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NYSPFP SSI Initiative: The Advanced Colon Bundle In-Person Conference

Good morning everyone. We are going to begin our program. It looks folks are still trickling in. I'm pleased to welcome all of you to the New York State Partnership for Patients Advanced Colon Bundle Surgical Site Infection Reduction In-Person Program, as well as welcome everyone that are at our remote sites. We have several remote sites that are receiving the program live or via web stream. If you're at one of those sites, we ask you to ask any questions through e-mail to Nancy Landor, N-L-A-N-D-O-R, @HANYS, H-A-N-Y-S.org. And we will be taking questions and comments throughout the morning.

So why are we here? Many of you may have joined us when Dr. Cima gave a webinar on April 2nd to talk about our advanced colon bundle. Our current surgical site infection rate in colon surgery is going the wrong direction. We are now at 27% increase as of data through November of 2013 in New York State. It is not unlike what's happening across the nation. But we have been asked by CMS and we see the need to focus on decreasing colorectal surgery, and we've brought some renowned specialists here for you today to present a bundled approach.

This slide shows hospital engagement networks, like the Partnership for Patients here in New York. These are the Partnership for Patients networks across the country, HENs, which are hospital engagement networks. And you see the red line in the center, that zero, if you look where they cross and then up to 60%. So the Partnership for Patients initiative across the country goal was to reduce all infection rates by 40%. New York does not appear on this slide any longer because we have failed to decrease it enough to be off the chart. So we would be all the way over to the left side of the chart, but we fell off it because other areas of the country are improving at a faster rate than we are.

We do have some very successful high-performing hospitals within the state. The top 75% of hospitals are performing with an 18.7% improvement. So we do have some hospital successes. We actually have some speakers from those hospitals here with us today. Dr. Michael Timoney will be here; he's flying in this morning and hopefully can get here from the airport to here from Lutheran Medical Center. And we have Mark Lema here also, from Roswell Cancer Institute in Rochester. And they're going to talk a little bit about ways that have been successful in their facilities. We have other high-performing hospitals as well. And we just need to all kind of all get into that direction.

Why a bundled approach? Dr. Cima is going to talk to you this morning also about why a bundled approach, but, really, it's because no one specific intervention is going to be reverse, no one or two specific intervention is going to prevent a colon surgical site infection. It really takes a group of interventions, multidisciplinary attention.

The New York State Partnership for Patients Advanced Colon Bundle consists of these items you see on your screen: normothermia, glucose control, antimicrobial prophylaxis, increased perioperative oxygenation, skin prep, clean standardized fascia close, and wound management. And I'm just going to tell you what's in your packet. On the left-hand side we have some resource documents for you. The first

one is a flowchart. That flowchart is very basic, but it does delineate for you the different phases of the operative experience, beginning with pre-admission testing and pre-admission area, pre-op, intra-op, and post-op.

And so we asked all of you to take a look at what's going on in your facility today. And I'm sure these current bundle elements are not the first time that you've seen them. I'm sure you've seen them in the past. However, you may not be monitoring and assuring ideal practice in all of the operative arena areas, so we broke this down for you. Those in bright blue are the bundle elements.

You also have the bundle elements on the advanced colon surgery bundle element sheet. That has the elements to the left and some standardized practices and interventions on the right. And then you have a resource guide, which has not been published before and not introduced on the previous WebExs. This resource guide, we hope you'll be able to hand to your surgeons who are not here. It references these studies and gives you the level of evidence supporting each of the bundle elements recommended as well as the research and studies for why a bundled approach has been successful. So that's a fairly long document, four to five pages long, but it does have all the citations for you on the evidence.

We also distributed, on April 2nd, a gap analysis for your facility. We did ask that folks attending today bring the gap analysis with you as well as be prepared to discuss and/or ask questions about the gaps you may have found in your facility. So if you did not bring it with you the gap analysis is there for you also. We ask you to take it back and/or think about what you know goes on in your operative arena today. And so that is there for you.

And it is with great pleasure that I introduce today Dr. Robert Cima, Professor of Surgery from the Mayo Clinic. Dr. Cima is a professor of surgery and consultant in colorectal surgery at the Mayo Clinic in Rochester, Minnesota. He's a California native who did his undergraduate work and medical school in California, obtaining his medical degree from Stanford University. He completed his general surgery training and a research fellowship at Harvard Medical School, and Brigham and Women's Hospital.

After his residency he completed a fellowship in colorectal surgery at the Mayo Clinic. He did go back to Brigham and Women's for a couple years before going back to Rochester, Minnesota, at the Mayo Clinic. He's very active in the surgery quality and safety programs within the Mayo Foundation. He's served for the last six years as vice chairman of surgery for quality and safety at the Mayo Clinic. And, without further ado, welcome, Dr. Cima.

Well I want to thank Maria and her team for the ability to come and talk to you and go over sort of the value of this type of initiative. I represented our foundation on the Joint Commission American College of Surgeons collaborative on colorectal surgery site infection reduction. And, really, that was a great experience because we brought seven major institutions from all parts of the country together and shared our data in a very open way with everyone. We went and ended up visiting all the sites, pretty much all the sites. And you really understand that there's a lot you can do in a collaborative forum like this. You bring different perspectives back to your own institutions and it really increases the ability to make change because you have the ability to talk about what others are doing, but do it from a firsthand point of view rather than just from a paper or something, an abstract that you see at a meeting.

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So what I want to do is sort of go over not only the literature but as an advocate for this type of initiative, and also then to show that there is something to be said for a collaborative at a very high level, but then really just like politics, all change is local. So what you have to is take that information, that engagement, and translate it into your local site. I'm going to go over what we did and basically some of the lessons learned from doing that.

Mayo is 150 years old this year. We're celebrating our 150th anniversary, and so it's really been a long tradition of collaboration. We were basically the first group practice in the country. We were shunned for that for a long period of time, but, still, that culture is there. And I think that, more than literature, is what really influences a success on these type of collaboratives. But it's certainly something that can be done together and has to be done together. It can't be done in isolation.

Sort of for the agenda for my talk today I want to talk about sort of colorectal surgical site infection. There's going to be a few slides that I repeated from the webinar just to make sure everyone can come up to speed at the same level. So, for those who were on the webinar, excuse me for the repetition. But, really, what's the scope of it? What's the impact? What do we know, and what we don't know?

Even though we've been doing surgery in the U.S. now for – modern surgery with anesthesia and asepsis since the turn of the century, around the 1900's, late 1800s, the 1900s, there's still not a lot we know about the physiology of surgical site infections. There is not a very good way to saying you're going to get a surgical infection. We have some general rules about who we think are higher risk, but when you look at all the literature, and we're doing a pretty extensive review right now at home, it's all over the map and everyone's experience is different. So in some institutions diabetes is a very strong risk factor. In other institutions it's not that strong. So why is that? Diabetes is diabetes. Well, I have my own personal biases about it, but I'm not going to go into that. But the realization is that we don't know everything, and so, because we don't know everything, designing systems to prevent it is difficult.

I want to talk about implementation and clinical medicine. A lot of people say, "Oh, well, you can bring consultants in that work from Motorola or IBM or Cardinal Health," and they come walking in and they've got their toolbox or toolkit and they sort of leave it at door. And then go by the ATM on the way out. And then three months later you're back at where you are. And I want to talk a little bit about that, as well as sort of what we did in partnership with the Joint Commission and the American College of Surgeons two years ago.

You know, how we define quality and health care is still up for debate. It's a lot of discussion about it. I just put this up so that we could all center ourselves on what we're really here for. This was a definition put forward by the Institute of Medicine, and I think as it tries to encompass what quality is all about, it's probably the best sort of general statement about what health care quality is. But how you really get down to operationalizing that is really in the aims of quality health care about it being safe, preventing avoidable injuries, reducing medical errors, effective, which means in the total sense of it being effective in that it gives you the optimal amount for what you're doing. You can be super effective, but does it really add value to the patient. And that's really what these all come down to is value. Is it really worth it? You can

spend gazillions of dollars on something, but does it really marginally make it better for the patient and society at large.

And then the other elements are patient-centered of course, efficient for the delivery to the patient, as well as the health care system in which it occurs. Timely, you want to make sure you can do it in a reasonable timeframe for the patient; as well as equitable. There's a lot of information on disparities, and we have to take that into account as a society, as well as that individual institutions.

Now, when you think about surgery, and this was the sort of mantra of surgeons for I would say the last 100 years, if not longer, was that the patient came to you to the hospital to the surgeon with a certain defined set of risks, the disease, their health, their diabetes, whatever you want to call it. But we always almost sort of blamed the patient for the bad outcomes because of what happened. And then there was a surgery, and it was sort of the impression was surgical skill was implied, that everyone was getting the same level. If you were a trained surgeon, this is what you had and this was the outcome. And this is sort of up until very recently the concept that has held. And what that means is if you're going to try and improve it, there's only two things you can do. You can either focus on the patient, try to optimize all the patient risk factors, or do something about the surgeon. And that's hard to do. Being a surgeon and working with surgeons, you know that they don't change and they all think they're doing the right thing. And, by and large, I imagine most surgeons are. But this is a very hard model to effect change in because there's only two levers and you really don't understand what the levers are.

The reality is though, and more and more information is coming out to support this, is that everything that we do in the hospital has an impact on outcomes and it's a system of care. And so basically I've sort of broken this down. This is some work done by Vincent and Darzi and Group, but I've sort of altered it with other literature to bring in. But there's the operation profile and then there's the hospital profile, in that the patient does come with certain risks, certain issues that interact in a very complex way with all of these different steps, and then you have the outcome. And the problem is when it's such a complex series of things is it's hard to identify one or two interventions that are going to make a difference.

But if you have this mindset that there are things beyond just the surgical field -- and don't get me wrong, what happens in the OR is a major contributor to outcomes. I mean, if you didn't make an incision you're not going to get an infection. But the fact is that is the patient completely optimized from a medical point of view? Do you have anesthesia practices that are helping the surgeon do the right thing in the sense of appropriate fluid management, keeping the patient warm? All of these things play into that. Do you have good resources for nurses on the floor, nursing colleagues? It's not only just what happens in the OR. It's how what happens in the OR interacts with the rest of the system.

And what's also more important or increasingly more important is just sort of what goes on in the OR. We know that there are things that happen in the OR that impact it that are not tangible in the sense of something you can document in the electronic record. But efficiencies and things like that, where people are communicating, where they're able to communicate effectively, where they're able to get the equipment in the room faster, because one of the big things that impacts surgical site infections, if you look across the literature, is operative duration. And anything that increases efficiency, that reduces surgical time in the OR, actually does play a role. So it's one of those things where something else that

you may not even think has to do with it, but it's that culture of efficiency and collaboration in the OR that also will impact outcomes.

So that's sort of the basis or sort of the framework of what goes on in modern health care, and one of the things we need to look at. And it's already sort of setting the stage for the idea that it's more than just going to be antibiotic timing or normothermia. So I'm going to move over to what the real topic is, surgical site infections. And this is just some general data. I'm sure everyone is aware of this, to some extent, that surgical site infections are a huge impact on health-care resources right now. SSIs in hospitalized patients account for a sizable minority but growing of hospital-acquired infections. And of course within surgical patients they are the highest contributor to hospital-acquired infections. With almost 40% of surgical patients, the reason why they get defined as having a hospital-acquired infection is because it's directly related to their surgical procedure.

This impact is significant, and I really think this is an underestimate of the data where this came from, from the CDC. The reason why is because it all depends on the definitions and how you look for things. CDC uses the Nissen system, which is a voluntary system. It's really heavily weighted toward hospital defined infections, as opposed to those that develop outside of the hospital because of the reporting mechanisms. I mean, there may be a lot more superficial infections than we actually know about because they come back to the physician's office or the clinic, or they go to some emergency room outside of their primary site and they open the wound, they start them on antibiotics, they end up setting up the visiting nurse, and none of that gets reported back. And so I really think these are underestimates.

Mortality, again, is a hard endpoint, again, heavily weighted toward in-hospital events. But 90,000 directly related to this is a bigger issue. And if you're underestimating the total impact of the actual numbers, then the dollars are really going to be underestimated. And so this is a direct cost estimate from CMS, again, I think probably a big underestimate.

As a colorectal surgeon, where my practice is exclusively colorectal cases, we always get tagged at the hospital as being the bad guys. And if you look at the literature, colorectal surgery does have a bad rap. It's consistently one of the highest SSI rates across all surgical practices. And what's dramatic is the range. When you look at the orthopedic literature for primary hip or knees the range is, like, from zero, which I rarely believe when I see it, so let's say close to zero, and, like, 2%. When you look at hysterectomy it's 3% to 7%, something like that. And you look at colorectal and it ranges from 3% at the lowest that I've seen, although I have seen a couple reports of a large series where they had zero, which, again, I take with a grain of salt, but as high as 48%.

So there was a large trial reported in the New England Journal of Medicine which basically had a trial trying to reduce SSI. It was a randomized trial. It was made it into the New England Journal. And the group that they were trying to reduce SSIs had an SSI rate of 48%. So that's very discouraging, where one and two patients had some type of infection. It also depends on how dedicated you are to finding the infection, but this was the range. I didn't include that because that was sort of an outlier. Most trials, most data, somewhere between 3% and 30%. The 30% is a high number and it's not that uncommon. I would say if you really asked me, pushed me, "What is the average SSI rate in the literature right now from

comprehensive review," I would say it's probably somewhere between 18% and 20% if you just look at the literature.

Again, what are the problems? People have said they've looked at the patient, and there's a lot of things that go into that. Now, nutrition, diabetes, obesity, whether or not they have a disease process or on medications that are immunosuppressant, age. Age is interesting in the sense that there's a lot of studies that say young age is a risk factor and then there's a lot of studies that say old age is risk factor. Our personal data at the clinic, we're just finishing looking at about 4,000 patients, and young age is a risk factor. And I can explain that because of our practice, but I'll talk about that a little bit later.

There's disease-specific risk factors. So you have a disease that comes in and you're infected already, like diverticulitis, or sometimes with inflammatory bowel disease, like Crohn's Disease where you may have systemic infection, or C. diff at the time you're operating on the patient, where they come in with a flare and they have C. diff. So you're already sort of behind the eight-ball as far as some type of infection. And then there's procedure specific. Is it an emergency case? Is it an elective case? Is it being done open versus minimally invasively?

The duration of the case is important, and the surgeon, surgeon experience. There's a lot of data. You know, we're talking about low volume/high volume surgeons as far as cost and complications. That also translates into colectomy. There's a new paper coming out in the "American Journal of Healthcare Quality" that actually looked, rather than mortality, which is sort of a bad endpoint for colectomy since only 1% or 2% of patients, less than 1% should die from elective colectomy, that it actually impacts outcome depending on volume of the surgeon as well as the volume of the institution. And they're not independent.

So what this tells us is there's no magic bullet. There is not going to be a single intervention. There was the SCIP data elements initially that came out that said, "Okay, this was going to be the end-all, the be-all," then it turned out for colectomy it wasn't or isn't as significant as they had hoped for. It is important and I'll go over that, but it's not necessarily going to be the magic bullet for us.

Implications, we all know what the implications are and why we're here. It's a huge sink in resources. Length of stay, the resources that go with that, increased cost, not to put anything aside from patient morbidity, you know, loss of ability to return work quickly if you're having to pack a drain, if you have to have a visiting nurse, if you have to have drains that are in that you have to go back for CT scans and sonograms. All of these are negative impacts on patient outcomes which, again, is what we're looking at from a quality point of view.

The other thing is readmissions, so there's a lot of rework, there's a lot of resources put back into that, coming through the emergency room a lot of times. And so all of these things are what we talk about are waste in the system. It's bad outcomes for the patient, returning to waste for the system, because whenever you have to do rework, whenever you have to correct an error, those are wasted resources and dollars that could be better spent elsewhere. The patient of course, we're patient-centered, and it's not a good outcome. It increases pain, increases complication. Certainly, it's one of the major risk factors for mortality. And there's some data in surgical oncology literature that says that it may impact long-term oncologic benefits.

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If I have a patient that has rectal cancer who needed neoadjuvant therapy who's supposed to get chemo starting 30 days after their surgery, and all of a sudden they've got a bunch of drains in, the oncologists aren't going to give them their chemo. And the data clearly shows that once you get out two months, three months from the primary surgery, there is no benefit to adding chemotherapy. And we know that if you don't get your complete chemotherapy course your oncologic outcomes are worse. So it not only has short-term outcomes, but for some of our patients, especially colorectal cancer patients, it has long-term oncologic outcomes. So an infection that they survive may actually reduce their lifespan related to their inability to complete their chemotherapy. And so people don't look at it necessarily with the long-term lens that they should. But this is a big problem for our cancer patients that have colorectal cancer.

So, given all of this that pays into SSI, the thought is that if you have multiple factors, you have a single intervention that you're going to try and design, it's not going to really have an impact on SSI. And that's one of the problems we face when we review the literature and when you go back to your institutions and talk to the surgeons. You're going to pull up on element and they're going to pull up about eight papers that say it doesn't matter, because I've been in these conversations. And the problem is you don't know what else they were doing in all those other papers. They were looking at one simple factor. They didn't control for anything else. And it may not matter, because there's going to be 20 things you need to really do to move the dial. And, unfortunately, that's not how the literature works right now.

