Northern Lincolnshire and Goole NHS Foundation Trust

Chief Operating Officer's Directorate
Surgery & Critical Care
Clinical Sciences

GUIDELINE FOR RECOMMENDED MELATONIN DOSAGE TO INDUCE SLEEP IN CHILDREN ATTENDING ELECTROENCEPHALOGRAM (EEG)

Reference:	DCG332
Version:	2.2
This version issued:	15/12/22
Result of last review:	Minor changes
Date approved by owner (if applicable):	N/A
Date approved:	16/08/22 / 04/11/22
Approving body:	Clinical Sciences Governance / Medicines & Therapeutics Committee
Date for review:	September, 2025
Owner:	Jackie Carpus, Head of Medical Physics
Document type:	Guideline
Number of pages:	12 (including front sheet)
Author / Contact:	Kamalakannan Jothi, Head of Neurophysiology

Northern Lincolnshire and Goole NHS Foundation Trust actively seeks to promote equality of opportunity. The Trust seeks to ensure that no employee, service user, or member of the public is unlawfully discriminated against for any reason, including the "protected characteristics" as defined in the Equality Act 2010. These principles will be expected to be upheld by all who act on behalf of the Trust, with respect to all aspects of Equality.

Contents

1.0 Clinical Guideline Summary

1.1 Children under the age of 2 have historically all been allocated a 2-hour appointment for a Sleep Electroencephalograph (EEG) at Diana, Princess of Wales Hospital, to enable natural sleep to be obtained. Parents are given instructions on how to prepare their child for the test i.e. not to let them sleep in the daytime beforehand and to bring anything with them which will aid sleep (bottles, dummies, etc). This is generally very effective, with sleep being achieved in most cases.

1.2 The use of melatonin to induce sleep (unlicensed, but widely used nationally for this purpose) is recommended for those children aged 12months and above, in which a sleep EEG is clinically necessary, but for those who do not achieve natural sleep in the first instance, or when parents have indicated they will not sleep in the day routinely or having difficulties in sleeping or disturbances at night time and melatonin medication might be required.

1.3 Melatonin can sometimes also be useful when the first EEG has been unsuccessful, or a child has been unable to tolerate one.

1.3.1 Sleep, EEG & diagnostic yield

1.3.2 Sleep effectively increases diagnostic yield:

- Where no sleep, EEG yield increased by 15% (this can be due to the effects of sleep deprivation or a more prolonged sleep recording).
- Unequivocal epileptiform activity not seen in resting record 20%.
- Exacerbation of epileptiform activity seen in resting record 22%.

1.4 In the majority of cases, the decision for the use of melatonin to induce sleep is made by the Referring Clinician or Neurophysiology Consultant or following consultation between the referring clinician and Neurophysiology Department. It is prescribed by the referrer (recommendation standard 6 of national audit).

2.0 Purpose

2.1 This guideline is for use in the Clinical Neurophysiology department based at Diana Princess of Wales Hospital, Grimsby (DPoWH) and the Paediatric Units in Northern Lincolnshire and Goole NHS Foundation Trust. The aim is to guide, support and advise staff when referring for melatonin assisted Sleep EEG for children and young people.

2.2 Criteria for requesting a Melatonin Induced Sleep EEG:

- In children aged 12 months and above who require a sleep EEG, but who failed or are unable to sleep naturally in the EEG department or ward.
- Children under or above 5 years of age who require a sleep EEG but are unable to sleep deprive.
- Children above 12 months who are unable to cooperate during a routine EEG recording.

2.3 Summary effectiveness and efficiency of sleep induction:

- High percentage achieves sleep (79%).
- Sleep deprivation with melatonin more effective in inducing sleep than either method alone.
- Sleep deprivation along with melatonin induces shortest mean latency to sleep.

3.0 Area

These instructions will apply to all personnel identified below and involved in children's services across the Northern Lincolnshire & Goole NHS Foundation Trust.

4.0 Personnel / Duties

4.1 This guideline is for use by all disciplines of Health Care Professionals caring for children across the Trust:

- Medical Staff.
- Clinical Neurophysiologists.
- Advanced Paediatric Nurse Practitioners.
- Registered Nurses.
- Pharmacy staff.

