Making the Transition to New Tubing Connectors Webinar

November 15, 2017

Welcome

Amber McEwen
California Hospital Association
Continuing Education

Continuing education will be offered for this program for compliance, nursing and risk managers.

Full attendance and completion of the online evaluation and attestation of attendance are required to receive CEs for this webinar. CEs are complimentary and available for the registrant only.

Faculty

**Debby Rogers, RN, MS, FAEN**, is CHA’s vice president of clinical performance and transformation. Ms. Rogers provides leadership in developing policy on clinical performance issues related to quality and quality measurement, case management, licensing and certification, and electronic health records. She also offers clinical and regulatory expertise in the transformation of health care delivery.
Rory Jaffe, MD, MBA, is executive director of the CHPSO Patient Safety Organization. Dr. Jaffe has extensive experience in both clinical care and health system leadership, and has served on a number of state and federal committees on topics such as patient privacy, EHR safety, EMTALA reform and others.

Faculty

Lisa Kelly is involved with the marketing and communications efforts for the Global Enteral Device Supplier Association (GEDSA) whose mission is to support and promote the safe and optimal delivery of enteral feeding and connectivity. In her role, she collaborates daily with transitioning hospitals, clinical organizations and enteral device manufacturers to provide the most recent updates on ENFit.
Faculty

Panelists:

**Angela Hill, RN, BSN**, is the Value Analysis Coordinator, Materials Management, for Valley Children’s Healthcare. She is responsible for the coordination of the value analysis program, including meeting overall program savings goals and individual team goals.

**Irma Alcaraz, RN, BSN, PHN, CPHQ**, is the quality improvement manager for inpatient nursing at Santa Clara Valley Medical Center where her responsibilities include proactive medical record audits to identify practice challenges, working with multidisciplinary teams on process improvement plans and ensuring quality care is provided to all patients.

**Lori Rhoades, BSN, RN, NE-BC**, is the director of nursing and patient care services for Sharp Home Infusion Services. Lori oversees the Home Infusion Quality and Performance Improvement Program to monitor and improve practices in the home infusion setting.

Overview

Debby Rogers, RN, MS, FAEN
California Hospital Association

Rory Jaffe, MD, MBA
CHPSO Patient Safety Organization
Prohibitions in California Law
(Health and Safety Code 1279.7)

Hospitals, acute psychiatric hospitals, skilled nursing facilities and specialty hospitals are prohibited from using connectors that would fit into a connector other than the type it was intended for, beginning:

- Epidural connector — Jan. 1, 2017
- Intravenous connector — January 2016
- Enteral feeding connector — July 1, 2016

An exemption for emergency or urgent situation is allowable if the prohibition would impair the ability to provide health care.

Patient Safety Plans
(Health and Safety Code 1279.6)

Hospitals, acute psychiatric hospitals, nursing facilities and specialty hospitals are required to develop, implement and comply with a patient safety plan for the purpose of improving the health and safety of patients, and reducing preventable patient safety events.

Tubing connector misconnections were required to be included, but beginning in 2016, that section is no longer operational.

Hospitals are encouraged to:

- Review patient safety plan to ensure that prevention of adverse events associated with these misconnections is adequately addressed
- Perform a risk analysis addressing the sustained availability of connectors and identifying methods to mitigate risk
- Identify needed staff training
Enteral Transition Survey

- 22% — Full transition (all units)
- 66% — Partial transition (greater than 50% of units)
- 12% — Beginning transition (less than 50% of units)
- Of those not fully transitioned, 69% plan to convert in 2017 or 1st quarter of 2018

Identified Barriers to Full Implementation

- Availability of equipment
- Complexity of supply chain and finding full complement of supplies
- Lack of tamper-proof syringes
- How to ensure access for patients with old tubing
Epidural Transition

A few hospitals reported making full transition to reengineered epidural tubing connectors.

ISO Standards

<table>
<thead>
<tr>
<th>80369 Small Bore Connectors</th>
<th>18250 Reservoir Connectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1 General requirements</td>
<td>-1 General requirements</td>
</tr>
<tr>
<td>-2 Gasses/Breathing systems</td>
<td>-2 Gasses/Breathing systems</td>
</tr>
<tr>
<td>-3 Enteral</td>
<td>-3 Enteral</td>
</tr>
<tr>
<td>-4 Urethral and urinary</td>
<td>(already in broad use)</td>
</tr>
<tr>
<td>-5 Limb cuff inflation</td>
<td>-6 Neuraxial</td>
</tr>
<tr>
<td>-6 Neuraxial</td>
<td>-7 Intravenous</td>
</tr>
<tr>
<td>-7 Intravenous</td>
<td>(“the spike”)</td>
</tr>
<tr>
<td></td>
<td>-8 Citrate for apheresis</td>
</tr>
<tr>
<td></td>
<td>-9 Irrigation</td>
</tr>
</tbody>
</table>

