RealClearHealth

# Op-ed: Medical Device Sterilization Is Critical for Patient Safety

SCOTT WHITAKER, PRESIDENT AND CEO, ADVAMED
MARCH 28, 2023

Americans are admitted to the hospital 33.4 million times and visit doctors one billion times a year. Almost all those visits require sterile medical equipment. Syringes for drawing blood. Catheters. Surgical tools. The sterility of these devices is critical to preventing potentially life-threatening infections. When infections do occur, especially in the hospital, with patients already suffering from what brought them in for treatment, the illnesses can be extremely serious. That's where ethylene oxide comes in.

Ethylene oxide gas, or EtO, is used to sterilize approximately 50 percent of the medical technologies – roughly 20 billion devices – required for patient care in the U.S. each year. Some medical devices can be sterilized using other methods. Others can't. For example, a syringe sterilized with radiation would shrink, turn yellow and brittle, and become unusable and unsafe.

EtO sterilization facilities process medical equipment in a proven, highly engineered way, with designated chambers for each phase and capture-and-destruction procedures for emissions. The facilities follow local, state, and federal regulations, with many exceeding these safety requirements.

EtO is in the news lately because the U.S. Environmental Protection Agency (EPA) has held meetings in some communities with sterilization facilities it has deemed to be of higher risk than others. Some of those meetings have justifiably generated questions among community members, as well as alarming news coverage driven by a misunderstanding of the science surrounding the cancer risk of EtO emissions.

The science is indeed complex, which is why it's even more important that the EPA and others are careful and thorough in their explanation of EtO's true risk to surrounding communities. Rhetoric not rooted in science could cause sterilization facilities to shut down unnecessarily, with disastrous consequences.

The shutdown of even a single facility could harm timely patient care. Only 100 or so EtO sterilization facilities across the U.S. handle the 20 billion, or 50 percent, of the products needed for patient care each year. The pandemic brought supply chain disruptions to hospitals and homes. A scramble for sterile medical devices would cause a true public health crisis.

AdvaMed
Advanced Medical Technology Association

The EPA's own assessment for EtO emissions risk is conservative. The EPA describes its assessment as a "worst-case scenario," requiring continuous exposure, 24 hours a day, for 70 years, to elevate the cancer risk of community members beyond that of communities without an EtO sterilization facility. This is based on modeling, not actual data. Also, the EPA has stated that it cannot account for everyday sources of EtO because existing measurement tools are inadequate.

That's a critical point in trying to identify actual risk: Ethylene oxide is literally all around us, whether you live near an EtO sterilization facility or not. It's naturally occurring, created by our own breath and living and decaying plants. It's a byproduct of everyday commercial items—school buses, lawn mowers, and gas and charcoal grills. In fact, the medical device sterilization process accounts for only one half of one percent of all commercial EtO use.

Two things would be true if every EtO sterilization plant in the U.S. were shut down: The average exposure to ethylene oxide would not drop significantly, and doctors and hospitals would lack many of the sterile supplies needed to treat patients, resulting in chronic delays in care.

The medical device industry has been working directly with the EPA and welcomes an updated regulation rooted in science and actual data. And yet, despite the critical need to preserve the EtO sterilization process today, the industry is looking to the future. We've found new ways to use less EtO, several companies are working with the FDA to develop alternatives, and technology to contain even more emissions is evolving.

Improving, saving, and extending patients' lives depends on innovation in the medical technology field, and that includes how best to safely sterilize devices. Our top priority is the patients we serve—and that includes ensuring the sterilization process is safe. We hope science prevails, the EPA hears an industry that has been safely sterilizing billions of medical devices for years, and patients continue to benefit from the sterile equipment necessary for safe, effective, and timely care.

*Scott Whitaker is president and CEO of AdvaMed, the Advanced Medical Technology Association, the largest trade association representing medical technology manufacturers.*

**Available Online:** http://bit.ly/3TPkA6E

AdvaMed
Advanced Medical Technology Association