So what do we know about lowering SSIs? There's a lot of things that play into that? So what I wanted to do is take a small brief period of time just to go over some of the elements in the data that support them. And the reason why I wanted to do that was because you're going to get these questions and you're going to get the pushback and you're going to get sort of why are we doing this and why does it matter. And so I think it's important, because I've reviewed this and I go over it with my partners, why some of the things we did. And some of the things are not included in this talk necessarily that go over everything that's in the bundle, but that's for different reasons and we can discuss that.

So the main areas I'm going to look at are these six areas: appropriate use of antibiotics, the skin preparation, normothermia, hyperoxygenation, mechanical bowel preps, plus or minus oral antibiotics, and optimizing glucose control.

I'm sort of a part-time historian. You can't be at the Mayo Clinic and not like history. So whenever I do a talk I like to set the frame from where we started and where we're going. And so it's been not quite 100 years since penicillin was discovered. We're coming up on that pretty soon. And I don't know if anyone saw the news, I think it was this past week, the WHO reported that we're going to be entering into the post-antibiotic era because of antibiotic resistance. And it all started because of this gentleman, Dr. Fleming. Because now bugs are being resistant, there's not a lot of antibiotics in the pipeline, and now they're worried that we're going to end up going back to what surgery was beforehand, before this time where routine infections killed patients. And that's why it makes this initiative even more important. If we can reduce infections by any means other than antibiotics, that's a plus.

So penicillin was discovered in 1926 after he came back from holiday. He basically had sort of stopped his experiments, went away for holiday for three weeks on the coast of England, went back to his lab and

was cleaning things up, and noticed in the Petri dishes that there was one sample that had a zone of death basically around it. The bacteria had been cleared out and he was wondering why. And that one question in his mind about why this happened in one Petri dish led to the discovery of penicillin, which is a byproduct of a mold that was bactericidal to most of the bacteria that he tried it against.

But the problem was it was very laborious to make. It was very difficult to make penicillin and it really wasn't until the 1940's where the process for fermentation that allowed them to do it came about. And it was dramatic what happened. Of course, 1940's was during World War II. It wasn't really pushed until 1943, where they actually were able to sustain the product in a way that could be transported to the battlefield. But it was dramatic, the impact it had. Patients who were dying were given penicillin, and within hours they could notice a benefit. Patients who had had gut shots, which was almost always fatal, were surviving. And it was hailed as the end to surgical infections. He received the Nobel Prize for this. And basically we entered into the antibiotic era right after World War II. The problem was, not so fast.

It did significantly reduce death rates from septic complications, so that's where death rates went down after surgery. But it didn't reduce the incidence necessarily of surgical site infections. That didn't really change that much, but the ability to recover from them was better because of antibiotics. But what happened almost immediately, within five years of introduction of penicillin widely being used in community hospitals, they started to identify resistant organisms. And now I'm sure you all know you go through your hospital and, you know, penicillin is basically given to kids, maybe not even kids anymore, because there are organisms that it just doesn't even work.

And what happened was SSI rates became pretty stable from 1970 to 2000, and it didn't matter what antibiotics you were using, the rates were the same. And the reason why is because we had no idea how to use them, which was surprising when you look back at it. But there really was not real good data on how antibiotics were used. So people were using them sort of before the patient even walked into the hospital they were giving them antibiotics. They were using them for two days after surgery, for seven days, fourteen days. Sometimes they didn't give them around surgery and they gave them only if you had an infection. So it was sort of indiscriminate use of antibiotics, which was the real problem.

And basically this is a paper, and you would think about it, well, modern era, 1992, "New England Journal of Medicine" came out with this paper, which was probably the first time it actually defined how antibiotics should be given around the time of surgery. This is what we call the Burke's Curve by Dr. Burke, who actually did this first study in 1961. And to show you how long things take from when he first identified it in 1961 to the time it made it into the New England Journal of Medicine in 1992. That's a long time for people not to know what to do. And basically what he found was that if you gave the antibiotics at a specific time around surgery -- here's the time of incision -- that the rate of infection had this pathway. If you gave them way too early, it didn't really matter. If you gave them right after the incision, it didn't really matter. And if you gave them hours later it had no impact.

So this Burke Curve is something that he introduced and it didn't even take effect, even though it made it into the literature in 1992, it was not standardized in most hospitals until the end of the 1990's, and that's where the idea behind the SCIP protocol really sort of came about. But you have to realize it wasn't that long ago. I mean, I hate to say it, 1992, I was just starting my residency when this came out.

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This has been updated multiple times now. And probably the best study came out of Switzerland, where they looked at sort of a cohort, a large population-based cohort. And basically you see the same sort of curve. What's interesting though is this downward curve, and that has to do with basically when you start closing there may be a benefit also at the serum level of closing, and that really impacts operative duration, and I'll talk a little bit about that. But what they found was optimal duration, and this is sort of a big model, was somewhere between 30 and 74 minutes. So they were playing with a little bit more range. They didn't do the 60 as the cutoff. But it's certainly 60 is right in the middle of what they were talking about.

The other thing that we don't talk a lot about but is clearly a benefit, and it's one of the things that we used to just give – I remember when I started, when we first -- when I training in Boston, so when the "New England Journal" came out you're like, "Oh, you have to read that. We had to do that." The big issue was, all right, so everyone gets a gram of Ancef. Well that was great. When Burke actually did the study Americans were a little bit thinner. And now a gram of Ancef was designed for the 70-kilo man, quote, unquote. There are very few 70-kilo men you operate on anymore. That's sort of the average weight from 1942 when the average weight of an American male was 147 pounds. We know that because that was from World War II, the U.S. Army was getting all these young people and they were all small. We're not that size anymore.

There's a lot of literature that supports the idea of weight-based dosing. And we had done that at our institution a number of years ago because we were seeing this. This was actually from a study that looked specifically at obese patients and the impact of a weight-based. So for anyone over 70 kilos, between 70 and 120, if you're going to give Ancef, you give two grams or you should give two grams instead of just the one gram. If you're over 120 they should get three grams. So you have to build that into the system. It's not just give it at the right time but it's the right dose, because what's important from the Burke study was that it was the serum concentration at the time that was important, of incision and closure.

So Armor Force did a study of obese patients, and basically what happened when they went up just in their weight-based dosing from one gram to two grams. And even though many of these patients should have gotten three grams, they didn't really think at that time to give three grams. But many of these patients were over 120 kilos. They saw a significant reduction. And I think if they had actually the modern analysis from our pharmacology colleagues they probably would have given a lot of these patients' three grams. And I can only speculate as to whether or not this five would have gone down a little bit lower. But, clearly, the appropriate use of antibiotics, and I want to stress the emphasis on "appropriate," not just the timing but the real dosing, is probably just as important if not more important. And a lot of hospitals don't have that built into their system.

There's a reason why there's a list of antibiotics that should be given for colorectal surgery, why the government has put out that list. Because, like I said, there was a lot of people just indiscriminately using antibiotics in the hospitals, how they were dosing and stuff. But they were also, whatever they were giving, there was no sort of standard approach.

And you have to understand what is the role of prophylaxis? The role of prophylaxis is not to treat a specific disease, which is what a lot of people go after in colorectal. If I remember, we'd get Ceftriaxone, we'd give all these third-generation things because we were worried about the bugs that grew out from infections. But that's not prophylaxis. Prophylaxis is treatment of what you come in with off the street. So it should be skin flora and routine bowel flora. You shouldn't be selecting for Pseudomonas, which is what we were trying to avoid when I was a resident. We would give these guys these huge gun antibiotics. And also probably because it was – those were the ones that were bringing us pizza on Friday night.

So, I mean, there was this influence that I might say has driven antibiotic utilization in the 1990s and early 200's. The drug companies were not too far off in how they would market these, but now I think people are a lot more savvy than we were then. But, really, this is an interesting study that looked at what was used and what was the rate of infection. And as you use the more general antibiotics, the ones that are Cefazolin, Metronidazole, you had lower rates than when you start using the more big-gun antibiotics. And the reason is because those big-gun antibiotics are so tailored towards the ugly bugs that it really doesn't impact necessarily with the same effectiveness the sort of general bugs. And so you're targeting the end result and not the upfront problem. And so there's clearly data in the literature now that says that what antibiotics you use as prophylaxis are important.

So now we've tried -- the government has tried to narrow that spectrum, and I think that's important for hospitals to understand, that there's a reason why they narrowed it. It not only has to do with cost, which is the benefit from using a lower-gun antibiotic, but also there's good data to support the fact that appropriate antibiotic selection, dosing, and administration, all three things, not just one, are important for effective SSI reduction because these are the ones that show up. So that's sort of the story about antibiotics. It's multiple steps, and I'm going to come back to this, multiple steps in doing things right that are important.

Skin preps, again, interesting, carbolic acid, which was Lister's big thing, where he introduced asepsis in England, and carbolic acid was what they were using. They would actually spray it into the room during the operation, as well as on the patient. Carbolic acid is pretty nasty stuff, and it's very effective at cleaning off the skin. So skin prep was recognized at that time, even in the 1800's, as being important.

Now there was this concept that was very common up until probably about 20 years ago where patients would clean themselves beforehand. Now, this is what we hygiene. It's not sterile, it's called hygiene. People start to laugh, "Well, yeah, that's important." Well, it is important. And the fact is is that how people define hygiene is different. And whether or not it makes the same sense to have someone just take a shower with Dial soap versus give them some type of soap, it's probably just the showering and getting everyone clean and getting that whole sense is important.

So we're moving back towards actually saying to patients we want to do this. And the reason why we want to do this, and we give them something, is because we want to start to engage the patient early. It's actually getting them to participate in their own care, as opposed to just say "Take a shower," and I'll go over what we've done. But a lot of places are going to this because, as I'll talk about later, it's low-hanging fruit that may have an impact. Low cost, relatively easy to implement, and something people understand,

and that already, once you start doing things like that, it makes change easier. Change management is difficult, and that makes it easy.

Now antiseptic versus antiseptic plus alcohol, now this is actual skin prep. This is not hygiene. This is skin preparation, which is how you distinguish things in the OR. And I just want to talk a little bit about that because there's been a lot of debate I'll say and some bad signs about what to do, or bad press about this, and I want to clear that up.

So Chlorhexidine showers, this is basically giving patients Chlorhexidine or any type of antiseptic solution, whatever you want. The only reason I use Chlorhexidine is because it's the most common. There are some iodine-based products that are also given to patients, the Betadines. Patients don't like those. They also have more incidence of reactions to them. So Chlorhexidine is sort of the generic one. And, as you can tell, there are lots of studies that have looked at this. And just like I said earlier about SSI rates, all the study's results are mixed. Some show great benefit. Some don't show any benefit.

By and large, if you look at it it's a discrete population where this is beneficial, where it's statistically beneficial. But that doesn't mean it's not beneficial for everyone. But, I mean, it really has driven closely. If you use this in conjunction with MRSA decontamination, especially for vascular surgery, cardiac surgery, thoracic surgery, these patients do better. The data would suggest that, that if you combine it, because they're at very high risk for these devastating superficial infections, and that's clearly in the literature; that combined, again, two elements, nasal decontamination and Chlorhexidine showers benefit these patients.

There is some literature in the orthopedic papers that support using a little bit higher concentration, these claws that have sort of impregnated stuff. Again, revision hips are the ones that benefit the most. Other ones do also, and so select case types. So if you look at the big meta-analysis and sort of come down here, there's a marginal benefit overall. And that's sort of where we are right now with this, because it's so hard to design an adequate trial that's going to look at it. The real question is, as we'll get back to later, is what's the downside versus the upside.

Operative skin prep, I'm not going to go into much detail about this. There's basically four types of preps available now on the market, two sets that alcohol in them, two sets that don't. And basically the favored comes down on those that have some type of alcohol base in them. And that sort of goes back to tradition where alcohol rub was the standard prep until about the 1960s, 1970s. Alcohol-based preps were standard. The only reason they got them out of the OR was because of fires. But they are, by and far, the use of alcohol was by far the best at reducing superficial surgical site infections. But the risk was devastating. So the downside risk was so high that they had to get rid of pure alcohol preps. And now most data would suggest either an iodine-based with alcohol or Chlorhexidine-based with alcohol is going to be the best benefit. The reason why is alcohol sterilizes the skin, but it doesn't prevent organisms from growing back because organisms are tough. The use of Chlorhexidine and iodine have variable bactericidal effects for up to 24 to 48 hours after surgery.

But the important thing about this, and I'll talk about this a little bit later, is you have to put these on correctly. So it's not just a matter of having the resident come in and slap on one of the sticks on there and we're done. If it's not done right, they don't work right, and there's some data to clearly show that.

But, overall, the data shows that an alcohol-based prep is better. What's interesting is neither company has sponsored a trial where they go head-to-head on the two alcohols. I don't think they ever will. But right now iodine, alcohol-based, and Chlorhexidine alcohol-based are probably your best ones, as opposed to pure iodine-based or pure Chlorhexidine-based. They're more expensive, of course, but you have to look as we go to -- you can't just look at the OR's cost center anymore because as we go to this era of episode of care payment possibly responsible for populations, those cost center numbers are going to get bigger across. So if a hospital ends up paying for a surgical site infection even though the OR cost center looks great because they're just using iodine, there's got to be a reconciliation somewhere.

There's sort of a little bit of glove issues; this was actually -- OR surgical gloves were not used until the turn of the 1800s to 190's. Basically, Johns Hopkins, William Halsted introduced surgical gloves made by the Goodyear company, especially for his nurse. The reason why, because they were using carbolic acid. She had a very bad skin reaction to carbolic acid. He would only operate with her. She said she couldn't operate unless she had something to protect her skin. She had to stop operating with Dr. Halsted. He couldn't operate without her, had someone from the Goodyear Rubber Company make these gloves for her. And then he began using them also. And then it became standard practice. Now, these are not what you would call the best tactile gloves. They still have these, if you ever get a chance to go to the Hopkins go to the museum there, they still have these gloves. They are in glass, of course, to see them.

And what was important was Halsted, by using carbolic acid, by using other techniques, reduced his surgical site infection rate -- this is before antibiotics -- to less than 1%. And these were when people had hernias and then were in hospital for 30 days. So the follow-up was meticulous. And Halsted and Hopkins became world-renowned for their low infection rate.

Now we sort of transition to say, "Well, the gloves are actually there to protect the patient from us and us from the patient," but the real question is does it have a role? And there's some interesting studies out there that said we all know about glove perforation but what does that impact? And what they found was actually, if you look at gloves, even for a thorascopic case, over a quarter of them have holes in them at the end of the procedure. And how did they find that out? I love this. They actually put a picture of it. They fill them with a set amount of water and then they squeezed each finger. And water would come streaming out of them. And you have to remember that what they found was the longer the case, if it was more than two hours, there were multiple holes in each glove, even though the operators didn't know about it. And so this group -- this was actually done in Canada -- basically recommended that they change the gloves every two hours. Now, the question became "Well, was that relevant to SSI?"

Well, the Basel Consortium, which is actually a number of hospitals in Switzerland, actually looked at this, and they looked at SSI rates in those that perforations and those that didn't. And what they found was that those that had perforation actually had a higher SSI rate. So this was actually the first literature that actually supported that. Now there is a caveat, and I put that there, was that many of these cases were clean cases. So we know in clean cases that there may not even be a role for antibiotics prophylaxis. And so they looked at that group in particular, and those cases where they did not give antibiotics were the ones that had the highest SSI rate.

So what's that tell you is that you can mitigate probably, to some extent, these with antibiotic prophylaxis. And these were for clean cases, so what about a contaminated case like a colorectal case? Can you really mitigate it with just antibiotics? I don't know. But the data is certainly there to suggest that there is a role that glove perforation may contribute to SSIs in very specific cases, but when you take it in aggregate the question is does it matter. But at least there's data to suggest that there is an impact on SSI.

Thermoregulation, there's also a lot of discussion about this. And really, again this is a multifactorial sort of thing. I put up on the far side why it matters, what we think the physiology is. This is all empiric yet. We're not sure 100%. But it's basically maintaining an adequate temperature, because your body works in a normal temperature range. The enzymes work at a normal range. The white cells work at a normal range. And there's lots of literature that looks at white cell migration, white cell effectiveness at releasing lysosomes.

Your body is designed to work around 37-degrees, and it's optimized for that. Millions of years of evolution, if you choose to believe that, have designed it to be optimal at that, and when we all of a sudden give them an antistatic, strip them naked into a room, vasodilate them, their temperature drops, their body isn't designed for that -- our patients' bodies I should say. And so there's a lot of empiric evidence that this works. But the problem is the strength of that evidence gets diluted to some extent by all the other risk factors that bring a patient in to having an SSI.

If you're diabetic and morbidly obese and your temperature drops below 36, I don't know if that's the main factor that's going to contribute to your SSI. It may be that you're morbidly obese and you have poor profusion and you have poor tissue quality and you're diabetic and there's a lot of things. So the problem with the studies is that you can't just take the 70-kilo man or woman and do all your studies on that person and say what regulation that normothermia is important.

