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Lecture:

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For a number of years, thought leaders in health care policy have been focused on the concept of value-based care, and the American College of Surgeons (ACS) has continually contributed to these discussions. In January, Frank G. Opelka, MD, FACS, Medical Director, Quality and Health Policy, ACS Division of Advocacy and Health Policy; Clifford Y. Ko, MD, MS, MSHS, Director, ACS Division of Research and Optimal Patient Care; and I had the opportunity to participate in a program at Harvard Business School’s Institute for Strategy and Competitiveness, Boston, MA. Leading the course was Michael E. Porter, PhD, who, with co-author Elizabeth Teisberg, first brought forth the concept of value-based care in *Redefining Health Care: Value-based Competition on Results*.

During the program, Dr. Porter offered several examples of how value-based care is already being applied in U.S. health care models. Interestingly, most of the case studies involved surgery, indicating that we as surgeons and the College as your representative organization already are on the leading edge of this movement. Implementing value-based health care will take a culture change across the entire health care system, but it is an achievable goal.

Creating value-based care

The reality is that most health care delivery models, not only in the U.S. but across high-income countries, have continued to make incremental changes to their payment and care delivery structures. The tendency over the last two decades has been to rely on siloed organizational structures, traditional management practices, and volume-based payment systems. Meanwhile, these practices and policies have failed to keep pace with advances in medical science and technology. In fact, value-based care has gotten lost in the complexity of the system and the pursuit of multiple goals, such as patient experience, safety, efficacy, access, research, and education and training. To transform health care, we need a single unifying goal that aligns all stakeholders.

That fundamental goal is to deliver high-value care to patients. Under the model that Dr. Porter has developed, value equals health outcomes that matter to patients divided by the costs of delivering these outcomes. The challenge before us, therefore, is to design a health care delivery system that substantially improves patient outcomes, both clinically and experientially, and that shifts competition to offering evidence that a course of treatment improves value.

Too often, we have focused on producing better outcomes at the hospital, care site, specialty, intervention, or broad patient population level. Dr. Porter posits that value is created in caring for each patient’s condition (acute or chronic) over the full cycle of care. His strategic agenda for creating value-based health care delivery comprises the following six interwoven components:

- Reorganize care around integrated practice units (IPUs) tailored to specific patient conditions, such as congenital heart disease, breast cancer, obesity, and so on.
- Measure outcomes and costs for every patient.
- Move to value-based payment models with bundled payments for conditions.
- Integrate multi-site care delivery systems.
- Integrate care across geography to improve value.
- Build an enabling information technology platform.

The ACS and our Fellows have been developing the processes and resources surgeons can use to implement the value agenda throughout the course of the organization’s 105-year history, guided by the ideal of serving all with skill and fidelity. We have been committed to the mission of safeguarding the care of the surgical patient and ensuring that sur-

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gical patients receive quality care in an optimal environment.

IPUs
With respect to implementing the model that Dr. Porter and his colleagues have proposed, the College has long advocated that surgical patients should receive care from dedicated, multidisciplinary teams organized around a medical condition or group of closely related conditions over the full cycle of care. This approach is a cornerstone of the IPUs, which are really the building blocks of value-driven care. We take steps to ensure that patients receive the right care at the right location from the right health care professionals at the right time. We have a Patient Education Program that surgeons can use to help patients prepare for their operations and their postdischarge care. These tool kits, our Strong for Surgery program, and our collaboration with the Agency for Healthcare Research and Quality to develop pathways for Improving Surgical Care and Recovery encourage patients and their loved ones to be actively engaged members of the surgical care team—from the time of diagnosis to recovery.

At present, the ACS has standards for IPU-like programs in trauma, cancer, breast disease, bariatrics, pediatric surgery, and geriatric surgery. Others in development include vascular, thoracic, complex gastrointestinal, emergency, and rural surgery.

Outcome measurement
Another hallmark of value-based care is measuring outcomes. The College has endorsed this concept since its inception. To this end, we developed four guiding principles of continuous quality improvement:

• Set standards of care that can be individualized by patient and that are backed by research
• Establish the right infrastructure with appropriate staffing levels, mix of specialists, equipment, and use of checklists
• Collect and analyze rigorous data that is drawn from medical charts, backed by research, derived from postdischarge outcomes, and continuously updated
• Verify that quality care is being delivered through external peer review

In 2017, we pulled all of these pieces together in one book, *Optimal Resources for Surgical Quality and Safety*† (also known as the Red Book), which walks providers through the five stages of surgical care, peer review, credentialing, team-based care and the factors that affect it, data collection and analysis, and much more. It also points surgeons and their institutions toward the resources that the ACS, government agencies, and other stakeholders offer to help ensure they are delivering highly reliable, patient-centered care. Perhaps the most well-known and farthest reaching ACS outcome measurement program is the ACS National Surgical Quality Improvement Program, which departments of surgery use to determine their greatest strengths and weaknesses and to arrive at solutions that lead to better outcomes.

It is important in building a value-based system to measure outcome from not only the clinical perspective, but also from the patient’s point of view. Did the outcome improve function and quality of life, eliminate pain, and enhance productivity? Did it meet the patient’s expectations? Patient Reported Outcomes Measures (PROMs) are being integrated into data collection for the College’s registries, which are being combined into a single platform for simplified use and better data amalgamation.

Cost measurement
In addition to measuring outcomes, Dr. Porter calls for measuring the actual costs of care for each patient—not just the sum of charges billed or collected. More specifically, cost should be measured over the full cycle of care for the individual patient and should account for the use of resources involved in a patient’s care (personnel, facilities, supplies, support services, and so on). Ultimately, Dr. Porter recommends the use of bundled payments—a concept familiar to most surgeons. Using

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the bundled payment model, a single risk-adjustment payment is provided for the overall care of a condition, covering the full set of services needed over an acute care cycle or a defined period of time and using real cost data and appropriate margins to determine price. This alternative payment model gives the individual surgeon control over downside risk and any potential upside margin. The College is developing and proposing payment bundles for surgical services not yet covered under the 60-day and 90-day global fee.

Other elements of value-based care
Delivery of value-based care also will be dependent on shifting from a confederation of standalone units and facilities to a clinically integrated system that concentrates, allocates, and integrates care across appropriate sites. More specifically, in mature, integrated health care institutions, each care delivery site focuses on providing a defined scope of services, partnering with sites—often on the same campus or at least nearby—to provide other services. The idea is to deliver the right service in the right location based on acuity level and resources while easing patient access to repetitive services. Care would be integrated across sites using an IPU structure.

Under the traditional care geography model, care is organized around specialties and interventions for each site, resulting in duplication of services. Value-based care geography models organize care by condition in IPUs, which serve as the hubs of service delivery, building systems for teams to direct patients to the most appropriate site.

For these elements to work effectively, we will need to create what Dr. Porter calls an enabling information technology platform that combines all types of data for each patient across the full care cycle. Electronic health records (EHRs) would need to be fully interoperable within and across networks, referring clinicians, and health plans, and make cost data shared and transparent.

Our responsibility
As surgeons, we are familiar with leading multidisciplinary teams and are becoming increasingly aware of our role in each phase of surgical care, from diagnosis

If you have comments or suggestions about this or other issues, please send them to Dr. Hoyt at lookingforward@facs.org.
Olga M. Jonasson, MD, Lecture:

A path toward diversity, inclusion, and excellence

by Joan Reede, MD, MS, MPH, MBA
This struggle toward justice and equity is long fought. It does not involve one incident; it does not involve one person or place in time, but many events culminating in change.

Editor's note: The following is an edited version of the Olga M. Jonasson, MD, Lecture that Dr. Reede delivered at Clinical Congress 2018 in Boston, MA. The lecture has been modified to conform with Bulletin style.

It is through understanding the policies and actions of the past that we can better identify the antecedents and precipitants of today’s challenges. These are persistent issues related to disparities and exclusions, marginalization and minimization, but also challenges that have been met, if not head-on then at least from multiple directions, to lead us to where we are today. Hopefully, we can use our understanding to create vehicles for change—ways in which we can move our professions, our institutions, and our society closer to the principles of social justice and equity. If we look at this circle of time, we know that injustice is not new, nor is the fight to right injustice.

From the Civil Rights Acts of 1875, 1957, and 1964; to the 1920 19th Amendment to the Constitution that allowed women to vote; the Voting Rights Act of 1965 that ensured that people like me, blacks, could vote; to Title IX in 1972 and the Americans With Disabilities Act in 1990, there is a continuous cycle and struggle toward justice.¹ This struggle toward justice and equity is long fought. It does not involve one incident; it does not involve one person or place in time, but many events culminating in change. This battle has included courageous individuals who are willing to be the first to enter, who are willing to lead and to foster real and sustainable change.

Firsts

As a high school, college, and medical student, I was unaware of the many firsts who charted a course that opened doors for people who looked like me: from Elizabeth Blackwell, MD, the first woman to earn a medical degree from a U.S. medical school in 1849,² to Mary Edwards Walker, MD, the second woman to earn such a degree from a U.S. school and the first woman surgeon in the U.S.³

Some of those firsts also occurred in Massachusetts, where I live and work. In 1889, Charles Eastman, MD, became the first Native American to receive a degree from a U.S. medical school. He would later go on to found 32 Native-American chapters of the Young Men’s Christian Association, and he helped to establish the Boy Scouts of America.⁴

When she graduated in 1864, Rebecca Lee Crumpler, MD, was the first African-American woman in the U.S. to earn a medical degree, and the first African-American woman to graduate from the New England Female Medical College, later known as Boston University.⁵ Twenty-five years later, Susan Picotte, MD, would become the first Native-American woman to become a physician.⁶

These individuals were not only first in terms of opening doors, but they continued to be firsts and to make significant changes in many ways.

Also in Massachusetts, Mary Eliza Mahoney, RN, graduated in 1879 from the New England Hospital for Women and Children, now Boston’s Dimock Community Health Center.⁷ She was the first African American to study and work as a professionally trained nurse in the U.S. She went on to co-found the National Association of Colored Graduate Nurses. In 1923, Susie Walking Bear, RN, graduated from Boston City Hospital’s School of Nursing, and in 1927 she became the first registered nurse of Crow descent and the first degreed registered nurse of Native-American ancestry.⁸

Turning to Harvard Medical School, Boston, often when I ask individuals, “When do you think Harvard Medical School became more diverse?” they say it had to be after passage of the Civil Rights Act of 1964, when actually the first blacks matriculated at Harvard Medical School in 1850. During the Civil War and Reconstruction, Edwin Howard, Thomas Dorsey, and later, in 1871, James Still (all MD) were the first African Americans to graduate from Harvard Medical School.⁹ Changes also were occurring at the dental school at that time. One of the two first matriculants at the dental school was Robert Freeman, DDS, who also was the first African American
to earn a dental degree at an American institution. He has another claim to fame—he invented the golf tee.

In this period of change, John DeGrasse, MD, was the second African-American physician to graduate from a U.S. medical school. He would become a commissioned physician in the Civil War, but he also was the first black physician admitted to a medical society—the Massachusetts Medical Society in 1854. An important point is that the American Medical Association (AMA), founded in 1845, excluded blacks. Several years ago, when I served on the Sullivan Commission on Diversity in the Healthcare Workforce and we were taking testimony from across the country, an AMA leader said, “I don’t understand why you all started that National Medical Association [NMA]. I don’t know why you just didn’t all join the AMA.” I had to inform him that in 1895, when the NMA was established, we were not allowed to join the AMA.

More firsts, more action, and more movement forward—and two amazing firsts, both affiliated with the Ohio State University School of Medicine, Columbus. Clotilde Dent Bowen, MD, was the first African-American woman to graduate from that school and the first African-American woman physician in the U.S. Army. Olga Jonasson, MD, FACS, was the first woman chair of the department of surgery at Ohio State. More firsts, such amazing women: Alexa Canady, MD, FACS, who gave the Olga M. Jonasson, MD, Lecture two years ago, was the first African-American woman neurosurgeon, and Antonia Novello, MD, was the first Hispanic woman U.S. Surgeon General.

It is important that our youth understand that there are people who blazed the trails that led to where we are today. Some firsts may actually be reading this article because of what they achieved in the past. But I also know that some of you will become firsts in the future. The role of the individual is important, but we should never underestimate the power of we, the power of standing up, the power of playing a role—of being seen and heard, be it in large and bold ways or small and deliberate ways. The power of being present was not and is not only about racial equality; it is not only about economic justice. It is about gender and disability and immigrant status. It is about being marginalized and excluded. It is about how we come together to form the power to create change.

So, you can talk about the “I,” like in the word individual, but we can talk about the “we,” W-E, in the word power, because it is what we can do collectively to create change that can be so important.

Some of you may know about the busing incidents that occurred in the 1960s and 1970s in Boston public schools. Well, Massachusetts banned segregation in public schools in 1855. We banned it, but in the 1970s we were fighting to end that same segregation. So, part of this story is about how we move forward.

The value of diversity and inclusion

Why is diversity important? Diversity and inclusion are important because they help us to realize our values, they help us to deal with complex issues and problems, and they ensure our viability as institutions and as professions.

I have been doing this work—improving diversity—for more than 25 years, and early on, in considering medicine and academic medicine, the thinking was that we needed more black physicians to treat more black patients, and we needed more Hispanic physicians to take care of Hispanic patients. But we were not thinking about the fact that we need more diverse physicians to be our department chairs and our deans and our presidents of institutions and leaders; the focus was on patients and communities.
I would put forward that we do need more diversity in terms of who is treating our patients, but it is not that a black patient needs to have a black physician. It is the responsibility of all of us to meet the needs of our patients. The equally relevant issue is how my presence as a black physician in an institution, an institution like Harvard, helps Harvard fulfill its responsibility and its mission.

So, I think of diversity not in terms of numbers, but rather about how diversity becomes embedded in the fabric of what we do. How should diversity be considered as we develop the policies, programs, and practices of our organizations? Not because it is Black History Month or National Hispanic Heritage Month or Women's History Month, but actually every day in our work, do we have a diversity lens? How does a mix of backgrounds help us realize our values of social justice and equity? A diversity lens helps us realize the goals of accountable representation and distributed justice and access to the benefits of our system.

Often, when I talk about diversity, people think I am talking only about race or ethnicity; or they will ask, “Are you here for women’s issues alone?” My response is, “What if I am a black woman?” All too frequently, we forget about intersectionality—that each of us has multiple identities. So, when I think about diversity, I think about how we can all bring the best of what we have to the work that we do.

**Who is in the room?**

Is diversity defined on the basis of gender, race, or ethnicity, or a different kind of training, a different kind of social network, language, culture? How do all of those aspects of who we are come together to help us be more successful in our education, in our research, and in our service? Diversity is about all of us. The question we should be asking is: Who is in or out of the room?

Dr. Jonasson often asked questions about who was in the room. When we ask who is in the room, we can get very comfortable if they look like us. I think we also need to start asking about who is not in the room. The need also does not end with getting into the room, but includes whether you have a seat at the table. All too often, women have been let into the room, but even when given a seat at the table, our voices are not heard. So, it is not just getting into the room and to the table; it is making sure our voices are heard. How can we be part of the conversation and part of the dialog to create change?

Diversity can help us solve complex issues. If you look at the work of Scott Page, Leonid Hurwicz Collegiate Professor of Complex Systems, Political Science, and Economics, University of Michigan, Ann Arbor, known for his research on the benefits of diversity, you think about asking different questions, looking through different lenses, different heuristics. Diversity is about how we come together, across disciplines, to solve and work on very complex issues and problems. We are better when we work together.

When I started doing this work in building diversity many years ago, people would say, “All right, Joan, you are talking about diversity, and you are talking about change in the demographics in our country, but that will happen in another century. It is a lifetime away. We don’t need to think about that now.” Well, we do.

By 2050, our nation is going to be majority-minority. I am a pediatrician, and when I look at Boston, it is already majority-minority. When we look at our children, at who has graduated from high school, who is going to go to college and to medical school, and who will become surgeons, it is an increasingly diverse group. If we don’t capture that potential, if we don’t
nurture those students’ interests, we won’t have those individuals for our profession and our future.

Looking at women and minorities based on reports from the U.S. Census, from our medical school graduates, our graduate medical education pool, our residencies and fellowships, and our practicing physicians, we see decreasing representation across all those groups. There isn’t parity. There isn’t adequate representation. I find that troubling.

But there is more to “unpack.” In our medical schools, we see a higher percentage of women at lower ranks, at the ranks of instructor and assistant professor, and the percentages drop when we look at the level of professor. Again, we need to disaggregate, we need to further unpack. When we look at women full professors among basic science and clinical faculty in 2015, we find only one Native-American faculty member (see Table 1, this page). In the basic sciences, 16 black women were full professors. In the clinical departments, we find 179 black women full professors. These departments are found in institutions that have historically and predominantly served minority populations, including Howard University, Washington, DC; Morehouse School of Medicine, Atlanta, GA; and the University of Puerto Rico, San Juan. Today, the U.S. has 229 African-American women full professors out of more than 170,000 faculty.16,17 We need to unpack; we need to disaggregate.

An additional issue that I want to stress, because it is so important, is the racial ethnicity of women department chairs. Although slightly better today, in 2015 there were 15 African-American women department chairs in the U.S., there were fewer than 30 Asian women chairs, and fewer than 25 Hispanic women chairs—a critical issue for all of us as we think about leadership and we think about the future.18

Barriers to diversity
What are some of the barriers to achieving diversity? At the individual level, we can think about resilience, preparation, opportunity—opportunity to explore, to dream, to think, to believe.

The Biomedical Science Careers Program (BSCP) was started after I gave a talk at the New England Board of Higher Education program at the Massachusetts Institute of Technology (MIT), which brought students together from across the northeast to think about careers in science, medicine, and graduate-level training. A young woman came to me at the time and said, “I didn’t know that there were black women physicians.” I said, “Did you know that there were black male physicians?” She said, “Yes,” and I asked, “How?” She said, “How does anybody know? The Cosby Show.” Just think about it. Her vision of the world was what she saw on television, so, I was this anomaly. I was an example of the fact that it was actually possible to be black, a woman, and a physician.

If we think about our society—the policies, the politics, and the economics—or we think about the culture and the policies within our institutions that historically excluded, and sometimes still exclude, minorities and women, the problem becomes clear.