ISO status as of 9/25/2017: Approved In Process Potential Work
Proprietary Concerns

• UK several years ago required non-compatible connectors for neuraxial use, but many problems arose
• Some styles of connectors caused usability issues during procedures
• Supply chain not standardized
  • Some hospitals received distal connectors without proximal mates and didn’t recognize it until a clinician could not successfully complete a procedure
  • Clinicians received surprises when new styles of connectors showed up
  • Patients transferred from one facility to another could face connection barriers if facilities using different proprietary connectors
• Until now (80369-1), there hasn’t been a standard technique for testing interconnection risk of proprietary connectors

GEDSA
Lisa Kelly
Global Enteral Device Supplier Association
GEDSA's MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity.

GEDSA Members

ABBOTT
A. HOPF
ALCOR SCIENTIFIC
BARD
BAXTER
B BRAUN
BOSTON SCIENTIFIC
CAIR LGL
CEDIC/ENTEK
CODAN
COOK MEDICAL
DALE MEDICAL

DEGANIA
ENTERAL UK
FRESENIUS KABI
HALYARD
ICU MEDICAL
INTERVENE
MEDELA
MEDICINA
MEDLINE
MEDTRONIC

MOOG
NEOMED
NESTLE
NUTRICIA
QOSINA
SMITH'S MEDICAL
UCOMFOR
VESCO MEDICAL
VYGON
VR MEDICAL/KENTEC
XERIDIEM
ENFit Global Adoption Status

Global Adoption is Well Underway with Europe Leading*

North America
- < 30%
- Primary concern over adequate supply
- Law (AB444) in CA effective July 1, 2016

Europe
- > 50% depending on market
- UK, Netherlands, France, Italy, Belgium >90% transitioned

South America
- < 5%
- Transition anticipated to commence in 2018

Eastern Europe, Middle East & Africa
- < 30%

Asia
- <5% adoption
- Transition anticipated to commence in '18
- 2019 for China & Japan

ANZ
- > 50% adoption

* Adoption rates are only rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world

Brochures, Presentations, FAQs & Checklists
www.stayconnected.org
Path to Compliance — Enteral Panel

Angela Hill, RN, BSN
Valley Children’s Healthcare

Irma Alcaraz, RN, BSN, PHN, CPHQ
Santa Clara Valley Medical Center

Lori Rhoades, BSN, RN, NE-BC
Sharp Home Infusion Services

Valley Children’s Hospital
ENFit Go-Live: October 2016

Angela Hill RN, BSN
Value Analysis Clinical Coordinator
ahill@valleychildrens.org
Identification of Task Force

- Created a “StayConnected” Task Force

- Utilized SharePoint

Task Force Members – Multidisciplinary Approach

- Home Health
- Inpatient Units
- Ambulatory
- Radiology
- Dietitian
- Project Management
- Pharmacy
- Physicians
- Value Analysis
- Education
- Quality
Task Force Scope, Objectives and Outcomes

- Identify products for transition
- Identify “off label” uses and solutions
- Standardize our enteral manufacturers
- Manage risks during/post transition
- Identify policies affected
- Identify education and communication needs

Education and Communication

- Identify key stakeholders

- Provided in variety of modalities
  - SBAR
  - Play Stay-tions
  - Just in Time (JIT) Sheets
  - Videos
Education and Communication

Challenges

• Information about ENFit
• Transition connectors and accessories for ENFit
• Delays in product availability
• Meeting times/Attendance
• Member changes during key transitions
• Follow-up on tasks, decision making
Supply Chain Implementation Team

- Initiated approximately 3 months prior to go-live

- Goals for the team:
  - Develop systematic approach to transition
  - Coordinate product changes through distributor/direct purchases
  - Provide smooth transition from Legacy to ENFit
  - Coordinate implementation with StayConnected Task Force
Challenges

• Item set-up
• Distribution stock
• Readiness of manufacturers with supplies
• ParEx/Inventory set-up
• Having both Legacy and ENFit available for Home Health

How Are We Doing?

• Hospital unit inventories are transitioned
• Pharmacy has transitioned
• Home Health continuing to transition their patients
How Are We Doing? (cont.)

