Policy Document Control Sheet

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Title	Prescribing and administration of End of Life medicines using a variable dose					
Version number	3.0					
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Approving Committee	Integrated Quality Assurance Committee					
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Document Owner	Macmillan Specialist Palliative Care Lead Nurse					
Lead Director or Associate Director	Sharon Morgan Associate Director of Nursing					
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Final approval

Chairman or Executive Sponsor's Signature	
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Name & Job title of Chairman or Executive Sponsor	Jeremy Cundall – Executive Medical Director
Approving Committee	Integrated Quality Assurance Committee
Signed master copy held at:	Corporate Records Office, Trust Headquarters, Darlington Memorial Hospital

PreviouslyPOL/CL.084

Version Control Table

Date Ratified	Version Number	Status
01/04/2011	1	Superseded
November 2016	2	Superseded
Sept 2017	3	Approved

Table of Revisions

Date	Section	Revision	Author
1/12/14	All	Amendments made to reflect the preferred usage of morphine. References to diamorphine removed throughout.	C Williams, Deputy Chief Pharmacist
03/11/2016	All	Amendments made to reflect changes in NESCN palliative and End of life Care Guidelines	Suzanne Vickers Macmillan Specialist Palliative Care Lead Nurse
12/12/2016	All	Change from 'sliding scale' to 'variable dose', review of all sections. Changed from Guideline to Procedure	Graeme Kirkpatrick (Chief Pharmacist) / Calum Polwart (Lead Pharmacist)
July 2017	All	All sections reviewed for accuracy and consistency of wording. Transferred to new template. Now a policy. Formerly know as POL/CL.084	Suzanne Vickers Macmillan Specialist Palliative Care Lead Nurse.

Contents

1 Introduction

Patients requiring symptom control towards the end of life (EoL) will often require a continuous sub-cutaneous infusion of analgesia and other medicines to minimise their symptoms. The dose of these medicines will commonly need to increase over time to account for increasing symptoms and increasing tolerance to the medicine. To minimise delays in accessing treatment, it is sometimes appropriate to prescribe medication with a variable dose range. A variable dose of a drug is where a dose range rather than a single dose is prescribed e.g. morphine 30-60 mg via syringe pump over 24 hours. It enables the dose of the drugs required for a patient's symptoms towards the end of life to be increased if necessary without the need to obtain a further prescription.

2 Purpose

This document is intended to provide guidance and support for increasing the dose of medications in response to increasing requirements for symptom. This procedure must be followed in any instance where a patient is prescribed a variable dose of an end of life medication.

3 Scope

The main anticipated environment for the use of this guidance is within the district nursing service. However, it may be used wherever there is limited access to appropriate prescribers. This procedure is to guide prescribers on how to prescribe a variable dose and to enable nurses to administer an appropriate dose from within the variable range. This procedure is not intended to guide prescribers in clinical decision making related to drug choice.

4 Definitions

TAPs: Teams Around Patients (formally District Nursing Teams)

Community Settings: This includes the Patients home, Residential Care Homes and the Community Hospitals within County Durham and Darlington Foundation Trust.

5 Duties

5.1 Line Managers, Professional Leads and Service Leads

Line Managers, Professional Leads and Service Leads are responsible for ensuring this procedure is implemented and monitored within their area of responsibility and remain responsible for the support and supervision of their staff. They must ensure that Nursing staff are assessed against the WASP competency framework (appendix B)

5.2 All Staff

All staff, including temporary and agency staff who administer medications against a variable dose, are responsible for:

- Complying with organisational policies and procedures. Failure to comply may result in disciplinary action being taken.

- Co-operating with the development and implementation of policies and procedures as part of their normal duties and responsibilities.

- Identifying a need for change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.

- Identifying their own training needs in respect of policies and procedures and bringing them to the attention of their line manager.

- Attending training / awareness sessions when provided.

