

Birth of a Standard:

Achieving Consensus on Safe and Effective Healthcare Technology

Martha Vockley

In principle, developing standards is a collaborative, dispassionate, and, not surprisingly, methodical process. In practice, birthing a standard can involve false starts, intense deliberations, unexpected revelations, and dramatic moments leading up to the ultimate goal: consensus on safe and effective healthcare technology.

For all the benefits of healthcare technology, problems related to its use can attract national and even international attention, prompting agreement that something must be done. Led by a standards-developing organization (SDO), technical experts work together to solve the problem using a standardized process, culminating in a published standard or series of related standards. Standards are technical documents, systematically structured and carefully crafted in precise language for clarity and usefulness domestically and abroad. However, published standards don't capture all of the human labor or ingenuity in the established process.

As an SDO, AAMI has steered many standards successfully from concept to completion. This article peels back the curtain on this process. First, it lays out why and how standards generally are created and go forth into the world. Then, it focuses on how the process has played out, and continues to play out, for a particular series of standards: ANSI/AAMI/ISO 80369, *Small-bore connectors for liquids and gases in healthcare applications*.

Why Do Standards Matter?

Voluntary consensus standards exist to address real clinical challenges and market needs for healthcare technology users and industry professionals. Standards define benchmarks for performance, processes, design, or some combination of these elements, helping people develop a shared understanding of how to meet expectations for safety and performance of products in the marketplace and in the field.

"Using the same products and processes in healthcare facilities and home care allows for the consistency and reliability of the products

for clinicians and other users," said Colleen Elliott, director of standards at AAMI. "Standards set expectations so that product developers and users know how products should perform, as well as the levels of performance needed for patient safety and quality." Standards also can affect workflow, supply chains, and costs, she added.

Standards come into the world deliberately. Every aspect of the process is spelled out, from organizational and individual responsibilities to document preparation, review, and approval, all within established timelines. The International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) define a six-stage process that applies to developing a new international standard or a new part of an existing standard, as well as to a technical specification, technical report, or publicly available specification¹:

1. **Proposal stage.** A new work item is proposed and accepted.
2. **Preparatory stage.** A joint working group prepares a draft, which is circulated to all members of a technical committee or subcommittee.
3. **Committee stage.** A committee draft is developed and submitted to national bodies for review and comment (first ballot).
4. **Enquiry stage.** A draft international standard is developed and submitted to national bodies for a vote and comments (second ballot).
5. **Approval stage.** The final draft is created and submitted to national bodies for a final up- or downvote (third ballot).
6. **Publication stage.** The standard is published. A "fast-track procedure" eliminates stages 2 and 3 for existing standards proposed for ISO/IEC approval in 18 to 24 months.

About the Author



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“Consensus: General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Note: Consensus need not imply unanimity.”¹

—ISO-IEC

The typical ISO/IEC standards development process is expected to take three years, within which more time is allotted for review and revision of early drafts and less time for later drafts. Throughout the process, joint working group, technical committee, and/or subcommittee members meet in person, usually at least once annually, and collaborate virtually between meetings to address technical issues, shape the standards documents, and come to consensus.

As a secretariat, AAMI's role is to keep the process moving by bringing experts on board to technical committees, scheduling meetings, monitoring activity, preparing and circulating drafts, collecting comments, and making sure every comment is addressed.

A technical expert, who is a member of the ISO or IEC technical committee or subcommittee that greenlights the process, is selected as a convener, who acts as the working group leader and neutral facilitator. He/she leads group discussions, makes sure all voices are heard, reflects different viewpoints back to the group, and summarizes options for decisions. The convener also keeps the group focused on what's best for public safety and for the standard, rather than on special interests.

