



Transcript for Joint Commission webinar: New ISO tubing connector standards – December 3, 2014

Dawn Glossa: Welcome everyone. We're pleased to have you at today's webinar on new ISO tubing connector standards. I am Dawn Glossa, Director of Communications and Corporate Marketing at The Joint Commission. The Joint Commission's recent *Sentinel Event Alert* on new ISO tubing connector standards highlights common causes of connection-related injuries and suggests strategies in preparation for the launch of the new ISO connector standards. Today, we look forward to continuing that discussion. Now I am very pleased to introduce our first speaker, Dr. Ronald Wyatt, Medical Director in the Division of Healthcare Improvement at The Joint Commission. Dr. Wyatt?

Dr. Ronald Wyatt: Thank you, Dawn. Also, thanks to those that help here at The Joint Commission, Caron Wong and Gidion Howell. Also, thank you all for attending this collaborative webinar. Adverse events involving various types of tubing and catheters have been reported for many years. Now there is an international effort to establish new ISO tubing connector standards. New connectors manufactured under ISO standards will make it nearly impossible to connect tubing delivery systems that serve different functions, thereby decreasing the tubing misconnections and improving patient safety.

In August of 2014, the Joint Commission issued *Sentinel Event Alert* No. 53. This *Sentinel Event Alert* is aimed at preventing and managing the risk of tubing misconnections. The alert reported on a literature search that revealed 34 various publications that featured 116 case studies involving misconnections directing enteral



feeding solutions into IV lines. These adverse events resulted in 21 deaths. These tragic events are preventable, and the alert describes common causes of connection-related injuries and suggests strategies in preparation for the launch of the new ISO connector standards. The Joint Commission recommends that facilities put organization-wide and/or system-wide standardized policies and procedures into place; and that staff are routinely educated on how to recognize and report risk. This includes reporting near misses, unsafe conditions and adverse events. The alert includes specific actions that can be taken by hospitals, ambulatory care facilities, home care providers and nursing care centers. This webinar is a collaborative effort by The Joint Commission, the Global Enteral Device Supplier Association, the American Society for Parenteral and Enteral Nutrition, the Institute for Safe Medication Practices, and the Sacred Heart Hospital in Pensacola, Florida, to help focus on ways to decrease the risk of tubing misconnections at your organizations. We hope that you find the information helpful. Thank you.

Dawn Glossa: Thank you, Dr. Wyatt. Our next speaker is Tom Hancock, Executive Director for the Global Enteral Device Supplier Association or GEDSA. He will be discussing the Stay Connected Communications Initiative and the enteral feeding device connector changes. Thank you for joining us, Tom.

Tom Hancock: Thanks, Dawn. The first slide I wanted to present was the four-step and three-phase approach that we're taking. Thank you for joining again. My name is Tom Hancock from GEDSA. GEDSA was formed recently in an effort to introduce these new standard connectors in a joint communication pathway. We've partnered with various groups that are on the phone here, represented in this collaborative effort. Our four-step and three-phase approach is Aware, Prepare, Adopt

and Measure. Awareness is really what it sounds like and that's really building awareness across the facility and the provider to all impacted clinicians, administration, administrators, supply chain, support staff, etc., and communicating all the basics, the who, what, where, when, why and how this will be impacted. Preparation, which is where we are at the moment and that is about assessing the processes and protocols that may need to be changed or adjusted.

Prepare is about proving the product changes and prepare materials in inventory management and then training clinicians and materials management and inventory and staff on these adjustments. Adoption is really about introducing the new connectors into the work stream and to reduce the tubing and tubing set misconnections and improve patient safety and transition and integrate to medical practice. Of course, once we execute all of this it's important to measure our success and the team's ability to adopt the changes and reassess how to improve the process for the next phase, and post execution monitoring metrics will be important. The reason why we do want to measure this, is that, yes, we will be doing this again.

On the next slide, we have essentially the three or multiple phases that we're taking – the first being enteral which is the focus for the call today, but to follow-up there will be other new connectors that you should expect to see. The neuraxial, which is like epidurals and regional anesthesia, will come next in Phase II, and then likely in Phase III will be respiratory products and others to follow. We do plan to follow the same pathway of Aware, Prepare, Adopt and Measure, and try to be consistent with the introduction across the various new connectors.

On the next slide, nutrition and connectors, I wanted to point this out just to be clear just in case some people are sitting back thinking, well, we made the change to new connectors already. Well, that is partially true and, in fact, there were changes made back in 2012 with the introduction on the nutrition end. We went from the spike which are the photographs in the top portion, from that to what's in the circle, the new cross-bite connectors. They have various names within the market, but they all have the same features, functionality and dimension. This prevents inadvertent use of IV tubing as an administration set. This will actually be considered in a different standard ISO18250, which is also under review today. You should have seen these changes already being made, by and large.

On the next slide, this is where our focus is going forward with the new enteral connectors. Our challenge today is that we provided a connecting system, a future connection that will be different and incompatible with what the current connection is today. In the gray circles you can see the step connector, also known as the Christmas tree connector that is probably very familiar with many of you and how that connects to a typical female feeding port. It's an open flexible material in a female port that the step connector connects into. In the future, the new ENfit connector, ENfit is EN for enteral nutrition and FIT for fitment. That's the name, a handle, so to speak, for the new ISO standard connector. On the administration set slide, the upper last portion of the circle, you have the female ENfit connector that comes from the administration set, and then on the lower right portion of the circle, you have the male ENfit connector, which will be on the end of the feeding tube, and the tube will connect as it's illustrated there.