5.3 Specialist Palliative Care Services

The Macmillan Specialist Lead Nurse is responsible for ensuring that the procedure remains up to date and must ensure it is amended to take into account any changes in palliative care guidelines.

The Specialist Palliative Care Team is also responsible for offering training in line with the requirements of the staff and organisation.

6 Main Content of Policy

6.1 Procedure for prescribing and administration of end of life care medicines as a variable dose

Many patients towards the end of life receiving medication by syringe pump will need an increase in the dose of medication to enable continued control of symptoms.

When a patient is receiving regular medication at a constant rate via a syringe pump it is sometimes necessary to give extra doses of medication to control any breakthrough symptoms. These are known as breakthrough doses.

The amount of medication given as breakthrough doses given over the last 24 hours can be used to estimate the required increase in syringe pump medication for the next 24 hours.

If the drug was prescribed as a variable dose, the increased dose can be given without a new prescription as long as the increase it is still within the prescribed scale.

The use of a variable dose prevents delay in the delivery of a required increased dose. This is especially important during the out of hours period when access to medical cover is limited and the patient is unlikely to be known by the prescribing doctor.

The dose range can be prescribed:

1 For use by a registered nurse without further consultation ***OR***

2 For use by a registered nurse following consultation with a doctor before the increased dose is used. If the prescriber intends for the nurse to speak to a doctor before increasing the dose then this should be clearly written by the prescriber on the prescription sheet / administration chart.

This procedure should not be used where there is any concern regarding pain that is non-responsive to opioid analgesics as increasing the dose could lead to opioid toxicity.

6.2 Prescribing information

Drugs will be prescribed as per the North of England Strategic Clinical Network (NESCN) Palliative Care Guidelines. These guidelines have been made widely available in a booklet and are also available electronically from this web address:

http://www.nescn.nhs.uk/updated-palliative-and-end-of-life-care-guidelines-published/

Prescribing decisions will also be in line with the principles of Deciding Right.

6.3 How to prescribe a suitable variable dose

Before prescribing or administration of an opioid analgesic the flow chart in appendix A should be followed.

Starting dose

The lower dose on the variable scale should be the total dose needed by the patient in the previous 24 hours converted to the appropriate equivalent dose for subcutaneous administration.

It is usually appropriate to prescribe a scale in which the highest dose is twice that of the starting dose.

- For example;*Morphine sulphate modified release tablets 30mg twice daily with two breakthrough doses of 10mg morphine sulphate given (i.e. 80mg morphine in 24 hours) is equivalent to morphine 40mg subcutaneously over 24 hours. In this example the lower dose would be 40mg morphine and the upper dose would be twice this dose i.e. 80mg*
- *The variable dose would be written on the prescription as 40mg to 80mg morphine.* Additional morphine would be prescribed as a breakthrough dose.
- Breakthrough doses are calculated as 1/6th of the 24 hour dose (rounded down to the nearest appropriate combination of ampoule strengths) and should also be written as a variable dose to ensure appropriate breakthrough medication is administered. *In the above example the breakthrough dose to give would be 5mg to 10mg morphine Subcutaneous (SC)/ As required (PRN) up to a maximum of once every hour (or as defined by the prescriber).*

6.4 Using the Variable Dose Policy for administration where a dose increase is required

The first dose administered must be at the lowest end of the variable dose (i.e. the starting dose).

If an assessment is made that the patient requires an initial dose at anything higher than the lowest dose of the prescribed variable dose then, before administration, an appropriate prescriber must be contacted and the following steps should apply:

- The registered nurse and prescriber should discuss and confirm a suitable starting dose within the prescribed scale.
- This should only happen in exceptional circumstances where the total oral dose of the medication (including breakthrough doses) given in the previous 24 hours is equivalent sub-cutaneous to a dose greater than the lowest end of the prescribed variable dose.