4.2 The duties and responsibilities are detailed in the subsequent sections of this guideline.

5.0 Referring Clinician

5.1 Prior to Requesting a Melatonin Sleep EEG:

- It is preferable that the clinician discusses the procedure with the parents prior to referral. This should include the need to give a second dose, if sleep is not achieved within 30 minutes.
- Outpatient referrals: The Clinician should write a prescription (including 2nd dose if needed), and send this to the parents, or directly to Lloyds Pharmacy for dispensing at the Diana, Princess of Wales Hospital or Scunthorpe General Hospital. The parents / legal guardian, once they have received an appointment for melatonin induced sleep EEG via post and / or telephone call, will then be asked to collect melatonin on weekdays only, prior to the allocated appointment time, usually the previous day and store them safely.
- Inpatient referrals: The referring clinician should prescribe the required dose (including 2nd dose if needed) on the inpatient prescription chart, which will then be clinically reviewed and dispensed by pharmacy, before being sent directly to the inpatient ward for administration.

- Medical or nursing or healthcare staff from Rainforest/ Disney Ward may bring melatonin from the ward to the department, if more appropriate. The examination appointment time will be liaised with the Neurophysiology staff and melatonin administered 20-30 minutes prior or during to the sleep EEG recording.

5.1.1 Unless clinically indicated. The recommended single doses are:

Children 12-24months	= 2 to 3mg dose per day
Children 2-4yrs	= 3mg doses up to 6mg per day
Children 5 and above	= 6mg doses up to 9mg per day
Additional or second dosage if the referring Clinician feels this is necessary	= up to extra 3 mg dose

5.1.2 **Guideline: NB modified release (long-acting) formulations of melatonin are not suitable for this indication.**
Melatonin is available as 1mg/ml unlicensed liquid, and 2mg, 3mg, or 5mg short-acting capsules and 1mg immediate release (short-acting) tablets, which may be suitable for some children. The maximum dose given is **usually up to 10mg per day** (NICE, BNF & BNFC, n.d.) but a second or additional dose may be given after 45 minutes if the first is unsuccessful (National Audit, 2014).

5.1.3 Parent/ legal guardian should receive clear information about Melatonin assisted sleep EEG study, and also given a copy of Melatonin Drug Package Leaflet and Information for the User and Unlicensed Medicines Patient Information Leaflet (IFP-0711), available on request.

5.1.4 Obtain and document **informed consent**. Parent/ legal guardian will be required to sign a consent form prior to administration of melatonin to the child.

5.1.5 Melatonin is given by parent/guardian or in exceptional circumstances given in accordance with department protocol by a trained Clinical Neurophysiologist or trained Nursing or Medical staff.

5.1.6 Healthcare professionals assisting or delivering sedation should have documented up-to-date evidence of competency including:

- Satisfactory completion of a theoretical training course covering the principles of sedation practice.
- A comprehensive record of practical experience of sedation techniques, including details of:
  - Sedation in children and young people performed under supervision.
  - Successful completion of work-based assessment.

5.2 Pre-sedation Requirement

It is essential to perform all of the following requirements before sedation:

- Assessment to establish suitability for sedation by assessing all of the following:
    - General sleeping pattern and routine.
    - current medical conditions and any surgical procedures.
    - weight (growth assessment).
    - past medical problems (including any associated with previous sedation or anaesthesia).
    - current and previous medication (including any allergies).
    - physical status (including the airway).
    - psychological and developmental status.
    - Seek advice from a specialist before delivering sedation if there is **concern** about a **potential airway or breathing problem**, for infants or if the child or young person has significant co-morbidity (American Society of Anaesthesiologists grade 3 or over). If in doubt, seek advice.
- Communication and patient/parent/carer information to enable them to make informed decision, offer them verbal and written information on all the following: proposed sedation technique; the alternatives to sedation and associated risk and benefits.
- **Psychological preparation of the child** should include information about; the procedure, what the child or the young person should do and what the healthcare professional will do; the sensation associated with procedure and how to cope with the procedure.
- Choose the most suitable sedation technique based on what the procedure involves, target level of sedation, contraindications, side effects, patient (or parent or carer) preference.
- Ensure the immediate availability of appropriate help, monitors and resuscitation equipment.

5.3 Before Administration of Melatonin Drug:

- Explain and discuss the procedure with the patient/ parent/ legal guardian.
- Check that the patient/parent/legal guardian has signed the consent form.
- Oral melatonin will be labelled by pharmacy with the name and strength of the preparation, the patient's name and the date.
- Put on gloves and an apron before commencing the procedure.