On the next slide, you'll see that the way we get from current to new, is through the use of a temporary transition connector, called the ENfit transition connector. What this allows is what we call backward compatibility. The ENfit connector can connect to the administration set that transition connector to allow the backwards compatibility. It looks strikingly similar to the step connector that we use currently. That will allow fitment into the current feeding tube port. Then, ultimately, we move to the new feeding tubes in the future.

On the next slide, we show what the U.S. enteral patient access estimated launch timing looks like. What you should expect to see is manufacturers that are members of GEDSA have aligned to introduce these new connectors along a similar path. The primary purpose for this is for patient safety. We want to ensure that within a full feeding system it's likely to have multiple connections that have to be made across multiple suppliers. It's important to introduce these new connectors along the same contacts. This is what you should expect to see from your suppliers, but as I'll mention probably several times throughout the call, it's important for you to reach out to your supplier representatives directly to understand their precise timing. The transition sets will be introduced in the very first part of next year, the first quarter next year. That will be what we call transition sets that will include both the female ENfit connector from the administration set side, as well as the transition connector or the adaptor that will fit backwards compatible into the current feeding tube. In the March to April time period, you should expect to see new sets of syringes being made available. These syringes will have the ENfit connection, the same female ENfit connection on the end. Again, that will allow fitment into the new feeding tubes. Those feeding tubes will be available in the June to July time period, where they'll be the introduction of the new ISO standard connectors. This is all in time

to meet the California deadline. Many of you have heard about this. There's legislation out there today that requires that these connectors be changed so that there's no longer compatibility to those that are not intended to connect. That deadline is January 2016. You will see that the change will be made over the course of 2015, so that we hopefully meet the deadline by January 2016, and you should expect to see the transition set ramped down by that time period.

The next slide, which is the ENfit transition connector. This transition connector allows fitment to current feeding tube ports and will be available in all administration sets. Regardless of which supplier that offers you administration sets, you should expect to see these transition connectors included in there. They will be used throughout the year of the transition.

On the next slide, it's important to just reiterate that there will be new syringes. Syringes for administered medicines, for flushing, for supplemental hydration, bolus feeding, anything through the enteral feeding tube will be required to have a new fitment on the end of the syringe. It will require the enteral-specific ENfit female connector. The oral luer cap tip syringes will no longer fit into the ENfit feeding tubes. These again will be available in the second quarter of 2015.

Next slide, the feeding tube, again a couple of specific details about this. We specifically made this a reversed orientation from a female to a male port on the feeding tube side of the lower right portion of the circle. It is also a locking and forcing function feature. What you would expect if you put these two connections together, you would feel practically that these are supposed to be connected. They will actually lock into place. All enteral

and multi-purpose ports must have this ENfit connector and they will be available in third quarter of 2015.

On the next slide, just a couple of points about preparing for the change. Some concerns are around distribution, adoption, conversion and compatibility. Some things to be thinking about are the ordering and stocking of supplies, identifying supplier part numbers and new item numbers that will be made available, and then adopting these new devices. Patient transfers between facilities and health care systems will be something that you want to pay close attention to, and ensure within the health care system that you've got the conversion to accept for these changes. Prepare and avoid potential delays in health care services, and then new staff orientation and education to the devices.

On the next slide, to recommendations. Really the main recommendation here is we want you to familiarize yourself, the organizations, with the new standards. Identify interdisciplinary teams and begin discussions about what the new connectors will look like, how you'll adopt them, what your process and procedures will look like, any protocol changes, and then utilize the resources. We do have a website that is <http://www.stayconnected2015.org> and that is on all the bottom of the slides. There are transition checklists, there are panel discussions, there are resources, FAQs, webinar links, and many opportunities for new resources for you. The Stay Connected Communications Initiative has a little bit more detail on that. This is a global communications program to introduce these new standard connectors across the globe. We are using the same Aware, Prepare, Adopt and Measure to facilitate the transition. Of course, this is for improving patient safety by reducing the risk of medical device

tubing misconnection. We started the awareness campaign in 2014 with enteral devices. Those devices will launch now in the beginning of 2015. Then they eventually will look to introduce the new connectors across the other areas, including neuraxial and respiratory applications. Again, here's the website.

On the next slide, I wanted to share with you briefly an example of one of our checklists. These checklists are by no means intended to be completely exhaustive, but rather help start the conversation around these connector changes and what you should be thinking about. This one in here in particular is a checklist for home care providers. We also have checklists for pharmacy, for clinicians, such as nurses and doctors, administration, as well as the home care patients themselves; and supply chain would be another one. We have this acronym of STEPS which would include looking at the prior communication and working with them, looking at training as well as education, what the process looks like, as well as supply management and looking at inventories and so forth. You'll see the various checklists all available on our website stayconnected2015.org, and then you'll also find the diagram of how you should expect to see the changes across the various components within a feeding system.

