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Melatonin use in typically developing (TD) children: International Pediatric Sleep Association (IPSA) Expert Consensus Recommendations for Healthcare Providers

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A B S T R A C T

Although melatonin is widely used globally for the management of insomnia in children and adolescents, there are few clinical guidelines available for healthcare practitioners, particularly in typically developing (TD) children. Because existing data are either sparse or inconclusive, a task force comprised of pediatric sleep researchers and clinicians was established by the International Pediatric Sleep Association (IPSA) to first examine the available literature and to then develop a set of evidence-based (when possible) and consensus-based recommendations to guide practitioners in decision-making regarding melatonin use in pediatric insomnia. The following recommendations regarding appropriate indications for melatonin in children, considerations regarding timing and dosage, safety issues and caveats in recommending use of melatonin in pediatric clinical settings, are presented as a companion to a Technical Report summarizing the available literature.

1. Introduction

The evidence supporting the use of melatonin in the typically developing (TD) pediatric population is limited and primarily based on children and adolescents with insomnia (broadly defined as difficulty initiating and/or maintaining sleep). A smaller body of literature also supports the use of melatonin, largely in adolescents, specifically for a circadian-based delay in sleep onset, although the distinction between the two disorders is not always clinically evident. Currently, there are a number of published general guidelines from professional medical organizations for practitioners and/or caregivers regarding the use of melatonin for insomnia in special pediatric populations, including children with autism and other neurodevelopmental disorders [1–3] and children with comorbid psychiatric disorders [4]. While some of the few published recommendations on the use of melatonin in TD children, including two recent sets of European expert consensus recommendations [5,6] have included some specifics regarding indications, dose, timing and contraindications, the focus tends to be on more generic storage and safety precautions [7]. It should also be emphasized the melatonin dosing recommendations in particular are subject to a number of important caveats that are outlined in the accompanying Technical Report [8]; these include the lack of and in some instances contradictory empirical evidence [9–11] individual factors such as differences in metabolism related to CYP1A2 [12] and the presence of endogenous melatonin in breast milk transferred to nursing children [13] and external factors such as the high level of variability in actual melatonin content in OTC products [14].

In light of the recent spate of articles regarding melatonin use in the pediatric population in general as well as the increasing global use of melatonin in children [15–19], caregivers, patients and pediatric healthcare providers frequently express the need for more guidance regarding the safety and efficacy of melatonin use in children. In addition, as melatonin is available without a prescription in countries such as the USA and China [20], and as the global access to melatonin on the internet is increasing], families often seek information from questionably reliable sources such as the internet and chat rooms and from family and friends rather than from medical providers [21,22].

In response to these information and clinical gaps, the International

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Pediatric Sleep Association (IPSA) created a Melatonin Task Force charged with developing the following expert consensus statements on the use of melatonin in TD children for a global audience The goals of these expert consensus statements are to help inform pediatricians, sleep specialists and other health care providers about melatonin use in TD children based on a review of available evidence as detailed in the accompanying Technical Report and to formulate a series of current best practice recommendations. An additional goal was to develop a parallel set of guidelines for caregivers and patients. The recommendations were reviewed and approved by the IPSA Executive Committee and Board of Directors.

1.1. Recommendations

Melatonin should be used only with the recommendation of and supervision from a medical provider; while melatonin is often viewed by parents as "natural" and safe, it should still be considered a medication.

