Trust Policy

Plymouth Hospitals NHS
NHS Trust

Policy for the Administration of Melatonin to Children for Sleep EEGs in the Neurophysiology Department

Issue Date	Review Date	Version
May 2017	May 2022	V.1

Purpose

To define the procedure and responsibilities of staff who request and perform sleep EEGs that are performed in the EEG department.

Who should read this document?

Consultant neurophysiologists, clinical physiologists, paediatric medical staff, pharmacy, epilepsy specialist nurses.

Key Messages

To improve the procedure for performing sleep EEGs using melatonin for patients by performing them in the neurophysiology department where the environment is more suitable. Additionally, the flow and number of patients can be increased by the department having control of the booking of these patients.

Core accountabilities	
Owner	Nicola Broomfield
Review	MAUC/ Paediatrics
Ratification	Director of Pharmacy – Simon Mynes
Dissemination	Neil Bloxham
Compliance	Neil Bloxham

Links to other policies and procedures

- The Medicines Management and Standard Procedures (2016)
- Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines (2013)
- Policy for the Self Administration of Medicines by patients (Adult and Paediatric (2013)
- Consent to Examination or Treatment (2016)

Version History

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents on StaffNET. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 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 despite it being an unlicensed medication.

Electroencephalographs (EEGs) are a recording of the brain's electrical activity. An activation procedure for EEGs is sleep. Sleep enhances the brain's activity and increases the yield for abnormality (Binnie *et al*. 2003). This is especially important in children (Panayiotopolous, 2005). The usefulness of Melatonin in gaining sleep has been recognised by the scientific and medical professional bodies and is recommended in this context (appendix 1).

2 Purpose

This training programme will ensure that fully qualified Clinical Physiologists will be competent to administer melatonin to patients requiring a sleep EEG. Once the skill has been learnt and consolidated, it is the Clinical Physiologist'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.

The rationale for changing the current procedure is driven by a desire to improve services and outcomes for patients. The current protocol is proving insufficient in terms of the environment, which often does not allow patients to sleep (due to excessive external noise from within the CYPOD), and waiting times. By moving the procedure to the Neurophysiology department, external noises and logistical factors can be better controlled to promote sleep. Additionally, an increase inpatient through-put will be achieved as currently only one patient per week can be accommodated on CYPOD.

3 Definitions

Electroencephalograms (EEGs) are recordings of brain activity, it is a painless and non-invasive procedure.

4 Duties

EEGs are performed by Clinical Physiologists, who are voluntary state registered with the Registration Council for Clinical Physiologists (RCCP). Clinical Physiologists undertake a four year BSc in Clinical Physiology (Neurophysiology) or equivalent and have to pass two professional competency examinations before they are fully qualified. Pharmacology, Biology, Pathology, Physics and Medical Instrumentation are some of the subjects covered. Additionally, there is one Clinical Scientist who has attained state registration with the Health and Care Professions Council (HCPC) following additional Masters qualification.

Sleep EEG in children are requested by Consultant Paediatricians from PHNT as well as the Community Trust who are responsible for ensuring the referral is appropriate and informing the patient, parent and carers of the planned investigation.

5 Policy for the Administration of Melatonin to Children for Sleep EEGs in the Neurophysiology Department

Current departmental policy is for all children requiring a sleep EEG to have a melatonin induced sleep EEG on the Children's and Young Persons Outpatient Department (CYPOD). This is at the request of Consultant Paediatricians who ultimately assess the need, indication and potential risks for the patient. The request is further triaged by senior clinical physiologists when the referral is received by the department.

Referrals for melatonin sleep EEGs are obtained from Paediatric Consultants. 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 referral form will act as the prescription (appendix 2), and should be preferably printed, signed and returned by internal post or hand to the Neurophysiology department. If this is not completed correctly, the department reserves the right to return the form for completion or to ask that the Consultant Neurophysiologist triage and sign the prescription.

The families or carers of children waiting for an appointment for the test are contacted by a Clinical Physiologist/Scientist to discuss and plan the appointment making any adjustments wherever practically possible. The essence of this conversation is to ascertain whether the child will tolerate electrode application while awake (after the melatonin has been given and the child is getting drowsy) or if the child will have to be asleep before electrode application can begin. This

will vary between each child and liaison with the parent is important. As well as this telephone conversation, full details will be sent with the appointment letter.