On the next slide, I wanted to just share with you the list of guests and members. The great news is most of the enteral suppliers are involved in this effort and active members of GEDSA. Some of the names will sound and look very familiar to you. Others may look foreign to you, and that's because they are foreign, in fact. This is a global initiative and we have companies from around the globe that are actively involved in this effort, and that's the point of sharing this slide with you. We do have other companies that we are trying to get on board with this effort as well, under the evaluating list. Stay Connected is also driven by industry supply chain, clinician and patient partnerships. We mentioned



some of the names, AAMI, the Association for Advancement in Medical Instrumentation, A.S.P.E.N., ISMP, The Joint Commission, Novation, Premier, NPSF, ASHP and several others, The Oley Foundation, have all been actively part of our effort to provide awareness around these new connectors and help the marketplace with preparation with the introduction of these new connectors. It looks like this time I'm going to pass the baton back to Dawn, I believe?

Dawn Glossa: Yes, thank you, Tom. It's my pleasure to introduce Peggi Gunter, Senior Director for Clinical Practice Quality and Advocacy for the American Society of Parenteral and Enteral Nutrition, or A.S.P.E.N. Peggi?

Peggi Gunter: Thank you so much for the opportunity to talk to you about getting prepared for these new enteral connectors. What I'd like to do is give you some clinical background about why we're doing this and talk to you a little bit about misconnections in general. In 2006, I was called by the FDA for a meeting with many stakeholders, The Joint Commission included, at the American Hospital Association. At that time, there was a lot of concern about luer misconnections, quite a few reports were coming in. We began to look at this from the perspective of the luer. What is a small bore connector? A small bore connector, which is the name of this whole standard, this 80369-1, is the ISO standard around small bore connections, the enteral connector of which is one. A small bore connector is a connector with an inner diameter of less than 8.5 mm. It's used to link or join medical devices, components and accessories for the purpose of delivering fluids or gases. Here you see a three-way stop cock with luer connectors on it. A luer connector is really a classic type of small bore connector used commonly in the health care setting. It's really a universal connector. That's a good

thing, it connects many things. But it's also a bad thing because it connects things that shouldn't be connected.

Next slide. Here, within the neonatal ICU there are many, many different types of therapies going on with multiple connectors that are seemingly very similar. You've got respiratory, IV, arterial, gastric, epidural, all of these kinds of connectors. Patients in ICUs can have 40 to 50 connectors in their patient care space. Nurses are making hundreds of connections a day with all of these different kinds of therapies. You can see, if the connectors are universal, that there would be a much higher risk of misconnection.

Next slide. I want to talk a little bit about enteral misconnections. What happened at that American Hospital Association meeting is we decided to write a paper for the *Joint Commission Journal* and specifically drilled down on enteral misconnections and came up with this definition that is: Enteral misconnection is an inadvertent connection between an enteral feeding system and a non-enteral feeding system, such as an IV catheter, peritoneal dialysis catheter, tracheostomy, medical gas tubing, etc. It's also known as a wrong route error or a small bore misconnection.

Next slide. Why is this important? The reason it's important is what the impact of misconnections are. This story was actually published in that *Joint Commission Journal* article that we wrote, that a woman who was 35 weeks pregnant was in the hospital for hyperemesis and had a ready-to-hang enteral feeding bag brought to the floor. The nurse assumed it was total parenteral nutrition, which looks very similar, grabbed IV tubing, spiked the bag, and hung the bag up to the patient's PICC line, and the patient and her fetus died. More recently, someone reported a story about a patient with a

routine carpal tunnel syndrome surgical procedure and went to the PACU. The PACU nurse hooked the blood pressure monitor up to the patient's IV, which caused an air embolus and killed the patient. The patient's daughter was a PACU nurse in a different facility. There are actually two sets of victims in all of these misconnection reports. The patient and their family, as well as the clinician involved. Clinicians never mean to make these mistakes, but they do, and the problem is, it's because they can.

Next slide. How do these misconnections happen? Some of them seemingly are very obvious, that you wouldn't intentionally put an enteral feeding set connector into a tracheostomy tube, but this indeed did happen. This is an FDA medical device safety calendar simulation of a report that they received about this error actually occurring. The picture on the right is a misconnection that I actually made in a simulation lab, where I took an enteral feeding set and hooked it into a Hickman catheter.

Next slide. Why did these things happen? What are the contributing factors? There are two sets of factors. One is a set of human factors. Health care clinicians, homecare caregivers of patients at home, get fatigued, they also get very distracted. They're trying to multitask, and get distracted from one task to another, and that can cause these misconnections to happen. Also, lighting is an issue. We try to make sure patients can sleep at night, and what happens is, the lights get turned down low, and a tube that may look like a feeding tube actually might be an IV tube. Lighting contributes to these.

The other factors that we can make a difference on, and that we are going to make a difference through these new standard designs, are the physical and design factors, that we not use compatible tubing between unlike systems. These issues as we talked about,

with more connectors being universal connectors, the use of IV syringes for oral medications, and universal spikes for different bags of different therapies.

