Training Programme for Clinical Scientists and Clinical Physiologists administering melatonin to Children for Sleep Studies

This protocol does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

INTRODUCTION

Melatonin is a natural hormone that is secreted by the pineal gland in the brain. The circadian rhythm for the release of melatonin is closely synchronised with the habitual hours of sleep. In humans, melatonin secretion increases soon after the onset of darkness and peaks in the middle of the night, gradually falling off in the second half of the night. This effect on sleep patterns has led to melatonin being recognised as a regulator of sleep cycles. It is this property that has led to the use of melatonin in the clinical environment

THIS PROTOCOL IS FOR USE BY THE FOLLOWING STAFF GROUPS :

Lead Clinician(s)

Kelly Bill	Clinical Scientist
Cheryl Bird	Specialist Epilepsy Nurse
Dr Sarah Green	Consultant Neurophysiologist
Alison Smith	Lead Pharmacist Medicines Safety

Approved by Specialty Medicine Governance Meeting on:	29th October 2024
Approved by Medicines Safety Committee on: *Where medicines included in protocol*	13th November 2024
Review Date: This is the most current document and should be used until a revised version is in place	13th November 2027

Key amendments to this guideline

Date	Amendment	Approved by: (name of committee or accountable director)
April 2021	Change in lead consultant, health care science staff are now registered with HCPC.	Kelly Bill
April 2021	Medicines Policy content updated with 2020 version, addition of product details including Appendix 2 letter re unlicensed product	Alison Smith
Sep 2024	Medicines Policy content updated with 2020 version 5.2.29 Unlicensed Medicines (MedPolSOP5)	Alison Smith
October 2024	Name changed from Dr Gowda to Dr Sarah Green. Updated references	

Electroencephalograph

Electroencephalographs (EEG) are a recording of the brain's electrical activity. An activation procedure for EEGs is sleep. Sleep enhances the brains activity and increases the yield of abnormality (Binnie et al, 2002). This is especially important in children.

Current departmental policy is for all children under the age of 3 years to have a melatonin EEG. Paediatric Patients may also have a melatonin EEG if sleep is an indicator for abnormality.

The EEGs are performed by Clinical Physiologists, who are voluntary state registered with the Registration Council for Clinical Physiologists (RCCP) or Clinical Scientists, who are registered with the Health Care Professions Council (HCPC). Clinical Physiologists have undertaken a BSc in Clinical Physiology (Neurophysiology) and Clinical scientists have in addition an MSc in Clinical Science or certified equivalence.

Fully qualified Clinical Physiologists/Clinical Scientists will undertake further training and assessment and once completed satisfactorily will be deemed competent to administer melatonin to patients requiring a sleep EEG. Once the skill has been learnt and consolidated, it is the Clinical Physiologist's/Clinical Scientist's responsibility to keep this updated, and discuss any learning needs or concerns with their manager. The learning record will be added to their personal development folders.

Referrals for melatonin sleep EEGs are obtained from consultant paediatricians and the paediatric epilepsy specialist nurse. General practitioners may only refer for a melatonin sleep EEG if the child has already been referred to the paediatric epilepsy service. It is their responsibility to provide the department with a completed prescription. It is also the referring clinician's responsibility to ensure that the patient/parents understand the benefits and risks of the administration of melatonin, and that the drug is an unlicensed drug for paediatric use.

The prescription is then taken to the Children's Outpatient Department at Worcester Royal Hospital by members of the Neurophysiology department trained to administer. The melatonin is dispensed from the medicines store cupboard in the Children's Outpatient Department, checked by two qualified Clinical Physiologists/Clinical Scientists and is administered to the patient by a qualified Clinical Physiologists/Clinical Scientists trained in the administration of melatonin.

ACCOUNTABILITY

The Clinical Physiologist/Clinical Scientist is personally accountable for all actions or omissions to the Patient under civil law; to their employer under the contract of employment and Trust policies and procedures, also to the Public under criminal law.

Clinical Physiologists are not at present regulated by a professional body however they are expected to have voluntary state registration with the Registration Council for Clinical Physiologists (RCCP) and adhere to the Association of Neurophysiologists (ANS) codes of conduct. The Trust does retain vicarious liability for the actions of the Clinical Physiologist following Trust policies and procedures.

The Clinical Scientist is regulated by the HCPC and must adhere to their code of conduct.