In trauma though it's clear, and that's very clear; that not only is there mortality reduced, but also their SSI rate is reduced. And the reason why this is interesting in trauma is because you have very good ways of adjusting for severity, you have very good data out there, and when you just put mortality aside, if you just look at SSI rates, normothermia was really a major factor in having SSI impact.

This is an area that I think -- the next area is inspired oxygenation. I think this is a little bit more controversial. I'm not saying that it's not worth a value, but I'm just saying that it's a harder sell, I think, when you go talk to people about it. Now, it's easy to do, but the data are mixed about it. The idea, again, is what your body is designed to do. A wound is a bad place for oxygen tension. Blood supply is poor. There's a lot of chemicals that sort of interfere with blood supply. And what the immediate goal is is to try and optimize that wound, optimize the condition for the wound. And the idea is if you drive -- increase oxygen pressure in the body, it's going to increase at the wound site better oxygenation. Oxygenation's important for wound healing, but also for killing of organisms because a lot of the materials that are secreted by the body in response to injury are oxygen radicals. You need to have oxygen in order to do that to kill organisms. And so the idea is to drive up the oxygen concentration in the wound by increasing the inspired FiO2.

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There was a large trial that looked at this, and this was one of the few randomized trials in this area. It was the PROXI trial. It was run out of France. And they did 80% versus 30%. Now, the big polls, I don't know where they came up with this 80%, because all the literature uses 80%. So they sort of say if you drive up your oxygenation up to 80%, inspired FiO2, during the operation and for two to three hours afterwards, you reduce SSIs.

It didn't sort of pan out in this study, which was type-two and type-three wounds. But when you look at specifically just colorectal, there was a marginal benefit if you did a subgroup analysis. So they basically said in colorectal alone, but it wasn't part of the original endpoints. So everyone sort of said, "Well, it's a secondary analysis and really are you sort of very picky and are you trying to find signal where there isn't any?" I don't know. The jury is still out on that. But, again, it's relatively easy to do. Oxygen is pretty cheap. There are some logistical issues that each hospital would have to do, because, really, if you're going to do it, 80% is the number that most people use. Whether you get there or not is different. And maybe it doesn't matter, but 80% is what's been used. But I say, again, you have to start looking at these things from a point of view of what can you do, what can everyone agree on that doesn't change practice, that everyone says is reasonable to do, that there's science behind it. So it might be something to do.

This was an actual subgroup analysis, and what they found was SSI rate, again, went from about 18% to 14%, but only in colorectal patients. And those patients had standardized antibiotic use, which was also interesting. Patients that had different antibiotics, it didn't pan out. So the question is, was it the antibiotics or the oxygen? I don't know. The numbers are so small that they couldn't say anything. But they did say with standardized antibiotic use.

This has come full circle again for colorectal surgery. And I've put it in there just because I'm sure someone's going to talk about it is whether or not to use mechanical bowel prep. And this is one of the areas that's almost like religion in colorectal right now. And I'm going to be going down to the American Society of Colorectal Surgeons meeting in the end of May in Florida. And I already looked at the abstract book, and there's probably 30 abstracts that deal with this. About half of them say do a bowel prep, half of them don't. And the data is all over the board. And so I really think it depends on your institution and your practice whether or not you should do a mechanical bowel prep.

I can say, for our institution, we haven't done mechanical bowel preps for the last five years. It's all part of our enhanced recovery after surgery protocols, which is a way of accelerating healing. I can't say what matters. We've actually had our SSI rate decline while we've been doing this, but I'm not an advocate one way or the other. I could do it either way. But the data would suggest, the most recent Cochrane Review says that there's no benefit to doing it. There's some work out of Michigan which basically said the opposite, and I'm just going to leave it at that. I think that's an institution-specific sort of detail.

Improved glucose control is really I think one of the fundamental things we need to be looking at. We know that this is -- even though I said earlier some institutions don't have diabetes as a major contributor, if you look across the board at the literature in surgical site infections, as well as specifically at colorectal, diabetes coming in is a risk factors, and is probably an indicator of poor control prior too, because the most sensitive indicator is not your baseline blood sugar the morning of surgery, it's your A1c. If your A1c is greater than 7.5 to 8, your risk of a surgical site infection goes up dramatically. And we're instituting

now, as part of a bundle to improve our SSI rate, in addition to what we've already done, really focusing on this.

But this is really a population-based thing. This has got to be done upfront. You got to monitor these patients and you have to decide whether or not they can get their glucose under better control. Now, you can't wait three months for the A1c to go down, but what it's a marker of is what exactly are they taking for their diabetes, should it be under better control? And it may take, according to our endocrinologist, it may be two weeks to optimize people so that you know when they come to surgery how much insulin they're going to need in the post-op period, because it's a hyperglycemic event.

So there's really, really good data to say if you know you can get better control during the event and you can keep their blood sugars under 180 during the hospitalization that that's going to improve your outcomes. And I personally think, having reviewed this, I think that's a real number. I think that's real data. I think it's hard to prove in big populations, but I think, in general, there's good science to support it. There is some clinical literature. And I think it's, again, something we can do that's not going to be a huge change management issues with people, that will improve their outcomes.

This is a very recent paper that, even in non-diabetic patients, if you look at hyperglycemia in the post-op period and those patients have less hyperglycemia, have less SSIs. So there's an understanding that blood sugar derangement impacts things, and that's one of the things that I think we can take away and try and focus on. So, like I said, if you have multiple ways of dealing with a problem, and multiple contributors, you're going to have to have multiple ways of working on it, because if you have a bundle of things you may be able to change SSI. Now what is the important thing about that bundle is it's not "This week we're going to only do this thing and then next week we're only going to do this thing." We have to do all the things at a high level of compliance for every patient, every time, and that's the challenge.

So what are the facts? The facts are that there's probably numerous things that contribute to SSI. The problem is we don't know what the relative contributions on each one is. We don't know what that relative contribution is in an individual patient. It may vary depending on those patient risk factors. So is it really important in a non-diabetic healthy runner that's coming in for an elective sigmoid colectomy for diverticular disease to monitor and securely monitor their blood sugar versus that 60-year-old type II diabetic retired bus driver who weighs 300 pounds who's coming in for their diverticulitis. But the point is you can't design a system based on each patient. You have to design a system in the hospital for all patients. So, yes, it is important, but the relative contribution of the hyperglycemia in that healthy 45-year-old runner is probably going to be less important than in the 65-year-old retired bus driver.

SSI rates are unpredictable too, that's the other thing. You can have all your diabetics that can line up – I can line up all my diabetics and I can't point out which one's going to have the SSI, and we've done everything the same. So we still don't understand everything. So, again, I want to go back to this. There's no single intervention that's going to work. So constantly applying multiple easily designed processes will, I think, have an impact. So that's what the bundle is about. That's what your colleagues here in New York have come together about.

What I'm going to say is that bundles are bundles, and they may be different. That doesn't mean they're wrong. It just means they're different. And what you really have to look at is the impact. These are some data on bundling. All of these were different hospitals, all of them were different bundles, and all of them had the same impact. They all reduced SSIs in their institutions. But what I'm going to say, again, is what they found was if you look at the individual compliance with elements, it was only when you got up to 70% or so that you had an impact. So you can't just do it once in a while for each patient. You go to try and do it for every patient the same way every time. This was sort of the impact; as bundle compliance went up, SSI rates went down. And it was statistically significant.

So now that's the background and I want to jump to our bundle. It's not "the" bundle, it's "our" bundle. It's different than other people's bundles. And it may not work at other places, and I'll go into that. But this is what we ended up doing. Change management is tough. And I'm sure everyone's shaking their heads. Especially with surgeons. And the first thing you're going to do is you're going to go home, and you've got your bundle book thing, and they're going to say, "Well, where's the level-one randomized control data for that element?" And you just got to get over to next steps, because there's a great article in the Lancet -- or, no, was it Lancet? Yeah, it was Lancet.

There's no randomized control trial that says jumping out of an airplane with a parachute is a good idea. There's a lot of empiric evidence that those people that jump out of airplanes that do not have functional parachutes, their risk of dying is significantly higher than those that come out with a parachute. Not zero, because there are people who have fallen out of airplanes without parachutes or functioning parachutes and have survived. So it's not zero. You can do it. But if you want to do it electively, because there's no randomized trial, I would suggest otherwise. Because you have to say, is there reasonable evidence to support it? Is it safe for the patient and the staff? So you don't want to do something that's not safe. Can it be implemented and sustained -- now, I want to emphasize the "sustained" part -- with minimal disruption to the existing processes? That's important. And does it make economic sense? I put that in there because that's the reality of medicine in the 21st century.

So if you can answer yes to all of these, then I would push back to those that say there's no randomized control data. It was because we're thinking that given that these are all true statements, that it's reasonable to try. And a willingness to try is perhaps the most important thing. And then you can always add on this one. I don't put that up first, but I always put it up. And if we find out that we don't need to do it, then we can easily reverse it and it's not going to cost us an arm and a leg, and it's not going to disrupt practice. So if you can honestly answer yes to these five questions or these statements, then what's the harm in trying? And that's how I address this when I talk about change management with my colleagues.

A couple things you need to understand though, and this is what they'll always is, "Oh, I had this one patient that I know that if the nurse had not taken off the dressing or did or did this or I did this, that was going to be the same." I've heard this. I listen to this all the time. I'm in meetings about it all the time. You have to understand that this is not just building a car, this is people. People are different. Interactions are different, and how things happen. So what you want to look at is common cause variation. You want to have data that reacts to what we think is natural variation in the system, not things that are completely out of the blue.

If there are those events and they're sustained, then you have to look into them. But these subtle jumps in SSIs, you got to live with them because it's a natural organism. The system that we care for -- health care is an organism. People don't look at it that way, but it is. It's got gazillion people in it, just like a body has a gazillion cells. They're people, how they interact, how they do things. What you need to try and do is bring order into the system to try and understand that variation, but you can't be jumping all over every little dot, and that's one of the things.

Complexity is great for education. It's great for cocktail parties. It's great for energy and cities. But it's terrible for quality improvement. And I don't want us to all be boots jack stepping, or whatever you want to call it, down the streets. But what happens is if everyone's doing something differently you can't make sense of what's going on. So you need to introduce order into the system. Now that's probably the toughest part, is getting people to follow a protocol, follow the rules, because in health care people don't like following rules.

But the more I've been doing this, the more I've found that most people just want to know what the rules are. And they want to be reminded or built into the system what the rules are, because they can't remember amongst all the things they have to remember to do every single time every patient comes by. And that was sort of our realization when we roll out change management, is you just can't put a list in front of people and expect them to remember. They'll remember for about a week, and then after that forget it, because they got too many other things to do. They got life going on. They've got the OR. They've got different patients. They can't remember all the things, so you have to build it into the system.

Because it's a complex problem it requires multiple people and different perspectives. It's not just a surgeon issue. Now, people go to the hospitals and say "It's a surgeon issue." Some surgeons think it's just a surgeon issue and they should be the ones to solve it. And my view is that no one's right. It's not a surgeon issue. It's everybody's issue. Everyone has something to contribute. The surgeons have a big part to contribute in doing the right operation, doing it in a timely fashion, and agreeing to the things around them. But it's got to be a lot of people. And what you really have to do is start off defining the current state. And when I mean defining the current state I just don't mean what your SSI rate means. What is your process for trying -- what is going on now, because I can guarantee, I probably can come to most of your hospitals and go through each OR and see that OR A is doing something subtly different than OR B, and OR C is doing things different than both of them. And these two surgeons who are partners are doing things differently. And that's the real issue.

The real issue is not what the SSI rate. The real issue is everyone's processes are different. And it's great because I've done this. I've visited with nurse managers and talked about their processes and they always come out with their "policy manual" about how we do things in our OR, and they go over everything. And then we go walk around the OR and their eyes are like this because what's in policy and what's in practice are different. And if anyone doesn't believe that, then you haven't worked in health care long enough.

So what I'm going to say is we a value stream map of everything. We really spend the time. I know people say, "Oh, we're going to sit in the room with the post-its and everything." Let me tell you, it is time worth spending. I, as a surgeon, believe it. I usually only make 20 minutes of those meetings. But when you get

the nurses and the CSTs and you get the pharmacists in the room, and some of our anesthesia colleagues, and they make the 20-minute meeting, there's a lot of information in there. There's a lot of things you can do. And the things that we've learned is if you're going to do interventions you got to make sure they can be placed easily into the system, that they can be done with high compliance, and they make economic sense. And I'm going to come back to these points, because this is what you're going to have to do at home to drive change.

What does it really mean to do this? You have to gain consensus that the points that we're discussing are all the same points, because everyone has a different perspective. You have anesthesiology colleagues looking at the operating room from this direction. You've got the surgeons looking at the operating room from this direction. You've got the circulating nurse looking from over here. You've got the scrub tech looking at it from this way. Everyone has a different perspective, and it's the same for the whole episode of care. Pharmacy looks at it differently than the pre-op nurses do. And so once you understand that it's easier to design elements.

Compliance is key. And if you're going to want compliance what's important is not only to design the bundle, but design a way of monitoring it. If you don't do that, you've lost. You might as well not even do it, because you can bring out a bundle and if you don't monitor or design into your system a way of easily monitoring, and that doesn't mean having someone go around with a clipboard every three months and try and do it; you will not sustain that because that person pretty soon is going to have another project that they're going to have to go through. And pretty soon it's going to be your SSI rates creeping up and then you're going to have to start all over again.

You need to be able to figure out, from the get-go, how to monitor that what we're saying we're going to do we are actually doing, because, if not, you're just like the nurse manager walking around with a policy manual. Because if you haven't figured out how to monitor on a monthly basis the department chair person, your surgical site infection people, they don't get a report that says "We use Chlorhexidine with alcohol 100% of the time," "We gave antibiotics appropriately," and not just your SCIP numbers. I'm talking about the real data from every single case. Then, if not, you're going to be sunk from the get-go. Long and short, make sure everyone knows what they have to do and does it.

A little bit about our practice. It's a full spectrum colorectal. It's not just cancer. We do everything. Eight board-certified colorectal surgeons now, a ninth one was just added, but this data goes over eight. We have dedicated colorectal operating rooms and we have two floors dedicated for our patients, same nurses, same floor, pretty much, 99% of the time our patients go there, which makes it a little different than other places -- a lot different than other places. But the principles are the same. What we found was we were doing things differently. This is the process we use.

This is not something we designed. This is basically Lean Six Sigma sort of approach. But it's something that we really adhere to. We basically clearly define our problems. We figure out our measurement strategy. We implement our improvements. We analyze our data. We implement our improvements. And then we enter into the control phase. And where I spend most of my effort is right here, to make sure that while we're doing this we have a way of monitoring all this stuff in real time, or at least in every three weeks, four weeks, get data to make sure we're doing it the right way.

You have to remember what your data is, too. That's the other thing. Is your data accurate and good? We had two data sources when we were trying to decide which one to use. We have our institutional data source, which is our IPAC, Infection Prevention and Control group. They monitor all our data. This is what usually gets reported up to the state or to CMS or whatever. They're the ones that come in and do the -- make sure everyone's wearing gowns for C diff. and they monitor your data.

And we are also part of the National Surgical Quality Improvement Program, which is NSQIP, which is a sample of our practice. It covers about 15% of our practice. It has mandated 30-day follow-up where they actually reach out to the patient, see what they're doing, how they're doing, have they gone to the doctor, why did they go to the doctor. They do all this follow-up. So it's much more active as opposed to being more passive. They have different triggers for what they define SSI is. So, again, depending on the data, it's going to be important how you define success.

Well, when we were setting this up I said to a team, I said, "Well, if it's sample, NSQIP's a sample, then it should fall in the IPAC because IPAC is supposedly 100% of our patients." We do about 4,300 colectomies a year. And so we thought, if 15% should be pretty good. They weren't. They were totally different. That doesn't mean they were wrong. It doesn't mean that NSQIP was right and they were wrong, or vice versa. It's just the definitions, the identification of the patient is different. So what does that mean for projects? That means you're never going to know reality. I'm convinced of that. We never know totality. But what you need to do is everyone needs to agree that we don't know what reality is, that you have to put those lenses on, and you have to understand that during your quality improvement project you've got to use the same stable dataset and it can't change. You can't all of a sudden say our IPAC rate is this, and then halfway through the project say "We're going to go to NSQIP," because it's going to screw you up and it will make people are frustrated once people are frustrated with the data.

Because I can tell you, first time I go to any meeting and I put out for my colleagues, the first thing I say, and I'm sure you all heard, "I don't believe the data." You got to get over that. You got to understand that there are limitations because someone shows up with this graph in one of your meetings, the whole project's shot. You got to be prepared. If you're going to negotiate, the most important thing about negotiating is being prepared, to know what your adversary is going to say. So you need to have this data available to you and you need to know what you're going to stick with and how to do it.

So we use NSQIP because we felt that it gave us a better perspective on the types of SSIs. Because the IPAC data was heavily favored towards deep infections but not superficial infections, stuff like that, that happened after hospitalization, especially in a practice like ours where over 40% of the patients come from over 500 miles away. They may show up at their emergency room somewhere and have something that our IPAC people never know about. So we wanted to use NSQIP because it was stable, it didn't change much, and it's a sample. And we were somewhere around 8%, 9% over six years beforehand. So we decided this is where we wanted to be.

