



# Panel Discussion Transcript

Healthcare Supply Chain Expo 2013

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Male: [Inaudible] September...

Dave: Hello everybody, good afternoon. I'm Dave Finley, I'm VP of supplier relations and business development for Premier. And I'm very privileged today to bring to you a panel that is a great example of true collaboration on a very important topic in an area that we all are constituents. And I think all of us as, even as consumers with family and friends who are patients in the healthcare industry are always reminded, and sometimes tragically reminded, that there are some consequences where, you know, safety is not upheld. So today we are bringing you... Really I think as, if you look forward with this venue and, and this forum, a great example of how we can work together to bring important change to the industry. So with that, I'd like to turn it over to our moderator, Gina Pugliese, Vice President of the Premier Safety Institute.

[Clapping]

Gina: Are there any questions?

[Laughter]

Gina: Well we're really excited that we're able to put this panel together and a very big thank you to our panellists that have taken time out of their day to come together and share with you very important information that we're gonna talk about today. Thank you Dave for the introduction. We're gonna be discussing national patient safety efforts and the implications of the new ISO/AAMI standards for small bore connectors to reduce tubing misconnections. You have a handout that has the bios of all the panellists and their pictures so you can match them up. And the, there is also a frequently asked questions document that we have prepared for this panel, we'll be releasing it here, which answers a lot of questions, some of which will be answered by the panel today.

So I'm gonna briefly introduce the panel and then we're gonna get started. We have Gerry Castro from the Joint Commission. Just smile and raise your hand [laughs]. So we have Scott from the FDA. We have Peggi Guenter from the American Society for Parenteral Enteral Nutrition (ASPEN). We have Tom Hancock who's from [inaudible] Health and he's coordinator of the cross-industry implementation of this. Tom? And we have Mary Logan who's the president of the Association for the Advancement of Medical Instrumentation. We have Brad Noe with Becton-Dickinson. He also co-chairs the US Technical Advisory Group for the small bore connectors. And last but not least, we have Dan Schwartz from the Survey and Certification Group, it's at the Centers for Medicare and Medicaid.

So let's, did I...

Male: Stephanie.

Gina: Stephanie, oh Stephanie.

[Laughter]

Gina: Oh my goodness.

Male: Let's not forget Stephanie.

Gina: Stephanie.

Male: Last but not least.

Gina: Last but not least, oh I am so sorry, Stephanie Hale from Novation.

Stephanne: That's okay.

Gina: Thank you. Oh my goodness gracious. I sincerely apologize. Okay... So there are a lot of different organizations and professional societies that have standards and guidance documents and practice guidelines and I have some of them listed here; governmental agencies, organizations professional societies. And then we also have healthcare facilities and healthcare providers that have customized policies and procedures on a variety of patient safety standards. If you go on the ARC website, you can find over 300 organizations that actually publish these guidelines and standards. And then we have ensures and purchases, purchases and consumers that are also getting involved in this, in, in these patient safety and quality issues. This safety and quality now has a little bit of teeth with the Patient Protection and Affordable Care Act, also known as Obamacare. We now have some focus more on safer and higher quality care at lower cost and now that's tied to payment and reimbursement.

Some of the key cost saving provisions in the new law are first of all value based purchasing. And some of those elements, the key elements are, right now we have a focus on, you know, how hospitals do on these various clinical standards and evidence base care and also on patient experience. We will see some of the other areas roll out later; mortality, hospital acquired conditions and new program for that and efficiency. We also have the hospital 30 day unplanned readmissions penalties that are gonna be, that started in October of 2012. And we have a brand new hospital acquired conditions penalty for the top 25% of hospitals with the highest rates. That's not gonna start until next year. Now that's gonna be in addition to the current hospital acquired condition policy and not getting the higher DRG payment that's been in effect since 2008.

So what's the financial impact of this? This is just a slide that kind of shows you across the next number of years of through 2020. What kind of financial impact this is gonna have on just, on Medicare [inaudible] and inpatients on these quality and safety measures; some of them increasing over time. The exact amounts in some of the future years are unknown at this point but you can see it's gonna be a huge impact on the healthcare dollar. So today we're gonna talk about one serious patient safety issue and that's tubing misconnections. And this is also called luer misconnections or small bore misconnections. And one example, this is when a tube from a medical device of one kind of a delivery system is connected to a delivery system of a totally different delivery system with a totally different function. Like inadvertently connecting an, a, an IV up to a enteral feeding tube and, with, creating the ability to put tube feeding into an IV and causing patient harm and potential death.

The problem with luer connectors, it's kind of good news and bad news, these are universal connectors in healthcare and they've made it easy to be able to connect everything in healthcare. The bad news is they've made it easy to connect everything in healthcare and this creates an opportunity for you to connect delivery systems that are not intended to be connected. Tubing misconnections are not currently part of the CMS hospital acquired conditions program for reduced payment but CMS has had a recent focus on this issue and we're gonna hear more about that from Dan Schwartz. But these are the list of organizations up here on this slide that have been involved in developing practice guidance and alerts and other resources on tubing misconnections. Many of these organizations are represented here on the panel. We even have a pending state law in California which we're gonna hear more about but unfortunately, none of these guidance documents, alerts, hospital policies and procedures or attention or focus on this issue has really eliminated the problem in patient harm which is why we're here today.