1.2. When to consider melatonin

1. Before considering melatonin, children should have a *thorough clinical sleep evaluation* to rule out other causes of chronic insomnia. For example, difficulty initiating sleep may be primarily due to or exacerbated by another sleep disorder (e.g., circadian-based sleep phase delay (particularly in adolescents), and restless legs syndrome symptoms), medical concerns such as late-day administration of stimulant medication and chronic pain conditions, comorbid mental health issues such as anxiety and depression, and environmental contributors (e.g., excessive noise, light in the sleeping space) and poor sleep practices (e.g., evening electronic media use, timing and duration of napping, a developmentally inappropriately early bedtime), In younger children, a particularly common issue is the development of a child's dependence on caregiver presence/intervention (feeding, rocking, physical proximity) in order to fall asleep, often termed sleep onset association behavioral insomnia of childhood. In none of these situations is melatonin likely to be either indicated or effective in lieu of other appropriate interventions.
2. A *systematic clinical sleep evaluation* includes at minimum a detailed sleep history, including current sleep schedule and sleep duration, sleep onset latency and night awakenings, evening/bedtime routines (including electronic media use), sleep environment manifestations of daytime sleepiness, previous treatments for insomnia symptoms and screening for potential symptoms of primary sleep disorders (e.g., snoring, restless sleep, evening leg discomfort/excessive movement). A 14-day sleep diary provides a "real time" assessment of sleep patterns and regularity.
3. Melatonin should be used only with the *recommendation of and supervision from a medical provider;* while melatonin is often viewed by parents as "natural" and safe, it should still be considered a medication.
4. In almost all circumstances, the *behavioral approaches should both precede and accompany any recommendations to use melatonin.* There is robust empirical evidence regarding the effectiveness of age-appropriate healthy sleep practices and parent-directed behavioral interventions [23,24] for children and adolescents with chronic insomnia disorder These should be considered the *first line treatment for insomnia in TD children.*
5. With very rare exceptions, melatonin *should not be administered to TD children under 2 years of age,* as the vast majority of symptoms of difficulty initiating and maintaining sleep in this age group are due to behavioral causes. In addition, there are no studies assessing efficacy and safety of melatonin in these young children. If this is felt necessary, close supervision by a sleep medicine physician is recommended.
6. Melatonin should *not* be used for sleep disorders other than chronic insomnia disorder and circadian rhythm sleep-wake disorders. Melatonin is not indicated for other sleep disorder such as sleep-walking and restless sleep.
7. Melatonin should *not* be used to "make sleep better" in children without sleep-related complaints.
8. Melatonin should *not* be recommended to force adolescents (i.e., who do not have a circadian rhythm sleep-wake disorder) to fall asleep earlier to accommodate early school start times

1.3. How to use melatonin

1. *Immediate release melatonin* should only be used for chronic insomnia disorder characterized by sleep onset delay.
2. The *prolonged release preparation of melatonin* (available in some countries) has been shown to also reduce night awakenings in children (specifically in children with neurodevelopmental disorders). While no randomized controlled trials of extended-release melatonin in TD children have yet been published, consideration could be given for use for night wakings in TD children if available based on extrapolation of the existing data.
3. The melatonin dose should start at the *lowest possible dose* (0.5 mg) and titrate up to maximum dose of 5 mg. Increases in the dose as clinically indicated may be made on a weekly basis. With caveat that there is currently limited data in TD children, the consensus recommendations for dose range by age are:
   Infants (0–2 years): Not recommended
   Toddler (2–3 years): Up to 1 mg
   Preschool (4–5 years): Up to 2 mg
   School-Age (6–10 years): Up to 3 mg
   Older School-Age and Adolescents: Up to 5 mg
4. If required, the usual *timing of administration* is 30–60 min before desired bedtime.

1.4. Safety considerations

1. Due to recent reports of serious adverse events from accidental or unsupervised melatonin ingestion, melatonin should be *safely stored and kept out of reach of children.* Caregivers should be cautioned not to transfer melatonin to a non-child-proofed container, and particularly never to mix "gummy" melatonin formulations with similar candy-like foods such as "fruit snacks".
2. Patients should be routinely asked about administration of *over-the-counter medications containing melatonin* (like "nighttime" cough syrups for children and "relaxation aids") to their children.
3. Practitioners should make caregivers aware of *substances that may interfere with melatonin metabolism* (Table 1 in the accompanying Technical Report) and thus increase or decrease bio-availability
4. In many countries, melatonin is available by prescription only and thus the assumption is that these formulations are subject to strict pharmaceutical standards and thus would be considered reliable. For those countries in which melatonin is available over-the-counter, and thus *unregulated,* families should use a product with *proper verification of dosage* by the standard organization in their country (such as the U.S. Pharmacopeia [USP] in the United States)ConsumerLab.com is a potential resource for independent test results, reviews, ratings, and comparisons of USA-based vitamins, supplements, herb and nutrition products, including melatonin, for consumers and healthcare providers. ConsumerLab.com is a potential resource for independent test results, reviews, ratings, and comparisons of USA-based vitamins, supplements, herb and nutrition products, including melatonin, for consumers and healthcare providers.
5. Due to the variability in *unregulated* melatonin content compared to label content, use of *on-line non-verified melatonin products* from countries such as the US should be discussed and discouraged
6. There are limited data on long-term effects of melatonin in TD children. Therefore, melatonin should be *used for as short a period as*

possible. Long-term use (i.e., more than 3–6 months) is not indicated in the vast majority of TD children. It is strongly recommended that longer-term use should be in consultation with a sleep provider whenever possible.