Think about that young woman who spoke to me that day at MIT. She did not attend MIT, but she was at the meeting. Think about images in popular culture and what these images tell our youth about what continued on page 18

<p>| TABLE 1. FEMALE BASIC SCIENCE AND CLINICAL FULL PROFESSORS IN U.S. MEDICAL SCHOOLS, 2015 |
|---------------------------------------------|---------------------------------------------|</p>
<table>
<thead>
<tr>
<th>BASIC SCIENCE</th>
<th>CLINICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total male and female full professors =</td>
<td>Total male and female full professors =</td>
</tr>
<tr>
<td>6,950</td>
<td>29,754</td>
</tr>
<tr>
<td>0 American Indian/Alaska Native</td>
<td>1 American Indian/Alaska Native</td>
</tr>
<tr>
<td>205 Asian</td>
<td>695 Asian</td>
</tr>
<tr>
<td>16 Black/African American</td>
<td>179 Black/African American</td>
</tr>
<tr>
<td>40 Hispanic/Latino</td>
<td>126 Hispanic/Latino</td>
</tr>
<tr>
<td>0 Native Hawaiian, Other Pacific Islander</td>
<td>0 Native Hawaiian, Other Pacific Islander</td>
</tr>
</tbody>
</table>

FIGURE 1.
MESSAGES WE SEND

Google image search for “smart person”

Google image search for “professor”

Google image search for “doctor”
is possible. I went to Google to grab some images, and I want to show you what came up (see Figure 1, page 17). Look at the images for “smart person.” What do you see? Look at the images for “professor,” and for “doctor.” The results were similar for “surgeon,” “chief executive officer,” and “president,” but not for “assistant professor.” I talked about this issue of intersectionality and the messages that we send our youth, so I Googled “professional hairstyles.” Look at the results in Figure 2, this page. What do you see? What do you see when you Google “unprofessional hairstyles?” So, I want you to think about the images that we send youth in the media.

There are barriers and challenges (see Table 2, page 19), there are stereotypes and stereotype threats, there is tokenism and lack of validation, isolation, and exclusion. Minorities are hyper-visible and invisible at the same time.

Microaggressions and disability bias
I co-led a two-day session centered on women of color in the sciences as part of a National Institutes of Health (NIH) course on mentoring women in the sciences. At the end of the first day, the individuals from the NIH who were sponsoring the course came to me and said, “You know, Joan, this is not working. We are not getting where we need to go. These women of color are talking about women’s issues.” I said, “Could it be that women of color have women’s issues?” They said, “Maybe.” So the next day we discussed other aspects of diversity. I came away from that meeting with the sense that, except for the moments when people were talking specifically about women of color, we could have been invisible and not present at the meeting. So, women are hyper-visible and invisible at the same time. How many of you have experienced this scenario: “That’s an excellent suggestion, Miss Triggs. Perhaps one of the men here would like to make it” (see Figure 3, page 20).

We also have a disability bias, which is often left out of discussions. I find this omission interesting, because people often think of disability in terms of mobility challenges. I bring up this issue because sometimes when I am at a meeting, people say, “Well, Joan, I hear you, but it’s not a big issue here.” Then the next person says, “Would you please sit on the other side of me because I can’t hear well in this ear.” The disabilities that we see in our patient populations exist in our colleague population, as well as in our student population.

Harvard’s response
I want to turn briefly to what we did at Harvard Medical School and the response within my office. I draw on the power of paying it forward, understanding our history and our past, and understanding that we have an opportunity to contribute to a better future.

I run the Office for Diversity Inclusion and Community Partnership. Part of what we do involves pipeline programs; but I have a problem with even the concept of “pipeline,” because people often talk about it as a
TABLE 2.
EXAMPLES OF BARRIERS AND CHALLENGES EXPERIENCED BY DIVERSE INDIVIDUALS

<table>
<thead>
<tr>
<th>Tokenism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stereotype</td>
</tr>
<tr>
<td>Stereotype threat</td>
</tr>
<tr>
<td>Lack of validation</td>
</tr>
<tr>
<td>Isolation</td>
</tr>
<tr>
<td>Exclusion</td>
</tr>
<tr>
<td>Microaggressions</td>
</tr>
<tr>
<td>Bias</td>
</tr>
<tr>
<td>Hyper-visibility</td>
</tr>
<tr>
<td>Invisibility</td>
</tr>
</tbody>
</table>

leaky pipeline. For me, a leaky pipeline means that I have driven my car someplace, and when I drive off, a puddle or pool is left behind. That is not people. That is like throwing people out. It is saying that because you took a wrong turn or something went wrong, you can never get back on track.

I think of careers as journeys. I want all of you to think about where you were in middle school or high school. At that time, did you know you would be where you are today? Did you go down one path and then switch to another, be it a major or a school or a field of interest? I know I struggled in medical school with whether to do surgery or pediatrics. I loved playing with the kids, and I loved surgery—the precision of surgery. I could have gone in either direction.

So, when we talk about a pipeline, I want us to move toward thinking of careers as having multiple points of entry, exit, and re-entry. I want us to think in terms of continuity—continuity across the academic continuum. It is wonderful to have programs for middle-school students or high school students or college students, but how do we bridge them to the next level? All too often, we maintain that we cannot find the kids, but that shortage is often because our programs are not linked to other programs targeting individuals at earlier stages.

I started the Minority Faculty Development program at Harvard Medical School in 1990. Several years later, some of the leadership came to me and said, “You know, Joan, you have not solved the diversity problem for Harvard.” My response was, “How many hundreds of years did you have to create the diversity problem at Harvard?” Diversity is not something that you wake up one morning, snap your fingers, and you fix; it takes consistency of effort over time. It takes collaboration, and understanding that if we are going to reach the kids who will be our future physicians, we need to get to them when they are in middle school and high school. We need to partner with the schools, and we need to make sure there is strong science teaching in the classroom.

When I looked at middle schools for my daughter, I visited several private schools. At one school, the head of science wanted to talk to me when he found out that I was at Harvard, figuring he could get an in at Harvard. Now, you know something about that private school, because there was a head of science. A student knocked on the door of his office, and because I wanted to observe how he interacted with the student, I said, “Why don’t you take his question?” The student asked about a problem he was having with the electron microscope. Later that same day, a group of science teachers from Boston Public Schools visited my office, and we discussed preparation for their school science fairs. The teachers told us what they had been given as supplies for the science fairs, which were primarily boxes of markers. So think about it: electron microscope versus boxes of markers. Are the children in Boston less bright, or is part of this problem related to lack of opportunity and exposure?

Achieving diversity is about being creative and not doing the same things we have always done. When...
individuals from training programs call me and say, “I’ve been trying to get diversity, and I just can’t find anybody.” I say, “What have you tried?” They will tell me, and I say, “What else have you tried?” “Oh, I’ve just been sticking with this.” “And how long have you been sticking with this?” “Oh, about 10 years.” “Has it worked?” “Nope, I’m just sticking with it.” The issue is: how do you examine what you are doing and do something different, and how do you start to recognize that if there is no diversity in your social network and that is the only network you use to find diversity, you’re probably not going to find diversity? So, how do you expand that network? Broadening contacts includes how we communicate, and for me this is an area that is hardest.

How do we communicate with the kids today? It needs to be very different than in the past. I do not use Snapchat or any other social media. I don’t even know how to use them. But people in my office know because it’s important. The BSCP program that I mentioned earlier was started with my office in conjunction with the Massachusetts Medical Society (MMS) and the New England Board of Higher Education. The MMS publishes the *New England Journal of Medicine*. I was at the MMS office, and they said, “You know, Joan, we need to let the youth know, let the teachers know that we are really interested in diversity, and that we want them in medicine and in science. Can you write an article for the *New England Journal of Medicine* about this?” How many high school students read the *New England Journal of Medicine*? So, how do we communicate with the students that we want to reach? We need to consider intersectionality and recognize the multiple forms of diversity, as well as focus on commitment—from the bottom up and from the top down.

Our educational outreach program includes curriculum development: curriculum development locally, curriculum development that is disseminated nationally, teacher professional development—and that includes programs during the academic year and in the summer for middle school and high school students. We also offer a clerkship program that brings students to Boston to participate in one-month rotations at Harvard Medical School-affiliated hospitals. In any given year, 10 to 15 percent—and up to 25 percent—of these students have matched to a residency, and some have gone on to serve as faculty. These outcomes provide an example of the importance of considering continuity across the academic spectrum (student, to trainee, to faculty) and of including consistency over time in the delivery of diversity programming (see Table 3, page 21).19

The Commonwealth Fund Fellowship is designed to prepare individuals who want to become leaders in health care and address issues of minority and vulnerable populations. Some of our success stories include Joe Bettencourt from the Disparity Solution Center; Monica Bharel, Commissioner of Public Health in Massachusetts; Yvette Roubideaux, MD, former director of the Indian Health Sections Service; and Nawal Nour,
TABLE 3.
SEVEN Cs FOR ADVANCING DIVERSITY
Harvard Medical School Department of Diversity Inclusion and Community Partnership

<table>
<thead>
<tr>
<th>Continuity</th>
<th>Consistency</th>
<th>Collaboration</th>
<th>Creativity</th>
<th>Communication</th>
<th>Consideration</th>
<th>Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>across the academic spectrum</td>
<td>of efforts over time</td>
<td>within and outside of the organization</td>
<td>built on evidence and innovation and not merely repeating what has not worked</td>
<td>across generations and cultures</td>
<td>of intersectionality and the multiple forms of diversity</td>
<td>across all levels of the organization</td>
</tr>
</tbody>
</table>


MD, founder of the first African Women’s Health Center in Boston. These are individuals who have been policy advisors to senators, and three of them head foundations. Other examples include Kim Rhodes, MD, FACS, a surgeon at University of California, San Francisco, and Mallory Williams, MD, FACS, a surgeon at Howard. Plenty of individuals want to enter leadership positions within our organizations. How do we identify them and nurture their interest? The vast majority of individuals who come for this fellowship hold academic appointments in medical schools or schools of public health. All of them have remained committed to vulnerable populations and minority populations. They publish. They get grants. They are visible. They are creating change.

BSCP is unique because it is focused on the idea that there are individuals out there with potential who are highly motivated, and we need to connect them with advisors and mentors. When I first proposed the concept, people at Harvard called it “Joan’s fantasy.” They would not even acknowledge that it could be a program; it was just a fantasy. The reality is that more than 14,000 students have come through this program. At our last conference, we had 1,200 students and more than 250 advisors; 45 of those advisors, who are now physicians and scientists, entrepreneurs, and heads of companies, had come through this program as students. BSCP involves collaboration between academics and industry. It is a collaboration that has lasted through Prop this and Prop that, and all the anti-affirmative action efforts, largely because it takes no public funding and is supported by the community—a community that comes together to address issues of diversity.

The New England Science Symposium (NESS) brings 300 to 400 students who are interested in research together at Harvard annually. There are college, medical, and graduate students, as well as post-docs. We have had as many as 80 post-docs in attendance. I tell you this because often when I go places, people will say, “I would if I could, but I cannot find any minorities. They are not out there.” I tell you: they are there.

The fact is that these individuals do excellent work. I am reminded of one of our scientists and leaders, who asked if the program was remedial. He then attended a NESS conference and later e-mailed me, saying that he spoke to someone he thought was post-doc for 15 minutes only to learn that he had been talking to a third-year college student. Talent is out there, and we need to identify it and nurture it and get these individuals to stay the course.

Lessons learned
What are some of the lessons I have learned over time? We need to recognize history and context. We need to be prepared to recruit, nurture, and retain a diverse workforce. We need to create cultures where individuals can feel valued and comfortable and in which they
At the individual level, we have to survive, so for me, addressing diversity is about self-preparation and self-preservation—thinking about career development, building resilience, and avoiding burnout.

can contribute. We each need to deal with our own biases and perspectives. We need to turn to data and evidence. We need to start building the evidence base for what we are doing and why we are doing it.

At the individual level, we have to survive, so for me, addressing diversity is about self-preparation and self-preservation—thinking about career development, building resilience, and avoiding burnout. Some of the research my office is doing involves asking if particular aspects of burnout are not being captured for people who are on the margins. We need to serve as mentors and sponsors and help build networks. For me, having and being a mentor or sponsor is like being one of the Power Rangers: it is the collective power of what we can do together, how we can dream and believe and actually act together.

Part of the work I do and my commitment to it is because of my story and about my journey. One of my fondest memories of my youth is walking down the railroad tracks behind my grandmother in Florida. She was a tall, proud, deeply spiritual black woman. One side of the road was paved, where the white families lived, and the other side of the road was crushed shell, where my grandmother lived. We would walk down these tracks together and go downtown, where I experienced the signs telling me where I could not go in or the counters where I was not supposed to sit. More recently, my uncle, my mother’s brother, gave me a ride to work, and he brought up this subject and talked about a friend of his, somebody named Jelly Roll, whom he called an old-timer. You have to understand that my uncle is 87, so when he talks about an old-timer, you really start to wonder. He told me that a long time ago Jelly Roll was talking to my uncle about seeing my grandmother for the first time walking down these railroad tracks, holding her grandmother’s hand. Her grandmother was born a slave, so that makes one think of the possible: here is this woman who was born a slave, and here is my grandmother who cleaned houses, and here I am a dean, a professor.

REFERENCES


continued on next page
As stewards of the health of our patients, our community and our nation, we must be committed to advancing social justice and equity.

We each have the power to achieve our potential if we recognize, learn from, and honor our past, and set our priorities in ways that are aligned with our purpose and our passion. Each of us can make a difference: a difference in our families, in our patients, in our community, the institutions where we work, the professional organizations that we have joined. We can make a difference in our nation and the world.

Dr. Martin Luther King, Jr.’s, words still ring true: “[T]oday our very survival depends on our ability to stay awake, to adjust to new ideas, to remain vigilant, and to face the challenge of change.” As stewards of the health of our patients, our community, and our nation, we must be committed to advancing social justice and equity. Over time, the march may take on different appearances, it may change due to technology and how we communicate, but we need to keep moving toward social change.

Each of us has an opportunity to be informed by our values, to be guided by a vision—a vision of equity, secured by our vigilance and understanding that we cannot turn our eyes away, maintained by our voice. Our voices need to be heard. It is not okay to just say, “I don’t like what is out there.” We need to do something about it and be strengthened by our victories, big and small. ♦

REFERENCES, CONTINUED


Improving global emergency and essential surgical care in Latin America and the Caribbean: A collaborative approach
In an era of sustainable development goals (SDGs), members of the global surgery, obstetric, and anesthesia (SOA) workforce have grown increasingly aware of its collective role in achieving universal health coverage (UHC). The combined results of Disease Control Priorities Number Three, The Lancet Commission on Global Surgery (LCoGS), and the World Health Assembly (WHA) Resolutions 68.15 and 70.35—which called for global efforts to strengthen the provision of universal access to emergency and essential surgical care—jointly contribute to a paradigm shift in global surgery. We are moving away from vertical initiatives focused on a single disease and toward transdisciplinary and cross-sectoral collaborations aimed at strengthening health care systems in a horizontal fashion without disease-specific silos.

Key contributions of LCoGS to the global health paradigm include six core surgical indicators and targets within the surgical system-strengthening framework of preparedness, service delivery, and financial impact.1 Furthermore, LCoGS recommends that each country develop and implement a strategic national surgical, obstetrical, and anesthetic plan (NSOAP) informed by the collection, monitoring, and evaluation of the six core surgical indicators.2 The value of consolidated efforts is progressively appreciated and realized in nascent national and regional efforts across low- and middle-income countries (LMICs), specifically in sub-Saharan Africa, Asia, and Oceania.2,3 Such progress is crucial to extend efforts to all LMICs where as much as 90 percent of the population may lack access to emergency and essential surgical care, and mortality rates of noncommunicable disease are disproportionately high.1

Latin American and Caribbean (LAC) nations are in various stages of national health strategy and SOA systems development in order to address the inequities in access to timely, high-quality, affordable surgical care.1 To address the challenges specifically in LAC nations, Latin American stakeholders met in December 2016 in São Paulo, Brazil, to identify barriers to surgical care and propose strategies for regional cooperation and development of surgical indicators measurement in order to create, improve, or enact policies and processes centered on strengthening surgical systems.4

Subsequently, Rutgers Global Surgery of Rutgers-Robert Wood Johnson Medical School, New Brunswick, NJ; the Program in Global Surgery at Virginia Commonwealth University, Richmond, VA; and the Program in Global Surgery and Social Change at Harvard Medical School, Boston, MA, formed a coalition committed to aligning goals with LAC partners that promote regional equity in surgical care through the collection, analysis, and interpretation of high-quality data based on the six core surgical indicators. Once the six indicators are collected and interpreted,
TABLE 1. LCoGS CORE INDICATORS AND ASSOCIATED TRAUMA PROGRAM/SYSTEM ELEMENTS

<table>
<thead>
<tr>
<th>Category</th>
<th>LCoGS indicator</th>
<th>Description</th>
<th>Proposed trauma program/system element focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparedness</td>
<td>1</td>
<td>The geographic accessibility of surgical facilities</td>
<td>Prehospital system and integration with hospital registry</td>
</tr>
<tr>
<td></td>
<td>2*</td>
<td>The density of specialist surgical providers</td>
<td>Acute care surgeon/fellowships; trauma program manager</td>
</tr>
<tr>
<td>Delivery</td>
<td>3*</td>
<td>The number of surgical procedures provided per 100,000 population</td>
<td>Trauma and emergent/essential hospital/societal registries</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>30-day perioperative mortality rates</td>
<td>Trauma and emergent/essential hospital/societal registries, formal trauma performance improvement and patient safety, and trauma morbidity/mortality review process</td>
</tr>
<tr>
<td>Impact</td>
<td>5*</td>
<td>The risk of impoverishing expenditure when surgery is required</td>
<td>Future work—Ministries of Health/education/finance and trauma/acute care surgery divisional business administration</td>
</tr>
<tr>
<td></td>
<td>6*</td>
<td>The risk of catastrophic expenditure when surgery is required</td>
<td>Future work—Ministries of Health/education/finance and trauma/acute care surgery divisional business administration</td>
</tr>
</tbody>
</table>

*World development indicators

EARLY ACTIONS OF THE LAIRC

- Facilitating coordination between LAC and North American stakeholders that is formalized through a global surgery system research protocol
- Simplifying research education and training pathways that focus primarily on establishing leadership of surgical systems strengthening in Latin America and the Caribbean
- Establishing a home to large-scale process lessons learned by working within a newly formed multinational and transdisciplinary hands-on learner-driven surgical systems research collaborative
- Unifying efforts that primarily focus on WDI collection, analysis, and interpretation as a means to inform the tactical development, implementation, and evaluation of NSOAP and its respective science

A national situational analysis is performed that quantifies an aggregate of system preparedness, service delivery, and financial risk protection.

