PREVENTING HARM FROM MEDICATION LOADING DOSES POLICY

Policy Type	Clinical
Directorate	Acute
Policy Owner	Chief Operating Officer Acute and Ambulance
Policy Author	Senior Pharmacist, Medicines Safety
Next Author Review Date	1st June 2023
Approving Body	Policy Management Sub-Committee 15th November 2019
Version No.	3.0
Policy Valid from date	1st November 2019
Policy Valid to date:	30th November 2023

'During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Advisory Group and where necessary other relevant Oversight Groups'

DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

Date of Issue	Version No.	Date Approved	Director Responsible for Change	Nature of Change	Ratification / Approval
14 Jun 13	0.1		Executive Medical Director	New Policy	Senior Lead Pharmacist meeting
05 Jul 13	0.1		Executive Medical Director	Approved at	Clinical Standards Group
25 Jul 13	0.1		Executive Medical Director	Approved at	Acute Quality & Risk
30 Jul 13	0.1		Executive Medical Director	Approved with changes to version control (p2), 9.3 change to Trust Executive Committee & Clinical Lead Dr Mark Pugh	Policy Management Group
23 Sep 13	1.0	16 Sep 13	Executive Medical Director	Approved at	Trust Executive Committee
07 Jul 16	1.1		Executive Medical Director	Reviewed policy ratified at	Clinical Standards Group
13 Sep 16	2.0	13 Sep 16	Executive Medical Director	Approved at	Corporate Governance & Risk Sub-Committee
27 Sep 19	2.1		Medical Director	Reviewed policy endorsed at	Clinical Standards Group
15 Nov 19	3.0	15 Nov 19	Medical Director	Approved electronically via voting buttons at	Policy Management Sub-Committee
29 Jan 21	3.0	15 Nov 19	Chief Operating Officer Acute & Ambulance	12 month blanket policy extension due to covid 19 applied with author review date set 6 months prior to Valid to Date.	Quality & Performance Committee
19 May 2021	3.0	15 Nov 19	Chief Operating Officer Acute & Ambulance	Extended policy uploaded and linked back with new cover sheet	Corporate Governance

NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust

Contents

1 Executive Summary

This policy has been developed in response to the National Patient Safety Agency (NPSA) Rapid Response Alert (NPSA/2010/RRR018) issued in November 2010 to prevent fatalities from medication loading doses. The document highlights those medicines considered to be 'critical medicines' although this is not an exhaustive list, and advises on how the medicines should be managed when prescribing, administering and monitoring.

The recommendations in the Rapid Response Report (RRR018) relate to all healthcare sectors and specialties and to patients of all ages, including children and neonates. Although issued in 2010, managing the loading doses for critical medicines is still a high risk area today.

Therefore, the purpose of this document is to ensure that loading doses for the 'critical medicines' listed in this policy are prescribed, administered and monitored safely by all staff involved in any stage of the medicine administration process.

2 Introduction

A loading dose is an initial larger dose of a medicine administered orally or intravenously to ensure a more rapid therapeutic response. It is usually given for a short period before therapy continues with a lower maintenance dose. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

Depending on the medication type, a single loading dose or a series of loading doses over several days may be required. The maintenance dose is then administered over the medium to long term to maintain effective levels of medication in the body tissues and fluids.

The need for both loading and maintenance doses creates complexity in prescribing, dispensing, administration and monitoring of medication and this complexity can increase the likelihood of human error.

Errors can lead to **over-medication** (where levels of the medication can build to excessive levels with toxic effects) or to **under-medication** (where harm can result from failure to effectively treat the patient's illness).

Between 1 January 2005 and 30 April 2010 there were 1,165 patient safety incidents related to loading doses reported to the National Reporting and Learning System (NRLS). Of these incidents, two were fatal, four caused severe harm and 102 caused moderate harm. A further fatality was reported by coroner's letter. The fatal and severe harm incidents all related to incorrect

loading doses; omitted or delayed administration of loading doses, or unintentional continuation of loading doses [1].

