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Case Study:

Overcoming Barriers of Adopting ISO 80369

Introduction

The high stress of an emergency room or ICU creates an environment in which the probability of human error spikes dramatically, adding a layer of risk to an already-tense situation. Asking medical professionals to make rapid diagnoses and decisions in that stress-filled state can lead to device misconnection, creating a high-harm state as deemed by the FDA. To prevent that risk, the FDA identified the responsible and necessary step of mistake-proofing small-bore medical device connections to improve patient safety. To that end, ISO 80369 was written to better define this process for applications ranging from enteral to neuraxial to intravascular/hypodermic, among others. The standard defines connector geometry and design changes, potential improvements and validation methods to ensure the risk of misconnection of small-bore medical devices is minimized, if not eliminated entirely.

While both the need for and benefits of the new standard are clear in principle, the industry has seen an unexpected challenge: the U.S. has been slow to adopt the standard in practice, due to lack of training, improperly specified geometries, poor supply chain, decreased scale economies of (now) different connector geometry, and/or hospitals resisting change. Manufacturers and government agencies have defined and validated solutions for the typical justifications that facilities (reluctant to adopt ISO 80369) cite: supply chain and availability, performance, and safety/cleanliness.

Barriers to Adoption

The Global Enteral Device Supplier Association (GEDSA) was formed in October 2013 with the mission to promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity. With members and support organizations backing the recent letter from the FDA and statement by CMS, GEDSA is kicking off a multi-step phase-out of legacy connectors, according to a recent webinar given by Premier. The presentation provided the current state of the ENFit® connectors, and addressed many of the barriers to facility changeover, including the following:

Supply Chain and Availability

Adequate lead time is usually the first stated concern, as supply chain disruption can be catastrophic to patient care. Facilities worry about whether their required geometries are tooled, and what quantity of inventory their supply base carries.

Performance

A perceived increase in feeding time with the ENFit® connector is an understandable concern by facility staff accustomed to using luer connectors. The newer connector has a smaller hole than the catheter-type syringe, a feature that supports some facilities' rationale for resisting adoption due to perceived performance reduction.

Safety/Cleanliness

With any holistic product change, especially in the medical device industry, safety is a principal concern. One of the drawbacks of the luer slip connectors is the opportunity for fluid to leak out during connection or operation. To compound this matter, the cleanliness challenge is well understood with the existing connectors; facilities have been reluctant to adopt the new fitting geometry in part due to the uncertainty around ENFit® connector leak rates. Also, the lack of robust historical data on safety failures creates a market reluctance to widescale adoption of the new fittings.

Application and Proposed Solutions

Location and Case Study Subject

Following the FDA's urging, McLaren Health Care in Grand Blanc, MI began implementing ENFit® with targeted supply chain messaging in late 2014. Phase 1 of McLaren's system transition was changing over tube

feeding sets. Phase 2, medically administered implements, was delayed due to the FDA approval process, but they began including communication about the changeover in meeting agendas to prep the facilities for the coming shift. Phase 3, implanted and nonimplanted tubes, also proceeded after FDA approval of redesigns. Below are examples of how McLaren Health addressed the common barriers to ISO 80369 adoption.

Supply Chain and Availability

To the overall question of component availability, GEDSA manufacturers have confirmed adequate supply, provided that healthcare facilities advise the required inventory quantity with sufficient lead time (8-12 weeks at present). As a result, with increased adoption of the connectors and/or the presence of new and additional suppliers, the lead times should be reduced by subsequent cost reductions due to increased order quantities.

McLaren approached the risk of supply interruption by recommending an initial order date and quantity of new parts for patient treatment centers. This initial order allowed facility staff to gain familiarity with the components while providing supply partners a chance to complete an order-to-shipment cycle. This order allowed a facility to smooth out logistics for component supply in advance of subsequent orders. McLaren also utilized a field rep specific to the product. The rep continuously educated physicians and their staffs with the release of each new connector part.

