



Physical Restraints Acknowledgement

Physical Restraint devices – such as safety vests and jackets, lap and wheelchair belts, and fabric body holders – may be beneficial to patients and their caregivers when used properly in settings ranging from nursing homes and hospitals to private homes. But with increasing reports of injuries and deaths resulting from misuse of the devices, the FDA is taking steps to ensure health professionals and consumers have the information they need to use these devices safely.

Scope of the Problem

The FDA estimates that at least 100 deaths from improper use of restraints may occur annually. And the FDA has received reports that many patients suffer burns, broken bones, and other injuries related to patient restraints. Many problems with restraint devices are never reported to the FDA. The agency has become aware of the magnitude of the problem from a variety of sources: the press, research in the field, the FDA's Medical Device Reporting (MDR) System. Most reported deaths have occurred when patients tried to get out of the restraints for some reason, such as to go to the bathroom.

Physical restraints are used with patients of all ages; however, most reported deaths and injuries have involved elderly patients living in nursing homes who were left unattended while restrained. At least one case is known of a child dying while being restrained.

In the reported deaths, the cause was often asphyxiation due to strangulation. In many cases, the patient strangled after sliding down between a mattress and side rail while apparently trying to get out of bed. In a few cases, the patient slid forward while sitting in a wheelchair or geriatric chair and was strangled by the restraining device. From the reports the FDA has received, it appears that increased awareness of the danger of misuse of patient restraints could prevent many death and injuries.

Uses for Restraints

Used properly, restraints have many benefits for patients and care givers in both institution and homes. Restraint may help protect the elderly from falls, which could result in injury or even death. If absolutely necessary, restraints also can help made medical treatment easier if a patient is temporarily uncooperative or highly agitated. If a patient is dangerous, restraints can protect other patients and staff from possible harm. Some patients feel safer and more secure, and need not worry about falling, if they use physical restraints.

If certain medical procedures are being done at home or in an institution, such as changing an intravenous line or giving an injection, restraints can be useful to enable a patient to stay still.

Misuse of Restraints

The misuse of physical restraints that can result in injury or death takes many forms:

Inappropriate patient selection. Putting a restraint on certain patients may actually worsen their condition. For example, a chronically agitated patient may become more agitated with a restraint.

Inappropriate use. Restraints should not be used unless necessary or when in the patient's best interests.

Inadequate monitoring. Patients can be injured if they are not adequately monitored over long periods while they are restrained. In fact, if restraints are being used to avoid monitoring patients, then they are being misused. If a restraint is used for too long, and the patient is unable to move, various health problems can occur, including decubitus ulcers, nerve damage, and incontinence. Sensory deprivation can cause psychological problems. Over time, mental and physical decline can occur. Patients in physical restraints need extra monitoring, not less.

Wrong type/incorrect application. Selecting the wrong type of restraint for a particular patient's needs or putting a restraint on backwards or upside down, or using the wrong size, also increases the chances for injury or death.

Recommendations

Whether physical restraints are used in homes or institutions, the following general recommendations should be followed:

- Find alternatives to using restraints whenever possible
- Use with patient or family consent
- Discontinue use as soon as feasible
- Observe patients in restraints frequently
- Remove the restraints as often as possible to allow for normal body functioning and daily activities
- Apply and adjust the restraints so that it is comfortable for the patient

Follow the manufacturer's direction to:

- Select the type of restraint's recommended for the patient's condition
- Use the correct size for the patient's weight and height
- Not the front and back of the restraint and apply correctly
- Tie knots that can be released quickly
- Secure bed restraints to the bedsprings or frame, never to the mattress or bed rail. With an adjustable bed, secure the restraints to the parts of the bed that move with the patient

Recommendations that particularly apply to institutions such as nursing home include:

- Define a clear, written institutional policy on the use of restraints and make it Available to patients or residents and their families
- Display this policy and other instructions in a highly visible location and in foreign language(s) as necessary
- Provide regular staff training-including demonstrations in proper use of restraints
- Obtain informed consent from patients or guardians before using restraints to prevent misunderstanding and to ensure cooperation
- Keep well-documented patient records including why, how, where and for how long the restraint was used. Also document every two hours in the nursing progress note that the restraints were loosened and the area restrained was inspected, skin care performed and patient position changed.
- Follow local and state laws regarding the use of these devices

Regulation of Physical Restraint Devices

Even though there have been many reports of problems with various types of patient restraints, existing evidence does not indicate that these problems are a result of any particular restraint type, model or manufacturer. Rather, injuries and deaths appear to be due to problems that could be prevented with user education, training with the device and better product labeling. Therefore, the FDA has no plans to recall any of these devices from the market.

Since good labeling is critical to effective staff training in institutions and proper use of restraints at home, the FDA is working with the industry to improve the labeling on restraint devices. New labeling will be required later this year. The goal is having clearer instructions, in different languages, with helpful graphics and other visual aids. Moreover, visible warning labels will need to be affixed to the restraint devices where users can readily see them.

Reporting Problems

Effective November 28, 1991, the Safe Medical Devices Act of 1990 requires all hospital, nursing homes, and acute-care facilities to report deaths related to the use of any medical device to the FDA and the manufacturer within ten (10) working days. They must also report serious injuries or illnesses to the manufacturer within ten (10) working days or the FDA if the manufacturer is not known.

Please report any misuse of patient restraints to your supervisor on staff immediately.