WAHT Medicines Policy (2024 version)

The following sections of the Trust Medicines Policy are particularly relevant, *however all staff should familiarise themselves with the overall content of the Policy.*

5.2.29 Prescribing unlicensed medicines and using a licensed medicine outside of its licence "off-label" (see MedPolSOP5)

For good clinical reasons it is often necessary to prescribe a medicine which does not hold a product licence (unlicensed use) or to prescribe a medicine outside the approved marketing authorisation ("off-label" use). It is accepted that such practice continues in order to provide the best care for patients. However, it is necessary that prescribers, pharmacists and nurses are aware of the increased risk and medico-legal implications associated with the use of Unlicensed Medicines. Unlicensed medicines should only be used when there are no licensed products available and if their use can be clearly justified clinically and pharmaceutically, to meet the special needs of individual patients. It is recognised that in some specialties, such as paediatrics and palliative care, there are a significant number of medicines used in an unlicensed way, however as their use is covered in recognised texts, they fall within a lower risk category. These include Palliative Care Formulary, British National Formulary and British National Formulary for Children. MedPolSOP5 describes how Unlicensed Medicines and medicines used off-label should be used within Worcestershire Acute Hospitals NHS Trust (WAHT) and sets out the responsibilities of all involved.

5.3 ADMINISTRATION OF MEDICINES

5.3.1 Overall responsibility

5.3.1.1 The prescriber has responsibility for informing the Assigned HCP-in-Charge of a clinical area about any new prescriptions that have been written and that he/she has not administered themselves. It is that HCP's responsibility to ensure that, if necessary, the medicine is ordered from pharmacy and that there is an appropriate member of staff available to administer the medicine at the prescribed times.

5.3.1.2 The Appointed HCP-in-Charge of the clinical area has responsibility for putting documented systems in place (i.e. Trust Medicine Policy Standard Operating Procedures, Trust Nursing Procedures plus appropriate local clinical area Standard Operating Procedures) for ensuring the safe and timely administration of medicines, for ensuring that medicines are available for administration when needed so that doses are not missed, this is particularly important for time critical medicines, and for allocating trained members of staff to administer medicines (or to supervise patient self-administration of medicines) at the prescribed times.

5.3.3 Competency and accountability

5.3.3.1 The Appointed HCP-in-Charge should ensure that nurses and any other persons authorised to administer medicines are competent in all aspects of the administration of medicines relevant to their level of authorisation, for example performing calculations. The person who administers a medicine is responsible and accountable for his/her actions.

5.3.4 Authorisation to administer medicines

5.3.4.1 Any appropriately trained and authorised member of Trust staff who has been assessed as competent to do so safely may administer medicines that have been prescribed by an authorised prescriber to an individual patient. The medicines may only be administered to that named patient. This principle applies to Trust staff at all levels.

5.3.4.3 The Medicines Safety Committee must approve the training and competency assessment procedure for each staff group. Training and assessment must be led by registered health-care

professionals who are themselves authorised to administer medicines and must be under the control of a Trust Lead Health-care Professional e.g. Chief Nursing Officer. Training and assessment records must be maintained together with a Trust register of persons authorised to administer medicines and the extent of this authorisation (that is which medicines and by which route of administration).

5.3.5 Administration procedures

5.3.5.1 Standard operating procedures (SOPs) must be in place for each staff group and/or clinical area describing a safe system for administering medicines which is designed to minimise the risk of errors and adverse incidents. For example, MedPolSOP20, 21 and 22 describe procedures for the administration of medicines on wards for adults, children and neonates. Suspected adverse drug reactions must be reported as patient safety incidents and following MedPolSOP15 'Reporting Adverse Drug Reactions'
5.3.5.2 The Appointed HCP-in-Charge of a clinical area is responsible for ensuring these SOPs are in place and that medicines are only administered by staff who have been appropriately trained, can demonstrate their competence, and have been authorised by the Trust to administer medicines.
5.3.5.3 Before administering any medicines the administering practitioner must check the allergy status of the patient and if in any doubt check in the patient notes and/or with the prescriber before continuing. Except in a life-threatening emergency, medicines must not be administered to a patient until their allergy status has been confirmed.