- Ensure strict adherence to a “no-touch” technique must be used when handling drugs especially when parent or neurophysiologist drawing up.

- In exceptional circumstances the contents of the capsule opened and mix with drink or food following parental/legal guardian consensus.

- For both in- and outpatients, the Clinical Neurophysiologist must check the Patient name and date of birth, patient hospital, NHS number, expiry date and batch number of drug. Ensure the does give is appropriate for the age and weight, also consider patient present state as well e.g. tired, drowsy and seek help if needed, from senior staff member.

- Neurophysiology staff must ensure all the documentation is completed at the time of administration. Please note, the wrist band is red if a patient has any known allergies and allergy status ***must*** be checked, before any administration.

- For inpatients, check the patient’s hospital number and date of birth on the wristband corresponds to the prescription chart and to the label (If there are any discrepancies including dosage, contact the prescriber or ward and or for OP, the Lloyds Pharmacist or for IP, DPoWH and SGH Pharmacist on rota.

5.4 During and After Administration of Melatonin Drug:

- Place all syringe(s) and any other equipment required on a clean trolley.

- Ensure and follow the **correct dose of melatonin as per (5.1.1 above) given** or drawn out of the bottle by parent or neurophysiology staff using a syringe. If needed, please seek help from senior staff member.

- Parent/legal guardian/Licensed Medical Practitioner including Doctor and Nurses **will only be allowed to** administer melatonin orally.

- Record details of the administration on the prescription chart and appropriate documentation by the person guiding or observing administration of melatonin only.

- Dispose of all used equipment according to local infection control and waste disposal policies.

- **Observe and monitor the patient’s comfort, respiration and ECG** throughout the procedure.

5.5 It is essential to use short acting melatonin and there are two ways in which this can be given. Immediate release melatonin is available in capsules and tablets which can be taken with a drink if the child is able to take solid dose-forms. Melatonin is also available in liquid form, which can be administered directly into the patient’s mouth, using an oral syringe. Consideration needs to be given with regards to which form is likely to be successful.

5.6 Possible Side Effects Taking Melatonin:

- Uncommon – Abdominal pain, abnormal dreams, anxiety, chest pain, dizziness, dry mouth, dry skin, dyspepsia, glycosuria, headache, hypertension, irritability, malaise, mouth ulceration, nausea, rash, restlessness, weight gain.

- Rare – Aggression, arthritis, electrolyte disturbances, flatulence, gastritis, haematuria, hot flushes, increased libido, hypersalivation, impaired memory, mood changes, muscle spasm, palpitation, paraesthesia, syncope, thirst, restless leg syndrome, visual disturbances and vomiting.

- Frequency not known – galactorrhoea, mouth oedema and tongue oedema.

5.7 Common Contraindications for Sedation:

- **Airway problems:** Actual or potential airway obstruction, e.g. snoring or stridor, blocked nose, small mandible, large tongue.

- **Apnoeic spells.**

- **Respiratory disease:** <94% SPO2 in air; Respiratory failure (high respiratory rate, oxygen treatment), inability to cough or cry, unstable myasthenia gravis.

- **High intracranial pressure.**

- **Major neurological or neuromuscular disease.**

- **Risk of pulmonary aspiration of gastric contents.**

- **Already sedated child** for e.g. sleepy child due to benzodiazepines used for epileptic fit – sedation may not be required at all.

- **Pregnant or breast feeding** ask your referring doctor before taking melatonin.

5.8 On Completion of the Test the Following Discharge Criteria Applies

Ensure that all of the following criteria are met before the child or young person is discharged from department or care:

- Vital signs (usually body temperature, heart rate, blood pressure and respiratory rate) have returned to normal levels and documented appropriately.

- The child or young person is awake (or returned to baseline level of consciousness) and there is no risk of further reduced level of consciousness.

- Nausea, vomiting and pain have been adequately managed.