We then defined what our goal was. A lot of people don't spend a lot of time doing this, but you need to. You need to define where you're starting from and what you want to achieve. You just can't say "We want to reduce SSI" because then you basically don't have a goal and then people can interpret it differently.

So you have to say, "As a group, what is our definition of success? What are we going to use for our data and are there going to be certain things we're going to exclude," like we wanted to exclude transplant patients that we ended up doing colectomies on acutely and stuff because we felt that that wasn't representative of our practice, because it's a rare thing but those patients are very high risk and, you know, it's not really reflective of colorectal SSI when you're doing a transplant -- when you're doing an acute colectomy in a patient that either just got transplanted or is getting prepared for transplant. That's a whole different kettle of fish. And so we thought we would exclude those patients. But once you set these rules up, you don't change them because then it's like the government. It's like CMS and the two midnight rule, you know, they keep on pushing it back and forth and doing all this stuff, you can't do that to people. Stay with it.

So we already had our measurement phase. We analyzed it. We said, well, we had 50% of our 10% was superficial, then we had organ, then deep, then combo ones. We looked at all the variables. The nice thing about NSQIP is that you don't have to do a lot of deep dive stuff. So when you go to your infection control people, they'll give you the patient number or identifier, they'll give you when the day of surgery was, they'll give you who the surgeon was, what the procedure was, and when they got readmitted with their infection, and maybe what the organism was. But they don't tell you anything about were they diabetic, why were you doing it, or anything like that. It's a lot of work. We didn't want to spend the time to deep dive on everyone. NSQIP does that for you; so if you have it, it's a good resource.

We looked at the variables. We looked at our practice. We looked at the things that we thought we could fix or what were important. And some things we can't fix. You just can't fix that Wisconsin weight problem that we have. They're just huge. And you just can't just do anything about it. We did find some interesting things though, and this is what I'd go back to about young patients. In our population we found that 50% of our practice that had SSIs were young, and it was because they were "colitics." We do a very high volume of ulcer colitis and Crohn's patients. We're known for that. We're a referral center for that. Those were the patients that were driving our SSIs. So the things that we really looked at that are important were what were their disease process, weight, and operative time. And you really can't change BMI.

What did this teach us though? It said we had to think differently, and I'll talk to you a little bit about what we did with colitis because now they are one of our low risk groups because we changed our strategy for operating. So sometimes you actually have to change the operation. If you keep on doing the same thing over and over and over again and try to expect different results, it's not going to work. And we had to actually change the operation.

We actually looked at our surgeons, my colleagues, and said, "What do we do?" I gave them this little survey, 21 questions. What do you do? Now what we found was we don't do anything the same, hardly. But what was interesting is we all trained together. We all practiced together. Every single one of us who's on staff there trained there, and we do things differently. And it wasn't like we were going to try and change everyone, but we tried to get standardization across the practice. We actually sat down and said, "Can we all use the same skin prep?" And the funniest thing was when I asked my colleagues, "How did you know what skin prep was," they said, "Well, I had to ask someone in my room." I said, "Well, do you care if we switch it?" They said, "I don't care," because it doesn't impact them. It's just what they've been doing for 20 years. And so you have to have those types of -- figure around the edges of who you're

negotiating with what they really value and what they don't value, and see if you can change as much as possible around the non-value things, because once you start negotiating about values you've lost. You just can't negotiate about values. You have to negotiate about interests, not values.

These were the principles. Basically, we wanted to go across the episode of care, not just focus on the OR. We wanted multiple stakeholders involved, because multiple stakeholders are involved. We wanted to engage staff, standardize, ensure high compliance with building it into the system so we could do audits, and we wanted to get frequent feedback. So basically every month everybody gets it. Pharmacy gets our SSI rates. The OR staff gets our SSI rates. I personally send out a letter -- an e-mail blast every month to everyone involved in the care of our patients about our SSI rates, not just my surgery colleagues.

This was our team, a lot of people. I don't know what your team's going to look like, but there are a lot of people here, from nurses on the floor to nurses in the clinic to the OR pharmacist to the staff pharmacist, a lot of people. These are the things we've decided to do. I'm going to go through them. And I know it's bad. And I think Maria has a better picture of this. But we did multiple episodes, multiple interventions across the pre-op, the peri-op, the intra-op, and the post-op, and I'm going to go over them really quickly.

We did pre-op Chlorhexidine packets. We'd give them to the patient, shower the night before, shower the morning of. I think actually the most important thing is this. It's a little booklet we give them. Of all the little booklets a patient gets, which is usually a big pack of things before surgery, this is the one they actually read because they have to do something with it. They have the packets of the special soap. And in it it not only talks about why they're doing this. It talks about hand hygiene, the importance of hand hygiene with their families. And what we saw was our hand hygiene compliance of family members and patients actually went up once we started doing this. Just giving them -- because you're engaging them in their own care. What is the thing we're trying to do in health care? Engage the person. This actually starts the conversation. And it talks about how we want them to take care of their wound post-op. The only reason they read it is because we tell them this stuff goes together. And it costs 73 cents. It makes economic sense, easy to implement, and when they come in and they check in in the morning the nurses on the pre-op checklist specifically asks the patient -- not the pre-op checklist -- in their intake form, electronically asks the patient "Did you take your Hibiclens shower, yes, no? Yes." So we have our audit completely done electronically.

The other thing we found was BMI, I told you BMI was a high risk factor. So now when a patient comes in and has a BMI greater than 30, even if they took their shower, they get wiped down with these SAGE wipes in the pre-op, in the area around their wounds. All right. Well, you say, "That's hard to remember." It actually comes automatically on the listing for the orders that are identified for the pre-op nurse. It basically comes in, the patient with BMI greater than 30, wipe this down. What's even more -- what we did recently was, basically when the pre-op orders are generated it actually looks into the electronic medical record -- this is not hard to do, your IT people will tell you -- and it looks to see if there's a BMI. If the BMI is greater than 30, it automatically populates this. So our pre-op nurses, who see, literally, hundreds of patients every week, don't have to go searching for it. It's right there in front of them. They don't have to remember it. It makes their life easy. That's all they want. They want to do the right thing, they just need to be reminded what the right thing is. So that's how we did it.

Pre-op antibiotic ordering, basically it's all done electronically through our listing process. But it basically -- what we expanded was not "Did you do it," but we actually give them, because it's a colorectal surgery associated with the surgeons that do colorectal surgery, we give them the list, all the different -- there's different options, but you have to fill out one of these. And it's also weight-based, and it tells you what the weight is. So it gives you what the recommendation is. Again, an electronic medical record has a lot of this stuff, it's just a matter of coordinating it or asking for it. They can do it quite easily. You tell us what the rules are, the business rules, but the business rules have to be stable. They can't be changing week to week, month to month. They have to be stable, because IT will not do "Oh, this week we're going to change it, next week we're going to do this." No, they don't like that. They say, "Give use the business rules, we'll design the logic, we'll put it in the computer." That's what they do. That's programming. Programming 101, and that's what they do. And basically it gives them the choices.

The other thing we did was we really felt that re-dosing was important. Operative time was the main thing. Our cases, on average, were three hours and 50-some-odd minutes. Well, if you looked at our -- that was our average operative time. That's the worst time in the world to be re-dosing, because our anesthesia colleagues are trying to get the patient off the table. They're starting to go into emergence. They're closing. There's other things. That's the time when people are going to forget to re-dose. So basically we said, "All right, the vast majority of our cases, they're at almost four hours, that's when most people are at re-dose," so we said, "We're going to do it at three hours," because what really is important is the tissue level of antibiotics at the time of closure. So if you're just coming in at nadir, that four hours, that doesn't help you. So we would re-dose at three hours. But we have that antibiotic pre-op ordered for a case that comes in directly out of our pre-op ordering that if at three hours this is already there, pharmacy already has it profiles, they send it basically directly to the OR. It's always easy to put it back in the Pyxis machine. Getting it's the hard part. And this is how we solve that. It's built into the system directly so that people don't have to remember how to do it.

Hair removal, I'm going to talk about that, standardized. This is where we found out from one of the guys that does it. Most of the time our residents don't do the skin prep because they're running around doing other things. So we have the people in the OR. And we said, "We don't want residents doing the skin prep. We want people that know how to do it." And it was interesting because we were sort of having this debate about which to use, Chlorhexidine, alcohol versus iodine. Iodine was actually a little bit -- I can't remember what it was. It was our contact. I stay out of that. But there was a difference. But what was really was surprising was we asked one of the guys -- one of the guys who was working in the OR said, "You know, Dr. Cima, there's a difference between these." I said, "What do you mean there's a difference?"

The Chlorhexidine-alcohol, if you read the package insert, which no one ever reads, it tells you specifically, it's only designed for a 13-by-13 size area. If you read the alcohol -- if you read the Betadine one, it's a 15-by-30-inch area. They're different. They look exactly the same. They have the same volume. The only difference is the color. But their effectiveness by the manufacturer is different. Well, if you've ever seen an abdominal case, it looks more like the blue one than the orange one, especially in Wisconsin or Minnesota, because these people have big bellies. So they may all look the same, but the devil is in the details. So which one you use may make a difference, because you may end up using more

of these -- you're going to use two of these to cover the same area as this. So the people that are putting it on need to know how to do it, they need to know the right surface area. So it just can't be that you're going to use Chlorhexidine-alcohol that you're just using one stick per patient, because you may not be using it right. If you're not using it right, you're not going to get the effectiveness out of it. So you have to look into the details.

We re-dose. I was talking about the re-dosing. Cefazolin, we re-dose. It's triggered off the first antibiotic. And our anesthesia providers, they don't have to be reminded to do it because it's very simple. They have an electronic anesthesia record, they programmed it. They said when we give our antibiotics, if we give cefazolin, we get a reminder at about two hours and 40 minutes, I think it is, up on their screen that says you've got to re-dose coming up in 20 minutes. They can pause it, just like your snooze alarm. You can hit it for nine minutes, it pops right back up. If they do it more than twice, it doesn't go away and they have to do it. It's simple reminder. We have 493 anesthesia providers at the Mayo Clinic. They can't all remember what to do. This is the reminder. Programming 101 is very simple if you have an electronic anesthesia record. Uh-oh, wrong button.

This was something one of our more senior nurses. She goes, "When I first worked here 30 years ago when we were doing colorectal we never used dirty instruments. You guys use dirty instruments all the time to close." I was like, "What do you mean?" She goes, "Well, you know, everything gets sort of contaminated when you're doing an anastomosis. Yeah, I don't hand you dirty instruments, but it's on the field, our gloves are contaminated. So we used to change." This is usually the biggest bone of contention when people talk about it, but we basically have a small closing tray of instruments that are kept off the field. And when we get to the point of closing they basically take off the dirty instruments, put towels down, we change our gloves, and they use these.

Now, I had a video, Maria, and everyone, I had a video to show, because when this got first introduced, oh, the hackles we got. "Oh, it's going to take forever." "It's going to take 20 minutes to do this." "It's going to be incredibly cumbersome." So we videotaped it after about three weeks of people doing it. It's two minutes and 41 seconds to do the whole thing. So the video actually shows it, but, unfortunately, because of technical issues we couldn't show you. But you'll be able to get it later, right, Maria? So this is just how we do it. And basically it just shows the process. But it does a couple of things. One is it stops everything at the end of the case, which, if you talk to the OR nurses and stuff, they like. It gives them a chance to sort of catch the counts up, get everything sort of stabilized, it calms everyone down. It's like quiet time in kindergarten. And then you start the closing, which I think is important, because that's actually where people spend the less time and I think that actually technically is one of the things that contributes to SSIs. I have no proof of that, but that's my personal belief.

You have to carry this onto the floor. We basically went with our nurses on our floor, "How do we get you engaged? What do we do?" We standardize when dressings are removed. We basically -- we used to all remove dressings the morning after surgery. There's some data, very poor data but data nonetheless, that says 48 hours is ideal. So we said, all right, post-op day two, dressings come off, the nurses chart it in their nursing documentation. The nurses get the patient up as part of our enhanced recovery pathway, they get them in the shower as soon as that dressing is off. We give them the special soap. The patients are all engaged in that. They know about their soap. We have these hand hygiene things up in the rooms.

30% of our patients have ostomies, so they're doing ostomy care. So, you know, all the stuff about that is important.

We basically have post-op standard order sets so that the nurses feel empowered to do all these steps. And it was important that they do all those steps and they track all of them. So the Foleys come out the morning after surgery on all of our cases, unless there's a specific order written not to because it was bladder surgery or something like that. Even our rectal cancers, they come out the morning after surgery, everybody. Our nurses have a protocol. They know they're not going to get in trouble if they do the protocol. It's a good environment. It's a healthy environment, and it moves along, and that helps. Patients go home with the bottle of soap.

We use multiple audit processes to make sure we're doing things, and we also looked at counterbalance, like did it take 20 minutes to do the closing tray? No, it doesn't. It takes two minutes and 41 seconds. We looked at our compliance with re-dosing. We went from 60% re-dosing to 100% re-dosing once we put the reminders in. And you don't have to do, like audits of 500 patients. Just do spot audits electronically, 30 patients, 20 patients, every third or fourth week, because people slip. Now some of these things they can't slip. Like the anesthesia reminder they can't slip because it locks their screen if they don't submit that they re-dosed. But some of these other things you can, like the dressing changing, you know, when the dressing's removed, that basically is now audited because from the nursing records. And our nursing colleagues monitor it. They've been tasked with monitoring certain elements, the showering and stuff like that, it's their responsibility, it's their accountability. They come to the table and say, "We were successful" or "We can improve," and they take it on. And that's what's been good about it.

Operative times, we did have a little blip in operative times, but we came back to normal. No difference in operative times once we started the closing process, and this is across all colectomies. The demographics of the patients, I want to show you, when we first started this we did two years before and a year afterwards, basically the same demographics. If anything, it was a little bit more complex cases by ASA. That was the only area, as well as blood transfusions were actually higher in the after implementation phase. And this is what happened. We started January 1st of 2011, using our NSQIP data. And basically this is an 18-month follow-up here or a 12-month follow-up, I can't remember. We're now two years out and it's basically unchanged. Our overall rate dropped in half. Now, it's not that the surgeons were different. It's not that the cases were different. It was basically we were doing a standardized process, everyone was involved, everyone was engaged.

Our superficial SSI, if you look at a lot of the things we did, they were directed at superficial. You know, the prepping, the skin, that re-dosing antibiotic. That's not going to fix an anastomotic leak. It's just not. It's going to direct at those. Now people say, "Well, it's not worth the money to do that." Well, look at it this way, we do 4,300 colectomies a year, if 5% of those got a superficial SSI versus 2% got a deep one, if we can reduce all those superficial to almost zero, and the deep ones don't change, we actually, from a financial point of view, come out ahead. From a patient point of view, the number of patients impacted is actually much greater. They have better outcomes. What was interesting was when we looked at our deep wound ones, they went down, too, and I have no way of explaining this. I'm not even going to try, because none of the things we directly specifically said to the surgeons would change how you operate.

Now I will say that we did do one thing for our colectomy patients, our UC patients. We basically now do three stages, as opposed to two stages, for our acute "colitics," which were the highest risk. So we take out the colon, leave the rectum in, we come back and do the pouch. Instead of it used to be a two stage operation, it's a three stage. But we do it that way. And we're like, "Oh, that's an extra hospitalization, an extra operation." Using our enhanced recovery pathways and looking at the overall morbidity, it actually has decreased length of stay, decreased cost in a three operation approach than a two operation approach. And we're going to be publishing that pretty soon, and it's impressive.

It's a complex problem. It requires lots of interventions. It requires – my view is it requires multiple steps that have to be done collaboratively. It has to be designed into the system of care, and you have to monitor compliance. If you don't monitor compliance it's just like having Cardinal or 3M or somebody come in, and when the consultants are there everything looks great, and when they leave, after going past the drive-thru at the bank, you're back to where you were three or four months later. And that's my personal view. That's our view at the clinic how we do it. The New York bundle has a lot of these same elements, it's different though. Doesn't mean it's better or ours is better or worse. It's all how you guys implement it. And so I wish you all the best. This is just sort of some of the lessons learned. We've already gone over this multiple times. And I hope I didn't bore you. I'll have my esteemed colleagues finish up and then we'll have questions. Thank you.

Hello. Dr. Cima, if it's okay we're going to see if we have any questions for you right now and then we're going to take a break, and then come back to the panel.

Oh, okay.

Was there anyone who had any questions?

Thank you. Dave Hanlen [ph] here. Just a quick question on the oxygenation perioperatively, what is the input? Is it an FiO2? Is it just an 80% -- you know, the PO2? What are you monitoring?

Well, that's why I was trying to say in the data, the papers. You know, at room air, if you're not sedated at room air you're oxygen level, if you monitor it is 98%. Once you get put on two nasal cannula it goes up to 100%. So the most important thing is monitoring it. The goal here is really to drive the partial pressure in dissolved serum and blood pie. But monitoring oxygen saturation is not the end-all to be-all, because it basically -- I mean, anesthesia colleagues know better than I, but once you're above a certain level it's a flat part of the curve. But all the studies have been inspired FiO2 of 80%. But the physiology behind that I defer to my anesthesia colleagues.