This analysis provides the evidence base for the multi-sectoral priorities set within formal process objectives of NSOAP development and implementation. The coalition’s activities culminated in formal regional recognition by the executive committee of the Panamerican Trauma Society (PTS) at its 29th Annual Congress in Brazil. The formation of a Global Surgery Sub-Committee at the 30th PTS Annual Congress in Mexico City marked a further milestone in inter-regional global surgery stakeholder evolution.

Goals from this academic global surgery coalition shaped what is now known as the Latin American Indicator Research Collaboratory (LAIRC) (see sidebar, this page). The LAIRC, formally launched March 2017 at Rutgers University, serves as a foundation for applying core surgical world development indicator (WDI) data collection, analysis, and interpretation in a systems-based surgical education and training research model. The LAIRC contends that academic global surgery program strategic planning for these purposes should target the development, implementation, and evaluation of NSOAP and respective components, which are SOA system workforce, service delivery, information management, infrastructure, governance, and finance.

In the second quarter of 2018, the LAIRC proposed that transnational global surgery learners (students, residents,
and fellows) and principal investigators at North America and LAC institutions partner and organize within learning networks called global surgery research units (GSRUs) for strategic planning. The GSRUs optimally provide an interconnected immediate prioritization and expansion of surgical systems research, and work in harmony using collaborative LAC WDI data collection, analysis, and interpretation, guided by a commitment to ultimately achieve NSOAPs.5

Building upon key goals that include organizing high-income country (HIC) and LMIC reciprocal teams in the LAC region, each LAC regionally specific GSRU and its members actively engender collaboration, with each specific nation’s researchers performing their surgical systems data collection, interpretation, and analysis. These researchers work on-the-ground, alongside multinational partners, without experiencing an isolation from the evidence base because of nascent systems research infrastructure or geographical location.6

This article highlights perspectives on the global surgery movement from seven LAC countries as a broad foundation for understanding barriers and successes to making population-level impact through these and other types of surgical system strengthening efforts. The achievements described in policy and practice guidelines development, research, and advocacy around the global surgery indicator and NSOAP framework, however, are only an introduction to this issue. By summarizing key aspects of LACs’ 2018 point of departure, the authors endeavor to optimize and scale discourse around indicator collection and NSOAP development, implementation, and evaluation; to disseminate surgical system science throughout LACs in 2019; and to build reproducibility through the early wins described in this article.

Report from the Bolivia collaborative
Since 2015, a collaborative effort between local stakeholders in Santa Cruz de la Sierra, Bolivia, and HIC academic surgeons have had a significant impact on nationwide health policy. This collaborative has used a bottom-up approach wherein partnerships—notably between five of the largest hospitals in the city of Santa Cruz de la Sierra—have facilitated access to regional data, identification of salient factors affecting public health, and a path to address these issues.

Local stakeholders and their academic collaborators from North America recognized the importance of an evidence-based approach to improve health care and generate better patient outcomes. To that end, prehospital data from the city’s morgue and inhospital all-cause mortality data were made more widely available to collaborating institutions. Importantly, local and statewide government officials, including the Minister of Health (MOH), identified the value of these efforts and supported a complete surgical needs assessment beginning in 2016.

This data-driven design to effect policy is exemplified in trauma care. The data showed that the greatest overall contributor to prehospital death is trauma, and 84 percent of all prehospital mortality events were conditions interpreted to be sensitive to a prehospital system improvement. Because Santa Cruz de la Sierra did not have a formal prehospital system, these data provided the impetus for legislation to establish the components of a prehospital emergency trauma and medical system in 2017.

The Bolivian team realized the value of the LCoGS indicators and framework for assessing surgical systems planning nationally; however, it also quickly realized that the existing data collection and information management tools were insufficient. To overcome this challenge, the team has since used a specific modification of the LCoGS indicators that was first applied to framing a trauma system data collection and analysis in Colombia (see Table 1, page 26). This modification provided a starting point in Bolivia for the value proposition of LCoGS indicators when specifically applied to regional injury care goals and legislation creation.7
TABLE 2. INDICATORS 2–6 IN THE YEAR 2014
FOR BRAZIL AND FOR EACH REGION

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Brazil</th>
<th>Region</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist surgical workforce density (SOA/100,000)</td>
<td>34.74</td>
<td>North</td>
<td>18.42</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Northeast</td>
<td>23.59</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South</td>
<td>45.81</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Central West</td>
<td>30.76</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>North</td>
<td>20 SOA physicians per 100,000 by 2030</td>
</tr>
<tr>
<td>Surgical volume (Volume/100,000)</td>
<td>4,433.44</td>
<td>North</td>
<td>3,518.58</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Northeast</td>
<td>4,190.93</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South</td>
<td>4,742.72</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Central West</td>
<td>4,163.59</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5,151.20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5,000 procedures per 100,000 by 2030</td>
</tr>
<tr>
<td>Perioperative mortality rate</td>
<td>1.71</td>
<td>North</td>
<td>1.12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Northeast</td>
<td>1.38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South</td>
<td>1.87</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Central West</td>
<td>2.13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.55</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>No target has been set. Will be re-evaluated on further data collection.</td>
</tr>
<tr>
<td>Percentage of population protected against impoverishing expenditure</td>
<td>79.39</td>
<td>North</td>
<td>73.85</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Northeast</td>
<td>68.70</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South</td>
<td>82.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Central West</td>
<td>81.39</td>
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<td></td>
<td></td>
<td></td>
<td>82.27</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>100% protection against impoverishment from out-of-pocket payments for surgical and anesthesia care</td>
</tr>
<tr>
<td>Percentage of population protected against catastrophic expenditure</td>
<td>84.58</td>
<td>North</td>
<td>82.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Northeast</td>
<td>78.49</td>
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<td></td>
<td></td>
<td>South</td>
<td>86.59</td>
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<td></td>
<td>Central West</td>
<td>84.77</td>
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<td></td>
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<td>87.15</td>
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<td>100% protection against impoverishment from out-of-pocket payments for surgical and anesthesia care</td>
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</table>

Report from the Brazil collaborative
Brazil has pioneered surgical indicator collection in Latin America using national, open-access databases. As a world leader in UHC, Brazil has a comprehensive single-payer and provider system, as well as a private care system, which has covered 27.9 percent of the population. Brazil’s public surgical system has met several key benchmarks (see Table 2, this page). However, geographic disparities in the provision of surgical care remain.

Measurement of the surgical indicators raised questions about data quality and the need for more granular information about the workforce. This finding led to follow-up studies in the Amazonas region, with a qualitative and quantitative assessment of surgical capacity at a randomized cross-section of 20 sites to compare national database statistics with on-the-ground realities. Additional studies to assess disparities revealed a maldistribution of health care professionals, with 75.2 percent of the surgical workforce located where only 40.4 percent of the population lives. As the issues faced by the Brazilian surgical systems are further characterized, specifically workforce issues, these research studies may be used to leverage policy change and advocate for the development of NSOAP components.

Many of Brazil’s global surgery efforts have focused on education and research capacity building. In the Amazonas, The Universidade do Estado do Amazonas (UEA) has accredited global surgery as a discipline. The program affords students and faculty recognized and protected time for global surgery—a crucial step in building sustainable academic global surgery competencies and careers.

Along with the work being done on access to surgical care, reports of variations in quality of care have created a new focus. Harvard University, São Paulo University, and UEA, alongside The Lancet Global Health Commission on High Quality Health Systems in the SDG Era, have worked to develop a set of indicators to measure quality of surgical care. The evidence-based indicators, worked into easy-to-use tools, are designed to be applicable to a range of hospital levels in the low-resource setting.
The global surgery team at UEA has piloted the feasibility of these tools to collect a baseline of surgical quality data at Hospital Pronto-Socorro 28 de Agosto in Manaus.

As the world’s fifth most populous country, organized into 26 states and a federal district, one of Brazil’s main challenges will be the coordination of efforts and priorities, and a regional or state-specific approach led by each state’s health secretariat may be more effective than a national effort. Nevertheless, in 2019, the focus is on coordinated collaboration between the Brazilian College of Surgeons, the Brazilian Society of Anesthesiology, and the Brazilian Federation of Gynecology and Obstetrics with an eye toward developing regional and national surgical plans. Ultimately, the progress presented herein, along with the anticipated improvements, will be evaluated at subsequent SOA Latin America meetings.

**Report from the Colombia collaborative**

Since 1993, the Colombia national health care system has depended on a mixed model of private and public organizations that deliver health care services financed primarily by payroll taxes.¹⁵ This universal health insurance system has resulted in a decline in the population’s out-of-pocket expenses from 40 percent of payment for health care services in 1995 to 9.6 percent in 2014.¹⁶ However, over the last two decades, many private insurance companies have declared bankruptcy, and the financial sustainability of this framework has become the subject of increased scrutiny by the health and economic sectors.

In 2002, the MOH developed professional working groups to strengthen national policy resolutions regarding emergency and essential health care services to treat the prevalent and high incidence of intentional injury associated with a multiregional civil war.¹⁷ Several years later, the National Resolution for Emergency Care Regulatory Centers (Resolution #1220 of 2010) defined local and regional administration to organize emergency care dispatch for initial emergency response and interfacility transfers.¹⁸ Resolution #2003, finalized in 2014, established a minimum standard for surgery and emergency services, which include a MOH committee’s periodic review and an update process on all aspects related to national equipment, infrastructure, and human resources. In addition, health care facilities and health care professionals are required to uphold minimum standards to acquire national-level authorization for providing surgery and emergency patient care services.

Further progress occurred when an open call was issued to fund the development of national guidelines related to emergency surgery in 2013. Colombia’s Clinical Practice Guideline in Severe Traumatic Brain Injury (TBI) charted national history with an inaugural funding effort to develop evidence-based technical documents for trauma care. In 2013 to 2014, the Colombian government, along with the IberoAmerican Cochrane Center in Spain and the Brain Trauma Foundation in the U.S., facilitated the development of a national guideline document for traumatic brain injury (see sidebar, page 30).¹⁹

The Colombia Statutory Health Law #1751 of 2015, which health care professionals, health care unions, and academic organizations supported, was promulgated as a new social contract between the nation’s citizens and the government. This legislation reprioritized the Colombian national government and the MOH’s health care sector law and policy formation.¹⁸,²⁰ As a result, the Integral Policy for Health Care was initiated to identify the most prevalent health determinants of all-cause, national mortality in the separate states.¹⁸,²¹

For each health condition identified, a strategy called Integral Route for Health Care was created...
to engage policymakers for the purposes of integrating national health promotion, prevention, and rehabilitation through health service systems of medical and surgical providers. The Integral Route for Health Care showed that the low number of specialists, high rate of interfacility transfer, and regional economic deficits contributed to the unaffordable type of primary and preventive medicine that was provided primarily in emergency rooms rather than at the community level. As a result, two main objectives were established: enhance promotion and prevention strategies for the most prevalent diseases at basic-level facilities, and enhance access to the specialized care needed in the various states and regions.

Because the four most prevalent health conditions are all noncommunicable, academic global surgery teams extended across Cali, Medellin, and Bogotá from 2016 to 2018. The experiential lessons learned helped to craft a LAIRC tool kit and identify the value of student research partnerships between university-specific chapters of the Global Surgery Student Alliance and InciSioN Colombia. The tool kit provided publicly shareable global surgery student checklists, a research protocol, an interinstitutional memorandum of understanding (MOU) template, and a call for a transparent indicator data collection, analytic and interpretative team formation, and completion of situational analyses for first steps in process mapping of NSOAP development and implementation. A strategic meeting was then convened in Bogotá, May 10, 2018—the Global Surgery in Latin America: Findings, Recommendations and Implementation of The Lancet Commission on Global Surgery Indicators Data Collection, Analysis, and Interpretation. As a result of this meeting, indicator collection was scaled up nationally and a Colombian surgical, obstetrics, anesthesia, orthopaedics, and

**COLOMBIA:**

**NATIONAL CLINICAL PRACTICE GUIDELINE IN SEVERE TBI**

- Delineates more than 15 evidence-based recommendations to minimize national variability in the diagnosis and management of severe TBI
- Demonstrates that the detrimental impact of ineffective or unsuccessful intubation of TBI patients in the prehospital setting is related to insufficient material resources and training in a majority of cities
- Represents an example of a national cost-effectiveness study for severe TBI management
- Reveals investment in improved ambulance resources and training is more cost-effective than paying for the complications of inaction; that is, not intervening or providing time-sensitive care in the emergency setting
- Promotes indicators that evaluate TBI service delivery quality and timeliness; that is, four-hour access metric for neurosurgical intervention
neurosurgical intersocietal formal commitment to global surgery was achieved, with a series of 2019 global surgery meetings planned to organize stakeholders in Colombia around specific SOA system study and priority. At a meeting December 5, 2018, in Bogotá, hosted by the Colombian MOH and Vice-MOH, LAIRC stakeholders and Colombian GSUs presented a completed process that achieved Colombia’s six core surgical indicators collection, analysis, and interpretation. These process activities have resulted in an ongoing government-academia discourse with respect to Colombian National SOA system strategy and development in 2019.

Report from the Ecuador collaborative
In 2008, Ecuador instituted a universal health care system, integrating various health care networks including the Ministry of Public Health, the Social Security Institute, military forces, national police, and nongovernmental and private health care facilities. Together, these organizations serve 16.39 million Ecuadorians; nevertheless, 36 percent of the population who live in rural settings often lack timely access to health care.23,24

To gain an in-depth understanding of the factors that obstruct the rural population’s access to surgical care in a country where universal health care is the standard model, the Program in Global Surgery and Social Change and the Master of Medical Sciences in Global Health Delivery Program at Harvard Medical School partnered with a diverse group of local collaborators at the forefront of rural surgical care delivery, as well as recipients of surgical services. Participants included the following:

• Nationally renowned Andean Hospital Homero Castanier Crespo and its leaders Renan M. Ulloa, MD (hospital director), Francisco Bravo, MD (associate director, general surgeon), and Juan F. Castanier, MD (general surgeon)

• Community health care workers and surgical patients from rural Andean, Coastal, and Amazon regions

• Community leaders, such as Angelina Chumpi, president, Coordination for Equity, Development and Social Action in the Amazon region

• The CINTERANDES, a mobile surgery program under the leadership of Anita Vicuña, MD (executive director, anesthesiologist), and Blasco Guzhñay, MD (chief physician)

These partnerships stimulated the development of a pragmatic research approach that allowed the collaborative to collect not only surgical indicators, but also in-depth qualitative data from local informants who can best describe their experience navigating the country’s UHC model. Results revealed complex biopsychosocial barriers and facilitators that shape the interface between the health care system’s ability to deliver surgical care and the patient’s ability to access care. The group encourages other LAC nations to harness diversity among research collaborators and to supplement indicator data collection with qualitative local data to understand and address hindrances to surgical care access.

Ecuador is unique in that it is the only Latin American country with an established mobile surgical program—the CINTERANDES Foundation, a nongovernmental organization (NGO) founded in 1990 by the late Edgar Rodas Andrade, MD, FACS.25 Through implementation of a fully functioning mobile surgical unit assembled on a 24-foot truck, Cinterandes offers free or low-cost surgical care to vulnerable populations, conducting more than 8,000 operations in remote, rural, and urban areas.26-28 This underused resource could be expanded to meet some of the country’s needs with cost-effectiveness measures to inform evaluation. It is a feasible surgical delivery model that other LAC nations could adopt to develop innovative methods to address the unmet
burden of surgical disease, especially in rural and remote settings.

Substantial developments in trauma and emergency services have occurred in Ecuador since the 1990s. The government improved prehospital and emergency care and created a robust 9-1-1 call system. However, along with other LAC nations, Ecuador needs robust surgical indicator data collection, and development and implementation of a NSOAP to achieve global surgery 2030 targets.

Report from the Haiti collaborative
Haiti is the only low-income country in the Americas. The 2010 earthquake that claimed more than 200,000 casualties further crippled Haiti’s fragile economy, while highlighting significant disparities in access to surgical care. Indeed, with a workforce of only 5.9 SOA providers per 100,000 population, most of whom practice in urban Port-au-Prince, Haiti’s SOA workforce amounts to less than one-third the recommended density. Consequently, Haiti’s surgical disease burden, which includes obstetric, traumatic, infectious, and noncommunicable conditions, remains largely unmet. Moreover, the nation’s fragmented health care system includes many NGOs that either initiated or expanded their operations with funding received after the earthquake. Their involvement has had a complex yet decisive impact on Haitian medicine.

National survey data indicate that up to 20 percent of seriously ill patients in Haiti are unable to receive care at a health care center because of excessive financial hardship (58 percent), prohibitive travel distance (12 percent), or excessive wait time (4 percent). These access barriers are compounded by the virtual absence of surgery from Ministère de la Santé Publique et de la Population (MSPP) policies prior to 2016 and systematic challenges, such as a dismal health care budget and a chronic workforce shortage aggravated by human capital flight. The Haitian Surgical Association has advocated for initiatives to address these concerns, calling for a modest increase in SOA financing and innovative education/training programs.

Of great concern is the fact that it is difficult to retain trained SOA professionals. According to MSPP data, for the last five years, Haiti’s teaching hospitals have trained approximately 20 new surgeons annually. Similar figures are noted for other SOA specialists. These physicians ideally should enter the workforce immediately upon completing their training; however, the expatriation of newly trained SOA providers into HICs continues to diminish local SOA labor density. Improved workplace conditions and higher salaries in HICs are among the causes of this brain drain. So, ironically, Haiti has become an LIC producing SOA providers for HICs.

The clinical isolation of private practice surgeons who remain in Haiti presents another dilemma. These surgeons, operating alone or with an assistant, see both their caseloads and revenue steadily decline as they lose patients to NGOs. The disguised joblessness of these professionals and a population with immense needs have created an enormous health care gap. This circumstance does, however, provide an opportunity to develop and implement a Haitian NSOAP that efficiently organizes and mobilizes all available resources toward durable solutions to these problems.