On the day of the appointment, the prescription is taken to the Pharmacy at PHNT where the melatonin is dispensed and collected by a Neurophysiology team member.

A lockable cupboard which is in a locked room is available for storage if necessary.

Melatonin is administered to the patient by either the parent/carer or the qualified Clinical Physiologist/Scientist trained in the administration of melatonin.

All patients attending for a melatonin sleep EEG will be recorded in the departmental day book. All documents relating to the episode; referral (with prescription), consent form, and final report will be filed in the department. A copy of the report will be filed in the patient's medical notes at the end of the episode. this will also be filed in the patient's notes.

Any adverse reactions or problems will be documented in the medical notes. If there is reason to suspect that the child needs medical attention, then the paediatric on-call registrar will be paged.

Accountability

The Clinical Physiologist/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.

The clinical physiologists are not at present statutorily regulated by a professional body; however, they are registered with RCCP and are expected to adhere to its code of conduct. They are also expected to adhere to the Association of Neurophysiological Scientists (ANS) codes of conduct. The Trust does retain Vicarious Liability for the actions of the clinical physiologist following Trust policies and procedures.

Who Can Administer Medicines?

"Any suitably trained member of staff in health or social care can administer medicines that have been prescribed, by an authorised prescriber, for an individual patient. The medicines can then only be given to that named patient. This principle applies to registered and non-registered staff at all levels. However, non-registered staff cannot administer medicines using a PGD, and cannot train to prescribe medicines".

(Department of Health, Medicine Matters March, 2006)

Plymouth `Hospitals NHS Hospitals Trust (PHNT) Policies

There are a number of PHNT policies relating to the protocol, including:

- The Medicines Management and Standard Procedures (2016)
- Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines (2013)
- Policy for the Self Administration of Medicines by patients (Adult and Paediatric (2013)
- Consent to Examination or Treatment (2016)

The following sections are particularly relevant; however, all staff should familiarise themselves with the overall content of all the related policies.

Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines (2013).
The Trust's Policy for the Procurement, Prescribing, Supply and Administration of Unlicensed Medicines (2013) sets the roles and responsibilities of the Trust and staff for this group of medicines. Section 1.1.3 states that 'for good clinical reasons the use of unlicensed medicines is widespread within hospitals and the community'.

1.2.1 A clinician has the right to use any material for any purpose in the treatment of his own patients, although he does so by his own responsibility.

2.2 Prescribers must ensure that:

- they are aware of the status of the medicine
- the use of the unlicensed medicine is justified by the clinical condition of the patient.
- Informed patient consent is gained.

4. Risk Assessment. All unlicensed medicines identified for use within PHNT will be risk assessed by the QA Pharmacist using the risk assessment tool. Melatonin is already in use within the Trust and therefore this has been completed.

5.6 Use of Unlicensed/ Off Label Products in Children
5.6.3 Clinicians prescribing in accordance with the latest edition of the BNF for Children will be considered to be working in accordance with Trust policy.
5.6.4. Clinicians using unlicensed/ off label products for children should ensure patients and carers have access to the relevant information sheet. (Appendix 3).

The Medicines Management and Standard Procedures (2016)
8. Personnel Authorised to administer medicines

Appropriately trained and competent staff are authorised to administer a range of prescribed medicines to patients. The range of medicines permitted will be specific to each clinical area and will be authorised by the MUAC after a risk assessment of the requested medicine.

9. Use of Medicines/Administration of Medicines

Medicines must be administered to patients in accordance with local procedures by one of the following:

- An authorised Practitioner, as detailed in section 8, who is trained and willing to undertake the procedure.
- Administration by the parent or carer.

The identity of the patient must be performed in accordance with Trust policy. The Trust policy for administration of medicines requires a full system of full checking by a second practitioner; the preparation, labelling of the medication, the prescription and patient identification. Ultimate responsibility remains with the administering practitioner.

9.13 Verbal Orders. On their own, a verbal order to administer a medicine are not acceptable.

12.6 Staff Training. It is the responsibility of line managers to ensure that staff participating in administration of medicines, are competent to do so.

13. Errors and Adverse Events in prescribing, dispensing, administration and monitoring of medicines. The following require completion of an Untoward Incident Report in line with the 'Management of Adverse Events Policy and Incident Management SOP'.