[Inaudible] is now. I'll be going over that. I'll just tell you very briefly, FiO2 does not equal PaO2, and we'll go over that.

Excellent talk, Dr. Cima. One of your slides showed clipping from nipples to the pubis. Is it really, really necessary or?

No.

Thank you.

It's just we have our orderlies, and if I say I want to do a – I'm doing a laparoscopic sigmoid colectomy, they're like, "Well, where's" – you know, so, again, we're big believers in systems approach. And, you know, the liver surgeons use the same sort of pre-op I do. And so the best though is I had -- you know, the problem with systems like that is they sometimes fail. And I had a guy who I was doing a transanal excision of a rectal polyp, and he was a police detective – homicide detective from Minneapolis. And he comes into the room and they're like, "He wants to talk to you." And I was like, "Why?" He goes, "He wants to talk to you." And my nurse in the room is like, "Well, he really, really –." I was like, "Fine, I'll come see him before they put him to sleep." And he's like, "I thought you told me this was going to be like a big hemorrhoidectomy," and I was like, "Well, yeah, it is." And he – then he lifts up his gown, they had shaved him from here to here. For three months I heard nothing bad about it from him, even though we got the polyp out. So, yeah, the orderly sort of got it confused and, you know, we ended up reporting it as a sentinel event. But, yeah, you don't need to.

Hi. Just a quick question. So I'm not a colorectal surgeon, but the principles seem to make sense to apply across the board. Why haven't you applied the bundles across the board to other specialties as well?

Well, we have actually. I mean, I wasn't asked to talk about that, but our hepatobiliary surgeons do a lot of the same things. So, I mean, we have our gyn oncologists have done the same thing. What a lot of our colleagues have done -- we actually did this in two phases. We did SSI separate from our enhanced recovery pathways, which we've instituted across the board at the clinic now over the last five years. And so gyn oncology colleagues, basically did both at the same time because there's a lot of elements that enhance recovery that you also want to ensure get done. And so they're all bundled in there. But we've tried to do a systematic approach to SSI reduction, all the re-dosing. You know, for the anesthesia group it was basically, "Hey, we don't want to build this in if we're not going to do it for everybody," so like the re-dosing, because it's hard for us to know patient A is a colectomy versus a right hepatectomy. So we basically went to the surgical practice and said, "Does anyone have concerns about this?" I have yet to meet a surgeon that says "Don't give more antibiotics." And so they were fine with it, they were like "Fine, as long as I don't have to do anything," which is always the other thing you hear, oh, I have to change.

Can you hear me?

Oh, yeah.

Okay. Do you use wound liners prior to – or when you exteriorize to do the anastomosis?

Oh, wound protectors.

Wound protectors.

We didn't make that part of the bundle. I couldn't say consistently if we do. You know, we do a -- I think, you know, I know from my personal practice, maybe I should go back and ask, you know, for when I do a

laparoscopic case we do exteriorize. We do an Alexis wound retractor in, but I don't know if everyone does that. That was not part of the bundle. I guess it could be if we wanted to. A lot of our cases are redo, redo, and so there's big open ones, a lot of Bookwalters. So I don't think we could say consistently we do that.

A couple of questions coming in from Albany. The first one is "Are there any contradictions to utilizing Bair Huggers in the OR?"

That's been a debate recently. I think it's mainly a commercial debate, because the guy that actually designed Bair Hugger is suing the people that bought it because he says they're infringing on a patent. So he's making up -- he's designed a new one. I think there's no contraindication. I think if it keeps a patient warm. We've gone, for economic reasons, to using the Bair Paws I think it is. It's a different system. And the patients love it. They come in pre-warmed and they love wearing that thing. And they carry it up with them from pre-op OR up to the floor, and the patients love it.

Thank you.

Any role for negative pressure wound closure techniques in obese patients?

That's a great question. We didn't specifically address it. We're actually looking at it right now for our abdominal wall reconstruction patients, our big parastomal hernias. I can tell you that the two of us that do most of those have gone to now using a negative wound pressure closure on those patients because the hernia patients, the number one predictor of a recurrent hernia is a wound infection. They have a lot of skin laxity from having these massive hernias. And so, rather than cut away skin, if we can get the fluid out seroma would morbidity is reduced. Now, I think the question is for primary, you know, just every case, we have not done that. But certainly for big patients, I don't know. The data out there is very limited. I know there's a number of orthopedic groups that are doing it on hip revisions. Plastic surgeons are doing it on breast reconstruction in breasts that have had radiation. But I can't tell you if it's, you know, really done. But for our parastomal hernias, which are usually massively obsess patients, that we are standardizing to that, but it's only been I'd say in the last 10 or 12 months that we've gone to that.

Is there a role for MRSA screening and decolonization? I know we're doing this in orthopedic cases. I don't think – I'd like to get your opinion on that in general surgery cases, colorectal.

Yeah, we looked at that as an institution and identified the high-risk groups. You know, we sort of "preatoed" it out. And the highest risk groups were vascular surgery patients, orthopedic patients who are getting revisional surgery or how have been hospitalized, and cardiac surgery patients. So only those groups of patients do we actively screen for MRSA. If you look at colorectal and you look at the bio grams -- now each institution is different, so I can only tell you from our experience. Our biogram MRSA is such a small percentage of our patients infections that we actually culture, and it's almost always in chronic rehabilitation patients that come from a rehab facility or something, that only then do we actively try and decolonize them. But for routine colorectal patients coming in off the street or from Iowa or whatever, the risk-benefit from an economic and treatment point of view is probably too low for us to do it for colorectal. But the three groups that I identified are the ones where we do it for all those patients.

Dr. Cima, thank you very much. I enjoyed your talk. I am a surgeon, not a colorectal surgeon. Oftentimes, as you mentioned, the institutions might look at the surgeons as both part of the problem and part of the solution. In regard to postoperative wound probing on elective colorectal cases, open cases, do you have any literature on that in terms of reduction of seromas and reductions of infections, number one? And one of the impetus for us being here certainly is that the Department of Health in New York State does keep track of these infection rates across hospitals. And so I'm wondering, looking at the numbers that you presented to us of the complication rates, what's reasonable, because I've looked at these numbers and it seems that there are a vast -- well I'd say there are a number of programs or hospitals across the state who have infection rates that are well below 5%. Am I to believe those rates? What would your comments on those things be?

Well, first one is the wound probing. Actually, one of the groups in the Joint Commission collaborative was Cedar Sinai, and Dr. Tophi (ph), who is their surgeon and champion for the meeting, actually had a paper out about routine probing of laparoscopic wounds. And basically what they do at Cedars is the wound sort of closed with a subcuticular, but with deep dermals, not a running subcuticular. And then they routinely, on day one and day two, sort of put a Q-tip in and -- a sterile Q-tip and drain the wound. And they saw significant reduction in seromas and in wound infection rates in their practice. You know, that has been reported. Now, these were all laparoscopic cases. They only do it for their laparoscopic cases, so, you know, small wounds. They also had nursing colleagues that would do this. Some nursing groups don't feel it's in their scope of practice to do it. So you get into all those types of issues about it. You have to decide what's best for the patient.

It's interesting, I went to the New England Consortium, I was invited to talk about SSIs. And in Maine when the state started tracking colorectal SSIs, they noticed this huge drop off after they started reporting in SSIs. And people were like, "We haven't even done anything yet." It turned out that then they went and looked at the documentations, they were leaving all the wounds open intentionally. So unintended consequences of performance measurements, because what was happening was patients were all going home with open wounds that they had to pack. There's got to be some happy medium. And so I can tell you what our practice is our practice is. All wounds are closed with a subcuticular stitch. If there's more than I think an inch of "subcu" there's some deep dermal stitches that are placed, and then subcuticular. We don't use staples. And that's our practice.

As far as the second question about leaving the data, that's always a tough question. When I look around at most of the places that do standardized institutional data reporting -- I go to hospitals, you know, like I was just at a major university in the Southeast, and they have three people dedicated to covering the entire practice. I worry about the data integrity across the country, not at that specific site but at every one. It's hard, because you don't know how good they are at each site. It's all voluntary, to some extent, and so it's tough.

Administrative data, now looking at administrative data, there's just a very nice paper that came out about comparing administrative data to clinical registry data for SSIs. Vastly different, you know, way overcalled in the administrative data. So getting our hands on data is tough, and that's going to be the hard part about statewide and national collaboratives, and I'm not sure the government really appreciates that.

There is more coming out on that at the college level, comparing actual stuff. We've already presented our stuff about the difference. So you have to rely on your data sources and everyone has to trust that they're the same. But I'm not 100% confident that as we do national reporting that that's actually the case.

A question coming in from Buffalo. They want to know if you're using any other kinds of warming things in the OR like solutions or room control, those kinds of things?

We don't routinely use heated fluids. We do have normothermia algorithms in all our ORs. So each OR has a digital thermometer, which was one of the simple things we did. We have 128 operating rooms. And we went from analog to all digital thermometers, and basically have an algorithm put together by our anesthesia colleagues. The patient's temperature is this, the digital thermometer goes up to X. When the patient's temperature is this, the digital thermometer comes down. First thing in the morning, our heating vac people, I don't know how they do it, but they're all programmable. The thing when people hate the room temperature is not when it gets to a certain temperature, it's that transition because it blasts warm air into the OR. So basically they programmed all the ORs at I think it's 4:30 in the morning, or I don't know what it is, they all heat up, and so they all go into a warm OR. And then during the day they get adjusted based on that algorithm designed by our anesthesia providers. Again, it's the standardization and everyone willing to do it. And now it's part of the workflow. I hear it all the time. "What's the patient temperature," you know, every 45 minutes they call it out, and then they adjust it as needed.

Thank you. A question coming in from Wellsville site. The bundle says subcuticular closure, can you speak to that a little bit? They're interested in any other types of closure.

You know, I'm not sure. I mean I'm always a big fan of doing what you do best and making sure everyone does it the same way. So I don't know where that came from in your bundle. Our practice has always been to do subcuticular closures, and I can tell you the reason why. It's because, you know, well over 50% of our patients, you know, 40 some odd come from greater than 500 miles away, they don't want to come back to have staples removed. That's the only reason we do subcuticular closure is because of our patient population. It has nothing to do with SSIs.

And that makes sense. One more question from the Albany. They're wondering has there been any pushback on resistance to Chlorhexidine?

From the patients?

Anyone.

We've been doing this now for five years, and I can tell you I've only had two reports from patients having some type of reaction to the Chlorhexidine. I don't know what -- you know, the patient defined it as a reaction, and so we marked it as something. I don't know if it was real or not.

Thank you very much. I was wondering, when you put your process into implementation, I'm assuming some of your patients came from outpatient, yet some came from the inpatient arena. Did you initiate these bundles for both at the same time?

Yeah. Yep. So what we ended up doing was -- so we have, like, for inpatients there's a checklist, and we've always had it there before checklists came in vogue, and basically it was for the inpatient nurses. So on a medical floor, when they have a patient going to the OR, those orders get triggered, sort of like a pre-op order set. So once the case is listed and the order sort of like having 18-gauge IV and they have to have all those things, and the site marking has to be done, and consent needs to be done, so we just added it to that. So they start the Chlorhexidine showers in the hospital and all that stuff.

[Inaudible] from the New York State partnership team because a couple of the surgeons talked about non-colorectal surgery. We have actually been monitoring cardiac, hip, and hysterectomy surgeries in the state, and they've been going down substantially. However, I will tell you that the bundle elements used in this were used for those as well. So there is some, you know, transportability that you can do between what we're talking about today and some of the other major surgeries that happen in the state.

Okay everyone, is there anymore questions in the room? At this time we're going to take a 15-minute break. The restaurant, if you need food or drink, is downstairs, and restrooms to the left.

[Break]

Okay, everyone, we want to keep our program on time. Thank you. And now we have for you and we're pleased to introduce Dr. Michael Timoney, who is the vice chair of surgery for quality at the Lutheran Medical Center. Dr. Timoney is a general and trauma surgeon in Lutheran Medical Center from Brooklyn, New York. He is also the vice chair of surgery for quality improvement. He has a particular interest in hernia surgery. He graduated from Columbia College and received his medical degree from Mt. Sinai. He did his fellowship in innovative surgery at Lutheran Medical Center. He's also a participant in the Clinical Quality Fellowship Program, a quality improvement training and professional development program, co-led by the greater New York hospital association in and the United Hospital Fund. Welcome.

Thank you. Thanks very much. I'm very honored to be here and very honored to be held in this esteemed company. Let me start again. Let me tell you a little bit about our efforts to reduce surgical site infections at Lutheran. And I'd like to put Lutheran into a little bit of a context to show that success is possible, even in sort of challenging circumstances. We are a 450 bed safety net hospital. What that means is that we an open door, offering access to patients regardless of their ability to pay. We have a large percentage of uninsured patients, of Medicaid patients, and patients who are, in fact, uninsurable. We're also a level-one trauma center and a teaching hospital, with a number of residencies, as well as a large number of medical students.

Lutheran is located in Sunset Park, which is a mixed residential and industrial neighborhood on the waterfront in Brooklyn, and we serve sunset Park, as well as a number of the surrounding neighborhoods around it. The population of Sunset Park is about 128,000 people, 23% of which live below the poverty line. We have a 10% unemployment rate in that neighborhood. We're ethnically very diverse, with about 33% identifying themselves as white, 44.5% are Latino, and 36% are Asian. e don't have the great pair mix in the world, with only 25% of our patients being privately insured, and 22% are absolutely uninsured, and another 36 are Medicaid patients.

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We first sort of embarked on our effort to really focus on surgical site infection reduction at the end of 2012, beginning of 2013, when we recognized sort of a mini outbreak, if you will, of postoperative infections, and we brought together an ad hoc committee of people, including myself, representatives from the operating room, staff, as well as the chief medical officer, infection control, and we started analyzing this string of infections. And we looked at them according to surgeon/surgery type, operating room, and we really couldn't find much in the way of identifiable trends, but this ad hoc committee really took on, and it became a monthly SSI meeting. And I think this has really been a cornerstone of any of the success that we've had at Lutheran.

It's an interdepartmental meeting with all levels of providers. We have scrub techs to chairmen at this meeting. It's an open forum, and everybody has an equal voice, with no hierarchy. The goal, of course, is to reduce SSIs through a change in the culture and process changes that are sustainable. The team, which meets, as I said, every month, consists of myself, an infection control head, as sort of co-chairs of the meeting. We have chairs of orthopedics, anesthesia, OB-GYN meet regularly, as well as representatives from colorectal surgery, infectious disease, the operating room nursing leadership, and coordinators for orthopedics, neurosurgery and vascular surgery. Very often our chief medical officer also tends, and, of course, quality assurance has a huge role in these meetings.

So from these meetings we've developed a colon bundle, and I've broken -- I'm sorry, I skill skipped a slide. This is sort of a timeline of some of the interventions that we have we've undertaken over the last year plus. And I'll just quickly go through them. One of the things that was noticed was that there was sort of irregularity as to what type of skin prep was used in the operating room, so we started to encourage and then mandate the use of Chlorhexidine skin prep for all surgeries below the neck and above the perineum.

We had some problems of appropriately choosing antibiotics for certain cases, particularly colorectal cases, and we developed a nurse-driven protocol, where the nurse gives the antibiotic to the surgeon and the anesthesiologist by protocol. This is sort of supplanted later by another process, which I'll get into a little more. But that worked as an interim process.

We reeducated everyone in the operating room on the technique of hand scrubbing, and we put a lot of signage up everywhere for timing the firsthand scrub of the day, and we instituted home Chlorhexidine bathing, as Dr. Cima has alluded to. We developed an antibiotic selection poster, which I'll, again, get into a little bit more detail a little later, but this helps guide our selection of antibiotics and the redosing of antibiotics. We developed standardized wound care instructions in the postoperative period, particularly for patients who are going home, and we've instituted protocols for type glucose -- well achieving normal glycemia for our hospitalized patients, and this has been a huge effort and it continue to go on.

And finally, we developed interoperative bundle, which we'll talk about in a little bit of detail. We also noticed some opportunities for improving our terminal cleaning of the operating rooms, and that has, I think, been helpful. We utilized a PDSA cycle to initiate any of these intervention, and they all sort of stand on the bedrock of the WHO checklist, which we used to discuss many of the elements that are going to affect, in the long run the outcome the patient and wound infection, for example, the expected

time of the operation, anticipating the need for redosing, blood loss needs, any other potential unexpected events that might occur. And, of course, we try, as best as possible to adhere to our core measures.

So this is our colon bundle, and I've broken this down into preoperative, interoperative, and postoperative elements of the bundle. What you see in red are the things that we have achieved to some degree or other, and in black are sort of the wish list items or things that we're currently working on. So as I mentioned, we have given -- we now give all of our patients who go through the pre-anesthesia testing area a package of wipes and Chlorhexidine and instructions on how to bathe themselves the night before surgery and the day of.