All, although it hasn't made it to the list of the CMS hacks yet, the CMS does use the national quality form list of serious reportable events to select hospital acquired conditions for future potential for reduced payment. And tubing misconnections are one example of these events, seriously reportable events, also called never events, under the category of product or device. And this would be when a patient death or serious injury happens associated with a device when it's used for anything other than what it's intended. So we could eliminate this problem if there could be a totally different connection for each delivery system to make it impossible to connect one delivery system with another. Sort of like they did, for those of you that remember, the leaded and unleaded gas. You know, change the shape and the size of the nozzle so you can inadvertently connect something that shouldn't be connected.

So for the rest of this session, we're gonna be focussing on new standards for small bore connectors. A series of standards for unique connections are being developed for each delivery system by an international group led by the International Standards Organization and the Association for the Advancement of Medical Instrumentation. A, an initial standard, kind of laying the ground work down for all of the upcoming standards has already been issued. The first standard that's gonna come out is for the enteral standards that will be released and we'll hear more about that from our panel. So our panel today is gonna focus on the implications of these new standards and the implementation and transition to products that meet the standard. And so let's get started.

I'm gonna ask you to hold your questions to the end. We're gonna save 10 or 15 minutes at the end for you to ask specific questions of the panel. We also are gonna have an opportunity after the session. The panellists have agreed to stay after and answer any more specific questions that you might have that we haven't been able to cover during the question and answer period. We will have two roving mics that'll be going around. Cathy Gosna from the Safety Institute and who's your, who's your co-conspirator for the mics...

Female: And Marilyn [inaudible]...

Gina: Marilyn Flacker from the Amy Foundation.

Female: Mm-hm, mm-hm.

Gina: And they will be the folks that will be with the roving mics so you can ask, ask questions at the end of the session. Okay so our first question is for Mary Logan. Mary this is a big panel and it includes leaders from a lot of different segments of healthcare. Could you start us off and put this into context about this issue we're gonna talk about today?

Mary: Sure. So I think Gina gave you a, a really, set the context for why we should care about tubing misconnections because there have been a lot of patient deaths and injuries. And to set the stage, kind of hint at what's coming. And what I think I would like to do is talk about why you should care and why you should stay in this room and listen to all the other presenters and, and then go home and, and talk about it. And go out in the hallway at the break and talk to your colleagues who think that drug shortages is more important because we don't think it is.

[Laughter]

Mary: So I'm gonna start by reading a very passionate piece of a letter that was sent to me by a nurse who had a personal experience with this. My name is Tricia Otstad and I've been an RN for 30 years. I'm currently the clinical supervisor of the PACU at Paradise Valley Hospital in Phoenix, Arizona. On June 5th of this year, she sent this to me last year and to several of us on the panel. On June 5th, my mother had outpatient surgery at a local surgery center. I was at work and received a call that my mother had coded in the PACU which was especially shocking as she was very healthy, vibrant and active and had only a very minor procedure for carpal tunnel done under a local anesthetic. We were informed by the surgeon and anesthesiologist that the PACU RN had hooked the blood pressure monitor into my mother's IV which caused an air embolism that killed her. I've worked the floor, the PACU, etcetera and I've never heard such a thing. But my research shows me that this has been an issue even after safety alerts went out in 2001. There's a lot of data of luer connection, misconnections that have caused patient injury and death. I am certain this is a grossly under represented issue. Imagine what it feels like, maybe some of you have to have this letter show up in your inbox and identify this kind of tragedy with a real person who works in healthcare and who is an RN.

I'm here today as president of AAMI because I'm so committed to this issue and Tricia really keeps me going. Her inspiration and her determination that no one else should die like her mom did really makes me wanna be here and ask you all to become champions of this cause. So luer connector; it's an amazing thing, it's universal. So I'm not technical so in my mind, I try to simplify things like this. And so for me, I'm simplifying it today for you to think about and why you should care because you're not the one doing these misconnections but why you should care. Think of it like a thumb drive. It's kind of a connector, it has data in it and you hook it up to your laptop or computer into a USB port. This is a universal device. We can all use the same one. I could give this to each of you and if your hospital doesn't prohibit its use for cyber security reasons, you can connect it into your computer. Imagine if California banned the use of USB, of this or maybe even differently said that every potential use of this device had a simple thumb drive had to have a different connection.

So in the case of the luer connector, there are seven different major uses. So think of it as if there were seven different kinds of USB ports and this only fit in one of them. Imagine your supply chain nightmare if you had two stock different USB ports for

every possible use, or thumb drive, sorry, every possible use of this. This is not even a patient safety issue. This would just be a supply chain nightmare. It would be a personal nightmare for all of us. Anybody who goes to make a speech, anybody who has to write a paper and share it, we all use these. There's going to be a supply chain nightmare when the new connectors come out unless the implementation is planful. You are the key to the door of the healthcare delivery organization that you work in or the health system that you work in or whatever other aspect of supply chain that you're involved in to making sure that the implementation is planful.

Everybody up here in this panel can write standards, can design new connectors, can scream and yell and shout and have sessions like this at events and create FAQs. We can't walk in the door of your healthcare delivery organization and do a thing without all of you. So that is the most important context for why you should care about this because that kind of dramatic change is coming. California has said that there can be no more universal connection because of the deaths from the universal connection being misconnected. So the industry has to make this change that would be equivalent to saying no more of the USB ports being universal. Patient safety has mandated that this be done. And it's gonna have an impact on you. So that's why we're all here today. We want to help you get ready so that you can go home and help your healthcare delivery organizations or where ever you work in supply chain start to think about what's coming and prepare for it in a planful way so that there isn't chaos. Thanks.

