Preoperative Preparation to Avoid Surgical Site Infections

Roundtable Moderator

Philip S. Barie, MD, MBA

New York-Presbyterian Hospital/Weill Cornell Medical Center

Editor-in-Chief of *Surgical Infections*

SIS A Surgical Infection Society Roundtable

Mary Ann Liebert, Inc. publishers

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Doctor Philip S. Barie is Professor of Surgery at Weill Cornell Medical College and an attending surgeon at NewYork-Presbyterian/Weill Cornell Medical Center. A long-time member of the Department of Surgery, Doctor Barie specializes in high-risk surgery, trauma, surgical critical care, surgical infections, hernia repair, and gastrointestinal surgery. Doctor Barie is extremely active in the department, participating on various committees, and he plays a leadership role in the training of general surgery residents. Doctor Barie is also active nationally and internationally as a member of more than 20 learned surgical societies, serving on the board of directors or as an officer of several. He is the immediate past president of the New York State Society of Surgeons. Doctor Barie is the Editor-in-Chief of *Surgical Infections*.

Doctor Kamal M.F. Itani is Chief of Surgical Service at the VA Boston Health Care System, a Professor of Surgery at Boston University, and a faculty member at Harvard Medical School.

Doctor Itani's primary research interest is in surgical infections, abdominal wall reconstruction, and health services research including surgical outcomes and clinical trials. He is the author or co-author of more than 200 peer-reviewed journal articles, editorials, and book chapters and is the lead investigator on several clinical trials.

Doctor William G. Cheadle is Professor of Surgery at the University of Louisville and the Program Director for the general surgery residency training program. He is also Associate Chief of Staff for Research, Development, and Education at the Robley Rex Veterans Affairs (VA) Medical Center. He has had an interest in infection and the early innate immune response to peritonitis and has had a VA funded basic research laboratory for over twenty-two years. He has been active in clinical investigations as well, and is the current President of the Surgical Infection Society.

Doctor Donald E. Fry is Professor Emeritus of Surgery from the University of New Mexico School of Medicine where he was the Chairman of the Department of Surgery for nearly seventeen years. He is currently the Adjunct Professor of Surgery at Northwestern University Feinberg School of Medicine in Chicago. His is currently Executive Vice President of Michael Pine and Associates, a healthcare think-tank in Chicago that is dedicated to improvements in the measurement of outcomes and to the design of alternative payment models for patient care.

Doctor Fry completed his medical degree at The Ohio State University in 1972 and his general surgery residency at the University of Louisville School of Medicine in 1977. Doctor Fry has authored over 270 journal publications and over 130 book chapters. His ninth edited book entitled *Surgical Infections* was published in 2013. Doctor Fry is Board Certified by the American Board of Surgery, and has been recertified in 1988, 1998, and 2008. He is a Fellow of the American College of Surgeons, and a Fellow of the Infectious Diseases Society of America. He is a member of the American Surgical Association and over twenty other academic societies. He is Past-President of the Association of VA Surgeons, the Shock Society, and the Surgical Infection Society of North America. He received the Career Achievement Award from the Ohio State University College of Medicine and Public Health in 1997.

Preoperative Preparation to Avoid Surgical Site Infections

Moderator: Philip S. Barie, MD, MBA [1]

Participants: Kamal M.F. Itani, MD,[2] William G. Cheadle, MD,[3] Donald E. Fry, MD [4]

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[2]*Treasurer, Surgical Infection Society; Chief of Surgery, Veterans Affairs Boston Healthcare System; Professor of Surgery, Boston University School of Medicine; Faculty, Harvard School of Medicine.*

[3]*President, Surgical Infection Society; Associate Chief of Staff, Research, Development, and Resident Education; Director of Surgery Residency Program, University of Louisville School of Medicine; Associate Chief of Staff for Research, Development, and Education, Robley Rex Veterans Affairs (VA) Medical Center.*

[4]*Past President, Surgical Infection Society; Executive Vice President, Michael Pine and Associates; Adjunct Professor of Surgery, Northwestern University Feinberg School of Medicine; Professor Emeritus of Surgery, University of New Mexico School of Medicine.*

Introductions of Participants

Doctor Cheadle: I am William Gerald Cheadle, Associate Chief of Staff for Research and Development and Resident Education, and a staff surgeon at the Louisville Veterans Affairs (VA) Medical Center; Professor of Surgery and Director of the Residency Program at the University of Louisville School of Medicine. I have a laboratory that has been investigating the early innate immune response to intra-abdominal infections for the last 25 years in Building 19 at the VA, founded by Doctor Fry. I am also the President of the Surgical Infection Society, a Past President of the Association of VA Surgeons, and the Vice President of the Southeastern Surgical Congress.

Doctor Fry: I am Donald E. Fry. I am Adjunct Professor of Surgery at Northwestern University Feinberg School of Medicine, and Professor Emeritus of Surgery at the University of New Mexico School of Medicine. But my real job is Executive Vice President of Michael Pine and Associates, a health care think tank in Chicago that designs models for measuring clinical outcomes and a new payment system for surgical care in the United States. I am approaching the 40th anniversary of my first research work on infections in surgical patients. I am a Past President of the Surgical Infection Society, Past President of the Association of VA Surgeons, Past President of the Shock Society, and a Trustee of the Surgical Infection Society Foundation for Education and Research.

Doctor Itani: I am Kamal Itani. First and foremost, I am a general surgeon. I am the Chief of Surgery at the VA Boston Healthcare System. I am a Professor of Surgery at Boston University School of Medicine and a faculty member at Harvard School of Medicine. My interest is in surgical infections in general, and specifically surgical site infection (SSI). I am also a Past President of the Association of VA Surgeons and currently the Treasurer of the Surgical Infection Society and the Surgical Infection Society Foundation.

Doctor Barie: *I am Philip S. Barie, Professor of Surgery and Professor of Public Health at Weill Cornell Medical College and Attending Surgeon at the NewYork-Presbyterian Hospital/Weill Cornell Medical Center, where my practice is in acute care surgery. I have a longstanding interest in surgical infectious diseases, and in particular the relation between host defenses and organ dysfunction. I am a Past President of the Surgical Infection Society, the Halsted Society, the Society of Critical Care Medicine, the Eastern Association for the Surgery of Trauma, and the New York State Society of Surgeons. I am currently the Executive Director of the Surgical Infection Society Foundation. I am also the Editor of* Surgical Infections.

EXPERT ROUNDTABLE DISCUSSION

Introduction to the Roundtable

The subject of this discussion is issues in the prevention of infection after surgery, with a focus on preoperative preparation of the patient. All participants on this panel are experts in surgical infectious diseases and have devoted themselves, not only to the study of the treatment of these infections, but to their prevention. All of the panelists are on the Editorial Board of *Surgical Infections*.

We have been making strides, but infection still is the most common complication of surgery; and, depending on the type of patient and the clinical circumstances, the rate of infection can range anywhere from 1%–2% to 15%. These infections thus remain a major problem.

Preparation of a Morbidly Obese, Diabetic Patient with an Abdominal Wall Hernia: Considerations

Let us consider a 55-year-old male smoker with a body mass index (BMI) of 35 kg/m^2 who has type 2 diabetes mellitus and is taking oral hypoglycemic agents. He does not know what his hemoglobin A_{1C} concentration is, and he does not check his blood glucose concentration. He presents for elective repair of a recurrent abdominal incisional hernia. His first and second operations were for complicated sigmoid diverticulitis. His third operation was a repair of a midline hernia with a dual-sided mesh using laparoscopic techniques.

The sigmoid resection, colostomy, and Hartmann pouch creation he underwent at age 47 was complicated by a non-Q-wave acute myocardial infarction in the immediate postoperative period, for which he underwent cardiac catheterization and placement of a drug-eluting stent. Eight years later, he still is taking aspirin and clopidogrel. The hernia measures 12 cm in diameter.

What risks does this patient face? What is the infection rate for surgery for a recurrent incisional hernia? How are you going to prepare the patient? What operation are you going to do?