As I mentioned we've instituted more stringent glycemic control protocol for our inpatients. Preoperative warming is something that is currently being worked on. Dr. Cima alluded to the device that warms the patient from the preoperative area through the operating room and postoperatively, and we're taking that through our value analysis. But the idea is to maintain a core body temperature that's not going to drop precipitously at induction of anesthesia. Again, we have a really good process in place for antibiotic administration in the preoperative -- before incision, with ensuring the correct antibiotic selection and correct weight-based dose.

As I mentioned, Chlorhexidine is mandated in and out for almost all of our operations and the patients all go through a standardized nickel bowel prep prior to surgery. Intraoperatively, of course, we actively warm our patients and we have the redosing schedule, which was not something we're routinely doing a year-and-a-half ago. Hyperoxygenation is another area that we're working with the anesthesiologists on to protocolize, as well as interoperative glucose control.

We do try and encourage the use of the wound protector for colorectal cases. I find that it actually helps me in laparoscopy when we do make the incision to expand the wound as sort of a mini retractor, as well as sealing off the subcutaneous tissue from seculent contamination. And we have a clean standardized fascia closure protocol. Again, postoperatively we're working on the warming device to carry through the operative experience. We have developed standardized wound instructions for the patients, which we really didn't have that long ago. Again, glycemic control is essential, and antibiotics are discontinued after a single dose, via our electronic medical record system. And we can probably anticipate that it will be expected that no postoperative doses of antibiotics will be the expectation in the near future. This is just a copy of the checklist, which I really do think is something that gets everybody on the same page. This is a nurse-driven checklist, and the operation does not proceed until the operating room is quiet and everybody introduced themselves and participates.

So one area of big effort for us was appropriate weight-based dosing, redosing of antibiotics, and appropriate selection. There were, I have to say, surgeons who just sort of made it up as they went along it seems, and we really had to work hard to kind of get everybody on the same page in terms of selection. And it took a lot of changing of old practice patterns, education of nurses, anesthesiologists, and surgeons. And we had to create a functionable and replicable process. So we'll go into a couple of the elements of what we've done. As I mentioned, we started with a nurse-driven selection protocol, which was a good start, as well as educating the entire operating room staff. But what really worked for us was to create a huge poster for antibiotic selection, and this gives the suggested antibiotics on our formulary,

certainly for the SCIP case and for other non-SCIP case as well. It also gives redosing intervals, as well as weight-based suggestion, and also highlights the antibiotics, which should not be redosed.

This is a poster that sits behind the anesthesiologist, and whenever there is a question, we can all go to it. And it's literature based, and we can all agree on what should be done. We do not, at Little Lutheran, have a software system on our anesthesia machines that reminds the anesthesiologist to redoes their antibiotics, so what we have done at the time of timeout we infuse the antibiotic, and after it's infused a timer, it's simply an egg timer, which is attached to the anesthesia machine is turned on, and at three hours, the device goes off and reminds everybody in the operating room that the patient needs a second dose of antibiotics.

Here is an example of our antibiotic selection poster, and you can see on the left in green are the SCIP cases, with the approved antibiotics that are on our formulary, as well as alternatives for beta actin allergies. On the right side are non-SCIP cases and their appropriate antibiotics. This portion of the poster reminds the team of redosing intervals, as well as the weight-based dosing regimen, and, again it reminds the team of the antibiotics that should not be redosed. This is what it looks like in totality. It probably is about a four-by-three foot poster, at least, and it sits behind the anesthesia machine, as I mentioned before.

So how did we do? In April we were down at around 20% of redosing, and with a lot of effort, we came up to about 80%, and, as sort of the Hawthorne effect died down, we dipped down. We had another round of reeducation. And my understanding is that the most current data has up in the high 90s for antibiotic redosing for cases that are longer than three hours. We also noticed that there are major opportunities for improvement in glycemic control. We took a look at the glycemic [inaudible] and the patients in our surgical ward, and we noticed a huge percentage of patients who had finger sticks that were above 180 once or on frequent occasions. And when we looked at why this was happening, it was clear that, really, the surgical team was only using a regular insulin sliding scale. And I think this is rooted in the fear of hypoglycemia in patients who are going to be on and off a PO diet, taken to the operating room, back and forth, may not be tolerating diet. It's also sort of a surgical culture, I think, and, again, a lack offal education on the importance of glycemic control.

So at our baseline, about 29% of our patients had finger sticks above 180. And the flip side of that is that very few of our patients were hypoglycemic, so we were trading hyperglycemia for lack of hypoglycemia. We began, then, to utilize an insulin protocol, which is simple, which uses a long-acting and intermediate-acting insulin, which is all weight-based, and a short acting correctional insulin. And we did see some improvements. I think we have a ways to go, but this has now become a hospital-wide effort. And, in fact, we have added a new nurse practitioner for diabetes in the hospital. And for a small hospital like ours to add a single STE is sort of a big deal. We have sort of a thin bottom line there, and this was just sort of a testament to the recognition of the need for a normal glycemia and the importance of our patients. We have a surgical ward nurse practitioners which alert our surgeons and the residents when patients re becoming hypoglycemic or are not placed on the protocol appropriately, and we have a daily hyperglycemia push report that's sent out top department leadership, as well as hospital leadership, to highlight particular patients that are becoming hyperglycemic or have frequent episodes.

We undertook a number of resident educational sessions, using our house endocrinologists, as well as the pharmacy, and industry as well. We've had a couple of ad hoc RCAs who are particularly problematic, and this has added a lot of insight as to particular problems that we can approach. And currently we are in the development of a hospital-wide much more in-depth protocol that is based on the work of Dr. Maynard at UCSD, and this protocol accounts for habitus, whether somebody is lean, has a normal habitus or is obese. It accounts for insulin naivety, what types of feedings they're on, and I think that we'll bring that into practice in the next couple of months.

So how did we do? The brown line on top is the patients who are normal glycemic, from 60 to 180. The blue line are the patients who have had episodes greater than 180, and what you want to see is those two lines separating. So we run a baseline, I think, probably in the mid-60s to mid-70s for normal glycemia, but with the institution of this protocol around October, we started to see some increase in our numbers of patients who are normal glycemic. I'm sorry, I don't have our most recent data, but I expect that this also be start to show a separation of these two lines. And what you can see on the very bottom, in red, are patients who are hypoglycemic. So, in fact, we did not produce more episodes of dangerous hypoglycemia, which is reassuring.

As I mention before, we instituted the use of Home chlorhexidine bathing, particularly for the bigger cases, colorectal cases, vascular, ortho, spine, for all the patients who go through our preadmission testing area. And, again, we mandated chlorhexidine skin prep prior to incision. And believe it or not, we did run into a lot of resistance from some of the surgeons about this because of that three-minute mandatory dry time. You would think that in a three-or four-hour long case that you wouldn't be such a big deal, but there was some outcry. But you can bring it into your workflow pretty easily. Of course, the hair is clipped not shaved prior to incision. The peri- and postoperative area of wound care, we do encourage the use of the wound protector. We do a lot of laparoscopy in our institution, and the Alexis wound protector does, as I said before, function to really hermetically seal the subcutaneous tissue away from and seculent contamination. And there is some pretty good data that demonstrates a benefit of the wound protector. It comes at an added cost to the procedure but not a significant cost. There's a larger product that can be used for the bigger incisions. It's a little bulky and unwieldy to use, but it also does serve to isolate the subcutaneous tissue away from contamination.

All our surgeons, students, and staff in the operating room double glove, and we have developed a clean standardized fascia closure. So at the time of anastamosis, a timeout is called, and everybody is brought to attention to the fact that we're performing the anastamosis. We isolate the instruments that are used for the anastamosis. Those are brought off of the field once the anastamosis is completed, and they're replaced as needed throughout the remainder of the case. After the anastamosis is completed, gloves, gowns are changed for the entire team. And, again, postoperatively, we have standardized wound instructions, and this is an example of sort of a checklist that the practitioner goes through to instruct the patients post operatively.

This is sort of our wish list slide here. So we do, in the interoperative area, actively warm our patients, but there's excellent data that shows that preoperative warming helps to maintain core body temperature during induction of anesthesia without a precipitous drop; therefore, aiding in oxygen delivery to the

tissue. So, again, we're in the process of working on that. This is just an example of one of the products that's out there.

So how did we do? We never had an extraordinary high rate of colon surgical site infections. We maintained a rate of about 2.5% to 3.5%, but with implementation of these processes, we were able, at lease for the last 14 or 15 months, to bring our rate down to 0.8%, with a single documented colorectal infection. It's interesting that this single case was one where Chlorhexidine was not used, the wound protector was not used, and the antibiotics were not weight based.

This is how Lutheran stands against the rest of New York. The hospitals that are participating in the Partnerships for Patients, Lutheran is down in red, with New York State being in blue line. So that's about it. I think it's possible to implement a functional colon bundle, even in hospitals that have inherent challenges.

So next steps, we're working on creating standardized colon prep instructions for patient and for provider. It's really remarkable how much variability there is in how people understand how the bundles should be produced and undertaken -- I'm sorry, how the bowel prep should be undertaken. Again, warming blankets are something that we're working on throughout the operative experience. Interoperative glucose monitoring, and hyperoxygenation are other areas that we're hoping to protocolize with our anesthesiologist. And the hospital-wide in-depth hypoglycemia protocol, I think will be very useful. And I think there's some opportunity to increase this process or to improve this process through the debriefing at the end of our case. Thank you very much.

And from the Canadian border and to get your poster and I already said that. Thank you Dr. Timoney. Pleased to present Dr. Mark Lema, chair of anesthesiology from the Roswell Park Cancer Institute. He is professor and chair of anesthesiology at the University at Buffalo, State University of New York. Dr. Lema received his medical training at Suny Downstate Medical Center and residency training at Brigham and Women's Hospital, Harvard University. He holds a PhD in physiology from University of Buffalo. He has lectured in more than 225 academic institutions throughout the world. He has authored or co-authored more than 175 scientific articles. He has served has the president of the Erie County Medical Society in 2011. He was the American Anesthesiology Society president in 2007. Thank you Dr. Lema.

Thank you, Maria. If I may have the first slide please, or we can just forget about. Is it me? I'm sorry. I beg your pardon. Here we go. That's easy. So I'm going to talk a little bit about the expanding role of the anesthesiologist, specifically in reducing colon SSIs. And I think you'll see throughout the short presentation of both the pathophysiology and physiology behind some of what we've been talking about today; that anesthesiology has been poised to assist in measures like this for quite some time.

Well it wasn't long ago, in the 1980s, where mortality from anesthesia itself was about 1 in 15,000 anesthetics. I went through that time. And both surgery and anesthesiology were focused, really, on the respective specialties. You might even say that they were two medical specialties divided by a common patient in the operating room, and then came along, around 1986, the combined Harvard University Hospital's adopted standardized monitoring, which was then quickly adopted by American Society of Anesthesiologists so that every operating room in the United States had the same type of monitoring

equipment. And over the decades what we had seen is that for ASA 1 and ASA 2 patients there's about a 1 in 200,000 morality from anesthesia alone. So that prompted the Institute of Medicine to actually cite anesthesiology 11 times in their quality report as being the model for safe practice in moderate to high-risk specialties.

Well anesthesiology has actually embarked on a new concept that is going to be tested, and I may say that the Mayo Clinic has taken the lead on this, and it's called the "Perioperative surgical Home." It's really the integrative practice model that's been proposed by the American Society of Anesthesiologists as potential solution to the disjointed and oftentimes costly perioperative system that we currently find throughout the integrated United States. This practice model is really defined, as most models nowadays, as patient-centered and physician-led in a multidisciplinary environment, and it's a team-based system of coordinated care that guides the patient throughout the entire surgical experience, and you will see a picture of that coming up.

They have five major goals using the perioperative experience as a portal and then identifying patients according to their acuity and comorbidities and risk factors in dealing with those appropriately. Of course, as we get more data-based evidence to suggest what appropriate clinical care would be, we would start delivering those protocols. We then would manage, coordinate, and follow up on perioperative care across all specialty lines, and then finally, as any program, one would have to measure and improve performance and cost efficiency.

So what it looks like essentially is the patient would be introduced to the process in the preoperative area and then would proceed through the interoperative, postoperative, and even long-term recovery, with the respective team members working in those areas that actually enhance this process. You can see the arrows down below leading to looking at quality improvement, what are best practices, of course, and then health-care analytics, taking a look at what you had seen earlier today by my surgical colleagues, showing a positive outcome data for the interventions that were made. And, of course, there are a number of micro systems that come in and out of the process for certain individuals, certain types of surgeries, and they are listed below, some of them obviously playing probably a greater role most of the time, and some playing maybe just a lesser role on specific patients.

So anesthesiologists, based on what they've been doing over the years and what their embarking upon, are really poised to play a pivotal role in the process of working with surgeons to reduce SSIs. The area specifically where anesthesiology providers can oversee and administer certainly include perioperative glycemic control. We do that at Roswell Park, up to the postoperative period. We look at perioperative normothermia. What Dr. Timoney showed are two devices that we actually use in the operating room and prior to going to the operating room. Perioperative tissue oxygenation is something that I think is sort of a new concept, and I'll go over that, at least in terms of actively delivering care to try and elevate tissue oxygen levels, and then the interoperative and postoperative antimicrobial prophylaxis, again, that's one of those metrics that we've been looking at for quite some time, and proud to say that we're in 95-plus area for that metric, and probably even higher at this point.

Well, again, this is nothing new to anesthesiologists. Here is a 2006 article in anesthesiology and it basically shows six factors where anesthesiologists can play a role in reducing surgical-site infections.

And as you can see, this colorectal bundle pretty much incorporates four of the six that anesthesiologists identified as helping in the over all perioperative scheme for all of surgery, and we'll briefly go over those in the next couple of slides.

In addition to that, the American Society of Anesthesiologists has produced and continues to update their recommendations for infection control for the practice of anesthesiology. It's in its third edition now. And except for the hyperoxygenation concept, the other three elements have been part of the recommendations for quite some time. So in most anesthesiology departments, and I'm always reminded if you've seen one anesthesiology department you've seen one anesthesiology department. They're that different. But in those that are organized that may have 400 or even 20 anesthesiologists, oftentimes you'll have a critical mass of providers so that you can implement some of these policies.

So with glucose control, the ASA recommendation, obviously considers diabetic patients to be at high risk and that this should be addressed preoperatively, and one should really seek to avoid the obvious, which is perioperative hyperglycemia. I think it may be obvious right now to us because we're in this program, but I think prior to the adoption of a lot of these new protocols that this was something that was casually addressed. The rationale, as was stated earlier, was that the increasing levels of hemoglobin A1c correlate with increased surgical site infections and that extreme hyperglycemia in the perioperative period has been associated as well with SSI risk.

Now this gives you a nice cartoon of what normal glycemia does. As you can see on the left side of the screen, the vascular system is used by the polymorthonuclear leukocytes to actually go to the wound site. That's supposed to be wound there, as you can see the retractor on the lower part, in case you were wondering what that was. But anyway, it chemotactically draws the white blood cells there, and then, of course, what we'll see are complement factors and immunoglobulins providing their role in the adequate treatment of any invasion, specifically bacteria in this case, to try and clear the area and prevent expansion of bacterial growth.

Well it's been described earlier, and we'll go through it very quickly, that diabetic patients certainly are at risk. We know that. And specifically they have impaired chemotaxis, and the chemotaxis is one thing, to get the white blood cells there, that's a chore. But also, when they're there, the white blood cells malfunction if you will, because increased phagocytosis of the bacteria, and they ultimately have low bactericidal activity. The glucose is a particular problem, and that a study on healthy adults showed that a glucose challenge showed a transient reduction in polymorthonuclear leukocytes at all lymphocyte subset counts in these patients in a transient way.

Hyperglycemia is known to deactivate immunoglobulins and actually blocks complement C action and insulin infusions work better as a sliding scale. There's a 66% reduction in sternal surgical site infections seen in cardiac patients, and those are the two studies there that you can see, and the others are if thoracic surgery, again quite some time ago, 1997 and 1999, to show the benefit of assiduously looking at glucose control.

Well the second part of that cartoon now, you can see fewer leucocytes in the area, and you can see that this immunoglobulins and the complement are blocked by the glycosylation. So in this regard, we now

start to see at least physiologic and pathophysiologic evidence to suggest that this isn't just a clinical observation but actually there have been scientific studies to show the benefit of monitoring this.

Well with respect to normothermia, again, it's fairly obvious but the American society of anesthesiologists recommend that we avoid hypothermia or putting in a more positive way, we promote normothermia, and what they described as hypothermia is anything below 36 degrees Celsius. That has been associated with increased SSI and the study by Kearse, which we'll just go over very briefly, really speaks to that. But what we specifically see with mild hypothermia is that vasoconstriction and decreased oxygen delivery to the wound space occur, and subsequently, impaired phagocytosis leukocyte function, which is oxygen-based, results. So this was the study by Kearse that was mentioned by Dr. Cima, and we're not going to go over it again. I'm just going to point out that under the results, hypothermia was 34.7 in these patients, versus normothermia, which was 36.6. And as was shown, 18 of 96 in the hypothermia group versus 6 of 104 in the normothermia group, had infections, and as Dr. Cima showed, it was almost 6%, versus 20%. What I'd like to expand on was that sutures were removed one day later in the hypothermia group, and 20% of the hypothermia patients were discharged two to three days later.