These errors relating to loading doses can be divided into a number of categories [2].-

- Incorrect loading dose prescribed or administered (41%)
- Omitted or delayed administration of loading dose (24%)
- Communication and documentation of loading dose and/or maintenance dose (9%)
- Maintenance dose prescribed / administered at an incorrect time (8%)
- Loading dose repeated in error (7%)
- Loading dose continued for maintenance without dose change (4%)
- Maintenance dose not prescribed / administered after loading dose (2%)
- Loading dose given but not required (2%)
- Administration rate of maintenance dose delivered as per loading dose (2%)

Further to these incidents, in November 2016 the NRLS issued a patient safety alert related to the risk of death and severe harm from error with injectable phenytoin[3] due to 2,200 incidents reported, including 2 deaths, 5 severe and 121 moderate harm incidents during 2014-2016. A review of these incidents identified 'Loading dose continued for maintenance without dose change' as one of the themes causing the reported incidents.

3 Definitions

BMJ	British Medical Journal
BNF	British National Formulary
BNFC	British National Formulary for Children
CPPE	Centre for Postgraduate Pharmacy Education
EPMA	Electronic Prescribing and Medicines Administration
JAC	Medicines management system
MHRA	Medicines & Healthcare Products Regulatory Agency
NRLS	National Reporting and Learning System
PODs	Patients Own Medicines
RRR	Rapid Response Report
SPC	Specific Product Characteristics

4 Scope

This document applies to all Trust employed staff involved in the prescribing, administration and monitoring of medicines used for loading doses and subsequent maintenance dose regimens.

5 Purpose

The purpose of this document is to ensure that loading doses are prescribed, administered and monitored safely by **all** staff involved in any stage of the medicine administration process.

6 Roles and Responsibilities

The **Chief Pharmacist** responsible for ensuring that all doctors, nurses and pharmacy staff are aware of the risks associated with loading doses

The **Pharmacy Education & Training Lead Pharmacist** is responsible for the delivery of training about the risks associated with loading doses.

All **Doctors or Non-Medical Prescribers** are responsible for prescribing and monitoring 'critical' medicines (see Appendix 1) which are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed correctly and in a safe and effective manner.

All **Nursing Staff** are responsible for administering 'critical' medicines (see Appendix 1) which are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed correctly in a safe and effective manner.

All **Pharmacists** are responsible for clinically screening and monitoring 'critical' medicines which are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed correctly in a safe and effective manner.

7 Policy detail/Course of Action

7.1 Communication

Before prescribing, all of the patient's medicines prior to and during their admission should be reviewed, the prescriber should be aware that the patient may already be taking one of these 'critical' medicines orally as part of their regular treatment. This should be a consideration when deciding on the loading dose required.

It should be noted that loading doses may depend on the pathology of the patient and concomitant medication, see 7.3 for prescribing information links.

Should a patient require a loading dose and subsequent maintenance dose of one of the critical medicines mentioned in this document, the prescriber must clearly document details of the loading regimen including dose, duration of treatment and when the maintenance regimen should begin, in the patient's medical notes. Details of required plasma medicine monitoring, biochemical tests and other patient monitoring should also be clearly stated and results recorded.

The approved name of the medicine, loading dose and duration of treatment must be clearly prescribed on the appropriate patient's prescription record.

Details of the patients loading regimen and maintenance regimen should also be documented and discussed at each nursing handover.

Written information concerning loading doses and subsequent maintenance doses, monitoring details and relevant results must be transferred **with the patient** to tertiary care centres, secondary care, and primary care settings e.g. include this information in the patient's discharge summary.

7.2 Critical Medicines

Medicines requiring a loading regimen and subsequent maintenance regimen used within the Trust have been risk assessed and a 'Loading Dose Critical Medicines' list compiled. This list contains those medicines considered to fit the definition of critical medicines which are likely to cause harm if loading doses and subsequent maintenance doses are not prescribed, administered and monitored correctly. This is **not** an exhaustive list and will be under constant review (see Appendix 1).