Gina: Thanks Mary. Peggi ASPEN's been on the frontlines with this issue for many years and this could be new for many of our supply chain colleagues. Could you just give us a couple of examples of these tubing misconnections?

Peggi: Sure. I'm gonna drill down just a little bit to enteral because that's the first one coming and tell you a little bit. In, in US hospitals in 2011, which is the latest AAHRQ National Inpatient Survey date, during 275,000 hospital stays, patients received tube feeding or what we call enteral nutrition. And about 13% of those were neonates. Many more patients receive enteral nutrition or tube feeding in homecare or long-term care settings. Over a 115 enteral misconnections have been reported in the literature since the first one in 1973. Clearly these incidents are under reported. I'd like to share a few examples of patient stories that were published in the front page of the New York Times in August of 2010. So don't think this is a hidden issue because this is really been out in the media as well. I'm not sharing private health, patient health information because it was in the front of the New York Times.

This first story is a story that I personally received a phone call from the patient's mother. Again, the patient's mother was a nurse which makes it even more difficult and I'm, I was, I'm a nurse. This is a mother of a 24 year old woman who was 35 weeks pregnant and also the mother of a, of another child who was 3 years old. This pregnant woman had severe nausea, vomiting and was losing weight throughout her pregnancy. She was in and out of the hospital often. During this hospitalization in 2006, she was ordered tube feeding but the nurse inadvertently connected the tube feeding formula up to her IV. Within 24 hours, both the mother and the baby were dead. Some other examples, general examples are, again, you've heard a few. Tubes intended to an inflate blood pressure cuffs have been hooked to IVs leading to deadlier embolisms. Intravenous fluids connected to tubes that deliver oxygen resulting in suffocation of a patient.

Another specific story in 2006, a nurse in the hospital in Madison, Wisconsin mistakenly put a spinal anesthetic into an IV line killing a young mother who was giving birth. Another concern is the similarity of the look of feeding and intravenous tubes. And that problem caused the near death of a premature infant in 2006 as well. The nurse mistakenly connected a bag of breast milk to an intravenous tube leading to this infant having blood clots, profuse bleeding and seizures for months. In all of these stories, there are really two sets of victims. There's the patient and their family as well as the clinician who caused this near death or death to the patient. Clinicians never mean, never intend to make these connections but they do because they can. Thanks.

Gina: Thank you. Brad Noe, do you have any additional perspectives to share from industry?

Brad: Yeah, thank you. The, if you, if any of you know Mike Cohen who is the president of the Institute for Safe Medication Practices, if you have, you don't or if you've never visited their website, I would strongly recommend that you do. Mike has been a incredible proponent of this and Mike actually was a [inaudible] of mine 20 some, 20 some odd years ago. And as a result of that, we've maintained a relationship. Mike was the one who interested me in coming to this. The reason I bring that up is because he is probably one of the loudest voices among many voices in this subject area. But I recommend you go to his website because on there is a litany. You're hearing different from Mary Logan, you're hearing from Peggi, you'll hear from others. But there is a litany. He is also a part of MedWatch. So you go on his website, you can start to see chapter and verse. There are checklists that are used as a statement of how to avoid medication errors. There's a whole series of events that they've done. They've done a recent webinar on this topic. The list in endless.

But I also wanted, one of the things I want to characterize is the amount of medication errors that are underreported and especially the near misses is staggering. This is literally the tip of the iceberg. What we're talking about is the tip of the iceberg. We've done market research on this topic with your facilities such as, that you represent. The number of times that you have a conversation over a cup of coffee where someone has said to you, "Oh yeah, well we had that happen." "Well did it report?" "Nah, it didn't get reported." "What did you do to avoid it [inaudible]?" "Well, we just didn't have time," or, "Well, we do these work arounds." And work arounds then comes into the conversation. And by allowing certain products and certain materials into the supply chain, we actually enable work arounds. So no one ever has the time to go back and fix it. So it got into the system.

So I would point that out to you as you go forward. And Mary, again, echoing what Mary said is working with your patient safety officers. Okay. Working with your risk managers to engage in this dialogue and start to work through your systems now to avoid the mad dash. Going forward is [inaudible] thing starts to come to [inaudible] in the timeframe that we'll be discussing later. But, again, it's the tip of the iceberg and the list is endless. So you all heard the term never events. Well, everyone has had a never event, whether or not it got reported or not is a different discussion. So...

Gina: Thank you. Gerry Castro, we know the Joint Commission's been actively involved in this issue. Could you tell us what plans the Joint Commission has for educating the healthcare community?

Gerry: Certainly, certainly. So you saw in one of Gina's slides that we released a sentinel event alert in, in... But there was not a date on that sentinel event alert. That alert went out to the field in 2006. And the title of that alert was "Tubing Misconnections Persistent and Potentially Deadly Occurrence". So we've had this problem on our radar screen for quite some time now. Since that time, there have been a number of what we call sentinel events and what Brad termed the tip of the iceberg. What you have to realize about these particular events is not only that they are under reported but they are almost always catastrophic, okay? So if it happens, it will almost always cause the death of the patient. I, I, I can't remember where I was at the time but somebody told me it's like pouring cement into the bloodstream and when a feeding tube is connected to an IV line or central, central IV line.