7. In order to avoid inappropriate long-term use, there should be *regularly scheduled frequent follow up assessment* of efficacy, side effects and consideration of periodic drug-free "holidays" to evaluate continued need for medication.

2. Summary

These recommendations for pediatric healthcare providers regarding melatonin use in children are intended to provide a framework for best clinical practices based on current knowledge. We strongly encourage more global data collection to better assess melatonin use around the world, and that also reflects important considerations such as cultural beliefs regarding children's sleep and melatonin, and the availability and quality of melatonin across regions. We acknowledge the need for and call for additional melatonin pediatric clinical trials, including those directly comparing melatonin with other treatments for insomnia such a behavioral interventions. Finally, we strongly support additional research to evaluate the long-term effects of melatonin on sleep, development and physiologic parameters to further guide safe and effective use in clinical practice.

A link to an accompanying set of recommendations regarding melatonin use in children specifically for caregivers posted on the International Pediatric Sleep Association (IPSA) website: https://pedsleep.org.

CRediT authorship contribution statement

Judith Owens: Writing – review & editing, Writing – original draft, Project administration, Conceptualization. **Narong Simakajornboon:** Writing – review & editing, Writing – original draft, Conceptualization. **Suresh Kotagal:** Writing – review & editing, Writing – original draft, Conceptualization. **Paul Gringras:** Writing – review & editing, Writing – original draft, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] Bruni O, Alonso-Alconada D, Besag F, Biran V, Braam W, Cortese S, Moavero R, Parisi P, Smits M, Van der Heijden K. Current role of melatonin in pediatric neurology: clinical recommendations. Eur J Paediatr Neurol 2015;19(2):122–33. https://doi.org/10.1016/j.ejpn.2014.12.007.

[2] Williams Buckley A, Hirtz D, Oskoui M, Armstrong MJ, Batra A, Bridgemohan C, Coury D, Dawson G, Donley D, Findling RL. Practice guideline: treatment for insomnia and disrupted sleep behavior in children and adolescents with autism spectrum disorder: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology 2020;94(9):392–404.

[3] Kotagal S, Malow B, Spruyt K, Wang G, Almeida CEB, Saldaña LMT, Blunden S, Narang I, Ipsiroglu OS, Bruni O. Melatonin use in managing insomnia in children with autism and other neurogenetic disorders-An assessment by the international pediatric sleep association (IPSA). Sleep Med 2024;119:222–8.

[4] American Academy of Child and Adolescent Psychiatry Sleep Disorders. Parents-Medication-Guide-web. www.aacap.org; 2021.

[5] Bruni O, Breda M, Nobili L, Fietze I, Capdevila ORS, Gronfier C. European expert guidance on management of sleep onset insomnia and melatonin use in typically developing children. Eur J Pediatr 2024:1–10. https://doi.org/10.1007/s00431-024-05556-w.

[6] Edemann-Callesen H, Andersen HK, Ussing A, Virring A, Jennum P, Debes NM, Laursen T, Baandrup L, Gade C, Dettmann J. Use of melatonin for children and adolescents with chronic insomnia attributable to disorders beyond indication: a systematic review, meta-analysis and clinical recommendation. EClinicalMedicine 2023;61. https://doi.org/10.1016/j.eclinm.2023.102049.

[7] Sundhedsstryelsen. National clinical recommendations for melatonin treatment of sleep disturbances in children and adolescents. 2022. Sundhedsstryelsen.

[8] Rishi MA, Khosla S, Sullivan SS. Health advisory: melatonin use in children. J Clin Sleep Med 2023;19(2):415.

[9] Shenoy P, Etcheverry A, Ia J, Witmans M, Tablizo MA. Melatonin Use in pediatrics: a clinical review on indications, multisystem effects, and toxicity. Children (Basel) 2024 Mar 9;11(3):323. https://doi.org/10.3390/children11030323. PMID: 38539358; PMCID: PMC10968776.