Although Haiti has yet to prioritize NSOAP creation, regional advocacy efforts in the LAC region offer potentially replicable models for NSOAP-driven health system strengthening. Against the backdrop of an evolving global surgery movement, the leaders of Haitian surgery are at a crossroads. On the one hand, they are challenged to address the country’s indisputable lack of access to essential, timely, and affordable SOA care; on the other hand, they are tasked with managing new and existing relationships with NGOs and academic partners from HICs that have invariably altruistic intentions, but...
variable cultural competence and often inadequate appreciation of the challenges facing this nation.

The specter of surgical colonialism is of particular concern in Haiti given its history. The realization of universal equity in access to surgical care for the people of Haiti will therefore require bold and visionary leadership from Haiti’s SOA community and larger health care sector. First, these leaders will need to make an inwardly focused commitment to using fundamental democratic structures to create innovative policies that facilitate the strengthening of SOA systems. Second, they will need to demonstrate an outwardly focused commitment to comprehensive surveillance of, and prudent engagement with, foreign partners in SOA capacity building so that their participation in Haiti’s surgical landscape empowers the country’s sustainable development, enables its national sovereignty, and promotes social justice for all Haitian patients and physicians.

Report from the Mexico collaborative

With a population of 119.9 million people, it is important that Mexico has made, and will continue to make, significant strides toward achieving UHC and combating inequality. However, the Mexican health care system has a balkanized structure that leads to inefficiency, regional maldistribution of resources, limited access in geographically isolated areas, and high administrative costs. Health care expenditures as a percentage of the gross domestic product in 2016 were 6.5 percent, and the share of out-of-pocket spending was 45 percent—the highest among Organization for Economic Co-operation and Development countries. Founded in 1943, the Mexican Social Security Institute is the nation’s largest social welfare agency. Multiple parallel subsystems coexist for other employed workers, the uninsured, and the unemployed, and private sector providers paid by private insurers or out-of-pocket by patients who decide not to use the densely crowded, suboptimally staffed, and underequipped facilities run by the government.

Mexico has a successful vaccination program that has dramatically reduced morbidity and mortality from childhood disease and also has made significant advances in maternal mortality. Life expectancy increased significantly during the 20th century, mainly because of improvements in public health and living standards. However, this trend has reversed recently because of an increase in homicides secondary to the violence unleashed in response to the government’s war on drugs. Life expectancy for men fell by 0.6 years between 2005 and 2010. The National Sectorial Health Plan issued in 2013 established the main goals of prevention and improved access to care. Still, other than programs directed toward surgical safety and descriptive statistics of surgical disease, there is no specific focus on analytical study that informs the development or implementation of plans that integrate surgical preparedness, service delivery, and affordability. Mexico’s new government, which took office at the end of 2018, has announced plans to abolish the country’s largest public insurance program, federalize state health subsystems, and gradually create a single health system to achieve UHC, but it is still uncertain whether the 2019–2024 National Health Plan will specifically address surgical needs.

Surgical workforce density is estimated at 40.6 per 100,000 population, well above the target set by the LCoGS; however, surgical volume has been reported to be significantly lower than the minimum of 5,000 procedures per 100,000 population set as a target for 2030 and established now as a core surgical WDI. To better understand the status of surgical practice in the country, offer clinical trials, conduct cohort studies, and support research and training, Hospital Español de Veracruz established the Center for Global Surgery Research. The center is supported by the National Institute of Health Research Unit on Global Surgery, a consortium between the...
Universities of Birmingham, Edinburgh, and Warwick, U.K. Together with GlobalSurg, a U.K.-based research initiative, and its international partners, Mexico is participating in high-quality, prospective, practice-changing international clinical studies. The Hospital Español de Veracruz’s Center for Global Surgery Research also has started assessing WDIs and conducting situational analyses across 50 hospitals in Veracruz with its own GSRU and LAIRC partnership. The group is actively engaging local stakeholders to further advance the goal of making surgery an essential component of the healthcare system and a public health imperative. Only through academic collaboration with surgeons and organizations in HICs and other LMICs is it possible to achieve meaningful improvements in the delivery of surgical care.

**Report from the Nicaraguan collaborative**
In 2015, the Nicaraguan ambassador to the United Nations Sustainable Development Summit proposed an International Campaign on Access to Safe Surgery to improve access to and delivery of surgical care. This proposition was issued in recognition of the magnitude of surgery-related deaths compared with fatalities from human immunodeficiency virus/acquired immunodeficiency syndrome, malaria, and tuberculosis combined. This proposal coincided with the efforts of the Nicaraguan MOH and Operation Smile—which for 20 years had been leading an increasing array of cleft surgery and education programs—and an MOU that calls for collaborative efforts to improve surgical capacity building specifically in underserved rural areas of Nicaragua.

During the first year of collaboration, life support training programs for all MOH perioperative health providers were offered through a train-the-trainer model, which reached 90 percent of the eligible workforce. Subsequently, district hospitals were targeted as the optimal, though often underused, physical location for providing surgical care to the majority of underserved people.

Then, a two-year pilot program called Cirugía Para El Pueblo (CPEP) commenced in 2017. This program deployed a comprehensive set of educational, equipment, and programmatic interventions...
to significantly expand access to and availability of impactful surgical care at rural primary hospitals in the Las Minas region of northern Nicaragua. Strong emphasis was placed on the following:

- Patient-focused care pathways using evidence-based and human-centered design
- Targeted field innovation, such as developing a biomedical technician role and curriculum specific to the district hospital context
- Community engagement, with initiatives such as weekly radio talks to educate the population on the benefits of surgery and the ability of local institutions to provide safe care
- Workforce training
- Investments in infrastructure and equipment, such as purified water delivery to the operating room (OR), surge-protected electrical supply, and building out an additional OR to combat bottlenecks

Existing Nicaraguan MOH management successes included the availability of most essential medicines. An aggressive maternal health strategy that provided better access to cesarean sections, which represented more than 50 percent of the surgical volume at the district hospitals assessed in Las Minas, reduced maternal mortality rates significantly. Moreover, no out-of-pocket

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All together moving forward
An increased network of coordination and collaboration in surgical indicator data collection, analysis, and interpretation will characterize the regional agenda for global surgery in LAC. The efforts described in this article strengthen the early characterization of interdependent NSOAP development, implementation, and evaluation that has been instituted over time. To facilitate a LAC context-specific agenda for
equitable surgical care access, a series of global surgery meetings will purposefully expand from these nascent national efforts, to incorporate LAC nations’ 2019 movement forward in the global NSOAP system science agenda. We are welcoming all countries’ transdisciplinary and multi-sectoral stakeholders to join this effort, report their particular national-level barriers and opportunities, and help break down the current silos that hinder SOA workforce assistance of MOH’s progress toward timely, quality, and affordable emergency and essential surgical care.

Links between research and partnerships such as the LAIRC, and the promotion and development of most national surgical societies across LAC, can generate the collaborative capacity to name, define, measure, reproduce, and strengthen NSOAP development, implementation, and evaluation more broadly. If we are able to standardize and disseminate a global health systems agenda for nationwide baseline surgical indicator collection and NSOAP in LAC, it ideally facilitates SOA-system advocacy for national-level governance and leadership in the provocative surgical and anesthesia policymaking and legislation urgently needed in the treatment of global noncommunicable disease.

The integration of national SOA indicator data into health care system strengthening platforms enables stakeholder, situational, and predictive analytics in the growing evidence and innovation basis of NSOAP and respective components; that is, workforce, service delivery, information management, infrastructure, governance, and finance. Most importantly, the evidence and innovation base vital to doing so is actively occurring within a newly defined collaborative that aligns the global academic surgery

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REFERENCES, CONTINUED


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community in an “experimental and empirical research environment in which scientists work and communicate with each other to design systems, participate in collaborative science, and conduct experiments to evaluate and improve systems.” Wulf and colleagues affirm with their statement that a collaboratory is in fact “a center without walls, in which the nation’s researchers can perform without regard to physical location, interacting with colleagues, assessing instrumentation, and sharing data.”

The global surgery indicator and NSOAP framework prioritizes this system-level thinking toward SOA preparedness, service delivery, and affordability, and offers a growing research context that aligns bottom-up with top-down processes in global surgery systems science. Given the growing recognition of global health and SOA system priorities in other parts of the world, activation of students, trainees, providers, institutions, and the public health, financial, and governmental sectors in the LAC region is crucial. The generation of transnational behavior consistent with value-based care structures, processes, and outcomes will engender social and financial responsibility through LACs’ emergency and essential surgical and anesthesia care.

Acknowledgments

Members of the Bolivia collaborative who contributed to this article include Sammy South, MD; Esteban Folanini, MD, FACS; Joaquin Monasterio, MD; and Mamta Swaroop, MD, FACS.

Members of the Brazil collaborative who contributed to this article include Rodrigo Vaz Ferreira, MD; Nivaldo Alonso, MD, PhD; Lina Roa, MD; Isabel Citron, BmBCh, MPH; and Fabio Mendes Botelho Filho, MD.
SUSTAINABLE CARE IN LATIN AMERICA

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Members of the Nicaraguan collaborative who contributed to this article include Neema Kaseje, MD; Jordan W. Swanson, MD, MSc; Ruben Ayala, MD, MSc; Nydia Betanco, BSN; Armando Siu, MD; and the Nicaraguan MOH.

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Collected papers of the ACS Metabolic Surgery Symposium
Part IV

Editor’s note: The Bulletin is publishing the collected papers from the Metabolic Surgery Symposium, which took place in August 2017 at the American College of Surgeons headquarters, Chicago, IL. This month’s articles focus on bariatric surgery and psychiatry and neurologic metabolic surgery. Next month’s articles will focus on metabolic surgery in private practice and international variations in metabolic surgery.
This article focuses on two primary topics related to the discussion of bariatric surgery and psychiatry. First, it addresses psychiatric issues of direct relevance to bariatric surgery, including the pharmacokinetic changes involved in the use of antidepressant drugs and the risk of alcohol abuse after certain bariatric operations. Second, the article looks at concerns about a procedure that involves potentially altering the vagus nerve, which provides an important bidirectional link between the brain and certain parts of the gastrointestinal tract. The procedure results in ongoing electrical stimulation of the vagus nerve as a treatment for severe, intractable depression.

**Bariatric surgery and psychiatry**

Psychiatric issues of direct relevance to bariatric surgery include factors of importance both before and after an operation. Although several of these factors raise concerns, they must be considered in the context of the clear benefits of bariatric procedures for most patients. The benefits of bariatric surgery include profound and usually well-maintained weight loss, and the amelioration or improvement in the many obesity-related medical and psychiatric comorbidities, such as diabetes and depression. A majority of patients experienced these benefits after bariatric surgery, as is well documented elsewhere in this collection of articles.
Medications and alcohol

Changes induced by the pharmacokinetics of medication following a bariatric procedure, such as the Roux-en-Y gastric bypass (RYGB), have been reported, mostly in association with administration of antidepressant drugs. Whether such changes occur after sleeve gastrectomy (SG) is still unclear. Antidepressants are the most common drugs used among candidates for bariatric surgery. In the Longitudinal Assessment of Bariatric Surgery (LABS)-1 study, 39.9 percent of patients were taking antidepressants; the second most common drug was a statin/lipid-lowering agent, and the third was beta blockers. Pharmacokinetic studies of sertraline, a serotonin reuptake inhibitor, and duloxetine—a serotonin/norepinephrine reuptake inhibitor—have been published. Both drugs were studied in groups of subjects who were nine to 15 months post-RYGB, and the kinetic results were compared with the areas under the curve obtained in obese subjects following single-dose administration of the drugs. All underwent P450 enzyme analyses to exclude slow and ultrarapid metabolizers. Results indicated that both drugs were malabsorbed after bariatric surgery. The clinical implications of these findings include the possible need to monitor the serum levels of some medications, as well as the need for clinical monitoring in case-dosage adjustments.

A related pharmacokinetic issue is alcohol absorption. A number of studies have shown that alcohol is absorbed more rapidly or achieves higher serum levels and sometimes has a longer half-life following RYGB but not after gastric banding procedures. Data regarding SG are still unclear. One RYGB study found that the peak serum levels following administration of modest amounts of alcohol occurred quite early, often in three to eight minutes, and were significantly higher than levels achieved after alcohol administration in nonbariatric surgery patients. This observation has been coupled with a growing awareness that certain forms of bariatric surgery are associated with increased rates of alcohol abuse, although most patients were free from this complication. These data suggest that alcohol use needs to be monitored closely after bariatric operations, particularly RYGB, and that patients with a history of alcohol or other substance abuse should be advised to pursue bariatric procedures with lower risks. Research in this area continues to evolve and may uncover more information about the causal factors involved and the means to mitigate risks associated with alcohol consumption.

Concern is growing about chronic opioid use in patients in general, including bariatric surgery patients. Data were reported after seven years from the LABS-2 study showing an increased overall use of opioids among bariatric surgery patients attributable to the initiation of postoperative drugs, as well as to the continuation of preoperative medications in a subgroup of patients. These findings have prompted renewed efforts to use nonopioids to manage pain in these patients.

Redundant skin folds

Another potential postoperative psychiatric concern is the existence of hanging redundant skin following bariatric surgery. Research demonstrates that most patients desire body contouring surgery in certain anatomic areas, in particular, the waist/abdomen (69.4 percent), the thighs (51.6 percent), the upper arms (46 percent), and the chest/breast area (43.6 percent). However, in the U.S., many patients do not receive body contouring surgery. The most frequently cited reason that patients do not receive this follow-up surgery is cost and lack of insurance coverage, which in the U.S. may necessitate out-of-pocket expenses. Consequently, patients should be made aware of such possible eventualities before surgery.

Psychiatric issues

A postoperative bariatric surgery issue that requires further investigation is the development of clinical eating disorders that resemble classic eating disorders, such
as anorexia nervosa and bulimia nervosa. The most common diagnoses are anorexia nervosa and atypical anorexia nervosa. Data are not yet available to determine the frequency of these disorders, but reported cases have been rare.10-12

Also of concern, and an impetus to facilitate bariatric surgery, is the high rate of depression in obese and morbidly obese bariatric surgery candidates.13,14 Previous publications from LABS-2 indicate that depression scores generally improve six months to a year after bariatric surgery, followed by some deterioration in this improvement between one and three years.15 Overall, rates of depression improve.

In some patients, however, the literature suggests an increased risk of suicide after bariatric surgery. A 2007 report by Adams and colleagues found that, at follow-up, overall mortality from various comorbidities (such as diabetes and cancer) was reduced markedly, while risk for suicide and accidents causing death increased threefold, although the increase was not statistically significant.16 Another report by Tindle and colleagues in 2010 looked at the prevalence of suicide among Pennsylvania residents reported to the Pennsylvania State Department of Health who had undergone surgery between 1995 and 2004. The suicide rate among bariatric surgery patients was 13.7 per 10,000 among men (U.S. norm 2.4) and 5.2 per 10,000 among women (U.S. norm 0.7), suggesting an increased risk.17

The reason for increased suicidality is unclear, but various reasons have been suggested, including persistence or recurrence of medical comorbidities, disinhibition secondary to alcohol abuse, antidepressant medication malabsorption, microbiome changes affecting the central nervous system (CNS), disappointment with weight outcomes or other outcomes, and worsening depression.13 The most recent data suggest that the risks may be at least partially attributable to the fact that many of these patients postoperatively report a history of self-harm and suicidal ideation prior to surgery.18 Therefore, these patients may represent a high-risk group. Yet, suicide remains a rare outcome among people in general, as well as among these bariatric surgical patients.

Cognitive function testing in the severely obese frequently shows impairment.... These conditions all improve significantly after bariatric surgery, although the mechanism for these impairments and subsequent improvements have yet to be established.

Vagal nerve stimulation
The second focus of this article involves the vagus nerve and its stimulation in the treatment of refractory major depression. Major depressive disorder is common, frequently begins in young adulthood, is often characterized by a chronic or recurrent course, and is usually accompanied by serious psychosocial impairment and substantial rates of suicide. Because of these factors, major depressive disorder is a public health concern around the world. Fortunately, a variety of interventions have been developed for these patients through the years, most introduced in the mid- to late-20th century.24 Treatment includes generally safe and effective antidepressant medications in a variety of classes, including inhibitors of the monoamine oxidase enzyme systems (MAO inhibitors); tricyclic medications, which represented the mainstay of treatment from the 1960s through 1980s; and serotonin-specific, mixed serotonin/norepinephrine, and norepinephrine-specific reuptake inhibitors, as well as new, atypical agents with novel mechanisms.24

Electroconvulsive therapy (ECT), which tends to be used in treatment-resistant patients, also is effective, but its use continues to carry a significant social stigma. Although it remains difficult to predict which patients will respond to which treatments, and treatment-matching algorithms based on genetic or other factors are evolving and only now becoming clinically applicable, most patients will respond to early interventions.25-27 However, a subgroup of patients, perhaps as many as 30 percent, will fail to respond adequately to repeated trials of antidepressant drugs, even when the medications are
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administered for a sufficient period of time and at adequate dosages, or to ECT when administered in an adequate trial. As a result, investigators have continued to develop other effective interventions. The group of treatment-resistant patients is generally characterized as having failed four adequate treatment trials, which may include ECT, and being symptomatic for at least two years.

Novel treatment approaches that have emerged in the last 20 years include forms of neurostimulation treatment that affect the CNS indirectly or directly (for example, through implantable electrodes). Various mechanisms have been postulated for the mechanisms involved in the effect, including monoaminergic and glutaminergic neurotransmission, neurotropic and neuroinflammatory mechanisms, as well as effects on various intracellular signaling pathways. A recent review found nine studies involving 100 patients treated with deep brain stimulation for depression involving five brain areas. So, the evidence to support this technique remains limited and suggests that such procedures should continue to be regarded as experimental.

Another such approach is vagus nerve stimulation (VNS). Substantial literature has been published on the development, rationale, putative mechanism(s) for, and efficacy of this approach, which now has Food and Drug Administration approval.