- A prescription error is found
- A patient is given a medicine that has not been prescribed.
- A patient is given the correct medicine but at the incorrect time.
- The patient has an allergic/ anaphylactic reaction to or demonstrates unforeseen/ unpredictable sensitivity to a medicine. In these cases, the reaction should be documented:
- In the medical notes
- By completing the green allergy chapter card kept at the front of the medical notes.
- By completing a MHRA Yellow card (in the BNF) for all adverse events with the new medicines (Black Triangle in BNF) and serious or unusual reactions with other medicines.

The person identifying a medicine related incident must take immediate steps to ensure that no further harm occurs and seek advice from the Doctor in charge of

the patient's care. In this case the on call Registrar for Paediatrics will be paged.

17. Training and Monitoring of the Medicines Management Policy and Standard Procedures.

The Service Line Manager holds responsibility for the clinical area and ensuring that staff are appropriately trained and competencies are maintained. Records of such training will be filed in personnel files as appropriate.

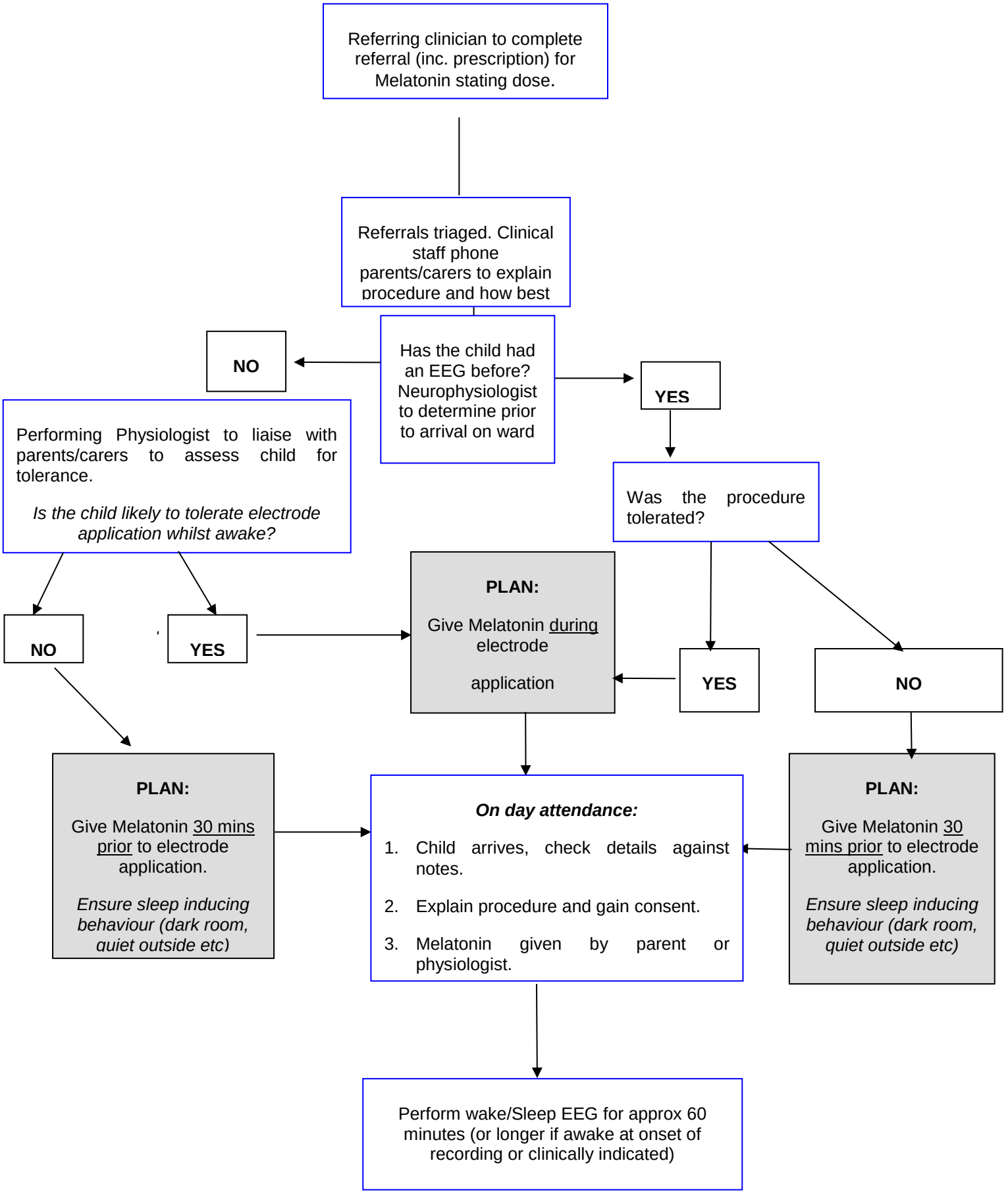
The matron for the Service Line is the nursing lead for the area.