There's sort of a triad that's really hard to separate, and that is hypothermia from hyperoxia and in the Marman paper in Anesthesiology in 2006, there is a major relationship between hypothermia and increased SSI, as was stated. And it it's, thought, really to be do to decrease in the subcutaneous tissue profusion mediated by that vasoconstriction. So these are sort of tied hand in hand. If you're cold you're vasoconstricted. If you're vasoconstricted, you can't get as much oxygen to the area where you want to go. And providing adequate oxygen delivery obviously would, then maintain, as I mentioned, this oxidative killing by neutrophils. So patients with subcutaneous, which is a tissue PO2, greater than 90 millimeters of mercury had no infections in the study that you see below by Hoff. While those with a tissue PO2 of somewhere between 40 to 50 milligrams of mercury had an infection rate of 43%. So I think that's where this whole concept of trying to promote as high a tissue oxygen level to the effected site will have benefit in reducing surgical site infections.

Well the other problem is that I said there was a triad. We talked about hypothermia and hyperoxia, but what about hypothermia and hypovolemia, which is not uncommon in the post-surgical period? So hypothermia causes vasoconstriction, as we said, which produces inadequate tissue oxygen in perfusion and reduced neutrophil migration. But blood loss and hypovolemia also leads to inadequate tissue profusion, so it's a double whammy, if you will. And overall, less oxygen and lower leukocyte migration will reduce the bactericidal effect by the neutrophils, subsequently resulting in bacterial infection. But if you're able to maintain normothermia, euvolemia, and some type of hyperoxia, one obviously will correct the deficits, and bacterial growth will be thwarted to a greater degree.

So this, again, was a study that Dr. Cima had referred to, and it was the database study that looked at patients from Medline [inaudible] Cochrane Collaboration. And this is not an easy study, as he alluded to, because they looked at over 2,100 articles and they could only find five randomized control studies that applied to this objective. Fortunately, they had about 3,000 patients, so it at least gave some credibility to the meta analysis. And what they showed was that in the control group there was about a 12% incidents of surgical site infection versus 9% in the high-tissue oxygenation, and you could see the recovery rates being 25% and 3%. In conclusion, they said that significant beneficial effect was seen in that they

recommended its use. But, again, I think it's somewhat equivocal as to just what the benefit is. And the problems with the study, of course, were variable use of antibiotics and blood loss among these studies were quite different. There was no standardized definition of infection, and significant improvement in all but one study showed SSI rates were increased. So, again, very negligible in terms of its benefit.

This isn't meant to be read, but we have also developed an antimicrobial prophylaxis for all of our surgeries at Roswell Park, which are almost exclusively oncology. Certainly it can be made available to those who have an interest in it. And this sits on the anesthesia machine so that it can be referred to at any point. We have another low-tech method of making sure that we redose, as some of you might have been on the webinar before, one can simply use two-inch take and put it on the anesthesia machine and write the times down. Again, anything that works. I like the idea of the timer. I certainly like the idea of having the system itself, Pisces, or whatever you're using, prompt you and nag you. But absent those, you shouldn't have a problem in figuring out some low-tech way to redose for antibiotics.

So, in summary, anesthesia personnel can play a key role in the perioperative setting to help surgical patients and surgeons in reducing surgical-site infections. And there are six ways, as I pointed out, where SSI reduction may be accomplished by prophylactic maneuvers by anesthesia personnel. The evidence in some of these areas are so strong that they've become quality measures. And as always, team work and effective communication among caregivers are essential for optimal patient outcomes.

Now before I close, the one thing I want to mention was the delivery of an FiO2 of .8, and there may be some confusion. I don't have a slide for it, but it's very easily discussed. If you're delivering a hundred person oxygen by nasal cannula you shouldn't be misled into thinking you're delivering 100% FiO2. The most you can deliver is probably somewhere between 28 or 30% delivered oxygen through naso cannula, and that's hoping that the patient isn't a mouth breather at that point. So you might want to then take the green mask with the holes on the side and put that on. Now you'll get the FiO2 somewhere up to 40%, and please don't cover the holes because then they'll be re-breathing CO2. Remember, respirations do two thing, it provides oxygen but clears carbon dioxide, so you don't want to stop carbon dioxide from escaping. And there's a certain amount of re-breathing of entrained air through those holes.

So to deliver enough FiO2 of .8 one probably will need to have a non re-breathing mask, and I think for those of us who use those or have used those, those aren't the most comfortable for patients in the perioperative period, or intubate them, or keep them intubated. That's the other way of delivering 1.0. So I think we're challenged by this high delivery of oxygen, and we'll certainly figure it out. But don't believe that just turning the oxygen on you're going to get these high FiO2s, and FiO2 is not PaO2, because there are a lot of people walking around with arterial oxygen levels of 100% breathing room air, and that's 21% oxygen. So I'll end there and turn the podium back over to Maria. Thank you for much for you're attention.

Our next section of program is actually open panel discussion for Q&A, as well as we'd like your feedback about the gap analysis. So we have a polling question. The remote location that are see this via web stream are also going to do the poll. And the question is, What did you identify as the key area of improvement in your facility? Is it glucose control, normothermia, antimicrobial prophylaxis, skin prep, increased perioperative oxygenation, clean standard fascia close or standardized wound management." And I'm just going to ask those in the room to raise your hand if it was glucose control. Good number

there. Normothermia? We have good control of normothermia in Syracuse. Antimicrobial prophylaxis, whether it be dosing, redosing times, any of that? A little there. Skin preparation? Increased perioperative oxygenation? And standardized wound -- I'm sorry, clean standardized fascia close? And then standardized wound management?

Do we have response from the other sites just yet?

Actually the Canadian Borders facility is going after number three, antibiotic prophylaxis.

Okay. So I think here in Syracuse we had a clear increased number around glucose control, and I thought if we could ask our esteemed panelists to each address some ideas around glucose control that we haven't talked about, or possibly some barrier that is might make the management of glucose control a little more difficult.

Well that's actually -- I went into a huge initiative we ear undergoing right now, or have been going for the last 18 months. The big concern is making sure people know what they're supposed to be doing, and avoiding hypoglycemia. Of all the things that we can do in a surgical patient, inducing hypoglycemia is perhaps the worst. It's significantly associated with really bad outcomes. Like it's one of the major predictors of mortality in surgical patients. But we've gone to basically, as Dr, Timoney talked about, where we've gone to using asbark [ph] how we deliver, did the type of intermediate acting agents. We are introducing probably in the next few months, basal bolus mechanisms, which is trying to make sure patients, every morning, get their basal-type insulin and avoid sliding scale. There's some more recent data suggesting that it's the variation -- not perhaps the absolute number but the variation and swings in glucose that actually make things -- are associated with bad outcome. So using a basal bolus approach, which requires education of the nursing staff, requires a sort of standardized dosing, requires carb counting in the hospital, so you have to get dietitians involved, you have get nurses educated on carb counting, and residents, and figure out how to do it, so there's a lot of things.

But a couple of things we're doing is hospitals in general don't do a very good job of really identifying diabetic patients. Even when we started our audits, we had 10% of our patients showing up to the day of surgery saying they were diabetics, and we did not have documented in a way that was easily attainable for our pre-op nurses. So that was an issue. Getting A1c's own every diabetic patient, we were at about 33 or 34%, I think, in our initial audit in getting A1c's within three months of surgery, so that was a big goal. Getting good documentation of what patients are doing for their insulin. Unfortunately, in a lot of patient populations, and I would imagine in New York with your population, it's very difficult. You know, insulin, insulin testing strips, those are expensive, and if you have uninsured population or Medicare population they may be checking their insulin on a once a day maybe not basis, and so you don't have a good idea of where they should be as far as insulin control. And that's a hard thing to recover. So those types of things up front, as much as you can do up front is going to help you in the long run, and that's where we're focusing our efforts.

Did you want to say something?

Well obviously it's easier said than done, and some of the things you need, certainly you need a cooperative pharmacy so that when you need the insulin it comes up in timely fashion. You need pumps readily available in the operating room. You need Glucometers so that you can take the glucose blood glucose when you need it. And when you have a glucometer, then you have to be certified by the hospital, so you have to do an annual in-service. So there's a lot to it. And then, of course, once you've put all that together, you have to measure it, and that clearly if you want a Hawthorne effect, just put a list of services and show their compliance and that probably is the single-most important factor that will get compliance, because no one wants to be at the bottom of the list. And that's what we did at Roswell Park, and I think it's safe to say that everyone's onboard and they take it very seriously, and we had a glycemic control ad hoc committee and still have it that show monthly -- near monthly statistics, and our intensive care unit physicians oversee that. But, again, Roswell Park is a different place, so you have top do what's right for your hospital, but that's one way of doing it.

I think that our efforts have been very gratifying in our hospital in terms of developing a protocol and implementing it, but it's extraordinarily challenging. There are so many components that enter into it. For example, what time the patient gets their finger sticks, what time this is reported, and any sort of lag between that time and when the patient is going to be administered some sort of insulin. So there are huge amount of logistical problems in developing a protocol for the inpatient. But I'd like to throw questions -- a couple of questions at Dr. Lema and Dr. Cima.

In your practice do you have any sort of thresholds at which you will not operate or you will, you know, intervene in some way; for example, if you an extraordinarily hemoglobin A1c, or if the patient comes to surgery on the day of surgery with a glucose in the 300s or so, do you have any sort of protocols in place for those patients?

Yeah. For elective cases, of course.

Yes.

This is all elective cases. For elective case that's going to involve an implantation like a prosthesis or something like that, if their A1c is greater than eight, they get shunted off to endocrine. We just don't do the procedure. If they show up the day of surgery with glucose greater than 300, they're seen by our endocrine or diabetes consulting service in the pre-op area. Their case is delayed, in conjunction with our anesthesia colleague surgeons and the endocrine people. If there's a driver for this, they understand it. If the patient didn't do what they were supposed to do, were have data on their A1c, then they may very well be cancelled or they may be delayed and instituted on a drip. We will use an insulin drip very quickly in these patients and put in the appropriate monitoring and everything.

As you said, the big issue -- one of our big issues was our anesthesia colleagues were, "Well we can do all this stuff." But if they need the recovery room, they just go to the floor and get not treated, why do it. And so you really have to have a comprehensive approach to it. And if there is a going to be an insulin drip, can you do an insulin drip on the floor. Can nurses manage that? Do they have to go to a monitored setting? Then you get into all these logistical areas. But, yeah, we have monitored very strict -- that even goes to smoking in some of our cases. Like I was saying earlier, if a patient is going to get a

reconstruction and they're going to get a skin flap, we check nicotine levels and we tell them beforehand, f the day of surgery you get a nicotine level and it's back, you're not going to getting surgery. It's part of the patient being engaged in their care. We know what the bad outcomes are. We know they're devastating to the patient and the institution, and we tell them. If you tell them the expectation up front, that's what you have to do.

One of the advantages of being a subspecialty hospital is that you can develop programs that are specific, you know, for your patient population and we have a preoperative testing center. We've had one for quite some time that's run by the anesthesiology department. So we can identify these patients in advance and actually order fasting, you know, blood sugars that are on the chart by the time we see the patient in the early morning. So that's real big boon because it's been addressed in two areas, now; one preoperatively and then early in the immediate preoperative process on the day of surgery.

I would say 300 is about right, but it's sort of a situational decision, as Dr. Cima said. People come from far off. We obviously are a smaller program that can follow patients in a postoperative way. If they're going to the intensive care unit we know they're going to clearly be on insulin protocols. But I would say that 300 would raise a red flag. Certainly if they came in that day of surgery with let's say endoscopy with a glucose of 300, we probably would have a discussion with the surgeon.

All the other sites across Upstate New York and glucose controls did come in high for some of the others. But there's a fair amount that came in for skin preparation as well, and a fair amount, especially from the Albany site, that came in for the clean fascia closing.

Would you like to address any of those things in any particular order; clean fascia close, skin prep?

I would say the skin prep one is -- I mean you have to just figure it out working your system. I think the data really are there to say that a alcohol-based preparation, despite the three-minute dry time, which I have heard, too, is a big issue, is one of those low-hanging fruits. Now there is a cost to that, both whether you go with iodine-based or alcohol-based, they're more expensive than just doing a Betadine wash and prep. Probably, you know, $5 or $6 difference per case I would estimate, depending on the contracts and stuff. But I really think that the literature out there is that an alcohol-based preparation is preferred in all procedures below -- without any mucosal membranes exposed, so below the neck and above the perineum. And an ostomy does not count according to the manufacturer. So if they have an ostomy, you can still used an alcohol-based prep, as long as you put a gauze over the ostomy site and don't paint over the stoma. So I think that's really going to be.

I'm sitting on the NQF. We're going to be meeting at the end of this month about the new surgery maintenance measures, and I haven't seen all the measures, but I bet you there's going to be a measure about using an alcohol base prep in the near future as a quality metric, so I think that's going to be coming. As far as the fascia closure, you know, there's always a lot of resistance to that. There's always a lot of discussion about that and about stopping and breaking. And you know, it's one of these things where it sort of makes common sense. The data out there is very limited on whether or not, so if people are going to start saying, "Well I want level-one evidence," there's never going to be any, and the cost of it. But I can tell you, we instituted it for all of our colorectal cases. We had to buy, in total. $14,000 worth

of equipment and pans. But those things are going to stay there for, like, 20 years probably. You know, those forceps don't go out of style, so you amortize that over you know, long cases, that's not a huge total investment, if it reduces SSIs. So I think the skin prep is going to be forced upon everyone. I think probably for good reason. The fascial closure, I think, is a tougher one to sell to people just because it's a major change in practice. But I think it's worthwhile. Certainly, our team has bought into it, but I think that's what I can say about those.

I agree. I think it's almost empirical that isolating the instruments that have been used for anastamosis away from the rest of the operative field just does make good common sense. Regarding the use of Chlorhexidine at home, again, you mentioned cost, and it really is nominal, and it's not added onto our patients at least. We provide this for them. You know, I think, for us, another area of concern and that we're going to working on is joint, and there's good literature out now that does show the benefit with home Chlorhexidine washes for, I think it's two days prior to surgery. So I think that's another thing that we can probably look forward to.

Is there any questions from the audience, please.

[
[Inaudible]

Yeah, irrigating a wound is standard, whether there's good data on it. Now there is some data that says that continuous antibiotic irrigation in multi-trauma cases reduces the incidents of intra-abdominal abscess forming. Now is that the same as elective, open the bowel to do the anastomosis, where the bowel is open for, you know, three minutes and there might be a little bit of spillage, did that equate with having to put drains in and having to do antibiotic irrigation? I don't think anyone would. I think that is one of those areas where, I think, most people do do irrigation, because, clearly, there was a look at using saline versus antibiotic irrigation. There's a number of studies that have looked at that in big groups of patients and didn't find any difference.

There are some smaller studies out of Europe that looked at if you used antibiotic irrigation, what type of abscesses formed, and they were different. And so there's a thought that maybe there is some benefit to what the organisms you grow out. But it didn't overall reduce the number of infections. The absolute number, the percentages were about the same, but the types of organisms that grew out were much easier to treat than the other ones, so I think most people would say good sterile technique, avoid contamination, and just make sure there's no gross contamination and irrigation would be normal. Then there's another group of people that say irrigating the abdomen is bad, so I don't know how to sell that.

I know we routinely use about a liter or two of saline after each case and wash it out. But if there's gross contamination, that's a whole different story throe. But for elective case I think basically good sterile, good technique, isolating technique, and we pack around the bowel when we're opening it, rather than just open it directly. So I think those are things that probably are equivalent.

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I agree with you. I think the literature for antibiotic irrigation is not that compelling. But at the same time, it's low cost and absolutely low morbidity. I don't think it's go to breed resistance, necessarily. So I think in our institution we just sort of leave it at surgeon preference.

If you're trying to push tissue oxygenation, I'm just curious from the panel what level of hemoglobin would you tolerate In a major abdominal case?

Well if the finger is a hundred percent oxygenated with the existing hemoglobin, that's probably adequate, so it's really hard to say. I think if you're at a point where you can't profuse because you don't have enough blood, I think that would be reflective in your PaO2, because, clearly, the body is going send the oxygenated blood to the organs that need it in a flight or fight or endocrine kind of situation. And generally the index finger or whatever finger you're using isn't essential to fight or flight. It's usually the heart, the lungs, the musculature. So that's really one level.

Now the question that you're asking is, I think, not just about blood but rheology, you know, how much hemoglobin can you get to the tissue with a carrier solution, whether it be diluted, you know, serum or plasma with whatever collate or crystalloid is being used. And I think it's safe to assume that as long as you keep your oxygen saturations up whenever you measuring them, that really warming and as close to euvolemia as you can determine will be the factors that are going to determine actual tissue oxygenation. That's the best I can answer that. I don't know if my colleagues have a better explanation for it.