Doctor Cheadle: This fellow is at about a 20% risk for a surgical site infection (SSI) because of his morbid obesity, diabetes mellitus that is likely out-of-control, and smoking. He has mesh present, and whether that can be used or whether it must be taken out, we do not know. If he does not have any intestinal symptoms that would push you to operate on him urgently, I would like to see him lose weight, stop smoking, get his diabetes under control, and then proceed.

We would need to do a number of things to prepare him. I like to prepare patients having ventral hernias repaired with mechanical bowel preparation. He should not be shaved, not even clipped, if possible. Bathing with chlorhexidine showers or application of chlorhexidine-alcohol wipes would be advantageous.

There are one or two things you can do during surgery. You can lyse all the adhesions, and then see if you can reattach the mesh to his fascia. Oftentimes, that does not work, so you may need to remove the mesh, take some of the small bowel off the mesh, and do a component separation or other type of abdominal wall reconstruction, which is an extensive operation.

Doctor Barie: *You are talking about an open operation.*

Doctor Cheadle: I am not a big fan of laparoscopic hernia repair. Maybe the other panelists can talk about that subject.

Doctor Barie: *Doctor Fry, what do you think is this patient's risk of infection?*

Doctor Fry: The literature on infections after ventral hernia repair is not trustworthy. My observation over a long career is that with all the risks present here, even for a clean procedure, we are looking at a 15%–20% SSI rate. [1] The morbid obesity issue is a big one, and you are going to place a foreign body in the incision, so there is a host of risk factors. Clearly, his risk for an infection will depend on when you perform the operation, whether you try to do what Doctor Cheadle has suggested, or whether you need to proceed more quickly. I question whether this patient should have an operation at all.

The clinical examination has to detail: Does he have a wide attenuated abdominal wall that is not at much risk for obstruction or incarceration? Should this patient simply be told to go home and sin no more? Because these patients may have horrific complications when you put a large sheet of mesh and if you separate the components of the abdominal wall with all these risk factors present, you have to be convinced that the operation is necessary, and then employ every recognized method to try to avoid infection.

Doctor Barie: *Aside from obvious indications to operate, such as intestinal obstruction or a enterocutaneous fistula that involves mesh, what would push you toward operating? An enlarging hernia? Skin thinning?*

Doctor Fry: One thing that would push it for me is whether the apparent hernia was disproportionately large to the fascial defect you can identify by physical examination. Is this patient likely to have small intestine or colon become incarcerated in this hernia, leading to a strangulation event?

Doctor Barie: *Let us follow up on your observation. What about the patient with chronic asymptomatic incarceration?*

Doctor Fry: Many of those situations have been managed over the years with expectant therapy: Not necessarily doing the operation if the patient has risk factors. If you have chronic incarceration, I would opt for repairing it, because you never know how things are going to evolve. If you have incarceration already, I would argue for doing something about it. But this patient has the risk, not only of infection, but of a fatal infection or other fatal event after a repair of a ventral hernia.

Doctor Barie: *Doctor Itani, you have written extensively on ventral hernia repair, the complications thereof, and the choice of mesh to use for implantation [1–5]. What is your perspective?*

Doctor Itani: Both Doctor Cheadle and Doctor Fry have made excellent points. Let me start with the risk factors. Smoking, diabetes mellitus, and a BMI of 35 are risk factors for SSI in general, including after ventral incisional hernia repairs, but this patient has other problems as well. The first one is having been operated on for diverticulitis. We do not know from the presentation whether he had a previous SSI, and there is evidence that a SSI prior to a hernia repair places the patient at higher risk for another infection. Knowing that is important, you can consider your choice of prophylactic antibiotic in this context.

Doctor Barie: *In fact, Doctor Itani, is it not true that the development of SSI in the postoperative period is itself a risk factor for failure of wound healing after hernia repair?*

Doctor Itani: Absolutely, SSI is a major risk factor for a hernia postoperatively. A second risk factor in this patient is that he has a drug-eluting stent and is receiving clopidogrel. If we have to operate on him electively, we must ensure that at least one year has passed since the stent was placed, so that we can stop the clopidogrel (and the aspirin, ideally) and prevent a postoperative hematoma that could become infected.

Doctor Barie: *Doctor Fry, do you believe that hematoma formation itself increases the risk of infection?*

Doctor Fry: Yes. There is a tremendous body of evidence on the adjuvant effects of hemoglobin—ferric iron from lysed erythrocytes, the rich pabulum that a proteinaceous environment creates [6,7]. I consider the bleeding risk in the operative site and hematoma as a serious technical issue that may confound this patient's postoperative care.

Doctor Barie: *Doctor Itani, would you repair this patient laparoscopically or by open surgery? And what mesh would you use?*

Doctor Itani: Randomized studies and analyses of large databases of laparoscopic vs. open incisional hernia repairs show the incidence of SSI after open repair to be significantly higher than after laparoscopic repair, perhaps as much as five-fold higher [8–10]. To decrease the risk of infection, I would be inclined to perform a laparoscopic repair. However, you have to take several things into consideration. As Doctor Fry and Doctor Cheadle both mentioned, should we operate on this patient at all? He would have to convince me that this hernia is disabling for me to proceed with surgery.

If it is a purely elective operation, I would proceed, as Doctor Cheadle mentioned, to mitigate the modifiable risk factors such as smoking and diabetes, and maybe ask the patient to lose some weight.

My preference would be to proceed laparoscopically, but there is risk with the laparoscopic operation, as the complications are going to be more serious than the ones resulting from an open operation. For example, bowel perforation or other injury during surgery is more likely during a laparoscopic operation. This is why Doctor Cheadle mentioned the importance of bowel preparation prior to surgery.

Doctor Barie: *Doctor Fry, would you proceed with bowel preparation?*

Doctor Fry: I would do a mechanical and an antibiotic bowel preparation.

Doctor Barie: *That is interesting. I do not do so in my practice.*

Doctor Itani: You asked about which mesh to use with mesh repair: The most favored mesh three to five years ago was an expanded polytetrafluoroethylene graft. Now, few surgeons would use this type of mesh.

Doctor Barie: *That is because it turns out to be not as resistant to infection as people believed?*

Doctor Itani: Yes [11]. Also, it does not incorporate as well, and with the risk of an infection, it does not hold well. So most hernia surgeons now use a composite mesh with one side compatible with bowel for a laparoscopic repair.

Doctor Barie: *There is no reason to use a composite mesh if you are doing open surgery?*

Doctor Itani: Not unless you enter the peritoneal cavity and place the mesh intraperitoneally.

Doctor Barie: *What about a bioprosthesis?*

Doctor Itani: Laparoscopically, the bioprosthesis is difficult to maneuver, and there is no evidence that it is in any way superior to synthetic prosthetic mesh.

Doctor Barie: *Doctor Cheadle, Doctor Itani just brought up an enterotomy as one of the risks in someone in whom you are going into the abdomen for the fourth time. If you had an enterotomy in the setting of a planned reconstruction of the abdominal wall with mesh, would you abort? Would you change from a synthetic prosthesis to a bioprosthesis? Or would it not change your intraoperative decision-making?*

Doctor Cheadle: I would close the enterotomy and then try to do a component separation, and probably would not implant mesh if I could get the fascia to the midline. If I could not, I would put the mesh in and probably drain it [12]. I still use polypropylene mesh as long as it is placed so as to not come in contact with the bowel. I would use a composite mesh if I had to place it adjacent to the intestine. So I probably would not abort, but I would treat the incision differently and would leave part of it open.

Doctor Barie: *Even if that means exposed mesh?*

Doctor Cheadle: Yes.

Doctor Barie: *Doctor Fry?*

Doctor Fry: I certainly would not be in favor of aborting the operation, because with a large ventral hernia that you have laid open, you have the world's biggest crisis, and how are you going to repair it or even get closure if you abort? The risk of an enterotomy in a patient such as this is not insignificant. I cannot give you a percentage, but you will see bowel segments frozen to each other, to the undersurface of the previous mesh repair, etc. That underscores why you have to go through the necessary preparations to have everything in order in the expectation that that might happen.