5.3.7 Checking of administration
Checking of administration by a second person who is also authorised to administer the medicine, or who is a pharmacist, is required when the medicine is to be:
- administered to a child under 12 years of age

5.3.11 Principles for the administration of medicines

5.3.11.1 Administration must only be according to a clearly written and unambiguous prescription (see also verbal orders, Patient Group Directions and Trust Protocols).
5.3.11.2 Any authorised person administering a medicine to a patient or checking the administration must be satisfied that she or he knows the therapeutic uses of the medicine, its normal dosage, side effects, precautions and contra-indications.
5.3.11.3 Medicines must be prepared at the time they are required, MEDICINES MUST NOT BE PREPARED IN ADVANCE OF ADMINISTRATION except antibiotic syrups or when it is done by pharmacy staff or when authorised by the Trust's Medicines Safety Committee.
5.3.11.4 For medicines being prepared to administer to patients with swallowing difficulties or via NG/PEG, see Trust NG and PEG Guidelines. The route of administration on the prescription must reflect the route of administration, as dispersing or crushing may render the medicine unlicensed.
5.3.11.5 Before administering a medicine, the person doing so and the checker if there is one must check:

- The identity of the patient, according to Trust Policy to identify all patients (including the use of standardised identity bands) WAHT-CG-019
- That the prescription meets the requirements of the Medicines Policy and the medicine is safe to administer.
- That the due dose has not already been given.
- The expiry date of the medicine has not passed (where a medicine has a 'once opened' expiry date this should be marked on the container)
- The patient is not allergic to the medicine.

5.3.11.6 Except in a life-threatening emergency, the patient's allergy status must be stated on the drug chart before any medicines are administered. If this is missing from the drug chart but a current record is in the patients' notes the nurse or midwife can copy this across signing and dating the entry on the drug chart. If there is no current record that can be transcribed, the nurse must confirm with the prescribing team before they administer any medicines. Wherever possible, the pharmacy team will support the process by ensuring allergy status is confirmed.
5.3.11.7 Ensure that the correct drug in the correct dose is given to the correct person at the correct time by the correct route and that the patient actually takes the medicine.

5.3.12 Doubts
5.3.12.1 If there is any doubt about the content or clarity of a prescription (or instruction to administer a medicine) the nurse or other person authorised to administer must contact the prescriber or his or her deputy before proceeding to administer the medicine. If there is still uncertainty a pharmacist must be contacted (including the on-call pharmacist outside pharmacy working hours). Unresolved uncertainty must be referred to the medical consultant responsible for the patient, without delay.

End of Medicines Policy content

Informed consent:

The Clinical Physiologist/Clinical Scientist will gain consent as per Hospital Policy and Department of Health guidelines on seeking consent and working with children. The rights and wishes of the child should be considered in line with the age of the child and their level of understanding.
It is Departmental and Trust policy to gain informed consent from all patients who require any clinical procedure performed within the ward areas or various departments
(WAHT-CG-075 Consent to Examination or Treatment); this consent should be documented within the Neurophysiology Report.

Patient participation:

The patient, parent or carer will be encouraged to ask questions and full explanations should be given. In the event of a Clinical Physiologist/Clinical Scientist being unable to answer the questions they will be referred to the referring clinician who will be able to address the patient's concerns or queries.

Administration Procedure

Melatonin Sleep EEG

A request form is received from the referring doctor or specialist epilepsy nurse stating that a Melatonin sleep EEG is required. A prescription is received stating the amount of Melatonin to be administered. The product used is an unlicensed oral sugar free 1mg/ml solution

Under 5 yrs - 4mg/4ml
5 years or over - 8mg/8ml

(NB There is a licensed product on the market, but this is not licensed for or suitable for use in children see Appendix 2).

The melatonin should be given 20 minutes before the investigation.

Administration of Melatonin

1. Two members of staff should dispense the melatonin. Both members must have had the necessary training and their signatures registered in the Melatonin record document, kept by the Neurophysiology Department manager.
2. The patient's date of birth, name and address should be checked against both the prescription and request form.
3. Melatonin in liquid form is stored in the medicines cupboard in the clean utility room in the children's outpatient. The controlled drugs record book should be completed appropriately and signed by both members of staff.
4. Check the dose against the prescription.
5. If administration by feeding tube is necessary the parent should be asked to administer (or contact the children's unit for a nurse to do so).
6. Perform a sleep recording EEG following the Departmental protocol.
7. Ensure the patient is fully awake and alert before leaving the department.