Working group and subcommittee members serve as volunteers, most of whom are employed in companies, trade associations, academic institutions, healthcare facilities, or advocacy organizations. Their work on a standard typically is a side job to which people can devote quite a bit of time over several years. Public and private sector organizations can donate considerable resources to standards development, including staff time, travel expenses, equipment, and technology. Ideally, they agree to put aside their competitive interests in developing standards because safety and effectiveness are in everyone's best interest. ISO likens the standards development process to a symphony, where many technical experts with different skill sets work in concert under a conductor: the SDO.²

Publication of a standard is really just the beginning of its life. Standards need to be announced, nurtured, and guided into the world. SDOs and advocates produce press releases, guidance documents, articles, and

marketing materials. They speak at conferences and webinars to explain and promote the standards to specific audiences, such as industry sector stakeholders, healthcare delivery organizations, professional associations, and patient advocacy groups. SDOs and advocates develop rollout plans and timelines for transitioning to a new standard, as well as means of gaining recognition of a standard by policymakers, regulatory agencies, or credentialing organizations.

Nonetheless, achieving awareness and adoption of a standard can take time. First off, reading and understanding technical documents takes practice. But moreover, thoughtful planning and, often, time and resources are needed to transition organizational practices and behaviors so they mesh with a standard. That's particularly the case when a standard affects an industry or multiple industries, with global companies, suppliers, customers, clinicians, and patients in the mix.

Creating the 80369 Series of Standards

The Challenge

The typical standards development process is straightforward: focus on a problem, bring a group of experts together, examine the issues, develop a solution, write a draft standard, send it out for broader review, respond to comments with revisions, and, typically through several rounds of comments and revisions, gain consensus to secure national or international approval.

The joint working group of ISO/Technical Committee (TC) 210 (*Quality management and corresponding general aspects for medical devices*) and IEC/SC 620 (*Electromedical equipment*) on small-bore connectors certainly satisfied the standard milestones in developing the 80369 series of standards. However, a number of twists and turns made for a more-than-standard process.

For starters, the heart of the 80369 standards is a legendary technology: the Luer connector. This granddaddy of all medical device connectors, originally intended to connect intravenous (IV) tubing to infusion pumps or hypodermic syringes, now is “widely used to attach medical devices, tubes, cath-

eters, syringes, and other accessories.”³ The Luer connector has been on the market for more than 100 years, and there are countless derivatives of different sizes and shapes.

The Luer connector’s staying power is rooted in its ease of use. Unlike many complex healthcare technologies, people need virtually no training to use this connector. Its male and female components fit together neatly. A slip or lock mechanism prevents leaks. Healthcare technology developers have expanded their use of this reliable workhorse in a range of applications beyond infusion pumps and syringes.

“The Luer worked great,” said Brad Noe, global marketing manager for hypodermic technology at Becton, Dickinson and Company (BD) and co-chair of the AAMI mirror committee to the joint working group for the 80369 standards. “It did exactly what it was supposed to do. It brought things together. It provided a consistency of medical practice globally. There are tens of billions of Luer-connected devices in use every year in the global healthcare market.”



Example of a Luer connector in a syringe.

Beginning at least two decades ago, however, tubing misconnections surfaced as a safety risk. Healthcare settings are busy places, where caregivers can be rushed, distracted, and tired, and where lighting can be dim. Patients are connected to multiple medical devices with Luer connectors that are difficult to differentiate. “In a few of the higher-risk environments, patients can have up to 90 different tubes attached to them in an ICU situation,” Elliott said. Clinicians refer to this as a tangle of “spaghetti.”

Connecting devices and tubing with Luer connectors is easy, but inadvertently misconnecting them is just as easy. Misconnections can be serious or deadly, as when a feeding

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tube is misconnected to an IV line, pumping liquid food into the bloodstream. Although such misconnections are uncommon, “there is consensus that they are underreported,” Elliott said, as are near misses—or misconnections that are discovered before a patient is harmed.

The challenge for standards developers, therefore, was twofold: 1) mitigate the potential for human error by engineering a better solution that prevented dangerous misconnections and 2) honor a century-old, widely used healthcare technology. Noe explained: “Most of the participants, whether U.S. or global, were sensitized to the fact that one of the mantras we tried to follow to the best of our abilities was to not disrupt medical practices.” In other words, the group did not want the standards to ruin the effective aspects of Luer connectors or wreak havoc in the global market.



“Standards matter because it’s important to have a safe and reliable interface between different parts of a medical device.”