I would repair it primarily. I would be comfortable doing this, because I would have prepared the intestine beforehand, and it probably would not change my choice of mesh: I would use the same composite or polypropylene mesh I had selected preoperatively.

Doctor Barie: *The literature on adhesiolysis of acute bowel obstruction suggests that the risk of SSI is approximately doubled when an enterotomy occurs during that procedure. Would you all agree with that?*

Doctor Cheadle: Yes, I wrote a paper on it 30 years ago. That was exactly what we found [13]. As a matter of fact, a gastrostomy tube also doubles the risk of infection.

Doctor Itani: The fact is that it is a recurrent hernia. We found in a univariable analysis that having had multiple hernia repairs put the patient at a higher risk for a SSI. This conclusion did not stand up in the multivariable analysis, however.

Doctor Barie: *Do you believe multiple repairs put the patient at higher risk for wound failure and recurrence?*

Doctor Itani: Yes.

Doctor Cheadle: But what about those patients who had a prior SSI? Do you not believe that they are at higher risk?

Doctor Itani: Absolutely they are.

Doctor Cheadle: Host defense plays into that.

Doctor Itani: Yes. And you might still have some of the bacteria in a dormant stage within the tissues. But to go back to your question about a bowel injury during the operation, I think a laparoscopic hernia surgeon would perform the repair laparoscopically, place the patient on an antibiotic, and come back 48 hours later to finish the repair. Of course, there is a tremendous risk in bringing a sick patient to the operating room twice.

Doctor Barie: *That is the approach we would tend to take as well. I agree with Doctor Fry that, having gone through so much effort to get this patient ready for surgery, we would like to not have to abort. Rather, I would prefer to get control of the injury, restore peritoneal toilet, and finish another time in the near future. I tend to give strong consideration to switching to a bioprosthesis from any synthetic prosthesis in that circumstance.*

Is Preoperative Weight Loss a Realistic Hope? What about Panniculectomy with Hernia Repair?

Doctor Barie: *Don, is it realistic to expect patients to lose weight preoperatively?*

Doctor Fry: In my view, this has never been successful. Even if you find the rare patient who does, and you do a nice uneventful hernia repair, he or she gains all the weight back, and the hernia recurs. The effort is not going to be rewarding. Obviously, this patient would benefit from losing weight for reasons beyond the hernia repair, given his type 2 diabetes mellitus and so forth. Particularly if he or she has a symptomatic hernia, the patient is going to be pressuring the surgeon to get it repaired without delaying for weight loss.

Doctor Barie: *In my practice, there are patients who ask for a panniculectomy at the time of their hernia repair, increasing the operative time, potentially increasing the blood loss, increasing the denervation of the abdominal wall—bigger wound, greater cytokine response. This joint procedure certainly cannot be done laparoscopically. Does anyone think this operation is advisable?*

Doctor Fry: I have done a substantial number of abdominoplasties in my days of doing gastric bypasses. I have done mesh repairs of relatively small hernias and then performed the abdominoplasty. I am exceedingly nervous about doing it, because—as Doctor Itani has found—the reduced infection rate of laparoscopic vs. open repair is the sheer difference in the linear centimeters of incision. When we do an abdominoplasty, the incisions start to get huge, and the probability of wound complications is greater. I cannot even tell sometimes whether it is an infection or not when the flaps turn dusky and become ischemic, as they sometimes do. The cultures may show a few colonies of *Staphylococcus epidermidis*, and you do not know what this means. It is a wound complication, and a wound complication because of ischemia in someone with underlying mesh is at risk of losing a lot. It would be nice not to combine the hernia repair and the abdominoplasty.

Doctor Itani: Doctor Michael Rosen has published a study showing that combining a panniculectomy with a ventral incisional hernia repair does result in higher risk of SSI; he advocates not doing these procedures during the same sitting [14].

Doctor Cheadle: The other thing is that the operative site for the hernia may be different from that for panniculectomy, so you need two incisions. This man might even be a candidate for gastric bypass at the same time as hernia repair if you can stop him from smoking and get his diabetes under control, and he really wants to turn his life around—and this is a typical Veterans Affairs patient—sometimes you can, and sometimes you cannot.

Importance of Diabetes Control

Doctor Barie: *The glycemic control literature indicates fairly clearly that hyperglycemia, even transiently, in the perioperative period is associated with a greater risk of infection. But some experts have argued that it is glycemic control in the perioperative period acutely rather than long term that is important. So when we speak of glycemic control, are we asking these diabetic patients to get their hemoglobin A_{1C} down to 6% or 6.5% preoperatively, or are we counting on meticulous glycemic control in the perioperative period?*

Doctor Fry: The original data on glycemic control from the Oregon Health Sciences Center related to perioperative control in cardiac surgery [15–17]. It was not continued for days on end; in my view, such glycemic control may be like preventive antibiotics. You need to control the environment at the time of the contamination, and after the incision is sealed with fibrin matrix following closure, it may be naïve to think glucose control is going to make much difference.

As to your second question about the A_{1C}: There is some evidence that an elevated hemoglobin A_{1C} value is associated with a higher SSI rate. But I take the position that the perioperative glucose concentration trumps the patient's A_{1C}; that the acute physiologic consequences of hyperglycemia and its impact on the innate host response are real, and that it is most important. However, I have never seen anyone put together both immediate and long-term glucose control to make sense of whether both short- and long-term glycemic control need to be incorporated.

Doctor Barie: *We have all cared for patients with good long-term glycemic control who become hyperglycemic, and are difficult to control in the perioperative period, because of the counterregulatory stress hormone response.*

Doctor Itani: I agree. Most of the studies on hemoglobin A_{1C} are Class II data from observational cohorts of patients. The evidence relates to glycemic control in the perioperative period, trying to achieve a blood glucose concentration of ≤ 180 mg/dL before and during surgery, and into the postoperative period.

Doctor Fry: The two are linked, and the hemoglobin A_{1C} concentration, if it is high, indicates it probably will be harder to maintain the blood glucose concentration, which we would like to see < 200 mg/dL and ideally between 140 and 180 mg/dL [18]. Importantly, the figure is a reflection of the patient's compliance with monitoring and treatment. As reimbursement incentives change, there is going to be more incentive not to do surgery on those who are morbidly obese and smoking with a high hemoglobin A_{1C} value, diabetes out of control, and anemia, because of their higher risk. Complications will be held against you and your hospital as increasingly we keep score.

The Underweight Patient

Doctor Barie: *Before we move on to the next area, let me change the case to make it a patient with a BMI of 17. The patient looks asthenic, perhaps even cachectic. Does that change your preoperative planning? What specifically would change?*

Doctor Itani: First, you have to make sure that the patient does not have an underlying cause for the low weight—such as cancer. Second, I would not proceed with surgery until the patient is in good shape nutritionally—normal serum albumin and prealbumin concentrations. The VA studies have shown that low serum albumin concentration is one of the greatest risk factors for a postoperative complication [19].

Doctor Barie: *If not the single most important. Is there evidence that short-term nutritional repletion can influence outcomes?*

Doctor Fry: There has always been a cloud hanging over nutritional support, namely, how long is long enough? As Doctor Itani pointed out, our studies also have demonstrated that protein–calorie malnutrition preoperatively, generally estimated by albumin or prealbumin values, is highly predictive of morbidity, particularly infectious morbidity [20].

The flip side is that if you take three or four weeks to try to replete these patients and restore the albumin acutely, does it necessarily reverse the entire pattern? We all believe that is true, but when you change something acutely with a dramatic intervention, does it always give you the result you want?

Doctor Cheadle: This patient would need to be worked up fully to determine the cause of cachexia to see if it can be reversed. I probably would try the enteral route first for nutritional supplementation because of the greater risk of infection using central venous catheters, although a peripherally inserted central catheter would confer less risk.

I agree with Don. Seeing as I do plenty of patients such as this who have reversible protein–calorie nutrition, I treat for four to six weeks, and then remove the catheter, and go through all the preparation we have talked about as an outpatient if the situation is reversible.

Doctor Itani: If this patient can take enteral nutrition, you would go with enteral nutrition?