7.3 Prescribing Critical Medicines which require loading and subsequent maintenance regimens

When prescribing a medicine listed in this policy as a 'Critical Medicine' which requires a loading regimen and subsequent maintenance regimen, the prescriber should consult the following information resources to ensure safe and effective treatment:

For Prescribing Information

Summary of Product Characteristics http://www.medicines.org.uk/emc/
Current British National Formulary https://bnf.nice.org.uk/
Current British National Formulary for Children
https://www.medicinescomplete.com/mc/bnfc/current/

For Administering Intravenous Medicines Information

Medusa Injectable Medicines Guide
http://medusa.wales.nhs.uk/?ID=d35b35c8fe4ec8a03486cced2a2680fe700

Summary of Product Characteristics http://www.medicines.org.uk/emc/

Current University College London Hospitals NHS Foundation Trust Injectable Medicines Administration Guide, available on each ward within the St Mary's Hospital NHS Trust.

For Therapeutic Medicine Monitoring Information

Current Medical Handbook St Marys NHS Isle of Wight

NHS Isle of Wight Pathology User Handbook
http://intranet.iow.nhs.uk/Home/Clinical-Support-Cancer-and-Diagnostics/Pathology/Cellular-Pathology

Summary of Product Characteristics http://www.medicines.org.uk/emc/
Current British National Formulary https://bnf.nice.org.uk/
Current British National Formulary for Children
https://www.medicinescomplete.com/mc/bnfc/current/

Information regarding prescribing, administration and therapeutic medicine monitoring is also available by contacting the **Ward Pharmacist** and the **Southampton Medicines Advice service http://intranet.iow.nhs.uk/Medicines-Information** .

8 Consultation

The loading doses policy has been prepared in response to the NPSA Rapid Response Alert (NPSA/2010/RRR018) to prevent fatalities from medication loading doses following consultation with senior medical and nursing staff

9 Training

This Policy for Preventing Harm from Medication Loading Doses does not have a mandatory training requirement but the following non mandatory training is recommended:-

Trust E-Learning Systems
Medicines management Clinical Medicines Scenarios
Medicines Management Maths & Medicines calculations assessment

Other useful online training:

Pharmacovigilance learning module	www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/pharmacovigilancelearningmodule/index.htm
Adverse medicine reactions (CPPE) (Pharmacist/Technician registration required)	https://www.cppe.ac.uk/programmes/l/adr1-e-01/
Numeracy skills for medicine calculations	www.qub.ac.uk/elearning/public/NumeracySkillsforMedicineCalculations/Year1GenericSkillsTest/
Dosage calculations tutorial for nurses	www.dosagehelp.com/

1. Prescribing legally and ethically e-learning. 2. Prescribing safely and accountably e-learning. (Pharmacist/Technician registration required)	www.cppe.ac.uk/learning/Details.asp?TemplateID=Non-Med-D-02&Format=D&ID=82&EventID=40251 www.cppe.ac.uk/learning/Details.asp?TemplateID=Non-Med3-D-02&Format=D&ID=82&EventID=40253

10 Monitoring Compliance and Effectiveness

This policy should be adhered to by all Trust staff involved with the prescribing, administering and monitoring of the critical medicines used for loading doses mentioned in this policy. Compliance to the policy will be reviewed by all Pharmacy Teams during regular ward visits using EPMA. Interventions, incidents and adverse events reported through Datix, the Trust electronic incident reporting system, will be reviewed and reported monthly at the Pharmacy Risk Meeting and any persistent issues reported to the relevant Trust Clinical Business Unit and Safety Experience and Clinical Effectiveness (SEE) Committee by the Chief Pharmacist or Medicines Safety Officer.