Much of the treatment literature on VNS consists of case reports and case series. Research in the area of VNS has accumulated somewhat slowly, owing to the difficulties in designing, implementing, and interpreting trials. However, some definitive work has been published. In 2013, Berry
Novel treatment approaches that have emerged in the last 20 years include forms of neurostimulation treatment that affect the CNS indirectly or directly (for example, through implantable electrodes).

and colleagues published a patient-level meta-analysis of studies evaluating VNS for treatment-resistant depression, which included an evaluation of six outpatient multicenter clinical trials, two of which involved the randomization of participants. As summarized in that report, outcomes were tracked from baseline out to 96 weeks with VNS + treatment as usual (TAU) (n = 1,035) versus TAU alone (n = 425). The conclusion was that for patients with chronic treatment-resistant depression, VNS + TAU results in remission rates that are modestly superior to those achieved with TAU.41

In 2017, Aaronson and colleagues published a five-year observational study of patients with treatment-resistant depression treated with VNS using prospective observational registry data from 61 U.S. sites. The study involved 795 patients with major depressive disorder of at least two years’ duration and/or who had experienced three or more depressive episodes. All of the subjects failed to respond to four or more depression treatments, including ECT. The registry represented the longest naturalistic study of efficacy outcomes in treatment-resistant depression and provided additional evidence that VNS has enhanced antidepressant effects compared with TAU in this severely ill outpatient population. Retention at one and five years favored the VNS group (93 percent and 61 percent versus 74 percent and 46 percent, respectively), as did the response rate (defined as ≤50 percent reduction in depression score; 67.6 percent versus 40.9 percent) and remission rates (defined as a final depression score using the Montgomery-Åsberg scale of 9 or less; 43.3 percent versus 25.7 percent). However, the response and remission rates increased gradually out to five years, with many patients showing minimal improvement for one to three years and less than 40 percent responding in the first six months. Relapse curves suggested deterioration in more than 50 percent at 3.5 years. Therefore, the advantage of VNS was clear, but again, as in the meta-analysis mentioned previously, far from dramatic.32

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Although various tuning parameters for the devices have been tried, the literature suggests some possible targets that can be used. A published review of some of the ethical issues in VNS addresses the complex topics of informed consent in this chronically ill, treatment-resistant population.43

Although the usual approach to administering VNS is to implant the pulse generator under the skin by tunneling in the upper chest wall and attaching the electrodes to the vagus nerve in the neck (invasive VNS), a transcutaneous approach also has been developed that involves attaching the device to the auricular concha to stimulate the auricular branch of the afferent vagus.44

In addition, an fMRI study has examined optimal placement, suggesting the cymba conchae as the preferred target site.45 Outcomes of a nonrandomized, controlled, pilot trial were published that suggest the efficacy of this approach.46

Although the mechanism(s) of efficacy of VNS have yet to be established, various mechanisms have been suggested, including an increase in gray matter in the hippocampus, activation of the insula, increased amygdala connectivity, and enhancement of noradrenergic activity outflow from the locus coeruleus.47-51 Nonetheless, the available evidence suggests that VNS is a reasonably effective approach for treatment-resistant depression patients, although the evidence remains limited.52

Conclusion
Changes in postoperative drug absorption require intense monitoring for alcohol misuse because of the hyperabsorption of alcohol. The malabsorption of certain antidepressants may require serum monitoring and dosage adjustments. Postoperative problems with hanging, redundant skin may indicate the need for referral for body contouring, which some insurers may not cover. The rare development of eating disorders such as anorexia nervosa after surgery may be of clinical concern. The use

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of electrical stimulation of the vagus nerve in severe depression, which can improve outcomes in a subgroup of treatment-resistant depression patients who have responded poorly to trials of drug therapy and/or ECT should be considered and requires surgical implantation of vagal stimulation devices.

Acknowledgments
This work was supported by the American College of Surgeons (ACS). The authors declare that they have no relevant conflict of interest.

We are grateful to the ACS for their generous sponsorship of the Metabolic Surgery Symposium and associated journal publication development. We thank Jane N. Buchwald, Chief Scientific Research Writer, Medwrite Medical Communications, Maiden Rock, WI, for manuscript editing and publication coordination. And we thank Patrick Beebe and Donna Coulombe, ACS Executive Services, for their expert organization of the Metabolic Surgery Symposium.

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Metabolic surgery was first defined in 1978 by Buchwald and Varco, who recognized that certain diseases, such as type 2 diabetes (T2D) and obesity, were metabolic in nature and that these complex conditions benefitted more from bariatric surgery than from weight loss alone. The encompassing idea of metabolic surgery has led to a growing interest in new procedures, devices, and therapies based on the physiologic changes observed after bariatric surgery. Among the metabolic surgery concepts under development (many described in this series of articles), are those that concern the nervous system, which has been shown to regulate certain metabolic functions. Therefore, bariatric procedures that alter normal neurologic functions should rightfully be included in the broad definition of metabolic surgery.

Despite the nearly century-old knowledge that the vagus nerve and the brain play significant roles in appetite, energy regulation, and body weight, the last 50 years of bariatric surgery have focused on the concepts of involuntary food intake restriction and/or nutrient malabsorption. Nearly all bariatric surgery procedures were developed solely as different methods for partitioning or removing part of the stomach to create a small reservoir and bypassing various lengths of the small intestine to reduce absorptive surface area and capacity.

Research conducted in the last two decades or so has shown that the vagus nerve (and possibly other nerves), the brain, and the neuroendocrine systems have significant control over body weight and metabolism. The growing worldwide obesity epidemic, along with the unwillingness of most potential operative candidates to undergo

HIGHLIGHTS

• Summarizes the development of neuromodulatory procedures to treat obesity and its comorbidities
• Outlines the role of neuromodulation to enhance or block normal physiologic functions
• Identifies the challenges and limitations of neuromodulatory therapies
• Describes total or partial vagotomy to treat T2D and obesity
conventional bariatric operations, has generated great interest in the development of novel therapies for obesity and its comorbidities.

This article reviews the state of development and results of these neuromodulatory procedures.

Neuromodulation

Neuromodulation refers to the application of patterned electrical impulses to target tissues, which may include the stomach, intestine, glands, nerves, or the brain. The electrical impulses can be altered to either enhance or block normal physiologic functions.

Gastric stimulation

One of the primary functions of the stomach is to break down and present partially digested food to the duodenum. Gastric contractions are regulated by the myoelectrical activity of the stomach, which consist of slow waves and spike potentials. Slow waves originate in the proximal stomach and propagate distally at regular intervals toward the pylorus. The slow waves determine the maximum frequency, propagation velocity, and direction of gastric contractions. In humans, the normal frequency of the slow waves is generally three cycles per minute. Spike potentials are strong action potentials that also propagate from the proximal stomach to the pylorus.

When a spike potential falls on a slow wave, a strong gastric contraction will occur, which may result in rapid gastric contractions, referred to as tachygastria, or slow gastric contractions, called bradygastria. Bradygastria is attributed to a decrease in the frequency of the normal gastric pacemaker. In contrast, tachygastria mainly originates from an ectopic pacemaker often located in the distal stomach. Normal gastric electrical activity propagates antegrade (from the proximal stomach to the distal stomach), whereas abnormal waves propagate retrograde and may disrupt the normal antegrade contractions. Because gastric emptying plays an important role in regulating food intake, gastric distension may inhibit eating.

Gastric electrical stimulation (GES) has been studied as a potential treatment for morbid obesity. Both antegrade and retrograde stimulation have been investigated. It is assumed that antegrade stimulation would entrain the normal slow waves. Antegrade stimulation has yet to demonstrate itself to be clinically successful for achieving weight loss, but it has been successful in the treatment of gastroparesis.

Retrograde GES yielded some degree of success in treating morbid obesity. It is assumed that retrograde stimulation may retard gastric emptying, resulting in early satiety and reduced food intake. It also is possible that retrograde GES results in fundic relaxation and distention, but the actual mechanism of action has not been proven in humans. To achieve retrograde GES, a pacemaker-like device is attached to electrodes implanted into the distal stomach. It is theorized that the electrical impulses propagate from the distal to proximal stomach, interfering with the normal antegrade impulses.

Continuous gastric electrical stimulation

Studies investigating the potential for GES to induce weight loss were performed in 1992 and first reported by Cigaina and colleagues in 1996. They demonstrated that high-frequency GES was safe and moderated weight gain in a growing porcine model. For the first 12 weeks of the study, no differences in food intake or weight were observed between study animals and a control group. However, after 13 weeks, study animals decreased their food intake and weight relative to the control group. After 8 months, food intake was 12.8 percent lower in study animals, and their weight was 10.5 percent less than the control animals.

In 1995, Cigaina performed the first human trial. Four women with a body mass index (BMI)
of 40 kg/m² or greater were implanted and monitored for up to 40 months. Platinum bipolar electrodes were implanted intramuscularly on the anterior gastric wall, adjacent to the lesser curve and proximal to the pes anserinus. An electrical stimulator was implanted in a subcutaneous pocket on the anterior abdominal wall. All four patients were permitted food and drink ad libitum. At 40 months after implantation, one patient had lost 32 kg, and a second had lost 62 kg. In the other two patients, malfunctions in their stimulator system were discovered.11

In 1998, a second study was performed in 10 patients, all with a BMI ≥40 kg/m². After implantation, all subjects were permitted food and drink ad libitum during three regular meals but told not to eat between meals. Sweetened and alcoholic beverages were discouraged. No significant complications or deaths occurred during the study. After 36 months of stimulation, the mean weight loss of all 10 patients was 24 percent of excess BMI (>25 kg/m²), which was maintained until battery depletion.12

Although Cigaina’s work was instrumental in introducing gastric stimulation for weight loss to the world, his studies were small, underpowered, and lacked statistical analysis.

U.S. 0-01 Trial
The first large multicenter, randomized, controlled, double-blinded trial was performed in the U.S. A total of 103 morbidly obese subjects were enrolled. One month after implantation, subjects were randomized to have their device activated or remain in the off mode. After seven months, the devices in the latter group were activated. Device settings were universal for all patients, and no dietary or behavioral counseling was provided. No deaths or complications occurred, and none of the patients experienced any adverse effects. However, 17 of the first 41 subjects were observed to have electrode lead dislodgements from the stomach wall. Interestingly, many patients admitted to having deliberately overeaten to discern whether their devices were activated. Despite the unintended consequences, 20 percent of the patients lost more than 5 percent of their total body weight, and the mean total weight loss was 11 percent after one year of stimulation.13

DIGEST
The U.S. Dual-Lead Implantable Gastric Electrical Stimulator Trial (DIGEST) was a smaller open-label investigation undertaken to evaluate a new device that had two leads (four electrodes) versus the previous...
single-lead (two electrodes) system (see Figure 1, page 50, and Figure 2, this page). In addition, a new lead-fixture technique was under investigation. A total of 30 morbidly obese subjects were enrolled at two clinical sites. Overall, patients experienced 15 percent excess weight loss at 38 weeks. However, results at the two institutions differed greatly. At one site, a mean excess weight loss of 30.4 percent at a mean follow-up of 9.5 months was achieved. At the other site, where a turnover of the research nurse position occurred, no significant weight loss occurred.14

SHAPE
A large prospective, randomized, placebo-controlled, double-blinded, multicenter trial was conducted, which involved 190 subjects who were randomized to either an active device or a placebo device. Again, GES was shown to be safe, but unfortunately, like the O-01 trial, the Screened Health Assessment and Pacer Evaluation (SHAPE) trial failed to demonstrate a superior weight loss for the study subjects with functioning devices versus the control group (~12 percent excess weight loss in both groups). However, in this investigation, a number of factors may have contributed to the disappointing results, including the fact that 26 percent of patients in the study group experienced exhaustion of their device batteries before the trial ended.15

Meal-activated GES studies
In addition to the study limitations of the investigations with the continuous retrograde GES, the lower than anticipated weight loss may have been a result of the 24-hour continuous stimulation leading to therapy tolerance or even resistance. To prevent this potential phenomenon from occurring, some GES systems were designed to be meal-activated. Hence, these devices lay dormant until the patient ate. Two such systems are in development: abiliti’s Closed Loop Gastric Electrical Stimulation (CLGES) system and the Tantalus Diamond device.16,17

The CLGES system includes the meal-activated GES and an accelerometer to monitor subject physical activity. A total of 45 morbidly obese subjects were enrolled in a multicenter, open-label trial. At 12 months, weight loss averaged 15.7 ± 7.7 percent of the baseline body weight. With stimulation, the number of disallowed meals and between-meal snacks was reduced (p <0.05), all levels of physical activity increased (p <0.001), and activity-based energy expenditure (303 ± 53 kcal/day on average, p <0.001) improved.16

FIGURE 2.
DES FOR BLOOD SUGAR CONTROL

A single bipolar lead (two electrodes) is laparoscopically implanted into the duodenal wall. Studies demonstrated that DES reduced both serum blood sugar and insulin levels after an oral glucose tolerance test. Sugar absorption was decreased and intestinal flow increased.
The Tantalus Diamond meal-activated GES device was developed with a focus on metabolic benefits other than weight loss. Glycemic improvements in patients with T2D were evaluated in a 48-week multicenter, randomized, blinded, crossover study. The outcomes for active devices were analyzed and compared with the results of inactive devices, which served as the controls. At six months, the subjects were crossed over. In the first 24 weeks, the two groups showed no difference in the change in HbA1C. However, when the GES was turned off in subjects with previously activated devices, the improved HbA1C values returned to baseline. In contrast, when the GES was activated in subjects who were in the control group, they maintained their improved HbA1C values.17

Duodenal stimulation and blood glucose control studies
Duodenal stimulation (see Figure 2) was evaluated for its potential effects on T2D. In one study, Khawaled and colleagues demonstrated that electrical stimulation of the duodenum of 33 male Sprague-Dawley rats, when activated immediately after a glucose tolerance test, resulted in a significant decrease in the rising phase slope and maximal value of serum blood glucose. Insulin secretion was decreased by 21 percent. In addition, the gastric emptying rate was decreased by 80 percent, and the intestinal flow rate was increased by 40 percent. Thus, duodenal electrical stimulation (DES) may reduce postprandial blood glucose levels by changing gastrointestinal motility to reduce available intraluminal glucose for absorption.18 Liu and colleagues found similar results in humans who were subjected to intestinal electrical stimulation. Nutrient absorption was decreased and intestinal transit was accelerated.19

The vagus nerve
The vagus nerve is the 10th cranial nerve and the longest cranial nerve in the body. It has numerous physiologic functions and has long been known to modulate gut function as well as body weight, appetite, and energy intake. The vagus nerve is considered the communication link between the gastrointestinal tract and the brain.

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appetite, and energy intake. It has been demonstrated that approximately 80 to 90 percent of vagal nerve fibers are sensory, bringing information from the gut to the brain, and the rest are motor, modulating intestinal motility, pancreatic enzyme secretion, and endogenous gluconeogenesis. Consequently, the vagus nerve is considered the communication link between the gastrointestinal tract and the brain.

Total or partial vagotomy
For more than 100 years, truncal and partial vagotomy procedures have been performed as a treatment for peptic ulcer disease prior to the introduction of H2 receptor-blocking medications. Along with the reduction of gastric acid, other physiologic changes were observed, one of which was loss of the gastric accommodation response to eating that regulates appetite and satiety. Vagotomized individuals also experience early satiation and decreased food intake. Furthermore, subjects experience inhibition of gastric contractions with delayed gastric emptying, resulting in the feeling of fullness and bloating. Chang and colleagues reported a series of 120 patients who underwent either complete or highly selective (partial) intra-abdominal truncal vagotomy, along with duodenectomy for refractory duodenal ulcers. The treatment goal was to reduce gastric acid secretion to enable the patient to eat without ulcer pain, thereby increasing their body weight back to its normal level. Interestingly, less than 50 percent of patients with complete vagotomy achieved their desired body weight gain, while 94 percent of those subjects with minimal vagal nerve interruption gained weight. This finding suggested that blocking vagus nerve function may inhibit weight gain.

Intestinal nutrient absorption also may be affected by vagotomy. Patients were found to have decreased fat absorption after complete vagotomy as compared with nonvagotomized patients or patients after undergoing highly selected vagotomies.

Gortz and colleagues discovered that truncal vagotomy had an appetite-suppressant effect. They observed in seven morbidly obese patients that truncal vagotomy resulted in reductions in body weight and caloric intake (from 2,800 kcal/day to 1,800 kcal/day in three months, and to 2,000 kcal/day at nine months after vagotomy). Interestingly, liquid calorie intake was reduced more than solid food intake. By nine months, liquid calorie intake was reduced by 50 percent, while solid calorie intake was only reduced by 27 percent.

Based on the growing knowledge that the vagus nerve plays a significant role in weight regulation, energy intake, and appetite, surgical vagotomy was investigated as a less-invasive therapy for treating morbid obesity than conventional bariatric surgery. In a group of morbidly obese patients, Kral and colleagues performed either a gastric partitioning procedure (vertical banded gastroplasty [VBG]) or the same gastric partitioning procedure with a truncal vagotomy. After one year of follow-up, the patients who had the vagotomies had a weight loss of 51 percent versus only 34 percent excess weight loss for those patients who only had the VBG (p <0.01). After 83 months of follow-up, the difference was even greater—61 percent versus 28 percent excess weight loss (p <0.001). This study and several more by Kral and others created great interest in vagotomy alone or vagotomy along with gastric partitioning as the long-awaited breakthrough in the treatment of morbid obesity.

Based on these and other findings, many surgeons added truncal vagotomy to conventional bariatric surgery, such as the gastric bypass and the VBG. However, the long-term benefits were inconsistent. Angrisani and colleagues found that the addition of a truncal vagotomy to the placement of a laparoscopic adjustable gastric band did not improve weight loss compared with just gastric banding at 12 or 18 months of follow-up. However, they also found that significantly more patients who underwent banding and vagotomy did not require band adjustments at six and 12 months as compared with the cohort of patients that underwent banding without vagotomy (50 percent and 35 percent, respectively, versus 20 percent and 8 percent, respectively). The differences at both endpoints were statistically significant (p = 0.034, p = 0.024, respectively).

