ISMP Medication Error Report Analysis

New Connectors Coming for Enteral Feeding Tubes

Marqibo and Risk of Errors

Angeliq Is Not a Birth Control Pill

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These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below.

Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

NEW CONNECTORS COMING FOR ENTERAL FEEDING TUBES

Later this year, the International Organization for Standardization (ISO) will introduce new design standards for enteral feeding device connectors. Introduction of the new connectors is crucial to patient safety, because the current Luer type connectors have a universal design that allows connections between devices that serve completely different functions (eg, enteral tubing connected to a tracheostomy tube inflatable cuff or an intravenous [IV] line).

The new enteral connectors will be introduced by The Global Enteral Device Supplier Association (GEDSA), an international group of enteral feeding device manufacturers, distributors, and suppliers that has worked closely with ISMP, The Joint Commission, the Association for the Advancement of Medical Instrumentation (AAMI), the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), Premier Safety Institute, Novation, and

the Oley Foundation, a nonprofit organization that supports persons requiring home IV infusions and tube feedings. Although tubing misconnections are less of a concern in the home, the new, safer connectors will be introduced globally. So it is important to understand how the change will impact hospital and home enteral nutrition. GEDSA has a campaign in place called Stay Connected 2014. The campaign goal is to ensure that, by the time the connectors reach the market, everyone who uses an enteral device will be aware of the change, be prepared to transition to the safer connector, and successfully adopt it.

The new global design standards ensure that all manufacturers of feeding tubes, enteral administration sets, and enteral syringes will use one standard design for the connector that will be universally adopted into practice. The enteral-specific design does not allow connectivity with any other type of connector. It also provides a locking feature that signals the

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appropriate connection has been made and remains in place. It has a female connector end for administration sets and syringes that fit into a male patient-access feeding tube port. The new standards will impact syringes as well as feeding tubes and feeding administration sets. Enteral-specific syringes with the new standard female connector will be required for connection to feeding tubes with the new standard male connector in order to administer feedings or flush lines.

These changes are part of a larger initiative that will later introduce standards for connectors that are used in other applications. The initiative is designed to reduce tubing misconnections by making sure devices for different delivery systems are not compatible. Tubing misconnections are rare, but when they occur, patient injuries can be serious, life-threatening, and even fatal.

Manufacturers have been working together to develop a plan for introducing the new connectors. Transition connectors or “adapters” are planned to allow new feeding/administration sets and syringes to connect to existing gastrostomy or jejunostomy tubes until the transition is complete. Feeding/administration sets with these adapters will start to be distributed in the fourth quarter of 2014. This will minimize any disruption to hospitals and consumers while allowing the use of the feeding tubes and feeding/administration sets already on hand until supplies are exhausted and the new ones are in place. Eventually, these adapters will be phased out.

All major enteral device manufacturers are expected to comply with the new ISO standards. During the fourth quarter of 2014, customers ordering enteral administration sets will receive transition feeding/administration sets. Syringes used for flushing and boluses will be available with the new connector during the first quarter of 2015, and new enteral feeding tubes with an ISO standard connector will be available in the second quarter of 2015. By January 2016, the transition to new ISO standard connectors will be complete. At that point, the current universal Luer connector will no longer be available for any enteral feeding applications. Visit the Stay Connected 2014 Web site for updates (www.stayconnected2014.org).

[We acknowledge Tom Hancock, Executive Director of GEDSA, for his collaborative work on this initiative and assistance with this article.]

MARQIBO AND RISK OF ERRORS

We have published reports of a number of serious and fatal errors over the years in which lipid-

based products were confused with conventional forms of the drug. For example, fatal mix-ups have occurred between liposomal and conventional formulations of amphotericin B as well as doxorubicin products. Although we have not learned of any actual events involving vincristine sulfate liposome injection (*Marqibo*) and conventional vincristine sulfate injection, a mix-up could happen. For example, an inexperienced pharmacist may receive an order for liposomal vincristine but use the conventional product instead, not recognizing the higher dosage recommendation for the liposomal product (for adults, the liposomal dose is 2.25 mg/m² vs the conventional dose of 1.4 mg/m²).

The liposomal product has a specific indication for the treatment of adults with Philadelphia chromosome-negative acute lymphoblastic leukemia, only under certain conditions. The drug also requires a highly unusual and complex 26-step process for dose preparation (see the package insert at <http://www.marqibo.com/>).

Although these limitations might seem to clearly differentiate this drug from vincristine sulfate injection, none of this matters if someone thinks it is the conventional form of vincristine sulfate that has been ordered. During new employee orientation, the differences between liposomal and conventional products should be covered. Orders for *Marqibo* are best communicated using both the proprietary and complete generic name, and the indication for use, the patient's weight in kilograms, height in centimeters, the mg/m² dose, and the final dosage calculation. Dose-checking alerts should be used in computer systems for both liposomal and conventional formulations. Consider adding an alert to question all doses that exceed agreed-upon dosing limits.

ANGELIQ IS NOT A BIRTH CONTROL PILL

Angeliq (drospirenone, estradiol) is a hormone-based medicine used to relieve the symptoms of menopause. We are aware of errors when it was prescribed improperly as an oral contraceptive. Our sister organization, ISMP Canada, recently received 2 reports. In each case, a physician provided a woman with samples of *Angeliq* to take as birth control. Both women took *Angeliq* for several months until the samples were finished. The mistakes were discovered when the women took prescriptions for further supplies of *Angeliq* to their pharmacies and referred to them as “birth control pills” (www.ismp.org/sc?id=330).

Figure 1. *Angeliq* package label.

Angeliq has a number of similarities to birth control pills that might have played a role in the mix-up. The labeling and packaging is similar in design to birth control pills (Figure 1). It's available as a 28-day blister pack. "Angeliq" also sounds like a woman's name, and many birth control pills also have female-sounding names (eg, *Portia*, *Yasmin*). In addition, neither the outer nor the inner package of the *Angeliq* sample pack has any information pointing out that the medicine is to be used for symptoms of menopause. Most important, the hormones contained in *Angeliq* appear similar to the ingredients in birth control pills – a progestin and estrogen component.

However, the dose of progestin in *Angeliq* is less than that used in birth control pills, and the potency of the estrogen used in *Angeliq* is also different from the potency used in birth control pills. Women using *Angeliq* instead of an oral contraceptive could become pregnant. That is exactly what happened to a woman we heard from recently through our consumer error reporting program (www.consumermed-safety.org). Her doctor had given her *Angeliq* for birth control, and now she believes she is pregnant. Notify individuals who might prescribe oral contraceptives about this risk. Ideally, consider a pop-up alert for prescriber order entry systems. ■