11 Links to other Organisational Documents

Medicines policy

Rapid Response Report NPSA/2010/018 Preventing fatalities from medication loading doses. Available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=92305

For preventing and reporting adverse events regarding critical medicines see appendix 3

12 References

[1] Rapid Response Report NPSA/2010/018 Preventing fatalities from medication loading doses. Available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=92305 [accessed 23rd September 2011]

[2] Rapid Response Report NPSA/2010/018 Preventing fatalities from medication loading doses. Supporting Information. Available at http://www.nrls.npsa.nhs.uk/alerts/?entryid45=92305 [accessed 23rd September 2011]

[3] Patient Safety Alert NHS/PSA/W/2016/010 Risk of death and severe harm from error with injectable phenytoin 9 November 2016. Available at https://improvement.nhs.uk/documents/496/Patient_Safety_Alert_-_Risk_of_error_with_injectable_phenytoin_v2.pdf accessed 7/9/19.

13 Appendices

Appendix 1 Loading Dose Critical Medicines

Appendix 2 Check high doses of unfamiliar and critical medicines

Appendix 3 Preventing Adverse Events

Appendix 4 Financial and Resourcing Impact Assessment on Policy Implementation

Appendix 5 Equality Impact Assessment (EIA) Screening Tool

Appendix 1

Loading Dose Critical Medicines

For the purpose of this policy concerning loading doses, the following medicines should be considered as '**Critical Medicines'**

- Aminophylline
- Amiodarone
- Digoxin
- Phenytoin
- Warfarin

Other medicines which require special consideration:

- Magnesium sulphate in the management of pre-eclampsia
- Paracetamol in paediatrics
  - Adalimumab, certolizumab,ustekinumab, dupilumab, secukinumab, guselkumab, infliximab
- Teicoplainin, tigecycline, caspofungin, amphotericin, voriconazole, vancomycin, gentamicin
- Azathioprine and ciclosporin for immunosuppression
- Leflunomide
- Flecanide, lidocaine, esmolol, hydralazine
- Dexamethasone for spinal cord compression
- Alteplase

This is **not** an exhaustive list and will be under constant review.

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Check high doses of unfamiliar and critical medicines

When administering medicines that are unfamiliar, you have a duty of care to ensure that the dose is correct. Loading or stat doses can be particularly critical. If you are in any doubt please check with the prescribing doctor or clinical pharmacist (call the duty pharmacist if necessary). This includes when using a patients own medicines (PODs) for administration.

For Example (This is not an exhaustive list).

- Doses of **digoxin** greater than **250microgram** daily in adults and greater than 125microgram in people over 70 years of age should rarely be seen.
- **Amiodarone** doses higher than **200mg** daily should be queried (the maximum licensed dose for maintenance is 200mg).
- **Phenytoin** doses greater than **500mg** daily should also be very unusual, although there may be wide inter-patient variability in phenytoin serum levels with equivalent dosage, so a wide range of doses is used.
- **Warfarin** doses may vary considerably between patients. It is advised that any newly initiated therapy at doses **greater than 5mg** should be considered abnormal.
- Doses of **prednisolone** over **40mg** would be unusual and high doses for **more than 5 days** should always be double checked.
- **Azathioprine** is rarely seen in doses over **150mg / day**
- **Leflunomide** is loaded at 100mg /day for 3 days. After this period it should **not be seen in doses over 20mg /day**.
- **Aspirin** would not normally be given long term at doses over **75mg/day.**

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PREVENTING ADVERSE EVENTS

The following critical medicines* need careful prescribing, administering and monitoring

Warfarin	**Gentamicin**
Aminophylline	**Amiodarone**
Phenytoin	**Carbamazepine**
Digoxin	**Teicoplanin**

*This is not an exhaustive list

Double check high doses of unfamiliar and critical medicines

When **administering** medicines that you are unfamiliar with, you have a duty of care to ensure that the dose is correct. Loading or stat doses can be particularly critical.

If you are in any doubt please check with the prescribing doctor or clinical pharmacist (call the on-call pharmacist if necessary). This includes when using a patient's own medicines (PODs) for administration.

Patients taking the above medicines often require blood tests to prevent harm and ensure effective treatment.