Doctor Cheadle: Of course.

Doctor Barie: *There are some data showing that as little as five days of enteral nutrition may reduce the risk of SSI in some of these patients [21].*

Skin Flora and Disinfection

Doctor Barie: *Preparation of the skin is a crucial aspect of the peri-operative period [22–24]. What organisms are we worried about when we focus on preventing SSI?*

Doctor Fry: We clearly are worried about gram-positive organisms, particularly staphylococci [25,26]. That is overwhelmingly the most likely pathogen to complicate a clean elective operation, and that is going to be the target of both antisepsis at the surgical site and systemic antibiotics, if one chooses to use such.

What I teach my residents is that the farther below the inguinal ligament you are, and the deeper you are into a body cavity, the more likely you are to have to deal with gram-negative bacilli as opposed to gram-positive cocci. That fact needs to be taken into account.

Doctor Itani: *Staphylococcus aureus* is going to account for 30% of all SSIs; coagulase-negative *Staphylococcus* is going to be about 13%, and *Enterococcus* spp. 11%. So the majority of the infecting organisms are gram-positive. You see *Escherichia coli* and *Pseudomonas* spp. to a much lesser degree.

Doctor Barie: *Our focus today is not on antibiotic prophylaxis as much as it is on skin antisepsis. Antibiotic prophylaxis is well established, both by data and by regulatory fiat. Don, having been so involved in this for such a long time, not only clinically and experimentally, but by having a hand in the regulatory process, do you have any thoughts about the state of antibiotic prophylaxis?*

Doctor Fry: The traditional principles still apply: That the drug, to be effective, has to be present in the site at the time of the contamination, and that continued drug administration afterward is not of value when you are doing clean operations.

Skin preparation has taken a new twist in the last 10 or 15 years with the emergence of methicillin-resistant *S. aureus* (MRSA). That should be taken into consideration within your own institution, but I think a systemic methicillin-susceptible *S. aureus* (MSSA) antibiotic peri-operatively is the appropriate choice in most centers.

Doctor Barie: *So you are speaking in terms of who, if anyone, should receive vancomycin as antibiotic prophylaxis?*

Doctor Fry: The vancomycin issue is not settled. The only randomized trial I know of in a high-MRSA environment is the Finkelstein study from Israel in open-heart surgery [27], and it is interesting that if you used vancomycin, you had the same infection rate as using cefazolin. You only changed the profile of the organism: The patients receiving vancomycin had MSSA, and the patients receiving cefazolin had MRSA. We still face a conundrum as to how we are going to deal with the continued emergence of MRSA as a pathogen in elective, clean SSI.

Doctor Barie: *I have always believed that antibiotics belong in the tissue, not on the tissue. Would any of you have any support for the practice of soaking a prosthesis in a antibiotic solution or irrigating the incision with a antibiotic-containing solution?*

Doctor Itani: There is no evidence supporting this practice. It is more a preference of the surgeon. I do not believe that irrigation with antibiotic solution or soaking the mesh with an antibacterial agent would reduce SSI. Actually, there are some interesting recent studies in cardiac and colon surgery where the investigators placed collagen sponges impregnated

with gentamicin in the surgical site and achieved no reduction in SSI [28,29].

Doctor Cheadle: The older literature shows that topical antibiotic administration is equivalent to systemic antibiotics, not better.

Doctor Barie: *Considering what we have just learned about the microbiology of SSI, and considering that every patient and every surgeon is going to perform skin preparation, as well as all the members of the surgical team, what are the options available, both for hand antisepsis and for preparation of the surgical site?*

Doctor Fry: Alcohol, chlorhexidine, and iodine are the three agents that have been studied recently [30]. Those can be used as skin and surgeon hand preparation. I like the French study published in *JAMA* about 10 years ago that showed that washing one's hands in soap and water and then applying greater than 67% alcohol was associated with the same SSI rate as scrubbing for ten minutes [31]. So I teach the residents, you can do whatever else you want, but douse those hands in alcohol every time [32].

And there is the great study that you, Doctor Itani, were part of, which showed chlorhexidine–alcohol solution was superior to povidone–iodine for surgical skin preparation [33]. That conclusion is from a randomized trial, so I always use those data. More recently, a meta-analysis of six studies, containing 5,031 patients who underwent clean-contaminated surgery, estimated that chlorhexidine-alcohol reduced SSI by 32% compared with povidone-iodine [34].

I do not shave the patient unless I must. The data on not shaving the surgical site came out more than 30 years ago [35], but the recommendation has been incorporated into our routine only in the last ten years.

Doctor Barie: *Doctor Itani, can you tell us about the aforementioned study in which you participated?*

Doctor Itani: Almost everyone agrees that an alcohol-based preparation is superior to elemental iodine or chlorhexidine alone. However, one has to be careful about the practice of applying the alcohol-based scrub on surgeons' hands, because my observation is that the cleansing has become so rapid and nonchalant that a surgeon will go by the sink and place the alcohol on his or her hands, and then do it again 30 seconds later in the operating room. It is important that surgeons wash their hands, including under the nails, with soap and water, at least during the first scrub prior to applying the alcohol and whatever other agent is used with the alcohol scrub. If they leave the operating room area to do other things, they should wash their hands again with soap and water prior to applying the alcohol-based scrub.

The study you mentioned is the largest randomized trial to examine 2% chlorhexidine plus 70% isopropyl alcohol as compared with 10% povidone–iodine scrub and paint [33]. This was studied in patients undergoing clean-contaminated surgery. The rate of infection in the povidone–iodine group was 16%, whereas with chlorhexidine-alcohol it was about 9%. This difference was statistically significant in relation to superficial and deep incisional SSI. It did not affect organ/space infection, which is a completely different entity and which, in my opinion, is related more to technical issues than to skin preparation.

Doctor Barie: *It seems there is a lot of enthusiasm among our panelists for using chlorhexidine. Chemically, what is its mechanism of action?*

Doctor Fry: It binds to and denatures proteins and degrades cell membranes [36]. It is non-specific, which is particularly a nice feature of the hexidine ring with the chlorine ions attached. It has a fairly broad spectrum of activity against microbes.

Doctor Barie: *You characterize chlorhexidine as a cell wall-active agent?*

Doctor Fry: Yes.

Doctor Barie: *And capable of membrane depolarization as a result of the sulfur-based ring?*

Doctor Fry: It binds to cell membranes, and depolarization is the consequence.

Doctor Barie: *There are some data, are there not, that in low concentrations, chlorhexidine may be more active against gram-positive bacteria, and that the gram-negative bacteria may require higher concentrations for efficacy?*

Doctor Fry: There is in vitro evidence obtained by examining microbial growth. I am not sure that we have seen clinical evidence that is true, but certainly, one is left with the belief that chlorhexidine is extraordinarily effective against gram-positive bacteria when applied topically.

Doctor Cheadle: Studies that compare chlorhexidine only, versus chlorhexidine with isopropyl alcohol [37–43], indicate that the alcohol is an important component [32].

Doctor Itani: A unique feature of chlorhexidine is its persistence on the skin. It does not have rapid bactericidal activity; that is provided by the alcohol in combination. The combination of the two provides immediate action, and the persistent action of the

long-term agent probably is unique to the combination. Chlorhexidine itself has slightly better activity against gram-positive and gram-negative organisms than iodine does.

Doctor Barie: *It is viricidal and fungicidal, as well, is it not?*

Doctor Itani: It is.

Doctor Barie: *Does the concentration matter? The agent is available in preparations from 0.1% up to 4%.*

Doctor Fry: There clearly is a bias that concentration matters. However, few clinical studies have compared different concentrations of the same preparation across a panel of patients. Generally, with comparative trials and looking at the various studies over time for intravenous sites, it has been the typical 10% povidone–iodine against the typical 2% chlorhexidine. There is not any good evidence to support the idea that concentration is important.

