



9

Insert needle in usual way. Please refer to the APO-go Skin Management Guide.

Different needles require different injection techniques

(needles vary according to local policy)

Infusion needles: Flow-safer infusion line (25 gauge orange butter fly needle), should be sited slowly and gently, into a pinched skin fold, at a 45 angle to the skin.

Thumb-tack needles, such as neria, should be sited slowly and gently into un-pinched skin at a 90-degreee angle. When using this type of needle, it is important to hold onto the infusion line tube just above the head (tack) of the needle, to ensure full depth of insertion.

To stop APO-go infusion

Remember to always remove the infusion line before the Pump is retracted.

To switch OFF before the infusion is finished:

1 Press and hold red (+) button to switch OFF

2 Take out the needle and infusion line

3 Press and hold blue (d) and grey (−) buttons together until display says "END", leave Pump with syringe on while plunger retracts - this may take several minutes. Wait until display says "OFF" and then remove plastic syringe from Pump

If the infusion has finished the Pump will show "END"

1 Take out the needle and infusion line

2 Press and hold blue (d) button, leave Pump with syringe on while plunger retracts - this may take several minutes. Wait until display says "OFF" and then remove plastic syringe from the Pump

The plastic syringe must stay on the Pump until the plunger has fully retracted.

Should there be any problems with the Pump, please contact the APO-go Helpline

APO-go Helpline 0844 880 1327 — 24 hours a day, 365 days a year

GENUS PHARMACEUTICALS

APO-go®

Park View House, 65 London Road, Newbury, Berkshire RG14 1JN **Tel: 01635 568 400**

Date of preparation: October 2012 APO-0812-1471

Subcutaneous Infusion by Assistant in APO-go Therapy using a Neria Infusion Line

Pre-insertion Considerations

- Explain procedure to patient
- Informed Verbal Consent
- Infusion Line – ensure all required equipment is available, clean, in date and all packaging is visually intact
- Wash hands

Select Appropriate Subcutaneous Infusion Site:

- ensuring sites are regularly rotated
- The following sites are the most commonly used as there tends to be more subcutaneous fat present:
  -Upper outer aspect of arms
  -Anterior abdominal wall (avoiding 1" area around umbilicus)
  -Upper outer aspect thigh
  -Scapula

The following sites are contra-indicated:

- Damaged skin for example: broken, reddened, bruised
- Evidence of nodule formation
- Hardened, scar tissue
- Bony prominences

Procedure:

1. Hold the needle by the line not by the plastic wings at the back of the device. This is because holding the wings can "pinch" the adhesive plaster.
2. Remove the adhesive cover.
3. Remove the needle cover.
4. Do not pinch the skin, this leaves a gap between the base of the needle and the skin causing strain on the needle.
5. Hold the top of the tubing between thumb and forefinger of one hand. Use finger of other hand to insert needle.
6. Push the needle straight in at 90 degree angle.