Subsequent to the initial dose, the nurse **should not** increase the dose if they have any concerns about doing so. The following steps apply for any dose changes

- For the initial dose and all subsequent dose changes the calculation, discussion and decisions must all be recorded clearly in the patient's records. Two knowledgeable and competent registered practitioners should be involved in the calculation and the calculation should be undertaken **independently.** The independent calculations should then be checked against each other to ensure the correct dose has been calculated. This safety check can be done by phone or other technology if necessary.
- The name and details of all healthcare professionals involved in the dose discussion and calculation should be recorded in the notes.

In the out of hours period there is an appropriate prescriber available through the urgent care centre (UCC) who dose adjustments can be discussed with. The appropriate prescriber can be contacted if there is any uncertainty about what to give or if the prescriber has requested that this is done before increasing the dose.

Out of hours access to consultant advice is provided by a commissioned professionals out of hours advice line. This is provided by Marie Curie Hospice in Newcastle and can be accessed between the hours of 17.00 and 09.00 Mon-Fri and 24 hours over the weekend and Bank Holidays. Marie Curie offer a Registered Nurse 'triage' with Medical support if required. Prescribing advice is offered to prescribing health professionals only. There is not a physical consultant presence. Prescribing advice will only be given to an appropriate prescriber. This is a 12 month Pilot May 2018

For the purposes of administration via a variable dose the dose increase is calculated by adding the breakthrough doses given in the previous 24 hours to the syringe pump dose. Consideration should also be given to the reason that breakthrough doses have been given to ensure an increase in dose is appropriate. Note: the dose of morphine in the syringe pump should **not be** increased by **more than 50%** of the dose given in the previous 24 hour syringe pump without first seeking advice from an appropriate prescriber.

If it is felt clinically, that the patient requires a greater dosage increase then an appropriate independent prescriber must be consulted to reassess the patient and, if necessary, to prescribe an increase in the medication.

CONTINUATION of example above:

- *The initial dose of morphine is 40mg in the syringe pump with 5mg Subcutaneous (SC)/ As required (PRN) for breakthrough pain.*
- *If two breakthrough doses had been required in the last 24 hours then the dose for the following 24 hours would be 50mg in the syringe pump and 5mg Subcutaneous (SC)/ As required (PRN).*
- *However, if five breakthrough doses had been given, rather than two, then the dose the following day would be 60mg in the syringe pump and breakthrough increased to 10mg Subcutaneous (SC)/ As required (PRN) as 1/6th of the new dose. Note that the calculated dose required would have been 65mg but this is more than a 50% on the previous dose.*

Dose increases should be recorded with the rationale behind the increase. If a calculation is performed (no matter how basic) the details of the calculation should be recorded clearly in full in the patient's records.

6.5 Breakthrough doses

As an additional safety measure the care of the patients should be discussed with an appropriate clinician if more than two breakthrough doses of any drug are needed in 4 hours. This will help define whether the patient requires reassessing at an earlier stage.

It is often appropriate to prescribe a variable dose for the breakthrough medication as well as the continuous dose (this may be more significant at higher doses).

http://www.nescn.nhs.uk/updated-palliative-and-end-of-life-care-guidelines-published/

120mg of morphine in the syringe pump with a variable dose of 120-240mg.

- *The initial breakthrough dose would be 20mg of morphine (1/6th of 120mg).*
- *As the dose given in the syringe pump increases up to 240mg the required breakthrough dose would increase.*
- *In this example the variable dose would be 20-40mg PRN as 20mg is 1/6th of 120mg and 40mg is 1/6th of 240mg.*

If a breakthrough dose is prescribed via a variable dose then the dose to be administered should be 1/6th of the 24 hour syringe pump dose.

If the calculated dose does not correspond with a whole vial of an available strength of morphine then the breakthrough dose should be rounded **down** to the nearest available vial (reducing waste and reducing difficulty in calculating the amount to be administered from the vial).