REPORTING AN ADVERSE EVENT

The following medicines are often prescribed in response to an adverse medicine event:

Beriplex	**Vitamin K**
Naloxone	**Flumazenil**
Dextrose/Insulin	**Calcium Resonium**
Calcium Gluconate	**Glucagon**
Hydrocortisone IV	**Chlorphenamine**
Topical steroid	**Hydroxyzine**
Digoxin antibody (Digifab)	**Danaparoid**
Omeprazole IV	**Gelofusine**
Idarucizumab (Praxbind)	

When any of these medicines are prescribed and administered please consider whether an adverse event has occurred and report to Pharmacy via the online Datix Incident Management System.

Adverse medicine reactions should also be reported to the MHRA via the Yellow Card Scheme (see latest BNF or Pharmacist for advice)
www.mhra.gov.uk/yellowcard

Appendix 4

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

Document title	**Policy for preventing harm from medication loading doses**

Totals	**WTE**	**Recurring £**	**Non Recurring £**
Manpower Costs	**0**		
Training Staff	**0**		
Equipment & Provision of resources	**0**		

Summary of Impact:
Nil

Risk Management Issues:

Improves patient safety with regard to prescribing, administering and monitoring medicines requiring loading doses.

Benefits / Savings to the organisation:
Savings in preventing potential litigation costs/extra bed days

Equality Impact Assessment

- Has this been appropriately carried out? YES
- Are there any reported equality issues? NO

If "YES" please specify:

Use additional sheets if necessary.

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

Manpower	**WTE**	**Recurring £**	**Non-Recurring £**

Operational running costs	0	0	0
Totals:	0	0	0

Staff Training Impact	**Recurring £**	**Non-Recurring £**
	0	0
Totals:	0	0

Equipment and Provision of Resources	**Recurring £ ***	**Non-Recurring £ ***
Accommodation / facilities needed	0	0
Building alterations (extensions/new)	**0**	**0**
IT Hardware / software / licences	**0**	**0**
Medical equipment	**0**	**0**
Stationery / publicity	**0**	**0**
Travel costs	**0**	**0**
Utilities e.g. telephones	**0**	**0**
Process change	**0**	**0**
Rolling replacement of equipment	**0**	**0**
Equipment maintenance	**0**	**0**
Marketing – booklets/posters/handouts, etc	**0**	**0**
Totals:	**0**	**0**

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:	**0**
Signature & date of financial accountant:	
Funding / costs have been agreed and are in place:	
Signature of appropriate Executive or Associate Director:	

Appendix 5

Equality Impact Assessment (EIA) Screening Tool

Document Title:	**Policy for preventing harm from medication loading doses**
Purpose of document	Improving the safety of clinical care for patients requiring medicines to be loaded and subsequent maintenance doses prescribed, administered and monitored.
Target Audience	Trust staff involved with Prescribing, dispensing, administering and monitoring loading doses of critical medicines.
Person or Committee undertaken the Equality Impact Assessment	Zoe Wells

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

All patients will benefit equally from improved safety around the prescribing, dispensing, administering and monitoring of loading doses of critical medicines and the subsequent maintenance dose regimen. There are no potential discriminating factors associated with this policy.

		Positive Impact	Negative Impact	Reasons
Gender	Men	*x*		
	Women	*x*		
Race	Asian or Asian British People	*x*		
	Black or Black British People	*x*		
	Chinese people	*x*		

	People of Mixed Race	*x*		
	White people (including Irish people)	*x*		
	People with Physical Disabilities, Learning Disabilities or Mental Health Issues	*x*		
Sexual Orientation	Transgender	*x*		
	Lesbian, Gay men and bisexual	*x*		
Age	Children	*x*		
	Older People (60+)	*x*		
	Younger People (17 to 25 yrs)	*x*		
Faith Group		*x*		
Pregnancy & Maternity		*x*		
Equal Opportunities and/or improved relations		*x*		

Notes:

Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact:			
		YES	**NO**
Legal (it is not discriminatory under anti-discriminatory law)			
Intended			

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:	
n/a	
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:	
n/a	
3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?	
n/a	
Scheduled for Full Impact Assessment	Date: 8/7/16 reviewed 10/9/2019
Name of persons/group completing the full assessment.	Zoe Wells
Date Initial Screening completed	