What we want to remind organizations out there is that if it can happen, it will happen. So what we're trying to do is produce another sentinel event alert that will coincide with the release of the, the newer devices so that we can help the organizations understand what to be looking for in, in, in the safer device. We would also encourage the organizations to put together team, implementation teams so that they can... And we will encourage them to actually talk to the vendors and talk to the GPOs about these devices and tell, and ask, and we will them to ask you folks, "Well what are the, what are the costs and benefits of implementation of this particular device?" So we would hope that in these types of discussions, they would also include not only the, the purchasers within their organization but also the frontline people that will be actually using it. So we, we look at, we will be looking for involvement from the frontline to the pharmacy folks to the nursing folks to, to the purchasers to the [inaudible] all along the continuum of care here is what we're gonna be looking for.

Gina: Dan Schwartz, could you tell us what CMS is working on right now related to this?

Dan: Sure. Well first, I work in the Survey and Certification Group at CMS which is part of the Center for Clinical Standards and Quality and the that center deals with a lot of the value based purchasing and financial incentives that Gina had mentioned before. But my group in Survey and Cert, we, we interpret healthcare facility regulations and develop policies that surveyors use to assess compliance with the regulations and we also provide training for the surveyor. So specifically in this instance, when I got the letter, the same letter that Mary had received, we wanted to raise awareness of this important patient safety issue. So CMS does not regulate small bore connectors. We don't incentivize their use but CMS does focus on patient safety and improve quality care along with efforts to decrease hospital acquired conditions. And one way I think to do this is to raise awareness of the issue.

And so earlier this year, we put out something called a Survey and Certification letter and that's a way that we communicate publicly. Policy changes [inaudible] of focus to state survey agencies to surveyors and, and really the healthcare facilities pay close attention to it because, attention to this because they are obviously interested in what we are finding to be important. And so last year we did release this letter entitled "Luer Misconnection Adverse Events". Again part, partly because of the letter that, that we received and we had quite a bit of discussion with Mary and folks at AAMI and also with the FDA before we published that letter.

And you might ask, "Well what is, you know, what does Survey and Cert really



have to do with this in the first place?" But healthcare facilities, specifically hospitals, have regulations called conditions of participation. And the one that's most applicable is the regulation [inaudible] with the condition of participation that talks about quality assessment and performance improvement programs and hospitals and that's CFR 482.21 and I won't read the whole regulation but I would suggest you might wanna take a look at it. The best way is go to ECFR.gov and click on the public health tab and go to 482 and you'll find all of the hospital conditions of participation. But this one briefly says that hospitals must measure, analyze and track quality indicators including adverse patient events and hospitals performance improvement activities must implement actions to prevent recurrence and communications that promote feedback and learning throughout the hospital. And this condition of participation I think provides the clearest link between the risk of products sold to healthcare facilities and the obligation of those facilities to mitigate the risk and improve patient safety.

So in this letter, and again, probably the best way to get this letter if you want to, to read it is just Google it. So it's Luer Misconnection Adverse Events Survey and Certification letter. And really what it does is it familiarizes surveyors with adverse events caused by small bore connectors, the errors that occur, examples of actions healthcare professionals can take to prevent recurrence. It asks surveyors to determine whether the facility has taken actions to ensure that there are systems in place to prevent recurrence of this type of adverse event. And it also points out that surveyors can encourage facilities to report problems involving luer misconnections to the FDA even if the, an adverse event did not occur. So any misconnection ought to be reported to the FDA. So it's my hope that raising awareness in this manner may prompt actions that protect patients before new connectors are available. And I think CMS may also be willing to communicate the coming changes based on new standards and industry efforts to develop products that prevent these adverse events from ever occurring again.

Gina: Scott Colburn, in addition to your role at FDA, you also co-chair the International Standards Group that's been working on these new designs. So what does this new design mean for the FDA and what's the timeline for, for release of the first standards?

Scott: Thank you Gina. And I think the first thing I just wanna put out there is remembering that this is an international effort and although our focus is primarily here and even this group, we talked about how we're gonna implement this in US, this began as an international effort. And it is because this market is a global market and the manufacturers involved and even our patients are, they travel and we need to think of this. And to put that into context and really about looking at the patient, where they can be mobile really puts into the reason of why do we work with China on this, why are we working with Australia and Europe. So it becomes very important.

And so then you start thinking about the solutions to fix the problems. Standards by and large are not designed specific. They are process oriented; how to sterilize, how to do risk management, how to do human factor studies, how to test for flexural strengths of a, of a material, so forth and so on. But most even deice specific standards are not design specific because they try to hold back. Sometimes that can create a negative, a, a negative blockade towards an ovation. But this is a separate issue where a design standard was absolutely necessary to be the only way to really fix the ability for two devices to not connect anymore.

And so like the luer standard that we've had in existence, what we needed to do is just kind of put it back into its original scope for vascular applications for example, and those areas where that would be taken care of. But where other clinical applications were needed, we needed to have a design specific standard to assess and to really validate the inability to create a misconnection. And that became very important. And it was not something that came right on the first day to realize. We realized this probably after learning of what a lot of our colleagues in Europe had done and, and, and their, and then going through this process. But in the end, it kept coming back to the need to create these design specific standards to raise the level of safety to where it needed and would allow industry of supply chain manufacturers to be able to look at which, which of these devices are safe in their application would not create the potential for a misconnection.