CONTINUATION of example above:

- *If from the 120-240mg scale a dose of 200mg is being administered*
- *The corresponding breakthrough dose would be calculated as 33.33mg (1/6th of 200mg).*
- *Although this is within the range of the prescribed, variable dose 30mg should be administered as this matches available ampoule strengths (30mg or 3x10mg).*

6.6 Other End of Life medication

Doses of medication other than opiates e.g. midazolam, levomepromazine, hyoscine butylbromide can be adjusted in the same way, as opioid analgesics, by the addition of breakthrough doses to the next syringe pump dose.

http://www.nescn.nhs.uk/updated-palliative-and-end-of-life-care-guidelines-published/

For other drugs the following initial scales would be appropriate:

Restlessness / agitation:

- midazolam 10-30mg over 24 hours via syringe pump with 2.5- 5mg *Subcutaneous (SC)/ As required (PRN)* up to a maximum of every hour.

Nausea and / or vomiting:

- levomepromazine 6.25-12.5mg over 24 hours via syringe pump and 6.25mg *Subcutaneous (SC)/ As required (PRN)* up to a maximum of once every 4 hours.

Respiratory tract secretions:

- hyoscine butylbromide 60-120mg over 24 hours via syringe pump and 20mg *Subcutaneous (SC)/ As required (PRN)* up to a maximum of once every 8 hours.

6.7 Safety measures for administration

Note these are in addition to the usual safety measures applied to the administration process which will be outlined in local service Standard Operating Procedures (SOPs) as well as the Medicines policy and NMC Standards for Medicines Management.

Safety measures for administration:

- **ALWAYS** seek advice* if unsure about any part of the process
- **ALWAYS** use the lowest dose on the variable dose scale first (for regular and breakthrough doses) – note exceptional circumstances in section 5.5
- **ALWAYS** round down doses to be administered (where rounding is necessary)
- **ALWAYS** seek advice* if the regular dose to be administered is more than 50% greater than the previous dose
- **ALWAYS** seek advice* if more than 2 breakthrough doses are required in 4 hours
- **ALWAYS** document calculations, discussions concerning treatment and any advice sought including documentation of professionals involved.

- **ALWAYS** ensure an independent second check on calculated doses and include documentation of professionals involved

- **DO NOT ASSUME** that a variable dose has been prescribed for breakthrough doses (it may be the intention of the prescriber to prescribe a fixed breakthrough dose regardless of the regular dose)

- **DO NOT ADMINISTER** outside of the written instructions on the basis of verbal communication. All instructions to administer must be written, signed and dated (see Medicines Policy) by an appropriate prescriber. Any required alteration must be made before administration.

***Advice = advice from an appropriate prescriber.**

7 Monitoring

7.1 Compliance and Effectiveness Monitoring

Compliance with this policy will be monitored as outlined in the table below.

7.2 Compliance and Effectiveness Monitoring Table

Monitoring Criterion	Response
Who will perform the monitoring?	TAPs Leads/Community Service Managers/Prescribers/Medicines Management/Specialist Palliative Care team
What are you monitoring?	Guidance within the policy is being followed and any issues flagged through trends analysis on safeguard and actioned as appropriate.
When will the monitoring be performed?	When a variable dose has been prescribed and policy actioned. Safeguarding incidents reports/Medicines Mangement audits
How are you going to monitor?	Guidance within the policy is being followed and any issues flagged through trends analysis on safeguard and actioned as appropriate.
What will happen if any shortfalls are identified?	Review practice/prescribing/action safeguarding incident reporting, medicine management audits and investigations to review any issues/recommendations
Where will the results of the monitoring be reported?	Care Group Governance meeting/Safety Committee/Quality Forum/individual TAPs meetings
How will the resulting action plan be progressed and monitored?	Lesson learned/Audits findings discussed/Quality Forum/TAPs meetings

How will learning take place?	Lessons learned/shared at TAPs Team meetings/apprasials/Quality Forum

8 Glossary of Terms

All defined throughout.