I don't know if I have an explanation. We did sort of look at this as an understanding where there was this sort of belief that you had to have a hemoglobin greater than ten, and residents were transfusing and all this stuff, and we were looking at a blood utilization. As an institution, we use more blood than some states do, unfortunately. And that's a huge driver of costs. And so working with our colleagues in cardiac and pulmonary and hematology and everyone, we now have basically a threshold of eight grams, unless, of course, the patient has bad cardiac disease or something like that. I mean it has to be individualized. But basically if a patient is up on the floor and the resident all of a sudden orders a unit of blood, if they don't have a baseline hemoglobin less than eight and there's the vitals and everything look fine, they're going to get a call from somebody in blood bank and say why are you giving this blood, because, you know, there's no indications. So we use the same thing in the OR, basically eight the cutoff.

I agree with you.

I think you also have to take into account, particularly in colorectal cases, colon cancer case, that transfusion becomes an independent risk factor for negative outcome. So I think you have to be really, really careful when you're transfusing these patients.

[Inaudible].

Well it varies depending on what the -- we actually look at the PaO2 more than the FiO2. But I would say we generally have somewhere many between 50% or below, because we usually have -- I should say 50% or above, I'm sorry. Because we usually have a 50/50 mixture of oxygen and air. So obviously you have a little bit more oxygen delivery with the 50%, certainly given nitrous oxide where there's no oxygen,

and it would be 50%. Sot's a little higher. So I would say somewhere between 50 and 70%. It's not something that in all cases the FiO2 is important. It's usually in trying to maintain the oxygen saturation.

I'd like to ask Dr. Lema a couple of questions regarding hyperoxia. Some of the resistance in our institution is the notion that hyperoxia is going to lead to atelectasis, which will lead to postoperative pneumonia, and I wonder if you could address that question. And the second question is, are you routinely taking ABGs on these patients, you insert an A line prior to surgery?

Well I think, first of all, I'd like to say that we haven't really looked at hyperoxygenation. I'm not up here promoting hyperoxygenation. It's something that, to be frankly honest with you, when this was rolled out it was introduced, and I'm looking at it now, so I'm almost -- I'm as new to this as you are. I think most anesthesiologists, nurse anesthetists, and recovery nurses will clearly look at oxygen saturation as being the indicator for adequate tissue oxygenation. Whether that's true or not remains to be seen, and this concept of hyperoxygenation at a .8 FiO2, at least as I understand it, really looks at a different concept in the delivery in the postoperative period, which means you're going to have to use devices that you probably aren't using now to deliver that, and you're going to be looking at FiO2 irrespective -- not totally irrespective, but irrespective of the PaO2. Because the PaO2 could be a hundred percent on 40% oxygen, you know, and you're going to drive it to 80% oxygen is still going to be 100%. And in that respect I would say, then, it's really going to be FiO2 driven. And the only way you the look at that are ABGs, or there are some transcutaneous measures for oxygenation that parallels arterial blood gas, but that's a whole different expensive technology. So I think it's going to be done empirically to be honest with you.

I think, if you think about it in this miss quip era coming up, outcomes are going to trump level 1A studies. There's no two ways about it. And people aren't going to necessarily care what the measurement is, but if you start to see a reduction by using .8 FiO2, it's like the parachute analogy, they're just going to do it.

Yes, please, you bring a mic. I'm not sure you get broadcast without being on the mic.

I'm just wondering is there an end time with the warming blankets and the bear and the air huggers? I mean is it just to PACQ? Do we want it to go back to the unit for a little bit, then we worry about the patient's temperature going in the opposite direction?

So most of the literature is interoperative data, so not what they did in the recovery room. The interesting things about these newer technologies is the patient control once they're awake. They actually have a little rheostat on it so they can turn it on and off, which is what they love and is a huge driver of satisfaction. And so they can actually cool it down -- not cool it down. There's not an active cooling component, but they can lower the heat, and so we're transitioning them all the way up to the floor, and patients will keep them on for a couple days, you know. So they're water resistance and -- not water -- stain resistant and stuff like that. The big thing is blood doesn't come off of them. So, you know, if they somehow get contaminated they should get a new one, of course, but the patients actually are carrying them. All our outpatient procedure patients, they put them on. Most of our outpatient rooms the patient stays in the same -- the chair that they get into it actually folds out into an OR bed, so they actually get moved into the OR beds, and then they come back out and they're sitting in the same chair. And basically

they wear that device the entire time they're there, and then when they get up they take it off and they're out the door. So they really like it.

I might to add too, I'm sure there's a number of people in audience that probably already know this, but one can actually use the gown for a heating device in the operating room as well on certain shorter procedures, such as breast biopsies, et cetera, by just lowering the gown below the surgical site area and continuing to heat the patient. So there's a bit of a savings there, and then, of course, put the gown back on Dr. Cima said. So there can be some cost-effective measures.

I'd like to start talking some questions from the different sites. We have a question that came in on eating and some recommendations about when to get the patient, you know, fluids and food starting to happen.

Yeah, we had trouble hearing. Did you say eating?

Yes. I'm sorry. Postoperative, when did you start feeding the patients?

That's a whole different topic. s I mentioned a couple times in our talks, we use an enhanced recovery pathway, and we don't -- all right there so there's a couple things. We don't have our patients not eat the day before. We have them have regular meals up until dinner. We don't do bowel preparation, so, again, you're going to get into this issue of bowel prep religion versus non-bowel prep religion. And we start feeding our colorectal patients in the recovery room. They wake up, and before they can leave, they get Graham crackers and water in the recovery room with oral pain medication, Tylenol. And that was actually a collaborative effort with our anesthesia colleagues, because we were asking them to change their -- we give them preoperative preemptive pain medication. They change somewhat their anesthetic in the OR, but it was only going to be predicated on the fact that we wanted to give oral pain medicines in the immediate post-op area. So you can't give a patients, you know, narcotics, oral narcotics on an empty stomach. I mean you can, but it doesn't work very well. So our rule was, all right, we're going to change our practice to accommodate multimodality pain management. And it's been -- I can tell you I've lived through the introduction of laparoscopic colorectal surgery, and I thought oh, -- everyone thought it was going to be transformative, and it wasn't. This is transformative, it really is, this, to my eye, my career, this has been the biggest benefit to the patient and outcomes that I've seen, is complete transition in how we care for the patient. So 88% of our colectomy patients never see IV narcotics once they leave the operating room. So that's a huge boon for our nursing colleagues, for the patients. So you have to be willing to change everything to do that. But we start feeding in the recovery room.

That question, that was fascinating. We have another question that came in from the Buffalo area about antibiotic irrigation into the wound.

I think we sort of talked about that, but, again, I don't think there's really great evidence that supports it. There's also not great evidence that speaks against it. So I think until something really definitive comes out, it's really dealer's choice as far as I'm concerned.

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We have another question that came in that ask that you just speak about the environmental pieces. We know that they're important. It was mentioned in a number of your different speeches. But do you any particular focus on environmental issues?

You know, we sort of presumed in our institution that there were very standardized procedures happening for cleaning the operating room, and there were. But we certainly did recognize opportunities to improve our terminal cleaning for every single operating room every single day. When we looked at our wound infections, I mean at least in hospital, we did not find particular environmental factors that were at play. There was no particular operating room. There was no set of instruments. So I mean it really, for us, has, more than anything, come down to technique and these other elements of the bundle that we talked about.

But one subtle point, some hospitals rotate their housekeeping staff, and that can be problematic. I think a dedicated housekeeping staff for the OR is important, and now that we're starting to look at surgical-site infections as miss quip data, the continuity of the cleaning process will become quintessentially important. I don't think you want people rotating from, you know, cleaning in the ambulatory waiting room and then coming in and cleaning the operating room.

I will make one point, if I may. We did recognize, again, some other opportunities in the joint world for improving the environment. There was a certain amount of traffic in and out of the operating rooms, so now when joints are being placed we have sort of, I'd like to say velvet, but they're not velvet, ropes that go in front of the operating room inside and out, so if you try and open the door you're stopped. We also saw that a lot of the staff were running around the OR in surgical gowns, which sort of blow behind them and, at lease in our minds, create sort of a turbulent air flow, and so we've updated those in the operating room. And everybody who wants to wear something to warm them in the operating room is given a sort of a surgical warm up to prevent that sort of trailing air flow behind the staff.

An interesting idea. Another question came in from Albany. One of the hospitals is getting resistance in chlorhexidine in terms of resistance, like, almost like an antibiotic resistance, but resistance to the antimicrobial.

So Chlorhexidine works by -- it doesn't interact at any physiologic level. It actually disrupts cell structure. Those types of agents are very hard to develop resistance to, and so it's a chemical sort of like alcohol in the sense of how it works. There is some sense out there, though, that it's effectiveness might be declining a little bit, but CDC still maintains that it's very effective, and so you don't develop resistance like you do to antibiotic. It's not a genetic alteration that fights the antibiotic, so it's theoretically it's possible, but the organism would have to completely redesign its cell structure, and so it's unlikely that those organisms are going to spend the energy to do that, so that's why the CDC says the chance is negligible.

Okay, and then last question that we have right now came in from Buffalo. I'm not sure exactly what they want, but they're talking a little about can you talk a little bit about the timing of the antibiotics, and I assume both the pre-op administration, as well as redosing.

I'll talk about it a little bit, at least in our hospital. I mean routinely, we infuse antibiotics just prior to incision. And, you know, you think about antibiotics working best when they've reach their maximal tissue profusion, but the data is pretty clear that you don't necessarily have to infuse the antibiotics one hour prior to incision. It can be given just before. You know, within a couple or a few minutes of incision. One area that has proven problematic for us, and maybe Dr. Cima can talk about it a little bit, is patients who require Vancomycin. You know, that does require some period of time prior to incision in order to prevent Red Man Syndrome, and in order to gain adequate tissue profusion. So, I'm sorry what was [inaudible].

The point you raised about discontinuing, I think, is going to be a big issue coming forward, you know, about not doing post-op antibiotics.

Well before I get to that, I mean we tried to simplify our intraoperative protocol, so we sort of split the difference. The redosing is based on half life. We use a couple of different agents that have different half lives. Rather than asking everybody to remember which agent requires redosing at X time versus Y time, we sort of made it X plus Y times two divided by two, so everybody gets redosed in the same timeframe. And, yeah, there is no, as Dr. Cima is alluding to, there is no evidence to suggest that postoperative prophylactic antibiotics has any benefit in terms of surgical site infection. Getting people to really understand that and buy into it is hard. So in our hospital, we limit the post-op antibiotics to a single dose. I really sort of see that as a weaning process toward know antibiotics postoperatively.

Yeah, I think that's going to be a big issue moving forward. Right now the SCIP literature, the SCIP requirements say within 24 hours. It doesn't say you have to give it. It just says it has to be discontinued. A lot of surgical practices around the country, the way they sort of negotiated this was, well, you can give it up to 24 hours. The CDC and a lot of the infection societies -- there's like three different major ones -- have been pushing, for a long time, for antibiotic stewardship, the fact that you shouldn't really even be giving any post-op antibiotics. The only place where it's actually been of marginal benefit has been cardiac surgery for sternal wound infections, or so they say. So I hate to think within the next few years there may be a national push, because, again, as I mentioned about antibiotic resistance and now the WHO getting involved, that antibiotic stewardship is going to be a huge issue for hospitals, and I think there myself be a push to say no post-op antibiotics, and we'll see how that goes. Because like I said earlier, never heard surgeons complain about not giving antibiotics, and when they're told not to I'm hope to be retired from my current position when that has to happens.

WE do have a couple comments.

Yes, I have a question. I'm curious to know about the role of pain management intraoperatively, immediately postoperatively, and then, of course, the next few days. To what degree do techniques in pain management influence or inform this discussion, not just from patient satisfaction but from objective data regarding outcomes?

Well this is the next iteration, part of the surgical home concept deals with that, is to keep pain service. The evidence is increasing to show that, in cancer specifically, certain cancer types will actually respond better in terms of tumor recurrence if one uses less opioids in the perioperative period, specifically breast cancer and prostate cancer. And the studies that are limited but nonetheless out there can show as much

as a 47% reduction or four-fold reduction. You know as well as I do that in the court of public opinion you don't need a lot of those studies for people to start demanding that they don't want opioids in the perioperative period, et cetera, et cetera. So that's one of the reasons why looking more at continuous infusion, peripheral nerve catheters, tap blocks, trance abdominal blocks are going to become more important in the perioperative period, and the opioids will play a lesser role, marketed lesser role intraoperatively and postoperatively, and even post discharge. And now with intravenous Acetaminophen, that's going a long way in reducing the opioid use. So I think that's about ready to break open probably in the next two to five years.

Very interest. Another question from Albany. On the outpatient center, the COPD patient, particularly in regards to O2 management. They're really asking any suggestions for pre-op management or inter-op? Do you do ABGs,? Do you require pulmonary function tests, that kind of thing?

What type of -- I didn't --

The asthma or COPD patient.

Oh, COPD, I'm sorry. Well, again, I think it's situational based, depending on what type of case you're doing. That's always clinical judgment, in my opinion. There are people who can be very ill and, you know, they have paronychia, and they're lancing that. I mean you're not going to go do a full court press to make sure that their oxygenation is fine. On the other hand, you have a patient who is undergoing a major abdominal procedure and you're going to have an arterial line in that patient, monitoring not only beat-to-beat blood pressure variability, but also samples should you have problems interoperatively. So, again, really and there's a constellation of factors and that's probably best done by sitting down with the personal that are involved in those cases and saying what works best. So it's really a specialty-by-specialty and then a case-by-case scenario, as I see it.

[Inaudible]. One big question, I mean we're talking about antibiotics given to humans, but I think the major issue of all the resistance that we're getting is the antibiotics that are giving to animals. I mean we're going to try to reduce the problem, but then if you have another hole somewhere else, as much as we can reduce the use of antibiotics for humans, if we're using it in an indiscriminate manner for animals, including all the antibiotics, including Ciprofloxacins and all this stuff, you know, we're not going to solve the issue of resistance -- you know, drug resistance or bacteria. And I don't know if we can do something on that.

Just as I'm sitting here thinking about all this, what percentage of wound infections culture out skin versus enteric organisms in colorectal surgery? Because there's a lot of attention to skin; showers two days later, every day, and I would think by 48 hours, the wound is sealed and, you know, what happened was interoperative. So I just don't have -- because so far I grow out from my wounds is mostly E. coli or some other gut organism. It's not usually staff or anything like that.

It's actually interesting though, in colorectal cases they've looked that. So there's a couple things. And this is one of the big things about mal preps, was, you know, when you're purging yourself there's organisms that get everywhere on your body. It's well documented. And they've actually looked at it. So you're right

most things aren't staff that grow out of wound infections. They're mainly contaminant. They're main bowel flora. t turns out, if you look at colorectal cases and you swab the skin during the case, you end up getting E. coli an stuff from the skin. So you're basically preparing the skin and the Chlorhexidine, like I said, has a lasting power, bactericidal power for about 48 hours, so it is a technique thing. It's about contamination from what you're doing from a surgical case that actually is what is inoculating that wound. So I think that's why you see a decrease.

Even though you're focusing on cleansing the wound, you're not focusing on cleansing the wound of all the normal wound organisms. You're actually preparing the wound for contamination and reducing the degree of contamination that can cause problems. So that's how our ID guys look at it when we talk about prophylaxis. They're saying you optimize everything you can, because no matter how good you are, Cima, you're still going to contaminate that wound. And we want to prepare the wound so that it can withstand that insult. And the more you can be technically skilled to avoid contamination, fine, but these other things are what's going to drive, because these types of organisms are not used to that harsh chemical environment. And so you're right, most of the wound cultures are organisms of bowel flora because of what we do. But there is some thought that preparing the skin appropriately prevents it from becoming an out of control sort of situation.

I just want to mention to everybody that's on, first of all, I'm sure we all share that I listen to this stuff all time and I still got all kinds of great new information and ideas today. But a lot of you are interested in the glucose control, and we just finished doing a four-session series on basal bolus control with Dr. Greg Maynard out of the Society for Hospital Medicine. It's on tape on the New York State Partnership for Patients website. It's very intense. It's very physician/pharmacy driven, so you're welcome to use those tapes for education of your docs and nurses and whoever is going to take the lead in doing basal bolus work.

I want to draw everyone's attention before you exit there is a New York State Partnership for Patients evaluation form, and I know some people had to jump out, but just a few brief points. First of all, I'd like to thank all three of our very esteemed speakers, Dr. Cima, Dr. Lema, and Dr. Timoney, thank you so much. My colleague in the back of the room stole my thunder a little bit, but there is some glucose control. That was one of my comments. She reads my mind. But also, there are extra packets available. As you're leaving, take as many as you like back to your colleagues that couldn't be here together.

This presentation will be available for download on the website after tomorrow. Tomorrow it's going to take place again in New York City, and then we'll post a recording of the video stream, as well as all of the materials from the presentation. So I urge you to take the gap analysis back to your facility. If you haven't done it, the gap analysis already, please do do that. Work with your New York State Partnership for Patients project manager, as well as use these materials and ask your project manager for anything further you need to bring this information back to your colleagues and staff at your hospitals.

So I'd like to thank everyone for being here today, and our esteemed speakers, and we'll continue to take questions for a bit longer and mingle, or you can e-mail your project manager, or any of the physicians actually if you have any further questions. So I thank you and have a great day.