Informed Consent:
The Clinical Physiologist/Scientist will gain consent as required by the Trust's 'Examination to Treatment, (2016)', This document states that It is not essential that written consent be gained for the use of unlicensed drugs; however, it is recommended best practice. The Trust's consent for for use in this setting is included in appendix 4, which should be filed in the patient's medical notes. Consent will be requested in the normal way with respect to the use of video recording, as all EEG equipment records synchronous video to enable clinical changes to be documented with EEG change. The relevant professional bodies Association of Neurophysiological Scientists (ANS) and British Society for Clinical Neurophysiologists (BSCN) set out further advice (appendix 5).

The rights and wishes of the child should be considered in line with the age of the child and their level of understanding.

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 being unable to answer the questions they will be referred to the referring clinician who will be able to address the patients concerns or queries.

Flow Diagram of Progress:


Referring clinician to complete referral (inc. prescription) for Melatonin stating dose.
Referrals triaged. Clinical staff phone parents/carers to explain procedure and how best
Has the child had an EEG before? Neurophysiologist to determine prior to arrival on ward
NO
YES
Performing Physiologist to liaise with parents/carers to assess child for tolerance.
Is the child likely to tolerate electrode application whilst awake?
Was the procedure tolerated?
NO
YES
PLAN:
Give Melatonin during electrode
application
YES
NO
PLAN:
Give Melatonin 30 mins prior to electrode application.
Ensure sleep inducing behaviour (dark room, quiet outside etc)
On day attendance:
1. Child arrives, check details against notes.
2. Explain procedure and gain consent.
3. Melatonin given by parent or physiologist.
PLAN:
Give Melatonin 30 mins prior to electrode application.
Ensure sleep inducing behaviour (dark room, quiet outside etc)
Perform wake/Sleep EEG for approx 60 minutes (or longer if awake at onset of recording or clinically indicated)

Training Competencies and Learning Log:

	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 Physiologist…… Date……			

Clinical Authorisation for the Training Plan and Procedure	
Lead Doctor	Name: Dr Carolyn Adcock/ Dr Gallichan Position: Consultant Paediatrician Signature: Date:
Neurophysiology Lead	Name: Nicola Broomfield Position: Clinical Scientist Signature Date:
Matron for Service Line	Name: Tim Parham Position: Matron Neuroscience Signature Date:
Lead Pharmacist	Name: Jaqueline Pope/ Peter Gray Position: Paediatric Pharmacist Signature: Date:
Clinical Educator (Paediatrics)	Name: Neil Bloxham Position: Paediatric Clinical Educator Signature: Date:
Clinical Director Neurosciences	Name: Dr Stuart Whetherby Position: Clinical Director Signature: Date:

6 Overall Responsibility for the Document

The Neurophysiology Service line manager is responsible for this document, reviewing practice and ensuring compliance.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the group or committee and ratified by the Director Non-significant amendments to this document may be made, under delegated authority from the Director, by the nominated owner. These must be ratified by the Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Sign Off

10 Appendicies

Appendix 1

ANS/BSCN Guidelines for use of Melatonin to induce sleep for paediatric EEG

Sleep EEGs can add diagnostically useful information for the identification and classification of seizures and epileptic syndromes. Natural sleep may be achieved unaided, but sleep promotion is often required: sleep deprivation and administration of Melatonin are methods commonly used, sometimes in combination.

In the 2013 National Audit Project, departments across the UK were surveyed about their current practice in performing paediatric sleep EEGs. A prospective service evaluation was performed to assess the efficacy of Sleep deprivation and Melatonin in inducing sleep and eliciting EEG abnormalities and seizures.