I emphasize, whether it is chlorhexidine or povidone–iodine, how it is used and applied and left to dry—the sustainable nature of the antiseptic—is an important variable. How many times over the years have I observed povidone–iodine placed on a site only to see the surgeon take a towel and wipe the site dry before the incision is made! I am certain that the antimicrobial activity has been totally compromised by that action. So Doctor Itani's comment is an important one. One of the problems in comparative trials is, are you or are you not going to let the agent dry on the skin before you start your manipulation?

Doctor Barie: *It is hard to leave it to dry when you are a surgeon with a scalpel in your hand.*

Doctor Fry: I understand, and many surgeons do not worry about infections until they happen. The culture needs to change to be more concerned about the presence of the antiseptic before the fact than about trying to put Humpty Dumpty back together after things have fallen apart.

Doctor Barie: *What about a single application vs. repetitive applications?*

Doctor Fry: I like Chuck Edmiston's study, which used repetitive applications [44].

Doctor Barie: *What did he mean by "repetitive application"?*

Doctor Fry: They used multiple applications over days at the surgical site, and the data show you get tremendous concentrations of chlorhexidine on the skin, and that its antimicrobial activity is more efficient. We probably have not applied any of these antiseptic agents the way we should.

It may be that the patient needs multiple preparations of the surgical site, even in the holding room before they go into the operating theater. Sequential applications of chlorhexidine, allowing it to dry, create enormous concentrations at the site and suppress microbial colonization.

Doctor Barie: *Is there any downside to repeated applications—allergy or dermatitis?*

Doctor Fry: Not that I am aware of.

Doctor Itani: There have been reports of some hypersensitivity to chlorhexidine, especially after the first application. It can range from local skin hypersensitivity, to anaphylactoid reaction [45]. Although these reactions are rare, we need to be aware of the possibility. With the thousands of operations that are performed every day, I have not encountered it at all. So it is an entity to be aware of, but I do not think it is common.

Doctor Barie: *Donald, chlorhexidine is often combined with an alcohol. Is there a combustion risk in the operating room?*

Doctor Fry: When there is no evidence, everybody's opinions are clearly formed by personal experience. I have seen two isopropyl alcohol fires in the operating room, and I have carried a lifelong passion about that subject. As I understand it, with the chlorhexidine–alcohol combination now being used, the risk has been reduced substantially. But one must be aware of the fact that everything must dry before surgery is started. You must not have preparation solution dripping down on the drapes and underneath the patient at the time of application, and then use electrocautery.

All of the arguments for isopropyl alcohol are correct—it is an incredibly fast-acting microbicidal topical agent. It does have the issue of causing rare fires in the operating room, and it once again speaks to *how* you use things being more important, perhaps, than which one you use.

Doctor Itani: It is an interesting point, because you mentioned earlier the fact that some might place the povidone–iodine and then wipe it with a towel. Applying the chlorhexidine-alcohol and allowing it to dry before draping the patient mitigates the risk of fire. This obligates the surgeon to wait.

Doctor Fry: And it dries much faster than iodine.

Doctor Barie: *Our hospital has a protocol for a three-minute wait after chlorhexidine-alcohol is applied to the skin before draping. Do you follow that practice, Doctor Itani?*

Doctor Itani: We do.

Doctor Barie: *Bill, do you follow that practice?*

Doctor Cheadle: I think it is almost automatic. By the time the circulator prepares the patient, the site is dry, and we are scrubbing and gowning and gloving and going through a time-out and draping the patient—that is almost three minutes in itself.

Doctor Itani: Don, I want to go back to the Edmiston study [44]. They had a group of patients who took showers with 4% chlorhexidine and another group that was wiped with 2% chlorhexidine twice before surgery. For individuals who cleansed twice using a 2% chlorhexidine polyester cloth, skin surface concentrations approached 350× the MIC_{90} for staphyloccal skin isolates.

Doctor Fry: That speaks perhaps more to the issue of how it is applied. It may well be that the beauty of adding the isopropyl alcohol to the chlorhexidine is more efficient drying. Edmiston's data raise the issue whether several applications allowed to dry fully would give the optimum antiseptic effect at the skin.

One of the questions about the 4% chlorhexidine shower is how much of it goes down the drain, literally. One of the things that bothered me as I have matured is that we get into bad habits, and the trivialization of the antiseptic management of the site before the incision has become a big issue for me. We probably have done a disservice not only to patients but also to residents we teach by not employing best practices ourselves, through hurrying in the operating room and patting things dry and canceling the antimicrobial effect—even if it affected 1% or 2% of the antiseptic, it could be substantial.

Doctor Barie: *Bill, as we evolve in an era where chlorhexidine is used more and more—it is used in intensive care units, it is used on wards, it is used in the operating room, it is used for general hand hygiene in the hospital—should we be concerned about the emergence of antimicrobial resistance to an antiseptic?*

Doctor Cheadle: The antiseptic certainly is being used widely. It is reasonable to be concerned, but the data show it did not happen in the studies that I have read [46,47].

We should be concerned, but as with any antiseptic, that has not been a focus of the way we have approached resistance against antimicrobials. It may be something we need to think about, but the in vitro data show little resistance over time.

Doctor Barie: *The evidence for the value of chlorhexidine in clinical medicine is substantial. Preparation of the skin before central line insertion is associated with a reduced infection rate. Coatings of catheters contain chlorhexidine. Several studies have now looked at the bathing of hospitalized patients, specifically, critical care patients, and shown that it is effective for the prevention of nosocomial infection, particularly with respect to staphylococcal infections [40,48].*

All of those studies use infection as an endpoint. But the skin preparation literature has not used that as a primary endpoint, and most people have focused on reduction in bacterial counts and the duration of reduced counts as a result of the preparation exercise. Is that a valid endpoint? Is it a valid surrogate endpoint for reduction of infection risk?

Doctor Cheadle: That is like using compliance measures and not looking at their effect on clinical outcome. There is an enormous amount of literature with all sorts of preparations, incise drapes [49] to microbial sealants, showing a reduction in colony counts [50]. The problem is the U.S. Food and Drug Administration (FDA) sometimes has allowed that figure to be a surrogate measure for SSIs, but a clinical correlation has not been demonstrated [51]. One has instead to look at the clinically important outcome, SSI.

Doctor Itani: I agree. Colony counts show that there is an effect, but the important endpoint is surgical site infection. The colony count studies are done for convenience, because you require much smaller numbers of patients than if you were to look at surgical site infection as the endpoint.

Doctor Fry: The density of organisms, the inoculum in the site, is only one variable that affects infection as an outcome. All organisms are not created equal. Different patients will have a different virulence profile of their colonizing organisms.

If you use lots of suture material at the site, it will amplify an inoculum that would otherwise not have caused an infection at all. And there is always the wild card of the host. Yes, we appreciate that diabetic patients and smokers have acquired host immune defects, but I am convinced there is a genetic defense program that each of us has, and in clean sites, you see that become manifest.

I like to refer to the famous Sørensen study in 1988 in the *New England Journal of Medicine* [51] showing that adopted children whose biologic parents died of infection have a dramatically elevated odds ratio of dying of infection themselves, even though no measurable immune defect presumably existed.

So there are multiple things that cause a SSI [52]. Bacterial inoculum certainly is one. But we are never going to take the SSI rate to zero, so we try to reduce it as much as we can. With all these other factors at play, it may be hard to show a reduction in the actual rate in a prospective trial.

Increasing Antimicrobial Resistance

Doctor Barie: *Another factor, particularly in hospitalized patients, is that the organisms that plague our patients have become increasingly resistant to antibiotics [53].* Staphylococcus aureus *has been afflicted by something that has been called minimum inhibitory concentration (MIC) "bracket creep," where a proportion of organisms within a susceptible inoculum are less susceptible than they used to be [25,26]. Some authors have suggested that change may correlate with the activity of chlorhexidine [46].*

Doctor Fry: I do not know whether that is true [54]. If, in fact, there is some link to chlorhexidine, it probably speaks to the issue of maintaining higher rather than lower concentrations in the application. If we have learned anything from antibiotics, it is that sub-therapeutic antibiotic administration results in the promotion of resistant organisms. One of the dangerous issues of going with lesser and lesser concentrations of chlorhexidine may well be the promotion of resistant species.