5.9 In the event of any adverse or allergic reactions or prolonged / frequent seizures or any other complications above immediately seek help from senior staff member or Paediatric Ward Doctor or Out of hours on call Doctor or call resuscitation team at **2222** and state medical emergencies until help arrives follow Paediatric Basic Life Support by following **Emergency Departmental Seizure Management Protocol:**

- **Please call for help immediately (do not leave the patient alone), please ring reception or colleagues or staff nurses' room or shout for help (proportionate to the type of emergency) and ask a staff member to put the medical emergency call-out and also making sure the resus trolley from the Medical Physics Services or Paediatric Assessment Unit (PAU) or Emergency Care Centre (ECC) and the oxygen cylinder is ready and connected with appropriate oxygen mask.**

- **Assess patient (airway, breathing, circulation, disability) – immediately put patient in recovery position and monitor vital signs including ECG and SpO2 and give oxygen.**

- **Ensure EEG and ECG leads are attached and that EEG is still recording along with the video; it is very important ensure that the video camera view is clear and not obstructed at any time.**

- **Time the seizure from its onset; be prepared to ring the Resus Team (stating Paed medical emergency) when seizure or attack is over 2 minutes long. Most of the time, seizures are self-terminating within a few minutes. Please do not restrain the patient whilst having seizure or attack and wait for it to finish.**

- **Continue to follow health and safety and basic life support until additional help and support arrives. If required, please ring on-call Paediatric registrar or Consultant or Specialist nurses onsite contacted through Trust switch board.**

- **If possible, follow ictal and post-ictal assessment, or else wait for the seizure to finish. Once seizure or attack terminated, please take detailed additional history from the patient and or witness statement from parent or family member or carer.**

5.10 **Storage:** If melatonin is to be given, it should be available at the time of appointment, stored safely in lockable drug cupboard in the department at EEG services (DPoWH) or remain in the relevant Lloyds Outpatient Pharmacy branch, within our hospitals, until collection.

5.10.1 Parents are not permitted to bring their own melatonin in, even if the child is already taking melatonin as a regular therapeutic drug, prescribed by a specialist or their GP.

5.10.2 In the possible event of choking or swallowing difficulties or allergic/adverse reaction or seizures, staff should adhere to their training in accordance with departmental and Trust protocols and procedures.

5.10.3 Staff should be aware of British National Formulary (BNF) guidance when melatonin is to be used to induce sleep.

5.10.4 This policy **MUST** be read in conjunction with the Trust's Incident Reporting Policy and Procedures for the Management of Staff Involved in A Medication Related Incident and Paediatric Basic Life Support.

5.10.5 Prior to all inpatients being transferred from the ward to the EEG examination, they must be risk-assessed by using Safe Transfer of Paediatric Patient (STOPP) Assessment Tool and must have a written treatment plan in place for the administration of buccal midazolam in emergencies.

5.10.6 Also, the paediatric team on Disney Ward must inform the Rainforest Ward staff members about potential high-risk patients being transferred for EEG study.

5.10.7 **For outpatients:** If the parents or carers have already been given and trained to administer Buccal Midazolam, they should follow this Information leaflet regarding administration of **Buccal Midazolam (Buccolam®)** (IFP-0343).

6.0 Monitoring Compliance and Effectiveness

6.1 The use of this guideline should be evaluated and reviewed in terms of its effectiveness and updated whenever appropriate, or when further guidance is received or regulations change.

6.2 Any areas where guidance is not followed will be identified via audit and actions taken to amend this immediately. In addition, a Trust incident form should be completed.

6.3 This guideline will be audited about six months after implementation to check compliance. Repeat audits will be done as and when considered necessary.

7.0 Associated Documents

7.1 Policy for the Purchase and Supply of Unlicensed Medicinal Products (DCP101).

7.2 Policy and Procedure for the Management of Staff Involved in A Medication Related Incident (DCP232).

7.3 Patient Information Leaflet for Unlicensed Medicines (IFP-0711).

7.4 Information for Patients – Buccolam® (Buccal Midazolam) – Advice for Parents and Carers (IFP-0343)

8.0 References

8.1 Drs Caroline Ross and Lesley Notghi, Melatonin, Sleep and EEG. Joint ANS/BSCN audit meeting October 2014. https://www.ansuk.org/wp-content/uploads/2018/03/2014-sleep.pdf

8.2 http://www.medicinescomplete.com/#/content/bnfc/_136842357?hspl=melatonin

8.3 ZENOBIA ZAIWALLA. Sleep deprivation versus melatonin to induce sleep during paediatric electroencephalography, Developmental Medicine & Child Neurology 2019, 61: 110–120.

8.4 Evangeline Wassmer et al. Melatonin is useful for recording sleep EEGs: a prospective audit of outcome, Developmental Medicine & Child Neurology 2001, 43: 735–738.