9 Associated Documentation

This guidance refers to the following CDDFT Trust policies and procedures:

- Policy for the Administration of Subcutaneous Medication Via T34 Syringe Pump and Bolus Injection
- Health Record Policy
- Trust Medicines Policy
- Procedure for witnessed administration of controlled drugs

This guidance refers to the following guidance, including national and international standards:

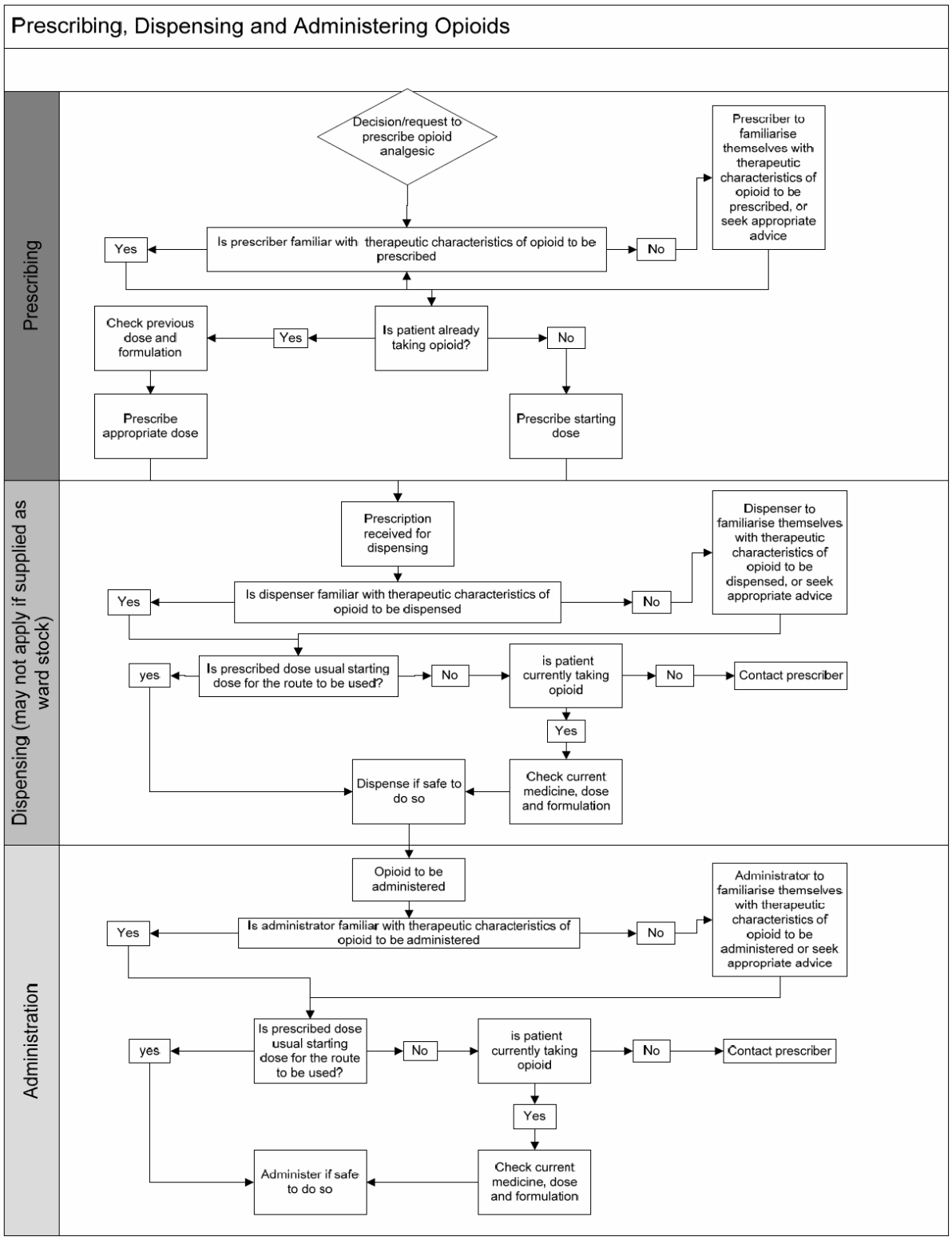
- Nursing and Midwifery Council (Jan 2015) The Code – Standards of Conduct, performance and ethics for Nurses and Midwives. London, NMC.
- Nursing and Midwifery Council (2015) Standards for Medicines Management. London, NMC
- Nursing and Midwifery Council (Jan 2015) NMC Record Keeping Guidance for Nurses and Midwives. London, NMC.

