Veterans Health Administration

Patient Safety Advisory

Issued by VHA Central Office

Advisory ID: AD22-01

Alerts and Recalls ID: PRO-17244

Date Issued: June 27, 2022

Item: **Conversion to enteral products (e.g., feeding tubes, adapters, syringes) with ENFit® connectors**

Specific Incident: Most of the leading manufacturers of enteral feeding administration sets that contain ENFit® Transition Connectors will stop providing the transition connectors with the sets starting in July 2022. These transition connectors allow enteral products with a female ENFit® connector to attach to legacy (older style) enteral feeding tubes with a female opening (see the Attachment). The production of legacy enteral products is expected to decline coinciding with this change. Therefore, facilities who have not made the full transition to enteral products having ENFit® connectors must transition to safer products per this Patient Safety Advisory. **The risk in delaying transition to enteral products with ENFit® connectors is two-fold: 1) increased risk of tubing misconnections, which can be fatal, and 2) inability to provide nutrition or medications to Veterans.**

General Information: On December 30, 2014, Patient Safety Advisory AD15-01 was issued by VHA Central Office. The Advisory informed staff that changes were being made to enteral product connectors in an international effort by the International Organization for Standardization, Standard 80369-3, to reduce the risk for tubing misconnections (Reference 5). Tubing misconnections, also called wrong route errors, occur when tubing intended for one product is inadvertently connected to another product (e.g., enteral administration set connected to a patient's intravenous (IV) line - delivering enteral formula into a patient's bloodstream).

The Advisory also advised facilities to form an interdisciplinary team to keep updated on the progress of industry's efforts in phasing these new products into the field and to begin planning for the transition to the new connectors. A subsequent frequently asked questions document (AD15-01 FAQs) was created, to address questions from the field pertaining to Patient Safety Advisory AD15-01.

The new enteral connector design was termed ENFit® and has since been incorporated into enteral products. The connector is specific to enteral products and is mechanically designed to be incompatible with other products' connectors (e.g., Luer connectors used in IV medication delivery).

Facility transitions to enteral products with ENFit® connectors (henceforth referred to as "ENFit® enteral products") have been prolonged since 2015 due to several factors. The factors include industry delays in product design and availability, cleaning concerns, staff and patient educational/training challenges, required coordination with private sector facilities, and competing priorities (e.g., pandemic response).

On August 11, 2020, the VHA Assistant Under Secretary for Health for Operations (AUSHO) issued a memorandum entitled "Enteral Feeding Tubes and Adapters transition to ENFit® (VIEWS 03144912)". The memorandum notified VISN and Medical Center Directors that manufacturers of enteral products had transitioned to ENFit® connections and that transition sets (to allow for legacy enteral products to connect with ENFit® enteral products in the interim) might not be manufactured as of January 1, 2021. The memorandum also directed facilities to transition to ENFit® products no later than January 1, 2021.

The purpose of this Patient Safety Advisory is to ensure that any VHA facilities that have not transitioned to ENFit® enteral products yet, complete the steps necessary to transition.

Recommendations:

Facilities shall review and complete the following recommendations or implement other measures to achieve an equivalent or increased level of safety (compared to that which would be achieved through implementing these recommendations) by close of business November 4, 2022.

NOTE: Facilities that have fully transitioned to ENFit® products, must still complete this Patient Safety Advisory in its entirety to verify these Recommendations (or equivalent) have been taken. Fully transitioned means that a facility is only placing ENFit® tubes (no longer placing legacy tubes) and stocking ENFit® supplies.