An unselected population of 711 patients from 51 participating Neurophysiology centres were included in the study.
The findings from the prospective study showed that sleep was achieved in 79% of all patients. Melatonin combined with sleep deprivation proved to be more effective in promoting sleep in comparison with either melatonin or sleep deprivation alone.

Sleep effectively improved diagnostic yield with unequivocally epileptiform activity not seen in the routine records of 20% of patients becoming apparent in their sleep records. There was no major difference in yield between the sleep methods used.
The following standards have been developed from the evidence obtained from this prospective study together with findings from the UK survey of current practice and other published literature.

Standard 1: Patients (parent/guardians) receive clear information about the sleep test by post
Guideline: The department liaises with parents/guardians by telephone

Standard 2: There is provision of sleep friendly premises appropriate to the age of the child/parents needs

Guideline: There is sensory soothing lighting or audio equipment to aid the sleep process
Standard 3: A minimum of 90 minutes is available for the appointment

Standard 4: Melatonin is prescribed by the referring Paediatrician or by the Consultant Neurophysiologist at the request of the referring Paediatrician

Standard 5: There is awareness of the BNF guidance when melatonin is to be used to induce sleep

Standard 6: If melatonin is to be given it is available at the time of the appointment and either stored in a locked medicine cupboard in line with local Trust policy or parents/nursing staff may bring it with them

Standard 7: Melatonin is given in the department by either a parent/guardian, a Clinical Physiologist trained to give melatonin, Nurse or other HCP

Standard 8: Melatonin is given at the start of the appointment (Usually around 20-30 minutes before the expected start of the recording)
Guideline: Up to 6mg may be given as first dose up to 5 years. Up to 12mg may be given in older children

Guideline: A second dose may be given after 45 minutes if the first is unsuccessful **Standard 9**: Protocols for dealing with seizures are in place
CP June 2015 V1.2

Appendix 2: Melatonin Sleep EEG Form

DIAGNOSTIC NEUROPHYSIOLOGY REFERRAL FORM

Melatonin Sleep EEG

Please ensure that all fields are completed, then print, sign and post this form to: EEG, Level 7, Derriford Hopsital.

Surname:
First Name:
Hospital Number:
NHS Number:

Consultant name:	
Hospital Trust:	
Telephone:	
Bleep:	
Date of decision to refer (RTT):	
Referred from:	
Referred by Letter?	☐
Referred from outpatients?	☐
Referred from Ward?	☐
Ward Name**:** Can patient attend at short notice?	☐

MELATONIN EEG	☐	***Melatonin Dose 1mg/ml*** ***Delete as applicable*** *5mg(5ml)under 5 years* *10mg(10ml) over 5yrs* *(consider 2.5mg (2.5ml)for small child under 3 years)*	**Prescriber:** **Signature:** **Date:**

GIVEN BY: **SIGNATURE:** **DATE:** **TIME:**	**CHECKED BY:** **SIGNATURE:**	**Patient/carer has been informed of: potential side effects and the unlicensed drug status ☐**
If the information provided is not correct and no dose stated/signature provided melatonin EEG will not be performed		

Date received by Diagnostic Neurophysiology Office:

CLINICAL QUESTION / REASON FOR REFERRAL

.

RELEVANT HISTORY AND INVESTIGATIONS (MRI, CT IMAGING ETC. DOES THE CHILD HAVE NG TUBE OR PEG?).

The more information you can give us; the more specific information we can give you in the report

Appendix 3. Patient Information (Unlicensed Medicines)

Patient Information Leaflet	Annex 3

Plymouth Hospitals NHS
NHS Trust

Pharmacy department

Patient Information

Unlicensed Medicines

Derriford Hospital

Derriford Road

Plymouth

PL6 8DH

0845155 8155

www.plymouthhospitals.nhs.uk

What is this leaflet about?
In the UK most medicines are "licensed" but some are not. This leaflet explains why medicines are licensed and why some useful medicines do not have licenses.

You will have been given this leaflet by your doctor or pharmacist because the medicine prescribed for you is not "licensed" or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for you and to answer any questions you may have.

Why are medicines "licensed"?
The makers of medicines must ask the government for a 'Marketing Authorisation' or 'Product Licence' if they want to sell their medicines in the UK. They show evidence to the government's Medicines and HealthCare products Regulatory Agency (MHRA) that their medicine works for the illness to be treated and does not have too many side effects or risks and has been made to a high standard.

