Level of Evidence
Clinical Guidelines
Royal Children's Hospital

The Hierarchy of Evidence

The Hierarchy of evidence is based on the National Health and Medical Research Council (2000) and Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

I Evidence obtained from a systematic review of all relevant randomised control trials.

II Evidence obtained from at least one properly designed randomised control trial.

III-1 Evidence obtained from well-designed pseudo-randomised controlled trials (alternative allocation or some other method).

III-2 Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.

III-3 Evidence obtained from comparative studies with historical control, two or more single–arm studies, or interrupted time series without a parallel control group.

IV Evidence obtained from case-series, either post-test or pre-test and post test.

V Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles.

Clinical guidelines are based on reviews of the best available evidence. **Level 1 evidence represents the gold standard for intervention studies;** however it is not available for all areas of practice and for some guidelines it may be appropriate to utilise results from studies with lower levels of evidence. Some clinical guidelines may also be informed by experts in the field, locally (RCH) and internationally (Journal articles) (expert opinion) etc. This NHMRC Hierarchy can be used to grade evidence. Please record details on the evidence table and return to Clinical Quality and Safety (CQS) with guideline draft. The Evidence table can be filled out electronically or printed and used as a hard copy.

Please contact Jody Smith Clinical Guideline and Path Coordinator on ext 6956 if you have any concerns or require assistance.

Hospital Clinical Guidelines
EVIDENCE TABLE

GUIDELINE TOPIC:

Please record all references used in developing the clinical guideline. This form must be filled out electronically and emailed to Jody.Smith@rch.org.au
NB: If you need assistance with completing this table, please contact Jody Smith on x 6956.

Reference ***(include title, author, journal title, year of publication, volume and issue, pages)***	**Method**	**Evidence level (I-V)**	**Summary of recommendation from this reference (point form)**
Example *Bloggs, J. Who's laughing now? A systematic review. Journal of Hilarity, 2004, 3 (2), 1-15*	*Systematic review of effectiveness of laughter as the best medicine*	*I*	• *There are few studies in this area* • *Moderate to strong evidence exists to support laughter as promoting wellbeing and overall health.* • *Type and amount of laughter: no current available evidence* **Example**
Holditch – Davis, D., Nan Barham, L., O'Hale, A., and Tucker, B. (1995). Effects of standard rest periods on convalescent preterm infants. *Journal of Obstetric, Gynaecologic and Neonatal Nursing*, 24, 424.	Randomised control trial	II	• More sleep and less active states during naps with regular rest periods. • Differentiation between day and night increases sleep • Further research required on the long-term effect of nap intervention
Rivkees, S. A., Mayes, L., Jacobs, H., and Gross, I. (2004). Rest-activity patterns of premature infants are regulated by cycled lighting. Pediatrics, 133 (4), 833-839.	Randomised control trial.	II	• Cycled lighting induces distinct patterns of activity and rest synchronised with the light-dark cycle. • Cycled lighting is preferable than continuous dim lighting in pre-term infants. • Exposing pre-term infants to cycled lighting does not disrupt sleep or organisation.
Onen, S. H., Alloui, A., Gross, A., Eschallier, A., and Dubray, C. (2001). The effects of total sleep deprivation, selective sleep interruption and sleep recovery on pain tolerance in healthy subjects. Journal of Sleep Research, 10, 35-42.	Cross over study	III-2	• Changes in sleep patterns may influence the perception of pain. • The lowering of pain threshold appeared to correlate with the duration of sleep deprivation.

Ma, G., Segawa, M., Nomura. Y., Kondo, Y., Yanagitani, M., and Higurashi, M. (1993). The development of sleep-wakefulness rhythm in normal infants and young children. Tohoku Journal of Experimental Medicine, 171, 29-41.	Longitudinal follow up study and transverse analysis of study group.	III-3	• In the early stage of infancy, the environmental factors are important for the normal development of the circadian rhythm. • 12 midnight to 4am is the absolute sleep period by 3 months of age.
Centre for Community Child Health. (2006). Settling and sleep problems. Practice resource. Downloaded from: www.rch.org.au/ccch on 14th May 2009	Practice resource	V	• Ninety five per cent of newborns wake every 3 – 4 hours at night and require an adult to help them go back to sleep. • Sleep habits are learned behaviours that are affected by biological and genetic factors and developmental changes. • Sleep consolidation begins between the hours of midnight and 5am.
Bertelle, V., Sevestre, A., Laou-Hap, K., Nagahapitiye, M. C., and Sizun, J. (2007). Sleep in the neonatal intensive care unit. Journal of Perinatal and Neonatal Nursing, 21 (2), 140-148.	Literature review	V	• Sleep has an important role in the development and function of the brain. • Sleep deprivation has a negative impact on health and development. • Mean duration of sleep cycles 40-70 minutes. • Observational indications of sleep states. • Cycled lighting may be a better environment to achieve a more physiologic homeostatic state. • Clustering of cares and interventions increase durations of rest periods
Davis, K. F., Parker, K. P., and Montgomery, G. L. (2004). Sleep in infants and young children: part one: normal sleep. *Journal of Pediatric Health Care*, 18 (2), 65-71.	Literature review	V	• Newborns sleep for 16 -18 hours in 24 hours. • Circadian rhythm emerges around 2-3 months when infants become increasingly responsive to environmental cues such as light and dark and social cues such as feeding, nap times, and night-time routines.
Lavie, P. (2001). Sleep-wake as a biological rhythm. Annual Review of Psychology, 52, 277-303.	Literature review	V	• Cycled lighting reflecting day and night helps develop normal transition to nighttime sleeping patterns.
Heussler, H. S. (2005). Common causes of sleep disruption and daytime sleepiness: childhood sleep disorders II. Medical Journal of Australia, 182 (9), 484-489.	Expert opinion	V	• Newborn babies sleep 16-18 hours in 24 hours. • Influences of daylight and dark cycles produce more wakefulness during the day. • 95% of infants will cry after waking and require a response to help them settle.

Merenstein, G. B., and Gardner, S. A. (2006). Handbook of Neonatal Intensive Care. Sixth Edition. Mosby Elsevier. United States of America.	Text book	V	• Consistent routines help to regulate the neonate's rhythms. • Neonates should not be woken while sleeping. If they must be woken, it should be during active sleep by gentle touch and talking. • Clustering of cares and interventions increase durations of rest periods • Quiet time assists neonates to become used to sleeping in dim and quieter environments.