Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities

FDA PUBLIC HEALTH ADVISORY

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2001
Compliance

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FDA Public Health Advisory[1]

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I. INTRODUCTION

This guidance is intended to alert hospitals, nursing homes, and other health care facilities to the hazards of medical gas mix-ups. The Food and Drug Administration (FDA) has received reports during the past 4 years from hospitals and nursing homes involving 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas (e.g., nitrogen) that had been mistakenly connected to the oxygen supply system. This guidance makes recommendations that will help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups.

II. BACKGROUND

On December 7, 2000, a nursing home in Bellbrook, Ohio, reported 2 patient deaths and 8 patients injured following a mix-up in their oxygen supply system. The nursing home had supposedly received a shipment of four cryogenic vessels[2] containing medical grade oxygen. Included in the delivery, however, was a cryogenic vessel of industrial grade nitrogen. The nursing home was running low on oxygen and sent a maintenance employee to connect a new oxygen vessel to the oxygen supply system. The employee selected the

[1] This guidance was developed by the Office of Compliance in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration.

[2] Cryogenic vessels are used to contain material that is stored at very low temperatures.

nitrogen vessel and discovered, correctly, that he was unable to connect the vessel to the oxygen system — as a safeguard, the connectors for oxygen vessels are specially fitted so they are compatible only with oxygen delivery systems. The employee removed a fitting from an empty oxygen vessel and installed it on the nitrogen vessel. He then connected the deadly product to the oxygen system. Several days later, 2 of the injured patients died from exposure to industrial nitrogen, bringing the death total from this one incident to 4.

On April 22, 1998, a hospital in Idaho discovered that a large cryogenic vessel of industrial nitrogen had been connected to the oxygen system supplying the operating rooms, labor and delivery rooms, and emergency room. The hospital discovered that the medical gas delivery person initially had been unable to connect the incompatible nitrogen vessel outlet fitting to the oxygen system, but had used a wrench to disconnect the nitrogen fitting and replace it with an oxygen fitting. Two patients died as a result of this medical gas mix-up.

In October 1997, a hospital in Nebraska received a shipment of medical grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial grade argon that was properly labeled. The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system. Without examining the label, the employee selected the argon vessel, and, discovering he was unable to connect the vessel to the oxygen supply system, he removed a fitting from an empty oxygen vessel, installed it on the argon vessel, and connected the deadly product to the oxygen system. Argon was administered to a patient undergoing minor surgery. The patient died.

On December 2, 1996, a childrens' home located in New York reported adverse reactions experienced by nine patients due to the inhalation of carbon dioxide. An employee of the home, asked to attach a large cryogenic vessel of medical grade oxygen, unknowingly selected a carbon dioxide vessel from the home's inventory. He noted that the fitting on the carbon dioxide vessel was not compatible with the connector on the oxygen system. Nonetheless, he removed an oxygen fitting from an empty vessel, installed it on the carbon dioxide vessel, and attached it to the oxygen supply system. Two patients were injured critically, and four patients experienced varying stages of respiratory distress.

All four cases reveal striking similarities:

- The person connecting the vessel to the oxygen system (e.g., the delivery person or the facility employee) was not properly trained and did not understand that connection incompatibility is a built in safeguard.

- Prior to installing the cryogenic vessel to the oxygen supply system, the person making the connection did not examine the drug label applied to the cryogenic vessel to ensure that the product was medical oxygen.

The Agency has identified additional practices that may contribute to continuing medical gas mix-ups resulting in injury and death:

- Although recommended by the Compressed Gas Association, many of the large cryogenic vessels used to contain medical gases do not have permanently brazed, or welded, connections or fittings that cannot be removed.

- Unfortunately, not all medical gas vessels are labeled using 360-degree wrap-around labels.

- Separate storage areas often are not provided either in the delivering vehicle or at the receiving facility to sufficiently separate medical grade products from industrial grade products.

As a result, many medical gases are improperly or poorly labeled; the wrong gases are delivered accidentally to hospitals, nursing homes, and other health care facilities; and poorly trained personnel are connecting the wrong vessels to oxygen supply systems, despite connection incompatibilities. Patients continue to suffer injury or death.

III. RECOMMENDATIONS

All of the incidents described above could have been avoided if a few simple safety procedures had been followed. It is important that ***all*** employees handling a medical gas be alerted to and reminded of the possible hazards associated with using medical gas.

The Agency recommends implementing the following:

1. If your facility receives medical gas deliveries, you should 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.

2. All personnel who will be handling medical gases should be trained to recognize the various medical gas labels. Personnel should be trained to examine all labels carefully.

3. If your supplier uses 360-degree wrap-around labels to designate *medical oxygen*, personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears such a label.

4. Make sure that all personnel in your facility who are responsible for changing or installing cryogenic vessels are trained to connect medical gas vessels properly. Personnel should understand how vessels are connected to the oxygen supply system and be alerted to the serious consequences of changing connections.

5. You should emphasize repeatedly that the fittings on these 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.

6. 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.

We urge you to take every opportunity to promote the importance of properly handling medical gases. Alert all personnel in your facility, but especially those who are directly responsible for handling medical gas, to the potential hazards involved.

IV. REPORTING ADVERSE EVENTS OR ERRORS TO FDA

Medical gases are prescription drugs. Therefore, all medical gas manufacturers who receive reports of death or serious injury associated with the use of medical gases are required under 21 CFR 310.305 and/or 314.80 to report those incidents to the FDA.

Hospitals, nursing homes, and other health care facilities should submit reports to CDER (301-594-0095) or directly to FDA's voluntary reporting program, MedWatch, by phone (800) FDA-1088, by facsimile (800) FDA-0178, or by mail to MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, Maryland, MD, 20857-9787.