How do the makers test medicines?
To be sure that a medicine works and is safe the maker has to try it first on a small number of people in what is called a 'Clinical Trial'. Information from clinical trials is given to the MHRA when the maker asks for 'Marketing Authorisation'.

Why don't all medicines have a licence?
There are several reasons why some medicines are used for illnesses or conditions not covered by their original licence. Also, some medicines do not have a licence at all.

Sometimes the clinical trial (and Marketing Authorisation) is for one illness but doctors find that the medicine works very well for another illness. These doctors use medicines for reasons that are not written in the Marketing Authorisation.

Some medicines have no licence at all. These may be medicines used for rare illnesses in which case it may be too expensive to have a clinical trial.

How do I know that these medicines are safe and will work?
This medicine may have been recommended by another doctor who is an expert, or your own doctor may have read information and research that says it is the best one for you. The Pharmacy Department will ensure that the medicine has been manufactured to a good standard and is of an acceptable quality.

How will I know that my medicine is not licensed?
Your doctor should tell you.

Unlicensed medicines may be made specifically or may be more difficult to obtain. Your pharmacist may tell you this and make special arrangements for you to get your medicines

Should I be worried about taking these medicines?
If you are still worried after reading this leaflet, please talk to your doctors or pharmacist. They are looking after you and have thought carefully about the best medicine for you.

What if I don't want to take unlicensed medicines?
Talk it over with your doctor and tell them what you are worried about. They can tell you more about the information or advice they have about the medicine. They can also tell you about other treatments available and why they think this is the best one.

Can I get more information about my unlicensed medicine?
Your pharmacist may have a special information leaflet about your medicine or illness. Please ask. Often there are support groups for people with a particular illness or condition. Ask your doctor, nurse or pharmacist for information.

If I am confused what should I do?
Talk to the person who gave you this leaflet (usually your doctor or pharmacist). Ask them to explain.

Further information may be obtained from:

1. Pharmacy Department, Derriford Hospital, Plymouth
2. NHS Direct (nhs.direct.nhs.uk)
3. Your GP or local pharmacy

How to obtain a further Supply of an unlicensed Medicine

If you require a further supply of an unlicensed medicine, please go to your GP to obtain a prescription. You will probably need to give the pharmacist one or two weeks to obtain the supply for you, so it is important that you do not let your supply run out before going to the GP.

Further information can also be obtained from the Pharmacy Department:

Tel 01752 439976

Appendix 4: Patient Consent form for Unlicensed Medicines

Plymouth Hospitals NHS
NHS Trust

Patient Consent Form for treatment with

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PATIENT INFORMATION

As the clinician in charge of your care, I consider that you may benefit from treatment with this product. This drug either:

. does not have a license from the UK or European medicines regulatory organisations and so is not allowed to be promoted/marketed within the UK; or (

. does have a license from the UK or European medicines regulatory organisations but it does not cover your condition and so the drug is not allowed to be promoted or marketed within the UK for your condition. (***Although the drug cannot be marketed it can still be used and there is evidence to support its use on specific conditions, such as yours.*** (*Dr. to specify here the following details: Purpose of medication..... Why the drug may be of benefit..... What side effects or risks may be involved..... Any other information that the patient should be aware of (e.g. need for monitoring) ....* (Dr..... Date..... Print name..... (**PATIENT CONSENT** (I .....(name of patient (please print)) confirm that I understand that [*name of drug*]..... is not licensed for marketing in this country and that I consent for it to be used as part of my treatment plan. (The Doctor supervising this treatment has satisfactorily answered all the questions I have about this medication and its status. (Name of Doctor (please print)..... Date..... Signature of patient..... Date..... (**PRESCRIBER INFORMATION** (

 For all 'High Risk' unlicensed medicines (see Pharmacy website for list of unlicensed (**medicines and their associated risk classification), a copy of this consent form MUST** (**accompany the first prescription to Pharmacy (or if an emergency within 72hours).** (

 Ensure that all incidents of patient adverse reactions are recorded and reported to

the MHRA via the yellow card scheme and through the Trust's incident reporting scheme (