—Hubertus Lasthaus, director of risk, safety, regulatory, and quality management for VitalAire

Hubertus Lasthaus, director of risk, safety, regulatory, and quality management for VitalAire, which makes respiratory therapy devices primarily for home care use and acts as a home healthcare provider, elaborated on the market reality for connectors. “Standards matter because it’s important to have a safe and reliable interface between different parts of a medical device,” said Lasthaus, a member of the joint working group whose company is headquartered in Germany. “This is so important nowadays. Twenty or 30 years ago, there was a manufacturer who manufactured the whole medical device—all the parts, all accessories, all the bits and pieces of a system. Nowadays you have so many people involved, so many companies involved, that you need this kind of interface between the parts and connectors.”

Process of Developing the Standards

Addressing the public health risk of tubing misconnections required a series of standards with requirements for both design and performance of the connectors for each clinical application. Design standards are unusual in the medical device field; most standards focus on processes or performance. Currently, the series of standards includes a general standard that lays out the rationale for the standards, standards for five applications (published or on track for publication), and a standard for test methods for each application:

- 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements* (published; second edition under development)
- 80369-2, *Connectors for breathing systems and driving gases applications* (under development)
- 80369-3:2016, *Connectors for enteral applications* (published)
- 80369-5:2016, *Connectors for limb cuff inflation applications* (published)
- 80369-6:2016, *Connectors for neuraxial applications* (published)
- 80369-7:2016, *Connectors for intravascular or hypodermic applications* (published)
- 80369-20:2015, *Common test methods* (published)

Launched officially in 2010, the process took more than five years, which is two years longer than the three-year norm. It took some time for the joint working group to find its footing.

“In the early stages, basically there were a bunch of engineers and a bunch of companies pitching designs, trying to prevent misconnections with Luers, which was the main goal when this work got started,” said Kyle Steele, senior product development engineer and product line manager of custom products at Nordson Medical and a member of the joint working group. “Somebody would come up with an idea, they’d prove that it doesn’t misconnect with Luer, but then another group working on a different application would come up with a design and it would misconnect with the first design. So then we would change the new design, and then it would misconnect with another one. While all this design tweaking was going

on, another group would make changes to the first design, bringing the group full circle. Looking at it from an engineering perspective, it was kind of mass chaos.”

The joint working group realized that a systematic engineering perspective was missing from the work. “Everyone had these ideas, probably good ideas, but everybody was working in their own isolated bubbles,” Steele said. “On top of that, nobody had really defined what a misconnection was.”

Previous standards (ISO 594-1:1986 and ISO 594-2:1998) had focused only on the design elements that ensured that components of a Luer connector worked together. These standards did not address misconnections, Weston Harding, R&D senior staff engineer at BD Medical, pointed out. Twenty or 30 years ago, the potential for misconnection had not garnered as much attention as it has since.

Therefore, rather than continuing with the separate teams working on separate applications, Steele, Harding, and a handful of other design engineers came together as a “CAD team,” shorthand for the computer-aided design software they used. They began applying the discipline of systems engineering to the misconnection problem. “We looked at the problem holistically, the components of the problem, how they connect,” Steele said.

The CAD team’s work revealed that the possibilities for misconnections were astonishing. To quantify the problem, the team first surveyed the marketplace to categorize the applications, sizes, and types of Luer connectors in use at the time. Then, the team used CAD software to develop a dimensional analysis tool to analyze those connectors. All told, they found more than 1,800 different combinations of outside and inside diameters of the male and female connectors. A locking male connector, for example, has three different internal diameters and at least two different external diameters, Harding said. “The only way to solve the problem was to look at them all at once,” he said. “The tool allowed us to screen all of these potential combinations quickly and tell us where the trouble spots were.” They found about 100 with the potential for misconnection, which became the focus for preventing misconnection with redesign and dimension adjustments.

Next, the CAD team used three-dimensional

“We looked at the problem holistically, the components of the problem, how they connect.”

—*Kyle Steele, senior product development engineer and product line manager of custom products at Nordson Medical*

(3D) modeling to simulate how the connectors could misconnect—and it wasn’t only the male and female tapers that could cause problems. Materials mattered as well. Plastic parts, for example, can deform and be jammed together to misconnect. The CAD team used 3D modeling to resolve a point of contention with enteral connectors, for which three new designs had been offered as solutions that would be incompatible with Luers. It turned out that all three designs would misconnect with Luers in different ways.