• Practice vs. Product
  – Staff submitting Patient Safety Alerts (PSA) on any issues we have related to ENFit products
  – Review issues to determine if it was a “practice” that needed to change or “product” issue related to new design

Lori Rhoades, BSN, RN, NE-BC
Director of Nursing & Patient Care Services
Sharp Home Infusion Services
Sharp HealthCare
Sharp Healthcare Comprehensive Services

- Four acute-care hospitals
- Three specialty hospitals
  - Women and newborn
  - Skilled nursing facility
  - Psychiatric
- Two rehab facilities
- Three home health agencies
  - Medicare-certified Home Care
  - Non-Medicare Home Infusion
  - Hospice
- Multiple clinics and Urgent Care
- Two medical groups and a health plan

Sharp Healthcare ENFit Process

Began October 2014 with Go-Live November 2016

**Phase 1**
Enteral Tubing Sets

**Phase 2**
Syringes

**Phase 3**
Enteral Feeding Tubes
Transition Successes

Interdisciplinary Team

Nursing
Pharmacy
Endo, IR, Surgery
Dietitians
Supply Chain
Medical Groups/Clinics
Pt Safety/Regulatory

Transition Successes (cont.)

Ongoing Task Force Meetings

Policies and Procedures
Closed Loop Communication
Joint Commission - Aware, Assess, Prepare, Adopt
Include other safety initiatives and key committees

Executive Sponsorship

SVP Clinical Effectiveness
Director of Clinical Safety
Closed Loop Communication Tool

Transition Successes (cont.)

Entity: ______________________________________
Name (Process Owner): ________________________

Please select the best option (1,2) that reflects status of implementation in your department using the following key:
1. Completed
2. In Progress: provide detail of current status (*What is the plan to complete? *What are the current barriers?)

<table>
<thead>
<tr>
<th>Education and Communication REQUIREMENTS (With Deadline Date)</th>
<th>ENTITY S I T E</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disseminate SBAR- Physicians (IR, Endo &amp; Surgery) and Clinicians (6/24/16)</td>
<td>Chula Vista</td>
<td>Coronado</td>
</tr>
<tr>
<td>*Additional information required if #2 is chosen</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Standardization

Gap Analysis

- Determine High-Risk Areas
- Identify products down to SKU level
- Reduce SKUs prior to implementation
- Single syringe for both ENFit and oral; Single supplier for peds and adult
- Crosswalk from old to new with part numbers
## Transition Successes (cont.)

### Supply Chain Crosswalk

<table>
<thead>
<tr>
<th>CURRENT PRODUCT OR DESCRIPTION</th>
<th>CURRENT MFG ITEM NUMBER</th>
<th>CURRENT LBR ITEM #</th>
<th>CURRENT SKU &amp; FACTOR</th>
<th>NEW PRODUCT OR DESCRIPTION</th>
<th>NEW MFG ITEM NUMBER</th>
<th>NEW LBR ITEM #</th>
<th>NEW SKU &amp; FACTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>20-9406</td>
<td>209406</td>
<td>CA 1</td>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>40-9406</td>
<td>409406</td>
<td>CA 1</td>
</tr>
<tr>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>20-7561</td>
<td>207561</td>
<td>BR10</td>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>40-7561</td>
<td>407561</td>
<td>BR10</td>
</tr>
<tr>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>20-8856</td>
<td>208856</td>
<td>BR10</td>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>40-8856</td>
<td>408856</td>
<td>BR10</td>
</tr>
<tr>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>20-8854</td>
<td>208854</td>
<td>CA 1</td>
<td>FUSE FEEDING TUBE, 5/16&quot; LUC TUBING (XI)</td>
<td>40-8854</td>
<td>408854</td>
<td>CA 1</td>
</tr>
</tbody>
</table>

---

### Communication and Education

**Customized Tools**

- Online Learning Modules
- SBARs and Product Alert Flyers
- Hands-On Training
- Link to Stayconnected.org website

---

*SHARP*
Lessons Learned

- Supply logistics align with Go-Live dates
- Educate first about global patient safety initiative
- Alert Post-Acute Continuum
- Clear accountability for tasks from planning to implementation
- Early coordination with Pharmacy
- Determine not just “who” will be impacted, but also “how”

Transition to Enfit Connections

Irma Y. Alcaraz, RN, BSN, PHN, CPHQ
Manager, Nursing Quality Improvement

GO PUBLIC!

County of Santa Clara
Santa Clara Valley Medical Center (SCVMC) is located in San Jose, CA. Considered the county hospital for Santa Clara County, it has a 574 licensed-bed capacity and a daily average census of 380.