8.5 Information about your EEG [DPOW] (IFP-0518).

8.6 Unlicensed Medicines Patient Information Leaflet (IFP-0711).

8.7 Guide for the Re-Use of Patients Own Medicines and Self-Administration (SAMPOD) (DCP022).

8.8 Policy for the Purchase and Supply of Unlicensed Medicinal Products (DCP101).

8.9 NICE / BNF Melatonin/Indications and dose and Unlicensed Usage (Online). Available from https://bnf.nice.org.uk/drugs/melatonin/#unlicensed-use

8.10 Drug Administration Performance Review Documentation (first error).

8.11 Guidance for the purchase and supply of unlicensed medicinal products - NHS Pharmaceutical Quality Assurance Committee 2004.

8.12 Drug Administration Performance Review Documentation (first error) (DCP232F).

8.13 Guideline for Children who Require Sedation (DCG102).

8.14 NICE / BNFC for Children, Melatonin Indications and dosage and unlicensed Usage (Online). Available from https://bnfc.nice.org.uk/drugs/melatonin/#indications-and-dose

8.15 Sedation in children and young people. Royal College of Anaesthetists. 02 August 2011. http://www.rcoa.ac.uk/news-and-bulletin/rcoa-news-and-statements/sedationchildren-and-young-people

8.16 Paediatric sedation. Sury M. BJA: CEACCP Volume 12, Issue 3Pp. 152-156. http://ceaccp.oxfordjournals.org/content/12/3/152.full?sid=ebe62bc6-88ba-4729-9894-8a4d92b54bcd

8.17 2021 Guidelines Paediatric Advanced Life support.

8.18 Status Epilepticus in Children and Young People (Aged 1 Month To 16 Years), Guideline on the Management of (DCG209).

8.19 Safe Transfer of Paediatric Patient (STOPP) Assessment Tool (WQN 1549).

8.20 https://www.nice.org.uk/guidance/cg137/chapter/1-Guidance#prolonged-or-repeated-seizures-and-convulsive-status-epilepticus-2

8.21 Buccolam (Buccal Midazolam) – Advice for Parents and Carers (IFP-0343).

8.22 Treatment Plan for the Administration of Buccal Midazolam (WQN 1116).

8.23 Check list for training carers in the use of Buccal Midazolam in the community.

9.0 Definitions

NPSA – The National Patient Safety Agency.

10.0 Consultation

10.1 Clinical Services Governance Committee.

10.2 Consultant Paediatrician- Trust-wide.

10.3 External & Locum Clinical Neurophysiology Consultants.

10.4 Pharmacy Services –Trust-wide.

11.0 Dissemination

11.1 Clinical Neurophysiology (EEG Services) Staff at DPoWH – Electronic, through the Intranet.

11.2 All Women & Children's Services staff – Electronic, through the Intranet.

11.3 All Pharmacy Services Staff – Electronic, through the Intranet.

12.0 Implementation

12.1 Clinical Sciences Governance Committee.

12.2 Women & Children's Services – Trust-wide.

12.3 Pharmacy Services –Trust-wide.

13.0 Equality Act (2010)

13.1 Northern Lincolnshire and Goole NHS Foundation Trust is committed to promoting a pro-active and inclusive approach to equality which supports and encourages an inclusive culture which values diversity.

13.2 The Trust is committed to building a workforce which is valued and whose diversity reflects the community it serves, allowing the Trust to deliver the best possible healthcare service to the community. In doing so, the Trust will enable all staff to achieve their full potential in an environment characterised by dignity and mutual respect.

13.3 The Trust aims to design and provide services, implement policies and make decisions that meet the diverse needs of our patients and their carers the general population we serve and our workforce, ensuring that none are placed at a disadvantage.

13.4 We therefore strive to ensure that in both employment and service provision no individual is discriminated against or treated less favourably by reason of age, disability, gender, pregnancy or maternity, marital status or civil partnership, race, religion or belief, sexual orientation or transgender (Equality Act 2010).

14.0 Freedom to Speak Up

Where a member of staff has a safety or other concern about any arrangements or practices undertaken in accordance with this policy, please speak in the first instance to your line manager. Guidance on raising concerns is also available by referring to the Trust's Freedom to Speak Up Policy and Procedure (DCP126). Staff can raise concerns verbally, by letter, email or by completing an incident form. Staff can also contact the Trust's Freedom to Speak Up Guardian in confidence by email to nlg-tr.ftsuguardian@nhs.net or telephone 07892764607. More details about how to raise concerns with the Trust's Freedom to Speak Up Guardian can be found on the Trust's intranet site.