And this is where we're at today with new design, with new sta-, connectors that have design specific criteria that we are in the process of this international standard that will be adopted in the United States identically, you know? So there isn't gonna be deviations. But we will be looking at these and then it'll, it'll come through into it's, into the [inaudible] of all the different devices that fit into the enteral applications, into the respiratory applications and so forth. And this is when, where we get involved with, you know, how do we implement this? When is always the big question. I get that asked by my colleagues at the agencies as well as from all, everyone across the table. Without the clear crystal ball, I can't give you the specific date but we are following the standards process and right now we are working, going to what's called the, one of the latter stages for a draft international standard. And we anticipate the first, and actually the timeline king is to my left here, the, the first iteration of these standards being published by the, kind of the last quarter of next year and then probably every quarter thereafter we'll start seeing these stands being published and ready to go.

The beauty of this, and this is kind of the picture of where we're at, we have a nice collaborative approach to this. And the industry groups from every clinical application are coming together and they're working towards not just how do we make the standard but how do we actually implement this. And that's the really key group in why we're here today because you are one of those key pieces. And I think Mary lined it up very importantly that you, this, this conversation cannot stop here. This is where, our, our, this is our first message to you and we wanna begin it, this conversation to continue on and, and have it grow.

Gina: Tom Hancock, what products are gonna be [inaudible] by these new standards? And could you give us a little bit of a snapshot of the timeline and how the supply chain folks are gonna get notified about this?

Tom: Sure. First, you might be wondering what, what's this guy doing up here with, with all these distinguished guests and panellists but I think the saying goes if at first you don't succeed, try, try again. Some of you may know that we did actually create [inaudible] standard connectors on, in enteral space on the nutrition access side. And I will tell you that was a painful process from a guy that was actually trying to implement it. And I think the primary reason was because each of the companies that were in that space, and it was limited to Abbott Nutrition, to Nestlé, to Covidien and a couple of others, and that, that process to kind of bring those new connectors out to market place was, was quite challenging because everyone had a different timeline, they had a different message and implementation was quite complicated.

So I'm not sure if anyone's familiar with that process but I wanna give you an idea. The magnitude, multiply that effort by 10 and that's the kind of impact that you will see going forward with the additional design standard changes in the new connectors. The products that will be impacted include respiratory, enteral, [inaudible] and cuff, Neuraxial, eretheral and the luer is gonna be maintained only within the intravascular and the hypodermic space. So if you are evaluating, assessing quality purchasing receiving, managing inventory supply, reimbursement; any of those related issues along the supply chain continuum... If you are in acute care, long-term care, homecare, if your manufacturer, supplier, distributor, GPO, [inaudible], facilities, [inaudible] and even patients, you're gonna be impacted. That's a pretty big list.

To give you an idea how much you will be impacted, you will likely see 2x to 3x the number of codes that you will have to be working with because you'll have a current code, you'll have a transition code and then you'll have a final code in terms of the products that you will see flowing through your supply chain. So hopefully that gives you a little bit of a perspective of just how much is going to be changing to get to where we need to be. It'll be stressful, it'll be challenging, you'll often ask, "Why, why are we doing this?" And I think it's really key for those in the room and those that are gonna bring this message back is that you have to get to the end state. And to get there, it may be a bit challenging but we have to get to this end state to reduce the risk and improve patient safety.

Gina: Thanks. Stephanie Hale, what advice do you have for your supply chain colleagues about what they should be doing right now to prepare?

Stephanne: Sure. So the primary recommendation that I would have is to begin to familiarize yourself with the standards. Do understand that knowledge gathering and knowledge sharing will be ongoing as new connectors are adopted and new connectors are introduced into the market. There will also be, we're also developing a transition plan and it follows the acronym APAM, A-P-A-M, Awareness, Prepare, Adopt and Measure. For the next six to eight months, we will be focusing on the awareness phase of the plan. So the prepare, adopt and measure will come later but right now, our focus is awareness. So begin to familiarize yourselves with the information that's out there and that's available. The good news is that you don't have to recreate the wheel. There is information out there. We launched the GEDSA website today, [GEDSA.org](http://GEDSA.org), [GlobalEnteralDeviceSupplierAssociation.org](http://GlobalEnteralDeviceSupplierAssociation.org).

So the FAQ document that you have available to you today is on that website. That will be the primary source of new information. So as new information is rolled out, new standards are adopted and new connectors enter the market, that will be the primary site for that information. I would recommend also understanding the historical issue surrounding tubing misconnections. That provides a, an understanding of the potential risks there are involved with, that are associated with not adopting the standards and the current risks that are involved to patient safety with the current landscape. So understanding the historical issues behind tubing misconnections. Those recommendations are for GPO colleagues and supply chain colleagues alike. Specifically for GPO colleagues, as we, as it's been alluded to earlier, it's a great idea to begin to identify decision makers and stakeholders and start having conversations. Whether they're external stakeholders, internal stakeholders, your hospital members, your partners and your customers, begin having conversations with them about the issue. Again, this will be monumental to the healthcare industry and the more information that is available the better equipped we are to handle those changes.

Begin looking at current practices for prevention in looking at the current devices there are used in the specific care areas within the facility. It's a great idea to start to develop a clinical profile of the therapeutic groups. So with enterals being first, looking at the clinical profile of the user, whether it's of the dietician, it's the pharmacist and the nurses, begin developing education plans that are tailored to the device groups and the delivery systems. A great tool is a survey. A great tool will be surveys and that enables you to understand the knowledge level as well as the readiness, readiness for adoption of the new standards. And understanding where your hospital members, partners and customers are.