- Ensure that where responsibility for ongoing care is to be transferred to the patient's General Practitioner, that the General Practitioner is informed of the unlicensed status of the medicine and that he or she is willing to accept clinical and legal responsibility for prescribing. (

- Ensure that continuing treatment is provided by the hospital if the GP will not accept responsibility for continuing care. (

File in the medical notes with Doctors record

Appendix 5

ANS Guidelines for Obtaining Informed Consent for Neurophysiological Investigations

Informed Consent

Informed consent is a phrase often used in law to indicate that the consent a person gives meets certain minimum standards. An informed consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action. In order to give informed consent, the individual concerned must have adequate mental capacity and be in possession of all relevant facts, including any possible risks, at the time consent is given. To ensure informed consent can be given Information regarding the investigation should be sent out along with the appointment letter usually at least one/two weeks prior to the appointment. This will allow the patient/parent/guardian to contact the department beforehand with any questions.

With regard to Electroencephalography (EEG) the test and provocation procedures should be explained thoroughly on the day of the appointment. This is in addition to the prior information sent out with the appointment letter. A further opportunity to ask questions should then be provided. Once any questions or concerns have been satisfactorily answered implied, verbal or written consent should be obtained and appropriately documented from the patient or person with parental responsibility/guardianship or accompanying carer/nurse prior to the investigation being performed.

Once children reach the age of 16, they can agree to examination or treatment just like adults. Gillick competency, identifies under-16s with the capacity to consent to their own treatment, provided they are mature enough to understand fully what is involved. In the case of young children informed consent should be obtained from someone with parental responsibility.

Informed Consent for a Patient who lacks Mental Capacity

The Mental Capacity Act introduced in 2005 defines a person who lacks capacity as someone with a temporary or permanent impairment or disturbance in the functioning of the mind or brain when a decision needs to be made. The Five Principles of the Mental Capacity Act which need to be considered are as follows:

1. 1) A person must be assumed to have capacity unless it is established that they lack capacity.
2. 2) A person is not to be treated as unable to make a decision unless all practicable steps to help them have been undertaken without success.
3. 3) A person should not be treated as unable to make a decision merely because they make a decision that other may regard as unwise or eccentric. Everyone has their own values, beliefs and preferences which may not be the same as those of other people.
4. 4) Any act or decision made on behalf of a person who lacks capacity must be done in their best interests.
5. 5) Before the decision is made it must be ascertained whether the outcome can be affectively achieved in a way less restrictive of the person's basic rights and freedom of action.

A person is considered to lack Mental Capacity and therefore unable to make a particular decision if they cannot do one or more of the following:

- Understand the information relevant to that decision
- Retain the information for long enough to make a decision
- Use or weigh the information as part of the process of decision making
- Communicate his/her decision (Whether by talking, using sign language or any other means).

If a patient lacks the mental capacity to understand the risks and benefits or the implications of what is required, then consent should be obtained from someone who is legally allowed to provide consent for that particular patient.

Independent Mental Capacity Advocate (IMCA)

The purpose of the IMCA service is to help particularly vulnerable people who lack the capacity to make important decisions about serious medical treatment. An IMCA is available for those people who have no family or friends who it would be appropriate to consult about those decisions. The IMCA represents the person who lacks capacity to make certain decisions. They are approved by the local authority and gather information, provide support to the

person concerned and make representations about the person's wishes, feelings, beliefs and values, at the same time bringing to the attention of the decision maker all factors that are relevant to the decision. They are also able to challenge the decision maker. The decision maker is normally the carer responsible for the day to day care, or a professional such as a doctor, nurse or social worker. If a person has been assessed as lacking mental capacity to make a decision then any decision made for, or on behalf of that person, must be made in their best interests.

What should consent be gained for?

With regard to an EEG (with video) consent should be obtained for provocation such as hyperventilation, photic-stimulation and sleep recordings either sleep deprivation or drug induced sleep. The patient should be informed of the risks and benefits of performing the provocation procedures along with the implications of not undertaking them. They should also be questioned with regard to contraindications.

Written consent should be obtained for video-monitoring ensuring that accompanying relatives/carers and/or nurses are made aware that they could be seen or heard on the video. Consent must also be given regarding how the recorded information obtained either EEG, video or both can be utilised following the investigation to best assist with:

Clinical Management

Information obtained is used solely for understanding and treating the patients' condition.

