Title: Subcutaneous Apomorphine in the treatment of Parkinson's Disease	
Standard Operating Procedure (SOP)	
Ref No: 2092	
Prepared by: Vicky Queen, Acute Parkinson's Disease Nurse Specialist	
Presented to: Service Delivery Unit (Medical Division) Paul Foster, Clinical Director of Pharmacy	**Date:** 20 October 2016 29 June 2016
Ratified by: Service Delivery Unit (Medical Division) Paul Foster, Clinical Director of Pharmacy	**Date:** 20 October 2016 12 August 2016
	Review date: 4 November 2018
Relating to policies:	

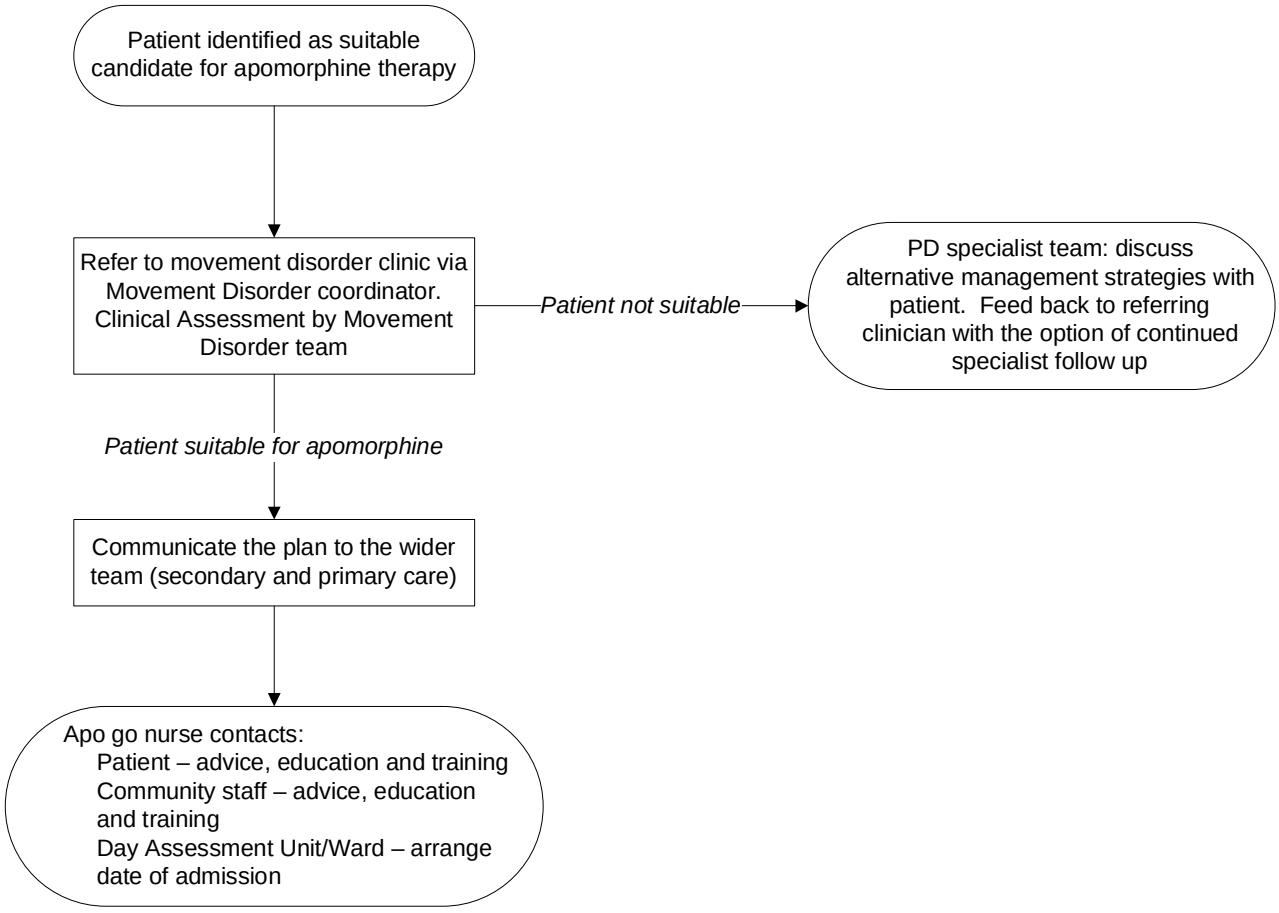
Purpose of this document:
To provide a clinical guideline relating specifically to apomorphine (APO-GO).The movement disorders team will assess patients and deem if they are suitable for apomorphine therapy. This team consists of Specialist Consultant Doctors (Care of the Elderly and Neurology), Acute Parkinson's Disease nurse specialist, community Parkinson's disease nurse specialist, Apo Go nurse and movement disorder coordinator. The Apo Go nurse's role is implemented via an honorary contract and the purpose of this role is to support and commence patients on apomorphine for the Trust.

