

Sleep Rituals

Many of the sleep rituals described in the communication [1] do not apply to pediatric age group. We do not expect most children, except adolescents, to indulge in consumption of alcohol, sleeping pills, and nicotine products. Presuming that most children would be expected to go to bed by 10 PM in night, not indulging in heavy exercise for six hours prior to sleep is not practical

because that is the time when they are expected to be out in the play grounds after doing their homework. It is necessary to suggest age specific sleep rituals applicable to our culture and social life.

ANUP MOHTA
mohtaanup@hotmail.com

REFERENCE

1. Sukumaran TU. Pediatric sleep project. *Indian Pediatr.* 2011;48:843-4.

Rickettsial Diseases in Central India

The paper by Rathi *et al.* [1] is an interesting attempt to develop a clinical score to diagnose spotted fever. However I am intrigued to note that the authors have taken Ethics approval from the Institutional Review Committee at Cooper University Hospital at Camden, USA.

NJ. The IRB at Cooper University Hospital was willing to review and approve this study as two of the investigators were from their institution, this was a retrospective review of the cases and the only concern in a retrospective study is loss of privacy for the subjects. Every effort was made to protect the privacy of the subjects in this study. The investigators at Cooper University Hospital received only de-identified data.

NARENDRA B RATHI
drnbrathi@hotmail.com

REFERENCE

1. Rathi NB, Rathi AN, Goodman MH, Aghai ZH. Rickettsial Diseases in Central India: Proposed Clinical Scoring System for Early Detection of Spotted Fever. *Indian Pediatr.* 2011;48:867-72.

It is pertinent to note that for a study conducted on patients from India in India, ethics approval should be sought from Ethics Committee based in India. If the hospital where the study was conducted does not have an Institutional Ethics Committee, an external Ethics committee based in India should have been approached for the same. Even if there are two co-authors are from Camden, according to Clinical Trials Registry -India (Personal communication), Review Committee at Camden is in no position to give ethical clearance to a study done on patients in India.

ANUP MOHTA
mohtaanup@hotmail.com

REFERENCE

1. Rathi NB, Rathi AN, Goodman MH, Aghai ZH. Rickettsial Diseases in Central India: Proposed Clinical Scoring System for Early Detection of Spotted Fever. *Indian Pediatr.* 2011;48:867-72.

AUTHOR REPLY

We agree that any clinical trial or prospective study should be approved by a local ethics committee. However, this report is not a clinical trial or a prospective study. Since there was no ethics committee in Akola to review this study, we approached Institutional Review Board (IRB) at Cooper University Hospital in Camden,

EXPERT REPLY

In normal circumstances the Institutional Ethics Committee (IEC) should be involved because it is not only the ethical issues in the protocol but also during the conduct of the study IEC has responsibilities to the enrolled subjects. All serious adverse events are reported to IEC and also there is role in deciding compensation as well as prevention of injuries to the patient from conduct of study. In the absence of IEC an independent ethics committee may be approached. However, it should be in a position to take up the responsibilities of Ethics Committee during the conduct of study, which may not be possible for an overseas ethics committee. Even for multi centric trials with same protocol which have ethical clearance from other Ethics Committees the clearance of IEC is required.

In present case however the study involves only analysis of retrospective data. No patients are being enrolled and there is no ongoing trial/study. Only important ethical issue is that the identity of study subjects is not revealed. It is possible to accept the