References:

- Palliative Care Guidelines – North of England Cancer Network NESCN 4th ed
  - http://www.nescn.nhs.uk/updated-palliative-and-end-of-life-care-guidelines-published/
- NPSA Rapid Response Report: NPSA/2008/RRR05 – Reducing Dosing Errors with Opioid Medicines – July 2008

10 Appendices

Appendix A: NPSA Flow Chart for Prescribing, Dispensing & Administering Opioid Analegisic



Appendix B: Assess Competency According to WASP Framework

W	WITNESSED	Observe or witness the competency – it is considered good practice that the practitioner will have had the opportunity to observe the procedure prior to being supervised.
A	ASSIMILATED	Understand the elements of the competency
S	SUPERVISED	Practice under supervision to demonstrate understanding: score as follows: 1 = NEEDS FURTHER PRACTICE 2 = SHOWS APTITUDE 3 = PROFICIENT
P	PROFICIENT	Competent in both knowledge and skill elements of the Competency.

ACTION		**W SCORE**	**A** SCORE	**S** SCORE	**P** SCORE
Knowledge and Understanding					
Demonstrates a working knowledge of medications used to control patient's symptoms at the End of Life: i.e. Characteristics of the medicine and formulation, usual starting dose, frequency of administration, standard dosing increments, symptoms of overdosage and common side effects.	To ensure Safe and Effective Evidence based practice				
Demonstrates a working knowledge of CDDFT Policies, procedures and guidelines including: Medicines Policy Controlled Drugs Policy Administration of Subcutaneous Medication via T34 Syringe pump and Bolus dose injection Use of Palliative Care Guidelines (North of England Cancer Network) NESCN 4th ed http://www.nescn.nhs.uk/updated-palliative-and-end-of-life-care-guidelines-published/	To ensure Safe and Effective Evidence based practice				

Performance Assessment - Monitor Patient Symptoms and Evaluate symptom control					
1. Assess the patient's physical, psychological and emotional condition, their response to the current treatment and any reactions or allergies which may have become apparent. 2. Check and confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This should be done for example with the patient or their representative, the prescriber and by reviewing medication records. 3. Assess the cannula / short line entry site and surrounding skin condition for any abnormal appearance and treat in line with local policy and guidelines 4. Check the syringe and infusion line for any abnormalities according to local policy and guidelines. 5. Confirm patient symptom control status and identify if an increase in dosage is required, this will be based on the previous 24 hours.	To ensure Safe and Effective Evidence based practice				
6. Ensure where a dose increase is intended, that the calculated dose is safe for the patient. Ensure dose calculations are documented in the patient records to identify rationale for increase i.e. Calculated by number of breakthrough doses required. No more than 50% higher than the previous dose 7. Recognise when you need help and seek from appropriate sources i.e. senior team member, GP or Specialist Palliative care team. 8. Communicate medication changes and gain consent					

from Patient and/or key person on changes to be made to medications and who to contact if any problems arise. 9. Record all details within the patient record according to Clinical Record Keeping & Healthcare Records Management Policy					
	DATE				
	ASSESSOR SIGNATURE				
	STAFF MEMBER SIGNATURE				

Appendix C: Equality Impact Assessment

Full Assessment Form

Division/Department:	Community Services
Title of policy, procedure, function or service:	Procedure for prescribing and administration off end of lifemedicines using a variable dose
Policy lead:	Macmillan Specialist Palliative Care Lead Nurse
People involved with completing the EIA:	Chief Pharmacist Specialist PalliativeCare Consultant Clinical lead Associate Director of Nursing Macmillan Specialist Palliative Care Lead Nurse Macmillan Educator

Type of policy, procedure, function or service:

Existing	☐
New/proposed	☐
Changed	x

Step 1 – Make sure you have clear aims and objectives 2

What is the aim of your policy, procedure, project or service?