We recently conducted a survey and 90% of the respondents of Novation members indicated that they did have policies and procedures in place for prevention. So that's great news. Our members are aware, the industry is aware of it somewhat but we do have a lot of work to do in educating members on the changes that are coming. I'll wrap up and say that ongoing assessment, ongoing analysis and evaluation of interventions will give you data and information to indicate where the education is needed. Again, I will refer you to the GDSA website, [GDSA.org](http://GDSA.org). That will be the primary source for new information. Thank you.

Gina: Thank you. Peggi, from a clinical perspective, what are some of the unintended consequences of, with this huge marketplace change?

Peggi: I think as we went along since 2006 trying to come up with this connector, our biggest concern was the lack of connectivity. What if you have one system that has this new connector in another system or another piece of equipment or a patient comes in with an old tube and they, and you're not able to, for instance, a patient comes into an emergency room. You don't have an adapter or you don't have something that you need and that patient sits there and is unable to get their medications and their fluids and, and formula because you don't have the right connection. I think that's the, one of the biggest concerns is making sure all the pieces all along the whole system process are able to match up, that you've got everything you need in the areas that you need. I love that idea about the surveys. Making sure that you find out where these systems are being used in every system. It may only happen a couple times but if that patient needs that piece of equipment in that area, it's really important.

Tom: I just wanna add one thing. I think, you know, also the clinicians, one of the biggest worries I have as a nurse and working in multiple different environments, even in the military is you don't want to allow the opportunity for the nurse to try to institute the work around. Bringing out the scissors or something because they don't have the right product in hand. That's what we really need to think about; having the right product at the right time in the right place. And that's a very important message because I can't tell you how common those scissors are in the back pocket for those, for the clinicians to pull out if they don't have what they need at the right time. It's, I think one of my biggest concerns for clinicians [laughs] to do.

Peggi: We nurses really know how to get things to stick together [laughs].

Mary: Yes. So from a, I'm a, a lawyer, I don't practice anymore but I think, still think about things from a legal perspective. And I remember being in a hospital about eight months ago and on, on the day I was there, a biomed had discovered a recalled Baxter pump in a ceiling tile. And it was what you could call hoarding, I guess. You jut never

know when you might need a recalled Baxter pump. And I have seen, also seen in a lot of, a lot of hospitals devices that are 15, 20, 25 years old that still work, sort of. And so you keep them around for a rainy day in case a newer device doesn't work or get's lost or broken. And that's where you're gonna have a lot of problems. If somebody's using an old device that they saved for a rainy day and it doesn't connect now with the newer whatever, and right when they need it, so the inventory issues I think create the possibility for an unintended consequence, an adverse incident because somebody wanted to keep and tried to use an old device with the new connector.

Gina: Brad Noe, what should be done with the existing inventory when all these products become available?

Brad: Good question and I'm sure one that everybody's starting to think through for a second. There's a number of things you can do with it. I suggest as Tom indicated that they'll be a series of event, of communications. Also, what Tom's been challenged with is putting together a cookbook, so to speak, or a tool kit to be able to help work with different, with industry partners, with your constituents, with your clinicians to be able to move through the product and work through the transition period. That's why, as a number of people are indicating, this is the start of the process.

We expect that, by an industry meeting as of last week, that we will be introducing enteral connectors some time in December of 2014 or January of 2015. That is, as may seem a year or plus away. It's around the corner. So as we work through this together and work through the systems, work down inventories, work up inventories. Keep in mind also that it'll be deciding when do you want to do that because you will also have conflicting programs to which you'll have to find time and resources to be able to execute that.

So the reality is, work with your industry partners. I am an industry member. I expect that you will be talking to me or talking to my sales people to be able to effectively do that. Triage your needs. Look at a number of things. There are ways of being able to work down the amount of possible outstanding inventory, etcetera, so that the impact is not as negative as you would think it would be. But again, stuff left behind could be somewhat detrimental for all those degrees. And so I think there's a number of things that you'll see, communications tools, basically assessment tools that will help trying to minimize disruption by that and basically inventory that's not basically useful. Okay.

Gina: Mary, could you tell us what these supply chain communities should do and, really, all of us when we get back to our organizations to prepare for this?

Mary: Well the first thing I hope you will all do is talk about this out in the hallway when you get back to your organization. I think someone earlier had mentioned get your patients' safety folks involved, your quality people, the chief nursing officer, anyone who could be impacted, anyone who has anything to do with connectors or the medical devices or the other supplies that are involved in connections. And just have a meeting. Hand out, you're gonna hear about some FAQs. Hand out the FAQs. Get a team going to start talking about what your organization needs to do to start preparing for this and what the implications will be so that it doesn't hit you in the face when it comes.

Gina: Thank you. As, as Stephanie Hale mentioned, there's lots of resources out there and many of the organizations here at the table are going to have resources. They'll be a communication plan that's gonna be published. For now, these are just a couple of websites where you can download the frequently asked questions that were passed out today as part of the handout. I'll also have the introductory slides and the pictures of the faculty on the Premier Safety Institute website which is the third and final website listed on the screen. So now we're gonna move into the questions and answers and Marilyn Flack from the AAMI foundation and Cathy Gosna from the Premier Safety Institute have mics ready to go if anybody has any questions they'd like to ask the panel. Dave...

Male: You did a really good job or [laughs]...

Dave E.: My first, er, I'm Dave Edwards and I'm with Premier and I applaud all of you for bringing this to us today. And for all, to me, this is one of the great examples of the industry coming together and working collaboratively short of before it gets legislated. Obviously the California legislation probably accelerated the pace but I think this is the best example I can think of of different parts with different constituents that serve different masters all coming together for the common good. And those heart rending stories were kind of the emotional underpinning that galvanizes action.

I guess I would ask all of you from your own unique vantage point, how do we accelerate what's gonna happen any way? Because it sounds like we're now to the point where you've gotten the attention of all the key stakeholders and we've now got real movement and kind of a deadline in mind. But how do we use these various channels and even industry forums like this to move it forward? Because it still feels like it's in pockets and it's, and it's still happening sort of in fits and starts and episodically rather than sort of an industry juggernaut all happening really quickly at one time. What can we all do to, to accelerate that?

Male: I would, I would say one of the efforts this had done is kind of expanded the stretch, kind of capacity of who, who are our stakeholders? But I think, you know, and to answer your question, I would say who are your stakeholders' stakeholders? Because that's kind of jumping onto the other side of the fence of what, what still needs to take place and that's kind of what the message here is is, you know, we're reaching out, you know, from an FDA point of view. Typically we go to the industry where we receive information from, from the medical community but our main stakeholder might be industry but here we're actually looking to go to the other side of what industry stakeholders are more, to, to really get that word out and to really start thinking in that. And then deliver that information back so that we can prepare and provide a better implementation plan for industry to get through the regulatory channels or so they can work with you on the supply chain considerations for their device lines. That would be one recommendation. Tom...

Male: Quality and stake [inaudible] within the institutions, talking to supply chain and quality, I'm sorry, or the quality and safety leaders within the [inaudible] out there. Talking effectively with supply chain management to institute these kinds of changes because that's been a gap historically.

Male: Yeah I think it is a gap and I think, you know, we're, we're actually kind of employing you guys to, to reach out. Reach across the, the, the isle, so to speak, right, to, to engage the facilities. I kind of mentioned before, we tried to launch the new

connectors from an industry standard. There was no kind of panel, if you will, right, up and down the, the, the group here. It was industry working on their own to try to implement this. And it was clearly, it wasn't done optimally. So what we're, we're asking, pleading here is that you do bring it back, you do talk to your quality folks. And that's the way we will get engagement and get involvement.

What I can tell you is, with the first group that's going out with the enteral, enteral connectors is industry did get involved. There was a similar launch in Europe that also is still in the process and not going well. So we're learning a lot from our mistakes and saying, "Here's how we have to do it differently." And the, one of the biggest things is we have to work collectively on a common launch time period, a common message, right? So we're not all saying something similar. We're saying the same thing. And that's actually my job is kind of the, we didn't really introduce GEDSA, it's Global Enteral Device Supply Association. And the idea is that kind of we're first out of the gate, so to speak, in the enteral space. But we do wanna carry that torch, if you will, from a small bore connector communications effort because we do think it's valuable for, for you all, all of our customers to hear one message and one theme.

And that when you talk to your suppliers, you're gonna hear the same thing. And you're gonna demand from your suppliers, "What's the plan, how are you gonna get me through this?" And then you all will be on the same page and you'll hear consistent message, whether it's one company versus another. But it's gonna take a joint effort from everyone. And I don't think it's something where you can necessarily point just to manufacturer, so to speak, and say, "Get us through this." It's gonna be a collective, you know, an effort. And we all understand that and so we're gonna collaborate on training materials and, you know, FAQs and websites and updates. And, and well we'll we continue to beat that drum but we need that to be done within the facility. So that's what we are pleading here.

Mary: So one of the things that is really challenging for all of us on the podium is how to create a sense of urgency. Drug shortage, that's urgent. Hospital acquired infections, that's urgent. We're trying to be on the front end of this so that it's not a crisis and chaos and chickens running around with their heads cut off because we, we know what would happen in that instance. But how do you create that sense of urgency?

So there is an inter, multidisciplinary organizational effort that includes all of us here on the podium but also some other organizations; the American Hospital Association, etcetera. And the Joint Commission is leading the coordinated communications effort. We need more though. We need other... The people who've had an incident in their hospitals with tubing misconnections get it. Others say, "What's the big deal?" So the more that you can all help get the word out to all of the other associations, your State Hospital Association, your State Purchasing Association, etcetera, etcetera... Ask the question, "What are you doing to help with tubing misconnections?" And let them try to answer that. That would be helpful.

Peggi: Another comment I have off what Tom might be able to explain better is that the plan of GEDSA is to reach out and not put all of this onus on you. I don't want you to feel like [laughs] you have to run over to your [inaudible] suite and yell and scream and raise the rafters. We're going to try to reach out. This whole panel is gonna try and reach out to many, many other organizations. Clinical, nurses, pharmacy, you know, risk managers, QA people, all the way up and down institutions so that you, so everyone is hearing the

same message, looking at the same launch date, hearing the same thing and working through the same processes. So, so...

Male: [Inaudible] felt like a [inaudible].

[Laughter]

Male 2: Nice.

Gerry: Yeah, you know, and I, I just wanted to add... So for those of you who are familiar with the Joint Commission, we have most leverage at, at the organizational level, right? So I think what's great about this effort is that it is a coordinated, collaborative approach and that we will be all sharing the same message. So the organizations will get this message and they will be asking you folks about this message as well.

Debra: Hi I'm Debra Williams from Premier. Great, great message. Scaring me half to death.

[Laughter]

Debra: [Inaudible] won't let anybody else...

Mary: Good, good.

Debra: [Inaudible] When I go into the hospital now, I'm gonna make sure they're connecting me to the right thing. [Laughs] But I'm, you know, as you guys were presenting a great presentation by everyone on the panel, I was mindful of the safety needle roll out. And I was at a hospital when that roll out occurred. And while I can appreciate that things like this effort has a little bit more coordination than that, I don't hear any conversations going on with the manufacturer of those devices. The hospitals had to incur some significant price increases when they were mandated to implement those safety needles. And so I'm wondering to what extent your discussions and collaborative, collaboration has included the medical device manufacturers themselves to help hospitals navigate and control costs as these mandates are being rolled out?

Tom: I'll, I'll try to tackle this and [inaudible] [laughs].

[Laughter]

Female: He is industry.

Tom: Yeah so first and foremost, so what I do have to say is that the pricing is at the sole discretion of the device manufacturer. And as an association, we, from [inaudible] perspective, we absolutely cannot talk about price. So you, you will not see any of that coming from the association or any of the manufacturers. I will say that unfortunately, this is a cost burden that the manufacturers will have to implement these standards. There is gonna be a change in price. To how significant that will be, it, it'll vary by



company a little bit and how they chose to pass that on or not is, it unfortunately is really up to them. And, and unfortunately, we cannot even get in, enter those conversations about, you know... Because we don't wanna look like we're colluding. And that's, that's very a frank and very serious com-, comment. I will say that, you know, the spirit of this is patient safety. It's not about finding an opportunity to raise price significantly. It's about the best I can answer that.

Brad: Yeah I, I, speaking as a manufacturer, and I appreciate your question. This is where the collective discussions with your suppliers whether it be BD or whoever, whoever that is, having those conversations now... First of all, make sure that they're engaged and are they going to be prepared to be able to deliver this? And then secondly, have those conversations. Think of it in two terms also. The benefit of a global standard is you get global economies of scale. So for both of this, we share in that and that's a good thing. All right. So we don't have to build proprietary systems. So for doing all one off, you're gonna pay one off pricing and that's a scary concept. Not including the clinical implications to go with, with disruption of therapy, etcetera.

But from a perspective of one of the things in looking at the design characteristics of these particular connectors was manufacturability. It's one thing to build it and build it so it can interconnect, the other thing is to build it so you can do it well and do it effectively. And we have heard constantly from you, from the users that people today have converted to proprietary systems or non-standardized systems and feel that the pricing was excessive. So we have been very sensitive to that. And while we can't talk about pricing, there is an underlying concern about adoption in the marketplace, all right? And we know that that's a barrier. So I appreciate that.

Gina: Okay, any, anymore questions? I guess we covered everything.

[Laughter]

Female: I have a question.

Gina: You have a question. Marilyn Flack...

Female: I'm, I'm glad you mentioned gearing up for this because since drug shortages was [inaudible] the sexy thing today, let's talk about if this could cause a shortage. What happens when, when manufacturers are ready to roll out the enteral connectors and two or three other manufacturers may not be. So some hospitals might have some of these [inaudible] of the hospital, not in another part. Another hospital might not have them. Is there any kind of coordinated effort going on to make sure we don't have a shortage?

Male: What I can tell you is that we have... I can't tell you precisely the number but I would have to say 99% of the market share has been represented on this industry effort, kind of collaborating from a standpoint of what the timing is for launch, okay? And this isn't been like last week. It's, we've been talking about launch dates for over a year now and aligning towards a date that we can all live with. And so is there an op-, is there a chance that someone gets behind and is not gonna be able to do it on time? Certainly. That's a possibility. But I will tell you that we've spent numerous meetings, numerous times communicating on a bi-weekly basis, in fact, what the timing is for launch because this is, this does have to be a coordinated effort because it's far more

likely that you have a giving set for enteral that connect to somebody else's tube, right? If you're one manufacturer, you're likely gonna connect to somebody else's tube. And so recognizing that, we felt like the aligning on the launch dates was as critical as the connectors themselves. So we're, we're doing our best to, to coordinate the timing.

Gina: Okay. I think we're ready to close our session. I wanna thank the audience for coming and joining us in, in this important panel discussion. And I'd like to also thank our panel again for coming and sharing their expertise today. And all the behind the scenes work that went into putting this panel together, the frequently asked questions, from everybody on the panel and behind the scenes folks, you know, at the FDA and AAMI and Novation and Joint Commission and others and the Safety Institute to really pull this all together and get all the materials developed for today. And, and so we're, we're eternally grateful for everybody's participation. And this is really a challenge moving forward. This is the first of its kind ever in the industry to launch something this big and we'll be learning a lot from the enteral launch, hopefully something from our European colleagues and continue to forge ahead. But the communications plan that May mentioned that Joint Commission is leading along with, [inaudible] health, the plans are underway and so we hope this is, that is a smooth roll out with as few bumps as possible. So thank you all very much for coming.

[Clapping]

Gina: And the panel is going to stay around if anybody has any additional questions that they haven't shared already.

Male: It's, it's a good panel.

Male: Yeah.

Brad: No, it was good. It was...

Dave: Thanks everybody. Again, thanks to our panel. And we have a session that we'll start in a little bit next door for the insights on mergers and acquisitions. But feel free if you like to stay and, and have additional questions for our panel. Thanks again.

Male: ...Old friend.

Male 2: Oh sure.

Male 3: Yes, that was great.



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