1. Share this Patient Safety Advisory with staff involved with enteral products. Staff who should be notified include the following, at a minimum and as appropriate:

    - Nursing staff who care for patients with enteral products or coordinate enteral outpatient care and supplies

    - Providers who place orders for enteral products

- Providers who place enteral access devices or enteral feeding tubes into patients (e.g., Gastroenterologists, Interventional Radiologists, General Surgeons, Radiologists, Residents)
- Pharmacy staff who issue and/or dispense enteral products
- Prosthetics staff who issue and/or dispense enteral products
- Logistics staff who are involved with enteral products
- Contracting/Procurement staff who communicate with suppliers of enteral products and accessories
- Dietitians who provide care and education and/or assist with supplies for inpatients and outpatients receiving enteral therapy
- Facility Nutrition Support Team members not otherwise listed here
- Health Information Specialists (HIS) (e.g., Clinical Application Coordinators (CACs)) who assist with electronic health record functionality (e.g., orders, quick orders, templates, menus) for enteral products
- Any other staff in areas where a patient may require care regarding their enteral product (e.g., clinics, Emergency Department)
- Biomedical Engineering, Quality Managers, Risk Managers, Facility Leadership, and Facility Administrators for situational awareness

2. Encourage collaboration between staff listed above to ensure a team approach throughout the process of transition.

3. Communicate expected usage with vendors of ENFit® enteral products to align implementation timelines and ensure product availability. **NOTE**: There are no national mandatory use products and no national contract for ENFit® enteral products. Therefore, if there are supply chain issues, facilities are free to explore other vendors' products.

4. Assess practices, education materials, and policies that will need to change at the facility to ensure a smooth transition to ENFit® enteral products (e.g., cleaning and care of enteral

products; some syringes are single-use; address low-dose administration needs (Reference 7)).

5. Place only ENFit® enteral tubes for the establishment of a new enteral feeding system and at the normal device replacement time in current patients going forward. Legacy enteral tubes are no longer to be placed in patients for feeding (including percutaneous endoscopic gastrostomy (PEG) tubes and jejunostomy tubes (J-tubes)). **NOTE**: Patients do not need to be scheduled for immediate replacement; rather, patients need to receive an ENFit® tube at replacement time. With clinical discretion, exceptions can be made for replacements for end-of-life care.

6. As applicable, inform partnering facilities (e.g., long term care facilities, private sector hospitals) and academic affiliates of your facility's expected timeline on transition.

7. If your facility has acute care or residential facilities (i.e., Community Living Centers (CLCs)), stock ENFit® enteral products for these locations.

8. Ensure transition connectors (for as long as they are obtainable) are available for patients that may present with legacy enteral tubes (e.g., from a community hospital).

9. Ensure enteral products are available for outpatients with ENFit® enteral tubes through Outpatient Pharmacy and the Consolidated Mail Outpatient Pharmacy (CMOP).

10. For patients who receive enteral products as outpatients:

    a. Develop and implement a standard process to notify and educate them before any new supplies are provided in-person or mailed to them.

    b. Ensure there is a process in place for timely follow-up with them (e.g., home visit, virtual visit, phone call) to verify proper set up and care of their enteral products.

    c. Provide them with a reliable way to contact a subject matter expert, including after hours, in case they have any questions/issues.

11. The **Patient Safety Manager** shall document on the VHA Alerts and Recalls desktop application that medical center leadership has reviewed and implemented these recommendations. The Alerts and Recalls desktop application can be obtained by submitting a yourIT ticket at https://yourit.va.gov/va, requesting VA Recalls 2.0.

Facilities can use 'Add Attachments' on the VHA Alerts and Recalls desktop application to share what specifically the facility did to meet the intent of this Patient Safety Advisory, especially if the facility implemented different recommendations than those listed above.

NOTE: If the new web-based Alerts and Recalls application is being utilized by any facilities during the time this Advisory is actively being worked, then the new application should be used in lieu of the desktop application.

Attachment: Legacy enteral products through final ENFit® transition

Additional Information: There are many resources to assist your facility enteral connector interdisciplinary team in transitioning to ENFit® enteral products:

- The Global Enteral Device Supplier Association (GEDSA), a coalition formed to help introduce new medical connectors, maintains a website (www.stayconnected.org) to help staff keep informed regarding connector changes and timelines. ENFit® Transition Checklists for facilities and institutions, home care providers, nurses and clinicians, patients and caregivers, pharmacies, and supply chain personnel can be found at https://stayconnected.org/enteral-enfit/. ENFit® educational webinars and presentations, as well as success stories, can be found at the previous link.