Research conducted in the last two decades or so has shown that the vagus nerve (and possibly other nerves), the brain, and the neuroendocrine systems have significant control over body weight and metabolism.
In an open-label, case-controlled study, Martin and colleagues compared a cohort of patients who underwent laparoscopic truncal vagotomy and adjustable gastric banding with a matched cohort that only underwent laparoscopic adjustable gastric banding. At a mean follow-up of more than 30 months, all of the vagotomy patients reported an absence of hunger, but the difference in weight loss was statistically insignificant (38 percent versus 36 percent of excess weight, respectively).27

Okafor and colleagues investigated the effects of vagotomy on patients undergoing Roux-en-Y gastric bypass surgery. They retrospectively reviewed the outcomes of 1,278 patients who underwent gastric bypass; 40 percent of these patients also underwent concomitant vagotomies. They, too, reported that vagotomy had no effect on the percentage of excess weight loss.28 Finally, Liu and colleagues observed that truncal vagotomy did not seem to improve glucose metabolism when added to sleeve gastrectomy in a cohort of diabetic rats.29

The inconsistent results observed for truncal vagotomy as a standalone or adjunct weight-loss therapy could suggest that a truncal vagotomy, which is permanent, may result in tolerance or even the activation of compensatory mechanisms that would overpower the effects of the vagotomy. Therefore, the ability to intermittently block vagal nerve signaling for a duration of time and then allow full recovery of vagal function might achieve the desired outcomes without the loss of efficacy over time, as tolerance or compensatory mechanisms may not develop.

**Programmable, reversible, vagal nerve blocking**

Because surgical vagotomy was irreversible, a device that could be implanted and reversibly block vagal nerve signaling (see Figure 4, this page) was developed. The vBloc system, also known as the Maestro System, comprises a programmable electrical pulse generator known as a neuroregulator, with leads and electrodes. The electrodes are laparoscopically secured around the vagal nerve trunks at the gastro-esophageal junction.
The electrodes are attached to the leads, which are connected to the neuroregulator, which is implanted under the skin on the lower chest wall. The procedure is relatively brief and several studies have demonstrated that it has fewer perioperative complications than nearly all other bariatric surgical procedures. When activated, the vBloc neuroregulator generates intermittent, high-frequency electrical algorithms that are applied by the small electrodes directly onto the intra-abdominal vagus nerve trunks. These algorithms reversibly block compound action-potential transmission, resulting in reduced appetite, food intake, and body weight.

vBloc therapy clinical trials
A number of animal and human studies validated the vBloc therapy. Subsequently, more than 600 human patients with morbid obesity were implanted and participated in several investigations. The first two human trials were the vBloc-RF1 study, a proof of concept trial, and vBloc-RF2 study, a safety and efficacy trial. Because these studies were feasibility investigations, this review focuses on the subsequent, clinically meaningful trials.

The Eliminating Medications through Patient Ownership of End Results (EMPOWER) trial was a prospective, randomized, double-blinded, sham-controlled investigation, which included 294 patients from 13 study centers in the U.S. and two patients in Australia who were laparoscopically implanted with the Maestro System. The neuroregulator used in this study was active only when the subject wore an external power source attached to a belt. Therefore, the subjects controlled the duration of therapy by how many hours they wore the power supply belt. They were instructed to use the external electrical power source for at least nine hours daily. After implantation, the subjects were randomized, with 192 subjects assigned to the treatment group and 102 to the control group. The primary endpoints of the trial were the percentage of excess weight loss and serious adverse events (also known as SAEs) at 12 months.

The vBloc therapy demonstrated itself to be very safe in this study, with no deaths or serious complications. After the 12 months of follow-up, comparable excess weight loss was achieved in both groups. Treatment subjects achieved a $17 \pm 2$ percent excess weight loss in contrast to $16 \pm 2$ percent in the control group. Post hoc analysis suggested that weight loss was correlated with hours of use, and almost half of the treatment group subjects used the therapy for less than nine hours daily. The post hoc analysis also revealed that the safety checks performed by the neuroregulators in the control group subjects delivered a minimal amount of electricity to the vagal trunks. This amount of electrical energy, although less than 1/1,000th of the energy delivered to the treatment group, still may have provided therapeutic effects.

Subsequent research with rat sciatic nerve demonstrated that the safety algorithm used for the control patients resulted in a 31 percent reduction in the amplitude of the action potential of the sciatic nerves. Hence, it is likely that the subjects in the control group may have, in fact, received some level of vagal nerve impulse blockade that may have led to the unexpected weight loss in the control subjects.

Although the weight loss achieved in the EMPOWER trial was moderate, it was accompanied by medically significant metabolic benefits. Hypertensive subjects demonstrated statistically significant reductions in systolic and diastolic pressures. The EMPOWER trial created as many questions as it answered, and a true analysis of reversible vagal blocking was yet to be achieved.

Ikramuddin and colleagues reported the results of a subsequent study, the ReCharge trial, which was designed to correct the earlier trials’ unanticipated design flaws. A next-generation neuroregulator with a rechargeable internal battery was used to reduce patient noncompliance. In addition, all control patients were treated as if they had electrodes implanted laparoscopically, even though no leads were implanted to eliminate any possibility of partial blockade.
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was 7.8 percent. At one year, it decreased 1 percent (p<0.0001), and at two and three years, the HbA1c was still reduced by 0.6 percent (p = 0.0026). Fasting plasma glucose dropped significantly from a mean of 151 mg/dL at baseline to 123 mg/dL at 12 months (p = 0.0003), 136 mg/dL at 24 months (p = 0.0564), and 133 mg/dL at 36 months.31,42,43

DBS
Deep brain stimulation (DBS) as a treatment for neurodegenerative conditions such as Parkinson’s disease, multiple sclerosis, essential tremor, and amyotrophic lateral sclerosis has been found to achieve weight loss. However, few animal and human trials have been conducted. Melega and colleagues investigated the effects of DBS of the ventromedial hypothalamus in overweight mini pigs. They discovered that the mini pigs subjected to DBS gained significantly less weight compared with a control group, 6.1 ± 0.4 kg vs 9.4 ± 1.3 kg (p <0.05). However, no significant differences in fasting morning blood glucose levels were detected.44

DBS also may influence blood sugar regulation. In a group of rats rendered diabetic by the administration of alloxan, transcranial DBS enabled those animals to maintain normal serum blood glucose levels compared with a control group that was rendered hyperglycemic by alloxan but did not receive DBS. Furthermore, the study results suggested that DBS may have normalized the functional state of damaged β-cells and their proliferation.45

DBS targeting different regions of the brain will likely elicit different results.46 In contrast to Lebedev and colleagues, who reported improved blood glucose homeostasis in diabetic rats with transcranial DBS, Diepenbroek and colleagues reported that DBS of the nucleus accumbens actually increased blood glucose levels. Furthermore, they discovered that a 10 μA output had no effect, but an increased output of 200 μA did increase blood glucose levels.47

Patients with Parkinson’s disease progressively lose weight over time. In a case control study, Strowd...
and colleagues reported that patients with Parkinson’s undergoing DBS of the sub-thalamic nucleus experienced weight gain, while control patients demonstrated weight loss. At 21.3 months follow-up, the DBS patients gained a mean of 2.92 ± 9.4 kg while control patients lost 1.82 ± 6.9 kg. The mean weight difference of 1.1 ± 2.5 kg was statistically significant (p <0.02).48

In 2002, Burneo and colleagues unexpectedly observed that vagal nerve stimulation in patients who suffered from intractable epilepsy resulted in weight loss; 17 of the 27 patients lost weight. Of the patients who lost weight, eight lost more than 5 percent of their body weight, and five patients lost more than 10 percent. Furthermore, the weight loss seemed to correlate with increased stimulator output current. 49

Limitations and challenges
Although neuromodulatory therapies have been under investigation for more than 20 years, they are far from reaching their full potential. Many questions remain that prevent these technologies from becoming more commonly applied in humans. A significant knowledge gap persists in understanding their mechanisms of action, optimal therapy targets, patient selection, and markers of efficacy (such as neuropeptides, gastric distention, electrocardiogram changes, and symptoms). These devices can be programmed in an infinite number of ways. For example, a device can be set to continuous output or triggered output. The voltage, current, pulse frequency, pulse width, pulse train length, and total energy delivered can be adjusted to effect. Although the most effective way to maximize weight loss remains to be determined, these interventions have been associated with an extraordinarily good safety profile. Given the high prevalence of obesity throughout the world, neuromodulation as a treatment modality likely will continue to develop, improve in efficacy, and become more commonly used in clinical practice.

Awareness of the concept of metabolic surgery and its benefits in the treatment of metabolic disorders,
such as T2DM, morbid obesity, and hyperlipidemia, is growing. The nervous system has significant control over many metabolic pathways including body weight, energy intake, and serum glucose control. It is readily perceptible that neurologic metabolic therapies as highlighted in this overview have potential to benefit patients with metabolic diseases.

Acknowledgments
This work was supported by the American College of Surgeons (ACS). The authors declare that they have no relevant conflict of interest.

We are grateful to the ACS for their generous sponsorship of the Metabolic Surgery Symposium and associated journal publication development. We thank Jane N. Buchwald, Chief Scientific Research Writer, Medwrite Medical Communications, Maiden Rock, WI, for manuscript editing and publication coordination. And we thank Patrick Beebe and Donna Coulombe, ACS Executive Services, for their expert organization of the Metabolic Surgery Symposium.

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Acute appendicitis is the most common surgical indication in the pediatric population, yet its perioperative management remains widely variable. Analysis of such variations in surgical management has introduced opportunities for quality improvement (QI) through standardized care. Numerous studies have shown initiation of standardized protocols has led to more efficient resource use and decreased inpatient costs, and use of enhanced recovery after surgery (ERAS) protocols has been shown to reduce recovery time by up to 30 percent. 

Although ERAS for adult patients is well publicized in literature, multidisciplinary fast-track protocols in pediatric surgery have been slow to generate the same enthusiasm. Recent studies have demonstrated the feasibility of same-day discharge (<24 hours) following laparoscopic appendectomy in children with uncomplicated appendicitis. However, few pediatric studies have used a standardized protocol that is comprehensive and adopts components from the ERAS bundle applied in caring for the adult population.

Levine Children’s Hospital (LCH), Charlotte, NC, implemented a QI initiative that uses an enhanced recovery protocol for noncomplicated pediatric appendicitis that was comprehensive (preoperative, intraoperative, postoperative) and took advantage of a dedicated recovery unit. Our goal was to provide a framework for implementation of a multidisciplinary standardized pathway.

Prior to implementation of our QI initiative, the hospital lacked standardized perioperative management for appendicitis, leading to a range of hospital and postoperative lengths of stay (LOS). Preoperative antibiotics were selected based on surgeon preference, while postoperative pain regimens, time to mobilization, and initiation of enteral nutrition were typically nurse driven. Beginning with a common pediatric surgical diagnosis, our goal was to create a standardized perioperative pathway that would reduce interprovider variability, increase compliance with high-quality evidence-based practices, and reduce patient LOS.

Putting the plan in place
LCH is a 235-bed children’s hospital that is affiliated with Atrium Health. As the largest pediatric hospital between Washington, DC, and Atlanta, GA, and the only Level I pediatric trauma center in the region, it serves as the tertiary referral center for pediatric care in North Carolina. In 2017, more than 14,000 perioperative cases were performed at this institution. LCH participates in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP®) Pediatric.

Recent emphasis has been placed on the delivery of value-based care. At our institution, adult ERAS protocols have been implemented in the divisions of colorectal and hepato-pancreato-biliary (HPB) surgery, among others, serving as motivation to providers to initiate a similar protocol in the pediatric patient population. In response to changing health care needs, we adopted the first pediatric surgery fast-track pathway at LCH and introduced a multidisciplinary bundle of initiatives to streamline and standardize high-quality surgical care.

A multidisciplinary team of physicians and nurses was formed, including members of the divisions of pediatric surgery, perioperative nursing, anesthesia, and emergency medicine. At initial planning meetings, team members identified potential areas for intervention based on evidence-based
practices as well as perceived barriers to discharge. Current guidelines, such as those for antibiotic regimen, also were used during the planning process. A standard fast-track pathway for noncomplicated appendicitis was created with initiatives to standardize care in each perioperative phase, from diagnosis to discharge. The team discussed the effectiveness and feasibility of implementing each initiative to reach a consensus on fast-track pathway components. A preexisting physical unit adjacent to the operating room was newly designated as the dedicated preoperative and postoperative recovery unit.

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<th>TABLE 1. STRATEGY FOR IMPLEMENTING ERAS FOR APPENDICITIS</th>
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<td>Preimplementation practices</td>
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<td>Preoperative patient/caregiver education</td>
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<td>Intraoperative urinary catheter</td>
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<td>Dexamethasone prior to induction to reduce postoperative nausea</td>
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<td>Ondansetron prior to anesthesia awakening to reduce postoperative nausea</td>
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<td>Dedicated pre-/postoperative recovery unit</td>
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In addition, the initial driver of culture change and nursing leadership to implement the pathway was under the direction of a single clinical nursing educator, who was critical to the planning process.

Implementing the pathway
An electronic health record (EHR)-compatible order set (power plan) was created to facilitate identification of fast-track pathway patients and standardize preoperative and postoperative medications given (see Table 1, page 61). This order set was introduced to all attendings and surgery residents, who then entered the power plan for all pathway patients.

Initiating a culture change was critical to the implementation and sustainability of the pathway. All staff, including nursing/nursing assistants, emergency department (ED) personnel providers, patient transfer, patient account representatives, environmental services, and guest relations received a one-hour session on the goals/benefits of enhanced recovery and perioperative phases of the noncomplicated appendicitis fast-track pathway. A total of 14 sessions took place and were facilitated by the clinical nurse educator for preoperative/postacute care unit (PACU).

During the implementation process, resource tools were provided in the form of education folders and a question-and-answer board where staff members could seek additional clarification. Nursing supervisors also were readily available for questions during the implementation process. After planning and implementing the pathway, the team met regularly to assess the effectiveness of the QI project and discuss changes to address barriers, following the Plan-Do-Study-Act format.

Resources used and skills needed
The involvement of pediatric surgeons, ED physicians, and perioperative staff was critical to the success of the fast-track pathway; thus, champions from each department contributed input and feedback during the implementation process. The task force met regularly before and during implementation to address feedback and troubleshoot obstacles. A clinical nurse educator for preoperative/PACU was instrumental in leading education sessions for perioperative staff and participating in monthly ED staff meetings and daily huddles prior to implementation.

No additional clinical costs were necessary to implement and maintain the QI program. The designated recovery unit was created from existing space in the PACU area. Although the project received no funding prior to implementation, grants to offset cost of recovery recliners are pending.

Results
The fast-track pathway was implemented June 1, 2017. Patients with ruptured appendicitis intraoperatively

FIGURE 1. MEDIAN LOS PRE- AND POST-PATHWAY IMPLEMENTATION

![Figure 1](image-url)
were excluded from the pathway. ACS NSQIP Pediatric data and EHRs were used to track results and adherence to the protocol, and fast-track patient outcomes were compared with a historical cohort of outcomes prior to implementation.

The reduction in median total hospital LOS and postoperative LOS are illustrated in Figure 1, page 62. Following implementation of the protocol, postoperative and total hospital LOS declined by 59 percent and 39 percent, respectively, without an accompanying increase in postoperative readmissions or complications. Compared with the median average LOS of two days (1.4–3.1) reported by a study looking at practices in more than 30 pediatric hospitals, our results showed a median hospital LOS of 14.7 hours following protocol implementation. More than 67 percent of fast-track protocol patients were discharged home immediately after morning rounds.

The changes in antibiotic treatment regimen, dexamethasone administration, urinary catheter utilization, and rescue pain medication are illustrated in Figure 2, this page. Compared with historical control patients, 86.9 percent of fast-track patients received the standardized dose of preoperative antibiotics in the preoperative holding area. Use of an intraoperative urinary catheter also was significantly decreased by more than 30 percent after protocol implementation.

Coordination with anesthesia resulted in a significant increase in the pre-induction administration of dexamethasone. Similarly, improved compliance with administration of ondansetron and ketorolac led to a significant reduction in postoperative nausea and vomiting indicated by a number of patients requiring antiemetics in the designated postoperative unit. Use of a stepwise multimodal analgesia regimen resulted in a 37 percent reduction in intravenous narcotics given postoperatively.

Following discharge, nurses made follow-up phone calls to 91.8 percent of patients at 24 hours and 7–10 days. Only 9.2 percent of fast-track pathway patients elected to follow up in the office; in comparison, all pre-pathway patients were scheduled for a postoperative clinic follow-up with a 41.4 percent no-show rate. Following implementation of our protocol, average direct variable costs per patient decreased from $3,116 to $2,982—a 4.3 percent decrease in patient cost. Over the monitored period, net cost savings were $8,174.

Barriers to implementation encountered during the initial phase included ensuring patients were admitted to the designated unit. Patients admitted to other inpatient floors where nurses were unfamiliar with the fast-track pathway were less likely to be compliant. After identification of the problem, numerous changes, including direct communication with bed management, were made to address potential issues.
Beginning with a common pediatric surgical diagnosis, our goal was to create a standardized perioperative pathway that would reduce interprovider variability, increase compliance with high-quality evidence-based practices, and reduce patient LOS.

Contributing factors. Pediatric surgery residents instructed ED charge nurses to admit patients to the fast-track unit while charge nurses in the designated unit monitored the ED board for patients with appendicitis. As staff members became increasingly familiar with pathway components and were able to observe direct benefits in enhanced patient recovery, the culture change and increased provider buy-in led to fewer setbacks over time.

**Tips for others**

- **Find the right team.** Assembling a multidisciplinary team with input from key providers was instrumental to the success of our QI intervention. In particular, buy-in from surgeons and perioperative nursing ensured patients with noncomplicated appendicitis were started on the fast-track pathway. Team members also were able to educate other staff and help drive the implementation process.

- **Engage patients and providers.** In addition to educating providers and ancillary staff, brochures and visual aids provided patients and family members with information on the goals of enhanced recovery and set patient expectations for postoperative care.

- **Make simple, sustainable changes.** To implement a pathway with multiple components dependent on the ordering physician, we created a standardized power plan that bundled all nursing orders and medications, including preoperative antibiotics, postoperative analgesia, and antiemetics. The power plan simplified the admission orders for physicians and minimized interprovider variability at our teaching hospital with different residents rotating through pediatric surgery each month.

- **Solicit regular feedback/communication.** Team members met every three months during pathway implementation to troubleshoot setbacks, respond to staff feedback, and evaluate progress. Initial results were shared with perioperative staff to highlight early improvements resulting from pathway changes and further encourage culture change.