Examples of the connector designs that the CAD team created using 3D modeling and presented to the joint working group.

For their work on this standard, AAMI awarded the CAD team a special Extraordinary Achievement Award for its “pioneering” and “tireless” work to eliminate significant patient safety hazard misconnections with small-bore connectors.

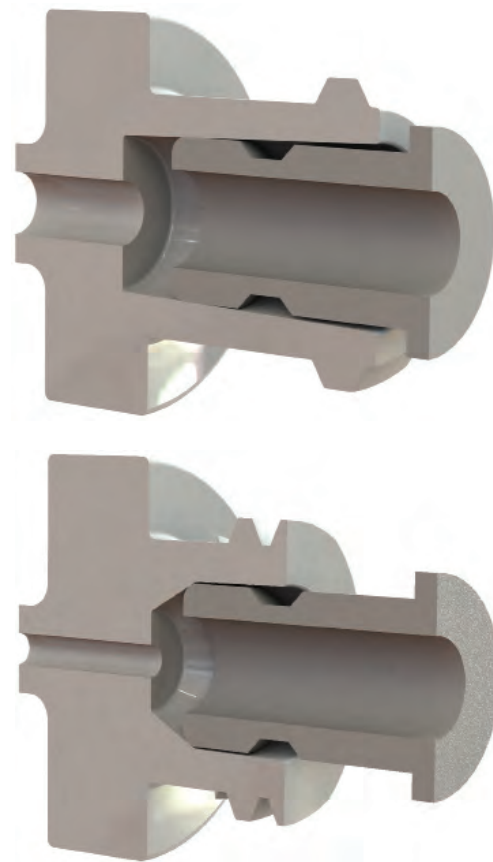
“At one point, committee members were actually trying to pursue three connectors for enteral,” Harding said. “But that didn’t make any sense because the idea of a standard is to standardize something. The idea is if you buy component A from one company and component B from another company, they will fit together. If you have three different official designs that are not compatible with each other, you’ve just defeated the whole purpose of having the standard.”

The CAD team’s work illuminated the scope of the problem and helped the standards developers begin to make significant progress. The team put together a massive spreadsheet and presented its 3D modeling to the full joint working group. “Once we put the graph up on the board and showed them visually what the problem was, it was very interesting that at that point the committee stopped arguing about it,” Harding said. In the end, the joint working group went with the enteral connector design with the least potential for misconnections and the one that could be modified most easily to eliminate the potential for misconnections.

For International Participants, an Even Longer Process

The 80369 series of standards built on the work of expert groups in Europe, the first of which started its work in the late 1990s. In 2000, a European Committee for Standardization (CEN) task group recommended using Luer connectors only for vascular applications and hypodermic syringes and replacing all other connectors used for other applications (CEN/CR 13825 report). Under the lead of the French Standards Institute (AFNOR), CEN then brought together a standards development group, which published a standard for general requirements for small-bore connectors in 2008.⁴

Hubertus Lasthaus has been involved in all of these efforts, along with the 80369 standards, since the late 1990s, when the European task force investigated incidents reported with Luer connectors. Small wonder, then, that he is impatient for the 80369-2 standard, which is still in the publication pipeline. For this biomedical engineer with a 35-year career focused on respiratory therapy and devices, this standard for breathing systems and driving gases applications represents a lifetime’s work in clinical settings and in industry.



Examples of the 3D modeling images created by the CAD team. The components used in the images are related to misconnections between limb cuff and respiratory connectors. The misconnection (*top*) and prevented misconnection (*bottom*) illustrated here resulted from the CAD team considering various solutions, presenting them to the full joint working group, and choosing the best design.

With a holistic understanding of the problem, the CAD team developed and then performed verification and validation tests of the final new designs for breathing systems and driving gas, enteral, limb cuff, and neuraxial connectors, with the Luer connector reserved only for IV or hypodermic applications and certain catheter retention balloons. The team did tolerance analyses to test interferences and develop safety margins for clearance between parts—tests the design engineers perform routinely in developing products for their companies. “I just never quite did it on this scale before,” Harding said.

This work covered not just the connection issues but also functional analysis of the performance of the new connectors. “Design alone won’t guarantee that a connector will function,” Harding said.

Responding to Stakeholder Concerns

Standards development is more than a technical exercise. The 80369 developers responded to a range of practical concerns from stakeholders that emerged in the process as well.

For Noe, whose expertise is sales and marketing, those concerns reflected the needs of connector makers and clinical users: “Would the new connectors be cost effective? Could manufacturers and suppliers actually make them? Would customers be willing to buy them? Are the connectors readily identifiable, usable, and cleanable?”

As the convener of the joint working group, Scott Colburn, director of standards management at the Food and Drug Administration (FDA’s) Center for Devices and Radiological Health, attended to these concerns. “His leadership was very strong,” Noe said. “It wasn’t overbearing; it was consensus building. But he has a clinical background, so he was constantly bringing his own fears and concerns into the room, not in a negative sense, but from an experiential standpoint.”

To address questions and concerns, the joint working group sought expertise from users. They included clinical enteral experts and committee members Peggy Guenther, senior director of clinical practice, quality, and advocacy at the American Society for Parenteral and Enteral Nutrition (ASPEN), and Stephanie Hale, senior clinical manager at Vizient. Guenther, for example, surveyed ASPEN members when the standards developers had questions about sterility and users’ ability to clean enteral connectors.

“We had to take into consideration the practical execution of the standards and put ourselves into the shoes of the users,” Noe said.

Facing Patient Opposition

That mindset was put to the test around the new enteral connector. A group of individuals who use enteral connectors for tube feeding at home came forward as stakeholders concerned about the use of the connector and how it could affect their quality of life.

Some tube feeders prefer to make their own “blenderized diets” with ordinary food at home, rather than using commercial products, explained Thomas Hancock, executive

director of the Global Enteral Device Supplier Association (GEDSA), a nonprofit trade association founded in 2013 to support the standards development process and the transition to the new standards. The tube feeders objected to the size of the new connector bore, which they believed would slow their feeding rates and add time to their feeding routines.

“There were also concerns over flow rates, the amount of pressure applied, the ergonomics of having to twist on the connection,” Hancock said. Many home users were concerned that the connectors were too small for such operations, while at the same time, concerns existed that the connectors might be too big for certain applications, particularly for administering small volumes of medication. They also had concerns about whether users were involved in the standards development process.

AAMI convened two special meetings with GEDSA and other committee members to explain the safety rationale for the series of standards and to answer questions and address concerns about the new enteral connector. AAMI also invited the users to join the standards development committee, Elliott said.

The patients’ concerns were taken seriously. GEDSA collaborated with the FDA, the Mayo Clinic, ASPEN, the Feeding Tube Awareness Foundation, the Oley Foundation, and manufacturers to establish a protocol for testing and comparing the 80369-3 standard connector to the legacy Luer connector. Two concurrent studies were conducted, one at Mayo and one at the FDA, to test a number of different commercially available products and typical blenderized diets, with identical protocols in each lab.

The results of these studies indicate consistent flow rates with the Luer and with the most common sizes of 80369-3 standard connectors, with slight variation depending on the manufacturer, Hancock said. Some reduction in flow rate occurs for the largest connector, but that connector has a market share of just 5%, he said.

It might be possible for users to stick with the legacy connector for home enteral feeding, if some manufacturers continue making them, Elliott said. If they do so,

AAMI’s Expanding Standards Portfolio

With ever more healthcare technology in the marketplace, the demand for standards is increasing as well. During the past few years, the AAMI Standards Department has completed about 75 international and domestic documents every year.

As an SDO, AAMI can’t turn down international projects, for which the association is nominated and approved by ISO member countries. On the domestic side, Jennifer Padberg, AAMI senior vice president of standards, is pausing new work as she evaluates the breadth of standards work in progress.

“As usual, whenever you’re doing things and you’re doing them well, they always tend to give you more and more and more, which has happened in this case,” Padberg said. “Our staff does a really good job with standards, so they’ve continually just added to their portfolio but without additional staff support. That’s the important challenge and opportunity going forward.”

Balancing patient needs and wants with patient safety in the growing home healthcare market is an increasingly important issue for standards developers.

however, the safety issues that the standards are intended to address may still remain. It is less common, but still possible, for tubing misconnections to occur in homes, such as for people using both enteral and IV connectors, Hancock said. “The broader issue is that people using medical devices travel,” he said. “Yes, people may be primarily at home but they also might have complications. They may end up in the hospital or they may go from the hospital to a postacute setting, like a long-term care facility. So, when they travel and go between settings, you really can’t have one solution that’s for the hospital and one that’s completely different for home care.”

Balancing patient needs and wants with patient safety in the growing home healthcare market is an increasingly important issue for standards developers. For example, Lasthaus believes that home healthcare is where the action is in the respiratory therapy market. “There are about 500,000 hospital beds in Germany, where different medical devices are in use,” he said. “But we have 5.6 million beds in home healthcare, where many more medical devices with small-bore connectors are used. That’s why standardization is so important. People think the medical device business is only in hospitals, especially on the political side.”

Separately, GEDSA member manufacturers helped address a concern raised by hospital pharmacists about dose accuracy

with the new connectors. The manufacturers collaborated on developing a dose tip design that fits within the 80369-3 standard. Third-party testing confirmed the ability to deliver an accurate dose substantially equivalent with enteral/oral tip syringes in use today, Hancock said.

Drama on the International Stage

At certain junctures, the 80369 series of standards had a bumpy ride toward international approval. The enteral standard went through an extra round of draft international standards, comments, and balloting by ISO member countries. The first draft international standard ballot passed by only one vote, following one country changing its vote based on how the comments were resolved.

“Changing a vote is permitted within ISO but it’s unusual,” Elliott said. “It’s also unusual that one vote would make the difference. The convener didn’t feel there was a strong enough consensus to move forward to the final ballot. A second draft international standard ballot was conducted to ensure strong consensus.”

Rolling Out the New Standards

Like other aspects of the standards development process, pushing the 80369 series of standards into practice has come with a unique set of circumstances and challenges. During the balloting process, many committee members were eager to get the standards completed because an external deadline loomed. In 2012, California enacted a law prohibiting healthcare facilities from using “intravenous, epidural or enteral feeding devices with connectors that fit into connection ports other than the type for which they were intended.”⁵

California lawmakers extended the deadline for compliance with this law several times in anticipation of the release of the 80369 standards, in order to give industry and healthcare delivery organizations time to transition to them. Indeed, the legislation referenced the standards development process in extending its deadlines, which were phased in for IV, enteral, and epidural applications in 2016 and 2017.

It’s also unusual that a handful of companies involved in the standards development

How to Get Involved in Standards Development

The AAMI standards program consists of more than 100 technical committees and working groups that produce standards, recommended practices, and technical information reports for medical devices.

Standards development work is a great way to contribute to your field. It also can be a smart career move, giving you an insider’s edge on the future of healthcare technology. You’ll learn from other experts, grow your network of peers, and gain resume-building experience.

There are many ways to get involved, and you don’t have to dive right in to a multiyear project. You can:

- Submit a new work item proposal.
- Join a technical committee.
- Review public review drafts.
- Attend meetings.

To learn about the AAMI standards program, visit www.aami.org/standards.

process came together as charter members to form GEDSA, which now has about 40 global member companies. In GEDSA, “the companies all place a priority on patient safety and agreed to collaborative to establish joint communication efforts for branding and marketing consistency across companies, which is pretty unusual,” Elliott said. The companies also worked collaboratively on launch timing and product availability of new standard connectors through the world, Hancock said.

GEDSA has taken the lead in communicating about and promoting adoption of the new enteral and neuraxial connectors with its Stay Connected initiative. This effort includes a website, webinars, monthly newsletters, monthly advocacy calls, and collaboration with several dozen other supporting organizations, including group-purchasing organizations in the United States whose members include virtually every hospital in the country as well as international groups.

Companies also are educating their customers about the 80369 standards. They have invested in improving their connectors to meet the standards, retool their equipment, and produce the new connectors. Likewise, organizations are educating their constituents and developing training.