Next slide. These reports first started in 1972 when an enteral misconnection was reported in the *Lancet*. Since then, you've seen these little starbursts across time where there have been reports of enteral misconnections, and despite warnings from regulatory and safety organizations, over time there continued to be more reports of enteral misconnections.

Next slide. I believe this is the paper that Dr. Wyatt was talking about. Some colleagues of mine and I pulled together all of the reported cases as of 2011, and there were 116 published cases just of enteral misconnections. As with most medical errors, these are probably highly under reported, and so we're dealing actually with a much larger problem than this case series indicates.

Next slide. This is actually a picture of a recent event that a colleague of mine sent me from New York, where an enteral feeding bag was hooked into an IV tubing and the reason is that the patient had a jejunostomy tube. The Jejunostomy tube, the end of it was actually a luer connector. The only way the nurse could infuse this enteral feeding was to build a hybrid of an enteral bag hooked into IV tubing. Thank goodness, in this particular case, the nurse did not hook this into an IV, but the potential risk of that happening is very high. This indicates an example of what we're trying to prevent.

Next slide. In that *Joint Commission Journal* we pulled out 24 cases from MEDMARX® data from early 2000 and looked at all the related factors and why these things happened. We talked about many of those. The important thing about this slide is to look

at the percent of sentinel events. Of the 24 cases that were reported in this series, 33 percent were sentinel events, that is, risk of permanent harm or actual death. People have said “well, there aren’t that many cases,” but the fatality rate is actually very high, so it’s of much greater concern that we do something about this.

Next slide. This is an enteral delivery system. Tom talks about that change in the top connector, that nutrition connector, we call it, the connector that goes into the reservoir. That has been changed in the market, for the most part. We are concentrating by making these new enteral connectors with the connectors that happen downstream. The catheter, the syringe that goes into the administration set, any extension tubing and that direct connection right to the enteral feeding tube. Those are the areas that we are concerned about, and are making these new connectors.

Next slide. Many folks have asked us ‘what about color? Can’t we just simply color enteral connectors or enteral devices of certain color to prevent that misconnection?’ And the answer is that manufacturers have tried to introduce color to trigger clinicians to think perhaps this color shouldn’t be put into an IV. However, color doesn’t really prevent that misconnection. Colors are not standardized across device types. There are three or four colors within enteral. Some of those colors are used for IV or respiratory devices, so this really defeats the purpose of color. Color is actually not required in the new connector standard.

Next slide. What the Joint Commission did in 2006 was talk about really calling for product manufacturers to make incompatible that would be by-design features to have working function design changes that would make those incorrect connections pretty

much impossible, to form a physical barrier, and that the entire line of connections has to be unique to prevent the mistakes in these connections. That's actually what the ISO process has done. We started in 2008 and have moved forward to where we are today. Now I'd like to turn it back over to Dawn.

Dawn Glossa: Thank you Peggi. I'm now happy to introduce our next speaker, Mike Cohen, president of the Institute for Safe Medication Practices. Mike?

Mike Cohen: Thanks Dawn, and thanks everybody for participating. I might start out by saying even though we have you on the phone today and we're real happy about that, there's still a lot of people out there at your hospitals or other hospitals that are not aware of this changeover that's about to take place. I keep running into that when I'm at meetings or somewhere out in the field. Please do all you can to communicate these changes that are coming. People do need to know about it, or else we're going to see some things like jerry-rigging as Peggi was showing in one of the slides. But these are exciting times to see this happening after years of having these misconnections. People are always saying, 'well, why don't you change the connector from just the luer that connects just about everything, to a different design?' Now, thanks to ISO and GEDSA here, we are going to see that happen. That is great. I know Tom and Peggi already talked about some of the process issues, but I wanted to go over just a few more over the next couple of minutes. One thing and I just want to emphasize this, I think Tom did kind of touch on it. But, once we have these new connectors in place, when unit dose liquids of meds are dispensed for patients with feeding tubes, obviously we're no longer going to be able to use an oral syringe because it won't fit the ENfit connector of the feeding tube. We've done a lot in the past to increase use of oral

syringes versus parental syringes for oral liquids because the issue of people inadvertently injecting oral liquid medications and enteral feedings etc., with the syringes over oral medications. Now, we're not going to be able to use them for every patient. That does present a little bit of a communication issue. I did want to mention that. People are going to need to be aware of this. You will not be able to use an oral syringe. Some people have been telling us that they're possibly looking into using an ENfit syringe for all oral liquids. That might be doable. I don't know how that will play out in some hospitals. They may, in fact, want to continue using oral syringes for almost all patients, but then those patients that do have a feeding tube in place use the ENfit syringe that will be compatible with the connectors on the ENfit tubing. That's something that we're still going to have to think about. It is something that you're going to have to think about as well. We are, however, absolutely recommending from ISMP, and I'm sure others as well, that these medications that are in liquid form continue to be dispensed wherever possible in a syringe that has a label on it, has a bar code. In other words, from pharmacy, that's packaged that way. Of course, some unit dose medications still come in dosage cups in the exact dose, and that might be something that's doable as well. But then you would need these new ENfit syringes to be available on the unit, which I think you're going to need anyway, because it's not only used for liquid medications, and I'll get to that in a minute. But we do want to push the idea of continuing to label with a bar code and the patient name and the drug name etc. so that it's available for bedside scanning. As I mentioned, if you do choose to dispense using an ENfit syringe for feeding tube patients and oral syringes for others, it is going to be particularly important that you have good communication methods between the patient carriers and pharmacy. That's going to be critical so that they know how to package these. They'll need to know which patients have feeding tubes. One of the things that can be done, obviously, is

checking on the unit a few times a day. Probably the best thing is to get prescribers to include with their oral liquid orders, via feeding tube, right within the order. That would be tremendously helpful and pharmacists and technicians would then be able to look for that and know what to package the oral liquid in.