- **Shift the culture to a nursing-driven recovery and discharge process.** This major change resulted from the recognition that nurses were able to assess patients for discharge readiness more frequently than surgeons who were limited to seeing patients between cases. Enabling nurses to initiate conditional discharge orders once patients met preset criteria allowed for earlier discharge and reduced LOS.

**References**


According to recent estimates, 140,000 Americans were diagnosed with colorectal cancer in 2018, and approximately 35 percent of these cases had regional lymph node involvement; that is, stage III disease at diagnosis.

Despite advances in population screening, surgical technique, and adjuvant chemotherapy, colorectal cancer remains the second-leading cause of cancer death in the U.S. According to recent estimates, 140,000 Americans were diagnosed with colorectal cancer in 2018, and approximately 35 percent of these cases had regional lymph node involvement; that is, stage III disease at diagnosis.1

The current standard of care for individuals with stage III colon cancer is surgical resection with curative intent followed by adjuvant chemotherapy with the regimen of FOLFOX (fluorouracil, folinic acid, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) for three or six months depending on tumor (T) and nodal (N) risk classification.2 Despite such treatments, approximately 30 percent of patients will succumb to recurrent disease.

Two primary pathways have been described for the development of colorectal cancer: chromosomal instability and microsatellite instability (MSI). MSI occurs in about 15 percent of colorectal cancers and results from deficient DNA mismatch repair (dMMR). Approximately two-thirds of MSI colorectal cancers are sporadic, and one-third are caused by Lynch syndrome. Lynch syndrome is the result of a germline mutation in one of four MMR genes (MLH1, MSH2, MSH6, PMS2) or in EpCAM.3 In sporadic MSI cancers, the MLH1 MMR gene is inactivated by methylation, and such tumors frequently carry BRAF (V600E) point mutations. MSI tumors are more likely to be right-sided colon tumors and poorly differentiated than microsatellite stable tumors, yet are associated with a more favorable prognosis.4 MSI tumors are hyper-mutated, resulting in an abundance of neoantigens that trigger increased numbers of tumor-infiltrating lymphocytes, indicating a robust anti-tumor immune response. Evidence indicates that the immune response fails to eradicate cancer cells because of an overexpression of immune checkpoint proteins by MSI tumors, which inhibit T-cell signaling and function.5 PD-1 (programmed death-1) is needed.
Evidence indicates that the immune response fails to eradicate cancer cells because of an overexpression of immune checkpoint proteins by MSI tumors, which inhibit T-cell signaling and function.

one such checkpoint protein that has been successfully targeted by pembrolizumab, an anti-PD-1 antibody, in the treatment of stage IV colorectal cancer with MSI.

PD-L1 (PD-ligand 1) is another checkpoint protein that MSI tumors overexpress, resulting in negative modulation of the host’s anti-tumor immune response. Atezolizumab is a humanized IgG monoclonal antibody that binds to PD-L1, thereby enhancing the T-cell response in immune-activated MSI tumors. This antibody has been administered to more than 3,000 patients in clinical trials with no dose-limiting toxicities observed. The addition of atezolizumab to an oxaliplatin-containing chemotherapy regimen is appealing because evidence suggests that oxaliplatin may prime the immune response by transiently increasing inflammation within tumors. Given that anti-PD-1 treatment results in frequent and durable responses in MSI metastatic colorectal cancers and other solid tumors, its evaluation in the adjuvant setting is being evaluated in MSI stage III colon cancers in the ATOMIC trial (Randomized Trial of Standard Chemotherapy Alone or Combined With

Atezolizumab as Adjuvant Therapy for Patients With Stage III Colon Cancer and Deficient DNA Mismatch Repair). The study hypothesis is that the combination of atezolizumab and FOLFOX may unleash the host immune response to kill hypermutated MSI tumor cells, thus improving upon the results obtained with FOLFOX chemotherapy alone.

Study design
The ATOMIC trial (Alliance A021502) is a randomized phase III study of standard chemotherapy (modified FOLFOX-6) alone or in combination with atezolizumab as adjuvant treatment for stage III colon cancer patients with tumors that are deficient DNA MMR with MSI. Eligible patients must have histologically proven stage III adenocarcinoma of the colon (any T, N1 or 2, M0) who have undergone an R0 resection. Deficient MMR status must be evaluated by immunohistochemistry (IHC) for MMR protein expression (MLH1, MSH2, MSH6, PMS2) demonstrating loss of one or more proteins. IHC testing may be performed locally or at a reference lab chosen by the study site. Patients with known Lynch syndrome are eligible for this study. Trial stratification includes tumor location (cecum/ascending, descending, sigmoid, or rectosigmoid colon), based on the surgeon’s operative description and other studies. Patients with rectal tumors are excluded from the trial.

Patients must begin adjuvant treatment within 10 weeks of surgical resection and can be enrolled and randomized before starting adjuvant mFOLFOX6 or before the second cycle of adjuvant mFOLFOX6, which serves to allow ample time to obtain results of MMR testing. Patients randomized to the control arm will receive standard of care mFOLFOX6 for 12 cycles (six months), and those randomized to the investigational arm will receive 12 cycles of mFOLFOX6 combined with atezolizumab and will continue atezolizumab as monotherapy for 13 additional two-week cycles to provide sustained activation of the immune system.

The primary endpoint of the study is disease-free survival with secondary endpoints of overall survival, quality of life, and adverse events. The study includes retrospective central confirmation of MMR status. Correlative science
objectives are incorporated within the study design and protocol. Patients will be followed for evidence of recurrence every six months for two years after study registration and then annually for three more years. Patients will be followed for survival for eight years.

The surgeon’s role
Surgical resection is the initial treatment for most patients with newly diagnosed colon cancer. The surgeon is responsible for ensuring that the patient’s disease is properly studied by imaging and that pathologic review includes testing of all colon cancers for MMR status. This enables decisions regarding further therapy and surveillance to be based on the risk of recurrence. Surgeons should be aware that inhibition of the PD-1/PD-L1 pathway offers the potential to improve outcomes for stage III colon cancer patients with deficient MMR and MSI status. Eligible patients should be counseled regarding participation in this exciting trial.

REFERENCES
One hundred years ago in July, a surgeon in Baltimore, MD, published a 770-page textbook, *Plastic Surgery: Its Principles and Practice*, reporting his personal experience and collecting from scattered sources the principles and methods of what was to become the discipline of plastic surgery. In the “preface” John Staige Davis, MD, FACS (see Figure 1, this page), wrote, “About ten years ago my friend J.M.T. Finney MD, [FACS,] who knew of my interest in plastic surgery, suggested that I specialize in this work. He said that every general surgeon was operating on these cases because they had to be taken care of, but that no one in this country was doing the work properly and that the field was undeveloped.”

In that preface, Dr. Davis broke with tradition and made two major disruptive proposals, and he did this in strong and forthright terms.

**Early efforts**

During World War I (WWI), plastic surgery was limited by regulation to maxillofacial reconstruction to meet the demand for treatment of the inordinate number of nonfatal maxillofacial injuries associated with trench warfare and developments in helmet technology. At the close of WWI, a multidisciplinary clinical team was established at Walter Reed Hospital, Washington, DC, for the wounded coming home with complex maxillofacial injuries. The groundbreaking work done in this unit helped define the standard of care for plastic surgery of the face and train the first generation of maxillofacial plastic surgeons.

But for years prior to the Great War, Dr. Davis was developing therapeutic approaches and experimental support for a wider scope of techniques in reconstructive surgery. Graduating from Johns Hopkins Medical School, Baltimore,
MD, in 1899, he completed a 12-month internship at Hopkins with William Osler, MD, FRCP, and William S. Halsted, MD, [FACS], followed by a three-year surgical residency at the Union Protestant Infirmary, Baltimore (later Union Memorial Hospital). At that time, surgical work being done in Germany was held in high regard, and in about 1901, Dr. Davis became interested in tissue grafting, flap transfer, and other surgical procedures being done in Berlin for the care of burns, chronic ulcers, vascular malformations, and facial and body defects. Treating patients with tissue loss and working in the Hunterian Laboratory through the courtesy of its head, Harvey Cushing, MD, [FACS], Dr. Davis was publishing about correcting burn scarring with skin grafts by 1907. His work was sufficiently recognized that when America entered WWI in 1917, the Surgeon General’s Office of the U.S. Army wrote to Dr. Halsted suggesting that Dr. Davis organize a course at Johns Hopkins to teach plastic surgery techniques to a select group of surgeons. Halsted refused, indicating it was unnecessary to train surgeons in these procedures.2

Textbook receives a chilly reception

In 1919, Dr. Davis amassed his own work with the advances in maxillofacial surgery coming out of combat experience and published Plastic Surgery: Its Principles and Practice (see Figure 2, this page). In doing so, he specifically disputed the professional restriction of plastic surgery to maxillofacial work with the following argument:1

During the war (1914–1918) plastic surgery was arbitrarily limited, by regulation, to maxillofacial reconstruction. This, it is true, is a very important part of the subject, but it must be remembered—and the fact should be emphasized—that plastic surgery of the trunk and extremities is equally important. The results may be less spectacular, but surely are just as vital to the patient. The field of plastic surgery extends from the top of the head to the sole of the foot, and no properly trained plastic surgeon would be willing to limit his work to the face alone.

The textbook was a scholarly achievement with 25 chapters, 864 illustrations, and more than 2,000 references covering craniofacial surgery, vascular malformations, hand surgery, trunk and extremity reconstruction, genitourinary procedures, wounds, and...
cosmetic surgery (see Figure 3, page 69). Dr. Davis’ conviction about the comprehensive scope of plastic surgery was to become the standard in the evolution of the specialty.

In addition to this revolutionary idea, Dr. Davis broke new ground by vigorously encouraging the separation of plastic surgery from general surgery. He was probably the first surgeon to restrict his practice entirely to plastic surgery and explained his conviction that the work required specialized training in the following statement:

> It has been commonly said that any surgeon who can successfully do an intestinal suture can do plastic surgery. Careful investigation of this point warrants the statement—without qualification—that few general surgeons do plastic surgery as it should be done. The possibilities are little understood by the practising physician, and hardly more by the general surgeon.... The time has come for the separation of plastic surgery from the general surgery tree. There should be a well-trained plastic surgeon on the staff of every large general hospital, in order that these patients may be cared for intelligently.

Dr. Davis paid a price for his unconventional ideas and outspoken opinions about plastic surgery. Dr. Halsted showed his aversion to the independent development of plastic surgery when Dr. Davis invited him to contribute a preface to the 1919 textbook; Halsted declined, stating there was no use for the book. Dr. Davis was on the faculty at Johns Hopkins Medical School for more than 20 years before being promoted to associate professor of surgery in 1923, and he was unsuccessful in obtaining a separate division of plastic surgery at Johns Hopkins Hospital. His operations and his teaching clinic were conducted at Union Memorial Hospital because no beds were assigned to plastic surgery at Johns Hopkins until 1943.

Dr. Davis rose above the chilly reception to his ideas and went on in later years to attain many honors, including appointment in 1946 to the Board of Regents of the American College of Surgeons. He was a founding member and first chair of the American Board of Plastic Surgery and in February 1938 presided at the first formal meeting of the Board. But without a doubt his most remarkable moment was in 1919 when he developed and published his vision of what plastic surgery could and would become.

**REFERENCES**

Many health care organizations have started to acknowledge that leadership and structural support for staff who recognize and report unsafe conditions are essential to creating a safety culture—a critical component of high reliability in health care.

Recently, The Joint Commission published Sentinel Event Alert, Issue 60: Developing a reporting culture: Learning from close calls and hazardous conditions, which explores guidance for health care organizations and leaders in establishing a psychologically safe environment that eliminates fear of negative consequences for reporting mistakes and actively encourages learning from “close calls” in patient care.*

Close calls happen more frequently than injurious events. Reporting close calls gives important information on active and potential weaknesses in safety systems from the perspective of care professionals. Furthermore, analysis of these close calls makes it possible to identify system weaknesses and to address daily workflow or systems use.†

**Creating a safety culture**
Surgeons have the opportunity to positively influence safety culture in at least three ways:**

- What we do individually working with patients and staff in the clinic or in the operating room (OR)
- What we do as leaders of an OR team to establish and advance these principles
- What we can do in formal leadership positions within our organizations (for example, chairperson, quality assurance chair, or chief medical officer)

According to the alert, The Joint Commission receives annual reports from health care staff about unsafe conditions that exist in their institutions—with the majority indicating that an institution’s leadership was unresponsive to these reports or to other early warnings. However, the alert states that many institutions “have begun to acknowledge or give positive recognition to staff


†The Joint Commission. Sentinel Event Alert, Issue 60: Developing a reporting culture: Learning from close calls and hazardous conditions. Available at: www.jointcommission.org/sentinel_event_alert_60_developing_a_reporting_culture_learning_from_close_calls_and_hazardous_conditions/. Accessed February 1, 2019.
The alert further states that leadership needs to focus on improving safety culture, emphasizing to staff that the need to report a safety issue outweighs the fear of repercussions.

It further states that to create a safety culture, it is critical to identify and report these unsafe conditions before they can cause harm and to trust that other staff and leadership will act on the report while also taking personal responsibility for one’s own actions.* The alert further states that leadership needs to focus on improving safety culture, emphasizing to staff that the need to report a safety issue outweighs the fear of repercussions.

According to the alert, “In a safety culture, health care organization leaders are ultimately responsible for developing highly reliable systems. In turn, staff members are personally responsible for what is considered largely under their control—making good choices when working within these systems.”

It also is important for leaders in an institution to be strong role models by making themselves accountable for their mistakes. This behavior shows the staff and unit managers that failure is inherent to the human condition and that by recognizing failure and addressing the root causes that led to it, we learn from our own mistakes, and we make the system better. It is what has been called “failing forward.”

**Taking action**
The alert suggests that leaders at health care institutions take the following actions:

- Review *Sentinel Event Alert*, Issue 57, along with the new alert and commit to implementing a safety culture at your institution.
- Communicate leadership’s commitment to building trust and reporting through a safety culture.
- Develop an incident reporting system, including close calls and hazardous conditions, that encourages reporting. This system should include a recognition program and provide a feedback loop so staff know that action is being taken to address or fix the identified flaw.
- Hold managers, leaders, and, where appropriate, staff accountable for addressing and eliminating errors and hazards identified by reporting and for continually improving the safety of the patient care environment.
- Ensure that leaders at all levels of the institution apply a standardized accountability process to assess the difference between system flaws, which are the cause of most errors and hazardous conditions, and at-risk or reckless behaviors.


*The Joint Commission. *Sentinel Event Alert*, Issue 60: Developing a reporting culture: Learning from close calls and hazardous conditions. Available at: www.jointcommission.org/sentinel_event_alert_60_developing_a_reporting_culture_learning_from_close_calls_and_hazardous_conditions/. Both the alert and the infographic may be reproduced if credited to The Joint Commission.

**Disclaimer**
The thoughts and opinions expressed in this column are solely those of Dr. Pellegrini and do not necessarily reflect those of The Joint Commission or the American College of Surgeons.
In recent years, the number of individuals carrying firearms in the so-called “appendix carry position”—which is located in the waistband halfway between the pants pocket and the waistband button—has increased. Whereas approximately 90 percent of the population is right-handed, most people place the firearm in the vicinity of the appendix. However, placement of a firearm in this location can have some serious consequences.

**Prompt surgical exploration recommended**

The anatomic location of the scrotum leaves it vulnerable to penetrating trauma that primarily occurs in the form of knife wounds, gunshot wounds (GSWs), and self-mutilation. While rare, isolated scrotal GSWs comprise 55 percent of all penetrating external genital injuries. Prompt surgical exploration is the general rule for penetrating trauma as it is often associated with concomitant injuries to the testicles and less commonly the urethra and penis.

Multiple case series have revealed that 71 to 91 percent of patients presenting with penetrating scrotal injuries undergo scrotal exploration. A large single-institution study shows that gunshot wounds are explored 78 percent of the time. This aggressive approach to promptly diagnosing potential testicular injury has led to a negative exploration rate of up to 39 percent. While nonoperative management with serial ultrasound imaging has been shown to be beneficial in select situations, no prospective data are available, given the scarcity of the injury, to suggest this technique replaces early scrotal exploration.

Testicular salvage rates after penetrating trauma is between 39 percent and 49 percent after prompt exploration, according to the literature. GSW salvage rates, however, have been reported to be as high as 75 percent, with the caveat that these injuries are more likely to be promptly explored and less likely to involve the blood supply or the spermatic cord. Primary management of testicular injury includes debridement of nonviable tissue and closure of the tunica albuginea around viable seminiferous tubules when possible. It also is important that the clinician recognize that concomitant urethral injuries are possible given the scrotum’s close proximity to the base of the penis and urethra. While rare, scrotal GSWs are important to recognize and explore promptly for the best cosmetic, reproductive, and endocrine outcomes.

To examine the occurrence of patients with scrotal gunshot wounds in the National Trauma Data Bank® (NTDB®) admission year 2017, medical records were searched using the International Classification of Diseases, 10th Revision Clinical Modification codes. Specifically searched were records that contained one of 192 nonwar-related E codes for penetrating injury and a diagnosis code of s31.3 (open wound of scrotum and testes). A total of 801 records were found; 687 records contained a discharge status, including 588 patients discharged to home, 34 sent to acute care/rehab, 34 sent with law enforcement, 10 sent to skilled nursing facilities; 21 died (see Figure 1, page 74). All of these patients were men, on average 29.8 years of age, had an average hospital length of stay of 6.2 days, an
intensive care unit length of stay of 4.5 days, an average injury severity score of 9.6, and were on the ventilator for an average of 3.7 days. Of those patients undergoing operative exploration, 66 orchiectomies were performed.

When patients present with penetrating injuries below the belt, it is best to check for a possible scrotal injury and consider the need for operative exploration.

Throughout the year, NTDB data are highlighted through brief monthly reports in the Bulletin. The NTDB Annual Report can be found on the American College of Surgeons website as a PDF file at facs.org/ntdb. In addition, information is available on the website about how to obtain NTDB data for more detailed study. If you are interested in submitting your trauma center’s data, contact Melanie L. Neal, Manager, NTDB, at mmeal@facs.org.

Acknowledgment
Statistical support for this column was provided by Ryan Murphy, Data Analyst, NTDB.

REFERENCES
Call for nominations for ACS Secretary and Treasurer positions

The 2019 Nominating Committee of the Board of Regents (NCBR) will be selecting nominees for the positions of Secretary and Treasurer of the American College of Surgeons (ACS). The deadline for submitting nominations is May 6.