Appendix 1 Worcestershire Acute Hospitals NHS Trust
Performance Assessment criteria for Clinical Scientist/Physiologists to administer melatonin

	1 Simulation	2 Practical observation	Comments
1. Clinician understands reason melatonin is being given and can explain this in simple terms to child and /or parent carer			
2. Clinician understands legal and ethical aspects of administration of medicines to children including informed consent			
3. Clinician understands pharmacokinetics and pharmacodynamics of melatonin and can identify potential adverse effects, and communicates this effectively to child and family/carer			
4. Clinician assesses and identifies any contraindications for administration of melatonin to each individual child e.g. allergy, drug interaction			
5. Clinician appropriately identifies child to whom melatonin is to be administered according to hospital medicines policy			
6. Melatonin is safely administered to correct child at correct time via oral route. If administration by feeding tube is necessary the parent should be asked to administer (or contact the children's unit for a nurse to do so)			
7. Clinician observes child appropriately following administration of melatonin			
8 Clinician ensures child and family safe to leave department following procedure			
9. Clinician appropriately documents all of above			
10. Clinician fully understands procedure and only administers melatonin according to the prescription and the procedure.			
11. Clinician demonstrates understanding of own accountability and responsibility when administering melatonin via procedure			
Clinical Skills Facilitator (please print)……. Signature…….Date…….. Clinical Scientist/Physiologist…… Date……			

DEPARTMENT OF PAEDIATRICS

Dr Andrew Gallagher
Consultant Paediatrician

Secretary: *Mrs Erica Brotherton*
Direct Line: *01905 760662*
Fax Number: *01905 760584*
Email: *Erica.Brotherton@nhs.net*

rshire Royal Hospital
Charles
Hastings Way
Newtown Road
Worcester
WR5 1DD

Our Ref: ACG/ELB

8 August 2019

Sarah Scott
Pharmacist
Pharmacy
Level 1
WRH

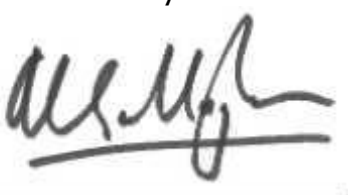
Dear Sarah

In keeping with our colleagues at Birmingham Children's Hospital, the Paediatric Department would like you to continue to supply the unlicensed product, **Melatonin Sugar Free Oral Liquid 1mg/ml** which is currently sourced from UL MEDS. We are aware that there is now a licensed liquid Melatonin preparation produced by Colonis. This is only licenced for adults with jetlag. The excipients contained within this liquid preparation, in particular the amount of Propylene Glycol is excessive and the maximum daily dose of Propylene Glycol could easily be exceeded, particularly in children with a lower body mass.

Please continue to supply the unlicensed product from UL MEDS, that we have been using for a number of years, to the paediatric population.

With best wishes.

Yours sincerely



Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.

REFERENCES

Binnie et al, *Arch Neurol.* 2002; 59: 1235-1239.

British National Formulary

Department of Health, www.dh.gov.uk/PolicyAndGuidance/fs/en

Training pack on melatonin administration, Birmingham Children's Hospital, Neurophysiology department 2005

The College of Pharmacy Practice 'Time capsule'
Chemist and Druggist Aug 1997

Worcestershire Acute Hospitals Trust Medicines Policy

MTRAC Summary sheet for Melatonin for the treatment of paediatric sleep disorders SS99/08

Int J Environ Res Public Health. 2023 Jan; 20(1): 552.
Published online 2022 Dec 29.

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Children's Outpatients
Epilepsy Nurse
Consultant Neurologist

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Specialty Medicine DMB
Medicines Safety Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	#	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Kelly Bill**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Kelly Bill	**Clinical Service Manager**	**k.bill@nhs.net**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Melatonin policy for Neurophysiology**			
What is the aim, purpose and/or intended outcomes of this Activity?	Administer melatonin for EEG recordings			
Who will be affected by the development & implementation of this activity?	❑ ❑# ❑ ❑	Service User Patient Carers Visitors	❑ ❑ ❑ ❑	Staff Communities Other _____

Is this:	❑# Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	Use of any previous Datix incidents – none
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Engagement with Neurophysiology staff and paediatric departments.
Summary of relevant findings	N/A

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		#		
Disability		#		
Gender Reassignment		#		
Marriage & Civil Partnerships		#		
Pregnancy & Maternity		#		
Race including Traveling Communities		#		
Religion & Belief		#		
Sex		#		
Sexual Orientation		#		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		#		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		#		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Kelly Bill
Date signed	25/11/2024
Comments:	
Signature of person the Leader Person for this activity	Kelly Bill
Date signed	25/11/2024
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval