Dawn Glossa, director of Communications and Corporate Marketing, The Joint Commission:
Welcome to today's webinar on the misuse of vials. I am Dawn Glossa, director of Communications and Corporate Marketing at The Joint Commission. The Joint Commission's recent Sentinel Event Alert highlights some of the contributing factors on the misuse of single-dose, single-use, and multiple-dose vials; and recommends potential strategies for avoiding and preventing infection. Today, we look forward to continuing that discussion. And now, I am very pleased to introduce our first speaker, Dr. Ana McKee, chief medical officer and senior vice president at The Joint Commission.

Ana McKee: Thank you. I'd like to thank you all for attending this collaborative webinar. The harm caused by the misuse of vials is well documented and widely known. Since 2001, 49 outbreaks have occurred and thousands of patients have been adversely affected by the misuse of single-dose, single-use vials, and single-use, multi-dose vials. Harm to patients from outbreaks of drug borne pathogens and associated infections, including the hepatitis B and C virus, meningitis, and epidural abscesses can be devastating and even deadly. Additionally, significant financial ramifications are incurred at the institutions where the misuse occurred. The Centers for Disease Control and Prevention (CDC) estimates that many more outbreaks from the misuse of vials goes unreported. Due to the serious consequences and the frequency of these events, The Joint Commission issued a Sentinel Event Alert on June 16, 2014, aimed at preventing infections from the misuse of vials. The alert describes the major factors that contribute to the misuse of vials of injectable medical products, and it details strategies related to policies and procedures, training and education, as well as the establishment of a safety culture that can help prevent the misuse of vials. We recommend that facilities put organizationwide standardized policies and procedures into place, routinely educate staff on how to recognize breaches, and emphasize the importance of reporting risk, including near misses and adverse events. This webinar is a collaborative effort by The Joint Commission, the CDC, Institute for Safe Medication Practices (ISMP), American Society of Anesthesiologists (ASA), and the Children's Hospital Colorado, to help focus on ways to more safely use vials in daily practice at your organization. We hope that you find this information helpful. And now, Dawn will introduce our next speaker.

Dawn Glossa: Thank you, Dr. McKee. Our next speaker is Jerrod Milton, vice president of Professional Services and chief pharmacy officer for Children's Hospital Colorado in Denver. Mr. Milton will discuss the pediatric hospital's work to safely use vials. Thank you for joining us, Jerrod.

Jerrod Milton: Thank you and good morning, my colleagues. I want to extend a warm Children's Hospital Colorado greeting to all of you. It's my pleasure to be here today and to share our approach to this topic.
Next slide, please. Before we begin, I would like to share a little bit about Children's Hospital Colorado and the scope of our pharmacy services to add some context to my presentation. Children's is a private nonprofit pediatric system of care. We currently operate a total of 593 inpatient beds, and these beds are subdivided across the five hospital system. The largest bed capacity exists at our main hospital campus in Aurora, Colorado. It's followed in size by our newly activated operations at Memorial Hospital Central in Colorado Springs, which is approximately 75 miles south of the metro Denver area. We also have inpatient beds at our north campus (which is located in Broomfield), beds within the Parker Adventist Hospital, beds near downtown Denver at St. Joseph Hospital, and a newly opened facility we call our south campus, in Highlands Ranch. Like many of you, I suspect a significant percentage of our overall patient care is delivered in the outpatient environment in various specialty care centers. In total, our current network of care locations number 17 throughout the state of Colorado, and our occupied physical space exceeds 2.4 million square feet.

Next. The scope of our pharmacy services is extensive and fully describing it would exceed the scope of this presentation. However, our primary goal is to provide the safest patient-specific medications directly to the bedside, and be ready to administer them as quickly as possible. In total, there are currently 104 full-time equivalents comprising the pharmacy work force. This includes specialized pediatric pharmacy professionals and an equal complement of pharmacy technicians. At our Anschutz medical campus, our services run around the clock, seven days per week. We de-centralized clinical pharmacy services geographically, which supports our medical service lines. We use Omnicell for automated dispensing, and have recently brought robotics into our drug distribution system. We fully operate five ISO class 7 clean rooms, and are poised to bring two more online in the next six months to support aseptic compounding of pharmaceuticals in our center of care.

Next. Approximately 39 percent of the 1.6 million total doses dispensed from pharmacy services are parenteral in nature. Sixty-five percent of these parenteral doses are dispensed directly from one of our ISO 7 clean rooms. The remainder either come to our anesthesiology mobile work stations (that's about 21 percent), or from various points of care Omnicell dispensing cabinets, which make up the remaining 14 percent.

Next slide. Children's uses pre-filled normal filling and heparin lock flush solutions and provides these devices as floor stock at appropriate point of care locations. Nursing staff are trained to treat these items as single-dose containers; that is, any volume of saline or heparin solution remaining after the port or IV line is accessed must be discarded as waste.
Next. The Pharmacy and Therapeutics Committee has empowered pharmacy operations to implement an objective scoring system in assessing the relative risk of distributing drugs requested for floor stock consideration. This tool is used prior to approving floor stock medication, and it evaluates a wide array of safety considerations, such as look alike/sound alike, the extent of various dose forms available, impact of overdosage should it occur, high-alert drug status, drug interactions, black box warnings, etc. If an item scores above the minimally accepted risk threshold, the request for floor stock is either declined or brought before the P&T Committee for final review and decision. Following the recent Joint Commission Sentinel Event Alert that was issued in June, another scoring criteria was recently added, and that is medication stability in the context of beyond-use dating for parenteral items.

Next slide. I’m very pleased at the level of training brought to nurses at Children's Colorado. Guiding principles employed for all vial types are presented on this slide. First, the vial septum should be disinfected by wiping every time prior to piercing with a needle. It's important to note that the manufacturer's vial cap does not ensure the vial septum is sterile. We use 70 percent isopropyl alcohol wipes and promote the importance of using friction when piercing the septum. The septum should be visibly wet and then allowed to air dry for 10 seconds prior to accessing. This next one is tricky. Unless clearly specified, do not assume any product meets multiple-dose criteria, even if it has preservatives in it.

Lastly, needles or other access devices are not to be left in the vial septum between uses in order to prevent gross contamination that may occur from room air. The photograph in this slide illustrates confusion that can occur with products that are presumed to meet multiple-dose criteria. Although this product does contain a preservative, if you read the fine print in the package labeling, it clearly states that once opened, it should be discarded within a seven-day period, not 28, which is the general standard for other multiple-dose products.

Next slide. Fundamentally, our staff receives training to treat single-dose vials as single-use vials. That is, once they are opened and a dose is withdrawn, any remaining solution is discarded as waste. There are a few exceptions which include medications that require reconstitution, such as some vaccines. Once the reconstitution steps are completed and the dose is withdrawn, the remaining solution is to be discarded as waste. In emergency situations for a single pediatric patient, our protocol allows for multiple doses to be withdrawn from a single-dose vial. Please keep in mind that kids are not small adults and generally require weight-based dosing and smaller aliquots. When this occurs, a new sterile needle attached to a new sterile syringe must be used for each entry into the vial. Lastly, single-dose vials opened in room air and their contents must be either used within one hour or discarded as waste.
Next slide. With respect to multiple-dose vials, our staff follows policies that generally limit beyond-use dating of injectable products to 28 days after the vial septum is pierced. Of course, if the product expiration date happens to be within this 28-day period, the shorter of the two days would be used. Multiple-dose vials are generally not used on multiple patients and strict aseptic techniques should be used when removing each dose from these vials. Staff are encouraged to discard open vials where questionable circumstances would lead to uncertainty in patient safety. At Children’s, we attempt to limit the extent to which multiple-dose vials are provided to unit floor stock. Currently, this includes flu vaccine and short-acting insulin. In the case of insulin, it is labeled for patients’ specific use before dispensing from the pharmacy. Other exceptions include some products provided anesthesiologists as well as Benzodiazepine and opiate reversal agents stocked in our emergency resuscitation carts.

Next slide. I’d like to briefly highlight six important principles we promote internally in order to ensure proper aseptic technique when opening vials in room air. First and foremost, remember the ABCs of proper hand hygiene. Use soap and water or waterless hand sanitizer that is 60 percent or greater in alcohol to cleanse hands. All aseptic parenteral medication administration warrants proper aseptic technique. All aspects of the storage and preparation environment of medications and related supplies should be kept clean. Needles and syringes should be stored within the manufacturer's outer wrapping so as to not compromise sterility. Open vials, IV solutions, and related supplies that may be involved in emergency managements should be discarded as soon as possible after the event. And lastly, protect the integrity of sterile drugs, sterile areas of devices, and do not allow them to come into contact with non-sterile objects or material.

Next slide. The training and orientation of staff here at Children's concerning infection prevention in the context of medication vials includes didactic course work. Our new graduates and newly hired nursing personnel go through this classroom teaching. We also employ what we call, "e-learning modules" and this is basically vignettes that are pushed out electronically to staff; and our annual competency program is electronic and required of all clinical staff. We also utilize something we call, "competency on the fly.” This is where leaders employ on-the-spot education to staff, as needed. This is usually when the manager notices noncompliance or questionable compliance with the protocol while rounding and takes remedial action in the moment.

Next slide. As confident as I am in our medication management and infection prevention programs, I acknowledge continuous process improvement opportunities always exist. After the recent Sentinel Event Alert on medication vial safety, our Medication Safety Committee convened to discuss it and looked for gaps in our program. Several opportunities were identified and they included honing our approach to staff
education and competency assessment. We think there may be a notable gap that exists with respect to
training and oversight and partnering with our anesthesiologists. Other opportunities involve the
pharmacy operation, particularly the rigor employed in monitoring a dynamic force inventory. Closer
screening of items substituted during product shortages is warranted. We're also going to consider more
explicit auxiliary package labeling before stocking. One of the soon to be opened pharmacy clean rooms I
mentioned previously is located in our main operating room. Once operational, our goal of providing
patient-specific medication to the bedside will be advanced. And lastly, we continue to reemphasize and
monitor compliance with the policy statements mentioned throughout this presentation.

Next slide. Thank you very much for your attention this morning. I will now turn the virtual podium over to
Dr. Joe Perz with the CDC.

Joe Perz: Thank you, Jerrod. This is Joe Perz speaking to you from Atlanta, Georgia. I'm very happy to
be with you. I have to say that here at CDC we were very pleased that The Joint Commission chose the
misuse of vials as a topic for a Sentinel Event Alert and we were very happy to help contribute information
to the development of the Sentinel Event Alert.

Next slide, please. I think that, as was made amply clear by the previous presentation, we need to all
consider that injections and infusions, parenteral medications generally, are absolutely essential to health
care delivery across the health care continuum. And considering that Children's Hospital, as was just
communicated, is dispensing over 600,000 doses of parenteral medication per year, think about how that
scales up across the state of Colorado, and then across the United States, in general. So, we're talking
about something on the order of billions of injections or infusions delivered each year for a range of
procedure types and in various settings.

Next slide. So, why is that important? Well, when we consider that one unsafe injection may present very
real risk to the patient receiving it and we consider the overall volume of injections delivered, then even a
small percentage of unsafe practices or, put another way, if there's adherence gap, however small, that
can translate to real risk. So, the slide summarizes information that's also contained in the alert, and this
is a survey that was conducted by a premiere safety institute just a couple of years ago. This was an
online survey of U.S. physicians and nurses, and we were very concerned to see that 1 percent of the
respondents stated that they sometimes or always reuse a syringe on a second patient. So, there's a
scenario where we aren't even talking about vial misuse per se, but direct reuse of a syringe from patient-
to-patient and the risks there are obvious. Perhaps more subtle for some, is the idea of indirect
contamination of a shared vial. So, again, we see that 1 percent of the respondents indicated they
sometimes or always reuse a multi-dose vial for additional patients after they have accessed it with a used syringe. So, again, think back on the previous statements regarding the necessity of always accessing a vial with a clean, sterile syringe every time a dose is drawn. And then finally, confusion around the appropriate uses of single-dose vials is something that has persisted; we've seen it in many outbreak investigations, as I'll summarize on the following slide. In this survey, 6 percent of the respondents said that they would use a single-dose or single-use vial for more than one patient. And I would add a comment that I believe that was probably an underestimate because, as we have found, many times people just look at a vial and generically think of it as a multi-dose vial. So, whether the respondents actually have been reading the labeling, which as we've been emphasizing, is a very important piece, is something to keep in mind when interpreting that statistic.

Next slide. So, again, to summarize: What is probably obvious to most of you, the idea that unsafe injection practices can lead to transmission of life-threatening infections. That's why we're putting this emphasis on this topic. The source patient oftentimes is somebody who may have a chronic infection. If we're thinking about blood borne pathogens, for example, that person can be a source of infection for other patients if we create a transmission chain. A transmission chain can include contaminated injection equipment, like syringes and needles, as well as medication vials. And again, the medication vials really deserve emphasis in this context. To prevent such transmission, one of the obvious opportunities is to reduce the amount of sharing. So again, I'd like to emphasize the points made by the previous speaker in terms of the unit-dosing and aspiring to actually eliminate sharing. For example, if a multi-dose of insulin is dispensed, a best practice would be to dedicate that and label it for a single patient.

Next slide, please. So, the U.S. experience here includes many outbreaks. The dots on the map represent areas where we've had either a viral outbreak or bacterial. I know a lot of us think about, clearly, the risks of things like hepatitis C in this context, but consider that over half of the U.S. outbreaks that have been identified to date actually involve bacterial infections; some of them quite serious in terms of their clinical consequences. The number of outbreaks continue to decline and in the alert, we used the number 49, but I can tell you that reports continue to come in to us despite all of our collective prevention efforts. Since 2007, also keep in mind, this is very pertinent, relative to the Sentinel Event Alert, about 20 outbreaks have involved multi-patient use of single-dose vials or containers. And frankly, that is a head scratcher in this day and age. If the vial is labeled single-dose, that means that FDA only approved it for use one time on a single patient. So, we shouldn't, frankly, be seeing outbreaks involving multi-patient use of single-dose vials, and yet they continue to be reported. And it's not just the numbers of patients infected, of course. We've had situations where contamination of vials, because of syringe reuse, has been identified; we've had situations where that's identified sometimes as part of the survey process. So,
not even that there’s an outbreak recognized, but unsafe practices identified, that triggers an ethical duty to warn and that is something that I think we’re seeing increasing recognition around and need for disclosure, and then providing, for example, an opportunity for patients to seek testing.

Next slide. Again, this whole idea of single-dose or multi-dose and providers paying attention to the important differences, that is something that we have developed material, educational materials, for in the context of the One and Only Campaign. The One and Only Campaign is mentioned in the alert and I wanted to include mention of it here. We have many materials that I think accredited facilities would find very useful as part of their educational efforts.

Next slide, please. Here’s another screenshot of an infographic that we developed specifically around the topic of single-dose versus multi-dose vials. And so, I would encourage you to look at this and consider it as a companion to The Joint Commission alert. There’s also a companion video that goes with this.

Next slide. And so, with that, I am going to thank you again. We would like to emphasize the materials in the One and Only Campaign are based on the CDC’s evidence-based guidelines. The safe injection practices that are emphasized there are all part of standard precautions, and we would very much welcome any of the accredited facilities to consider joining the campaign. There is an option to join as a member, and we would very much encourage that. We have also benefited greatly from partnership in the campaign from ISMP, now The Joint Commission, as well as the FDA. Thank you very much.

Dawn Glossa: Thank you, Joe. Our next speaker is Mike Cohen, President of the Institute for Safe Medication Practices. Mike?

Mike Cohen: Thanks very much. I want to start out with a couple of comments. First of all, even before I do that, I wanted to let you know about something that's come up over the last 24 to 48 hours. In that recent Sentinel Event Alert, number 52, there was a statement under the column, “Multiple-Dosage Vials,” that only vials clearly labeled by the manufacturer for multiple-dose use can be used more than once, and that's true. Insulin vials currently, if you look at the actual container label, they do not say, “multiple-dose.” However, they are multiple-dose, and I wasn't even aware, and I think people weren't, that they're not marked that way. And apparently, they don't have to be; that's something else that we learned recently, but that's another story. But at any rate, we did learn yesterday from one of the manufacturers, Lilly (Eli Lilly and Company), that they are, in fact, multiple-dose vials. They sent us a letter and we’ll talk to The Joint Commission about the best way to get that info out. We also have something set up with one of the other companies that manufacture insulin vials, and then we'll set something up with the others, and also with FDA. We did talk to FDA as well and they're aware, so we'll get those things properly marked. But I
did want to talk about vials in general. And before I go into my slides, first, I don't think that these breaches that we've seen in the *Sentinel Event Alert* aren't really happening or aren't happening today.

I absolutely believe we're doing better; thanks largely to the efforts of The Joint Commission and CDC and others that have worked on this. Pat on the back to them really. But I can remember back mid-career for me, back in the 90s, when there was a dermatology study published, and I think it was *Archives of Dermatology*, that showed, and this was a simulation, but when they observed dermatologists actually using multiple-dose vials, 25 percent would draw up the medication, inject the local anesthetic around the area that they were working, and then go back into the vial with the same needle and syringe, and thus contaminate the vial in most cases. So, I found that shocking at the time and it's been a concern of ours at ISMP even before that, but certainly it's a big one. And so, we're really happy about all the activity, as well. Like I say, I think we are doing better. We don't use as much heparin, for example. That was a source of a problem for IV catheter ports. We do use some, obviously. And I would also say, by the way, that if you looked at a group of medications that were the most problem, I would say it would be the local anesthetics, the flushes that we use, saline flushes, whatever, heparin when it is used, and that's probably a handful of drugs that most often are the ones that cause the problem. So, good to keep in mind.

And then another issue also with the multiple-dose vials, it's not just infection control, but also harm potential from medication; that's our area of expertise obviously. But if you think of some of the disasters that you've read about in the media, some of the cases that we've had reported and we put out in our newsletter, epinephrine vials, Lidocaine vials, and other local anesthetics, etc., and a lot of it is because very frequently we're using large multiple-dose containers on the nursing units. It's somewhat convenient, maybe there's some cost considerations there, etc., and then we're putting them back in stock. But I always remember a case that we had here in the Philadelphia area quite a few years ago, but it was probably one of the worst medical disasters I've seen or that we've read about, I should say. And what had happened there was, it was in the dialysis unit and they intended to give Mannitol injection to three different patients and little did they know that the bin marked, "Mannitol," actually had Lidocaine 50 milliliter vials in it. So, three patients in a row were given large doses of Lidocaine. I think it was 2 percent. And in each case they went into cardiac arrest in short order. And I think that, just to remind people, one of the major strategies that we promote is to minimize the consequences of inertia. So, by either eliminating large multi-dose vials or multi-dose vials, in general, and going to single-use vials wherever possible or certainly going to, as Jerrod said, unit-dose syringes (and Joe Perz did as well), you can minimize the consequence of inert. If we had 10 milliliter Lidocaine syringes or Lidocaine vials, the units they were mixed up with another 10 milliliter product, they would not have led to a death. So, that's
another thing to be looking at. We still see the large volume containers of epinephrine and we've had these ratio expression mix-ups with 1 to 1000, 1 to 10,000 confused, and, unfortunately, sometimes leads to very, very large doses that wouldn't be possible if you were using a one ml vial or two ml vial. And so, please do keep that in mind.

But let me go on to the next slide. And I want to talk about some of the issues that we still have presented to us or that we observe ourselves. We have a group that goes out and visit hospitals at their request to help them with some safety issues that they might perceive or to look at their medication systems. And we will do observations and work with the staff there and try to point these things out, things that they may not see.

So, I'm wanting to talk about some of these on the next couple of slides. So these, unfortunately, are out there, and like I say, don't think that they're not happening. I think you do need to be careful with your observations, getting out there on rounds around the organization and off the beaten track, to the cath lab, in the OR; that is part of the big track, I guess, but to different areas where multiple-dose vials and single-dose vials might be used.

The first issue is, of course, people using multiple-dose vials and not dating them or using multiple-dose vials and dating them with the date open, instead of the beyond-use date. Remember, there's an expiration date the manufacturer has on the label, and then once the multiple-dose vial cap is removed, you have 28 days beyond which you should not be using that, and those vials must be so labeled so that people know. And it's sooner if the manufacturer has in their labeling that it's only good for 14 days, then that's what you need to stick to at this point. And there may be some research out there that allows an extension; that's a different story entirely. We think it should be something that people could go by, because it's usually for stability, and there might be science behind that, but that may not be accepted by your department of health, if they happened to do an inspection for certain circumstances.

The second thing, and I guess part of that is failure to swab the needle for the injection ports. I know that's on the slide, but that needs to be done just like the vial septums before connecting a syringe. And as far as vials, of course, we need to do that, but rarely do practitioners allow that diaphragm or injection port to dry before inserting the device into the vial. So, that's something else you might want to observe or you might want to see that done. Also, preparing doses and where they're prepared – on top of the automated dispensing cabinets sometimes or on top of the drug cart, a computer on wheels, what have you – rather than in an area that's actually set up for drug preparation. Obviously we promote pharmacy dispensing in unit-dose or pre-filled syringes that are prepared and labeled and now with the bar code systems, you're really going to want to take advantage of that because you want those medications scanned. But
obviously, on occasion, we do need to see these medications used in the inpatient area. You want to minimize it as much as possible and make available the most ready-to-use system, but that still does happen and, unfortunately, we can't get away from that.

Single-dose vials not discarded after the volume has been withdrawn; sometimes left on countertops again. I just want to point out that sometimes we do still see these in stock, and one of the issues, I think, may be the people that are cleaning up. They may not be looking at the labels as carefully; even perhaps some of the nursing associates who might be tidying up the area after drug preparation and they may put something back on a shelf, for example, where they know it might belong. That's something you need to bring them into the fold, as well, and make sure they're aware of the restrictions on reusing single-dose vials, for example. And then we even have people that are really not familiar with the difference between single-dose vials and multiple-dose vials, so obviously that needs to be part of the training program.

One of the things we've seen around the OR, in particular, are syringes that are pre-drawn and stored somewhere, like in an anesthesia cart. They'll open a drawer and there they are. Usually they'll be dated; some of these are prepared for possible cases in radiology or the cath lab, not necessarily in the OR; but then they're not used and they're left around until the next day. So, this is something that you need to look for. That's not something that would be acceptable, unless it's something that's been made, as Jerrod said, this is a measure of the amount of particles of air and we have the laminator flow hoods, for example. He said that he had a class 7 room, which is even higher purification level than the typical laboratory or pharmacy laminator flow hood, but that's a safe place to make them, certainly not at the bedside.

Also, one thing we've run into, and we were shocked to see this, apparently it's a habit that I guess it's hard to break in some cases, but people walking around with syringes in their scrub suit pockets. We just saw that recently when visiting a hospital and spoke to the individual. And sometimes it could be a drug, like Propofol or something, that we have had specific infection control issues with when they're not handled carefully. And then, vials with syringes and needles, and the vial adaptors or transfer devices that are stuck into the vial septum and fluid is removed. They are left in the vial as a way to still have the needle sticking through it, and you've heard others talk about that. That's an issue. It's like the Grand Canyon for organisms to get through. So, you want to look for that as well.

Next slide, please. Other issues are when pharmacies use bulk packages and then saving them for reuse. Keep in mind pharmacies should be doing this in an ISO class 5 environment, and there are specific time limits that pharmacists are familiar with that have to be followed. In an ambulatory care
setting, people would take a saline bag and use that as a common source container to prepare flush solutions. That way, you don’t need to buy unit-dose syringes that are already labeled or have the pharmacy prepare them, and it certainly does save on costs; but it certainly also could cause contamination of the contents of the bag. They later came out with transfer devices that could be used. We don't think any of them are a safe way to go. So, it's not something you want to see, but yet we just saw that a few weeks ago in a hospital and we reminded them that's not a safe thing to do. We're talking about the liter bags or 500 milliliter bags. By the way, you can’t get them anymore. But at any rate, that's not something you want to see.

And then, just a couple more issues such as using the single-dose vials in the pharmacy clean room for more than six hours after initial puncture. We still see that when we're visiting the pharmacy. And I want to say something about insulin pens. As you well know, we've had a lot of these situations; I might call them outbreaks. Fortunately, we haven't seen any actual infections with the virus traced to an index case, but that possibility is a certainly. This has involved thousands of patients, sometimes detected after several years of this happening where they reuse a pen on multiple patients. If you don't have extensive processes to make sure that this isn't happening, that you're educating everyone on a constant basis, that you’re monitoring for this, this is not something you want to use. I will tell you, you're not going to be able to avoid pens. We have a number of items. We've had U500, which has always been in a vial, and had problems with that. Now, we're going to have a pen of U500, fortunately, and we're going to have pens of U200 of insulin, new concentrations of insulin. So, these are all going to be requiring pens and there are other substances that are already in pens as well. So, it's something that, even if you don't use pens for insulin, you’re going to be using pens for other drugs and you’ll want to look at your policies and make sure that you have safety processes in place. I'll stop with that.

Dawn Glossa: Thank you, Mike. And now, we're going to hear from Dr. Mark Singleton from the American Society of Anesthesiologists. Dr. Singleton?

Mark Singleton: Thank you. Good morning or good afternoon. I said good morning or afternoon because I'm not sure – I think we’re kind of split here in terms of the audience. I actually I am in San Jose, California, where I've practiced anesthesiaology for nearly the past 30 years. I'm a pediatric anesthesiologist, so it's appropriate that one of our speakers represent a children's hospital. But I also, in my practice, have taken care of adults, as well as children, and a fair amount of my practice is taking place in the ambulatory setting. I also want to say that I think it's very appropriate that an anesthesiologist is included in this conversation, because of the unique environment in which anesthesia providers
practice their craft. We're probably the only – one of the few groups of physician providers – that draw up and administer medications as the central act of our practice.

The administration of an anesthetic typically involves multiple medications, even a simple anesthetic usually involves several different ones. And the bulk of those are packaged in medication vials. So our specialty takes potential contaminations, misuse of medication, and best practices very seriously. Fifteen years ago, the Institute of Medicine published its landmark paper, "To Err Is Human," and in that paper, it singled out anesthesiology for its contribution to patient safety and patient safety is a very central element of the principles that are promulgated by the American Society of Anesthesiologists. It is important that one of the elements of this Sentinel Event Alert that was published last June by The Joint Commission on the proper use of medication vials focuses on a culture of safety, and I think that's something that is a central element, and the speakers that have come before me this morning have all talked about how we need to change our practices and change our habits. I'm a professor of anesthesiology at Sanford University and have been for many years, and I'm gratified to say that I've seen a big change in how our residents and trainees and fellows appreciate their responsibility for maintaining safe practices. And in doing so, they contribute significantly to reducing the risk of infections. It's also appropriate for anesthesiology to be included in this conversation because many of the events that have been described where transmission of either bacterial or viral infections has been introduced from one patient and transmitted to multiple others involve the setting of the administration of an anesthetic, either in the hospital or, very commonly, in an outpatient setting. I think there is closer scrutiny in a hospital environment than there is an ambulatory environment, for many reasons. Oftentimes, an ambulatory setting is lacking (especially in freestanding settings) the capabilities of an onsite pharmacy. We prepare medications in the operating room. Our work station involves both clean administration of medications, where sterility is primary; and also within our close proximity, we're managing a patient's airway. We are dealing with all sorts of potential contamination. So, a big effort to change the culture has been to identify within that workplace clean places where medications can be drawn up and separated from areas where contaminated instruments have been used to manage the airway, to the other things that are important in the administration of an anesthetic is performed. So, again, changing the culture is extremely important.

I'm going to ask for that first slide to be advanced. So, these slides that I'm going to be presenting are nothing that hasn't been said before, but a few important principles that we want to promulgate. The use of single-dose vials for parenteral medications, whenever possible, instead of multi-dose vials. That seems to be the direction that manufacturing is taking, and we certainly promote that. The use of antiseptic alcohol wipes on the surface of vials has already been mentioned, and it's certainly extremely important.
The next slide highlights some things that we would caution against; not administering medication from single-dose vials or to multiple patients. We try to take that one step further in our practice; that is, we have patients coming into an anesthetizing location, one after the other. Our practice is to eliminate all medication vials that have been opened in the administration of an anesthetic or sedations to one patient so that they are all discarded, every element of medications that are opened between patients. If that's done, it should provide a very big barrier to contamination between patients.

I should also mention, since we talked a little bit about the administration of medications to children and the practice of pediatric anesthesia, when we provide anesthetics and sedation in the pediatric setting in places and for procedures that adults don't often get anesthetics and sedation. So, we're in environments outside of the operating room site, frequently administering medications for anesthesia, that include radiologic imaging screens, the cath lab and endoscopy suites, lots of places where adherence to sterility is very important. We would certainly never condone combining leftover contents for later use.

Next slide. Regarding multiple-dose vials, again, this has been emphasized – we always use sterile needles or syringes each time a vial is entered. So, sterility is key. Again, antiseptic wipes for the surface prior to penetration.

Next slide. We would certainly promote storing all of these containers under manufacturer's recommendation. Again, dispose of all syringes, needles, and medication vials at the end of the episode of care. Most of the medications that we use don't support bacterial overgrowth. So, one exception to that, and it is a huge exception, is Propofol. It's probably the most widely administered medication in the conduct of an anesthetic for sedation and it is one that is a tremendous medium for bacterial overgrowth. I've been to surgery recently, in the hospital where I work, and I've seen large vials of Propofol, which have been accessed by a plastic trocar, and that trocar is left in the vial. It's usually capped, but not always, and I think this is a big place where we need to change our practices. Propofol is a gigantic problem, and it really needs to be separated and paid extra special attention to. That brings up the last element on this slide – discard if sterility is compromised or questionable. As in the slide, all the drug shortages that we've had in the last several years and continue to have, practitioners have been naturally reluctant to discard medications that are in short supply. I think that we have to be extra cautious in working with our pharmacies in the hospital to develop conservation practices for medications that keeps sterility at pro forma, and do that on a hospital-wide basis.

The next slide says, "Use manufactured prepared syringe packages wherever possible rather than medication vials." I think it's been a very encouraging development on the part of manufacturers that they
are supplying single-dose medication in pre-filled syringes, often bar coded. I think this is a great advance for us in terms of reducing and eliminating the potential for infection. Not only do the bar codes help to identify these medications, but they are packaged in single-dose aliquots and already in syringes. We would like to see all the medications that we use packaged in ready-to-administer syringes. Also, selecting the smallest and most clinically appropriate size vial available when purchasing is an important role that the hospital or facility can aid in helping to prevent infections.

Next slide. We would urge manufacturers to produce vials in appropriate sizes to reduce waste. There are a lot of drugs that we use that come in very large containers, when all we need is a small amount to administer to a single patient. So, this is an area where manufacturing can really help us. And again, as we said many times, do not use multi-dose vials on multiple patients. The last thing I'd like to just touch on is the one-hour rule for medications drawn up in a non-ISO 5 environment. The operating room and anesthetizing locations are very unique environments within a facility. Where patients are anesthetized is just different from every place else or even the emergency room or other principle care parts of the hospital, which probably are the most similar. The American Society of Anesthesiologists has been engaged for the last year in formal discussions with the United States Pharmacopeia to recognize that environment and to develop some language that recognizes that environment in this one-hour rule; because I can tell you that there are, all across this nation every single day, violations of the one-hour rule that occur in operating rooms in every hospital. And to develop an evidence-based mechanism that works is going to require that conversation, so that's an ongoing process. I thank you very much for your attention and happy to participate in the question and answer. Thanks.

**Dawn Glossa:** Thank you, Dr. Singleton. We would now like to take questions. In addition to the speakers you just heard, we also have on the line Elizabeth Claverie-Williams, chief of the Infection Devices branch of the FDA, and her colleagues who are able to take questions as well. Due to the large number of participants on today's call, we ask that you limit yourself to one question.

**Operator:** Our first question will come from Kirk Glesher, Radford Health System.

**Kirk Glesher:** My question is concerning contrast media in radiology. Can contrast media from a single container in injector systems be used on multiple patients in the radiology department? Thank you.

**Mike Cohen:** I can partially answer that, at least. There are some situations where in the labeling it is mentioned. I think we ran something like this in the ISMP *Medication Safety Alert* a couple weeks ago; there is a new type of container that is meant for use in radiology and other areas where contrast media is
used with a power injector, and I'm trying to think of the exact term. It is specific to radiology – imaging
bulk package it's called, rather than a pharmacy bulk package. Pharmacy bulk package has labeling that
mentions that it should be used in the pharmacy specifically, and it has been used outside of the
pharmacy, so there is at least some labeling that FDA has allowed for some uses with certain devices,
but now we have the new container and I think we'll probably see more of that by different manufacturers.
The FDA can comment on that more.

**Dawn Glossa:** Next question?

**Operator:** Our next question will come from Tonya McKinney, New Mexico VA Health System.

**Tonya McKinney:** Would we be able to get a copy of these slides?

**Dawn Glossa:** Yes, you will. They're going to be up in the next week or so, and they will be on The Joint
Commission website.

**Tonya McKinney:** Thank you very much.

**Dawn Glossa:** You're welcome.

**Operator:** Thank you. Our next question will come from Pat Gaylor, Medical University of South Carolina.

**Pat Gaylor:** I have a question; I think it's for Mike, but we have these smart site devices that are left in
the diaphragm of multi-dose vials between uses. Are these acceptable? Are you familiar with these?

**Mike Cohen:** Yeah, I am. It's like a vial adaptor so you could use it to withdraw into multiple syringes from
that vial or -

**Pat Gaylor:** (overlapping) And it remains in the diaphragm.

**Mike Cohen:** Yeah, exactly. And these fit over the barrel of the vial.

**Pat Gaylor:** Yes.
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Mike Cohen: I'm just not familiar with that particular brand. Do they have a one-way valve? When you're not using it, it's only available for flow when you use the pressure of the syringe?

Pat Gaylor: Yes, yes.

Mike Cohen: Yeah. That's what it's meant for, so you could keep it in the vial. However, I just don't know enough to be able to give you an answer. It does seem to me that since that's what it was made for and that it's probably okay, but I'm sorry, I'm not familiar enough with it to know the total answer, but I know what you're talking about.

Pat Gaylor: Okay. All right. Thank you.

Joe Perz: This is Joe Perz from CDC. That's a question that we get as well, and really we need to defer to the FDA-approved labeling. And so, I would defer to our FDA colleague, if they wish to add a comment. But certainly there's no room for leaving a needle in the septum of a vial. Mike made the point earlier, I think the term he used was "that's the Grand Canyon," as far as microbes are concerned. So, that would be our chief concern, and then with method vial access devices or spikes, please make sure that the end users are following the instructions in labeling very carefully. Obviously, outside of a pharmacy hood, you would not want to see that in a single-dose vial, for example.

Mike Cohen: Yeah. These are used, too, to facilitate the use of needleless systems, so that's another reason to use them. And I know that they are pretty widely used that way.

Operator: Our next question will come from Ruiz Valdez, Comanche County Memorial Hospital.

Robert Durnell: Actually, this is Robert Durnell. My question regards CMS and Medicare and basically their guidelines that came out regarding oncology medication. They instructed us to try to schedule patients that are getting high cost drugs on the same day to decrease drug waste. Is there anyone from CMS or Medicare there with you now that can tell us what's the guideline now from Medicare?

Joe Perz: Robert, this is Joe from CDC. We don't have a CMS colleague on the line with us, so we can't answer that directly. I think we would infer that there may be issues in terms of drugs that are expensive in nature or in short supply, and I think the key there is to work closely with pharmacy. As far as scheduling, I can't really comment if that may or may not be practical. But in order to potentially stretch the contents of the single-dose vial, the only safe way to do that is following USP standards in the
appropriate pharmacy setting. So, I think it speaks to the need to integrate with pharmacy and I'm thinking back on Jerrod's presentation, and I think that was a fine example. He may have further thoughts.

**Jerrod Milton:** Thank you, Joe. I actually was going to weigh in on that and basically can only echo what you've said. Hopefully, you do have pharmacy support there and they can help you stretch those scarce resources and minimize the waste, because if it's done in an ISO environment under laminator flow, you have more than an hour and, in many cases, you can even stretch it beyond that if you have stability and product sterility data to support your practice.

**Robert Durnell:** Okay. Thank you.

**Elizabeth Claverie-Williams:** This is Liz Claverie-Williams. If I may make a general comment about a question that came up a few minutes ago, I'm from the FDA. One thing that we want to highly recommend is that the hospitals make certain that they follow the labeling, because the labeling will tell the user exactly how they should use the device. So, make sure that if it's labeled single-use, it's used as a single-use.

**Operator:** Our next question will come from Anne Stapleton, Harris Hospital.

**Chris Bolt:** Hi. This is Chris Bolt. I want to know the position on a single-dose vial that's technically used more than once. I know there are some people that use a 30 cc vial of Marcaine and draw it up into a large syringe in OB, and then use that syringe more than once. That syringe is kept up with the label and stuff like that, but I didn't know what the position on something like that would be from the people there.

**Mark Singleton:** This is Mark Singleton. Are you talking about OB, meaning an epidural analgesia?

**Chris Bolt:** Yes, for bolus. They're 10 to 12 cc's or something like that and there's a 30 cc vial, and the whole vial would be drawn up, is my understanding, is how they do it. And -

**Mark Singleton:** And it's for the same patient to use?

**Chris Bolt:** I'm assuming it's labeled and dated and all that stuff. It's stuff that I've heard that other people do.
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Mark Singleton: This is Mark Singleton. It is common for laboring mothers who are getting continuous infusion of epidural analgesia to need intermittent bolus injections to augment the ongoing analgesia during labor. The same sterility practice that we would adhere to in the operating room for any other drug needs to be in place. I personally use a sterile syringe, draw up an aliquot of bolus injection at the time that I administer that injection when the patient needs it. I think that it presents an unacceptable hazard to have medication, especially in the labor room, where you don't have the control that you have in an operating room. That's not a secure environment. You have family members; you sometimes have several generations of people in there celebrating the birth of a new family member. It's an environment that requires extra scrutiny, and I think that most anesthesia departments are trying to really take care to practice very sterile techniques. So, all of the principles that are applied to sterility apply to that setting, and perhaps even more so. I can also tell you that the epidural space is not a place where you want to have an infectious process take root, and the consequences of a bacterial epidural abscess are catastrophic.

Chris Bolt: Thank you.

Operator: Our next question comes from Joan Wood, Hospice Surgery Center.

Joan Wood: Hi. I have a question regarding the multiple-dose vials good for 28 days. What day do we label them? Do we label them the day that we open it, or the day they will expire in 28 days?

Jerrod Milton: This is Jerrod. I can address that. You should label it, if you know that it has a 28 day stability, with a "beyond-use" date. So, you're basically marking it with kind of a new expiration date. So, if it was today's date, you would add 28 days to that and that's how you would mark the vial.

Joan Wood: Okay. Thank you.

Pam: Hi. This is Pat from The Joint Commission. We also have several frequently asked questions on our website that address that very issue, if you'd like to take a look at those.

Operator: Our next question will come from Jennifer Trenton, Community Medical Center.

Jennifer Trenton: Hello. We have a question about multi-dose insulin vials. In doing a risk assessment to look at moving from using a floor stock vial that we use for multiple patients, it was identified that we're concerned with having so many vials out on the floor for multiple patients. In our current process, we
looked closely at it from an infection control standpoint, and it involves us keeping the vial in the medication room. A sterile syringe is used for each patient to drop the dose, and then the syringe leaves the room and is administered to the patient. We're never having a syringe come back into the med room. So, we just wanted folks' thoughts on the use of a multi-dose vial in this fashion, if a risk assessment has been done.

**Mike Cohen:** This is Mike. That sounds reasonable to me, if you're using vials in that way. There is at least one manufacturer that makes a much smaller vial than the 10 ml. I think it's a 3 ml vial; that might help a little bit.

**Jennifer Trenton:** We've looked at that. We really appreciated the article that has come out that has said that sometimes those vials have been misinterpreted as single-dose vials. Another one of our concerns is that that's a big shift in practice for our staff; not that we couldn't overcome it. We just wondered if that was deemed an acceptable practice if we had done the appropriate monitoring and documentation of our risk assessment.

**Mike Cohen:** Yeah. I mean, not bringing the vial into the patient room or in a patient area or anything, it seems to me – I'll let Joint Commission interpret it – but it sounds fine to me, if you're labeling it and everything.

**Pat:** Hi. This is Pat from The Joint Commission and I agree with Mike. The date issue is making sure that that multi-dose vial does not enter the immediate patient care area, which would be the patient room. So, as long as you're taking it separate and you're not bringing the syringe back, then you're fine.

**Jennifer Trenton:** Okay, great. Thank you so much.

**Operator:** Our next question will come from Judith Gast, Georgia Regents Medical Center.

**Judith Gast:** The question I have is on medications. We're actually using medications as a multi-dose vial for multiple administrations on different patients. Is there anything in the literature that says that is an infection control issue? And what is the common practice?

**Joe Perz:** This is Joe with CDC. If the vial is, in fact, labeled as a multi-dose vial, I think the ideal practice might be to only dedicate it to a single patient. Now, that's not always practical and I think the previous question addressed that issue, to some degree. So, if it really is labeled and approved by FDA as a multi-
dose vial, while we might prefer that that vial not be shared by multiple patients, you are allowed to do that. Joint Commission may want to add a comment, but I think the key, again, is handling that multi-dose vial in a way that you maintain the sterility of the contents. That includes restricting manipulations to a central medication area, if you are using it for multiple patients.

Judith Gast: Thank you.

Operator: Our next question will come from Gail Morrissey, Dana Farber Cancer Institute.

Gail Morrissey: Hi. We have all the same questions for our MRI, CAT scan, and nuclear imaging department regarding one particular device that was approved by the FDA, but we have concerns about how to Medrad™. It uses a multi-dose, a bulk-dose vial, of radioisotope that goes inside the Medrad machine. There is one line that is connected to that vial that is never changed in between patients and an end line, which is called the patient administration set, which is about 12 inches, maybe 18 inches. It’s changed between patients. We’re wondering if this is meeting the standards. Is it okay to just get the FDA, which approved it back in the 80s? Or what should we look at?

Dawn Glossa: Elizabeth, can you answer this question?

Elizabeth Claverie-Williams: Yes. Hi. This is Liz Claverie-Williams from FDA. We highly recommend that you follow the labeling and the instructions for use that have been approved for the manufacturer.

Gail Morrissey: Okay. So, you’re allowing the use of that same tubing in between patients?

Elizabeth Claverie-Williams: There’s different device manufacturers that may have requested different things from us. So, while I respect your general question, there’s no general answer, other than the fact that each of these particular devices you’re talking about, you would really have to look at the approved labeling, as well as the instructions for use.

Gail Morrissey: So, is the approved labeling ever changed by the FDA? Do they go back in and re-look at a product or device?

Elizabeth Claverie-Williams: So, what we do here at FDA – every label for every device that we approve, and it doesn't matter what the device is – every label is exclusive for that particular application
that has been submitted by that sponsor. You always have to check the labeling of every device that you use because different manufacturers may request a review of different items, different claims, and etc.

**Mike Cohen:** This is Mike. In our August 14 issue, we did comment on the new imaging bulk package for use with these tower injectors, like the Medrad you were just mentioning. And so, there is some information there specifically, and I'm not sure that it's on our website, but I'll make sure that it gets in our newsletter section on our website so you can read it. But we do talk about the pharmacy bulk package and the imaging bulk package and the approval and the labeling, as was just mentioned. So, that will be pretty helpful. I don't want to read it here.

**Elizabeth Claverie-Williams:** Yeah. Thank you.

**Mike Cohen:** And we put it in our newsletter for August 14.

**Gail Morrissey:** Okay. Thank you.

**Jerrod Milton:** And Mike, this is Jerrod. I just wanted to make two other points in that respect. From a risk standpoint, this may be an opportunity for you to also engage your infection prevention team to take a look at your practice after you look at the package labeling, and then similarly to what Mike said, which specifically is imaging bulk packages, you need to be very careful about the stand time of the solution once you attach to the auto injector. I think some of them have up to a 10 hour stand time, and you would want to be dating and putting the time that product will expire on the bulk container when you hang it.

**Gail Morrissey:** Okay. Thank you.

**Operator:** Our next question will come from Susan Catrair, USA Medical Center.

**Susan Catrair:** My question is to confirm the length of time from when syringes are pre-drawn, like samples, Lidocaine, if that comes from accessing it, filling the syringe, and administering -- one hour?

**Jerrod Milton:** This is Jerrod. It depends. If you're doing it in open room air, typically it's a one-hour expiration from the time that you've drawn it into the syringe. Once you attach it to the patient, the USP standards allow you to complete the infusion, even if it goes beyond an hour. But the best practice, from my standpoint, is use it within an hour if it's done in open room air, if it's actually drawn up in open room air.
Susan Catrair: Okay. Thank you.

Joe Perzel: This is Joe Perzel at CDC. I wanted to add a comment, because something that we also hear about is the idea of batching syringes off of the Lidocaine multi-dose vial, and then also Mike raised during his portion of the presentation, in the context of batching off a container of flush solution. And I would say that in both those cases, if we are drawing batches of syringes that we need to be extremely careful that we may actually be crossing a line over into pharmacy practice. There are a lot of issues pertaining to the way that those are drawn, labeled, handled, stored, etc., so a word of caution there. And in particular, with the saline flush, the flush bags are, generally speaking, preservative-free and, again, they are not labeled as multi-dose vials, so they're not an appropriate source of drawing flush for multiple patients with the possible exception of it being done appropriately under pharmacy conditions. Just wanted to add that.

Mark Singleton: This is Mark Singleton. I want to also chime in on this issue. From the point of view, as an anesthesiologist and someone else who works in critical care settings, and getting back to the culture of safety that we need to constantly be evolving, it's been the practice to have medications drawn up and at the ready for any kind of situation that could develop. And that has led to the practice over the years of people drawing up medication, labeling them appropriately, and putting them in a drawer and sort of forgetting about them until it's time for them to be used. And this is what I was referring to about this continual violation of the USP “one-hour rule.” I think that as we better train ourselves and our residents, that medications can be drawn up at the time that they're needed, in the amount that they're needed, as we convince manufacturers to produce medications in pre-filled syringes so that the process of us drawing the medication up at the point of care and having it be ready for whatever eventuality might take place, that is the culture that we need to work on changing. Manufacturing can help us. The industry can help us. And we can help change our own behaviors, but it's an ongoing process.

Susan Catrair: Let me add another question to this. If pharmacy fills the syringes, how long is the timeline that it has to be used?

Mark Singleton: It depends on the environment in which it's drawn up.

Jerrod Milton: Assuming that it's done in an ISO-classified environment and inside of a clean room, the pharmacy would be able to tell you what the stability is and they should be labeling it as such; what the beyond-use date is. It's definitely longer than one hour, probably in the case of Lidocaine. So, that's
where, again, there's an opportunity for you to partner with pharmacy and I'm sure they can help you out, if you have a clean room, or a pharmacy that's capable to do that nearby.

**Susan Catrai:** Very good. That helps a lot. We presently have a 50 ml. Lidocaine vial that is when it's used once, then some of our anesthesiologists haven't been discarding it. So, we're looking for a way to prevent them from using it on multiple patients and the pre-drawn sounded like a good opportunity, and a better opportunity if we had pharmacy draw those out in ISO. Is that correct?

**Jerrod Milton:** Yes. I think you have a tremendous opportunity there. And they probably would be happy to help you.

**Susan Catrai:** Thank you.

**Dawn Glossa:** We have time for one more question.

**Operator:** Our last question will come from Ron Lowerly, Novant Health.

**Ron Lowerly:** Would someone like to comment on the practice of pre-spiking IV bags with administration set in the OR arena? Some people recommend adhering to a one-hour limit there in light of USP immediate use provisions. However, the APIC position paper refers to that as controversial.

**Mike Cohen:** Yeah. It's not just in the OR. It's done commonly with chemotherapy, where a pharmacy will prepare the bag and spike it, and then dispense it that way and inside it is a blocked bag, for example. And that may be used within an hour. But it is made under the hood; that's the other issue, too.

**Joe Perz:** I was going to add that this is, again, a reminder about looking at labeling. I know of examples of IV solution bags that have statements on them saying clearly, "Do not remove overwrap until ready for use," "sterility not guaranteed after the packaging's removed," and so consider that as well.

**Jerrod Milton:** I was going to say that I think best practice would be to spike the bag and hang it on the patient as soon as you possibly can. I know that, in some cases, it's not always practical to do that, but the rule, from a USP standpoint, I believe is if the bag is spiked, it needs to be hung and running on the patient within an hour.

**Ron Lowerly:** Thank you.
Dawn Glossa: All right. Thank you to 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 replay today's webinar along with the slide presentation will be posted on the Joint Commission's website within the next week. You can find it on the web page where the Sentinel Event Alert on vials is posted. Thank you again and have a great day.

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