Position responsibilities

The responsibilities of these two positions are follows:

• The Secretary shall oversee the minutes of the annual meetings of the members, give notices in accordance with the provisions of law and the Bylaws of the ACS, keep the records and corporate seal, and perform such other duties as may from time to time be assigned by the Board of Regents. The Secretary has the co-responsibility with the Executive Director to provide such oversight.

• The Treasurer shall oversee, in conjunction with the Chief Financial Officer, the funds of the College under the supervision of the Finance Committee and shall make such reports to the Finance Committee, the Executive Committee of the Board of Regents, and the Board of Regents as may be required. The Treasurer will attend the meetings of the Board of Regents and will have a reporting relationship to both the Finance Committee and the Executive Director. The College shall purchase a bond or insurance coverage to ensure the faithful performance of the duties of the office of Treasurer. In the absence or inability to act as the Treasurer, the duties of the Treasurer shall be performed by such person and in such manner as the Finance Committee may direct.

Criteria for consideration

The NCBR will use the following guidelines when considering potential candidates:

• Nominees must be loyal members of the College who have demonstrated outstanding integrity and medical statesmanship along with an unquestioned devotion to the highest principles of surgical practice.

• Nominees must have demonstrated leadership qualities that might be reflected by service and active participation on ACS committees or in other components of the College.

• Members of the NCBR recognize the importance of achieving representation of all who practice surgery.

• The College encourages consideration of women and other underrepresented minorities.

All nominations must include a letter of recommendation, an up-to-date curriculum vitae, and a personal statement from the candidate detailing ACS service and the name of one individual who can serve as a reference. Any attempt to contact members of the NCBR by a candidate or on behalf of a candidate will be viewed negatively and may result in disqualification. Applications submitted without the requested information will not be considered.

Submit nominations to secretaryandtreasurer nominations@facs.org. If you have questions, contact Lynese L. Kelley, Director of Leadership Operations for the NCBR, at lkelley@facs.org or 312-202-5203. ♦
Balazs “Ernie” Bodai, MD, FACS, recently received a FIERCE Award at the Biden Cancer Summit Welcome Reception in Washington, DC, for his efforts to improve breast cancer survivorship. More specifically, the award was given to Dr. Bodai for his efforts to persuade Congress and the U.S. Postal Service to issue the Breast Cancer Research Stamp to support breast cancer research and for his leadership to improve health and lower the risk of recurrence of breast cancer. Survivorship awards were presented based on those whose work helps the patient through the social, emotional, financial, and/or medical effects of surviving cancer. The Biden Cancer Initiative’s FiERCE Awards recognize and celebrate those individuals who have had a transformative impact on the lives of cancer patients.

Read more about Dr. Bodai at the Cure Breast Cancer, Inc. website at bit.ly/2HViJMn.

In January, the Presidential Leadership Scholars (PLS) program, which brings together leaders from various fields to collaborate and learn about leadership through the experiences of U.S. Presidents George W. Bush, Bill Clinton, George H.W. Bush, and Lyndon B. Johnson, selected 60 scholars for the program’s fifth class. Among these scholars were Maya Babu, MD, MBA, director of adult neurotrauma, Massachusetts General Hospital, Boston, MA, and Associate Fellow of the American College of Surgeons; and Joseph V. Sakran, MD, MPA, MPH, FACS, director, emergency general surgery; associate chief, division of acute care surgery; and assistant professor of surgery, Johns Hopkins Hospital, Baltimore, MD.

According to the PLS website, “Scholars were selected based on their leadership growth potential and their personal leadership

projects aimed at improving civic engagement or social good by addressing a problem or need in their community, the country, or the world.” Drs. Babu and Sakran will travel to the noted presidential centers to learn from former presidents, administration officials, and leaders in business, civics, and academia about ways to strengthen their impact on their communities.

Read more about the PLS program and a full list of 2019 scholars on the program website at bit.ly/2t6NrIn.

Dionisios Vrochides, MD, PhD, FACS, FRCSC, a hepato-pancreato-biliary surgeon and vice-chair, quality outcomes, Carolinas Medical Center, Charlotte, NC, in November 2018 was inducted as president of the U.S. chapter of the ERAS (Enhanced Recovery after Surgery) International Society for the 2018–2020 term.

Dr. Vrochides will oversee the expansion program of ERAS
that includes both ERAS-qualified centers and ERAS centers of excellence. He also will be responsible for optimizing the collaboration with the ERAS International Society and will lead efforts to optimize analytics as related to compliance and outcomes.

Dr. Vrochides drove efforts at Atrium Health’s Carolinas Medical Center to implement ERAS protocols within the hepatopancreato-biliary service, which led to the hospital becoming the first ERAS Society-accredited center of excellence in the U.S. in 2016 and one of the world’s 23 ERAS centers of excellence overall. Teams use ERAS pathways in major surgical disciplines including colorectal, hepatobiliary and pancreatic, head and neck, and urologic surgery. Dr. Vrochides and his team have trained numerous health care institutions in successful ERAS implementations. Read more about Dr. Vrochides on the Atrium Health website at bit.ly/2UJnHOZ.

ACS and MacLean Center offer fellowships in surgical ethics

The American College of Surgeons (ACS) Division of Education is offering fellowships in surgical ethics with the MacLean Center for Clinical Medical Ethics, University of Chicago, IL. The MacLean Center will prepare two surgeons for careers that combine clinical surgery with scholarly studies in surgical ethics beginning with a five-week, full-time course in Chicago in July and August 2019. From September 2019 to June 2020, fellowship recipients will meet weekly for a structured ethics curriculum. In addition, fellows will participate in an ethics consultation service and complete a research project.

Application materials are due March 15. For additional information about this fellowship, contact Patrice Gabler Blair, MPH, Associate Director, ACS Division of Education, at pblair@facs.org.

Coming next month in JACS and online now

Enhancing patient outcomes while containing costs after complex abdominal surgery: A randomized controlled trial of the Whipple accelerated recovery pathway

Harish Lavu, MD, FACS; Neal S. McCall, MD; and co-authors report their findings in the April issue of the Journal of the American College of Surgeons (JACS) that using the Whipple accelerated recovery pathway reduced hospital length of stay, time to adjuvant therapy, and cost in selected pancreaticoduodenectomy patients without increasing readmission risk.

This article and all other JACS content is available at journal.acs.org.
Register for 2019 ACS Residents as Teachers and Leaders Course

Registration is open for the 13th annual Residents as Teachers and Leaders Course hosted by the American College of Surgeons (ACS) Division of Education. The 2019 program, March 29–31 at the ACS headquarters in Chicago, IL, is designed specifically for surgery residents and will address the essential nonclinical skills—teaching and leading—that are required for success as surgeons and members of the health care team.

The course faculty, composed of nationally renowned clinical and educational professionals, will provide an interactive learning environment. Residents will learn to lead a team more effectively, resolve conflict, be better teachers, give constructive feedback, and apply these skills during and after residency. This course is targeted at mid- to senior-level residents, but all are welcome to attend.

Registration information and a brochure are available on the course web page at facs.org/residentsteachers. The number of participants is limited to allow ample interaction with faculty and to facilitate networking, so early registration is encouraged.

Contact Steffanye Hawbaker Mack at shawbaker@facs.org or at 312-202-5424 with any questions.

♦

Be part of the conversation

Tap into the College’s collective knowledge anytime, anywhere, and on any device.
Age of liver transplant donor might not matter
HealthDay, October 23, 2018
"Those who accepted an older organ had a 61 percent lower risk of death during the study period than those who declined an older organ, the investigators found. "The study was scheduled for presentation Monday at an American College of Surgeons meeting, in Boston [MA]. The research should be considered preliminary until published in a peer-reviewed journal."

Canadian researchers take scalpel to opioid prescribing for surgical patients
CBC News, October 24, 2018
"In a study presented Wednesday at the American College of Surgeons Clinical Congress in Boston, researchers from Western University [London, ON] showed that the STOP Narcotics protocol halved the amount of opioids prescribed after two types of outpatient surgery, while still adequately treating most patients’ post-operative pain."

Communities with mass shootings share 4 common traits, study shows
Inverse, October 24, 2018
"Mass shootings are senseless tragedies, but doctors suspect these events aren’t as random as they appear. And they’re wielding data to back up their claims. “In a presentation on Tuesday at the American College of Surgeons Clinical Congress 2018, Stephen Markowiak, MD, presented an independent analysis of national data on the communities affected by mass shootings— shootings in which four or more people were killed—since 2005.”

London, [ON], researchers develop protocol to drastically reduce opioid prescriptions
Global News Online, October 24, 2018
"The study involved 416 patients at London Health Sciences Centre (LHSC) and St. Joseph’s Health Care London who underwent laparoscopic cholecystectomy or open hernia repair and is being presented Wednesday at the American College of Surgeons Clinical Congress. It’s also published in the Journal of the American College of Surgeons."

STOP Narcotics protocol takes scalpel to opioid prescribing for surgical patients
Vancouver Sun, October 24, 2018
"In a study presented Wednesday at the American College of Surgeons Clinical Congress in Boston, researchers from Western..."
University showed that the STOP Narcotics protocol halved the amount of opioids prescribed after two types of out-patient surgery, while still adequately treating most patients’ post-operative pain.

**UT researcher links public health of communities to likelihood of mass shootings**  
*University of Toledo News, October 25, 2018*

“‘The communities that have suffered through mass shootings tend to be much less healthy than the national average, both from a standpoint of physical health and mental health,’ [Stephen] Markowiak [MD] said. ‘We need to think about this problem through the lens of public health and encourage more objective research.’

“He presented his research findings Oct. 23 at the American College of Surgeons Clinical Congress 2018.”

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**Cleveland Clinic hospital shortens stay for major surgery by not using opioids**  
*Becker's Hospital Review Online, October 25, 2018*

“Cleveland Clinic Akron (Ohio) General Hospital surgeons created a treatment protocol that sends patients home after colorectal operations without any opioids, which led to shorter hospital stays, researchers reported at the American College of Surgeons Clinical Congress.”

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**Scientists pinpointed factors that put a community at risk of a mass shooting—and found 2 gun laws that could make a difference**  
*Business Insider, November 10, 2018*

“Because these deadly events have become so common in the U.S., a team of researchers from the University of Toledo in Ohio set out to look for patterns or similarities among communities that have dealt with a mass shooting.

“They looked at 155 mass shootings in the U.S. (defined as an event with four or more fatalities, excluding the shooter). Their research, which was presented at the American College of Surgeons Clinical Congress last month, found several factors that are clearly associated with a higher risk of a mass shooting.”

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**Correction**


A sentence on page 46 should have read, “Generally, investors use these criteria to determine whether to withdraw from an agreement or not to invest in ventures that have ties to industries such as tobacco, conflict diamonds, and petroleum products.”

Also, the correct name of USAID is U.S. Agency for International Development.

In addition, Dr. Sarkar’s author bio should have indicated that she is the general counsel of Millennium Partners, Charlottesville, VA. The editors regret the errors.
Professional Protection Portfolio

“The ACS Insurance Program provided both me and my spouse a really good value for life insurance at very competitive rates. I wish I had utilized this program earlier in my career.”
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The American College of Surgeons (ACS) is accepting applications through May 15 for the inaugural Gerald B. Healy, MD, FACS, Traveling Mentorship Fellowship. Colleagues and friends of Dr. Healy, Past-President of the ACS and Past-Chair of the Board of Regents and an Honorary Fellow of the Royal College of Surgeons and the Royal College of Surgeons in Ireland, have established funding for the annual mentoring fellowship program in his honor.

Mentorship is one of the hallmarks of academic and professional success. This program is intended to help young surgeons develop new ideas, innovative approaches, and well-informed attitudes about safety, quality, and professionalism via visits to successful mentors.

The Gerald B. Healy Traveling Mentorship Fellowship will be used to visit and engage with one or more successful mentor(s). The award, in the amount of $5,000, will cover the recipient’s travel and per diem costs and subsidize lost revenue from days away from clinical duties.

Application requirements
Applicant requirements are as follows:

- Applicants must be U.S./Canadian Fellows or Associate Fellows of the ACS and hold an academic rank no higher than associate professor.
- Mentors must be U.S./Canadian Fellows of the ACS or, if in a nonsurgical (microbiology, anatomy, and so on) or nonmedical (business, law, and so on) field, be appropriate for the research and education needs of the applicant.
- Applications must consist of the following items, to be e-mailed to the Scholarships Administrator at scholarships@facs.org as a single PDF document:
  - A one- to two-page essay describing why the applicant is interested in participating in this program
  - A joint statement from the mentor and mentee about their commitment to the relationship, including a description of the anticipated plan for the mentorship and approximately how the funds will be utilized
  - A brief curriculum vitae (10 or fewer pages) for the applicant and biosketch for the mentor

Awardee responsibilities
The recipient will submit reports as requested to the College for submission to the Bulletin of the American College of Surgeons, detailing their experience, lessons learned, and preserving such thoughts of the week for the edification of future generations of surgeons.

A financial report will also be provided at the end of the award period; the traveling fellow may use the funds to subsidize travel and per diem for mentor visits, or to replace lost revenue from clinical duties. The latter purpose is taxable.

Applications are due by May 15. A single traveling fellow will be selected, and all applicants will be notified of the outcome of the selection process by June 30.

Visit the Gerald B. Healy Traveling Mentorship Fellowship webpage at facs.org/member-services/scholarships/special/healy for more information. Questions also may be submitted to scholarships@facs.org. ♦

Apply for Gerald B. Healy, MD, FACS, Traveling Mentorship Fellowship

Dr. Healy
Apply for ACS/SVS Foundation/NIH Research Career Development Award

The American College of Surgeons (ACS) has announced a program that will provide supplemental funding to individuals who receive a National Institutes of Health (NIH) Mentored Clinical Scientist Research Career Development Award (K08), a Mentored Patient-Oriented Research Career Development Award (K23), or a Mentored Research Scientist Development Award (K01).

This award is directed at surgeon-scientists working in the early stages of their research careers. The award requires cosponsorship with the Society for Vascular Surgery (SVS) Foundation of a three-, four-, or five-year period of supervised research experience that may integrate didactic studies with laboratory or clinically based research.

This award program will help to facilitate the career development of individuals pursuing careers in surgical research by enhancing salary support over and above that offered by the K08/K23/K01 mechanism. Awardees must be members in good standing of both the College and the SVS.

Applications are accepted by the remaining 2019 NIH K-Series deadlines—June 12 and October 12. Applicants must submit a copy of the completed NIH application to the SVS grant administrator, who will provide the application to the College. Applicants must advise the SVS Foundation grant administrator of the NIH’s decision regarding their application.

For details, contact the SVS Foundation grant administrator at SVSFoundation@vascularsociety.org.

Apply for ACS/Triological Society Clinical Scientist Development Award

The American College of Surgeons (ACS) and the Triological Society have announced a competitive grant program to provide supplemental funding to otolaryngologists-head and neck surgeons who have received a new NIH (National Institutes of Health) Mentored Clinical Scientist Development Award (K08/K23), or have an existing award with a minimum of three years remaining in the funding period as of October 1, 2019.

This award is being offered as a means to facilitate the research career development of otolaryngologists-head and neck surgeons, with the expectation that the awardee will have sufficient pilot data to submit a competitive R01 proposal prior to the conclusion of the K-award. This award provides financial support in the amount of $80,000 per year for up to five years, or for the remainder of the term of existing grants, to supplement the K08/K23 awards. Funding is dependent upon receipt of meritorious applications.

The application deadline is May 20. For further details, visit the Triological Society’s website at www.triological.org/researchgrants.html or contact info@triological.org.
# Calendar of events

*Dates and locations subject to change. For more information on College events, visit facs.org/events or facs.org/member-services/chapters/meetings.

## March

**Jamaica Chapter**  
March 14  
Kingston, Jamaica  
Contact: Dr. Colin Abel, colinabel@hotmail.com

**Northern California Chapter**  
March 15–16  
Berkeley, CA  
Contact: Christina McDevitt, nccacs@att.net, northernca.chapter.facs.org

**South Florida Chapter**  
March 16  
Fort Lauderdale, FL  
Contact: Elektra McDermott, elektra.mcdermott@gmail.com, sfc-acs.org

**Florida Chapter**  
March 22–23  
Orlando, FL  
Contact: Brian Hart, bhart@floridafacs.org, floridafacs.org

**Maryland Chapter**  
March 23  
Annapolis, MD  
Contact: Wanda McKnight, wanda@marylandacs.org, marylandacs.org

**Germany Chapter**  
March 26  
Munich, Germany  
Contact: Dr. Tobias Keck, tobias.keck@uksh.de

**Peru Chapter**  
March 27–29  
Lima, Peru  
Contact: Dr. Jaime Herrera-Matta, scgperu@gmail.com

**Chapter Officer Leadership Program**  
March 30, 7:30 am–1:00 pm  
Washington, DC  
Contact: Luke Moreau lmoreau@facs.org

**Qatar Chapter**  
April 26  
Doha, Qatar  
Contact: Dr. Hiba Abdel Aziz, habdelaziz@hamad.qa

## April

**Lebanon Chapter**  
April 6  
Beirut, Lebanon  
Contact: Dr. Ahmad Zaatari, zaatari@gmail.com

**Egypt Chapter**  
April 6–8  
Cairo, Egypt  
Contact: Dr. Mohey Elbanna, esbs.egypt@gmail.com, egyptianchapter-acs.com

**Indiana Chapter**  
April 12–13  
Carmel, IN  
Contact: Tom Dixon, dixonest71@gmail.com, www.infacs.org

**Japan Surgical Society**  
April 18–20  
Osaka, Japan  
Contact: JSS Secretariat, jss2019@congre.co.jp

## May

**Minnesota Surgical Society**  
May 3–4  
Red Wing, MN  
Contact: Janna Pecquet, janna@mnsurgicalsociety.org, mnsurgicalsociety.org

**North and South Dakota Chapters**  
May 3–4  
West Fargo, ND  
Contact: Leann Benson, leann@ndmed.com

## Future Clinical Congresses

- 2019  
  October 27–31  
  San Francisco, CA

- 2020  
  October 4–8  
  Chicago, IL

- 2021  
  October 24–28  
  Washington, DC
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Cluster Programs

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