This document is intended to provide guidance and support for increasing the dose of medications in response to individual requirements for symptom control in end of life care. This procedure must be followed in any instance where a patient is prescribed medications on a variable dose. Nurse Independent Prescribers with the appropriate prescribing competency can prescribe using this method in these settings as can doctors.

Who is the policy, procedure, project or service going to benefit and how?

Patients. A variable dose is the prescription of a drug with a dose range rather than a single dose e.g. morphine 30-60 mg via syringe pump over 24 hours. It enables the dose of the drugs required for a patient's end of life care to be increased if necessary without the need to obtain a further prescription.

What outcomes do you want to achieve?

Safe prescribing, dispensing and administration of medication at end of life.

What barriers are there to achieving these outcomes?

This is a revised equality impact assessment on an existing policy already in practice.

How will you put your policy, procedure, project or service into practice?

This is a revised equality impact assessment on an existing policy already in practice.

Step 2 – Collecting your information

What existing information / data do you have?

Complete policy document.

Step 2 – Collecting your information continued… 3

Using your existing data what does it tell you?

Policy complete

Step 3 – What is the impact

Is there an impact on some groups in the community? (think about race, disability, age, gender, religion or belief, sexual orientation and other socially excluded communities or groups)

Ethnicity or race

No impact identified

Gender and transgender

No impact identified

Age

No impact identified

Disability

No impact identified

Step 3 – What is the impact continued… 4

Religion or belief

No impact identified

Sexual Orientation

No impact identified

Marriage and Civil Partnership

No impact identified

Pregnancy and Maternity

No impact identified

Gender Reassignment

No impact identified

Other socially excluded groups or communities e.g. rural community, socially excluded, carers, areas of deprivation, low literacy skills

No impact identified

Step 4 – What are the differences?

Are any groups affected in a different way to others as a result of the policy, procedure, project or service?

None identified

Does your policy, procedure, project or service either directly or indirectly discriminate?

Yes [ ] **No** [X]

If yes how are you going to change this?

Step 5 – You're almost there – now you need to consult!

Who have you consulted with?

Consultation with a range of community staff service managers, Palliative care consultant, Pharmacy

If you have not consulted yet please list who you are going to consult with

NA

How are you going to consult with specific groups or communities?

Consultation took place during policy development prior to policy approval

Step 6 – Make a decision based on steps 2 - 5

If *you are* in a position to change or introduce the policy, procedure, project or service clearly show how it was decided on

Through consultation with staff, professional groups and review through and Clinical Policy Steering Group

What are the main effects and benefits?

The standardisation of practice to promote safety and quality of service in medicines management practices.

If *you are* in a position to introduce the policy, procedure, project or service but still have information to collect or actions to complete to ensure all equality groups have been covered please list

All information complete in approved policy

Step 6 – Make a decision based on steps 2 – 5 continued … 6

If *you are not* in a position to introduce the policy, procedure, project or service what action are you going to take?

NA

How are you going to monitor this policy, procedure, project or service, how often and who will be responsible?

This policy will be audited in line with organisational requirements and will be reviewed in three years.

Step 7 – Congratulations you've made it! Now publish your results

Once completed this EIA should be signed and forwarded to Jillian Wilkins, Equality and Diversity Lead. jillian.wilkins@cddft.nhs.uk.

Please ensure that this assessment is attached to the policy document to which it relates.

This EIA has been completed by:	Suzanne Vickers, Heather Parkin, Calum Polwart
Approving Director/ Ass Director:	Sharon Morgan

Date:	Nov 2016	**Contact number:**	