Next slide. One of the questions that's come up with the oral syringes and the tips that they have, we have to withdraw liquids from stock bottles, 4 oz., 16 oz., whatever. To do that you have to have a bottle adapter so that the oral syringe will fit into that bottle adapter and you can turn the bottle and withdraw the liquid into the syringe and then fill it. But we weren't sure until just recently that we were going to have these bottle adapters. As we actually expected, in fact we will, we did learn from at least one company and I'll mention them because they're the only ones that I know so far that have come to us and said they will have it. That is the NeoMed Company. They will have the associated equipment. That also includes by the way the caps for the syringes so that they can be capped and transported. We know that other manufacturers will have these as well, we hope certainly by the time the oral syringes are in use next year. Or, I'm sorry, the ENfit syringes are in use next year. But we do expect that that will happen. We don't think that's going to be a problem. There was some information that we put out about three or four months ago that they were not yet available, which was true at the time. But now, companies have come around and we've been assured, in fact, that will be available. There will be other means of dispensing that I kind of alluded to earlier. A dosage cup is dispensed and a nurse can draw that up if the ENfit syringes are available on the unit. That would be important, but again, if you're using a bar code system, which I think about 75 percent of the hospitals do bedside scanning, you'd have to have a good system for getting a bar code on that, and I'm not sure that all of us could do that at this

point. One thing we don't want happening, obviously, is to go back 20 years ago and have bottles going up to the nursing units. You still need the dosing cups and unit dose syringes, etc.

Next slide. There are some other uses for these syringes – flushing lines and supplemental hydration and bolus feeding. All of that might be needed. I'm thinking you're definitely going to need these syringes on the units as well as in the pharmacy. At the top of the slide there I mention the unintended consequences again. If people aren't familiar with this, and this could be temps, individuals who didn't attend this session, a training session you are holding. There's going to be that possibility of jerry-rigging. You don't want to see that happen, obviously. Therefore, you're really going to have to pay attention to make sure that people are aware of this and involved in the training before they are in a position where they'd be able to misunderstand and try to make something fit that shouldn't. Then, that requires reinforcing the purpose of the change that Peggi made very, very clear in her slides. I think people really are looking for this. Obviously everyone wants to protect the patients from harm and protect themselves from a horrible situation of being involved in a tragedy. I don't think this is going to be a big problem getting people aware of it.

Finally, the next slide please. I just wanted to mention, and I think Tom touched on this, too. There are resources out there for training, websites, etc., the Stay Connected. We've put some information out a few times. I know The Joint Commission had the recent *Sentinel Event Alert*. Peggi's group A.S.P.E.N .has put information out consistently. Then purchasers and suppliers, you want to make sure that those folks are aware in your hospital. I'm sure that they've heard about this. You want to make sure

they know what to purchase. It looks like this is something for a safety committee or a committee that's involved with transition where you can put all these pieces together. I think we're going to have success. Sure, like anything else, there might in fact be unintended consequence, rather. But I have to say we've been watching this pretty closely and enjoying participating with the other groups on the call. It's been a very, very organized systematic effort by GEDSA. They really tried to think things out very well. I don't anticipate that we're going to have many problems, but it certainly could happen. Let's all stay on top of this. Thank you very much. Dawn?

Dawn Glossa: Thank you, Mike. Now we're going to hear from Amy Wilson and Sarah Amole from Sacred Heart Hospital in Pensacola, Florida. Amy and Sarah?

Amy Wilson: Thank you all for allowing us to share our journey with you all today. One of the things that I hope that Sarah and I can accomplish is walk you through the details of what we are doing as an organization to get ready for these changes with the ENfit connectors. I'd also like to take the time to thank GEDSA, A.S.P.E.N., ISMP and Joint Commission for what they've done at a national level to help us as health care providers to keep our patients safe, and also to keep our clinicians safe. Because as pointed out earlier, when these type of errors occur in organizations, there are always two people affected – the patient and their family, as well as the clinician who made the error, who never comes to work to make those types of errors. We're very appreciative for everything that's been done at the national level.

A little bit about us as an organization. We are a referral center hospital located in Pensacola, Florida. We actually also have a children's hospital at Sacred Heart as well. And we happen to be one of three hospitals in the Sacred Heart Health System, which also includes a medical group and a long-term care facility. That has proved to be important as we talk about who our stakeholders are in representing everyone at the table when we go to make these changes within our organization. We are also part of the Ascension Health Family as well. We've heard a lot in the presentations prior to ours about the background and rationale as to why these changes are being made. My biggest concern as a nurse, and also being responsible for the care that's being provided in our organization, is the jerry-rigging that was discussed earlier. I've seen these things happen primarily due to not having the right supplies and resources available for our nurses and our other clinicians. That is something that I keep at the forefront of my mind, and also try to make sure that these things don't occur in our facility.