Specialist Hospital Teaching

Information can also be used to help train healthcare professionals who work within the trust.

Wider Publication

Information can also be used for teaching other healthcare professionals outside of the trust such as presenting interesting cases at scientific meetings. However, a more detail consent would be required for this to ensure the patient understands exactly what the data will be used for.

Acknowledgments

Carling, B. Deprivation of Liberties Safeguards (DoLS) Medical Division Clinical Governance Manager. University Hospital of North Staffordshire NHS Trust.

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Further Information

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10 References and Associated Documentation

ANS Guidelines for Obtaining Informed Consent for Neurophysiological Investigations

ANS/BSCN Guidelines for use of Melatonin to induce sleep for paediatric EEG

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Panayiotopolous C. P. (2005) The Epilepsies: Seizures, Syndromes and Management

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

Worcestershire Acute Hospitals Trust Training Programme for Clinical Physiologists (2012)

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	**Policy for the Administration of Melatonin to Children for Sleep EEGs in the Neurophysiology Department**
Date Finalised	23 May 2017
Previous Documents	
Action to retrieve old copies	NA

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff		Vital Signs, TrustNet	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	
	Does the style & format comply?	
Rationale	Are reasons for development of the document stated?	
Development Process	Is the method described in brief?	
	Are people involved in the development identified?	
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	
	Is there evidence of consultation with stakeholders and users?	
Content	Is the objective of the document clear?	
	Is the target population clear and unambiguous?	
	Are the intended outcomes described?	
	Are the statements clear and unambiguous?	
Evidence Base	Is the type of evidence to support the document identified explicitly?	
	Are key references cited and in full?	
	Are supporting documents referenced?	
Approval	Does the document identify which committee/group will review it?	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	
	Does the document identify which Executive Director will ratify it?	
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	
	Does the plan include the necessary training/support to ensure compliance?	
Document Control	Does the document identify where it will be held?	
	Have archiving arrangements for superseded documents been addressed?	
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	
	Is there a plan to review or audit compliance with the document?	
Review Date	Is the review date identified?	
	Is the frequency of review identified? If so is it acceptable?	

Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	25 May 2017
Title	**Policy for the Administration of Melatonin to Children for Sleep EEGs in the Neurophysiology Department**
What are the aims, objectives & projected outcomes?	To improve on existing arrangements for performing sleep EEGs for children by moving the procedure to the EEG department. This is based on relevant evidence gathered from national guidelines and literature. Liason, advice and training has been sought from professionals from within the Trust and other NHS Trusts (including a paediatric specialist Trust).
Scope of the assessment	
Collecting data	
Race	Consideration will be made if information provided to patients/ carers is required in a different language. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Religion	There is no evidence to suggest that there is an impact on religion or belief and non-belief regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Disability	Consideration will be made if information is required in different formats for people with disabilities/ learning disabilities. Carers will be encouraged to participate in the sleep EEG procedure where applicable. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Sex	There is no evidence to suggest that there is an impact on se regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Gender Identity	There is no evidence to suggest that there is an impact on gender identity regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Sexual Orientation	There is no evidence to suggest that there is an impact on sexual orientation regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Age	There is no evidence to suggest that there is an impact on age regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.

Socio-Economic	There is no evidence to suggest that there is soci-economic impact regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Human Rights	Carers will be encouraged to participate in the sleep EEG procedure where applicable. Data collected from Datix incident reporting and complaints will ensure this is monitored.
What are the overall trends/patterns in the above data?	No comparative data has been used to date which means that no trends or patterns have been identified.
Specific issues and data gaps that may need to be addressed through consultation or further research	No gaps have been identified at this stage but this will be monitored via data collected from Datix incident reporting and complaints.

Involving and consulting stakeholders	
Internal involvement and consultation	MAUC, Neurosciences Matron, Paediatric Consultants, Neuroscience Clinical Director
External involvement and consultation	Consultation with Birmingham Children's Hospital and Worcester General Hospital
Impact Assessment	
Overall assessment and analysis of the evidence	Consideration will be made if information provided to patients/ carers is required in a different language. Consideration will be made if information about medicines management is required in different formats for people with disabilities/ learning disabilities. Carers will be encouraged to participate in the management of medicines for those patients that require it.

Action Plan

Action	Owner	Risks	Completion Date	Progress update