- The VHA Nutrition Support Team prepared an ENFit® Toolkit located on this SharePoint site: https://dvagov.sharepoint.com/sites/VHANutrition/NFS/Clinical_Nutrition/Nutrition%20Support%20Team/ENFit%20Toolkit/Forms/AllItems.aspx?viewpath=%2Fsites%2FVHANutrition%2FNFS%2FClinical%5FNutrition%2FNutrition%20Support%20Team%2FENFit%20Toolkit. The toolkit provides information on getting started, developing inventory/supply management, education, and overcoming challenges, as well as additional ENFit® resources.

Source: The Global Enteral Device Supplier Association (GEDSA)

References:

1) Department of Veterans Affairs, Veterans Health Administration (VHA). Patient safety advisory AD15-01: Changes coming to enteral feeding product connectors to prevent tubing misconnections (2014). Available at: http://vaww.ncps.med.va.gov/Guidelines/alerts/Docs/AD15-01EnteralTubingConnectors.pdf. Accessed June 14, 2022.

2) ECRI. Implementing the ENFit initiative for preventing enteral tubing misconnections (2017). Available at: https://www.ecri.org/components/HDJournal/Pages/ENFit-for-Preventing-Enteral-Tubing-Misconnections.aspx?tab=1. Accessed June 14, 2022.

3) GEDSA. Enteral feeding connectors (ENFit®): Design changes | research | tools for implementation (2022). Available at: https://stayconnected.org/enteral-enfit/. Accessed June 14, 2022.

4) GEDSA. REVISED ENFit® connector conversion schedule: U.S. and Canada legacy connector production phase out dates (no date provided). Available at: https://stayconnected.org/wp-content/uploads/2020/09/200914_REVISED_ENFit%C2%AE_Connector_Conversion_Schedule_U.S._Canada_Legacy_Connector_Production-Phase_Out_Dates-1-1.pdf. Accessed June 14, 2022.

5) International Organization for Standardization. ISO 80369-3:2016. Small-bore connectors for liquids and gases in healthcare applications – part 3: Connectors for enteral applications. Abstract available at: https://www.iso.org/standard/50731.html (full standard requires purchase). Accessed June 14, 2022.

6) The Joint Commission. Sentinel event alert, issue 53: Managing risk during transition to new ISO tubing connector standards (2014). Available at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_53_connectors_8_19_14_final.pdf. Accessed June 14, 2022.

7) U.S. Food & Drug Administration (FDA). Potential for medication overdose with ENFit low dose tip syringe: FDA safety communication (2021). Available at: https://www.fda.gov/medical-devices/safety-communications/potential-medication-overdose-enfit-low-dose-tip-syringe-fda-safety-communication?utm_medium=email&utm_source=govdelivery#rec. Accessed June 14, 2022.

8) U.S. Food & Drug Administration (FDA), Center for Devices and Radiological Health. The FDA encourages use of enteral device connectors that reduce risk of misconnection and patient injury (2018). Available at: https://wayback.archive-it.org/7993/20180908081253/https://www.fda.gov/downloads/

MedicalDevices/ResourcesforYou/Industry/UCM619782.pdf. Accessed June 14, 2022.

9) VHA National Center for Patient Safety. Frequently asked questions (FAQs) for patient safety advisory AD15-01: Changes coming to enteral feeding product connectors to prevent tubing misconnections (2015). Available at: http://vaww.ncps.med.va.gov/Guidelines/alerts/Docs/AD15-01FAQ.PDF. Accessed June 14, 2022.

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ATTACHMENT: Legacy enteral products through final ENFit® transition

Diagram courtesy of GEDSA