Next slide. The first step in being successful in this journey is really doing an assessment of your current state and risk medication. While we're really focusing on ENfit connectors, currently we have lots of tubing that has the potential to be misconnected. One of my other priorities is not only to focus on the enteral feed changes, but also to ensure that I'm doing everything we can at our organization to eliminate any tubing misconnection. One of the resources that's been provided to all of us as health care providers, and it's listed in the Joint Commission's *Sentinel Event Alert*, is the Tubing Misconnection Self-assessment for Healthcare Facilities that was developed by ISMP and Baxter. If you've not had the opportunity to look at this, I would encourage you to do so. This is a very good resource. It actually walks you through step-

by-step on how you can evaluate all tubing connections in your organization and look for ways to mitigate the rest. Once you've completed that step, then it's really about implementing the best practices. Some of the best practices that we're currently utilizing at Sacred Heart are the oral syringes that you guys have already heard about on the conference call today. We have enteral pumps with built-in flushes to keep the nurses from actually having to swap back and forth between syringes and enteral feed. We are labeling all of our lines currently and we're using the yellow-coded tubing for our epidurals. We're also using separate epidural and PCA pumps to prevent any kind of tubing misconnections there. That's been something else that has occurred in facilities and been near misses as well.

We're also doing independent double-checks on all of our high-risk medications, which also include the rates. We've had a lot of success with this because we're actually conducting the independent double-check at the bedside with the patient. These are all ways that we're currently mitigating our risk and also helping teach our nurses about these types of situations. Another important component is really educating all of your associates and your staff about the risk of these inadvertent tubing misconnections. If clinicians don't believe these can happen, or if they've never seen these things can happen before, then they don't know to be looking out for these. They don't know to be using their high reliability behavior. It's also important that education is provided to all of your associates about equipment and supplies, and not modifying that equipment and supplies when they don't work – really how to get help if they need help with a situation.

Probably the most important thing that has helped us with all of our serious safety events is really our culture of safety that we've been working on and high reliability training. For

those organizations out there who have not started this journey, I would highly encourage you to do this. Not only will it help you with your tubing misconnections, it will help you with all your safety events in your organizations and really eliminating those. We actually have daily health log safety huddles. Every shift has their own department level huddles. Any time staff has concerns about things such as we're discussing today, or other concerns related to the care they're providing to their patients, then they're able to discuss these in a non-punitive environment and give information and access to answers very quickly. All of our staff have already been trained in high reliability. We are teaching them during high risk opportunities that they use behavior as STARVV: Stop Think Act Review Validate and Verify. Call us if they have a concern and really stop and go on. Really empowering your front-line staff to be able to stop, call and ask for help and to escalate when they need to.

I would like to now introduce one of our nurse managers, Sarah Amole. Sarah has been our champion at Sacred Heart, not only at our hospital in Pensacola, but across our health system as we go on this journey for enteral tubing connectors. Sarah is going to walk us through the process that we're using for our conversion. Sarah?

Sarah Amole: Good morning. Thanks, Amy. Go to the next slide. We've already talked about the background for the enteral application. That's going to be the first one, the first phase of the ISO connector standards that we're going to deal with first. I apologize. This is an outdated timeline that we're dealing with. Thank you, Tom, for giving us the updated one in your slide presentation, and that is available on the webpage. It does have an updated expectation of the timeline for us.

Go to the next slide. The first step that we took here at Sacred Heart Hospital was to research the standard. Amy Wilson did a great job of as soon as the information came to her she disseminated it quickly to those of us in the clinical areas so that we could begin working on it. Like it was already mentioned, a lot of us are on this call today, but I think that there are still a lot of facilities or departments in facilities that don't know about this change. The good news is, you don't have to do extensive literature or research. You don't have to go out there and dig through piles and piles of information to find what it's all about. It's all very, very well collected and put together by The Joint Commission for us already and by GEDSA for us already. Everything is available in the *Sentinel Event Alert* that went out from The Joint Commission as well as the Stay Connected website. I thought I was in trouble because I had the 2014 website listed here, but I just tried the stayconnected2015.org link and it connects you to the same website. You can use either one of those links to get to the website. They have beautiful illustrations, beautiful timelines, beautiful resources, the checklist that you just showed was wonderful. The first step that we did was to research the standard. Why are we making the change? Why is it important to us as health care workers at the bedside for us to make the change? All of these wonderful organizations have done a great job compiling that information so it's all really easy to find and follow.