1. Scope of this SOP:
This guideline is designed to inform staff caring for patients with complex Parkinson's Disease (PD) of the referral pathway for the consideration of apomorphine treatment. The guideline also provides information for nursing staff caring for patients undergoing apomorphine challenges and details the protocol of the challenge itself. This guideline will be useful to: consultants in neurology and care of the elderly caring for complex PD patients, neurology ward staff and PD specialist team members.

2. Competencies required:
It is the duty of all staff referring patients for apomorphine therapy and those staff involved in assessing and initiating therapy to be familiar with these guidelines.

3. Procedure / Steps:

Referral pathway for assessment:



Prior to the Apomorphine Response Test:

GP role (to be requested by Apo go nurse)

- Arrange baseline ECG
- Arrange baseline FBC, LFT and Coomb's test
- Prescribe domperidone 10mg t.i.d for 3 days prior to the test
- Plan for follow up ECG after 2 weeks on apo go.
- Plan for 3 monthly bFBC, LFT and Coombes test.

Apo go nurse role

- Book day case/treatment room for challenge.
- Ensure patient aware that morning medications need to be omitted on the day of the challenge
- Ensure patient is aware they should stop driving if apomorphine causes somnolence.
- Notify Pharmacy of Apo pens ordered for response test.

Acute Consultant /Acute Nurse Specialist role

- Prescribe apomorphine 10mg/ml 1x 5ml syringe or APO-GO pen on prescription chart.
- Supply infusion lines and sharps bin.
- Set up home delivery for future prescriptions.

Guidelines on the apomorphine response test.

- Ensure patient has understood the indication and potential side effects of the procedure and has signed their consent for the test to proceed
- GP to check ECG (apomorphine carries the risk of prolongation of the QT interval therefore QT interval should be normal prior to the test (0.33-0.44 sec or <11 small squares) and results of full blood count, liver function and Coomb's test (apomorphine can be associated with haemolytic anaemia therefore blood tests should be carried out 4-6 monthly whilst on therapy)
- Check patient has omitted morning medications and has taken three days of pre-treatment with domperidone 10 mg t.i.d.
- Assess baseline motor function e.g. UPDRS motor score
    - Timed walk (if safe to do so based upon patient's symptoms)
    - Timed finger tapping test
- Check lying and standing blood pressure (BP)
- Administer 1mg APO-GO. Repeat motor and BP assessments after 30 minutes and observe for side effects.

- If there is no or a poor response, give a subsequent dose of 2-6mg APO-GO if appropriate. Repeat the motor and BP assessments after 30 minutes and monitor for side effects.
- Increase the dose in incremental steps every 30 minutes (i.e. 1.0mg, 3mg, 5mg, 6mg, 7mg) Stop when a positive response is seen. If at 7 mg there is no response, then the patient is termed a non-responder.

Positive apomorphine Challenge

A challenge is positive if the following is seen:

- An overall improvement of at least 30% of UPDRS motor score (part III).