In order to protect for sufficient inventory quantities, McLaren Health proposed parallel methods for supply ordering. They also included external stakeholders, such as home care, hospice or physician offices, to improve the response to the change in those entities. Educating these discharge entities also helped smooth the transition for patients to move out of the healthcare facilities while maintaining reduced misconnection risk. McLaren communicated timelines to relevant stakeholders to ensure they were aware of when they should expect each component change.

Despite this planning, however, McLaren Health faced a supply interruption in its Phase 3, due to manufacturer delays in development and production release of the full product lines of implanted and nonimplanted tubes. This important issue could be mitigated by either partnering with a company to manage the supply chain and its resiliency or validating a second-source supplier.

Performance

Despite the smaller hole in the ENFit® connector, the flow rate of the enteral fluid should not change with the new connector geometry so long as the patient hole is the smallest in the circuit. Because the flow rate and pressure are similar to those of existing devices, healthcare staff should not experience adverse changes to the overall procedure and time needed to administer enteral fluids. In addition, the fluid transfer performance through the new connectors has been validated by both the FDA and Mayo Clinic. The connectors provide accurate dosing in NICU applications and offer an option for a low-dose tip (LDT) that can deliver performance equal to the standard application.

In their recent update in a Premier webinar, McLaren Health did not cite specific data in performance comparison between the luer fittings and the ENFit® designs. However, they also did not mention a feeding time increase, which would have been a major roadblock to implementation. This indicates that the level of flow with the new connectors was likely within a reasonable margin of error from the original fitting.

Safety/Cleanliness

Testing of blenderized diets showed no safety risk. Positive connections, or those not relying on frictional resistance for sealing, eliminate the risk of fluid leakage out of the device's control volume. Like any feeding apparatus, facilities must conduct proper and frequent cleaning of devices, tubes, and connectors. Stayconnected.org has defined an effective cleaning procedure for the ENFit® connector to ensure fluid circuit contamination does not impact the treatment.

McLaren encountered a safety opportunity with some ENFit® manufacturers color-coding their products, despite the FDA's guidance to the contrary. Color-coding does not passively design out the misconnection risk, as a facility staff member still has to identify the color for a given room lighting condition and the connector's position among the many fluid lines. The user then has to manually interpret the proper application of that specific color. Furthermore, as there is no standard for color-coding of ENFit® connectors, the application of green (e.g.) connectors might not be the same for a secondary-sourced part than it is for the primary-source supplier. This discrepancy could further compound the risk.

Assessment and Recommendations

McLaren Health Care has done a great job in defining a plan to adopt the ISO 80369-3 standard, touting planning, communication, and a cold-turkey approach when switching to ENFit® connectors. No changeover of this magnitude is without bumps in the road, but the three-phase process they implemented showed:

- The importance of creating a communication plan on the front end of a product change to everyone associated with the facility's new connector strategy
- The value of assigning application-specific reps to walk facility staff through the new changes
- The dangers of relying on color-coding, especially with multiple supplier-sourced components
- That any change or disruption to the day-to-day procedure initially in place resulting from initiating a changeover is worth navigating due to the opportunity to protect patients from the ever-increasing risk of device misconnection
- Adoption of the standard is possible, and as more facilities make the change, the U.S. can enjoy the same scale economies and safety rates as Europe around this issue
- While the intent of the ENFit® fitting design is to remove opportunities for human error, it is equally important to remove human error sources when changing over to the new fitting style to preserve patient safety

References

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How Does Qosina Help You Comply with ISO 80369?

Qosina stocks an extensive line of components that are ISO 80369-3, -6 and -7 compliant. We closely monitor developments to the ISO 80369 standard and add new products on a regular basis. For ISO 80369-7, if you find a Qosina part that you need and it is not ISO 80369-7 compliant, please contact us to find out if we are able to test and/or modify the component. Additional fees may be required based on volume.

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