The second step on the next slide was for us to identify our key stakeholders. Amy mentioned that we are a facility that has a lot of different departments. We have a couple hospitals. We have some outpatient facilities. We have a specialized children's hospital. It was important for us to take a couple of minutes and really think about who in our facilities were going to be our key stakeholders. It's difficult to disseminate information to all of those people and staff members of those organizations, but it was important to us to find key people from each department, from each facility, who we could talk to, would

get information from them, and then they would help us disseminate back to the team. All of our different people created a core team to plan for and communicate the change. We have nursing departments represented from our pediatrics, outpatient departments, and long-term care. Then we have key stakeholders from our purchasing department and supply chain; distribution, materials; internal management is going to be essential to making this change successful; our pharmacy department; and our education department, for helping get the nurses prepared. Then our vendor also touching base. We have various vendors that we use at our facilities so touching base with each of them, making sure that you have good communication and a good team set up to start with. The next step, Step 3 that we took at Sacred Heart in Pensacola, was to perform a really basic gap analysis that helped us identify what our existing deviations and opportunities were. It was really just a 3-step process. On one side we listed what is our overall strategic goal or initiative. All of that's been given to us already by GEDSA and by ISO. Where are we hoping to get? Then in the next column we identified what we have. What's our current state of practice? We had to be careful here that we didn't make assumptions. I work in the main hospital in Pensacola. I can't make assumptions that our sister hospital in the Emerald Coast, not too far away from us, uses the same equipment that I use. We had to be very careful to list all the departments and the individual equipment that they use, the pumps that they use for the equipment, all of that. Then in the next column we listed the deficiency. Where are our opportunities between where we want to get and what we have right now. Based on those three columns, we created an action plan that helped us identify what our opportunities are and how we're going to bring it from our current state to what our goal is. It's really simple spreadsheet that can be made in any single place that you work. Step 4 is kind of the adopt practice for us in the goals from GEDSA. That's follow through. You make your gap analysis. You have to

do something with that. We take our gap analysis, our action plan, and then with the team that we have already established, we have regular meetings to stay on track and to ensure that we're making progress. You can't just make a gap analysis and then cross your fingers and hope that it gets implemented well. We have to communicate frequently to stay on track and make sure we're going in the right direction – a proactive approach, looking at the timeline that's been updated for us. We're trying to stay ahead of the game and not be reactive. It's important for us to have realistic deadlines. We can't make changes happen overnight. We realize with vendors and supply chains there's always going to be some flexibility and change needed. You have to have realistic deadlines for your organization.

Then you have to engage with your vendor. What an important part the vendor is to this process to help make that crosswalk where your supplies are and where they need to be. Your vendor is going to be key to making this successful and has been for us as well. Then you need to troubleshoot barriers as they arise. If you start to see the new transition pieces, as you start to see the new equipment and how it works with what you already have, you need to start troubleshooting barriers. Get hands-on with any of the equipment as soon as possible. If you can get samples, if you can get early stuff shipped to you before you put it out on your units, making sure that you play with it, and that you touch, feel and see what you have to work with and how it all connects. Do that as soon as possible with your team and all the various departments to make sure we're on good footing. Then you want to formulate an education plan to follow-up after the implementation, it is important for follow through.

The education plan that we have here at Sacred Heart Hospital on the next slide, thanks, is based on our product manufacturers and based on the updated estimations of when our products will be available to us, which is January 2015. We have an online education module here at Sacred Heart in Pensacola that is available to all nursing staff. Our education department does a great job using the information that's available on the websites, compiling it into a quick online education module that all the nursing staff can be required to complete, and it lets them do some post-testing, and really tests their knowledge of what they're learning about. Then we plan to do hands-on return demonstration competency with all nursing staff. It might vary depending on the department you're in, but whether in your staff meeting, or as a group, or however it works best for your area, getting hands-on with your staff before you put it on the unit and letting them demonstrate that competency and how it works and how you're going to connect everything and the reason for why is important. Also, we want to incorporate it into our orientation for all new hires after the roll out. You have to think about all the people that are going to come on after this has been implemented. How can you make sure that they have the information and they know how to be safe in their work? Like Amy said, you have to continue your safety culture and your high reliability work – all the training that you do just reinforce it through every change that you make.

Step 5 is the last step and that's one of the most important ones and to get the measure step is to follow-up after implementation to ensure safety and success. It's important for us as leaders and people over our departments to round frequently after this implementation takes place to ensure that nurses are using it correctly and that they understand how to use it correctly; and that we haven't figured out any new barriers or any new safety concerns once we start using it. You want to track and report any issues

to the appropriate people. Then you're going to continually review your ISO standards. Keep in touch with the Stay Connected website, getting updates, making sure you're not missing any information. Engage with your vendors to make sure all is successful. Review best practices from other organizations. We're all going to learn together on this one. Using the best practices that we come up with is going to be important, which is why today's webinar is so helpful for us. Then you want to mitigate inadvertent tubing misconnections that might come up as we start to implement this. Those are our steps here at Sacred Heart Hospital that we've been able to implement so far in our journey to implementing the new standard. Thanks.

Dawn Glossa: Thanks. We would now like to take questions. I do want to let everyone know that these slides and a recording of this webinar will be available in the next couple weeks.

Operator: First question comes from Jill Casanova with McKennan Hospital.

Jill Casanova: I was wondering on the prestate of the connectors you demonstrate that we use a stop cock in between our administration set and our feeding tube. Usually we use that stop cock to administer medications or flush the tube. Is there going to be a stop cock that has the ENfit connector, or will we always have to disconnect the administration set from the feeding tube to give medications?