Following a positive response test a patient will be discharged with the response pack of Apo Go pens at a dose agreed with the Apo Go nurse and prescriber. Subsequent prescriptions will be provided via the home delivery service.

It is the GP responsibility to undertake the follow up ECG, after 2 weeks on Apo Go and 3 monthly blood tests (FBC, LFT and Coombes test). This information will be detailed in a clinical letter to GP following a positive response test and this will be the responsibility of the Apo Go nurse to send this communication.

When considering a continuous infusion to include waking day (12-16 hours) variable flow or 24hour infusion, the following table can be used as a guide.

Infusion rates for the APO-GO ambulatory infusion pump (supplied by Brittania pharmaceuticals)

mg APO-GO per hour	ml of diluted solution per hour (flow rate)	Hours/minutes running time (100mg in 20 ml syringe)	Hours/minutes running time (50mg in 20ml syringe)
1.0	0.2		
1.5	0.3		
2.0	0.4		25.00
2.5	0.5		20.00
3.0	0.6		16.41
3.5	0.7		14.17
4.0	0.8	24.58	12.30
4.5	0.9	22.13	11.07
5.0	1.0	20.00	10.00
5.5	1.1	18.10	9.05
6.0	1.2	16.40	8.20
6.5	1.3	15.22	7.41
7.0	1.4	14.17	7.09
7.5	1.5	13.20	6.40
8.0	1.6	12.30	6.15
8.5	1.7	11.46	5.53
9.0	1.8	11.07	5.34
9.5	1.9	10.31	5.16
10.0	2.0	10.00	5.00

If a patient is admitted as an inpatient who is already having Apomorphine the ward staff should seek the advice of the acute PDNS, consultant or Apo go nurse.

Contraindications to the use of apomorphine

- Respiratory depression
- Dementia
- Psychosis
- Hepatic insufficiency
- Known sensitivity to apomorphine
- Pregnancy
- Patients under 18

Special warnings and precautions

- Use with caution in renal, pulmonary or cardiovascular disease and patients prone to nausea and vomiting.
- Extra caution is needed in elderly or debilitated patients who may be more at risk of developing side effects.
- Apomorphine can lead to marked hypotension therefore caution is needed in treating patients with cardiovascular disease, patients on anithypertensives and those with a pre-existing tendency to postural hypotension.
- Apomorphine is associated with local subcutaneous reactions which can sometimes be reduced by rotating the site of injection and massaging the skin.
- Haemolytic anaemia has been reported in patients taking apomorphine and levodopa. Coombs tests and liver function tests should be performed at 3-monthly intervals.
- Patients suffering with neuropsychiatric disturbances may find that this is exacerbated by apomorphine.
- Impulse control disorders (ICDs) have been described in patients taking dopamine agonists including apomorphine. Patients should be screened for ICDs prior to starting therapy and at regular intervals thereafter. Patients and their carers must be made aware of this potential side effect and this advice must be clearly documented.
- Apomorphine can cause somnolence: in this event patients should not drive and exercise caution when operating machinery.
- Since apomorphine, especially at high dose, may have the potential for QT prolongation, caution should be exercised when treating patients at risk for torsades de pointes arrhythmia.

- Apomorphine hydrochloride contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm. It also contains sodium at less than 1mmol (23mg) per ml, i.e. essentially 'sodium-free'.

4. Monitoring tool:

Standards:

Item	%	Exceptions
Pre test ECG and coombes test arranged	100	None
Complications rates/causes (e.g nausea, hypotension) recorded.	100	None

Equality Statement.
The Trust is committed to preventing discrimination, valuing diversity and achieving equality of opportunity. No person (staff, patient or public) will receive less favourable treatment on the grounds of the nine protected characteristics (as governed by the Equality Act 2010): Sexual Orientation; Gender; Age; Gender Reassignment; Pregnancy and Maternity; Disability; Religion or Belief; Race; Marriage and Civil Partnership. In addition to these nine, the Trust will not discriminate on the grounds of domestic circumstances, social-economic status, political affiliation or trade union membership.