Our Journey

- SCVMC went live on April 24, 2017
- Unit-specific needs
- Product challenges
- Multiple vendors
Switching Products

- First vendor enteral feeding tube (red)
- Second vendor enteral feeding tube (green)
- Education
- Change in process

What is Enfit?

ENFit Enteral Connector

Will only be compatible with other enteral devices

Feeding Set/Syringe End

Feeding Tube End
Stocking Issues

- Old stock (red tubes) remained on units
- Staff and nurse leaders asked to remove old stock
- Past initiatives required old stock to be used up before switching
Community Outreach

SCVMC Outcome
The New 80369-6 Connector (NRFit)

- Looks exactly like a Luer connector, but:
  - About 20% smaller
- May have yellow color
  - Color used for convenience only, not useful for safety
  - Many devices use colors and have conflicts (e.g., different IV catheter sizes colored differently)
Traditional Male “Luer Slip” vs. “Luer Lock”/No Collar vs. Collar

Recommendations

• Prepare by assessing systems processes and protocols that may need to change

• Be aware that several neuraxial uses may require specialized equipment
  • Blood patch (one-way adapters have been used in UK)
  • Caudal anesthesia
Materials Management Changes

- More SKUs
- Need to identify where neuraxial uses occur
- Recommend facility-wide rollout rather than ward by ward

Potential Materials Management Surprises: Neuraxial

- Intravenous/hypodermic supplies may currently be used for neuraxial uses without the knowledge of materials management
- May be asked to supply neuraxial connectors for chemical nerve ablation use, such as in a pain clinic
- Pharmacy, clinician-users and materials management need to coordinate plans
Other Potential Neuraxial Materials Management Surprises

• Spinal needles may be used for non-neuraxial purposes
  – E.g., amniocentesis, joint space aspiration

• California law only requires the new connector for epidural uses

• Inventory neuraxial uses and supply needs
  – At a minimum, survey oncologists, anesthesiologists, pain specialists, interventional radiologists and ED physicians

Caution
Proximal Spike Same as IV Spike

- No change in proximal spike, so both neuraxial and intravenous administration sets can attach to neuraxial and intravenous solution reservoirs
- Accidentally mixing intravenous and neuraxial sets in a bin could lead to wrong route errors
- Recommendations:
  - Manufacturers plan to prominently distinguish connector type (NRFit) on the label
  - Pharmacy can package neuraxial fluid reservoirs with neuraxial sets (e.g., rubber band together)
  - Consider whether stocking neuraxial sets on wards is wise or not (e.g., risk of mix-ups in bins)

Risks Not Fixed with NRFit Connectors

- Misfilled syringes or fluid reservoirs
- Order written for wrong route, or pharmacist fills right order in wrong syringe
- The new connectors are a component of “defense in depth” for potentially disastrous events, not a substitute for current defenses
Thank You

Debby Rogers, RN, MS, FAEN  
California Hospital Association  
drogers@calhospital.org

Rory Jaffe, MD, MBA  
CHPSO Patient Safety Organization  
rjaffe@chpso.org

Lisa Kelly  
GEDSA  
info@gedsa.org

Angela Hill, RN, BSN  
Valley Children’s Healthcare  
AHill@valleychildrens.org

Lori Rhoades, BSN, RN, NE-BC  
Sharp Healthcare  
Home Infusion Services  
Lori.Rhoades@sharp.com

Irma Alcaraz, RN, BSN, PHN, CPHQ  
Santa Clara Valley Medical Center  
Irma.Alcaraz@hhs.sccgov.org

Questions

Online questions:  
Type your question in the Q & A box, press enter

Phone questions:  
To ask a question, press *1
Upcoming Programs

Critical Decision Points:
The Intersection of Law Enforcement and Patient Care
Webinar
November 29, 2017
10:00 a.m. – 12:00 p.m., Pacific Time

This program demystifies state and federal laws that govern law enforcement access to patients or patient information. Participants will gain valuable information to make confident decisions and take away tips to advance working relationships with law enforcement. For additional information, visit www.calhospital.org/law-enforcement-web.

Upcoming Programs

Navigating the New Centralized Licensing Application Process
Webinar
December 12, 2017
10:00 – 11:30 a.m., Pacific Time

Learn about changes to the licensure application process. A panel from the California Department of Public Health’s Centralized Application Unit will share the most common issues applicants encounter and provide a roadmap for completing the application process in a timely manner. For additional information, visit www.calhospital.org/navigating-centralized-licensing-process-web.
Thank You and Evaluation

Thank you for participating in today’s seminar. An online evaluation will be sent to you shortly.

For education questions, contact Amber McEwen at (916) 552-7578 or amcewen@calhospital.org.