Sentinel Event Alert

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Sentinel Event ALERT

Medical gas mix-ups

The Joint Commission received two reports of medical gas mix-ups in 2000 that resulted in the death of four patients and injury to five patients. In the past four years, the Food and Drug Administration (FDA) has received four reports that resulted in seven deaths and 15 injuries. In early April 2001, the FDA issued a Guidance for Hospitals, Nursing Homes, and other Health Care Facilities--Public Health Alert (1) that focuses on its reports of medical gas mix-ups, their common causes and the FDA's recommendations for preventing occurrences. This alert is being distributed to help spread the word to health care organizations about steps that can be taken to prevent deaths and injuries from compressed gases, which include industrial and medical grade gases. Medical grade gases are considered prescription drugs and include oxygen, compressed air, carbon dioxide, helium, nitrogen and nitrous oxide. These medical gases are either used in medical treatment and procedures, or to power medical equipment. Industrial grade gases should **never** be used medically. Medical gases come in many different types of vessels, but three of the FDA's four cases involved cryogenic vessels and their connectors, so this alert will focus on the problems associated with those vessels.

Common causes

The FDA's public health alert highlights several common causes in its cases of medical gas mix-ups that are related to 1) lack of proper training of personnel responsible for the delivery, connection or identification of medical grade gas vessels, 2) removal of gas-specific connectors, and/or 3) improper labeling (in one case) or storage of medical gas vessels. Three of the FDA's four cases involved maintenance or delivery personnel who were not trained to recognize built-in safeguards--specifically connection incompatibility. Connectors for cryogenic oxygen vessels are specially fitted so that they are compatible only with oxygen delivery systems. In most cases, the health care organization's personnel responsible for medical gases were not trained to recognize the labeling used to identify the grade or type of gas in vessels. In some cases, medical grade and industrial grade product vessels were stored together, and the wrong grade gas was selected or delivered accidentally.

The FDA, the Compressed Gas Association (CGA) and medical gas manufacturers are exploring new safeguards, including silver brazed connections on cryogenic vessels that are impossible to remove. The CGA is a safety and standards organization for medical and industrial gases; its membership includes manufacturers of medical and industrial gases and equipment, as well as distributors. In December 2000, the CGA issued SB-26 (2), a safety bulletin that recommends the use of silver brazed connections on cryogenic liquid cylinders in medical gas service. Other safeguards being considered are standardized color-coding and better labeling of cryogenic vessels. While a health care organization has no control over labeling used by its medical gas supplier or the training of its medical gas delivery personnel, there are measures that an organization can take to help prevent deaths or injuries from medical gas mix-ups.

Expert recommendations

The FDA recommends the following procedures be taken to prevent medical gas mix-ups at health care organizations.

With respect to personnel training, all employees who handle medical gases:

- Should be alerted to and reminded of the possible hazards associated with using medical gas.
- Should be trained to recognize and carefully examine medical gas labels.
- Should be trained to make sure each vessel they connect to the oxygen system bears the proper label--if your supplier uses 360-degree, wrap-around labels to designate medical oxygen.
- Should be trained to connect medical gas vessels properly if they are responsible for changing or installing cryogenic vessels. These personnel should understand how vessels are connected to the oxygen supply systems and be alerted to the serious consequences of changing connections. Adapters must never be used to make a connection.

With respect to equipment and gas storage:

- If your facility receives medical gas deliveries, store medical grade products separately from industrial grade products. The storage area for medical grade products should be well defined with one area for receiving full cryogenic vessels and another area for storing empty vessels.

> *"Ideally, a practitioner licensed by state law, such as a pharmacist assistant, a pharmacist technician, or a trained designee, should check the gas before use to ensure that the patient is receiving the correct medical grade gas."*
> *--**Duane Sylvia**, consumer safety officer, FDA Office of Compliance, Center for Drug Evaluation and Research*

- The fittings on cryogenic vessels should not be changed under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem.
- Once a cryogenic vessel is connected to the oxygen supply system, but prior to introducing the product into the system, a knowledgeable person should ensure that the correct vessel has been connected properly.

"Ideally, a practitioner licensed by state law, such as a pharmacist assistant, a pharmacist technician, or a trained designee, should check the gas before use to ensure that the patient is receiving the correct medical grade gas," says Duane Sylvia, consumer safety officer with the FDA's Office of Compliance at its Center for Drug Evaluation and Research.

Recommendations

Joint Commission recommends that organizations address the recommendations with respect to personnel training, equipment and gas storage as listed above.

References

1. Guidance for Hospitals, Nursing Homes, and other Health Care Facilities-Public Health Alert, April 2001; U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research; available at http://www.fda.gov/cder/guidance/4341fnl.htm
2. SB-26; December 8, 2000; Compressed Gas Association; available for purchase by non-members for $6 at the CGA Web site, http://www.cganet.com/, or by calling 703-412-0900.

Published for Joint Commission accredited organizations and interested health care professionals, Sentinel Event Alert identifies the most frequently occurring sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

During the on-site survey of accredited organizations, JCAHO surveyors assess the organization's familiarity with and use of Sentinel Event Alert information. Organizations are expected to (1) review each Sentinel Event Alert, (2) consider the suggestions, as appropriate to the organization's services, and (3) implement the suggestions, or reasonable alternatives, or provide a reasonable explanation for not implementing relevant changes.

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