The profile of patients is changing, both for MRSA and for methicillin-susceptible organisms. Around 1.5 million people in the United States are in nursing homes. We have half a million persons on hemodialysis. We have a population of patients coming into the hospital for operations who have healthcare-associated MRSA colonization. We have to be aware how microflora has changed with the environment before they came to us as patients, and how that microflora may be impacted by what we use in caring for them.

Doctor Barie: *We can expand that argument by pointing out that perhaps one-third of healthy individuals are nasal carriers of staphylococci, and as many as 5% to 10% of those patients may be nasal carriers of MRSA. If a patient gives a history of SSI or a previous soft tissue infection—a furuncle or something like that—does that change the risk? Does that change your approach to the patient? What about screening? What about decolonization [55]?*

Doctor Fry: This is really a Pandora's box. The issue is screening. You can show that we have a certain number of people with nasal carriage, and there are advocates for decontamination. The problem with the decontamination studies is that they report only staphylococcal infections, and there are some individuals, of whom I am one, who believe that when you decontaminate, you simply replace the staphylococci with other organisms, and that overall infection rates may not change.

So the problem with nasal screening—which, I might add, is now required in Illinois—is, what do you do when it is positive? Does that change your systemic antibiotic choice? It probably should. But does nasal decontamination really change the outcome? I would like to see more studies on the subject.

Doctor Barie: *Some also have argued that any decolonization program ought to do something to cut down the bacteria on the skin, not just in the nares, but by incorporation of chlorhexidine bathing as part of the regimen.*

Doctor Fry: I agree completely; although where is the evidence that if we inhale some mupirocin for a couple of days, it will change what is on the skin? The other thing is that aerosolizing mupirocin probably is going to create the next generation of mupirocin-resistant staphylococci. Topical antibiotics are a great way to create resistance also. I hearken back to when Harlan Stone used topical gentamicin in the burn unit in the late 1960s at Grady Health Systems in Atlanta, and for six months, it was wonderful, but all the organisms then became resistant to gentamicin [56].

So topical use of antibiotics on a long-term, sustained basis has some downside liability. That is why I like the antiseptic concept. The antiseptic is a nonspecific binding agent. It is not inactivated by beta-lactamase or some other enzyme. I think it has a better long-term future than topical antibiotics, for example.

Doctor Itani: A VA study tested all patients who went into the hospital and changed care within the hospital, testing them for MRSA colonization [57]. What helped is that patients who tested positive were cohorted, and isolation practices were performed. This raised awareness among the staff, and it prevented the spread of MRSA. Universal precautions were applied. Hand washing was prevalent, and the protocol reduced MRSA infections.

Doctor Fry: My argument against that practice would be: Why are we not exercising those same levels of prevention in everybody we are caring for?

Doctor Cheadle: Cohorting has helped in controlling MRSA outbreaks in burn and intensive care units. But you are talking about two kettles of fish here—outpatients to whom you might be applying certain principles to reduce SSI, versus cohorting in inpatients to prevent blood stream infections, urinary tract infections, and ventilator-associated pneumonia.

But I agree with Don and Kamal that the mechanism by which chlorhexidine-alcohol works is much less likely to induce resistance than topical antibiotics, and therefore would be more helpful when applied universally. There are good data to show that topical chlorhexidine is effective in reducing nosocomial infections [40,48], particularly central line infections [58].

Doctor Barie: *Bill, we have been speaking about the chlorhexidine data in some of these infections in critical care settings and whether those data can be extrapolated to the*

surgical suite. We also have talked about surrogate endpoints of bacterial skin colonization and whether that is a useful endpoint for infection in some of the prospective skin preparation studies. How do you, as a general surgeon, incorporate data from, for example, a study of joint replacement into your general surgery practice? To what degree are these studies relevant and applicable across surgical specialties?

Doctor Cheadle: We go back to some of the original studies, including Burke's study of a number of patients who underwent thoracotomy and laparotomy [59]; if you culture the site carefully at the end of the operation, you find that every one of them has *S. aureus* in it. Every study has quoted about the same rate, 25 colony-forming units. Now, 25 colony-forming units may not mean much in an inguinal hernia, laparotomy, or cholecystectomy, but it may mean a great deal when a foreign body is being placed, such as prostheses for hips and knees and in vascular surgery. Where the consequences of an infection are dire—in the eye or the brain, for example, in which the prosthesis may have to be removed because the biofilm incorporates it—it becomes much more important.

Do Patients Perform the Assigned Preparation?

Doctor Barie: *The surgical landscape has changed utterly in the last quarter century. When we panelists were residents, everyone was admitted the night before, even before minor surgery, and stayed the night after. Obviously, that does not happen now. About 70% of operations in the United States are performed on an ambulatory basis, and perhaps another 10% with a same-day admission. How has that changed preparation of the patient?*

Doctor Fry: The major issue has been that patients have to be responsible in some respects for their own preparation—showering and preparation for going into the hospital [60]. It is not appropriate relative to clean surgery, but for intestinal surgery, it has meant that patients have to do their bowel preparations and so forth at home.

Doctor Barie: *Has that been a factor in the reduced enthusiasm for mechanical bowel preparation?*

Doctor Fry: There is no question that has been the major impetus for the bad feelings that have been expressed by many people over bowel preparation. Ambulatory surgery, the increasing prevalence of same-day surgery, mean that we need to be reliant on the patient to do some of the preparation.

The good news is it means we have now limited their exposure to the healthcare environment before the operation, and we have limited their exposure to the environment when the procedure is over. We send them out of the hospital.

So it has been a two-edged sword. It surely has made knowing the true rate of SSI difficult, because garnering that information when patients are sent home quickly becomes difficult.

Historically, according to the literature, patient compliance with bathing at home the night before the operation has not always been high [23], but many of those comparisons were with bar soap and water.

Doctor Barie: *Do you believe that looking at this literature and seeing a historical lack of success is a function of ineffectiveness, or that the issue really is what you alluded to previously, that you are not sure what the patient is doing because a lot of the antiseptic goes down the drain? How can you be sure that the patient is even compliant with directions?*

Doctor Fry: We do not know. That is why bowel preparation came under so much criticism, because you can tell readily in the operating room if the bowel preparation has not been done correctly. Whether the skin preparation has been done correctly at home is a problem. Whether the application of the antiseptic in the operating room has been done correctly also can be a problem. It has been only within the last decade, for example, that color has been added to chlorhexidine. That was one of the advantages of povidone–iodine: You could tell when you missed some swipes. You could not determine that before with chlorhexidine.

The failures of bathing and preparation outside of the hospital represent inconsistency in how the antiseptic is applied, and if that were more uniform, it would facilitate showing a benefit. But let us understand, once again, we are going to reach a point where we will have the 25 staphylococci there, regardless of what we do. Then the issues of the adjuvant effects in the site, from how the surgeon behaves, the patient's intrinsic response, what the character of their colonization is, become factors that probably are going to drive SSI rates.

The topical antiseptic preparation before the patient comes to the hospital really ought to work, but we have to become enthusiastic in telling our patients that is what they must do, that being casual about this preparation is putting themselves at risk.

Can We Improve Compliance?

Doctor Barie: *Are there any things that we can do to improve compliance? We have to convince our patients that they must take responsibility for being a partner in their preoperative preparation, and that we believe it is important for them to adhere to certain behaviors.*

We live in an era where communication with patients can happen in many ways. But that is a double-edged sword. Electronic mail is not secure. Much has been written about using text messaging and whether it is a violation of patient

Mobile Messaging: A Tool To Increase Patient Compliance

To optimize patient care by improving patient compliance, clinicians are turning increasingly to mobile messaging to remind and instruct patients. Most American adults—91%—have a mobile phone, and more than one-half are smartphones. Moreover, according to a recent Pew Research Center study, 44% of mobile phone owners have slept with their phone next to their bed to ensure they didn't miss any calls, text messages, or other updates during the night [1]. Health care teams are finding the ready availability of mobile phones and other digital tools an effective means to reach patients with reminders, instructions, and other information. Several studies have demonstrated the beneficial effects of text message reminders in relation to patient compliance [2–4]. Preoperative preparation is one area where patient compliance with instructions is crucial, and mobile messaging can be useful.