Peggi Guenter: This is Peggi. My understanding is that many of the new feeding tubes will come out with a medication port on the side. My understanding is that

perhaps those folks that make enteral, not more stop cocks, but there are enteral type three-way valves available on the market. Perhaps folks will make them with the ENfit connector. Tom might be able to address that a little bit. There will be other accessories in the market so to speak, but they will need to have the ENfit connector on them.

Jill Casanova: Okay, thank you.

Operator: Our next question comes from Sue Land from Calliton General Hospital. Ms. Land your line is open.

Sue Land: Yes, we had a question about checking a residual on tube feeding for nasogastric tubings. Will these connectors be able to perform or will the stringent vehicle perform those safety precautions?

Peggi Guenter: We've done flow studies through these connectors and the flow for both some commercial blenderized diets as well as what we think are stomach contents and checking residuals, for the most part, flow through these connectors fairly well.

Sue Land: Okay, thank you very much.

Operator: Again, to ask a question please press *1 now. Our next question comes from Leslie Grave with the Hendrick Medical Center.

Leslie Grave: Yes. When we last spoke to our vendor who is Covidien I believe, they said that the FDA had not approved the transitional catheter. Has that been approved, the 510 paper, if that's approved?

Tom Hancock: This is Tom Hancock. Just to clarify the transition connector, which is that adapter that goes on the administration set, has been approved by the FDA. It sounded like you mentioned a catheter. To my knowledge the tube catheters, you might call them, I'm not sure if any of them have been approved as of yet. But, I would not necessarily anticipate that to occur until sometime into next year. The tubes won't be introduced until June or July time period next year.

Leslie Grave: Okay, thank you.

Operator: Again, if you'd like to ask a question please press *1 now. Our next question comes from Kelly Horton with the VA.

Kelly Horton: Hi, you know, we've all had those emergency situations where a tube falls out and the ER person uses a red rubber catheter, which is great for emergencies, but not for long term. It sounds like that won't really be an option any more. Would that be correct?

Tom Hancock: I think that's correct. I think what you'll need to do is to make sure procedurally that you work through those types of issues that pop up. During the transition period, if it's a connection that's similar to the enteral feeding system, with the transition connector, you will be able to make that connection. But again, that's a

transition period that should last more like a year, so that by 2016, you should resolve that issue within your hospital.

Peggi Guenter: This is Peggi Guenter. Often, patients are sent home with any kind of tube that is available. I think that we're going to have to make some changes in home care to make sure that either the patients have a similar tube to the tube that's in place for an emergency tube fall-out situation, or that the minute that they put that tube in to stent, the stoma stent, the opening to the feeding tube that they immediately go to an Emergency Department and have the tube replaced with a tube that can be compatible with these connectors.

Operator: Our next question comes from Donna Scott from the St. Claire Health System.

Donna Scott: Yes, can you explain in more detail about the transition set or connection that's becoming available in the first quarter?

Tom Hancock: Sure. This is basically what we've come up with as an industry is a way to transition the marketplace from the current set of connections to the future connections, the ISO standard ENfit connector. The transition connectors as we describe it, is the ENfit transition connection was made specifically so that it would fit into the female ENfit connector that will be on your administration set. Starting January, February, March, sometime in that timeframe, you need to check with your suppliers, check with your Nestle or Covidien representative and ask them when specifically they should expect to see the transition set. The transition set simply means that it has the

transition connector in there as well as the ENfit female connector which allows compatibility forward into the new ENfit system and then backwards into the current feeding tube.

Your administration set today has a step connector on the end, okay? That allows it to fit into the current feeding tube, the female open feeding port as I describe. I'm not sure how best to describe that. But it's a flexible open port that is on a G-tube and then G-tube peg. The way we're transitioning the market is, we are first starting with changing over the administration set. We purposely want to introduce new administration set connectors first with these transition connector. The transition connector is going to allow that backwards compatibility. It will look, operate and function the same way that your current step connector functions today. The difference is that once the feeding tubes are finally available starting in third quarter of 2015, that with ENfit connector on them, you will no longer need that transition connector. What we wanted to do is ensure that you had the ability to connect from the current feeding tube as well as the new feeding tube when it becomes available. That's the benefit of the transition connector and the transition sets that are made available first.

Donna Scott: Okay, thank you very much.

Operator: Our next question comes from Allix Geneslaw with Memorial Sloan Kettering Cancer Society.

Allix Geneslaw: Can you tell me if Covidien has developed a connector for the high-low endotracheal tubes specifically for the port that suctions the subglottic substance?

Tom Hancock: I cannot. That's a wonderful question that you should direct toward your Covidien representative. What we're trying to do is offer you the general guidance in terms of thinking about the transition. But any product-specific information or questions that you have you do need to direct it specifically to that manufacturer.

Allix Geneslaw: Thank you.

Operator: At this time we have no further questions.

Dawn Glossa: All right. Thank you. I want to thank everyone who took the time to participate in today's webinar. And thanks to all of you who listened in. We hope it was of value to you. A link to a replay of the base webinar along with the slide presentations will be posted on the Joint Commission website within the next two weeks. You can find it on the webpage for the *Sentinel Event Alert* on New ISO Tubing Connector Standards. Thank you again, and have a great day.

Operator: Ladies and gentlemen. That concludes today's presentation. You may disconnect your phone lines and thank you for joining us this morning.

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