The Trust is committed to ensuring all services, policies, projects and strategies undergo equality analysis. For more information about equality analysis and Equality Impact Assessments please refer to the Equality and Diversity Policy

References:

1. Cotzias et al. 1976. Treatment of Parkinson's Disease with aporphines. Possible role of growth hormone. NEJM 294 (11): n567-572
2. Dewey et al. 2001. A randomised double blind controlled trial of subcutaneously injected apomorphine for Parkinsonian off states. Arch Neurol 58: 1385-1392
3. Stibe et al. 1988. Subcutaneous apomorphine in parkinsonian on-off oscillations. Lancet 1: 403-406.
4. Tyne et al. 2004. A 10-year retrospective audit of long-term apomorphine use in Parkinson's Disease. J Neurol 251: 1370-1374.

Amendment History

Issue	Status	Date	Reason for Change	Authorised
1	New	4 November 2016		Service Delivery Unit – Medical Services Paul Foster, Clinical Director of Pharmacy

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS South Devon and Torbay Clinical Commissioning Group

Torbay and South Devon NHS NHS Foundation Trust

Rapid Equality Impact Assessment *(for use when writing policies and procedures)*

Policy Title (and number)	**Subcutaneous Apomorphine in the treatment of Parkinson's Disease (2092)**				
Policy Author	Vicky Queen				
Version and Date (of EIA)	Version 1 date 29/06/2016				
Associated documents (if applicable)	n/a				
RELEVANCE: Does the aim/purpose of the policy relate to each of the aims of the Public Sector Equality Duty?					
· **Eliminate unlawful discrimination or other conduct prohibited by the Equality Act 2010**					Yes ☐ No x
· **Advance equality of opportunity between people from different groups**					Yes ☐ No x
· **Foster good relations between people from different groups**					Yes ☐ No x
SIGNIFICANCE AND IMPACT: Consider the nature and extent of the impact, not the number of people affected.					
Does the policy affect service users, employees or the wider community? (if no, proceed to sign off)					Yes x No☐
Does the policy affect service delivery or business processes?					Yes x No☐
Does the policy relate to an area with known inequalities (deprivation/unemployed/homeless)?					Yes ☐ No x
EQUALITY ANALYSIS: How well do people from protected groups fare in relation to the general population? ***PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below***					
Is it likely that the policy/procedure could treat people from protected groups less favorably than the general population? (see below)					
Age	Yes ☐ No x	Disability	Yes ☐ No x	Sexual Orientation	Yes ☐ No x
Race	Yes ☐ No x	Gender	Yes ☐ No x	Religion/Belief (non)	Yes ☐ No x
Gender Reassignment	Yes ☐ No x	Pregnancy/ Maternity	Yes ☐ No x	Marriage/ Civil Partnership	Yes ☐ No x
Is it likely that the policy/procedure could affect particular 'Inclusion Health' groups less favorably than the general population? (substance misuse; teenage mums; carers; travellers; homeless; convictions; social isolation; refugees)					Yes ☐ No x
Please provide details for each protected group where you have indicated 'Yes'.					
What if any, is the potential for interference with individual human rights? none **(consider the FREDA principles of Fairness/ Respect/ Equality/ Dignity/ Autonomy)**					
RESEARCH AND CONSULTATION					
What is the reason for writing this policy? (What evidence/ legislation is there?) none					
Who was consulted when drafting this policy/procedure? Lead consultants, Pharmacy, community Parkinson's nurse specialists. **What were the recommendations/suggestions?** Detail from MHRA added					

ACTION PLAN: Please list all actions identified to address any impacts		
Action	**Person responsible**	**Completion date**

AUTHORISATION			
Name of person completing the form	Vicky Queen	**Signature**	VEQUEEN
Validated by (line manager)	Sue Bramwell	**Signature**	SBRAMWELL