From the Clinician, Direct to the Patient

Proper education and instructions for preoperative patient care originate from the patient's surgeon, and sometimes from the facility where the operation has been scheduled. Traditionally, this education has been provided in the form of paper handouts. Electronic delivery of information or instructions to a smartphone allows patients to receive pertinent information at the optimal point in time—i.e., the evening before the patient is scheduled for surgery. Mobile messaging also allows customization of content for the individual patient and the timing of delivery based on knowledge of the patient and individual patient goals.

Ensure Compliance

When implementing mobile messaging with patients, clinicians must ensure they are in compliance with federal regulations—i.e., the Health Insurance Portability and Accountability Act (HIPAA)—and have taken care to minimize risk. This can be done by obtaining prior patient consent, informing patients of all possible fees imposed by their wireless carrier, and determining with legal counsel that privacy will be maintained [5]. Surgical centers can create their own system in-house or use a commercial system (of which there are several) to send information and reminders to their patients via text message, e-mail, or pre-recorded telephone call [6].

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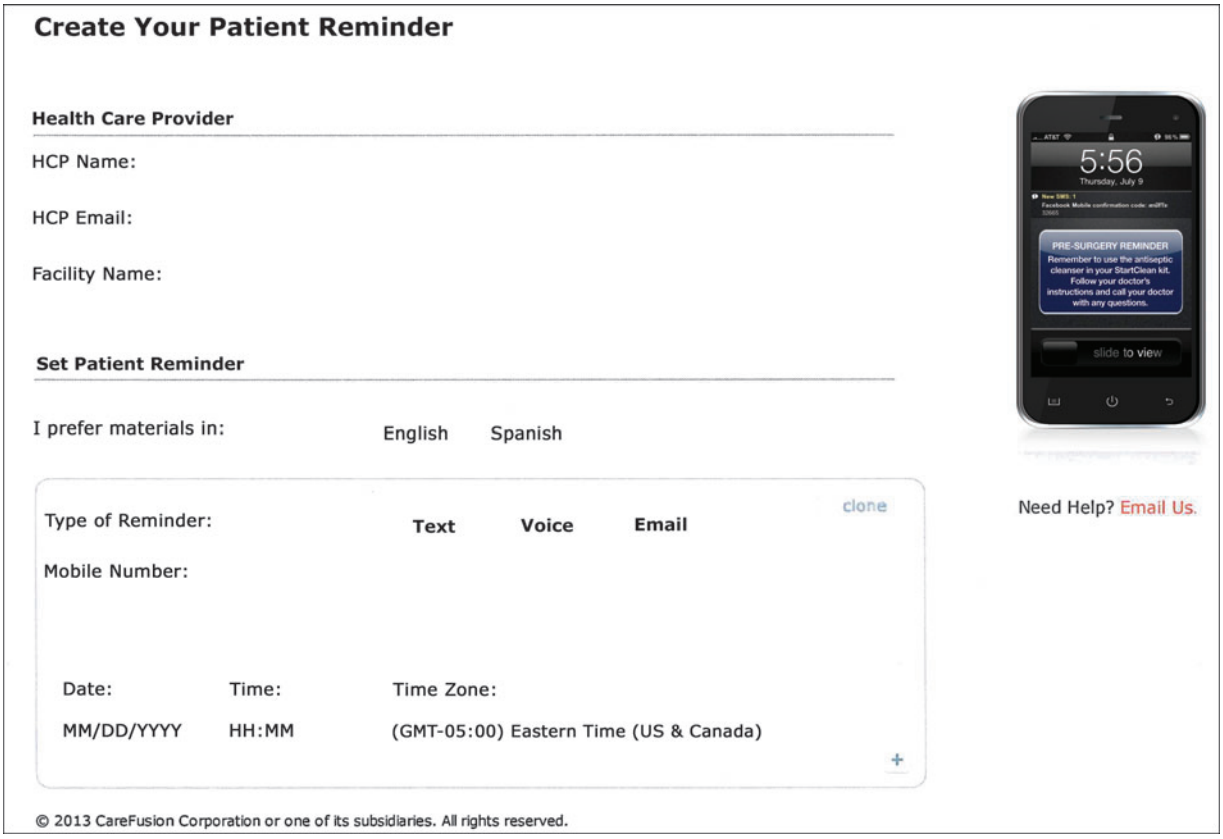
confidentiality. Is there any role for social media and these other new forms of communication to help our patients understand or be reminded of their responsibilities as their surgical date approaches?

Doctor Fry: The penetration of social media across the vast expanse of the patient population is now uniform. We live in an environment where LinkedIn, Facebook, and e-mail are prevalent, but I am sure that not all patients in Cook County Hospital will benefit because of a lack of access.

It is the physician making the case that these actions are important to the person's health and outcome, and trying to convince the patient that this is part of her or his responsibility. I had some obesity surgery patients who suffered SSIs and were in tears because they were convinced they had failed in the topical application of the antiseptic. The communications had shifted how they viewed an infection. I am not sure all the social media in the world will trump a convincing physician.

Doctor Cheadle: This teaching can be done through hospital mechanisms, nurses and nursing assistants, and then getting in touch with the patient's significant other, because often, that person will be the one who ensures the patient does what has been asked.

As long as you have the data to back it up, certainly, social media can help. I have several patients on Facebook and in my cell phone, and there are disasters I have taken care of with that assistance for a long, long



Example of Patient Reminder

time. Once you start making clear what is standard and what is to be expected of you prior to the operation—nothing orally after midnight, for example—you certainly can follow the rule of bathing yourself with these sponges ahead of time. So it is doable in a certain patient population; perhaps not in others.

Economic Aspects of SSIs

Doctor Barie: *Doctor Fry, you have an abiding interest in health economics as it relates to outcomes, and you have written about the economic consequences of SSI [61]. What have you to tell our readers about the cost?*

Doctor Fry: It depends on which operation you are talking about. The cost for a groin hernia infection ordinarily is substantially less than the cost of an infected total hip or mediastinitis following a heart operation. The added healthcare cost of a SSI may be a few thousand dollars with clean, relatively minor elective cases but can soar into the tens of thousands of dollars when you are talking about hips and sternums and infected vascular grafts. There would be a very strong case to be made that reducing SSIs will reduce cost.

Now, having said that, I also emphasize that about one-third of SSIs that occur after colon surgery are not associated with an excessive length of stay in the hospital, nor with higher cost. Even among operations of a single type, there is a vast continuum of physiologic and economic consequences.

We need to start studying economic consequences, because I wonder whether the infections we are preventing are all the superficial ones, and that the deep, catastrophic stuff continues. That argument may be applied to systemic antibiotics as well as to antiseptics. I have been encouraging the idea of more stratification or classification of SSIs so that we know what categories are being prevented when we view clinical trials. If we are not impacting deep infections, we have to look in greater detail into the issues.

Doctor Barie: *Cost can be looked at from the perspective of the payor, from the perspective of the hospital, and from a societal perspective—the greater good. That brings us to the notion of cost-effectiveness and the possibility that in order to get a better outcome, you have to spend some money [62]. It is not always about cutting expenditures down to the bare bones. Do you believe that it can be justified in the case of SSI prevention to add cost upfront to make sure the patient is prepared optimally?*

Doctor Fry: There is no question that is true. I have published a comprehensive evaluation of thousands of hospitals and millions of patients where we

identified hospitals that have suboptimal outcomes [63], and suboptimal-outcome hospitals always are low-cost hospitals. There is also a group of hospitals that are overshooting the moon: 15%–18% of hospitals doing elective surgery will run three standard deviations above the national mean but have no measurable improvement of the quality of their outcomes.

So, a strong case can be made that institutions performing should put more money into prevention. One has to walk a fine line. I do not think prevention is overdone—that, I believe, can fall into imaging, laboratory, radiology, needless consults, and medical clearance, what I like to call the "gratuitous consult." But the fact is that preventive strategies that have clearly been documented as effective cannot be short-circuited, because they pay an outcome dividend, and, indeed, a cost dividend to society.