However, transitioning to the standards is proving to be a “chicken-and-egg” dilemma for companies and healthcare facilities, Hancock said. Many manufacturers and suppliers have ramped up their production and inventories of the new connectors, but many healthcare delivery organizations are in a wait-and-see mode. “Some hospitals comment, ‘Until every device in a feeding system is ready with adequate supply, I’m not going to make any changes or attempt to train staff on this,’” Hancock said.

That stance is understandable but frustrating, Noe said. Healthcare facilities do not want to have old and new connectors in stock, which could be extraordinarily confusing and potentially dangerous. Indeed, there is a cautionary precedent for this scenario. A few years ago, the United Kingdom jumped the gun on the standards by rolling out several different, incompatible connectors from several suppliers, against the advice of manufacturers. On top of that, hospitals had

maintained their inventories of earlier-generation connectors. Bedlam ensued, with angry clinicians uncertain which connectors to use. “It was like trying to perform a procedure by working out of a fish tackle box,” Noe said.

Thus, until the new connectors are widely adopted, companies are maintaining inventories of the legacy Luers and the new connectors, which is expensive. “It’s classic economic supply and demand,” Noe said. “Customers aren’t willing to transition; therefore, they’re willing to stick with the old stuff. Theoretically, there’s no mandate on the part of any regulatory body or adjudicating body right now to say, ‘You shall.’ Any wording typically is, ‘You should.’”

“Without a mandate, widespread adoption of the enteral connectors is likely to drag on—that is, until there is another event,” Hancock added. “We strongly encourage hospitals, skilled nursing facilities, and home infusion companies to recognize that facilities should protect against misconnection occurring under their watch, when everyone knows there is a better solution out there to drastically reduce the risk of a misconnection from ever occurring again.”

Therefore, although most of the standards are published, efforts to shepherd them into the marketplace and clinical practice continue. To that end, on July 26, GEDSA hosted a meeting with hospitals, distributors, home infusion companies, group purchasing organizations, and manufacturers, as well as a number of supporting organizations (AAMI, American Gastroenterological Association, Association for Professionals in Infection Control and Epidemiology, American Society of Health-System Pharmacists, American Society for Parenteral and Enteral Nutrition, Children’s Hospital Association, California Hospital Association, California Hospital Patient Safety Organization, Feeding Tube Awareness Foundation, Institute for Safe Medication Practices, and Oley Foundation) and federal agencies (Centers for Medicare & Medicaid Services [CMS], FDA, and Department of Veterans Affairs). The objective of the meeting was to remove barriers to adopting this voluntary standard and understand what it would take to transition the entire market to safer connectors. After rich dialogue spotlighting



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Supplier Association

the varying, and sometimes competing, perspectives inhibiting adoption, the group concluded that a future deadline for mandatory adoption would be the only pathway to a single, safer enteral feeding system. A regulatory mandate from FDA, CMS, The Joint Commission, and/or Centers for Disease Control and Prevention would remove the current stagnation that is negatively affecting all areas of the market and allow the healthcare community to focus on the next connector standard introduction.

Final Thoughts

Standards development is a necessary endeavor to improve patient safety and set expectations for product performance, processes, and design. For intractable problems of global import, standards can be the last resort for defining a solution.

The 80369 series of standards both exemplifies the standards development process and illustrates the idiosyncratic nature of any particular standard. A few committee members have devoted careers to developing standards, but most had never been involved in the process before. Although career moves created some turnover, most participants stayed involved and engaged throughout the more than five-year process, Elliott said. Many continue to champion the standards they shaped.

Undoubtedly, the process can be circuitous, confounding, and contentious. But it can be inspiring and rewarding in equal or greater measure.

“At the end of the day, the standards process in this case is kind of like sausage being made,” Noe said. “It ain’t pretty, it may turn you off a little bit, but it can turn out really well.” He is particularly proud of 80369-1, the general standard, which took more than two years to get right. “It tells a story of why these connectors were created.”

Recognizing the importance of the project elevates the process, despite the obstacles. “This is about reducing the likelihood of patient harm and death,” Noe said. “This is not just about building a new widget. Every one of us, our extended families, can be subject to bad situations, so it is beholden on us to do the best we possibly can to reduce that from occurring. We have a generational responsibility to do that.” ■

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