Patient Restraints: Suggestions From The FDA.

The U.S. Food and Drug Administration has published a number of suggestions for how patient restraints should be used in healthcare facilities. The FDA's suggestions are only *advisory* at the present time.

The FDA supports a "prescription" requirement, under which restraints may be applied only by licensed healthcare providers under physicians' orders. Physicians' orders should specify the appropriate restraint type, duration of application and circumstances of use.

The FDA has no comment at this time on the appropriate frequency for patients under restraint to be monitored.

Although restraints, when safely applied, must be tied securely, it is also vital that care providers be instructed to use knots which can be easily *untied* in the event of an emergency. The FDA is considering regulations to require patient restraints to have clasps which caregivers can quickly unfasten.

Selection of the appropriate size and type of restraint, particularly with vest restraints, is critical for safe and effective use. It may be helpful for the brand and types of restraints to be standardized for all units of a particular facility. Clinicians as well as purchasing agents should consult medical practice guidelines for selection of restraints, although no source is cited for this in the literature other than the FDA's own safety alert in 1992.

The FDA advises that patients under restraint must not be allowed to smoke. Further, family members and visitors should be cautioned not to furnish smoking materials to patients in restraints and that they themselves should not smoke around patients who are in restraints. The problem can be particularly acute when oxygen is in use.

Caregivers should be particularly vigilant with any patient in restraints who has a history of setting fires to the room, to furnishings, to the patient's own person or to the restraints as a means of attempting to get free of them.

The FDA encourages the use of posters and other visual aids in the training of staff who will care for patients who are in restraints, especially where staff would not be expected to gain full benefit from complicated verbal instructions, or from instructions presented only in English. Posters and other visual aids should be readily noticeable in patient rooms, nurses stations and physical therapy areas.

The FDA is considering regulations to require approved staff training materials to be provided by manufacturers along with restraining devices themselves, as a part of the FDA approval process for sale of restraint devices. It encourages healthcare facilities to make full use of any training aids and in-service presentations currently being made available by manufacturers and their representatives.

Due to numerous reports of serious injuries and patient deaths, the FDA has changed its regulations and will now require pre-market approval of all patient-restraint devices.

For the time being, the FDA has a number of advisory suggestions for healthcare facilities in which patient restraints are used, based upon studies the FDA has conducted, published literature, and public comments the FDA has been receiving to proposed regulations published in 1992.

FEDERAL REGISTER, March 4, 1996
Pages 8432 - 8439.

Patient Restraints: Caregiver Faulted For Neglecting To Re-tie Patient's Restraint, Leading To Assault On Another Caregiver.

The Court of Appeals of Wisconsin ruled recently that a nurse's aide could sue for being assaulted by a patient, after an occupational therapist neglected to re-tie the patient's restraints after an aborted therapy session. The aide's ability to sue was limited by the fact she technically had no legal right to file a personal injury lawsuit against the hospital, her own employer, for an on-the-job injury. However, in this particular case, the occupational therapist did not enjoy a similar technical immunity from suit and could be sued by the aide.

The aide's job was to sit with the patient, a liver transplant recipient. He was described in the court record as not lucid, but "loud and extremely uncooperative." It had been charted that he had begun throwing things around the room on a prior occasion when he had managed to get an arm free from his restraints.

The occupational therapist had to discontinue her therapy session with the patient because he became uncooperative. However, she neglected to re-tie his restraints completely before she left the room.

As the therapist left, the aide returned to the room to continue sitting with the patient. When the aide approached to assist him with a glass of water, he grabbed her and punched her in the face and head.

The decision whether or not to restrain this patient was not for the occupational therapist to make. That decision, according to the court, had already been made by someone else. After unfastening the patient's restraints, there was a legal duty to see that the restraints were securely refastened before leaving the patient's room. **Walker vs. University of Wisconsin Hospitals, 542 N.W. 2d 207 (Wisc. App., !995).**