Polysomnography Entails No More Than Minimal Risk

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DEAR EDITOR,

IN THE PREVIOUS ISSUE OF *SLEEP*, MEHRA AND STROHL[1] DOCUMENTED THE INCIDENCE OF ADVERSE EVENTS FOR NOCTURNAL POLYSOMNOGRAPHY (PSG). Out of a total of 16,084 PSG studies, 56 potentially serious adverse events and 1 fatality were noted. Even though this incidence rate is very low,[1] it should be pointed out that none of the reported events appeared to be related to the PSG procedure per se. The distinction between adverse events noted *during* PSG and adverse events occurring *due to* PSG is important, because documentation of the incidence of adverse events may affect to what extent PSG is considered appropriate as a component of standard clinical care. Furthermore, such documentation may affect whether PSG is deemed acceptable in research studies, as reviewed by ethical committees and institutional review boards (IRBs).

The *Common Rule*—the regulations governing the protection of human subjects in the United States of America (Code of Federal Regulations title 45 part 46)—allows research involving *no more than minimal risk* to be reviewed by IRBs by means of "expedited review procedures" [45 CFR 46.110(b)(1)].[2] A list of categories of research that may be reviewed through expedited review procedures has been published in the Federal Register [45 CFR 46.110(a)].[2] Category 4 in this list is "Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice [...]."[3] Examples include "(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy" and "(d) electrocardiography, electroencephalography, [...]."[3] By these criteria, standard PSG constitutes no more than minimal risk in research on human subjects.

Based on their findings, Mehra and Strohl[1] advised that "training, written procedures, basic life support certification, continuing education, and procedures for handling medical emergencies or adverse events noted during polysomnography or in scoring are prudent."[1] These important recommendations notwithstanding, the data presented by Mehra and Strohl[1] should not be taken to imply that the PSG procedure per se constitutes greater than minimal risk. In fact, these same data appear to support the regulatory criteria by which PSG proper is designated to involve *no more than minimal risk*.

REFERENCES

1. Mehra R, Strohl KP. Incidence of serious adverse events during nocturnal polysomnography. Sleep 2004;27:1379-83.
2. Office for Human Research Protections. Code of Federal Regulations title 45 part 46. Protection of human subjects. Available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. Accessed November 28, 2004.
3. Office for Human Research Protections. Categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review procedure. Available at http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm. Accessed November 28, 2004.

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