[10] van Geijlswijk IM, van der Heijden KB, Egberts AC, Korzilius HP, Smits MG. Dose finding of melatonin for chronic idiopathic childhood sleep onset insomnia: an RCT. Psychopharmacology (Berl) 2010 Oct;212(3):379–91. https://doi.org/10.1007/s00213-010-1962-0. Epub 2010 Jul 29. PMID: 20668840; PMCID: PMC2952772.

[11] Kimland EE, Dahlén E, Martikainen J, Célind J, Kindblom JM. Melatonin prescription in children and adolescents in relation to body weight and age. Pharmaceuticals (Basel) 2023 Mar 6;16(3):396. https://doi.org/10.3390/ph16030396. PMID: 36986495; PMCID: PMC10058986.

[12] Minich DM, Henning M, Darley C, Fahoum M, Schuler CB, Frame J. Is melatonin the "next vitamin D"?: a review of emerging science, clinical uses, safety, and dietary supplements. Nutrients 2022 Sep 22;14(19):3934. https://doi.org/10.3390/nu14193934. PMID: 36235587; PMCID: PMC9571539.

[13] Wong SD, Wright KP, Spencer RL, et al. Development of the circadian system in early life: maternal and environmental factors. J Physiol Anthropol 2022;41:22. https://doi.org/10.1186/s40101-022-00294.

[14] Erland LA, Saxena PK. Melatonin natural health products and supplements: presence of serotonin and significant variability of melatonin content. J Clin Sleep Med 2017 Feb 15;13(2):275–81. https://doi.org/10.5664/jcsm.6462. PMID: 27855744; PMCID: PMC5263083.

[15] Hartstein LE, Garrison MM, Lewin D, Boergers J, LeBourgeois MK. Characteristics of melatonin use among US children and adolescents. JAMA Pediatr 2024;178(1):91–3.

[16] Stierman B, Mishra S, Gahche JJ, Potischman N, Hales CM. Dietary supplement use in children and adolescents aged ≤19 Years - United States, 2017-2018. MMWR Morb Mortal Wkly Rep 2020 Oct 30;69(43):1557–62. https://doi.org/10.15585/mmwr.mm6943a1. PMID: 33119556; PMCID: PMC7641005.

[17] Kimland EE, Bardage C, Collin J, Järleborg A, Ljung R, Iliadou AN. Pediatric use of prescribed melatonin in Sweden 2006-2017: a register based study. Eur Child Adolesc Psychiatry 2021;30(9):1339–50.

[18] Barretto JR, Gouveia M, Alves C. Use of dietary supplements by children and adolescents. J Pediatr (Rio J) 2024;100:S31–s39. Suppl 1(Suppl 1.

[19] Bruni O, Breda M, Malorgio E, Brambilla P, Ceschin F, Di Pilla A, Elia M, Ferri R. An online survey among general pediatricians on melatonin use in children with chronic insomnia. Eur J Paediatr Neurol 2024;48:40–5.

[20] Skrzelowski M, Brookhaus A, Shea LA, Berlau DJ. Melatonin use in pediatrics: evaluating the discrepancy in evidence based on country and regulations regarding production. J Pediatr Pharmacol Ther 2021;26(1):4–20.

[21] Glass A, Attrill C, Magee C, Blunden S. Factors associated with melatonin use in child sleep disturbance: a survey of Australian parents. Sleep Med 2023;107:330–7.

[22] Carson M, Moore M, Cicalese O, Dunnewald M, Varker A, Mindell JA, Williamson AA. Variation in Twitter posts referencing pediatric sleep aids. Sleep Health 2023;9(4):451459. https://doi.org/10.1016/j.sleh.2023.04.009.

[23] Lunsford-Avery JR, Bidopia T, Jackson L, Sloan JS. Behavioral treatment of insomnia and sleep disturbances in school-aged children and adolescents. Child Adolesc Psychiatr Clin N Am 2021;30(1):101–16. https://doi.org/10.1016/j.chc.2020.08.006.

[24] Meltzer LJ, Wainer A, Engstrom E, Pepa L, Mindell JA. Seeing the Whole Elephant: a scoping review of behavioral treatments for pediatric insomnia. Sleep Med Rev 2021;56:101410. https://doi.org/10.1016/j.smrv.2020.101410.