Doctor Cheadle: You can look at it from the other end, too. This is 2013, and the costs of urinary tract and central line infections are not going to be reimbursed. Yet these certainly are on the hospital's bill. There is a cost in terms of reimbursement to the hospital, as well [64].

Doctor Fry: I hope these punitive measures will be short-lived. The long-abiding solution is going to be episode-based payment, so that hospitals and physicians get paid a fixed sum that is risk-adjusted to the patient's profile. Our concept has been to create the surgical warranty—the probability of a bad outcome in a high-quality institution times the cost—and you tack a warranty onto every episode payment [65].

Now if a hospital, instead of having the whip, uses the carrot—better outcomes and efficient use of resources improve the institutional margin. Relative to everything we have talked about in the prevention of SSI and of other hospital-acquired infections, you can make the case that we have not turned the dynamic on its head. Instead of negative reinforcement, let us give them an incentive to fix it, because they will when there is a financial reward for cost-effective care.

Doctor Cheadle: I could not agree more. There is still the incentive there. It is just that it is the carrot instead of the stick. An investment ahead of time will increase your margin if the intervention is efficacious. So if the data are there, it is worthwhile doing, because that will lower the cost overall.

Doctor Itani: The direct cost of an SSI, which, you say is on the order of $35,000, and the rate of SSI is close to 3% overall—for every 100 patients, you are paying close to $100,000 in direct cost for those infections. It does not consider other factors—the effect on society, the effect on work. Typically, a patient with a SSI is going to be out of work for close to eight weeks, so that is an enormous cost. If you can prevent it by simple measures, such as proper antibiotics, proper skin preparation, proper showering or application of an agent, reducing the rate from 3% to 2%, you are saving a tremendous amount of money; and the measures you use become cost-efficient.

Other Measures

Doctor Barie: *Are there other best practices in surgical infection prevention we would like to mention in closing? We have not talked about temperature control. We have not talked about local warming of the surgical site, as just two examples, yet many practices have been shown to be important [22].*

Doctor Itani: There are many issues one needs to address in the surgical patient [52]. I do not believe that one element alone is going to prevent SSI. It is the combination of many of those elements in a bundle that is going to create a proper environment to prevent SSI.

Doctor Cheadle: The VA team training has shown the multi-factorial nature of causes and prevention of SSI [66], and that surgical morbidity can be reduced. Many of these interventions by themselves have not been proved in randomized trials, but with the cohesion of the team and raising awareness of how important it is to prevent these events, it is possible to reduce SSI. The totality of these actions is working where each individual one alone might not. If you put the proper antibiotic use, proper skin preparation, proper surgical scrubbing, and aseptic techniques together, and each member of the team contributes—if they see a break in the technique, they do something about it—it is greater than the sum of the individual components.

Doctor Barie: *Do you recommend preoperative bathing with chlorhexidine for your patients? And is it your opinion that we all should be doing so?*

Doctor Cheadle: It is good to bathe before an operation. The data are not there to support routine use of that procedure, but the data are accumulating to support routine use of topical chlorhexidine preoperatively.

Doctor Fry: In the past, I have used it selectively because of my perception of the risk the patient posed. I emphasize again that whether it is a patient application or whether we are doing it in the hospital, we need to examine the rigor with which we make sure it is done right. My suspicion is that pre-hospital antiseptic management of the surgical site should be of benefit. My concern is that a concept has been discredited with the prospective studies, because we have had no quality control of whether patients applied the antiseptic preoperatively, and we need to go into a new dimension in how we are going to do these trials.

Doctor Itani: Despite the evidence that Doctor Fry is mentioning, I still deal with a special patient population, and I believe the chlorhexidine bottle that we give them is an incentive for them to apply it and shower before surgery, so we do so routinely.

Doctor Fry: I agree with chlorhexidine applied topically, but I repeat that we give patients stuff to use, but we do not necessarily spend the time providing directions about how to use it, maybe in part because we do not know either. My personal bias is that the failure of the trials is likely to represent a failure of the application process.

Doctor Cheadle: That is why I am in favor of applying chlorhexidine as soon as the patients hit the door for their preoperative testing and workup the day of surgery, because then you know you have gotten it done. It should kill the organisms within 30 seconds.

Doctor Itani: Bill, would you treat just the site of the surgery, or the whole body?

Doctor Cheadle: I certainly would do the surgical site and three or four inches around it.

Doctor Barie: *I agree with Doctor Fry that risk stratification is important. Not every operation and not every patient are created equal, and there certainly are minor operations that carry almost zero risk of SSI.*

That said, I was circumspect about the bathing literature until the epidemic of community-associated MRSA had swept the nation. Recent data suggest that nearly 60% of soft-tissue infections presenting to emergency rooms in the United States are caused by community-associated MRSA [67]. We do not have data yet to support a change in our antibiotic prophylaxis prescribing practices [68,69], but I see patients with community-acquired MRSA soft tissue infections in my clinical practice all the time. When they are outpatients, we screen them. We decolonize those patients with mupirocin topically in the nares and chlorhexidine body washes. I have observed—admittedly, a casual observation—that it is effective in eradicating the infections in those patients and keeping them from coming back.

My opinion about topical chlorhexidine antisepsis of the skin has changed in the last decade, and increasingly, I am in favor of it. I believe it is still a testable hypothesis in many circumstances, but one that is intriguing enough to make testing worthwhile.

Doctor Itani: Phil, you mention the nares, but how about the axilla and perineal area? We know that 3% of patients are colonized only in the perineum, and you would not know this unless you test that area.

Doctor Barie: *We have done screening cultures of the intertriginous areas and found the yield to be low. I believe the chlorhexidine body washes take care of the problem, even if you do not screen in that circumstance.*

Doctor Fry: I would like to raise a different twist on the nasal colonization. It has been curious to me that 30% or 35% of patients are nasal carriers, and that healthcare professionals working in ICUs have the same nasal carriage rate as people walking in off the street. I would like to ask the question to this distinguished group: Is that a patient phenotype who is going to have an infection rate that exceeds that of the population in general? Is that the phenotype of the relatively immunodeficient patient?

Doctor Barie: *It may or may not be an immunodeficient phenotype, but there are data from Sam Eric Wilson's group in Southern California that show that patients who are nasal carriers have higher infection rates than non-carriers [70].*

Doctor Fry: I believe that. I wish that everybody reporting SSI rates with nasal decolonization would report all infections, not staphylococcal infections only. There are some reports suggesting that the overall infection rate does not change. You just reduce the staphylococcal infection rate. Nasal decontamination does what it is supposed to do. But if it is a phenotypic expression, you may not be changing the overall postoperative infection rate in those patients. You are just changing the organism.

Doctor Barie: *Or alternatively, any change that you make may be transitory.*

Doctor Fry: That is correct.

Participants Disclosure Statements

Dr. Itani has served as an advisory board member for Forrest Pharmaceutical. His institution has received research support for his role as principal investigator on projects from Merck, Cubist, and Lifecell. Dr. Itani has also received honoraria from Strategic Health and MedEDirect for development of educational material.

Dr. Fry has been both a speaker and a consultant to Ethicon in the last twelve months. He is on the Speakers Bureau for Merck and has spoken under their sponsorship in the last twelve months. Dr. Fry has been a consultant to the IrriMax Corporation in the last twelve months.

Dr. Cheadle has no competing financial interests to disclose.

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APPENDIX

How to use your StartClean cleansing kit

Doctor's instructions:

Insert instructions here

Your surgery time:

i.e. 9:00 am CST

Your surgery location:

i.e. Memorial Hospital. Chicago IL

Your cleansing area:

Keep out of eyes, ears and mouth. For external use only.

Start preoperative bathing:

Su	M	Tu	W	Th	F	Sa
☐	☐	☐	☐	☐	☐	☐

1

Thoroughly rinse the area to be cleansed.

2

Apply the minimum amount of product necessary to cover the area, and wash it gently

3

Rinse the area again thoroughly

4

Repeat this process as directed by your provider

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